Designing wearable medical devices for safe, effective, and satisfying use

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Executive Summary

Human factors focuses on adapting products to match the user's needs and preferences. Wearable medical devices form a close, sometimes intimate relationship with the wearer. This makes wearable medical devices a prime target for human factors specialists' research, design, and evaluation efforts.

From ancient times people have worn all kinds of objects, including weapons, containers, and ornamentation. Some objects have been tucked into clothing. Some have been worn on a belt of some sort. Some have been worn on the back or around the neck. Little has changed in modern times; there are only so many ways of wearing something.

How would you know if a wearable item (product, device, tool) matched the needs and preferences of the intended user? You would have to know something about the wearer, the worn item's purpose, the use environment, and any related tasks to be accomplished. The safe, effective, and satisfying use of wearable medical devices, now and into the future, will hinge on the effective application of human factors during the device's development.

Types of wearable medical devices

The market for wearables is growing fast; many of the world's largest technology firms are investing heavily. So what are some of the most common wearable medical devices?

An increasingly common one is the **insulin infusion pump**. There are already many types on the market, with both physical and digital elements, all of which deliver a programmed stream of medication to people with diabetes to control their blood sugar levels. These compact devices, about the size of a deck of cards, normally clip to a belt or waistband and send insulin through a thin tube to an infusion site. Their ability to stay in place during vigorous activity (e.g., jogging, playing basketball, mountain climbing) is important, as is battery life between charges.

Another common device is the **hearing aid**, although they are so well-established as a product class that they might not immediately come to mind when contemplating wearables. Yet, they certainly are worn – over the ear and/or in the ear canal – and may be in near-field communication with a smart phone with which users can vary their mode of operation. These devices also must stay in place during vigorous activity. They must be exceptionally comfortable because they often are worn continuously during waking portions of the day, and

perhaps during sleep as well. Their relative invisibility can be an important design consideration to many users who might otherwise feel self-conscious about the need for such assistive devices.

A relative newcomer in the wearable medical device market is **smart watches** with heart monitoring capability. These devices started as a technology and fashion statement by early adopters and are starting to become more pervasive as their utility grows. Being able to monitor heart function appears to be what some would call a superior, indispensable "killer app," but we're actually talking about an app, with its attendant hardware, that can save a life. Current offerings make heart rate monitoring seem almost fashionable itself; part of the recent embrace of biometrics among those focused on well-being and the associated uses of technology. These kinds of wearables need to be comfortable, but they also have to provide a modicum of psychological comfort. Consider, for example, how a wearer might react to her watch indicating she is experiencing a heart arrhythmia that, if not addressed quickly, could be fatal. Depending on how the device communicates, which might include messages being sent to a healthcare provider or even first responders, an early warning from one's smart watch could be reassuring – at least to some extent – or actually be the cause of panic (see our later comments on learning how to use devices).

There are many more examples of wearable devices that can monitor, diagnose, and treat medical conditions and other health concerns, including:

- Drug patches that help people quit smoking
- Exoskeletons that help people who suffered a stroke re-learn to walk
- Headgear that alert a user if s/he is leaning sideways and could fall
- Attachable pods, bands, and clips that monitor respiratory and heart functions
- Masks that keep a person's airway under positive pressure to prevent apnea (temporary cessation of breathing)
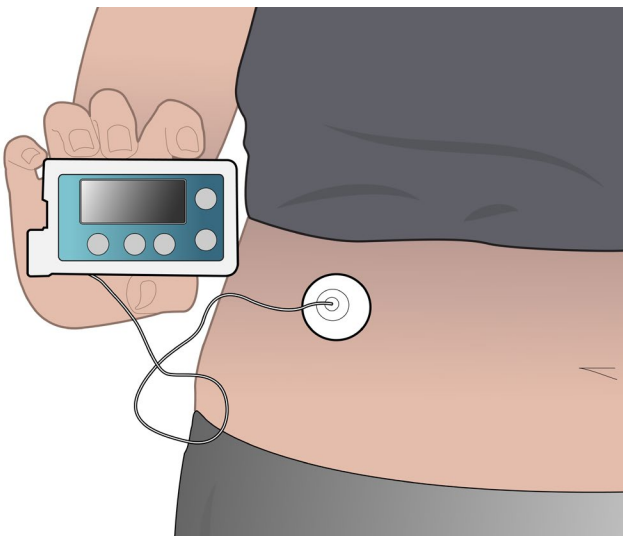- Splints that keep a person's limb or spine in place

