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Technical Information Report

AAMI TIR9:1992

Evaluation of clinical systems for invasive blood pressure monitoring

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Association for the Advancement of Medical Instrumentation
1110 N. Glebe Rd., Suite 220
Arlington, VA 22201-4795

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TIR9 Evaluation of Blood Pressure Monitoring Systems

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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A. William Paulsen
Tommy Cooper

Members:
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Gregory Welyczko, Ohmeda Anesthesia

Alternates:
Charles Foltz, Abbott Critical Care Systems
Roy Hayes, SpaceLabs Medical, Inc.
Jeffrey P. Milsap, CCE, Ohmeda Anesthesia

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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

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

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.

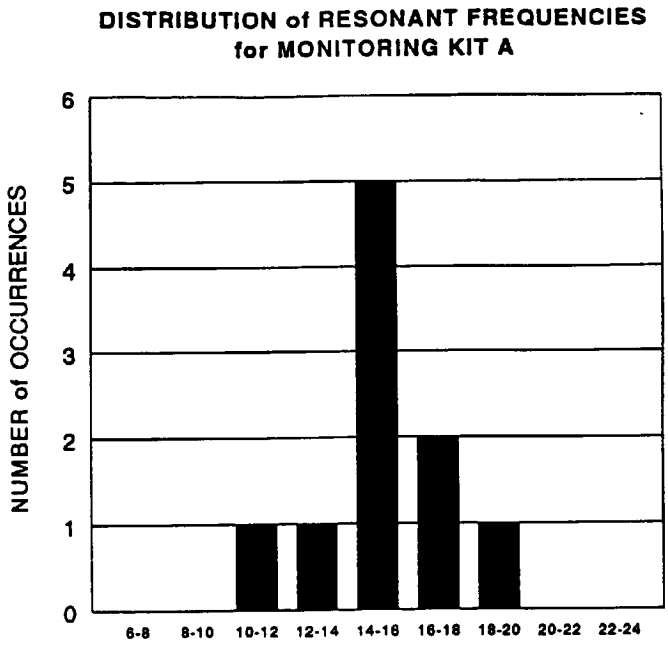


Figure 1A — Resonant frequency (Hz)

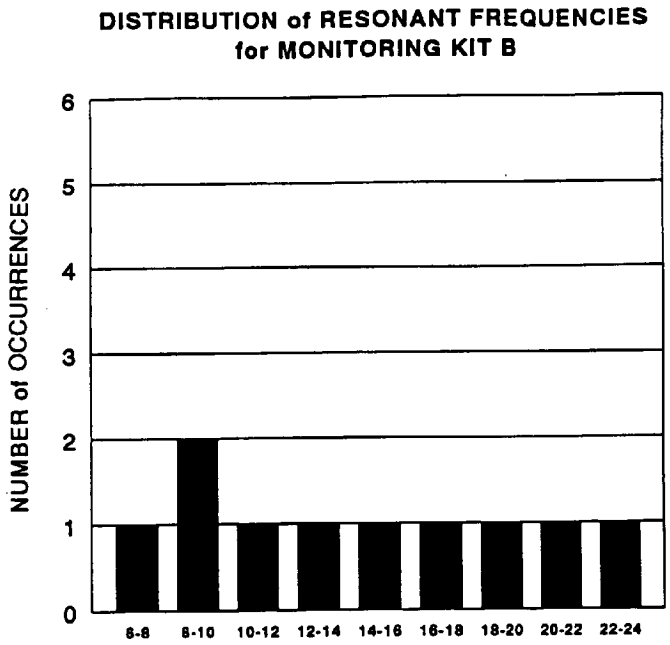


Figure 1B — Resonant frequency (Hz)

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.

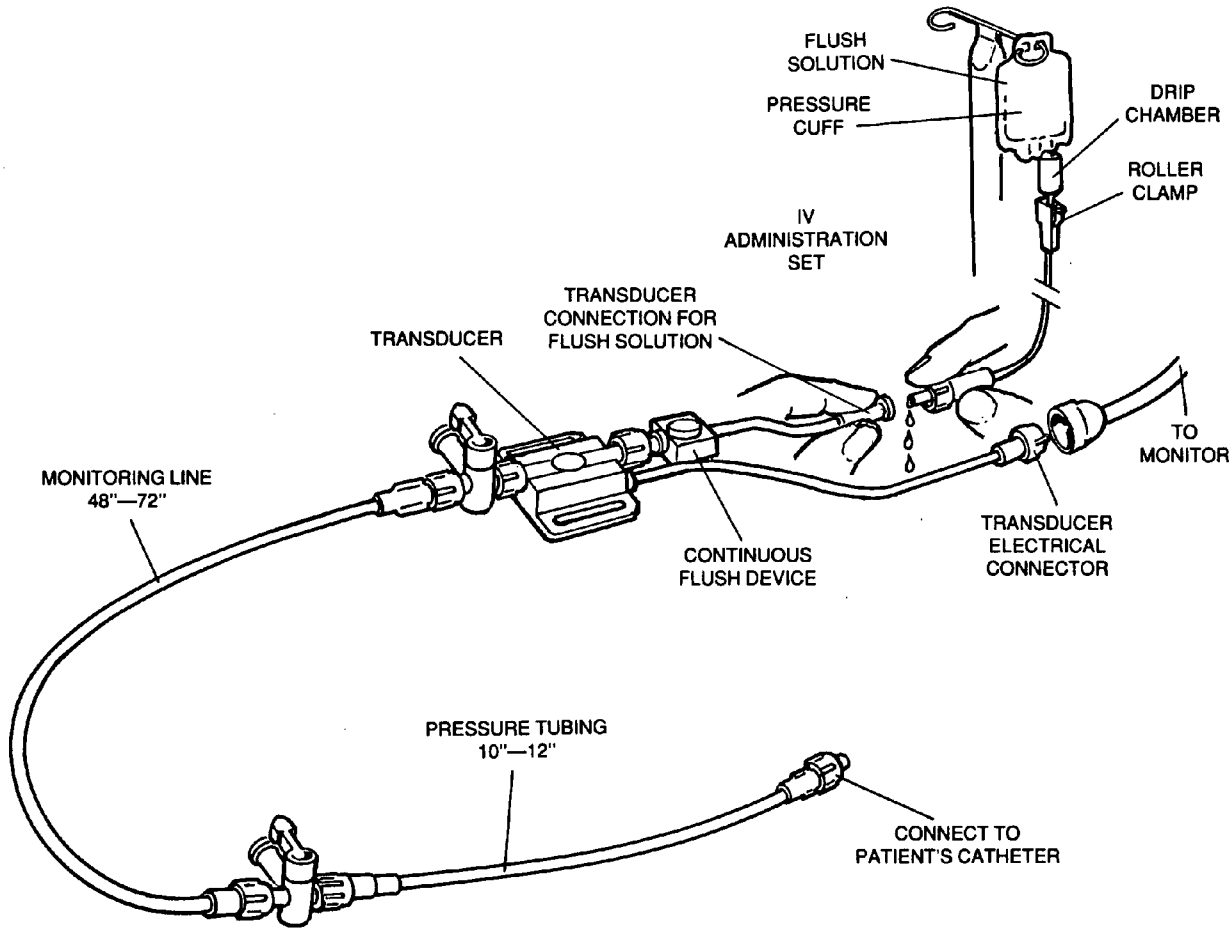


Figure 2 — Transducer-tubing system

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

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

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

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

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.

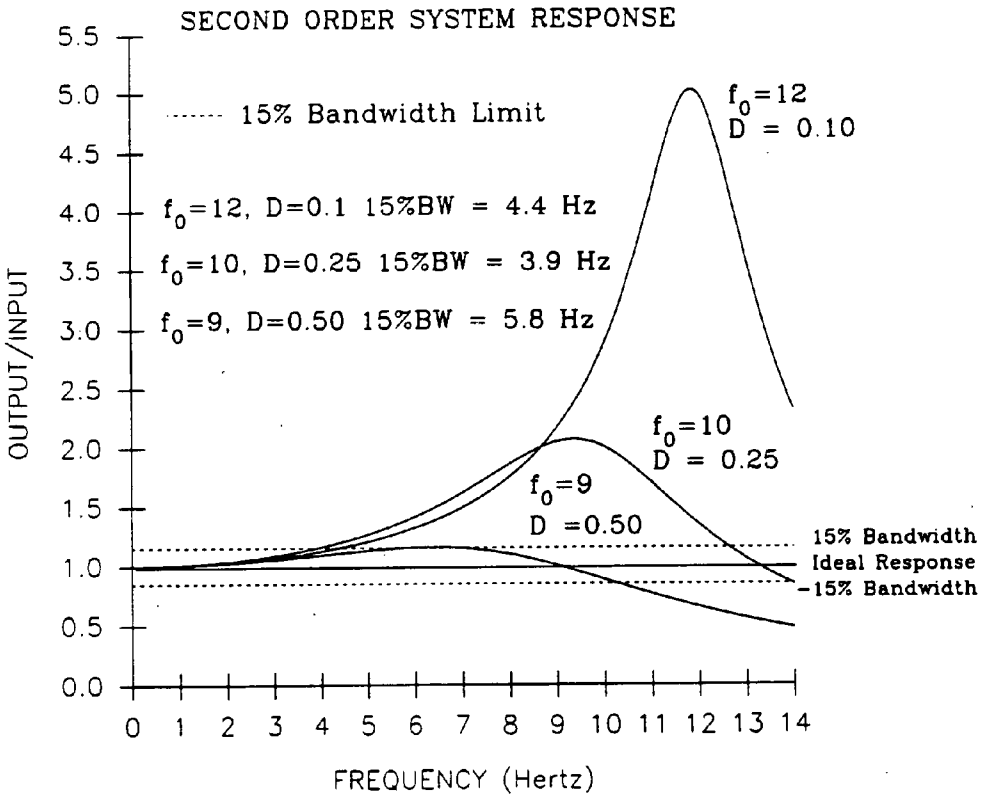


Figure 3 — Typical figuring response curve
(Provided courtesy of A. William Paulsen, PhD)

