



Safety Concerns Associated with Wearable Technology Products

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1 EXECUTIVE SUMMARY

The 21st century promises to be a time of incredible advances in technology and consumer product innovation, and wearable products will provide users with a wide range of new functions to enhance their lives. In January 2017, the Commission published a staff report, *Potential Hazards Associated with Emerging and Future Technologies*,¹ which identified wearable technology, along with a number of emerging consumer products and technologies, as an area to analyze, prioritize, and possibly manage for potential safety issues.

Although wearable technology includes a myriad of products that are rapidly developing, it is not a new concept. Commonly used products, such as wrist watches and ear phones, are considered wearable technology. However, with advances in electronics, software, and batteries, these technologies have become less obtrusive and have enhanced capabilities. These capabilities, which include complex data collection and wireless communication of data, are now being integrated into more products. Given the wide range of products, staff has attempted to categorize wearable technology products – often referred to as “wearables” – by product function and product type. Because wearables are worn on or close to the body, they may present potential hazards. Staff is aware of incidents and recalls associated with wearable technology. Several fitness trackers and smart watches have been recalled due to skin irritation. Fitness trackers and wireless headphones have been recalled due to overheating batteries. Skin irritation and overheating batteries comprise the majority of known incidents with skin irritation being the most predominant. There have been a few incidents where sharp edges were reported on the smart watch/fitness tracker bands.

Staff’s research found that wearables, such as health trackers, communication products, cross reality products (e.g., virtual reality and augmented reality or VR/AR), audio products, and gaming products, will have a global market value of \$108 billion by 2023.² Consumers are interacting with these innovative products in new and unprecedented ways, leading to enhanced connectivity, convenience, and user experience. Wearables may incorporate many product functions and foreseeable uses, creating challenges for clearly delineating regulatory jurisdiction. Staff is working closely with other agencies to understand and resolve potential jurisdictional issues.

Standards development organizations, such as ASTM International and Underwriters Laboratories (UL), are well-positioned to lead the development of consensus standards to help guide a wide range of stakeholders, including manufacturers, importers, and private labelers of wearables, in the best ways to design safety into their products. Staff is engaged with ASTM International and UL on safety standards development for various wearable consumer products.

¹ https://www.epsc.gov/s3fs-public/Report%20on%20Emerging%20Consumer%20Products%20and%20Technologies_FINAL.pdf

² Wearables: The New Frontier in Health Tracking, Futuresource Consulting, CES Daily, January 7, 2020.

As researchers and manufacturers commercialize new and innovative products, staff continues to monitor this technology. As part of that effort, staff will consider the health and safety implications of wearables and conduct the appropriate safety evaluations, including product testing, to ensure that CPSC understands and addresses potential hazards.

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2 INTRODUCTION

Wearable technology (wearables or wearable tech) is a term that describes consumer products that are worn on, applied to, or implanted or inserted into the body, and incorporate innovative features. Some wearables collect or provide information to the consumer and may be directly or indirectly connected to the internet.

Staff's research found that wearables, such as health trackers, communication products, cross reality products (*e.g.*, virtual reality (VR) and augmented reality (AR)), audio products, and gaming products, will have a global market value of \$108 billion by 2023.³ Consumers are interacting with these innovative products in new and unprecedented ways, leading to enhanced connectivity, convenience, and user experience.

2.1 WHAT ARE WEARABLES?

Wearable technology is not a new concept. Commonly used products, such as wrist watches or earbuds, are considered wearable technology. However, due to recent advances in software and hardware, including miniaturization of products, improved batteries, wireless connectivity, and increased sophistication of sensors, these technologies have become less conspicuous, and have greater capabilities. This generation is witnessing introductions of new types of wearables – from e-textiles to fitness trackers, to altered-reality gaming – fueled by innovations in manufacturing, sensing, energy storage, and advancements in materials. Wearables may provide consumers with myriad benefits; however, wearables can also expose consumers to new or increased hazards.

Wearables represent a wide range of products, and no single definition for these products exists. In general, a wearable can be described as a product that includes a chemical, electronic, or mechanical function that is worn on, applied to, or implanted or inserted into, the human body. Consumer applications of these products include: activity tracking, performance enhancement, and other methods of affecting the consumer's senses and interactions.

