PROVISIONAL PATENT SPECIFICATION

Title: *LactaSense – Continuous Lactic Acid Monitoring System Using Biodegradable Microneedle Arrays*

FIELD OF THE INVENTION

The present invention relates to the field of biomedical sensing and wearable health monitoring. More particularly, it concerns a flexible, skin-adherent microneedle patch for continuous, noninvasive measurement of lactate concentration in interstitial fluid through enzymatic electrochemical sensing, combined with integrated low-power electronics and wireless data transmission.

BACKGROUND OF THE INVENTION

Monitoring lactate concentration provides critical insight into metabolic performance and fatigue. Elevated lactate levels correlate with anaerobic metabolism and physical overexertion. Current lactate measurement technologies rely primarily on intermittent blood sampling or indirect estimation via heart rate or oxygen consumption. Such approaches are invasive, discontinuous, and impractical for continuous monitoring during physical activity.

Existing point-in-time lactate analyzers, such as handheld meters, require blood pricks and interrupt training, while indirect wearables infer lactate thresholds from secondary parameters lacking accuracy. Continuous glucose monitors have demonstrated feasibility for biochemical sensing through the skin, but no analogous system for lactate provides real-time, continuous operation over multiple weeks.

Therefore, there exists a need for a painless, reliable, continuous lactate monitoring system capable of real-time data transmission without interrupting activity, maintaining biocompatibility, and operating over extended wear periods.

SUMMARY OF THE INVENTION

The invention provides **LactaSense**, a flexible, biodegradable microneedle patch capable of continuously monitoring lactate levels in interstitial fluid. Each microneedle is composed of staged-dissolution polymer layers—such as polyvinylpyrrolidone (PVP), poly(lactic-co-glycolic acid) (PLGA 50:50 and 75:25), and polycaprolactone (PCL)—that degrade sequentially to expose fresh sensing surfaces weekly for approximately one month of operation.

The microneedle tips are coated with a conductive enzymatic sensing layer containing lactate oxidase immobilized within a polymer matrix. Lactate present in interstitial fluid reacts enzymatically to generate hydrogen peroxide, which is detected amperometrically by integrated electrodes. The resultant current is converted into a digital signal by a potentiostat and analog-to-digital converter (ADC) housed on a flexible printed circuit board (PCB). A microcontroller with integrated Bluetooth Low Energy (BLE) transmits readings wirelessly to a paired mobile device for visualization, calibration, and cloud synchronization.

The invention integrates these components into a single adhesive patch that conforms to the skin, operates painlessly and noninvasively, and continuously provides lactate data to a smartphone or cloud platform for athletic training, clinical monitoring, and metabolic analysis.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 – *Exploded Cross-Section of LactaSense Patch*
Shows the layered architecture including the breathable waterproof polyurethane film, flexible PCB with microcontroller, potentiostat, BLE module, thin-film lithium battery, conductive

contact pads, polymer microneedle substrate, biodegradable microneedles, adhesive layer, and skin strata.

FIG. 2 – *Layered Biodegradable Microneedle with Staged Dissolution*
Illustrates the four polymer layers—PVP, PLGA (50:50), PLGA (75:25), and PCL—representing sequential dissolution stages over a 4-week period. A lactate oxidase + conductor region at the tip converts lactate to hydrogen peroxide for electrochemical detection.

FIG. 3 – *Electronic Signal Flow of LactaSense Patch*
Depicts the top-row signal chain from electrodes through the transimpedance amplifier, ADC, and microcontroller/BLE module. The bottom row includes the power source and smartphone interface, with dashed lines indicating power distribution and solid arrows indicating signal flow.

FIG. 4 – *BLE Data Path and Mobile Integration of LactaSense System*
Shows the full data flow from the patch to the smartphone (BLE 5.0), cloud storage, and user dashboard for analytics and visualization.

DETAILED DESCRIPTION OF THE INVENTION

1. Microneedle Structure, Composition, and Staged Dissolution

The microneedle array comprises four layers of biodegradable polymers configured for sequential dissolution to maintain continuous operation over approximately 30 days. Each microneedle measures approximately 400–800 µm in length, sufficient to penetrate the stratum corneum and access the interstitial fluid without contacting blood vessels or nerves. The needle tip radius is less than 30 µm to minimize insertion force and ensure painless application.

The staged-dissolution profile is achieved through material composition:

- **Outer layer:** Polyvinylpyrrolidone (PVP) for rapid hydration and dissolution within hours, initiating immediate sensing contact.
- **Intermediate layers:** Poly(lactic-co-glycolic acid) (PLGA) 50:50 and 75:25 providing controlled degradation over successive weeks.

