# THE USE OF FLUID-FILLED CATHETERS AS REFERENCE BLOOD PRESSURE MONITORS

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***Abstract***

*The standard ISO 81060–2:2018 allows the use of invasive blood pressure monitoring systems as reference gauges in clinical trials of automated non-invasive automated sphygmomanometers. The reference measuring system is subject to requirements for a maximum permissible error of ±2 mmHg, and the resonant frequency and damping coefficient must also be characterized. The 'catheter-sensor' system used in clinical practice only has defined parameters required by the standard for the chamber with the pressure sensor. The characteristic parameters of the whole measuring system cannot be defined even when the type of catheter used is known, because after every irrigation the system changes the values of its natural frequency ($f_n$) and damping ratio ($\zeta$). These parameters directly define the frequency response of the system, its resonant frequency and the damping coefficient. The characteristic parameters of the 'catheter-sensor' system were defined on the basis of an analysis of a second-order linear model and the measurement of the step response of the real system. Measurements have shown that repeated irrigation of the same 'catheter-sensor' system can change the value of the system's natural frequency by tens of Hz. In well-irrigated systems, the accuracy required by the standard was met. The following values were determined for this system: $f_n$ = 38.8 Hz and $\zeta$ = 0.130. In the second case, when the system was probably affected by air bubble compliancy, the measurement accuracy was much lower. The discovered deviation was tens of mmHg. This system had $f_n$ = 6.5 Hz a $\zeta$ = 0.281.*

***Keywords***

*'catheter-sensor' system, step response, damping ratio, natural frequency*

## Introduction

Fluid filled catheters, pressure transducer and patient's monitor are the most often used a measuring set for the direct blood pressure monitoring. Fluid-filled catheters sense pressure waves in the arterial bed through hydrodynamics from the catheter tip to the sensor diaphragm and finally electric signal from the sensor is sent to a patient's monitor. The accuracy of the pulse wave transmission is hindered by the mechanical properties of the catheter, saline and the pressure sensor membrane. Not even state-of-the-art materials and production processes can guarantee undistorted pressure wave transmission by the 'catheter-sensor' system, because it is impossible to eliminate the transformation of the pressure wave after its transfer through the hydrodynamic system. This fact reduces the accuracy of the measuring system.

IBP (invasive blood pressure) monitor test of the correct functioning can be performed using special simulators. There are two categories of the IBP simulators. The first are hydraulic or pneumatic systems which generate mechanical waves. These systems allow to set a form, frequency and amplitude of the mechanical waves, wherewith a blood pressure simulation is achieved. The second categories insert electronic systems which generate a signal which simulate output signal from the pressure transducer during IBP measuring. These simulators allow to perform testing, calibration and zero setting of the IBP monitors [1]. But certain cases demand to have knowledge about frequency characteristic of the IBP measured system. So, fluid-filled catheters with a transducer measuring the pressure in a chamber outside the patient can be used as reference gauges in clinical trials of automated non-invasive sphygmomanometers pursuant to ISO 81060-2:2018. This test evaluates the compliance of systolic resp. diastolic pressure values obtained by the reference gauge with systolic resp. diastolic pressure values obtained by the tested gauge. The standard defines a maximum permissible error of ±2 mmHg for reference pressure measuring instruments. The standard also requires determining the resonant frequency and



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the damping coefficient of the reference measuring system [2]. These parameters bear essential information about the accuracy of the given measuring system.

The accuracy of the system (measuring with a dynamic quantity) depends on the maximum frequency at which the system is able to measure without unwanted transformations or the loss of information. In order to determine the required minimum frequency range of the measuring device, it is necessary to know the highest frequency component of the measured signal that carries the relevant information for its accurate reconstruction.

Fig. 1 shows one blood pressure wave period (cardiac cycle) and a synthesized curve from its first six harmonic components, obtained by a Fourier transform (FT). The amplitudes of the harmonic functions are given in percentages, where a harmonic function with a funda-mental frequency (first or fundamental harmonic) has one hundred percent amplitude modulation.

