Safety and Ergonomics in a Wearable Electronic Device

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When designing a wearable electronic device, engineers must meet many safety and design parameters in order to ensure the safety and comfort of the device's wearer. The field of wearable devices has become commercially popular recently with the massive increase in personal biosignal trackers for fitness and health conscious people. The reporting accuracy and safety of these devices is often questioned, something the Azure Team needed to consider in its design of such a device.

Current safety standards in wearable devices

The negative effects of electromagnetic field radiation (EMF) on the human body has been a controversial topic for several decades for two reasons. First, there is a lack of understanding of electromagnetic radiation in the general population that causes several misconceptions about the safety of EMF. Similar to the "vaccines cause autism" campaign, several groups and "conspiracy theorists" are convinced that the world is turning a blind eye to the issue of EMF safety because technology companies stand to gain from the increased use of this type of technology. Although most of the perceived medical and environmental dangers of EMF were found to be caused by other factors, a fear of EMF remains. Second, many of the experiments done are not controlled. Many different factors can affect reproductive outcomes and uncontrolled, closed-group experiments are difficult and unethical to perform. Technology must always be understood and controlled before it is used, especially if it is for health monitoring.

Only recently has the monitoring of wearable devices and their safety restrictions become taken seriously, with the large proliferation of the technology on the market. These risks range from physical to cybersecurity risks and must be addressed before technology can be put onto the market. Several private organizations are aiming to take control of this regulation process by issuing "safe wearable" certifications, one of which is the safety organization UL (Underwriters Laboratories), which recently began a wearable devices consulting department (Monoist, n.d.).

Electromagnetic Theory and Biochemistry

Much speculation exists as to whether immersion in electric and magnetic fields is safe, especially regarding potentially adverse effects on fetal and child health. Power frequency fields have become ubiquitous in the home and workplace, which make it difficult to track and study people with increased exposure. Some epidemiologic studies have been conducted to determine whether increased risks of cancer, neurodegenerative disease, arrhythmia, or mortality rates can be linked to higher exposure to EMF.

In a controlled study done on rats, impregnated rats were exposed to differing levels of EMF, such as those consistent with signals from a mobile telecommunication system. During the gestational period, the body weights of the rats in all three control groups were nearly identical, as was the lactation period. No adverse effects were observed on general conditions of the rats and all groups had similar birth indices. No notable external abnormalities were measured, except for a missing tail in the low exposure level group. All organs of the pups and dams were examined after several days and no abnormalities were discovered (Takahashi et al., 2010).

As part of its normal functions, a human body will produce tiny electrical currents through chemical reactions and electrical impulses. Electric fields affect these currents as they would with any other flow of charged particles. However, the induced currents are not strong enough to cause any notable changes, even under a high voltage power transmission line. Due to

the growing health concerns over this topic, the World Health Organization (WHO) launched an interdisciplinary investigation in 1996, to further explore and assuage public concerns. Although WHO is still researching the long-term effects of EMF radiation, it finds there is no direct data linking any diseases or reproductive failures to exposure (WHO, 2015).

The amount of electricity a person can withstand depends on several factors: their health, the electrical current strength and exposure time, presence of moisture, enter and exit points. Humans can feel the effects of electricity at extremely low levels, levels easily found within common household appliances.

Ergonomics

Ergonomics, also known as human factors, is the scientific discipline focused on understanding human interaction with their surrounding environment. With personal wearable medical devices, not only must safety be ensured, but the device must be comfortable and easy to wear as well. The device should not hinder daily activities and should not adversely affect the wearers ability to complete their tasks. Such systems may therefore be virtually invisible and run without notice by the wearer and others, while maintaining full functionality.

Parameters to keep in mind while designing these devices include:

- Visibility: The product when worn should not be too obtrusive and should be fully integrated with the wearer's outfit and clothing preferences.
- Weight: The wearer's comfort and mobility should be unaffected and the product should be easy enough to wear or carry.
- Acoustics: The product must not make too much noise and should be fully operable without being annoying.
- Materials: The product must be both comfortable enough to wear and able to maintain functionality for long periods of time.
- Ease of use: The product must be flexible enough to put one, take off, replace or move around, yet still be secure.

Summary

The high proliferation of these technologies in the consumer market makes it difficult to monitor the safety and usability of these products, especially those built for medical purposes. There is a high level of risk involved with wearable devices that society does not immediately understand and appropriate monitoring administrations must be put into place, rather than taking the companies word that their products are safe. As the Azure Team designed a medical device intended for medical use, it had to consider a wide variety of requirements. Devices created for the intent and purpose of medical and diagnostic devices must pass stringent federal testing. These tests and federal processes take years to complete. The maximum current and temperature requirements are much lower and

Table 1: Conceivable potential risks of wearable devices

Category	Conceivable Electric Risk
Electric Shock	Since those products are in direct contact with the skin, even mild electric shocks may be harmful to humans.
Burns	The internal temperatures of these devices may rise during use, which may cause irritation and problems to skin directly in contact with the device.
Fire and Explosion	Depending on the situation and the batteries used, there is a risk of sudden temperature increase, ignition or explosion of these devices.
Acoustic Sound Pressure	Risk of causing disability, such as hearing loss due to excessive sound pressure.
Chemical Reactions	Risk of rash when skin comes into contact with metal or synthetic fibers.
Radio Frequency Exposure	Risk of increase in core body temperature, electric shock, high frequency burns due to continuous exposure to high frequency fields.
Human Factors	Risk of skin cuts, scratches, and skin inflammation

therefore more difficult to design as well. Devices that do not undergo these processes are not necessarily more dangerous, but are not labeled as medical devices and are not given the stamp of approval for hospital use, even if they perform the function required of them. Although strict, these federal regulations exist for a reason and must be adhered to, as the creators of these devices are now responsible to uphold the one rule of doctors; do no harm.

References

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