- **Base layer:** Polycaprolactone (PCL) for structural stability and terminal biodegradation.

The polymers are cast sequentially in micromolds using layered casting or spin-coating, forming mechanically stable, bonded interfaces. Each layer dissolves to expose a new enzymatic sensing region at weekly intervals, enabling four distinct sensing stages per patch. Microneedles are mounted to a polymer substrate that interfaces with conductive pads on the flexible PCB (FIG. 1).

2. Enzymatic Electrochemical Sensing Chemistry

Each microneedle incorporates a working electrode coated with lactate oxidase (LOx), immobilized within a conductive polymer or hydrogel matrix such as polyaniline (PANI), Nafion, or poly(HEMA). The enzyme catalyzes the oxidation of lactate to pyruvate, producing hydrogen peroxide (H_2O_2). The resulting redox reaction generates a current proportional to lactate concentration.

A reference electrode (Ag/AgCl) and counter electrode complete the three-electrode configuration. Redox mediators such as Prussian Blue or ferrocene derivatives facilitate electron transfer at low potentials (~0.35 V vs Ag/AgCl), improving selectivity and minimizing interference from other electroactive species. A permselective Nafion layer prevents interference from urate, ascorbate, and acetaminophen. Stabilizers (e.g., BSA, trehalose) maintain enzymatic activity over multi-week operation.

Typical performance parameters include:

- Sensitivity: ~1–2 µA/mM over 0.5–25 mM range
- Response time (t_{90}): < 60 seconds
- Limit of detection: < 0.1 mM
- Drift: < 5% per week under physiological conditions

The enzymatic coating is concentrated near the needle tip for localized sensing within interstitial fluid (FIG. 2).

3. Electronics, Potentiostat, and Power Management

The sensing current (10^{-9}–10^{-5} A) is converted to a voltage signal by a low-noise transimpedance amplifier (TIA) such as the TI OPA333 or Maxim MAX9913. The potentiostat circuit maintains a constant bias between working and reference electrodes (approximately 0.35 V). The amplified signal is digitized via a 12–16 bit ADC integrated within or external to the microcontroller.

A microcontroller with integrated BLE (e.g., Nordic nRF52832 or TI CC2640R2F) manages sampling, data averaging, and wireless transmission. Sampling occurs at 0.2–1 Hz, sufficient for the slow kinetics of lactate dynamics. Firmware filters high-frequency noise through digital averaging and low-pass analog filtering.

Power is supplied by a thin-film Li-ion battery (≈ 30–100 mAh). Power management ICs regulate voltage at 3.3 V. The device employs aggressive duty-cycling, sleeping between measurements to achieve average currents < 100 µA, enabling approximately 30 days of operation per patch (FIG. 3).

4. Wireless Data Pathway and Mobile/Cloud Integration

The BLE subsystem implements a custom GATT service modeled on the Bluetooth Continuous Glucose Monitoring Service (CGMS). The primary characteristics include:

- **Lactate Measurement Characteristic:** current lactate concentration (16 bit, in 0.01 mM units), timestamp, and status flags.
- **Lactate Sensor Status:** battery level, sensor stage, and calibration state.
- **Control Point:** app-initiated recalibration or data retrieval commands.

Each reading (4–8 bytes) is transmitted at intervals of 5 seconds during exercise and 1 minute during rest. The firmware caches readings if the phone disconnects and retransmits upon reconnection. BLE connection intervals and peripheral latency are configured to minimize radio-on time, extending battery life.

The smartphone application receives data, performs temperature compensation (≈ 2–4% per °C correction), and maps interstitial fluid lactate to estimated blood lactate using a dynamic baseline algorithm. Data are uploaded to a cloud analytics platform for long-term tracking, trend visualization, and predictive fatigue modeling (FIG. 4).

5. Mechanical Construction and Biocompatibility

The patch layers comprise:

- **Top Layer:** Medical-grade polyurethane film, breathable and waterproof, providing mechanical protection.
- **Adhesive Interface:** Silicone or acrylic pressure-sensitive adhesive with high moisture vapor transmission rate (MVTR) to prevent skin irritation.
- **Middle Layer:** Flexible polyimide PCB containing electronic components, bonded by lamination or medical-grade adhesive.
- **Bottom Layer:** Microneedle substrate aligned to conductive pads using conductive epoxy or anisotropic conductive film.

The overall thickness is ≤ 3 mm, allowing flexibility and skin conformity. The patch adheres securely for 30 days while remaining water-resistant during sweating or showering. All materials comply with ISO 10993 for biocompatibility and IEC 60601 for electrical safety. The microneedles dissolve completely, leaving no sharp waste.