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,

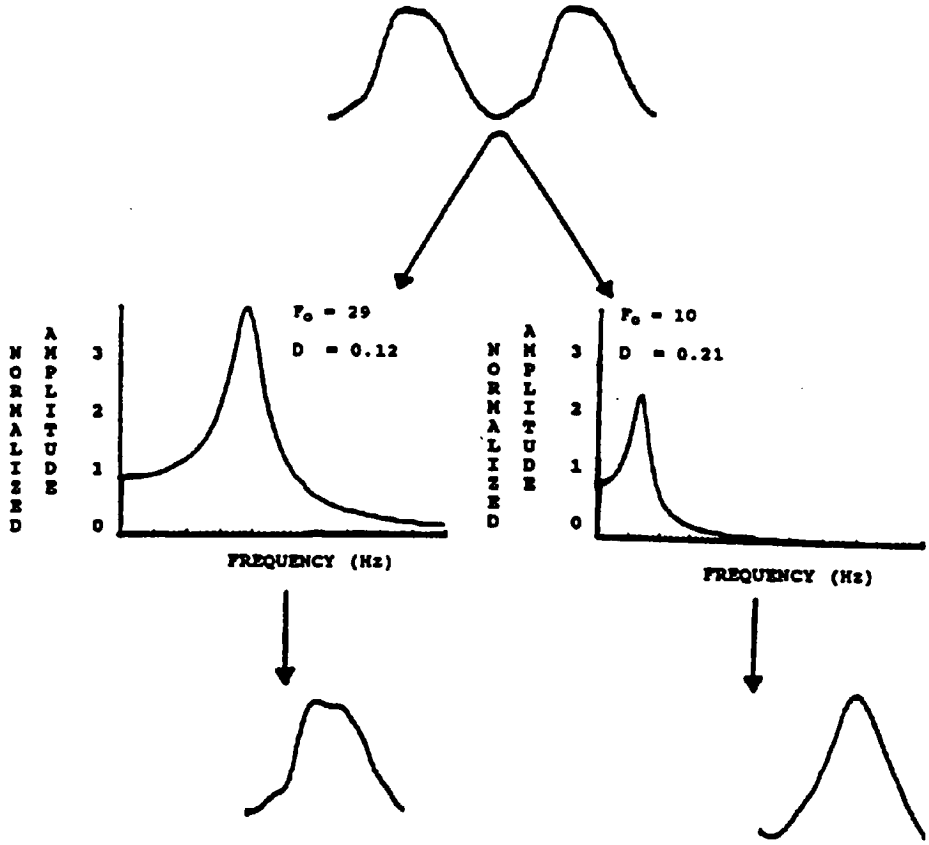
the systolic and diastolic pressures (the waveform minimums and maximums) begin to approach the mean blood pressure. At this stage, the dynamic response disappears, leaving the static response which measures only mean blood pressure.

In general, decreasing the resonant frequency, even as damping increases, causes increased distortion of the waveform until the damped resonant frequency is below the first harmonic. At this point, the waveform has been transformed from a pressure waveform to a sine wave, and eventually to a mean pressure tracing.

6 Factors that degrade monitoring system performance

Monitoring system performance can be degraded by anything that decreases the flat bandwidth, and in general anything that decreases the resonant frequency and/or damping coefficient. Increasing compliance, inertance, and damping all cause the resonant frequency to decrease.

Air bubbles that are trapped in the monitoring system during filling, or added later by manual flushing or continuous flush devices, add undesirable compliance to the system and tend to decrease the resonant frequency and increase the damping coefficient. Although this combined effect might be desirable in some cases, the resonant frequency typically falls faster than the damping increases, resulting in a very undesirable condition. Figure 5 demonstrates the effect of adding microliter air bubbles of various sizes to a transducer-tubing system. As more and more air is added to the system, the decrease in resonant frequency produces larger and larger errors in the systolic pressure, even though damping is increasing at the same time. Eventually, so much air could be added that the system produces only damped sine waves. Air bubbles definitely diminish, not enhance, the performance of blood pressure monitoring systems.



mmHg	Percent	Error	mmHg	Percent
2.5	1.2	Systolic	43.8	24.8
-6.1	-24.6	Diastolic	-19.1	-77.2

Figure 4 — Waveform distorted by two different system responses
(Provided courtesy of A. William Paulsen, PhD)

Figure 6 illustrates the system response of four different monitoring systems made from two different line lengths and two different tubing compliances. Compliance added to the system by using soft lines (e.g., intravenous extension set tubing) reduces the resonant frequency of the system. Also, the longer the length of tubing, the lower the resonant frequency. The greatest flat frequency response in figure 6 is provided by the system labeled 60 cm "stiff."

Figure 7 demonstrates the relationship between tubing length and resonant frequency for the highest quality pressure monitoring tubing in the industry at the time of data collection (considering the tubing alone and not the entire transducer-tubing system). The shape of the curve is typical, and is a characteristic hyperbola. The resonant frequency improves most dramatically when the line length is shortened from 1 foot to a few inches. When the line length is increased from 7 feet to 8 feet, there is a relatively small degradation in frequency response. As this figure illustrates, the best pressure monitoring line is very short and has a very low compliance (i.e., stiff).

Continuous flush devices provide the ability to monitor blood pressure without periodically having to flush the line manually. Without flushing, clot formation at the tip of the catheter would dampen the waveform and increase the likelihood of thromboembolism. Continuous flush devices have three main advantages: (1)

they minimize clot formation in the blood vessel at the catheter tip, which reduces the likelihood of a dangerous embolus being dislodged during a manual flush by syringe; (2) when the devices are installed so that they flush across the transducer diaphragm, they eliminate stagnant pools of fluid that are breeding grounds for bacteria and hazardous infections; and (3) they permit uninterrupted and unattended monitoring of intravascular pressure.

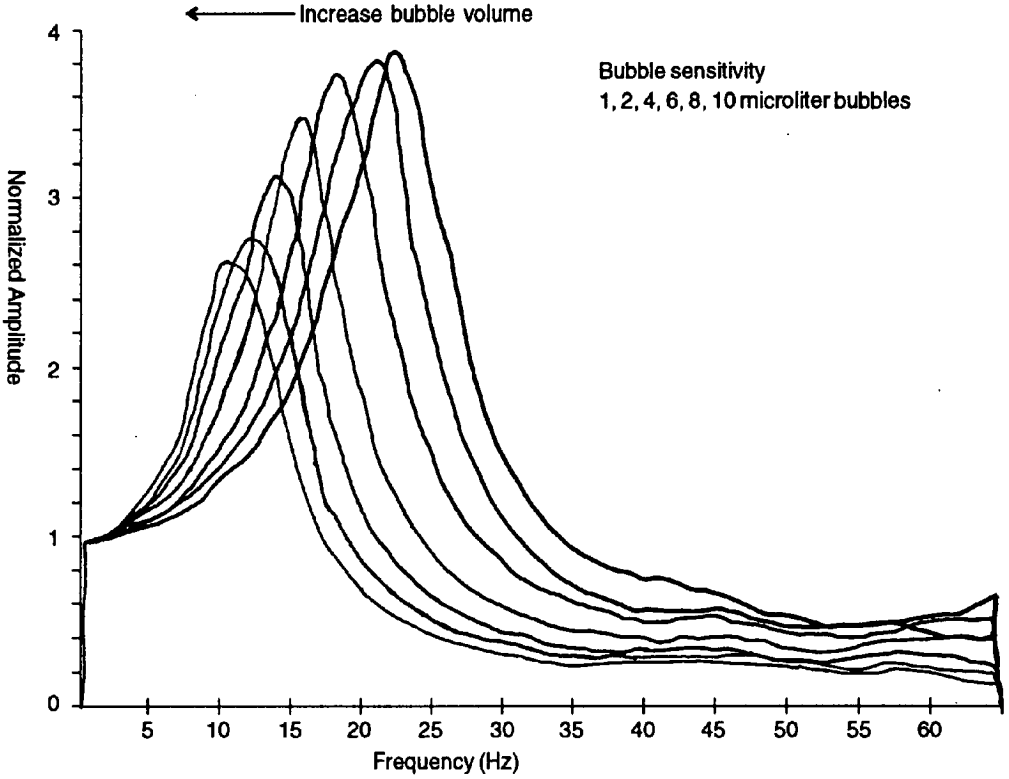


Figure 5 — Effect of adding air bubbles to transducer-tubing system
(Provided courtesy of A. William Paulsen, PhD)

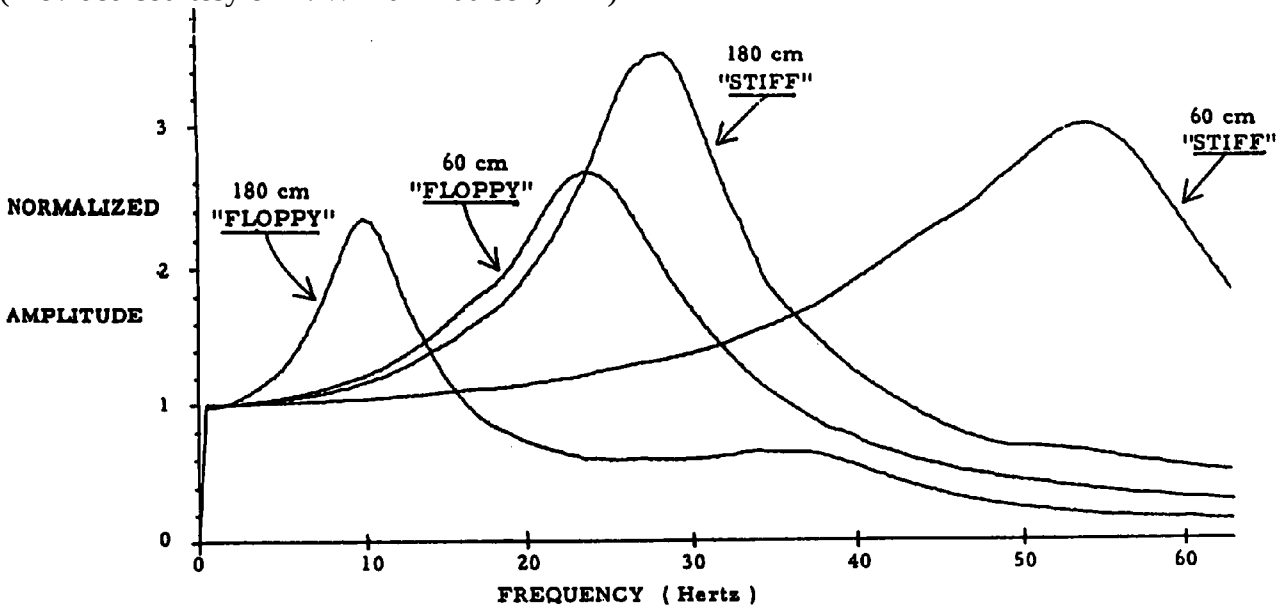


Figure 6 — Effects of tubing compliance and length upon system response
(Provided courtesy of A. William Paulsen, PhD)

