# CLINICAL AND LABORATORY EVALUATION OF FOUR CATHETER-TRANSDUCER SYSTEMS

by

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#### ABSTRACT

This study was conducted to examine four cathetertransducer systems and their variations that were found clinically. The dynamic response characteristics ( $f_n$ and  $\swarrow$ ) were determined for each system in both a laboratory and clinical setting. These dynamic response characteristics provided information about each system in regard to its ability to faithfully reproduce a pressure waveform.

From this study it was found that the simpler catheter transducer system has more adequate dynamic response characteristics and thus was more capable of faithfully reproducing the pressure waveforms. The membrane dome was found to be equal in function with the nonmembrane dome provided that the manufacturer's recommended method of attachment, i.e., water instillation on the transducer diaphragm and pressure distension of the dome membrane, was adhered to. It was determined that extension tubing was detrimental to the system's dynamic response characteristics and, moreover, impedes faithful waveform reproduction.

With regard to the pulmonary artery catheter transducer systems, it was found that the use of extension tubing results in an undesirable elongation of the system. In all clinical trials of the pulmonary artery cathetertransducer systems, the dynamic response characteristics were overdamped.

Finally, it was ascertained that dynamic response testing may be easily performed in the clinical setting and provides valuable information with regard to the adequacy of each system. This testing allows for determination of the accuracy of the reproduced waveform to the original patient waveform.

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### CHAPTER I

# INTRODUCTION AND REVIEW OF LITERATURE

### Problem Statement and Purpose

The catheter-transducer system is a widely used tool in the critical care area for directly assessing intravascular pressures. The purpose of the catheter-transducer system is to obtain the intravascular pressure signal, transform it into an electrical signal, display the signal as a waveform and derive parameters such as systolic and diastolic pressure. The system provides the clinician with hemodynamic data in an understandable and meaningful The final waveform displayed is intended to be an form. exact representation of the intravascular pressure. The extent to which the recorded pressure waveform and the actual intravascular pressure signal differ is attributed to measurement error. The degree of measurement error of a system may be significantly reduced by improvements in the system and new technological advances. However, because of mechanical limitations, measurement error can never be completely abolished. It is therefore desirable

that the catheter-transducer system possess the highest degree of fidelity possible in order that the measurement error may be as low as possible and patient care not jeopardized. A number of investigators (Frank, 1903; Wood, 1950; Fry, 1960; Yanof, 1963; Latimer & Latimer, 1969; Shapiro & Krovetz, 1970; Gardner, 1981) have examined the components of the catheter-transducer system and have determined criteria necessary for accurate waveform reproduction. The catheter-transducer system studied by these investigators utilized a transducer dome without a membrane which maintains a fluid continuum from the intravascular pressure source to the sensing diaphragm of the transducer. Recently, disposable membrane dome devices have been developed which separate the fluid column in the catheter system from the transducer membrane. These devices have received widespread acceptance and are routinely used in the critical care area since they provide microbiological and electrical isolation from the transducer. Since the development of this membrane dome device, there has been only one study (Fox, 1978) published which speaks to the effects of this device on the fidelity of the catheter-transducer system. Little is published about the effects of the membrane dome on the dynamic response characteristics of the catheter-transducer system. Therefore, little is known about the extent of measurement error involved when this device is used.

The purpose of this study was to examine four catheter-transducer systems as well as the variation of these systems that may be found clinically. These four catheter-transducer systems differ from each other by at least one, and sometimes several, characteristics. The dynamic response characteristics of all four systems and their variations were determined clinically and in the laboratory. Furthermore, each system was evaluated to determine if its dynamic response characteristics were adequate for faithful waveform reproduction.

#### Review of Literature

### Catheter-Transducer System

The catheter-transducer system has been defined by a number of investigators (Geddes, 1975; Fry, 1960; Piemme, 1963; Gardner, 1981) as a simple mechanical system. Mass, friction and elasticity are the three factors which determine the dynamic characteristics of the catheter-transducer system. A model which portrays the catheter-transducer system is a mass which must be suspended vertically or have two spring elements and is free to move on a frictionless surface. One side of the mass is attached to a spring which is connected to a support. The other side of the mass is connected to a rod to which a dashpot, the frictional element, is attached. This provides viscous damping. This model is illustrated in

Figure 1.

If a force is applied to the mass and then quickly released, the mass will initially move from its position of equilibrium and eventually return to its original position. Fry (1960) effectively discusses the relationship between this model and the catheter-transducer system. The mass is the fluid in the catheter, the spring is the stiffness of the transducer diaphragm and the dome device, and the viscous damping (frictional component) is the resistance to fluid flow in the catheter lumen.

The catheter-transducer system is ordinarily composed of rigid tubing of specified length, a continuous flush device which keeps the catheter patent, a stopcock to allow for blood withdrawal and a dome device which serves to couple the fluid with the transducer diaphragm.

At the catheter tip, pressure is exerted by the blood in the intravascular space on the fluid in the catheter. In keeping with Pascal's law, which states that a change in pressure at any point in an enclosed liquid results in a like change at every other point in the liquid, pressure is transmitted to the transducer diaphragm which is displaced proportionate to the pressure. Pressure is converted to an electrical signal by the transducer.

Due to the pumping action of the heart, intravascular pressure consists not only of a static but also a dynamic component. When an increased pressure is applied at the



Figure 1. Model of the factors (mass, friction and elasticity) which portray the catheter-transducer system. Reprinted with permission of John Wiley and Sons, Inc. Publishers. Geddes, L.A. & Baker, L.E. <u>Principles of applied biomedical</u> instrumentation (2nd Ed.). New York: John Wiley and Sons, 1975, pp. 584-605. catheter tip, it causes a small movement of fluid in the catheter. This fluid movement shifts along the length of the conduit as the pressure wave is transmitted to the dome chamber and applied to the transducer diaphragm. The diaphragm acts like a spring and will "give" or displace in proportion to the applied pressure. This displacement is converted to an electrical signal (voltage) by the transducer. Therefore, the transducer is measuring membrane displacement or "give" which is directly proportional to pressure. The change in voltage is then amplified and displayed.

In both the model discussed above and the cathetertransducer system, the "mass" of the system will move out of equilibrium and return either quickly or slowly, and may oscillate and overshoot about its equilibrium position before coming to rest. The type of movement that is exhibited in either system is dependent upon the interrelationships among the spring, mass and frictional components.

### Natural Frequency

The frequency at which oscillation will occur in the system is termed the natural frequency  $(f_n)$  of that system. Equation 1, derived by Geddes (1970) describes the  $f_n$  when a nondistensible catheter and transducer system are connected.

$$f_n = \frac{1.4 \times 10^3 d}{\sqrt{Vd \times L}}$$
 (1)

From this equation, it is apparent that the natural frequency  $(f_n)$  will increase if the volume displacement (Vd) and length of the catheter are decreased and diameter of the catheter increased (Equation 2)

$$\oint f_n = \frac{1.4 \times 10^3 d}{\sqrt{4 \text{ Vd} \times L}}$$
(2)

If any element in the system is more compliant, (  $\blacklozenge$  Vd) or the diameter of the catheter is decreased, the system will resonate at a lower frequency (Equation 3)

$$\oint f_n = \frac{1.4 \times 10^3 d \oint}{\sqrt{\oint Vd \times L}}$$
 (3)

With application of sinusoidal pressure at varying

frequency, the response (amplitude ratio) of the system is augmented by this tendency to oscillate (Figure 2). If the frequency components of the input wave are near the natural frequency of the system, the amplitude ratio will be increased and the input wave distorted. If the frictional component of the system is low, the amplitude ratio will be even greater at the natural frequency. At frequencies greater than the natural frequency, the amplitude ratio will decline. A system such as this is termed an underdamped system.

In the ideal catheter-transducer system, it is desirable to use a highly incompressible fluid such as air free saline so that an increase in pressure will result in fluid movement rather than in fluid compression. If air bubbles exist in the catheter-transducer system, the pressure pulse is dissipated in air bubble compression rather than diaphragm displacement. The result is a "smoothing out" or "damping" of the actual pressure waveform. This can result in an underestimation of the amplitude of the actual pressure pulse waveform.

### Damping Coefficient

Damping is any means by which the energy of the oscillating diaphragm is dissipated such that the amplitude ratio is decreased. Equation 4 (Geddes, 1970) describes the damping coefficient ( $\zeta$ ) of a catheter-



Figure 2. Transient response with various degrees of damping: a) ? =1.0 critical damping; b) ? =0.2; c) ? =0.5. Reprinted with permission of John Wiley and Sons, Inc. Publishers. Geddes, L.A. & Baker, L.E. <u>Principles of applied</u> biomedical instrumentation (2nd ed.). New York: John Wiley & Sons, 1975.

transducer system

$$\zeta = \frac{1.36 \times 10^{-5}}{d^3} \sqrt{Vd \times L}$$
 (4)

- - d = diameter of the catheter
  - L = length of the catheter

Energy dissipation or damping occurs due to increased volume displacement (  $\blacklozenge$  Vd) and increased length of the catheter (  $\blacklozenge$  L). Small reductions in diameter of the catheter lead to a large increase in damping coefficient (sometimes overdamped) since the diameter is cubed in the denominator (Equation 5)

$$\bigstar = \frac{1.36 \times 10^{-5}}{\checkmark d^3} \quad \checkmark \forall d \times L \checkmark$$
(5)

In an overdamped system, the amplitude ratio is decreased as the frequency approaches  $f_n$  (See Figure 2).

An underdamped system results from a decreased volume displacement, decreased length and/or increased diameter of the catheter (Equation 6)

$$\oint = \frac{1.36 \times 10^{-5}}{4 d^3} \quad \forall Vd \times L \downarrow$$
 (6)

In an underdamped system, the amplitude ratio is increased as the natural frequency is approached. Optimal damping results in a constant amplitude ratio for increasing frequency to a point close to the natural frequency. The damping coefficient ( $\zeta$ ) is a number which refers to the degree of damping that a system possesses. For damping,  $\zeta$  is between 0.65 and 0.80 (Geddes, 1975; Wood & Sutterer, 1960).

### Waveform Reproduction

The arterial pressure pulse which is generated from cardiac contractions, is a complex periodic waveform (See Figure 3). Periodic waveforms are composed of a series of sine and cosine waves, the sum of which, equals the original waveform. Fourier analysis is the mathematical means of dissecting a periodic waveform into its basic components. The fundamental, or first harmonic, is the sine wave having the same frequency as the original wave. The second harmonic is the sine wave that is twice the frequency of the fundamental. The third harmonic is three times the frequency of the fundamental and so on.

When the fundamental and a sufficient number of harmonics are added together, the original waveform is reproduced. Waveforms with sharper deflections are composed of higher frequency sine wave components and thus more harmonics. The square wave, with its sharp deflections



Figure 3. Dissection of a periodic waveform into its basic components. Reprinted with permission of Geddes & Baker, <u>Principles of applied bioinstrumen-</u> <u>tation (2nd ed.). New York: John</u> Wiley and Sons, 1975.

requires the most frequency components to reproduce. The square waveform changes from zero to some value instantly, then this value is maintained for a period of time and falls to zero again in an instant. Fourier series reduces the square wave to the fundamental component and a large number of harmonics. As the frequency of the harmonics increase, the amplitude of harmonic decreases, and therefore, contribute less to the reproduction of the original wave. In order that a pressure waveform be reproduced with a high degree of fidelity, the cathetertransducer system must be able to respond to the fundamental frequency and enough of the harmonics to accurately reproduce the waveform. The more smaller amplitude, higher frequency harmonics that the system is able to reproduce, the more similar will the reproduced wave be to the original wave. Piemme (1963) states that the dicrotic notch of the aortic pressure wave contains frequency components above 10 Hz. Therefore, a catheter-transducer system must be able to respond to frequences greater than 10 Hz so the dicrotic notch is not distorted.

How many harmonics must the system be able to respond to in order that the waveform be reproduced with enough fidelity to portray an accurate hemodynamic picture? It is generally conceded by a number of authorities (Wood, 1950; Wiggers, 1924; Leraand, 1962; Piemme, 1963) that almost all of the essential information in

a physiologic pressure waveform is contained within the first ten harmonics. Therefore, a system for pressure measurement must be able to faithfully reproduce harmonics that are at least ten times the frequency of the fundamental. As seen in Figure 4, in order to do this, the  $f_n$  of the system must be much higher than the highest harmonic frequency. For example, at a heart rate equal to 120 beats per minute, the tenth harmonic is 20 Hz. At a heart rate equal to 180 beats per minute, the tenth harmonic equals 30 Hz. Therefore, it appears that the  $f_n$  of a system must be greater than 25 to 30 Hz in order to accurately reproduce waveforms at a faster heart rate. Moreover, the  $f_n$  required is dependent on the ( $\mathcal{C}$ ) damping coefficient of the system.

The catheter-transducer system utilized clinically can be characterized as an underdamped system,  $\mathcal{G} = 0.20$  – 0.30 (Gardner, 1981). Gardner emphasized the interrelationship between the damping coefficient and the natural frequency of a system and demonstrated how the interrelationship between these two parameters determines the system's fidelity. An operating band developed by Gardner indicates the natural frequency and damping coefficient within which a catheter-transducer system must operate for recording accurate arterial pressure waveforms. This graph is illustrated in Figure 5. The area labeled "adequate dynamic response" is required for faster heart



Frequency

Figure 4. Amplitude distortion at  $f_n$ .



Figure 5. Dynamic response characteristics necessary for faithful waveform reproduction. Reprinted with permission of Gardner, R.M. and <u>Anesthesiology</u>. Gardner, R.M. <u>Anesthesiology</u>, March 1981, <u>54</u>, 227-236.

rate waveforms and for waveforms with a very rapid pressure rise during the systolic upstroke. The area labeled "marginal dynamic response" may be adequate for slower rates or nominal systolic upstrokes. From this graph, it is evident that if the system has a higher natural frequency, the damping coefficient acceptable can have a wider range and still faithfully reproduce the waveform.

Studies by Wood and Sutterer (1960), Hansen (1949), Shapiro and Krovetz (1970), Fry (1957), Sinozaki, Deane and Mzuzan (1980), Crul (1960) and McCutcheon (1972) determined the sensitivity and dynamic response characteristics of catheter-transducer systems. In all of these studies, the system utilized a nonmembrane dome such that the fluid in the catheter was in direct contact with the transducer diaphragm. Recently, a dome device was developed which consists of a compliant membrane which separates the transducer diaphragm from the fluid There are no studies in the literature which column. report the sensitivity and dynamic response characteristics of a catheter-transducer system utilizing this device. A study by Fox, Morrow, Kacher and Gilleland (1978) determined the sensitivity and frequency response of a transducer with a membrane only dome attached. The catheter and extension tubing were not attached. Their results showed an increase in transducer sensitivity error

with the use of the membrane dome. This study also found that the frequency bandwidth exceeded 20 Hz in 25 out of 28 membrane dome/transducer combinations. However, the addition of tubing, stopcocks, catheter and flush device will lower this frequency response. As stated by Fox et al. (1978), "the presence of this membrane introduces the potential disadvantage of significantly altering the static and/or dynamic accuracy of the pressure measurement system" (p.67).

### Potential for Static and Dynamic Pressure Errors

Blood pressure has both static and dynamic components. High fidelity recording of blood pressure requires faithful reproduction of both of these components.

Static pressure is the constant force per unit area which does not change over time. In the catheter-transducer system, fluid in the vascular system exerts a constant pressure at the indwelling catheter tip. This is the residual pressure and is independent of the flow and velocity of the fluid. Static accuracy is the reliability of an instrument to faithfully reproduce the static pressure signal. Sensitivity is the output voltage that is generated in response to a given change in pressure. Sensitivity is one component of static accuracy. Another component of static accuracy is offset which is the ability to maintain a zero baseline. In the catheter-transducer system that utilizes a membrane dome, there exists a definite potential for static pressure error due to both sensitivity and offset error. This potential for static pressure error exists because of the following factors: a) dome misapplication, b) compression of fluid between the transducer diphragm and the dome membrane, c) uncoupling of the dome transducer interface, d) mounting the transducer-membrane dome apparatus above the zero reference level and e) size variability of the dome.

