Carsten Tautorat, Sebastian Kaule, Jörg Kaminsky, Klaus-Peter Schmitz, Niels Grabow and Wolfram Schmidt*

Pressure sensor emulator to improve long-term stability of heart valve testing systems

Abstract: Fluid mechanical characterization of artificial heart valve prostheses requires reliable measurement of temperature, flow and pressure at normal heart rate. *In vitro* fatigue test procedures of artificial heart valve prostheses can take several months with up to 400 million cycles to assess valve performance and durability under simulated cardiac conditions at increased pulse frequency. In both cases, a minimum of user interventions for recalibration are required. In these tests, pressure data are collected for hydrodynamic heart valve characterization and for closed-loop control of pressure loading. In our study, the improvement of commercial heart valve testing systems (Vivitro Pulse Duplicator, Vivitro Labs Inc. and VDT-3600i, BDC Laboratories) is considered by substituting the built-in disposable pressure sensors (lifetime: one week) by long-term stable sensors.

The selected highly accurate sensors (86A, TE Connectivity Corp.) provide amplified, linearized, calibrated and temperature compensated analog output signals. Their stainless steel construction allows for high media compatibility with corrosive liquids. Due to different sensitivity characteristics, these sensors are not fully compatible to the testing devices. To overcome this limitation, application-specific emulator interfaces were developed to connect the new sensors to the data acquisition part of the validated valve testing systems. To stay consistent with manufacturer's device and software specification, we

utilized fast analog signal conditioning, including scaling, offset calibration, out of range alarm and status indication. Compared to the originally equipped pressure sensors, emulator parameters, such as pressure range, precision, resolution and accuracy remained unchanged or even improved. For system verification the response characteristic, long-term stability and dynamic properties were examined in comparative studies.

Keywords: pressure, sensor, valve, heart, testing, prosthesis

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1 Introduction

In vitro bench testing of heart valve prostheses involves the simulation of physiological loading conditions in order to assess hydrodynamic and durability behavior with dedicated test equipment. Integrated software-controlled data acquisition systems are used for monitoring the loading pressures. These semi-rugged sensor applications with corrosive saline-type solutions have high requirements on reliability and accuracy, since component failure can lead to time-consuming and expensive false-negative or even worse false-positive results in valve durability and design verification testing. Therefore, periodic inspection, recalibration and frequent component replacement due to the short sensor lifetime are required.

Our application note presents the replacement of the disposable pressure sensors for the Vivitro Labs pulse duplicator system (Vivitro Labs Inc., Canada) and the VDT-3600i valve durability tester (BDC Laboratories, Denver, USA) by highly accurate industrial sensors for repeated long-term *in vitro* use.

***Corresponding author: Wolfram Schmidt:** Institute for Biomedical Engineering, Rostock University Medical Center, Friedrich-Barnewitz-Str. 4, 18119 Rostock, Germany, e-mail: wolfram.schmidt@uni-rostock.de

Carsten Tautorat, Niels Grabow: Institute for Biomedical Engineering, Rostock University Medical Center, Friedrich-Barnewitz-Str. 4, 18119 Rostock, Germany

Sebastian Kaule, Jörg Kaminsky: Institute for ImplantTechnology and Biomaterials e.V., Friedrich-Barnewitz-Str. 4, 18119 Rostock, Germany

Klaus-Peter Schmitz: Institute for ImplantTechnology and Biomaterials e.V., Institute for Biomedical Engineering, Rostock University Medical Center, Friedrich-Barnewitz-Str. 4, 18119 Rostock, Germany

2 Material & Methods

2.1 Heart valve testing systems

2.1.1 Vivitro Pulse Duplicator

The data acquisition system of the Vivitro Pulse Duplicator consists of the pressure measuring system AmPack and the I/O Module [1]. Three pressure sensors (aortic, ventricular and atrial) are connected to the AmPack for signal conditioning, including user selectable filtering, adjustable scaling and shift calibration, as illustrated in **Figure 1**. The AmPack output signals are three single-ended analog voltages (U_{out}) with a linear pressure-to-voltage conversion of:

$$U_{out}[V] = 0.06 \frac{V}{\text{mmHg}} \times p[\text{mmHg}] - 6 V \quad (1)$$

The pressure p is limited to 250 mmHg, see **Table 1**. AmPack and I/O Module are electrically connected with three BNC cables. The I/O Module converts the amplified and filtered analog sensor signals into digital pressure data.

