Tips on Usability, Safety and Compliance

DESIGNING BETTER MEDICAL DEVICES

BOSTON UX

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RESHAPING MEDICAL DEVICE DEVELOPMENT

Growing Influence of UX Design

The medtech industry is among the most traditional. Product development has historically followed a classic, top-down waterfall approach focused squarely on the technology, not the user. Though greater attention is paid to usability these days thanks to FDA guidelines and compliance regulations, some device manufacturers continue to view user experience (UX) design, which puts the spotlight on the user, as an unnecessary expense.

Fortunately, that's rapidly changing as more companies take steps to establish a strong UX

focus on their product design teams, increasingly embrace usability-centered design, and incorporate more agile, feedback-driven processes in order to deliver better, safer, lower-risk products.

SHIFTING PARADIGM

Medical device design has long been the purview of the product manager and the engineering team. If the device worked as intended and was delivered on time, it was deemed a success. But the paradigm is shifting as more and more medical professionals seek devices akin to the gadgets they're accustomed to from the consumer market.

With the emergence of the Internet of Things (IoT), people have developed an appetite for rapid innovation and the smart products that have resulted, from connected doorbells that can capture package thieves on video and stream to a homeowner's phone in real time to virtual assistants that can automatically reorder groceries and supplies.

That's why medical device users, including physicians, nurses and technicians, increasingly expect Amazon-level usability in the products they touch. This is especially important when it comes to lower-risk Class I and II medical devices, which account for 90% of medical devices. (When it comes to high-risk Class III devices, which "sustain or support life, are implanted, or present potential unreasonable risk of illness or injury," patient safety not user ease is essentially the sole concern.)

And medtech firms are hopping on board. They appreciate that **a well-designed user interface (UI) can go a long way toward ensuring safety by enhancing usability and limiting the potential for human error, thus mitigating use risk.** They're eschewing super-complicated devices with a million functions that are time-consuming to learn in favor of intuitive devices that are easy to use. (Guidance from the FDA regarding device usability is also playing a role in manufacturers' growing willingness to adopt UX design best practices.)

The goal for medtech firms is not so much to create cool-looking devices, though aesthetics may play a role in the design of some medical devices, such as those targeted toward non-professional users. (Think devices like consumer-level glucose meters or simple home-use blood pressure monitors.) It's more to build devices that offer exceptional usability that enable doctors, nurses, technicians and other caregivers to deliver outstanding patient care.

That's good news, not only for users but also for corporate bottom lines.

An expanding FDA definition of "medical device" includes not just devices used to monitor conditions or deliver treatment but also a wide range of software and apps (some used to capture and manage sensitive patient health and financial data). That means medical devices are having a far greater impact on an entire enterprise.

As a result, device design these days is a C-level concern.

EMBRACING UX

A growing chorus of medtech companies, from Philips Medical to Siemens Healthineers appreciate that creating well-designed user experiences help ensure that a device is easy to use, which is as important as engineering a device to operate properly.

These companies understand that in addition to creating safer products, **focusing on UX leads to less error-prone products that address actual end-user requirements rather than perceived requirements; enhances usability, a huge selling point; and compresses development timelines.**

The proof can be seen in design-driven companies like Apple and Kaiser Permanente, which have outperformed the overall market by a significant margin. They have bested the S&P 500 by 211% over a 10-year period, according to the Design Management Institute's Design Value Index Study.

UX investments made early shrink a product's time to market by as much as 50%.*

THE TAKEAWAY

Today's medical device manufacturers are increasingly concerned with delivering best-in-class design and giving more than lip service to the principles of UX design as a way to ratchet up usability and differentiate their products in a competitive market.

Taking a UX-first approach to medical device development allows manufacturers to create high-performing and profitable products by giving users what they need—clear, intuitive UIs that support better patient outcomes.

*Source: Strategic Data Consulting

Chapter 1

A SMOOTHER PATH TO APPROVAL

Understanding FDA Guidance

One of the biggest challenges medical device manufacturers face is getting their device certified by the U.S. Food and Drug Administration (FDA) as ready for market. Since patient safety is paramount, the FDA has put in place an array of standards that cover the aspects of product development related to human factors and software engineering processes in order to ensure that new medical devices are safe and effective for their intended uses.

Before exploring the various standards, you should be aware of the perspective the FDA maintains. At the highest level, the FDA considers a medical device to be a piece of hardware that takes in data, either from sensors or people, performs processing on that data, and outputs information to people, possibly completing additional actions like administering fluids to a patient.

