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WEARABLE MEDICAL DEVICE

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ABSTRACT

The phrase "wearable" denotes the ability of a gadget to be sustained by either the wearer's body or clothes. Phones now come with sensors like gyroscopes, accelerometers, microphones, and cameras, as well as the computing ability to evaluate the data generated by these sensors thanks to technological breakthroughs. Moreover, Bluetooth and other short-range radio technologies have improved battery life, allowing the development of smaller devices with data logging and action-triggering capabilities. These wearables and apps can be used for health and fitness as well as "mHealth" services that may eventually include applications in medicine and healthcare. Health-conscious individuals all over the world are widely utilizing these devices. As a result, information about their existence, functions, usages, and benefits is progressively spreading among the general public. However, these devices tend to be more accessible to those belonging to affluent societies who can afford their procurement and use. The wearable gadget industry is anticipated to grow, more individuals will have access to cutting-edge technologies. There may still be a safety coverage gap, though, because wearables-related rules and standards are still being defined. Customers may be unduly exposed to wearable gadget dangers as a result of this gap. The regulatory framework for medical devices is described in this article, along with an outline of its main requirements, limitations, evaluation parameters, and considerations in respect of wearables.

Keywords: Wearable device, Healthcare industry, Medical Image Storage Device, Evaluation

INTRODUCTION

What is a Medical Device?

A medical device is well-defined as an article that includes instruments, devices, implements, machines, contrivances, implants, in vitro reagents, parts, or accessories that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals. These devices have the purpose of influencing the structure or function of the human or animal body and do not achieve their primary purpose through chemical action inside or on the body. Moreover, their primary intended purposes are not dependent on being metabolized **[1]**.

Can a Medical Device be an app?

The stand-alone software is covered by the medical device regime, according to recommendations published by the European Commission and the UK's regulatory body, the Medicines, and Healthcare Products Regulatory Agency (MHRA). Since the intent of the manufacturer is a crucial aspect of the explanation of a "medical device", the MHRA has compiled a list of keywords in its guidance that could aid in determining whether an app qualifies as a medical device. The list includes terms like "diagnoses" and "monitors", as well as more basic terms such as "alarms" and "converts". **[2]**

Example- If an app utilizes a phone's camera to capture an image of a skin area, compares it against a database of recognized skin conditions, and attempts to provide a diagnosis of the user's condition, the app would probably be classified as a medical device.

What are Wearable Medical Devices?

An autonomous, non-invasive gadget that executes a specific medical function, such as monitoring or helping over an extended period, is referred to as a wearable medical device. According to the definition of "wearable," a gadget may be worn on the body or as a piece of clothing **[3]**.

Examples – Fitbit Surge, Muse Headband

Can a wearable be a "medical device"?

A device that primarily collects data, such as measuring heart rate or motion, is unlikely to be considered a medical device on its own. However, if the device has a medical assessment function or is utilized as an accessory to a medical device (e.g., a wearable specifically designed by the manufacturer to use it with a medical device app), it is probable that it would be subject to the medical device regulatory outline. Medical wearables connect electronic patches to the skin and use sensors, actuators, software, & actuators to track a patient's health, spot abnormalities, and even cure medical diseases **[4]**.

For example - It is unlikely that a wearable device would be categorized as a medical device if it only measures and records body temperature without attempting to indicate or diagnose any medical condition. A "smart thermometer," on the other hand, is likely to be classified as medical equipment if it measures and records body temperature while simultaneously attempting to determine whether the user has a medical condition.

DISCUSSION

i. Medical Device Regulations in the USA

The Food and Drug Administration (FDA) in the USA regulates medical devices to guarantee their efficacy and safety. This program is managed by the Center for Devices and Radiological Health (CDRH), a division of the FDA.

Based on the amount of risk they represent to patients; medical gadgets are divided into three types. Class I, Class II, and Class III devices fall into these categories, with Class I being thought to have the lowest associated risk and Class III being thought to have the most. As a result, regulatory supervision expands when devices advance from Class I to Class III.

In this regard, most of the Class I devices are not required to submit 510(k) premarket notification submissions, but the majority of Class II devices must. Class III devices, on the other hand, must go through the Premarket Approval Application (PMA), and those that are exempt from the PMA must send FDA a 510(k) notification **[5]**.

ii. The Australian TGA medical device approval procedure

Medical device and in vitro diagnostic (IVD) manufacturers who wish to sell their products in the Australian market must ensure that their products are listed on the Australian Register of Therapeutic Goods (ARTG), which is regulated by the Therapeutic Goods Administration (TGA). If a manufacturer has already obtained the European CE Marking for their product, the TGA approval process may be simpler, as Australia recognizes the CE Marking.