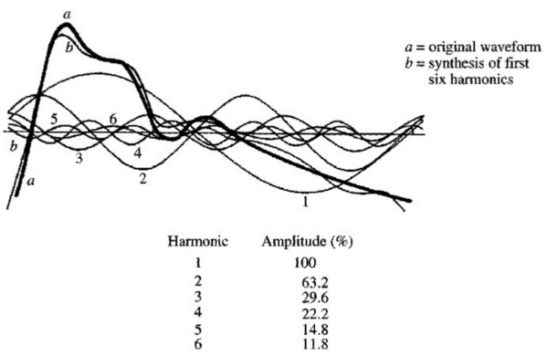


*Fig. 1: a) Blood pressure curve; b) Synthesized blood pressure wave curve [3].*

It is clear that the synthesized signal does not exactly copy the original pressure curve, and the difference in both amplitude and phase is visible. The above indicates that even higher harmonics carry the necessary information for accurate signal reconstruction. According to Hansen, Frye and Gabe, only the use of measuring systems with zero amplitude-frequency response up to frequencies higher than at least the tenth harmonic can ensure the required measurement accuracy [3–5]. However, McDonald and Geddes argue that accurate blood pressure measurements can only be provided by systems with a frequency response greater than the 15th harmonic component of the blood pressure wave [6, 7]. In their article from 1971, Gersh et al. state that the amplitude-frequency response of the 'catheter-sensor' system for measuring the pressure in the heart chambers must be flat up to the 20th harmonic [8]. Finally, IEC 60601-2-34:2011 accepts devices for invasive blood pressure monitoring with a frequency response ranging from 0 to 10 Hz [9]. However, this range only applies to transducers without connected catheters. The blood pressure sensors themselves completely cover the minimum frequency range for accurate signal reconstruction. Their necessary connection to the catheter reduces the natural frequency of the measuring system.

An alternative solution, which is also the most accurate for invasive blood pressure measurement, is so-called TIP catheters. This type of catheter measures the pressure with a pressure sensor located on its tip. This means that it is in direct contact with the blood, thus suppressing the negative effects of hydrodynamic elements present in fluid-filled catheters. The upper cut-off frequency of a TIP catheter reaches 10 kHz, with a resonant frequency up to 50 kHz [10]. However, due to the high cost of this type of catheter and the short life of these intravascular sensors, the use of this measuring system in clinical practice is very limited.

The issue of the frequency response of cardiovascular catheters appeared in the second half of the 20th century. In his article from 1981, Gardner analyzed the effect of catheter frequency characteristics on the results of invasive blood pressure measurements. He designed and implemented a method for measuring the frequency response. This method was based on measuring the periodic harmonic pressure signal with a reference pressure sensor and a 'catheter-sensor' system. This article also investigated a method of determining the characteristic parameters of the measuring system (natural frequency and damping ratio) using the system's unit step response. Based on an analysis of the measured data, Gardner designed a 'catheter-sensor' system model in the form of an electrical RLC circuit [11]. Combining the proposed model with experimental measurements allows us to determine the natural frequency and damping ratio of the system. These two parameters provide complete information on the quality of the transmission of the measured pressure wave through the catheter to the measuring chamber.

The main goal of the study was to assess conditions that can affect the accuracy of the direct blood pressure measuring from the point of view of the using the “catheter-sensor” systems as a reference method for clinical investigation of intermittent automated non-invasive sphygmomanometers.

## Methods

### 'Catheter-sensor' system model

The resulting shape of the mechanical waves that propagate through the 'catheter-sensor' system depends on the inertial, elastic and resistive properties of the system.

Fig. 2 shows an analog electrical circuit, which is a lumped-element model of the second-order system.

The properties in the given model are presented using quantities of inertance, compliance and resistance.

Inertance describes the inertial properties of a given object, namely the ability of a system to maintain the direction and magnitude of forces acting in it.



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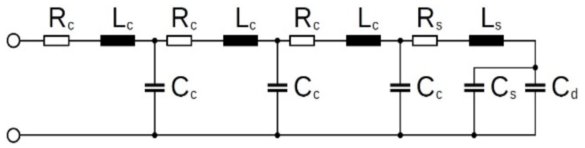


*Fig. 2: Analog electrical model of the 'catheter-sensor' system, where indexes mean: 'c' is the catheter, 's' is a sensor chamber and 'd' is a diaphragm of the sensor (according to [12]).*

The following formula represents mechanical inertance:

$$L = \frac{\rho l}{\pi r^2}, \tag{1}$$

where $\rho$ is the density of the liquid (saline), $l$ is the length of the tube in meters, and $r$ is the radius of the internal cross-section of the tube in meters [12].

Compliance can be defined under the condition that the change in pressure and thus the volume in the given system is so fast that there is no heat exchange with the environment. The formula for determining mechanical compliance is as follows:

$$C = \frac{\Delta V}{\Delta P}, \tag{2}$$

where $\Delta V$ is the change in volume of the body and $\Delta P$ is the pressure difference at the inlet and outlet of the system [12].

Assuming there is laminar flow of incompressible fluid in the system, i.e. assuming parabolic velocity distribution along the entire tube, the relation for calculating the mechanical resistance can be defined as follows:

$$R = \frac{8\eta l}{\pi r^4}, \tag{3}$$

where $r$ is the radius of the internal cross-section of the tube, $\eta$ is the dynamic viscosity of the liquid and $l$ is the length of the tube in meters [12].

Fig. 2 shows a model that considers all of the mechanical properties described above for both the catheter and the pressure sensor. As the formula for compliance (2) shows, the size of a given parameter for different parts of the system will only depend on the change in the volume of these components. The sensor chamber and the catheter itself are made of rigid materials that almost eliminate a change in volume when the pressure in the system changes, namely:

$$\Delta V_c \rightarrow 0 \Rightarrow C_c \rightarrow 0, \tag{4}$$

$$\Delta V_s \rightarrow 0 \Rightarrow C_s \rightarrow 0, \tag{5}$$

where $\Delta V_c$ is the change in volume of the catheter and $\Delta V_s$ is the change in volume of the sensor chamber.