The FDA categorizes medical devices into three classifications based on the level of risk a device poses to an end user:

- Class I: low-to-moderate risk, such as beds and stethoscopes. According to the FDA, 47% of medical devices fall under this category and 95% of these are exempt from the regulatory process.
- Class II: moderate risk, such as ultrasound machines. 43% of medical devices fall under this category.
- Class III: high risk. These devices usually sustain or support life, are implanted or "present potential unreasonable risk of illness or injury." Examples include implantable pacemakers, cardiac monitors and defibrillators. 10% of medical devices fall under this category.

USE ERRORS

Clinical settings are typically fast paced and often noisy, creating difficult working conditions. Though clinicians are among the best-trained professionals, they are also human and this environment makes it a challenge for practitioners to perform to perfection. They are further challenged when new devices introduced into their environment behave differently than previous devices to which they'd grown accustomed.

Even if the software in a medical device performs flawlessly as designed, there are still times when the person using the device may commit use errors. These errors can be unintentional, such as a lapse due to distraction, or can result when the

user completes an intended action correctly but the action isn't appropriate in the circumstances of the moment.

Depending on the type of device being used, these kinds of use errors can have potentially lethal consequences. So, while use errors may only cause an inconvenience in the case of a Class I device, errors using Class III devices can result in fatalities.

This is where human factors becomes critical, as good design can mitigate use error. Through proper analysis and design, known or likely data input errors can be anticipated and prevented. If errors do occur, they should be rapidly detected and users should have an avenue to quickly correct them. Data displays should be designed to be easy to read, quick to understand and cause no confusion of meaning. Following design processes intended to achieve these results are a best practice that should be followed by any medical device manufacturer.

REGULATING DEVICE DEVELOPMENT

The ultimate authority for regulating medical devices in the United States comes from federal laws and regulations. For instance the Federal Food, Drug and Cosmetic Act establishes the three-tier risk-based classification system that applies different levels of rigor in approving devices.

Since part of the FDA's mission is to help manufacturers achieve the highest possible levels of both safety and effectiveness, the agency issues regulations based on these laws. For instance, *Code of Federal Regulations Title 21, Part 860* regulates device classification, while *Title 21, Part 820* regulates quality management systems for medical device manufacturers.

However, neither laws nor regulations provide the detail necessary for manufacturers to know exactly what they must do in order to build a safe and compliant device.

To fill the gap, the FDA provides guidance in two important ways.

1. FDA procedures for approving medical devices rely on "voluntary consensus standards." These generally come from Standards Developing Organizations (SDOs), which operate both nationally and internationally. Two national standards organizations in the U.S. are the American National Standards Institute and the Association for the Advancement of Medical Instrumentation. The international bodies that develop medical device standards include the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), among others.

While the FDA does not enforce these voluntary standards, it does have a formal process for recognizing them and encourages adherence. The agency takes conformance into account when considering submissions. (Note that not all standards attain FDA recognition.)

Among the most important of the FDA-recognized standards specific to human factors for medical devices is *ANSI/AAMI HE75 Human Factors Engineering—Design for Medical Devices.*

2. The FDA publishes its own "non-binding" guidance documents to help manufacturers understand the agency's thinking and approach. For instance, FDA publication 1757, *Applying Human Factors and Usability Engineering to Medical Devices*, provides and overview of human factors engineering processes the agency expect device makers to follow.

SOFTWARE AS A MEDICAL DEVICE

A change introduced in 2016 as part of the *21st Century Cures Act* is the definition of Software as a Medical Device (SaMD). This is a new category of regulation, looking at software intended to be used for "one or more medical purposes that perform these purposes without being part of a hardware medical device." This category includes software used for diagnosis and treatment of injuries and is considered to be "low risk" by the FDA.

With these new regulations, certain types of software are no longer considered medical devices, such as lifestyle and wellness apps and wearable devices, and are now free from regulation.

These changes are part of the Digital Health Innovation Plan established by the FDA's Center for Devices and Radiological Health (CDRH). **The plan is an effort by the FDA to foster innovation and streamline the process for getting low-risk products to the market.**

A major part of the plan is the Software Precertification (Pre-Cert) Pilot Program, which looks at the technology provider more than the specific product and aims to certify companies with a proven track record of quality.

The goal is to permit companies that become certified to get products into the marketplace faster while still maintaining the same level of quality that the current regulatory process produces.