A study by Fox et al. (1978) demonstrated the magnitude for sensitivity error in the membrane dome/transducer In this study, several commonly used techniques set-up. of membrane dome attachment were tested for sensitivity. The nonmembrane dome which can only be attached using one technique was also tested for sensitivity. For this technique of nonmembrane dome attachment, sensitivity error was less than the 1% specified by the manufacturers for all transducer/nonmembrane domes tested. Of the seven transducer-membrane dome combinations tested, three had at least one attachment technique that resulted in less than 1% sensitivity error. The remaining combinations with various attachment techniques had sensitivity errors greater than 2%. Depending on the specific attachment technique, transducer sensitivity as high as 4.9% was noted.

Since it is possible to attach the membrane dome to the transducer by several different techniques, clinicians who use these devices are likely to make the attachments differently even if one specific technique is recommended by the manufacturer. Deviation from the recommended technique is even more likely if the technique is cumbersome and time consuming. The study by Fox (1978) evaluated only the transducer and dome combination. Catheter, tubing, flush device and stopcocks, which also affect static accuracy were not examined with the transducerdome combinations. According to Health Devices (1979) a total inaccuracy in pressure measurement of 5% may be acceptable. This total inaccuracy is the accumulation of contributions from static and dynamic factors. Since transducer sensitivity error is only one of the components of static inaccuracy, it should be held to a minimum of 1% (Fox et al., 1978). Because of this, a 2% sensitivity error is unacceptable.

The transducer measures static pressure according to the force which is exerted at its membrane. The liquid layer present in the interface between the transducer diaphragm and the dome membrane may become compressed if the membrane is not distended prior to the attachment of the transducer. This compressed liquid will exert a force upon the transducer diaphragm and thus affect the static pressure measurement. This pressure is reflected

in the zero baseline measurement and may shift the zero baseline as high as 100 mm Hg. This was demonstrated in both Bentley and Gould membrane domes in a study by <u>Health Devices</u> (1979). Distension will displace the air and fluid from the dome membrane and transducer diaphragm, thus preventing compression and static pressure error. Again, it becomes evident, that a slight deviation in attachment technique can result in significant static inaccuracy, in this case, shift in the zero baseline of considerable magnitude.

There exists yet another potential for static pressure errors in using the membrane dome. This error was discovered by Sisko, Hagerdal and Neufeld (1979) in a clinical incident. The patient's arterial blood pressure was being monitored by a Gould Statham P23Db transducer connected to a Gould-Statham disposable membrane dome, Ta 1009D. It was noted initially that the patient's blood pressure was 220/110 mm Hq. After anesthesia had been induced and surgery begun, the patient's pressure fell to 160/90 mm Hq. Five minutes later, the pressure was 90/25 mm Hq. The arterial wave was unchanged in shape. There were no kinks, bubbles or back bleeding noted in the pressure lines. Flushing produced no changes. Dopamine was being prepared for administration to treat the hypotension when a manual cuff pressure revealed a pressure of 160/95 mm Hg. The monitor tracing

continued to be 80/15 mm Hg. It was then discovered that the membrane dome had loosened. Tightening the dome did not alter the arterial waveform shape but resulted in an elevation of the tracing on the oscilloscope. This case report indicates that uncoupling can result in static pressure errors rather than dynamic inaccuracies. The magnitude of static pressure error, as shown by this case, can be significant enough that drastic treatment measures may be initiated as a result. The potential for this type of error occurring is significant when one considers that no changes in waveform appearance present to give the clinician a clue that a malfunction in the system exists.

It has been observed, clinically, that if the transducer-membrane dome apparatus is mounted on a manifold above the level of the catheter insertion site another static pressure error may result. Mounting in this position causes a negative pressure at the transducer which consequently exerts a vacuum on the dome membrane causing it to pull away from the transducer diaphragm. Hence, the transducer will sense a negative and inaccurate pressure. For this reason, some transducer manufacturers specify a pressure range from -50 mm Hg. It is obvious that this potential could result in significant static pressure errors.

Size variability of the dome may result in static pressure rerror since pressure is equal to force/area.

Since area =  $\pi d^2 / 4$  a small change in diameter (d) results in a large change in the area and thus a large change in pressure sensed.

Potential for dynamic errors exists with use of the membrane dome. With the membrane dome, there is a much greater possibility of trapping air bubbles in the dome-transducer interface. These bubbles are difficult to detect and remove. Air bubbles increase compliance ( $\blacklozenge$  Vd) and thereby decrease  $f_n$  and increase  $\overset{\circ}{\Sigma}$ 



Smoothing of the waveform and possible loss of the dicrotic notch due to loss of the high frequency components results. In a study by Gardner (1981), three membrane dome systems were tested for natural frequency and damping coefficient. The results are outlined in Table 1.

If these results are plotted on the Gardner graph (Figure 5), none of these systems even fall within the "marginal dynamic response" range. The systems are under-damped and the  $f_n$  is unacceptably low.

In the results of the study by Fox et al. (1978),

### Table l

### Dynamic Response Characteristics of Three

PA Catheter-Transducer Systems

	fn	3
Hewlett-Packard Trans- ducer, Dyne Membrane Dome, 5 Fr. 2 lumen PA catheter	9.5	0.32
Hewlett-Packard Trans- ducer, Hewlett-Packard Membrane Dome, 5 Fr. 2 lumen catheter	10.0	0.30
Bell and Howell Trans- ducer and Membrane Dome, 4 Fr. 2 lumen PA (47) catheter	12.0	0.30

Note. Gardner, 1981. Reprinted with permission of Gardner, R.M. and <u>Anesthesiology</u>. Gardner, R.M. Direct blood pressure measurement --Dynamic response requirements. <u>Anesthesiology</u>, 1981, <u>54</u> (236), 227-236.

the frequency bandwidth of the transducer-dome combinations varied according to the method by which the dome was attached. According to Health Devices (1979), the membrane dome should not limit the transducer frequency response to less than 40 Hz. According to Fox (1978) it is the fluid-filled tubing which limits the system's bandwidth most severely. In the results of the Fox study, 12 out of 28 membrane dome transducer combinations resulted in frequency bandwidth less than or equal to 40 Hz. All attachments made without fluid interface or membrane distension demonstrated a bandwidth less than 40 Hz, two combinations had bandwidths as low as 12.2 Hz and 14.8 Hz. The Bell and Howell membrane dome transducer combination had a frequency bandwidth less than 40 Hz regardless of the attachment method. Three transducer dome combinations had this restricted bandwidth when only membrane distension and no fluid interface were used. From this data, it is apparent that there exists a significant potential for dynamic errors with this device due to the reduction in frequency bandwidth.

It appears that the magnitude and potential for errors in dynamic accuracy is not only due to increased potential for air trapping in the membrane-diaphragm interface but also related to the method by which the membrane dome is attached to the transducer. A fluid interface with membrane distension appears to be

necessary to ensure adequate dynamic response.

Figure 6 details how the catheter-transducer system operates to monitor pressure waveforms. From this conceptualization, the degree of variance that can exist in the system is evident.

The pressure source provides the system with the sinusoidal pressure waveform at varying frequencies. In the laboratory, this pressure source is a pressure pulse generator. The patient provides the pulse waveform in the clinical setting.

The basic catheter-transducer system is composed of a) a catheter, which resides in the vascular space; b) extension tubing; c) a continuous flush system, which maintains catheter patency; d) a dome device which couples the fluid filled tubing to the transducer diaphragm; and e) a transducer, which converts the diaphragm movement into an electrical signal.

Clinically, an infinite number of variations to the basic system can be found. First, variations in the type of catheter utilized are common. The catheter may be a short peripheral line, a long central line or a pulmonary artery catheter. Second, a system may exist without extension tubing, or with varying lengths of tubing, i.e., 36 inches, 72 inches, and 80 inches. Third, continuous flush systems can differ. Until recently, only the inline flush device was available for clinical use.


Figure 6. Conceptual framework. \*Figure 8 depicts the 4 catheter-transducer systems tested; \*\*4 methods of attachment (see text for description).

Recently, a flush system which is mounted on the dome and activated by a lever, can be found in clinical use. Fourth, the catheter may be attached to the transducer by either a membrane or nonmembrane dome device. The nonmembrane dome provides for a fluid continuum between the catheter tip and the transducer. There is only one method by which the nonmembrane dome may be attached to the transducer. The membrane dome interrupts the fluid continuum and allows the formation of a compartment between the dome membrane and the transducer diaphragm. There are four possible methods by which the membrane dome may be attached to the transducer. These are:

 Instillation of water on the transducer diaphragm and dome membrane pressure distension prior to dome attachment (W/P)
 Instillation of water on the transducer diaphragm prior to dome attachment (w)
 Dome membrane pressure distension only prior to dome attachment (p)

4. Neither water nor dome membrane pressure distension (n).

Fifth, there are many different transducers found in the clinical setting. Two commonly found transducers are the Bentley M-800 and the Statham P23id.

Each catheter-transducer system possesses unique dynamic response characteristics which are dependent

upon the components of the system. These characteristics (f and  $\xi$  ) determine the quality of the reproduced wave-The  $f_n$  and  $\zeta$  may be described as <u>adequate</u> in which form. case the system possesses these characteristics may be capable of faithfully reproducing a waveform that has a rapidly rising upstroke and rapid heart rate (further elaboration of this concept is contained in Figure 10). The  $f_n$  and  $\frac{1}{2}$  may be described as <u>marginal</u>, in which case the system is only capable of faithfully reproducing a typical arterial or pulmonary artery waveform (Figure 9, appearing later in the text elaborates marginal systems). The  $f_n$  and f may be inadequate, that is, <u>underdamped</u> or overdamped. The underdamped system will distort the waveform resulting in overshoot and oscillation (Figures 32, 33, contained in Appendix A). The overdamped system will produce a waveform with a decreased systolic pressure and loss of fine detail (Figures 30, 31 in Appendix A).

This study examines four different catheter-transducer systems to determine which elements in a system foster high-fidelity and which elements decrease fidelity. The systems were labeled as either X, Y or Z. With system X, 36 or 80 was used after the letter to designate the catheter transducer system extension tubing differences, i.e., X-36 refers to 36" tubing and X-80 refers to 80 inch tubing. The letters n and m designated the type of dome used. n was used for nonmembrane domes and m was

was used to designate membrane domes. When PA catheters were used, the designation PA was written after the system symbol, i.e., X-36 PA.

#### Systems

Figure 7 illustrates the systems employed in this research. System Y-n employed a central line catheter which was connected directly to the flush device. The flush device was then attached to the nonmembrane dome which coupled the system to the transducer. This system allowed for a fluid continuum between the catheter tip and the transducer diaphragm. System Y-m is similar to system Y-n with the exception that a membrane dome was used rather than the nonmembrane dome in the laboratory. All four methods of attachment were instituted with the membrane dome (W/P, w, p, n).

System X-80n utilizes a short peripheral catheter which was attached to an 80 inch long extension tubing. The tubing was connected to an in line flush device which was in turn attached to the nonmembrane dome in the laboratory. The nonmembrane dome coupled the system to the transducer which allowed a fluid continuum between the catheter tip and the transducer diaphragm. System X-80m is similar to system X-80n with the exception that a membrane dome was used rather than the nonmembrane dome in both the laboratory and clinical setting. The

#### Y-n

- 1. CAP catheter
- 2. No extension tubing
- 3. Intraflo flush device
- Bentley nonmembrane dome (used in laboratory and clinical settings)
- 5. Bentley transducer

#### Y-m

Same as Y-n except for #4 Y-m utilized Bentley membrane dome (used in laboratory only, all four methods of attachment: W/P, w, p, n).

#### X-36

- 1. Cook catheter
- 2. 36" Pharmaseal tubing
- 3. Intraflo flush device
- 4. Bentley membrane dome (laboratory - W/P attachment) (clinical - attachment unknown)
- 5. Bentley transducer

#### <u>X-36 PA</u>

Same as X-36 except for #1. Edwards Swan-Ganz catheter utilized instead.

## <u>X-80n</u>

- 1. Cook catheter
- 2. 80" Cobe tubing
- 3. Intraflo flush device
- Bentley nonmembrane dome (used in laboratory setting only)
- 5. Bentley transducer

### X-80m

Same as X-80n except for #4. X-80 m utilized Bentley membrane dome (Used in both laboratory and clinical setting, all four methods of attachment in laboratory setting: W/P, w, p, n. Unknown method of attachment in clinical setting.

### <u>Z</u>

- 1. Deseret catheter
- 2. 72" Gould tubing
- Gould critiflo flush device
- Gould membrane dome (laboratory - W/P attachment) (clinical attachment unknown)
   Statham transducer

### Z – PA

Same as Z, except for #1. Edwards Swan-Ganz catheter utilized instead.

Figure 7. Description of the four catheter-transducer systems and their variations that were tested in the laboratory and clinical settings. method of attachment in the clinical setting was unknown, in the laboratory setting all four methods of attachment were instituted with the membrane dome.

System X-36 was similar to system X-80m except that the catheter was attached to a 36 inch piece of extension tubing rather than the 80 inch tubing. System X-36 PA, the pulmonary artery catheter was used rather than the short peripheral catheter. Also, only W/P membrane dome attachment was used in the laboratory for both systems X-36 and X-36 PA.

In System Z, a short peripheral catheter was attached to a 72 inch piece of extension tubing which was directly connected to a membrane dome device. Characteristic to this system was a flush lever which was mounted directly on the dome. The membrane dome attached the catheter-tubing system to the transducer. In the laboratory, the membrane dome was attached using water instillation and pressure (W/P). The method of attachment was unknown in the clinical setting. System Z-PA was similar to system Z except that a pulmonary artery catheter was used rather than the short peripheral catheter.

A diagrammatic representation of the four catheter transducer systems utilized in this study appears in Figure 8.



Figure 8. Diagrams of the four catheter transducer systems.

Specific research questions are as follows.

### Research Questions

1. Will the dynamic response characteristics of system Y-m and system X-80m and the dynamic response characteristics of system Y-n and system Y-80n be adequate in the laboratory setting?

Will there be a measurable difference between system Y-m and system Y-n?

Will there be a measurable difference in the dynamic response characteristics between system X-80m and system X-80n?

2. Will the dynamic response characteristics for each method of membrane dome attachment (W/P, w,p,n) be adequate for system Y-m?, for system X-80m?

Will there be a measurable difference in the dynamic response characteristics among the four different methods of membrane dome attachment for system Y-m? for system X-80m? 3. Will the dynamic response characteristics of system Y-n in the laboratory setting and of system Y-n in the clinical setting be adequate?

Will there be a measurable difference in the

dynamic response characteristics of system Y-n in the laboratory and system Y-n in the clinical setting?

4. Will the dynamic response characteristics of system X-80m (W/P attachment) in the laboratory setting and of system X-80m (unknown attachment) in the clinical setting be adequate?

Will there be a measurable difference in the dynamic response characteristics between system X-80m (W/P attachment) in the laboratory and system X-80m (unknown attachment) in the clinical setting?

5. Will the dynamic response characteristics of system Z (W/P attachment) in the laboratory setting and of system Z (unknown attachment) in the clinical setting be adequate? Will there be a measurable difference in the dynamic response characteristics between system Z (W/P attachment) in the laboratory and system Z (unknown attachment) in the clinical setting?

6. Will the dynamic response characteristics of systems Y-n, X-80m, X-36m and Z in the clinical setting be adequate? Will there be a measurable difference in the dynamic response characteristics between system X-36 PA (W/P attachment) in the laboratory setting and of system X-36 PA (unknown attachment) in the clinical setting?

8. Will the dynamic response characteristics of system Z-PA (W/P attachment) in the laboratory setting and of system Z-PA (unknown attachment) in the clinical setting be adequate? Will there be a measurable difference in the dynamic response characteristics between system Z-PA (W/P attachment) in the laboratory and system Z-PA (unknown attachment) in the clinical setting?

9. Will there be a measurable difference in the dynamic response characteristics of system X-36 PA and system Z-PA (attachment unknown in both systems) in the clinical setting?

#### CHAPTER II

### METHODS AND PROCEDURES

### Design

A quasi-experimental approach was used. A two group post-test only was followed.

# Schematic of Systems Set-Up and Sample

The following details each of the system set-ups with the number of systems (N) that were used.

