Wearable Technology Products: The Path to Certification and International Market Approval

Wearable technologies have come a long way since the fictional two-way wristwatch radios depicted in comic strips in the 1940s.[1] Today, wearable technology products include watches that can access data wirelessly from a smart phone and wristbands that can track fitness activities or monitor critical health indicators. Digital eyeglasses now on the market provide users with Internet search information on the fly or take pictures, all without having to resort to separate handheld devices. And, industrial applications of wearable technologies are helping to keep people safe in potentially dangerous work environments.

The worldwide market for wearable technology products is expected to increase dramatically over the next several years, with some estimates exceeding more than $100 billion (USD) in annual sales by 2018.[2] However, taking advantage of this major market opportunity also requires a comprehensive understanding of the mandatory evaluation and testing considerations applicable to the components and materials used in wearable technology products. In addition to regulatory compliance issues, meeting product performance and reliability expectations will be essential for widespread acceptance in the marketplace. Finally, since most wearable technology products rely on wireless technologies, privacy and data security will be of paramount importance.

The consequences for failing to plan for all mandatory testing requirements that apply to wearable technology products can be significant. Entry into target markets can be delayed by customs officials, and non-compliant products can be impounded or confiscated.

Wearable technology products that have not been thoroughly evaluated also pose unnecessary risks to users, potentially resulting in product recalls and returns and reputational damage that may be difficult to repair.

This white paper summarizes the evaluation and testing requirements and considerations applicable to wearable technology products. The paper begins with an overview of the various applications for wearable technologies, along with future economic estimates for the global wearable technology marketplace. Then, the paper discusses the various safety and performance considerations applicable to wearable technology products, the potential risks they pose to users, and the key areas of testing generally required for market access. The white paper concludes with recommendations for manufacturers on achieving compliance for their wearable technology products.

[1] See "Dick Tracy's Watch: The Most Indestructible Meme in Tech Journalism," Time Magazine, February 11, 2013. Web. 7 August 2014. http://techland.time.com/2013/02/11/dick-tracys-watch-the-most-indestructible-meme-in-tech-journalism/.

[2] "Wearable Technology: 2014," Generator Research Limited, 29 January 2014. Web. 15 November 2014. http://www.generatorresearch.com/report/wearable-technology-2014/.

What Are Wearable Technologies?

Wearable technologies include products such as accessories, fashion apparel and sensors incorporating computing and advanced electronic technologies that can be worn or maintained in close proximity to the body, and that are intended to extend the functionality of a product and enhance the quality of life.

Today, wearable technology products are used in a wide range of consumer, healthcare and industrial applications. Among the most popular products are so-called "wearable web" products, such as smart watches and smart eyeglasses. These products enable users to quickly and easily capture, share and access information in real time and regardless of their location. As such, these wearable technology products provide additional access points to the emerging "Internet of things" (IoT) ecosystem and contribute to its expansion and potential usefulness.

Another important wearable technology product category includes personal health and fitness products. This category covers products that monitor heart rates or other vital signs, daily physical activity, and even individual sleep patterns. Wrist bands are currently the most common form of wearable technology for health and fitness products, but some types of smart clothing that perform many of the same functions are also finding their way to the market. [3]

In addition to the wearable web, fitness and healthcare products, wearable technologies are also being used to increase productivity and protect workers in potentially hazardous industrial environments. Wearables such as heads-up displays, wristband terminal devices and (once again) smart clothing can actively monitor the work environment, and provide a user with real-time data regarding potentially hazardous conditions while there is still an opportunity to implement preventative measures. Wearable technology products are also in use in military operations, providing soldiers with continuous information about battle conditions, troop movements and potential attacks.

The estimated market potential for wearable technologies varies considerably depending on the source but is significant nonetheless. Projections for total annual sales of wearable technologies by 2018 range between $60 billion (USD) [4] and $101.2 billion (USD),[5] up from just $8-10 billion (USD) in 2014. Most projections predict that the greatest growth during this period will occur in wearable web products, such as smart watches and eyeglasses. However, at least one

[3]See "Ralph Lauren Surprises World with High Tech Polo Shirt," Crunchwear.com, August 25, 2014. Web. 15 November 2014. http://www.crunchwear.com/ralph-lauren-surprises-world-high-tech-polo-shirt/.

[4]"Wearable Technology—Market Assessment," an HIS Whitepaper, IHS, Inc., September 2013. Web. 15 November 2014. http://www.ihs.com/info/sc/a/wearable-technology.aspx.

