Functionality, Specification And FME(C)A Of A Health Monitoring Device - Apple Watch As A Case Study

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I. INTRODUCTION

Heath monitoring devices are instruments used by medical doctors to diagnose, monitor, or treat diseases and other health-related issues. However, with the advent of smart devices, individual patients now have the ability to monitor their own health and, as a result, can communicate health conditions with their doctors more quickly. This work focuses primarily on the functionality and specification of a smart health monitoring device (apple watch), as well as performing FME(C)A (Failure Modes, Effects, and Criticality) Analysis of the device.

II. GENERAL REQUIREMENT FOR A WEARABLE DEVICE

There are some general requirements for developing wearable systems or devices such as apple watch which include;

- ***Wearability*** - device should be lightweight and small in size.
- ***Reliability*** – there should be a high accuracy in medical signals to ensure that they are reliable.
- ***Ease of Use*** – the device should be designed to be user-friendly or effortlessly to use.
- ***Fault tolerance*** – the device should produce reliable results under any circumstances.
- ***Good signal reception*** – as most wearables are designed with sensors, they should be able to record vital signals and predict patient health conditions.
- ***Scalability*** – the device hardware should be able to upgrade and software update should be possible.

III. APPLE WATCH SERIES-7

The Apple Watch is a smart device or wearable smartwatch that offers users a variety of functions. It can send text messages, read emails, and make phone calls. It also has powerful applications that assist users or patients in detecting early warning signs of health problems. There have been several series of the device since its initial release by Apple Inc. in 2015, and up to this current series-7 with new functionality called electrocardiogram (ECG) application. The watch works in tandem with iPhone device running iOS within a range of approximately 10 meters and connections are possible using Bluetooth and Wi-Fi network. Unlike the iPhone user interface where screen navigation is easy and user can type text message or an email, the Apple Watch interface was designed to be worn on wrist, typing an email or text is not possible and navigation is done only tapping, swiping and scrolling using a button attached on the side of the watch.

IV. APPLE WATCH SPECIFICATION AN FUNCTIONALITY

Water Resistance: Apple Watch Series 7 have a water resistance rating of 50 meters under ISO standard 22810:2010. This means that they may be used for shallow-water activities like swimming in a pool or ocean. However, they should not be used for scuba diving, water-skiing, or other activities involving high-velocity water or submersion below shallow depth.

Blood Oxygen Measurements: are not intended for medical use, including self-diagnosis or consultation with a doctor, and are only designed for general fitness and wellness purposes.

ECG Application: and irregular rhythm notification require the latest version of watchOS and iOS, and are not intended for use by people under 22 years old. The ECG app is available on Apple Watch Series 4 or later (not including Apple Watch SE). The irregular rhythm notification is not designed for people who have been previously diagnosed with atrial fibrillation (Afib).

GPS + Cellular: can use a cellular connection for Emergency SOS. To use Emergency SOS on an Apple Watch without cellular, your iPhone needs to be nearby. If your iPhone isn't nearby, your Apple Watch needs to be connected to a known Wi-Fi network and you must set up Wi-Fi Calling. Wireless service plan required for cellular service.

Battery Capacity: Apple Watch All-Day Battery Life testing was conducted by Apple in August 2021 using preproduction Apple Watch Series 7 (GPS) and Apple Watch Series 7 (GPS + Cellular), each paired with an iPhone; all devices were tested with prerelease software. Battery life varies by use, cellular coverage, configuration, and many other factors; actual results will vary. See Table I for full specification.

TABLE I. APPLE WATCH SERIES-7 SPECIFICATION

Features	*Properties*
Display	Type: Retina LTPO OLED, 1000 nits Size: 1.9 inches Resolution: 484 x 396 pixels Protection: Sapphire crystals glass Always-on display
Platform	OS: watchOS 8.0, upgradable to 8.4 Chipset: Apple S7 CPU: Dual-core GPU: PowerVR
Memory	Card slot: No Internal: 32GB
Communication	WLAN: Wi-Fi 802.11 b/g/n, dual-band Bluetooth: 5.0, A2DP, LE GPS: Yes NFC: Yes Radio: No USB: No
Body	Dimension: 45 x 38 x 10.7mm Weight: 42.3 g (41mm), 511.5 g(45mm) (1.48 oz) Build: Glass front, ceramic/sapphire, crystal back, stainless steel frame SIM: eSIM 50m water resistant ECG Camera: No
Features	Accelerometer, gyro, heart rate, barometer, altimeter. Ultra-Wideband support\
Battery	Type: built-in Li-ion 309mAh Charging: Wireless
Network	Technology: GSM/HSPA/LTE

There many health-related functionalities of the Apple Watch series-7 which includes the following:

Heart rate notifications. Apple Watch checks for unusually high or low heart rates in the background, which could be signs of a serious underlying condition. This could help you and your patients identify situations which may warrant further evaluation. If a patient's heart rate is above 120 bpm or below 40 bpm while they appear to have been inactive for 10 minutes, the user will receive a notification. Patients can adjust the threshold bpm or turn these notifications on or off. All heart rate notifications — along with date, time, and heart rate — can be viewed in the *health* app on iPhone.