Step-1

The classification of a medical device in Australia can be determined by using Schedule 2 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002. If a device has already obtained European CE Marking, its classification in Australia is likely to be the same. The TGA generally accepts a CE Marking certificate from a Notified Body as part of the device registration process.

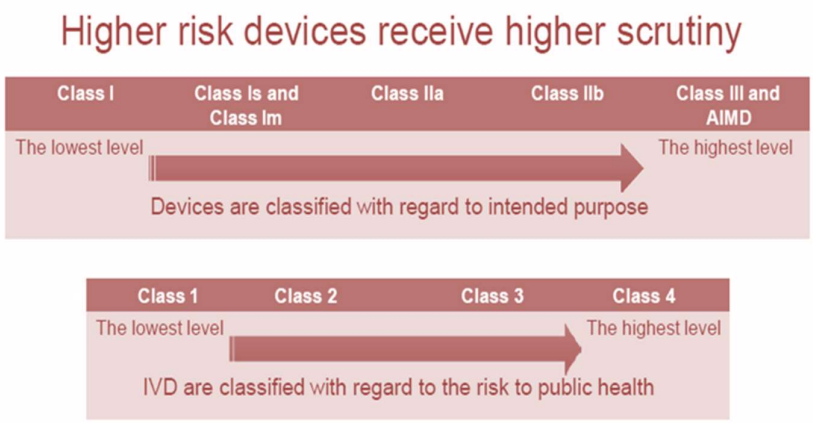

Figure 1: Risk-based regulation and classification

Step-2

To register your device with the TGA in Australia, you must have a local presence or designate an Australian Sponsor. The role of the Sponsor is to assist with the device registration process, act as a point of contact between the manufacturer and the TGA, and ensure that their name is included on the device and its labeling.

Step-3

When submitting your application, please make sure that you have completed and gathered all essential paperwork, including the Technical File or Design Dossier (for Class III devices) and the Declaration of Conformity.

Step-4

Sponsors are required to submit the manufacturer's evidence, which is the CE Marking certificate, for TGA's review and acceptance in the eBS system, except for Class I non-sterile, non-measuring devices.

Step-5

The TGA will conduct a Level 2 Application Audit for Class III devices, wherein they will review the design dossier.

Step-6

The local sponsor must submit a Medical Device Application using the online eBS system to apply for all kinds of medical devices in Australia. The application must be submitted with the required application fee and include a Planned Purpose statement, categorization, and GMDN code.

Step-7

The TGA will assess your submission once you submit it and decide whether to accept it or reject it. If your application is accepted, the TGA will provide you with an ARTG Certificate of Inclusion, which contains a unique Australian ARTG listing number. Also, your entry will be posted to the ARTG database on the TGA website.

Step-8

You can start advertising your gadget in Australia once it has been registered with the TGA and received their approval. You should be aware that, provided no alterations are made to the device that would render the

ARTG listing invalid, your registration is perpetual. To keep your listing, you must also make sure that a valid CE Marketing certificate (if applicable) is on file with the TGA and that the yearly ARTG listing fee is paid **[6]**.

iii. The US FDA'S Perspective on Wearable Medical Devices

Many existing wearable devices are classified as Class I or II by the FDA and are exempted from the 510(k)-filing procedure. These classes of devices must comply with the FDA's so-called overall controls. However, the FDA has chosen to exercise decision in the case of devices covered by the subsequent guidance guidelines. The two documents are:

A. Final Guidance for Low-Risk Devices Policy on General Wellness; and

B. Final Guidance for Medical Device Data Systems (MDDS), Medical Image Storage Devices, and Medical Image Communications Devices.

Moreover, Appendix B of the FDA's Mobile Medical Application (MMA) Final Guidance states that the agency will use enforcement discretion in the case of devices that are categorized as "mobile apps" and fulfill the criteria for medical devices but are not "mobile medical applications" (MMAs). Just a tiny portion of devices are truly classified as MMAs and are subject to FDA rules. The FDA fully aims to enforce these standards because they fall within the Food, Drug, and Cosmetic Act, which defines medical devices in section 201. (h) **[7]**.