MEDICAL DEVICE BEST PRACTICES

Understanding the metrics that the FDA is applying is certainly a large part of the challenge facing medical device designers, but the most important part is executing to meet those metrics. Achieving high standards of quality in design is necessary to satisfy many FDA requirements because device safety is fundamental to a well-designed product.

At a high level, these three best practices in design thinking should be applied to the creation of all medical devices regardless of class:

1. Know the users
2. Focus on the users
3. Make errors as impossible as possible

Wilfred Hansen implored designers to "know thy user" back in 1971, and that remains a foundational notion in UX to this day. Designers and users typically bring different perspectives and experiences—different backgrounds and educations, different goals, different work environments.

UX design is more than making things “look pretty.” While aesthetics are important, it is the focus on usability that is critical.

That’s why designers must learn everything they can about what the user is doing and thinking while working, even observing users in the wild. A clinician working in a noisy, high-stress ICU will think and act very differently than a designer wearing headphones and cranking the latest death metal while working at a desktop computer screen.

Once a designer fully understands the user, he or she must focus the design on what will be most beneficial to that user.

The functions and workflows of a system must support the user in their tasks, making the use of these systems streamlined and stress free.

If a first responder EMT has to spend several seconds struggling to figure out an interface, making a critical task take longer than it should, the consequences could be dire.

So while design decisions like color and fonts can make an application look new and modern—making the person who pays for the system feel they are getting their money’s worth—every decision should first support usability for example readability at the necessary distances and lighting conditions that the system will be used in.

THE TAKEAWAY

Patient safety is the foremost concern of the FDA, and the agency is busy modernizing measures to improve medical device safety while creating more-efficient pathways for device makers to bring their products to market.

The takeaway for device designers is this: **preventing possible use errors before they occur should be the primary concern. And doing that means following the FDA's guidance.**

Though daunting, making sense of and complying with the FDA's alphabet-soup while adhering to well-established industry best practices, will allow device makers to create safer, higher-quality products. The payoff: by delivering better patient outcomes, well-designed devices will enjoy a smoother path to FDA approval and accelerated time to market.

Chapter 2

LIMITING MEDICAL DEVICE RECALLS

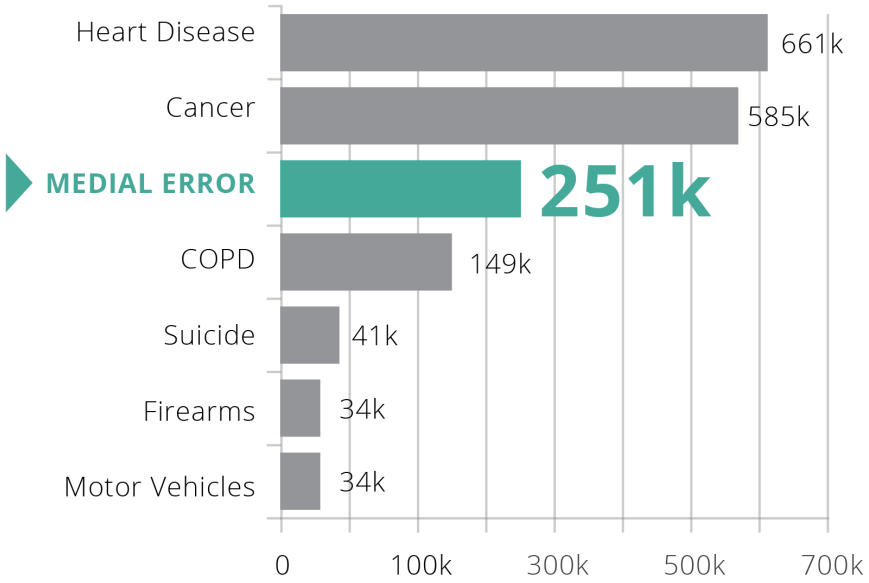
Focus on Usability

Building great software has always been challenging. Building software that safeguards patients while flawlessly controlling sensitive embedded and connected medical devices—from room-sized proton radiation systems to portable automatic external defibrillators (AED)—magnifies the challenge. It should be no surprise that design issues cause many device recalls.

So how do you mitigate potential problems when designing a medical device user interface (UI)? Begin with a strong focus on usability.

IMPORTANCE OF USABILITY

According to researchers Martin A. Makary and Michael Daniel of Johns Hopkins University, medical error is the third leading cause of death in the U.S.[1] They put the number at approximately 251,000 deaths per year. Many of these deaths (as well as non-fatal injuries) are caused by "misuse" of medical equipment.



