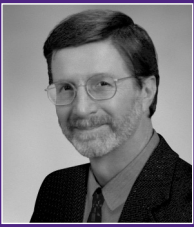


The Symbiq™ (Next-Generation) IV Infusion Pump

About the Author



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A Feature-Filled "Intelligent" Pump Developed with and for the End-User

The Institute of Medicine (IOM) has challenged medical device manufacturers to more fully utilize a user-centered (also known as human-factors) design in device development. In the case of infusion pumps, the end-users, primarily nurses, provide the chief input influencing design of the pump interface and the hardware itself. The Symbiq pump's development involved potential users and stakeholders at every phase of the design cycle to an unprecedented extent. Acting upon this input of several hundred potential users and stakeholders resulted in a feature-filled, user-friendly infusion pump.

What motivated Hospira to invest valuable resources in a user-centered approach? The primary motivation was to design a state-of-the-art infusion pump that would represent a quantum leap in terms of ease of use and improved patient safety. Over the past 20 years, the user interface in many infusion pump designs has been the subject of negative commentary due to difficulties in setup and programming.

In the fall of 2002, Hospira undertook a large-scale effort to "reinvent" the infusion pump. The purpose of this effort was to create an infusion pump that was easier to set up, manage and monitor and easier to use safely, helping caregivers avoid device-related medication errors. Clearly, there was a need for a new-generation infusion pump based on the sobering medication error statistics of the Institute of Medicine, United States Pharmacopeia and Institute for Safe Medication Practices (ISMP).¹⁻³

What is involved in a user-centered design? Before the first design drawings, the Hospira development team was in the field interviewing nurses, anesthesiologists / physicians, nurse and pharmacy managers, hospital administrators and biomedical engineers, listening to their insights on the advantages and disadvantages of existing infusion pumps

and what they thought was needed to produce the "ideal" infusion pump. At the same time, the Hospira team members conducted interviews in and made detailed observations of diverse clinical settings to understand user workflow issues related to infusion pumps. The data gathered from these initial activities were then used in the conceptual development phase.

Early in the design process, flow diagrams were created for every potential task performed on the infusion pump. Use Error Risk Analysis highlighted those tasks likely to have high risk to patients, and these tasks were prioritized for further scrutiny during the design process. Performance measures of success were established for these high-risk tasks (e.g., "ninety percent of experienced nurses will be able to insert the cassette the first time with minimal training") and then assessed via hands-on device testing involving clinically experienced nurses.

Usability evaluations involved tests of

- the graphical user interface (GUI) (including lettering, colors, tabs, scroll bars, buttons, start-up screen, pop-ups, on-screen help)
- audible alarms (evaluation of melodies versus pure tones)
- visual alarms (lettering, colors)
- LEDs (light-emitting diodes) and lighting
- LCD (liquid crystal display) readability, and
- ergonomic features (e.g., mounting hardware, stacking, cassette loading, multiple pump connection).

Usability issues requiring iteration

(i.e., testing, redesign, retesting, etc.) included

- audible alarms
- visual alarm displays
- complex multistep programming
- time entry widgets
- access to the emergency stop button
- flashing rates of LEDs for pump status
- symbols conveying "out of limit" conditions, and
- critical parameters for distance viewing.

For the GUI, a large 8.4 inch (on the diagonal) color LCD display with resistant touch screen input was selected. Optimal font sizes and type, as well as viewing angles (horizontal / vertical) and display brightness under various use scenarios, were determined from the hands-on experiments of clinical nurses in realistic-use settings. This feedback resulted in a display that is legible from up to 12 feet away. Screen navigation is enhanced by incorporating variable-speed scrolling.

Potential users indicated a need for more effective visual and auditory alarms to alert to fault conditions. The Hospira team adopted the recommendations of a recently approved international standard for medical device auditory alarms (IEC 60601-1-8:2003) to use unique melody patterns for infusion pumps to distinguish these from other potentially proximate devices (e.g., ventilators, vital sign monitors). Auditory and visual alarms were subjected to rigorous testing by potential nurse users to evaluate effectiveness and acceptability.