Figure 1: Illustration of a wearable device with a physical connection to the user

Applying human factors engineering to wearable medical devices

All of these products can benefit from human factors engineering, most obviously because the user will interact with them in a very personal way. The quality of interaction with these devices is paramount. Additionally, many of these products cannot be sold until they receive approval from the appropriate regulatory authorities, such as the US Food & Drug Administration (FDA) in the USA and Notified Bodies in the European Union. Both authorities require manufacturers to apply human factors (aka human factors engineering, usability engineering) during product development and ultimately to validate that a product is safe and effective.

Exactly how should the manufacturers of wearable medical devices go about applying human factors in their development process? Best practices that have evolved in the 60-year-old discipline of human factors, plus recent guidance from regulators and standards bodies (e.g., IEC, AAMI), provide clear direction. In summary, manufacturers should take the following steps:

Figure 2: Illustration of early concept sketches for a device that is worn on the head.

1. **Conduct user research.** In the US, the Quality System Regulation that applies to medical devices[1] calls for manufacturers to ensure that "...proper design of the user interface of a device is critical to address the user's needs." This is best done by "systematic consideration of human factors in the development of the device user interface." Note that regulators consider the user interface to include "all aspects of a device (including its labeling) that users see, feel and hear when operating the device."

   To address this legal requirement, manufacturers have been compelled to conduct a greater amount of early research to determine user needs and convert them into design specifications. Today, an insulin pump manufacturer might hear from the intended users that the device should emit a loud alarm tone if its battery comes within one hour of exhaustion. This feedback can then be converted into a design specification (a "design input" according to FDA's terminology).

   User research methods include individual and group interviews, observations of people interacting with comparable devices, field research, diary studies and surveys. The focus of user research could be on a problem space where no current solution exists or on innovation opportunities for an existing product. User research methods elicit user preferences, pain points, opportunities and potential risks--all valuable inputs to product user requirements.
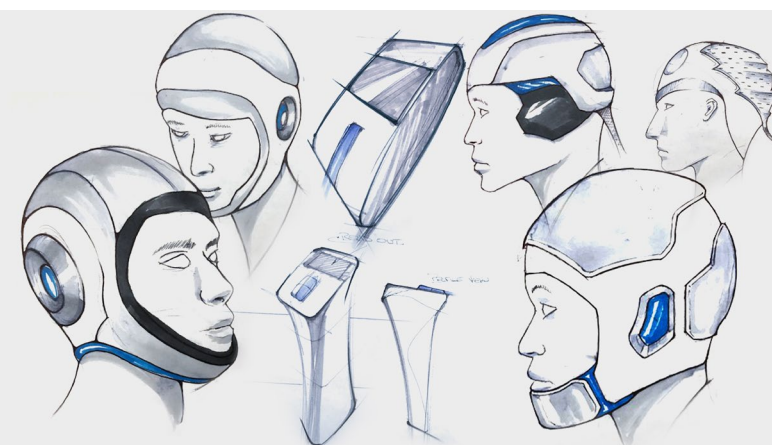
2. **Manage use-related risk.** ISO 14971:2007, titled "Medical devices -- Application of risk management to medical devices," advises manufacturers to perform a rigorous analysis of device-related risks. Use-related risk management calls for manufacturers to examine potential use-related hazardous scenarios, such as an insulin pump's battery becoming exhausted and, consequently, failing to deliver insulin on the prescribed schedule.

    This approach to risk management recognizes that failed user interactions can be as detrimental as failed electromechanical components. In other words, designing to ensure that a wearable medical device user hears an alarm can be just as important as designing a set of gears so they are unlikely to jam.

    Use-related risk management calls for the identification of all imaginable use errors that may occur during various scenarios of device use, considering the potential harm of such use errors, and then pursuing design solutions that reduce or altogether eliminate the chance of the use error occurring. As compared to other aspects of risk management, great attention is paid to reducing the chance of failures that could cause great harm (i.e., injury or death) without regard to the likelihood of the use error.

    Likelihood of a use error emerges as an important factor only after best efforts are expended to eliminate a risk altogether, but that perfection in this regard is unattainable. At that point, a low likelihood of use error may be cited as a basis for claiming to a regulatory body that the residual risk–-the persistent chance of a harmful event occurring–is reasonably low.

