# Technical Information Report

AAMI TIR9:1992

# Evaluation of clinical systems for invasive blood pressure monitoring

AAMI Association for the Advancement of Medical Instrumentation

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**Evaluation of Clinical Systems**
**for**
**Invasive**
**Blood Pressure Monitoring**

Association for the Advancement of Medical Instrumentation

AAMI TIR No. 9—1992

# Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring

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This technical information report was developed by the AAMI Blood Pressure Monitoring Committee. Committee approval of the standard does not necessarily imply that all committee members and reviewers voted for its approval. The committee currently has the following members:

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## EVALUATION OF CLINICAL SYSTEMS FOR

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# 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

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errors in the estimation of the waveform parameters.

Unlike static errors, dynamic measurement errors do not vary from the correct value by a constant or constant percentage. These errors are most often associated with exaggerated (falsely elevated) systolic pressures and dP/dt. Dynamic errors result from changes in the system performance over time (for example, system response degradation resulting from the use of a continuous flush device), or changes in the system requirements imposed by changes in the patient's heart rate and contractility. The dynamic response is critical for measuring the parameters of a rapidly changing pressure, such as systolic and diastolic pressures and the rate of rise (dP/dt) of a blood pressure waveform, but has virtually no effect on mean blood pressure.

The errors attributed to a system that is not capable of an adequate dynamic response can create serious problems with patient management. Many clinicians are concerned about the systolic pressure because it is the pressure that relates to the maximum stress placed on vascular suture lines following heart and vascular surgery, and on vascular abnormalities like aneurysms. Systolic pressure, however, is the most difficult to measure accurately and is very often associated with gross errors (false elevation) resulting from distortion introduced by the measurement system. Unfortunately, when nurses communicate blood pressure to physicians they typically report only systolic pressure. Mean pressure would be a better choice because its accuracy does not depend upon adequate frequency response.

In order for the system to perform adequately, the physical components have to respond more rapidly than the event being measured. However, system dynamic response is affected by the inherent physical properties of the fluid, tubing, and transducers. The fluid that fills the system provides the inertance of the system. The distensibility of the walls of the tubing, any included air bubbles, and the deformable part of the continuous flush device make up the compliance of the system. The fluid viscosity caused by the movement of fluid within the system makes up the resistive component of the system.

The inertance and compliance elements interact with simple resistive elements to produce damped resonance within the monitoring system. Resonance, which results in selective amplification of certain frequency components of the blood pressure waveform, is then responsible for distortion of the waveform that leads to incorrect values of systolic, dP/dt, and possibly diastolic pressures.

Usually the inertance and compliance of the transducer itself can be neglected because they are so very small, compared to the inertance and the compliance of those components of the plumbing required to connect the system to the patient. The resonant frequency of many transducers without tubing and fluid is approximately several kilohertz (kHz). However, when high-pressure tubing, stopcocks, and a cannula are added to the transducer, the resonant frequency typically drops into the range of 6 Hz to 30 Hz. (The drop in resonant frequency, if low enough, will result in significant distortion of the pressure waveform and could lead to improper clinical management of the patient.)

## 2 The evaluation process and statistical sampling

The evaluation process consists of two phases: (1) engineering evaluation of system performance; and (2) evaluation of ease of use and acceptance by clinicians. The second phase is very subjective and usually performed by soliciting comments from physicians and nurses as to ease of use, reliability, and confidence level. The relative weight given to the engineering evaluation compared to the clinical evaluation will have to be negotiated. A system that is technically superior is not in the patient's best interest if clinicians cannot intuitively use it to produce that superior response.

Each disposable blood pressure monitoring system that is to be evaluated (for example, 10 kits for each system) should be configured exactly the way that it will be applied to the patient. A system should never be accepted for evaluation under the assumption that small differences (e.g., an extra stopcock, or an extra foot of tubing, or extra 6-inch extension tubing) will not make any difference. *Only the system that is configured exactly the way that it is intended to be applied to the patient should be evaluated*. Each system intended for comparison should be configured the same way. If the clinicians have no particular concern for the

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configuration, the optimal configuration can also be determined through the evaluation.

