Smartguard

An athletic performance metric intra-oral smart device

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Executive Summary

This project proposes the development of a smart mouthguard that integrates biometric and biochemical sensing into a single, compact, intraoral device. Unlike wristbands or chest straps, the mouthguard form factor provides access to saliva, a medium with strong correlations to blood chemistry, while also offering a stable environment for accurate optical and thermal measurements. The device combines infrared PPG for heart rate and HRV, oral temperature sensing for both core body temperature and respiratory monitoring, impedance-based hydration tracking using gold electrodes, and an experimental disposable lactate cartridge. Data fusion with an onboard IMU enables estimation of steps, intensity, calories, and recovery metrics, while wireless BLE transmission ensures seamless integration with mobile apps.

Market research highlights growing demand for accurate, portable metabolic tracking, with precedent set by devices such as the Oura Ring, ORB Mouthguard, VO_2 Master, and Apple Watch. However, none bridge the gap between physiological monitoring and biochemical sensing. This product aims to fill that gap, providing athletes and health-conscious users with non-invasive access to metrics that previously required clinical testing. While regulatory pathways depend on whether it is classified as a wellness product or a medical device, the initial focus will be on consumer wellness to accelerate prototyping and reduce regulatory burden. Estimated prototype costs are approximately $200–300 per unit in low volumes, with a long-term electronics BOM under $30 at scale.

Version History

- V1.0 Initial Release
- V1.1 Prototype Schematic Update
    - Updated design changes and text
    - Added experimental schematics
    - Added software block diagrams
    - Added BOM

Background

There is a growing need for a portable, non-intrusive metabolic analyzer that goes beyond the capabilities of current consumer wearables. Metrics of interest include both traditional physiological signals and biochemical markers. The oral cavity is relatively stable in temperature and biochemistry making it an ideal testing ground. There is no external light or hair and the body provides natural EMI shielding. Biochemical sensing of saliva is what sets this project apart, it allows measuring of data that previously required blood analysis and is more reliable than sweat bio sensing.

The proposed device gives the user the capability to measure the following metrics: heart rate (HR), conductivity (Hydration), lactate, motion, respiration, body temperature. From this raw data, derived metrics such as heart rate variability, resting heart rate, respiratory exchange ratio, training zone status, recovery time, step count, distance, intensity, and calorie expenditure can be estimated. Together, these measurements would give athletes and health-conscious users a more complete picture of performance and recovery than current wrist or chest-based wearables while being less intrusive than blood testing.

Approach

HR will be measured using an optical photoplethysmogram (PPG) with an infrared light emitting diode (IR LED). Orienting this device on the gingiva can provide an accurate stable measurement with 16% drift according to studies. Oral temperature sensing is done with a digital IC and can detect temperature swings from breathing as well as core body temperature should the mouth be closed for at least one minute. Motion sensing is done through an inertial measurement unit (IMU) which outputs data in the form of angular rates, acceleration rates, and is capable of detecting steps, tilt, taps, and wakes on motion. Lactate sensing is the most ambitious part of this project as it is still in the experimental phase but current studies prove it is both possible and more reliable than sweat lactate sensing. Using a 3-pin custom electrode which measures saliva concentrated in a channel can provide regular non-intrusive collection of salivary lactate levels.

Design criteria include small form factor for comfort, smooth surfaces for ease of cleaning, cost effectiveness to make the product marketable, a sealed silicone body to contain the electronics with a wireless charging circuit and only exposing the electrodes when necessary. These constraints will guide the hardware development architecture and ensure the device can function as both a practical research prototype and a path toward consumer-grade manufacturability.

Research

Current Research

This project investigates the potential of a mouthguard-based biosensing platform for non-invasive health monitoring during exercise. The oral cavity offers a stable environment and access to saliva, which carries analytes that reflect blood composition. Prior studies have shown feasibility for detecting lactate, glucose, and uric acid in saliva, as well as heart rate monitoring with intraoral photoplethysmography (PPG). These findings suggest that a mouthguard could track exercise intensity and recovery by combining biochemical and physiological signals.

Salivary lactate is particularly promising, with strong correlation to blood lactate, making it useful for monitoring training load. Glucose and uric acid can also be detected, though enzyme stability and fouling remain challenges. Oral PPG has demonstrated performance comparable to wrist wearables, though sensor placement and motion artifacts must be managed. Prototype salivary sensors have already achieved wireless transmission via Bluetooth at low cost, highlighting manufacturability potential.

