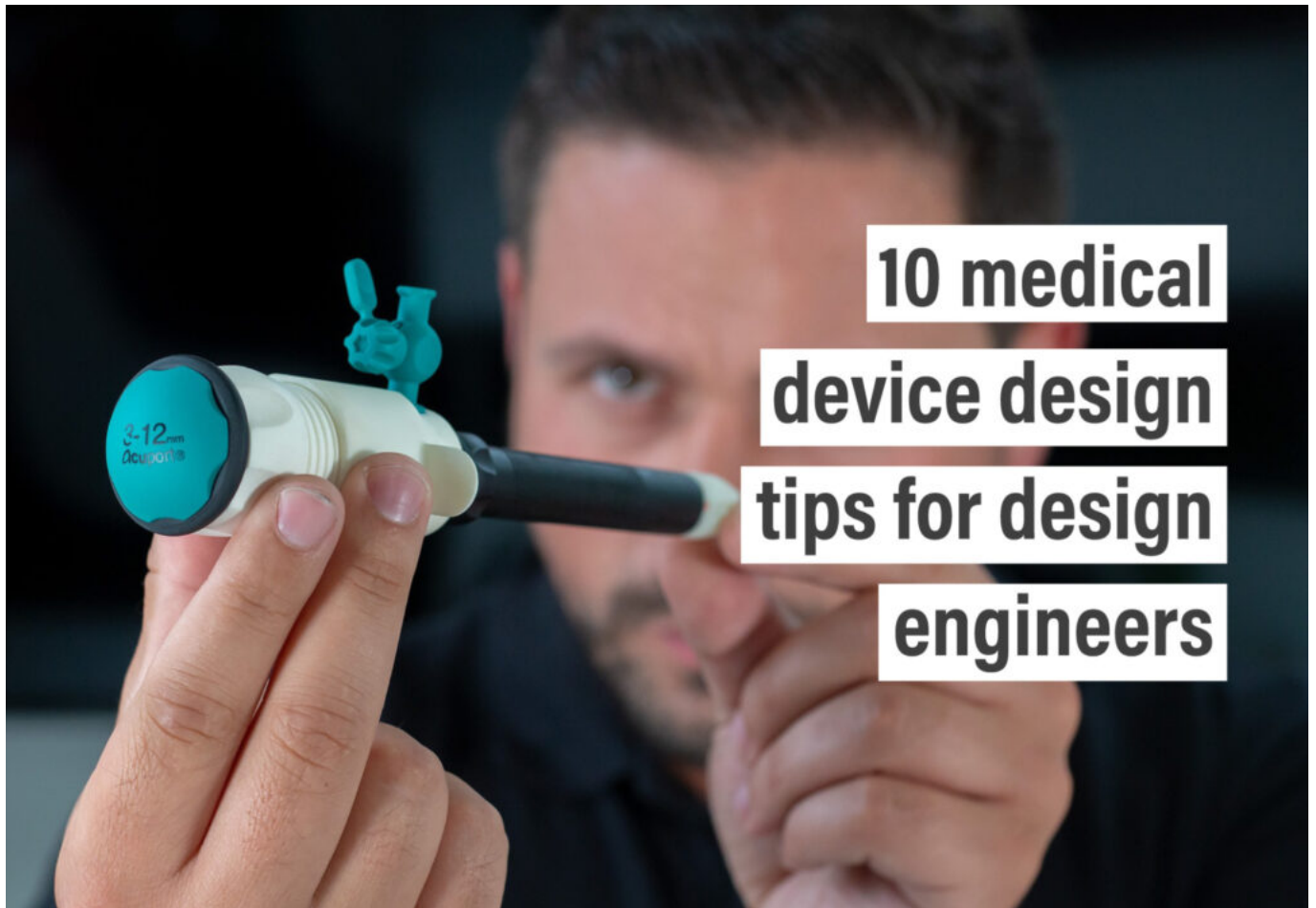


10 medical device design tips for design engineers



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Reading time 17 mins

Key Points

- Learn the dynamics of the healthcare industry from both the end-user and developer perspectives, and understand the terminology needed for effective communication

- Remember that technology literacy is different from health literacy
- Resolve a problem or an unmet need, prioritise smooth functionality and simplicity, and reduce cognitive load to facilitate user engagement
- Include animation and automation appropriately
- Track changes to all design files and features – especially when collaborating with a team – to avoid complications and help with compliance
- Be objective (personal preferences don't justify design decisions), and ensure that the product adds value (e.g. eco-friendly, sustainable design)

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Last updated Jun 12, 2023

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Medical device design is a constantly evolving area of engineering that must regularly adapt to technological advancements. With Moore's Law ^[1] (computing speed and capacity doubles every year)

playing out, the medical device industry is developing just as quickly and impacting the dynamics of healthcare diagnosis, prevention, and treatment. Existing products get upgraded features yearly, and novel products are introduced to the market. These innovations not only aim to tackle complex and challenging issues, but also ensure better sustainability, reliability, and carbon neutrality (or even negativity).