Laboratory Setting. Systems Y-n, Y-m, X-80n and X-80m (Research Questions 1 and 2). Systems Y-n and X-80 n were tested utilizing a nonmembrane dome in the laboratory. Both systems were also tested utilizing the membrane dome in the laboratory. The four methods of membrane dome attachments were evaluated in the laboratory using systems Y-m and X-80m (see below).

nonmembrane dome	system Y-n N=4	system X-80n N=1
membrane dome	system Y-m (W/P) (w) (p) (n) N=5	system X-80m (W/P) (w) (p) (n) N=5

Laboratory and Clinical Setting. Systems Y-n, X-80m, Z (Research Questions 3,4,5). Three systems were tested in the laboratory and clinical settings. System Y-n was evaluated with the nonmembrane dome in both settings. Systems X-80m and Z were evaluated with the membrane dome (W/P) method of attachment in the laboratory and unknown attachment in the clinical setting (See below).

	laboratory	clinical
nonmembrane dome	system Y-n (N=4)	system Y-n (N=28)
membrane dome	system X-80m (W/P attachment)	system X-80m (attachment un- known)
	(N=5)	(N=10)
	Z (N=2)	Z (N=21)

<u>Clinical Setting</u>. Systems Y-n, X-80m, Z (Research question 6). Four systems were tested in the clinical setting as they were found in that setting. For the membrane dome, method of attachment was unknown (See below).

Y-n	X-80m	X-36m	Z
nonmembrane	membrane	membrane	membrane
dome	dome	dome	dome
(N=28)	(N=10)	(N=14)	(N=10)

Clinical and Laboratory Setting. Systems X-36 PA, Z-PA (Research Questions 7,8,9). Systems X-36 PA and Z-PA were tested in the laboratory and clinical setting using the membrane dome. The W/P method of attachment was used in the laboratory setting and unknown method of attachment in the clinical setting (See below).

	Laboratory	Clinical
membrane dome	X-36 PA (W/P attachment)	X-36PA (unknown at- tachment)
	(N=2)	(N=8)
	Z-PA (W/P attachment)	Z-PA (unknown at- tachment)
	(N=2)	(N=10)

### Conceptual Definitions

#### Nonmembrane Dome

A nonmembrane dome is a plastic adapter head which connects the transducer with the fluid column in the catheter tubing system. This dome couples the fluid with the transducer diaphragm and allows for a fluid continuum from the diaphragm to the pressure source.

#### Membrane Dome

A membrane dome is a plastic adapter head which connects the transducer with the catheter tubing system. This dome has a plastic fluid isolating membrane which separates the transducer diaphragm from the fluid inside the catheter tubing system. The purpose of this membrane is to provide microbiological and electrical isolation protecting the sterile fluid in the dome chamber from the transducer diaphragm. The membrane eliminates the need for transducer sterilization.

### Method of Attachment

The method of attachment was the procedure followed in attaching the membrane dome to the transducer.

### Dynamic Response

The response of the catheter transducer system to the dynamic components of the pressure waveform is termed dynamic response.

# Natural Frequency (f<sub>n</sub>)

Natural frequency is defined as the frequency at which oscillations of the mass will occur

$$f_n = \frac{1.4 \times 10^3 \text{ d}}{\sqrt{\text{Vd x L}}}$$

The mass will oscillate at a frequency and amplitude dependent upon the volume displacement (Vd), the length of the catheter (L) and the diameter of the catheter (d).

# Damping Coefficient (5)

The damping coefficient is a number which characterizes the degree of damping that a system possesses. Damping is the degree of energy dissipation due to friction and/or compliance.  $\zeta = 1.0$  is defined as critical damping,  $\zeta > 1.0$  is considered overdamped and  $\zeta < 1.0$ is defined as underdamped

$$\zeta = \frac{1.36 \times 10^{-5}}{\sqrt{Vd \times L}}$$

Damping is also dependent upon the volume displacement (Vd) and the length (L) and diameter (d) of the catheter.

### Transducer

A transducer is a device that converts mechanical energy to electrical energy thus allowing electronic amplification and recording of the pressure waveform. The transducer used in this study is a strain guage which employs resistive elements. As the resistors are stretched, the resistance increases as the diameter of the element decreases. The stress, or load, is the displacement of the transducer membrane by mechanical force, the strain is the change in resistors length that results from this displacement. This stretching produces an increase in its electrical resistance. These resistors are connected in a Wheatstone Bridge circuit and balanced until are the resistances are equal, that is, output voltage equals zero. When pressure is applied to the diaphragm, there is a change in the resistance which unbalances the bridge and a change in output voltage results. This change in voltage is amplified and recorded.

### Marginal Dynamic Response

Marginal dynamic response is the range of dynamic response characteristics necessary for a catheter transducer system to reproduce waveform A (Gardner, 1981) as exactly as possible without visual distortion. Waveform A is a typical arterial or pulmonary artery pulse waveform (Figure 9).

### Adequate Dynamic Response

Adequate dynamic response is the range of dynamic response characteristics necessary for a catheter-transducer system to reproduce waveform B as exactly as possible without visual distortion. Waveform B has a rapidly rising systolic upstroke and rapid heart rate (Figure 10).



Figure 9. Dynamic response characteristics for adequate waveform reproduction of waveform A. This plot shows the ranges of damping coefficients and natural frequencies which do not distort the pressure waveform (stippled area). For the underdamped region (lower left) the pressure waveform has over shoot (increase in systolic pressure) and "ringing" while for the overdamped region (upper area) there is loss of fine detail in the waveform, as well as a decrease in systolic pressure. For the waveforms shown in this figure, in one there is a maximum overestimation of systolic pressure of 14 torr and in another an underestimate of diastolic pressure of 2 torr. Scale on the right allows conversion from amplitude ratio to damping coefficient. Reprinted with permission of Gardner, R.M. and Anesthesiology. Gardner, R.M. Direct blood pressure measurement -- Dynamic response requirements. Anesthesiology, 1981, 54, 227-236.



Dynamic response characteristics for adequate Figure 10. waveform reproduction of waveform B. A plot similar to Figure 9 but for waveform "B". Note that the natural frequency must be considerably higher (above 13 Hz) and the range of damping coefficient for adequate dynamic response is much more restricted. This results from the rapid pressure rise during systole and the rapid heart For the waveforms shown there is a rate. maximum error of 15 torr overestimate in systolic and 3 torr underestimate in diastolic Reprinted with permission of pressure. Gardner, R.M. and Anesthesiology. Gardner, R.M. Direct blood pressure measurement --Dynamic response requirements. Anesthe-<u>siology</u>, 1981, <u>54</u>, 227-236.

### Catheter

A catheter is a long and narrow open lumen tube which resides in the vascular space for the purpose of receiving the pressure waves and transmitting them to the transducer. This device also permits blood withdrawal and fluid administration.

### Extension Tubing

Extension tubing is defined as tubing of varying lengths and compliance used for the purpose of connecting the catheter to the transducer.

### Operational Definitions

#### Nonmembrane Dome

The nonmembrane dome utilized in this study was a Bentley model number D-210.

#### Membrane Dome

The membrane domes utilized in this study were Bentley model D-240 and Gould Critiflo model #TA1015D-F.

### Method of Attachment

Four different procedures for attachment were employed in the research design:

 Instillation of water on the transducer diaphragm and dome membrane distension with pressurized normal saline prior to attachment of of the membrane to the transducer (W/P).

2. Instillation of water on the transducer diaphragm prior to attachment of the membrane dome to the transducer (w).

 Dome membrane distension with pressurized normal saline without instillation of water on the transducer diaphragm prior to attachment of the membrane dome to the transducer (p).
 Neither water instillation on the transducer diaphragm nor membrane distension with pressurized saline prior to attachment of the membrane dome to the transducer (n).

### Dynamic Response

Dynamic response was measured by the damping coefficient and the natural frequency.

### Natural Frequency

The natural frequency was determined by measuring and recording the f<sub>n</sub> by taking the period of one cycle and dividing this value into the paper speed (See Figure 11)

 $f_n \approx \frac{Paper speed mm/sec}{one cycle measured in mm}$  Hz.



Figure 11. Method for determining f and S from a flush signal. Direct blood pressure measurement - dynamic response requirements. Reprinted with permission of Gardner, R.M. and <u>Anesthesiology</u>. Gardner, R.M. <u>Anesthesiology</u>, 1981, 54, 227-236.

### Damping Coefficient

The damping coefficient was determined by measuring and recording the  $\mathcal{G}$  by taking the ratio of successive successive peaks of the oscillations  $A_2:A_1$ . This number could then be plotted on a scale and the damping coefficient was thus derived (See Figure 12).

### Maginal Dynamic Response

The marginal dynamic response was the obtained natural frequency and damping coefficient of the cathetertransducer system plotted as points on the graph (See Figure 5). If the point fell within the range outlined and designated as marginal, the catheter-transducer system was determined marginal.

### Adequate Dynamic Response

Adequate dynamic response was the obtained natural frequency and damping coefficient of the cathetertransducer system plotted as points on the graph (See Figure 5). If the point fell within the range outlined and designated as adequate, the catheter-transducer system was determined adequate.

### Overdamped

Overdamped was defined as the obtained natural frequency and damping coefficient of the catheter-transducer system plotted as points on the graph (See Figure 5).



Equation 1 is the equation which describes the oscillation of a second-order system to a step response.

$$P(t) = Po - \frac{Po}{(1-\zeta^2)^3} e^{-\zeta^2 \pi f_n t} \sin (2\pi f_n (1-\zeta^2)^3 t)$$
(1)

If this equation is solved at three successive peaks, that is, where t equals  $\label{eq:solution}$ 

$$t_{1} = \frac{1}{2f_{n}(1 + \zeta^{2})^{\frac{1}{2}}} \quad t_{2} = \frac{1}{f_{n}(1 - \zeta^{2})^{\frac{1}{2}}}$$
$$t_{3} = \frac{3}{2f_{n}(1 - \zeta^{2})^{\frac{1}{2}}}$$

then by subtracing the difference and taking the ratios

Ratio = 
$$\frac{A_2}{A_1} = \frac{e^{-\frac{\zeta}{2}\pi}}{(1-\zeta^2)^{\frac{1}{2}}}$$
 (2)

By solving this equation the damping coefficient is

$$\zeta = \frac{-\ln\left(\frac{A_2}{A_1}\right)}{\left(\tau\tau^2 + \left[\ln\left(\frac{A_2}{A_1}\right)\right]^2\right)^{\frac{1}{2}}}$$
(3)

A graphical solution of equation three is reflected in the graph above.

Figure 12. Graphical solution of equation for damping coefficient. Reprinted with permission of Gardner, R.M. and <u>Anesthesiology</u>. Gardner, R.M. Direct blood pressure measurement -- Dynamic response characteristics. Anesthesiology, 1981, <u>54</u>, 227-236. If the point fell within the range outlined and designated as overdamped, the catheter-transducer system was determined overdamped.

### Underdamped

Underdamped was defined as the obtained natural frequency and damping coefficient of the catheter-transducer system plotted as points on the graph (See Figure 5). If the point fell within the range outlined and designated as underdamped, the catheter-transducer system was determined underdamped.

#### Flush Device

The flush devices used were CFS-03, Intraflo (Sorenson Research Company, Salt Lake City, Utah) and TA 1015 T, Critiflo Dome (Gould Inc., Medical Products Division, Oxnard, California 93033).

#### Catheter

The catheters used were CAP Intrafusor, catalog number 310-018. 18 GA 1 meter length (Sorenson Research Company); Cook catheter, catalog number 13623, 18 GA 5.5 inch length; Deseret catheter, catalog number 2854, 16 GA. 5.25 inch length; and Edwards Swan-Ganz catheter, catalog number 44166 7 Fr. 4 lumen thermal dilution balloon tipped flow-directed catheters.

### Extension Tubing

The extension tubing used in this project were Gould Critiflo monitoring kit, model number TAK 1560T, 72 inch tubing length; Pharmaseal pressure monitoring tube, catalog number P136, 36 inches; and Cobe pressure monitoring tube, catalog number, 41-066, 80 inches.

#### Instruments

### Catheters

The catheters used were:

 CAP Intrafusor, catalog number 310-018,
 GA., 1 meter length (Sorenson Research Company, Salt Lake City, Utah 84115)
 Cook Catheter, catalog number 13623, 18 GA.
 5.5 inch length (Cook Inc., Bloomington, Indiana 47402)

Deseret Angiocath, catalog number 2854,
 GA., 5.25 inch length (The Deseret Company,
 Salt Lake City, Utah 84070)
 Balloon tipped flow directed catheter,
 catalog number 44166, 7 French, 4 lumen
 thermal dilution balloon tipped flow directed
 catheter, 110 cm length (Instrumentation
 Laboratory, Inc., Lexington, Mass., 02173)
 Model 93A-131-7F.

### Continuous Flush System

Two continuous flush systems were used in this research project:

 CFS-03, Intraflo (Sorenson Research Company, Salt Lake City, Utah 84115), and

2. Critiflo dome, model TA1015T (Gould Inc.,

Oxnard, California 93033).

These systems maintain a continuous fluid column through the catheter and allow for dynamic repsonse testing of the catheter system.

### Nonmembrane Dome

The nonmembrane dome selected for use in this study was the Bentley D-210 (Bentley Laboratories, Inc., Irvine, California 92714).

#### Membrane Domes

The membrane domes used in this project were: 1. Bentley D-240 (Bentley Laboratories Inc., Irvine, Calfironia 92714), and

 Gould Critiflo Dome TA1015T (Gould Inc., Oxnard, California 93033).

### Transducers

The following fixed sensitivity transducers were employed in this research. They were checked and recalibrated after each use.  Gould P23 Id, (Gould Inc., Oxnard, California 93033)

2. Bentley Trantec Model 800 (Bentley Laboratories Inc., Irvine, California 92714)

#### Extension Tubing

The following types of extension tubing were used in this study:

Cobe model number 41-066, 80 inch length
 (Cobe Monitoring Company, Anaheim, California
 92806)

 Pharmaseal pressure monitoring tube, catalog number P136, 36 inch length (Pharmaseal Inc., Toa Alta, Puerto Rico, 00978)

3. Gould pressure monitoring kit, TA 1560T, 72 inch length (Gould Inc., Oxnard, California, (93033)

### Monitors

The monitors used were the following:

1. Hewlett-Packard, model number 7830 4A, 4
channel (Palo Alto, California, 94304) (Holy
Cross Hospital)

2. Hewlett-Packard (Gardner, 1970) described in the article "Instrumentaion for computerized Heart Catheterizations", 7.5 volts, DC excitation voltage (LDS Hospital)

3. Hewlett-Packard, model number 780-7A, 2 channel (Palo Alto, California, 94304) (Veterans Administration Hospital).

### Pressure Simulator

The pressure simulator selected for use in this project was the Blood Pressure Systems Analyzer, model 601, (Bio-tek Instruments, Inc., Shelburne, Vermont).

### Sweep Frequency Generator

The sweep frequency generator employed in this study was the Hewlett-Packard model number 3312 A function generator. The ranges were from 0.1 Hz to 13 megaHz. The 1-50 Hz continuous sweep was utilized.

### Two-Channel Recorder

The Gould model 2007 two-channel recorder was selected for use in this research. It is a direct writing two-channel pen recorder (Gould Inc., Instruments Division, Cleveland, Ohio 44114).

# Amplifier

The amplifier used was a Validyne Carrier Amplifier, model number C019.

### Analog to Digital Converter

A Hewlett-Packard analog to digital converter

model number 3437A was used.

#### Computer

The computer selected for use in this project was a Hewlett-Packard desk top computer, model number 9845B, system 45B.

### Plotter

A Hewlett-Packard digital plotter computer controlled, model number 9872A was used in this study.

#### ECG/Blood Pressure Simulator

The FOGG ECG/Blood pressure simulator, model number M7136 was used in this project.

#### Procedures

### Data Collection and Site

The laboratory portion of the study was carried out at Sorenson Research Company in Salt Lake City, Utah. Permission was granted by the director of research and development. This aspect of the study was carried out without the use of human subjects. The data collection began in January, 1982 and continued until the entire sample had been tested. All measurements were made by the investigator. Al nonmembrane domes were attached to the catheter-transducer system and tested for dynamic response. All membrane domes were attached to the catheter transducer system following four different methods of attachment, and each tested for dynamic response.

The clinical portion of the research project began upon approval of the Human Subjects Committee. The investigator met with and explained the study to the medical directors and head nurses of the critical care units involved in the study. The purpose and goals of the proposed research were reviewed only with the directors and head nurses. In order to prevent the Hawthorne effect, the nursing staff was not made aware of the underlying purpose of the project.

