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The engineer's guide to wearables: Lessons learned from design mishaps.

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Lessons learned from design mishaps.

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Patient-centered care is becoming ubiquitous in the healthcare industry. We're shifting from a "doctor knows best" culture to one in which patients seek multiple opinions, highly-tailored treatment options and ways to monitor their health themselves. Every day, internet forums are frequented by people seeking ideas for how to manage their disease better. Overall, patients and their caregivers are looking for convenience, disease or health management that fits their lifestyles, and the ability to connect with their providers privately and discreetly via electronic messaging.

Change in healthcare and the pace of medtech innovation is moving faster than ever. Like clinicians, wearable device design engineers have an important role to play in healthcare today. Device manufacturers must continually evolve their offerings to keep pace.

Wearable medical devices that help patients monitor and manage chronic illness are the conduit between a medical professional's treatment plan and the patient's ability to maintain an independent, active lifestyle; but, in order to allow for such a routine, wearables have to meet several requirements. Patients need devices that easily integrate into their daily lives and are personalized, easy to use and comfortable with long-lasting power.

We know that designing a device that checks all of these boxes is no easy feat. That's why we've compiled our knowledge from working with design engineers and device manufacturers around the world to develop this guide. You will learn about a wide array of missteps your peers have encountered when bringing a wearable medical device to market, and more importantly, how to avoid them. We'll discuss the importance of addressing system design, how materials work together, device manufacturability, and how to keep the patient top-of-mind to help innovators like you get it right. Our goal is to help you innovate wearable technologies that improve people's quality of life and eliminate stressors.

Checking the boxes on user needs.

Life-proofed

Patients strive to live without constantly thinking about their illness. As technology becomes smarter and more advanced, patients expect devices to minimize the inconveniences of around-the-clock disease management. In order for a device to do so successfully, it needs to be built in a way that seamlessly integrates into the patient's everyday life. Devices should be water-resistant and resilient after long wear times. A slim profile that maintains flexibility and durability can help resist edge lift and improve aesthetics. Devices need to withstand the ins and outs of daily life, including resisting the impact of bumps, tugs and pulls. Materials and components that shield, dampen and absorb energy can help with the life of the device.

Comfort

People look for comfort in everything from shoes to beds to cars – wearables are no different. Excessive itching, rubbing or irritation will not be tolerated. Pain associated with removal also needs to be minimal, and time between wearable changes should be maximized. Materials can help improve comfort by being stretchy, breathable and reducing moisture build-up. Poor system design can often lead to feeling uncomfortable, whether it's with the device's size, interface, or breathability (itchy or irritated skin).

Ease of use

Operating a device needs to be easy and intuitive. If a user can't understand how to use a device and operate it without difficulty, it doesn't matter how advanced the technology is. When devices are straightforward, users can adopt consistent and sustained use more quickly. Managing the number of buttons and confirmations, for example, is important. And if the system is complexly designed, it could lead to non-compliance or the patient getting the wrong dose. We recommend working with partners well-versed in user experience, including a sophisticated converter that is able to consult on ease of production and usability.

Personalization

While some patients prefer a discrete device, others want to proudly sport one that is bold and colorful. Regardless of which end of the spectrum they're on, at the end of the day, most patients want their device to be a reflection of who they are. This can be challenging for device manufacturers looking to produce on a mass scale. Luckily, workarounds are available. For instance, cover tapes can lend themselves well to mass production, while offering a personalized touch.

Long-lasting power

It's inconvenient and frustrating – and can be dangerous – for patients to have to frequently change or recharge their device. It can mean going hours without the data critical to monitor their health. Devices with better power management may yield more consistent data and may cost less per unit to make and maintain over the device's lifetime.

