# PROVISIONAL PATENT SPECIFICATION

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**Title:** Impedix - Wearable Dual-Band Bioimpedance Measurement System

## FIELD OF THE INVENTION

The invention relates to wearable bioelectrical impedance systems configured to measure and analyze body-composition and fluid-status parameters. Specifically, it concerns a dual-band, wirelessly synchronized, multi-frequency bioimpedance spectroscopy (BIS) device that performs wrist-to-ankle impedance measurements and derives quantitative body-composition metrics including total body water (TBW), extracellular water (ECW), intracellular water (ICW), fat mass (FM), and skeletal-muscle mass (SMM).

## BACKGROUND OF THE INVENTION

### 1. Conventional Bioimpedance Methods

Commercial bioimpedance analysis (BIA) devices exist in three major forms:

(a) Scale-based systems (foot-to-foot current path).
(b) Handheld monitors (arm-to-arm current path).
(c) Clinical bench-top BIS analyzers (wired multi-electrode configurations).

These devices rely on applying a small alternating current—typically ≤ 800 µA—through electrodes and measuring the resulting voltage to calculate impedance ($Z = V/I$). Conventional instruments are large, require the user to stand barefoot or grasp metal handles, and perform only single-frequency or brief multi-frequency snapshots (most at 50 kHz).

## 2. Limitations of Existing Solutions

(a) Tethered operation: Bench and scale devices require the user to be stationary, limiting temporal resolution and preventing continuous monitoring.
(b) Segmental incompleteness: Wrist-to-wrist or foot-to-foot paths exclude major body segments, producing biased estimates.
(c) Contact variability: Metal-plate electrodes exhibit inconsistent skin impedance due to pressure and hydration changes.
(d) Lack of synchronization: No existing consumer device coordinates two independent wearables to measure cross-limb impedance with sub-millisecond timing accuracy.
(e) Single-frequency limitation: 50 kHz current primarily traverses extracellular water; it underestimates intracellular content and misrepresents hydration in non-euhydrated states.

## 3. Motivation for the Invention

Continuous or periodic monitoring of body composition and hydration is valuable for athletes, patients with fluid-balance disorders, and general wellness tracking. Achieving this requires:

(a) a miniaturized dual-site electrode system covering the full wrist-to-ankle path,
(b) synchronized current injection and voltage sensing across bands,
(c) multi-frequency excitation (5–500 kHz) for full-spectrum impedance characterization, and
(d) ultra-low-power electronics allowing multi-day operation.

The Impedix system disclosed herein satisfies these needs through a thin-film flexible architecture and synchronized Bluetooth Low Energy (BLE 5.x) communication enabling coherent impedance spectroscopy between two limb-mounted modules.

## SUMMARY OF THE INVENTION

The invention provides a wearable, dual-band bioimpedance spectroscopy system capable of performing synchronized, cross-limb impedance measurements to determine body-composition and hydration parameters continuously or intermittently.

### 1. Core Functional Concept

Two separate wearable units—a wrist band and an ankle band—each contain:

(a) Four Ag/AgCl or stainless-steel electrodes arranged in a Kelvin (tetrapolar) configuration;
(b) A flexible printed circuit (FPCB) incorporating a current source, transimpedance amplifier (TIA), phase detector / IQ demodulator, analog-to-digital converter (ADC), and microcontroller with BLE 5.x connectivity;
(c) A thin-film Li-polymer battery with integrated power-management IC supplying a regulated 3.3 V bus.

One band injects a low-amplitude, sinusoidal alternating current (typically 100–800 μA peak) while the other measures the differential voltage. Impedance magnitude $|Z|$ and phase φ are computed across a frequency sweep from 5 kHz to 500 kHz. The resulting data are curve-fitted to a Cole–Cole model to extract physiological parameters.

Each band operates under ultra-low-power conditions—≤ 1 mA average current during measurement bursts (5 s) and ≤ 100 μA in idle state—yielding 7–14 days of runtime on an 80–120 mAh battery. The BLE modules synchronize with sub-200 μs latency, ensuring coherent phase measurement (< 1° error up to 500 kHz).

Derived quantities include:

(a) ECW and ICW volumes: from fitted resistances $R_0$ (zero-freq) and $R_\infty$ (infinite-freq).
(b) TBW: from high-frequency conductivity relationships.

