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Comparison of the dynamic performance of the HemoDraw® Plus closed blood sampling system with three other systems

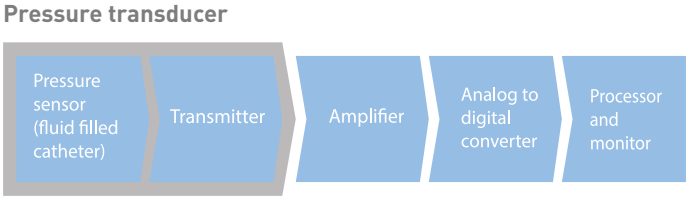
White Paper

INTRODUCTION

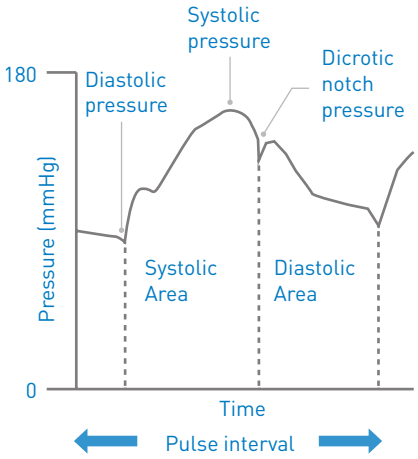
Arterial pressure measurement is a mandatory step in the evaluation of hemodynamics as it gives primary information about the performance of the cardiovascular system and tissue perfusion[1]. It is of clinical importance that the accuracy of the system used to monitor arterial pressure should be as high as possible regardless of the medical condition[2,3]. In critically ill patients and in patients undergoing high-risk and major surgery, direct intra-arterial blood pressure measurement via an intravascular sensor device is considered the gold standard. This approach allows real-time continuous information on the pumping action of the heart, including systolic and diastolic blood pressure and valve closure[4]. Such devices allow beat-to-beat measurements even in patients being administered inotropic or vasoactive drugs, or in cases of abrupt changes in blood volume, arterial tone, or arrhythmias[3,5,6]. Invasive blood pressure measurements are considered more accurate than non-invasive systems (oscillometric technique) in certain situations, such as hemodynamic instability, severe hypotension, increased arterial stiffness, and obese patients[2,5-8].

Direct-intra-arterial blood pressure is commonly measured using a catheter-transducer system that detects a pressure wave generated by cardiac contraction (Figure A)[4]. The pressure wave is transmitted through fluid-filled tubing and stopcocks to a sensing diaphragm of the pressure transducer. The pressure deforms the diaphragm producing alterations in electrical resistance that can be converted into an electrical signal which can be recorded/monitored. The intra-arterial blood pressure system must be able to detect and transmit the high frequency components of the arterial waveform (at least 24 Hz) in order to precisely represent the arterial pressure wave[9]. The cardiac parameters that can be measured with a typical arterial pressure waveform from a healthy individual include systolic pressure, diastolic pressure, pulse, dicrotic notch pressure, heart rate, and ejection time of the left ventricle (Figure B)[4].

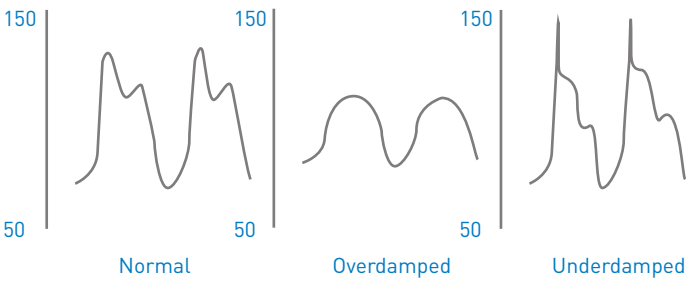
A.



B.



C.

