

U.S. Consumer Product Safety Commission

New Product Trends: Wearable Technology Jacqueline Campbell



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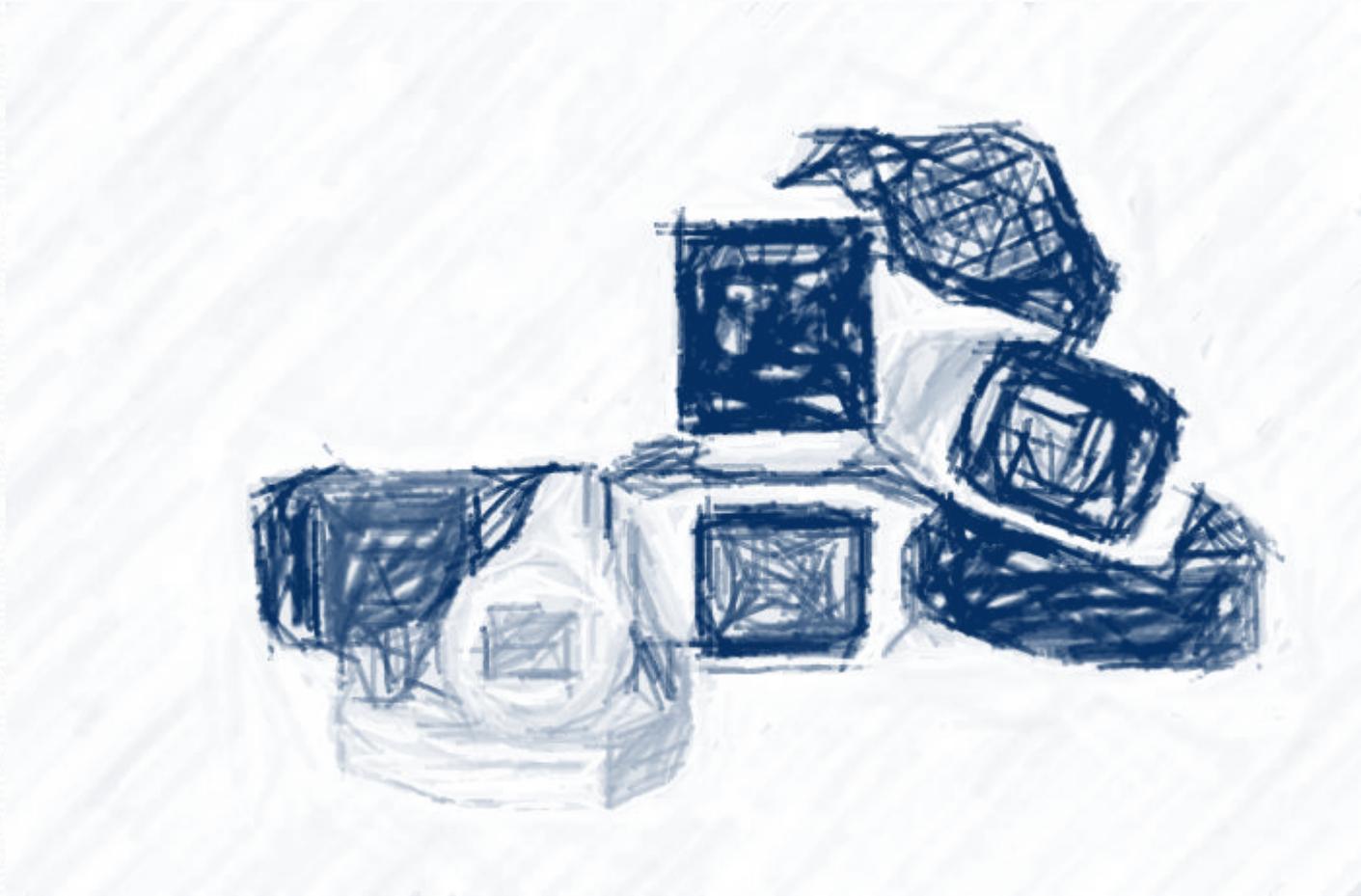
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The slides in this presentation are intended to be used in a training event with verbal elaboration by a knowledgeable presenter. The slides highlight key U.S. product safety requirements for this discussion. The text is not a comprehensive statement of legal requirements or policy and should not be relied upon for that purpose. You should consult official versions of U.S. statutes and regulations, as well as published CPSC guidance when making decisions that could affect the safety and compliance of products entering U.S. commerce. Note that references are provided at the end of the presentation and a handout on phthalates prohibitions in children's toys and child-care articles is also available.

