Continuous Monitoring of Placental Blood Flow

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Clinical Population: Pregnant women with known or suspected placental blood flow complications.

Unmet Needs

Pregnant women with placental blood flow complications are at risk of reduced oxygen and nutrient delivery to the fetus, which can affect growth and development.

While routine ultrasounds are usually performed during pregnancy, they only provide snapshots in time. Changes in blood flow can occur between visits, leaving potential issues undetected. Continuous monitoring of maternal blood flow makes sure that the placenta is delivering enough oxygen and nutrients and allows clinicians to respond quickly if perfusion (the flow of blood through the placenta) is reduced.

Although ultrasound is safe,it usually needs to be performed in a hospital or clinic, and factors like scheduling, cost, and accessibility make it difficult to use for real-time monitoring.

Why Continuous Blood Flow Monitoring Matters

Even short-term reductions in perfusion can have clinical consequences. Continuous monitoring helps clinicians to observe trends over time, making it possible to detect gradual declines before they reach critical levels and intervene earlier.

Proposed Device

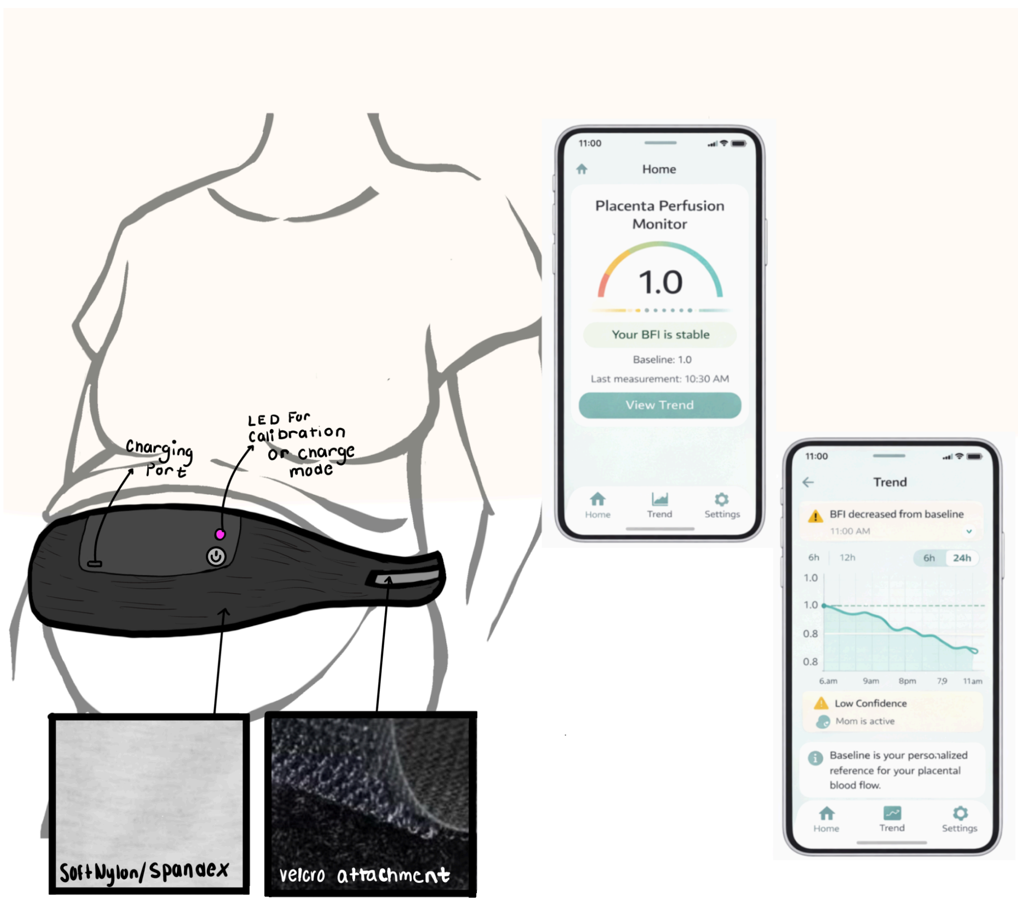
We propose a soft, adjustable belt worn around the abdomen that uses **Diffuse Correlation Spectroscopy (DCS)** to continuously track placental blood flow. The belt sends data to a smartphone app, showing real-time trends, history, and alerts if blood flow drops, helping clinicians intervene early. It’s comfortable, non-invasive, and personalized.

