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Trends in Wearable Biotechnology

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1. Introduction

Wearable technology, whether for entertainment or medical purposes, is continuing to grow in demand and popularity. Wearables are becoming smaller, less expensive, and more common in our daily lives.

With the increasing demand of consumers to monitor and track their own health and vital signs, use of wearable technology has more than tripled in the last four years. According to research from Insider Intelligence, more than 80% of consumers are willing to wear fitness technology. We are also seeing the rise of biosensors as a new innovation in wearable medical devices.

We have only begun to explore the various uses of wearable technology, with potential future innovations including using clothing to power devices, and the use of artificial intelligence as personal assistants, or in various medical devices. But with new innovation, regulation will follow.

This white paper looks at the increasing number of wearable devices on the market today. It gives an overview of the different categories of wearable technology, from entertainment and athletic applications to healthcare.

2. Overview

From calculator watches in the late 1970's and digital hearing aids in 1987 that were the pioneers of wearables, to today's Bluetooth earbuds, smartwatches and smart glasses, wearable tech has become more and more common in our daily lives.

Wearable devices have also come to include James Bond type devices such as tie pins with a video camera, earrings with hidden microphones, and glasses with Bluetooth audio and video capabilities. New technological marvel wearables such as Apple watches and Fitbits have gained significant traction with consumers.

Some of the newest forms of wearable technology, such as wearable fitness trackers, are wristbands equipped with sensors to keep track of the user's physical activity and heart rate. Wearable devices include such products as Fitbits, smartwatches, phones and Google glasses. Medical innovations such as insulin pumps, cardiac monitors, pacemakers and biosensors have also entered the everyday marketplace.

One of the newest innovations are biosensors, sensor-embedded smart fabrics making wearables less intrusive and noticeable. Smart fabrics can be used to make shirts, jackets, pants, socks, or even shoes. These smart clothes can be folded and stretched and not interfere with function. Data collected from the wearer's body can include heart rate, blood oxygen level, blood glucose level, blood pressure, body temperature, and activity.

A waterproof, bandage-like sweat sensor that tells the wearer when to replenish electrolytes and fluids has also been developed. This patch sensor collects and analyzes an athlete's perspiration as they exercise in any environment, including swimming.

3. Wearable Technology Applications

Wearables are most associated with the health and wellness sectors. Smartwatches, like a Fitbit or Apple watch, have pioneered the way we track everything from heart rates to our daily steps. Most current wearable tech falls into 3 applicable categories: entertainment, athletic or medical. Medical and healthcare uses will be addressed in the next section of this white paper.

Entertainment wearables

Smart glasses/sunglasses are still largely considered novelty devices, but they also reflect the most futuristic parts of the wearable gadget world. They were designed to bring the wireless connectivity and imaging we use on our home computers and cellphones into the frames and lenses of our eyewear. They may also double as a pair of headphones, or a high-tech wearable that supports augmented-reality experiences.

Gaming is one of the biggest emerging frontiers for wearable technology. Virtual reality (VR)/ augmented reality (AR) headsets are the most common form of wearables in the industry. Wearable technologies that are really starting to take off in the gaming industry are haptic devices. These devices provide tactile feedback to a gamer in real-time. This means that a device takes advantage of a gamer's sense of touch by providing force or vibrations to a user. Haptic vests, gloves or suits make gaming more realistic.

Even tattoos can serve as wearable tech. DuoSkin is a fabrication process that enables anyone to create customized functional devices that can be attached directly on their skin as a tattoo type decoration. These tattoos use gold metal leaf, a material that is inexpensive, skin-friendly, and robust for everyday wear. It has been used for three types of on-skin interfaces: sensing touch input, displaying output, and wireless communication.

Headphones have experienced an enormous evolution, going from the bulky over the ear models to today's Bluetooth enabled wireless earbuds.

Athletic wearables

Smart jackets are being made to automatically cool or warm the body based on body temperatures taken from sensors throughout the jacket. Smart rings are giving people a stylish way to track their steps or measure their sleep habits.