Overall, mouthguard biosensing represents a promising alternative to chest straps and wristbands, which often struggle with accuracy and lack biochemical data. While barriers remain, such as enzyme longevity, biofouling, power, and integration, the most viable first targets are salivary lactate and heart rate monitoring, forming the basis for a functional prototype.

Market Research

Recent products highlight both the feasibility and commercial appeal of compact biometric wearables. The ORB Mouthguard has already proven that a mouthguard form factor with a flex PCB can function in real world prototypes, validating the concept of intraoral electronics. The Oura Ring shows that consumers value compact, continuous monitoring of heart rate and temperature, and that miniaturized health tech can succeed at scale. The VO_2 Master demonstrates that athletes are willing to pay for portable hardware that delivers advanced metabolic insights previously limited to labs. Meanwhile, the Apple Watch underscores widespread consumer demand for multi-metric biometric tracking in a mainstream device. Together, these benchmarks reveal a market opportunity: unlike existing devices, a smart mouthguard can uniquely combine accurate heart rate and HRV monitoring with direct access to salivary biomarkers such as hydration and lactate. This positions the device as a bridge between consumer wearables and professional grade metabolic testing.

Patents Research

Several existing patents cover aspects of intraoral biosensing, and there is partial overlap with this proposed mouthguard design. For example, WO2014110548A1 / US10517525B2 claims a diagnostic mouthguard incorporating temperature, pH, and inertia sensors, while WO2019005808A1 focuses on saliva collection chambers with reagent-based biochemical sensing. These overlap with this design's use of oral temperature sensing, IMU motion tracking, and a disposable lactate cartridge. However, they do not claim optical PPG for HR, conductivity sensing for hydration, or the broader fusion of metrics such as VO_2 estimation, HRV, or recovery analysis. The overlap is therefore limited to specific sensing modalities and the general idea of embedding biosensors into a mouthguard.

To avoid infringement, the design will emphasize differentiation in both sensor types and implementation. Guidelines include: (1) relying on optical PPG for HR/HRV rather than pH or pressure sensing; (2) implementing a novel disposable electrode cartridge with distinct geometry, contact scheme, and enzyme handling different from claimed microfluidic reagent reservoirs; (3) focusing on conductivity-based hydration sensing, which is not present in existing patents; and (4) framing temperature and IMU use as supporting signals for PPG and lactate fusion rather than as standalone diagnostic features. By clearly positioning the device around optical and electrochemical innovations not directly claimed in existing filings, the prototype reduces overlap risk and establishes technical novelty.

Regulations

If positioned as a medical diagnostic, the smart mouthguard could fall under FDA Class II, but if marketed as a wellness device it may face lighter regulation. In either case, intraoral materials must be ISO 10993 biocompatible, the Li-ion battery must follow IEC 62133/UL 2054 safety standards with proper protection and charging, and the BLE radio must comply with FCC, ETSI, and Bluetooth SIG requirements. These considerations define the safety, wireless, and materials framework needed to bring the product to market. To mitigate regulatory risk, the product can initially be positioned as a fitness and wellness tracker rather than a diagnostic medical device, reducing the burden of FDA Class II approval. This strategy allows for faster prototyping and early market testing, while leaving open a future path to medical certification if clinical validation supports expanded claims.

Hardware

1. **Chip Selection**
   - **MCU/BLE**: Nordic nRF52840 module – Raytac MDBT50Q-1M (BLE 5.0, low power, large flash/RAM, well documented SDK).
   - **Optical PPG**: ADPD4100 AFE with Osram SFH2704 and SFH4045N
   - **Temperature**: MAX30205 digital sensor
   - **IMU**: TDK ICM-42688-P for motion gating, cadence, and step estimation.
   - **Electrochemistry**: AD5940 for differential pair conductivity channel.
   - **Lactate Cartridge** (experimental): LMP91000SDE_NOPB AFE, custom micro-insert (est. 10 × 5 × 1.5 mm) with gold and Ag/AgCl electrodes. I/O pins: WE, CE, RE, ground, shield, detect.

2. **Power System**
   - **Battery**: 3 pin ≤50 mAh Li-ion pouch cell (with built-in PCM).
   - **Power Management**: TI bq51003 with WR121210-27M8-ID RX coil, TI BQ24075 Li-ion charger. TPS62840YBGR 3.3VDC buck converter, TPS7A02(18+30)PDQNR for quiet analog rails.
   - **Case**: Wireless charging case with WT151512-22F2-ID TX.
   - **Safety**: Battery & on-chip BMS with NTC temp monitoring.
   - **Power optimization**: duty-cycled PPG, burst-mode IMU, intermittent impedance sweeps, low power mode.