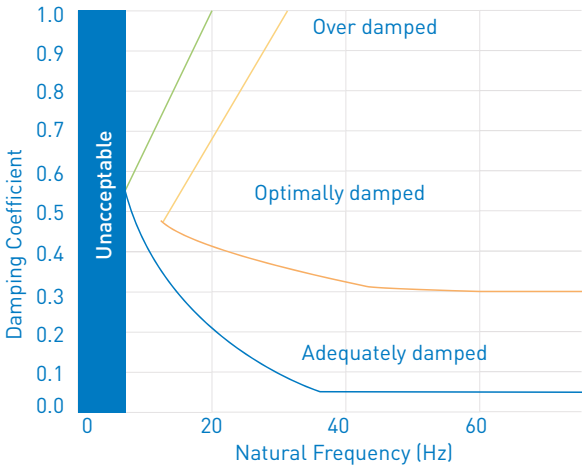


To have minimal error in the arterial pressure waveform, the catheter-transducer system needs to be accurate, sensitive, linear, and have minimal drift[10,11]. Errors in measurements can be due to system calibration errors, altered pulse traveling (arterial dissection or stenosis) and artifacts resulting from movement or inappropriate dynamic response of the fluid-filled monitoring systems[10,11]. Of these possibilities, the major contributor to inaccuracy of arterial pressure waveform are in the dynamic response of the hydraulic system/pressure transducer (i.e., fluid and diaphragm)[4,9].

A waveform has two dynamic response components: natural frequency and damping coefficient[4,9]. The natural frequency of an intra-arterial blood pressure measuring system is the number of oscillations per unit time occurring without any dampening and is determined by the properties of its components [4,9] Most commercially available systems have a natural frequency of about 200 Hz but this is reduced by the addition of three-way taps, bubbles, clots, and additional length of tubing. The dampening coefficient is related to the time taken to dampen the waveform. Due to specific characteristics of a system (i.e., length of cannula or tubing, compliance, fluid inertia, fluid resistance) a system can be underdamped, overdamped, or optimally damped (Figure C) [4]. If a system is optimally damped, a pressure waveform can return to its baseline waveform after being perturbed [4]. If a system is underdamped, the pressure wave tends to reverberate leading to an overestimation of systolic pressure and underestimation of diastolic pressure [4]. If a system is overdamped, the waveform flattens resulting in underestimation of systolic blood pressure and over estimation of diastolic blood pressure [4].

Figure 2. depicts a Gardner plot which shows the relationship between natural frequency and dampening coefficient for a system indicating the dynamic response[4,10]. An optimally damped system has a high natural frequency to permit for the largest possible range in damping coefficients. Commonly for systems not requiring a fast response (such as those used in adults), natural frequencies >30 Hz are accurate (yield arterial pressure within 1 mmHg of real pressure), and an absolute minimal frequency that can lead to an adequate waveform is 7 Hz.[4,10]. A dampening coefficient of 0.5 is an adequate level of dampening for the widest range of natural frequencies[4,10].

FIGURE 2. GARDNER PLOT INDICATES THE DEGREE OF PRESSURE WAVE DAMPING AS A FUNCTION OF NATURAL FREQUENCY AND DAMPING COEFFICIENT FOR PATIENTS WITH NORMAL HEART RATE. (FROM [10])



METHODS

The dynamic performance of the HemoDraw® Plus system, Competitor A, B, and C systems were evaluated using a "square wave" test as described by Gardner et al.[10] A blood pressure simulator was used. Each individual system was set up and carefully filled with saline to eliminate bubbles, and then tested three times. Square waves were generated by attaching a signal generator to a pressure generator. Square waves were recorded and natural frequency and damping coefficients calculated using the following equation[12]:

$$D = -\ln(A2/A1)/(\pi 2 + [\ln(A2/A1)]2)1/2$$

Where A1 is the amplitude of the first peak and A2 that of the second peak.

The mean of the three tests were plotted against the Gardner plot.

RESULT AND DISCUSSION

A representative wave form from the HemoDraw® Plus System and competitors A, B and C are shown in Figure 3. Each system produced a unique waveform indicating differences in the natural frequency and damping properties across systems. Plotting the dynamic performance (natural frequency vs. dampening coefficient) of each system on the Gardner plot, indicated that the HemoDraw® Plus system has better frequency response than the other three systems, as the damping coefficient and natural frequency fall within the adequate range for recording accurate arterial pressure waveforms (Figure 4). The difference between systems likely represent different physical characteristics including diaphragm properties, arterial catheter, and elasticity of the system. The fact that competitors A, B and C are underdamped indicates that these systems may overestimate systolic blood pressure, particularly in patients with high heart rates[13]. The finding that Competitor C is underdamped is consistent with a prior study that investigated the dynamic performance of the Competitor C system and also found it to be underdamped (median damping coefficient 0.324 and median resonance frequency 12.5 Hz)[13].

FIGURE 3.