The data collection for the systems were carried out in the clinical setting within which they existed. The catheter-transducer systems were tested for dynamic response according to the procedure outlined in the protocol. For systems that utilized the membrane dome in the clinical setting, the method of membrane dome attachment was unknown to the investigator. Verbal consent (See Appendix B) was obtained from each subject. Human Subjects considerations are outlined in Appendix B.

The hospitals were checked each day for new catheter-transducer systems in use. The measurements were made at times that were convenient for the patient as well as the nursing staff.

#### Protocol for Laboratory Setting

1. Assemble instrumentation components.

The Biotek model 601 blood pressure simulator is connected to the sweep frequency generator. Both the reference transducer and the actual cathetertransducer system being tested are attached from the Biotek 601 to the Validyne carrier amplifier which is connected to the Hewlett-Packard model 1223A Oscilloscope. The system is assembled to the Hewlett-Packard analog to digital converter and to the desktop computer. The digital plotter is connected to the computer following standard procedure.

### 2. Determine and record:

2.1 date and time
2.2 type of system (X-80, X-36, Y, Z)
2.3 Type of dome (membrane/nonmembrane)
2.4 Method of attachment (W/P, w,p,n)
2.5 Temperature of the room

3. Measurement procedure

3.1 Nonmembrane dome catheter-transducer system

3.1.1 Assemble components of the cathetertransducer system: System Y: CAP catheter, Intraflo flush device, saline source, Bentley nonmembrane dome, Bentley transducer.

System X-80: Cook catheter, Cobe extension tubing, Intraflo flush device, saline source, Bentley nonmembrane dome, Bentley transducer.

3.1.2 Attach catheter-transducer system to instrumentation setup.

3.1.3 Remove all air bubbles visual to the eye.

3.1.4 Apply sinusoidal varying pressure waveform at 20 mmHg peak to peak and frequency range from 0 to 50 Hz.

3.1.5 Determine  $f_n$  and  $\zeta$  and obtain recording (See Figure 13 for sample recording). 3.1.6 Repeat steps 1-5 until both system Y and system X-80 have been tested.

3.2 Membrane dome-catheter transducer system (W/P)

3.2.1 Assemble components of catheter transducer system for systems Y-m and X-80m (Follow protocol under 3.1.1) and Z. System Z -- Deseret catheter, Gould critiflo pressure monitoring kit, saline source, Gould transducer.
3.2.2 Attach dome to the transducer by instilling water on the transducer



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diaphragm to form a meniscus and distend the dome membrane by pressurizing the saline source to 300 mmHg. Then attach the dome to the transducer by screwing on until finger tight.

3.2.3 Attach catheter-transducer system to instrumentation set-up.

3.2.4 Remove all air bubbles visual to the eye.

3.2.5 Apply sinusoidal varying pressure at 20 mmHg pressure peak to peak and frequency range from zero to 50 Hz. 3.2.6 Determine  $f_n$  and  $\frac{7}{3}$  and obtain record-

ing.  $\frac{1}{n}$  and  $\frac{1}{2}$  and obtain record-

3.2.7 Repeat steps 3.2.1-3.2.6 until system Y, system X-80 and system Z have been tested.

3.3 Membrane-dome catheter-transducer system (w) Follow steps 3.2.1 through 3.2.7 except for step 3.2.2 in system Y and system X-80 only. Instead of step 3.2.2, attach the dome to the transducer by instilling sterile water on the transducer diaphragm to form a meniscus. Attach dome by screwing on to the transducer until finger tight.

3.4 Membrane dome catheter-transducer system (p)

Follow steps 3.2.1 through 3.2.7 except step 3.2.2 for system Y and system X-80 only. Instead of step 3.2.2, attach the dome to the transducer by first distending the membrane by pressurizing the saline source to 300 mmHg and then attaching the dome to the transducer by screwing on until finger tight. Do not instil water on the transducer diaphragm. 3.5 Membrane dome catheter-transducer system (n). Follow steps 3.2.1 through 3.2.7 except step 3.2.2 for system Y and X-80 only. Instead of step 3.2.2, attach the dome to the transducer by screwing on until finger tight. Do not instil water on the transducer diaphragm nor distend the dome membrane.

3.6 Membrane dome catheter-transducer system (W/P) PA lines. Follow steps 3.2.2 through steps 3.2.7. Instead of step 3.2.1 assemble components of catheter-transducer system for system X-36 PA and system Z-PA. System X-36 PA: Edwards Swan-Ganz catheter, Pharmaseal extension tubing, Intraflo flush device, Bentley membrane dome, Bentley transducer. System Z-PA: Edwards Swan-Ganz catheter, Gould Critiflo monitoring kit, saline source, Gould transducer.

### Protocol for Clinical Setting

- 1. Determine and record
  - 1.1 Date and time
  - 1.2 Type of dome used (membrane/nonmembrane)
  - 1.3 Components of the catheter-transducer
    system
- 2. Measurement procedure

2.1 For both membrane and nonmembrane cathetertransducer systems, proceed as follows:

2.1.1 Holy Cross Hospital

Remove transducer from Hewlett-Packard monitor number 78304A and plug the transducer into Hewlett-Packard monitor number 78413A.

2.1.2 LDS Hospital and Veterans Administration Hospitals.

The bandwidth of both of these monitors is large enough to allow for frequency testing, therefore, there is no need to plug the transducer into a different monitoring system.

2.1.3 Plug the two channel strip recorder into the monitor.

2.1.4 Record arterial pressure waveform on the strip recorder.
2.1.5 Flush the catheter-transducer system at least three times, timing each flush to be during the diastolic runoff period as shown in Figure 14.

2.1.6 Measure and record the f<sub>n</sub> by taking the period of one cycle and dividing this into the paper speed (See Figure 11).

 $f_n = \frac{paper speed mm/sec.}{one cycle measured in mm.}$ 

2.1.7 Measure and record the 5 by taking the ratio of successive peaks of the oscillations A2:Al (See Figure 11). This number can then be plotted on the scale and the 5 derived (See Figure 12).

2.1.8 Record all measurements on the data flow sheet at the time of measurement (See Figure 15 for sample recording) 2.1.9 At Holy Cross Hospital, unplug the transducer from monitor 78413A and plug back into monitor 78304A. Ensure that the system is functioning optimally at completion of the data collection.



Figure 14. Example of proper flush signal during diastolic runoff period. Reprinted with permission of Gardner, R.M. and <u>Anesthesiology</u>. Gardner, R.M. Direct blood pressure measurement -- Dynamic response requirements. <u>Anesthesiology</u>, 1981, <u>54</u> (236), 227-236.

100 mmHg

Figure 15. Examples of flush testing obtained from system Y-n in the clinical setting ( $f_n \sim 27 \text{ Hz}, \ensuremath{\,\overset{?}{_{\sim}}} = 0.26$ ).



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#### CHAPTER III

#### RESULTS

The data obtained for each system in both the laboratory and clinical setting is listed in the tables that follow. Descriptive statistics, i.e., mean and standard deviations, were performed on the data. The data was also plotted on the Gardner graph (Gardner, 1981) in the figures that follow. From each graph, it was determined if the mean dynamic response was adequate, marginal or inadequate, i.e., underdamped or overdamped. The percentage of systems that were adequate, marginal or inadequate was also determined from these graphs. The results are reported in relation to the research questions that they pertain to.

# Laboratory Setting: Systems Y-n, Y-m, X-80n, X-80m

## Research Question One

Will the dynamic response characteristics of system Y-m and system X-80m membrane dome (W/P) and the dynamic response characteristics of system Y-n and system X-80n, nonmembrane dome be adequate in the laboratory setting? Will there be a measurable difference in the dynamic response characteristics between system Y-m (W/P) and system Y-n?

Will there be a measurable difference in the dynamic response characteristics between system X-80m (W/P) and system X-80n?

Systems Y-n, Y-m. The mean dynamic response for both membrane and nonmembrane dome systems was marginal (See Table 2 and Figure 16). There was no measurable difference between system Y-n and system Y-m dynamic response characteristics. Both systems were <u>marginal</u> and therefore, capable of reproducing waveform A, but not waveform B (See Figures 9, 10).

Systems X-80m, X-80n. The mean dynamic response for both membrane and nonmembrane dome systems indicated that the system was underdamped, therefore, not adequate (See Table 3, Figure 17). There was no measurable difference between system X-80n and system X-80m dynamic response characteristics since both systems were underdamped and therefore, would distort waveforms A and B (See Figures 9, 10).

#### Research Question Two

Will the dynamic response characteristics for each method of membrane dome attachment (W/P, w, p, n) be adequate for system Y-m, for system X-80m?

Dynamic Response Characteristics of System Y-n using the Nonmembrane Dome and

System Y-m using the Membrane Dome with Four Different Methods

of Attachment (W/P, w, p, n)

Membrane Dome								Nonmembrane Dome			
Dome #	Nothing		Pressure		Water		Water and Pressure		Dome #	f <sub>n</sub> Hz	<u>ک</u> ل
	f <sub>n</sub> Hz	3	f <sub>n</sub> Hz	43	f <sub>n</sub> Hz	3	f <sub>n</sub> Hz	5			_
1 2 3 4 5	3.6 3.6 3.5 3.6	OD OD OD OD	18.8 16.2 17.6 17.1 8.6	0.40 0.43 0.40 0.43 0.63	25.4 24.9 24.8 22.6 20.1	0.32 0.30 0.31 0.32 0.35	33.1 24.9 24.4 23.3 20.7	0.25 0.32 0.32 0.31 0.34	1 2 3 4	16.8 25.9 22.2 24.7	0.44 0.30 0.32 0.29
Mean S.D.	3.6	OD*	15.66 4.06	0.46 0.10	23.56 2.21	0.32	25.28 4.66	0.31 0.03		22.4 4.04	0.34 0.07

Note. \* = overdamped. System Y-n = CAP catheter, no tubing, intraflo flush device, nonmembrane deome, Bentley transducer. System Y-m = CAP catheter, no tubing, Intraflo flush device, membrane dome, Bentley transducer.  $C.V. = \frac{4.04}{22.4} = .18 = 18\%.$ 



Figure 16. Dynamic response characteristics of system Y-n using the nonmembrane dome and system Y-m using the membrane dome with four different methods of attachment (W/P, w, p,n). System Y-n: CAP catheter, no tubing, Intraflo flush device, nonmembrane dome, Bentley transducer. System Y-m: CAP cathter, no tubing, Intraflo flush device, membrane dome, Bentley transducer.

Dynamic Response Characteristics of System X-80n using the Nonmembrane Dome

and System X-80m using the Membrane Dome with Four Different Methods

of Attachment (W/P, w, p, n)

Membrane Dome X-80m							Nonmembrane Dome		X-80n		
Dome #	Notl	hing	Pres	sure	Wa	ter	Water Press	and ure	Dome #	f <sub>n</sub> Hz	14
	f <sub>n</sub> Hz	Y,	f <sub>n</sub> Hz	Ľ,	f <sub>n</sub> Hz	V.	f <sub>n</sub> Hz	K.			
1 2 3 4 5	15.7 10.3 11.2 12.4 13.7	0.12 0.17 0.16 0.14 0.13	20.5 15.4 19.2 17.4 20.1	0.11 0.11 0.11 0.11 0.11	14.2 10.4 19.7 12.5 13.2	0.13 0.17 0.10 0.15 0.14	19.7 14.3 19.6 17.7 16.4	0.10 0.14 0.11 0.11 0.11	1	21.3	0.11
Mean S.D.	12.66 2.13	0.14 0.02	18.52 2.11	0.11 0.004	14.00 3.48	0.14 3.48	17.54 2.28	0.11 0.02			

Note. System X-80n: Cook catheter, 80" Cobe tubing, Intraflo flush device, nonmembrane dome, Bentley transducer. System X-80m: Cook catheter, 80" cobe tubing, Intraflo flush device, Membrane dome, Bentley transducer. Coefficient Variation =  $\frac{2.28}{17.54}$  = .13 = 13%.



Figure 17. Dynamic response characteristics of system X-80n using the nonmembrane dome and system X-80m using the membrane dome with four different methods of attachment (W/P, w, p, n). System X-80n: Cook catheter, 80" Cobe tubing, Intraflo flush device, nonmembrane dome, Bentley transducer. System X-80m: Cook catheter, 80" cobe tubing, Intra-flo flush device, membrane dome, Bentley transducer.

Will there be a measurable difference in the dynamic response characteristics among the four different methods of membrane dome attachment for system Y-m? for system X-80m?

<u>System Y-m</u>. The dynamic response for (p) was adequate, for (w) and (W/P), <u>marginal</u> and for (n), overdamped which was not adequate (See Table 2 and Figure 16). A measurable difference in the dynamic response characteristics among the four methods of attachment did exist. The (n) method of attachment would dampen both waveform A and B. The (w) and (W/P) method of attachment would faithfully reproduce waveform A but not waveform B. The (p) method of attachment would faithfully reproduce both waveforms A and B (Figures 9, 10).

System X-80m. The mean dynamic response characteristics for all four methods of attachment in system X-80m were underdamped and therefore not adequate (See Table 3 and Figure 17). A measurable difference in the dynamic response characteristics among the four methods of attachment did not exist. All four dynamic response characteristics would potentiate ringing and systolic overshoot in both waveform A and B (Figures 9, 10).

# Laboratory and Clinical Settings: Systems Y-n, X-80m, and Z

#### Research Question Three

Will the dynamic response characteristics of system Y-n in the laboratory setting and of system Y-n in the clinical setting be adequate? Will there be a measurable difference in the dynamic response characteristics of system Y-n in the laboratory setting and system Y-n in the clinical setting?

The mean dynamic response characteristics for system Y-n in both the laboratory and clinical setting were marginal (See Table 2, 4 and Figures 16, 18). There was no measurable difference in the dynamic response characteristics in either setting as both would adequately reproduce waveform A but not waveform B (Figures 9, 10). Figure 19 depicts the distribution of the data. The mode  $f_n$  nearly equalled the mean  $f_n$ , whereas the mode  $\mathcal{G}$  was lower than the mean  $\mathcal{G}$ . The mode  $f_n$  and  $\mathcal{G}$  fell in the marginal range.

#### Research Question Four

Will the dynamic response characteristics of X-80m (W/P attachment) in the laboratory setting and of X-80m (unknown attachment) in the clinical setting be adequate?

Will there be a measurable difference in the dynamic response characteristics between X-80m (W/P attachment) in the laboratory and X-80m (unknown attachment) in the

Dynamic Response Characteristics of System Y-n,

Nonmembrane Dome, in the Clinical Setting

Number	Log Page	f <sub>n</sub>	3
1	8B	25.0	0.27
2	9A	31.0	0.24
3	9B	25.0	0.30
4 5		23.0	0.39
C S		13.0	0.50*
0 7		19.0	0.35
0		14.0	0.40
0	120		0.00*
10	147	20.0	0.20
11		33 0	0.32
12	157	21 0	0.24
13	15R		0.23
14	164	13.0	0.50*
15	168	23 0	0.36
16	17A	25.0	0.27
17	18A	13.0	0.42
18	188	11.0	0.50
19	19A	33.0	0.26
20	198	25.0	0.27
21	20A	21.0	0.36
22	20B	33.0	0.26
23	21B	35.0	0.26
24	22A	16.0	0.43
25	<b>2</b> 2B	25.0	0.29
26	23A	33.0	0.24
27	<b>23</b> B	19.0	0.33
28	24A	13.0	0.46
	Mean*	22.2	0.35
	S.D.	7.1	0.10

Note. \*the 5 was estimated from the flush signal. Coefficient variation =  $\frac{7.1}{22.2}$  = 3.2 =32% System Y-n = CAP catheter, no tubing, Intraf:

System Y-n = CAP catheter, no tubing, Intraflo device, nonmembrane dome, Bentley transducer.



Figure 18. Dynamic response characteristics of system Y-n in the clinical setting. System Y-n = CAP catheter, no tubing, Intraflo flush device, nonmembrane dome, Bentley transducer. 96.4% marginal dynamic response; 3.6% adequate dynamic response. Mean fn = 22.2 Hz; mean % = 0.35.



Figure 19. Histograms of dynamic response data from system Y-n, nonmembrane dome, in clinical setting.

clinical setting?

