GadgEon

**Engineering
Smartness**

UNIT TESTING & 62304 DOCUMENTATION for IoMT

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Version 01

Unit Testing & 62304 documentation for IoMT

One of Healthcare provider was working on a new product that could do Remote patient monitoring, using a device to collect vitals like ECG, Respiration & Temperature. This data was periodically retrieved by iOS/Android app and uploaded to cloud for monitoring and Analysis. They needed support in expediating FDA and 62304 process especially in Unit testing of all components

Solution Description

- Developed a unit test framework which covered each key unit in embedded, mobile and cloud areas:
  - Wireless, Medical sensors like ECG, Respiration & Temperature in embedded side
  - Data retrieval/aggregator, cloud push, user interface in Android/iOS app
  - Data processing/filtering, user management, plotting etc on the Linux based cloud server.
- Each unit could be independently verified for input/output, code coverage etc
- Corresponding documentation, code traceability, risk assessment etc needed for 62304 process were also created and submitted to FDA

Outcome and Benefits Delivered

- An augmented team worked closely with development team to cover key aspects of unit testing and 62304 documentation of each unit
- While the core team focused on development. A parallel team ensured independently verification of unit and ensured high quality output of each unit after fully understanding the internals and requirements of each unit.
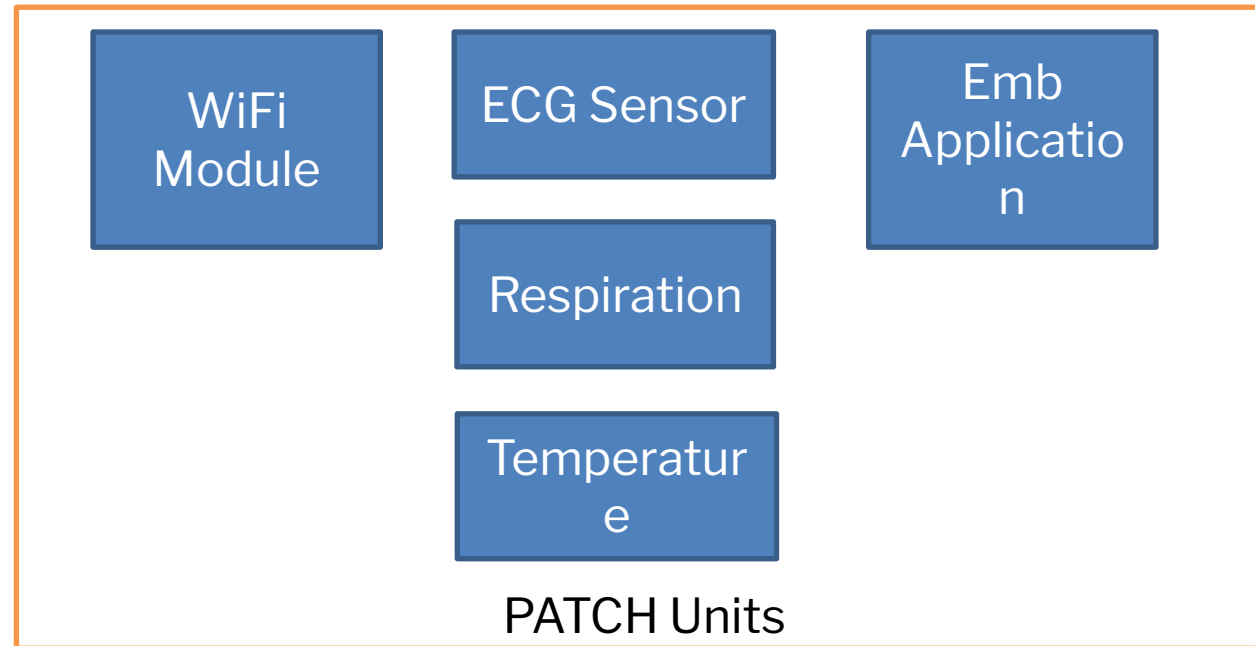- Parallel team for unit testing and documentation ensured faster submission to FDA and other testing bodies
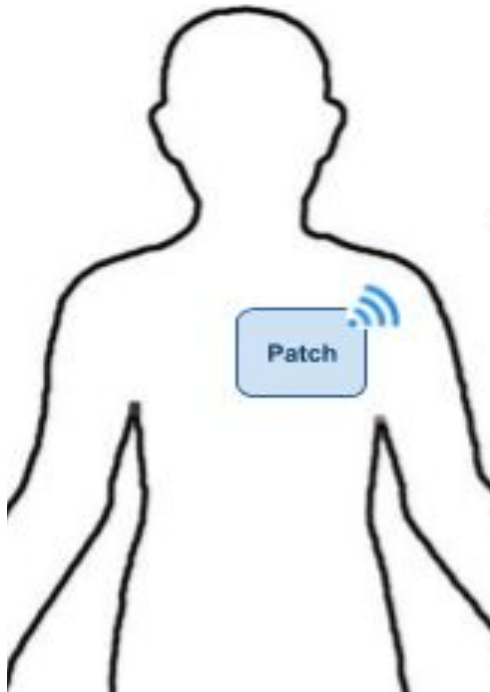
System Description