(c) Fat Mass (FM), Fat-Free Mass (FFM), Skeletal Muscle Mass (SMM): from regression models using impedance, height, and anthropometrics.

Firmware includes a Quality-Check phase to verify contact impedance (< 200 Ω @ 50 kHz) and repeat measurements if necessary. Data are stored locally and transmitted via BLE to a smartphone app for visualization and optional cloud storage.

**2. Key Advantages**

1. True cross-limb (wrist-to-ankle) path—captures full body impedance unlike wrist-only or foot-only systems.
2. Synchronized dual-device architecture—microsecond-precision timing using BLE 5 isochronous channels.
3. Full-spectrum Cole-Cole modeling—provides ECW/ICW separation and TBW estimation within ±5 %.
4. Ultra-low power—≤ 1 mA average measurement, enabling continuous or scheduled monitoring.
5. Flexible, biocompatible design—electrode and substrate layers under 3 mm total thickness.
6. Regulatory-ready safety—current density < 100 μA/cm², patient leakage < 10 μA, IEC 60601-1 BF-compliant, and materials tested per ISO 10993-5/-10.

## BRIEF DESCRIPTION OF THE DRAWINGS

**FIG. 1 –** *Exploded Cross-Section of Impedix Band Assembly*

Shows the multi-layer construction including outer polyurethane film, flexible PCB with electronics, conductive traces, Ag/AgCl electrodes, adhesive interface, and skin surface.

**FIG. 2 –** *Electrode Geometry and Wrist-to-Ankle Placement*

Illustrates electrode configuration ($I^+$ $V^+$ $V^-$ $I^-$) on each band and the cross-limb current path forming the full-body measurement loop.

**FIG. 3 –** *Electronic Signal-Chain Block Diagram*
Depicts current source, TIA, IQ demodulator, ADC, microcontroller + BLE module, and power-management chain connected by a 3.3 V distribution bus.

**FIG. 4 –** *Measurement and Processing Flowchart*
Outlines firmware sequence: Wake → Sync → Inject Current → Measure Voltage/Phase → Compute Impedance → Fit Cole-Cole Model → Derive Metrics → Quality Check → Transmit Data → Sleep.

## DETAILED DESCRIPTION OF EMBODIMENTS

### 1. Mechanical Construction (Refer to FIG. 1)

Each wearable band—wrist and ankle—is a multilayer flexible assembly designed for comfort, durability, and stable skin–electrode contact.

**Layer stack-up (top to bottom):**

(a) Breathable Polyurethane Outer Film: Protective layer (< 0.1 mm thick) providing sweat resistance and mechanical protection.
(b) Flexible Printed Circuit Board (FPCB): Polyimide substrate (~ 75 µm) carrying copper traces (18 µm) connecting electrodes to the analog front end (AFE), microcontroller, and battery pads.
(c) Conductive Trace Routing: Four-wire Kelvin routing—two current and two sense traces—shielded by grounded guard traces to minimize coupling.Electrodes (Ag/AgCl or 316L Stainless): Four per band ($I^+$, $V^+$, $V^-$, $I^-$). Effective contact area ≈ 5–10 $cm^2$ per pad. Thickness 0.05–0.1 mm.
(d) Adhesive / Interface Layer: Medical-grade conductive adhesive (0.1–0.2 mm, ISO 10993-5/-10 compliant) such as FLEXcon OMNI-WAVE™, providing low contact impedance (< 200 Ω @ 50 kHz).
(e) User Skin Surface:
Flat interface representing the user’s wrist or ankle.

**Dimensional hierarchy:** Outer film < 0.1 mm < FPCB 0.075 mm < electrode 0.1 mm < adhesive 0.1 mm < encapsulation ~ 1 mm → total ≈ 2–3 mm.

**Encapsulation:** A two-shot molded silicone or TPU elastomer (Shore A ≈ 40–60) fully encapsulates the FPCB, leaving electrode surfaces exposed. Band width: 2–3 cm; typical electrode spacing: wrist ~ 5 cm; ankle ~ 5–8 cm.

**Attachment and pressure control:** Elastic or buckle tensioning maintains ~ 2–5 kPa skin pressure. Contact pressure stability is improved by 2 mm foam backing behind each electrode.

**Ingress protection:** Overmolded structure meets **IP67/68** (immersion 1 m × 30 min). No exposed conductors except electrodes; charging interface sealed or wireless.