<u>System X-80m</u>. The mean dynamic characteristics for system X-80m in both the laboratory and clinical setting were underdamped and therefore indadequate (See Tables 3, 5 and Figures 17, 20). Since the dynamic response for the system in both the laboratory and clinical setting falls within the underdamped range, the differences between the means are not considered measurable. Both systems in each setting are inadequate for reproducing waveform A and B (Figures 9, 10). Figure 21 depicts the distribution of the data. The mean  $f_n$  was lower than the mode  $f_n$  and the mean  $\zeta$  was higher than the mode  $\zeta$ . The mode  $f_n$  and  $\zeta$  fell in the marginal range.

#### Research Questions Five

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Will the dynamic response characteristics of system Z (W/P attachment) in the laboratory and of system Z (unknown attachment) in the clinical setting be adequate? Will there be a measurable difference in the dynamic response characteristics between system Z (W/P attachment) in the laboratory and system Z (unknown attachment) in the clinical setting?

System Z. The mean dynamic response characteristics for system Z in both the laboratory and the clinical setting were underdamped (See Tables 6,7 and Figures 22, 23). Thus the systems were not adequate for faith-

Dynamic Response Characteristics of System X-80m and

System X-36 (membrane dome) in the Clinical

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	-					C I
~	-	-	-	_		~
						_

	X-8	3 0 m				X-36m	
Num- ber	Log Page	f <sub>n</sub>	3	Num- ber	Log Page	fn	3
1 2 3 4 5 6 7 8 9 10	75A 78B 79B 80A 80B 82B 86B 88B 91A 93A	18.0 25.0 13.0 8.0 15.0 17.0 25.0 25.0 25.0 20.0	0.22 0.16 0.17 0.60 0.14 0.16 0.28 0.18 0.22 0.14	11 12 13 14 15 16 17 18 19 20 21 22 23 24	77B 81A 83A 84A 84B 85B 86A 88A 89A 89A 89B 90B 87A 87B	$\begin{array}{c} 33.0\\ 21.0\\ 17.0\\ 33.0\\ 14.0\\ 13.0\\ 25.0\\ 33.0\\ 33.0\\ 6.0\\ 25.0\\ 17.0\\ 33.0\\ 25.0\end{array}$	0.16 0.25 0.19 0.25 0.22 0.30 0.29 0.25 0.18 0.50 0.21 0.21 0.21 0.28 0.60
Mean S.D.		19.1 5.68	0.23 0.13	Mean S.D.		22.7 8.93	0.25 0.08

Note. System X-80m = Cook catheter, 80" Cobe tubing, Intraflo flush; membrane dome (method of membrane-dome attachment was unknown), Bentley transducer. System X-36m= Cook catheter, 36" Pharmaseal tubing; Intraflo flush; membrane dome, Bentley transducer. Coefficient Variation =  $\frac{5.68}{19.1}$  = .30 = 30%

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Figure 20. Dynamic response characteristics of system X-80m (membrane dome) in the clinical setting. System X-80m = Cook catheter, 80" tubing, Intraflo flush device, membrane dome, Bentley transducer. Results = mean  $f_n = 19.1 \text{ Hz}$ mean  $\mathcal{L} = 0.23$ . 60% were inadequate, 40% were marginal.



Figure 21. Histograms of dynamic response characteristics from system X-80m data obtained in the clinical setting.

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Dynamic Response Characteristics of System Z Membrane Dome (W/P) in the Laboratory Setting

Number	f <sub>n</sub> (Hz)	3
1	15.3	0.16
2	18.4	0.12

<u>Note</u>. System Z = Deseret catheter, 72" Gould tubing, Critiflo flush device, Gould membrane dome, Statham transducer-

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Number	Log Page		f <sub>n</sub>	3
1	50A	an tean ann an tean an tean an tean an	17.0	0.23
2	53A		6.0	0.50
3	53B		17.0	0.26
4	54B		8.0	0.26
5	55A		7.0	0.30
6	56A		7.0	0.26
7	57A		9.0	0.23
8	58B		7.0	0.27
9	59B		8.0	0.23
10	60A		8.0	0.30
11	60B		17.0	0.29
12	61A		25.0	0.23
13	61B		25.0	0.20
14	62B		20.0	0.23
15	63A		21.0	0.22
16	64A		11.0	0.21
17	65A		13.0	0.22
18	65B		13.0	0.26
19	66B		17.0	0.20
20	67B		13.0	0.24
21	68A		9.0	0.26
		Mean	13.2	0.25
		S.D.	5.9	0.03

Dynamic Response Characteristics of System Z Membrane Dome (Unknown attachment) in the Clinical Setting

Table 7

Note. System Z = Deseret catheter, 72" Gould tubing, Critiflo flush, membrane dome, Statham transducer. The \* value was estimated from the flush signal.



Figure 22. Dynamic response characteristics of System Z in the laboratory setting using the membrane dome (W/P) attachment. System Z = Deseret catheter; 72" Gould tube; Critiflo flush device; membrane dome; Statham transducer.  $F_n = 15.3 \text{ Hz}$ ; 18.4 Hz; S = 0.16; 0.12.



Figure 23. Dynamic response characteristics of system Z membrane dome (unknown attachment) in the clinical setting. System Z = 72" Gould tubing, Critiflo flush device; membrane dome; Statham transducer. Results: mean  $F_{n} = 13$ . Hz; Mean Y = 0.25; 71.4% inadequate; 28.6% marginal. ful reproduction of either waveform A or B (Figures 9, 10). Since the mean dynamic response for the systems in both the laboratory and the clinical setting fell within the underdamped, inadequate range, the differences between the means are not considered measurable.

## Clinical Setting: Systems Y-n, X-80m, X-36m and Z

### Research Question Six

Will the dynamic response characteristics of system Y-n, system X-80m, System X-36m and System Z in the clinical setting be adequate?

Will there be a measurable difference in the dynamic response characteristics among the four systems?

System Y-n. The mean dynamic response for system Y-n (clinical) fell within the <u>marginal</u> range. Of the systems tested, 96.4% fell within the marginal range, and 3.6% fell within the <u>adequate</u> range. Therefore, 100% of the systems were at least capable of reproducing waveform A (See Table 4 and Figure 16).

System X-80m. The mean dynamic response for system X-80m (clinical) fell within the underdamped range. Of the systems tested, 60% were <u>not adequate</u>, (50% underdamped, 10% overdamped), for faithful reproduction of either waveform A or B. Forty percent of the systems demonstrated a marginal dynamic response and therefore, capable of reproducing waveform A (See Table 5, Figure 20).

System X-36m. The mean dynamic response for system X-36m (clinical) fell within the <u>marginal</u> range. Of the systems tested, 4% were <u>adequate</u>, 53% fell within the marginal range and were, therefore, capable of faithfully reproducing waveform A. Forty-three percent were not adequate to faithfully reproduce either waveform A or B (See Table 5, Figure 24). Figure 25 details the mode f<sub>n</sub> and Z which also lies in the marginal range.

System Z. The mean dynamic response fell within the underdamped range. Of the systems tested, 71.4% were <u>not adequate</u> for faithful reproduction of either waveform A or B. Twenty-eight point six percent were marginal and capable of reproducing waveform A (Table 7, Figure 23).

# Laboratory and Clinical Setting: System X-36 PA and Z-PA

#### Research Question Seven

Will the dynamic response characteristics of system X-36 PA (W/P attachment) in the laboratory setting and of system X-36 PA (unknown attachment) in the clinical setting be adequate? Will there be a measurable difference in the dynamic response characteristics between system X-36 PA (W/P attachment) in the laboratory

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Figure 24. Dynamic response characteristics of
 system X-36m, membrane dome (unknown
 attachment) in the clinical setting.
 System X-36m = Cook catheter; 36" tub ing, Intraflo flush device, membrane
 dome, Bentley transducer. Results:
 f = 22.7 Hz; S = 0.25, 43% inadequate,
 53% marginal and 4% inadequate.



Figure 25. Histograms of dynamic response characteristics from data obtained from system X-36m in the clinical setting.

setting and system X-36 PA (unknown attachment) in the clinical setting?

The mean dynamic response characteristics for system X-36 PA in both the laboratory and clinical setting were not adequate for faithful reproduction of either waveform A or B (See Tables 8,9 and Figures 26, 27). There was a measurable difference between the two systems since system X-36 PA in the laboratory had an inadequate natural frequency and system X-36 PA in the clinical setting was overdamped.

#### Research Question Eight

Will the dynamic response characteristics of system Z-PA (W/P attachment) in the laboratory setting and of system Z-PA (unknown attachment) in the clinical setting be adequate?

Will there be a measurable difference in the dynamic response characteristics between Z-PA (W/P attachment) in the laboratory and Z-PA (unknown attachment) in the clinical setting?

System Z-PA. The mean dynamic response characteristics for system Z-PA in both the laboratory and clinical setting were not adequate for faithful reproduction of either waveform A or B (See Tables 8,10 and Figures 26, 28). There was a measurable difference between the two systems since system Z-PA in the laboratory had

Dynamic Response Characteristics of Systems X-36PA in

the Laboratory Setting Using Membrane Dome (W/P)

	System 2	X-36 PA	System Z-PA				
•••	f <sub>n</sub> (Hz)	3		f <sub>n</sub> (Hz)	z		
	7.9	0.39		8.1	0.32		
	7.3	0.37		8.9	0.36		
Mean	7.6	0.38	Mean	7.5	0.34		
s.D.	0.3	0.01	S.D.	0.6	0.02		
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Note.	System	X-36	PA :	=	PA catheter; 36" Pharmaseal
	-				<pre>tubing; Intraflo flush device;</pre>
					membrane dome; Bentley trans-
					ducer.
	System	Z-PA	:		PA catheter; 72" Gould tubing,
					Critiflo flush device; membrane
					dome; Statham transducer.



Figure 26. Mean dynamic response characteristics of system X-36 PA and System Z-PA membrane domes (W/P) attachment in the laboratory setting. System X-36 PA = PA catheter; 36" Pharmaseal tubing; Intraflo flush device; membrane dome; Bentley transducer. System Z-PA = PA catheter; 72" Gould tubing; Critiflo flush device, Membrane dome; Statham transducer. Results = system X-36 PA, mean f = 7.6 Hz; mean S = 0.38; system Z-PA: Mean f = 7.5 Hz; mean S = 0.34.

Dynamic Response Characteristics of System X-36 PA

Using the Membrane Dome (Unknown attachment)

Number	Log Page	f <sub>n</sub>	3
1 2 3 4 5 6 7 8	75B 76A 77A 81B 93B 90A 91B 92B	$\begin{array}{c} 4.0\\ 5.0\\ 6.0\\ 11.0\\ 6.0\\ 4.0\\ 6.0\\ 4.0\\ 4.0\end{array}$	OD OD OD OD OD OD OD
	Mean S.D.	5.8 2.17	OD

in the Clinical Setting

Note. System X-36 PA = PA catheter; 36" Pharmaseal tubing; Intraflo flush device; membrane dome; Bentley transducer.



Figure 27. Dynamic response characteristics of system X-36 PA membrane dome (unknown attachment) in the clinical setting. System X-36 PA = PA catheter; 36" tubing, Intraflo flush device; membrane dome, Bentley transducer. Results = 100% overdamped. Mean  $f_n = 5.8$  Hz; Mean  $\mathcal{L}$  = overdamped.

# Dynamic Response Characteristics of System Z-PA

Membrane Dome (Unknown Attachment) in the

Number	Log Page	f <sub>n</sub>	3
1 2 3 4 5 6 7 8 9 10	51B 54A 55B 56B 58A 59A 62A 63B 64B 66A Mean S.D.	2.0 6.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 10.0 4.9 2.0	OD OD OD OD OD OD OD OD OD OD

Clinical Setting

Note. System Z-PA = PA catheter; Gould 72 inch tubing; Critiflo flush device; Gould membrane dome (method of attachment unknown) and Statham transducer.



Figure 28. Dynamic response characteristics of system Z-PA membrane dome (unknown attachment) in the clinical setting. System Z-PA = PA catheter; 72" Gould tubing; Critiflo flush device; membrane dome; Statham transducer. Results = 100% overdamped; mean  $f_n = 4.9$  Hz; mean  $\Im = overdamped$ .

had an inadequate  $f_n$  and system Z-PA in the clinical setting was overdamped.

#### Research Question Nine

Will there be a measurable difference in the dynamic response characteristics of system X-36 PA and system Z-PA (unknown attachment in both systems) in the clinical setting?

System X-36 PA, Z-PA. The mean dynamic response characteristics for both systems were nearly equal, therefore, no measurable difference existed. Both systems were overdamped and therefore not adequate for faithful reproduction of waveform A or B (See Tables 9, 10 and Figures 27, 28).

## Interpretation of Results

## Laboratory Setting: Y-m, Y-n, X-80m, X-80n (Research Questions 1 and 2)

Evaluation of two systems utilizing membrane dome (W/P attachment) and nonmembrane dome devices enabled comparison of these two systems under ideal conditions. The membrane dome device proved to be functionally equivalent to the nonmembrane dome device when tested in both the Y and X-80 systems in the laboratory setting.

The laboratory provided a setting in which the investigator had complete control over both the time element and the degree of vigilance by which these domes were attached. This control allowed for near perfect coupling of the dome to the transducer diaphragm. The membrane was properly distended and water carefully instilled prior to dome attachment. There was no air bubble entrapment in the dome-transducer interface. Hence, under ideal conditions when time is taken and vigilance observed, the membrane and nonmembrane domes are equally capable in their function.

<u>System Y-m</u>. If the ideal method of membrane dome attachment (W/P) is deviated from, the membrane dome loses its parity of function with the nonmembrane dome. The results of Y-m in the laboratory setting suggest that if the ideal method of attachment (W/P) is slightly deviated from by applying water only (w) or pressure only (p), the coupling of the dome membrane to the transducer diaphragm is still adequate to allow for faithful reproduction of the typical waveform A. However, the natural frequency is not as good as the (W/P) attachment system. The (n) method of attachment clearly prevented transducer diaphragm-dome membrane coupling thus giving rise to such poor dynamic response characteristics (See Table 2, Figure 16).

Of interest is the superior dynamic response characteristics of the (p) attachment method. In reviewing the data on Table 2, it appears that the results were

skewed by trial number five in which the  $f_n = 8.9$  Hz and  $\leq = 0.63$ . In all likelihood, an undetected air bubble in the catheter-transducer system was responsible for these findings. An air bubble would increase the damping coefficient and decrease the natural frequency (equations 3 and 5).

X-80m. The dynamic response characteristics for a) the X-80m system, all methods of dome attachment and b) X-80n system were underdamped. Since the exact same membrane dome, nonmembrane dome, transducer and flush device were used in both the Y-m and Y-n evaluations, in which the dynamic response characteristics were marginal, it seems unlikely that these components were at fault. Rather, some other component of X-80m and X-80n gave rise to these results. If these components are such that an inadequate dynamic response results for that system, then the type of dome used or the method of attachment does not further compromise the system. Hence, it could not be determined in X-80m if the method of dome attachment had any effect on the dynamic response characteristics of the system. However, since the fn of (w) and (n) methods of attachment are lower by at least 4 Hz than the other methods of attachment, (w) and (n) seem to compound the system's incompetence (See Table 3 and Figure 17). The further f<sub>n</sub> decline and slight increase in damping coefficient due to poor

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coupling and air bubble entrapment, thus increased Vd can be explained by equations 3 and 5.

Comparison of like systems in the laboratory setting and the clinical setting allowed for an estimation of the system's simplicity and thus, the degree of human factor error that influences a system's dynamic response characteristics. Because the investigator assembled and performed all of the dynamic response testing in the laboratory, human factor errors were minimized. In the clinical area, however, the systems were assembled and operated by a number of different nurses, physicians and technicians which predispose the system to increased error due to human factors.

## Laboratory and Clinical Settings: Y-n, X-80m, Z, (Research) Questions 3,4,5)

The mean dynamic response characteristics were nominal for Y-n in both the laboratory and clinical settings (See Tables 2 and 4; Figures 17 and 18). These dynamic response characteristics were adequate to reproduce typical arterial and pulmonary artery waveforms at moderate heart rates. Appendix A, Figures 33 and 34, demonstrate how the waveform is faithfully reproduced at a heart rate equal to 60 bpm. When the heart rate is increased to 120 bpm, the systolic pressure is overestimated by 6 mmHg or there is a 15% error due to the

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distortion. Heart rates equal to 150 bpm, produce a 20% error due to distortion thus a systolic overestimation of 8 mmHg. Hence, Y-n will produce a minor degree of waveform distortion in the typical waveform at faster heart rates.

