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Originally Published [MD&DI](#) October 2007

## HUMAN FACTORS

# Catching the Human Factors Fever

**More device companies are incorporating human factors into their product development processes. There are a variety of reasons to do so, but also many reasons why some are still holding out.**

[Erik Swain](#)

Only a few years ago, human factors was a discipline virtually ignored in the medical device world. Device design was a field dominated by engineers, and their main concern was whether the device functioned properly or not. How easy it was to use, how well it fit into a caregiver's workflow, and whether the design contained the potential to prompt use errors were factors considered secondarily, if at all.

But that is changing. More device companies are incorporating principles of human factors and ergonomics into their designs. Some are hiring human factors experts for their staffs, while others are using consultants. More devices go through some form of usability testing before hitting the market. And FDA has begun refusing to accept "it was a user error, not a design problem" as an excuse for problems in the field.

Take Hospira (Lake Forest, IL). Its practices are becoming more the norm than the exception, it seems. "Human factors is an integral part of our device development process," says Steven Pregulman, MD, medical director of device development. "We work with end users early and often before we even have working prototypes. We work with focus groups and single users." In fact, to ensure that all user feedback is accounted for, Hospira's policy is to document each and every comment and note whether it was heeded or disregarded, he says. "If we did not have a system like that, it would be too easy to sweep everything under the rug."

There are a number of reasons why the human factors discipline is finally catching on in the medical device industry. Unfortunately, there are an equal number of reasons why it still hasn't caught on in parts of the sector. What follows is a look at some of the trends that are forcing medical device manufacturers to change their design practices, and should force those who haven't to reconsider.

### Acceptance

There is plenty of evidence to show that the principle of human factors is part of the medical device design process more than ever before.

"Our customers are much more receptive than they used to be" to incorporating human factors in their designs, says Steve Guerrero, industrial design manager for Foster-Miller Inc. (Waltham, MA), a firm that assists companies with product development. "There is greater awareness of it now, and enlightened firms understand that they need it. We want industrial design and human factors principles incorporated into the process from day one, not treated ad hoc. And more of our customers are seeing the light."

"Companies are getting in tune with trying to get it right the first time," because they are beginning to understand how costly a redesign forced upon them by use errors can be to the bottom line, adds Bob Andrews, Foster-Miller's medical



**The management system for total parenteral nutrition from B. Braun Medical Inc. has software that performs conversion calculations and checks limits.**

division manager.

“A big driver is patient safety and ease of use,” says Joel Bartholomew, manager of OEM product development for B. Braun OEM Div., B. Braun Medical Inc. (Bethlehem, PA), a contract manufacturer that also helps device firms with design. “If you can make your device more intuitive to use, you will usually make it more safe.”

Also, says Guerrero, the increasing competitiveness in certain sectors of the device industry is contributing to added use of human factors in design. “As one company adopts the philosophy, others are following suit,” he says. “Before, this was usually greeted with ‘do we really have to?’ Now, they understand how this helps competitiveness and reduces costs.”

“In general, more and more human factors people are finding themselves in healthcare organizations,” from hospitals to device companies, says human factors engineer Laura Lin Gosbee of Red Forest Consulting (Ann Arbor, MI). “That creates pressure and may impact adoption decisions. Some hospitals are conducting usability tests before they purchase.” If hospitals have more people on staff who understand the value of human factors, poorly designed products may be eschewed, she notes.

Another factor in human factors program adoption is FDA’s decision to go after firms whose designs have caused too many use errors. At the AAMI/FDA annual conference in March 2007, CDRH’s top human factors official, Peter Carstensen, said failure to follow proper human factors guidelines will bring enforcement action from the agency if too many use errors occur as a result.

He cited the case of Cardinal Health’s Alaris Medical Systems division, whose Alaris Signature Edition Gold infusion pumps had a defect called “key bounce,” in which a button pressed on a keypad could appear twice, causing an improper infusion. When FDA asked the firm to fix the problem, the firm said it would add a warning about the condition in the labeling. That wasn’t good enough for the agency, Carstensen said, because the consequences of the use errors could be great. So FDA went to court and got four models of the pump seized. The firm then issued a recall.