The only highly flexible element of the system is the sensor diaphragm. It can be said that its compliance is so high compared to the compliance of the catheter and the sensor chamber that their influence in the given model is negligible.

In the next step, formulas 1 and 3, defining the inertance and resistance of the 'catheter-sensor' system were analyzed. As the relevant relations show, the physical quantities that affect the inertance and resistance are the length and inner radius of the given system elements. The inner radius of the examined catheters is 0.595 mm, and the minimum length is 200 mm. The inner radius of the chamber containing the pressure sensor is 1.4 mm, and its length is 38.4 mm. The given quantities and formula 1 can be used to determine the ratio between the inertance of the shortest catheter (smallest inertance) and the inertance of the chamber:

$$\frac{L_c}{L_s} = \frac{\rho \cdot 0.2 \cdot \left(1{,}4 \cdot 10^{-3}\right)^2 \cdot \pi}{\pi \cdot (0{,}595 \cdot 10^{-3})^2 \cdot 0.0384 \cdot \rho} \approx 29. \tag{6}$$

The following is a calculation of the ratio of the resistance of the shortest catheter (the smallest resistance) and the resistance of the chamber, according to formula 3:

$$\frac{R_c}{R_s} = \frac{\eta \cdot 0.2 \cdot \pi \cdot \left(1{,}4 \cdot 10^{-3}\right)^4}{\pi \cdot (0.595 \cdot 10^{-3})^4 \cdot \eta \cdot 0.0384} \approx 160. \tag{7}$$

The above calculations show that the inertance of the shortest examined catheter is about 29 times greater than the inertance of the chamber. The resistance of the shortest catheter is 160 times greater than the resistance of the chamber. As the formulas clearly show that the longer the elements the greater the relevant parameters, it is clear that the resistance ratio (or inertance) of the longer examined catheters and the corresponding chamber parameters will be even higher. The theoretical calculations and the nature of the connection of individual system components (series connection) allow us to state that the influence of inertance and resistance of the chamber is minimal in comparison with the same properties of the catheter. Based on the above, the model from Fig. 2 can be simplified as follows:

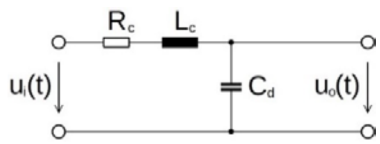


*Fig. 3: Simplified 'catheter-sensor' system model.*

As Fig. 3 shows, the resulting model is a mechanical analog of an electrical RLC circuit. The following relation applies to the input and output voltage:

$$u_i(t) = \frac{L_c C_d d^2 u_o(t)}{\mathrm{d}t^2} + \frac{R_c C_d \mathrm{d}u_o(t)}{\mathrm{d}t} + \mathrm{u}_o(t). \tag{8}$$

Next, we define the transfer function of the RLC circuit as the ratio of the Laplace transform of the output to the input of the system:



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$$F(p) = \frac{U_{\text{out}}(p)}{U_{\text{in}}(p)} = \frac{1}{C_d L_c p^2 + C_d R_c \text{p} + 1}. \qquad (9)$$

It is a dynamic, time-invariant, second-order linear system with two poles and no zero. The natural frequency in Hz at which the amplitude of the output signal of the system will be maximum at undamped oscillation was further defined for the system [12]:

$$f_n = \frac{1}{2\pi\sqrt{L_c C_d}}. \qquad (10)$$

The damping ratio of the system was defined next [12]:

$$\zeta = \frac{1}{2} R_c \sqrt{\frac{C_d}{L_c}} \qquad (11)$$

Finally, we can modify the transfer function by introducing the natural frequency, the damping ratio and the DC gain ($G_{DC}$) into the relation:

$$F(p) = \frac{\omega_n^2 G_{DC}}{p^2 + 2\zeta\omega_n p + \omega_n^2}, \qquad (12)$$

where $\omega_n$ is the natural frequency of the system in rad·s$^{-1}$.

In our case, the unit step function of the measured quantity was used as the input signal. The response to this type of signal is a transient characteristic of the system that allows you to determine the natural frequency and damping ratio.

The above parameters were further determined experimentally.

## Evaluated catheters and pressure sensor

Diagnostic catheters for extravascular blood pressure measurement consist of a flexible tube with an outer diameter of 4 to 8 French, depending on the patient's condition and the location of the pressure sensing. The length of intravascular catheters for extravascular pressure sensors can range from 10 to 125 cm [12]. Mechanical and geometric parameters of catheters have a fundamental effect on the accuracy of the transmission of pressure changes from the catheter tip to the sensor. The manufacturer usually provides information about basic parameters on the distal connector for connecting the chamber.


*Fig 4: Diagnostic catheter from Cordis – Infinity series [13].*

As Fig. 4 shows, the values of four parameters are listed on the connectors:

1. maximum guidewire diameter in inches (1 inch = 25.4 mm),
2. catheter length in cm (the length is measured with an upright catheter, from the end of the connector (the narrowest part) to the tip,
3. maximum pressure value (when injected) in psi (1 psi ≈ 6894.757 Pa ≈ 51.715 mmHg),
4. outer diameter of the catheter in Fr.