Note in Table 4 that the  $f_n$  of the Y-n in the clinical setting exceeds 30 Hz in approximately 21% of the systems tested. Table 2 depicts the  $f_n$  of the laboratory setting in which the maximum  $f_n$  obtained was 25 Hz. It was expected that the systems in the laboratory setting would demonstrate higher natural frequencies due to the investigator control factor. It may be that the improved  $f_n$  in some of the clinical systems was due to the time element.

Most likely, the air bubbles were evacuated from the clinical systems over time because of repeated flushing of the system. Furthermore, the air bubbles may have become dissolved in solution. In any case, the resulting decrease in volume displacement would account for the improved  $f_n$  seen in the clinical systems (Equation 3).

The coefficient variance for Y~n laboratory systems was nearly half of that of the Y-n clinical systems. The larger variance in the Y-n clinical systems was probably due to the difference in operation time for each system. A system that was in operation over a longer

100

time period may have a better dynamic response because of decreased air bubbles in the system. The coefficient of variance was small in the laboratory systems since the systems were assembled and remained operational only long enough for the testing to be performed. Perhaps, if the systems in the laboratory had remained assembled and retested in the morning, the natural frequency obtained in the morning sample might have been higher. Since the amount of time that each system was in operation in the clinical setting was not recorded at the time of testing, it cannot be ascertained if the improved natural frequency of some systems was the result of decreased air bubbles in the system over time.

The results also indicate that the human factor error was minimal in the clinical setting since the mean dynamic response characteristics of the systems in the laboratory and clinical setting were nearly equal. This implies that the system was reliable, yielding consistency upon repeated measures in various settings and with various operators. Human factor errors were held to a minimum with this system because of its relative simplicity. The nonmembrane dome eliminated the cumbersome, multistep process of membrane distension and fluid instillation in the interface compartment. Absence of tubing eliminated another potential hiding place for trapped

air bubbles. Absence of tubing also eliminated one step in the assembly process, thereby clearly enhancing the efficiency of the system set-up in clinically urgent situations.

The mean dynamic response character-System X-80m. istics were underdamped for system X-80m in both the laboratory and clinical settings (See Tables 3 and 5 and Figures 17 and 20). These dynamic response characteristics are inadequate and will not faithfully reproduce even the typical arterial waveform. Appendix A, Figures 32 and 33 demonstrate how a waveform, heart rate equal to 60 bpm, is distorted by 10-20% or 4-8 mmHq. At a heart rate equal to 120 bpm, the systolic pressure is overestimated by 30-35% or 12-14 mmHg. A heart rate equal to 150 depicts extreme waveform distortion with a 40-50% or 16-20 mmHq overestimation of systolic pressure. This waveform may falsely indicate systolic hyper-Note also that the reproduced waveforms in tension. Figures 31 and 32 have considerable oscillations. It is possible that one of the oscillations may be mistaken for a dicrotic notch which may lead to undesirable consequences, i.e., premature or delayed intra-aortic balloon inflation.

Since the inadequacy of the dynamic response characteristics was similar in both the laboratory (W/P) setting and the clinical setting (unknown attachment), human

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factor error can be ruled out as contributing cause for the underdamped characteristics. One would expect, if human factor error were responsible, that the dynamic response characteristics would have been adequate in the laboratory where human factors were controlled for.

The inadequacy of system X-80m was related to one or more of the components in the catheter-transducer system that was not susceptible to human factors. The catheter used in this system was shorter in length than the catheter used in system Y-n. According to the literature and the theory (Equations 1 and 4), this catheter would have offered a more optimum dynamic response. Therefore, the catheter can be disregarded as a reason for the underdamped characteristics.

Since the tubing in this system is extraordinarily long, 80 inches, overdamped characteristics were expected (See Equation 5). System X-80m contradicts this equation. Reasons for the discrepancy between the equation and the results obtained are unclear. The increased length was consistent with the extremely low  $f_n$  found in system X-80m (See equation 3). Thus, the extension tubing seems to be the incriminating element in the system X-80m that encouraged the underdamped characteristics. Every other component in system X-80m, except the extension tubing, had been used in one or more

of the other systems and yet no other system demonstrated such extremely low damping coefficients. Evidently, some characteristic of the extension tubing in HCH-80m fosters a decreased damping coefficient and the increased length drastically reduces the  $f_n$ .

The membrane dome method of attachment was unknown in the clinical setting and may have contributed to some of the poor responses noted in the clinical setting. If attachment methods such as (w) and (n) were employed rather than the recommended (W/P) method, the  $f_n$  may have been further adversely affected as discussed previously in the text.

System Z. The mean dynamic response characteristics were underdamped for system Z in both the laboratory and the clinical setting (See Tables 6 and 7). The dynamic response characteristics were inadequate and will not faithfully reproduce even the typical arterial waveforms. Similar to System X-80m, Appendix A, Figures 31, 32, demonstrate the effects of an underdamped system on waveform reproduction.

For system Z in both the laboratory (W/P) and the clinical setting (unknown attachment), human factor error can be ruled out as the cause for the underdamped characteristics.

The inadequacy of this system must be attributed to either the extension tubing, flush device or both.

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Since the catheter has similar characteristics to the catheter in system X-80m, the catheter can be ruled out as contributing to the poor response. The tubing in this system is also extraordinarily long, 72 inches, which would have been suspected, according to equation 5, to increase damping. The findings for this system are inconsistent and contradictory to the equation. However, the obtained  $f_n$  coincides with the expected  $f_n$  when length is increased (See equation 3). As stated previously, the reasons for the discrepancy between the damping coefficient equation and the obtained results are unclear.

It appears that the tubing and the flush device are the main factors contributing to system Z's inadequacy. The flush device employed in system Z was mounted on the dome and functioned by squeezing a lever, rather than by pulling a valve stem as with the in line flush device employed by the other systems. Squeezing the lever works to provide an unrestricted pathway for fluid. With the in line flush device, quickly releasing the stem, abrubtly closes the system to the high pressure source thus stimulating a square wave signal. This allows for dynamic response testing. The lever flush in system Z may not have as abruptly closed the system and thereby malfunctioned as an acceptable method of dynamic response testing. This may have falsely reflected system Z as

underdamped. However, this is highly unlikely since the laboratory dynamic response characteristics for X-80m, which were obtained by sine wave testing, were the same as the clinical dynamic response characteristics.

The flush device may be implicated as a factor encouraging the inadequacy of system Z. Since the volume displacement of this device was not known, its contribution to the inadequacy could not be estimated. However, this device cannot be disregarded and further study is necessary concerning its effect on dynamic response.

Most likely, tubing plays the major significant role in provoking the extremely low natural frequency in both systems Z and X-80m.

Another important factor which must be explored is the effect of air bubbles on the system. Note the slightly improved damping coefficient found in the clinical systems over the laboratory systems (0.25 vs. 0.14). Since air bubbles were vigilantly removed from the system by the investigator in the laboratory, air bubbles in the clinical systems probably account for this discrepancy. Air bubbles were visible to the naked eye in a number of clinical Z systems. These bubbles were especially evident in the dome near the membrane. Air bubbles have a detrimental effect because they increase the volume displacement and thereby increase the damping coefficient (See equation 5). This provides an excellent example of the dramatic effects that air bubbles can exert on any system. In an underdamped system, these air bubbles may prove to be beneficial to the system as the result is an increased damping coefficient to the marginal or adequate range, while not decreasing the  $f_n$  too much. This was seen in system Y-m (p) in the laboratory setting in which the dynamic resonse was increased to the adequate range on the graph.

Conversely, air bubbles can be deleterious to a system's response if the volume displacement is increased to such an extent that overdamping occurs. Loss of waveform detail and decreased systolic pressure results. This is depicted in Figures 29 and 30 contained in Appendix A.

# Clinical Setting: Systems Y-n, X-80m, X-36m, Z (Research Question 6)

When systems Y-n, X-80m, X-36m and Z were compared, system Y-n was without a doubt, the most superb system in so far as simplicity and faithful waveform reproduction were concerned. System Y-n and Systems X-80m and X-36m had mean dynamic response characteristics that were marginal. System Z had mean dynamic response characteristics that were underdamped. However, X-36m could not be depended on for adequacy since nearly one

half of the systems evaluated were severely underdamped. Systems X-80m and Z were grossly inadequate for waveform reproduction as 60% and 70% of the systems evaluated, respectively, were incapable of reproducing even waveform A. Hence, a large portion of the systems tested were inadequate for faithful waveform reproduction.

Upon examining the four systems, Y-n was found to have several characteristics which accounted for its high fidelity. One was lack of extension tubing. This was by far the most important and influential characteristic. Tubing can be detrimental to a system's response. The results of X-80m and Z suggest that the longer tubing length will decrease the natural frequency. A study by Gardner (EMB, 1982) indicates that increased length will also increase the damping coefficient. Further study is indicated on a system in which the length of tubing is the only element varied so that its effect can be determined. The decreased f unfavorably depreciates the systems' fidelity. The addition of tubing to the catheter-transducer system alters the dynamic response characteristics by moving the response up and to the left on the Gardner graph. In some cases, the dynamic response of the system may be affected by the addition of tubing to the extent of nullifying the high fidelity components.

Another characteristic responsible for system Y-n's

high fidelity was the minimization of potential "hiding places" for air bubbles to lodge. The tubing component is the largest volume compartment in the catheter-transducer system. Consequently, the greatest potential for air bubble entrapment occurs there.

The third characteristic beneficial to the dynamic response characteristics of Y-n was its simplicity of use. Again, the lack of tubing eliminates the tedious task of examining and removing air bubbles. The nonmembrane dome eliminates the cumbersome, multistep attachment process associated with the membrane dome. Hence, in times of immediate need, system Y-n has the advantage of being assembled promptly and with minimal error.

The other three systems were somewhat similar to each other in that they employed long lengths of tubing and membrane domes. As discussed earlier, the tubing seems to be the major factor responsible for the poor response of these systems due to the length factor. The inadequacy of systems X-80m, X-36m and Z may also have been related to membrane dome usage. Perhaps the membrane dome was not attached to the system following the manufacturer's recommendation (w/p), but by another method described earlier. Clearly, attachment of the dome without water or membrane distension (n) will have detrimental effects on the system's dynamic response characteristics. In times of clinical urgency,

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time and vigilance required to complete the recommended steps may be sacrificed for expeditious system assembly.

## Laboratory and Clinical Setting: Systems X-36 PA, and Z-PA (Research Questions 7,8,9).

Two PA catheter systems were examined in both the laboratory and the clinical setting. The obtained dynamic response characteristics of both systems in both settings were unexpected and astounding. Neither system X-36 PA nor system Z-PA in the laboratory setting possessed an adequate natural frequency or damping coefficient to allow for faithful reproduction of any waveform. (See Table 8, Figures 26 and 27). The  $f_n$  for both system X-36 PA and system Z-PA were so low that even optimal damping would not have enabled faithful waveform reproduction!

Systems X-36 PA and Z-PA were grossly overdamped and the f<sub>n</sub> was unbelievably low in the clinical setting (See Tables 9 and 10, Figures 27 and 28). It is inconceivable that natural frequencies as low as two to five Hertz and to a maximum of 11 Hertz can exist in today's pressure monitoring systems! It is also inconceivable that every PA catheter-transducer system examined in the clinical setting was found to be overdamped! Appendix A, Figures 29 and 30, demonstrates waveform distortion as a result of overdamped dynamic dynamic response characteristics. In Figure 29, note the smoothing of the reproduced waveform and the loss of fine detail. At a heart rate of 60 bpm, the systolic pressure may be decreased by as much as 30%. Note in the most extreme case in Figure 29, heart rate equal to 150 bpm, the systolic pressure is underestimated by 70%. In the pulmonary artery, where a pressure of 30/12 may be found, a 70% underestimation in systolic pressure results in an obtained pressure of 21/12. This decrease in systolic pressure will alter the mean pressure value obtained and may influence the treatment measures instituted. By visual inspection of these waveforms alone it becomes evident how systems with overdamped characteristics can be deleterious to waveform reproduction.

There are several reasons for the overdamped responses that were found. One is the PA catheter length. Since the catheter must be long (ll0 cm) to reach the desired position in the pulmonary artery, the  $f_n$  will be decreased and the damping coefficient increased.

Another contributing factor was the use of extension tubing. Adding to an already exaggerated catheter length, 36 inches of tubing in X-36 PA and 72 inches in Z-PA, the resulting length is over nine feet! The effects of this increased length on the damping coefficient and the natural frequency are dramatic. The length factor is without doubt, the major characteristic responsible for such poor system response.

Although the components of both X-36 PA and Z-PA were different brands, they were equal in their inadequacy. The overall length in X-36 PA was two-thirds the length of system Z-PA, yet the  $f_n$  was deficient in both cases.

From the data, it appears that both systems are subject to human factor error. In the clinical setting, the  $f_n$  was even more reduced and the damping coefficient further increased when compared with the laboratory data. More than likely, the error rests in insufficient removal of trapped air bubbles from the system. The most exaggerated instance observed in the clinical setting was a natural frequency of two Hertz and an overdamped system in every case.

Extension tubing is very detrimental to the PA catheter-transducer system's dynamic response characteristics. The original purpose of isolating the transducer from the patient by inserting extension tubing is no longer warranted. Air bubbles which are more likely to become trapped in a longer system, further deteriorate the dynamic response characteristics. Vigilant removal of air bubbles is imperative in order to preserve the fidelity of the system.

#### CHAPTER IV

CONCLUSIONS, IMPLICATIONS AND RECOMMENDATIONS

#### Conclusions

The membrane dome device is comparable with the nonmembrane dome device provided that sufficient coupling of the dome membrane to the transducer diaphragm is effected. From this study, this is accomplished best by distension of the dome membrane and instillation of water in the interface compartment. In the clinical setting, vigilance in attachment must be emphasized especially since the attachment procedure for the membrane dome is more cumbersome and time consuming.

There appears to be a great many inadequate catheter transducer systems in clinical use. Three of the four systems tested were inadequate for waveform reproduction nearly 50% of the time. It is apparent from the results of this investigation, that extension tubing is largely reponsible for this inadequacy. Extension tubing has deleterious effects on the dynamic response characteristics.

For example, the excessive lengthening of the

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system brought about by extension tubing addition decreases the natural frequency and overdamps the system. There seems to be no practical use for this extension tubing. As evidenced by system Y, all of the clinical responsibilities of the monitoring system can be executed without this component. By mounting the transducer close to the catheter insertion site, the extension cord from the transducer enables sufficient mobility for the patient requiring pressure monitoring.

As discussed previously, system A offers the greatest simplicity, ease of assembly and expeditious use. Because the nonmembrane dome lacks the interface compartment and because no extension tubing is used, system A minimizes the air entrapment potential.

The use of extension tubing for PA lines seems undoubtedly detrimental to the system's response. The resulting increased length of the system due to the long PA catheter and extension tubing decreases the natural frequency and overdamps the system thus rendering the system incapable of faithfully reproducing <u>any</u> waveform. This is especially true as seen in clinical situations because of the further increase in volume displacement due to trapped air bubbles. Vigilance on the part of the operator must be absolute to rid the system of trapped air and excessive tubing which are detrimental to the dynamic resonse and thus deleterious to waveform reproduction.

Throughout this study, various types of pressure monitoring systems have been evaluated for dynamic response characteristics. It would have been an impossible task to examine every component of every system against each other. This study has demonstrated that there is a high degree of inadequacy in the typical pressure monitoring system, especially the PA pressure systems. There was no system found that possessed sufficient dynamic response characteristics capable of faithfully reproducing waveform B. In this era of advanced technology, continued efforts must be directed at refining the pressure monitoring system to achieve this goal.

#### Limitations

The limitations of this study relate to measurement error. Since there were a large number of flush signals that required hand measurement, fatigue may have contributed to any errors made.

Another limitation may have involved investigator bias. The investigator may have preferred one system over another and therefore biased the results and measurements. At least three measurements were made on each system to help eliminate any effects of bias. In the laboratory, bias was controlled for since the computer measured the characteristics and provided the results.