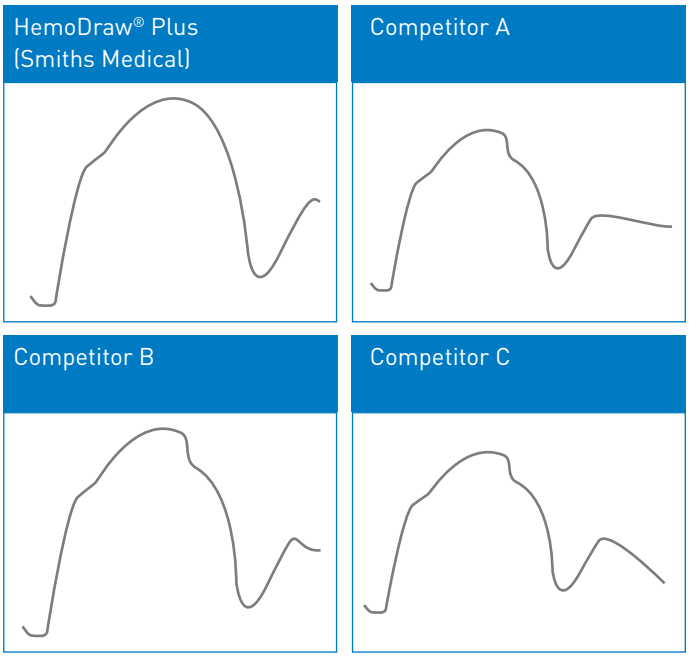
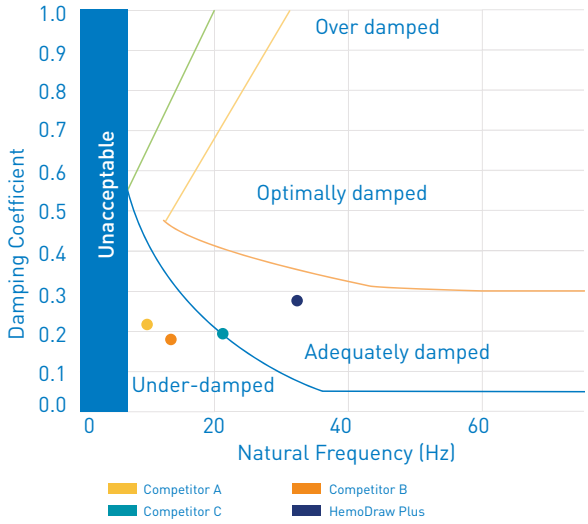


FIGURE 4. DYNAMIC PERFORMANCE OF THE HEMODRAW® PLUS SYSTEM, AND COMPETITORS A, B AND C



On a practical level, it is important for the healthcare provider to be aware of the high incidence of underdamped arterial waveforms in critically ill patients[14]. Simply looking at the waveform does not provide sufficient information for a person to determine the adequacy of the dynamic response[10]. Underdamping is often overlooked and may lead to inappropriate therapeutic approaches such as lack of fluids and/or vasoactive/inotropic support in true hypotension, or the treatment of false hypertension with a subsequent reduction in tissue perfusion pressure[7,14]. One study found that the incidence of underdamping in patients undergoing major vascular and cardiac surgery was about 31%, and the mean overestimation of systolic blood pressure was 38.5 mmHg (range, 2 to 77 mmHg)[14]. In contrast, in patients without underdamping the overestimation of systolic blood pressure was only 4.1 mmHg (range 1.5 to 15 mmHg)[14]. A difference of >10 mmHg of actual arterial pressure is clinically relevant, and >20 mmHg is clinically unacceptable[7]. In addition, to system-specific technical reasons for underdamping, clinical reasons must also be considered as some conditions can impact the blood pressure measurement, including chronic arterial hypertension, polydisterctual arteriopathy, and chronic obstructive pulmonary disease [COPD][14]. Sedation can also affect measurements; however, it has a protective role in that it can lessen underdamping[14].

In summary, faithful representation of the arterial pressure waveform and subsequent measurement of blood pressure values are of great clinical importance in modern medicine, particularly in intensive care and anesthesiology. The findings of the in vitro experiments of this study indicate that the HemoDraw® Plus system shows better frequency response compared to competitors A, B and C, suggesting it has the highest accuracy for direct measurement of intra-arterial blood pressure.

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