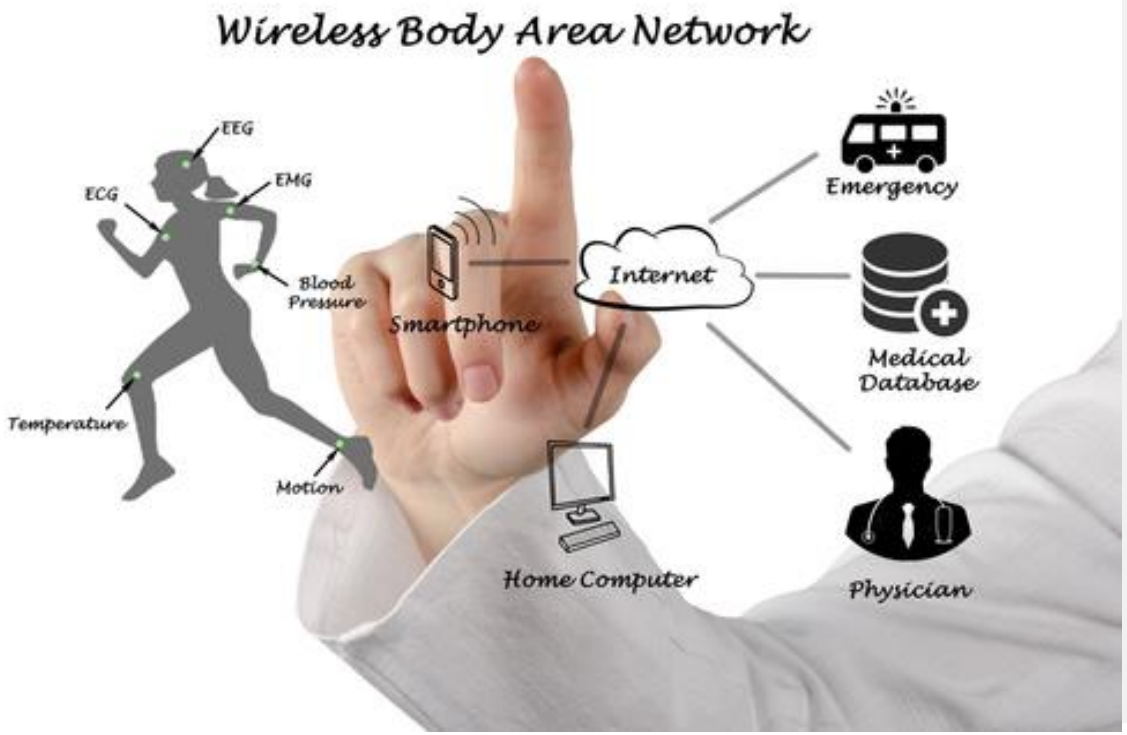

GadgEon
Engineering Smartness



Medical Standard software development

A Real time health monitoring product required IEC 62304 standard complaint software for FDA approval.

Challenge

- Develop a highly reliable IEC 62304 software development cycle compliant software for a medical product

Outcome

- Develop an Embedded Firmware and Mobile app for Real time ECG and Respiration monitoring
- The embedded biosensor patch firmware and mobile app was taken through IEC 62304 development cycle with all necessary documents needed for FDA
- The embedded biosensor firmware was written in highly efficient and power optimized way to make the patch work on coin cell batteries for multi day operation.

Medical Software Development process

- IEC 62304 – Medical software life cycle process to cover
  - SW development
  - SW maintenance
  - SW risk management
  - SW configuration management
  - SW problem resolution
- Gadgeon develops medical complaint software by taking software development through all phases of IEC 62304

WHAT DID GADGEON DO?	PLATFORMS/ TECHNOLOGIES USED
1) Architect the entire solution and provide the appropriate risk mitigation solution for developing the embedded firmware and mobile application	Requirement feasibility analysis, Architecture development, identification of functional components, identification OTS for embedded firmware and mobile app and verification strategy for them. Risk analysis and Risk mitigation plans for software components.
2) Design and Develop the Mobile app and user work flow in highly convenient fashion for medical personal usage. Integrated custom Heart rate/Respiration Rate algorithms . Developed easy to understand Alert/Alarm functionalities for managing critical medical events	The output screens and waveform made highly accurate for medical personal use by stabilizing OTS software like coreplot. Customized usage of OTS Heart rate algorithms.
3) Developed a highly reliable embedded firmware with optimized code for maximum power save to operate on low power batteries. Developed core DSP libraries that runs on fixed point mode for usage in signal compression.	Implementation of fixed point CIC,FIR filters on cortex-M0, extracting bio-sensor data from ECG and Respiration sensors and sending data using WiFi using an custom IPC between two cores of the SoC.
4) Design and development of both embedded firmware and mobile app was taken through medical standards for helping the product complaint for FDA	Used IEC 62304 process for developing the software , medical standard complaint process are in place for updating software, risk management/mitigation and maintenance of the software.

GADGEON SYSTEMS INC
881 Yosemite Way, Milpitas, CA 95035, USA

CONTACT - USA
Wes Schropp – VP Sales : +1-408-621-2570

CONTACTS - INDIA
Hari Nair : +91 9895 01 58 80 | Sreenandh : +91 9747 08 66 88

GADGEON SMART SYSTEMS PVT LTD
VI 405/E1, Fathima Tower, Malepally Road,Thrikkakara PO, Kochi, Kerala, INDIA, Pin: 682 021

sales@gadgeon.com