In order to proceed with the engineering evaluation of a disposable system for monitoring blood pressure, an adequate number of monitoring kits from each source under consideration should be tested. Kits from two different lot numbers should be included in the test. The purpose of testing multiple kits from different lots is to provide some assurance that the mean data is truly representative of the average response of each particular system. Only after the average response has been determined can a comparison between systems be made. While the exact number of kits to be tested cannot be predetermined, at least 10 kits from each source (5 from each lot) should be tested. The monitoring kit sample size could be estimated through statistical methods if the purpose was to demonstrate statistical significance between parameters of monitoring kits from each source. However, statistical significance is irrelevant to the process of this evaluation. For example, a statistically significant difference between two systems with mean resonant frequencies of 60 Hz and 80 Hz would not produce a significant effect upon the ability to measure accurately human blood pressure. Both would be quite adequate. On the other hand, two mean resonant frequencies of 8 Hz and 6 Hz, which might not be statistically significantly different, will have dramatic effects upon the ability to measure blood pressure accurately. The emphasis is therefore on estimation of the mean parameters, not statistical comparisons.

The goal of choosing an appropriate sample size is to produce some assurance that the calculated mean is truly representative of the average response of each particular system. The system should, on the average, perform according to the measurements made. Figure 1 demonstrates a method to determine the adequacy of the sample size following the evaluation of 10 kits of the same configuration from each source. The goal is to obtain a histogram (probability distribution function) that is normally distributed around some mean value, as in figure 1A. A rather poor distribution of data is pictured in figure 1B (uniform distribution), where the data falls randomly in the range, not providing any assurance as to the typical or average response. If the data, when plotted as a histogram, appears more like a uniform distribution (figure 1B) than a normal distribution (figure 1A), more data should be collected. In general, enough data should be collected to provide assurance of what the average system response will be each time the system is assembled. If more data is collected and the histogram continues to appear as a wide-range uniform distribution (figure 1B), then it might be valid to assume that the response of the system is very sensitive to the technique of assembly.