[5]"Wearable Technology: 2014," Generator Research Limited (see note #2)

estimate puts potential sales for wearable technology devices incorporating advance body sensors for healthcare applications (just one segment of the wearable technologies market) at more than $1 trillion (USD) annually within 20-30 years.[6]

What Do Wearable Technology Products Have in Common?

Despite the wide range and diversity of devices now or soon to be available, most wearable technology products share two essential characteristics. First, they are "wearable," that is, they can be easily worn by an average person without impeding normal functions or everyday activities. Second, they are "smart," meaning that they incorporate both processing and communications technologies that enable them to process and communicate data and other information independent of other devices.

These characteristics, common to all wearable technologies, are supported by three core enabling technologies, as follows:

- Sensors—Microelectronic devices designed to monitor a specific physical, electrical or chemical element and to transmit data on changes in that element over time.
- Processors—Low-powered, microprocessors that can receive and collect sensor-generated data, analyze it for further action or generate signals to alert the wearer.
- Communications—Wireless technologies and protocols that enable information to be transmitted or received from a wearable technology device linked to a smart phone, handheld device or other type of computing platform for further processing and analysis.

When bundled together, these core enabling technologies result in a variety of compact wearable technology products that are not only capable of performing an array of functions but that are also comfortable to wear. Indeed, further advances in these core technologies, such as miniaturization and processing speed, will open a path to even more advanced wireless technology products and applications in the future.

What are the Potential Safety Hazards Associated with Wearable Technologies?

While the combination of multiple technologies in a compact, wearable platform can offer users advanced capabilities, it can also expose them to a number of potential safety hazards. In most instances, the degree of risk is greater than comparable, non-wearable devices since wearable technology products are intended to be worn or placed in close proximity to the human head or body. Specific safety risks related to wearable technology products include:

- Electric shock—Most energized devices can pose a risk of electrical shock due to worn or defective circuitry or accidentally exposed components. When a device is designed to be worn or placed in close proximity to the human head or body for a prolonged period of time, the risk of unsafe electrical shock is clearly more significant.
- Burns—The temperature of components in electrical devices often increases through use. In addition, wearable technology products typically incorporate powerful microprocessors and other modules in a compact format that are likely to produce elevated operating temperatures. Again, this is a particular concern for devices that have been designed to be worn against the skin or eyes, or in close contact with the human head or body.
- Fire and explosion—Most wearable technology products rely on battery power to allow the user to have freedom of movement. However, under certain conditions, lithium-ion batteries can overheat and explode or burst into flames.
- Acoustic sound pressure—Earbuds and other hearing components incorporated into wearable technologies can produce unsafe sound pressure levels when improperly calibrated, leading to temporary or permanent loss of hearing.
- Chemical reactions—Materials used in the construction of wearable technology products, such as certain metals and synthetic fabrics, can contain chemicals that may cause a reaction when they come in extended contact with the skin, resulting in rashes or other allergic

[6] "Wearable Technology: 2014," Generator Research Limited (see note #2)

responses. In addition, the prolonged use of devices can sometimes result in sensitivity to elastomer materials, or cause bacterial buildup. Reactions such as galvanic corrosion can also occur when sweat mixes with electrical current between metals.

- Exposure to electromagnetic energy—Continuous and prolonged exposure to even low doses of electromagnetic energy has been linked to potentially adverse health effects.
- Human factors—Mechanical design factors in wearable technology products, such as sharp corners and edges, device housings and straps, may produce cuts, irritate the skin or cause discomfort following extended use.
- Hazardous environments—Like all wireless transmitters, wearable technologies rely on radio transmissions. If not powered down in potentially-explosive environments, their presence can lead to catastrophic consequences.

Testing Applicable to Wearable Technologies

As a result of the hazards identified above and other potential risks, evaluating the safety of wearable technology products involves a variety of different tests to demonstrate compliance with the regulatory requirements. In addition to safety considerations, the testing of wireless technology products also typically includes a number of performance assessments to evaluate the quality of the integration of multiple technologies to assess whether a given device will perform as promised. When combined, the testing and assessment of wearable technology products can result in a lengthy and complex process.