Design engineers around the globe strive to produce new and improved ideas for medical devices. This article is a compilation of ten simple but essential medical device design tips that engineers should consider when working on the design process.

1. Learn the dynamics of the healthcare industry

Just like we have a 'Know Your Customer (KYC)' approach in business, we need to know the ins and outs of the healthcare industry to align our focus on medical device design. As a design engineer, it would be prudent to learn about the dynamics of your market from both end-user and developer perspectives. There are many challenges when working on a product for a global market. Universal Healthcare coverage ^[2] varies from country to country, and the type of insurance available is related to the funding allocated to R&D or investment that facilitates innovation.

Medical device design industry innovation generally relies on government funding and R&D investment from medical equipment manufacturers. National universities and the healthcare systems affiliated with them play a crucial role in helping to generate innovative ideas. At the same time, investment in R&D is usually motivated by client feedback and market trends. In addition, the acquisition of start-ups by big-name or established companies helps to streamline the design process.

For example, you have a brilliant idea capable of having a meaningful impact. However, you are still struggling with funding: the journey from ideation to minimum viable product (MVP) may take years and years. The same would be quicker with an established company that has the people, network, and finances to bring your idea to life.

2. Understand the terminology

Just like us in the product design world, healthcare professionals use acronyms and jargon regularly. Keep these terms in mind during your research. Consider developing an internal glossary to help you and your team better understand your users and communicate more effectively.

Also, there could be variations in the terminology used by different professionals (e.g. designers, developers, end-users). Let us imagine a scenario in which we are revamping the design of an existing product based on customer feedback. The end-user might be a physician who is accustomed to using medical terminology (superior, inferior, anterior, posterior), a physicist or a chemist who is used to referring to directions as left, right, up down, or cartesian coordinates (i.e., +X, -Y) and so on.

As a design engineer, you must be knowledgeable of all different terminologies and the link between them.

Also, there could be variations in terminology depending on your market (i.e., the country/culture of the potential end-users of your product). If we are developing something for global use, we must be mindful of those cultural or regional differences in terminology. It may also be helpful to consider which market has the highest turnover for the products you are designing. If we look at the percentage of medical device companies worldwide ^[3] that expect select countries to have the strongest growth in sales, the USA and Europe have the highest percentage, followed by China. Thus, you may want to use terminology suitable for American or European customers or modify it accordingly for different regional markets.

3. Remember: Technology literacy is different from health literacy

There is a race between the development of global technology and its application to the UI/frameworks used in healthcare products. We continue using software built several years ago, which was developed based on outdated frameworks. One reason for this may be the delay in the approval of new software to ensure its compliance with privacy, confidentiality, and security requirements specific to healthcare. Due to the challenges with compliance requirements, large companies are hesitant to rethink frameworks and adopt recent technologies.

Despite that, we have seen significant transformations, starting from terminal-style green screens used to process expensive insurance claims; to smartphones, tablets, and laptops with data-intensive applications used by medical staff in a hospital emergency room. However, we must remind ourselves that a medical device interface is not a design experiment. Even the most tech-savvy users can struggle with healthcare devices. Ensure you're not relying on the assumption that your users' understanding of technology will automatically help them understand your healthcare product.

You should avoid pure medical and super technical jargon and keep it simple. These steps will help prevent future usability issues, especially when designing medical UX for users who are not medical professionals. Elements on the screen should always behave as the user expects. As users get familiar with it, they can adopt the newer features. For example, getting used to common UI conventions for mobiles and tablets might be easier. But designers need to know where to draw the line.

For mainstream consumers, the UI framework now offers a lot of affordability (think Android or Apple Application Design). However, medical device users must be at ease in finding where to click for Yes, or No even if they are unfamiliar with the recent technology. You may use elements like traditional button shapes and drop shadows to incorporate interaction styles. Also, you can use traditional styles and behaviours for navigation, pagination, grids, drawers, toggles, etc. The key, again, is that all of these elements should also be placed where the user expects them.

4. Resolve a problem or an unmet need

To make a medical device sellable, you need to start with a question: what design issues are the current users facing? It would be worth doing research through a literature survey into problems with existing medical devices, recent developments, and their limitations. You could also conduct a study (or one-on-one interviews) for feedback from potential clients. Again, the suitable method to identify the problems or unmet needs depends on your target market.

Sometimes, design issues can dump an innovative idea that still has merit. Going through the recent recalls for medical devices might give you ideas on how the problems could be resolved. Attending conferences, design workshops, competitions, and other such events is another way to generate ideas. All these measures will help you identify problems or discover unmet market needs. Feel free to go over the design thinking approach (Empathise, Define, Ideate, Prototype, Test), which we have summarized in [a white paper here ^{\[4\]}](#).

