The Evolution of a Clinical Grade Wearable Vital Signs Monitor and the Role of Advanced Microelectronic Packaging Techniques to increase functionality

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Wearable Device Monitors

- Step counters
- Heart rate
- Blood oxygenation

Barriers to Technology Adoption

- Lack of clinically meaningful data/accuracy
- Patient Acceptance
  - Discomfort due to physical size
  - Robustness
- Physician Acceptance
  - Usefulness of data
  - Data monitoring schemes
  - Timeliness of data delivery
  - Lack of extended diagnostic parameters
  - Perceived as toys

Desirable Features

- More clinically meaningful data
- Reduction in physical size
- Charging schemes could be improved
- Easy Data transfer
- Reduced Cost

Professional Wearable Device
Biovotion

- Supplies actionable information towards predictive intelligent health monitoring.
- Automatic connection and operation.
- Wireless charging.
- The device and band can be attached with one hand easily around your arm.
- Combine state of the art cybersecurity, GDPR compliance and cloud based services – forming a next generation medical IoT solution
- Everion® is CE medical class 2a approved as well as FDA 510(k) exempt listed as a medical device.

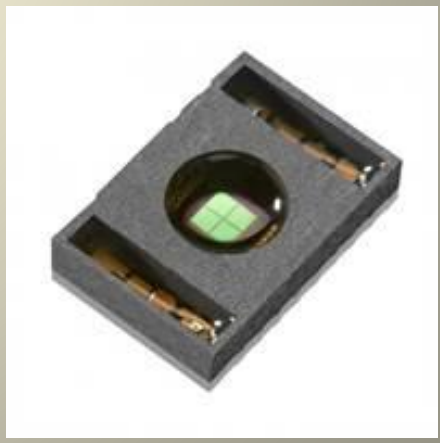
Clinical Data Collected

- Tracks Heart rate, Heart rate variability, Inter-beat intervals, Blood oxygenation, Respiratory Rate, Blood Pulse Wave, Steps and Motion, Skin temperature, Skin blood perfusion and various scores (stress, sleep).
- Biovotion's solutions connects patients and providers throughout the continuum of care. From primary to hospital and home care. Dedicated, disease specific solutions for better health outcomes.

On Board Sensors

- Off the shelf optical sensor

The operation of the optical sensor is based on photoplethysmography (PPG), an HRM method which measures the pulse rate by sampling light modulated by the blood vessels, which expand and contract as blood pulses through them.

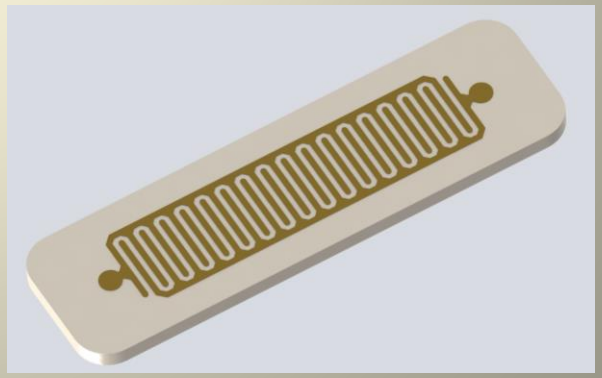


On Board Sensors

- Custom GSR sensor

The GSR sensor (**galvanic skin response**) was designed on a ceramic substrate for biocompatibility reasons. The sensor was over molded into the plastic case.

Skin resistance varies with the state of sweat glands in the skin. Sweating is controlled by the sympathetic nervous system, and skin conductance is an indication of psychological or physiological arousal. If the sympathetic branch of the autonomic nervous system is highly aroused, then sweat gland activity also increases, which in turn increases skin conductance. In this way, skin conductance can be a measure of emotional and sympathetic responses.