Topics

- What Is Wearable Technology?
- New Product Trends
- Regulatory Landscape
- Voluntary Standards Activity
- CPSC Activity

What Is Wearable Technology?



What Is Wearable Technology?



What Is Wearable Technology?



What Is Wearable Technology?

Smart electronic devices that can be worn on the body as implants or accessories.

- *Wikipedia*

A small computer or advanced electronic device that is worn or carried on the body.

- *Dictionary.com*

A technology that is worn on the human body.

- *Techopedia.com*

Electronic technologies or computers that are incorporated into items of clothing and accessories which can comfortably be worn on the body.

- *Wearabledevices.com*

The Internet of Things (IoT)

- The interconnection via the Internet of computing devices embedded in everyday objects, enabling them to send and receive data. *Oxford Dictionaries*



Product Trends: Textiles



Product Trends: Textiles



Product Trends: Textiles

Fashion and

Function



Product Trends: Textiles

Illuminated pajamas treat newborns



“Babies who suffer from jaundice after birth are treated with shortwave light.

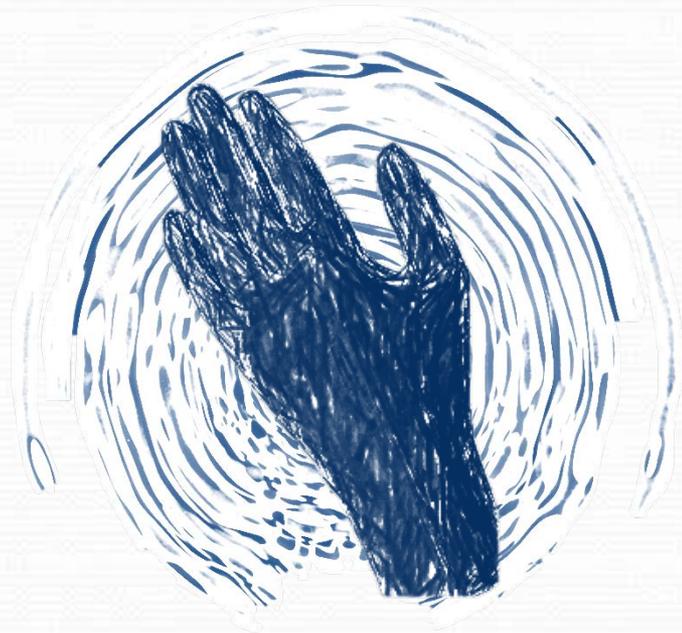
Empa researchers have now developed illuminated pajamas that replace the treatment in an incubator.

This means newborns can get healthy while warm and happy in their mothers' arms.”

<https://www.empa.ch/web/s604/photonic-textiles-for-newborns?inheritRedirect=true>

Product Trends: Textiles

E-gloves to protect workers from dangerous vibration levels



“...“Prolonged use of power tools can result in a variety of musculoskeletal, neurological and vascular disorders,” said Professor Tilak Dias, who leads the university’s Advanced Textiles Research Group.

...“But by using smart textiles, it could be possible to detect with accuracy when a worker is exposed to damaging levels of vibrations and help prevent such conditions occurring in the first place.”

...Sensors to be tested as part of the research include vibration sensors which are only two millimetres long and accelerometers. They will be encapsulated in micro pods before being embedded into the yarns, which are knitted into gloves.”