Examples of companies utilizing smart technology include:

- Samsung is developing smart shirts capable of diagnosing respiratory diseases and smart shoes that monitor running form
- Consumers can already purchase Siren Socks - smart socks that can detect developing foot ulcers
- Nadi X smart pants by Wearable X are yoga pants that vibrate to improve form during yoga exercises
- Naviano smart swimsuits provide alerts when the user should apply sunscreen, among many other kinds of smart clothing
- Tommy Hilfiger has developed a location-tracking feature for its Tommy Jeans Xplore line of clothing. This was based on a marketing strategy that would reward frequent wearers with more Tommy Hilfiger products

Other examples of smart clothing include:

- *Smart socks:* Socks that can detect which part of your feet are receiving the most pressure during your run and can send this data to a smartphone app
- *Smart shoes:* Pizza Hut has experimented with limited edition sneakers that can order pizza
- *Smart work clothes:* A smart business suit that can exchange digital business cards, unlock phones, and interact with other devices
- *Smart sleepwear:* Sleepwear that absorbs heat from the wearer's body while releasing infrared light to increase sleep quality and improve muscle recovery
- *Smart activewear:* T-shirts that connect to a smartphone app to record fitness activity and recommend new workouts to the wearer
- *Smart swim goggles:* Gives real time feedback on training, such as calories, cardio info, split times, distance and more
- *Smart ski goggles:* Goggles may show a variety of things including your speed, location, altitude, text messages, and location

- *Dive computers:* Wristwatch sized computers became available as early as 1997. These devices gave divers a complete source of information, including depth, decompression and tank pressure in a single device using wireless transmission. Dive computers significantly extended bottom time by continuously re-calculating no-decompression limits throughout the dive making for safer diving

4. Wearable Healthcare Applications

Wearable technology in healthcare includes electronic devices that consumers can wear, like Fitbits and smartwatches, and are designed to collect the data of users' personal health and exercise. On your wrist or in your pocket, is a piece of technology that can monitor several biological factors 24 hours a day, including your:

- Heart rate
- Exercise performed
- RHR
- Sleep cycles
- Steps taken
- Calories burned
- Stress level

These devices can even send a user's health information to a doctor or other healthcare professional in real time. With the increasing demand of consumers to monitor their own health and keep track of their own vital signs, use of wearable technology has more than tripled in the last four years. According to research from Insider Intelligence, more than 80% of consumers are willing to wear fitness technology.

Cardiac monitoring

Pacemakers can be considered an example of the first wearable technology. Technology has greatly improved over the original devices to the point where they can now be equipped with wireless technologies that can transfer data in real time. The pacemaker's data can be accessed immediately by patients and doctors to provide insights about the device and the patient's vital signs, such as current heart rate, device activation, and battery life.

Additionally, new devices have been miniaturized to the size of a large pill or vitamin. Whereas the original model in 1958 weighed over half a pound (253g) and was worn around the neck, today's models can weigh as little as 0.07 ounces (2g) and can be implanted in the heart itself.

In 2017, Apple launched the Apple Heart Study app to monitor users' heart rhythms and alert those who are experiencing atrial fibrillation. In 2020, Apple's Series 6 watch included a new blood oxygen saturation monitoring feature, new native sleep-tracking capabilities, a faster FDA-approved electrocardiogram sensor, and upgraded heart health monitoring features.

Wearable electrocardiogram (ECG) monitors are one of the newest innovations for consumer electronics, and differ from smartwatches, in their ability to measure ECG. For example, the Move ECG is able to measure an electrocardiogram and send the reading to the user's doctor, as well as detect atrial fibrillation. It's also able to act as a fitness device that tracks pace, distance, and elevation, as well as automatic tracking for walking, running, swimming, and biking.

Kardia, a home ECG device, is currently sold on Amazon. Kardia Mobile (previously AliveCor Heart Monitor) is intended to record, store, and transfer single-channel ECG rhythms. Kardia Mobile also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). Kardia Mobile is intended for use by healthcare professionals, patients with known or suspected heart conditions, and health-conscious individuals.