A. General Wellness: Policy for Low-Risk Devices, Final Guidance

A "general wellness" product, according to this FDA Guidance paper, is a gadget that:

1. Upholds or promotes an overall state of well-being or a healthy activity without making any mention of disorders or circumstances or
2. While referring to diseases or ailments, it sustains or improves functions connected with a general state of health. This second category is divided into two sub-divisions because a healthy life promotes, tracks, and/or encourages choice (s). It might

a. Assist lowers the likelihood of developing certain chronic illnesses or disorders and

b. Help people manage such illnesses or conditions successfully **[8]**.

B) Final Guidelines for MDDS, Medical Image Communications Devices, and Medical Image Storage Devices

The FDA normally does not enforce the broad regulations since there is little danger for:

1. Medical device information system (MDDS) (21 CFR 880.6310)
2. Medical image storing devices (21CFR 892.2010)
3. Medical image infrastructures devices (21 CFR 892.2020)

The Guideline offers examples that show an MDDS as a device—which may be hardware or software—that carry out tasks such as displaying, storing, and converting formats of medical device data following pre-established requirements. It does not, however, regulate or modify the settings or features of any linked medical equipment.

- Software that keeps track of previous blood pressure measurements so that a healthcare professional may review them later (also known as automated storage and recovery of medical device data);
- Computer programs that convert the digital data produced by pulse oximeters into a readable digital format. (i.e., the electronic transfer of data from medical equipment from one formation to another according to pre-established specifications).

Devices connected to the active patient observation of devices are not included in MDDS. The Guidance, for example, gives the following examples of active patient monitoring (i.e., demands a prompt response) devices nurse measurement station in an intensive care unit that collects and transmits data from a bedside hospital display. An instrument that informs a carer to take immediate therapeutic action in a home environment by receiving and/or displaying data, alarms, or alerts from a monitoring device.

The FDA downgraded MDDSs from Class III (the maximum risk level) to Class I in 2011. (The category with the lowermost risk). After making this judgment, the FDA has become more knowledgeable about this technology and determined that "these devices offer a minimal hazard to the public," which formed the basis for the agency's choice to exercise implementation discretion. The following categories of devices are exempt from the MDDS guidance:

1. Items designed for energetic patient specialist care;
2. Medical data modification devices; or
3. Control devices for any linked medical device's functions or parameters **[9]**.

iv. Applications

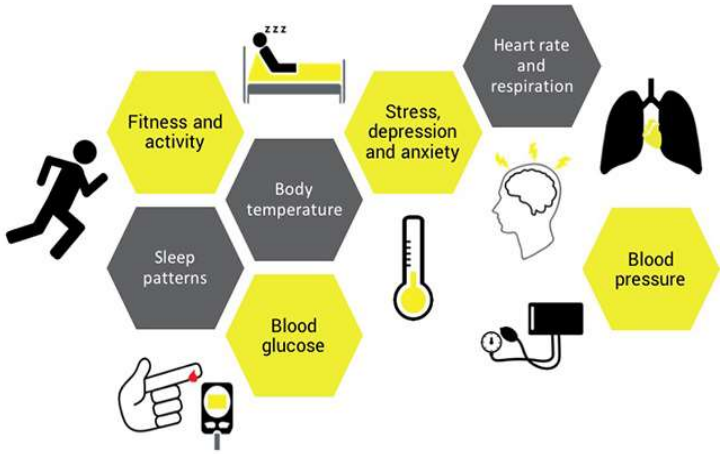

Figure 2: Applications for consumer health wearables

This segment highlights a variety of wearable medical applications and technologies that are also undergoing commercialization or are currently on the market.

1) **For experiencing the best night's sleep**

The tale of Sleeping Beauty shows how a good night's sleep may be essential to the survival of civilizations. Sleep is essential for maintaining a healthy brain, body, looks, and general well-being, according to research. Sleep monitors keep track of many sleep-related activities, such as when you go to sleep, get up, and spend time in deep sleep. The amount of sleep a person gets determines how refreshed they feel, while other people are more concerned with how much deep sleep they obtain. Everyone must come up with a solution because everyone has different sleeping preferences **[10]**.

Pebble Time: The Pebble Timeline of smartwatches includes sleep monitoring among several built-in health-tracking applications. Pebble Health, which was created in collaboration with Stanford University academics, can automatically track your sleep habits, providing information on when you go to bed when you experience full deep sleep, and when you wake up.