<https://www.ntu.ac.uk/about-us/news/news-articles/2017/03/e-gloves-to-protect-workers-from-dangerous-vibration-levels>

Product Trends: Textiles

Self-Organized Frameworks on Textiles (SOFT): Conductive Fabrics for Simultaneous Sensing, Capture, and Filtration of Gases

Merry K. Smith and Katherine A. Mirica

Department of Chemistry, Burke Laboratory, Dartmouth College, Hanover, New Hampshire 03755, United States

J. Am. Chem. Soc., 2017, 139 (46), pp 16759–16767



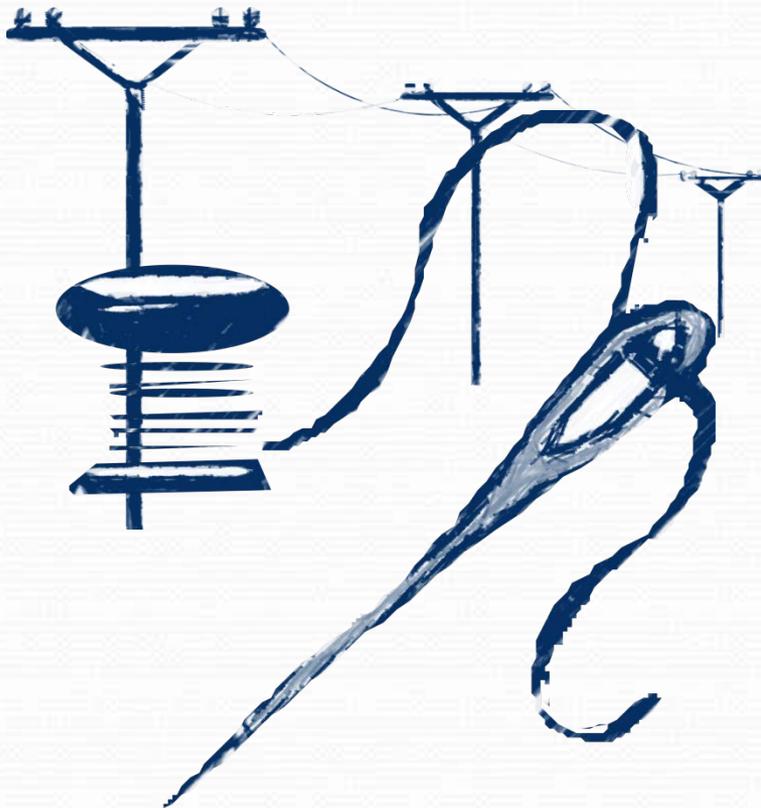
“...the chemistry team of Katherine Mirica and Merry Smith describe the creation of new smart fabrics – named SOFT, for Self-Organized Framework on Textiles – in what is noted as the first demonstration of simultaneous detection, capture, pre-concentration and filtration of gases in a wearable that uses conductive, porous materials integrated into soft textiles.”

<http://www.innovationintextiles.com/new-electronic-textiles-could-offer-advanced-protection/>

Product Trends: Textiles

Harvesting electrical energy from carbon nanotube yarn twist

Shi Hyeong Kim, Carter S. Haines², Na Li², Keon Jung Kim, Tae Jin Mun, Changsoon Choi, *et al.*
Science 25 Aug 2017: Vol. 357, Issue 6353, pp. 773-778



“The rise of small-scale, portable electronics and wearable devices has boosted the desire for ways to harvest energy from mechanical motion. Such approaches could be used to provide battery-free power with a small footprint. Kim et al. present an energy harvester made from carbon nanotube yarn that converts mechanical energy into electrical energy from both torsional and tensile motion. Their findings reveal how the extent of yarn twisting and the combination of homochiral and heterochiral coiled yarns can maximize energy generation.”

<http://science.sciencemag.org/content/357/6353/773>

New Product Trends

According to a recent forecast of the market by IDTechEx,

“The increasingly diverse market for wearable devices will reach over \$150bn annually by 2027.”

