

Application Of Human Factors Engineering In Medical Product Design

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Advancements in medical instrumentation are often judged on technical factors such as increased accuracy or increased capabilities without regard to the operator, or to the degree of knowledge or training required to make the instrument perform all of the advanced functions for which it was designed. Because patient safety and efficient use of an instrument are ultimately determined by the operator, it is imperative that medical instruments be designed not only with capability and functionality in mind, but with the operator in mind as well. Such operator-oriented product design is accomplished most comprehensively and efficiently by the integration and application of *human factors engineering* into all phases of the development cycle of medical instrumentation. This paper describes the step-by-step human factors design process with examples from the design of a specific family of intravenous infusion devices.

Index Under: Human Factors Engineering; Design, Medical Devices; Ergonomics; I.V. Infusion Device Design.

INTRODUCTION

As medical instrumentation has become more complex, there has been a corresponding increase in operational problems for the user. This has become particularly apparent with the proliferation of microprocessor-based medical instruments which have increased product capability and flexibility. While these products offer the potential for more effective clinical therapy, such increased capability and flexibility often have resulted in products which are difficult to use. This, in turn, has limited the effectiveness of these products and increased the inherent possibility for human error.

This paper addresses the discipline of *human factors engineering*, also called ergonomics, and describes how this discipline can be integrated into the design and development of medical instrumentation. The objective is to produce a product with an effective, efficient, and safe user/product interface. In the following discussion, the development cycle for medical instrumentation will be explored using, as examples, three specific products that were significantly affected by human factors engineering.

HUMAN FACTORS ENGINEERING DEFINED

Human factors engineering is the application of scientific knowledge of human capabilities and limitations to the design of systems and equipment to produce products

with the most efficient, effective, and safe operation. In addition, human factors engineering is the consideration of the methods and procedures involved in the use of these products and their operating environment.

The human factors techniques used to accomplish these goals identify and address all possible points of interface between the user and the equipment. For most products, the typical *interface points* include instrument control panels and displays, operating procedures and instructions, the operating environment, and user training requirements. The human factors engineer must include a careful study and analysis of all information required to operate a particular system, the operational characteristics of that system, and the skill levels of the anticipated users. Only then can the human factors analysis assist in the design to achieve the optimum user/product interface.

THE IMPORTANCE OF HUMAN FACTORS ENGINEERING TO MEDICAL INSTRUMENTS

When designing new medical instruments, several criteria must be kept in mind:

1. Medical instrumentation must be easy to use and understand. This is particularly important in a hospital environment where there are three different work shifts per day, possible product use seven days a week, and