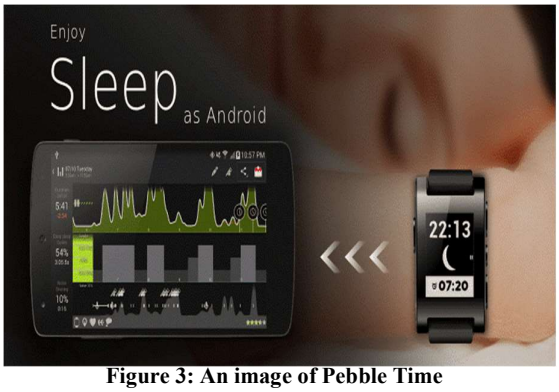

Figure 3: An image of Pebble Time

2) For staying fit and energetic

The most well-known and often used medical wearables are activity trackers for athletes and those who exercise regularly. Most smartphones currently have applications that measure your daily steps, whether you run (even to catch the bus) or ride your bike. The best ways to keep active and healthy may be determined with the help of beautiful graphs and charts that activity trackers can provide together with the ability to monitor your heart rate **[11]**.

Fitbit Surge: Because of its amazing features, Fitbit is a highly well-known fitness tracker company. Together with phone and text alerts, an optical heart rate monitor, step tracking, and sleep monitoring, this bracelet also keeps tabs on your activities. Also, it has GPS to track outside activities, so you won't need to bring a phone. The tracker links you to a group of individuals with whom you may exchange fitness-related ideas and even compete to be the fittest. It is simple to use, trustworthy, and user-friendly.

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Figure 4: An image of the Fitbit Surge

3) For getting rid of stress in your life

In today's fast-paced world of constant impulses and distractions, pressure is one of the biggest health risks. Asthma, heart disease, obesity, diabetes, digestive problems, migraines, and anxiety are just a few of the conditions that stress has been linked to. It lessens your emotional well-being, disrupts your sleep, and inhibits your ability to concentrate. Everyone is affected, even me. Yet, stress may be effectively managed with the use of technology.

PIP: a little gadget that gives you quick feedback on your level of stress. With the help of its Android app, you may learn how to manage stress by actively relaxing and turning a gloomy scenario into a happy one. For a few minutes, just place the PIP gadget between your thumb and index finger to quantify skin conductivity. The quicker the situation changes, the less stressed you are **[12]**.

Figure 5: An image of PIP

4) For maintaining blood pressure optimal

One of the utmost prevalent chronic diseases in the world is hypertension. In the US, there are around 80 million people with high blood pressure. Home blood pressure monitors are often used by medical professionals and people to control high blood pressure, from medication titration to supporting dietary and lifestyle modifications.

Withing Blood Pressure: one of the latest connected goods to reach the marketplace. It involves an app that utilizes Bluetooth to link to the blood pressure recorder. The app tracks your weekly steps taken, blood pressure, and heart rate. One of Withing's many helpful features is the option to set the monitor to take three measurements and provide the average, which is in line with medical advice. Also, you may program reminders for activities like taking prescriptions and checking your blood pressure **[13]**.

Figure 6: An image of Withing Blood Pressure

5) For a healthy heart maintenance

Your heart pumps around 100,000 times every day. You may forecast and even prevent a wide range of illnesses, including catastrophic disorders like heart attacks, by allowing smart gadgets to monitor, measure, and evaluate the health of your heart.

AliveCor Heart Monitor: The AliveCor Heart Monitor is a compact and simple device that you can connect to the casing of your phone to do an electrocardiogram using your phone. The app that goes with it is broken up into three sections: ECG recording, data collection, and a helpful instructional portion. When you have symptoms that you've already addressed with your doctor, this gadget proves to be helpful. For instance, palpitations might occur without warning, and the essential information from actual instances can provide healthcare practitioners with important insights **[14]**.

Figure 7: An image of the AliveCor Heart Monitor

6) For the effective meditation

By now you already know how important stress management is to your healthy life. There are several ways to effectively lower your stress level, so you should take your time choosing the best strategy. Popular techniques like meditation have been shown in studies to be effective in reducing feelings of stress, hopelessness, and anxiety. Technology may help you to create a peaceful state of mind, even if you may not want it to interfere with your brain.