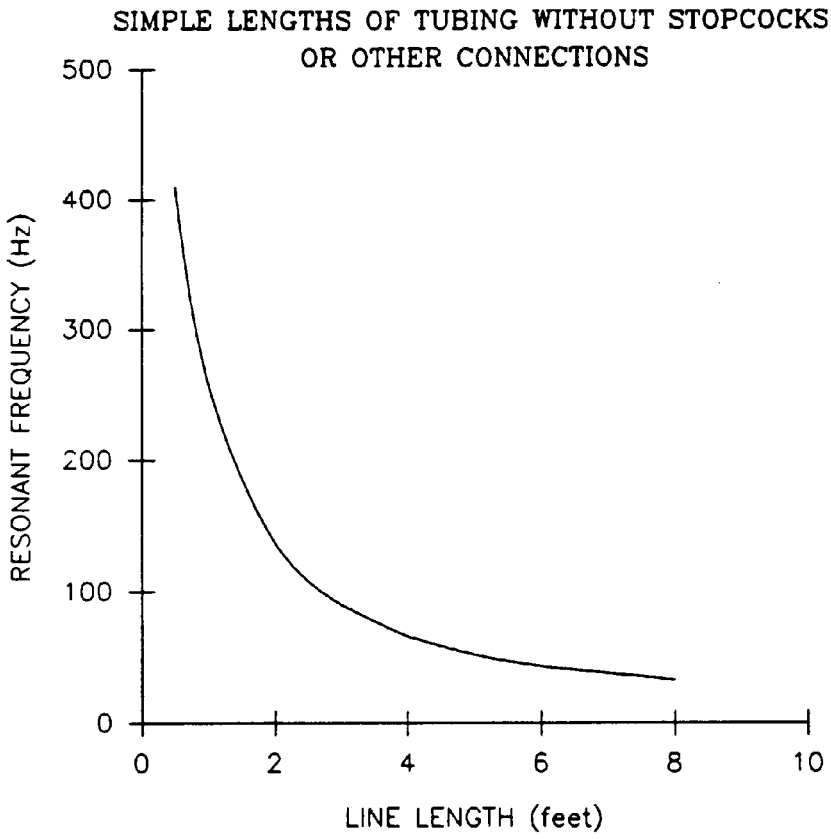


Figure 7 — Relationship between tubing length and resonant frequency

(Provided courtesy of A. William Paulsen, PhD)

The disadvantage of continuous flush devices is that they add compliance to the monitoring system by two mechanisms: (1) they have a deformable (compliant) seal that allows a high speed flush when needed; and (2) they continually introduce air bubbles into the monitoring system, thereby degrading system performance. These effects are illustrated in figure 8. Air bubbles are introduced to the patient monitoring line from the flush solution. Because all of the air in the flush administration set and bag cannot be removed, when the bag is pressurized to 300 mmHg or 400 mmHg, the air is forced into solution and becomes saturated at this high pressure. When the fluid passes through the orifice in the flush device the pressure immediately drops to the patient's mean blood pressure (approximately 100 mmHg), which is about 200 mmHg to 300 mmHg lower than the pressure at which the air was in equilibrium in the bag. When the pressure drops, the air in the flush solution comes out and forms bubbles in the transducer dome or tubing where the flush device is installed, thereby degrading the system response as a function of time.

Changes in temperature also affect the performance of the monitoring system. As temperature increases, air bubbles expand, increasing compliance as a result of the inverse relationship between gas solubility in water and temperature. Tubing compliance usually increases as well, although the quantitative importance of changes in tubing compliance is not known. The temperature effects are not negligible since patients moving from cool operating rooms into post-anesthesia recovery units or intensive care units (ICUs) are typically placed in a warm environment in an attempt to help them regain their body temperature. There are easily 10 to 15 degrees Fahrenheit difference between operating rooms and post-anesthesia recovery units and ICUs.

7 Devices used to improve system response

Several devices have been introduced to minimize or eliminate resonance from the transducer-tubing system response. These devices either add variable resistive damping to the system or variable amounts of

compliance.

The variable resistive devices attempt to apply critical damping to the system, thus providing the greatest flat response or largest bandwidth. Adding too much damping decreases the flat bandwidth, but without the resonance that produces exaggerated systolic blood pressures. The application of too much damping also decreases the pulse pressure (systolic minus diastolic pressure) and causes the systolic and diastolic pressures to approach the mean pressure, making the waveform appear sinusoidal and slow to rise.

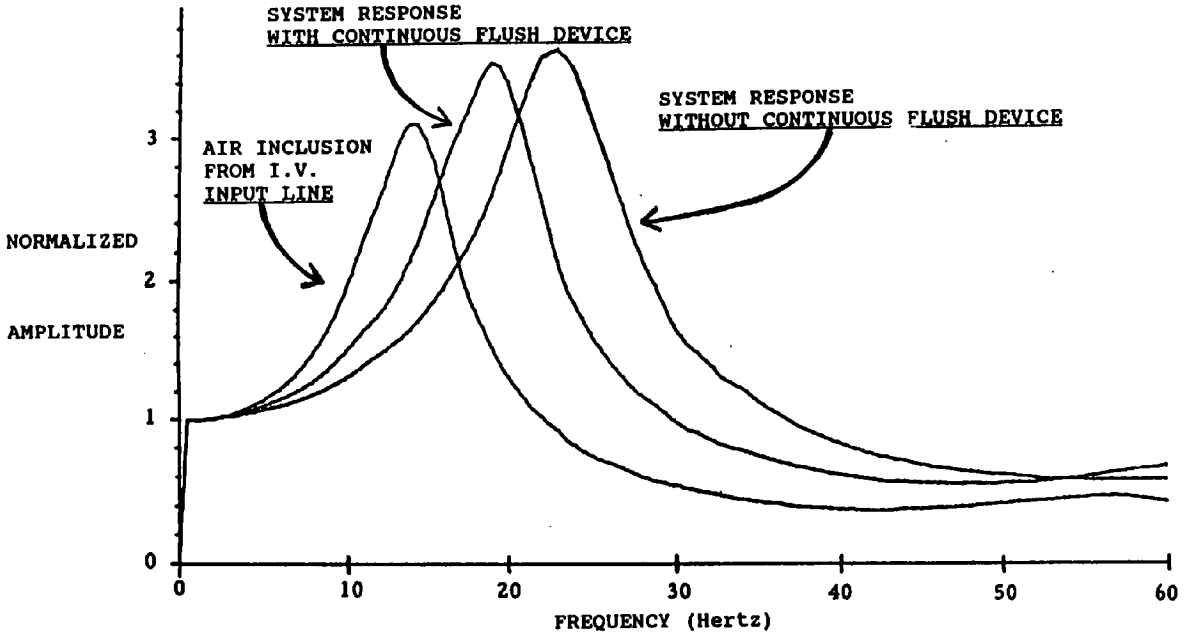


Figure 8 — Effect of adding a continuous flush device to a standard clinical system
(Provided courtesy of A. William Paulsen, PhD)

The purpose of adding compliance to the system is to cancel the reactive component of inertance. When the reactive components of both compliance and inertance are in series and equal, they cancel each other and produce a system that effectively has no storage elements and is simply resistive. A purely resistive monitoring system has no resonant characteristics and therefore no waveform distortion. Adding too much compliance has the undesirable effect of producing another resonant system that is dominated by compliance instead of inertance.

The practical difficulties of employing these mechanical devices to "tune" the transducer-tubing system are: (1) they are very difficult for many clinicians to tune exactly correctly; (2) they undermine confidence in the monitoring system in the clinician's eye because they can significantly change the systolic pressure as they are being adjusted, raising questions about system reliability; and (3) they are costly in that the price is added to each disposable kit; the yearly expense could be considerable.

Electronic filtering, which uses various cutoff frequencies to eliminate waveform distortion, has been applied to many patient monitors to reduce the systolic pressure errors. Figure 9A illustrates the resonant characteristics of a transducer-tubing system recorded from a high-fidelity pressure amplifier (DC to 450 Hz). Figure 9B is the response of the same system, but connected to a pressure amplifier with a 12 Hz low-pass filter. In this case the filter removes the resonance and provides a flat response to just beyond 20 Hz. The rationale here is that a low-pass filter with a cutoff frequency below the system resonant frequency will eliminate all waveform distortion. This is true if the filter frequency could always be below the system resonant frequency. However, the system resonant frequency might fall as low as 5 Hz to 6 Hz, and that would require an electronic filter with a cutoff frequency of 5 Hz or less. Few people feel comfortable choosing a fixed low-pass filter of 5 Hz or less, fearing that the waveform is being unnecessarily damped (lower systolic pressure and lower pulse pressure, and slower rate of rise of the waveform). When the

system resonant frequency falls below the cutoff frequency of the filter, the filter is of no value in diminishing the distortion of the blood pressure waveform. Therefore, choosing a filter with a cutoff frequency of 12 Hz will be totally ineffective if the normal system resonance is 6 Hz to 10 Hz, as is typical in many medical centers.

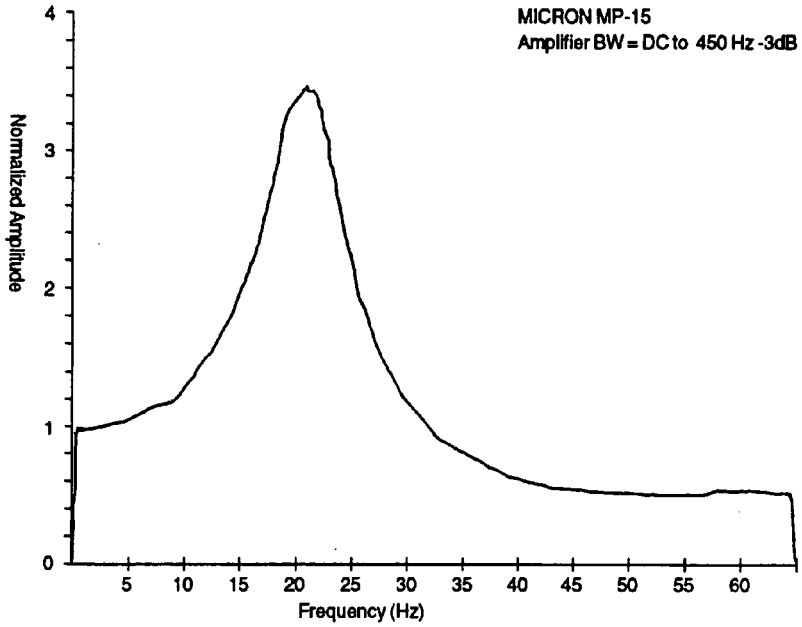


Figure 9A — Resonant characteristics of transducer-tubing system
(Provided courtesy of A. William Paulsen, PhD)

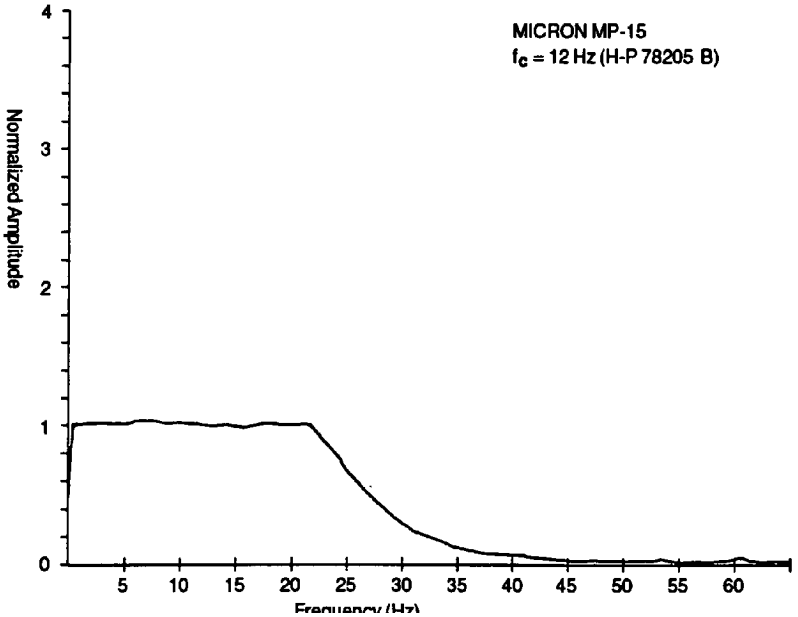


Figure 9B — Resonant characteristics of transducer-tubing system
(Provided courtesy of A. William Paulsen, PhD)

8 Failure modes

8.1 Out-of-box failures

Transducers that are found to be non-functional immediately after removal from sterile packaging are considered to be out-of-box failures. The failure mechanism for these units could be the silicon sensor, electrical connections, plastic components, or the assembly process. These failures are usually detected during initial setup when the transducer performance is tested with a patient monitor.