The device continuously measures Blood Flow Index (BFI), a relative measure of how fast red blood cells are moving in the placenta. Instead of providing a single value, the system tracks changes in BFI over time, which is more clinically meaningful for monitoring placental perfusion.

Each patient establishes a personal baseline by wearing the device at rest for 5–10 minutes. Future measurements are compared to this baseline:

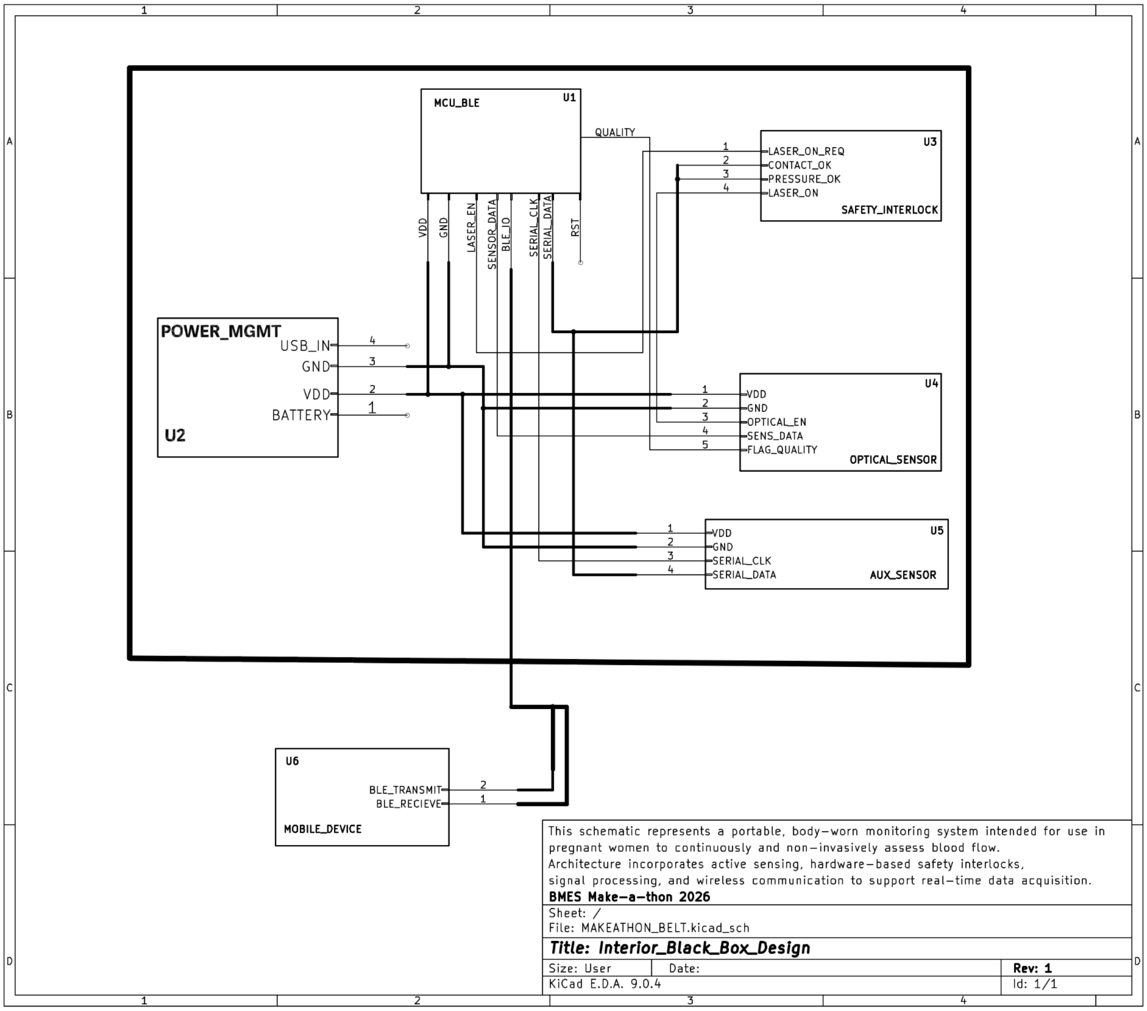
Belt Features:

- Adjustable Strap:
    - Made of soft, elastic nylon and bamboo-spandex material (similar to postpartum support belts). Non-invasive, only gentle contact.
    - Lightweight and ergonomic for comfort during daily activities and sleep.
    - Velcro straps allow adjustment to fit changes in belly size throughout pregnancy.
    - LED above the power button indicates calibration or battery charging status.



