Project Synopsis

Multi-Analyte Microneedle Biosensor & Reusable Applicator Ecosystem

Low-Cost, Non-Invasive Continuous Maternal and Neonatal Metabolic Monitoring

Institution: Addis Ababa University (AAU)

Team: Aeterna omni3

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1. Introduction

Continuous metabolic monitoring during pregnancy and infancy could meaningfully reduce preventable maternal and neonatal deaths, yet it remains largely inaccessible in resource-constrained settings such as rural Ethiopia.

To address this challenge, we propose a "Lab-on-a-Patch" system: a minimally invasive, multiplexed dermal biosensor paired with a reusable mechanical applicator. The system is designed to provide continuous metabolic monitoring through the measurement of glucose, lactate, and ketones, with the goal of making continuous metabolic screening more accessible to rural health posts while reducing per-patient cost and disposable waste.

2. Problems Identified

Current continuous glucose monitoring systems and applicators present several limitations for resource-constrained maternal and neonatal healthcare.

- **Needle trauma:** Commercial CGMs commonly use 5–8 mm steel introducer needles, which can cause pain and needle-related anxiety, potentially reducing compliance among infants and pregnant mothers.
- **Diagnostic blind spot:** Existing devices primarily measure glucose, limiting clinicians' ability to identify concurrent warning signs associated with conditions such as neonatal sepsis, preeclampsia, or severe dehydration.
- **Material and cost waste:** Conventional applicators are often single-use plastic-and-steel assemblies that are discarded after one insertion, increasing per-unit cost and generating unnecessary biohazard waste in rural clinics.

3. Proposed Solution

The proposed system consists of a **multi-analyte microneedle biosensor, electronic pod, reusable applicator, disposable cartridge, and mobile dashboard**.

The microneedle array is designed to access interstitial fluid while remaining minimally invasive. Three electrically isolated sensing zones are used to detect different metabolic biomarkers:

- **Glucose:** Glucose oxidase (GOx)
- **Lactate:** Lactate oxidase (LOx)
- **Ketones:** Hydroxybutyrate dehydrogenase (HBDH)

The signals from these sensing zones are processed using multi-channel electronics and transmitted through **Bluetooth Low Energy (BLE)** to a mobile interface.

4. Technical Design

The sensing layer consists of a 3D-printed polymer microneedle array, with a proposed tip height of approximately 500–700 µm, mounted on a flexible polyimide substrate.

The electronic pod incorporates:

- Multi-channel potentiostat IC, such as an ADuCM355-class device
- Analog-to-digital conversion
- Bluetooth Low Energy SoC
- Coin-cell battery
- Sealed IP68-rated polycarbonate housing

The reusable applicator consists of an ABS handle, stainless-steel firing spring, and neodymium alignment magnets. A minimal-plastic disposable cartridge tray holds the patch while allowing the main applicator mechanism to be reused.

For the Phase 2 demonstration, an ESP32 or Arduino Nano, BLE module, 3D-printed handle and cartridge, and a basic mobile application interface will be used.

5. Prototype Development

The project will be developed through several stages.

First, the microneedle array geometry, sensing-zone layout, and applicator mechanism will be finalized using CAD modeling and literature-based parameters.

The electronic prototype will then be developed using a microcontroller-driven BLE circuit capable of transmitting simulated real-time glucose, lactate, and ketone trend data to a mobile dashboard.

The mechanical prototype will be 3D printed and assembled with the alignment magnets and a non-hazardous spring mechanism to demonstrate silent, low-force actuation.

Because full enzymatic validation is outside the scope of the current competition phase, the enzyme sensing zones will initially be represented through a macro-scale visual model.

6. Expected Results and Impact

As a concept-stage project, experimental biosensor data has not yet been collected. However, the proposed design is intended to provide several advantages.

The disposable cartridge is projected to reduce disposable plastic volume by more than 75% compared with commercial single-use applicators. The 0.5–0.7 mm microneedle height is

designed to reach interstitial fluid while remaining above major nerve endings and blood vessels, supporting minimally invasive application.

By combining multiple metabolic measurements in one patch with a reusable applicator and wireless data transmission, the system aims to provide a more comprehensive monitoring approach that could be suitable for resource-constrained healthcare environments.

7. Limitations and Future Work

The project is currently at the concept and prototype-development stage. Several important aspects therefore remain to be experimentally validated.

Current limitations include:

- No experimental enzymatic validation data
- Unproven multi-day biofouling resistance
- Unvalidated signal stability and cross-talk between the three sensing zones
- No finalized per-unit cost model

Future work will include:

- Benchtop enzyme-stability and biofouling testing
- Optimization and validation of the three sensing zones
- Development of a sterilization protocol for the reusable applicator
- Detailed cost-per-unit analysis for field deployment
- Small-scale clinical pilot testing in a rural Ethiopian health-post setting

The cost analysis has not yet been completed, so no prototype or final per-unit cost is claimed at this stage. It is explicitly included as part of the project's future work once the design and material requirements are sufficiently finalized.

8. Conclusion

The Lab-on-a-Patch concept proposes a reusable and minimally invasive platform for continuous monitoring of glucose, lactate, and ketones. By combining a multiplexed microneedle biosensor, reusable applicator, wireless electronics, and mobile monitoring interface, the project seeks to address both the diagnostic limitations and material waste associated with existing monitoring approaches.

Further technical validation, cost analysis, and clinical testing will be required before the system can be considered for real-world deployment.