

PROVISIONAL PATENT SPECIFICATION

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 $\leq 800 \mu\text{A}$ —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 ($< 1^\circ$ error up to 500 kHz).

Derived quantities include:

- (a) ECW and ICW volumes: from fitted resistances R_0 (zero-freq) and R_∞ (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 ($< 200 \Omega @ 50$ 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 $\pm 5\%$.
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 $< 100 \mu\text{A}/\text{cm}^2$, patient leakage $< 10 \mu\text{A}$, 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 $\approx 5\text{--}10$ cm^2 per pad. Thickness $0.05\text{--}0.1$ mm.
- (d) Adhesive / Interface Layer: Medical-grade conductive adhesive ($0.1\text{--}0.2$ 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: $I_{peak} = 0.1 - 0.8 \text{ mA}$ 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 $J = I/A \leq 100\mu\text{A}/\text{cm}^2$, 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 $\pm 0.5\%$, 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 k Ω –100 k Ω , input noise $< 10\text{ nV}/\sqrt{\text{Hz}}$.
- (c) IQ Demodulator / Phase Detector: Performs synchronous demodulation to compute in-phase (I) and quadrature (Q) components. Phase resolution $\leq 0.1^\circ$, magnitude accuracy $\pm 0.1\%$.
- (d) Analog-to-Digital Converter (ADC): ≥ 16 -bit Σ - Δ ADC sampling 1 MS/s; ENOB ≥ 14 bits; input range $\pm 1\text{ V}$.
- (e) Microcontroller + BLE 5.x Module: Example SoC: Nordic nRF52840. Clock accuracy $\pm 20\text{ ppm}$. 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 $\rightarrow 3.3\text{ V}$ bus, efficiency $> 90\%$.
- (c) Power distribution: Dashed feeder lines supply analog and digital domains with LC filtering (cutoff $\approx 10\text{ kHz}$).

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

Synchronization timing: BLE time alignment ≤ 200 μ s (max), typical ± 10 μ s. At 500 kHz, 10 μ s 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 μ s resolution). Secondary (ankle) band acknowledges and enters measurement mode with phase alignment ≤ 200 μ s.
- (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, $\pm 0.3^\circ$ 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_∞ : 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_∞ 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 $|Z(f)|$, $\phi(f)$, 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 ($\leq 20 \mu\text{A}$).

5. Calibration and Validation

Phantom calibration: Resistive–capacitive network ($R = 500 \Omega$, $C = 1 \mu\text{F}$) used to verify amplitude/phase linearity. Measured $|Z|$ error $< 0.3 \%$, phase error $< 0.2^\circ$ across full band.

Human validation: Compared against Xitron 4200 BIS reference and DXA (Hologic Discovery). Mean error $\pm 3.8 \%$ TBW, $\pm 4.2 \%$ ECW, $\pm 4.5 \%$ ICW, correlation $R^2 = 0.92\text{--}0.95$. 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: $t = \frac{80\text{mAh}}{0.094\text{mA}} \approx 851\text{h} \approx 35\text{days}$

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

7. Safety and Regulatory Compliance

- (a) Current density: $\leq 100 \mu\text{A}/\text{cm}^2$ per electrode.
- (b) Leakage current: $< 10 \mu\text{A}$ per IEC 60601-1 Type BF.
- (c) Isolation: $\geq 1 \text{ M}\Omega$ 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: $< 1^\circ\text{C}$ 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 ($5 \text{ frequencies} \times |Z| + \phi$ 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 \rightarrow DynamoDB \rightarrow 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 $\leq 200 \mu\text{s}$;
- (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_{∞} , 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 $50 \mu\text{s}$.
- (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 $\leq 1 \text{ mA}$ during active measurement and $\leq 100 \mu\text{A}$ 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 μ F 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