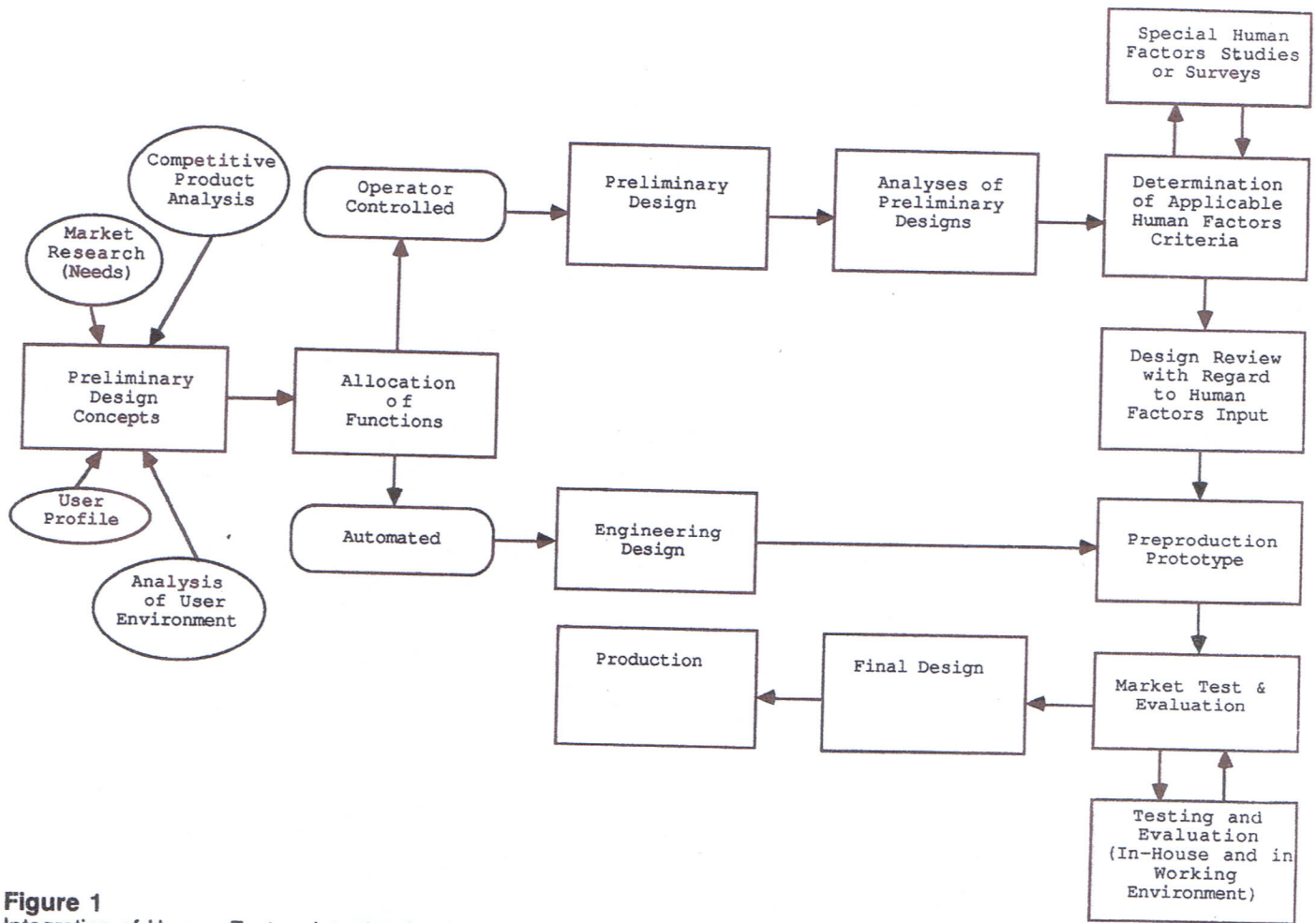


Figure 1
Integration of Human Factors into the development process.

where the users range widely in their knowledge of the proper use of the product.

2. The need for feedback (such as indicators, audible tones, and diagnostic information) which allows the user to determine that the instrument is operating properly is essential.
3. The instrument's operating environment must be closely evaluated, defined, and understood. This includes size limitations, compatibility with other equipment, the potential need for portability, and possible patient or visitor tampering which may dictate special considerations during the design process.

Using these criteria, it is obvious that an effective, efficient, safe product cannot be developed without at least some human factors considerations.

INTEGRATION OF HUMAN FACTORS ENGINEERING INTO THE DEVELOPMENT PROCESS

To be effective, human factors engineering must be an integral part of the product development process from concept through production. Figure 1 describes how there can be comprehensive human factors involvement in product development.

Preliminary Design Concepts

During this phase of the project, the human factors engineer works with market researchers, helps to formulate and implement questionnaires, conducts interviews with potential users, evaluates comparable competitive products, and analyzes industry and regulatory standards. A close examination is made of the proposed operation of the potential product relative to the range of skills, educational background, and experience levels of the intended users. The possible environments in which the product will be used are then identified.

Allocation of Functions and Preliminary Design

During this phase, the human factors and design engineers determine which functions will be automatic, and which will require manual points of interface between the operator and the instrument. The *points of interface* are those operations the user has to monitor and control in order to obtain the desired output or feedback from the instrument.

The preliminary design is then analyzed relative to both the operating environment and the skill level of the most untrained operator. This task is performed by taking draw-

ings or artist sketches into the operating environment and obtaining reactions from potential users.

If funding and scheduling permit, this phase of the project also should include a study using a preliminary prototype of the product. Evaluation of the prototype by 20 to 30 potential users will provide information on potential operating errors, the degree of difficulty of use, and other important performance variables.