In this report, staff describes its work characterizing and categorizing the wide range of wearables and their potential hazards.

2.2 JURISDICTION AND REQUIREMENTS

2.2.1 Jurisdiction

Jurisdiction over certain wearables is not always clear. Determining which agency has jurisdiction over a product is important, because jurisdiction may dictate the regulatory requirements for a given product. Accordingly, staff continues to collaborate with other federal

³ Wearables: The New Frontier in Health Tracking, Futuresource Consulting, CES Daily, January 7, 2020.

agencies, as well as industry, to better understand the function of wearables and potential jurisdictional issues. For example, depending, in part, on the manufacturer's claims and intended uses, some wearables, such as electronic skin patches that can monitor blood glucose levels and assist insulin delivery, may be considered "medical devices"⁴ and would fall under the jurisdiction of the U.S. Food and Drug Administration (FDA). As consumer wearables add more advanced features, like glucose monitoring, it becomes more difficult to distinguish a consumer product from a medical device.⁵ Another example includes wearables intended to improve memory and cognitive function through electrical stimulation of the brain.⁶ Based on staff-level discussions, depending on the marketing claims, the FDA could consider such products to be medical devices.

2.2.2 Requirements

There are no specific U.S. federal consumer product safety technical regulations and few voluntary safety standards generally applicable to wearable technologies. However, CPSC can recall wearables⁷ that are under CPSC's jurisdiction, if they present a *substantial product hazard*.⁸

Stakeholders, including manufacturers, distributors, importers, and retailers should determine whether any safety standards and regulations exist and what approaches are available for ensuring product safety. For example, an e-textile that is a consumer product must meet the requirements of 16 CFR part 1610, *Standard for the Flammability of Clothing Textiles*. If the wearable is a children's toy, it must meet the requirements of 16 CFR part 1250, *Safety Standard Mandating ASTM F963 for Toys*.

3 CATEGORIZATION OF WEARABLES

Staff categorized wearables by their functions, product types, and potential hazards. A specific function may be incorporated into various product types. Evaluating the function of wearables is staff's first step in identifying potential product hazards. Staff's categorization scheme includes products for data collection and storage, communication and repulsion, monitoring and alerting,

⁴Non-invasive, adhesive patch promises measurement of glucose levels through skin without finger-prick blood test, April 9, 2018 <https://phys.org/news/2018-04-non-invasive-adhesive-patch-glucose-skin.html#j>

^{5,6} Wexler A., 2015 A pragmatic analysis of the regulation of consumer transcranial direct current stimulation (TDCS) devices in the United States, *Journal of Law and the Biosciences*, Volume 2, Issue 3, 1 November 2015, Pages 669–696, <https://doi.org/10.1093/jlb/lsv039>

⁷ In 2014, the CPSC, in conjunction with Health Canada, issued a recall of the Fitbit Force because some users reported allergic reactions resulting in redness, rashes, or blistering where the skin was in contact with the tracker.

⁸ <https://www.cpsc.gov/Business--Manufacturing/Recall-Guidance/Duty-to-Report-to-the-CPSC-Your-Rights-and-Responsibilities>.

performance enhancement, and neural stimulation. Some products included in the following categorization scheme may be considered medical devices, and thus, are not under CPSC's jurisdiction. Staff notes that, to date, no products have been categorically excluded from CPSC jurisdiction, and jurisdictional determinations must be made on a product-by-product basis, typically determined by a manufacturer's marketing claims, health risk associated with the product, and other factors.

3.1 PRODUCT FUNCTIONS, TYPES, AND POTENTIAL HAZARDS

Staff is aware of incidents and recalls associated with wearable technology. Several fitness trackers and smart watches have been recalled due to skin irritation. Fitness trackers and wireless headphones have been recalled due to overheating batteries. Skin irritation and overheating batteries comprise the majority of known incidents with skin irritation being the most predominant. There have been a few incidents where sharp edges were reported on the smart watch/fitness tracker bands.