3. **Flex PCB Design**
   - **Rigid-Flex Stack-up**: 4-layer (Sig – GND – GND – Sig) with central 2-layer polyimide flex core continued into bends.
   - **Orientation**: PPG near gums, BLE near mouth opening, Qi coil separate with keep-out zone, electrodes near saliva channels. Upper palatial vault for large bodies, thin bodies only between teeth and lips, focus rigid bodies near upper canines' molars for comfort.

4. **Case Design**
   - Boil-and-bite style EVA dental resin with ISO 10993 silicone coating.
   - Exposed gold electrodes in microchannel for conductivity sensing.
   - Replaceable lactate cartridge dock with magnetic pogo pads.
   - Smooth external surface that's easy to clean.
   - Comfortable to wear for extended periods.

Software

Data Acquisition

Physiological and biochemical signals are collected through high-resolution ADC sampling, with filtering applied to suppress noise and motion artifacts. Motion data from the IMU provides gating so that heart rate and biochemical measurements are only accepted during stable intervals. Bad data is rejected automatically, and signal-to-noise ratio is optimized before data is prepared for transmission. Zephyr RTOS will be explored for efficient task management and process timing.

See the following block diagrams for programming reference guides: IMU (Fig. 5), oral temperature (Fig. 6), heart rate (Fig 7), hydration (Fig 8), lactate (Fig. 9), and app (Fig.10).

