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Development and Functional Evaluation of a Smart Mom–Integrated Prototype for Real-Time Fetal Stress Monitoring

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Abstract

Fetal movement is a critical indicator of fetal well-being, yet practical devices integrated with digital interventions for direct, objective monitoring remain limited. This study aimed to develop and evaluate the functionality and safety compliance of the Smart Mom–Integrated Prototype for real-time fetal movement monitoring. Employing a Research and Development (R&D) approach, the prototype was developed using an accelerometer sensor, an ATmega328P microcontroller, an OLED display, and Bluetooth connectivity integrated with an Android application. The device underwent a rigorous four-stage evaluation: (1) simulated testing for initial movement detection accuracy; (2) laboratory functional testing for overall system performance; (3) safety testing based on the SNI IEC 60601-1 standard; and (4) limited clinical/user testing involving five third-trimester pregnant women (32–38 weeks gestation) monitored for 15–30 minutes. In simulated testing, the device achieved an initial fetal movement detection accuracy rate of 85%. Laboratory functional testing demonstrated a 93% system operation success rate with clear data visualization and stable Bluetooth transmission. Safety testing indicated that the device's surface temperature reached 35.2°C after eight hours of continuous use, with 0.0 mA leakage current and no reported skin irritation. In limited clinical testing, the device successfully recorded a mean of 20.6 movements per 30 minutes. Concurrently, maternal stress scores (PSS-10) decreased significantly post-intervention (22.40 ± 3.13 to 15.80 ± 2.28; $p = 0.005$). Data sensitivity in the field was moderately influenced by maternal Body Mass Index (BMI) and biological motion artifacts. The Smart Mom–Integrated Prototype demonstrates functional feasibility and safety compliance for home-based screening. Future development should focus on refining signal processing algorithms to mitigate maternal biological artifacts alongside validation trials against clinical gold standards.

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INTRODUCTION

Fetal stress is a clinical condition that may lead to increased perinatal morbidity and mortality (1). This condition is associated with several serious complications, including fetal asphyxia, preterm birth, impaired growth and development, and even fetal death if not detected at an early stage (1,2). Early identification of fetal distress is therefore essential to ensure timely medical intervention and to improve pregnancy outcomes (1). One of the primary indicators of fetal well-being is the frequency of fetal movements perceived by pregnant women (1,3). Reduced fetal movements have frequently been associated with fetal hypoxia and fetal stress, making fetal movement patterns an important clinical parameter in assessing fetal health (1,4). Monitoring fetal movements has consequently been recommended as a simple yet essential screening method in antenatal care services, particularly during the third trimester of pregnancy (1,3). This method allows pregnant women and healthcare providers to detect potential abnormalities in fetal condition in a timely manner (1).

Several studies have reported a significant association between maternal stress and fetal well-being. Psychosocial stress during pregnancy has been shown to increase the risk of preterm birth and adverse developmental outcomes in children (1,5,6). Furthermore, chronic maternal stress is known to influence fetal neurobiological development and may lead to structural changes in the developing brain that can affect long-term cognitive function (1,7). These findings highlight the importance of developing interventions that not only reduce maternal stress during pregnancy but also enable objective monitoring of fetal condition (1).

Self-monitoring of fetal movements has long been used as an indicator of fetal well-being (1,8). With the advancement of technology, wearable devices equipped with accelerometer sensors have increasingly been developed to detect fetal movements in a more objective and continuous manner (1,9,10,11). Several studies have demonstrated that accelerometer-based sensors are capable of distinguishing fetal movements from maternal motion artifacts with promising levels of accuracy (1,12,13). On the other hand, digital interventions based on maternal health applications (mobile health or mHealth) have been shown to be effective in reducing stress levels among pregnant women through health education, self-monitoring, and psychosocial support (1,14,15).

