

The logo for GadgEon, with 'Gadg' in blue and 'Eon' in orange.

Engineering Smartness

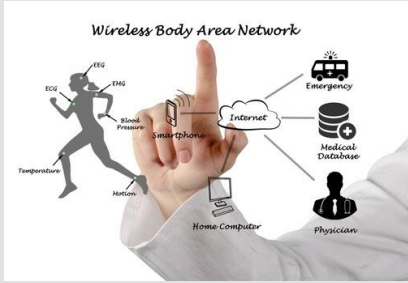
# MEDICAL STANDARD SOFTWARE DEVELOPMENT

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Version 01



# Medical Standard Software Development



A Real time health monitoring product required highly reliable IEC 62304 standard compliant software for FDA approval

## Solution Description

- Gadgeon developed embedded firmware and mobile app for real time ECG and respiration monitoring in accordance with medical standards required for making the product compliant for FDA
- Followed IEC 62304 software life cycle process for development with all the mandatory documentation.
- Multichannel ECG and Respiration data from the body-worn sensor is reliably transmitted over Wi-Fi to the Mobile App
- Embedded firmware was developed with optimized code for maximum power saving so that it can operate on low power batteries.

## Outcome and Benefits Delivered

- The patch could work on coin cell batteries for multi day operation as the embedded biosensor firmware was written in highly efficient and power optimized way
- Mobile app and user workflow was designed and developed in line with the requirements of medical practitioners
- Highly accurate waveforms display in the App enabling better informed decisions for healthcare givers .
- Real time alerting in the event of critical medical events



# The Solution / System Description

Gadgeon developed medical complaint software by taking software development through all phases of IEC 62304

- IEC 62304 – Medical software life cycle process to cover
  - SW development
  - SW maintenance
  - SW risk management
  - SW configuration management
  - SW problem resolution

## Software Architecture

- Architected the entire solution and provided the appropriate risk mitigation solution for developing the embedded firmware and mobile application.
- This includes Requirement, Gathering & Analysis, Uses cases, Architecture development, identification of functional identification OTS for embedded firmware and mobile app and verification strategy. Risk analysis and Risk mitigation plans for software components was done.



# System Description

## Mobile App Development

- Mobile app and user workflow was designed and developed in line with the requirements of medical applications
- Integrated custom Heart rate/Respiration Rate algorithms.
- Developed real time alerting in the event of critical medical events
- Customized usage of OTS Heart rate algorithms.
- High accurate output waveforms by stabilizing OTS software like coreplot enabling better informed decisions for medical practitioners

## Embedded Firmware

- A highly reliable embedded firmware was developed with optimized code for maximum power saving so that it can operate on low power batteries.
- Developed core DSP libraries that run-on fixed-point mode for usage in signal compression.
- Implementation fixed point CIC,FIR filters on cortex-M0.
- The biosensor data extracted from ECG and Respiration sensors are transferred using Wi-Fi by the means of a custom IPC between two cores of the SoC.
- Design and development of both embedded firmware and mobile app in accordance with medical standards required for making the product complaint for FDA
- Followed IEC 62304 software life cycle process for development.

# THANK YOU



For More Details, Let's Connect



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