After users have seen the illustrations or operated the preliminary prototypes, it is very important to obtain their subjective reactions to the product through questionnaires and structured in-depth interviews. Where appropriate, focus-group meetings can be held to address the subject. The information obtained, along with applicable information from human factors textbooks (McCormick, 1970; Morgan, 1963; Woodson, 1964), should be used to evaluate the product design.

Pre-Production Prototype

Once the product has been evaluated, a pre-production prototype should be built, or the earlier prototype updated for further evaluation and market testing.

Market Test and Evaluation

This phase of the project involves not only the actual product testing, but also a thorough evaluation of the feedback from the market test by both human factors and marketing as well as by engineering personnel.

Final Design

During this phase of the project, the design is finalized by incorporating any changes resulting from the marketing test and evaluation.

Production

Finally, the product is produced and placed on the market. While the product is in production, human factors involvement should continue to monitor product performance, analyze proposed design changes, and assist in the establishment of appropriate user training programs.

AN EXAMPLE OF THE HUMAN FACTORS DESIGN PROCESS

Quest Medical, Inc. included extensive human factors input throughout the design and development cycles of their family of state-of-the-art I.V. infusion devices. The Quest Model 1001 Intelligent Infusor[®], the Model 2001 Intelligent Infusor[®], and the Model 521 Intelligent Pump[™] (Figure 2) were designed to volumetrically administer intravenous (I.V.) fluids to patients undergoing fluid therapy. The Models 1001 and 521 control a single fluid while the Model 2001 provides for automatic sequential delivery of two different solutions at different rates.

In all cases, this is accomplished by integrating microprocessor circuitry and complex algorithms into the instrument's design and by interfacing it with a cassette which is an integral part of the disposable I.V. administration set.

In spite of the potential complexity of these microprocessor-based products, a human factors design process resulted in easy-to-use products. Fluid is delivered according to the VOLUME and RATE selections entered using the control panel, and all of the pertinent information is clearly displayed. Ease-of-use was accomplished by focusing human-factors efforts on the following areas:

Product Operation and Allocation of Functions

There were extensive discussions with both hardware and software engineers regarding which functions the microprocessor-controlled devices would perform and which tasks the user would need to perform to ensure proper operation of the devices. These discussions included the theory of operation of these devices as well as the limitations in the available display technologies.

User and Operating Environment Analyses

The nurse and the hospital environment were the next focus of the human factors design project. As discussed previously, there is a large variation in educational backgrounds and skill levels within a typical hospital nursing staff. Thus, it was decided that the products could not be complex in operation or appearance since either of these factors could intimidate some users. (Previous human factors studies have shown that computer-related or complex products can be designed to be considerably more "user friendly.") (Le Cocq, 1977) The human factors analyses determined that the Quest devices should include:

1. Easily identified, non-intimidating, and easy-to-use controls.
2. Clear, concise instructions.
3. Integral prompting messages which direct the user through the procedures required for the correct use of the instrument and facilitate self-training.
4. Displays which clearly indicate all functions which are available to the user.
5. The elimination of displays that the operator cannot control or that are not necessary for proper instrument operation.

The hospital environment also was a major factor in this human factors instrument design. Review of competitive instrumentation, user feedback and industry publications indicated that susceptibility of I.V. instrumentation to fluid spillage was responsible for high failure rates and potential liability concerns. Therefore, the case was designed to eliminate leakage in the event of fluid spillage. It was also determined that inadvertent instrument tampering by patients or hospital visitors could create potential patient hazards. Therefore, the designs included a protected on/off



Figure 2
Quest Family of Infusion Devices.



Figure 3
Quest Model 1001 Intelligent Infusor® Control Panel.

switch and a limited keyboard lockout feature when an instrument is in operation. Feedback was obtained from a committee of nurses to evaluate their acceptance of the new and preliminary design concepts.