The typical indications for sensor or electrical connection failure are that the monitor cannot be zeroed or that it does not respond when a pressure is applied to the transducer. Other indications of failure might be less obvious. The monitor could zero and indicate a response to applied pressure on the transducer, but the measured pressure might be inaccurate, as indicated by a significantly high or low reading for a known applied pressure. The pressure signal on the monitor could be unstable, indicated by a significant zero drift or noise.

The obvious indications for plastic component or assembly process failure are that the transducer leaks fluid under pressure or disassembles during mechanical debubbling procedures. Other less obvious indicators might include cracks or crazing in plastic parts, black specks embedded in plastic components, large particles in the fluid pathway, and poorly matched luer fittings. There are, of course, other indications of failure in plastic components or assembly processes.

The out-of-box failures are usually a very small percentage (less than 1 percent) of the total number of transducers utilized. The causes for these failures are not easy to determine. These out-of-box failures can occur even with an adequate quality assurance program that meets all the requirements for Food and Drug Administration (FDA) good manufacturing practices (GMPs). Some of the potential causes are human factors in manufacturing and quality assurance, stress from sterilization processes, and exposure to environmental and mechanical stress during shipment.

It is important to be aware of the potential for out-of-box failures during an evaluation. However, with the low percentage rate of out-of-box failures, it would be very difficult to compare the rate of out-of-box failures for different manufacturers based on the relatively small number of units used during an evaluation. A better way to determine out-of-box failures might be to poll some users of the specific devices of interest. Caution should be exercised when polling users, because discussions with non-technical people could yield erroneous information.

8.2 Overpressure

Transducers could be subjected to relatively high pressures during setup procedures with fluid-filled transducer and tubing sets. Pushing the stopcock onto a transducer dome luer port, which has a small cross-sectional fluid area (typically .0064 sq. in.), results in a mechanical advantage such that a force of 1 pound could theoretically produce a pressure greater than 150 pounds per square inch (psi) (7755.1 mmHg). The excessive pressure results from attempting to compress a relatively incompressible fluid (water) in a rigid walled container (very low compliance transducer dome). In reality, the walls of the transducer dome are somewhat compliant and the water does compress slightly, resulting in pressures of approximately 800 mmHg.

These high pressures can damage transducers by rupturing the thin diaphragms of the silicon sensors used in disposable pressure transducers. The metal diaphragms and sensing elements of reusable pressure transducers can also be damaged by these high pressures. Several approaches have been taken to prevent overpressure damage to transducers. One approach has been to utilize a silicon sensor with a very high overpressure withstanding capability (greater than 120 psi). Another approach incorporates an overpressure relief valve in the transducer. One implementation of the overpressure relief valve uses a rubber sleeve over a vent hole on one of the transducer luer ports that expands to release fluid under high-pressure conditions. Another method for incorporating an overpressure relief valve integrates the relief valve into the flush device and releases fluid back into the infusion bag. This method for overpressure relief has been used successfully when the flush device is integrated into the transducer dome or is attached directly to one of the transducer luer ports without a stopcock.

8.3 Externally applied fluids

Blood pressure transducers are used in an environment where the exterior of the transducer body and

electrical connector are intermittently exposed to fluids such as blood, saline, and dextrose. The electrical connector must have a moisture-proof seal to protect it from these conductive and corrosive fluids. A connector failure due to moisture is usually indicated by loss of signal on the patient monitor. The monitor can also indicate a very large positive or negative offset (possibly off-scale).

Another possible failure mode occurs when fluid is introduced (or drawn in by capillary action) into the vent-side calibration port on the transducer. Some transducer manufacturers provide this external port, which is connected to the atmospheric vent side of the sensing element, so that the transducer can be calibrated without compromising sterility. When fluid enters the vent tube, the resulting failure is less obvious than a failure of the electrical connector. The transducer could exhibit baseline changes with temperature or atmospheric pressure changes. For example, the baseline could be affected when a high or low pressure weather front changes the atmospheric pressure. The apparent sensitivity of the transducer might also change as the fluid column moves when pressure is applied to the transducer as a result of the surface tension between the fluid and the vent tubing.

8.4 Mechanical shock

Transducers are susceptible to failure from mechanical shock that can occur during use or shipment. Mechanical shock during use can occur when a transducer is dropped onto a hard surface or is hit with a metal instrument to assist in debubbling. The shock generated by dropping a disposable transducer from a height of 4 feet to 5 feet onto a concrete floor can be as high as 4,000 G. The sensing element or delicate interconnecting wires can be broken by extreme mechanical shock. An indication of shock failure is that the patient monitor cannot be zeroed or the transducer signal does not respond to applied pressure. For disposable pressure transducers, the diaphragm of the silicon sensor can shatter under extreme mechanical shock. The sensing element in reusable transducers can be damaged by extreme mechanical shock, resulting in high zero offset, inaccurate pressure measurement, or no response from the transducer.

9 Evaluating system performance

9.1 Description of static response test methods

9.1.1 Drift test

This test is divided into two parts: (1) drift during the manufacturer's recommended warm-up period; and (2) drift after the warm-up period. In order to sort out monitor drift from transducer drift, the monitor should be powered on for at least two hours prior to beginning these series of tests. It is also recommended that a blood pressure simulator or simple T resistive network, using components capable of adequately dissipating the applied power, be connected to the monitor for the same duration as the transducer is connected for the drift test, and that the test actually be started with the simulator.

NOTE—The simulator does not require a warm-up period.

This test should be run on at least three samples from each system being investigated. The samples (1, 2, 3) from the different sources (A, B, C) should be interleaved such that the order of evaluation should be (for three sources): Simulator, A1, B1, C1, A2, B2, C2, A3, B3, C3, Simulator.

Test Protocol (following at least 2-hour warm-up period for monitor)

a) Connect the pressure simulator, or resistor network, to the monitor and zero the pressure channel;

b) Start timing the 30-minute monitor drift period;

c) Observe the pressure reading for one hour or if not possible, then for at least 30 minutes and record the maximum deviation from zero;

d) Fill the transducer and tubing system with flush solution in the usual manner;

e) Clamp the continuous flush line so that no fluid will flow into the transducer during the test period, and close the stopcock at the patient end of the monitoring line to eliminate inadvertent hydrostatic pressure variations;

f) Connect the transducer to the monitor and zero the pressure reading on the monitor (make sure that there is no pressure inside of the transducer before the patient stopcock is closed);

g) Start timing the warm-up drift period according to the manufacturer's suggested warm-up time;

h) At the end of the manufacturer's specified warm-up time period, record the pressure reading from the monitor on the form, and re-zero the transducer;

i) Begin timing the drift for one hour or if not possible, then for at least 30 minutes. On the form, record the maximum deviations from zero that occur in either the 1-hour or 30-minute observation periods.

9.1.2 Sensitivity test

The purpose of this test is to assure consistent sensitivity among transducers from a given source. At least five transducers from each source should be evaluated. Unlike the drift test, the sources do not need to be tested in any particular order. Transducers used for the drift test or the dynamic response test can be used in this test.

a) Fill the transducer and tubing system with flush solution in the usual manner, or use the same transducer as was used for the drift test;

b) Observe the fluid/air interface; eliminate any bubbles, which impact the reading due to surface tension effects;

c) Clamp the continuous flush line so that no fluid will flow into the transducer during the test period, and connect the stopcock at the patient end of the monitoring line to a reference pressure source such as a calibrated mercury manometer or calibrated electronic gauge. A mercury manometer with the zero properly adjusted or a pressure manometer with an accuracy of at least 0.2 percent of the reading, and 0.1 mmHg resolution is required for this test;

NOTE—To calibrate a device to 1 percent tolerance, the reference measuring device should have at least five times better accuracy, i.e., 0.2 percent.

d) Connect the transducer to the monitor and zero the pressure reading on the monitor and the calibration gauge or mercury manometer;

e) Increase the pressure to 100 mmHg as read from the calibrated gauge or mercury manometer and record the monitor reading. Increase the pressure to 200 mmHg and again record the pressure from the monitor. Allow the transducer to return to zero pressure. If the monitor does not read zero ± 1 at this point, re-zero the transducer and repeat this procedure. If the monitor does not read zero ± 1 the second time, the transducer might have a serious hysteresis problem. Since the pressure transducer standards (AAMI, 1986a and b) allow variations of ± 2 percent reading from the actual pressure or ± 1 mmHg, whichever is larger, the return to zero should also be permitted to be within this range;

f) Wait until the end of the warm-up period and repeat step e. There should not be any significant change in the sensitivity of the transducers;

9.1.3 Atmospheric vent water susceptibility

This test is intended to determine the susceptibility of the transducer to water or fluid entering the vent tube and causing drift and sensitivity changes. This test can be performed on as few as two transducers that have been used for previous tests.

a) Fill the transducer and tubing system with flush solution in the usual manner, or use the same transducer as was used for the drift test or the sensitivity test;

b) Clamp the continuous flush line so that no fluid will flow into the transducer during the test period, and connect the stopcock at the patient end of the monitoring line to a reference pressure source such as a calibrated mercury manometer or calibrated electronic gauge. Eliminate bubbles as necessary;

c) Connect the transducer to the monitor and zero the pressure reading on the monitor and the calibration gauge or mercury manometer;

d) Expose the vent tube to water by pouring water over the opening (at least 500 ml of fluid);

e) Increase the pressure to 100 mmHg as read from the calibrated gauge or mercury manometer and record the monitor reading. Increase the pressure to 200 mmHg and again record the pressure from the monitor. Allow the transducer to return to zero pressure. If the sensitivity changes or if the monitor does not read zero ± 1 mmHg at this time, there might be a serious problem with the way that fluid is entering and becoming trapped in the vent tube.