In selecting the cassette loading system, Hospira listened to potential users and adopted a semi-automatic process for ease of loading and protection against free-flow delivery. A flow stop is automatically engaged upon closing of the cassette carriage, and an audible alarm and touch screen messages occur if improperly loaded. A unique LED-based lighting system was embedded into the cassette loading compartment in order to visually communicate general pump status to the user. The selection of LED colors, the use of steady versus flashing conditions and the distance over which these LEDs would have to be visible was based on user input during realistic testing conditions.

Even the organization of IV tubing did not escape the notice of the Symbiq™ infusion system's design team. Upper and lower IV tubing guides are placed on the pump to facilitate tubing traceability and line management, helping to avoid tripping over the lines by patients, staff and visitors. These guides also help to prevent line contamination by keeping excess tubing off the floor.

The special pole and pole-mounting hardware for the infusion pump also completed user input and testing. The hardware design utilized ergonomic science to enhance the safety aspects for the end-user. For example, a rapid travel mechanism was incorporated

to help reduce the risk of repetitive stress injury of the wrist, which can occur with manual tightening of a traditional screw-type mechanism. The addition of an integral clutch prevents overtightening of the clamp, and the clamp itself allows rotation of the pump for ease of transport. In addition to providing input on individual components of the infusion pump, users "tested" device prototypes by performing specific tasks that mimicked clinical practice. If targeted performance measures were not achieved with a given task, that particular task was studied again and the device modified until users performed above the acceptable threshold.

Additional Features

Advanced features are incorporated into the Symbiq pump, such as the capability for intermittent, delayed-start, multistep infusions and interchannel sequencing. With the latter feature, channels can be run in any order, providing superior versatility.

Medication Management System Features

The Symbiq pump represents advanced IV infusion technology, with features designed to reduce pump-related medication errors.

The heart of the Symbiq pump's safety system is the Hospira MedNet® software that offers programmable drug libraries specific to the clinical care areas (CCAs) or patient population types within the healthcare institution. The capacity for up to 40 different CCAs with up to 400 different medications per CCA provides tremendous versatility for a customized approach to facility-wide patient safety. The Symbiq pump helps to assure safety software compliance by requiring drug library selection during pump programming.

Typically, a multidisciplinary team composed of pharmacists, nurses, physicians and other interested parties develop the drug libraries to promote the institution's medication best practices and guidelines. These drug libraries can be tailored to specific patient populations throughout the distinct patient care areas within the institution. For example, a particular medication can be assigned different dosing parameters depending on the unit where the patient is managed. Library modification is easily accomplished, with little "downtime".

During initial pump programming when the CCA is selected, the safety software will automatically engage the drug library designed for that particular CCA. Once the desired medication is selected, safety features such as "soft" and "hard" upper and lower drug dosing and dosing rate limits are in place. If an attempt is made to program outside of the medication's recommended "soft" limits, a warning appears on the screen. If the selected dosing exceeds "hard" limits, the pump cannot be activated. "Hard" limits cannot be overridden unless the institution specifically chooses to allow this (e.g., overriding may be allowed in selected CCAs or by authorized individuals after input of a passcode). At the end of the programming process, a final confirmation screen appears, to which the programmer must respond before the infusion can start.

The Hospira MedNet safety software was also developed to enhance quality improvement (QI) initiatives and assessment. All programming on a particular pump is recorded, enabling the creation of sophisticated event-log reports that can include drug identification and dosing data, frequency of "soft" and "hard" limits alerts and overrides and overall drug library compliance rates. Wireless capability offers remote data transfer, streamlining the data management process. This can help in preventing medication errors in near "real time" and supporting timely end-user re-education. Additional efficiency features include device preprogramming, utilizing the Symbiq pump's stand-by mode and electronics upgrading with electronic board swapping on-site, similar to what occurs with a personal computer. Lastly, the open architecture of the Hospira system supports interfacing with a variety of hospital information systems.

Conclusion

Extensive human-factors engineering and the results of iterative testing with frontline users were incorporated into the design of the Symbiq infusion system, which was awarded both the 2007 Medical Device Excellence Award and the Human Factors and Ergonomics Society 2006 User-Centered Product Design Award.^{4,5} Symbiq offers a broad array of features designed to help increase patient safety and quality of care, working with Hospira MedNet software to support hospitals in defining and applying their best clinical practices in healthcare delivery.

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