6. Calibration and Data Processing

The system supports one- or two-point calibration based on user input or automatic baseline correction. During periods of rest, baseline current is assumed to correspond to ~1 mM lactate; firmware adjusts accordingly. A redundant “blank” electrode (without enzyme) measures background current for drift subtraction. The mobile application maintains a conversion model: Lactate (mM) = $(I - I_0)/S$, where I_0 is baseline current and S is sensor sensitivity determined during factory calibration.

Algorithms compensate for temperature and diffusion lag (~5–10 minutes between ISF and blood lactate). The corrected data are displayed in real-time graphs and may trigger alerts when approaching user-defined thresholds.

7. Use and Application

The user applies the patch on the upper arm or torso using a single-press applicator. The microneedles painlessly penetrate the stratum corneum without bleeding. The patch remains functional for approximately one month, transmitting lactate readings continuously to the smartphone application. The patch is intended for athletes, patients, and clinicians seeking continuous biochemical monitoring for fatigue management, metabolic assessment, or rehabilitation.

POTENTIAL CLAIMS

1. A wearable microneedle patch comprising:
   (a) a biodegradable microneedle array formed of staged-dissolution polymer layers;
   (b) a lactate oxidase–based enzymatic electrochemical sensor integrated on said microneedles;
   (c) a flexible printed circuit board comprising a potentiostat, analog-to-digital converter, microcontroller, and Bluetooth Low Energy transceiver; and
   (d) a thin-film battery and adhesive polyurethane film, wherein the patch continuously measures lactate concentration in interstitial fluid and wirelessly transmits data to an external device.

2. The patch of claim 1, wherein the microneedles comprise sequential layers of PVP, PLGA (50:50), PLGA (75:25), and PCL configured to dissolve at weekly intervals, exposing fresh sensor regions over a four-week period.

3. The patch of claim 1, wherein the lactate oxidase enzyme is immobilized within a conductive polymer matrix selected from polyaniline, poly(HEMA), or Nafion and includes

redox mediators to detect hydrogen peroxide at low potential.

4. The patch of claim 1, wherein the electronics operate at a sampling rate of 0.2–1 Hz and transmit data over BLE using a GATT-compliant lactate measurement profile.

5. The patch of claim 1, wherein the system applies temperature compensation and baseline calibration algorithms to correct for enzymatic drift and interstitial-to-blood delay.

6. The patch of claim 1, wherein the device operates continuously for at least 30 days using a battery capacity under 100 mAh through duty-cycled firmware.

7. A method of continuous lactate monitoring comprising:
   (a) applying the patch of claim 1 to a user's skin;
   (b) allowing the microneedles to access interstitial fluid;
   (c) measuring electrochemical current proportional to lactate concentration; and
   (d) transmitting the resulting data to a mobile or cloud platform for real-time visualization and analysis.

ABSTRACT

A continuous, noninvasive lactate monitoring system is disclosed, comprising a flexible microneedle patch with staged-dissolution biodegradable polymer layers for multi-week operation. The microneedles incorporate a lactate oxidase–based enzymatic electrochemical sensor that converts lactate in interstitial fluid into measurable current. Integrated low-power electronics on a flexible substrate amplify, digitize, and transmit the data via Bluetooth Low Energy to a smartphone for calibration, temperature compensation, and cloud integration. The device enables real-time biochemical monitoring for athletic, clinical, and wellness applications without blood sampling or user intervention.