To focus efforts on addressing the potential safety hazards to consumers, it is important for designers and manufacturers to understand the function and potential hazards associated with each type of wearable. Potential hazards associated with a wearable are influenced largely by where and how consumers wear or apply the product to the body, and the functions and the types of technologies manufacturers use to carry out the intended purpose of the product. Staff's product-type categories organize products by their proximity and level of interaction with the body. These categories include accessories, articles, patches, imbeds, and inserts. In addition to categorizing wearable by product type, staff identifies the potential hazards associated with the intended use of each type of product. These hazards include chemical, electrical, and electromagnetic field-light, radio frequency, sonic, thermal, and vibration.

3.1.1 Accessories

Consumers wear accessories on the body that are loosely attached and easily removed. Data collection is a primary function of most wearable accessories. Fitness trackers, for example, have become immensely popular for measuring fitness-related data, such as: heart rate, distance traveled, and calories burned. Other examples of wearable accessories include alerting devices, such as wrist bands that provide a warning when the user is exposed to potentially harmful levels of ultraviolet radiation (UV) from the sun. Consumers can typically transmit information from wearable accessories to a cellular phone, computer, or other data storage device. Wearable accessories may use non-ionizing radiation, such as radio frequencies, which are less energetic than devices providing cellular phone transmission.⁹ Although the acute energy potentially transferred to the body from non-ionizing radiation is typically relatively low, wearable

⁹ Weil, 2017. How Safe Are Fitness Trackers. August, 2017 <https://www.drweil.com/health-wellness/balanced-living/exercise-fitness/how-safe-are-fitness-trackers/>

accessories may be worn directly on the skin for extended periods of time.¹⁰ Additionally, given the prolonged dermal exposure and typical uses, the materials in these products may leach during physical activity, as the user sweats and the product rubs against the user's skin, resulting in irritation, rashes, or allergic reactions. Staff is also concerned about the dermal uptake of compounds that may cause systemic toxicity, as well as the potential for electrical components to heat up and cause consumers mild discomfort or burns.

3.1.2 Articles

A wearable article is any fabric, clothing, or textile that contains electronic technology and is worn on the body. Examples of articles include coats, jackets, dresses, skirts, and pants. Staff anticipates that biomonitoring is one of the primary functions of these products. Similar to wearable accessories, many wearable articles collect information on physiologic functions, such as heart rate and neurologic activity.

Relative to accessories, articles commonly allow manufacturers a larger surface area for embedded sensors and sampling, affording these products higher measurement accuracy and increased variety of data measured. Staff anticipates that the ability of articles to be more precise in measuring data may be of particular importance in athletics. For example, sensors can monitor and assess physical performance, in addition to protecting athletes, by providing a warning when an athlete exceeds an over-exertion threshold.

The human skin is the largest organ in the body and provides protection to our internal organs. Light-emitting fabrics use light to enhance the "style" of a piece of clothing, and some manufacturers' market light-emitting fabrics for therapeutic applications.¹¹ Consumers wearing light-emitting fabrics may experience irritation or burns of the skin, if the light emitted is too intense for sensitive populations. In general, staff is concerned that irritation, thermal burns, and allergic reactions may occur with many materials, especially as the fibers begin to wear from friction and from being laundered. As the materials degrade, performance and impact on the skin may change, releasing chemicals or particles bound in the fiber matrix more easily, resulting in greater chemical exposure to the wearer.

3.1.3 Patch

Wearable patches, are applied directly to the skin, fingernails, or toenails permanently or semi-permanently (such as "tattoos"), and incorporate electronic circuitry. A common use of patches is for identification purposes. For example, amusement parks may use semi-permanent patches for managing access to rides or areas. Other applications include health and fitness, including physiological monitoring or delivery of health supplements or drugs. In the past, some patches have delivered compounds to the body, such as nicotine; however, new "smart" patches can

¹⁰ Devices emitting non-ionizing radiation are under the jurisdiction of FDA, Center for Medical Devices and Radiological Health (CDRH).

¹¹ Shen, 2013. Luminous fabric devices for wearable low-level light therapy. *Biomedical optics-express*, 4 (12), 2925-2937.

include biomonitoring. Patches are attached directly to the skin, and in some cases, they are intended to be attached for long-term use. Given these factors, the likelihood of exposure to any potential harmful materials could be greater, compared to other wearable products.