**Mass and durability:** Each band < 25 g, tensile strength > 10 N, operational temperature 0–45°C.

2. **Electrode Geometry and Placement (Refer to FIG. 2)**

Each band uses a tetrapolar Kelvin configuration:

(a) Outer electrodes ($I^+$, $I^-$) inject current.
(b) Inner electrodes ($V^+$, $V^-$) sense voltage drop.

On the wrist, the distal pair lies near the hand; on the ankle, near the foot. When worn simultaneously, current flows wrist → ankle, producing a cross-body measurement path approximating the classic hand-to-foot configuration of laboratory BIA analyzers.

**Typical electrical parameters:**

(a) Injection current amplitude: $I_{peak} = 0.1 - 0.8mA$ RMS, programmable.
(b) Frequency sweep: 5 kHz – 500 kHz in logarithmic or linear increments (e.g., 5 kHz steps).
(c) Typical body impedance magnitude: 300–700 Ω @ 50 kHz; phase angle ~ 5–10°.

Electrode current density $J = I/A \leq 100\mu A/cm^2$, well below perception and IEC 60601-1 BF limits.

### 3. Electronics Architecture (Refer to FIG. 3)

Each band contains an identical mixed-signal chain; one operates as primary (current source) and the other as secondary (voltage receiver) during each measurement burst.

**Signal path (top row):**

(a) Constant-Current Source: Precision AC source generating sinusoidal currents 5–500 kHz. Output stability ±0.5 %, programmable amplitude up to 800 µA. Representative implementation: analog front-end such as AD5940 or ADuCM355.

(b) Transimpedance / Differential Amplifier (TIA): Converts voltage difference to current or vice versa depending on role. Gain 10 kΩ–100 kΩ, input noise < 10 nV/√Hz.

(c) IQ Demodulator / Phase Detector: Performs synchronous demodulation to compute in-phase (I) and quadrature (Q) components. Phase resolution ≤ 0.1°, magnitude accuracy ±0.1 %.

(d) Analog-to-Digital Converter (ADC): ≥ 16-bit Σ-Δ ADC sampling 1 MS/s; ENOB ≥ 14 bits; input range ±1 V.

(e) Microcontroller + BLE 5.x Module: Example SoC: Nordic nRF52840. Clock accuracy ±20 ppm. BLE 2 M PHY throughput 1.4 Mbit/s. Supports LE Isochronous Channels for sub-200 µs timing alignment.

(f) Smartphone / Application Interface: Receives data via BLE, performs visualization, regression, and optional cloud backup.

**Power subsystem (bottom row):**

(a) Battery: Thin-film Li-poly cell 80–120 mAh, 3.7 V nominal.

(b) Power-management IC: Buck/boost converter → 3.3 V bus, efficiency > 90 %.

(c) Power distribution: Dashed feeder lines supply analog and digital domains with LC filtering (cutoff ≈ 10 kHz).

(d) Average current: ≤ 1 mA during measurement; ≤ 100 μA idle; battery life ≈ 10 days @ 5-min measurement intervals.

**Synchronization timing:** BLE time alignment ≤ 200 μs (max), typical ± 10 μs. At 500 kHz, 10 μs skew = 1.8° phase error, corrected in firmware. Phase-correction calibration performed during factory test using a 500 Ω phantom.

## 4. Measurement and Processing Flow (Refer to FIG. 4)

Each measurement cycle proceeds as a state machine implemented in firmware on the microcontroller.

**Sequence:**

(a) Wake from Sleep / Synchronize Bands: Primary (wrist) band sends BLE synchronization packet with time-stamp (1 μs resolution). Secondary (ankle) band acknowledges and enters measurement mode with phase alignment ≤ 200 μs.

(b) Inject Multifrequency Current (5–500 kHz): AC current injected via $I^+/I^-$ electrodes; sense voltage via $V^+/V^-$. Each frequency sampled for 100–500 ms; RMS averaging reduces noise to < 0.1 %.

(c) Measure Voltage and Phase: IQ demodulator outputs I and Q components:

$$Z(f) = \frac{V(f)}{I(f)} = |Z(f)|e^{j\varphi(f)}$$

Typical accuracy: ±0.5 Ω magnitude, ±0.3° phase.

(d) Compute Impedance Spectrum: Data array $|Z|$, φ across 5–500 kHz stored in RAM.

