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Influence of different test gases in a non-destructive 100% quality control system for medical devices

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Abstract: The purpose of this research is to evaluate the detectability of defect membranes in intravenous (IV) infusion filter systems. The device under test (DUT) protects critical ill patients and has a high priority for the risk management of intensive care units. The developed quality control system stands out from other filter integrity methods because no method located on this topic represents such a simple, reliable, fast and non-destructive technique, examined without liquid. The invented method works as a pressure driven test and uses gas to identify defects. Previous studies have demonstrated the capability of detecting various types of errors. In this paper the influence of different test gases on the detectability of smallest defects is presented.

Keywords: 100% quality control infusion filter system; non-destructive.

1 Introduction

The infusion therapy is a medical treatment which corrects the water and electrolyte balance of a patient, is used as total parenteral nutrition and delivers drugs rapidly. Intravenous infusion filters ensure the purity of such solutions and restrain particles, air bubbles, bacteria and bacterial endotoxins. Infusion therapy is operated from emergency medical service, nursing staff and doctors. It handles fluid from some millilitre up to 3–4 litres per hour. Unfortunately it is an inherent but critical issue of the IV system that it provides a direct route to the blood stream and thereby to all vital parts of the patient. Backhouse et al. reported in the late 1980's about large numbers of particles contained in infusion solutions. Furthermore he stated that the source of particles is divided in extrinsic and intrinsic contaminants. Extrinsic result from manufacturing and packaging and intrinsic are introduced while preparing and dispensing the infusion and medicine. His proposed answer to this issue was the integration of a microfiltration process in form of an infusion filter in the fluid system right before the catheter [1].

De Jong et al. conduct research which show that particles, introduced through infusion therapy without filtering, recover in brain, lung, liver and kidney [2]. Sasse et al. present findings which indicate a decrease of infection rate by using infusion filters [3], which can be linked to a lower duration of hospital stay, nursing time and consequentially costs. By contrast Foster et al. reference surveys which do not prove any evidence on reduced morbidity and mortality [4]. A summary of the medical need, pros and cons and benefits of filter systems is discussed in [5].

Infusion filters are purposed for single use and produced million times a year. In the present case their period of use is 120 h. They consist of an air-venting 0.02 µm ePTFE-membrane and a liquid filtering membrane with a pore size of 0.2 µm positive charged Nylon, see Figure 1.

At present these filters are quality controlled by random sample using the bubble point test [6]. In a previous paper we presented a new invented test method and rig which works with air instead of liquid and is non-contaminating and thereby non-destructive. The quality control system is designed to control a DUT within 10 s or less, has a high reliability of the appropriated measurement equipment, detects a wide variety of defects and fulfils all requirements on a 100% quality control [7].

This paper examines the influence of different test gases instead of air to detect one of the most challenging fault errors, laser drilled holes in the fluid filtering membrane with a diameter of 2 µm.

2 Methods

Before detecting faulty systems a plenty of supposed operative filters is measured. These results represent the

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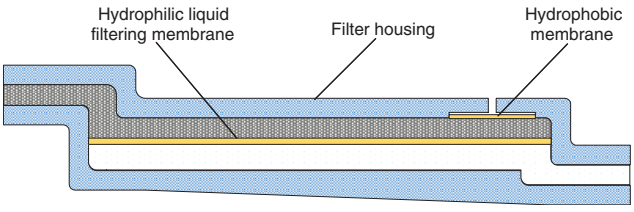

Figure 1: Longitudinal-section of the infusion filter system.

baseline for the quality control. A plenty of filters with known faults, like holes in the membrane, is investigated the same way. The measured volume flow of these filters is then opposed to the baseline. If the measured flow through a defect system deviates sufficiently from the supposed operatives the DUT is considered as inoperable.

2.1 The test rig and gas

The test rig, shown in Figure 2, is developed as a pneumatic system. The volume flow is induced by gauge pressure (1–5) and controlled by a high-precision pressure regulator (6). The controller can be substituted. The presented studies are carried out within a range of 0–500 mbar inlet pressure. The adjusted pressure is read off at the pressure sensor (7) which is arranged right before the closed valve (8). The volume flow through the investigated filter system (9) is measured approximately 10 s by the flowmeter (10), which operates on the principal of a laminar flow element. It consists of an air filter (11) to protect the system and an absolute pressure sensor (12) additionally. The reservoir (13) serves as a connecting point for a dewpoint transmitter (14) and a temperature sensor (15).

Synthetic air, argon and nitrogen are applied as test gases, which are provided as bottled gas (Linde AG). The investigations are examined to compare the influence of different atomic mass and viscosity on the detectability of defect filters.

2.2 Volume flow and prediction model

The volume flow in litre per minute (lpm) is stated under standard temperature and pressure conditions (STP), which means 1013 mbar absolute pressure (1 atm) and 0°C (273.15°K), to ensure comparability of the measurement results within different dates, ambient conditions and places.

