

Investigations on the Flow Behaviour in Intravenous Infusion Filters

Thomas Pollack, Hermann Seitz

Abstract: To develop a quality control for intravenous infusion filters is the aim of the project. For that reason a test method and a test rig to investigate the flow behaviour are developed. After performing flow tests inoperable filter systems can be identified reliable.

Keywords: non-destructive quality control; infusion filter

Introduction

In medicine the intravenous therapy is the infusion of liquids into the vein of a patient. It corrects electrolyte imbalances, replaces liquids or delivers medical substances. An infusion filter (figure 1) ensures the purity of an intravenous solution and prevent air from entering the bloodstream. The development of a non-destructive and non-contaminating 100% quality control of the production volume of the infusion filters is the objective of this project. For that reason a method had to be developed to separate functioning filters from inoperable ones and a test rig which has to meet specific requirements were built. Furthermore the flow behaviour of the filter systems is investigated with high purity gases. After measuring a specific quantity the characteristic flow behaviour of each considered filter type is uniquely defined. From now on every system with deviating flow curve can be sorted out and defined as inoperable.



Figure 1: infusion filter

Methods

The test rig meets several requirements. It has to avoid the contamination of the tested filter systems, has a precision pressure control and is equipped with high accurate sensor systems. Figure 2 shows the test rig and every necessary component.

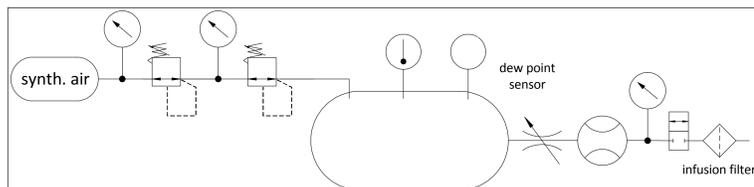


Figure 2: flow test rig

The proceeded tests are equal to a flow test. A defined pressure is given at the valve inlet, the valve is opened and the volume flow is measured. The procedure is repeated with an inlet pressure between 10 and 110 mbar (relative). All studies are carried out under the same conditions (e.g. temperature, dew point, operator, high purity gas).

The tested filter type (RF48) consists of a 0,2 µm PET-membrane with a surface area of 13,5 cm² and a 1 cm² sized 0,02 µm air separation membrane.

Results

Figure 3 shows the test reading and the resulting standard deviation of five filters of the same type. They all have the same characteristic flow behaviour and an amount of variation from the average less than seven percent.

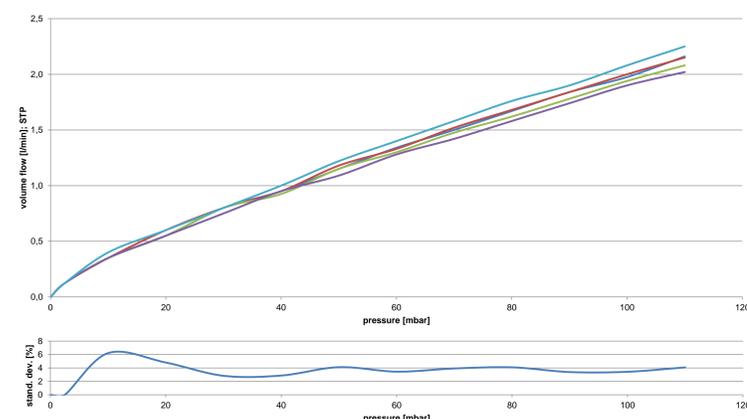


Figure 3: test reading and standard deviation RF48; synth. air

In the next step two knowingly inoperable infusion filters were tested. Both were manipulated and had a hole in the air separation membrane. Images of the damaged membranes are shown in figure 5. Only one of the nonconforming filter systems could be identified. The flow curve of the other one lies in the range of the functioning system.

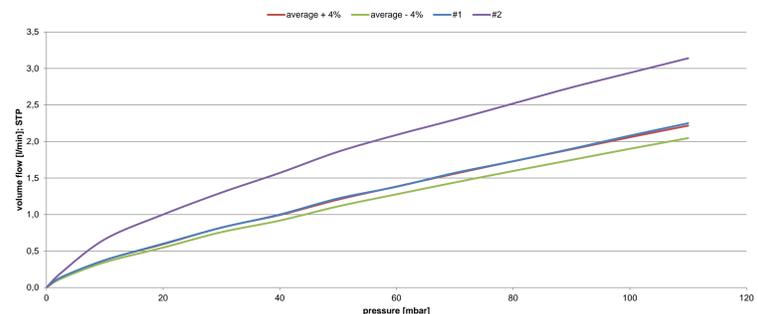


Figure 4: detection of different flow curves of two knowingly inoperable infusion filters

To solve this problem and to identify the inoperable one the test rig had to be changed. The position of the valve was changed. It is now installed behind the infusion filter. Until this moment the measured volume flow consisted of two parts. The main flow through the water filtration membrane and the beside flow through the air separation membrane

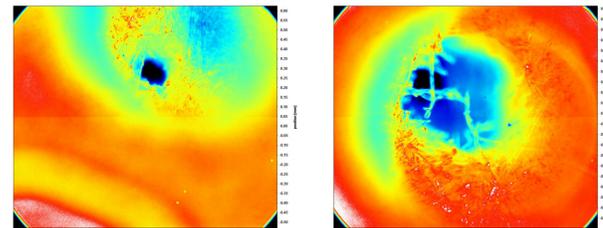


Figure 5: damaged air separation membranes

Now a new characteristic flow curve were measured and compared with the two inoperable ones. Figure 6 shows the significant deviation between the functioning and the damaged filters.

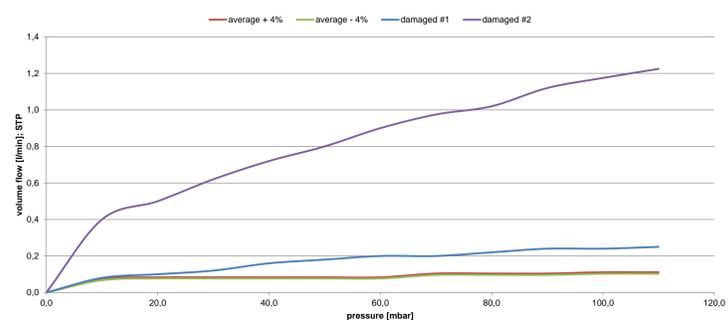


Figure 6: characteristic flow curve air separation membrane, flow curve inoperable filters

Conclusion

In order to develop a quality control for intravenous infusion filters their flow behaviour has been investigated. For that reason a test method was developed, a test rig was built and the characteristic flow behaviour of each filter type was identified. In the submitted study two manipulated filters had been detected clearly as inoperable.

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