

Product Design: Beyond Esthetics!

Is medical product design a superfluous exercise to merely bring “eye-pleasing” features to brighten the workplace of busy providers? Private outpatient centers may have valid reasons to be patient friendly and seek alluring products. Acute centers also seem to opt for better design as well. In fact, device vendors take pride in reaping many prominent design awards when not long ago such awards were the exclusive domain of consumer products.

Why should vendors care about good design? So they can please patients and providers? Or is a more mature industry forcing manufacturers to get out of technology-driven and prototype-looking products because esthetics is increasingly the differentiator along with price?

This issue highlights the key drivers impacting product design from user empowerment to patient experience.

Market Overview: Product evolution: design with function

The evolution of medical devices over the last 25 years has benefited from improvements in integrated circuit power. The images below of historical and current views of equipment help illustrate the improved user interfaces, leading to better user and patient interaction.

Impact of Vital Sign Monitoring Advances:

Producing accurate, timely measurements of blood pressure, temperature, and O2 saturation has been achieved by: improved measurement algorithms, less confounded by patient conditions; providing multiple functions reducing the amount of equipment staff must carry; and transferring measured patient data to electronic nursing applications, eliminating transcription errors.

On Left: 1976 - DINAMAP® 825

On Right: 2002 - DINAMAP® ProCare



Images provided courtesy of GE Healthcare

Impact of MRI Advances:

Shorter, larger bores have reduced patient anxiety, lessening movement. Parallel processing with multiple coils increases patient throughput. Advances in technologist workstations have made clinical study set-up more standardized, improving image quality and reliability.

On Left: 1994 - MAGNETOM Vision

On Right: 2004 - MAGNETOM Espree



Images provided courtesy of Siemens Medical Solutions

Impact of Ultrasound Advances:

Improvements in probes, image processing capabilities, the introduction of color Doppler and 4D acquisition make study results more dependable and easier to interpret accurately. Highly portable devices broaden access to ultrasound beyond the hospital environment.

On Left: 1975 - Mark I System
First pulsed Doppler system

On Right: 2004 - iU22



Images provided courtesy of Phillips Medical

CASE STUDY: New Concept Testing

- The Client: A worldwide leader in ultrasound imaging.
- The Challenge: Although the company has performed in-house concept testing and produced various product design options, the product development team was unsure about the market potential and which concept would be most likely to create the optimal market demand.
- Our Solution: The MarkeTech Group (TMTG) provided its technology assessment consulting and marketing research expertise. Working with the design team and the product leader, the Group created concept testing sessions that brought together the clients with in-house ultrasound applications specialists and various physician groups.
- The Impact: The ability of TMTG to implement Technology Assessment methodologies applied to clinical and business planning was crucial in this concept testing exercise. The client benefited from the market planning recommendations which included product design selection, product positioning, and market prioritization.



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Bo Saxberg, CEO of DDO Strategic Services, LLC and Advisory Panel Member for IFTF (Institute for the Future)

Q: How do provider organizations cope with staff shortages?

A: There are an increasing number of care-giver layers, such as physician assistants (PAs). Increasing the number of professional layers may minimize cost while improving quality for many types of healthcare services. The concept is to save money by shifting care activities from one professional layer to a lower one.

Q: Following this care activities shift to less trained staff, it seems that equipment OEMs are designing medical equipment to hide complexity from the user, for example, make operation more intuitive. In the light of this observation, which product design benefits should OEMs focus on?

A: I think OEM vendors should look at all this within the context of the adoption cycle. They need to target user time-efficiency first, and then consider better outcomes (avoiding malfunctions, self-trouble shooting, etc.). Care professionals fight for better outcomes if the device does NOT slow them down. Time is KEY! OEMs must understand the clinical workflow and the contextual use of their products.

Q: If OEMs continue to develop smarter, more automated, and user-centric devices, what pitfalls may occur?

A: Product liability is a key issue. Anytime you create a "smart" device or an IT solution, FDA steps in and takes a hard look. It is certainly true for DSS and any intelligent software. But another pitfall includes the shift of training cost from the providers to the equipment vendor. The critical question asks what is the vendor's level of sensitivity to risk and cost, and what does the vendor want to do? Yet another issue involves the question of what professional layers can use this new technology.

