TAKING THE HOSPITAL OUT OF THE HOME

How a Health Care Company Redesigned a Medical Device for Home Use

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An emerging concern of critical importance is the application of best practices regarding human factors in the design of medical devices for use in the home. If the medical device is very complex or counter-intuitive to use, it can often result in errors and lead to safety issues. Research findings indicate that lack of attention to human factors and contextual considerations during product development may lead to dangerous errors that have the potential for patient injury – or even death.

The application of user interface design principles and the participation of health care practitioners in the design and testing phases are very important. In addition to increased safety, an added benefit of this approach is the likelihood that good user-interface design will increase usage by patients and reduce the cost of worsening patient problems due to non-compliance.

This article has important implications for product developers, medical equipment manufacturers, and the medical and health care professional communities because of its implications for optimal product usage and user safety. The following project is a case in point and highlights some of the challenges faced in developing medical devices for home use, the methods used to overcome this problem and the benefits of doing so.

**CHALLENGES OF DESIGNING A MEDICAL PRODUCT FOR HOME USE**

User interfaces for consumer products and medical products should take into consideration not only the user and their abilities but also the context of use (the lighting, temperature, user-position, humidity, noise, etc.). Familiarity with the way most products operate also influences the way a person may use a new product or machine. That’s why it is important for the product developer to analyze all of this information in order to design an interface that prevents people from making mistakes. Interfaces that have not been tested sufficiently by users may fail to pick up on what may be confusing, misleading or illogical and lead to errors. In the case of a software product, it may be possible to “undo” the action and not cause too much harm.

A medical device can be used safely and effectively only if the interaction between the operating environment, user capabilities and device design is considered and integrated during the development stages. Many devices have rows of mechanical controls and displays. The designer should consider the ability of users to: quickly and properly identify controls and switches; read displays accurately; and associate controls with their related displays. Desirable features include functional grouping of controls and displays, unambiguous labels and easy-to-operate keys. Clear instructions and effective warnings are important. To simplify the design or user interface is actually quite challenging. Sometimes creators can get carried away by the various functions that can be offered and tend to put it all in, even when most users may only use a few main functions. In these cases, most of the rarely used buttons and functions should ideally be hidden away, keeping the user-interface simple and clear, with only the critical operations up-front.

**THE NEED FOR A NEW MACHINE**

Fisher & Paykel is an iconic New Zealand company that has launched several radical innovations over the years both in its appliances division and its health care division. The well-known dish-drawer dishwashers, fridges and washing machines, along with a number of pioneering health care products, have provided the company with a steady stream of innovations for the global market.

Fisher & Paykel Healthcare Corporation Limited (New Zealand) has recently introduced its new ICON continuous positive airway pressure (CPAP) devices for the treatment of obstructive sleep apnea (OSA).

CPAP machines have typically looked like medical appliances largely due to the fact that they are made by manufacturers who also make hospital medical equipment. In the hospital, this is a good thing. But in the home – and more especially beside the bed – these devices are not suitable.

The implications of the “medical looking” CPAP machines meant that sales were slow, and it was clearly time to work on improving the design to suit the home environment.

An international survey found that people thought a medical device in their home should not look “medical” or in any way reflect their illness, and this shed light on the way toward a new product design. The answer was to develop a radically new CPAP machine that would make people feel like things were normal in their home again. And so the ICON CPAP model range was born.

**HOW TO DEVELOP THE RIGHT PRODUCT FOR THE RIGHT CONTEXT**

Medical devices are now entering the space occupied by consumer electronics because they’re perceived as more “pleasurable” to have and use in the home. The ICON range integrates leading technologies into a stylish, compact and intelligent device to deliver a better night’s sleep for OSA patients. The F&P ICON also includes a digital clock, alarm and music playing capabilities to improve the user’s experience and enhance patient adaptation to CPAP therapy.

“The ICON combines both style and technology to fit unobtrusively into the home setting,” said Michael Daniell, Fisher & Paykel Healthcare’s CEO. “It has a very small footprint and incorporates innovative technologies.”

The product range spans three models: Auto, Premo and Novo. The Auto detects interruptions to normal breathing, and provides the appropriate positive airway pressure to meet the breath-by-breath needs of the patient with full efficacy and compliance reporting. The Premo model provides fixed pressure therapy with efficacy and compliance reporting, and the Novo provides basic compliance reporting.

The ICON products also includes Fisher & Paykel’s InfoSmart technologies, which provide a full range of communication and compliance reporting options, including data transfer and web-based compliance monitoring.

One of the main problems with the previous design was the size of the product; it was too big for the bedside table. This meant that the bedside table was often totally taken up with the CPAP machine, so there was no room left for anything else. People also had trouble operating the device because the on/off button was on the top of the unit and out of sight when the patient was lying on the bed. People did not like the visible tubes and of sight when the patient was lying on the bed. People did not like the visible tubes and medical look” of the product in their homes. The culmination of more than two years of intensive research and development, the ICON™ is a revolution in CPAP machine design. Looking no more obtrusive in your bedroom than a clock-radio, its shape allows for a fully internal humidifier – reducing...
the noise and improving efficiency – and makes it something that fits comfortably at your bedside.