Devices that meet these system-level needs are already well on their way to success, and learning from the following missteps will help keep them on that trajectory

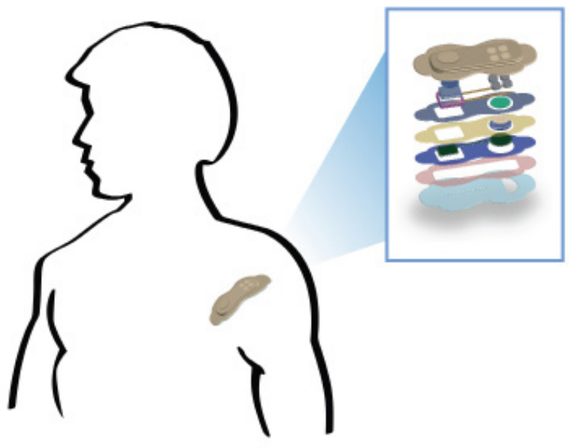
Lessons learned: 14 missteps and how to avoid them.

1

Designing non-compatible or poorly integrated systems

When designing your device, it is important to consider the total system. This encompasses the individual materials (including adhesives), the design and the manufacturing process. Without doing so, you could miss opportunities to optimize the manufacturability of your device. A poorly integrated system can also result in a cascade of other problems that can affect comfort, ease of use, performance, user adoption, physical size and more.

For example, choosing the right adhesive solution and partnering with a converter that has expertise with the materials you are considering during the design phase can present opportunities to optimize the stacking and layering of the materials you select, which can improve their assembly and performance.



2

Wrongly defining market needs

It's too often that medical device companies over-generalize their devices in an attempt to achieve what they think users want. This becomes problematic when it results in an over or under-designed device. Your innovation will have a greater chance of succeeding with strong data that drives healthcare decisions.

For starters, identify the problem your device will help solve. All key stakeholders need to have a deep understanding of the problem being solved and be unified in a vision that guides every decision. This will help to save time, avoid cost overruns and keep everyone on the same page going forward.

From there, have discussions with those involved in conducting research to coordinate efforts. You must understand what the end user really needs and wants out of the device performance before going into design. Make sure the research sufficiently backs up your decisions that address user preferences, such as whether patients want a discrete device or one that can be personalized to match their style. Additional design nuances, such as insights to make application and removal easier, could improve the device and how well it's received by users. Research can also help determine, and potentially navigate, end-use factors you can't control, including a patient's culture, overall health, potential demographic issues and the environment in which they live.

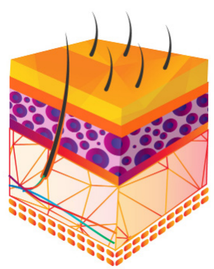
Keep in mind that initial research isn't an "end all, be all" process. It should be an ongoing effort that incorporates different types of input, from quantitative to behavioral research. Check in with the research team regularly to find out what new information they've uncovered and what data reaffirms previous assumptions. If any

voice of customer data is available, it should be mined for comments on challenges, support issues, technical requests and other feedback; social media and user support groups also can provide valuable insights. Design and innovation are iterative processes, and current data is essential to improve over time.

The unfortunate reality is that research can get expensive. But having to make design changes late in development – or creating a device that fails once it's in market – will also have drastic, if not worse, consequences that affect time and budget. It's in your best interest to make the investment on the front end, rather than deal with negative repercussions down the road.

3 Not taking skin seriously

Many of us like to believe skin is impervious. But it's not. Skin is our primary barrier to the external world and is our first line of defense against infection and damage. It's the body's largest organ and helps regulate many key functions such as body temperature and internal fluid balance. It is like a conveyor belt for moisture and skin cells as they transition from the deeper levels of the dermis to the top layer of the stratum corneum. We create new layers of skin as the old layers exfoliate every 10 to 20 days for an average adult.



Designing a device that will be worn on skin for extended periods of time needs to account for the nature of skin and limit potential damage that could occur during the device's lifetime. Too strong of an adhesive can injure skin upon device removal. Too weak of an adhesive can result in the device falling off, increasing the cost to the patient or inadequate care if a replacement isn't available. A device and adhesive design that does not account for breathability can unintentionally trap moisture that can cause irritation or maceration, further injuring the skin. Make sure your design factors in all of these needs as early as possible to improve the experience with and performance of the device throughout its wear time. It'll also improve patient compliance.

4 Not incorporating the device's wear time into every decision

When we advise on a project, wear time is always a top consideration. All other decisions depend on it – from what type of adhesive will be best for the application to the device's housing material.