On Board Sensors

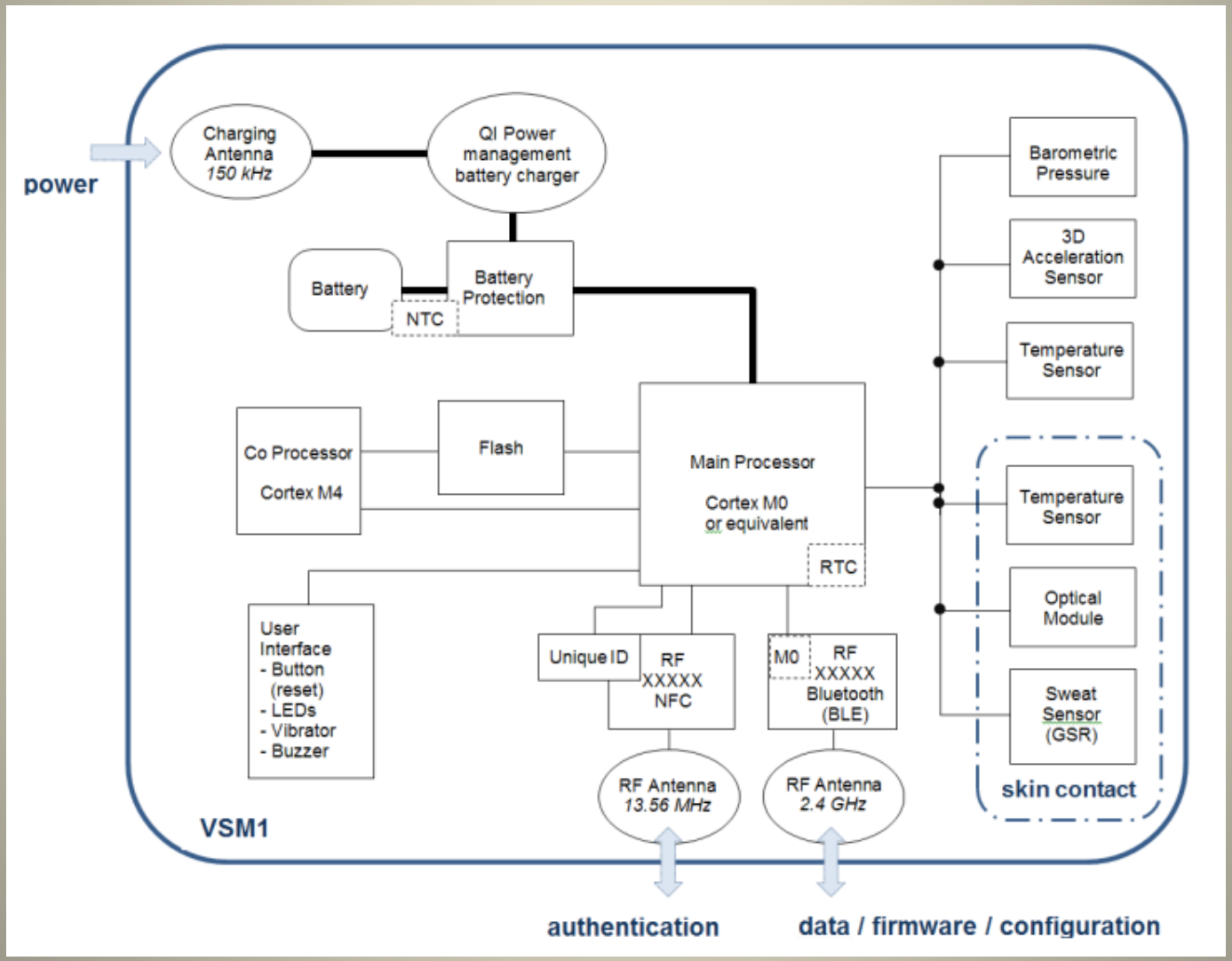
- Other off the shelf sensors:
  - *The on-board accelerometer*
  - *The on-board temperature sensor*
  - *Skin temperature sensor*
  - *The on-board absolute (barometric) pressure sensor*

Human Interface Peripherals

- *User reset switch*
- *User LEDs*
- *Buzzer*
- *Vibration motor*
- *NFC*

The reset switch does not involve any software as it is a device requirement that the reset function be managed in hardware only.