3. **Apply human factors in the course of design.** As suggested above, the best way to protect device users from harm is to eliminate risks through design. Secondary and weaker solutions include implementing physical guards of some sort, placing labels near hazards, and training people to operate a device with due care.

    Therefore, early in the process of developing a wearable medical device, considerable attention should be paid to designing a high-quality user interface that presents users with few if any opportunities to commit a particularly harmful use error. And fortunately, there is a large volume of guidance on the topic of good user interface design. One such source is ANSI/AAMI HE75:2009, titled "Human factors engineering – Design of medical devices." This publication offers general guidance on human factors techniques, but also provides lots of detailed guidance on designing such user interface elements as alarms, control panels, workstations and graphical user interfaces. Guidance of this sort can help a wearable medical device manufacturer make sure that any pushbuttons or touchscreen targets are not too small, that onscreen text can be read at the expected viewing distance, and that a potentially broad soundscape of beeps, chirps, and click sounds can be heard and that their meaning is clear.
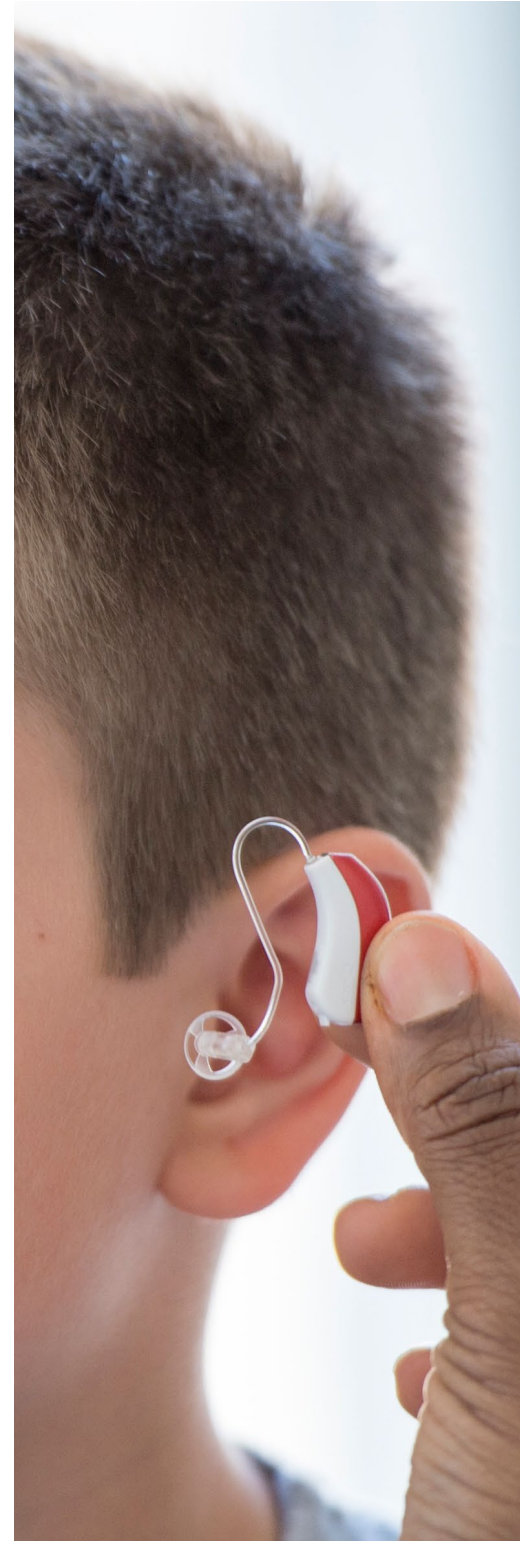
4. **Evaluate the user interface, iteratively.** Major regulatory guidance documents, national and international standards, and pertinent textbooks all communicate the same message, which is to conduct iterative evaluation of a user interface. The message makes intuitive sense. After all, an electromechanical component such as a pump will undergo stress testing to make sure it functions reliably. Why not a user interface as well? The obvious answer to this question is: "Yes. It makes great sense to call upon intended users to operate a device and see whether they can use it as you intend."

