

“And the future of health is on your wrist” - Apple

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Introduction

Over the years, wearable devices (smartwatches) have become increasingly popular and one of the most promising tech devices on the market, especially from the healthcare perspective. Top tech companies such as Apple, Google (Fitbit), Samsung understood the potential of wearable health devices and have significantly invested in this domain. What started off as a watch that performs simple tasks like receiving and making phone calls/messaging, this device can now track fitness activities and get notifications, listen to music, use the built-in GPS, and make contactless payments. This paper will provide an in-depth analysis of the Apple Watch in the healthcare context, going through the technologies and use cases, ethical issues, and possible recommendations to address these ethical issues.

Technology and Use Case

A smartwatch can be used to measure health related metrics as the wrist has veins and arteries to easily measure pulse and to detect blood pressure. Apple Watches have been evolving tremendously in the health wearable sector, with new features launched every year. The health metrics that can be measured through the smartwatch will be automatically synced with the Health App on the iPhone. Along with measuring health metrics, apple watches and the health

app can be used to store medical information about the user. The Medical ID feature in the apple watch 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. These critical medical information include general patient info, severe conditions, medications, allergies, organ donor preferences, and emergency contacts.

The health metrics that a smartwatch can measure are

- a. Electrocardiogram (Heart Rate and Heart Rate Variability (HRV) [1] - The Electrocardiogram records the electrical activity of the heart. This is helpful for patients who experience rapid or skipped heartbeat, or receive irregular rhythm, useful to detect hypertension/myocardial infarction. The ECG app uses the electrical heart sensor built into the Digital Crown and the back crystal of Apple Watch to record a waveform similar to Lead I ECG [Id.]. The Apple Watch monitors heart rate by using green LED lights built in the wearable device. The lights reflect on the skin to detect the pulse and changes in blood volume; this is turned into the heart rate number [Id.]. The app then provides the results 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 [Id.]. The ECG cannot identify conditions such as heart attacks.

- b. Mobility and Cardio Fitness [2] – The Apple Watch initially started by measuring steps, distance travelled, active minutes of the user, through the accelerometer and GPS tracking. Along with this, Apple Watches can now measures
- i. Walking Speed - Walking Speed can be used to track recovery of acute health events and monitor changes over time such as aging and disease progression
 - ii. Step Length - Step Length is a marker of compromised mobility for types of neurologic and musculoskeletal conditions and can help predict falls and fears of falling [Id.].
 - iii. Double Support Time - Double Support Time is the proportion of time that both feet are touching the ground during walking [Id.].
 - iv. Walking Asymmetry - Walking asymmetry takes place when the user relies on the contralateral limb during walking [Id.].

Cardio fitness estimates the user's VO₂ max in ml/kg/min by measuring the heart rate response to physical activity [3].

- c. Oxygen Saturation (SpO₂) [4] - This is used to measure the blood oxygen saturation level. The blood oxygen level represents the percentage of oxygen red blood cells carry from the lungs to the rest of the body. Most people have a blood oxygen level of 95%-100%. A higher value is better as it means that the blood is more efficiently able to transport oxygen to muscles and organs. To calculate this health metric, the optical heart sensor also consists of blood oxygen measurement capabilities. During a blood oxygen measurement, the back crystal shines red and green LEDs and infrared light on the wrist [Id.]. Photodiodes then measure the amount of light reflected back [Id.]. Complicated algorithms use this data to calculate the color of your blood. The color determines your

blood oxygen level — bright red blood has more oxygen, while dark red blood has less [Id.].

- d. Respiratory Rate [5] - Also known as the Breathing Rate (Number of breaths you take per minute). Apple watch can track the user's breathing rate, helpful to detect early signs of conditions such as sleep apnea and chronic lung disease. The Apple Watch measures the respiratory rate through its inbuilt accelerometer and is calculated during normal activity and sleep [Id.].
- e. Sleep Tracking [6] - Used to provide insight into sleep. It is connected with the Sleep App on the iPhone that can be used to create a sleep schedule. The watch also uses the accelerometer to detect the user's movement while sleeping and also the sleeping respiratory rate data to analyse breathing patterns (number of breaths per minute while asleep) [Id.].
- f. Fall Down Detection [7] - The Apple Watch can now detect if the user has fallen by analysing data from a combination of accelerometer and gyro. If the Apple Watch detects that the user is immobile for about a minute after the fall, it begins a 30-second countdown, while tapping the user on the wrist and sounding an alert [Id.]. After the countdown, the Apple Watch automatically contacts emergency services (only if wrist detection service is turned on by the user) and plays an audio message that informs emergency services that your Apple Watch detected a hard fall and shares your current location as latitude and longitude coordinates [Id.]. The user's Medical ID information will also be shared with the emergency call if the user has given permission.