9.1.4 Connector leak test

This test is intended to determine if the electrical connector where the transducer connects to the electrical cable is waterproof such that fluid that drips or spills onto the connector will not affect the measured pressure. The same transducers that have been used for other tests, *except for the vent test*, can be used for this test. One or two transducers and cables from each source can be used for this test. New cables are preferred since old, worn cables can leak. Leaky, worn cables should be replaced immediately.

a) Fill the transducer and tubing system with flush solution in the usual manner, or use the same transducer as was used for the drift test or the sensitivity test, but not the vent test;

b) Clamp the continuous flush line so that no fluid will flow into the transducer during the test period, and connect the stopcock at the patient end of the monitoring line to a reference pressure source such as a calibrated mercury manometer or calibrated electronic gauge;

c) Connect the transducer to the monitor and zero the pressure reading on the monitor and the calibration gauge or mercury manometer;

d) Pour 500 ml of normal saline or other conductive solution over the connector within 30 seconds;

e) Note if the zero has changed in response to wetting the connector;

f) Increase the pressure to 100 mmHg as read from the calibrated gauge or mercury manometer and record the monitor reading. Increase the pressure to 200 mmHg and again record the pressure from the monitor. Allow the transducer to return to zero pressure. If the sensitivity has changed or if the monitor does not read zero ± 1 at this time, there might be a serious fluid leak problem in the connector;

g) Perform a visual inspection of the connector after it has been taken apart to see if fluid has entered the connector.

9.2 Description of dynamic response test methods

The actual procedure used to evaluate each monitoring kit should be based upon practical clinical applications of the monitoring system. Testing the system under controlled conditions—assembling a monitoring system on the bench using a flush of carbon dioxide, then filling with degassed normal saline using the utmost care—is useful for determination of the maximum performance that could be expected from the system. This approach, however, bears little resemblance to how the system will be filled and used clinically. While it is sometimes useful to know the ideal upper limit of the frequency response of the monitoring system, it is not representative of system performance as applied to the patient. The procedure

should be as similar as possible to the normal setup of the system using the personnel who routinely perform the setup. The following general procedure is recommended:

a) Find 10 people who routinely assemble invasive patient blood pressure monitoring systems (fewer may need to be used; if so, avoid any bias by not selecting people who are especially meticulous or especially careless to assemble additional systems);

NOTE—careless people should be retrained or excluded from performing this task routinely.

b) Hand the first person one kit from each source to be evaluated, including the one currently being used, unless this kit has been eliminated from consideration;

c) Ask the first person to assemble each system complete with pressurized flush solution as if he or she were going to use the system on a patient. Be sure to use the solution administration set provided with the transducer kit for each test, or the one that will be used with the kit decided upon. This is an important consideration because different drip chambers could have different abilities to exclude air bubbles from the flush line during filling and power flushes;

d) Alternately switch or randomize the order in which the systems are assembled. For example, if the first person assembles the current kit first, have the second person assemble the second kit first, etc.;

e) Once the first person assembles both systems (or as many as are being compared), proceed with the engineering analysis and complete the data collection before having the second person assemble the next series of kits. This is to prevent the effects of continuous flush devices from degrading system performance over time, and to ensure that as few factors are changed as possible (e.g., temperature) from the time of initial setup.

Several methods are available for determination of the frequency response for fluid-filled transducer and tubing systems. Some of these methods are intended for engineering laboratory bench testing, while other more simplified methods are intended for use in the routine clinical environment. The tests intended for engineering laboratory bench testing (including the swept sine wave, step, and impulse response tests) require specialized instruments for performing the tests. The more common tests, such as the pop test (Grossman and Baim, 1991), snap test (Gardner, 1981), and simplified step test, utilize readily available devices for generating an input signal and recording the response of the system.

The engineering laboratory test methods are intended to evaluate the design of transducers, tubing sets, and catheters. They may be used to determine the effect of adding a component to an existing system or of changing the material or physical design of a system component. These tests are intended to be performed under highly controlled conditions so that small changes in the system response can be readily discerned. For these laboratory tests, the system is typically flushed with carbon dioxide and filled very slowly with degassed water (boiled under a vacuum for at least 48 hours), avoiding any bubble formation. These methods require the use of a commercially available pressure waveform generator, a signal or pulse generator, and a precision waveform measurement system such as a digital oscilloscope or a personal computer for acquiring the system response. This system can also be used to test clinical system responses, but this degree of measurement precision is unnecessary in this application.

Simplified test methods are provided below, and are intended for measuring the system response in a clinical environment. These methods are suitable for measuring the system response after initial setup and debubbling by monitoring technicians or nurses as described above. The input pressure waveform for each test is generated using a readily available monitoring component such as a syringe in the pop test, a flush device in the snap test, and a stopcock in the simplified step test. The system response is measured by using a chart recorder of adequate frequency response that would typically be associated with the patient monitor.

9.2.1 Impulse response test

NOTE—This test methodology is provided principally for information and completeness. Due to the nature of the methodology a reasonable understanding of digital signal processing is required to ensure reasonable results.

Impulse response testing is the basis for many forms of engineering analysis and can be adapted for use in testing catheter-manometer system performance. The frequency response of a system can be determined directly by exciting the system with an impulse (Dirac Delta) that for theoretical arguments has an infinite amplitude and is infinitely narrow. The true Dirac Delta contains all frequency components at uniform amplitude, which permits application of the impulse to a system to provide the frequency response over a large frequency spectrum. In practice, the Dirac Delta can only be approximated by a pulse of some finite amplitude and width. As the pulse width decreases, the frequency content increases and permits the frequency response of the system to be viewed over a larger range of values. A pulse width of 2 to 5 milliseconds will generally provide a large enough range of frequencies to produce a meaningful system response analysis of most catheter-manometer systems.

Equipment necessary to perform this analysis includes a pulse generator, a hydraulic pressure generator, a large bandwidth (DC to 250 Hz) pressure amplifier, and a computer capable of sampling 1,000 points per second with at least 12-bit resolution. Figure 10 illustrates the required equipment.

The computer must be equipped with software capable of performing Discrete Fast Fourier Transform (DFFT) analysis, either mixed radix if the number of samples taken cannot be controlled, or radix 2 if the number of samples can be made equal to a power of two. The mixed radix DFFT is more versatile but much slower than a simple radix 2 DFFT. The frequency response is typically displayed as two plots: magnitude of the DFFT versus frequency, and phase of the DFFT versus frequency. The following relationships can be used to determine the sampling rate and frequency resolution:

$T = n * dt$ T -> Total time of the sample record

n -> number of samples taken

dt -> time between samples (sampling interval)

$$Fmax = n/2 * df$$

where: Fmax -> Bandwidth or maximum frequency of the display

df -> Frequency resolution or the number of Hz between frequency points

The time and frequency domains are related by:

$dt = 1/(2*Fmax)$ and $df = 1/T$

For example, a frequency resolution of 0.5 Hz and a 200 Hz bandwidth could be obtained by computing the number of sample points required from:

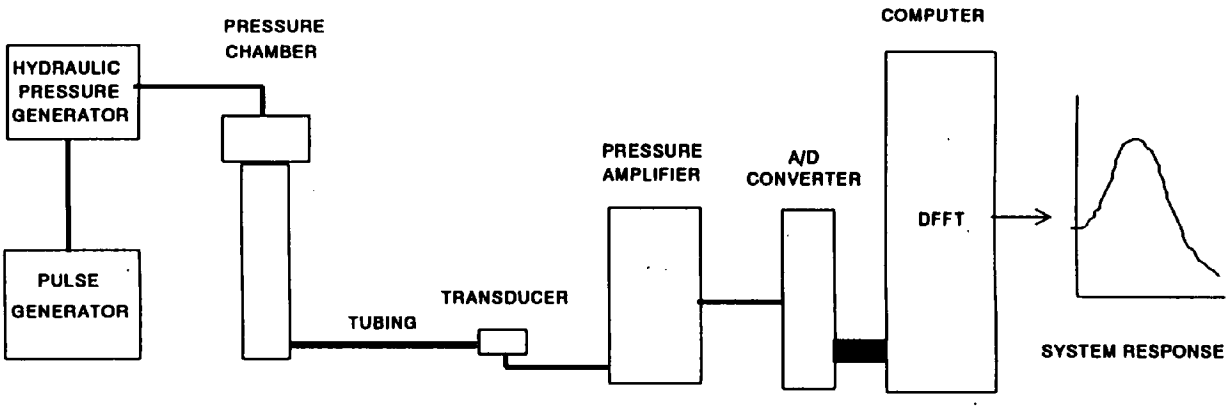


Figure 10 — Equipment for impulse response test

n/2 = Fmax / df n/2 = 200 / 0.5 therefore n = 400

dt = 1/(2 * Fmax) dt = 1/(2 * 200) therefore dt = 0.0025

The sampling interval is 2.5 milliseconds, equivalent to a sample rate of 400 Hz. There are two major points: (1) the desired bandwidth must be limited to the flat bandwidth of the pressure amplifier, or the frequency response will not be limited to the catheter-manometer system but will include the entire catheter-manometer-amplifier system response; and (2) to avoid high frequency components from being folded over inappropriately into the low frequency spectrum (aliasing), there must not be any frequency components within the sampled waveform above half of the sampling frequency (the Nyquist sampling rate is two times the highest frequency component of the signal being sampled). Aliasing can be prevented by employing a low pass filter to limit the high frequency components relative to the sampling rate. In this case the low pass filter is inherent in the pressure amplifier and causes the pressure signal to be bandlimited to less than 200 Hz.

An alternate method of assembling the system is that pictured in figure 11, where a catheter tip reference transducer is placed in the hydraulic pressure chamber and connected to an identical pressure amplifier as the test transducer. Under these conditions, the DFFT of the transducer under evaluation is divided by the DFFT of the reference transducer before the magnitude and phase is computed. This approach improves the flat response of the entire measurement system by normalizing the data for the limitations of the hydraulic pressure generator.

9.2.2 Swept sine wave test

The sine wave test, while performed in the time domain, is converted to the frequency domain; in other words, the response of the transducer and tubing set is measured as a function of the frequency of the input signal. A pressure waveform generator capable of producing a variable frequency sine wave pressure signal is used in this test to apply a signal to the patient catheter, which is connected to the transducer via the tubing set. The amplitude of the transducer output signal is monitored as the frequency of the input pressure signal is swept from low to high frequency. A typical swept sine wave frequency plot of a fluid-filled monitoring set is shown in figure 12.