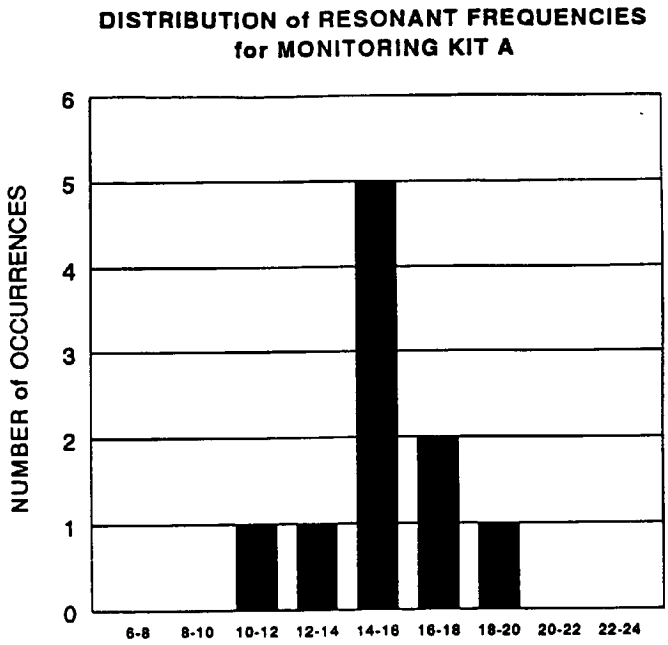



**Figure 1A — Resonant frequency (Hz)**

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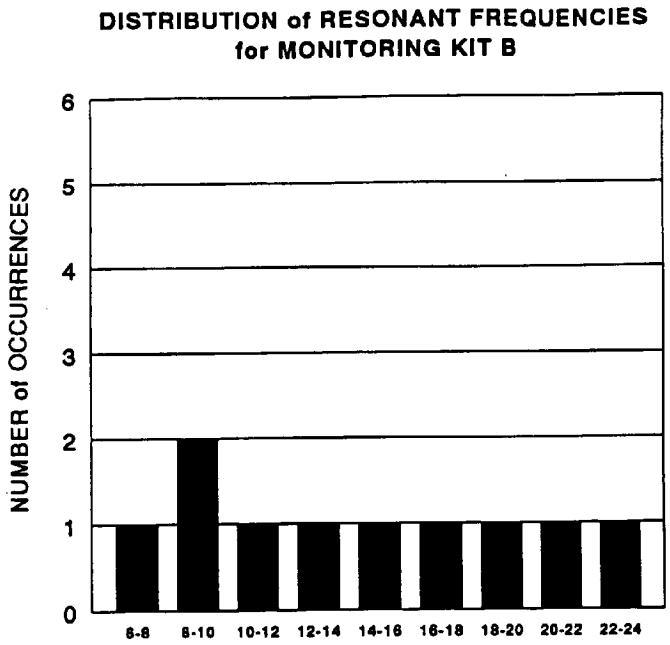



**Figure 1B — Resonant frequency (Hz)**

General rules of thumb for creating a histogram are:

If the calculated mean of the data is greater than 14, then divide the histogram into 9 bins that are 2 Hz wide with the calculated mean value residing in the center bin.

OR

If the calculated mean of the data is less than 14, then divide the histogram into 9 bins that are 1 Hz wide and centered on the calculated mean.

# 3 Description of the transducer-tubing system and potential problems

## 3.1 Description of the system

The transducer-tubing system, as illustrated in figure 2, is typically composed of a short length of tubing connected via a stopcock to a long length of high-pressure monitoring tubing which is relatively stiff, a stopcock to connect the tubing to the transducer, a transducer, some form of continuous flush device that permits fluid to flow through the transducer, and a solution administration set that delivers heparinized (1 to 2 units/ml) normal saline to the system.

Normal saline is a good universal flush solution, although any isosmotic solution (285 mOsm [milliosmoles] to 305 mOsm) can theoretically be used. Glucose-containing solutions are usually avoided because the glucose provides fuel for metabolism and growth of bacteria. Special considerations are necessary for various groups of patients. For example, liver failure patients typically are not given heparin or lactate in their flush solution. Solutions such as sterile water that have osmolarities far below 285 mOsm can cause red cells to burst and should not be used. While the rate of fluid administration from the continuous flush device during normal operation is too low to cause many problems with any flush solution being administered, a power flush might provide a high enough flow rate to cause concern.