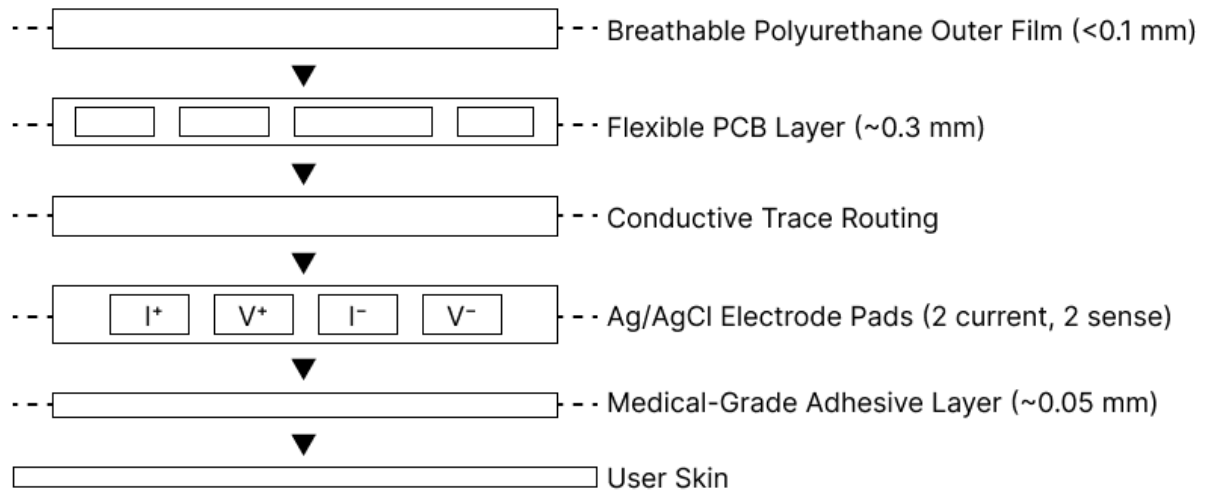


FIG. 2 – Electrode Geometry and Wrist-to-Ankle Placement of Impedix System

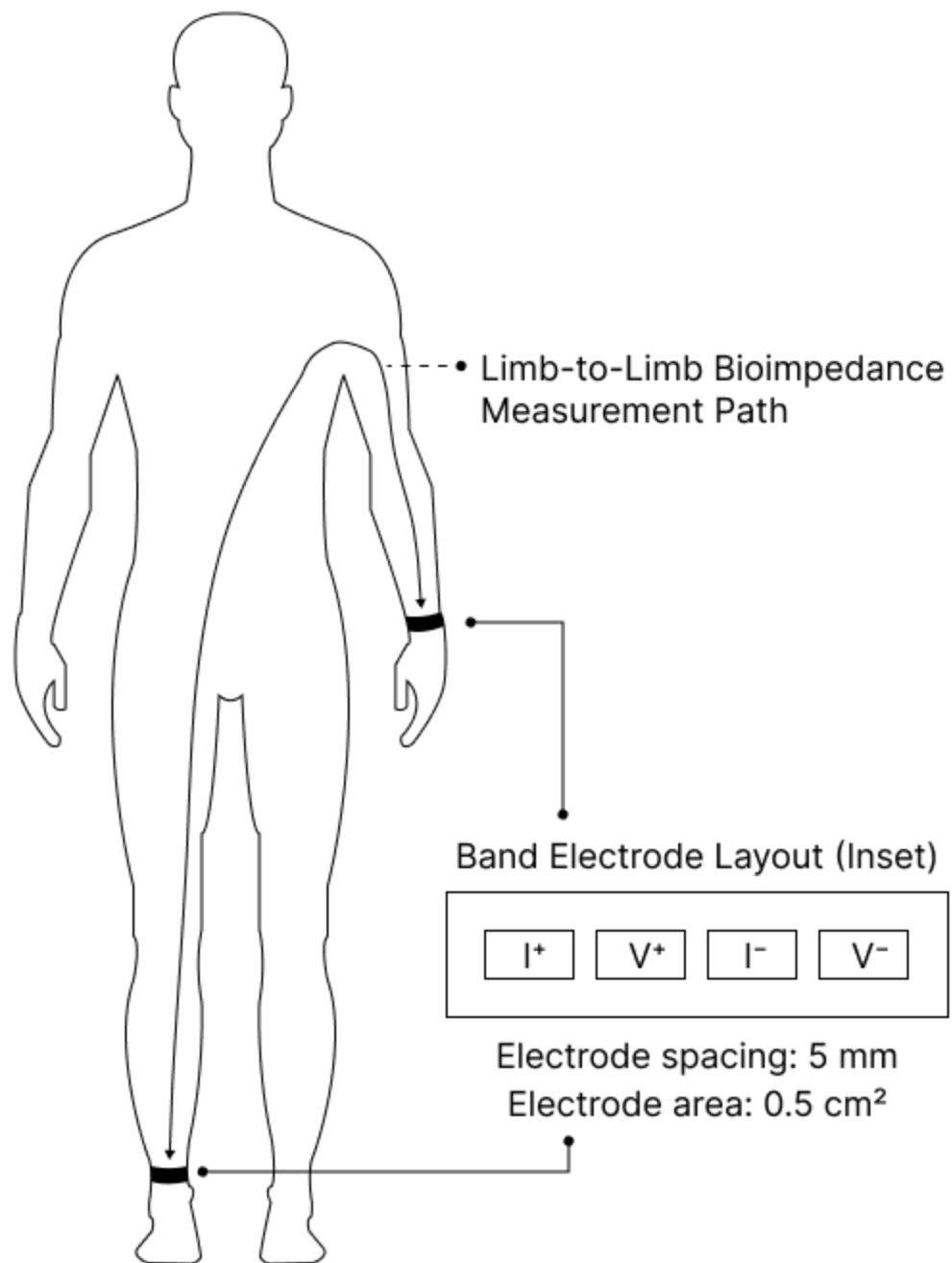