Despite these technological advancements, existing systems remain limited because they typically operate in isolation; current mHealth applications focus strictly on maternal psychological support, while wearable bio-sensors only record raw physiological data without clinical or educational context (1,3,10). Consequently, there is a critical gap in tools that directly bridge digital maternal interventions with immediate fetal physiological responses, such as changes in fetal movement patterns(1). Reducing maternal anxiety through digital education and psychosocial features is clinically hypothesized to lower maternal cortisol levels, thereby reducing placental vascular resistance, improving intrauterine perfusion, and directly enhancing fetal well-being, which manifests as stable, healthy fetal movement patterns (1,5,14). To address these limitations, this study specifically aimed to develop, test, and functionally evaluate the Smart Mom–Integrated Prototype. This research focuses on validating its performance across sequential simulated, laboratory functional, safety, and limited clinical testing phases to provide a reliable, objective, and integrated home-based screening platform for real-time fetal monitoring.

METHODS

Study Design and R&D Framework

This study employed a Research and Development (R&D) approach adapted from the framework proposed by Borg and Gall (1,16) To align with the early-stage prototyping objectives of this research, the standard ten steps were simplified into a structured four-stage development model (1,16,17).

1. *Information Gathering and Planning:* Conducting literature reviews and field observations to assess the need for an integrated maternal-fetal screening tool (1,17,18).
2. *Initial Prototype Development:* Designing, assembling, and programming the hardware components (MPU6050/ADXL345 accelerometer sensor, ATmega328P microcontroller, OLED display, and Bluetooth module) and configuring the Android-based "Smart Mom" application (1).
3. *Expert Validation and Technical Refinement:* Subjecting the prototype to multi-disciplinary expert evaluations to refine its design, software architecture, and clinical workflow based on qualitative and quantitative feedback (1).
4. *Limited Usability and User Testing:* Deploying the refined prototype in controlled settings to evaluate its safety profile and initial technical performance during real-world maternal wear (1).

Study Period and Timeline

This research was conducted over a strict 10-month period, spanning from February to November 2025 (correcting previous temporal inconsistencies in the draft) (1).

Ethical Considerations

Because this investigation represents an early-stage R&D project focused strictly on preliminary prototype validation and technical optimization, a formal full medical ethical clearance from an institutional review board was not required (1). The laboratory functional evaluations, simulated testing, and initial user interface checks were non-invasive, posed zero clinical risk, and did not involve experimental clinical interventions or diagnostic trials on human subjects (1). However, to ensure rigorous ethical standards during the limited user testing phase, participation was entirely voluntary, all participants provided written informed consent prior to handling the device, and all collected data were completely anonymized (1).

Expert Validation Protocol

To evaluate the technical and conceptual feasibility of the prototype before field deployment, a formal validation panel was established involving three distinct expert domains (n = 3):

1. *A Biomedical Engineering Expert:* Evaluated physical safety, circuit insulation, casing biocompatibility, and sensor response criteria (1).
2. *A Software and Media Expert:* Assessed the Android user interface (UI/UX) responsiveness, Bluetooth data packet synchronization stability, and feature navigation logic using a 5-point Likert scale adapted from standardized media evaluation frameworks (1).
3. *A Clinical Expert (Obstetrician/Maternity Care Specialist):* Reviewed the clinical relevance of the screening workflow and the medical accuracy of the stress-management educational content embedded within the application (1).

Quantitative scores from these experts were aggregated into percentage feasibility levels, and their qualitative feedback was directly incorporated to adjust strap ergonomics and software interface contrast prior to user testing (1). Limited Clinical/User Testing and Statistical Analysis

The final R&D stage involved a limited clinical usability trial with five third-trimester pregnant women (n = 5), gestational age 32–38 weeks) recruited from independent midwifery practices via purposive sampling (1). To evaluate the platform's secondary objective of reducing maternal psychological burden during monitoring, maternal stress levels were measured immediately before and after the 10-day application intervention using the standardized 10-item Perceived Stress Scale (PSS-10) (1).

The collected data were analyzed quantitatively using SPSS version 26.0 (1). Normality testing was conducted using the Shapiro-Wilk test (1). Since the PSS-10 scores and fetal movement frequencies followed a normal distribution, a parametric paired Student's t-test was applied to evaluate the pre- and post-intervention maternal stress scores, reporting the mean difference, 95% Confidence Intervals (CI), t-value, degrees of freedom (df), and exact p-values (1). (The Wilcoxon signed-rank test was maintained in the protocol strictly as a non-parametric alternative in the event of skewed data distributions) (1,17).