DRAWINGS

FIG.1 – Exploded Cross Section of LactaSense Patch

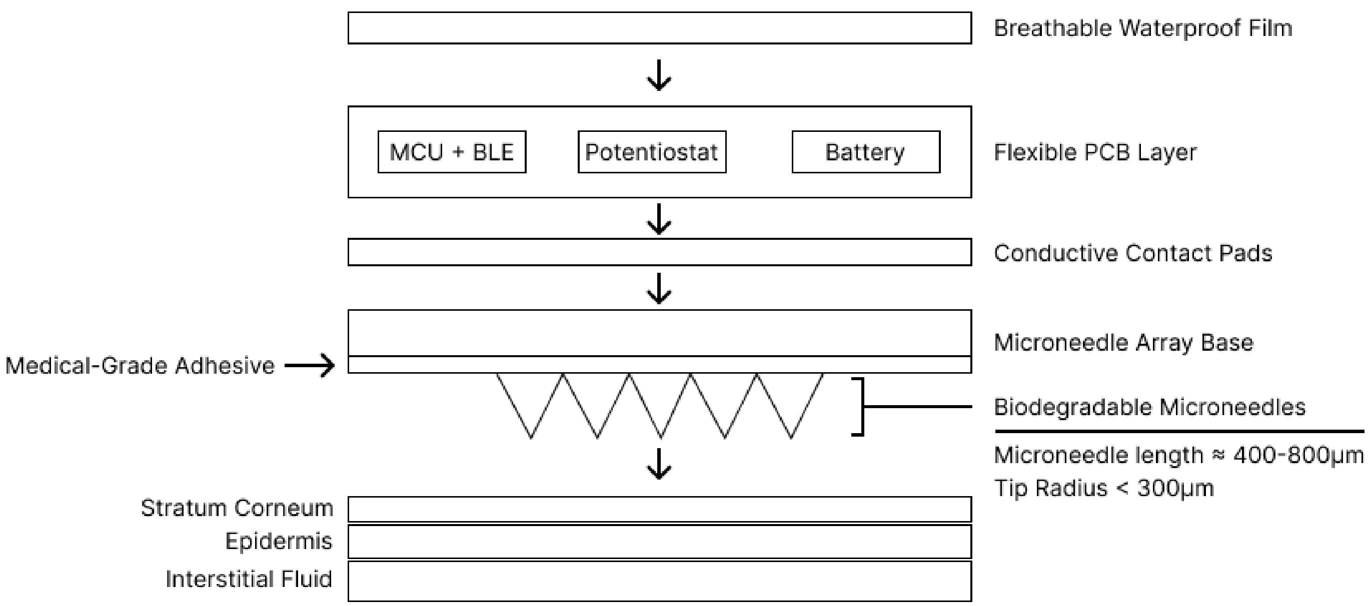

FIG. 2 – Layered Biodegradable Microneedle with Staged Dissolution