With an inlet pressure of 500 mbar the flow regime of an IV infusion filter is assumed to be turbulent. Regarding its longitudinal-section (Figure 1) it gets obvious that the flow path is not a pipe with a long and continuous diameter, which is necessary to establish a laminar flow profile. Immediately after the housing entry a change in flow direction in form of an elbow occurs. After that the volume flow reaches the interior housing, which means a sudden expansion of the flow area. At this point it has to be assumed that the flow separates from the wall and forms vortices, right before it arrives the flat sheet membrane in form of porous structure and manages its way through the laser drilled holes in form of an orifice [11]. The measurement results confirm that the pressure decay of a compromised membrane is less than the undamaged and let more gas passing through.

The focus of this paper is in the presentation of the experimental results. Further work will focus on the required formulas which will be used to calculate the turbulent volume flow of gas through the operative and faulty filter systems.

2.3 Investigated membrane systems and types of failure

As mentioned above investigations are executed on one typical filter system, the RoweFil 120 (RF120; RoweMed AG, Parchim, Germany). The volume flow of three different gases through 24 supposed operative systems is measured to define the baseline. The fault error ‘hole in membrane’ is produced in two modes, shown in

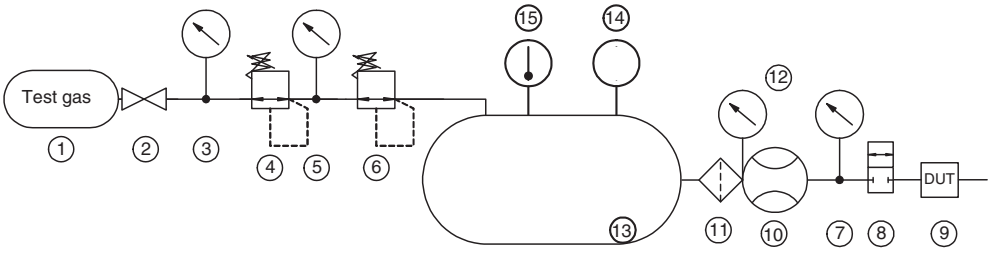

Figure 2: Pneumatic diagram of the test system.

Table 1: Properties of test gases at 1 bar and 0°C [8–10].

Test gas	Atomic mass [u]	Density [kg/m^3]	Dyn. viscosity [10E-6 Pa*s]
Synth. air	–	1.275	17.2
Argon	39.948	1.784	21.0
Nitrogen (N2)	28.013	1.234	16.6

Table 2: Quantity and description of investigated systems.

Name	Characteristic	Qty.
RF120	0.2 Nylon ± 0.02 ePTFE	24
RF120/1	1 laser drilled hole in 0.2 Nylon+ membrane	18
RF120/5	5 laser drilled holes in 0.2 Nylon+ membrane	17

Table 2. Before assembling the filter system, the positive charged Nylon membrane is perforated one or five times by a picosecond laser (TruMicro 5 × 50, TRUMPF Laser- und Systemtechnik GmbH & Co. KG, Ditzingen, Germany) using a high-precision micromachining system (GL.5, GFH GmbH, Deggendorf, Germany).

3 Results and discussion

As mentioned above extensive tests with assumed operative filters were conducted before identifying filter systems with controlled defects under influence of different test gases.

3.1 Operative filter systems

Figure 3 presents the results of tests with assumed operative filter systems using synthetic air, argon and nitrogen.

As expected the volume flow is linear dependent on the inlet pressure. The test gases differ in their viscosity which results in different gradients of flow curves.

Within a range of < 2.0% at 500 mbar the relative standard deviation, presented in Figure 4, seems small enough for a distinct identification of defect systems and demonstrates a high reproducibility of the volume flow.

Figure 5 illustrates the measured values of 24 operative systems at 500 mbar inlet pressure fitted as histogram. The mean value is 4.98 lpm dry and clear air (STP) and the standard deviation is ± 0.07 lpm.

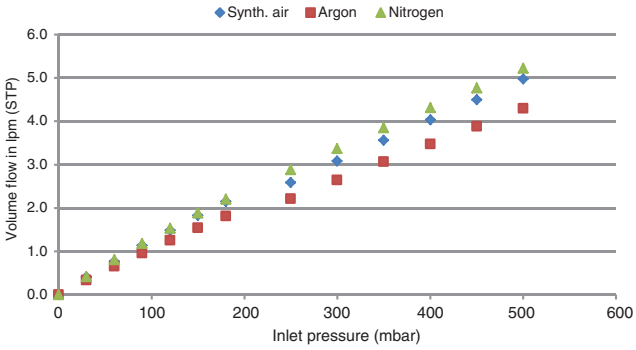

Figure 3: Average volume flow from 0 to 500 mbar.