Health and fitness information in the Health app is stored automatically in iCloud (iOS 11 and above) [8]. Information is encrypted as it goes between iCloud and your device and while it's

stored in iCloud. The data that is stored in iCloud is Health data (heart rate information, sleep tracking, step counts, elevation, etc), sources and connected devices, Medical ID, activity rings, workouts, stand hours, and activity achievements [Id.].

Apple is the leading company in data privacy and security and currently, there have not been any issues with respect to the security aspects of Apple Watches. They have ensured strict encryption techniques while data moves and lands in the cloud and data can only be shared to others if the user explicitly provides permission [9].

Ethical Issues

Is the Apple Watch really a Medical Device and if so, how accurate is it?

FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States [10]. Medical devices are classified into three classes, Class I, II, and III. Regulatory control increases from Class I to Class III as Class I includes devices with the lowest risk and Class III includes those with the greatest risk [Id.]. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval [Id.].

An interesting “loophole” is if the company states that the product is for fun (not serious), or for general “wellness,” they don’t have to go through that process to get FDA clearance or approval. They can’t claim that it can diagnose or treat any medical conditions, but they can launch it to market. This is the path chosen by Apple. They stated that their device is offering up health information and not diagnosing diseases. [11]

The FDA does interfere when firms want to use apps to influence/affect the medical care someone receives. The ECG (or EKG) feature in the Apple Watch does however belong here as this feature to flag abnormal heart rhythm and Apple submitted a De Novo request to the FDA for regulatory classification of the ECG app in early August. [12]

The FDA determined that for the uses of the ECG app outlined by Apple, the ECG app can be classified as a Class II device [Id.]. Since it is classified as a Class II device, Apple just requires the FDA clearance and not approval as FDA approvals are reserved for Class III products or technologies that are deemed to be a higher risk but also carry a higher potential benefit to the user. [13]

To satisfy the FDA clearance process, Apple had to provide and publish data showing that the feature could flag atrial fibrillation [Id.]. Doctors and experts were able to examine the information, and there are dozens of published research studies closely examining how well the watch can actually detect dangerous heart rhythms [Id.].

Interestingly, since the pulse oximeter is just a wellness product, Apple did not have to get FDA clearance/approval [Id.]. One of the reporters of The Verge felt concerned when he could not find much data regarding how well the Apple Watch's pulse oximeter worked compared to other devices on the market. He further stated that anecdotal reports from people testing the Apple Watch found that the pulse oximeter feature isn't accurate and can be hard to use.

From this, we can gather that Apple Watch is an amalgamation of FDA clearance and non FDA clearance health features. The distinction between a feature used for wellness (non FDA cleared) and one used for medical monitoring (FDA cleared) is critical. Features used for wellness purposes are not cleared or approved by experts while medical monitoring features are approved

by experts. The issue that persists with this is that users are unaware of which health metrics are FDA cleared and hence poses the question of data accuracy. This confusion is created by the i) the user's ignorance to research more ii) Apple's marketing that blurs this distinction. Without understanding this distinction, users will strongly rely on all the health metrics measured by the watch. People who may need to see a healthcare professional for a serious undiagnosed health issue might not do so as the watch might be indicating that everything is fine.

Another reason for less data accuracy is the logistical challenges that arise due to smart watches. For example, if the user does not excessively move their arms while walking, the watch might not be able to accurately track the user's step count. Another case is if the Watch is too loose, the accelerometer might register too much movement and hence it is important to make sure the watch is at a comfortable and correct fit [14]. Also, ensuring that the user enters the correct information such as your weight, height, age, and gender will be critical to ensure accurate tracking of activities.

