

# Design and Implementation of Medical Instrumentation

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**W**ITHIN our society is a technical subculture that has brought about a significant increase in the quality, as well as complexity, of medical care. Society's demands for quality medical care, and the common belief that "more is better," have spurred the development of medical instrumentation. Industry, medical, legal, academic, and governmental sectors have, in either cooperation or conflict, been responsible for the development of sophisticated medical instrumentation, for example, imaging that can twist the body inside out, put it back together, and provide a high-resolution digital picture with patient information skillfully and artfully printed on it. On the other hand, in some cases a "calibrated eyeball" and a pair of tweezers are sufficient diagnostic and therapeutic tools to solve the patient's problem.

Medical personnel responsible for patient care and for the instrumentation necessary to provide that care are often technologically subverted. Nurses are spending more time with instrumentation and less time with the patient. The progression to "he can't be turning blue because the ventilator is working and the monitor is not alarming" is not off in the future—it's happened...and the patient is blue!

The engineer, particularly the biomedical engineer, is in a unique position to assist in the growth and safe use of medical instrumentation. If he becomes familiar with the mechanisms of instrument failure and success, and methodically reviews each new design with these in mind, the result will be safer, more effective, and more useful instrumentation.

## PERFORMANCE PROBLEMS

The failure of instrumentation to perform its intended function can be the result of component failure, design flaws (electrical, mechanical, or software), interference (from patient, equipment, or environment), or operator error.

### Component Failure

Current production and quality control test procedures among manufacturers are such that component failure leading to instrument malfunction is more common than it should be. As experience and automation make manufacturing and quality control test procedures more efficient, the incidence of component failure should decrease substantially.

### Design Flaws

Electrical, mechanical, and software design flaws that go undetected by the manufacturer, but are discovered by the user, are usually the result of poor design coordination, a deficiency in the structure of the manufacturer's prototype design and evaluation procedures, or a lack of understanding of clinical need and limits.

Often, too little thought is given to assessing the risk-benefit ratio of selected performance and control features. Improper instrument design almost ensures that, at some time, the device will be misused. An example is the inclusion of an unmarked "alarms off" position at the lower adjust-

ment of an alarm limit control. A user not familiar with the subtleties of operating that device may think that such an adjustment will result in an alarm setting at a value just lower than the last marking. Even if the function of this control is clearly defined in the operator's manual, it is not inherently obvious to the user. Thus, if misapplication or misuse does occur, some responsibility rests with the designer.

The use of microprocessors has made the job of developing and implementing "glitch-free" instrumentation that much more difficult. Most medical device manufacturers have limited experience in the quality control methods necessary to test computerized instrumentation. In addition, completely testing such systems (as is often done with aeronautic or spacecraft instrumentation) is quite expensive; it can be difficult to decide which procedures are really necessary for inclusion in specific medical instrumentation quality control procedures.

The flowchart shown in Fig. 1 illustrates a model for the design, evaluation, and implementation of a medical instrument. This model should be used only as a guide, and changes (additions and deletions) to fit the actual need of the particular instrument under development should be made as needed.

It is imperative that personnel from engineering, clinical testing, and marketing specify the task definition. Many errors, which would otherwise be detected later in development or after the product is introduced into the field, can be discovered and dealt with, perhaps more cost-effectively, if users, designers, evaluators, and business and marketing personnel interact at the outset. Such interaction can reduce later costs (for example, modification or retrofitting), resulting in a lower product development expenditure by the manufacturer, a lower acquisition cost for the user, and an overall reduction in expenditures for health care. A classic mistake by manufacturers has been to rely heavily on a single consultant. If his advice fails to meet practical and business needs, the instrument may be both clinically and financially unsuccessful.

Although it is not uncommon for biomedical engineers to control prototype development because of their experience with engineering design and knowledge of physiological systems, it is a mistake to exclude others from this process. Critical decisions involving trade-offs and implementation are made during prototype development; an aggressive open-door policy to promote discussion among engineers, clinicians (users), and consultants can result in a consensus and informed decisions. Periodic review of prototype status by the consulting and developing groups, including a discussion of issues and solutions, may eliminate what might otherwise become serious future problems.

Prototypes must be evaluated in steps, from least to greatest risk and from least to greatest difficulty within each step. It is unwise and unsafe to jump directly from prototype development to actual clinical trial. Safety, performance, and human factors characteristics must first be explored in laboratory and simulated environment evaluations. Such testing can be expensive, and may be abbreviated for simple devices or when substantially equivalent devices have already been tested. (Considerable discussion over whether two devices are "substantially equivalent" is often warranted.) Decisions to modify evaluation procedures should be made by the interdisciplinary group during task definition, so that such decisions can be legitimate and informed.

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