3.1.4 Imbed

Consumers apply imbed wearables beneath their skin, such as subdermal radio frequency products for identification and entry. Although the term “imbed” is commonly used interchangeably with “insert” (discussed below), staff distinguishes the two, based on application of the device under the skin, versus into an existing body portal (*e.g.*, oral placement).¹² Staff is concerned that the subdermal placement of imbeds allows even greater exposure to chemicals, relative to products placed on the skin, due, in part, to long-term use and access to the bloodstream, where potentially harmful compounds can circulate to targets within the body for physiologic effects. Furthermore, the insertion and removal of an imbed may increase infection opportunities. Staff is also concerned that if imbeds contain batteries or another source of energy, the products could cause burns or other harm to surrounding tissue.

3.1.5 Insert

Insert wearables are placed into existing body orifices, such as the ears or mouth. Consumers have used inserts for many years; hearing aids are one example. Even with this well-known insert, technological innovations have vastly improved hearing aid performance and enhanced their capabilities. Hearing aids are now being marketed to consumers without impaired hearing. For example, “augmented hearing” or “hearable” products allow users to enhance and control their sense of hearing, including blocking out user-determined background noise.¹³ Staff is concerned that consumer exposure to sound, electric, electromagnetic, and chemical product properties may be hazardous when in contact with sensitive body areas or during the process of insertion or removal.

3.2 DATA SECURITY

Many wearables connect to the internet, and, likely unbeknownst to users, can have the same vulnerabilities for data security as with other connected products. “Data Security,” as used in an Internet of Things (IoT) product, concerns all of the data stored in, or moving in or out of a connected product, which could include those impacting the safety of the product. This includes:

- Operational instructions (software)
- Consumer-originated data (biometrics, settings and preferences, multiple-user identification)
- Environmental metrics (*e.g.*, location, temperature, atmosphere, energy)
- Manufacturing/product data (*e.g.*, serial numbers across products)

¹² Medium.com.

¹³ C|NET. *Hearing aids are getting smarter*. April 2018.

Data Security and the concept of product “hazardization” is more fully described in the recent staff document: *Status Report to the Commission on the Internet of Things and Consumer Product Safety*.¹⁴

4 STAFF ACTIVITIES ON WEARABLES

Staff has conducted and continues to engage in a range of activities focusing on wearables. The following is a brief summary of staff efforts.

4.1 PUBLIC BRIEFING TO THE COMMISSION

On November 20, 2019, staff briefed the Commission on the potential hazards associated with wearable technology products.

4.2 VOLUNTARY STANDARDS DEVELOPMENT

Staff actively participates in the development of consumer product consensus-based standards, and voluntary standards for wearable tech products are no exception.

- In December 2019, staff sent letters to UL and ASTM International requesting that these standards development organizations also consider the development of standards, certification programs, or best practices guidance associated with the safety of wearables products. On February 27, 2020, staff met with ASTM leadership to discuss approaches to standards development for wearables.
- Underwriters Laboratory (UL) has formed a Standards Technical Panel (STP) for standards pertaining to one form of wearables under the STP 8400, *Virtual Reality, Augmented Reality and Mixed Reality Technology Equipment*. Staff recently joined STP 8400 and is actively participating in the STP meetings.
- UL 2710 *Sustainability for Portable Electronic Products* has formed an STP to evaluate the sustainability performance and life-cycle management of portable electronic products. Staff will participate in the development of the standard.
- ASTM subcommittee D13.50, for Smart Textiles, has developed a standard on terminology for smart textiles and is considering standards regarding durability of smart garment electrodes under certain conditions. Staff has a membership on D13.50 and is actively participating on the subcommittee.
- ASTM subcommittee F08.53 on Headgear Sensors is developing a standard for the use of force sensors in helmets and other headgear. Staff has participated on and also served as a task group chairman under this subcommittee.

¹⁴ Status Report to the Commission on the Internet of Things and Consumer Product Safety. September 2019. <https://www.epsc.gov/s3fs-public/Status-Report-to-the-Commission-on-the-Internet-of-Things-and-Consumer-Product-Safety.pdf>.