In this sine wave response plot, three parameters are measured to determine the natural frequency (F_n) and damping coefficient (D). These parameters are the magnitude (M_p) of the peak amplitude, the frequency (F_p) at which the peak amplitude occurs and the magnitude (M_l) of the pressure signal at low frequency ($F_p/10$). The relative magnitude (M_m) is calculated by simply dividing the magnitude at the peak by the amplitude at low frequency. The natural frequency and damping coefficient are related to M_p, F_p and M_l by the following equations:

$$M_m = M_p/M_l \qquad (1)$$

$$D = \left| \frac{1-(1-(1/M_m^2))^{0.5}}{2} \right|^{0.5} \qquad (2)$$

$$F_n = F_p /(1-2D^2)^{0.5} \qquad (3)$$

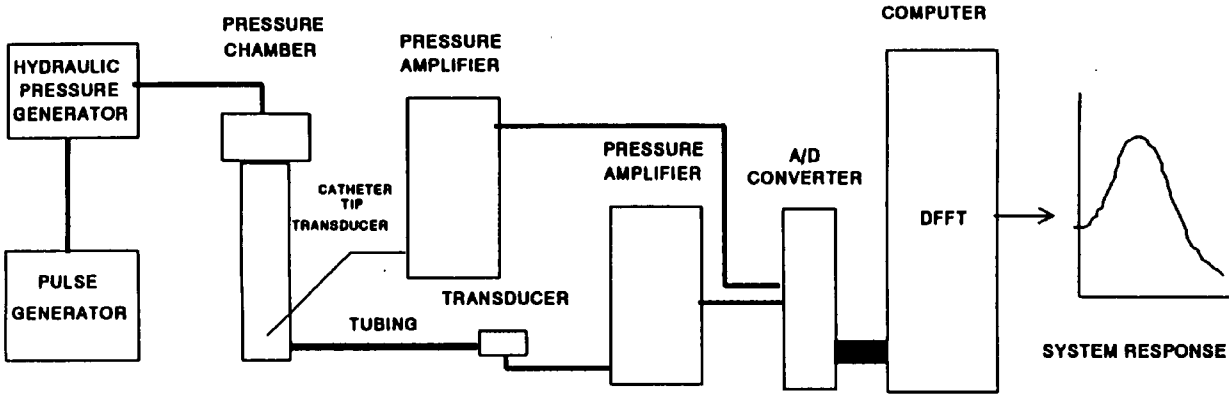


Figure 11 — Alternate method of assembling system for impulse response test

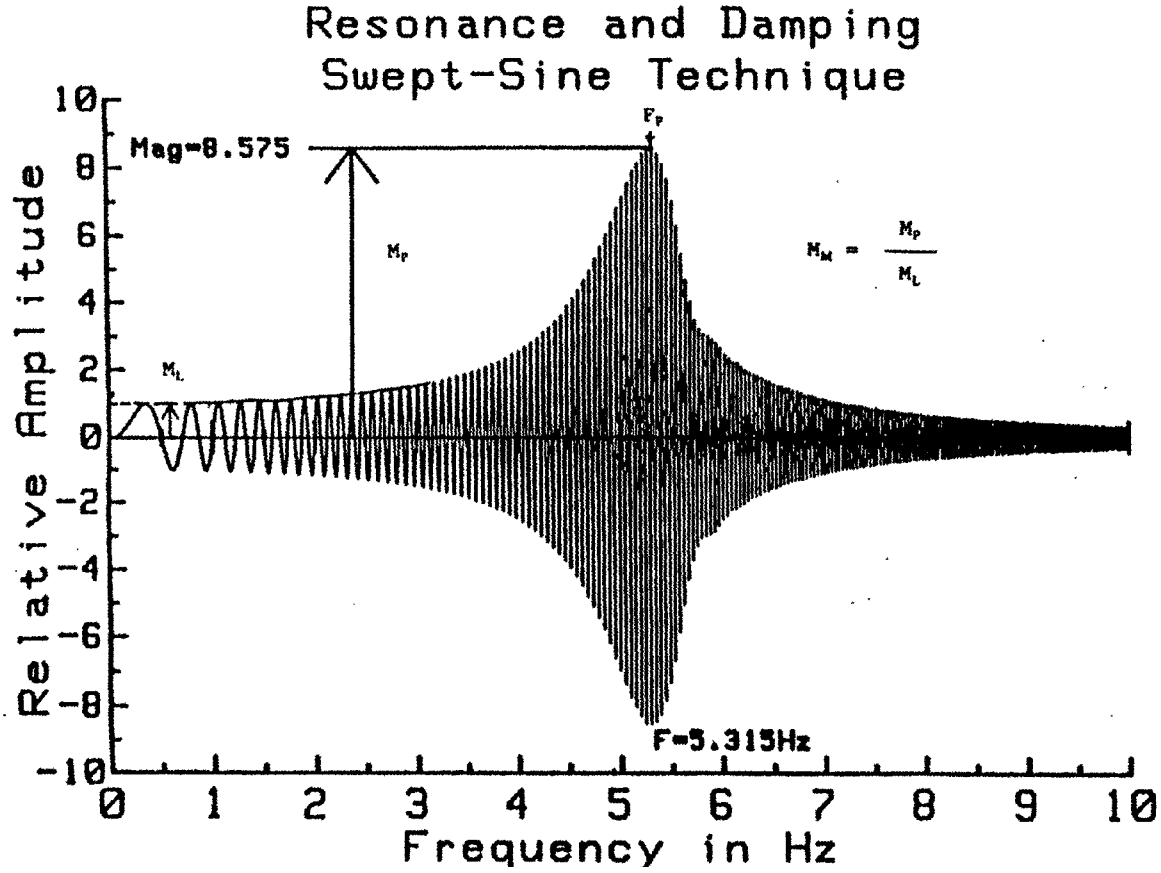


Figure 12 — Typical swept sine wave frequency plot of a fluid-filled monitoring set
(Provided courtesy of Bruce Taylor, PhD)

The following example calculation is taken from the swept sine wave response in figure 12:

$M_p = 8.575$, $F_p = 5.315$ Hz, $M_l = 1.0$

$M_m = 8.575/1.0 = 8.575$

$$D = \left| \frac{1 - (1 - (1/8.575^2))^{0.5}}{2} \right|^{0.5} = 0.058$$

$F_n = 5.315 /(1-(2)(.058)^2)^{0.5} = 5.333$ Hz

Test Protocol

Measure the relative magnitude (M_m) and frequency (F_p) at the maximum amplitude point of the frequency plot of a monitoring system.

Equipment Required

- Pressure generator: Millar MPG-30, multifunction pressure generator or Biotek 601;
- Oscilloscope: digital storage, 1 µV/division;
- DC power supply: 10V/100mA;
- Stopcock;
- Syringe.

Equipment Setup

a) Turn on the power supply and set the DC voltage to 10.0 V ± 0.5 V;

b) Turn on the oscilloscope and allow it to warm up;

c) Follow the operator's manual to set up the pressure generator. Be sure to flush all air bubbles from the pressure chamber per the operator's manual;

d) Connect the transducer interface cable to the power supply and oscilloscope as shown in figure 13. Position the transducer baseline in the center of the screen;

e) Connect the patient end of the monitoring set (the setup previously assembled by the technician or nurse) to the pressure chamber and flush all air bubbles from this connection.

Test Procedure

a) Set the pressure generator for a sine wave output of 1 Hz or less at a reasonable amplitude on the oscilloscope (typically a major division at which the amplitude can be read easily). Increase the frequency until the pressure signal rises to a maximum amplitude;

b) Measure and record the peak amplitude (M_p) of the pressure signal at this maximum point;

c) Measure and record the frequency of the sine wave (F_p) at the peak amplitude;

d) Decrease the frequency of the pressure waveform to about one-tenth of F_p (or a point where amplitude does not change with frequency). Measure the peak amplitude (M_l) of the pressure signal;

e) Compute the relative peak amplitude (M_m), the damping coefficient (D) and the natural frequency (F_n) using equations 1, 2, and 3, respectively.

An alternative method of performing the swept sine wave test is to include a reference transducer in the pressure generator. This step is particularly useful if the pressure generator does not have an adequate flat frequency response in the range of frequencies that are of interest. The reference transducer signal amplitude is measured at the same resonant frequency as the test system (M_r measured at F_p), and at a point where the amplitude does not change with frequency (off resonance where M_1 was measured). A correction factor for the test system is developed by dividing the reference transducer signal amplitude at resonance (M_1/M_r). The peak amplitude measured in step b (M_p) is multiplied by the correction factor (M_1/M_r) * M_p.

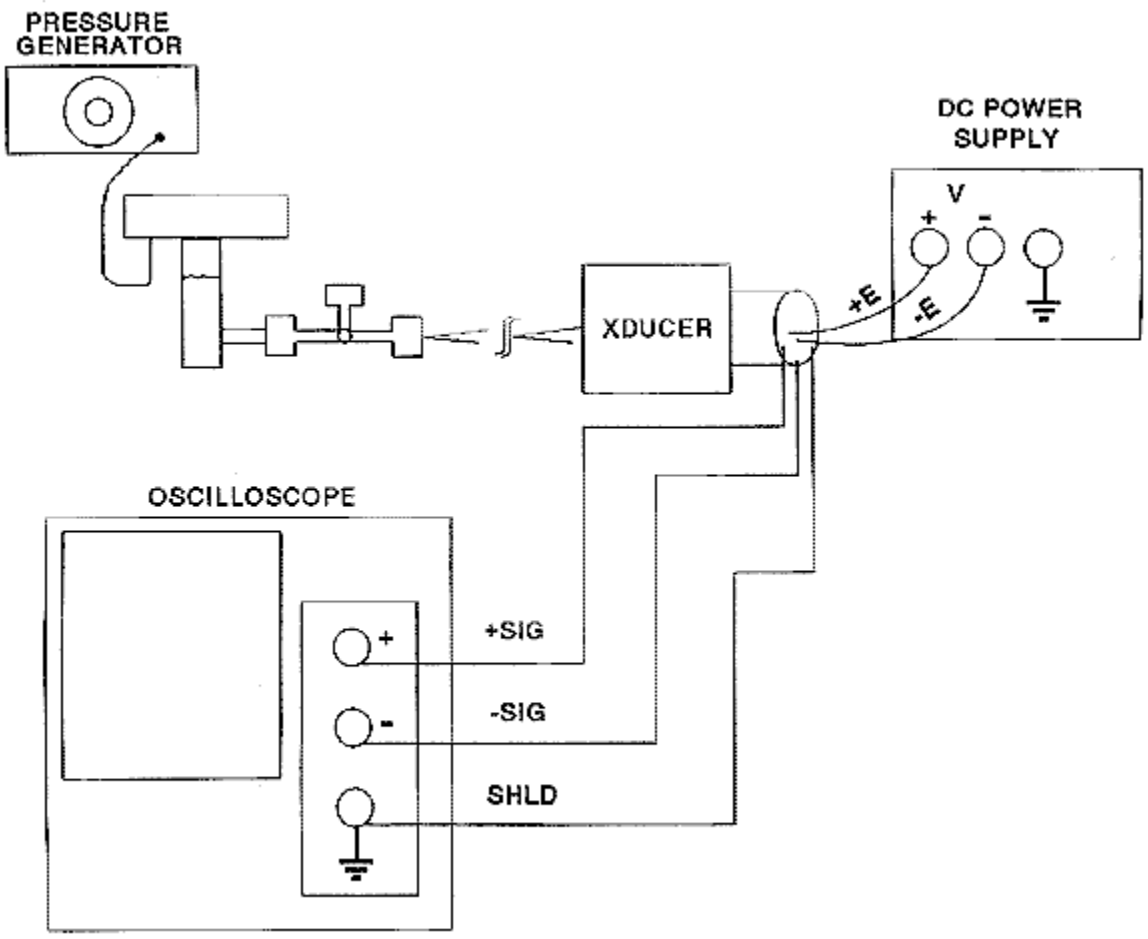


Figure 13 — Method of connecting transducer interface cable to power supply and oscilloscope

9.2.3 Step response test

The step response test is performed in the time domain; in other words, the transient response of the transducer and tubing set is measured with respect to time for a step change in the pressure input. The transient response of a second-order system to a step input is characterized by the natural frequency (F_n) and damping coefficient (D). The normalized response curves in figure 14 show the effect of the damping coefficient on the transient time response of a second-order system to a step input. As the damping coefficient gets smaller, the system oscillates more wildly.

