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.

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. Core features are heart rate (via intraoral PPG using 850–940 nm IR light on the gingiva or buccal mucosa), heart rate variability (derived from interbeat intervals), and oral temperature (both for detecting inhale/exhale cycles and estimating core temperature when the mouth is closed). Biochemical sensing is enabled through saliva, which provides access to hydration status (via four-electrode AC impedance conductivity sensing) and lactate levels (via a disposable enzyme electrode insert measured through an amperometric front end). From these raw signals, derived metrics such as resting heart rate, respiratory exchange ratio (RER), training zones, recovery time, step count, distance, activity intensity, and calorie expenditure can be estimated using IMU data and sensor fusion. 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.

Approach

The mouth was chosen as the sensing site because it offers unique advantages over alternatives like wristbands or sweat patches. The oral cavity is relatively stable in temperature and shielding, reducing ambient light noise for PPG and providing a protected environment for electrodes. Saliva is easier to collect and more closely correlates with blood chemistry than sweat, enabling meaningful biochemical sensing for lactate, hydration, and potentially other analytes. Unlike chest straps or wristbands, which can be inaccurate under motion and cannot measure biochemistry, a mouthguard form factor allows simultaneous access to both physiological and biochemical signals. Design criteria include non-intrusiveness (a thin diagnostic guard rather than a bulky protective one), robust hygiene (smooth surfaces, replaceable enzyme cartridges, peroxide cleaning compatibility), cost-effectiveness (standard wearable-class ICs and fabrication methods), robustness (sealed, potted electronics with inductive charging), and user comfort (boil-and-bite EVA base with flexible PCB islands). These constraints guide the hardware 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 photoplethysmography (PPG) for HR/HRV, four-electrode 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).
    - **Optical PPG**: ADPD4100 AFE with Osram SFH4253/4273 IR LEDs (850/940 nm) + Vishay VEMD5510C photodiode.
    - **Temperature**: MAX30205 digital sensor
    - I**MU**: TDK ICM-42688-P for motion gating, cadence, and step estimation.
    - **Electrochemistry**: AD5940 for 4 PPG electrode channel
    - **Lactate Cartridge** (experimental): LMP91000SDE_NOPB, custom micro-insert (10 × 5 × 1.5 mm) with gold WE/CE + Ag/AgCl RE. I/O pins: WE, CE, RE, shield, detect.
    - **Power Management**: TI bq51003 wireless RX coil + TI BQ24075 Li-ion charger.
    - **LDO**: TPS7A02 for quiet analog rails; TPS7A0215PDQNR for digital rails.

2. **Power System**
    - ≤50 mAh Li-ion pouch cell (with built-in PCM).
    - Wireless charging case (Qi-compatible, bq51003 receiver in mouthpiece).
    - **Safety**: integrated charger IC with NTC temp monitoring.
    - **Power optimization**: duty-cycled PPG, burst-mode IMU, intermittent impedance sweeps.

3. **Flex PCB Design**
    - Rigid-flex design: three or more rigid islands linked by 2-layer polyimide flex.
    - Rigid stack-up: 4-layer (Sig – GND – GND – Sig) with central flex core continued into bends.
    - More expensive but allows enhanced form control of the final product.

4. **Case Design**
    - Boil-and-bite EVA resin with ISO 10993 silicone coating.
    - Exposed gold electrodes in microchannel for conductivity sensing.
    - Replaceable lactate cartridge dock with spring contacts or pogo pads.
    - Smooth internal surface that's easy to clean.

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.

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

Section	Function	Part	Size	Specs	Notes
Compute & Storage	MCU + BLE	Raytac MDBT50Q-1M V2(nRF52840)	10 × 16 mm module	BLE 5.0, 64 MHz, 1 MB Flash, 256 kB RAM	Mature wearable SoC, SDK support
Optical (PPG for HR/HRV)	AFE	ADPD4100BCBZR7	LGA-24, 3 × 3 mm	Multi-channel PPG, ambient light rejection	Flexible timing/LED drive
	IR LEDs	Osram SFH4253 (850 nm), SFH4273 (940 nm)	0603/0805	10–60 mA pulsed drive	Compact, good radiant flux
	Photodiode	Vishay VEMD5510C	3.2 × 2.4 mm	NIR-optimized, low capacitance	Best match for 850–940 nm
Temperature	Oral Temp	MAX30205MTA	TDFN-8	±0.1 °C accuracy, I^2C	Direct saliva/oral temperature
	Battery Temp	Semitec 103AT-2	10 kΩ NTC bead	JEITA compliance	Bonded to pouch cell
Motion	IMU	TDK ICM-42688-P	2.5 × 3 × 0.9 mm LGA	6-axis, low noise, 20 µA LP mode	Motion gating, cadence, HRV quality
Saliva Electrochemistry	EIS	AD5940	LFCSP-40, 5 × 5 mm	AC impedance, 3/4-electrode support	Single IC covers hydration
	Potentiostat	LMP91000	WSON-14	Configurable TIA for WE/RE/CE	Dedicated lactate channel
Power & Charging	Battery	Li-ion pouch	30–50 mAh,	~30 × 10 × 2 mm, Integrated	Custom size

			custom	PCM, NTC	
	Charger	BQ24075	QFN-16 3x3mm	Linear charger, NTC input	Handles Li-ion safely
	Wireless RX	BQ51003YFPR	QFN-20	Qi-compliant, 5 V out	Lives in charging case
	LDO (analog/digital)	TPS7A02/ TPS62840	SOT-563	25 µA Iq, 200 mA/ 60 nA Iq 750 mA	Drive analog and digital sep.
Electrodes & Cartridge	Conductivity	Custom Au electrodes	Flush pads	4-contact Kelvin cell	Fixed channel
	Lactate Cartridge	Custom insert (~10 × 5 × 1.5 mm)	~10 × 5 × 1.5 mm	WE/RE/CE + detect, 6–8 pins, Disposable	Enzyme based