Another push came when IEC 60601-1-6 came out in 2006, says Michael Wiklund, PE, CHFP, president of Wiklund Research & Design, Inc. (Concord, MA). That subsection of the standard on medical electrical equipment deals with usability. “That meant that not only does FDA want you to adhere to human factors standards, but in order to get a CE Mark, you must meet the IEC standard, which now includes usability.”

“In addition to the seizures, there have also been [usability-related] recalls, and pushback on PMAs and 510(k)s,” adds Wiklund. “Notified bodies are also paying attention. Companies are feeling the pain.”

A pending standard, HE 75, is expected to further codify human factors procedures—and increase expectations for industry.

## Barriers



**C.R. Bard’s one-handed biopsy tool incorporates safety features and ergonomics.**

One impediment that remains is that some firms see human factors studies as superfluous work that can delay a product launch if something goes wrong, says Pregulman. What they don’t understand, he says, is that “failure in a human factors test is a good thing. It prevents us from bringing bad ideas to market. We can be proud that we failed some aspect of the test and made our product better as a result of it.”

Others balk for cost reasons, says Wiklund. “Some companies seem reluctant to spend the appropriate amount of money to create great user interfaces, or even good ones.”

Research indicates that employing a human factors program could help save hundreds of thousands or even millions of dollars per project.<sup>1</sup> It also helps with user adoption, says Pregulman.

While the economic carrot might be there, too often the economic stick isn’t, says Gosbee. “The problem is that device companies are different from the consumer product companies. They don’t have to bear the brunt of the problem if people are not able to use their product. The hospital does. So there is little economic impact for them. They won’t get returns like [they] would with consumer products. Hospitals are usually stuck with contracts. The best they can do is to decide to go in another direction next time.”

## Factors in the Field

Despite such barriers, a number of trends in hospital care and home care are prompting changes in medical device

design approaches. It has been well-documented that a nursing shortage in U.S. hospitals has encouraged some devices to be redesigned to account for nurses having less time to spend with each patient.<sup>2</sup> Other conditions are emerging as well.

“There is a redirection in operating-room personnel from an assistant’s standpoint,” says Miller. “Because of the nursing shortage, a surgeon’s assistant is often another doctor or a doctor-in-training. They may not be used to performing the surgical assistant’s task. That means the simpler the device is to open and deliver, the better.”

Likewise, says Wiklund, functions that used to be performed by registered nurses are now being performed by people with less training, such as nurses’ assistants and technicians. “This puts pressure on manufacturers to... consider the experience and skills of users, so they won’t make errors.”

The use of electronics in more devices has had an effect on the operating environment, too, says Guerrero. “Physicians have to be in the sterile field, so industry has had to develop electronic control interfaces that can withstand autoclaving or be sealed inside a sterile bag and be in the sterile field,” he says. “This gives physicians total control over the instrument, as opposed to having to verbally direct someone who is not in the sterile field to interface with the instrument.”

The sheer number of electronic devices is itself presenting a problem, says Bob North, chief scientist for Agilis Consulting (Colorado Springs, CO). “In an environment like the operating room, multiple alarms present a problem,” he says. “Not everyone is on the same page with regard to alarm types or priority. When multiple devices are hooked up to a patient, there is no ‘central switchboard’ concept, and it is hard to figure out what should take precedence. As a consequence, sometimes caregivers turn alarms off. It may make sense to them, in order to weed out the information they need to do their job. But the absence of those alarms may mask something about a patient’s state.”

The answer, he says, is not necessarily to make devices less sophisticated, because their advances are needed. Rather device manufacturers need to think more about the other systems their devices will be used with, and where the potential for confusion might exist, such as in a busy operating room.

