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UNIT 1- FUNDAMENTALS OF MEDICAL INSTRUMENTS

GENERAL CONSTRAINTS IN DESIGN OF MEDICAL INSTRUMENTATION

Medical equipment are primarily used for making measurements of physiological parameters of the human body and also in some cases a stimulus or some kind of energy is applied to the human body for diagnosis and treatment. Some of the important factors, which determine the design of a medical measuring instrument, are:

• Measurement Range: Generally the measurement ranges are quite low compared with non-medical parameters. Most signals are in the microvolt range.

• Frequency Range: Most of the bio-medical signals are in the audio frequency range or below and that many signals contain dc and very low frequency components.

These general characteristics of physiological signals limit the practical choices available to designers of medical instruments. Besides, there are some additional constraints, which need to be

considered while designing a measurement system for medical applications. Some of these are:

Inaccessibility of the Signal Source: One of the major problems in making measurements from a living system is the difficulty in gaining access to the source of the physiological variable being measured. For example; measurement of intracranial pressure in the brain requires the placement of a sensor in the brain, which is quite a difficult task. Besides, the physical size of many sensors may put a constraint for its use on the area of interest. Evidently, such inaccessible physiological variables must be measured indirectly. The typical example of making indirect measurement of blood pressure on the brachial artery is that of using cuff based Korotoff method. In such cases, corrections need to be applied to data that might have been affected due to the indirect measuring

process.

Variability of Physiological Parameters: Physiological variables of interest for measurement from the human body are rarely deterministic as they are generally time-variant. In other words, many medical measurements vary widely among normal patients even when conditions are similar. Therefore, the physiological variable must be represented by some kind of empirical, statistical and probabilistic distribution function. Many internal anatomical variations exist among patients and therefore, the variability of physiological parameters from one patient to another is a normal observation. Therefore, statistical methods are employed in order to establish relationships among variables.

Interference among Physiological Systems: Many feedback loops exist among physiological systems and many of the interrelationships amongst them contribute to this inherent variability of physiological signals. In other words, stimulation of one part of a given system generally affects all other parts of that system in some way. Also, unlike many complex non-medical systems, a biological system is of such a nature that it is not possible to turn it off and remove parts of it during measurement procedure to avoid interference from undesirable physiological signals.

Transducer Interface Problems: All measurement systems are affected in some way by the presence of the measuring transducer. The problem gets compounded while making measurement on the living system where the physical presence of the transducer may change the reading significantly.

Also, the presence of a transducer in one system can affect responses in other systems.

Adequate care needs to be taken while designing a measuring system to ensure that the loading effect of the transducer is minimal on the source of the measured variable.

High Possibility of Artifacts: The term artifact refers to an undesirable signal that is extraneous to the physiological variable under measurement. The examples of artifacts are: 50 Hz electrical interference, cross talk and noise generated within the measuring instrument. A major source of artifacts in medical instruments is due to the movement of the subject. Many of the transducers are sensitive to the movement and therefore, the movement of the subject result in generating spurious signals, which may even be large enough to obscure the signal of interest. This type of situation puts a heavy demand on the signal conditioning part of the measurement system.

Safe Levels of Applied Energy: Nearly all biomedical measurements require some form of energy to be applied to the living tissue or some energy gets applied as an incidental consequence of transducer operation. For example, ultrasonic imaging techniques depend upon externally applied ultrasound energy to the human body. Safe levels of the various types of energy on the human subjects are difficult to establish. However, designers of medical instruments depend upon a large number of studies carried out by numerous researchers, which establish the threshold of adverse affects by the applied energy.

Patient Safety Considerations: Medical instruments have to be physically connected to the patient in some way or the other. In case it happens to be an electric or electronic equipment, the possibility of an electric shock hazard is very strong unless adequate measures have been taken in the design of the equipment. In addition, the equipment is used by non-technical medical and paramedical staff and their safety needs also to be ensured. Various organizations at national and international level have laid down specific guidelines to provide for the safety and effectiveness of the medical devices intended for use on human subjects.

Reliability Aspects: In case of life saving equipment like defibrillators, their failure to operate or provide desired output can become a potential life threat for the patient. Therefore, equipment must be reliable, simple to operate and capable of withstanding physical abuse due to transportation within the hospital or in the ambulances and exposure to corrosive chemicals.

Human Factor Considerations: As a result of the increasing complexity of medical devices and systems, the demand on physicians and paramedical staff using the equipment have continued to grow. The equipment requires a high amount of information exchange between itself and the user in order to monitor and control the technical functions of the system. Furthermore, medical staff generally have only little experience in working with complex technical system. There is a risk that the medical staff is not able to master the equipment adequately for every task. This inadequacy

can increase the probability of error and reduce the quality and reliability of a clinical procedure. As a result, the desired or intended performance of the whole system may not be achieved due to deficiencies in man-machine interaction. The user interface design issues therefore assume more and more importance in case of medical equipment.

Government Regulations: During the initial stages of introduction of technology and a range of

diagnostic and therapeutic devices in the medical field, there was almost no government control on their design, testing and sales. Situation is rapidly changing and government regulations are being introduced to ensure that the equipment perform their intended

function and are safe to operate and function. Designers of medical instruments should therefore be fully conversant with all such regulations on a particular product or system issued by national and international agencies. It is thus obvious that there are many factors that impose constraints on the design of medical
instruments. In addition to these, there are general considerations, which need to be considered into the initial design and development of a medical instrument. These factors are:

Signal Considerations*:* Type of sensor, sensitivity, range, input impedance, frequency response, accuracy, linearity, reliability, differential or absolute input.

Environmental Considerations*:* Signal-to-noise ratio, stability with respect to temperature, pressure, humidity, acceleration, shock, vibration, radiation etc.

Medical Considerations*:* Invasive or non-invasive technique, patient discomfort, radiation and heat dissipation, electrical safety, material toxicity etc.

Economic Considerations: Initial cost, cost and availability of consumables and compatibility with existing equipment.

Obviously, a project for a commercial medical instrument is quite complex which must take into consideration several factors before it is launched for design and development. In addition, the association of the engineering design team with motivated medical professionals is essential for the success of the project. This association is useful not only during the development process, but also for the clinical trials of the product so developed.