For ease of measurement, a square wave is often used as an approximation of a step input. Commercially available pressure waveform generators produce a square wave pressure for this purpose. The positive and negative portions of the square wave must last long enough so that the waveform transition (from positive to negative or vice versa) only occurs after the flat plateau of the square wave returns. A square wave input provides the advantage of yielding a repetitive step response signal which can be observed on an

oscilloscope without storage capability.

The overshoot and frequency of the damped oscillation are the measured parameters used to compute the natural frequency and damping coefficient from the transient response. As indicated in figure 15, the overshoot (M_o) is the amplitude (M_p) of the peak of the first oscillation minus the final amplitude (M_f) of the response. The overshoot is normalized by dividing this difference by M_f, resulting in equation 4 below:

$$M_o = (M_p - M_f)/M_f = (M_p/M_f) - 1 \qquad (4)$$

The time (t_p) between two of the peaks of the damped oscillations is used to compute the damped natural frequency F_d.

$$F_d = 1/t_p \qquad (5)$$

The natural frequency and damping coefficient are related to these measurements by the equations below:

$$D = \frac{-\text{In}\,(M_O)}{(\pi^2 + (\text{In}\,M_O)^2)^{0.5}} \qquad (6)$$

$$F_n = F_d/(1-D^2)^{0.5} \qquad (7)$$

where ln is the natural logarithm function.

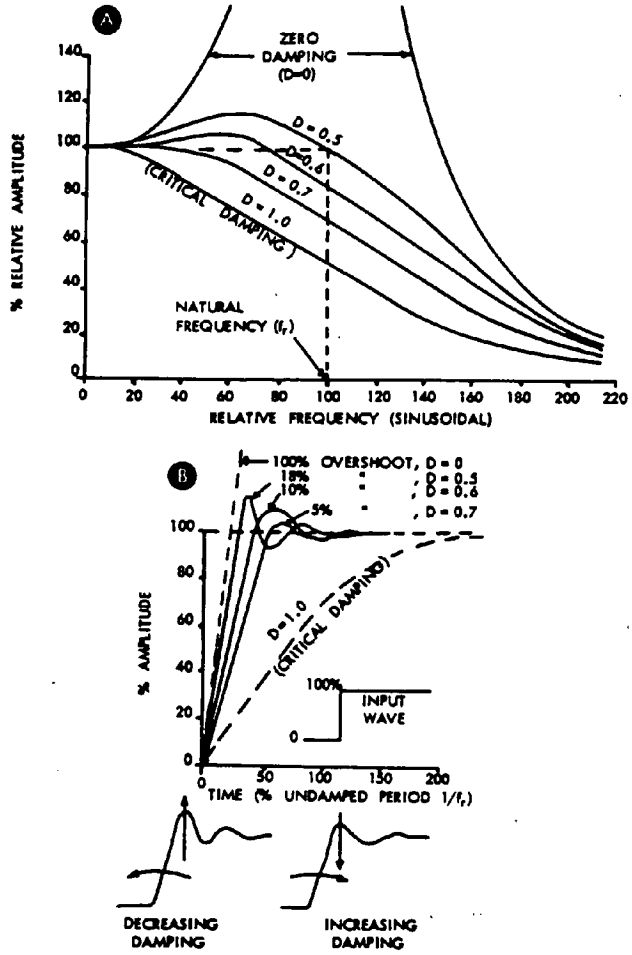


Figure 14 — Sinusoidal and step-wave responses in a resonant system with various degrees of damping. A, sinusoidal frequency response. B, step-wave response.

(Borrowed with permission from "The Direct and Indirect Measurement of Blood Pressure," L.A. Geddes, ME, PhD, Year Book Medical, 1970)

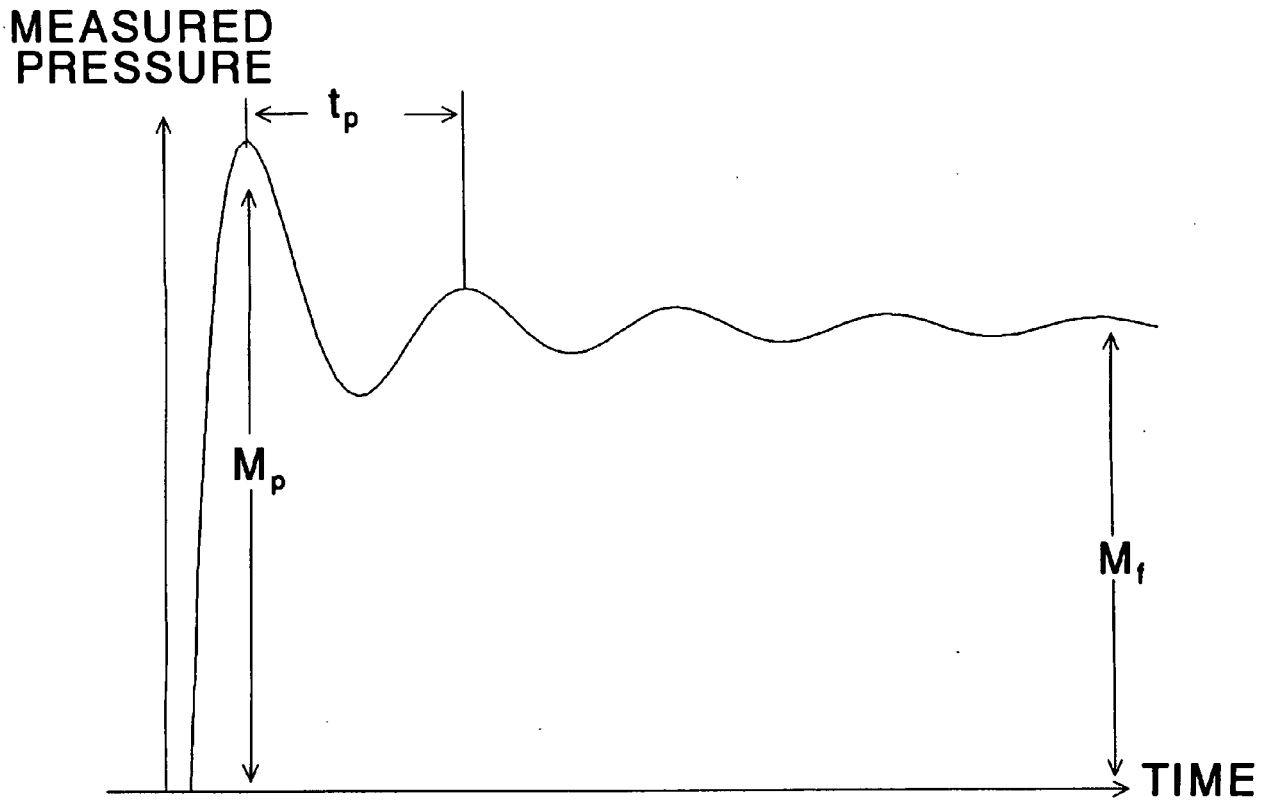


Figure 15 — Measured parameters for step response

Test Protocol

Measure the overshoot (M_o) and damped natural frequency (F_d) of the monitoring system response to a square wave input.

Equipment Required

- Pressure generator: Millar MPG-30 or Biotek 601;
- Oscilloscope: digital storage, 1 µV/division;
- DC Power Supply: 10V/100mA;
- Stopcocks;
- Syringe.

Equipment Setup

a) Turn on the power supply and set the DC voltage to 10.0 V ± 0.5 V;

b) Turn on the oscilloscope and allow it to warm up;

c) Follow the operator's manual to set up the pressure generator. Be sure to flush all air bubbles from the pressure chamber per the operator's manual;

d) Connect the transducer interface cable to the power supply and oscilloscope as shown in figure 13. Position the transducer baseline in the center of the screen;

e) Connect the patient end of the monitoring set (the setup previously assembled by the technician or nurse) to the pressure chamber and flush all air bubbles from this connection.

Test Procedure

a) Set the pressure generator for square wave output at a frequency of 2 Hz;

b) Measure and record the time (t_p) between peaks of the damped oscillations;

c) Measure the amplitude of the first peak (M_p) and the final amplitude (M_f) of the response curve;

d) Compute the overshoot (M_o) and damped natural frequency (F_d) using equations 4 and 5;

e) Compute the damping coefficient (D) and natural frequency (F_n) using equations 6 and 7.

9.2.4 Simplified step response test

The simplified step response test is similar to the step response test in that it measures the system response with respect to time. The simplification resides in terms of the equipment required to perform the test. The simplified step response is generated by pressurizing the transducer and tubing set, then releasing the pressure via a stopcock through the intraarterial catheter located at the patient end of the tubing. Releasing the pressure in this fashion generates a pressure step response in the negative direction, and has the same effect as using a pressure generator to input a step change in pressure at the patient catheter. The damped natural frequency and the damping coefficient of the system can be determined from the transient response signal generated by this pressure step.

A typical response curve for this pressure step input is given in figure 16. The indicated parameters A^1, A^2 and t_p are used to compute the natural frequency (F_n) and damping coefficient (D) via the following equations:

$$D = \frac{-\ln (A^1/A^2)}{(\pi^2 + (\ln (A_1/A_2))^2)^{0.5}} \qquad (8)$$

$$F_n = (1/t_p)/(1-D^2)^{0.5} \qquad (9)$$

NOTE—these equations are very similar to those used in the step response test (6 and 7).