Depending on the construction or intended use of a particular device, the assessment of wearable technology products can include some or all of the following tests:

- Product safety—At a minimum, this includes evaluating and testing a device for electrical shock and mechanical hazards. Some wearable technology products, such as wearable medical or health and wellness devices, may be subject to additional product safety assessments.
- Electromagnetic compatibility (EMC)—Regardless of their power source, electrical devices must not create unintended electromagnetic interference with other electrical devices, and must also be immune to electromagnetic interference from other devices. Due to the environment in which wearable medical, health and wellness devices are used, it is recommended that testing be conducted for both emission and immunity characteristics.
- Specific absorption rate (SAR)—Certain wearable technology devices incorporating wireless technology are often subject to testing to determine the amount of electromagnetic radiation produced by a device under the most extreme use conditions at a given distance from the human head or body.

Most jurisdictions have similar, if not exactly the same, requirements for product safety and EMC. But the European Union (EU) has far more stringent requirements than other countries regarding chemical content and issues related to environmental impact. On the other hand, the U.S. Food and Drug Administration (FDA), by many accounts, has the most rigorous regulations for medical, health and wellness devices.

- Wireless interoperability—Wearable technology products transmit data to other devices via wireless technologies and protocols. Wireless interoperability testing evaluates a particular technology's effectiveness in exchanging information with other compatible wireless technologies.
- Privacy and data security—In addition to wireless interoperability, securing private information during wireless transmission has become a primary concern. Privacy and security testing evaluates potential vulnerabilities that could make a wearable technology product a target for malicious cyber or physical layer attacks.
- Energy efficiency—Users expect wearable technology products to operate for reasonable periods of time between recharging, thereby requiring devices to use available energy as efficiently as possible.
- Chemical content and biocompatibility—The components and materials used in wearable technology devices may include chemicals which can be harmful as a result of prolonged exposure. A chemical content assessment identifies levels of potentially harmful chemicals in these materials.
- Environmental and sustainability considerations—Wearable technology products that use materials from environmentally sustainable resources and minimize end-of-life environmental waste are important considerations for many buyers.

Additional Testing and Certification Issues

As if the wide and diverse range of tests applicable to wearable technology products were not enough, a further complication is the lack of consistency regarding specific regulatory requirements and standards in major world markets. Most jurisdictions have similar, if not exactly the same, requirements for product safety and EMC. But the European Union (EU) has far more stringent requirements than other countries regarding chemical content and issues related to environmental impact. On the other hand, the U.S. Food and Drug Administration (FDA), by many accounts, has the most rigorous regulations for medical, health and wellness devices.

In cases where mandatory regulations addressing certain risks have not yet been implemented, compliance with industry standards may impose de facto requirements on manufacturers of wearable technology products. This is certainly the case regarding wireless interoperability and co-existence with other wireless devices and, to a lesser extent, data privacy and security. While the same standards requirements may be applicable in many target markets, standards are subject to revision over time to reflect new technologies as well as the emergence of previously unidentified risks.

Even within a given target market, regulatory approval authority can be dispersed among a number of different government authorities. In the U.S. for example, EMC and other spectrum-related issues fall under the jurisdiction of the U.S. Federal Communications Commission (FCC). Energy usage is addressed in the voluntary ENERGY STAR program

administered by the U.S. Department of Energy. For wearable technology products categorized as medical devices, the U.S. FDA is the responsible authority.

Finally, regulations and standards often fail to keep pace with advances in technology. This gap becomes a challenge for manufacturers of products that incorporate a number of different technologies into a single package. And, the challenge can become even greater for manufacturers of wearable technology products, who are likely to introduce product innovations more rapidly in an effort to gain user acceptance.

Steps to Ease International Market Access

As the above section illustrates, the path to certification and international approval of wearable technology products is likely to be complex and time-consuming. Further, because of the different technologies employed in wearable technology products and the diversity of applications and intended uses, it is impossible to prescribe a single testing regime that will address every requirement in every target market.

