User Interface Design in Medical Devices

A Medical Device to Detect Noise Sensitivity

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Introduction

With the rise in popularity of mobile applications and the increasing number of internet-connected devices in circulation, there has been a huge increase in the number and complexity of user interfaces that we interact with daily. For the most part, these interactions are relatively low stakes: we browse our Facebook feed to see what our friends are up to; we interact with our smart home thermostat to turn on the heat when it gets chilly. The worst outcome of encountering a bad user interface in these cases is mild frustration or making an easily correctable mistake such as turning on the air conditioner instead of the heater. However, there is one space where bad user interface design could have serious consequences: in medical devices. With the rise in internet connected "smart" devices, so too has there been a rise in "smart" medical devices. Physical interactions with buttons, switches, and knobs are being replaced by touch screen interfaces at breakneck speed not just in our homes, but also in our hospitals. This race to adopt more "modern" touch screen interfaces can have disastrous consequences when the proper care is not taken to assure that such an interface is unambiguous and resistant to user error. For example, external infusion pumps (used to deliver fluids to a patient both in medical facilities and at home) almost always include a touch screen interface. According to a Food and Drug Administration (FDA) document from 2010, there have been "numerous reports of confusing or unclear on-screen user instructions, which may lead to improper programming of medication doses or infusion rates" (FDA, 2010). These reports were in large part responsible for the FDA launching its "Infusion Pump Improvement Initiative" that same year.

The possible dire consequences of an improperly designed user interface in a medical device necessitate great care when designing any such interface. The purpose of this document is to present the differences between creating user interfaces for consumer electronics and for medical devices and report some best practices when designing user interfaces for medical devices.

Background

User interface design is as old as the computer itself but as computer screen size and quality have increased over the years, there has been a gradual shift from utilitarian design (that is, maximizing the information presented onscreen) to interface designs that prioritize beauty or simplicity. This can easily be visualized by comparing the simple green on black computer terminal interfaces of the 80s to the multicolored and highly detailed mobile applications we have today.

There are many different styles used in modern interface design. Two of the most prominent are flat design and skeuomorphic design (Valerie, N, 2018). Interfaces that use flat design are built using simple geometric shapes that do not necessarily resemble real-world interface components (i.e. buttons, knobs, switches). Most mobile applications and websites today primarily use flat design as it includes a minimal amount of extraneous graphical elements and so lends itself to creating uncluttered and visually striking user interfaces that can still convey a great deal of information. In contrast to flat design, skeuomorphism uses shadows, gradients, and other micro-details to make interface components look like

their real-world counterparts to varying degrees:

Figure 2: Skeuomorphic vs. flat design calculator applications (Justin, B, 2019)

User interfaces designed in a strictly skeuomorphic style more closely represent a physical interface so they can be more intuitive if the user has encountered that same physical interface in the past. Flat design, on the other hand, allows for more information to be presented to the user at a time but is often only intuitive to those users who have experienced it before. Many successful designs use elements of both skeuomorphic and flat design.

Another aspect of interface design that is of vital importance to a design's success is testing. User acceptance testing is the process through which most modern user interface designs are validated and sometimes iterated and improved upon. Test procedures vary but most involve some sort of supervised interaction with the interface by a user who has never seen it before. A designer then asks questions to make sure the design successfully conveyed the desired information to the user. These tests can be vital to eliminating ambiguity in designs and preventing a designer's preconceptions about how a product will be used from negatively impacting the final design.

Design Process

At present, the design process for medical device user interfaces is largely similar to the design process for user interfaces in consumer electronics. Both processes consist of the same basic steps: Research, Empathize, Create, Test, and Develop (Fen, 2019):

Research

Research is essential to creating a useful design. It allows you to gain an understanding of your end user's needs and their motivations behind these needs. In the case of medical devices, research must include talking to the users of the device (i.e. the patient if it is an at-home device such as an insulin pump, or a doctor if it is for use in a hospital) and clinicians who will be monitoring use of the device. Researching in both groups is vital to avoid any serious miscommunications about what a patient should or should not be able to control within the user interface.

Empathize

Building empathy with the end-user involves building user profiles and scenarios in which the user will be using the interface. This helps the designer focus on the important interactions and present the most relevant data first. When creating a user interface for a medical device, these profiles should include hypothetical medical data about the patient as well as standard demographic information.

Create

The next step is to create a "wireframe" or a simple black and white model of the user interface. In a medical device, function should precede form in all cases. This means that in many cases data should be presented as prescribed by a medical professional not as dictated solely by a designer.

Test

After the wireframe has been created, it should be transferred to a full-color design mockup of the interface that is real enough for a prospective user to interact with. For a medical device, this means that the interface should be presented on a screen with a similar size and resolution to the intended final display to rigorously validate sizing and readability. Once this mockup has been created, it should be presented to users in a usability test to ensure that the user can operate the interface as intended and is not confused about the meaning of any portion of the interface. This step should be iterated on many times until all ambiguity and frustration is eliminated.