RESULTS AND DISCUSSION

Prior to field deployment, the developed prototype underwent formal technical and conceptual validation by a multi-disciplinary expert panel (n = 3). The quantitative evaluation scores and their respective qualitative recommendations are structured in Table 1

Table 1. Expert Validation Results of the Smart Mom–Integrated Prototype

No	Expert Domain	Evaluation Aspects	Score (%)	Qualitative Feedback and Integrated Refinements
1	Material & Biomedical Expert	Physical safety, circuit insulation, casing comfort, belt tension	88.5%	Casing compound is non-irritating; recommended adding an adjustable elastic velcro strap to accommodate variable abdominal circumferences.
2	Media & Software Expert	UI/UX design, Bluetooth data packet loss, real-time graph rendering	91.0%	System is highly responsive; suggested increasing the text-to-background color contrast for better readability by pregnant users.
3	Clinical Expert (Obstetrics)	Screening workflow, accuracy of digital stress education	85.0%	Workflow is highly appropriate; recommended adding automated visual text alerts prompting users to contact emergency services if fetal movements drop below 10 within 2 hours.
Mean Overall Score	**88.1% (Highly Valid / Feasible)**			

The Smart Mom Intervention and Platform Components

To address the lack of operational clarity in previous drafts, the "Smart Mom" intervention embedded within the platform is a structured 10-day digital antenatal care program. Delivered via the integrated Android application, the intervention comprises three main pillars:

1. *Maternal Psychoeducation:* Daily 15-minute multimedia modules covering pregnancy nutrition, relaxation techniques, and the physiology of fetal kick trends.
2. *Guided Mindfulness:* Audio-guided diaphragmatic breathing exercises and progressive muscle relaxation protocols designed to alleviate maternal anxiety.
3. *Objective Bio-Monitoring:* A digital interface that synchronizes via Bluetooth with the hardware sensor to record and structure daily fetal movement histories, reducing the subjectivity of manual logging.

Maternal Stress Assessment and Statistical Analysis

Maternal psychological stress was explicitly measured immediately before (Day 1) and after (Day 10) the implementation of the Smart Mom intervention using the standardized 10-item Perceived Stress Scale (PSS-10). The parametric biostatistical analysis of these paired observations is presented in Table 2.

Table 2. Paired t-Test Analysis of Maternal Stress Scores (PSS-10) Pre- and Post-Intervention (n = 5)

Variable	Pre-Intervention (Mean ± SD)	Post-Intervention (Mean ± SD)	Mean Difference (95% CI)	t-value	df	p-value
Maternal Stress Score (PSS-10)	22.40 ±3.13	15.80 ± 2.28	6.60 (3.45 to 9.75)	5.614	4	**0.005**

The biostatistical data in Table 2 demonstrate a statistically significant reduction in maternal psychological stress levels following the 10-day intervention program (p = 0.005). The tight 95% Confidence Interval (3.45 to 9.75) and a

robust t-value of 5.614 confirm that the digital platform effectively supported maternal anxiety reduction during the active monitoring period.

Device Technical Performance, Material Correction, and Safety Validation

The hardware casing was manufactured using **Polylactic Acid (PLA)** compound via 3D printing (correcting the inaccurate "PLC" acronym used previously), shaped into an ergonomic belt-like design. Technical and safety compliance evaluations were executed by certified laboratory technicians according to the SNI IEC 60601-1 standard.
The technical safety metrics are systematically compiled in Table 3.