If it's a stick-to-skin device, wear time is even more important because the substrate, skin, is unlike any other. In contrast to non-living substrates, like metals or plastics, skin moves, breathes and completely regenerates itself regularly. On top of that, not all skin can tolerate the same level of external irritation. Despite age, overall health and other uncontrollable variables, skin needs to be able to function as normal, particularly if a device will stay adhered for longer than a day or two.

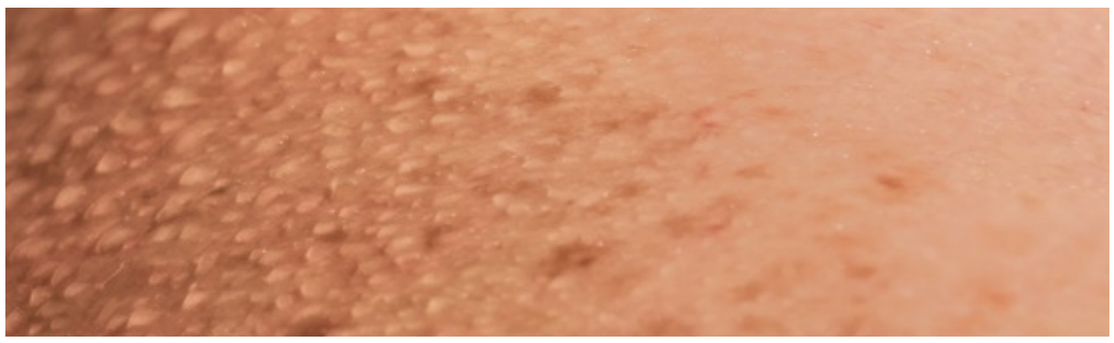
It's a tall order, but there are a few ways your design can accommodate skin's needs.

For starters, incorporate breathable backing and adhesive combinations wherever possible, as they will allow moisture to move through the tape system. Moisture vapor transmission rates (MVTRs) help indicate how breathable a tape system is. However, wearable devices on top of a tape system may alter moisture vapor transmission levels. You should use a skirt (or extended edge) around the device rather than cutting the tape to the device's exact size. Doing this helps preserve the skin's ability to flex and move, while maintaining a strong bond between the adhesive and skin. It can also help reduce failures when the device is knocked against a doorway, for example.

Relatedly, you can enable a longer wear time if your device's layers are compatible with your intended user's skin viscoelasticity – how skin takes in and releases energy over time and in different temperatures. When you don't consider viscoelasticity, the user's skin may stretch as a response, resulting in hyper-elastic material performance.

Beyond stick-to-skin applications, wear time influences a wide variety of design decisions, including power management, material selection, application and removal, and overall durability.

When in doubt, your materials supplier should be able to help you make the right decisions.



5

Using incompatible materials

Depending on the device's materials, issues may not arise until after the device is manufactured and out in the market. This is troublesome because, at this point, it's too late to make cost-effective changes.

To proactively determine compatibility, start with your substrate material. Materials most commonly used for medical devices are:

Polyethylene [LDPE, HDPE]: Comfortable, low- and ultra-low-density versions are soft to the touch, easy to work with and reasonably priced.

- Compatible with: Most adhesives, but it may require pre-treatment or priming to make a strong bond. Heat seals well to other similar polymers.
- Incompatible with: High heat, such as steam or autoclave sterilization.

Silicone: Popular, but tough to stick to.

- Compatible with: Other silicone-based polymers and silicone-based adhesives.
- Incompatible with: Can't be heat sealed to other substrates and very few other substrates or adhesives will bond well to it, although there are some primers that can help.

PVC: Resistant, clear and flexible, but difficult to dispose of and can negatively interact with other materials.

- Compatible with: Other PVC layers.
- Incompatible with: The plasticizers that make PVC soft and flexible tend to migrate into most adhesives and some substrates, such as polyethylenes and polyurethanes, causing adhesion and/or interface failures.

Polyester [PET]: Moldable, clear, protective and easy to adhere to, but hard and inflexible.

- Compatible with: Most adhesives will adhere well to clean polyester [PETE]. Heat seals to fibrous nonwovens, but most non-PET films will require a compatible heat seal interface layer to bond well.
- Incompatible with: There are a few chemicals, but in general inert.