Blood pressure monitoring

Omron Healthcare started marketing HeartGuide in 2019, the first wearable blood pressure monitor. Though it might look like a smartwatch, HeartGuide is an oscillometric blood pressure monitor that measures blood pressure and daily activity, i.e. steps taken, distance travelled, and calories burned.

Glucose monitoring sensors

A continuous glucose monitor (CGM) is a small wearable device that tracks your glucose throughout the day, allowing you to track highs and lows and to chart your blood sugar levels.

The device automatically checks your blood sugar every 5 minutes and displays your levels on a screen. It is also accessible to iPhone and Android users through use of an app.

A person with diabetes can be informed every five minutes regarding the fluctuation of blood sugar. Combining this data with the ability to automatically dispense insulin whenever the blood glucose begins to rise, it allows the user to keep the glucose level within normal limits on a continuous basis. This becomes a much more effective method for dealing with diabetes.

Insulin pumps/monitoring systems

New diabetes management technology may emerge incorporated into smartwatches, smart shoes and socks, and perhaps even contact lenses.

Cancer detection

University of Michigan researchers have recently created a wearable device that can continuously collect and examine circulating tumor cells (CTCs) in the blood. These cancer cells are typically obtained via blood samples to provide a biomarker for treatment, but this wrist-worn prototype could potentially screen patients' blood for a few hours to obtain only the CTCs of interest.

Portable dialysis

AWAK Technologies, a Singapore based medical technology company, recently received FDA Breakthrough Device designation for their wearable and portable dialysis device. Called the AWAK Peritoneal Dialysis device, or AWAK PD, the technology uses AWAK's patented sorbent technology and offers a convenient means of dialysis for renal disease patients.

Artificial Intelligence

The FDA has defined Artificial Intelligence (AI) as the science and engineering of making intelligent machines, especially intelligent computer programs.

Machine Learning (ML) is defined as an AI technique that can be used to design and train software algorithms to learn from and act on data. Software developers can use machine learning to create an algorithm that is 'locked' so that its function does not change, or 'adaptive' so its behavior can change over time based on new data.

AI and ML technologies have the potential to transform health care by utilizing the enormous amount of data generated by the healthcare system. One of the primary benefits of AI/ML in software is its ability to learn from experience, and its capability to improve performance.

Examples of medical devices utilizing this technology are:

- The wireless device, Current, measures a patient's pulse, respiration, oxygen saturation, temperature and mobility. The device, an upper-arm wearable, is already used in hospitals and measures a patient's respiration, pulse, oxygen saturation, temperature and movement. This provides physicians with real-time updates regarding their patient's

health, allowing them to handle any complications almost immediately. This technology utilizes machine learning to analyze the data it collects and to detect problematic changes in the data

- A wearable sensor and AI program has been developed to detect a specific cardiovascular disease using a wearable wrist biosensor. The condition, hypertrophic cardiomyopathy, can cause serious complications and is commonly unrecognized in the clinical setting

Biosensors

Biosensors are the new innovation for wearable medical devices that are much different from existing wrist trackers and smartwatches. The Philips' wearable biosensor is a self-adhesive patch that allows patients to move around while collecting data on their movement, heart rate, respiratory rate, and temperature.

Portable sensors may be available as gloves, clothing, bandages, or implants. They can create two-way feedback between the doctor and patient. These sensors would enable continuous and noninvasive health monitoring and potential diagnosis from the data provided by physical motion and body responses.

Research from Augusta University Medical Center showed that this wearable device registered an 89% reduction in patient deterioration into preventable cardiac or respiratory arrest. This demonstrates the ability wearables have to improve patient outcomes and possibly reduce staff workload.

5. Conclusion

To date we have only begun to explore the various uses of wearable tech. Using clothing to power various devices, and the use of Artificial Intelligence in various medical devices, or as personal assistants, are all possible future innovations.

Wearable technology, whether for everyday life or for medical purposes, is continuing to evolve and becoming less expensive, smaller and more commonplace. From entertainment to medical applications, wearable technology is clearly in everyone’s future.

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Jerry is a Senior Regulatory Consultant with 20 years experience in regulatory and standards interpretation, spanning the fields of consumer products and environmental investigation.

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