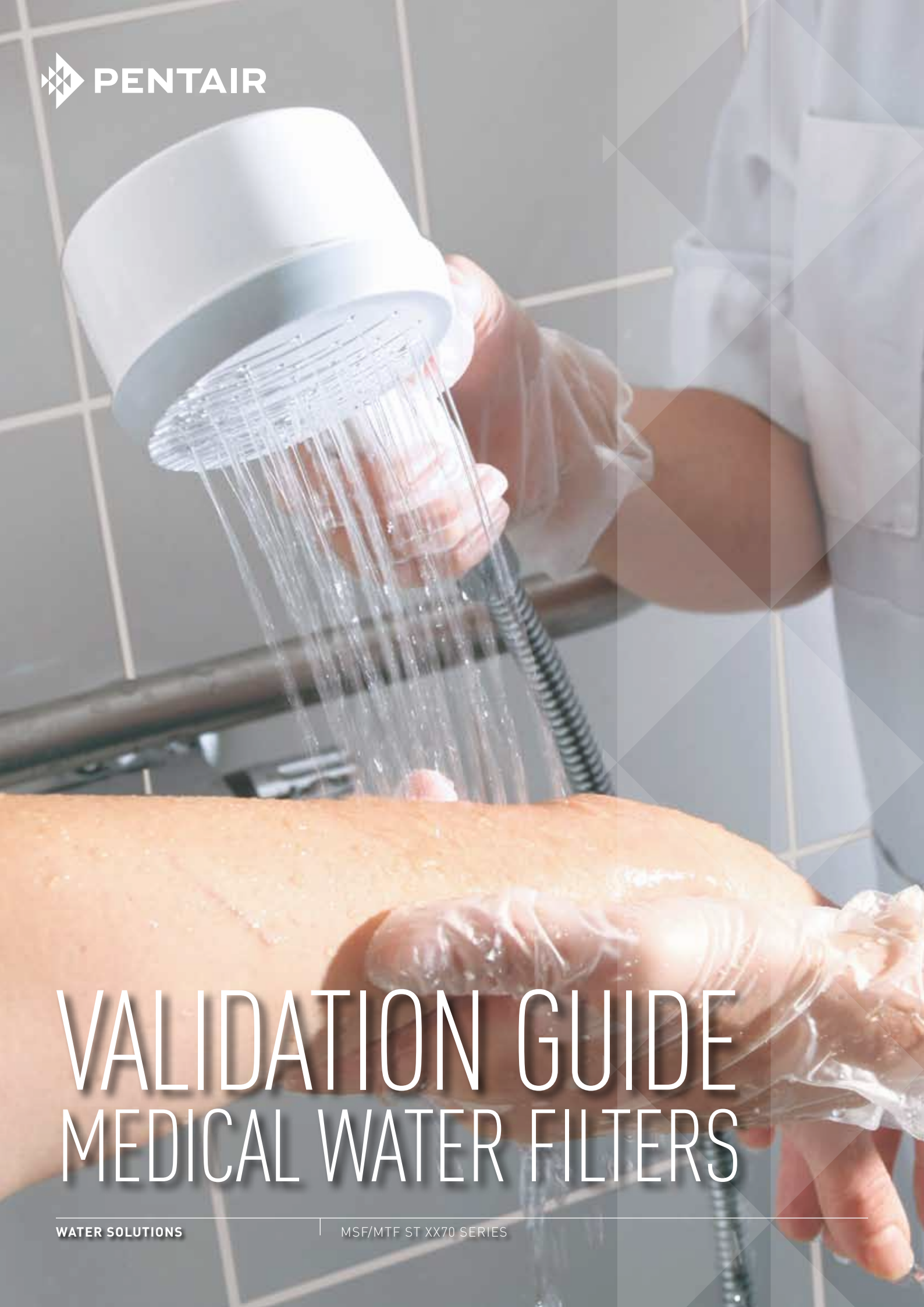
PENTAIR



VALIDATION GUIDE
MEDICAL WATER FILTERS

WATER SOLUTIONS | MSF/MTF ST XX70 SERIES

VALIDATION GUIDE
MEDICAL WATER FILTERS

MSF/MTF ST SERIES

TABLE OF CONTENTS

1. INTRODUCTION

From the purification plant to the actual point-of-use water passes a variety of piping and distribution systems. Although initially the microbial load at the outlet of the plant is often relatively small, a high microbial count can be found at the end of this chain. Many of these microorganisms are harmless, but opportunistic pathogens like *Pseudomonas aeruginosa, Legionella pneumophila* and several fungi can been found as well. Microorganisms can accumulate on surfaces and grow to form a so-called biofilm. These biofilms are very difficult to remove by chemical or heat shock treatments and regularly release microorganisms in the water for further colonization. From the water phase opportunistic pathogens can reach humans via drinking, inhalation of aerosols and bathing. This, in turn, can lead to infections and diseases like legionellosis.

Pentair Medical Water Filters contain capillary microfiltration membranes with a pore size of 0.2 micron, which effectively retain bacteria and fungi. While water molecules pass through the porous wall of these hollow fiber membranes, the pores retain microorganisms and other particular contaminants. The Pentair Medical Water Filters provide easy and reliable protection at the last possible moment before patient contact. The Medical Water Filters are available in two configurations, as a ShowerFilter and as a TapFilter.

This validation guide summarizes tests that have been performed for validation and qualification of the Pentair Medical Water Filters. All tests have been performed with regular off-the-shelve products.

2. MICROBIOLOGICAL TESTS

2.1 Retention of Pseudonomas diminuta (ASTM F838-05)

Membranes retain all particles that are larger than their pores and allow passage of water and smaller particles. Thus retention of a small bacterium should be evaluated as a worst case scenario. Testing with the small bacterium *Pseudonomas diminuta* was performed by Vitens laboratory, the Netherlands, an ISO 17025 accredited lab. The tests were performed under test conditions specified in the ASTM F838-05 protocol for the validation of 0.2 µm sterilizing grade filters.