Clinical Implications

A number of implications appear evident from the results of this research. One of the major implications is the vigilant removal of air bubbles from the cathetertransducer system upon assembly and whenever air presents itself in the system. This is crucial because of the deleterious effects that bubbles have to the system's fidelity. Air bubbles are the biggest factor responsible for increasing volume displacement. Hence, their presence will increase the damping coefficient and decrease the natural frequency in accordance with the amount of air in the system.

This study has disclosed beneficial information regarding extension tubing. The purpose of extension tubing is to allow greater freedom of mobility from the transducer to the catheter. It seems, from this study, that the deleterious effects that tubing plays on dynamic response far outweigh this advantage. The necessity for adding extension tubing to the system must be seriously and individually considered. Routine use of tubing is contraindicated. Rather, the transducer may be attached to the patient in close proximity to the catheter and the extension cord from the transducer may be utilized for the purpose of freedom of movement. Ironically, in one of the clinical settings investigated, the transducer was attached to the patient and the 80 inches of tubing wrapped into a coil and taped between the transducer and catheter! It is recommended that tubing be eliminated as a routine component for both the arterial and most expecially, the PA catheter systems. In instances when tubing is necessary to stabilize and prevent kinking of the catheter, a 6-12 inch length is recommended.

As stated previously, clinical use of the membrane dome is acceptable provided adherence to a strict protocol of water instillation and dome membrane distension is adhered to. It is suggested that the membrane dome be disconnected every shift and the (W/P) method of attachment utilized in reconnection. This would ensure each operator that the status of the attachment was acceptable.

The necessity for fast flush testing to ensure adequate dynamic response characteristics is reemphasized here because of its importance in ascertaining accuracy. This testing should be incorporated in the protocol of every critical care area that utilizes invasive pressure monitoring. Pressure monitoring becomes useless if confidence cannot be placed in the data received. This simple test is essential especially when treatment is based on the pressure data. Performing this test

provides the caregiver with documented evidence that the system is accurate. The caregiver is then able to rest assured that treatment is appropriate. Although technology has come a long way, interpretation and evaluation still rest in the hands of the nursing and medical staff. The system is not "magic" and blind faith cannot be substituted for hard evidence especially when the data is so critical for treating the patient.

#### Implications for Education

This study has illuminated a number of measures imperative to nursing practice. Nurses who operate pressure monitoring systems must be extensively educated in regard to the theoretical and practical bases of func-When one understands the basic concepts behind tion. this operation, one is more likely to assemble and operate equipment according to the recommendations. For instance, if the nurse can be educated about the effects that air bubbles have on dynamic response, air bubble removal may be performed with more vigilance and may assume a higher priority in the overall operation of the monitoring system. This rationale holds true for the use of the membrane dome devices. Understanding the importance that water instillation and membrane distension play on adequate coupling will lead to the recognition of the necessity of this task. Hence, this step

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is less likely to be neglected in times of urgent need.

Educating the nurse in the matter of dynamic response characteristics and fast flush testing is of the upmost importance. Every person who is responsible for interpreting data obtained from the pressure monitoring system is responsible for assuring that the obtained data is an accurate representation of the actual data. Dynamic response testing is simple, safe and easily incorporated into the calibration measures. By performing the fast flush testing with each obtained pressure measurement, one is assured of the system's adequacy and that the obtained measurement is accurate. If the fast flush testing produces dynamic response characteristics which are not adequate the operator can troubleshoot the system, i.e., remove excessive tubing length, air bubbles, reattach membrane dome according to protocol, until the obtained characteristics are at least marginal.

In conclusion, it is imperative that comprehensive knowledge of the pressure monitoring system and methods of evaluating accuracy be included in the repertoire of any care provider responsible for the critically ill patient.

### Recommendations for Further Study

There are a multitude of studies which could be done on the various catheter-transducer systems in

existence. With the recent development of more flush devices, clinical evaluative studies would render valuable information in regard to their adequacy of function and effects on dynamic response. Whether these varied flush devices are sufficient to perform fast flush testing is important to study. Since the fast flush testing provides the clinician with valuable information, it must be determined if each and every flush device has the characteristics required to perform this testing, i.e., instantaneous closure of the system to the high pressure source when the valve snapped shut.

Studies need to be performed solely on tubing and the effects of tubing length. By stabilizing all of the components and varying only the tubing, both length and material, some definite conclusions could be reached regarding its effect on dynamic response.

Another important area for research is the effect of air bubbles. By instilling known quantities of air, correlation could be drawn between the amount of air and the effect on dynamic response.

There exists, on the horizon of pressure monitoring, a device known as an Accudynamic (Gardner, 1981). This device allows for adjustment of damping coefficient without decreasing natural frequency. Hence, systems could be optimized provided the natural frequency were greater than approximately ten hertz. Studies need be performed once this device becomes available to determine its ability to optimize catheter-transducer systems in the clinical setting.

Finally, a strongly recommended area of research lies in the education of dynamic response testing in the clinical setting. It is suspected that the clinical dynamic response characteristics of monitoring systems would improve dramatically as a result of this education. If dynamic response testing were incorporated in critical care units as a routine task, invasive pressure monitoring systems could reach the ideal.

EXAMPLES OF THE EFFECT OF DYNAMIC RESPONSE CHARACTERISTICS ON WAVEFORM REPRODUCTION

APPENDIX A

Figure 29. Waveform Reproduction with Overdamped Dynamic Response Characteristics: (a) Trial 1, (b) Trial 2.





30% error

pulse pressure = 25 mmHg
output waveform

heart rate = 150/minute pulse pressure = 40 mmHg input waveform

pulse pressure = 16 mmHg
output waveform

heart rate = 150/minute

pulse pressure = 40 mmHg
input waveform

pulse pressure = 12 mmHg
output waveform



$$f_n = 8 Hz; \ \mathbf{y} = 1.45$$

Heart rate = 60/min.

Pulse pressure = 36 mmHg input waveform

Pulse pressure = 36 mmHg
output waveform

10% error



Heart rate = 120/min.

Pulse pressure = 40 mmHg input waveform

Pulse pressure = 28 mmHg output waveform

30% error

Heart rate = 150/min.

Pulse Pressure = 40 mmHg
input waveform

Pulse Pressure = 26 mmHg
output waveform

35% error

(b)

Figure 30. Waveform Reproduction with Underdamped Dynamic Response Characteristics: (a) Trial 1, (b) Trial 2.



 $f_n = 19 Hz; = .10$ 

Heart rate = 60/min.

Pulse pressure = 40 mmHg input waveform

Pulse pressure = 44 mmHg output waveform

10% error

Heart rate =  $120/\min$ .

Pulse pressure = 40 mmHg
input waveform

Pulse pressure = 52 minHg output waveform

30% error

Heart rate = 150/min.

Pulse pressure = 40 mmHg input waveform

Pulse pressure = 56 mmHg output waveform

40% error



Figure 31. Waveform Reproduction with Marginal Dynamic Response Characteristics (a) Trial 1, (b) Trial 2.

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 $f_n = 25 \text{ Hz} \ \textbf{S} = .20$ 

Heart rate = 60/min. Pulse pressure = 40 mmHg input waveform

5% error

Pulse pressure = 42 mmHgoutput waveform



Pulse pressure = 46 mmHg output waveform

Heart rate = 120/min.

input waveform

15% error

Pulse pressure = 40 mmHg



Pulse pressure = 40 mmHginput waveform

20% error



Pulse pressure = 48 mmHg output waveform



 $f_n = 16 \text{ Hz} \ \mathbf{y} = 0.45$ 

Heart rate = 60/min

Pulse pressure = 40 mmHg input waveform

Pulse pressure = 42 mmHg output waveform



Pulse pressure = 44 mmHg



output waveform

Heart rate = 150/min.

Pulse pressure = 40 mmHg input waveform

15% error

Pulse pressure = 46 mmHg output waveform

APPENDIX B

HUMAN SUBJECTS CONSIDERATIONS

The catheter-transducer system is routinely used in critically ill patients for monitoring intravascular pressures. The system incorporates a continuous flush system which maintains a patent catheter for pressure monitoring and/or repeated blood sampling. The continuous flush system is designed to infuse slowly (3cc/hr) into the catheter to prevent clotting. The flush device has a 1-cm stem which, when pulled allows a nonrestricted pathway from the fluid source to the catheter and thus a rapid flush. This rapid flush is employed clinically to: a) fill the plumbing system with fluid and flush air out of the system, b) clear blood from the catheter after withdrawal, c) verify a proper blood pressure waveform. Release of the flush stem allows the valve to snap back to its original shape, blocking the flush pathway.

In order to determine accurate waveform reproduction by the catheter-transducer system, it is necessary to determine the system's dynamic response. This can be accomplished in the clinical setting by pulling the stem on the flush valve. This opens the system to the saline source, which is under 300 mmHg pressure. Quickly releasing the stem closes the system to the pressure source and produces a step change in pressure. The catheter-transducer system will oscillate near its natural frequency allowing for measurement of the natural frequency and damping coefficient of the system.

The activation of the flush valve is routinely and commonly performed in the clinical setting by the nurses and physicians as part of observing and maintaining the hemodynamic monitoring system. Activating the flush valve for the purpose of determining dynamic response characteristics will not impose any risk to the patient beyond those already associated with the cathetertransducer system. The only effects of this testing on the patient is that he/she will receive at most an additional 15 cc of normal saline due to flush activation. Since there will be no system manipulation, other than what is commonly and routinely done, informed patient consent should not be necessary. Every effort will be made to do data collection during the shift time when flush valve activation is routinely done thus circumventing any additional intrusion upon the patient. If at any time, the data collection does interfere with patient care or comfort, the investigator will discontinue the data collection on that patient. Patient confidentiality will be maintained.
## Verbal Informed Consent

My name is Nancy Colosimo Gibbs. I am doing a study for a masters thesis in nursing. The purpose of this study is to determine whether this specific type of pressure monitoring system measures blood pressure as accurately as possible.

## Procedure for Testing

There is a flush valve on the catheter-transducer system (demonstrate on a model for the patient) that will be opened and closed very quickly. This will allow approximately 2 cc of fluid to infuse each time the valve is opened. In doing so, an oscillating waveform characteristic of this system can be recorded on a strip recorder. This waveform can then be measured and therefore the accuracy of the pressure monitoring system determined. The entire procedure should last from three to five minutes.

There will be no pain or risk involved. This is a procedure routinely performed several times during the day by the nursing medical personnel at this hospital. The potential benefit of this will be the determination and documentation of the catheter-transducer to accurately measure blood pressure.

Strict confidentiality will be maintained. Any and all inquiries you may have concerning this procedure will be answered by the investigator.

Your participation in this study is completely voluntary and you are free to withdraw or discontinue participation in the study at any time. APPENDIX C

COPIES OF WAVEFORMS OBTAINED FROM

LABORATORY TRIALS

Figure 32. Laboratory waveforms of Y-n (nonmembrane dome) (a) Trial 1, (b) Trial 2, (c) Trial 3, (d) Trial 4.



MONITORING KIT TECHNICAL EVALUATION FOR NARCY GIBBS MS THESIS RESEARCH SALT LAKE CITY, UTAH 18 GA SORENSON CAP NONE BENTLEY M 800 TEMPERATURE IS 71 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 7.0 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 9.3 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 12.2 Hertz. MARCH 06 11:34:57 AM MARCH 06 11:34:58 AM Ao = 1.67 Peak Amp = 2.96 Peak freq = 23.55 Damping coeff= 0.30 Natural freq = 25.9



Ø3/Ø6/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH 18 GRUGE SORENSON CAP REGULAR DOME TRY #2 BENTLEY M 800 TEMPERATURE IS 72 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 5.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 7.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 10.2 Hertz. A0 = 1.92 Peak Amp = 2.43 Peak freq = 13.14 Damping coeff= 0.44 Natural freq = 16.8



03/09/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS UNVIERSITY OF UTAH NS THESIS RESEARCH 18 GAUGE SORENSON CAP REGULAR DOME BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 6.2 Hertz. RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 8.1 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 10.6 Hertz. Ao = 1.64 Peak Amp = 2.73 Peak freq = 19.85 Damping coeff= 0.32 Natural freq = 22.2



UNIVERSITY OF UTAH MS THESIS RESEARCH 18 GRUGE SORENSON CAP REGULAR DOME- CLEANED BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 7.0 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 8.7 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 11.8 Hertz. Ao = 1.67 Peak Amp = 2.99 Peak freq = 22.51 Damping coeff= 0.29 Natural freq = 24.7 Figure 33. Laboratory waveforms of Y-m (membrane dome) (n): (a) Trial 1, (b) Trial 2, (c) Trial 3, (d) Trial 4, (e) Trial 5.



Frequency (Hz)

03/06/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH 18 GAUGE SORENSON CAP MEMBRANE-DRY NO P #1 BENTLEY M 800 TEMPERATURE IS 72 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 3.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 4.7 Hertz. MARCH 06 1:07:14 PM MARCH 06 1:07:15 PM



MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH 18 GAUGE SORENSON CAP MEMBRANE-DRY NO P %2 BENTLEY M 800 TEMPERATURE IS 72 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 4.7 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 5.6 Hertz. Ao = 1.41 Peak Amp = 1.29 Peak freq = 2.47



EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH 18 GAUGE SORENSON CAP MEMBRANE-DRY NO P #3 BENTLEY M 800 TEMPERATURE IS 72 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 3.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 3.6 Hertz. Ao = 1.46 Peak Amp = .90 Peak freq = 2.13 Damping coeff= 0.30 Natural freq = 2.4





Figure 34. Laboratory waveforms of Y-m (membrane dome) (p): (a) Trial 1, (b) Trial 2, (c) Trial 3, (d) Trial 4, (e) Trial 5.



MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH 18 GAUGE SORENSON CAP MEMBRANE-DRY P #1 BENTLEY M 800 TEMPERATURE IS 73 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 6.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 8.3 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 10.8 Hertz. A0 = 1.71 Peak Amp = 2.34 Peak freq = 15.54 Damping coeff= 0.40 Natural freq = 18.8



Damping coeff= 0.43 Natural freq = 16.2



MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH 18 GAUGE SORENSON CAP MEMBRANE-DRY P #3 BENTLEY M 800 TEMPERATURE IS 73 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 5.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 7.0 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 9.7 Hertz. A0 = 2.01 Peak Amp = 2.75 Peak freq = 14.50 Damping coeff= 0.40 Hatural freq = 17.6



03/09/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS UNVIERSITY OF UTAH MS THESIS RESEARCH 18 GRUGE SORENSON CAP MEMBRANE-DRY P #4 BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 7.0 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 7.0 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 9.8 Hertz. Ao = 1.65 Peak Amp = 2.12 Peak freq = 13.56 Damping coeff= 0.43 Hatural freq = 17.1



MONITORING KIT TECHNICHL EVALUATION FOR MANCY GIBBS UNVIERSITY OF UTAH MS THESIS RESEARCH MARCH 09 7:04:50 PM 18 GAUGE SORENSON CAP MEMBRAHE-DRY P #5 BENTLEY M 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 8.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 9.1 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 10.5 Hertz. MARCH 09 7:04:51 PM Ao = 1.75 Peak Amp = 1.79 Peak freq = 3.92

Damping coeff= 0.63 Natural freq = 8.6 Figure 35. Laboratory waveforms of Y-m (membrane dome) (w): (a) Trial l, (b) Trial 2, (c) Trial 3, (d) Trial 4, (e) Trial 5.



Ø3/Ø6/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH 18 GRUGE SORENSON CAP MEMBRANE-HATER NO F #1 BENTLEY M 800 TEMPERATURE IS 72 RESPONSE OF SYSTEM FLAT +>- 5 % UP TO 7.6 Hertz. RESPONSE OF SYSTEM FLAT +>- 10 % UP TO 9.7 Hertz. RESPONSE OF SYSTEM FLAT +>- 20 % UP TO 12.5 Hertz. MARCH 86 2:07:00 PM A0 = 1.80 Peak freq = 22.63 Damping coeff= 0.32 Matural freq = 25.4



MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH 18 GAUGE SORENSON CAP MEMBRANE-WATER NO P #2 BENTLEY M 800 TEMPERATURE IS 72 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 7.7 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 9.8 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 12.3 Hertz. Ao = 1.64 Peak Amp = 2.85 Peak freq = 22.48 Damping coeff= 0.30 Natural freq = 24.9



MS THESIS RESEARCH UNIVERSITY OF UTAH 18 GAUGE SORENSON CAP MEMBRANE-WATER NO P #3 BENTLEY M 800 TEMPERATURE IS 73 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 7.1 Hertz. RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 9.3 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 11.9 Hertz. RO = 1.24 Peak Amp = 2.10 Peak freq = 22.32 Damping coeff= 0.31 Natural freq = 24.8





03/09/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS UNVIERSITY OF UTAH MS THESIS RESEARCH 18 GAUGE SORENSON CAP MEMBRANE-WATER NO P #5 BENTLEY M 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 6.1 Hertz. RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 7.4 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 7.4 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 10.0 Hertz. Ao = 1.77 Peak Amp = 2.71 Peak freq = 17.53 Damping coeff= 0.35 Natural freq = 20.1 Figure 36. Laboratory waveforms of Y-m (membrane dome) (w/p): (a) Trial 1, (b) Trial 2, (c) Trial 3, (d) Trial 4, (e) Trial 5.