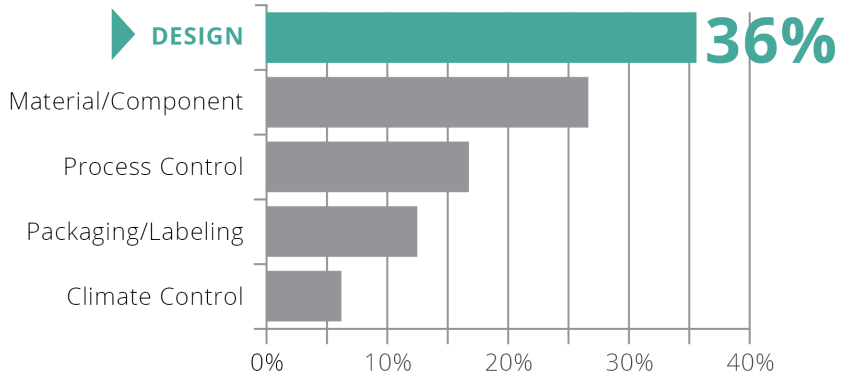
Source: Martin A Makary, Michael Daniel. BMJ 2016; 353: i2139 (03 May 2016)

Researcher Jeffrey B. Cooper writing in BMJ,[2] suggested that although the incidence of outright functional equipment failure may be low, "machines can have shortcomings or faults in design that encourage human error."

For example, the Food and Drug Administration (FDA) reported that **between 2005 and 2009 infusion pumps and related devices accounted for 35% of medical errors** that resulted in significant patient harm. The agency said a large number of the adverse events stemmed from "programming errors attributed to poor device usability." Essentially, that's human error arising from a poorly designed UI.

Design problems (relating to both hardware and software) accounted for more than a third of overall medical device recalls—with a large proportion of recalls traced to usability and the design of the user interface. Here's an example: because of a confusing UI clinical staff enters patient weights in pounds rather than kilograms, a mistake that results in medication overdoses.[3]

CAUSES OF DEVICE RECALLS IN FISCAL YEARS 2010-2012



Source: FDA, CRDH. 'Medical Device Recall Report FY2003 to FY2012'

The mismatch between user needs and the design of the device's UI is the likely cause of unintentional use errors. According to *Human Factors Engineering—Design of Medical Devices*[4], medical devices that are not designed with usability in mind are frequently "unsafe, prone to use error, difficult to use, difficult to learn to use, or detract from user efficiency or satisfaction."

And according to the FDA, making design modifications to a device and its UI are generally the most effective means for eliminating or reducing these types of use-related hazards. So, applying usability design techniques is one of the best ways to guard against use errors and the harm they can cause.

WHAT IS USABILITY?

Usability is defined as the ease of use and learnability of a designed object. Highly usable device controls function like a lens that makes information and processes crystal clear, allowing users to stay focused on their work.

Usability results from user-centered design, a discipline that has evolved along with the software industry. **User-centered design makes technology serve human clinicians and patients rather than making humans strain to adapt to the technology.**

It may seem obvious that usability should be a top priority for medical devices. But, unfortunately, devices with poor usability still find their way into the market, posing serious risks to patients.

A CHILLING, REAL-WORLD EXAMPLE

At 4:30 pm on Feb. 27, 2000[5], a heavily pregnant Danielle McCray was admitted to Tallahassee Memorial Hospital for what should be a joyous event: the birth of a child. To ease the discomfort of labor, at 6:45 pm that evening she was connected to a patient-controlled analgesia machine, a programmable infusion pump.

Just eight hours later, at 2:30 am on Feb 28, instead of delivering a healthy baby, McCray was pronounced dead from a morphine overdose.

How did this happen? While human error was cited, the facts of the case point to deeper issues with the infusion pump's usability and UI design. For instance, the pump required up to 27 programming steps. How could someone reasonably have been expected to safely operate this device?