2.1.1 Test description

Membranes were challenged with a high microbial load of at least 10^7 bacteria per cm^2 effective filtration membrane area. The bacteria were suspended in a pressure vessel and passed through the filters. Influent and different effluent samples were collected and analyzed at Vitens Laboratory. The samples were plated and incubated for 48 hours at 30°C after which an identification and enumeration of *Pseudomonas diminuta* was performed. The test was performed in triplo.

2.1.2 Test results

In Table 1 the enumeration results of the influent and effluent samples taken during this test are summarized. The influent samples all meet the criterion of 1 x 107 CFU/cm^2. The effluent samples are taken from a mixture of the first 5L of effluent water and of the filtrate after 5L. In both types of effluent samples no P. diminuta was detected.

Table 1: Retention of Pseudomonas diminuta by Pentair Medical Water Filters performed in triplo according to the ASTM F838-05 protocol.

	Influent			Effluent			
				After SL suspension filtrated		Mixed sample from 5L	
Filter	Total CFU load	CFU/cm^2	CFU/L	CFU/L	Log reduction	CFU/L	Log reduction
1	4×10^{10}	3.33×10^7	8×10^9	<100	>7.2	<100	>7.2
2	4×10^{10}	3.33×10^7	8×10^9	<100	>7.2	<100	>7.2
3	3×10^{10}	2.5×10^7	6×10^9	<100	>7.2	<100	>7.2

2.1.3 Conclusion

No bacteria were detected in effluent samples resulting in a log reduction >7.2 for all the samples. This meets the international standard for microbial water purifiers retention of log 6.

2.2 Microbial retention over the life time of the product

As the ASTM F838-05 test only tests at one point in time it is important to see what the microbial retention of the product is over its defined life time. The tests below are conducted on different microorganisms for a period of 70 days to show the product retains the same microbial retention over its total lifetime.