The formal name for this type of testing is usability testing. Ideally, a wearable medical device will be exposed to a lot of such testing, starting when there might be several concepts in development, continuing when one concept has been selected and refined, continuing still when the now functional device is nearing completion and there are just a few details warranting further evaluation, and finally when the device is ready for validation as being safe and effective. Regulatory bodies focus considerable attention on the results of this final evaluation, which is variably called a "human factors validation test" or "summative usability test," the terms being synonymous.

The ingredients in a well-designed usability test are:

- Sample of intended device users
- Appropriate use environment, which could be a simulated or actual home, professional setting, or a public space
- Use scenarios that are realistic, and call upon the test participants to perform myriad tasks to accomplish an overall goal
- Specialists who lead the test activities, collect data, and identify the root cause of any use problem

Accordingly, a usability test of a smart watch that analyzes a user's heart rhythm might include people who experience arrhythmias and, therefore, are likely consumers. Such a test could:

- Occur in a research lab set up to look like a living room
- Call upon users to initiate an analysis of their heart rhythm and then determine if they need to seek medical attention
- Be designed and run by a test team comprising a leader/administrator and an analyst who documents test results, very often in real time
- Capture feedback on aspects of wearability such as comfort, convenience, conspicuity, as well as the value of specific features

Call to action

The pace of development in the wearable medical device space is encouraging, sparked by advances in software, sensors, component miniaturization, battery technology, and wireless communication. Related to this progress, device user interfaces seem to be getting better as well, building in part on best practices exhibited in the consumer product world where there has generally been more design freedom and risk-taking because the products are not regulated. However, vigilance is needed. The standard of care among user interface designers of medical products has to be higher than that exercised when designing and developing non-medical devices. This standard applies to wearable and non-wearables.

It is not as though good user interface design of a digital camera is not important, but a digital camera is unlikely to cause harm. However, the stakes are generally higher when considering the potential of a wearable medical device to cause harm. For example, an exoskeleton's attachment straps could come loose and eventually cause the user to fall; a baby apnea monitor could sound its alarm too quietly to attract a parent or guardian's attention; a drug patch could be applied to an inappropriate part of the body, preventing proper medication absorption. Use errors involving the setup, placement on the body, activation, use, and removal from the body of wearable medical devices can all have adverse health consequences. That is why managing use-related risk is so necessary, and likely to be practiced more intensively when developing medical wearable devices as compared to a non-medical device.

All this emphasis on human factors might sound like an expensive proposition. It could be expensive when one considers how things have been done in the past: a time when few manufacturers had heard of the discipline and even fewer understood and practiced it. Back then, a company might not have spent anything on human factors and counted on its engineering team to produce something "appropriate" based on their general knowledge

and creativity. This approach produced some fine medical devices, but it did not do so reliably. Wearable medical devices were arguably more primitive and posed significant user interaction and satisfaction issues. Moreover, some induced use errors that lead to injuries and deaths.

Flash forward to the early 21st Century: we have wrist-worn computers, regulators that enforce human factors requirements, and vigorous competition among manufacturers who are investing in user experience quality. In this context, it may be argued that a company could hardly over-invest in human factors. A solid investment can yield the following benefits:

- Smoother pathway toward regulatory approval
- Increased match to user needs
- Reduced chance of expensive, late-stage design changes
- Positive first reactions to the device from prospective customers
- Satisfied customers who drive up a brand's reputation
- Reduced chance of harm to customers
- Reduced demand on customer support resources
- Fewer returns
- Reduced risk of a product liability claim

These benefits may begin accruing before a wearable medical device has even been launched, and certainly afterward. Applying human factors early and throughout the device development process is key. But, getting the user interface design right is pivotal. Below, we present some basic design guidance to manufacturers, which may be considered the "tip of the iceberg" in terms of the full body of knowledge on the topic.

Suggestions for wearable medical device design

1. **Accommodate different-sized people.** A wearable medical device might be targeted toward children or adults, males or females, and lighter- and heavier-built individuals. There is plenty of anthropometric data available for these populations that can guide manufacturers to build into a device the necessary adjustability, or to offer different sized produces (e.g., small, medium, large, and extra-large models, or child and adult models).

