Technical Information Report

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Evaluation of clinical systems for invasive blood pressure monitoring

AAMI
Advancing Safety in Health Technology

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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

EVALUATION OF CLINICAL SYSTEMS FOR

INVASIVE BLOOD PRESSURE MONITORING

1 Introduction

This document reviews fundamental considerations regarding the evaluation of invasive blood pressure monitoring systems for use with patients. The goal of the evaluation is to determine which monitoring system (or kit) will, on the average, perform the best at any specific institution in the hands of those people who are responsible for assembling the system immediately before patient use. The document is intended for biomedical equipment technicians (BMETs) and clinical engineers (CEs) who are part of the decision-making process regarding the selection of complete invasive blood pressure monitoring kits (tubing, stopcocks, transducers, and continuous flush devices), or individual components. The intent is to provide guidelines for decision making and methods of engineering evaluation. The test methodologies range from needing little to no specialized equipment to using hydraulic pressure generators with personal computer data acquisition and processing. This document will only briefly address more advanced approaches such as impulse response testing using hydraulic pressure generators and mixed radix Discrete Fast Fourier Transform (DFFT) analysis. These advanced techniques are particularly useful for those wishing to investigate individual components to optimally tune the system as a whole using products from many different sources.

The objective of any patient monitoring system is to provide high-fidelity measurements that accurately reflect the physiologic state of the patient. Whether discussing measurements obtained through electrocardiograms or invasive blood pressure monitors, the purpose is to connect to the patient a system with adequate frequency response to reproduce the desired event faithfully. Unfortunately, this is a difficult task for invasive blood pressure monitoring to accomplish.

Two basic elements are involved in faithful reproduction of physiologic pressures:

- Static response is concerned with the ability of the monitoring system to accurately determine average (mean) blood pressure or constant pressure.
- Dynamic response is concerned with accurately reproducing rapid changes in pressure, such as the blood pressure waveform and associated parameters such as systolic pressure, diastolic pressure, and rate of rise (dP/dt).

NOTE—dP is the mathematical form representing the change in P or change in pressure. dt is similar for the change in t or time. Therefore, dP/dt is the change in blood pressure P divided by the change in time or the time interval.

Static measurements are much easier to make accurately than dynamic measurements. For example, the mean arterial blood pressure could theoretically (not an acceptable practice due to the risk of exposing the patient to mercury) be measured accurately with a simple mercury manometer connected to an invasive pressure catheter even though this type of system has almost no frequency response. Also, the central venous pressure can be measured with a simple water manometer. Static measurement errors vary from the correct value by a constant or constant percentage. If the static error is known, users can simply subtract or add a constant or constant percentage at any time from the measurement to obtain the correct value. Static measurement errors result from: (1) improper zeroing of the transducer (for example, failure to re-zero after warm-up of the transducer); (2) improper sensitivity of the transducer or monitor; or (3) failure to set the zero level of the transducer to the level of the right atrioventricular valve (estimated using the mid-axillary line).

The components of mean pressure that vary with time (such as respiration) are very slow and easy to measure compared with the dynamic response—rapid changes in the blood pressure waveform produced by each beat of the heart. Since dynamic responses such as systolic and diastolic pressure and the rate of rise are computed from the basic blood pressure waveform, errors in reproduction of the waveform will result in