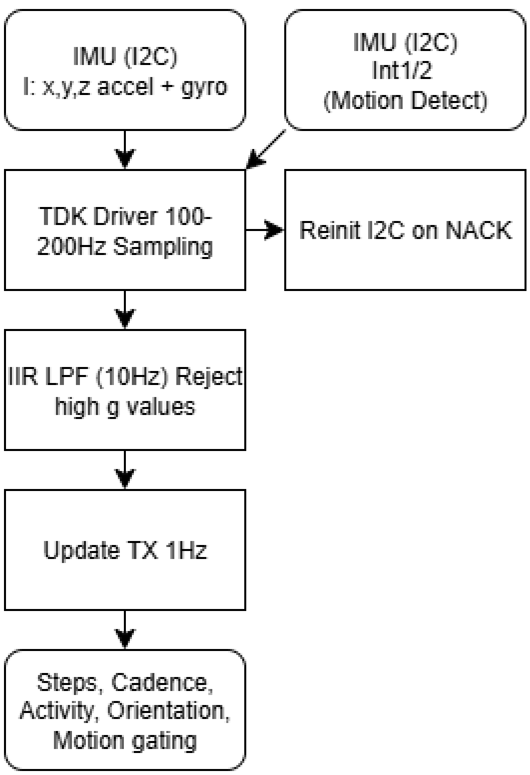

Figure 5: IMU Data Processing

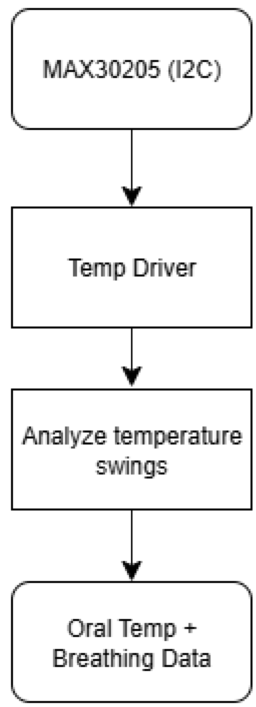

Figure 6: Oral Temperature

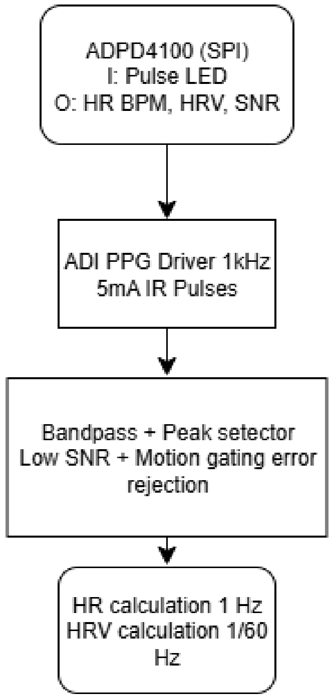

Figure 7: PPG

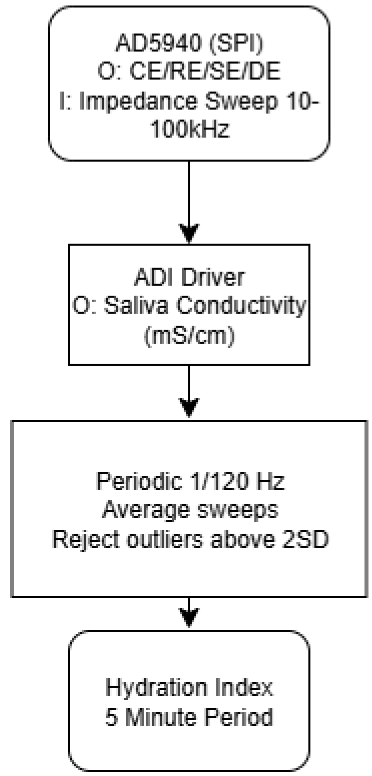

Figure 8: Hydration

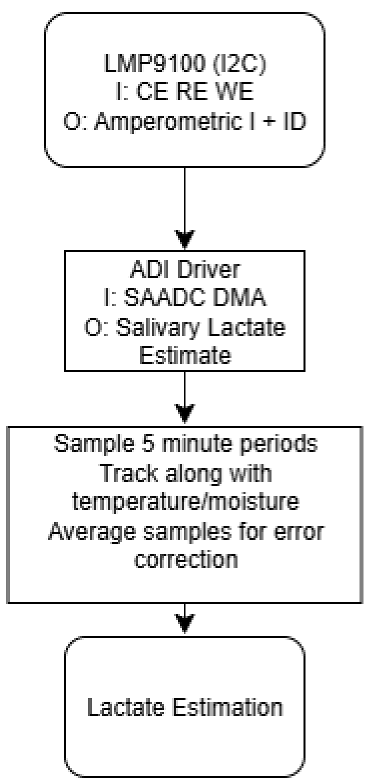

Figure 9: Lactate

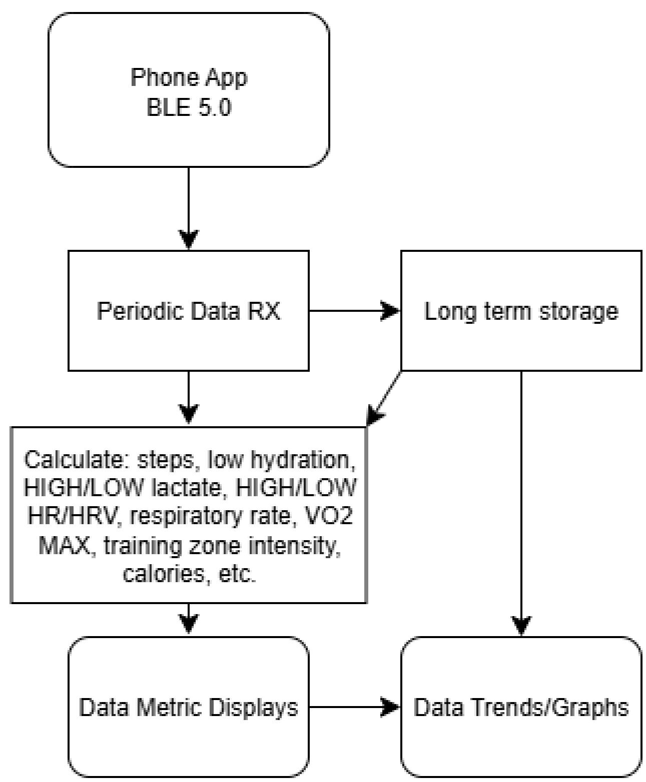

Figure 10: Phone App

Power Management

A dedicated power management layer coordinates duty-cycling of the optical, electrochemical, and motion ICs. Components not in use are placed into low-power sleep modes, with wake-on-event programming used to reactivate them when needed. This strategy extends battery life without compromising the quality of captured data.

BLE 5.0 Communication

Communication with the companion iPhone app is handled over Bluetooth Low Energy 5.0. Transmission protocols distinguish between continuous streams, such as heart rate, and periodic data, such as hydration or lactate levels. Timing and packet handling are optimized to maintain reliability while minimizing energy consumption.

Device Setup and OTA Updates

The software supports simple user onboarding, including calibration routines for baseline measurements. Secure over-the-air updates via BLE 5.0 allow firmware to be revised in the field, enabling performance improvements, bug fixes, and new features without requiring changes to the hardware.