The resulting control panel designs for the Quest Models 1001 and 2001 are shown in Figures 3 and 4 respectively. The important human factors benefits of these designs are:

1. Overall Control/Display Approach

The membrane touch-sensitive switch panel was designed with a close display/control relationship so each arrow on the control panel is an individual switch which is located immediately adjacent to and below the display it controls. This makes programming the RATE and VOLUME a much easier task than if the controls were remotely located from the display.

Previous human factors studies (Le Cocq, 1976) on similar consumer products indicated that the optimum rate at which electronic displays can change and still maintain accurate setting control is 2 Hertz. This rate was used in all of Quest's infusion devices.

2. Display Design

The blue-green, vacuum fluorescent, alphanumeric displays were selected for their clarity even in a brightly illuminated room since each one displays pertinent data, prompting messages, or alarm conditions.

3. Graphic Displays/Mimics

Graphics and *mimics* also were used to simplify the use of Quest's devices. On the Model 1001, the RUN switch is shaped like a typical I.V. fluid container, as shown by Figure 3. And, on the Model 2001, which can deliver two solutions (Figure 4), the membrane switch panel depicts a mimic, or graphic, of two containers (one large, representing the primary container,

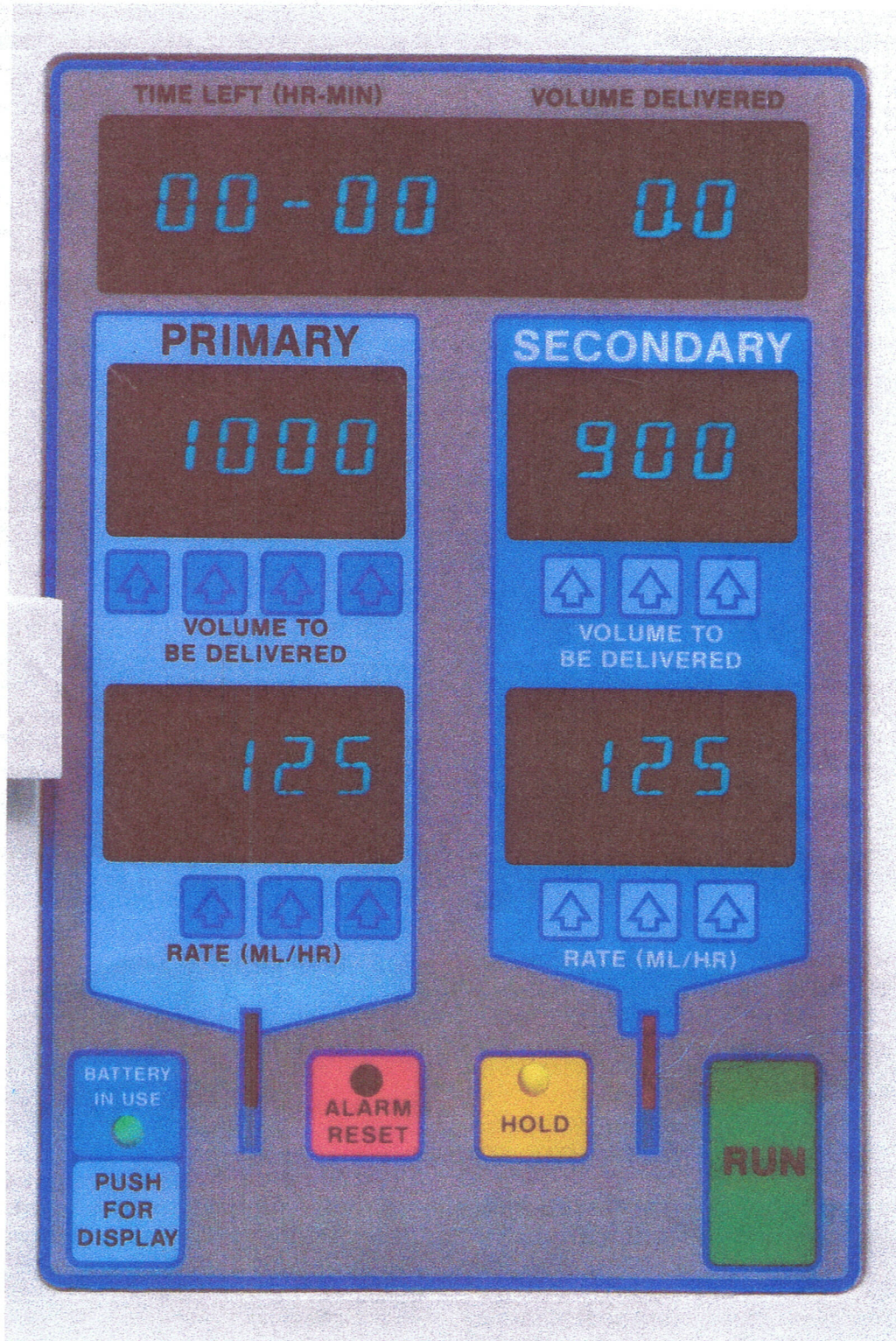
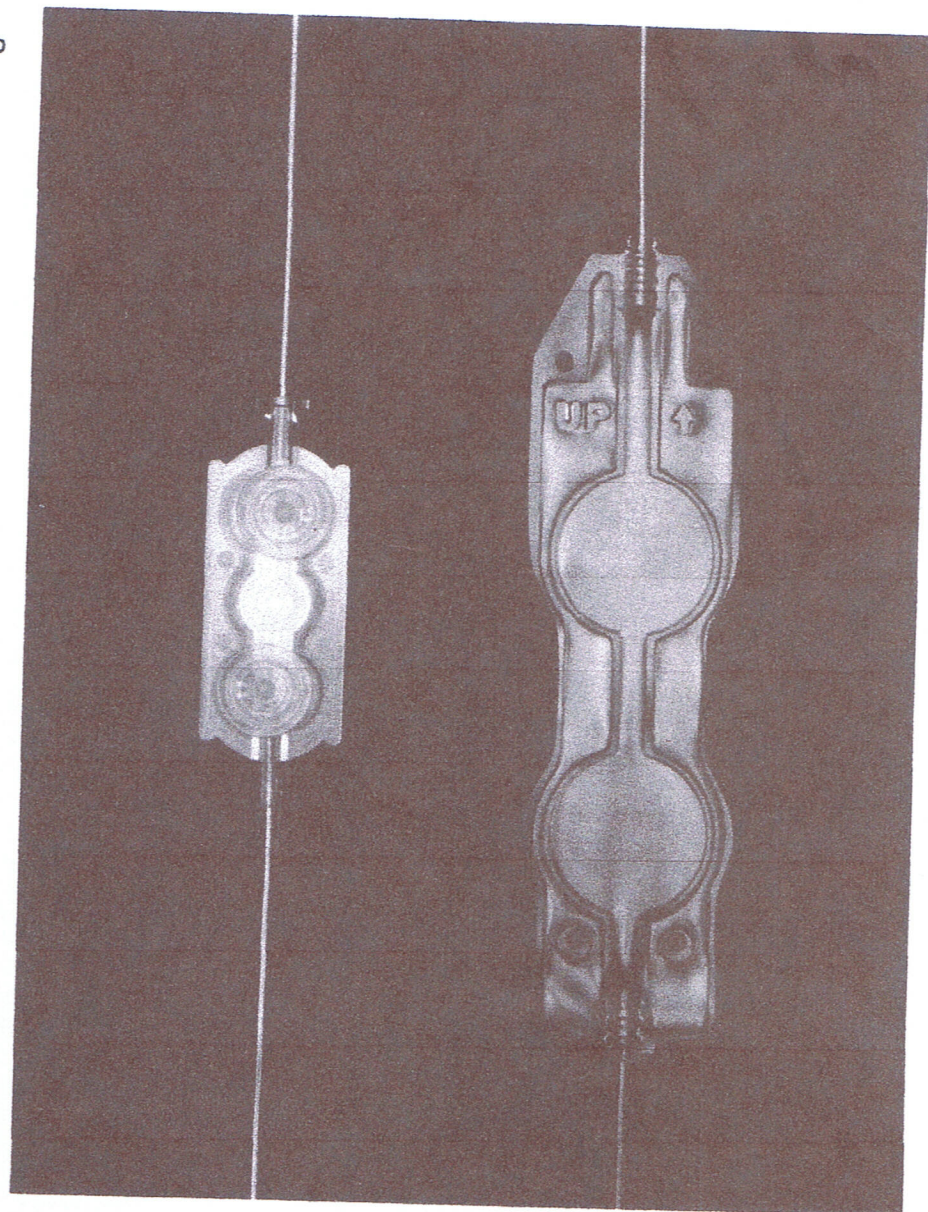


Figure 4
Quest Model 2001 Intelligent Infusor® Control Panel.