The Wireless ECG system consists of 3 Components Patch(Medical device), Mobile app, Cloud server

Patch
Patch is a coin cell operated wearable device which collects 4 lead ECG and Respiration and temperature from human body. Patch digitize data and transmits it over WiFi. Unit test and documentation were done for each of the below units
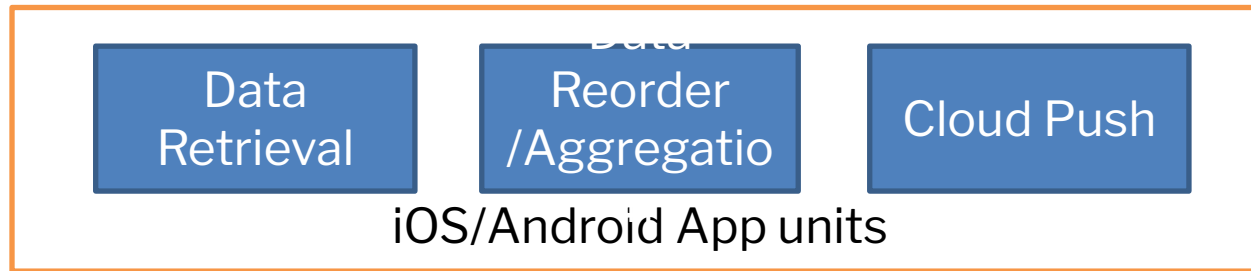

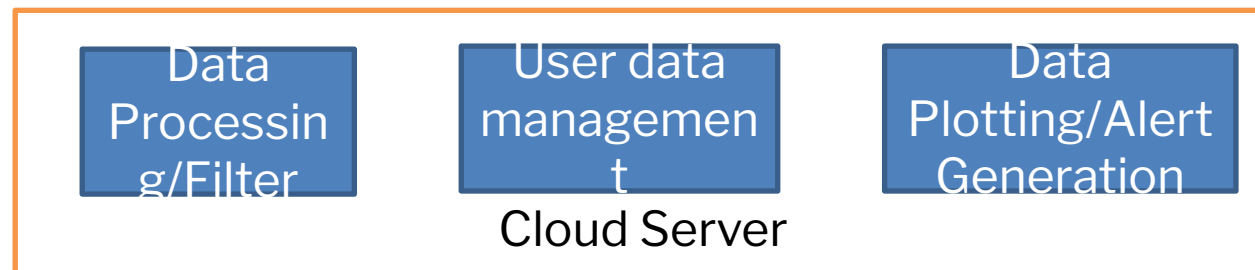| WiFi Module	ECG Sensor	Emb Application
	Respiration	
	Temperature	

PATCH Units

System Description

Mobile phone - receiver

Receiver unit collects the data from a patch in periodic manner without wasting power in patch. Also maintains user related information and cloud upload.

Data Retrieval	Data Reorder /Aggregatio	Cloud Push

iOS/Android App units

Cloud Server

Linux based server aggregates all data from different patches and displays it in near realtime for healthcare staff to monitor

Data Processing/Filter	User data management	Data Plotting/Alert Generation

Cloud Server

Unit test & Documentation coverage

- Gadgeon unit test team checked the Interface requirements, Logical/Arch design, Performance & Timing aspects and developed detailed unit tests

- Automated unit test framework using python was created . It could trigger predefined unit tests on FW, Mobile or Cloud components. Helped in independent development of each unit with automatic verification and clean integration of the units.

- Static Analysis, Code coverage etc were done using opensource tools like Clang, Gcov, Android Lint etc

- Requirement traceability up to code level were captured, risk assessment of units were done and 62304 documentation with proof of unit test execution were created and submitted for FDA/CE etc

THANK YOU

For More Details, Let's Connect

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