Polyurethane [PUR]: Flexible, soft and can withstand sterilization. Ideal for wound dressings.

- Compatible with: Most adhesives (may be better with “free” or transfer-type adhesives that will stretch and move with the PUR film versions).
- Incompatible with: Fatty acids and oily materials can be absorbed causing PUR films to swell and weaken. Doesn’t heat seal because it has a very high melting point.

With skin as a substrate, the materials used in the device must meet biocompatibility requirements per country regulations and/or industry standards, such as ISO 10993, and not be manufactured with materials of concern, such as latex or animal derived materials.

Discuss all materials you plan to use with your material supplier as early in the process as possible. Feedback from your material supplier will ensure you’re headed in the right direction and reduce the likelihood of compatibility problems later in the scale-up process.

6 Treating adhesive selection as a trivial exercise

The mindset “tape is tape” is a dangerous oversimplification when designing a wearable medical device. From how an adhesive performs in different situations to how it interacts with other device materials, adhesive influences the device’s overall functionality and accuracy. Adhesion is part of a system, so it’s important to understand how each layer of the system contributes to the overall adhesion performance. If adhesive selection isn’t thought about early in the design process, it can result in manufacturing issues, device malfunctions and possibly harm to the user.

Manufacturing issues: If a selected adhesive is very soft, it can gum up equipment during converting and down-line production processes, leading to unforeseen added costs and delays due to unscheduled stops and cleaning. Additionally, softer adhesives may require manufacturing equipment to run at slower speeds, which adds to the run times and increases the overall cost of goods. Precoating/pretreating the converting dies with durable release surfaces, protecting contact rollers with low adhesion wraps, chilled rollers/air blowers and using thread-up designs that avoid contact with the adhesive surface can help avoid these issues. Partnering with a converter or third-party manufacturer that has expertise and is knowledgeable in working with your chosen materials can help ensure you are using the right adhesives for your design, optimizing manufacturability and maximizing yield throughout.

Device malfunctions: A device that sticks to skin needs to stay adhered for its intended duration of wear in order to successfully fulfill its purpose. If an insufficient adhesive is used, the device can prematurely fall off. This could potentially cause a missed reading or dose of a life-saving medication. Additionally, an inappropriately selected adhesive that adheres components together can result in parts shifting, failures during or after sterilization or, worse, the device falling apart.

Harm to the user: Skin is a sensitive substrate, so it’s important to choose the right adhesive system to avoid a potential medical adhesive-related skin injury (MARSI). MARSIs can occur from

improper skin preparation, incorrect adhesive selection and errors when the device is applied or removed improperly. MARSI ranges in severity from mechanical skin irritation to skin stripping and tension blisters. Once a patient experiences pain, they may not want to use their device again or recommend it to others, so make sure you consider the peel force to pain correlation. Some adhesives fall in a “sweet spot,” offering less pain for a given level of removal force.

Fortunately, it’s possible to avoid these outcomes by carefully and thoughtfully choosing the best adhesive for each application. Before embarking on the design process, consult with your material supplier on the substrate’s unique characteristics, the type of environment in which your device will be used, the age range and general health of users, location on the body and its intended wear time.

7 Not evaluating power source options early enough

It is problematic and potentially life-threatening for users of wearable devices who are managing chronic illnesses to lose power on their device. The decision to make a device rechargeable or battery operated is not one to make lightly. There are a variety of design and user implications to consider, such as space available for a battery, power available between charges or battery changes, and charging options.

To help determine whether your device should be rechargeable or battery operated, consider the following questions:

- Can we optimize the electrical or optical system to require less power?
- How big would the battery need to be?
- How long would it need to last or how often would it need to be changed?
- What charging options do you have (plug in, wireless, from other devices, motion/light power charging, etc.)?
- Would the user easily be able to remove the battery to recharge it?

Devices with better power efficiency can enable more frequent data collection. Power efficiency can also translate to a smaller battery and device, contributing to a slimmer profile that increases patient comfort.

8 Choosing an incompatible sterilization method

Not every device needs to be sterilized, but if it does, the entire construction should be designed to be able to withstand the sterilization method.