Q: Even if the staff shortage is resolved, are the trends in product development described likely to achieve sought-after care quality and outcomes?

A: Everything depends on the time horizon. It is hard to say if the changes will occur regardless of staff shortage, but a large forcing function is the increasing cost of healthcare. I think a big trend is the training and education issues: it will be device and workflow specific. There will need to be more flexibility, eventually just-in-time training models, enabling users to quickly come up to speed on new products and evolving features of existing products, in order to realize the desired quality results from using the products in their workflow.

Healthcare providers can learn from other industries in terms of training and education. I think vendor-led initiatives will occur for market differentiation reasons. Vendors are better positioned to champion workflow changes because they have a longer term view due to R&D and manufacturing planning, and can truly influence healthcare.

For more information on Institute for the Future, please visit: www.iff.org/people/hh_panel.html

Long version of this interview: www.themarketechgroup.com/minute/tmtg-min18-Saxberg.pdf

ON THE HORIZON: New Challenges Put Pressure on Designers

HIGHLIGHTS

Changes in the U.S. workforce are altering the health delivery landscape:

- 30 states had a shortage of RN's in 2000; this is expected to climb to 44 by 2020.
- Allied health professionals represent 60% of the healthcare workforce, a shortfall of up to 2.5 million workers expected by 2020.
- The ratio of potential caregivers to the elderly population will decline by 40% between 2010 and 2030.
- Home care aides held about 700,000 jobs in 2004; expected to be one of the fastest growing occupations through 2014.

AT STAKE!

Other healthcare factor's challenging medical device developers and designers:

- Diagnostic and care workplace: continues to move from acute care facilities to freestanding clinics, physician's offices, long-term care facilities, and patients' homes.
- Medical error reduction pressure: as providers monitor and report adverse events, medical device vendors have increased exposure for design defects.
- Product liability: neither complying with FDA/ISO standards nor meeting "industry custom" is a sufficient defense; instead, the "safer-alternative design" legal standard prevails.
- Federal healthcare R&D funding: doubled in the past decade; capital market changes favors investments in product-line extensions and acquisitions, not long term R&D.

SO WHAT?

Future medical device product design can only succeed if these requirements are satisfied:

- Since healthcare workers will be fewer in numbers, less educated, spread thinner and working in step-down environments with different workflows, device design must correspond to these emerging use environments.
- Mitigating product liability must entail both a proactive and preventative effort; understanding how these cases are currently being litigated has implications for many stages in the design process.
- Ultimately the application of most medical devices is dependent upon operators; staff training and acceptance must be primary objectives within the scope of the design process.

Sources: US Dept. of Labor, Institute of Medicine, HRSA, Nursing Institute

THE ASSOCIATE CORNER: The Changing Designer Landscape

When a manufacturer brings a new product to the market, it is expected to have great technology, be easy to use, be inexpensive and have a gazillion features! Market pressures and the FDA demands that the products be safe to use with less operator error.

In general the principles of design have not changed over the years but as the designer gains more industry knowledge and the R&D manager develops new tools or methods to help solve problems, ultimately they both try to uncover the true "unspoken needs" of a user and produce innovative design solutions that are relevant to this market today. In recent years new steps have been added to the design process:

1) User research - to assure we are focusing on the correct user and his/her needs, the designer has expanded front end research prior to concept development. This includes activities like persona development, contextual research, and workflow analysis.

2) Product concept validation - a fast and repeated iteration of "design-model-test" helps to evolve the product concept. All fidelities of models, mock-ups and prototypes can be validated with customers using a participatory approach if the testing criteria are well defined in advance.

So the role of the designer continues to evolve under these new circumstances. He/she still strives to produce an elegant solution that is extremely functional, but also wants to make sure he/she is designing the appropriate solution that resonates with the intended market and its users. That forces the designer to be flexible, modify the design process, developing tools to establish better user requirements and product specifications.

Stephen Hooper, CEO of Designfairs USA, has been designing award winning medical products for a global market for over 23 years. Designfairs is a full service product development agency that often works with TMTG. For more information, go to www.themarketechgroup.com/info_press.php