Electrohysterography Evaluation For Maternal Assessment (EEMA)
M&T Final Analysis Report

Description: Electrohysterography Evaluation For Maternal Assessment (EEMA) is a BMI-agnostic contraction monitoring device that collects uterine muscle activity and provides high-quality insights to physicians via mobile platform.

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1. Need & Value Proposition

- **1.1 Need – Problem Statement**

In 2024, 1,000,000 high-BMI mothers will go into labor in the United States[1]. The current standard for non-invasive fetal monitoring during labor, TOCO, is significantly less effective for mothers with a higher BMI, as abdominal adipose tissue hinders accurate pressure measurements. Studies show that TOCO monitoring yields "difficult monitoring" in 30% of obese women (BMI >35) compared to 0% in non-obese women and produces poor-quality readings for over 25% of monitoring time in 36% of obese patients[2]. With more than half of pregnant women in the U.S. classified as obese (BMI >30), this represents a critical unmet need.

The primary invasive alternative, IUPC, requires membrane rupture, increasing the risk of complications such as placental abruption[3]. When non-invasive monitoring fails, physicians often resort to C-sections, which carry additional risks. There is an urgent need for a reliable, BMI-agnostic, and non-invasive solution.

From a financial perspective, labor complications increase costs for both patients and hospitals by requiring extended inpatient care, additional infrastructure (e.g., hospital beds), and extra staff, including nurses and surgical teams.

- **1.2 Value proposition**

EEMA provides BMI-agnostic, real-time contraction data to support better clinical decisions and equitable maternal care, lowering the risk of labor complications and labor-related costs.

.2. Stakeholders

- ○ High-BMI Mothers in Active Labor
  - ■ Ensures accurate, non-invasive contraction monitoring, reducing risks and improving care.
- ○ Nursing Personnel
  - ■ Reduces workload by eliminating TOCO setup and IUPC oversight, allowing focus on critical tasks.
- ○ Obstetric Physicians
  - ■ Provides real-time contraction data remotely, enabling faster, more informed decisions.
- ○ Hospital Managers

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[1] Driscoll AK, Gregory ECW. Increases in prepregnancy obesity: United States, 2016–2019. NCHS Data Brief, no 392. Hyattsville, MD: National Center for Health Statistics. 2020

[2] Vanner, T., & Gardosi, J. Intrapartum assessment of uterine activity, Bailliere's clinical obstetrics and gynaecology, 1996

[3] Rood, Kara M. MD; Gee,. Use of Intrauterine Pressure Catheters (IUPC) Increases Risk of Post-Cesarean Surgical Site Infection [9B]. 2017

- Lowers costs by reducing reliance on TOCO, IUPC, and unnecessary C-sections.
  - ○ Health Insurance Companies
    - Minimizes payouts for unnecessary interventions by improving labor assessment accuracy.

3. Market Opportunity

The global fetal monitoring market was valued at $3.4 billion in 2022 and is expected to grow to $6.2 billion by 2032, with a compound annual growth rate (CAGR) of 6.2%[4]. In the United States alone, the market accounted for $1.8 billion in 2022, with growth driven by rising pregnancy-related complications, advancements in monitoring technology, and government efforts to improve maternal health[5]. A major factor fueling this growth is the increasing demand for non-invasive devices, particularly for high-BMI pregnancies, where traditional methods like TOCO often fail due to interference from abdominal adipose tissue[6].

The industry is led by key players such as GE Healthcare, Philips (Avalon series), Siemens (FM20), and Huntleigh (Sonicaid series). Device prices range widely, from basic Dopplers starting at $200 to advanced electronic systems costing over $20,000. Refurbished equipment, offered by companies like CeviMed and SOMA Tech, provides more affordable options for smaller hospitals and clinics. With a focus on addressing diverse patient needs and improving healthcare outcomes, the fetal monitoring market is poised for sustained growth.

4. Customer Segment – Market Sizing & Growth Estimation

The target market for EEMA is the United States hospital system, specifically OB/GYN departments, where over 50% of pregnant patients are classified as obese, highlighting the need for BMI-agnostic monitoring. This market is also highly receptive to innovation, with a 6.2% CAGR projected in fetal monitoring technologies, making it an ideal entry point for EEMA.

Within this market, EEMA will target larger hospitals that manage multiple active labor patients simultaneously. These facilities stand to benefit most from reduced decision-making time, fewer complications, and lower operational costs, enabling staff to better allocate resources and manage patient care efficiently.