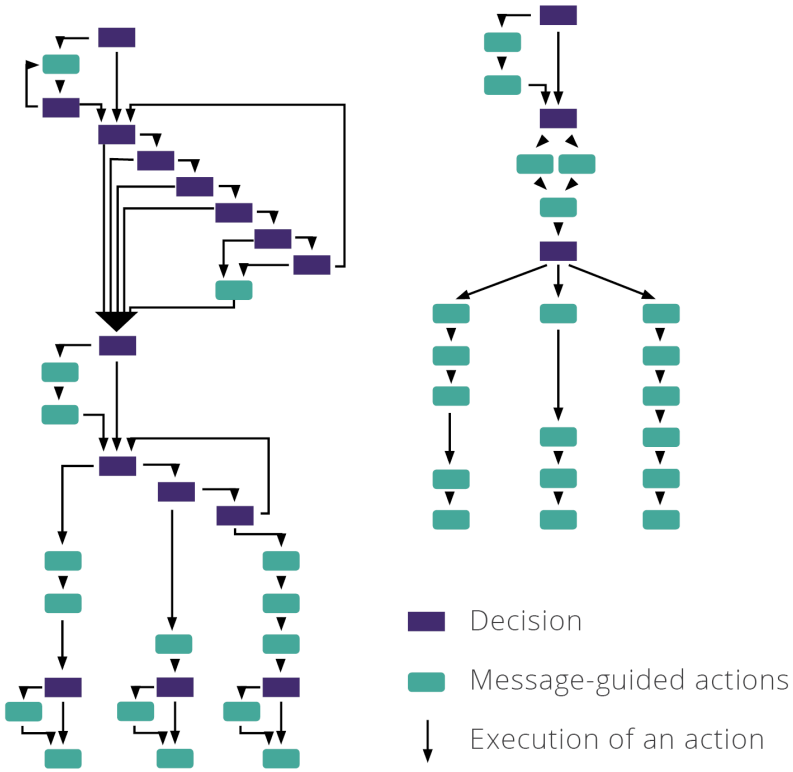
And McCray and her care team were not the only ones who had issues with this device. During a 12-year period, improper programming of this pump caused at least 65 deaths, with estimates suggesting that as many as 667 people may actually have died using it.

Human error had caused 68% of the fatalities and serious injuries associated with this device. The manufacturer had received prior warnings, including one in 1996 calling out potential interface issues, and another in 1997 suggesting the device was "susceptible to misprogramming."

Though the device-maker's view was that the problem was not the design, but rather lack of user training, the company agreed to make design modifications to the UI. These included:

- A dialog structure with fewer steps
- A dialog overview showing the user's location in the programming sequence
- Better command feedback
- Easier error recovery
- Clearer labels and messages

OLD DEVICE INTERFACE (L) VS REVISED INTERFACE (R)



Source: Vicente 2006.

The results of these design modifications were dramatic. The number of required programming steps decreased by 55% and user errors dropped by 56%. Most significant, the specific programming error that had been linked to patient deaths was eliminated. Clearly, usability and effective UI design matter.

ARE YOU ASKING THE RIGHT QUESTIONS?

If you want to bolster usability, start by asking the right questions—and then test carefully. (Usability testing—a requirement to ensure the device is safe and meets government standards—is beyond the scope of this ebook.)

Here's a brief list of some questions to ask, which are applicable to an existing device if you are considering creating a generational product or to a high-fidelity prototype if you are developing something new.

- How easy is it to learn to use the device?
- How soon will the intended user feel comfortable using the device?
- Once learned, how efficiently can the device be used?
- Do users remember how to use the device after several days, weeks or months of non-use?
- Does the device prevent users from making errors or help users recover from their errors?
- Is the device design appropriate for the capabilities and limitations of users?
- Are users satisfied with the device?

Getting the right answers to these questions requires a disciplined, user-centered approach to design. This means applying the right expertise at the right time in the product development cycle. As we have seen, failing to do so can have tragic consequences.

TAKEAWAY

When designing medical devices, always remember: the goal of clinical users is to improve patient outcomes. Period. Prioritizing usability and incorporating a user experience carefully designed to mitigate user error is the path to success.

References

[1]Martin A Makary, Michael Daniel, BMJ, May 2016
[2]https://qualitysafety.bmj.com/content/11/3/277
[3]FDA white paper, Infusion Pump Improvement Initiative
[4]HE75 a.k.a. ANSI/AAMI HE75:2009/ (R)2013
[5]Vicente, 2006

Chapter 3

MEDICAL DEVICE DESIGN CONSIDERATIONS

Ensuring Usability and Safety

To be safe and reliable for patient care, medical devices must have accurate device functionality and clinical performance. Think of it as accurate data in/accurate data out. But for the human users of devices—doctors, nurses, technicians, caregivers—that means being able to apply the device to a patient correctly and effectively, and also being able to accurately see and understand the output from the device.

