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Mock loop for bubble generation in a centrifugal blood pump for fault simulation

Abstract: In extracorporeal blood circulation intensive care treatments, the occurrence of gas within the circulation is one known major hazard. This gas volume can cause severe harm to the patient like infarctions. Consequently, within risk assessment for these treatments gas bubbles are usually addressed by either constructive or signal based approaches. All signal-based approaches do have in common that they need a sufficient amount of data to be parameterized. These data can only be acquired in animal trials or laboratory experiments, as they could result in harm to patients.

Hence, we designed a mock loop, which is automatically able to create annotated data of gas bubbles injected into an extracorporeal circulation. We were able to run this setup with a periodicity of 15 seconds, which results in 240 annotated measurements per hour. For the evaluation, we created 1095 bubbles of varying sizes (0.3 to 0.5 ml). The elaborated setup enables us to produce a great amount of annotated data, which is shown to be comparable to manually generated data in a convenient and fully automated manner.

Keywords: mock loop, bubble detection, extracorporeal circulation, annotated data.

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1 Introduction

In extracorporeal intensive care treatments, blood is pumped outside the human body. One possible hazard of these systems is the intrusion of gas to the blood circulation **Fehler! Verweisquelle konnte nicht gefunden werden.**. This gas volume can cause infarctions, like stroke or heart attack, if it gets to the patient's body.

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There are different established ways of addressing this fault. Mostly, constructive measures are carried out, like a bubble trap or a bubble filter close to the restitution of the blood to the patient [2]. The other established way is to introduce additional sensors to the circulation. Either there are flow sensors that can detect gas bubbles or a dedicated bubble sensor is equipped to the system. If a gas bubble is detected, the circulation is either shut down in an emergency manner or the blood volume containing the bubble is redirected to a reservoir with the help of a switching valve.

We recently introduced a new neural network based algorithm, which is able to detect gas bubbles within an extracorporeal circulation by analyzing the rotational speed measurements of the driving motor of a centrifugal blood pump [4]. Hence, we do not need to mount any additional sensor to the setup.

In order to use a neural network the algorithm has to be trained to the problem first. Therefore, a sufficient amount of annotated training data is obligatory. Up to now, we only gathered annotated data of gas bubbles in an extracorporeal circulation from animal trials. Hence, we were only able to get a very little amount over the course of several years.

One possibility to negotiate this deficit is the augmentation of the data. By doing this, one has to be careful in order to still obtain data that is useful for the training of a neural network [3]. Especially, since there is no profound knowledge about augmentation of data from the field of intensive care medicine.

To overcome this shortage of annotated training data we enabled our existing mock loop to automatically inject defined gas volumes into the circulation.

2 Experimental Setup

The test rig used for this work aims to reflect the main aspects of an extracorporeal circulation. It consists of the basic setup of a reservoir, a blood pump (DP 2, Medos, Heilbronn, Germany) and can be extended to meet the needs of the conducted research. The working fluid is a mixture of the heat transfer medium (basis: ethylene glycol) Glysofor N (Wittig Umweltchemie GmbH, Grafschaft-Ringen, Germany) and distilled water. The resulting viscosity of 2.7 mPa.s is comparable to that of blood at 37 °C [6]. Certainly, it is only a model that, in this case, neglects the non-Newtonian flow properties of blood.

In the presented work, the test rig setup is used as mock circulatory loop, with the reservoir as substitution for the patient's body. In addition to the basic setup, an inline flow sensor (axial-turbine VISION 2000, BIO-Tech, Vilshofen, Germany) was brought to the system in order to control the bloodflow [4]. Alternatively, an ultra-sonic sensor can be employed. However, we use the inline sensor in the mock loop because of financial reasons.

In order to introduce defined gas bubbles into the circulation we used compressed filtered air at a pressure of 0.4 bar with a solenoid fast-switching valve (MHE3-MS1H-3/2G-M7-K, Festo, Esslingen, Germany). A microcontroller controls this valve. Hence, our presented mock loop is able to create a vast amount of measurement data of gas bubbles introduced in an extracorporeal circulation mock in an automated way.