<https://www.idtechex.com/research/reports/wearable-technology-2017-2027-markets-players-forecasts-000536.asp>



Regulatory Landscape

Definition of a Medical Device



U.S. Food and Drug Administration
Protecting and Promoting *Your Health*

According to Section 201(h) of the Food, Drug & Cosmetic (FD&C) Act, a medical device is:

- an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
 - **intended for use in the diagnosis of disease or other conditions**, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - **intended to affect the structure or any function of the body of man or other animals**, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.



Consumer Product Safety Commission

Consumer Product Safety Act, 15 U.S.C. § 2051:

- (1) to protect the public against unreasonable risks of injury associated with consumer products;**
- (2) to assist consumers in evaluating the comparative safety of consumer products;
- (3) to develop uniform safety standards for consumer products** and to minimize conflicting State and local regulations; and
- (4) to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

What is a **consumer product**? 15 U.S.C. § 2052:

any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise;

Regulatory Landscape

Relevant exclusions from the definition of *consumer product*:

- Pesticides
 - Federal Insecticide, Fungicide, and Rodenticide Act and § 3 of CPSA
- Drugs, devices, or cosmetics
 - Federal Food, Drug, and Cosmetic Act and § 3 of CPSA
- Risks of injury associated with electronic product radiation emitted from an electronic product.
 - Public Health Service Act and § 31 of CPSA

Regulatory Landscape

Examples of Excluded Products:

- Insect repelling wrist band
 - Pesticides are under EPA Jurisdiction.
 - A Pesticide is defined as:
 - Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. 7 U.S.C. § 136(u) (2012).
 - A "pest" is defined as:
 - (1) any insect, rodent, nematode, fungus, weed, or
 - (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (unless on or in living man or other living animals) which the Administrator [of the Environmental Protection Agency (EPA)] declares to be a pest. Id. § 136(t).

Regulatory Landscape

Examples of Excluded Products: (continued)

- Brain Stimulator head band
 - Device under FDA Jurisdiction
 - Headphones or electrodes in a headband that send electronic current.
 - Advertised for use to:
 - “Improve your memory, perform better at work or at school, or even learn new information up to twice as fast.”
 - Advertising also stated use for treating medical conditions:
 - “Research is developing in regard to debilitating disorders such as Parkinson’s disease, PTSD, OCD, Alzheimer’s, Dementia, Schizophrenia, effects from stroke, epilepsy, traumatic brain injury, and more.”

Regulatory Landscape

Examples of Excluded Products: (continued)

- UV emitting Electronic Product – FDA Jurisdiction
 - Any wearable that is an “electronic product” that allegedly creates a risk of injury from electronic product radiation (such as UV light).
- Products that relate UV information
 - Jurisdiction depends on hazard.
 - Physical products (bracelets, necklaces, charms) are consumer products, but the harm must be associated with the product (i.e., burn, laceration).
 - Consumer reliance on “bad” information unlikely addressable by CPSC.
 - Digital products (software) are probably consumer products, but we would need to investigate each case, including the nature of the alleged risk of injury.

Voluntary Standards and Certifications

- International Society of Testing and Materials, American Section (ASTM)
 - D13.50 – Smart textiles <https://www.astm.org/COMMIT/SUBCOMMIT/D1350.htm>
- American Association of Textile Chemists and Colorists (AATCC) <https://www.aatcc.org/test/etextiles/>
- Institute of Electrical and Electronics Engineers (IEEE)
 - International Roadmap for Systems and Devices <https://irds.ieee.org/>
- IPC-Institute Connecting Electronics Industries
 - D-70 E-Textiles Committee <http://www.ipc.org/CommitteeDetail.aspx?Committee=D-70>
 - D-72 E-Textiles Materials Subcommittee <http://www.ipc.org/CommitteeDetail.aspx?Committee=D-72>
- UL
 - *Wearable Technology Products: The Path to Certification and International Market Approval (2015)*
<http://www.northamerica-ul.com/your-industry/wearable-technology/>
- TÜV SÜD
 - <https://www.tuv-sud.com/activity/testing/wearable-technology-wearable-device-testing-and-certification>

CPSC Activity

Home » Recalls »

Fitbit Recalls Force Activity-Tracking Wristband Due to Risk of Skin Irritation

[En Español](#)



Note: On February 20, 2014, Fitbit Inc. announced a refund program for the Fitbit Force. This news release serves as the official recall announcement. Consumer contact time has changed, effective 1/11/16.