Number 5 in the Fig. 4 shows the catheter tip with a certain resistance to mechanical stress and change of shape.

Modern materials are used in the production of the catheter, which must ensure the required mechanical properties and biocompatibility. One material used in the manufacture of the catheters is Teflon. This is the trade name for polytetrafluoroethylene from DuPont Company. Other biocompatible polymers that are sufficiently rigid to eliminate changes in catheter volume under pressure but also sufficiently flexible for easy penetration and movement within the blood vessel are used in the manufacture of catheters.

A multi-purpose 5 French diagnostic catheter from the Infinity series (Cordis, US) with a nominal length of 125 cm and an inner diameter of 1.19 mm was used in the experimental part of the article. A TrueWave (Edwards, US) pressure transducer chamber was chosen to read the pressure signal from the catheter. This pressure transducer is a single-use chamber. Its case is made of rigid plastic to reduce compliance. Special requirements are placed on this type of device for invasive blood pressure monitoring. The list of required parameters and the corresponding parameter values specified by the TrueWave chamber manufacturer can be viewed in the following table:

*Table 1: Required parameters of transducers according to IEC 60601-2-34:2011 [9] and values specified by the manufacturer [14].*

| Parameter | Values listed by the manufacturer | Minimum values according to the standard |
|---|---|---|
| Operating pressure range | –50 mmHg to 300 mmHg | –30 mmHg to 250 mmHg |
| Nonlinearity and hysteresis | up to ±1.5% of reading or ±1 mmHg | up to ±4% of reading or ±4 mmHg |
| Natural frequency | > 200 Hz | > 10 Hz |
| Output Drift | ±1 mmHg in 8 hours | ±1 mmHg in 8 hours |



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As the above table shows, the transducer completely covers the requirements of IEC 60601-2-34:2011. However, the values of these parameters are only valid for the pressure transducer without a connected catheter. And as you can see, only the chamber parameters can cause a measurement error in mmHg.

The above diagnostic devices were chosen for experimental measurements due to their widespread use in clinical practice.

### Description of measuring device

In this article, the step response was chosen as the main tool for analysis of the 'catheter-sensor' system due to the relatively easy implementation of the experiment and the high amount of data that can be obtained from this characteristic. The technical implementation of the measuring device and the measuring procedure were designed according to Robert A. Peura's work [11].

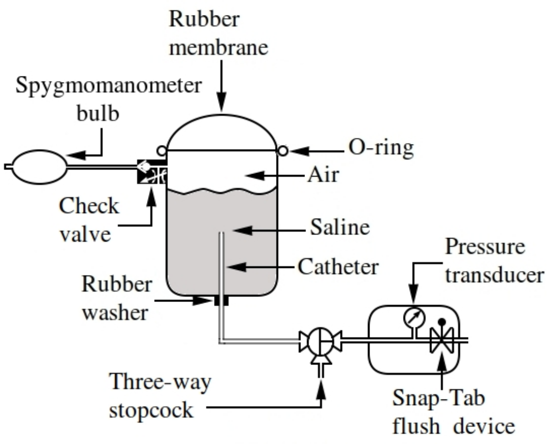


*Fig. 5: Method for measuring the step response of the 'catheter-sensor' system (according to [12]).*

Fig. 5 shows a diagram of the test device used for measuring the transient response of a 'catheter-sensor' system. The catheter is placed in a rigid cylindrical vessel (an aluminium bottle was used in the research work) with an open neck via a screw connector with a rubber seal. The whole system is filled with saline. Excess fluid is removed by a three-way stopcock. A rubber membrane is placed on the top part of the vessel, which is attached with a special plastic O-ring. Pressure is increased in the system with a sphygmomanometer bulb. Finally, after the inflated rubber membrane breaks, the pressure in the system abruptly drops and the response of the 'catheter-sensor' system is monitored.

The signal from the pressure chamber was read and processed by an MP35 (BIOPAC Systems, US) measuring unit. This device can sense electrical signals with an amplitude ranging from ±200 µV to ±2 V. The BIOPAC system includes a device amplifier with the amplification factor from 10 to 50000. Before amplification, the signal is filtered by an analog low-pass filter with a cut-off frequency of 20 kHz, and a high-pass filter that eliminates unwanted DC signal components. Signal transmission to the computer is provided by a USB interface. This interface also allows control of the MP35 measuring unit with the BSL PRO v3.7 software. The input channels used, the signal amplification, the sampling frequency from 1 Hz to 100 kHz and the measuring time can be set in the program. BSL PRO also allows us to monitor the measured signals in real time and digital filtering (programmable digital filters) [15].