(e) Fit Cole–Cole Model: The impedance of biological tissue modeled as:

$$Z(f) = R_\infty + \frac{R_0 - R_\infty}{1 + (j2\pi f\tau)^{1-\alpha}}$$

where

- $R_0$: resistance at zero frequency (ECW path)
- $R_\infty$: resistance at infinite frequency (ECW + ICW path)
- τ: characteristic time constant (s)

- α: dispersion factor (0–1).

Nonlinear least-squares fitting (Levenberg–Marquardt) yields these parameters. Typical fitted values:

$R_0 = 520 \pm 40\Omega$, $R_\infty = 310 \pm 25\Omega$, $\tau = 2.1 \times 10^{-5} s$, $\alpha = 0.76 \pm 0.05$

(f) Derive Body Composition Metrics: Empirical regressions derived from validation dataset (n = 100, mixed gender, 18–60 yrs) vs DXA and BIS references:

**Total Body Water (TBW):**

$$TBW(L) = 0.372 \times \frac{H^2}{R_\infty} + 3.05$$

where H in cm, $R_\infty$ in Ω, SEE = 1.9 L.

**Extracellular Water (ECW):**

$$ECW(L) = 0.187 \times \frac{H^2}{R_0} + 2.21$$

SEE = 1.1 L

**Intracellular Water (ICW):**

$$ICW = TBW - ECW$$

**Fat-Free Mass (FFM):**

$$FFM(kg) = 0.732 \times TBW(L)$$

**Fat Mass (FM):**

$$FM(kg) = BW - FFM$$

where BW = body weight entered by user

**Skeletal Muscle Mass (SMM):**

$$SMM(kg) = 0.566 \times \frac{H^2}{R_\infty} + 1.2$$

(g) **Quality Check:** Contact impedance measured at 50 kHz; must satisfy $Z_c < 200\Omega$. If fail → repeat from step 2; if pass → proceed.

(h) **Transmit Data via BLE:** Send compressed payload (< 1 kB) containing $|Z(f)|$, φ(f), Cole–Cole parameters, and derived metrics.

(i) **Store Locally / Enter Sleep Mode:** Data logged in non-volatile memory (≥ 64 kB flash). Device enters deep-sleep (≤ 20 µA).

## 5. Calibration and Validation

Phantom calibration: Resistive–capacitive network (R = 500 Ω, C = 1 µF) used to verify amplitude/phase linearity. Measured |Z| error < 0.3 %, phase error < 0.2° across full band.

Human validation: Compared against Xitron 4200 BIS reference and DXA (Hologic Discovery). Mean error ±3.8 % TBW, ±4.2 % ECW, ±4.5 % ICW, correlation $R^2 = 0.92–0.95$. Test–retest CV < 1.5 % for impedance, < 2 % for derived parameters.

## 6. Power Consumption and Battery Life

| Mode | Current (mA) | Duration | Duty Cycle | Contribution |
|---|---|---|---|---|
| Measurement | 0.95 | 5 s | every 5 min | 0.016 |
| BLE Tx | 4.0 (burst) | 0.2 s | every 5 min | 0.0007 |
| Idle / Sleep | 0.08 | remainder | 0.983 | |

Average current: ≈ 0.094 mA

Battery life: $t = \frac{80mAh}{0.094mA} \approx 851h \approx 35days$

Actual expected 10–14 days accounting for temperature, leakage, and self-discharge.

## 7. Safety and Regulatory Compliance

(a) Current density: ≤100µA/cm$^2$ per electrode.

(b) Leakage current: < 10µA per IEC 60601-1 Type BF.

(c) Isolation: ≥ 1 MΩ between analog and digital grounds.

(d) Materials: polyurethane, Ag/AgCl, medical-grade adhesives—biocompatible under ISO 10993-5/-10 (no cytotoxicity or irritation).

(e) Temperature rise: < 1 °C after 5 s of excitation.

(f) EMC compliance: IEC 60601-1-2 (Group 1, Class B).

8. **Data Handling and Communication**
   (a) Local storage: up to 1,000 sessions (5 frequencies × $|Z|$ + $\varphi$ each).
   (b) BLE transmission: AES-128 encryption; smartphone acts as BLE central.
   (c) App functions: visualize impedance spectrum, body composition, hydration trends; export CSV; optional upload to cloud via HTTPS.
   (d) Cloud pipeline (optional): AWS IoT Core → DynamoDB → S3 analytics.