For the injection of the gas bubbles, we utilized a Y-connector that was placed prior to the pump in the circulation. The basic circulation flows in the connector through one of the upper branches of the Y and issues into the common bottom branch of the Y. The remaining branch of the connector was used for the injection of the gas. In this remaining branch, we placed a cannula and sealed it in a way that the tip of the cannula is located in the center of the circulation (see Figure 1).

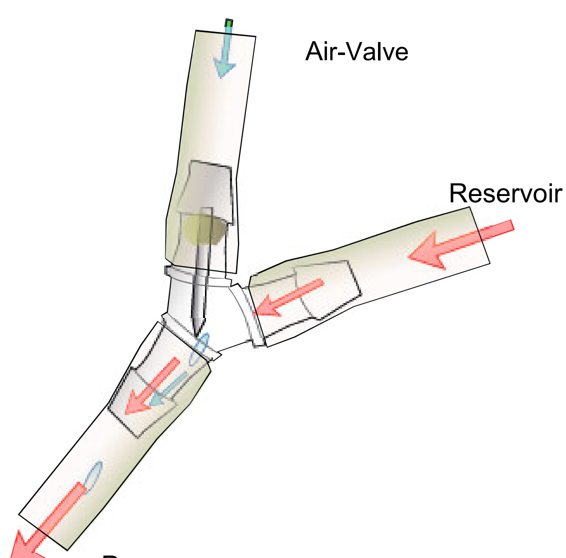

Figure 1: Y-connector used for the injection of gas bubbles to the circulation

Hence, we inject the bubbles in a sharp angle, which aided the detachment of the gas bubbles from the cannula tip. This way we could prevent forming of bigger bubbles over

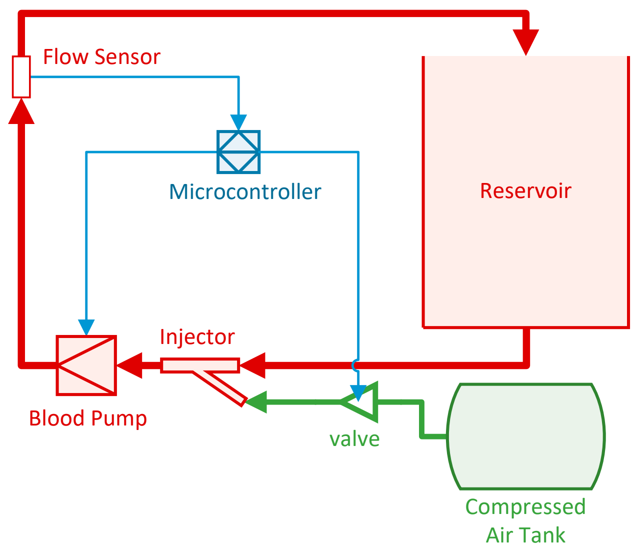

Figure 2: Schematic of the presented mock loop

the course of more than one planned injection. In addition, a nozzle with an inner diameter of 10 mil (0.254 mm) was placed prior to the cannula in order to restrict the gas flow. By this measure we sustained more uniform results.

Figure 2 shows the schematic connection of the presented mock circulatory loop. All parts in contact with the blood surrogate liquid are inked in red. The compressed air parts are depicted in green color and the data and control flow connections are shown in blue color.

3 Measurements and results

As an initial point, we manually took measurements for different gas volumes. We injected bubbles ranging in volume from 0.05 ml up to 0.5 ml in 0.05 ml steps. In this series, we could identify volumes starting at 0.2 ml. Since the smaller injected volumes could not be reliably detected neither in the measurement data nor visually in the circulation, we did start the automation with a volume of 0.3 ml of injected gas.

The injected volume of gas can be influenced directly by the opening times of the solenoid fast-switching valve. In addition, the volume is also influenced by the fluid-dynamic parameters, namely the viscosity of the fluid, the local pressure situation in the fluid at the cannula tip and the flow resistance and compliance resulting out of the whole setup. In order to avoid a change in these parameters by introducing