Develop

Finally, the interface should be implemented on final hardware and a user acceptance test should be conducted. This is the time when the user interface should be verified with the end user and medical professionals under as many different conditions as is

practical. Review of the interface by many demographics will ensure that there are no issues that could result in harmful consequences.

Best Practices

Now that we have looked at the full interface design process, let us focus on the "Create" phase and discuss some best practices when it comes to designing user interfaces for medical devices. This is by no means an exhaustive listing. Rather, it is a sampling of the most important design practices when it comes to creating interfaces that are effective and safe. These practices are all designed to avoid the two most dire user interface pitfalls: ambiguity and unchecked user input errors.

In the wider discipline of user interface design, there is an ongoing debate over "form versus function." That is, should an interface be designed to look beautiful or to present information to the user in the most efficient way possible. While this is not often a one-or-the-other proposition, in most cases either form or function is hampered to benefit the other. In the case of medical devices, this is a central sticking point that must be addressed when designing.

In the abstract sense, this is a very easy question to answer: Function should always take precedence over form! However, it is much harder to put into practice than one may at first think. Often, popular design trends can compromise function in favor of form in very subtle ways that, if not examined closely by a medical device interface designer, could have disastrous consequences. Take, for example, a humble text input field. A current trend in interface design is to have the placeholder text on an input field act as the field label to cut down on layout complexity (Valerie, N, 2018), as demonstrated here:

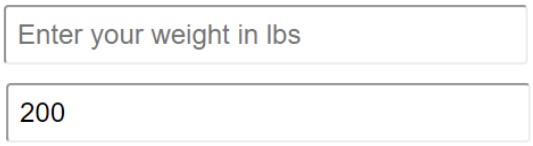

Figure 3: Text input field without *and with data entry (form first)*

On the surface, this looks like a harmless design pattern that can help keep visual clutter to a minimum. However, this pattern is indeed a prioritization of form over function because it leads to ambiguity once data is entered into the field. Once data has been typed into the field, the placeholder text disappears, and the user is now required to remember what the data in that field represents and what the units of the data are. If this interface was used, for example, in a check-in form at a hospital and the device was handed to a clinician with data already filled in by the patient, the clinician would be required to have in-depth knowledge of the form in order to verify that the patient did not make a mistake when inputting their data. A better solution is to place a label above or beside the field so that it never disappears, thus removing the ambiguity:

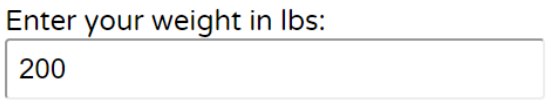

Figure 4: Text input field (function first)

Another very important consideration when designing medical device user interfaces is text size and typeface selection. Since many medical devices, especially home-use ones, are used by the elderly, the text size must be large, and the typeface must eschew style in favor of legibility. While this can lead to an interface looking less "modern," it is necessary to make sure anyone who is an intended user of a medical device can accurately discern the text onscreen (Valerie, N, 2018).

A similar tradeoff must also be struck between branding and functionality. Branding can refer both to the presence of the company's brand mark in the interface and to the appearance of the user interface itself. That is, within an interface, branding can be as simple as keeping a consistent typeface for text or a consistent size to graphical elements. Take this example from the Tufts University website (at two different screen sizes) where branding was prioritized over function:

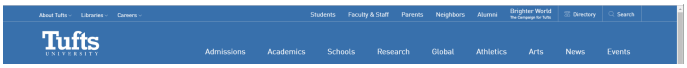

Figure 5: Tufts University website full width (https://www.tufts.edu)

Figure 6: Tufts University website reduced width (https://www.tufts.edu)

As you can see, when the website was scaled to a smaller screen size, the Tufts University logo remains the same size while the text size of the navigation menu is scaled smaller to fit. The smaller navigation text is less accessible to those with visual impairment and therefore sacrifices usability. In a medical device

interface, this would not be an acceptable tradeoff - the navigation text size should have been prioritized over keeping the brandmark on screen.

One final practice to consider is the use of skeuomorphic design to ease the transition to a digital medical device from a physical one that performs a similar function. If a designer creates the digital user interface by taking cues from the physical device's interface or even copying it entirely, the interface will already be familiar to the user. Using components that function in a similar way to physical components can reduce ambiguity. For instance, using tabbed navigation with tabs that look like the tabs on a manila folder would increase the usability of the navigation system for a first-time user because the interface resembles a physical interface with which most users would already be familiar.

Conclusion

In the wider discipline of interface design, there are not often grave consequences for a mistake. Interfaces are created, iterated, released, and then iterated more. Beta testing programs even allow every-day people to obtain relatively untested prerelease software, often including interface bugs. These comparatively loose quality standards are generally accepted as standard because they allow for experimentation and innovation in interface design. In the world of medical device interfaces, however, there is no room for such relaxed standards. Any interface software release must be carefully tested and verified to ensure that there are no mistakes or ambiguities because one simple interface ambiguity could, in the worst case, cost someone their life. But if a designer is careful and thorough, it is possible to create interfaces that both delight the user and fulfil all of their medical needs.

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