2.1



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MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH 18 GAUGE SORENSON CAP MEMBRANE-WATER P #1 BENTLEY M 800 TEMPERATURE IS 73 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 9.3 Hertz. RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 11.9 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 11.9 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 15.3 Hertz. MARCH 06 1:48:19 PM MARCH 06 1:48:20 PM AO = 1.90 Peak Amp = 3.94 Peak freq = 30.96

Damping coeff= 0.25 Natural freq = 33.1



MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSIT: OF UTAH 18 GAUGE SORENSON CAP MEMBRANE-WATER F #2 BENTLEY M 800 TEMPERATURE IS 72 RESPONSE OF SYSTEM FLAT +-- 5 % UP TO 7.1 Hentz. RESPONSE OF SYSTEM FLAT +-- 10 % UP TO 9.3 Hentz. A0 = 2.05 Peak Amp = 3.35 Peak freq = 22.10 Damping coeff= 0.32 Natural freq = 24.9



MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH 18 GRUGE SORENSON CAP MEMBRANE-WATER P #3 BENTLEY M 800 TEMPERATURE IS 73 RESPONSE OF SYSTEM FLAT + - 5 % UP TO 6.9 Hertz. RESPONSE OF SYSTEM FLAT + - 10 % UP TO 8.7 Hertz. RESPONSE OF SYSTEM FLAT + - 20 % UP TO 11.8 Hertz. RO = 2.04 Peak Amp = 3.39 Peak freq = 21.80 Damping coeff= 0.32 Hatural freq = 24.4



03/09/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS UNVIERSITY OF UTAH MS THESIS RESEARCH 18 GAUGE SORENSON CAP MEMBRANE-HATER P #4 BENTLEY M 800 TEMPERATURE IS 76 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 7.0 Hertz. RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 7.0 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 8.8 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 11.1 Hertz. MARCH 09 6:01:32 PM Ao = 1.65 Peak Amp = 2.76 Peak freq = 20.86 Damping coeff= 0.31 Natural freq = 23.3



03/09/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS UNVIERSITY OF UTAH MS THESIS RESEARCH 18 GAUGE SORENSON CAP MEMBRANE-WATER P #5 BENTLEY M 800 TEMPERATURE IS 76 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 5.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 7.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 10.2 Hertz. RO = 1.66 Peak Amp = 2.62 Peak freq = 18.18 Damping coeff= 0.34 Natural freq = 20.7 Figure 37. Laboratory waveform of X-80n



Frequency (Hz)

03/09/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS UNIVERSITY OF UTAH MS THESIS RESEARCH ARTERIAL REGULAR DOME BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 6.3 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 6.3 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 8.2 Hertz. A0 = 1.85 Peak Amp = 8.67 Peak freq = 21.05

Damping coeff= 0.11 Natural freq = 21.3 Figure 38. Laboratory waveform of X-80m (membrane dome) (n): (a) Trial 1, (b) Trial 2, (c) Trial 3, (d) Trial 4, (e) Trial 5.



03/09/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR MANCY GIBBS UNIYERSITY OF UTAH MS THESIS RESEARCH ARTERIAL MEMBRANE-DRY NO P #1 BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 4.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 6.2 Hertz. Ao = 1.82 Peak Amp = 7.72 Peak freq = 15.47 Damping coeff= 0.12 Natural freq = 15.7


Ø3/11/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNVIFRSITY OF UTAH ARTERIAL MEMBRANE-DRY NO P #2 BENTLEY M 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 3.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 4.6 Hertz. Ao = 1.99 Peak Amp = 6.04 Peak freq = 10.05 Damping coeff= 0.17 Natural freq = 10.3



Ø3/11/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNVIERSITY OF UTAH ARTERIAL MEMBRANE-DRY NO P #3 BENTLEY M 800 TEMPERATURE IS 75

RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 4.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 5.6 Hertz. AO = 1.85 Peak Amp = 5.79 Peak freq = 10.94 Damping coeff= 0.16 Natural freq = 11.2



Ø3/11/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH ARTERIAL MEMBRANE-DRY NO P #4 BENTLEY M 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +-- 5 % UP TO 3.6 Hertz. RESPONSE OF SYSTEM FLAT +-- 10 % UP TO 4.7 Hertz. RESPONSE OF SYSTEM FLAT +-- 20 % UP TO 5.6 Hertz. Ao = 1.92 Peak Amp = 6.88 Peak freq = 12.19 Damping coeff= 0.14 Natural freq = 12.4



Ø3/11/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MARCH 11 9:13:31 PM MS THESIS RESEARCH UNIVERSITY OF UTAH ARTERIAL MEMBRANE-DRY NO P %5 BENTLEY M 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.4 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 4.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 5.4 Hertz. Response OF SYSTEM FLAT +/- 20 % UP TO 5.4 Hertz. Response of system flat +/- 20 % UP TO 5.4 Hertz. Response of system flat -- 20 % UP TO 5.4 Hertz. Response o

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Figure 39. Laboratory waveforms of X-80m (membrane dome) (p): (a) Trial 1, (b) Trial 2, (c) Trial 3, (d) Trial 4, (e) Trial 5.



03/09/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS UNIVERSITY OF UTAH MS THESIS RESEARCH ARTERIAL MEMBRANE-DRY P #1 BENTLEY M 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 5.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 6.4 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 8.3 Hertz. MARCH 09 9:17:22 PM MARCH 09 9:17:23 PM Ao = 1.93 Peak Amp = 8.94 Peak freq = 20.23 Damping coeff= 0.11 Natural freq = 20.5



Ø3/11/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNVIERSITY OF UTAH ARTERIAL MEMBRANE-DRY P %2 BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 3.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 4.7 Hertz. MARCH 11 5:42:44 PM Ao = 2.05 Peak Amp = 9.15 Peak freq = 15.23 Damping coeff = 0.11 Natural freq = 15.4



Ø3/11/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NARCY GIBBS MS THESIS RESEARCH UNVIERSITY OF UTAH ARTERIAL MEMBRANE-DRY P #3 BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 5.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 7.6 Hertz. MARCH 11 6:59:33 PM Ao = 2.55 Peak Amp = 12.43 Peak freq = 18.98 Damping coeff= 0.10 Natural freq = 19.2



Ø3/11/82 NG

MONITORING KIT TECHNICAL Evaluation for Nancy gibbs MS Thesis Research University of Utah Arterial

MEMBRANE-DRY P #4 BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +2- 5 % UP TO 4.5 Hertz. RESPONSE OF SYSTEM FLAT +2- 10 % UP TO 5.4 Hertz. RESPONSE OF SYSTEM FLAT +2- 20 % UP TO 6.9 Hertz. MARCH 11 8:16:27 PM MARCH 11 8:16:28 PM Ao = 1.92 Peak Amp = 8.65 Peak freq = 17.14 Damping coeff= 0.11 Natural freq = 17.4



MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH ARTERIAL MEMBERANE-DRY P 45 BENTLEY M 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 6.1 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 8.1 Hertz. MARCH 11 9:34:20 PM A0 = 1.12 Peak Amp = 5.25 Peak freq = 19.85 Damping coeff= 0.11 Natural freq = 20.1

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Figure 40. Laboratory waveforms of X-80m (membrane dome) (w): (a) Trial 1, (b) Trial 2, (c) Trial 3, (d) Trial 4, (e) Trial 5.



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MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS UNIVERSITY OF UTAH MS THESIS RESEARCH ARTERIAL MEMBRANE-WATER NO P #1 BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 4.6 Hertz. MARCH 09 9:53:49 PM RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 6.3 Hertz. Ao = 1.65 Peak Amp = 6.54 Peak freq = 13.94 Damping coeff= 0.13 Natural freq = 14.2



MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNVIERSITY OF UTAH ARTERIAL MEMBRANE-WATER #2 BENTLEY M 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 3.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 4.6 Hertz. RO = 1.64 Peak Amp = 4.99 Peak freq = 10.08 Damping coeff= 0.17 Natural freq = 10.4



MONITORING KIT TECHNICAL EVALUATION FOR NARCY GIBBS MS THESIS RESEARCH UNVIERSITY OF UTAH ARTERIAL MEMBRANE-WATER NO P #3 BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.8 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 5.7 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 7.7 Hertz. MARCH 11 7:39:56 PM Ao = 1.91 Peak Amp = 9.17 Peak freq = 19.53 Damping coeff= 0.10 Natural freq = 19.7



Ø3/11/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH ARTERIAL MEMBRANE-WATER NO P #4 BENTLEY M 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 4.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 5.6 Hertz. RO = 1.40 Peak Amp = 4.75 Peak freq = 12.18 Damping coeff= 0.15 Natural freq = 12.5



Ø3/11/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NAHCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH ARTERIAL MEMBRANE-WATER NO P #5 BENTLEY N 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.5 Hertz. MARCH 11 10:11:07 PM RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 4.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 5.6 Hertz. A0 = 1.89 Peak Amp = 6.99 Peak freq = 12.91 Damping coeff= 0.14 Natural freq = 13.2 Figure 4]. Laboratory waveforms of X-80m (membrane dome) (w/p): (a) Trial 1, (b) Trial 2, (c) Trial 3, (d) Trial 4, (e) Trial 5.



03/09/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS UNIVERSITY OF UTAH MS THESIS RESEARCH ARTERIAL MEMBRANE-WATER P #1 BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.7 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 5.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 7.6 Hertz. MARCH 09 9:35:49 PM Ao = 1.98 Peak Amp = 9.69 Peak freq = 19.50 Damping coeff = 0.10 Natural freq = 19.7



MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNVIERSITY OF UTAH ARTERIAL MEMBRANE-HATER P #2 BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.7 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 4.7 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 6.3 Hertz. MARCH 11 6:01:59 PM Ao = 2.60 Peak Amp = 9.50 Peak freq = 13.98 Damping coeff= 0.14 Natural freq = 14.3

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MONITORING KIT TECHNICAL EVALUATION FOR HANCY GIBBS MS THESIS RESEARCH UNVIERSITY OF UTAH ARTERIAL MEMBRANE-WATER P M3 BENTLEY M 800 TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.8 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 6.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 7.7 Hertz. MARCH 11 7:19:53 PM MARCH 11 7:19:54 PM Ao = 2.47 Peak Amp = 11.48 Peak freq = 19.33 Damping coeff= 0.11 Natural freq = 19.6



Ø3/11/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH ARTERIAL MEMBRANE-WATER P #4 BENTLEY M 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.7 Hertz. RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 5.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 5.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 7.8 Hertz. A0 = 2.47 Peak Amp = 11.37 Peak freq = 17.45 Damping coeff= 0.11 Natural freq = 17.7



Ø3/11/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR NANCY GIBBS MS THESIS RESEARCH UNIVERSITY OF UTAH ARTERIAL MEMBRANE-WATER P #5 BENTLEY M 800 TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.7 Hertz. RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 5.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 5.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 7.8 Hertz. MARCH 11 9:53:05 PM A0 = 1.19 Peak Amp = 5.25 Peak freq = 16.14 Damping coeff= 0.11 Natural freq = 16.4

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Figure 42. Laboratory waveform of X-36PA (membrane dome) (w/p): (a) Trial 1, (b) Trial 2, (c) Trial 3.



MONITORING KIT TECHNICAL EVALUATION FOR MS THESIS RESEARCH SWAN GANZ 3 FT TUBING MEMBRANE-WET PRESSURE BENTLEY M 800 TUBING 3 FEET TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.3 Hertz. RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 4.5 Hertz. A0 = .77 Peak Amp = 1.07 Peak freq = 6.60 Damping coeff= 0.39 Natural freq = 7.9



Ø3/25/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR MS THESIS RESEARCH SWAN GANZ 3 FT TUBING MEMBRANE-WET PRESSURE BENTLEY M 800 TUBING 3 FEET TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 2.9 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 2.9 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 2.9 Hertz. MARCH 25 U:10:56 PM A0 = .69 Peak Amp = .59 Peak freq = 4.55 Damping coeff= 0.12 Matural freq = 4.6



03/25/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR MS THESIS RESEARCH --SWAN GANZ MEMBRANE WATER-PRESSURE BENTLEY M 800 TUBING 3 FEET TEMPERATURE IS 73 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.3 Hertz. RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.3 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 3.3 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 4.5 Hertz. Ao = .67 Peak Amp = .98 Peak freq = 6.23 Damping coeff= 0.37 Natural freq = 7.3 Figure 43. Laboratory waveform of X-36PA (nonmembrane dome)





Ø3/25/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR MS THESIS RESEARCH HCH SWAN GANZ 3 FT TUBING NONMEMBRAHE DOME BENTLEY M 800 TUBING 3 FEET TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +-- 5 % UP TO 3.4 Hertz. RESPONSE OF SYSTEM FLAT +-- 10 % UP TO 4.5 Hertz. RESPONSE OF SYSTEM FLAT +-- 20 % UP TO 5.5 Hertz. A0 = .72 Peak Amp = 1.08 Peak freq = 7.31 Damping coeff= 0.36 Natural freq = 8.5 Figure 44. Laboratory waveforms of Z (membrane dome) (w/p): (a) Trial l, (b) Trial 2.



MONITORING KIT TECHNICAL EVALUATION FOR MS THESIS RESEARCH ART 16 GA 5.25 IN MEMBRANE-WET PRESSURE STATHAM P23ID CRITIFLOW TUBING 3 FEET TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 5.4 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 6.9 Hertz. MARCH 25 7:32:15 PM MARCH 25 7:32:16 PM Ao = 1.04 Peak Amp = 4.23 Peak freq = 10.15 Damping coeff= 0.12 Natural freq = 18.4



Ø3/25/82 NG

MONITORING KIT TECHNICAL Evaluation for

MS THESIS RESEARCH ART 16 GA 5.25 IN MEMBRANE-WET PRESSURE STATHAM P23ID CRITIFLOW TUBING 3 FEET TEMPERATURE IS 74 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 4.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 5.6 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 6.3 Hertz. MARCH 25 7:13:12 PM MARCH 25 7:13:13 PM Ao = 1.23 Peak Amp = 3.85 Peak freq = 14.88 Damping coeff= 0.16 Natural freq = 15.3 Figure 45. Laboratory waveforms of Z-PA (membrane dome) (w/p): (a) Trial 1, (b) Trial 2, (c) Trial 3.



MONITORING KIT TECHNICAL EVALUATION FOR MS THESIS RESEARCH SWAN-GANZ MEMBRANE-WET PRESSURE STATHAM P23ID CRITIFLOW TUBING 3 FEET TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO RESPONSE OF SYSTEM FLAT +/- 10 % UP TO A.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO A.6 Hertz. Ao = 1.18 Peak Amp = 1.87 Peak freq = 6.66 Damping coeff= 0.33

Natural freq = 7.6



TEMPERATURE IS 75

RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.4 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 3.4 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 4.5 Hertz. Ao = 1.22 Peak Amp = 1.99 Peak freq = 7.23 Damping coeff= 0.32 Natural freq = 8.1



Ø3/25/82 NG

MONITORING KIT TECHNICAL EVALUATION FOR MS THESIS RESEARCH SHAN-GANZ MEMBRANE-WET PRESSURE STATHAM P231D CRITIFLOW TUBING 3 FEET TEMPERATURE IS 75 RESPONSE OF SYSTEM FLAT +/- 5 % UP TO 3.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 10 % UP TO 3.5 Hertz. RESPONSE OF SYSTEM FLAT +/- 20 % UP TO 4.7 Hertz. Ao = 1.34 Peak Amp = 2.01 Peak freq = 5.94 Damping coeff= 0.36 Natural freq = 6.9 REFERENCES
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