### Measuring the step response of the system

A unit step function device was mounted on a stable table surface to eliminate mechanical disturbances in the measured signal. The chamber with the catheter was attached to the wall at the height of the device. This placement eliminates the effect of hydrostatic pressure. The electrical connector of the chamber was connected to the first channel of the BIOPAC measuring unit via an Edwards-DSUB cable. The measuring unit was connected to a computer via a USB interface. The first channel was activated in BIOPAC PRO v3.7, and the amplification factor was set to 1000. A sampling frequency of 20 kHz was set.

The aluminium bottle was filled with saline through the catheter and the top opening of the bottle to a level just below the check valve (17 cm above the bottom of the bottle). Once filled, the three-way stopcock was returned to its original position, thus connecting the chamber, catheter and tool to form a pressure jump. A plastic extension with an inflatable balloon and a seal was screwed onto the top opening in the device. Latex balloon with a diameter of 13 cm were used for the measurements. The sphygmomanometer bulb connected to the check valve was used to increase the pressure in the system, which increased the volume of the inflatable balloon. After the measurement was switched on in BSL PRO, a lighter was used to explode the pressurized balloon. The explosion of the balloon caused the system to open abruptly and resulted in a sudden pressure drop.

The step response was measured on catheters that are 125 to 20 cm long. The catheter was shortened by 5 cm for the measurements. To maintain the same catheter extension in each measurement, the device creating a unit step function was placed '$l_c$ – 10 cm' away from the chamber, where $l_c$ is the length of the catheter in cm. To verify the reproducibility of the experiment, measurements were performed on multiple catheters of the same type and the same batch. Measurements were repeated at least three times on each catheter for each length.

### Postprocessing and data analysis

The signals measured as the system's response to the unit step function were filtered by a lowpass FIR filter with a cut-off frequency of '$f = f_r + 200$ Hz', with respect to the minimum natural frequency of the



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pressure sensor and the frequency spectrum of the signal.

For the purpose of analyzing and calculating the transfer function, the amplitude of the signals was normalized to a range of –1 to 1.

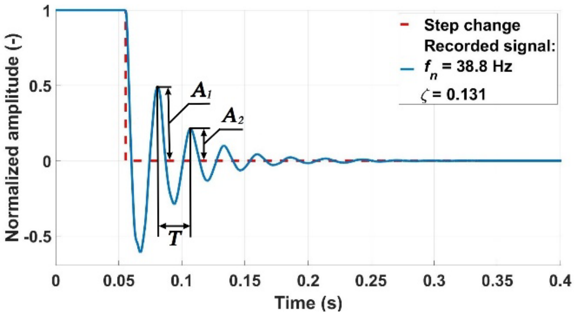


*Fig. 6: 'Catheter-sensor' response to pressure jump (catheter length 125 cm).*

Fig. 6 shows the system's response to the pressure jump. The figure also shows the amplitudes of the first positive waves of the step response ($A_1$ and $A_2$) and the time interval between them (T) in seconds.

The method by Webster [16] was used to determine the damping ratio of a second-order system:

$$\zeta = \frac{ln(A_1) - ln(A_2)}{\sqrt{4\pi^2 + (ln(A_1) - ln(A_2))^2}}. \quad (13)$$

The following relation applies to the natural frequency of a second-order linear system [16]:

$$f_n = \frac{1}{T\sqrt{1-\zeta^2}}. \quad (14)$$

The above formulas were applied in the MATLAB programming environment within the algorithm for calculating the damping ratio and the natural frequency of a second-order system. Because the experiments have shown that the studied system is poorly damped, we can further define the resonant frequency of the second-order linear system as follows [17]:

$$f_r = f_n\sqrt{1-2\zeta^2}. \quad (15)$$

Finally, the damping coefficient is defined by the following relation:

$$\delta = \zeta\omega_n. \quad (16)$$

The determined parameters (natural frequency and damping ratio) were used to define the transfer function of the second-order linear system. The obtained transfer function was implemented in the MATLAB programming environment (version 9.5).

## Results

Experimental measurements were conducted in this study, which allowed us to determine the natural frequency and damping ratio of the 'catheter-sensor' system.