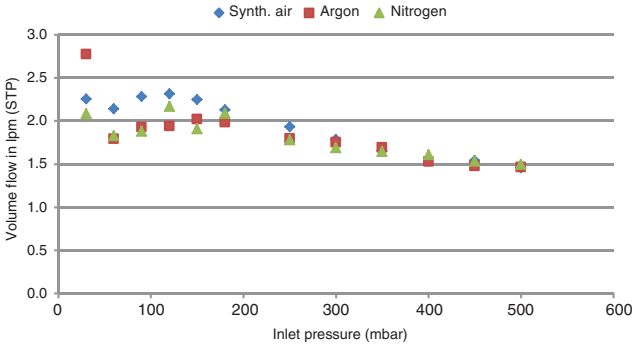

Figure 4: Relative standard deviation from 0 to 500 mbar.

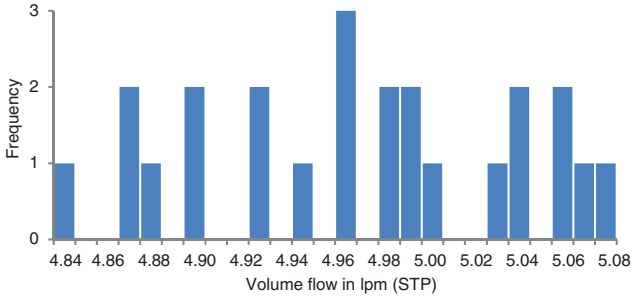

Figure 5: Histogram of 24 RF120 at 500 mbar; **synth. Air.**

3.2 Detecting smallest defects

As mentioned before the measurement results of operatives and knowingly defect filters are opposed to one another to demonstrate the capability of detecting faulty systems.

Figures 6–8 present the test results. Every defect system is detected independent of the applied test gas. The volume flow of all knowingly fault error systems has a higher flow instead of the supposed operatives.

While argon has the lowest volume flow at 500 mbar inlet pressure it has the largest gap between operatives andinoperable with 0.11 lpm (STP). Table 3 displays the measured values at 500 mbar.

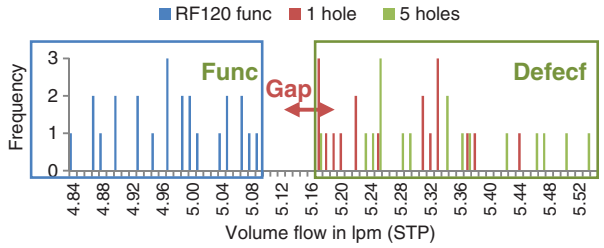

Figure 6: Histogram of 59 RF120 at 500 mbar; **synth. Air.**

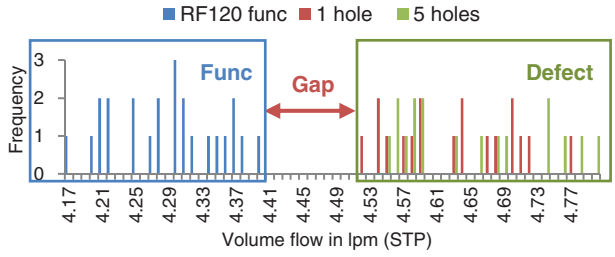

Figure 7: Histogram of 59 RF120 at 500 mbar; **argon.**

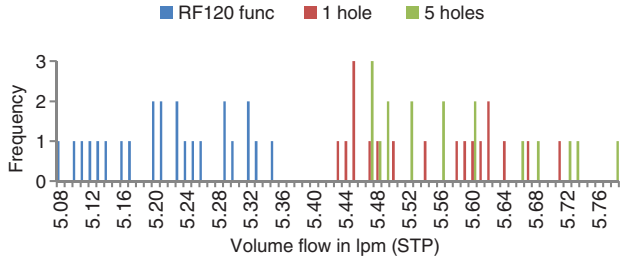

Figure 8: Histogram f 59 RF120 at 500 mbar; **nitrogen.**

Table 3: Measured values of volume flow of different test gases.

Gas	Avg. flow [lpm] STP	Rel. std. dev. [%]	Gap [lpm] STP
Synth. air	4.98	1.5	0.07
Argon	4.29	1.5	0.11
Nitrogen	5.22	1.5	0.07

4 Conclusion

Previous studies with synthetic air have shown a growing gap between operatives and faulty systems with an increase of inlet pressure. The present paper investigated the influence of test gases with different viscosity and atomic mass on the reliability of detecting errors.

The examined tests demonstrate the well-known relationship between viscosity and volume flow. The higher viscosity of argon compared to nitrogen and air leads to a lower average volume flow. A greater gap when using nitrogen was expected. It is assumed that the higher volume flow of nitrogen leads to a greater turbulent flow regime and therewith reduced flow through the laser drilled holes.

The presented test method and rig have shown its capability of detecting smallest defects. The potential of changing the test gas and widen the measurement range makes the presented quality control system suitable for a wide variety of measurement tasks and devices under test.

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