Phone app

The companion app will serve as the primary interface for data visualization and diagnostics, retrieving continuous streams from the mouthguard over Bluetooth Low Energy. Core physiological metrics will include heart rate, HRV, oral temperature, respiratory rate, and activity data derived from the onboard IMU. Biochemical sensing will provide hydration trends from conductivity measurements and, in later iterations, salivary lactate levels from a disposable cartridge. From these signals, the app will calculate derived diagnostics such as estimated VO_2, respiratory exchange ratio, training zones, recovery time, step count, distance, activity intensity, and calorie expenditure. Results will be presented in an intuitive dashboard, with both real-time monitoring and long-term trend analysis to help users track performance and recovery.

Budgeting

BOM

ID	References	Footprint	Count	Value
1	C30,C11,C10,C1,C3,C33,C27,C13,C22	C_0603_1608Metric	9	10uF
2	J4	N/A	1	SWD
3	C39,C32,C42,C36,C2,C35,C43,C37,C40,C41	C_0603_1608Metric	10	1uF
4	L2	L_0603_1608Metric	1	2.2uH
5	C38,C28,C29,C31,C14,C34,C12,C9	C_0603_1608Metric	8	.1uF
6	R3,R6	R_0603_1608Metric	2	0
8	R9,R10,R13,R14,R12,R11,R16,R15,R8,R7	R_0603_1608Metric	10	4.7K
10	U2	BGA56N40P7X8_356X416X55N	1	AD5940BCBZ-RL7
11	R5	R_0603_1608Metric	1	1.13k
12	U5	SON50P400X400X80-15N	1	LMP91000SDE_NOPB
13	U9	BGA6N40P3X2_146X96X50N	1	TPS62840YBGR
14	R20,R21,R22	R_0603_1608Metric	3	22
15	C17,C16	C_0603_1608Metric	2	100nF
16	C5,C8,C4,C21	C_0603_1608Metric	4	4.7uF
17	U1	VQFN-16-1EP_3x3mm_P0.5mm	1	BQ24075RGT
18	R4	R_0603_1608Metric	1	1.18k
19	U7	XCVR_MDBT50Q-1MV2	1	MDBT50Q-1MV2
20	D2	LED_SFH_4045N-VAW	1	SFH_4045N-VAW
21	J5	JST_PH_S3B-PH-SM4-TB	1	S3B-PH-SM4-TB
22	R24	R_0603_1608Metric	1	10k
23	U6	SON65P300X300X80-9N	1	MAX30205MTA_
24	R1,R2	R_0603_1608Metric	2	27
27	D3	SFH2704	1	SFH_2704
28	R17	R_0603_1608Metric	1	267K
29	U10	IC_TPS7A0230PDQNR	1	TPS7A0230PDQNR
30	R23	R_0603_1608Metric	1	100k
31	IC1	BGA35C40P5X7_214X311X56	1	ADPD4100BCBZR7
32	C45,C44	C_0603_1608Metric	2	12pF
33	U8	IC_TPS7A0218PDQNR	1	TPS7A0218PDQNR
34	C26,C25	C_0603_1608Metric	2	Tuning
35	C6,C7	C_0603_1608Metric	2	47nF
36	C15	C_0603_1608Metric	1	.1uF X7R
37	U4	PQFN50P300X250X97-14N	1	ICM-42688-P
38	C19,C20	C_0603_1608Metric	2	10nF
39	R18	R_0603_1608Metric	1	150K
40	Y1	Crystal_SMD_0603-2Pin_6.0x3.5mm	1	16MHz
41	C18	C_0603_1608Metric	1	2.2uF X7R

42	C24,C23	C_0603_1608Metric	2	220nF
43	U3	BGA28N40P7X4_300X188X50N	1	BQ51003YFPR
45	R19	R_0603_1608Metric	1	1K
46	N/A	Li Ion Pouch	1	50mAh
47	N/A	Lactate Electrode	2	Au + Ag/AgCl
48	N/A	Hydration Electrode	3	4 pin Au tip
49	N/A	Charging Case	4	TBD

Cost of Prototype

Developing a first working prototype of the smart mouthguard is expected to cost on the order of $200–300 per unit at small batch volumes. The bulk of this expense comes from low-volume rigid-flex PCB fabrication, assembly, and custom enclosure work. The device will need to go through multiple stages of prototyping to ensure proper wiring, EMI, safety, and metric testing. At scale, once the design is validated, the per-unit cost would drop significantly, with electronics closer to $25–30 each before housing and finishing. Note that this does not include the cost of the experimental lactate sensing cartridge.