2.2.1 Test description

To test the microbial retention over the lifetime of the filter a dedicated setup was developed and tests were performed based on the NSF protocol P231 protocol for microbial water purifiers. Membranes were challenged with a high microbial load three times per week over a period over 70 days, the indicated lifetime of the product. Effluent microbial concentrations were measured and compared to influent concentration to determine the log reduction. Tests were performed on the clinically relevant *Legionella pneumophila* and *Pseudomonas aeruginosa.*

2.2.2 Test results

In table 2 the log reduction is shown over the duration of the test, 70 days. Results are shown for the samples taken at the start of the test and for every week. Extended results of this retention tests can be found in the management summaries issued by Vitens laboratory. These are added as appendices to this validation guide.

Table 2: Log reduction values for the retention of L. pneumophila

	Sample 1	Sample 2	Sample 3
Start of the test	>6.8	>6.8	>6.8
After 1 week	>7.6	>7.6	>7.6
After 2 weeks	n.d.**	n.d.**	n.d.**
After 3 weeks	>7.1	>7.1	>7.1
After 4 weeks	>7.0	>7.0	>7.0
After 5 weeks	>7.1	>7.1	>7.1
After 6 weeks	>7.1	>7.1	>7.1
After 7 weeks	>7.2	>7.2	>7.2
After 8 weeks	>7.3	>7.3	>7.3
After 11 weeks	>7.1	>7.1	>7.1

***no data due to error in sample analysis*

Table 3: Log reduction values for the retention of Pseudomonas aeruginosa

	Sample 1	Sample 2	Sample 3
Start of the test	>6.4	>6.4	>6.4
After 1 week	> 7.3	> 7.3	> 7.3
After 2 weeks	>6.0	>6.0	>6.0
After 3 weeks	>6.8	>6.8	>6.8
After 4 weeks	>6.8	>6.8	>6.8
After 5 weeks	>8.1	>8.1	>8.1
After 6 weeks	>6.1	>6.1	>6.1
After 7 weeks	>6.7	>6.7	>6.7
After 3 months	>7.3	>7.3	>7.3

2.2.3 Conclusion

For *Legionella pneumophila* and *Pseudomonas aeruginosa* a reduction of more than log 6 was obtained for the complete 70 days, compliant with international standards.
The management summaries of the clinical tests issued by Vitens laboratory are added as appendices

2.3 Clinical tests

In order to evaluate the Pentair Medical Water Filters for their actual use, clinical tests were performed in a hospital with an increased Legionella species count in water from showers.

2.3.1 Test description

Water samples were taken from 5 different clinical wards in the hospital showing that 50% of the water coming from showers in these wards were contaminated with Legionella species. In two of the highly contaminated wards ShowerFilters were placed and the water was monitored for a 35 day period. Weekly samples were taken both directly from the waterline and from effluent water of the Medical Water Filters. The samples were analyzed for Legionella species at Vitens laboratory.

2.3.2 Test results

The results in tables 5 and 6 show the influent and effluent values of weekly samples taken from ShowerFilters placed at two different wards, coronary and urology respectively. The influent data is of samples taken directly from the water line. The effluent data is of samples collected from the same water line but filtered with ShowerFilters.

Table 4: Results of the clinical tests at the coronary ward

Week	Shower nr.	Influent *(Legionella CFU/L)*	Effluent *(Legionella CFU/L)*
0	I	8,400	<100
	II	36,000	<100
1	I	20,000	<100
	II	35,500	<100
2	I	13,000	<100
	II	22,500	<100
3	I	42,000	<100
	II	11,000	<100
4	I	8,000	<100
	II	5,300	<100
5	I	15,500	<100
	II	7,700	<100

Table 5: Results of the clinical tests at the urology ward

Week	Shower nr.	Influent *(Legionella CFU/L)*	Effluent *(Legionella CFU/L)*
0	I	100	<100
	II	2,900	<100
1	I	1,600	<100
	II	3,900	<100
2	I	7,300	<100
	II	1,200	<100
3	I	350	<100
	II	6,700	<100
4	I	< 100	<100
	II	1,400	<100
5	I	100	<100
	II	600	<100

2.3.3 Conclusion

Results obtained during weekly tests over 35 days showed that 23 of 24 water samples from showers from several departments contained *Legionella, while Legionella* count in all water samples from the Medical ShowerFilter were below the detection limit. It was concluded that also in the clinical setting microorganisms are completely retained by Pentair Medical Water Filters.