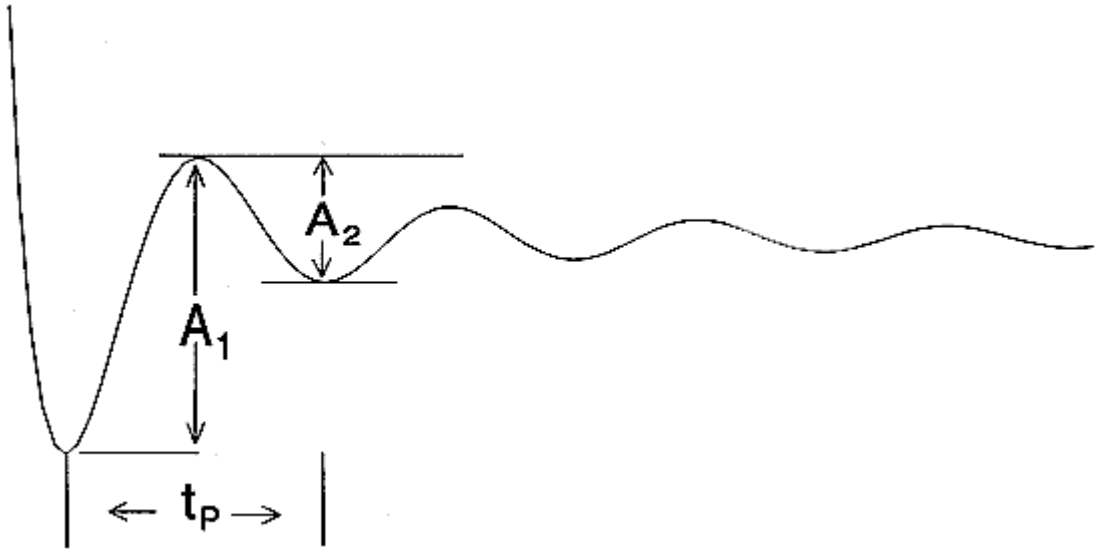


Figure 16 — Measured parameters for simplified step response test

Test Protocol

Measure the relative amplitudes A_1 and A_2 and the time between peaks (t_p) of the transient response of a transducer and tubing set for a negative pressure step.

Equipment Required

- Patient Monitor

  —Blood pressure channel with low-pass filter disabled and frequency response of 100 Hz, minimum

  —Chart recorder with 50 mm/sec speed and 100 Hz frequency response and with adequate offset range to display negative peak of step response;

- Alternately, a storage scope or chart recorder with a frequency response of 100 Hz may be used to display the waveform for measurement;

- Stopcock.

Equipment Setup

a) Turn on the power to the patient monitor and allow it to warm up for 15 minutes;

b) Connect the transducer cable to the monitor;

c) Open the transducer to atmosphere and zero the monitor;

d) Place a stopcock on the patient end of the tubing, between the patient catheter and the tubing.

Test Procedure

a) Close the stopcock at the patient end of the system and allow the pressure to rise to 300 mmHg from the pressurized bag of flush solution that was assembled with the system by the technician or nurse;

b) Turn on the chart recorder at 50 mm/sec to begin recording the waveform;

c) Very rapidly open the stopcock at the patient port with a sharp turn;

d) Stop the recorder and measure A_1, A_2 and t_p on the chart paper;

e) Compute the damping coefficient (D) and natural frequency (F_n) using equations 8 and 9.

10 References

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Annex A — Overall performance evaluation summary

All tests should be performed with the transducer-tubing system filled with normal saline as if it was going to be applied to a patient.

I. Static testing of the transducer

A. Manufacturer recommended warm-up time _____ minutes

(Data are the maximum drift from among the 3 trials)

1. Drift during warm-up time _____ mmHg/hr or mmHg/30 min
2. Drift after warm-up _____ mmHg/30 min (next 30 minutes)

B. Transducer sensitivity

(Data are the mean sensitivity errors from among the 5 trials.)

0 mmHg _____ 100 mmHg _____

200 mmHg _____ percent sensitivity error _____

C. If there is a back side calibration port, does it function properly (without leaking)?

_____

D. Exposure of the transducer-cable connector to water type of failure

_____

_____

E. Exposure of vent or back side calibration port to water.

1. Is water drawn into the port by capillary action? _____
2. Does the zero change? _____

3. Does the sensitivity change?_____

II. Dynamic response of the transducer

Kit 1 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 2 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 3 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 4 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 5 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 6 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 7 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 8 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 9 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 10 assembled by: _____ Bandwidth (15%) _____ Hz

For 10 kits: Computed average bandwidth (15%) _____ Hz

If variability of the data after 10 samples is unsatisfactory:

Kit 11 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 12 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 13 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 14 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 15 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 16 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 17 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 18 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 19 assembled by: _____ Bandwidth (15%) _____ Hz

Kit 20 assembled by: _____ Bandwidth (15%) _____ Hz

For 20 Kits: Computed average Bandwidth (15%) _____ Hz

Dynamic Response Evaluation Worksheet

Kit 1 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 2 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 3 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 4 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 5 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 6 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 7 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 8 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 9 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 10 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 11 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 12 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 13 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 14 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 15 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 16 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 17 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 18 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 19 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Kit 20 f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

Average: f_0 _____ Hz Damp Coef _____ Bandwidth (15%) _____

	WARM-UP DRIFT	OPERATING DRIFT	SENSITIVITY ERROR	VENT TUBE WATER	CONNECTOR WATER	AVERAGE Fn	AVERAGE D	AVERAGE BW
SOURCE A								
SOURCE B								
SOURCE C								
SOURCE D								
SOURCE E								
SOURCE F								

Figure A.1 — Summary Data

Annex B — Basic language program for calculation of dynamic response

```
1 REM This Is The Program For Computing The Resonant Frequency
2 REM And Damping Coefficient From Swept Sine wave Data
3 REM
5 PRINT "Input Mp, Fp, M1"
```

```
10 INPUT Mp, Fp, M1
15 LET Mm=Mp/M1
20 LET D1=SQR(1-(1/Mm^2))
25 LET D=SQR((1-D1)/2)
30 LET F1=SQR(1-(2*D^2))
35 LET F0=Fp/F1
40 LET B=4*D^2-2
45 LET BW=SQR((-B-SQR(B^2-.975425))/(2/F0^2))
50 PRINT "Fn = ";F0;"Hz ";"D = ";D;" 15% Bandwidth = ";BW
55 END
```

```
1 REM Step Response Test Basic Language Program
2 REM
5 PRINT "Enter Mp, Mf, tp"
10 INPUT Mp,Mf,tp
15 LET M0=(Mp/Mf)-1
20 LET Fd=1/tp
25 LET D=(-LOG(M0))/SQR(9.8696+(LOG(M0))^2)
30 LET F0=Fd/SQR(1-D^2)
35 LET B=4*D^2-2
40 LET BW=SQR((-B-SQR(B^2-.975425))/(2/F0^2))
45 PRINT "Fn = ";F0;"Hz ";"D = ";D;" 15% Bandwidth = ";BW
50 END
```

```
1 REM Simplified Step Response Basic Language Program
2 REM
5 PRINT "Enter A1, A2, tp"
10 INPUT A1, A2, tp
15 LET D=(-LOG(A2/A1))/SQR(9.8696+(LOG(A2/A1))^2)
20 LET Fd=1/tp
25 LET F0=Fd/SQR(1-D^2)
30 LET B=4*D^2-2
35 LET BW=SQR((-B-SQR(B^2-.975425))/(2/F0^2))
```

```
40 PRINT "Fn = ";F0;"Hz ";"D = ";D;" 15% Bandwidth = ";BW
45 END
```

Annex C — Derivation of the 15 percent bandwidth calculation for a second-order system given the damped resonant frequency and damping coefficient

The assumption is being made that the transducer-tubing system can be approximated reasonably well by a second-order system response. Under many circumstances this assumption is strictly correct. For example, when bubbles are added to the system and distributed along the length of the tubing, higher order system responses are observed (fourth- and sixth-order systems). However, the second-order approximation of a higher order system by using the lowest measured damped resonant frequency will yield a conservative estimate of the bandwidth that should be acceptable within the framework of the purpose of this document.

Given the second-order system response where:

D = damping coefficient

j = square root of -1

jW = the imaginary radian frequency in the frequency domain

s = Laplace operator or being in the Laplace domain

T = transfer function or system response

Wn = natural frequency (radians)

W = radian frequency

$$T(s) = \frac{Wn^2}{s^2 + 2\,D\,Wn\,s + Wn^2}$$

Let s = jW

$$T(jW) = \frac{Wn^2}{(jW)^2 + 2\,D\,Wn\,jW + Wn^2} = \frac{1}{(1-(W/Wn)^2) + j\,(W/Wn)\,2\,D}$$

The magnitude response of T(jW) can be expressed as:

$$|T(jW)| = \sqrt{(\text{real})^2 + (\text{imaginary})^2}$$

$$|T(jW)| = \frac{1}{\sqrt{(1-(W/Wn)^2)^2 + 4\,D^2\,(W/Wn)^2}}$$

We are trying to find the frequency at which the 15 percent bandwidth occurs. To do this we set the magnitude response equal to 1.15 and solve the equation for the frequency.

$$(1.15)2 = \frac{1}{(1 - (W/Wn)^2)^2 + 4\,D^2\,(W/Wn)2}$$

Substituting $W = 2\,\pi\,f$ and $Wn = 2\,\pi\,fn$ and simplifying

$$1.3225 = \frac{fn^4}{4\,D^2\,f^2\,fn^2 + (f^2 - fn^2)^2}$$

Solving for f yields four roots. The pair of roots at the lowest f provides the 15 percent bandwidth that we are looking for, since that is the point where the magnitude crosses the 15 percent limit on its way to the resonant peak. The pair of roots with the higher f occurs when the magnitude response crosses the 15 percent bandwidth on the descent from the resonant peak.

$$f = -0.208514\ fn \sqrt{2\sqrt{529\ D^4 - 529\ D^2 + 100} - 46\ D^2 + 23}$$

$$f = 0.208514\ fn \sqrt{2\sqrt{529\ D^4 - 529\ D^2 + 100} - 46\ D^2 + 23}$$

$$f = -0.208514\ i\ fn \sqrt{2\sqrt{529\ D^4 - 529\ D^2 + 100} + 46\ D^2 + 23}$$

$$f = 0.208514\ i\ fn \sqrt{2\sqrt{529\ D^4 - 529\ D^2 + 100} + 46\ D^2 + 23}$$

Basic Program for Computation of 15 Percent Bandwidth Given fn and D

```
10 INPUT f0, d
20 LET f=0.208514*f0*SQR(-2*SQR(529*d^4-529*d^2+100)-46*d^2+23)
30 PRINT "Given f0 = ";f0;" and D = ";d;" 15% Bandwidth = ";f
40 END
```