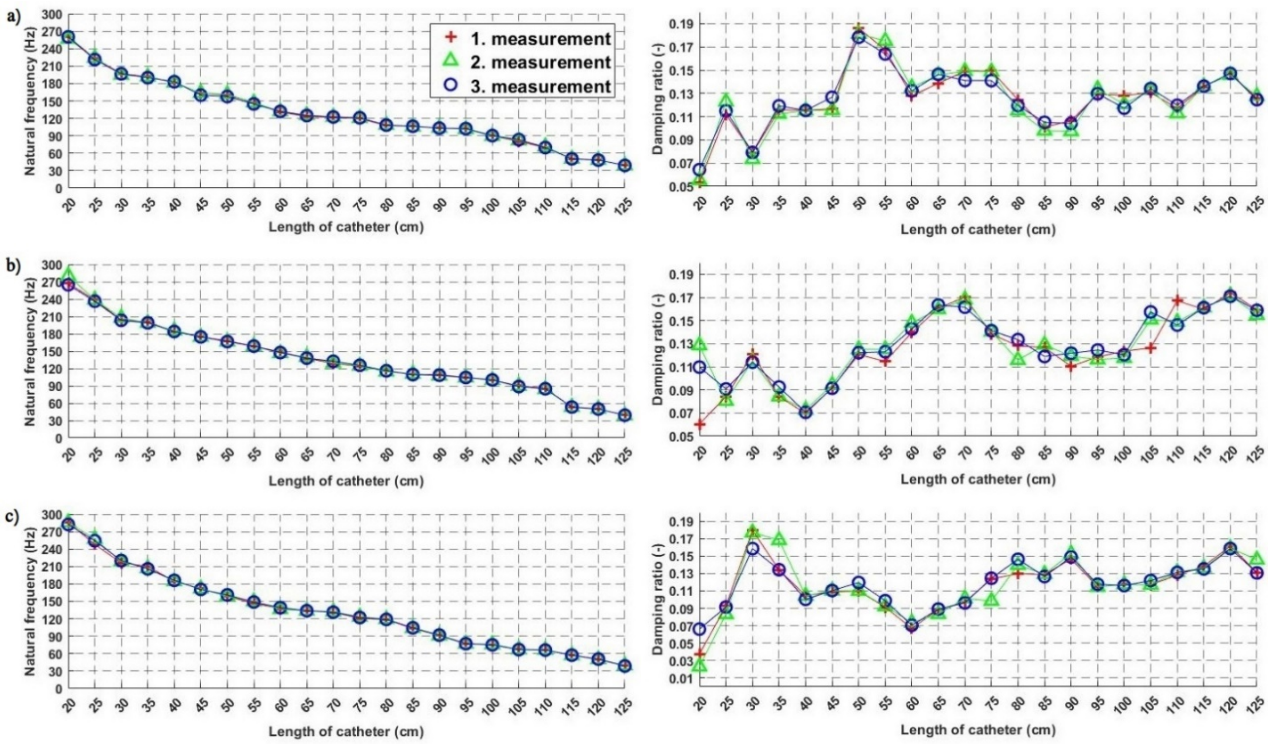


*Fig. 7: Natural frequency and damping ratio depending on the length of the catheter: a) first catheter b) second catheter c) third catheter.*



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Fig. 7 shows the results of measurements and calculations of parameters with the method by Webster for three identical catheters with lengths ranging from 20 to 125 cm. The measured data show the dependence of the natural frequency of the system on the length of the catheter: as the length of the catheter decreases, the natural frequency of the whole system increases.

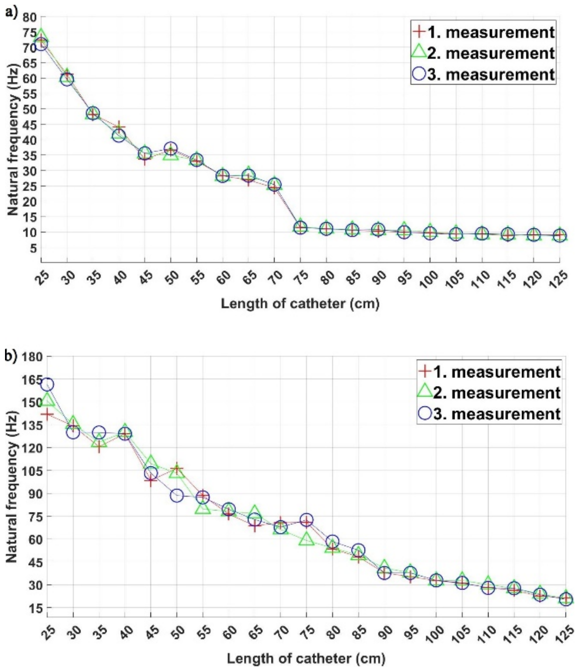


*Fig. 8: Natural frequency depending on the length of the catheter: a) fourth catheter b) fifth catheter.*

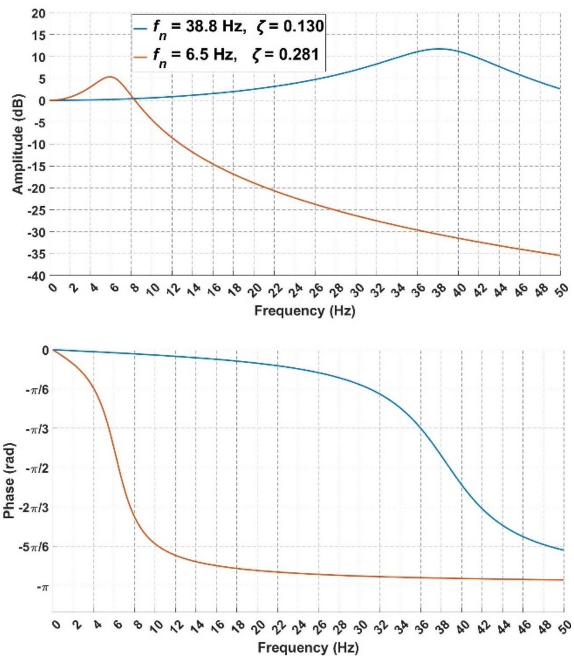


*Fig. 9: Frequency response (magnitude and phase) of one differently irrigated 'catheter-sensor' system.*

Fig. 8 shows the results of the natural frequency of the 'catheter-sensor' system determined according to the method by Webster from the signals obtained by measuring the step response of two other catheters.