2. **Ensure signal detection.** Various wearable medical devices produce audible, visual, and tactile signals. When such signals serve a safety-related purpose, it becomes imperative for the signals to draw attention reliably, just as it is important for them to have good sensitivity (i.e., picking out abnormalities) and specificity (avoiding false positives). This means that visual signals must be in the line of sight and stand out from the background, audible signals must be loud enough and stand out against ambient noise, and that tactile signals are profound enough to grab attention when there are other things competing for attention. In many cases, the best solution is to communicate critical information (e.g., low battery) using multiple channels of communication. For example, a device might produce a flashing icon on its screen, beep, and vibrate all at once to indicate battery low.

3. **Enable cleaning.** There might or might not be cause for concern about the cleanliness of a smart watch, but it certainly is a concern regarding a CPAP mask that treats apnea, for example. Depending on the type of device, it may be quite important for it to stay relatively clean and/or enable easy cleaning. Sometimes, this means that it needs to be easy to disassemble a device for immersion in soapy water. In other cases, it might mean that the materials can handle cleaning with strong disinfectants. And, it might be important to remind people to clean their device by pasting a warning to that effect right on the product.

4. **Discreet (inconspicuous) appearance.** While some wearable medical devices might also be perceived as fashionable objects, most will not. Usually, the user will wish the device was invisible. Stopping short of this goal, it may be important for the device to be small, appear to be some kind of consumer product as opposed to medical device, and give no tell-tales about its actual function. Still, there may be cases when users are quite comfortable with their medical condition and make their use of devices conspicuous. Therefore, making a wearable medical device discreet may be something to explore during the user research phase of a development project.
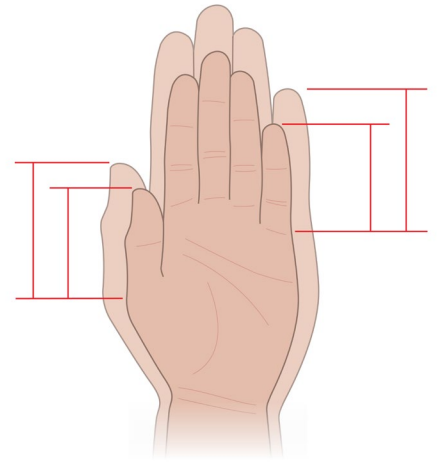

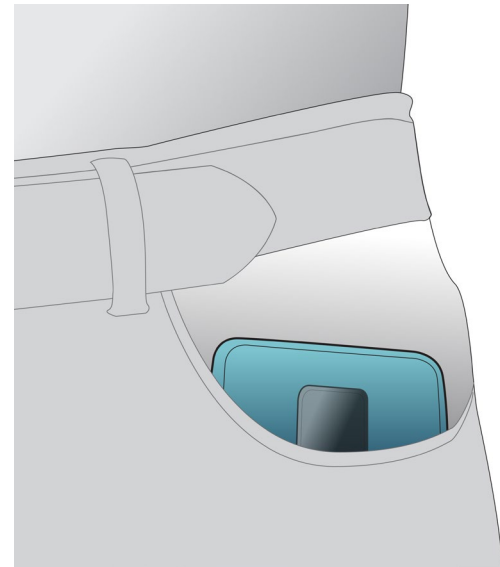Figure 3: Example ergonomic drawing depicting hand size differences

Figure 4: Illustration of a wireless device carried in a slim and discrete manner

5. **Prevent inadvertent actuation.** Devices with touchscreens, actual buttons, and other physical controls might be vulnerable to inadvertent actuation of functions. For example, bumping the device against a subway turnstile could potentially turn it off if it is not protected against this outcome. Effective protective measures include locking touchscreens, placing covers over buttons or recessing them, requiring continuous control actuation for several seconds before there is a functional change, and requiring two actions (e.g., a confirmation) to trigger an intended result.

6. **Make it intuitive to use.** This guideline is particularly important and might be vexing at the same time. Maximum intuitiveness is almost always the design goal and one that sometimes eludes product designers. It can be quite difficult to make a device intuitive to use when it has even a modicum of functional complexity. Fortunately, there are plenty of products that people can operate correctly on the first try without the use of instructions, chiefly due to the effective application of human factors. Greater intuitiveness arises as the result of eliminating extraneous functions, providing positive feedback to users as they interact with the device to keep them on the right track, matching user population expectations (presenting functions in already familiar ways), and conducting iterative usability tests to identify and fix any causes of confusion and use error. The end-product is one that is not just intuitive but also one that can induce a strong emotional connection between the user and product. As such, the application of human factors aligns nicely with the emergent design philosophy called emotional design, whereby the goal of delighting the user ranks high along with making a product usable.