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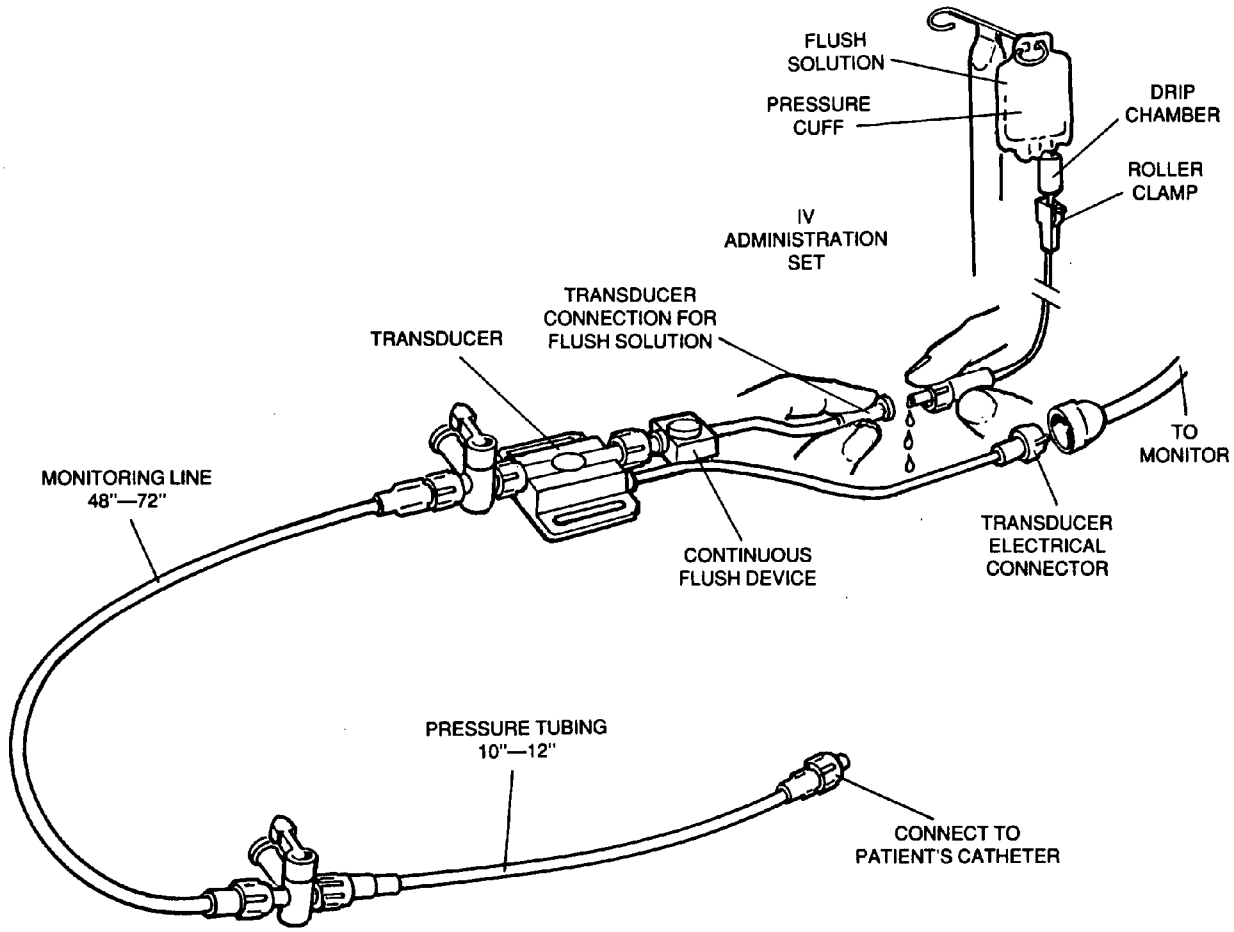



**Figure 2 — Transducer-tubing system**

The 6-inch or 1-foot extension tube connected to the long length of monitoring line by a stopcock is used to provide a blood sampling port close to the patient.

## 3.2 Potential problems

Stopcocks and the junctions created by connecting pieces of tubing together, or tubing to catheters, create serious obstacles to producing a high-fidelity monitoring system. Tubing junctions and stopcocks typically produce regions where normal flow is not maintained, such as where the bore of the plastic tunnel leading to the hole through the handle is not molded to create a smooth transition between stopcock port and the hole in the handle. The lack of stopocks with true tapered ports (supposedly related to leaking at the junction) creates a flow abnormality that results in stagnation and bubble trapping, even during a power flush.

New kits with "laboratory sampling sites" can include ports of highly compliant polymer that will reseal after puncture by a needle or blunt cannula, and in addition, can include a large dead space reservoir volume. Both of these features can degrade system performance. These new integral sampling systems should be carefully investigated, because they could add to the compliance and inertance of the system.