Irregular rhythm notifications: The irregular rhythm notification occasionally checks for signs of irregular rhythms that may be suggestive of atrial fibrillation (AFib). This feature won't detect all instances of AFib but may catch something that can provide your patients with an early indication that further evaluation may be warranted. Irregular rhythm notifications use the optical heart sensor to detect the pulse wave at the wrist and look for variability in beat-to-beat intervals when the user is at rest. If the algorithm repeatedly detects an irregular rhythm suggestive of AFib, your patient will receive a notification and the date, time, and beat-to-beat heart rate will be recorded in the health app. The irregular notification feature has been granted De Novo classification by the FDA for users 22 years and older in the U.S. with no prior history of AFib.

ECG app: With the ECG app on Apple Watch Series 4 or later*, patients who experience symptoms such as rapid or skipped heartbeat, or receive the irregular rhythm notification, can capture an ECG and record their symptoms. This real-world data can enable you to make more informed and timely decisions regarding further evaluation and care.

The ECG app uses the electrical heart sensor built into the Digital Crown and the back crystal of Apple Watch Series 4 or later* to record a single lead ECG similar to a Lead I ECG. The ECG app then provides a result of sinus rhythm, atrial fibrillation, atrial fibrillation with high heart rate, or poor recording, and prompts the user to enter any symptoms such as rapid or pounding heartbeat, dizziness, or fatigue. The waveform, results, date, time, and any symptoms are recorded and can be exported from health app as a PDF to share with a clinician. If the patient notes symptoms that indicate a serious condition, they are prompted to immediately call emergency services.

Mobility and Cardio Fitness: Mobility and cardiovascular fitness can be strong indicators of overall physical health and a predictor of long-term well-being. Apple Watch and iPhone can provide estimates of mobility metrics to give you and your patients a better understanding of how they impact mobility today and provide tools to monitor these factors over time. Mobility metrics include Cardio Fitness (VO_2 max), Six-Minute Walk Distance, and other metrics used to measure walking quality (Walking Speed, Step Length, Double Support Time, and Walking Asymmetry). These metrics can be utilized for research and app development with the user's permission.

Fall Detection: When a hard fall is detected with Apple Watch Series 4 or later, an alert appears and allows the user to easily call emergency services or dismiss the alert. If the user is unresponsive for about a minute, an emergency call will be placed automatically and a message will be sent to the user's emergency contacts. All falls detected are recorded in the health app. This feature is automatically enabled for users 55 years and older and can be turned on for anyone in the Apple Watch app on iPhone.

Medical ID: allows first responders and emergency room clinicians to access critical medical information from a patient's iPhone lock screen or Apple Watch without requiring a passcode, and without compromising patient privacy. Patients can list important information such as allergies, medications, conditions, organ donor preferences, and emergency contacts by setting up Medical ID in the Health app on iPhone.

V. FAILURE MODES ,EFFECT AND CRITICAL ANALYSIS FME(C)A FOR APPLE WATCH

Failure Modes and Effects Analysis (FMEA) is a technique that consider the failure of any component within a system and track the effects of this failure to determine its ultimate consequences however, FME(C)A is an extension of FMEA which takes into account importance of each component as

well as determines the probability and frequency of failure occurrence.

TABLE II. FEM(C)A FOR APPLE WATCH SERIESS-7

FMEA								
Product Name: Apple Watch Series-7								
Component	**Failure Mode**	**Effects of Failure**	**Causes of Failure**	**Solution**	**S**	**O**	**D**	**RPN**
CPU	Over-heating	Device crashes/Physical screen damage	Exposure to high temperature	cooling	6	1	4	24
Memory	Device is slow	Device crashes	Overloaded apps	Free up memory	5	1	3	15
Microphone					6	2	1	12
Wi-fi	Device is slow	Lost connectivity		Hotspot	1	3	8	24
Touch Screen	Loss of input	Device cannot be controlled	User Error	Replace touch screen	6	5	3	90
Buttons	Broken	Device cannot be controlled	User Error	Voice Command /Replace buttons	3	6	3	36
Accelerometer / Gyroscopic Sensor	Broken	Failed movement detection		Replace touch screen	6	5	3	90
Optical Pulse Sensor								
Battery	Unfirm contact with terminal	Poor charging capacity	Hard hit on the ground		6	1	4	24
Loud-speaker	Unclear	Bad sound output	Exposure to dirty	Replace				
Taptic engine								

S = Severity rating (1 to 10)
O = Occurrence frequency (1 to 10)
D = Detection Rating (1 to 10)
RPN = Risk Priority Number (1 to 10) = S * O * D

REFERENCES

[1] Support.apple.com. 2022. *Apple Watch Series 7 - Technical Specifications*. [online] Available at: https://support.apple.com/kb/SP860?locale=en_US [Accessed 16 March 2022].

[2] US National Library of Medicine National Institutes of Health. 2022. [online] Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6839437/ [Accessed 16 March 2022].