7. **Accommodate impairments.** Logically, people who use wearable medical devices might have medical conditions that bring with them perceptual and motor impairments. In other words, they might have some difficulty seeing, hearing, and/or feeling things. For example, someone with diabetes might have (1) macular degeneration and cataracts making it more difficult to read a small button symbol or small text on a screen, (2) loss of high frequency hearing that is common among older individuals, and (3) loss of sensation at the fingertips (i.e., neuropathy). As another example, someone with Parkinson's Disease is likely to exhibit dyskinesia in the form of a tremulous index finger.

8. **Make pairing easy and secure.** Many wearable medical devices have wireless communication functions. This means they might need to be paired with a smartphone. This process needs to be straightforward for people who are not necessarily tech-savvy and use their smartphone only in basic ways. It becomes important for the smartphone to lead the user through the pairing process in a step-by-step manner that does not require the user to know interactions that require more substantial experience with such technology. The pairing process should also protect against incorrect and unauthorized pairings, which is also the concern of cybersecurity specialists.
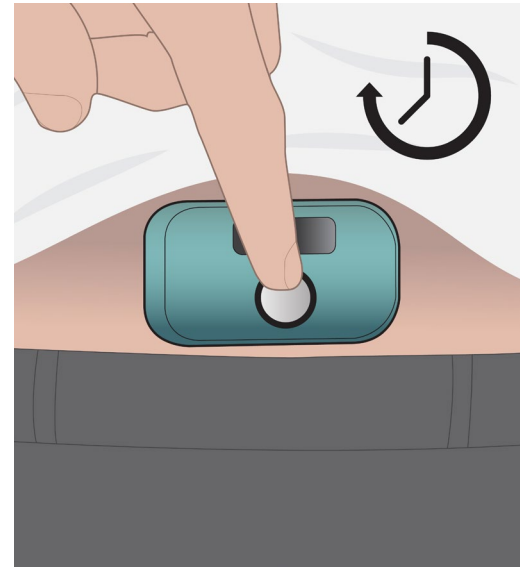

Figure 5: Illustration of an on-body device requiring continuous control actuation for a functional change
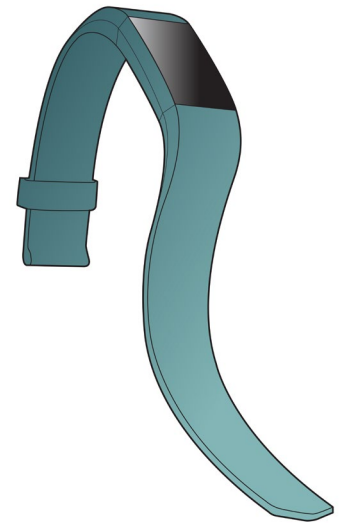

Figure 6: Illustration of a wrist-wearable with an ergonomic, soft, and comfortable form factor

9. **Ensure secure physical connections.** A wearable medical device might be a single object that "solos," or it might include multiple components and perhaps even tubes, wires, and/or cables. CPAP devices are a good example of the latter, as are certain types of heart monitors. In such cases, it is essential for the components to stay connected. This outcome can be facilitated by making it clear which components connect, providing strong, positive feedback when they are properly connected as opposed to not. For example, a cable and its associated port can be shape-coded to indicate that they go together and prevent misconnections; the cable can connect with a distinctive "click" sound and feel; the manner of connection can make it visually apparent if the connection is incomplete or comes undone. Moreover, electronics can be incorporated into such a device to detect proper connection and warn against anything less.

10. **Make it stay put.** Quite a few devices need to be strapped or adhered to the body. Having one of them come loose can be annoying at a minimum, and hazardous in some cases. For example, a device collecting hemodynamic data (e.g., breath rate, oxygen saturation, blood glucose level, heart rate) would not be able to function properly due to sensor dislocation. Also, a drug patch that partially or completely detaches from the skin would cease delivering medication. Therefore, devices should be tested to confirm that they will stay where they are placed for the expected direction.

