



# DESIGN VS. HUMAN FACTORS: MEDICAL DESIGN'S CHICKEN AND EGG



**H**ow do you get a medical device to be easy to use? Great design! How do you reduce risk and prevent injury in medical devices? Design. (There's even a risk standard that says so: ISO 14971). How does a medical device become widely accepted by a consumer market? That's right—through design!

Inarguably, design is the means by which human factors is applied, and human factors is the means by which a design is verified and validated. It is the ultimate chicken and egg situation.

## **An Unbalanced Approach**

The fact is that design, the physical and graphical way a product is put together, is the most important element in every measure of success for a medical device. Through innovative technology design, we have new opportunities to advance clinical care. Through advanced material exploration, we have the opportunity to improve manufacturing processes, device functionality, and clinical utilities and outcomes. Through industrial and interaction design, we have the opportunity to provide products that respect the user and their expectations.

Nonetheless, in medical device design it is commonplace to hear more about applying human factors than design. In this field, we rarely discuss design aesthetics, the qualitative beauty of a medical device. Rather, we focus on developing a set of design rules based upon research. In a highly simplistic view, the conversation generally starts with the impetus to understand user needs through contextual inquiry, magically coming up with a few concepts and then testing them with users. The application of human factors processes ultimately results in a validated, usable medical device. But do users really desire the device? Do they enjoy using it? Is the device itself appreciated as a designed object?

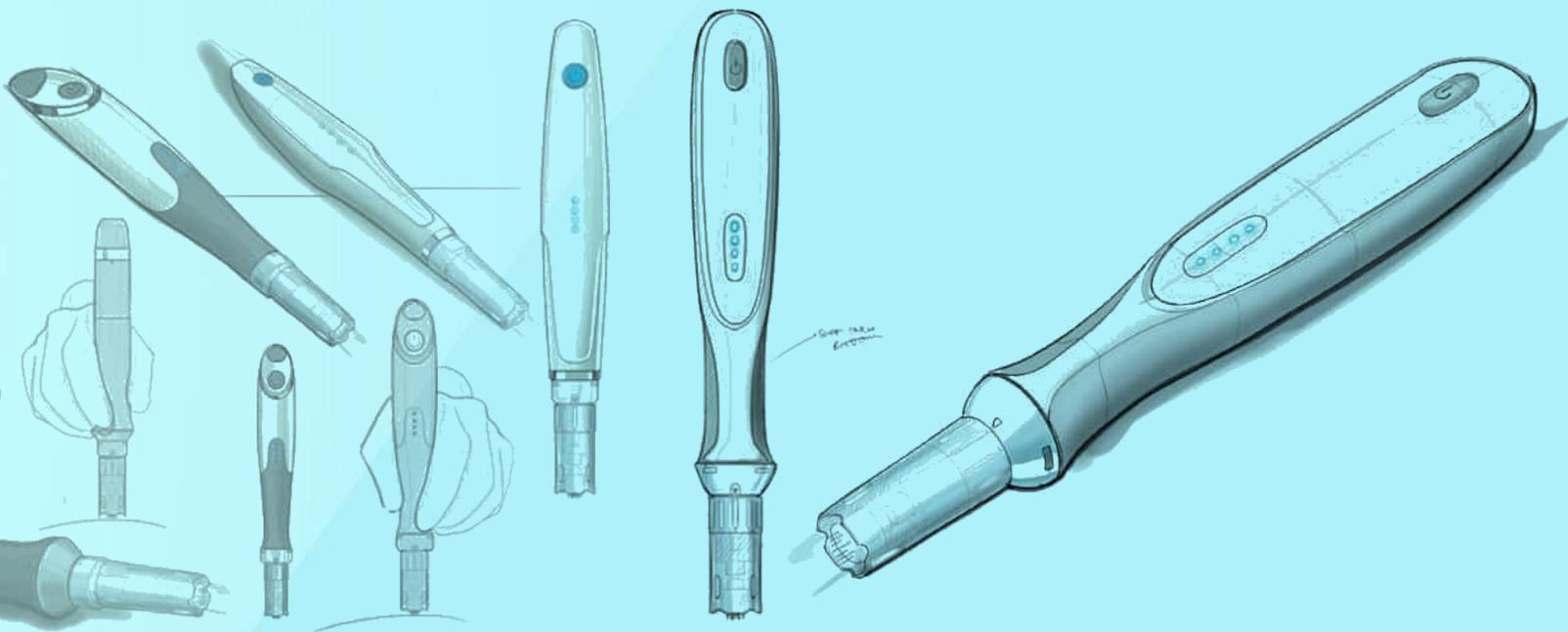
In some early educational circles, there is a philosophy that a child can learn from testing; that is to say, if you want a child to learn vocabulary words, you have them briefly study, give them a quiz, show them what they missed and have

them take the quiz again hoping for a better score. In this example, no real change occurred between testing because there was no true commitment to learning. The same can be said for a device design that is tested with users and then retested without a true commitment to change. In medical devices, there seems to be a trend wherein human factors is the golden rule. Because usability testing is mandated by regulatory agencies, it becomes the focus—the driving force that can be viewed either as a tool or as another task that must be done.