FIG. 3 – Electronic Signal-Chain Block Diagram of Impedix System

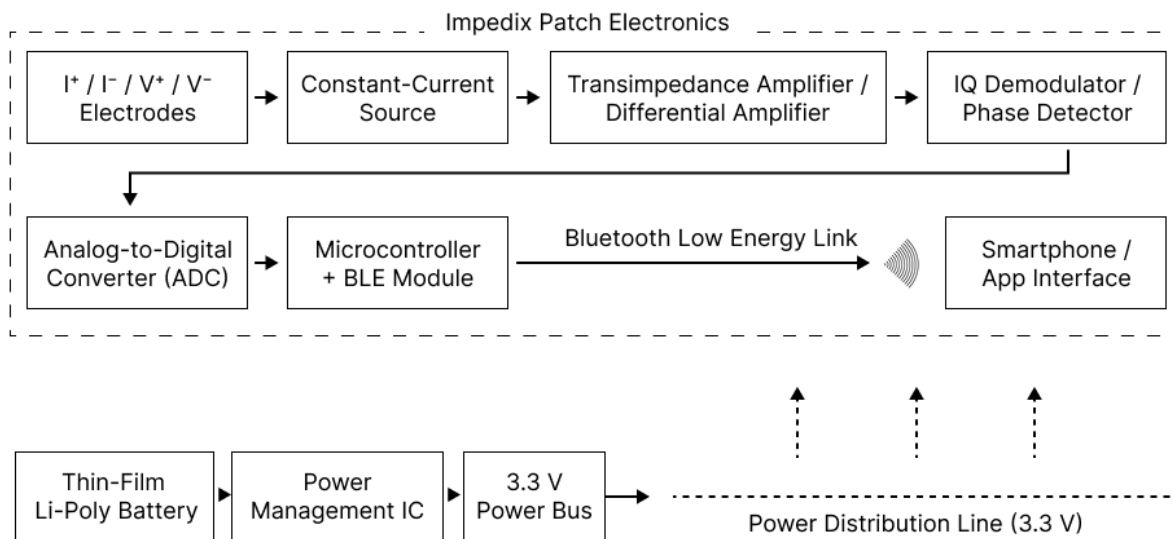


FIG. 4 – Measurement and Processing Flowchart of Impedix System