Figure 5
Acc-Q-Metric® Cassette (left) and Pump
Cassette (right).



and one smaller container, representing the secondary container).

Below each of these images, is an array of four green LED's that flash in sequence from top to bottom simulating fluid flow. The rate of this sequence varies depending on the flow rate. The perceptual effect of this apparent downward motion, of flow, is referred to as the Phi Phenomenon (Candland, 1968).

4. Display Color Coding

In addition to the VOLUME and RATE setting switches, there are four operational controls that are color coded. The RUN switch is green (indicating go), and the ALARM RESET switch and LED are red (indicating stop) since fluid delivery is stopped whenever the instrument goes into the alarm mode and since pressing this switch stops the audible tone of the alarm. The HOLD switch and LED are yellow (indicating caution) since being in this mode enables the instrument settings to be changed. The BATTERY IN USE LED

is green to indicate that the device is running even when it is unplugged and the large displays are extinguished.

5. Control Panel Display Labeling

All displays and switches are clearly labeled with capital letters throughout. Included in the labeling are the units associated with the applicable display, for example: ML/HR (milliliters per hour).

6. Audible Alarms

When a problem occurs, a pulsating, audible alarm serves as an additional cue for the user. At the same time, the red ALARM LED illuminates and an alarm message is displayed indicating the nature of the problem. This prompting message flashes off and on at a 2 Hertz rate.

Learning-Transfer from One Product Design to Another

The same control panel design techniques, human factors features, and operational procedures were maintain-

ed on all three of the Quest instruments because the same individuals could routinely be required to operate any of the instruments. Distinctive control panel colors are used to clearly differentiate the various instruments from one another.

Cassette Installation

Important human factors features also were included in the instrument/cassette interface design. For example, with the symmetrical design of both the infusor and pump cassettes, shown in Figure 5, any problems with side-to-side orientation were eliminated.

Instruction Manuals and Labels

The instrument operation manuals and the instruction labels that appear on the equipment also were evaluated during the human factors design for both clarity and accuracy. This was done by comparing each manual or label with the corresponding product to ensure that all instructions were clear from the user's standpoint, and that they correlated with actual instrument operation. Recommendations for specific changes were then incorporated into the final manuals and instruction labels.

Market Tests & Evaluations

Finally, acceptance of the human factors designs of the I.V. infusion products was measured by both customer evaluations and third-party evaluations. In June, 1985, the **Emergency Care Research Institute (ECRI)** published a comparison of infusion controllers, including the Quest Model 1001 infusor, and stated, "The Quest unit has exceptional accuracy, is easy to use (e.g., flow rate calibrated), and has excellent human factors design (e.g., lighted, individual displays)," (ECRI, 1985). In this author's opinion, the acceptance and positive evaluation of these particular product designs confirm the value of human factors engineering as a major part of the medical product development process.

CONCLUSIONS

By incorporating human factors design procedures and criteria into the design and development process, medical

instruments can be more responsive to user needs, have a lower possibility of human error, thus making them safer to use, and easier to operate. Human factors engineering should be a routine part of all new medical product design.

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BIOGRAPHY

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Andrew D. Le Cocq currently is an Assistant Project Engineer with the Fort Worth division of General Dynamics and a private human factors consultant. He received his B.S. degrees in Mechanical and Industrial Engineering from the University of Washington, and his Master of Automotive Engineering degree from the Chrysler Institute of Engineering. In addition, he has been involved in designing wireless robotic devices, 3-D video viewing systems, computer products, airplane cockpits, and closed captioning equipment for the hearing impaired. He holds three patents, has applied for two others, and is an active member of the Human Factors Society.

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