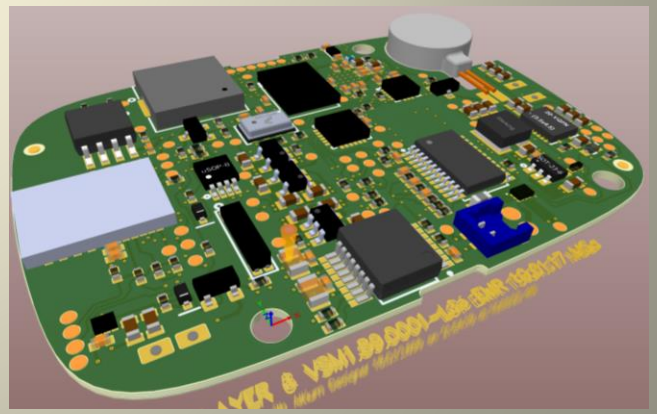
Block Diagram of System Architecture



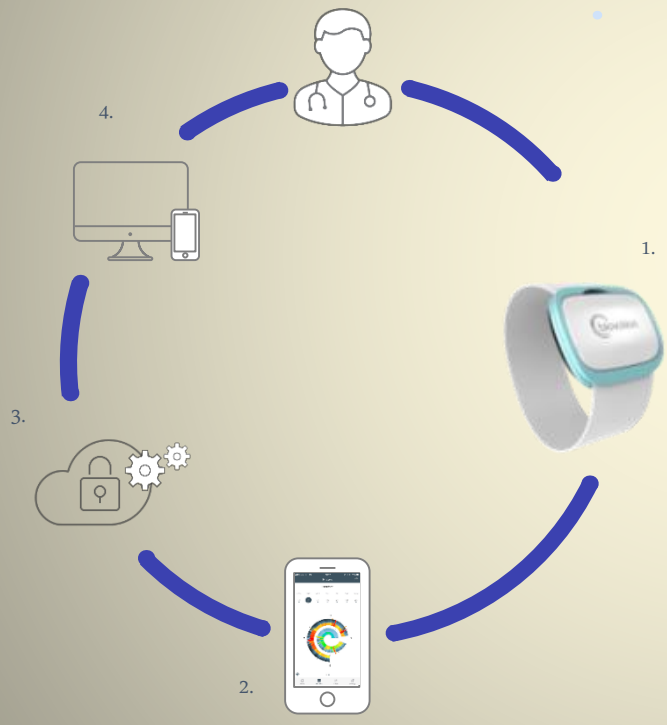
Underlying Technologies

The solution that was chosen for Biovotion project:

- One main rigid HDI PCB with components down to 0201 size, with 0.5 mm BGAs pitch, 160 components.
- Two flexible PCBs from which one is an NFC antenna, custom designed for the desired shape of the enclosure and one flexible PCB to interconnect the optical sensor of the device with the main PCB
- One Ceramic substrate PCB that allows the position of one sensor directly on the skin of the user



Interface of Bracelet to Phone and to Healthcare Professionals



1. Continuous measurements and data storage of up to 5 days.
2. Set up is done via a QR code.
3. Data transfer via BLE to app on mobile device for data visualization and as gateway, the BLE protocol supports real time streaming
4. Secure transfer to Biovotion backend (HIPAA/GDPR compliant)
5. Access of data through APIs. Data visualization on Dashboards for care teams/Healthcare professionals

Charging and Telemetry Schemes

A dedicated charger was designed in order to charge the device.