In other words, it is essential for medical devices to not only function flawlessly but offer impeccable usability in order to utilize the functionality effectively. In sum, hand-in-hand with accurately functioning, a medical device needs to have high usability, which is achieved through interface and human factors design.

But many devices fall short because it's a challenging and detailed design task.

SAFETY IS A PRIORITY

If you have ever tried to use the simplest of devices, for example an over-the-counter pulse monitor that clips on a finger, you know there are some tricks to using it. It fails if the position of the clip on the finger is a little off, or if the wrong finger is used. And then there's recognizing if the battery is weak. And it always takes a moment for the device to give an accurate reading, so you need to allow adequate time. In other words, even a super-simple device can present usability challenges.

As noted in chapter 2, medical error is the third leading cause of death in the U.S. and many of these deaths (as well as non-fatal injuries) are caused by "misuse" of medical equipment. What causes misuse? According to researcher Jeffrey B. Cooper, "machines can have shortcomings or faults in design that encourage human error."

That means **many of those errors could be prevented by a combination of adequate training and more usable, intuitive interface design.**

As patient care evolves to include more types of settings, such as clinics, nursing-care facilities and even private homes, more types of users (e.g. emergency personnel, non-medical caretakers and patients themselves) must be able to safely use these devices.

DESIGN FOR THE HUMAN FACTORS

That's where human factors design—design that optimizes human usability and overall system performance—comes in. Some of the benefits of human factors considerations in medical device design include:

- Safe electrical connections or battery use
- Accurate application of the device to the patient
- Ergonomic design for physical ability of user and the shape and size of the patient
- Easy-to-understand device functionality
- Easy-to-interpret visual representations

START WITH DEVICE ERGONOMICS

Because many medical devices are portable, have moving parts and need to be applied to the human body in a variety of mechanical ways, such as with adhesive, straps or clips, the physical design of the device parts matter greatly to the usability.

Considerations include:

- Physical strength of the user to handle, maintain or hold the device
- Physical measurements of the device as it applies to the user (size of hand, size of fingers, etc.)
- Physical measurements of the parts of the device that touch the patient (weight, height, limb length and girth, etc.)

CONSIDER CONTEXT OF USE

Medical devices are used in clinical and non-clinical environments, public locations, moving automobiles and other environments that have conditions which may affect usability. Some environmental use contexts are:

- Devices can be fixed in a location or they can be portable, on wheels or carried by the user
- Devices may be used in a moving vehicle, submitting the device, user and patient to jostling or even more extreme movement

- Environmental lighting may be bright or dark, which can affect the device's visibility
- Environmental noise level may be high, affecting the device's alarms, or audible feedback that the user needs to hear

MAKE INTERACTIVE SCREENS EXPLICIT

Interactive screens on medical devices present many of the same basic challenges as any Graphical User Interface (GUI), including clarity, readability and error recovery. Some issues of particular relevance to medical device GUIs:

- Explicitness is a must. Subtlety may be appropriate in some visual interfaces, but medical devices require extreme clarity and explicitness so there is no question of the meaning.
- Colors have meaning. For example, red is a universal color for getting attention and therefore is often used for signaling danger. Colors need to be used appropriately for their cultural meaning on medical devices since users typically are interpreting quickly, under stress with little time to think past their instantaneous interpretation.

- Colors perception in humans has physical influences. For instance our eyes see red easiest, so it is often the first color seen in a field of colors. Also seeing red raises our blood pressure slightly. For both those reasons, red is a good choice to signal danger.

- Because of the variety of contexts of use mentioned above, screen graphics need to also apply to the possible contexts of use, be it in darkness or lightness, or at a far or close distance from the screen.

THE TAKEAWAY

Medical devices require impeccable usability in order to be safe for use with patients. Hand-in-hand with accurately functioning, a medical device needs to have high usability. That means a clear focus on interface and human factors design is essential despite the challenges involved.

ABOUT BOSTON UX

At Boston UX, we design compelling touchscreen interfaces for high-impact embedded and connected medical, industrial and consumer devices.

Specialists in intuitive interface design for touch- and voice-powered smart devices, our designers have deep knowledge of the engineering and business complexities that impact product development. This allows Boston UX (**www.BostonUX.com**) to design products that don't just work, but deliver a powerful user experience.

Companies like MilliporeSigma, Intel, Boston Engineering, ZOLL Medical Corporation and Casenet have felt this power firsthand.

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If you'd like to learn more about Boston UX or want to schedule a meeting to speak with a representative, give us a ring or drop us a note. We'd love to hear from you!

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