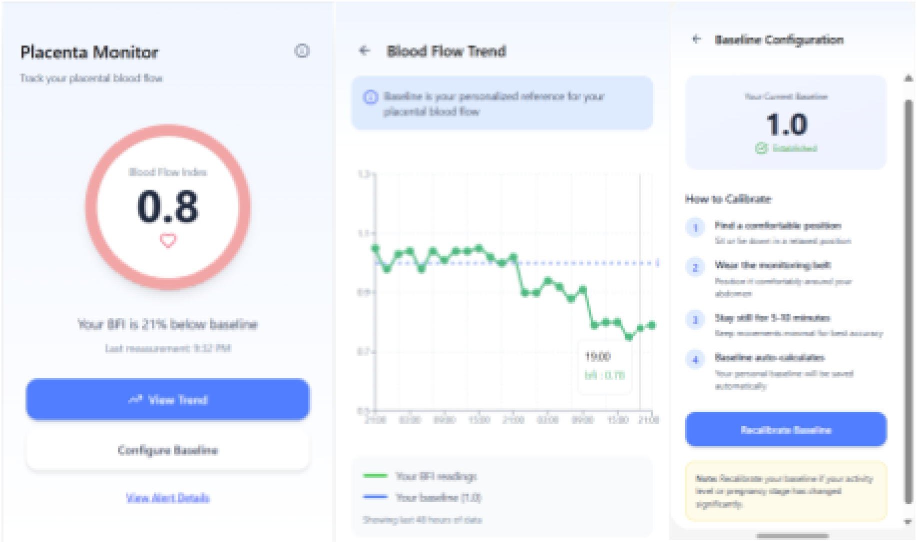
- Electronics “Black Box”:
    - Compact hub attached to the strap that houses all functional components:
        - NIR(Near-Infrared) laser diodes for light emission
        - Photodiodes for detecting scattered photons
        - Optical fibers to allow flexible sensor placement

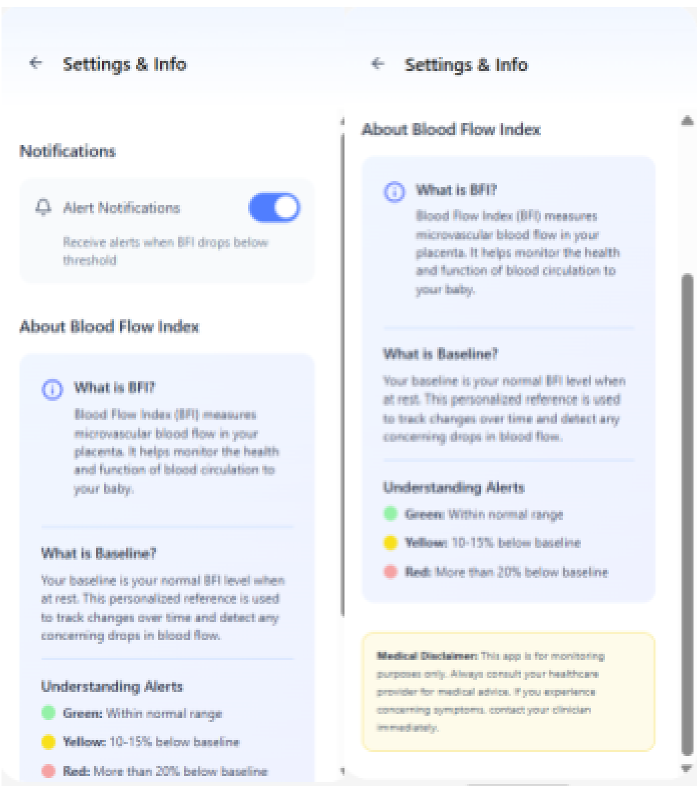
- Central electronics hub containing control PCB (Printed Circuit Board), battery, and wireless module



App Features:

- Home Screen: Displays real-time Blood Flow Index (BFI). Higher BFI indicates more blood flow; lower BFI indicates reduced perfusion.
- History Tab: Shows blood flow data over days and weeks, allowing users and clinicians to track trends.
- Alerts Tab: Provides active alerts, clinical guidance, and contact information for the care team.