Design

Prototype

The prototype will be developed in staged iterations to ensure both functional validation and user comfort. Stage 1 will be the fabrication of an experimental rigid only PCB, which will be programmed and bench-tested to verify basic operation and optimize the software. Once functional, the device will undergo stage 2: immersion testing in controlled solutions to configure and validate data acquisition parameters for optical, impedance, and temperature sensing. Finally, stage 3 will include a one size fits all boil-and-bite template, into which a rigid-flex PCB will be integrated for in-mouth trials.

This version will be tested with a group of up to 10 individuals to measure the following metrics: Heart rate and HRV derived from oral PPG will be benchmarked against chest strap electrodes during rest, exercise, and recovery; Salivary lactate measured with the disposable cartridge will be compared against interval sampled blood lactate values obtained through finger-prick tests, allowing assessment of correlation and lag; Hydration and oral temperature trends will also be logged along with comfort and usability feedback.

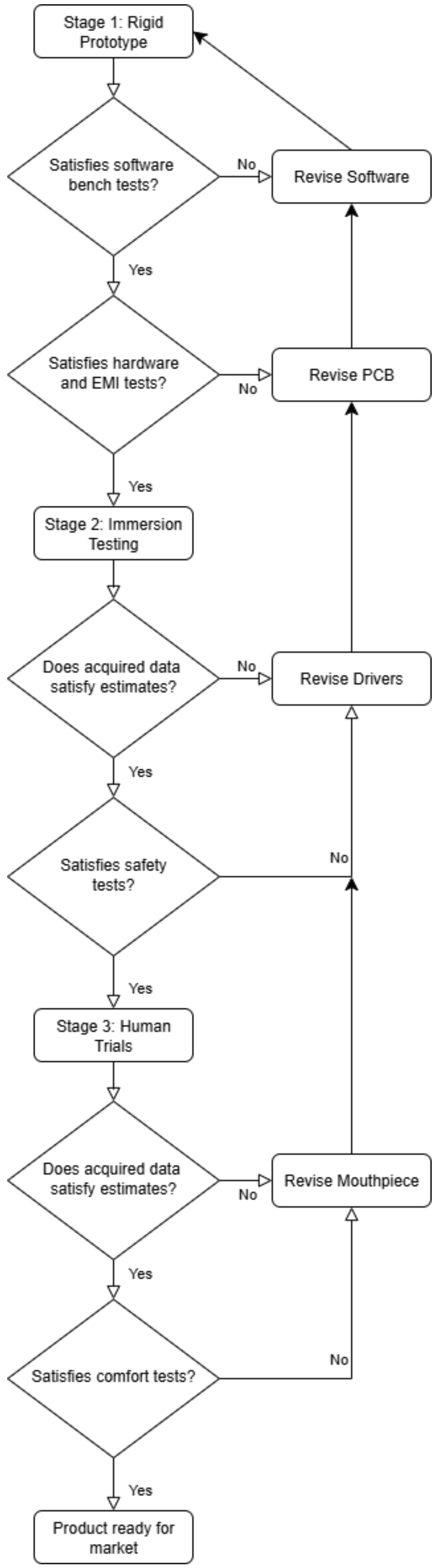

Figure 4: Prototype Stage Block Diagram

Hardware Block Diagram

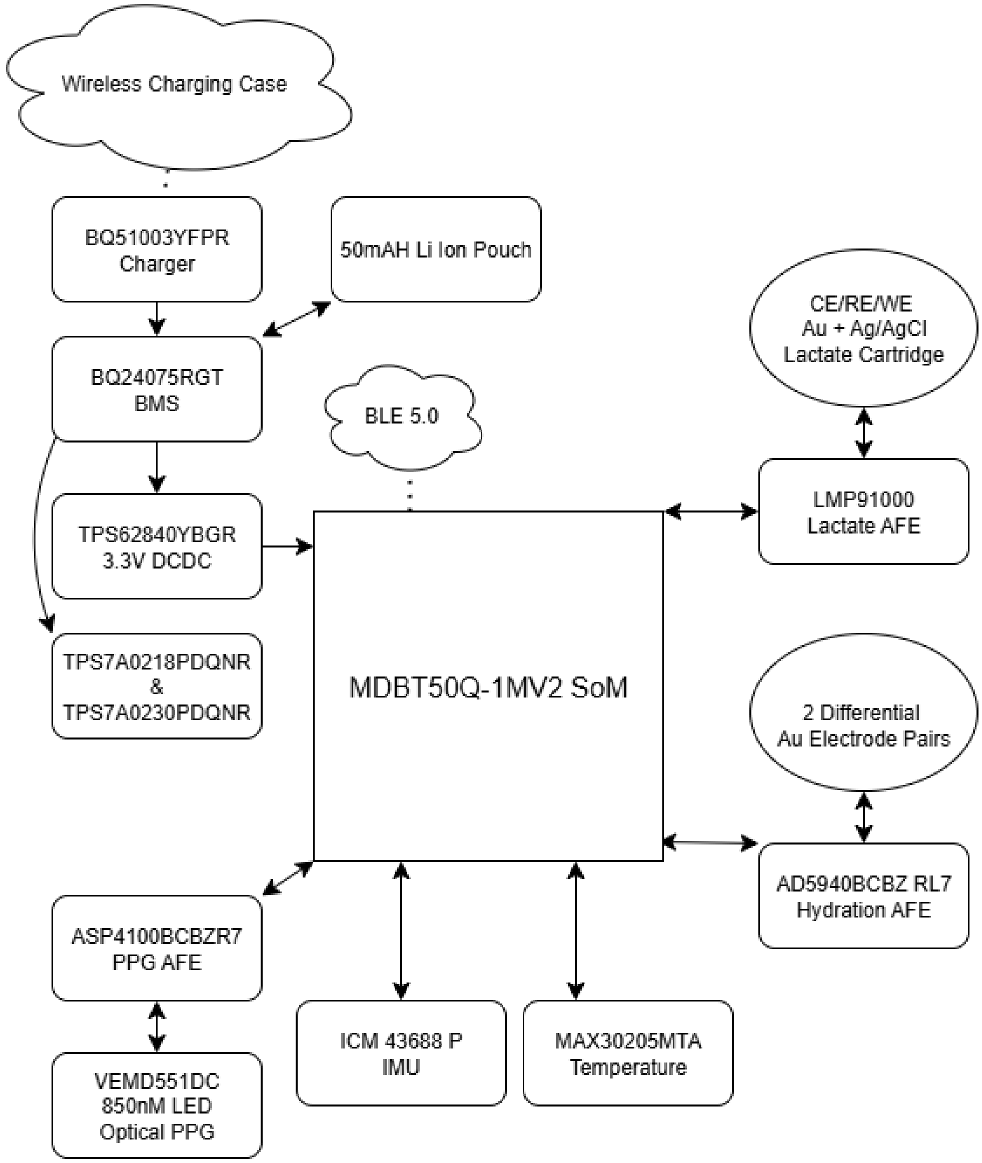

Figure 1: Hardware System Block Diagram

Experimental Stage 1 PCB

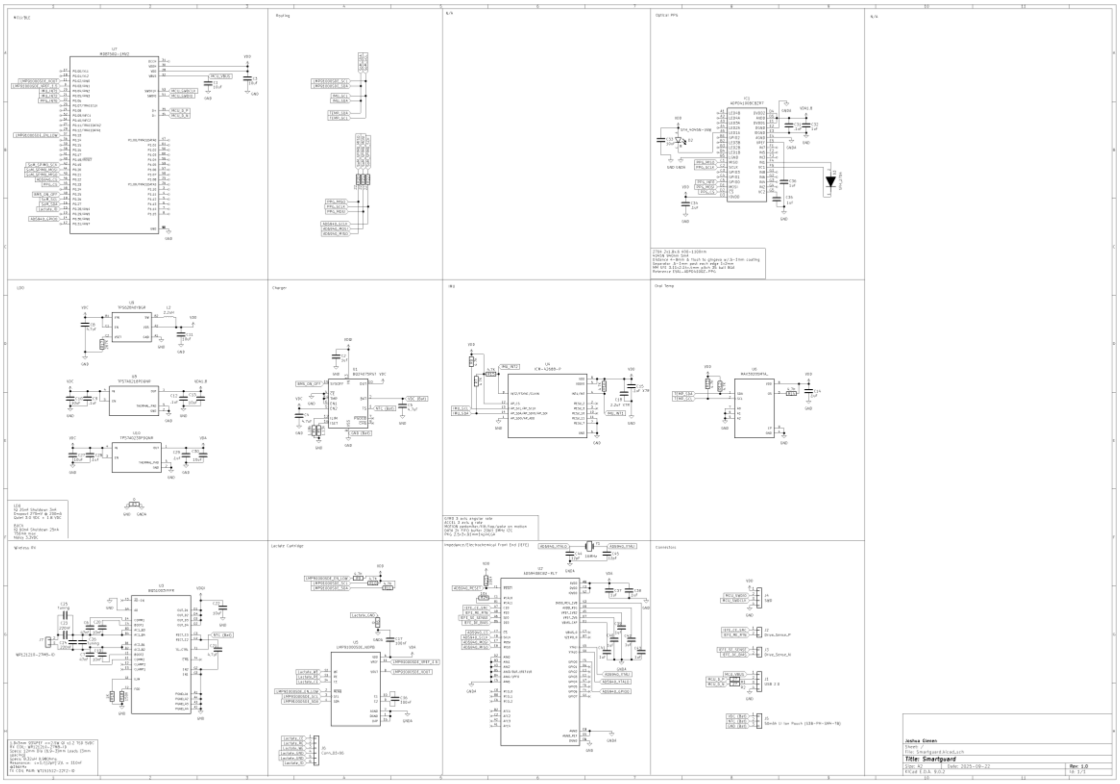

Figure 2: Circuit Schematic

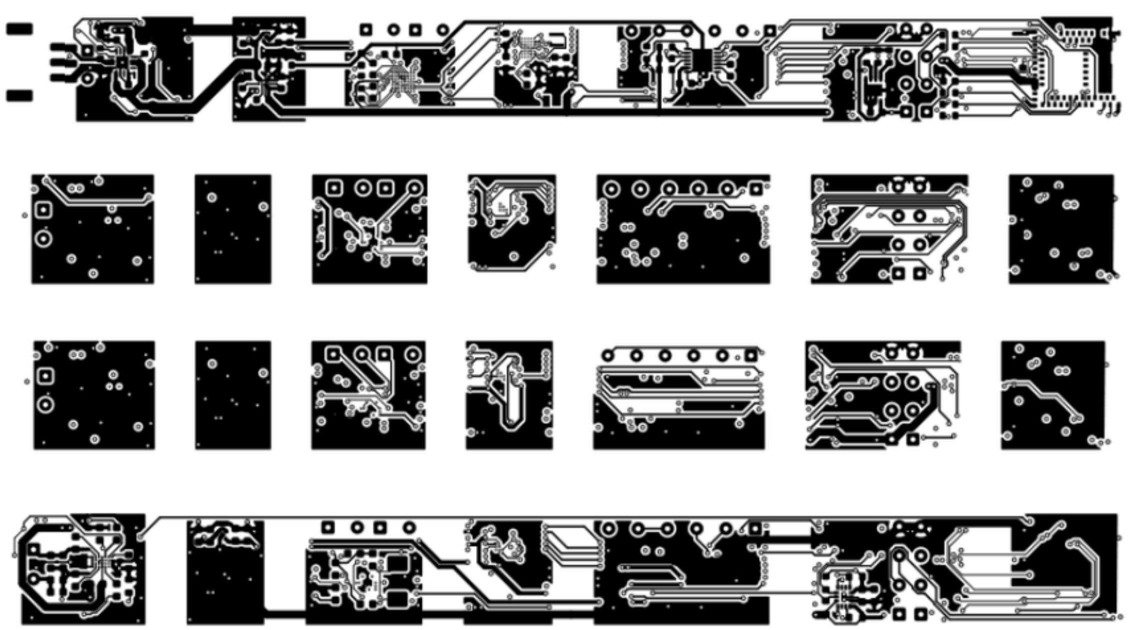

Figure 3: 4 Layer Rigid-only gerber view with flex 2-layer zones

Conclusion

This proposal outlines the design of a smart mouthguard that combines physiological and biochemical sensing into a single, compact, intraoral platform. Unlike existing wearables such as wristbands and chest straps, the device leverages saliva as a medium that closely correlates with blood chemistry, enabling access to metrics such as hydration status and lactate in addition to heart rate, HRV, temperature, and activity. This fusion of biochemical and physiological monitoring positions the device as a bridge between consumer wellness products and laboratory-grade metabolic analyzers.

Market research confirms the viability of the mouthguard form factor through prior prototypes and commercial products, while highlighting a clear gap in the integration of salivary biosensing. A thorough component selection process has defined a manufacturable 3 stage prototype architecture, with attention given to regulatory, safety, and cost considerations. While challenges remain, such as the experimental cartridge design, and avoiding patent infringement, the proposed design demonstrates both technical feasibility and strong market impact.

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