

Wearable Devices and Usage - BLOG



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Wearable devices allow users to view results by syncing the devices with matching apps in their smartphones

INTRODUCTION

As more users are taking awareness of their own health, increasingly wearable devices have become popular amongst all ages. With different brands and names in the market, their use varies and has tripled in the last few years [7] making it advantageous for the user. These devices not only collect exercise variables like steps walked or calories burned but have now increased their use to assist physicians in their diagnosis and to customize drug delivery [6]. In order for these devices to be sold legally in the market, the U.S. Food and Drug Administration (FDA) needs to approve the specific function that aids in diagnosis and customizes drug delivery.

Types & Users 4,7

The selection of the wearable is dependent on the user's needs and the metrics they are hoping to monitor; however, most activity trackers are available for all ages, including kids.

In order for these devices to match the user's lifestyle, there are multiple variations: colored watch faces, variety of band colors, stylish bands, fitness bands, and female/male bands. Users can view results by syncing the devices with matching apps in their smartphones. Some of the most common uses are listed below:

- **Activity trackers:** wristband with sensors that can sense physical activity and heart rate.
- **Watches:** with corresponding app to monitor heart rhythms and alerts for atrial fibrillation detection. Newer models include monitoring of blood oxygen saturation, sleep tracking, and an EKG sensor. They can also serve as an extension of their phone and receive texts, make phone calls, set alarms, etc.
- **EKG Monitors:** for EKG, can also detect atrial fibrillation, and send results to a physician when synced.
- **Blood Pressure Monitors:** keeps track of blood pressure and steps, distance traveled, and calories burned. It can save several readings and can then transfer to an app.

- **Patches:** self-adhesive with biosensors to collect movement like heart rate, respiratory rate, and temperature.
- **Drug delivery:** personalized to control dosage.

APPROVALS

Before these wearable devices go out to the market, they need to be clinically tested and approved. They are not FDA regulated if their intended use is for general wellness [8]. But if their intended use is to assist in diagnosing, FDA will review these functions only.

A multi-site clinical trial is done to meet certain objectives, such as if the device can detect the specific function for it being approved. For example, the EKG software in one of the monitor wearable devices, was clinically tested in a human clinical trial to evaluate the software's ability to detect atrial fibrillation, an irregular heartbeat that can lead to cardiovascular damage in patients.

Bench and clinical testing demonstrated it is substantially equivalent to devices in the market and is classified as a Class II with a 510(k) clearance [1]. However, they are subject to several control requirements.

Given its wide usage and benefits for the patient, in order to sell these devices in other countries, proper regulations need to occur. For example, in order to sell these wearable devices in the European Union, CE marking applies only if specifications exist and the wearable device meets all the requirements [3].

SUBJECT UNDERSTANDING

In human clinical trials, the subject needs to understand where the data is going. Even after the trial is complete, or using the device that is already in the market, the data collected is not just for the user to view, it also goes to their physicians if they choose to, and manufacturers once the device is synced with the app.

Subjects need to be compliant in order to get the best data and need to work closely with their study site to address technical issues, should they arise, in order to maintain the study data integrity. Patients need to understand the device's intended use.

CONCLUSION

These devices have empowered the user to be more conscious of their cardiovascular health, nutrition, and daily activities. Even though these devices can help decrease hospital admissions, sometimes immediate treatment is needed, and the user needs to take action. Manufacturers need to also follow proper requirements for their usage.

Sensors for these devices will only be enhanced and improved as time goes by. This enhanced technology and more data from the increased number of users, can then be used to identify certain variables for future studies, remote monitoring of patients, or better control in a future pandemic [2].

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