Before a blood pressure monitoring system is adopted for use throughout the medical center, the requirements of all potential users should be understood. For instance, neonatal intensive care units (NICUs) often employ motor-driven syringe pumps instead of relying on typical continuous flush devices. Syringe pumps are typically set to deliver approximately 1 ml/hour. One reason that NICUs often use motor-driven syringe pumps is that volume infusion in neonates is critical. The volume of fluid that a typical continuous flush device adds to the patient can vary from 1 ml/hour to 8 ml/hour, with a power flush capable of delivering from 50 ml/hour to 120 ml/hour. These devices provide obviously rather poor volume control. Another advantage of the syringe pump is that an alarm will sound when the fluid in the syringe is

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about to run out, avoiding a potential air embolism. The potential problem of air infusion is also solved by the syringe pump, since the syringe can be filled without air anywhere in the system. With the standard continuous flush device, the flush solution is pressurized and the air/water interface results in a new equilibrium between air (bag and drip chamber) and gas dissolved in the flush solution. When the pressure drops across the limiting orifice in the flush device to the patient's mean arterial pressure, the gas comes out of solution and forms bubbles in the system, thereby degrading the system response as a function of time (see page 21). Difficulties associated with using a motor-driven syringe pump are related to the ways that it can be connected to the monitoring system. If it is connected to the system without a high-resistance orifice to isolate the infusion pump from the transducer, then the monitoring system performance can be severely degraded by the additional compliance and inertance. The decrease in resonant frequency might result in enormous systolic pressure errors. Alternatively, the system could become severely overdamped, such that the pressure waveform appears sinusoidal with the systolic pressure decreased and the diastolic pressure increased, both approaching the mean pressure.

Kits intended for direct monitoring of pressure within the ventricles in the brain and drainage of cerebrospinal fluid do not include flush devices for three reasons: (1) In these applications, a continuous infusion of fluid (even 3 ml/hour to 6 ml/hour) is absolutely contraindicated. The purpose of placing a catheter directly into the brain ventricle is to drain cerebrospinal fluid, thereby lowering pressure inside of the brain. Adding fluid to the brain could compromise cerebral blood flow leading to permanent brain damage or death. (2) There is a risk of lethal infection within the brain from germs flushed into the ventricles from a contaminated stopcock, piece of tubing, or the transducer. (3) A continuous flush is meant to prevent the catheter tip from clotting. Under most circumstances there is no chance that cerebrospinal fluid will clot the catheter tip, therefore there is no need for a device to prevent clot formation.

## 4 The static response

The static response of a transducer is an indication of how well the transducer measures a constant pressure. Static pressure errors (except for non-linearity and hysteresis) vary from the correct value by a constant percentage. Static errors do not depend upon patient parameters or vary over short periods of time. Static pressure measurement errors are not related to the frequency content or particular waveform characteristics of the blood pressure. During pressure measurements on patients, common static errors can come from incorrect zeroing of the monitor; incorrect leveling of the transducer with the tricuspid valve (right atrioventricular valve) position (approximated using the mid-axillary line); an incorrect calibration factor set in the monitor; an incorrect transducer calibration factor; or long-term drift. On the bench, static errors can come from drift, transducer sensitivity errors, and monitor excitation errors. In the case of non-disposable transducers, the monitor could play an important role in drift problems. In general, monitors have different excitation signals and voltages that can cause thermal instability in some transducers. However, with currently-available, disposable transducers and monitor-specific cables, the signal conditioning electronics in the cable usually compensate for differences in each monitor's performance.

The most common method of transducer calibration is to apply a known positive pressure to the dome of the transducer, that is, the connection normally used to measure the blood pressure. Some manufacturers include a calibration port through the atmospheric vent on the back side of the pressure sensor. Static errors can be assessed using either port, with special consideration for the possible pitfalls when using the vent port. As described below, if water enters the vent port, changes in apparent transducer sensitivity and zero offset could occur that render the measured pressure inaccurate. The evaluator must be careful about leaks during calibration in these systems, as this could provide misleading information concerning drift. Leaks in the atmospheric vent of course do not interfere with normal transducer operation, as venting to atmospheric pressure is the purpose of the vent.