THE UP-FRONT USER AND CONTEXT STUDIES

This new platform of products (see Figure 1) included a specific stage at the beginning of the development process (Input Definition Phase) where product usability and desirability were incorporated, taking up about 30 percent of research and development time, as opposed to the mere 5 to 10 percent that other companies take.

The design process began with a “vision” of a product that patients wanted to have beside their bed, and an emphasis on usability and development of the product form in the Input Definition Phase. Fisher & Paykel’s product developers spent a lot of time with users in sleep labs and hospitals with clinicians, and the insights gleaned from these interactions helped create initial requirements and technology inputs.

Simple spatial cardboard models were built to determine the form factor that best fitted the user environment and the bedside table. Usability analysis led to the large dial user-controls that could easily be found and operated – even during the night while lying down. Use scenarios were storyboarded, and actions like opening the humidification chamber lid and entering user menus were acted out in a bedroom situation at night to ensure that the best possible experience was provided. Role-playing by the designers and simulations of the environment were a big part of the research.

Computer-aided design (CAD) renderings were used to develop various concepts based on the user research for the most desirable CPAP. Full-size block models were made at each stage to get the real picture of the product and how it fitted into its environment. Three major shape iterations and more than 80 detailing iterations were made during the detail design phase. After that, CAD was used to design in features and iterate ideas using rapid prototyping.

User surveys in New Zealand, Australia and the United States were then used to hone the designs to the final shape, usability and colors. These surveys were conducted as mini in-depth interviews, and they used visual models to prompt discussion around preferences of style, color and image. A discussion guide was used to make sure the interview stayed on track. The 30-minute, one-on-one interviews were aimed at understanding why patients preferred certain colors and shapes over others. Patients had to choose between different machine shapes and color variations as well as various control and display placements. Patient surveys were done in the sleep laboratory because participants were in an environment similar to their bedroom with similar ambient conditions. This was important because environmental context can change perceptions of how well a product fits that environment.

The Development Phase began with detailed mechanical, electrical, production and software engineering design and concurrent tool-making, allowing critical real-life testing at an early stage. This iterative phase with lab and in-house testing ensured that the product met the appropriate requirements, many of which were dictated by standards bodies, such as the U.S. Food and Drug Administration and European Medical Device Directives. Production machinery and processes were developed as the part designs firmed up, and the production environment began running small volumes of preproduction product for validation purposes.

The Design Outputs phase involved final testing of product requirements, final user validation and a full specification of the device, including part and tooling drawings, production process, and validation of the entire manufacturing process.

FROM USER-DESIGN TO DELIGHT

The points below are considered at the beginning of the project in terms of design elements.

**Figure 1: User-centered Front-end Development Process**

(Project Time: 30% Input Definition Phase, 70%
Development, validation and production, 100% being the completion of the device.)

- **New Product Features:**
  - The “vision” – best aesthetic possible, ornamental and decorative
  - The easiest way to operate this device – usability
  - Use environment – the bedroom
  - Form factor, smallest footprint
  - Colors – bedroom colors
  - Material choices to reflect aesthetics
  - Basic CAD models only
  - Build full-size models rather than rely on CAD renderings
  - ThermoSmart and heated tube – get more humidity to user and less condensation on the tube
  - Built-in alarm clock/mp3 player – Wake up to music in the morning

Users described the auto-adjusting pressure for personalized treatment during sleep as one of the best advances in CPAP technology. It detects when a user is waking up and drops pressure accordingly to aid the transition back to sleep.

Manufacturing and design are co-located at the same open plan location, which is a huge advantage because of positive gains in communication and joint project ownership. Multiple iterations of the design were carried out rapidly due to the proximity of these functional groups.

Rapid prototyping involving in-house prototype tooling and soft tooling technologies were also used to speed up the process. Working closely with suppliers was critical to introducing new technologies and
processes that allowed our vision to develop into a reality.

Intellectual property (IP) protection was one of the major areas of concern throughout development. Close relations and frequent in-house meetings with IP attorneys helped protect ideas as they emerged from the drawing board.

REDEFINING THE PERCEPTION OF MEDICAL DEVICES

An in-house study showed that medical devices that don’t make a person feel like a patient and don’t look like hospital equipment are seen as more desirable. Patients are looking for medical devices to use in their home that appear natural and normal in the context of a home. Patients do not want to enter their bedroom and be reminded that they are sick and unwell.

BENEFITS OF THE NEW PRODUCT

Patient compliance is better than before and user errors have been minimized. Manual operations have been deliberately kept simple to reduce user errors. The number of selection buttons was limited, and user-interface buttons were designed to be large for ease of use and maintenance.

Decisions on user-interface were made based on user tests and the study of the product in its context.

“We are delighted with the positive response to ICON from CPAP users, clinicians and home care providers, and we have introduced the range into our international markets,” said Fisher & Paykel Healthcare CEO Daniell.

CONCLUSIONS

The context in which a medical product is used within a home and the proper fit within that environment led to a new product – one that looks more like a clock radio than a medical device. Good product development practice involves medical device users in studies and tests to achieve optimal design.

This article and the featured example demonstrate the value of considering the user-interface and operation context during design and development, particularly for medical devices since they require accuracy in usage and compliance. The example clearly showed the benefits of the initial user and contextual research, resulting in the rapid uptake of the new machine in New Zealand and Australia. Patient compliance increased as a result of a more easy-to-use and aesthetically pleasing product.

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