A large decrease in natural frequency can be seen in comparison with the results shown in Fig. 7. Fig. 8b also shows deviations in tens of Hz and more with the same catheter length.

Fig. 9 shows the frequency response of the 'catheter-sensor' system, with good ($f_n$ = 38.8 Hz) and poor ($f_n$ = 6.5 Hz) system irrigation. The graphs show that in a poorly irrigated system, the frequency response changes starting at 1 Hz. This fact leads to a significant transformation of the measured signal.

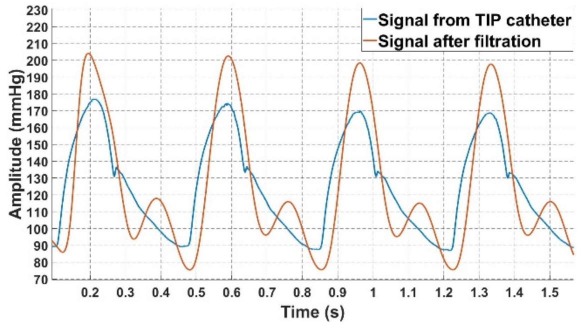


*Fig. 10: IBP curve from the TIP catheter and its course after filtration by a system with fn = 6.5 Hz and with ζ = 0.281.*

This is confirmed by the curve of the signal from the TIP catheter after filtering through a filter modelling the behavior of a poorly irrigated 'catheter-sensor' system. Fig. 10 shows a clear difference in the amplitude of two signals and the phase shift between them.

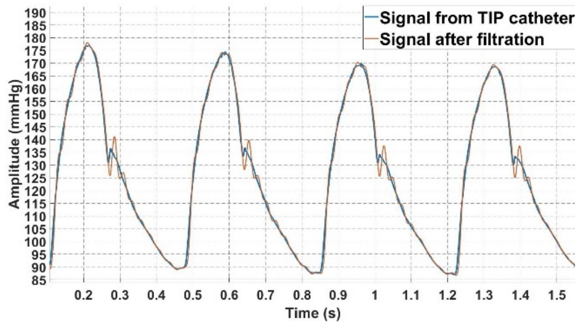


*Fig. 11: IBP curve from the TIP catheter and its course after filtration by a system with fn = 38.8 Hz and with ζ = 0.130.*

In comparison with the previous signal Fig. 11 shows curve after filtering by a system modelling a well-irrigated system, the signal curve is almost identical to the original pressure signal from the TIP catheter—deviations of diastolic or systolic pressure are in tenths of mmHg. The changes are only visible in the dicrotic notch, where the pressure wave changes faster (higher harmonic components).



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## Discussion

The experiment results show that the accuracy of IBP measurement by the 'catheter-sensor' system increases with falling catheter length. It can also be argued that poor quality of preparation of the measuring equipment (the presence of air bubbles in the system) reduces the natural frequency below the permissible limit (according to [9]).

The natural frequency and damping ratio were determined under the assumption that the behavior of the system corresponds to a second-order linear system, electrical analogy—RLC circuit. The measurements were performed using catheters of different lengths to reveal the dependence of system parameters on the catheter length. The tendency for the system's natural frequency to change the shorter the catheter is does not allow us to reject the hypothesis that an RLC circuit (as an electrical analogy) can simulate the behavior of a 'catheter-sensor' system and, in fact, largely confirms this assumption. This also confirms that the use of shorter catheters will provide more accurate blood pressure measurements. However, longer catheters are necessary to measure blood pressure in the aorta, which necessarily leads to a reduction in the natural frequency and an increase in the damping ratio of the measuring system.

Another factor affecting the accuracy of blood pressure measurement is the technical parameters of the measuring chamber. Only nonlinearity of the pressure sensor can cause an error of more than 2 mmHg. Zero drift of the sensor may reduce or increase the value of the measured pressure by 1 mmHg. This is why each chamber must be calibrated with a sufficiently accurate pressure gauge before use.

In addition to the undesirable properties of the medical devices used, medical staff working with the 'catheter-sensor' system may be a source of measurement errors. In invasive measurement of arterial pressure, it is important to ensure that the catheter tip and sensor are positioned at the same height. The chamber with the pressure sensor must be at the same height as the left ventricle. The correct setting of the phlebostatic axis eliminates the undesirable effect of hydrostatic pressure. The incorrect placement of the catheter tip in the vascular bed may also cause errors in blood pressure measurements. It is important that the catheter inlet is parallel to the blood flow. Otherwise, an error caused by dynamic pressure occurs, which can be in units of mmHg when measured in the aorta.