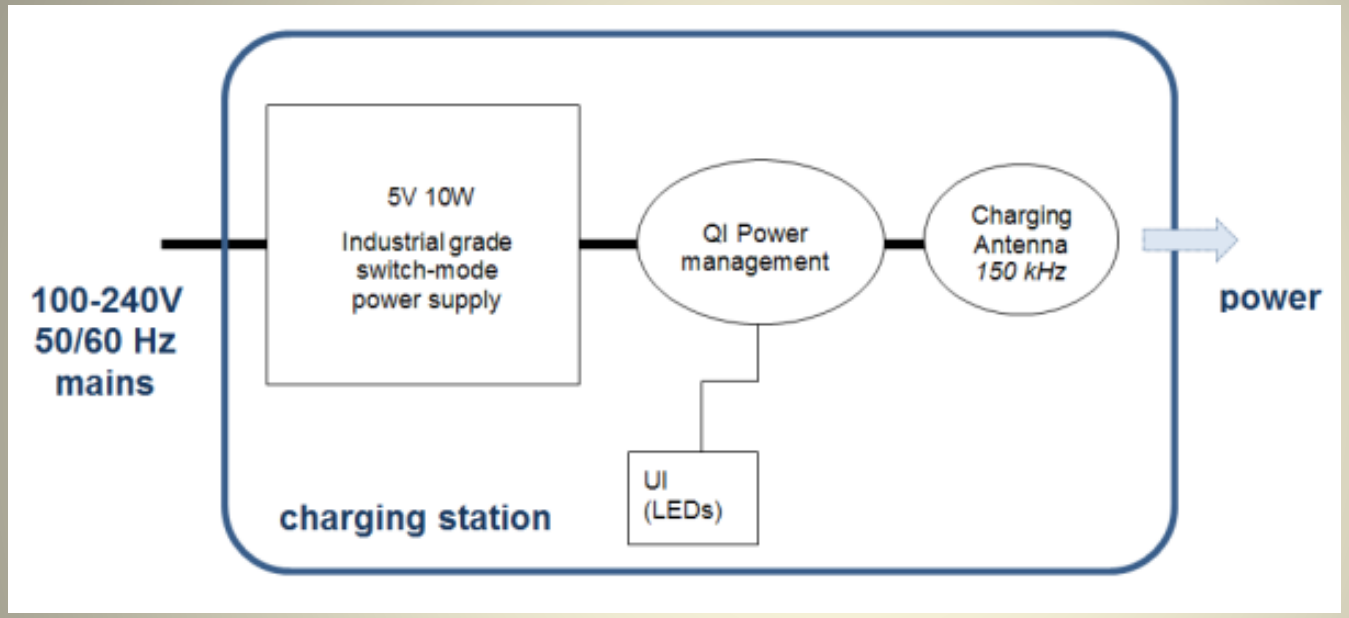
Power and charge management
- Coil antenna
- Charge management IC (QI)
- Rechargeable battery

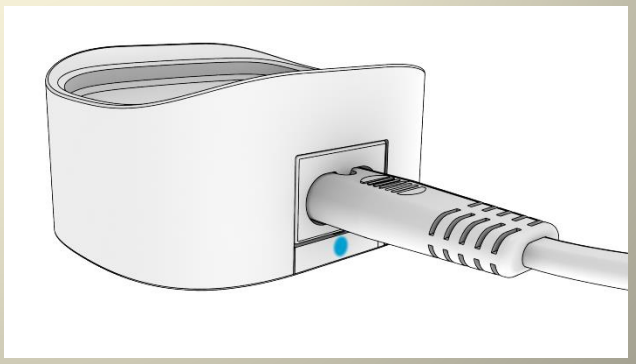
Software functions in relation to this section are:
- Battery state monitoring
- Monitoring of different system voltages

Additionally, the very QI standard involves a unidirectional communication from the Biovotion device to the charging station.

***Qi** (pronounced / CHEE; from the Chinese word qi, "energy flow") is an open interface standard that defines wireless power transfer using inductive charging over distances of up to 4 cm (1.6 inches), and is developed by the Wireless Power Consortium.*

Charging and Telemetry Schemes





Plan for Next Generation

Intra-aortic stimulation implant - Technical Features:

- PCB Features
  - Type – HDI, Flex (2.3mm x 16mm)
  - Layers – 6
  - Via's – blind/buried/blind
  - Line spacing 0.075/0.075
- Assembly features
  - Component size SMD 0201
  - Core assembly technology SMD

Contributions

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