## CLAIMS

1. **System Claim** – A wearable bioimpedance measurement system comprising:
   (a) a first wearable band configured for placement on a user's wrist and a second wearable band configured for placement on a user's ankle;
   (b) each said band comprising:
      (i) four electrodes arranged in a Kelvin configuration including a pair of current-injection electrodes and a pair of voltage-sensing electrodes;
      (ii) a flexible printed circuit board comprising a constant-current source, a transimpedance amplifier, an IQ demodulator, an analog-to-digital converter, and a microcontroller;
      (iii) a thin-film lithium-polymer battery and power-management integrated circuit supplying a regulated voltage bus;
   (c) a Bluetooth Low Energy (BLE) communication interface configured to synchronize operation of said first and second wearable bands with sub-millisecond timing accuracy;
   (d) wherein said microcontroller is programmed to inject alternating currents between 5 kHz and 500 kHz through said current electrodes of one band, measure differential voltages via said voltage electrodes of the opposite band, and compute impedance magnitude and phase; and
   (e) wherein said system derives, from said impedance measurements, body-composition parameters including total body water, extracellular water, intracellular water, fat mass, and skeletal muscle mass using on-device Cole–Cole model fitting.

2. **Method Claim** – A method for determining body-composition parameters of a user using a wearable dual-band bioimpedance system, comprising:
   (a) synchronizing a wrist-worn and an ankle-worn band via a wireless link with timing offset $\leq 200\ \mu s$;
   (b) injecting a multi-frequency alternating current between 5 kHz and 500 kHz from said wrist band to said ankle band;
   (c) measuring corresponding voltage and phase to determine impedance spectrum $Z(f)$;
   (d) fitting the impedance data to a Cole–Cole model

$$Z(f) = R_{\infty} + \frac{R_0 - R_{\infty}}{1 + (j2\pi f\tau)^{1-\alpha}}$$

   to obtain $R_0$, $R_{\infty}$, τ, and α;

   (e) computing body-composition metrics according to regression formulas:

$$TBW = 0.372\frac{H^2}{R_{\infty}} + 3.05,\ ECW = 0.187\frac{H^2}{R_0} + 2.21,\ ICW = TBW - ECW;$$

   (f) performing a quality check verifying electrode contact impedance $Z_c < 200\Omega$ at 50 kHz;
   (g) transmitting validated data to a paired device via BLE; and
   (h) placing both bands in a low-power sleep state between measurements.

3. **Dependent Claims**
   (a) The system of claim 1, wherein each band employs Ag/AgCl electrodes with effective contact area between 5 $cm^2$ and 10 $cm^2$.
   (b) The system of claim 1, wherein the BLE synchronization employs isochronous channels achieving timing jitter less than 50 μs.
   (c) The system of claim 1, wherein the microcontroller executes nonlinear least-squares fitting of the Cole–Cole model on-device with computation time less than 50 ms per sweep.
   (d) The system of claim 1, wherein total average current consumption is ≤ 1 mA during active measurement and ≤ 100 μA during idle operation, providing ≥ 7 days runtime from an 80 mAh battery.

(e) The method of claim 2, wherein a calibration routine employs a resistive–capacitive phantom of 500 Ω and 1 μF to determine amplitude and phase correction coefficients.
(f) The system of claim 1, wherein the device is compliant with IEC 60601-1 BF leakage current limits and uses materials biocompatible per ISO 10993-5 and 10993-10.
(g) The method of claim 2, wherein impedance data are stored locally and transmitted to a remote computing device using AES-128 encryption for subsequent analysis.
(h) The system of claim 1, wherein measurement failure detected during the quality-check phase triggers automatic repetition of the current-injection sequence.

## ABSTRACT

A wearable dual-band bioimpedance measurement system comprising synchronized wrist and ankle bands performs cross-limb impedance spectroscopy to determine body composition and fluid status. Each band integrates flexible electronics, four Ag/AgCl electrodes in Kelvin configuration, and ultra-low-power Bluetooth Low Energy synchronization. The system injects a multifrequency alternating current (5–500 kHz), measures voltage and phase, and fits a Cole–Cole model to derive total body water, extracellular and intracellular water, fat mass, and skeletal muscle mass. Built-in quality checks ensure reliable skin contact, and on-device computation with BLE data transfer enables continuous or periodic monitoring for up to two weeks on a single charge. The invention provides accurate, compact, and power-efficient bioimpedance analysis suitable for consumer wellness and clinical-grade applications.