The experiments revealed a problem that cannot be suppressed or neglected, because it significantly changes the behavior of the 'catheter-sensor' system. This problem is air bubbles in the system. Their existence was revealed when the repeatability of the experiments was tested. For this purpose, the experiment was performed on the same system, under the same conditions and in the same way several times in a short time interval (several minutes). The only change was that the system was refilled with saline before each experiment. A new value of natural frequency and damping ratio was measured with each new experiment. Small differences between the measured values can be explained by random errors and limited accuracy of measuring devices and parameter calculation methods. However, the difference between some experiments was much larger—tens of Hz in the case of natural frequency (see Fig. 8). These differences between results in one experiment cannot be caused by random variables. The only logical explanation for the change in the system's behavior is the existence of other impedance not described in the model. An air bubble is the only highly compliant element that can change parameter values. It is clear that air bubbles in the catheter reduce the natural frequency and increase the damping ratio of the measuring system (see formulas 10 and 11 and Fig. 9). As Fig. 10 shows, poor irrigation of the system leads to significant transformation of the pressure signal after it passes through the catheter. It is clear that such high changes in the amplitude of the pressure curve are unacceptable for a reference blood pressure monitor. However, as Fig. 11 shows, a well-irrigated system allows highly accurate blood pressure measurement.

Also, other authors [11, 12, 18] notice in their studies effect of air bubbles on the behavior of the 'catheter-sensor' system. In addition to above, Nichols et. all remarks that microbubbles markedly affect to the effective volume elasticity of the system, because a pressure sensor diaphragm has a relatively poor volume displacement. Probability of existence air bubbles in the system could be reduced by an using of saline from which most, of the dissolved air has been removed by boiling [18].

Inverse filtering of the measured pressure signal could be a solution to a poorly irrigated system. However, as mentioned above, every irrigation of the 'catheter-sensor' system will result in new natural frequency and damping ratio values. A universal inverse filter with constant parameters is therefore not a solution to this problem. A determination the dynamic frequency characteristic of a 'catheter-sensor' system using a step function of pressure, or some form of a sine-wave generator with a wide range of frequencies [18] are non-applicable in clinical practice, because these methods are technically demanding and time-consuming. However, there is a methodology for measuring the transient response of the 'catheter-sensor' system directly in the patient's bloodstream. The quick opening and closing of the valve (Snap-Tab flush device) of the measuring chamber causes an abrupt change in pressure in the whole system [19]. Performing this maneuver between the dicrotic notch and the inotropic component allows us to obtain the transient response of the system, which we can use to obtain the necessary parameters for determining the frequency response of the system.



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Finally, it should be noted that the transient response was measured on a catheter that was directly connected to the measuring chamber. In clinical practice, an extension tube is used between the chamber and the catheter. It is clear that connection of the extension tube will reduce the natural frequency of the system. For a TruWave measuring chamber with a standard 12-inch (approx. 30.48 cm) tube without a catheter, the manufacturer lists a natural frequency value of 40 Hz [14]. However, based on the known connection of impedance elements L and R in the model, it can be assumed that the connection of the extension tube would increase the inertance and resistance of the system by the values of the corresponding parameters of this tube. An increase in the overall compliance of the system can be expected due to the lower rigidity of the extension tube. These factors reduce the resonant frequency and increase the damping coefficient of the system used for invasive blood pressure measurement in hospital facilities.

## Conclusions

The analysis of the applicability of fluid-filled catheters as reference blood pressure gauges in this article was based on the measurement of the step response.

The obtained natural frequency and damping ratio values indicate a fairly high accuracy of the system for use as a reference gauge in clinical trials. However, this is under the condition of perfect irrigation that eliminates air bubbles in the catheter. Poor chamber and catheter irrigation quality reduces the accuracy of the system, as both the high and low frequency components of the measured signal are transformed. Changes in the transmission of lower order harmonics mostly affect the volume of the pressure curve. In the case of a steeper curve of the dicrotic notch, the transformation of the higher frequency components of the signal means a change in the shape of the pressure curve. The above signal changes may result in an error in the measurement of systolic and diastolic pressure values from units to tens of mmHg.

In order to meet the conditions imposed on the reference blood pressure monitor and to generally increase the accuracy of the measurement, the 'catheter-sensor' system must be well irrigated. Measurements have shown that a measuring system with a natural frequency near 40 Hz can guarantee very high accuracy in measuring blood pressure. The method of measuring the transient response and determining system parameters by Webster can be used to control the quality of system irrigation. The extension tube connected between the chamber and the catheter increases the overall impedance of the measuring system (reduces the natural frequency and increases the damping ratio), so its use is not recommended. It should also be noted that the use of shorter catheters increases the accuracy of blood pressure measurements due to lower inertance and a lower probability of air bubbles.

The experiments have shown that the accuracy required by the standard (±2 mmHg) can be achieved even with long fluid-filled catheters (e.g. 125 cm). However, the following conditions must be met: good system irrigation, the use of accurate measuring equipment and proper measurement methodology. Based on the above, it can be argued that a fluid-filled catheter system with a measuring chamber can be a very promising reference pressure gauge in clinical trials of automated non-invasive sphygmomanometers.

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