5. Prioritise smooth functionality and simplicity

There are several risks and challenges associated with the use of healthcare products. End-users tend to be sceptical of a new product until it has been clinically tested for several years. This is because the functionality of healthcare products directly affects how patients are diagnosed, monitored, treated, and more. Even consumer products like wearable fitness trackers affect how people understand, monitor, and report their health. Errors due to a user's lack of understanding of the product or the user's interface can have unintended and grave consequences.

Design complexity is one of the most common issues faced by users of a new product (or an upgraded version of an existing one). As medical device engineers, this knowledge prompts us to create easy-to-use products with simple and adaptable functionality. To achieve this, one should find users for testing who are more experienced and diverse.

6. Reduce cognitive load

As a device engineer, you want the user interface to contain all of the important information needed to operate the device easily and safely. However, too much information can distract, confuse, or overwhelm users. This is often the case with many legacy medical device interfaces designed by engineers without UX oversight. Reducing the user interface to the bare minimum (e.g. fewer buttons, text, flashing lights) might be best. Complex diagrams can cause users to miss or misunderstand valuable information. If you have multiple alerts, avoid overwhelming users by displaying them all at

once.

Determine what the most crucial information is and extract that for the user. This may vary depending on the level of use. In general, the observed value (e.g. 120) should be much larger than the label (e.g. beats per minute). This keeps the user focused and helps keep things organised. Certain features may be required only when interacting with the device (i.e. in active mode), while others may also be helpful in standby mode. So, consider introducing both active and standby modes. In short, device design is efficient and user-friendly if it presents minimal cognitive load. It would help if you also considered specific ISO guidelines on the ergonomics of the UI design, [which can be found here ^{\[5\]}](#).

7. Include animation and automation appropriately

Adding animation(s) to your design is usually a good idea. Animations guide users to a specific action and reassure them that their device is working correctly. Now, you may be wondering what function an animation can serve; here are some ideas:

- GIF or short video on how to continue with a specific task
- Give feedback that the user completed a task successfully
- Animated infographics showing the inner workings of device/treatment delivery
- Live data animations such as vital signs can reassure viewers that their device is not frozen
- Troubleshooting: Animated diagrams naming the specific parts of the device that need attention and direct the user to appropriate actions

Also, if a repetition or chain of processes can be automated, ensure you allow automation. If users have to click or press a button 10 times unnecessarily, it will frustrate them. It also has a possibility for errors or failures. However, there could be instances where the user must confirm a specific action and click on 2 or 3 buttons to achieve it. Automation in such cases may put your design at risk of improper use or even non-compliance. Therefore, introduce both animation and automation appropriately.

8. Track changes

While collaborating with a team of professionals on a large prototype, it is essential to maintain proper documentation, version control, and attribution of all changes to files and features. It may be very tedious, but it saves you a lot of time in the long run. Also, it's generally a compliance requirement by regulatory bodies such as the MHRA and FDA. Here are some steps you can take to

make documentation run smoother.

Once the design reaches a stable stage, document the changes and detail the functionality. With re-versioned files, share the designs with stakeholders daily or weekly (depending on your team or company protocols). Remember, ad hoc uploading of designs to the cloud can create a versioning/mapping nightmare. The file version number should be displayed on all user interface screens.

As part of your documentation, record who requested a feature change and when; what action (if any) was taken; and who made it. The standardisation body (e.g. ISO, JCIA, BSI) relevant to your industry or product will have already outlined the standard operating procedures (SOPs) you should have in place. You can usually find this in the quality control manual for your company or organisation.



9. Be objective

Your personal preferences must not justify design decisions for medical devices. Ideally, you should have a design objectives list to follow. You can find various templates and ideas for creating such a list for yourself online ([a helpful resource is available here^{\[6\]}](#)). Also, if you follow all the international guidelines, your design should be objective by default.

Throughout the design process, objective reasons for design decisions – both denounced and current – should be documented and addressed in design reviews. You should cite the reference guidelines in reports, audits, and assessments. This helps improve your design workflow and also attracts stakeholders.

10. Add value

While the goal of any medical device is to make life easier for end-users, one that simply functions properly isn't enough – especially when there are multiple competitors on the market. To stand out, it's necessary to think beyond the primary use of your device. Cybersecurity, sustainability, eco-friendliness, using safe materials, avoiding fire hazards, etc., will all add value to your design. Also, it will be helpful to survey all of the stakeholders who will be engaging with and promoting your product/service.

Before launch, or even before submission to a regulatory body (or for patent), circulate information to various stakeholders to find out any improvement opportunities. As is often the case, value addition could be a make-or-break factor for your medical device.

Are there any useful design tips that we missed out on that you find useful? Feel free to share in the comments section below. If you're interested in learning more about the design process, take a look at our recent blog on [how to consider human factors ^{\[7\]}](#), or [signup to our newsletter for notifications](#).

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