There are three main types of sterilization used with wearable devices – ethylene oxide gas, e-beam and gamma radiation.

Ethylene oxide gas involves putting devices into sealed chambers to kill bacteria. It's time-consuming, and there is potential for residual gas, but it can have a lower impact on materials compared to other methods. Radiation is a faster process, and both e-beam and gamma irradiation effectively kill bacteria. The downside is that radiation exposure alters the performance of most adhesives, other commonly used materials and most pharmaceuticals.

With this in mind, thoroughly test all of the materials you're planning to use with your desired sterilization method to confirm compatibility and show how their performance could potentially change. What it ultimately comes down to is when and where your device will be worn. With other devices, however, it's possible to temporarily remove the drug, sterilize the device and then right before application, add the drug back in to the device or aseptically fill the device post-sterilization.

9 Failing to consider how a device will be disposed of

Proper disposal of a device is a safety and environmental concern, particularly if the device is single-use, includes a needle and/or administers a drug. In America, and for diabetes alone, it's estimated that 6.5 million people dispose of needles and syringes every day with most of that waste heading to the landfill. Without a national program for safe disposal, sanitation workers and communities are at risk.[1]

When designing a device, focus on its entire lifespan from inception to disposal. Think critically about your device's components, materials and intended function to determine what tweaks you can make for safe disposal and possibly recycling.

Consider the following:

- **Device make-up:** Consider if the system should be disposed as a biohazard and whether components can be disassembled for recycling.
- **Wear time:** Elongating wear time, when possible, can help decrease waste.
- **Power source:** Determine if your device can be rechargeable.
- **Needle disposal:** If your device or applicator uses a needle and/or administers drugs, make sure the instructions for use (IFUs) clearly state how to safely dispose the device and applicator.

10 Issues with light interference

If your device uses optical sensors, you may need to be concerned about light from unwanted wavelengths or directions can cause optical interference. It can come from ambient light sources or from using multiple light sources within the device (otherwise known as optical cross-talk). Not only can it cause signal to noise degradation but also require more power to function. Use directional and wavelength filters on the LED or sensor to significantly improve the sensor system's performance.

Because wearables are thin and flexible, it's often assumed that there isn't sufficient thickness to be able to control optics. However, miniaturized optics for ultra-thin applications are commonly used in consumer electronics, like mobile phones. It's possible to use the same technology in the medical devices, increasing the sophistication of the device.

Optics can also be used to affect the angular light distribution of light sources and of light in the skin. You can also control the

optical sensor's angular field of view, as well as co-optimize the optical source and detector. Managing light's characteristics can decrease the problem of subcutaneous light scattering to minimize noise or to ensure light interacts sufficiently with tissue before the device takes its measurement.

Detecting fluorescence, such as from subcutaneous markers, is becoming increasingly important, too. Use optical films to help increase signal discrimination of one or more wavelengths.

11

Failing to consider other outside interferences

There are many potential dangers wearables need to be protected against in order to function properly. Wearables that incorporate electronics are particularly susceptible to outside interference from optical or electrical sources.

Let's start with an everyday threat to wearables – water. Most, but not all, wearable devices need to be water-resistant, regardless of whether they're a transdermal patch, concussion sensor or continuous glucose monitor. Wear time, intended use and environmental conditions come into play here, as well. If a patch is only meant to stay adhered for a few hours and won't come into contact with moisture, water resistance is less important. For devices with longer wear times, however, sealing the device is necessary so users can, for example, bathe, sweat and swim. Devices with electronic components often need to be coated with a protective layer before they are sealed into the device.

Another everyday danger is static electricity because it can build up and negatively affect the device's performance. Just as you would with other non-medical devices, incorporate static shielding and discharge on the electronics; this is very important to people working around flammables.

A relatively new threat is hacking and violation of personal privacy regulations. We hear about it all too often in the media. Any device connected to the internet could potentially be hacked and compromised. Medical device manufacturers should proactively mitigate cybersecurity risks and ensure safeguards are in place.[2]

12

Creating a cumbersome or unintuitive application process

When it comes to determining how a device will be applied, you should let the customer insights from your market research guide the way. It's painfully apparent – sometimes literally – when this doesn't happen.