Data Interpretation Pathway:

1. Continuous BFI measurements are collected by the belt
2. Data is compared to the patient-specific baseline:
   - Measured over 5–10 minutes at rest to set a patient-specific baseline
   - Can be updated periodically as pregnancy progresses.

3. Percent changes in BFI are calculated
4. Alerts are generated when thresholds are crossed
5. Data is visualized in the app for clinicians to review trends

Safety, Usability, and Accessibility

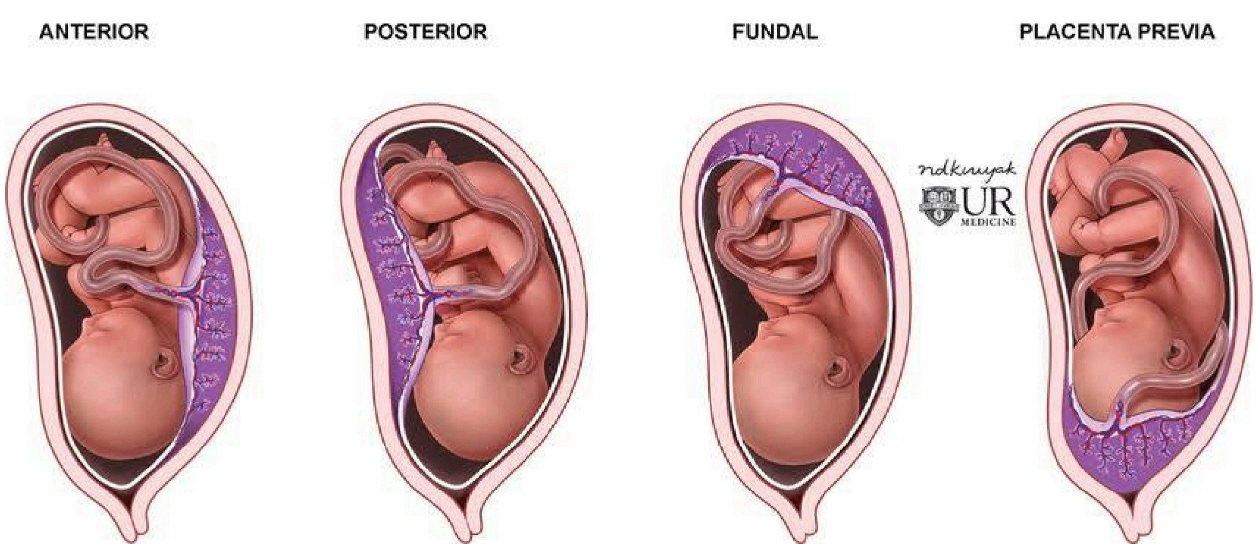
- Fully non-invasive with no skin penetration
- NIR laser power kept within established safety limits for pregnancy
- Black sensor housing blocks ambient light and prevents overheating (in Schematic)
- Encrypted data storage in app protects patient privacy
- Designed for home use, reducing the need for frequent hospital visits

Power, Sustainability & Long-Term Use

The belt is designed to be reusable throughout the entire pregnancy, reducing waste and cost compared to single-use adhesive patches. After proper cleaning and sensor replacement if needed, the device can be safely reassigned to other patients, making it more sustainable. This reusable design improves accessibility while lowering long-term material use and overall healthcare costs. The belt also uses a rechargeable battery, reducing disposable battery waste.

Anatomical Placement

Placental position directly impacts signal quality. Anterior placentas (placenta is attached to the front wall of the uterus, closest to the maternal abdomen) provide the strongest measurements because the near-infrared light travels a shorter distance through tissue. In contrast, posterior (back wall of the uterus) and fundal placentas (top of the uterus) require the light to pass through more maternal tissue, which can weaken the detected signal and increase noise. For low-lying (near the cervix) or lateral placentas(attached to the side walls), reliable



measurements may not always be feasible, representing a key limitation of the device.

Sensor Selection

We chose Diffuse Correlation Spectroscopy (DCS) sensors because they measure blood flow directly, instead of relying on indirect signals like pulse or oxygen levels. The system uses near-infrared (NIR) laser diodes (750–850 nm), which safely pass through tissue to reach the placenta without any radiation risk. Single-photon detectors were selected for their ability to pick up tiny fluctuations in light caused by moving red blood cells, making it possible to detect even small changes in placental blood flow. Together, these sensors allow continuous, non-invasive monitoring.