A management summary of the clinical tests issued by Vitens laboratory is added as an appendix.

3. CHEMICAL RESISTANCE

3.1 Test description

In order to test the chemical resistance of the Medical Water Filters they were exposed to chlorine concentrations of 1200 ppm hypochlorite for 10 h and compared to blanks of unused filters and filters flushed for 10 h with tap water. Samples were evaluated both externally and internally for discolorations and defects, while furthermore membranes were evaluated by tensile strength measurements.

3.2 Test results

The Medical Water Filters exposed to 1200 ppm hypochlorite were compared to blanks. No defects or discolorations were found (Fig. 1). Also tensile strength of the membranes was the same for both hypochlorite exposed and unexposed membranes.

Figure 1: Evaluation of shower filter for defects and discolorations

3.3 Conclusions

Exposure to 1200 ppm hypochlorite for 10 h does not negatively influence the Medical Water Filters. Therefore it can be concluded that the Medical Water Filters are compatible with this chemical treatment.

4. FLOW RATE AND PRESSURE TESTS

4.1 Test description

In order to evaluate the flow rate, both Medical TapFilters and Medical ShowerFilter were flushed with tap water at increasing pressure. Tests on the Medical ShowerFilter were performed with and without a 6 L/min flow restrictor, which is recommended for water saving purposes. Tests on the Medical TapFilter were performed with the compulsory flow restrictor of 4 L/min.

4.2 Test results

Results of the Medical ShowerFilter and Medical TapFilter are shown in Figure 2 and 3 respectively.

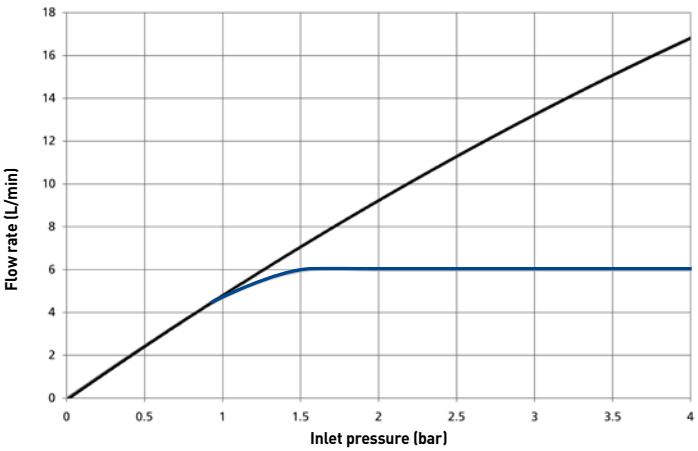


Figure 2: Flow rate-pressure curve of the Medical ShowerFilter with (blue) and without (black) a 6 L/min flow restrictor

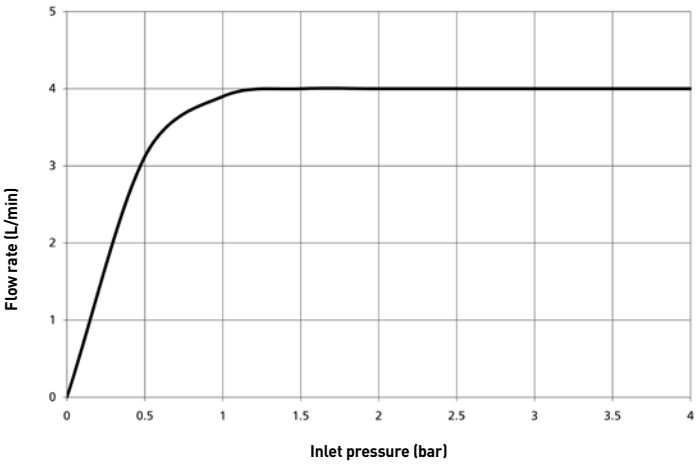


Figure 3: Flow rate-pressure curve of the Medical TapFilter with a 4 L/min flow restrictor

4.3 Conclusions

The Medical Water Filters show increasing flow rates with increasing pressure, where flow rate is leveled off at the desired level by use of a flow restrictor.