Consider your end user, their capabilities and what actions your device will require. If your end user has arthritis, they may struggle with handling smaller devices and parts. Or maybe the end user needs to be able to adhere the device to the back of their arm on

their own. Cumbersome and unintuitive applications can result in device failures or misapplication, like the adhesive sticking to itself or the liner being challenging to remove – not to mention a frustrated user.

Questions to consider include:

- Will the device be applied by a trained professional or the end user?
- Can the device be applied with one hand or two?
- How many steps are involved in the application?
- Is skin preparation required?

Reducing the number of steps is essential to creating a simple system that people can get right the first time. First impressions are critical to sustained compliance and providing the health benefits of the device.

You won't always need to completely reimagine your device to accommodate its application method. One simple solution could be to add a thumb tab during converting or another quick mechanism that makes application easier.

Some application methods are more complicated than others, and there's just no getting around it. Clear instructions can make all the difference in these situations. Make sure they're written comprehensively for the end user. While technical jargon may work for a healthcare provider, your everyday user will benefit more from straightforward, easy-to-understand instructions. Diagrams and video tutorials can also be helpful. Remember a drawing or photo really can be worth a thousand words – not everyone reads or has the skills to read instructions correctly.

13 Running accelerated-aging testing at too high of a temperature

Aging device prototypes and components at 120° Fahrenheit (50° Celsius) for nine weeks is typically recommended for the equivalent of one year during accelerated-aging testing.[3] [4] There's a lot of information available on accelerated aging but remember that the materials you choose are intended to be worn by people and are not usually designed for the same temperature ranges that are required by automobiles and aerospace components. Testing at a higher temperature (around 150°F or roughly 70°C) is acceptable for those materials because they may actually be used under similar conditions. Raising the temperatures for accelerated aging can save some time because it's faster. However, with medical materials, including adhesives meant for stick-to-skin applications, running accelerated-aging tests faster may produce inaccurate results. Be patient with the time testing takes, so your results are reliable. And remember to run natural aging in the finished packaging at the same time.

We recommend referring to country regulations, device-specific guidance documents and industry standards to ensure stability protocol and testing is run for the appropriate amount of time with a statistically valid sample size and sufficient lot variation of the finished device. Your material suppliers should also be able to provide a shelf life for their materials.

In addition, using test samples from multiple lots will help produce a reliable representation on how a material will perform. Without lot variation, test results won't be as comprehensive or accurate.

14

Failing to foresee manufacturing process implications

Thinking through how a device will be manufactured early in the process can help you avoid redesigns, delays, cost overruns and issues during the scale up for commercialization process. For example, if a manufacturer selected a tape with a backing because of how it looked and felt without considering the technical specifications, the misstep could be that the tape was selected without completing multiple internal wear studies and testing whether the backing was compatible with the desired bonding technique. Had this step been addressed earlier, the manufacturer could have learned how to best select materials and avoided the headache and lost time.

Conclusion

As fellow engineers and scientists, we understand that device design is an iterative process that involves making mistakes. It's human nature and how we learn. Thomas Edison famously said, after inventing the incandescent light bulb, "I have not failed. I've just found 10,000 ways that won't work." Although your timeline and budget likely won't accommodate 10,000 attempts, as a design engineer, you know the importance of harnessing his persevering spirit.

Medtech innovation will continue to open new doors for all of us in years to come. More advanced materials and technologies are certain, but what will remain constant is the great attention to detail and foresight required by designing, testing and manufacturing medical devices. Every step and person involved in the process will have an impact. Work with an interdisciplinary team that includes experts in adhesives, optics, electronics, converting and engineering, so you can gather intel from various perspectives and anticipate complications and needs.

Managing a chronic illness can be a full-time job, and it shouldn't be further complicated by monitoring devices. By focusing on patient needs, selecting materials thoughtfully, and planning proactively, you can improve the quality of life for people who really need it.

References

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3192588/
2. https://www.fda.gov/medical-devices/digital-health/cybersecurity
3. https://www.astm.org/Standards/F1980.htm
4. https://www.mddionline.com/general-aging-theory-and-simplified-protocol-accelerated-aging-medical-devices

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