In July 2021, an article from The Verge [15] claimed that the “black box” data obtained from Apple Watches posed research inconsistent problems. JP Onnela, a Harvard biostatistician, found that the heart rate variability data collected during the same time period appeared to change without warning. As the algorithm behind measuring these health metrics remains a mystery to users, it is impossible to know what is in them, hence, the black box. Mr. Onnela wanted to explore the possibility of using commercially available wearable devices and hence his team wanted to check how severe the data issue variability is. As a test, Mr. Onnela checked in on heart rate data his collaborator Hassan Dawood exported from his Apple Watch [Id.].

Instead of displaying the raw data collected by the watch, the product usually only lets researchers export information after it has been analyzed and filtered through an algorithm of some kind. Companies also do change their algorithms regularly without warning as they are not super incentivized to tell customers how and when they're changing things. While checking on the heart rate data on his collaborator, Onnela was surprised to see a huge difference in the measurements. Apple did not have an explanation for the discrepancy, other than potential issues with the third-party app used to export the data. Though this was one informal example and not a published research study, this article is important to open the eyes of the public to use such devices with caution.

How do doctors feel about the rise in Apple Watches for healthcare?

As the Apple Watch markets itself as a self-help tool, it can be interesting to understand how these devices can go hand in hand with experts' guidance and advice. Doctors and clinicians have mixed views on how patients gather and present information from "quasi"-medical aspirational wearable devices. While most doctors feel that it is a great way to have a 24/7 health monitoring device, doctors are not trained and not aware of how to use this information when patients bring their stats to a doctor [16]. A story published in the MIT Technology Review supports this case as it found that doctors from a number of specialties are unsure what to do with data such as counted steps [Id.].

Cardiologist Dr. Kevin Campbell [17], felt that while the Apple Watch is a great way to engage patients, it cannot be considered as a medical device. The data that is produced by the Apple Watch is not in the correct format for Doctors to easily use and key data points that are required by a physician to diagnose a problem are not measured [Id.]. Hence, there exists a significant gap

between what data medical experts require to diagnose a problem and what technology companies think medical experts require.

Another concern doctors have with health wearables in general is that patients with Apple watches are heavily dependent on the readings that they visit doctors less often [18]. A study examined a treatment group, 125 people with atrial fibrillation and a heart-monitoring wearable, such as the Apple Watch, who visited the University of Utah Health during a 90-day period, and compared them to a control group of 500 people with the same condition and similar characteristics, but no wearable [Id.]. Results showed that users with heart-monitoring wearables are not more likely to visit a doctor about a health condition with their heart and these users are more likely to undergo medical procedures [Id.].

Is the Health Data Safely Collected? [19]

Apple, being one of the top companies for data security and privacy, made sure that the health data that is being collected from the watches is stored safely on iCloud. Apple does not have the ability to read user health and activity data synced to iCloud. Users can

- a. Choose iCloud to keep data up to date where data is encrypted while in transit and at rest.
This option can be enabled or disabled by the user [Id.].
- b. Choose to back up data to an iTunes encrypted backup on computer [Id.].

Users can also choose to share the data to third party apps trusted by the user, family, friends, and healthcare providers [Id.]. All third-party apps through privacy policy must explain why they are requesting access to Health data. Users have full control over the data that is shared with these third-party apps and can be modified at any time. There is also transparency in which third-party

apps have granted access to Health app data and manage what data is shared and received from these third-party apps [Id.].

To healthcare providers, any Health app data chosen to share will be encrypted and stored by Apple on a dedicated server [Id.]. This ensures that Apple can securely share this data with the healthcare organization chosen by the user [Id.]. Apple does not maintain or have access to the encryption keys for data that is stored on our servers and shared with your healthcare organization and cannot decrypt, view, or otherwise access this data [Id.].