5.1 Management Summary ASTM F838-05

Management Summary

Pseudomonas diminuta removal on Pentair Medical Water Filters

Introduction

Three Pentair Medical Water Filter cartridges, containing Capfil Microfiltration Membranes type MF 02 M12 LE sp, were tested according to ASTM International, Designation: F838-05: "Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration".

The tests were performed in order to prove that the cartridges can quantitatively retain large numbers of organisms (10^7 organisms per cm^2 of effective filtration area required area required by ASTM F 838-05).

Methods

The testing was performed on three cartridges from October 20th, 2008 onward.
The tests were performed with bacteria *Pseudomonas diminuta* (ATCC 19146) as specified in ASTM F838-05. The test set up an protocol were compliant with the ASTM F838-05 standard.
The feed and filtrate samples taken from the challenge tests were analyzed by Vitens Laboratory, Leeuwarden, the Netherlands, an ISO 17025 accredited laboratory. As the surface area of the membranes in these filters is around 1000 cm^2 a suitable feed stock of *Pseudomonas diminuta* was made to meet the test's requirements. The analysis of the samples was conducted within 24 hours after the testing.
Detection and enumeration of the *Pseudomonas diminuta* was done according to ISO 9308-1.

Test results

Filter	1	2	3	1	2	3
Filter load CFU/L	8×10^9	8×10^9	6×10^9	8×10^9	8×10^9	6×10^9
	After 5 L suspension filtrated			Mixed sample from 5 L		
Effluent CFU/L	<100	<100	<100	<100	<100	<100
Log reduction	>7.2	>7.2	>7.2	>7.2	>7.2	>7.2

Note: The table above presents the results of the *Pseudomonas dimunita* challenge experiments, using data from the analytical report of Vitens. The ASTM standard states a challenge of 10^7 bacteria per cm of effective filtration area (partition 4, page 1). As can be seen from the table all cartridges perform according to the standard.

Management Summary

Conclusion

No *Pseudomonas diminuta* were found in any of the samples resulting in a log retention of >7.2. This proves the Pentair Medical Water Filters perform according to the ASTM F838-05 standard for membrane filters.

5.2 Management Summary Legionella pneumophila retention tests

Management Summary

Legionella pneumophila removal on Pentair Medical Water Filters

Introduction

Three Pentair Medical Water Filter cartridges, containing Capfil Microfiltration Membranes type MF 02 M12 LE sp, were submitted to a long term microbial challenge test at Vitens Laboratories, Leeuwarden, the Netherlands, an ISO 17025 accredited laboratory. Tests were performed in order to prove that the cartridges have a bacterial retention level of ≥log 6 for the bacteria *Legionella pneumophila* for a period of 11 weeks.

Methods

The test was performed on three cartridges from 2nd July 2009 onward. Tests were performed under test conditions selected to show the long term performance of microbiological water purifiers.

First the cartridges were flushed with 50 L filter sterilized water, followed by a challenge of 5 L water with a minimum concentration of 8×10^8 *Legionella pneumophila* (serotype 9) per liter. Effluent samples were taken at the end of the challenge followed by flush with 200 L filter sterilized water. The procedure was repeated 3 times a week for a period of 8 weeks followed by a final sample in week 11. The feed and effluent samples taken from the challenge tests were analyzed by Vitens Laboratories, Leeuwarden, the Netherlands. Analysis of the samples was conducted within 24 hours after the testing. Detection and enumeration of the *Legionella pneumophila* (serotype 9) was done according to NEN 6265:2007.

Management Summary

Test results

The table below displays the results of the *Legionella pneumophila* challenge experiments, using the data from the analytical report of Vitens.