“You have to understand the context in which your device is being used,” North says. For example, “if you are building a ventilator, have you modeled all the interactions of your device with the other typical ICU devices? What devices are going to be next to yours? What process does the hospital use to integrate your device into their suite? Manufacturers need to do very comprehensive modeling and analysis of ebb and flow.”

With more and more medical product being used in the home environment, device manufacturers can no longer assume that their products will be used by a healthy person with expertise in the field, says Andrews. “Devices must not only be easy to use from an ergonomic and physical standpoint, but from a visual standpoint too,” he says. That, says Guerrero, means larger and clearer displays and larger buttons might be necessary on some interfaces.

### Shining Examples

There have been a number of exemplary devices in recent years that have achieved status because of strong human factors work. Guerrero and Andrews cite these designs by Foster-Miller customers:

**The Breastflow bottle feeding system from The First Years (Stoughton, MA).** The design began with a study of how the human breast actually functions. A two-piece nipple was designed to effectively duplicate the fluid delivery functions of the human breast, incorporating a process similar to that of a basketball pump. The nipple’s elastomer material was composed of the same type of silicone used in traditional bottle nipples, but with a durable exterior that makes consistent use possible and sanitizing easier. When the baby squeezes the nipple, an inlet valve closes while an outlet valve opens, allowing the milk to flow. When the child ceases suckling, the nipple expands, the outlet valve closes, the inlet valve opens, and the milk again enters the nipple, mimicking the functions of breast feeding.

**A one-hand biopsy tool from C.R. Bard Inc. (Murray Hill, NJ).** For the one-hand concept to work, a simple design where all mechanisms fit into the handle was needed. The company studied both ergonomics and human behavior. The handle required solid housing made of a rigid material but also a flexible grip made of a resilient material. Both elastomeric and rigid polymers were selected to accommodate a design that could be replicated through injection molding. The product can be either cocked or triggered by the surgeon from either the top or side of the tool with one hand. To make the tool reliable and safe, a safety latch was built right into the handle.



**The Breastflow feeding system from The First Years duplicates a human breast to ease acceptance.**

**An insulin injector pen from Becton, Dickinson & Co. (Franklin Lakes, NJ).** User studies enabled a product designed for those with poor dexterity and poor eyesight. It can deliver an adjustable dose of insulin with a single plunge. It also has an audible operating feature for visually impaired users and low-cost injection-molded parts to keep costs down.



**Hospira kept human factors in mind when developing its award-winning Symbiq infusion system.**

Another product lauded for its great attention to human factors is Hospira's Symbiq infusion system, which won a Medical Design Excellence Award in 2007. Infusion pumps, as noted above with the Alaris example, have had a number of problems with use errors, so Hospira employed an extensive human factors program during the development of this product. "We used very large fonts and very well-researched colors and contrasts," because the nursing population is aging and many nurses have poor vision, says Pregulman. "We tried to take into account everything that goes on in the hospital."

Another 2007 MDEA winner that garnered praise for its ease of use was the Pinnacle total parenteral nutrition (TPN) management system, made by B. Braun Medical Inc.'s hospital division. The system includes a custom-designed software package that assists the user with the entry of TPN orders. The software performs the conversion calculations and checks limits. "TPN formulations can be complex, requiring numerous calculations. The system helps eliminate calculation errors to reduce incidence of drug incompatibility," says Bartholomew. "Many product features and software design developments are a result of the focus to improve patient safety." (More about the MDEA winners can be found in the April 2007 edition of MD&DI.)

### Suppliers Use Human Factors Too

Not only are more medical device manufacturers keeping human factors and ergonomics in mind when designing their products, but more component suppliers are too.

Z-Man Corp. (Grand Rapids, MI) got into the medical field when advised that its ergonomic pinch clamp design would work very well for medical applications.

Nurses usually need to open pinch clamps with one hand. But doing so with the traditional pinch-clamp design can be very difficult, says Gerald B. Zervas, president of Z-Man Corp. "The problem is that you must come around from one side, grasp the clamp and the tubing line between the forefinger and the base of the palm, cock your thumb, push, and release," Zervas says. "But you can accidentally pull or push on the tubing line," which could make a catheter become unstable or even dislodged.