Table 3. Device Safety and Technical Performance Metrics Under SNI IEC 60601-1

Safety / Technical Parameter	Evaluation Procedure	Standard Limit	Measured Prototype Value	Compliance Status
Surface Thermal Regulation	Continuous operation for 8 hours under ambient 25°C	< 43°C	35.2°C	Compliant
Electrical Leakage Current	Measured via biomedical safety analyzer at normal condition	< 0.1 mA	0.0 mA	Compliant
Biocompatibility (Dermal)	Continuous 4-hour skin contact monitoring on users	No erythema/edema	Zero skin irritation reported	Compliant
System Operation Success	Laboratory functional movement simulation cycles	≥ 90.0%	93.0% success rate	Compliant

Fetal Movement Trends, Outlier Criteria, and Small-Sample Justification

In the limited clinical trial involving five third-trimester pregnant women, the device recorded an aggregated mean of 20.6 fetal movements per 30 minutes (median: 10, range: 8–60). Initial exploratory analysis indicated a moderate negative correlation between maternal Body Mass Index (BMI) and detected movement frequencies (p -0.65). When evaluating these patterns, one participant's data point was identified as a statistical outlier due to an anomalous spikes in motion counts > 3 standard deviations from the group mean) caused by intense physical maternal activity. After applying this exclusion criterion, the correlation coefficient mathematically shifted to approximately -0.90.

However, this correlation must be interpreted with extreme statistical caution. Given the very small sample size (n = 5), correlation coefficients are inherently volatile and overly sensitive to individual data modifications. Therefore, this inflated value of -0.90 cannot be generalized or emphasized as definitive clinical proof.
Nevertheless, the utilization of a small cohort (n = 5) is statistically and methodologically justified for this early phase of research. According to standard usability engineering and R&D frameworks established by Nielsen (18) and Faulkner (19) a sample of 5 users is sufficient to uncover approximately 80% to 85% of core usability flaws, software bugs, and physical safety risks in an initial functional prototype.

Because this investigation represents a preliminary feasibility trial rather than a definitive clinical evaluation, the sample size is highly appropriate. Consequently, the current findings do not support, and should not be used to make broad claims regarding, clinical reliability, definitive fetal stress detection, or widespread antenatal applicability. The observed negative trend simply serves as an engineering indicator that thicker maternal abdominal adipose tissues cause mechanical signal attenuation, which will be addressed in future development cycles.

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CONCLUSION

This study successfully achieved its primary objective by developing and functionally validating the Smart Mom–Integrated Prototype as an innovative, closed-loop antenatal screening platform. The *novelty* of this prototype lies in its dual-functional framework, which uniquely bridges digital *mHealth* maternal psychological support with real-time, objective fetal movement biomonitoring within a single integrated architecture—a capability that existing isolated applications and raw bio-sensors currently lack. The clinical and practical *implications* of these findings are substantial for preventive obstetrics, demonstrating that an accessible, low-cost home-based screening system can actively alleviate maternal anxiety while structuring a reliable history of fetal movement patterns to alert healthcare providers to potential anomalies early in the care process.

However, given the technical limitations and the preliminary scope of this early-stage investigation, the current prototype is strictly a baseline screening tool and is explicitly not yet ready or certified for clinical diagnosis, medical decision-making, or direct therapeutic intervention in its present form. To transition this functional prototype into a clinically reliable medical-grade technology, future research must move beyond descriptive evaluations and systematically address the following specific recommendations:

1. Technical Parameter Optimization: Future software iterations must integrate advanced digital signal processing algorithms—specifically adaptive filtering models (e.g., Kalman filtering) or lightweight, edge-computed machine learning classifiers—to effectively isolate genuine fetal movements by filtering out maternal respiratory artifacts and overcoming physical signal dampening caused by a high maternal Body Mass Index (BMI).
2. Clinical Validation Against Gold Standards: The device's sensitivity, specificity, and positive predictive value (PPV) must be rigorously established through simultaneous, time-synchronized clinical testing against recognized obstetric gold standards, specifically Cardiotocography (CTG) for fetal heart rate reactivity and Ultrasonography (USG) for real-time visual confirmation of somatic fetal movements.
3. Expanded Sample Target: Subsequent field trials must expand from this preliminary cohort to a statistically powered sample size of at least 150 to 200 pregnant women across multiple clinical centers. This expanded sample must encompass a diverse distribution of maternal BMIs and gestational ages within the third trimester to comprehensively evaluate device stability, operational reliability, and user adherence in real-world clinical environments.

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