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 (1–5 units). The bulk of this expense comes not from the electronic components themselves—most of which are standard wearable-class parts totaling under $50—but from low-volume rigid-flex PCB fabrication, assembly, and custom enclosure work. 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. The first step will be the fabrication of an experimental rigid-flex PCB, which will be programmed and bench-tested to verify basic operation. Once functional, the device will undergo immersion testing in controlled solutions to configure and validate data acquisition parameters for optical, impedance, and temperature sensing. A custom-fit mouthguard will then be created using a boil-and-bite template, into which a second-generation flex PCB will be integrated for in-mouth trials.

This version will be tested with a group of 5-10 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 simultaneous 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.

Block Diagram

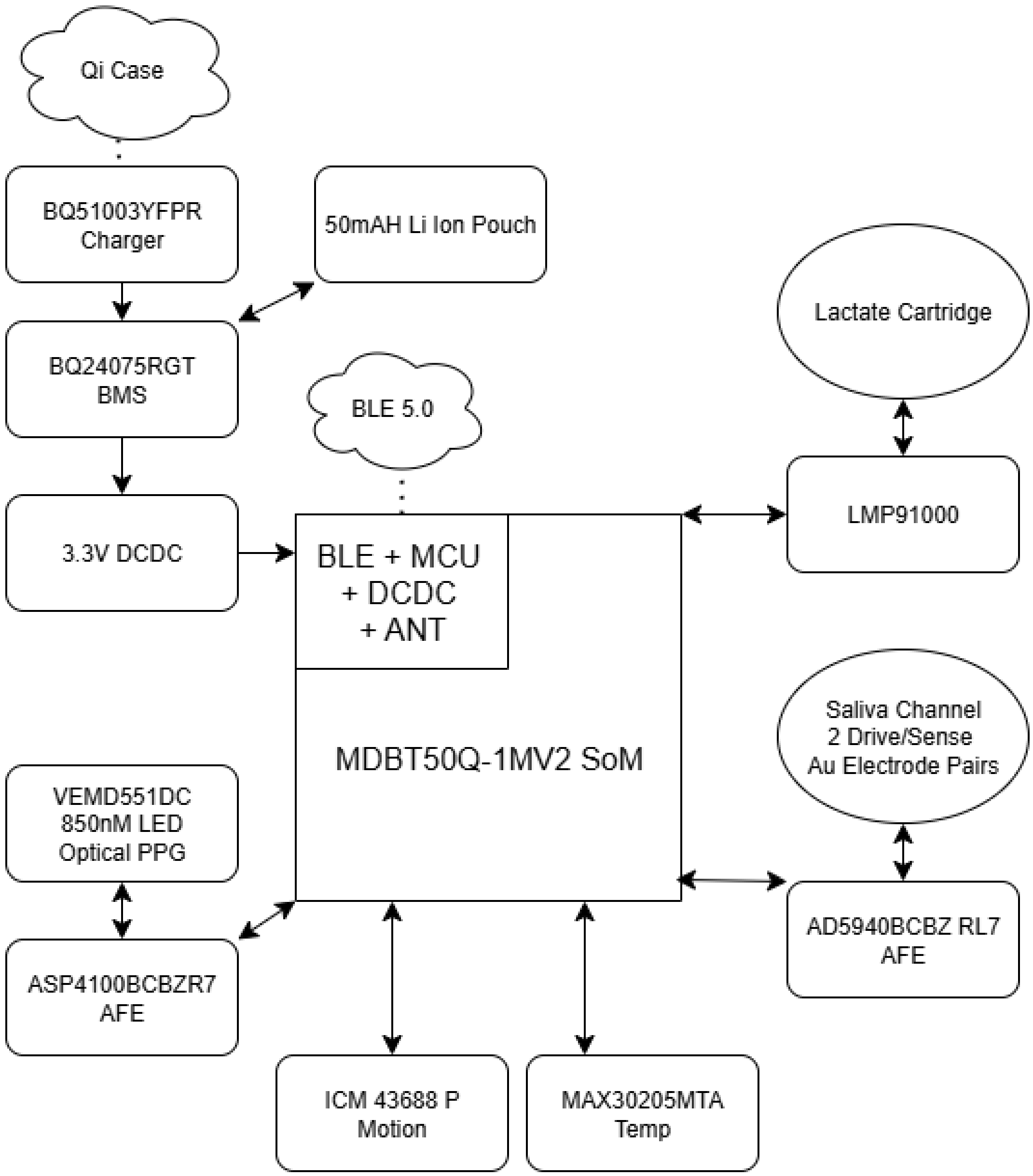

Figure 1: System Block Diagram

Experimental PCB Diagram

TODO

Experimental 3D Images

TODO

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 unique 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 initial prototype architecture, with attention given to regulatory, safety, and cost considerations. While challenges remain, such as enzyme stability, fouling, and regulatory pathway selection, the proposed design demonstrates both technical feasibility and strong potential market impact. The next steps will involve building and testing an initial prototype, validating sensor performance against gold-standard references, and refining the design toward manufacturability.

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