



## Medical Device & Diagnosis Industry

### Blending Form and Function: Good Design Starts with Usability

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Good design can often mean the difference between the success or failure of a product. Defining good design is often subjective, but customers know intuitively what works and what doesn't. The MDEA jurors noted that some of the winning products excelled particularly in their design, providing a significant improvement over currently available products.

"Industrial design encompasses the creation of a product's physical form and its points of user interaction," said juror Michael E. Wiklund, vice president of human factors research and design for the **American Institutes for Research** (Concord, MA). "Invest in industrial design, and you get a product that satisfies the intended users on several levels, including intuitiveness, effectiveness, efficiency, and appeal."

He stressed that medical devices should have appeal in addition to satisfying a functional requirement. He explained that some clinicians spend several hours a day operating medical devices, so devices need to be "a glove fit" with the task requirements and the users' preferences. Products that are easy to use make people more effective at their jobs. "Products that are hard to use are the source of user complaints. They run up the cost of training and induce user errors that can place patients at risk and cause equipment damage and material waste," Wiklund added.

The jurors noted that although some design changes are incremental improvements to existing devices, the improvements are such that they offer a real and tangible benefit to the clinician or patient. "Many products were beautifully designed but not very innovative, and many products were very innovative but poorly designed. We tried to choose for awards the few that fell into both categories," said Stephen B. Wilcox, PhD, founder and principal of **Design Science Consulting Inc.** (Philadelphia).

As they identified products deemed superior in design, the term ease of use came up often. It emerged as a core element of what determined good design. "Ease of use is the quintessential aspect of how I would evaluate a product's excellence," said juror Tor Alden, principal at **HS Design Inc.** (Gladstone, NJ). "If it's not easy to use," he added, "no matter how valuable it may be to doctor, nurse, or patient, it has not reached award-winning status."

He noted, however, that ease of use is not black and white. "Depending on the class

of instrument or the complexity of the task, successful 'ease of use' products may require training." When usability is done right, Alden said, the user can adapt to the process and retain the process steps quickly. He stressed that usability is also tied heavily to the intuitiveness of a device. "Color-coded attachment points, common interfaces among product lines, icons, and cheat sheets all come into play," he explained.

"I think that it's fair to say that ease of use was a key criterion that we required for design awards. The only exception was if the product was so new and revolutionary that we gave it some slack vis-à-vis ease of use," said Wilcox.

"But," Wiklund added, "you would expect the manufacturer to follow right away with an version optimized for usability." Wiklund also noted that clinicians do not have time to waste using products that increase their mental and physical workload. "Accordingly, I view ease of use as an essential characteristic of an award-winning product."

"When talking about perception, look and feel and personality are words often used," Alden said. "We believe all products have a personality, similar to the way people do. Some are friendly, some are approachable, some are easy to deal with, and some require more energy than they are worth." In medical design, approachability, intuitiveness, ease of use, and strategic value are the most critical aspects, he explained. Products that exhibit all these qualities will create superior demands by the user and thereby stimulate sales and create brand loyalty. "Design excellence, in my opinion, must have all these components," he stressed. The winning products described in the sections below go far toward satisfying those criteria.

### **Audicor Cardiograph Expansion System**

The Audicor cardiograph expansion system, manufactured by **Inovise Medical Inc.** (Newberg, OR), provides primary-care and emergency medicine physicians with automated detection and reporting of heart sounds and ECG information. It is designed to aid in timely diagnosis of congestive heart failure (CHF), acute coronary syndrome (ACS), myocardial infarction, and left ventricular hypertrophy.

"It's really a clever little device," said juror Wilcox. "You replace two of the leads of an ECG and it plugs right into the system. It puts an additional line on the ECG, which provides heart sounds."

One of the goals for the Audicor product was that it made use of the same patient preparation and hookup procedures as a normal 12-lead ECG, according to Sue Hart, director of development for Inovise Medical. "In order to do this, it meant that our sound sensors had to double as normal ECG electrodes," she said. "Our design of the sensor, in fact, handles this through two of the additional ECG channels that the targeted electrocardiographs provide."

Hart pointed out that not all electrocardiographs provide more than 12 ECG channels. Only certain models used for pediatric hookups and research have the



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extra channels. "If we had not combined ECG electrode capability into the Audicor sensors, the ECG technician would have had to apply two standard electrodes as well as two sensors in the V3 and V4 positions," she added.

Wilcox noted that the device was particularly well suited for nonspecialists. "It has a built-in microprocessor that uses algorithms to process the ECG for noncardiologists," he said. "For example, those in the ER might not be able to read an ECG in the sophisticated manner a cardiologist would."

Hart said the mounting options were key to the design. Because the unit runs on four different cardiograph models, each with different form factors, the company designed four separate mounting schemes. "The challenge here was to minimize kludge as much as possible for each unit, while also accommodating easy use," said Hart. "Our goal was to be able to upgrade existing carts at user sites as well, so each design was constrained to attributes of those carts."

Emergency departments and primary care physician were seen as the natural targets for patients with early or symptomatic indications of ACS and CHF. "To best provide diagnostic value for these heart conditions, our product had to be designed with its users and user environments in mind."

Hart said that most U.S. emergency departments use the four cardiographs that the Audicor CE runs with. To preserve the existing features of these cardiographs, she said, "it meant that one of the design goals had to be minimal interference with normal, intended cardiograph use."

"This is a new technology that improves clinical care in a very simple and clever way," commented Wilcox.