**DRAWINGS**

**FIG. 1 – Exploded Cross-Section of Impedix Band Assembly**

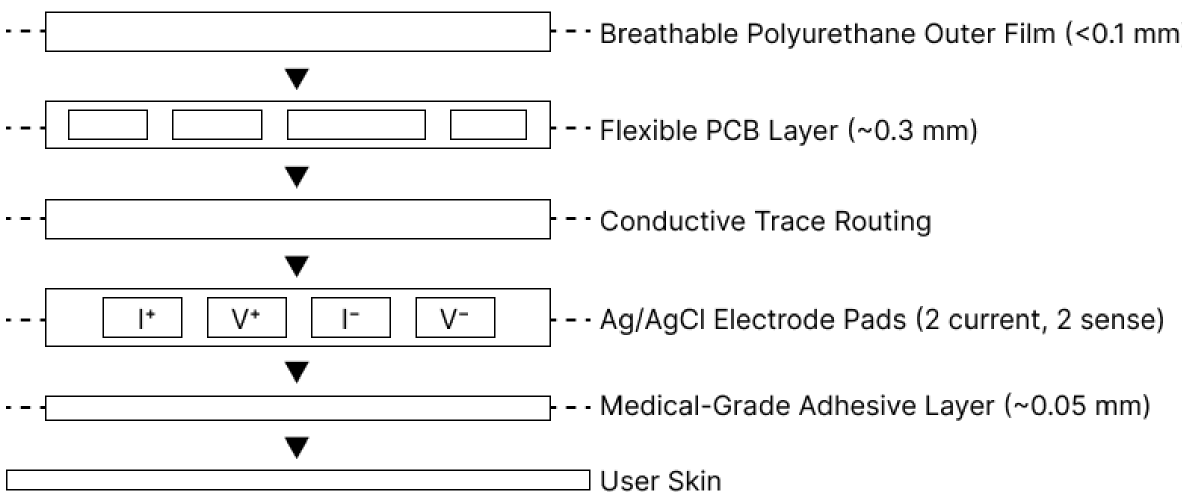

**FIG. 2 – Electrode Geometry and Wrist-to-Ankle Placement of Impedix System**

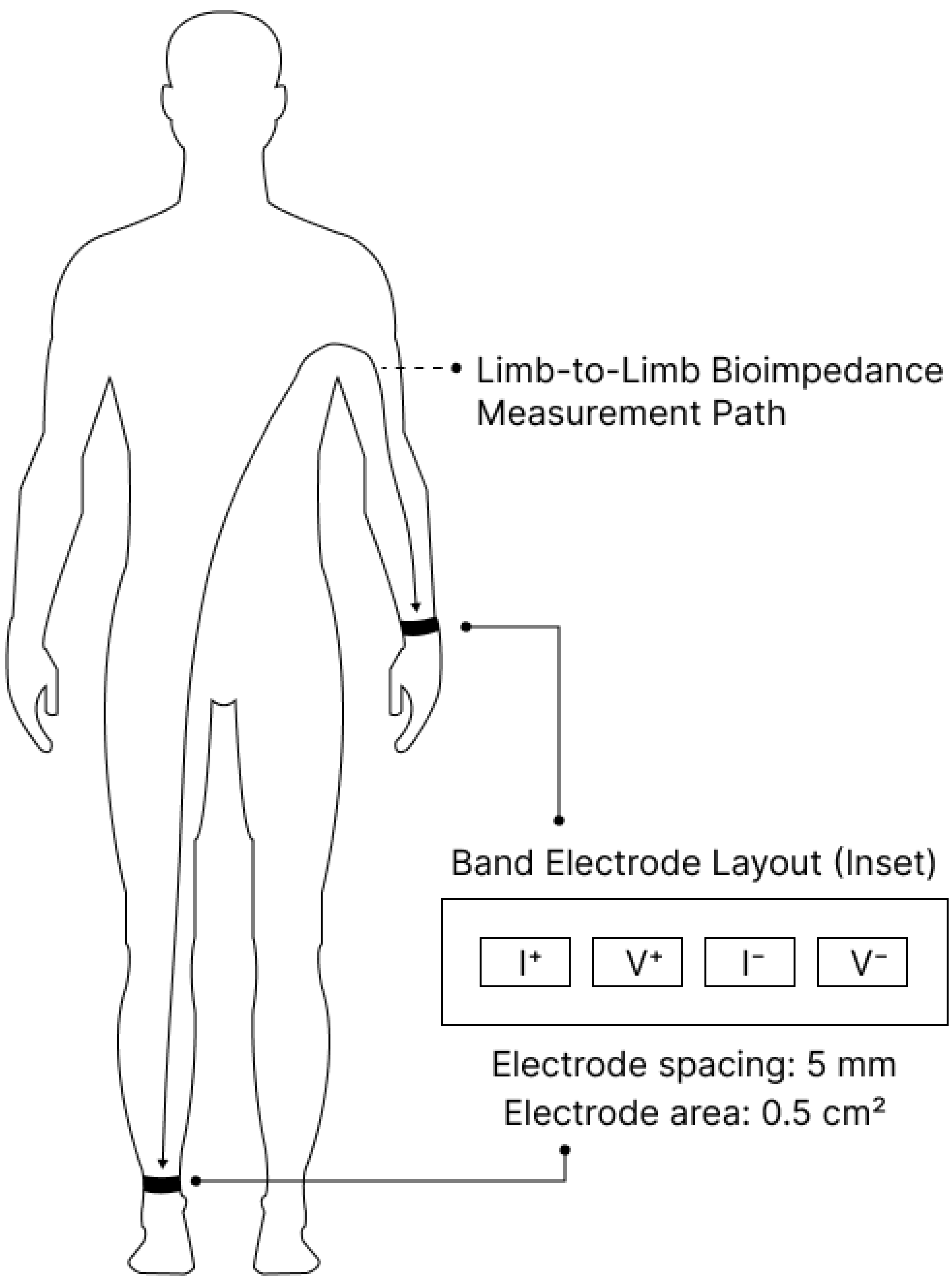