For example, we may notice a few weaknesses while designing a medical device but choose to wait until after the human factors testing before making modifications that optimize the aesthetics of the design. We justify the wait for various reasons, such as internal politics or time constraints. Once we have the results, we may assess whether to actually implement any changes because doing so may be viewed negatively or belittled by our peers (such as they will have no impact on safety or will delay the development timeline for no apparent reason). Once the test results are compiled, we consider the testing itself: Was it a valid test? Were the right people in the test? Was the test set up accurately? Was the prototype functioning at the right specificity? We might find many reasons why a test fails in our human factors processes. We might find we have conditioned ourselves to accept mediocre design that is functionally safe yet doesn't provide an optimal use experience. And why? Because often human factors methodology tests only to acceptability, and perhaps preference. We rarely, if ever, have an opportunity to truly assess the attributes of a design that leave a guttural feeling of enjoyment in using a medical device—specifically, its aesthetics and the design itself as a designed object.

## **Envisioning a New Reality**

But what about the dreamers in healthcare? What is our responsibility for innovative medical device design? Consider for a moment the design theory of form follows function and fulfills fantasy (a great line by my academic colleagues). This theory is a challenge for medical device designers because



our healthcare providers, our physicians, do not live in any type of fantasy world (thankfully). If asked to dream of a new reality for their delivery of care, physicians may be a bit rusty; they simply do not have the luxury to go away and think about their clinical problems per se (consider how a surgeon's job is to act immediately, for example). Rather, they seek solutions they know have worked previously, albeit perhaps from unrelated cases. They may be risk adverse; after all, their work may have serious consequences.

It is the job of the designer to understand the clinical science and then envision a new reality: to enable a medical device user to enjoy the delivery of care, such as to easily and accurately perform surgery, to be unafraid to self-inject, to enhance the caregiving love given to those in need. This is the job of a medical device designer. It includes the responsibility to push for features that are important to the use experience as a function of emotional response that may be counter to cross-functional group think yet respectful to clinical science.

Designers must not be afraid to fully execute the inherent value of their design processes. They must consider the limitations of a user group (i.e., human factors) as uncovered by their knowledge, skills and abilities and reach beyond that: Strive for more than just acceptability in the context of the socio-cultural beliefs of a user group and more than the "don't make me think" mantra of device users and aim for designed experiences that embody artistry and elegance.

Technological advancement will always offer new opportunities for innovative design. However, in order to be successful, innovative technology development must work with innovative design. Good design makes products useful. This is true whether designing a consumer product or a medical device. The design must meet not only functional criteria but also the psychological and aesthetic criteria. In doing so, usefulness is emphasized.

The aesthetic quality of a medical device is integral to its usefulness. Every day people use devices intended to support their well-being, but that intention translates to

reality only if the devices are well executed and beautiful. This includes being unobtrusive; the devices themselves are neither works of art nor decorative objects. Rather, their design is thorough to the last detail; nothing is arbitrary. Care and accuracy are inherent in the use experience. A well-designed medical device is self-explanatory to the extent possible. It is understandable with as little design as possible, concentrating on the essential aspects that assist the user in making the right decisions or actions while preventing potential negative outcomes. Good medical device design celebrates simplicity in respect of the user.

As medical device designers, we have fully embraced Raymond Loewy's MAYA ("most advanced yet acceptable") principle, which theorizes that a product design is bound by functional constraints of math and materials logic, but its acceptance is constrained by social expectations. This is especially true in medical devices. While this theory provides a strong foundation, it is time we give better appreciation for the functional ornamentation (the form semantic) in medical devices. It's time to acknowledge that through design we can cause an emotional reaction—a feeling of delight or surprise over the object's function and beauty.

My approach to design is admittedly biased on the human and centered on the delivery of care. Throughout my career, I have worked on both sides of the fence, design and human factors. I have worked alongside physicians, nurses and healthcare workers within a Level 1 trauma center and for large corporations and a consulting group. A consistent truth runs through these experiences: Design and usability go hand and hand.

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