Filter	1	2	3
	Log retention of effluent samples		
Start of test	>6.8	>6.8	>6.8
After 4 days	>7.0	>7.0	>7.0
After 5 days	>7.5	>7.5	>7.5
After 1 week	>7.6	>7.6	>7.6
After 1 week and 4 days	>8.6	>8.6	>8.6
After 1 week and 5 days	>7.5	>7.5	>7.5
After 2 weeks	n.d.	n.d.	n.d.
After 2 week and 4 days	>8.5	>8.5	>8.5
After 2 week and 5 days	>7.2	>7.2	>7.2
After 3 weeks	>7.1	>7.1	>7.1
After 3 week and 4 days	>7.0	>7.0	>7.0
After 3 week and 5 days	>6.9	>6.9	>6.9
After 4 weeks	>7.0	>7.0	>7.0
After 4 week and 4 days	>7.1	>7.1	>7.1
After 4 week and 5 days	>7.1	>7.1	>7.1
After 5 weeks	>7.1	>7.1	>7.1
After 5 weeks and 4 days	>6.9	>6.9	>6.9
After 5 weeks and 5 days	>7.0	>7.0	>7.0
After 6 weeks	>7.1	>7.1	>7.1
After 6 weeks and 4 days	>7.0	>7.0	>7.0
After 6 weeks and 5 days	>6.4	>6.4	>6.4

Management Summary

After 7 weeks	>7.2	>7.2	>7.2
After 7 weeks and 4 days	>7.2	>7.2	>7.2
After 7 weeks and 5 days	>7.4	>7.4	>7.4
After 8 weeks	>7.3	>7.3	>7.3
After 11 weeks	>7.1	>7.1	>7.1

n.d.: no data due to an error in sample analysis

Conclusion

The retention results are all above log 6.4, which is more than the required >log 6. Thus it can be concluded that the Pentair Medical Water Filters meet the set retention requirements for *Legionella pneumophila*.

5.3 Management Summary Pseudomonas aeruginosa retention tests

Management Summary

Pseudomonas aeruginosa removal on Pentair Medical Water Filters

Introduction

Three Pentair Medical Water Filter cartridges, containing Capfil Microfiltration Membranes type MF 02 M12 LE sp, were submitted to a long term microbial challenge test at Vitens Laboratory, Leeuwarden, the Netherlands, an ISO 17025 accredited laboratory. Tests were performed in order to prove that the cartridges are capable to achieve a minimum retention level of ≥log 6 for *Pseudomonas aeruginosa* for a period of 3 months.

Methods

Tests were performed on three cartridges from 24th January 2011 under test conditions selected to show the long term performance of microbiological water purifiers. First the cartridges were flushed with 50 L filter sterilized water, followed by a challenge of 5 L water with a minimum concentration of 2 x 10^8 *Pseudomonas aeruginosa* per liter. Effluent samples were taken at the end of the challenge followed by flush with 200 L filter sterilized water. The procedure was repeated 3 times per week over a period of 8 weeks followed a final sample after 3 months. The feed and effluent samples taken from the challenge tests were analyzed by Vitens Laboratory, Leeuwarden, The Netherlands. Analysis of the samples were conducted within 24 hours after the challenge.

Management Summary

Test results

The table below displays the results of the *Pseudomonas aeruginosa* challenge experiments, using the data from the analytical reports of Vitens Laboratory.

	Log retention of *Pseudomonas aeruginosa*		
Cartridge	**1**	**2**	**3**
Start of test	>6.4	>6.4	>6.4
After 1 day	>6.4	>6.4	>6.4
After 3 days	>6.4	>6.4	>6.4
After 1 week	>7.3	>7.3	>7.3
After 1 week and 1 day	>7.0	>7.0	>7.0
After 1 week and 3 days	>6.9	>6.9	>6.9
After 2 weeks	>6.0	>6.0	>6.0
After 2 weeks and 1 day	>7.4	>7.4	>7.4
After 2 weeks and 3 days	>7.0	>7.0	>7.0
After 3 weeks	>6.8	>6.8	>6.8
After 3 weeks and 1 day	>7.3	>7.3	>7.3
After 3 weeks and 3 days	>7.1	>7.1	>7.1
After 4 weeks	>6.8	>6.8	>6.8
After 4 weeks and 1 day	>6.7	>6.7	>6.7
After 4 weeks and 3 days	>6.8	>6.8	>6.8
After 5 weeks	>8.1	>8.1	>8.1
After 5 weeks and 1 day	>8.1	>8.1	>8.1
After 5 weeks and 3 days	>7.8	>7.8	>7.8
After 6 weeks	>6.1	>6.1	>6.1
After 6 weeks and 1 day	>6.1	>6.1	>6.1
After 6 weeks and 3 days	>6.3	>6.3	>6.3
After 7 weeks	>6.7	>6.7	>6.7
After 7 weeks and 1 day	>6.2	>6.2	>6.2
After 7 weeks and 3 days	>7.0	>7.0	>7.0
After 3 months	>7.3	>7.3	>7.3