**FIG. 3 – Electronic Signal-Chain Block Diagram of Impedix System**

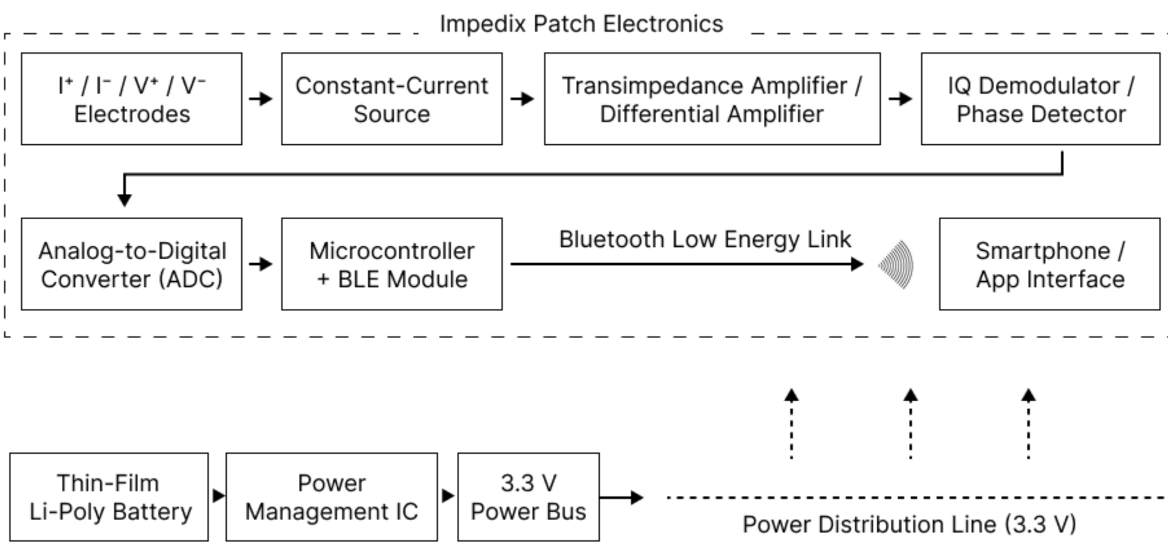

**FIG. 4 – Measurement and Processing Flowchart of Impedix System**