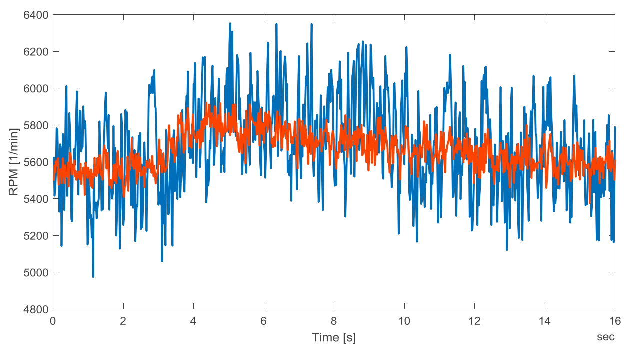

Figure 3: Rotational speed diagram whilst a manual injection of 0.3 ml of air at t = 2 s and the median signal over

new measurement equipment we chose to adapt the behavior of the automatically injected gas bubble to the behavior of the manually and controlled injected gas volume from the starting point. As evaluation, we compared the two classes of manually generated 0.3 ml gas bubbles (n=17, cf. Figure 3 **Fehler! Verweisquelle konnte nicht gefunden werden.**as example) and the automatically generated ones (n=200, cf. Figure 4**Fehler! Verweisquelle konnte nicht gefunden werden.** as example) by the means of the root mean square error (RMSE). Within the class of manually generated bubbles, we achieve a median RMSE to the median rotational speed signal of 202.8 min^{-1}. In comparison of the automatically generated bubbles to the median of the manually generated, we get a median RMSE of 268.7 min^{-1} respectively. Based on this result and an average rotational speed of 5 568 min^{-1} we assume the automatic generated bubbles to be comparable to the manually generated ones.

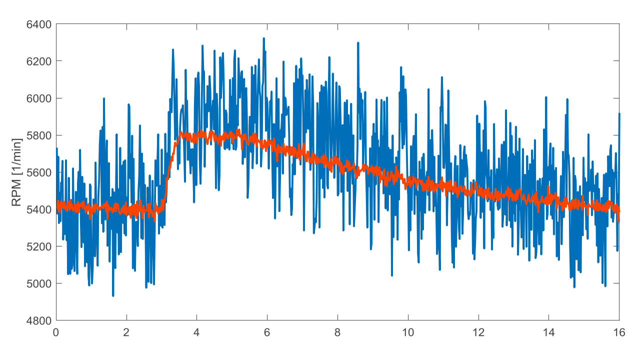

Figure 4: Rotational speed diagram whilst the automatic injection of 0.3 ml of air at t = 2 s and the median signal over all measurements

The presented measurements were taken at a flow of 2.5 liters per minute within the mock loop. Which correlates to an average flow setting in extracorporeal lung support settings.

An injected gas bubble takes approximately one second to reach the pump head at the given flow. When leaving the pump head the bubble takes another four seconds to arrive at the reservoir. The time the gas bubble spends within the pump head can only hardly be predicted. Therefore, sufficient time is needed between two injections of gas bubbles into the circuit in order to ensure the subsequent measurements do not influence each other. For this reason, the periodicity of the measurements is 15 seconds in our evaluation. Thus, annotated data of 240 bubbles can be automatically created per hour.

As motivated before the neural network based approach was chosen to reduce the number of needed sensors. Consequently, in our evaluation, we only recorded the point in time of the injection, the equivalent volume of gas and the measured rotational speed of the pump's motor.

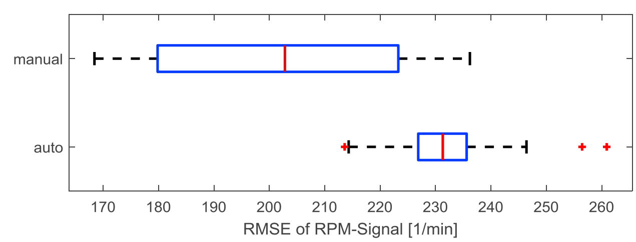

Figure 5: Boxplots of the RMSE's of the two different classes

As a final evaluation, we compared the RMSE of the rotational speed in a window of 16 seconds of the different classes to each other in detail. Figure 5 shows the associated boxplots. The dimension of the RMSE for both classes of data is comparable, with a slightly higher median within the class of automatic generated bubbles. The nozzle we introduced in the system did succeed in terms of inducing consistent results.

In addition, the variance of the errors is, as it was to be expected, significant smaller for the automatically generated bubbles. On the other hand, by the utilization of the presented setup an arbitrary number of measurements can be generated with no change in effort concerning the number of bubbles.

Author Statement

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