**Suppliers such as Value Plastics are adopting human factors principles to provide OEMs with better service.**

Z-Man had developed a more sophisticated pinch valve for the laboratory market. Contacts from that market encouraged the company to make the valve for the hospital market. But the firm had been making the laboratory-market valves for \$3-\$4 per valve, while the traditional clamps for the hospital market were selling for \$0.02 each. Given the volume of pinch clamps that are used in hospitals, even the most progressive buyers weren't going to pay that much of a premium. But after an intense design effort, the firm got its valves down to a competitive price.

The new clamps have release tabs that a nurse simply squeezes in order to open. That means opening can be done easily with one hand from any angle, and the user is much less likely to accidentally pull or push on the tubing when opening the clamp, says Zervas. In use testing, 76% of nurses said they preferred the new clamp to the traditional one, while the remainder said they had no preference, he adds.


The new clamp hasn't become the standard yet, however. It has captured about 30-40% of the medical market, but should get more, Zervas says. "OEMs don't want to change unless they have to, and nurses and doctors usually don't have much say [in specifying components for medical devices] unless there is a lawsuit or another motivational reason," he says.

So there's still a lot of convincing to do. Zervas adds, however, that FDA has assured him that kit manufacturers will not have to apply for a new 510(k) if they decide to switch pinch clamps.



Value Plastics Inc. (Fort Collins, CO), which makes fittings and connectors for plastic tubing, decided to incorporate human factors into its component designs as a way to gain a competitive advantage, says Jim Pisula, vice president of marketing.

"For example, we saw an opportunity in connectors for non-invasive blood-pressure materials," he says. "The existing designs worked but were not easy to use. We thought we could do better. So



**Connectors from Value Plastics improved after the company consulted with engineers and end-users.**

we took our idea to end-users, and we asked them what they did and talked about what they liked. We got engineers and end-users together, so the engineers could see how the end-users actually used the product. We asked whether there was a better alternative that we could still manufacture. It turned out there was, and it was adopted fairly rapidly in an industry that does not change all that much.”

It helped, he says, that “as OEMs are demanding more from their suppliers, that has given us an additional opportunity to show how good we are.”

Suppliers might assume that doctors and nurses will not want to take the time to talk to them, but that is often not the case, says Pisula. “Doctors and nurses have very specific opinions about what they like and what they don’t like, and if you ask them for their opinions on things, they are usually happy to give them,” he says. “You can also work on the relationships you already have—maybe you have a neighbor who works in a hospital.”

“You need to devote time to observe,” says North. “It can be tough to get access to hospitals, but you must at least conduct interviews. More hospitals are building simulation rooms, and you should try to take advantage of those. You have to uncover information from users about the context of how your device is used. These things are usually missing.”

### Conclusion

More device companies are committing to human factors programs, and that will benefit caregivers and patients in the long run. But mere acceptance of human factors programs won’t be enough. The next step is to integrate usability findings with the risk management process.

“Even if you have [human factors] religion, you may not have use error/risk management religion,” says North. “Some manufacturers that embrace human factors think that absolves them of use-error risk. But just because a product is usable and aesthetically pleasing does not mean that you understand the errors a user could make. And that’s what FDA cares about,” he says.

“Ease of use translates to a reduction of use errors, but not at the ‘sharp end.’ By all means, do usability studies. But FDA will want to know about the ones that fail. What was the failure, and what is the risk that it could kill someone? Likewise, do [failure mode and effect analysis] and hazard analysis, but realize that those aren’t geared toward human error,” says North. “There isn’t a whole lot of connection between usability science and risk management, and there needs to be. We have to tether our balloon to the risk management balloon.”

*Erik Swain is editor-in-chief of MD&DI.*

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2. Erik Swain, “[Nursing Shortages and Device Design: A Hidden Connection](#),” *MD&DI* 26, no. 10 (October 2004): 104–111.

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