An important consideration concerning disposable transducers is the connection between the transducer and the nondisposable transducer cable. Since this connection is usually close to the transducer body, the

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potential for exposure to water, flush solution, and blood is significant. If conductive fluids come in contact with the electrical connections, the transducer will display a range of responses from complete failure to large offsets, and could possibly display bizarre waveforms with no pressure applied. This condition can have severe consequences in the clinical management of the patient when the fault is less than complete failure. For this reason, part of the examination of the transducer should include a test for fluid leakage around the transducer-cable interface. This is best observed during a static test rather than during a dynamic evaluation.

Drift is usually a slow, time-varying change in the pressure reading from the monitor when the pressure being applied to the transducer is constant. Some manufacturers specify that a warm-up time of 5 to 15 minutes is necessary to stabilize the transducer, at which time the drift approaches zero and the transducer becomes more stable. A lengthy warm-up time might not be a problem for routine cases where the transducer can be prepared ahead of the patient's arrival. However, the warm-up time can cause problems in emergency situations where a patient needs immediate invasive pressure monitoring, or the patient needs to be transported with a different transducer. In situations when the pressure drifts downward or upward, this warm-up drift could obscure the true blood pressure and might result in inappropriate clinical management of the patient.

The following examples present methods of assessing drift:

a) Following a suitable warm-up period, apply atmospheric pressure to the transducer. The monitor should display 0 mmHg. If it displays 10 mmHg one hour later, then the transducer has drifted 10 mmHg/hour.

b) Using a mercury manometer, pressurize a transducer to 100 mmHg on the manometer. The monitor should display 100 mmHg. If it displays 80 mmHg after 30 minutes, then the transducer might have drifted 20 mmHg/30 minutes.

1) This drift is validated if the manometer continues to read 100 mmHg and the monitor reads -20 mmHg when the pressure is removed.

2) If the monitor reads 0 mmHg when the pressure is removed and only reads 80 mmHg when the system is pressurized to 100 mmHg on the manometer, then the transducer's sensitivity has changed over time.

An electrical calibrator (i.e., a pressure simulator) must be used to sort out sensitivity changes and drift in the monitor from sensitivity changes and drift in the transducer.

A leak in the tubing system can be confused with transducer drift. For example, if the continuous flush port is not occluded, the pressure that the transducer is measuring will decrease and appear as a leak or a drift problem as fluid is displaced backward from the transducer dome into the flush solution administration set. However, in the presence of a leak the manometer reading will usually track the pressure being displayed on the monitor. The continuous flush port also creates problems when it is connected to a pressurized bag of fluid and the administration set tubing is not occluded. In this case, the pressure will rise until enough fluid has entered the transducer and manometer to make the transducer and manometer pressures equal to the bag pressure.

A transducer sensitivity error is also categorized as a static measurement error. It can be determined after the transducer is zeroed by pressurizing the system to 100 mmHg and recording the reading. The sensitivity error can be computed by the formula: $E_s = 100 \times (P_m - P_a)/P_a$, where $P_m$ is the measured pressure and $P_a$ is the applied pressure (i.e., 100 mmHg). Sensitivity errors could be caused by the transducer or monitor. Transducers are calibrated to produce an output of 5 microvolts (µV) per volt (V) of excitation per applied mmHg of pressure. The standard sensitivity of a resistive- or semiconductor-type transducer is expressed as: $5\ \mu V \cdot V_{excitation}^{-1} \cdot mmHg^{-1}$ (compared to $40\ \mu V \cdot V_{excitation}^{-1} \cdot mmHg^{-1}$ for Hewlett-Packard variable

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differential transformer and quartz-type transducers). The monitor contributes to sensitivity errors when the combination of excitation voltage and amplifier gain is not exact. A few monitors permit the user to adjust the sensitivity of the monitor to compensate for different transducer input and output impedances and calibration factors.