Figure 1: Simplified block diagram of the Vivitro Pulse Duplicator

2.1.2 VDT-3600i Valve Durability Tester

The VDT-3600i system contains up to six independent testing stations for computer-controlled valve pressure loading and wave shape modulation. On each station a pair of pressure sensors is located at the inlet (–) and outlet (+) of the valve prosthesis for measuring pressure differences of the fluid flowing through. All sensors are electrically connected to one of three bridge modules NI-9237 (National Instruments) containing the signal conditioning required to power and measure four bridge-based sensors simultaneously [2]. The accessible analog circuit part of the VDT-3600i is limited to the pressure sensor output signals, as illustrated as blue box in **Figure 2**. As a result, the emulator has to simulate 12 piezo-resistive Wheatstone full-bridge arrangements ($p1-, p1+, \dots, p6+$) with extremely low differential sensor output voltages, see **Equation 2**.

Figure 2: Simplified block diagram of the VDT-3600i

$$U_{out}[\mu V] = 50 \frac{\mu V}{\text{mmHg}} \times p[\text{mmHg}] \text{ for } 10 V \text{ excitation} \quad (2)$$

2.1.3 Comparison of test systems

The simplified block diagrams in **Figure 1** and **Figure 2** of both heart valve testing systems are quite similar. Software-controlled fluid actuators are coupled with pressure and flow monitoring. Conditioning systems are installed for defined loading pressures and wave shape modulation with a wide range of testing frequencies (load cycle rates, **Table 1**) [1, 2].

It is not described in the user manuals, but we assume that pressure sensor chips of the BP Series from Merit Medical Systems (Utah, USA) are used in both systems. This piezo-resistive Wheatstone bridge sensor with custom pressure ranges is temperature compensated and dielectric gel protected. The minimum operating product life is specified with one week [3]. It can be installed into any custom pressure device housing, such as the single-use polycarbonate luer lock housing of the originally equipped sensors. For system implementation additional circuits are required for signal amplification, filtering and sensor calibration.

Table 1: Heart valve testing systems [1, 2]

Parameter	Vivitro Pulse Duplicator	VDT-3600i Valve Durability Tester
Load cycle rate	1 to 3 Hz	1 to 50 Hz
Number of sensors	3	12 (pairwise)
Original sensor range	-50 to 250 mmHg	-362 to 3878 mmHg
Emulator range	0 to 220 mmHg	0 to 3750 mmHg

2.2 Pressure sensor emulator

2.2.1 Development

We have intended to improve the reliability of pressure measurements without degrading performance and handling

of the heart valve testing systems. Our modifications are based on hardware substitutions without changes in the data acquisition software. To imitate the originally equipped sensors we connect the emulator analog outputs prior to signal digitization. Therefore, we use the specified electrical interfaces of the testing device. A distributed modular multi-component system simplifies this approach. Emulators contain filtering, offset calibration and scaling circuits individually for each pressure sensor, as shown in **Figure 3**.

Figure 3: Schematic block diagram of the emulator

With offset adjustment and scaling the sensor output signals are converted into the specific pressure-to-voltage sensitivity of the originally equipped sensors. We use precision operational amplifiers with low offset and low voltage drifts for all crucial analog electronic circuits. The emulator features inspection flaps for recalibration.

Pulse Duplicator

For Pulse Duplicator measurements the emulator operates similar to an amplified sensor with integrated signal conditioning from 0 to 220 mmHg, relevant for blood pressure measurements. Low-pass signal filtering with cutoff frequencies between 30 Hz and 100 Hz is recommended [1]. Therefore, sensor signals are low-pass filtered with a second order RC-filter (-3 dB cutoff: 34 Hz). The signal conditioning device AmPack is no longer used.

VDT-3600i

The operating range of the sensor emulator is from 0 to 3750 mmHg, see **Table 1**. A differential amplifier is exclusively used for the VDT-3600i to convert the single-ended sensor signal to a differential full bridge signal, as seen **Figure 3**. Apart from parasitic low-pass filter effects, the sensor signal of the VDT-3600i emulator is currently not filtered, due to the following signal conditioning in the NI-9237 bridge modules. Scaling is calculated and installed for an excitation voltage of 10 V.

The VDT-3600i emulator is necessarily equipped with digital electronic circuitry. This controller-based digital part is used for monitoring (e.g. excitation voltage and missing sensors) and controlling functions without a connection to the computer. If the software-controlled excitation voltage deviates from the 10 V ($\pm 1\%$) the sensor outputs are reset to zero. A display serves as a user interface showing system status and error messages.