5. Competiton and Differentiation

5.1 Competitive Analysis Framework

[4] https://www.alliedmarketresearch.com/fetal-monitoring-market
[5] https://www.gminsights.com/industry-analysis/fetal-monitoring-market
[6] https://www.marketsandmarkets.com/Market-Reports/fetal-monitoring-market-35700261.html
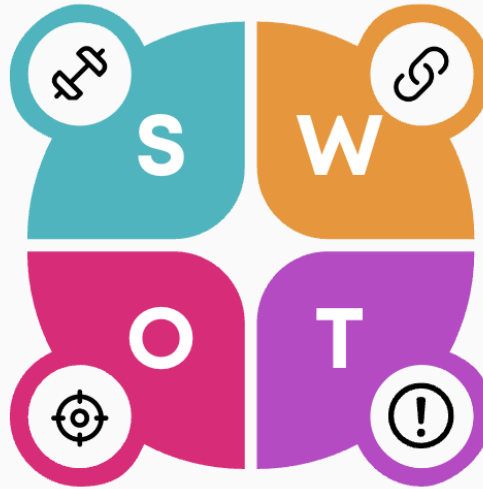
EEMA SWOT Analysis

Strengths
- Non-invasive and BMI-agnostic.
- 90% contraction detection accuracy.
- Machine learning for event differentiation.
- Real-time data with a digital dashboard.
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Weaknesses
- Growing $6.2B maternal health market.
- High demand for BMI-agnostic solutions.
- Partnerships with large hospitals.
- Global market expansion potential.

Opportunities
- No patent protection.
- Scalability challenges given complex hardware.
- Limited clinical validation.

Threats
- Competition from major players.
- Regulatory delays.
- Budget constraints in hospitals.
- Data privacy and integration concerns.

5.2 Differentiation table

Criteria vs Competitor	TOCO (GE Healthcare)	IUPC (Intran Plus)	Palpation & Patient Annotations	EEMA
BMI-agnostic	No	Yes	Yes	Yes
Non-invasive	Yes	No	Yes	Yes
Provides smart insight (calculates contraction frequency, strength, etc)	No	No	No	Yes
Cost (USD)	$500	$2,233	$0	~$200

6. Intellectual Property (IP)

The EEMA team does not plan on filing for a patent, given the associated costs and long timelines. However, EEMA would be eligible for a utility patent based on its novel method of commercially using EHG technology for contraction monitoring on proprietary hardware and software. This eligibility is supported by the United States Patent Act (35 U.S.C. §101), which grants patents for new and useful processes, machines, or compositions of matter, provided they meet criteria for novelty, non-obviousness, and utility.

7. Cost Breakdown and Estimation

Component / Service	Description	Estimated Cost (USD)	Reference / Link
Electrodes (dual channel)	Medical-grade surface EMG electrodes (including adhesive materials)	20.0	https://mms.mckesson.com/product/1232500/Personal-Medical-4630
Signal Processing Circuitry	Amplifiers, filters, op-amps, protection components	18.0	https://www.quarktwin.com/blogs/integrated%20circuit/understanding-op-amp-filters-from-basics-to-advanced-applications/447
Printed Circuit Board (PCB)	Custom 2-layer board, small-batch manufacturing	15.0	https://jlcpcb.com/
Microcontroller / Raspberry Pi	Raspberry Pi Zero W (or similar) for data handling	12.0	https://www.raspberrypi.com/products/raspberry-pi-zero-w/
Battery and Power Circuit	Rechargeable battery, charging module, power protection	10.0	https://www.amazon.com/Makerfocus-Charging-Lithium-Battery-Protection/dp/B071RG4YWM
Mobile App & Dashboard Software	Per-unit amortized cost of app development and maintenance	25.0	Custom Development
Machine Learning Model Deployment	On-device ML inference logic, licensing, and updates	15.0	Custom Development

Enclosure (Casing)	Medical-grade silicone or ABS plastic housing for comfort & hygiene	18.0	https://www.takachi-enclosure.com/products/TWN
Connectors & Wiring	Internal wiring, sensor plugs, and shielded connectors	5.0	Various Suppliers
Packaging & Labeling	Single-use sterile packaging, user instructions	7.0	https://medpak.com/sterile-packaging/
Regulatory & QA Testing Allocation	Per-unit cost share of regulatory compliance, QA checks	15.0	Internal Allocation
Assembly Labor (Low-Volume)	Manual or semi-automated unit assembly labor	20.0	Internal Labor
Contingency/Overhead (5%)	Miscellaneous (shipping, shrinkage, tools, etc.)	10.0	Internal Allocation
TOTAL		200.0	

8. Revenue Model

EEMA will be sold as a B2B product, targeting hospitals and OB/GYN departments through a top-to-bottom go-to-market approach. By leveraging its low unitary cost of $200, EEMA can be priced competitively while maintaining a healthy 80% profit margin, ensuring both affordability and profitability. Additionally, optimizations such as the PCB design and an efficient database structure help drive variable costs to a plateau, further strengthening EEMA's long-term financial sustainability. Despite its significantly lower price point than traditional TOCO machines, EEMA provides superior performance, making it an attractive investment for healthcare institutions.

To incentivize bulk purchases and full-department adoption, EEMA employs a tiered pricing model that offers increasing discounts for hospitals buying multiple devices. A single device will be priced at $360, while hospitals purchasing multiple units will receive discounts based on volume: 2–5 devices at $340 each, 5–15 devices at $300 each, and 15–20 devices at $260 each. This structured pricing strategy encourages large-scale implementation, reducing per-unit costs for hospitals while maximizing adoption and accessibility in labor monitoring.