## 5 The dynamic response

The transducer-tubing system employed to measure blood pressure contains hydraulic elements that contribute to resonance within the system. Resonance is an undesirable characteristic present in invasive pressure monitoring systems that selectively amplifies certain frequency components of the blood pressure waveform to create a distorted waveform. The greatest distortion usually occurs as artifactual elevation of the systolic pressure and the maximum rate of rise of the pressure waveform (dP/dt).

In order to produce resonance, two types of energy storage components must be present and one must be releasing its stored energy while the second is taking up energy for storage. In an electrical circuit, these two storage devices are known as capacitors and inductors. The capacitor stores energy in the form of an electrostatic field while the inductor stores energy in the form of an electromagnetic field. In a hydraulic (fluid) system the compliance, which stores energy in the elastic walls of the tubing or in the compression of an air bubble, is analogous to electrical capacitance. Inertance in a fluid system is analogous to electrical inductance, and is a result of the mass of fluid contained in the system being put into motion by the force generated from the applied pressure. Both compliance and inertance need to be present to create a resonant system. A third element, resistance, is another component of both hydraulic and electrical systems. Resistance in a hydraulic system is the result of viscous dissipation of energy as heat. As the fluid moves through the tubing, conducting the pressure to the transducer diaphragm, the water molecules experience friction as they drag each other along the length of the tube. Dragging water molecules along the tube's inner surface is more difficult than dragging them against each other (water molecules at the tube surface have zero velocity), which accounts for the fact that smaller diameter tubes have higher viscous resistance losses than larger diameter tubes. The friction created by viscous drag dissipates energy that would otherwise be available for storage in the compliance and inertance elements. This resistive energy dissipation is referred to as damping. Damping in a transducer-tubing system is a function of tubing diameter, length, volume displacement of the transducer, compliance of the system, and viscosity of the fluid used to fill the system.

A typical frequency response curve is illustrated in figure 3. The x axis represents the frequencies (Hz) introduced into the system (or the frequency components of a pressure waveform). The y axis is the response (output divided by the input) to a sine wave input to the system at each frequency from the x axis. When the amplitude of the y axis is greater than 1, the output signal is larger than the sine wave applied to the input. When the amplitude equals 1, the output is the same as the input (perfect amplitude reproduction). Lastly, when the magnitude of the y axis is less than 1, the output is attenuated or smaller than the input signal.

The peak amplitude of the system response is generally the resonant frequency, and in the case of figure 3, specifically the damped resonant frequency. The amplitude of the peak is a function of the damping within the system—the lower the damping coefficient, the higher the amplitude. The bandwidth is that frequency range over which the system response is unity or 1 (ideal amplitude reproduction). The bandwidth is usually specified within some tolerance such as 15 percent. In this case, the bandwidth is the range of frequencies (starting at zero) that include magnitudes of the system response as great as 1.15 or as small as 0.85. The dashed lines illustrate the 15 percent bandwidth limits. The bandwidth is specified as that range of frequencies up to the point where the system response exceeds either +15 percent or -15 percent. In this example, the bandwidth is approximately equal to 4.4 Hz for $f_0$ = 12 and damping coefficient (D) = 0.1.

Figure 3 illustrates three different second-order responses and an ideal response. The ideal response is perfect reproduction of the measured event, regardless of the frequency of the input. The three second-order

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responses demonstrate the effects of changing the resonant frequency ($f_0$) and the damping coefficient (D).

Most discussions concerning the performance of transducer-tubing systems involve the parameters of resonant frequency and damping. The absolute bandwidth may be a better parameter in the sense that it describes the flat response of the system. High resonant frequencies and large damping coefficients are desirable, but how high and how large? The answer is the highest and the largest that will produce the greatest flat bandwidth. Figure 3 illustrates the confusion that can occur when discussing simply resonant frequency and damping, and incorrectly assuming that the highest resonant frequency results in the greatest bandwidth. Choosing the second-order system that would be preferred for monitoring blood pressure would be easy from the options pictured in figure 3. Clearly, the second-order response that has the lowest resonant frequency and the highest damping coefficient best approximates the ideal response. Note that the highest resonant frequency is not always the most desirable system response. In this case, the 15 percent bandwidth is approximately 5.8 Hz for the system with $f_0 = 9$ and D = 0.5. The system response labeled $f_0 = 10$ with D = 0.25 has a 15 percent bandwidth of 3.9 Hz.