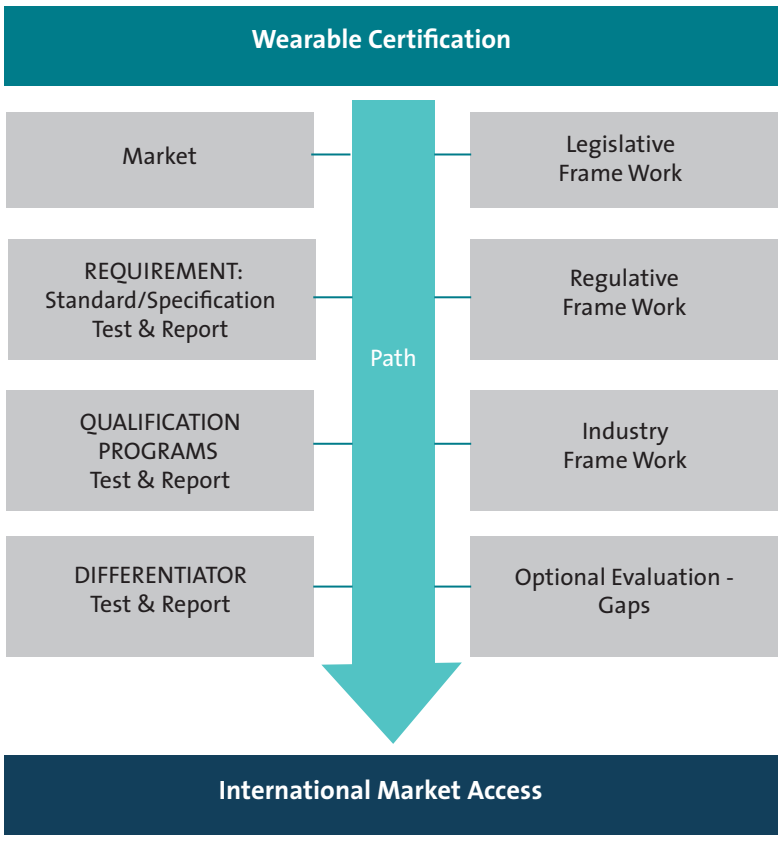
Nonetheless, manufacturers and distributors of wearable technology products can take a number of actions to streamline the testing process and facilitate product approval in target markets. These actions include:

Initiate planning at the beginning of the product design and development process—No single action offers a better return in reducing product approval time than initiating compliance planning at the earliest possible stages of the product development process. Early compliance planning can bring a critical perspective to important design decisions, and can help to establish a realistic timetable for market introduction.

Create a detailed product profile and risk assessment—All product development efforts benefit from a comprehensive assessment of the potential risks and hazards that a given product poses to users. In addition to identifying areas of concern, a thorough risk assessment can also potentially lead to design modifications or changes that mitigate or entirely eliminate a given risk, thereby easing the compliance process.

Identify target geographic markets—The complexity and duration of the approval process depends in part on the specific geographic markets where a wearable technology product is targeted for sale, since technical requirements vary from market to market. By identifying and prioritizing target markets, manufacturers and distributors can better estimate the time and effort required to obtain requisite approvals.

Specify additional customer performance requirements and expectations—In



addition to testing for compliance with regulatory requirements, manufacturers and distributors should also incorporate into their testing plans any anticipated performance requirements and expectations of buyers and end users. Doing so can help make the overall testing process more efficient, and minimize the potential impact on product schedules from unanticipated testing requests.

Seek expert guidance—Finally, manufacturers and distributors of wearable technology products should seek guidance from knowledgeable, independent experts as early as possible in the product development process. A qualified third-party should possesses not only expertise in each of the core enabling technologies, but also knowledge of the regulatory requirements of primary target markets around the globe, In addition, a qualified third-party should have broad testing capabilities available to streamline testing activities required for a given product.

Conclusion

The worldwide market for wearable technologies will experience significant growth in the coming years, providing technology manufacturers with abundant opportunities to bring to market exciting and innovative products. However, since wearable technology products incorporate multiple advanced technologies in a single package, testing for regulatory approval is almost certain to be more complex and time-consuming than for comparable non-wearable products.

Wearable technology product manufacturers can reduce the likelihood of encountering unexpected delays in bringing their products to market by taking a proactive approach to meeting regulatory compliance requirements. An experienced testing organization can provide expert guidance in identifying what testing is required and facilitating the product approval process.

UL offers a complete range of testing services for wearable technology products, and has a comprehensive knowledge of the regulatory approval process in key target markets. In addition, UL provides specialized testing services for energy efficiency, product performance and reliability. UL capabilities also extend to support quality and safety initiatives across global supply chains through product inspections and factory audits.

For additional information about UL's services for wearable technology products, contact:
***Carolyn Arndt**,*
Global Marketing Manager, Consumer Technology Division, at Carolyn.Arndt@UL.com, or
***Michael Suter**,*
European Marketing Manager, at Mike.Suter@UL.com.
You can also visit our website www.ul.com/wearables.