Muse headband: The brain-sensing headband improves your meditation technique by giving you immediate input on how your mind is functioning. The Muse is not some futuristic headgear that aims to alter your brain, as some have suggested. Instead, Intraexon, the company that created it, wants to instruct you on how to alter it. Simple steps are involved in the process. Using the Muse headset, you conduct breath control exercises while listening to the sounds of waves (neutral), storms (bad), and tweeting birds (good), which stand for your degree of focus and calmness. The Muse offers feedback to help you calm your racing thoughts if they are too busy **[15]**.

Figure 8: An image of Muse headband

v. Design Challenges

Two crucial characteristics set apart wearable medical devices from further medical equipment. Initially, they are wearable, which indicates that they will be used in a range of settings and should be cozy, undetectable, autonomous, and small while posing a few technological issues. The second is that the patient has a significant impact on how they should be used, which has significant design inference for their ease of setup and use as well as the kind and mode of delivering medical care to the patient while they are being used. Ultimately, just like with any commercial product, its acceptance and use will be influenced by several financial factors.

Wearable medical devices have several design issues and technological challenges since they are used in dynamic and often demanding environments. In a variety of situations, including the home, the hospital, and the sports field, numerous devices are used. Others can be taken at certain times, such as while you are exercising, sleeping, or in high-risk circumstances. The following technical concerns need to be resolved

- Biomedical sensors: These are used to measure physiological and kinesiological characteristics. They must be non-invasive, dependable, compact, wearable, and compatible with the device.
- Making decisions on the kind and quantity of data that will be captured, kept, and disseminated is a part of data handling.
- Decision support refers to specially created algorithms that combine and examine medical data to provide guidance. They frequently employ fuzzy logic or neural network models.
- Feedback response relates to decisions made about the format, frequency, and standard of feedback provided to patients.
- Telecommunications: This refers to the link between the device and the health care provider and between the

sensors and the device. Also, it tackles issues with standards and interoperability, such as how well the devices can communicate with already-prevailing hospital information systems.

- Physical Design concerns the challenges of a garment's physical form, size, weight, and ergonomics. For certain gadgets, this process also includes putting wearable parts on the body and fastening them to the user.
- Autonomy: Addresses the power requirements of the gadget, which must be satisfied for predetermined periods of usage **[16]**.

vi. Potential risks of wearable technology products

Wearable expertise devices have the potential to significantly advance the user's excellence of life, but they also carry a few hazards **[17-20]**.

Table 1: Potential concerns associated with wearable technology

Category	Conceivable potential risk
Electronic shock	**Even little electric shocks from those goods might be harmful to people's health because they are maintained in clothing or in close touch with the skin.**
Burns	**Wearable items have a significant tendency to increase in temperature while being used, which might put the skin in direct touch with the product in danger.**
Fire and blast	**There is a chance of a temperature elevation, fire, or explosion dependent on the circumstance or atmosphere in which batteries are utilized.**
Acoustic sound pressure	**Users run the danger of being disabled due to extreme sound pressure, such as losing their hearing.**
Chemical reactions	**If the skin encounters metal parts in the product resources or chemical compounds in synthetic fibers, etc., there is a danger of adverse reactions like a rash.**
Radio-frequency exposure	**Nonstop exposure to electromagnetic field energy carries the danger of rising body temperature, electric shock, high-frequency burns, etc.**
Human factors	**Sharp edges and corners pose a danger of skin cuts, scrapes, and irritation depending on the product's design.**
Hazardous location	**Most of the products rely on wireless connectivity. If the product power is not properly set, there is a danger of igniting, especially if they are used in an area where there is an ignition hazard.**

CONCLUSION:

The number of wearable medical and fitness gadgets endures rising, with more and more being used in various fields. The FDA acknowledged this and responded to this aspect of the digital revolution by issuing guideline documents to cover these topics. By doing this, the FDA has scaled down its enforcement efforts directed at lower-risk medical devices, which could encourage the creation and use of wellness wearable technology in the future. The use of medical device wearables is also rising because they can provide clinicians with critical information via cutting-edge presenting technologies, they can help keep patients out of the hospital and decrease readmissions, and they can reduce health care costs by shortening the period that patients and clinicians must spend together. Meeting the

desired practical requirements and the necessity for wearability are frequently trade-offs in their design. Therefore, creating radars and other hardware elements that enhance their wearability, usefulness, dependability, and security is a significant task. Manufacturers must stay up-to-date on the changing compliance environment and the creation of new standards and regulations due to the rise of wearable devices and other technological breakthroughs and their influence on laws and standards.

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