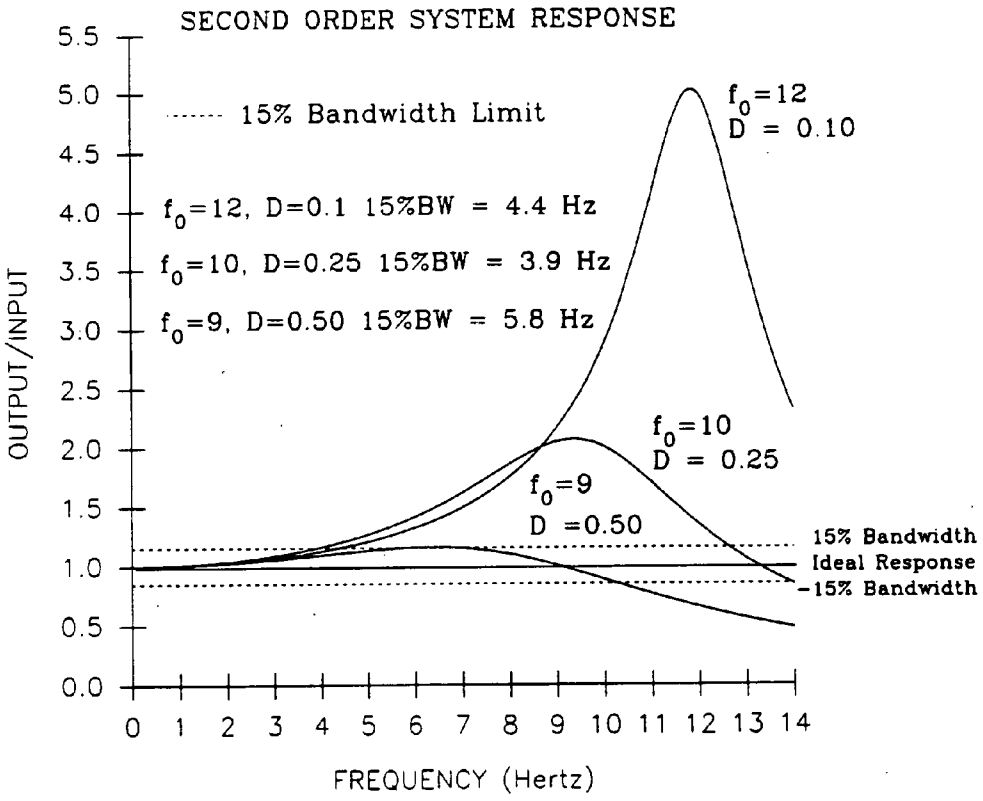



**Figure 3 — Typical figuring response curve**
(Provided courtesy of A. William Paulsen, PhD)

To generalize, one might assume that the greater the damping, the better system performance relative to the ideal response. However, as damping increases, the damped resonant frequency falls. As the resonant frequency falls, the waveform distortion increases. This happens because the amplitudes of the pressure waveform's lower frequency dominant harmonics are amplified more as the resonant frequency approaches the waveform's fundamental frequency. Figure 4 demonstrates how a waveform is distorted by two different system responses: (1) resonant frequency of 29 Hz with a damping coefficient of 0.12; and (2) resonant frequency of 10 Hz with a damping coefficient of 0.21. The table within figure 4 provides systolic and diastolic errors caused by each system response in mmHg and percentages.

More and more of the high frequency information contained within the pressure waveform is discarded as most of the response is significantly attenuated. As more and more frequency components are attenuated,

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