Fitbit Force activity-tracking wristband

Name of product:

Wireless activity-tracking wristband

Hazard:

Users can develop allergic reactions to the stainless steel casing, materials used in the strap, or adhesives used to assemble the product, resulting in redness, rashes or blistering where the skin has been in contact with the tracker.

Remedy:

Refund

Recall date:

March 12, 2014

Recall number:

14-129

[Report an Unsafe Product](#)

Hazard:

Users can develop allergic reactions to the stainless steel casing, materials used in the strap, or adhesives used to assemble the product, resulting in redness, rashes or blistering where the skin has been in contact with the tracker.

CPSC Activity

- Defining Products
 - Scope
- Risk Categorization
 - Function of Product
 - Location on Body
- Potential Hazards
 - Identification of Hazard Patterns
 - Consequences



CPSC Activity

- On January 18, 2017, CPSC staff published *Potential Hazards Associated with Emerging and Future Technologies*, a white paper identifying potentially new, increased, or decreased consumer hazards associated with emerging technologies.
 - May be found at: https://www.cpsc.gov/s3fs-public/Report%20on%20Emerging%20Consumer%20Products%20and%20Technologies_FINAL.pdf
- Wearable technologies were identified as an area of focus.

What Is Wearable Technology?

- CPSC staff defines wearable technology as:

Any chemical, electronic, magnetic, or mechanical (CEMM) non-medical consumer technology product primarily intended to be worn, applied, etc.



Risk Categorization: Location

- Arm
- Body
- Ear
- Eye
- Finger
- Fingernail
- Foot
- Genitals
- Hand
- Head
- Leg
- Mouth
- Neck
- Skin
- Waist
- Wrist
- Miscellaneous



<https://ipdl.gatech.edu/projects/smart-ballet-shoe>

Where on the body will the product be worn?

Risk Categorization: Product Function

- Aesthetic
- Biomonitoring
- Body armor
 - Anti-ballistic
 - Anti-cut
 - Anti-impact
- Anti-puncture
- Chemical-Resistance
- Communication
- Computing/Integrated circuit
- Electrical Generation, Storage, Conduction
- Entertainment
 - Audio
 - Other
 - Television/Gaming
- Environmental Monitoring
 - Chemical
 - Radiation
 - Temperature/Humidity
- Flame-Resistance
- Heat/Cold Generation, Reflection, Dissipation
- Insect-Repellant
- Light Creation/Dissipation
- Liquid-Resistance
- Physiological Effects
- Other

What does your product do and how will a consumer use it?



Potential Hazards: Hazard Pattern

- Biological
 - Post-use biological exposure, mold, bacteria, particles
- Electrical
 - Shock, electroporation, electromagnetic radiation
- Inorganic and organic compound
 - Chemicals, metals, particles
- Light
 - Light, radiation
- Magnetic field
- Multiple (explosion)
- Sonic/noise
- Thermal
 - Fire, heating
- Vibration
- Other



What exposure hazard might be expected?

Fitness Tracker Apparel

- Assumptions:
 - Consumer product for adults
 - Film and electronics embedded as sensors
- CPSC Requirements
 - GCC
 - Clothing Textiles Flammability (16 CFR part 1610)
- Other Considerations
 - Any applicable voluntary standards for safety (electrical)
 - Impact of wear on safety performance (laundering, abrasion, etc.)
 - Interaction with skin (sensitivity)
 - Other???



Summary

- Wearable Technology is a quickly evolving landscape.
- Regulatory jurisdiction is dependent on many factors.
- CPSC staff is working to understand risks and hazards for consumer wearable technologies.
- Carefully evaluate new technologies when you are sourcing products!

Contact Information

U.S. Consumer Product Safety Commission



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