Conclusion

All samples show a retention performance above the goal of log 6. In all cases no *Pseudomonas aeruginosa* passed the membrane. It can be concluded that over a period of at least 3 months Pentair Medical Water Filters meet the retention requirements for *Pseudomonas aeruginosa*.

Management Summary

Clinical evaluation of Pentair Medical Water Filters

Introduction

During a routine check on 18 June 2009 *a* contamination with *Legionella* species was detected in the effluent of several showers in the Medical Spectrum Twente hospital, location Ariënsplein, the Netherlands. After this detection all showers were replaced by Pentair Medical Water Filters. This situation was considered suitable for a clinical evaluation of these Water Filters.

Methods

For this clinical evaluation five clinical wards equipped with the Pentair Medical Water Filters were chosen for further analysis. At each ward the effluent of two showers was analyzed for the presence of *Legionella* species one week after placement.

Furthermore, at two wards two showers were weekly evaluated for a period of five weeks, the recommended replacement interval of the product. All samples were collected and analyzed for the presence of *Legionella* species by culture according to NEN 6265:2007, by Vitens Laboratory, Leeuwarden, the Netherlands, an ISO 17025 accredited laboratory. The detection level of *Legionella* with the applied method was 100 cfu/ L. Influent samples were taken from the piping at the point where a shower is attached. Effluent samples were taken from the Pentair Medical Water Filters placed. Analysis of all samples was done within 24 hours.

Results

Results for 5 clinical wards after 1 week of use are shown in the table below.

Ward	Shower number	Influent (*Legionella* cfu/L)	Effluent (*Legionella* cfu/L)
Coronary	I	8.600	<100
	II	8.700	<100
Urology	I	1.600	<100
	II	<100	<100
Oncology	I	9.500	<100
	II	4.900	<100
Infectious disease	I	<100	<100
	II	<100	<100
Elderly nursing	I	<100	<100
	II	<100	<100

Management Summary

Results during 5 weeks of use are shown in the table below.

Ward	Week	Shower number	Influent (*Legionella* cfu/L)	Effluent (*Legionella* cfu/L)
Coronary	0	I	8.400	<100
		II	36.000	<100
	1	I	20.000	<100
		II	35.500	<100
	2	I	13.000	<100
		II	22.500	<100
	3	I	42.000	<100
		II	11.000	<100
	4	I	8.000	<100
		II	5.300	<100
	5	I	15.500	<100
		II	7.700	<100
Urology	0	I	100	<100
		II	2.900	<100
	1	I	1.600	<100
		II	3.900	<100
	2	I	7.300	<100
		II	1.200	<100
	3	I	350	<100
		II	6.700	<100
	4	I	<100	<100
		II	1.400	<100
	5	I	100	<100
		II	600	<100

Conclusion

Fifty percent of the influent samples of the 5 wards were contaminated with *Legionella* species, while in the effluent samples no *Legionella* species were detected after 1 week usage. Furthermore, at two wards for a five week period 95% of influent samples were contaminated while again no *Legionella* species were detected in the effluent samples taken from the Pentair Medical Water Filters. Effective *Legionella* species retention by the Pentair Medical Water Filters was shown in this clinical study.

FILTRIX BV
P.O. BOX 741, 7500 AS ENSCHEDE, NETHERLANDS WWW.FILTRIX.COM