- ASTM subcommittee F15.75, for Connected Products, is currently drafting a guidance document for consumer products that are connected to the internet. Staff actively participates on the subcommittee.
- ASTM F24 on amusement rides and devices has a task group on VR/AR. This group is looking at the development of standards related to the use of VR/AR in amusement rides and related consumer initiated consumer activities in commercial amusement environments.
- IPC E-Textiles Workshop and Standards Meeting, Philadelphia, PA, September 2019. The IPC is a trade association representing printed circuit board manufacturers and electronic manufacturing service companies, their customers and suppliers.

4.3 COLLABORATION WITH FEDERAL AGENCIES

Staff recognizes that the regulatory framework of many wearable products is unclear and requires coordination with other federal agencies. For example, the FDA regulates products that are considered medical devices, and products such as fitness trackers may have features that blur the lines between consumer products and medical devices. CPSC staff has met with FDA staff, and established regular meetings to discuss issues of jurisdiction and consumer education.

CPSC staff participates in interagency meetings coordinated through the National Nanotechnology Coordination Office (NNCO), which has a working group on sensors; many of these sensors are incorporated into consumer products. Additionally, agencies such as the Department of Defense (DOD) have concerns regarding the impacts of wearable products on military personnel, and their safety approaches have relevance for non-military consumers.

Given the vast amount of mutual interest among federal agencies, staff continues to work towards more formal interactions.

4.4 STAKEHOLDER OUTREACH

Staff continues to communicate with stakeholders about potential hazards associated with wearables. Staff's outreach activities include conferences, workshops, and panels, such as:

- Department of Commerce, Smart Fabrics Summit, April 2020 (staff participating on standards panel by webinar).
- American Association for the Advancement of Science 186th Annual Meeting, February 2020. Staff presentation on wearable technologies and product safety.
- Staff attendance at the Consumer Electronics Show (CES), January 2020.
- 2020 Consumer Product Safety Professional Certification Webinar Series (St. Louis University) *Technology & Product Safety Perspectives: Consumer Products, Data Analytics and Standards/Certifications*.
- Risk Management Group staff gave a presentation at the International Consumer Product Health and Safety Organization's (ICPHSO) 2020 Annual Symposium, February 2020.

The presentation highlighted some of staff's work on various emerging hazards, including wearables.

- 2019 Consumer Product Safety Professional Certification Webinar Series (St. Louis University), *Wearable Products: A Case Study In Enhancing Your Safety Culture With Best Practices For Assessing Risks Associated With Emerging Technology Products*.
- ASTM International Smart Textiles Workshop, June, 2019.
- Public meeting with Facebook Oculus, April 30, 2019.
- In 2018, staff wrote a short article in which staff suggested best practices for designing wearable technology products with safety in mind.¹⁵

5 SUMMARY

As researchers and manufacturers commercialize new and innovative wearables, staff will continue to monitor this technology, considering the health and safety implications of these products, and to conduct the appropriate safety evaluations, including product testing, to ensure that CPSC understands and addresses potential hazards. As noted in Section 3, these products pose potential hazards, ranging from skin irritation to potential serious impacts on the central nervous system.

As CPSC adapts to this changing market, jurisdiction over any class of wearable product will be an ongoing challenge, because it depends on a product's specific function and marketing claims. Staff is working closely with other agencies to understand, delineate, and resolve jurisdictional issues as they arise.

Staff believes that standards development organizations, such as ASTM International and UL, are well-positioned to lead the development of consensus standards to help guide a wide range of stakeholders, including manufacturers, importers, and private labelers of wearables, in the best ways to design safety into their products. To that end, staff is engaged with ASTM and UL on the development of safety standards and guidance documents for wearables.

Through joint efforts with other standards development organizations and our federal partners, staff is better situated to anticipate, prevent, and react to hazards involving wearables within CPSC's jurisdiction.

¹⁵ Adair, P., Campbell, J., & Thomas, T. (2019). *Wearable Technologies: Design for Safety from Concept to Consumer*. ADK Product Safety and Recall Directory, 69-70.