2.2.2 Selected sensor

The selected highly accurate sensor type 86A (TE Connectivity Corp.) is a small profile, media compatible, piezo-resistive silicon pressure sensor packed in a stainless steel (316L) housing [4]. The sensing package utilizes silicone oil to transfer pressure from the stainless steel diaphragm to the sensing element. An application-specific integrated circuit (ASIC) is used for temperature compensation, offset correction and provides an amplified, linearized output signal of 0.5 to 4.5 V, which makes the sensors interchangeable without recalibration. Fast response and high durability are conflicting requirements for choosing a suitable pressure sensor. The response time of the 86A sensor is adequate for a load cycle rate below 5 Hz. The temperature operating range from room temperature to $+40^\circ\text{C}$ is an easy to meet requirement due to the integrated temperature compensation from 0 to 40°C .

2.2.3 Sensor housing

Analogous to the originally equipped sensors, our emulator sensors are connected to the test fixtures with standard luer lock, as seen in **Figure 4A**. Therefore, our sensors are installed in a lathe machined PTFE part, forming a small volume of 5 ml with a shortened luer lock syringe barrel, as illustrated in **Figure 4B**. O-rings are used for sealing. As a result, the modular sensor assembly can be dismounted for sensor cleaning or replacing. A screwable scaffold stabilizes the assembly for a working pressure up to 5 bar (see **Figure 4B**). The sensor is filled with fluid, e.g. distilled water before using.

Figure 4: Pressure sensor type 86A

A: Sensor connected to valve testing system (Pulse Duplicator) with luer lock. B: Sensor with and without housing.

3 Results

3.1 Calibration

Both heart valve testing systems including their specific emulators were two-point calibrated following manufacture procedures with static pressure. In the first step the offset was fine-adjusted to give the desired output voltage at 0 mmHg. In the second calibration step the scaling was adjusted at 200 mmHg (Pulse Duplicator) or 750 mmHg (VDT-3600i) for the target output voltage. We use standard 3-way stopcocks for bleeding all air from the sensor, for zero balancing to atmospheric pressure before use and for connecting a manometer as reference. All static pressure measurements (calibration, drift) were verified with a GMH3151 manometer (Greisinger electronic GmbH, Germany) with 0.25 % full scale accuracy.

3.2 Long-term drift

The Pulse Duplicator has been used exclusively with the developed emulator for two years with no need for recalibration. Measured pressure data were checked periodically exposed to atmosphere and to defined pressure values to ensure no drift has occurred. So far, the long-term stability of the VDT-3600i emulator has been studied for one week at different static pressures, leading to positive results. We expect that the higher dynamic load in valve durability tests will lead to earlier sensor drift or sensor failure.

3.3 Response time

We performed dynamic square wave tests (80 to 140 mmHg) using a blood pressure system calibrator Model 601A (BIO-TEK Instruments, Inc. Winooski, USA) to specify the ability of the emulator to respond to fast pressure load reversals. The response time of the sensor signals was determined by an oscilloscope (MSO4024, Rigol Technologies Inc.). The unfiltered sensor signals of the 86A as well as of the originally equipped sensor connected to the AmPack have shown significant overshoot and subsequently a damped oscillation with a resonant frequency of approximately 70 Hz (86A) and 250 Hz (original) in water. The pressure waveforms return to baseline within five oscillations. Emulator electronics eliminates the oscillation effect to a minimum in the sensor signal due to filtering. However,

necessary filtering increases the response time whereby load cycle rate is limited. 34 Hz signal filtering increases the response time of the 86A sensor to 22 ms (original sensor: 12 ms). The 10 ms longer response time of the 86A reduces the load cycle rate below 5 Hz.

4 Conclusion

Two emulator solutions were presented for different heart valve prosthesis testing systems. The developed sensor emulator circuits have shown to be precise, long-term stable and well suitable for use in test equipment for class III medical implants. Calibration intervals can be substantially extended as practically experienced with the Pulse Duplicator. However, the 10 ms longer response time of the selected sensor 86A reduces the maximum load cycle rate below 5 Hz. Higher cycle rates can only be achieved with faster sensors that can be easily integrated to the emulator due to the elaborate electronics. The costs for the replacement with industrial sensors are minor in comparison to the significant improvement in long-term reliability and maintenance costs.

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