11. **Make it comfortable.** An obvious need manufacturers may not always meet is simply making a wearable device comfortable. For example, a device should not chafe the skin due to having sharp edges or lacking the necessary pliability. It should not cause heat build-up and sweating. It certainly should not cause an allergic skin reaction, as some materials will do. Also, to the extent feasible, the product should not be too heavy as to hinder normal body movement.

12. **Make failures detectable.** When a consumer product fails, the user might be annoyed but is unlikely to suffer significant harm. However, this cannot be said of a wearable medical device which, if it fails, could cause major harm. Therefore, it is important for devices to make failures detectable, perhaps in multiple ways including audible, visual, and tactile signals.[2] Such alerts will enable the user to take corrective action as soon as possible.

A word about the user

So much for the device, but the user will need to learn how to use their device. We've known since the 1960s[3] that becoming competent in any skill (in this case using a wearable medical device) follows a staged process of learning, with the goal of being "unconsciously competent," as follows:

- Unconscious incompetence - user is unaware that they cannot use a device safely, or that they are in an "unsafe" use scenario

- Conscious incompetence - user is aware that they cannot use a medical device safely, or that they are exposed to a potentially hazardous scenario

- Conscious competence - user is aware that they are using the medical device safely, or that they are taking the appropriate steps to resolve a potentially hazardous scenario

- Unconscious competence - user is unaware that they are using the medical devices safely; they are getting on with their lives and not consciously interacting with the device

Why is this model of skill learning important for wearables? Because the user forms a close personal bond with a wearable technology. With interventional devices such as those for ambulatory drug delivery, the user is in a position of placing a very high level of trust in the technology. The user interface (UI) is critically important in guiding users away from harm and towards safe use. The UI must raise awareness (move from the unconscious to the conscious) and teach the user how to use the device safely (moving from a vulnerable to protected state of ability).

Imagine a person with diabetes is wearing a device that monitors their blood glucose. Of course, one key feature must be to alert a user if they are becoming hypoglycaemic. As we know, there is a small window of time in which the user must correct the hypoglycaemia to avoid serious harm. So, what's the role of the UI here? It can be summarized as three "rules" for safe use, as shown below.

Three rules for avoiding harm when using wearable devices	Key design requirements for the UI	Possible design options for a blood glucose device
Users must be aware that they are heading towards a hazard; in other words, unless they take some corrective action the risk of harm will increase.	Attract users' attention in a timely way and persuade them to focus on the scenario involving the device. The UI must enable users to understand that the "state" of the device has changed, and that it cannot be ignored.	Provide sensory feedback (sound, illuminated display, vibration) that is distinctly different from the sensory feedback during "normal running" of the device.
Users must understand how to correct the situation; how to avoid harm by adjusting the device in the way that the manufacturer intended.	Provide a clear, unambiguous pathway, with single, obvious steps that the user must take. Avoid negatives (for example, avoid "do not push the red button").	Use simple instructions that impart urgency but not alarm. Avoid lengthy textual instructions, using graphics where possible. Each action must be immediately proceeded by a binary "pass" or "fail" signal to enable users to obtain confirmation that they are heading along the path intended by the manufacturer.
Users must know when they have achieved a "safe resolution."	Communicate to users that they have returned to a safe state, in which they are not required to make any further adjustments. They can shift their attention to continuing with their lives as normal.	A signal that communicates that the user has completed the pathway to safety and no further action is required from the user.

Summary + Conclusion

Wearable medical devices are not an entirely new thing. Holter monitors, worn by people to collect heart rhythm data for 24 hours or more, have been around for over twenty years. Still, the wearable medical device landscape is changing rapidly. The future is certain to be one in which an increasing number of medical devices that have traditionally stayed in place will become mobile, carried on the bodies of people who can go about their daily life while the devices do their jobs. Making this vision come true will call upon people to be quite inventive regarding electromechanical and computing matters, but also from a user interface design, and more broadly, user experience design perspective. Therefore, wearable medical device developers are well-served to make significant investments in human factors.

For more information about human factors research and design, visit us at HumanFactors.EmergobyUL.com.

End Notes

1. Code of Federal Regulations Title 21 (**CFR21 820.5**)

2. Featherstone, Richard. **Mobile Devices and Use- Related Risk – Time to Reinstate Detectability?** Copyright © 2018 Frederick Furness Publishing Ltd, www.ondrugdelivery.com.

3. Reynolds (1965) Learning and teaching in the practice of social work (2nd Edn). New York: Russell and Russell

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