

Status of regulations and issues for Wearable Technology Products

Current status of the wearable technology products market

As semiconductor technology has become miniaturized and more energy-efficient in recent years, wearable technology products have rapidly grown more common. Ranging from ordinary consumer products to medical devices, their applications continue to increase, making our lives more convenient.

The big home appliance stores are beginning to set aside retail space just for those products. Many products are coming out that offer excellent design and fashion sense on top of function.

The wearable technology products market is showing signs of dramatic growth, particularly in the industrialized nations. The world market for wearable technology products (as measured by units shipped by manufacturers) is forecasted to grow from 23.28 million units in 2014 to 223.9 million in 2017. The forecast for Japan is 13.1 million units in FY2017, roughly five times the 2.75 million-unit figure for FY2014. (Note 1)

People are starting to *wear* mobile products on their bodies that they once *carried*. In this sense, the rise of wearable technology products offers not only many conveniences but also many risks.

This paper discusses the risks, the current state of regulations, and issues associated with wearable technology products.

Potential Hazards of wearable technology products

While wearable technology products have the potential to dramatically improve the lifestyle of the user, they could also expose the user to many potential risks.

Table 1 lists some conceivable potential risks of wearable technology products.

Table 1: Conceivable potential risks of wearable technology products

Category	Conceivable potential risk
Electric shock	Since those products are in direct contact with the skin or are kept in clothing, even mild electric shocks may cause a risk to human health.
Burns	The internal temperature of wearable products has a strong tendency to rise during use, which may cause a risk to skin in direct contact with the product.
Fire and explosion	Depending on the situation or environment in which batteries are used, there is a risk of sudden temperature increase, ignition, or explosion.

Acoustic sound pressure	There is a risk to cause disability, e.g. hearing loss, to users as a result of excessive sound pressure.
Chemical reactions	There is a risk of side-effects like rash if the skin comes into contact with metal component in the product materials or chemical substances in synthetic fibers, etc.
Radio frequency exposure	There is a risk to cause an increase in core body temperature, electric shock, high-frequency burns, etc. as a result of continuous exposure to electromagnetic field energy.
Human factors	Depending on the product design, there is a risk of skin cuts, scratches, and inflammation from sharp edges and corners.
Hazardous location	Those products depend largely on wireless communications. Particularly if they are used in a location with an ignition hazard, there is a risk of ignition if the product power is not appropriately adjusted.

Evaluation and testing of wearable technology products:

As a result of the above potential hazards, evaluating wearable technology products might involve a variety of different tests. Depending on the structure of those products, their evaluations can result in a length and complex processes in order to demonstrate their conformance.

Evaluations and testing of wearable technology products are categorized as below (the category may depend on the product's structure and use).

1. Product safety: In light of product safety it is necessary to evaluate the risks primarily of electric shock, burns, ignition, explosion, and human factors. Some wearable technology products, such as wearable medical devices, may be subject to additional product safety assessments.
2. EMC (Electromagnetic Compatibility): Regardless of their power source, electrical products must not emit unintended electromagnetic waves and cause other electronic devices to malfunction, and they must be immune to electromagnetic interference from other electrical products.
3. SAR (Specific Absorption Rate): Wireless devices that are normally used within a certain distance from the head or body are subject to testing to measure the electromagnetic wave absorption rate.
4. Wireless interoperability: Wearable technology products that use wireless technology and protocols to transmit data are subject to wireless interoperability testing to evaluate the

effectiveness of their data transmission.

5. Privacy and information security: In addition to interoperability, securing private information in wireless communications is crucial. It is necessary to perform privacy and information security testing to evaluate potential vulnerabilities of wireless communications.
6. Energy efficiency: To ensure that wearable technology products can be used for a certain period of time after recharging, they are subject to evaluation to determine how efficiently they use energy.
7. Chemicals: It is necessary to analyze and evaluate contained chemicals that have a harmful effect on human health over long periods of use and to determine the degree of potential risks for a exposure to chemicals contained in wearable technology products.
8. Environment and sustainability: The environmental sustainability of materials used in wearable technology products and the degree to minimize end-of-life environmental waste are important considerations in many ways.

Followings are examples of regulations and evaluation standards for wearable technology products.

- Product safety
 - Information technology equipment (IEC 60950-1, IEC 62368-1)
 - Medical equipment (IEC 60601-1)
 - Batteries (IEC 62133) etc.
- EMC (Electromagnetic Compatibility)
 - Japan Radio Law
 - USA FCC Part 15, subparts B and C
 - Europe R&TTE Directive, EN 300328, EN 301489-1/-17, EMC Directive, EN 61000-6-1, EN 61000-6-3 etc.
- SAR (Specific Absorption Rate)
 - FCC Part 2.1093, EN 50360, EN 62311 etc.
- Interoperability
 - Bluetooth
 - Wi-Fi
 - Qi
 - PMA
 - CAT (Carrier Acceptance Test), etc.
- Privacy and information security
- Energy efficiency
 - Measurement of battery characteristics, product battery life, etc.
- Chemicals

- CA Proposition 65, RoHS Directive, REACH, etc.
- Environment and sustainability
 - UL 2887, etc.

In October 2014, UL issued UL 2887 (Sustainability Outline for Wearable Electronics Products) as Outline of Investigation to serve as an environmental standard for wearable technology products (Note 2). The Outline is used to certify sustainability of such wearable technology products as smartwatches and smartglasses.

Regulations and concerns for wearable technology products:

The adoption of regulations on wearable technology products has just begun, and is mainly taking place in the advanced nations. Therefore, the evaluation testing for the above-mentioned risks have not yet conducted sufficiently and widely in global market.

Different nations and regions are adopting their own regulations with different degree of severity. It is therefore necessary to design and develop products with careful preparation and consideration.

Those requirements for evaluation testing to product safety and EMC/wireless considerations are very similar in global scale. The EU, however, has very severe regulations on chemicals contained in electrical products, and place high importance on evaluating their environmental impacts.

Recently, there are a growing number of devices exchanging vital data wirelessly in medical care settings. These wireless medical equipment that processes vital data (pulse, blood pressure, etc.) is another example of the products incorporating wearable technology.

The federal government in the US is keenly aware of the need to establish guidelines in this area. For example, the FDASIA workgroup (ONC, FCC, FDA, etc.) is in the process of establishing standards such as AAMI/UL 2800 (Medical Device Interoperability) as based on the FDA Safety and Innovation Act.

Conclusion:

This paper has discussed potential risks, the regulations and evaluation tests for wearable technology products and addressed the issues that manufacturers and distributors need to consider carefully.

Currently, the regulations on wearable technology products are not yet completely established. Therefore, manufacturers and distributors of these products need to be careful about the followings.

- Analyze risk and regulations from the initial stages of product design and development
- Build a detailed product profile (intended use, operating environment etc.) and perform risk analysis
- Identify the target geographic markets where you intend to launch the product

- Specify any additional requirements (performance testing etc.) unique to the target customer and market
- Select an expert third party with wide-ranging knowledge and experience in the regulations and testing of wearable technology products

With its knowledge and years of experiences, UL offers a complete range of testing, certification and global regulatory conformance services for the potential risks of wearable technology products and helps manufacturers and distributors to get their products into foreign markets in a timely manner.

Note 1: adapted from Yz Flash, Winter 2015 (No. 62), p. 2 published by Yano Research Institute Ltd.

Note 2: Outline of Investigation is a set of requirements used in evaluation and certification until UL Standard is issued. It is also referred to as Subject. The Outline of Investigation is issued as an official UL Standard after further examination and voting by the Standards Technical Panel(STP) .