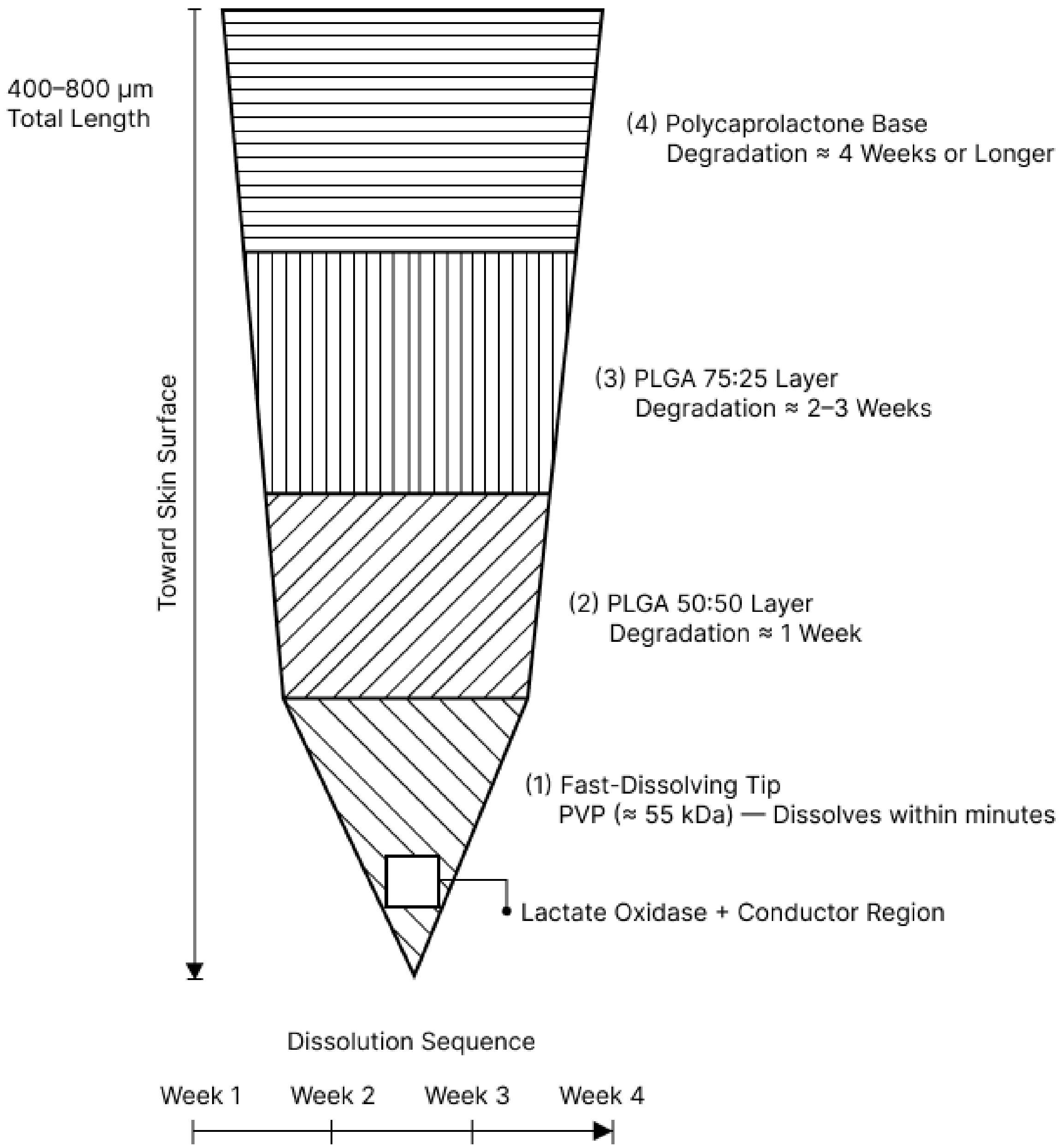

FIG. 3 – Electronic Signal Flow of LactaSense Patch

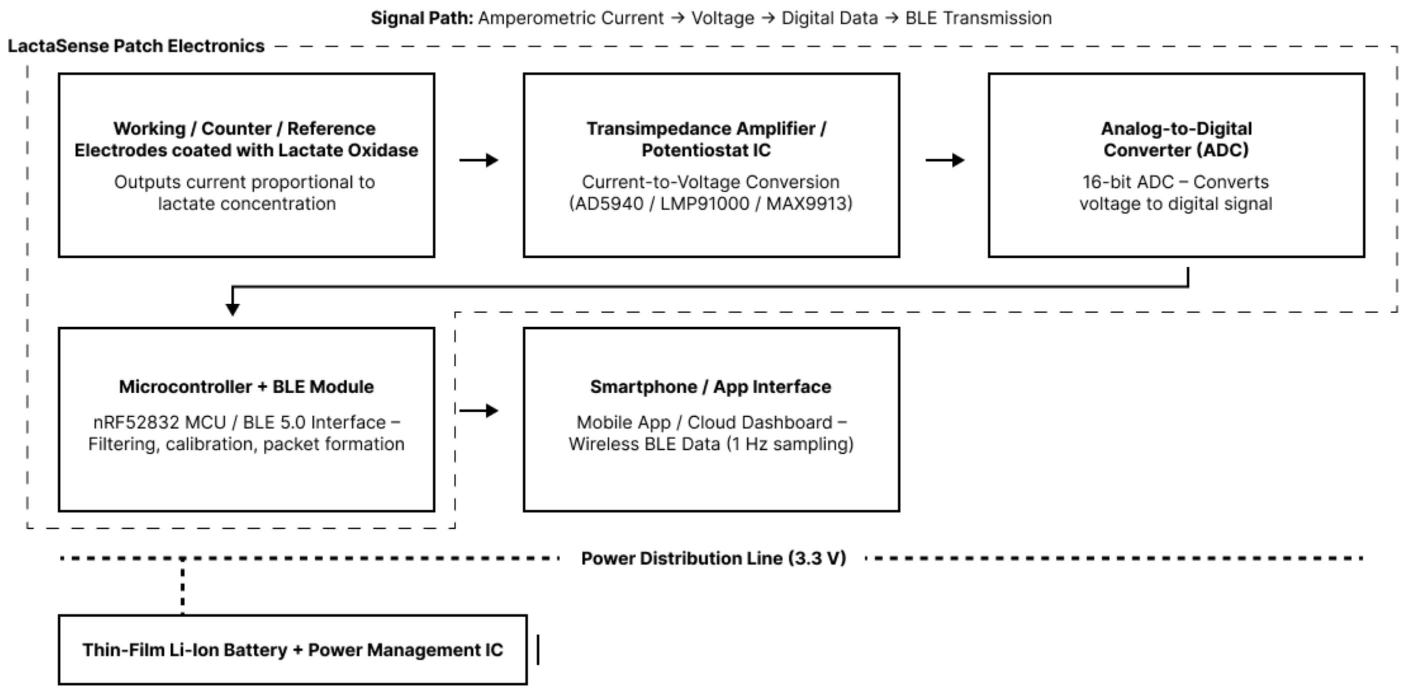

FIG. 4 – BLE Data Path and Mobile Integration of LactaSense System