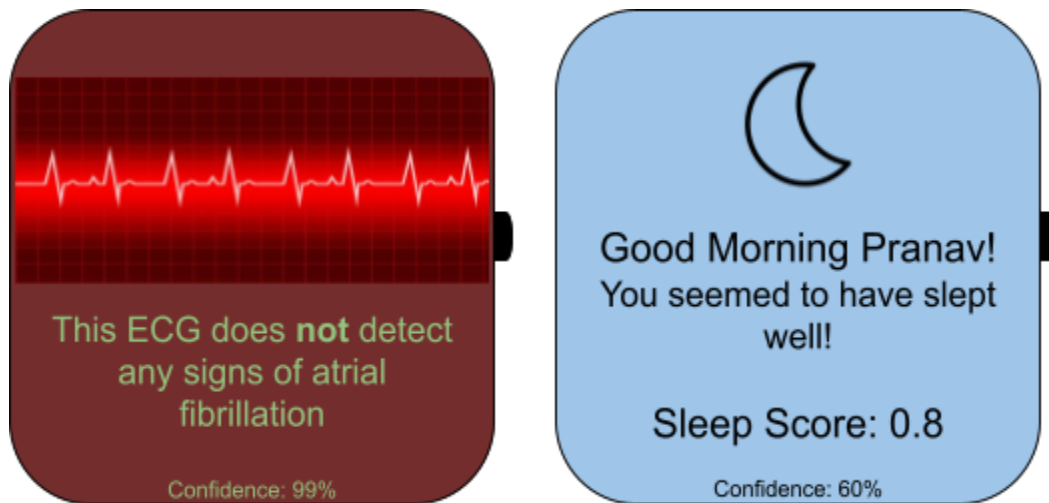
Recommendations

With annual updates and frequent modifications, Apple Watches are actively improving the quality and creating new possibilities. However, it is important that Apple clearly address some of these ethical issues to ensure that users are not misled. Here are some recommendations I feel Apple should undertake to address these issues.

Providing Full/Clear Transparency to Users

It is important to clearly distinguish the features that are FDA cleared to those that are not. This will help users understand the level of accuracy each feature holds. If FDA clearance is not the best metrics to measure data accuracy, then being able to differentiate between features have the larger measurement confidence intervals to those that have small measurement confidence intervals.

One way they could implement this is by mentioning the algorithm's confidence while alerting the user. For example,



These two prototypes could be one way to show the model confidence while displaying measurements to the user. Mentioning the “Confidence: 60%” could be a great way to indicate chances of error in the reading.

Another level of transparency Apple should indicate is some level of detail in the algorithms they use while measuring these health metrics. This will be extremely helpful to doctors, clinicians and researchers who use these measurements for diagnosis and to publish research. If this information is provided, researchers would feel more confident in using these devices as a mode of collecting patient health data and can publish compelling insights and findings.

Improving Data Accuracy

Another major recommendation which Apple has been doing over the years and should continue to do is improving the measurement accuracy of its features. Through rigorous R&D, Apple should identify new technologies and concepts that can significantly increase the accuracy of the sensors and data. To help bring a more stronger healthcare perspective in their products, the CEO of Johnson and Johnson, Alex Gorsky joined Apple as one of their board of directors in Nov

2021 [20]. This partnership would enhance Apple Health and help identify techniques to help discover more accurate algorithms and measurements. Along with having Mr. Gorsky, I feel it will be crucial to also appoint a Doctor as a part of Apple Health. This will ensure that the readings and measurements from Apple Watch can be cohesive in providing patient diagnostics by Doctors. Their inputs would also be crucial in understanding the format in which data should be presented, as one of the major issues is that Doctors are unable to make sense of most of the metrics coming from these watches. Having a diverse background of board members and decision makers would really help improve the quality of Apple Watches.

Conclusion

The emergence of smartwatches have taken the health tech industry by surprise. Numerous health metrics can be measured and stored by a watch to help users keep in charge of their health. Though this has a huge benefit to society, it is also crucial to understand and spread awareness of its limitations. Users should not completely trust all health measurements as it is susceptible to error. The Apple Watch is meant to be a great aid for doctors and not as a replacement. While, there are ethical issues that arise about data inaccuracy and the black box algorithms, Apple have taken some great steps to help address these issues. Appointing the Mr. Gorsky as the board of directors will certainly provide a more holistic approach while designing and improving upcoming features for the Apple Watch. In terms of security and privacy, Apple has been a top company, ensuring that user Health data is not misused/mistreated by others. Apple Watch has surely gone through a revolutionary transformation and it will be exciting to see the incredible innovations in the upcoming years.

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