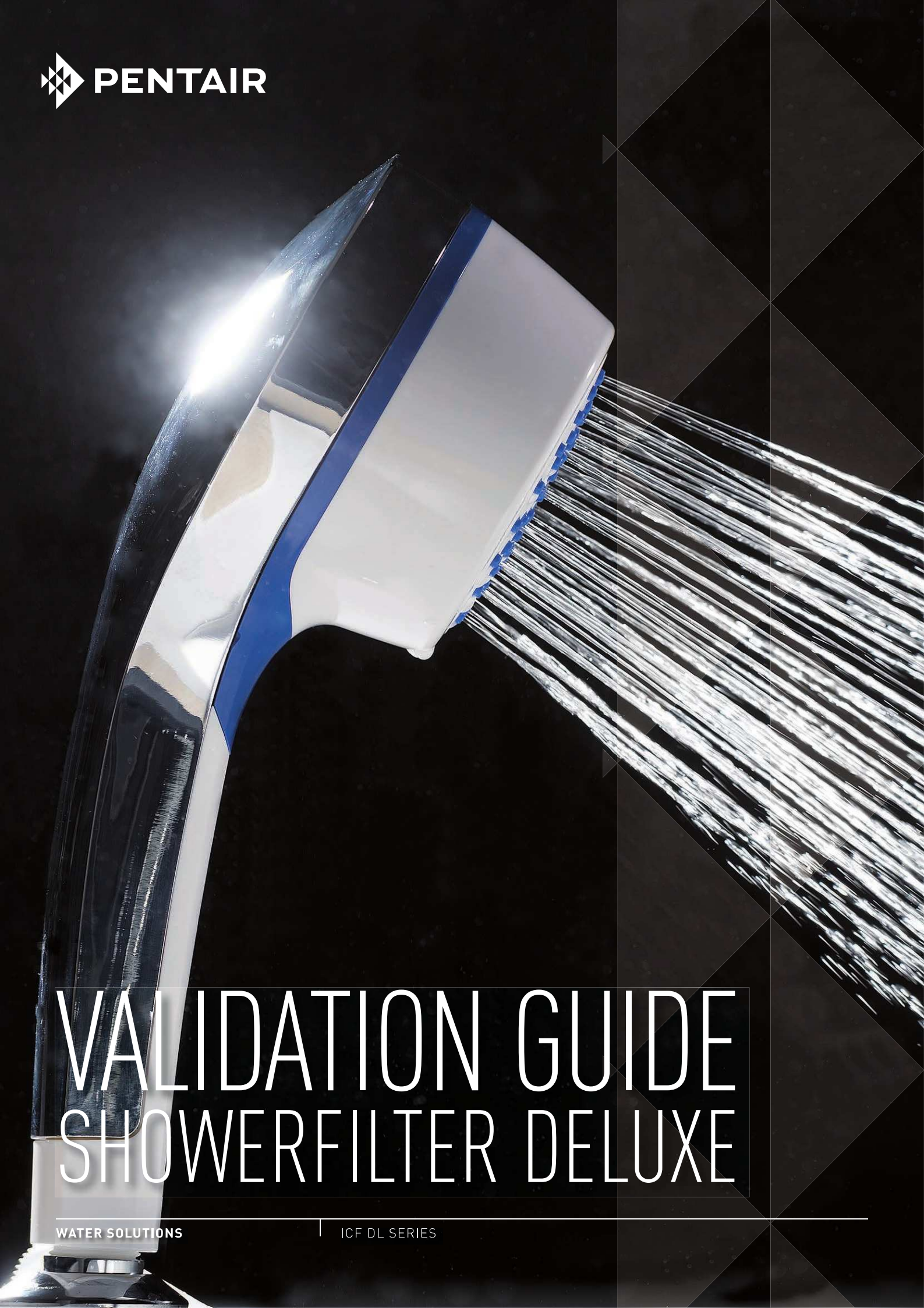
PENTAIR



VALIDATION GUIDE
SHOWERFILTER DELUXE

WATER SOLUTIONS

ICF DL SERIES

INTENSIVE CARE
FOR YOUR HOSPITAL WATER

Patient safety in hospitals is of vital importance, especially in high-risk areas such as hematology, oncology, burn units and intensive care units.

One of the main concerns is the risk of bacterial infections which can be caused by microbiologically contaminated shower and tap water. Waterborne pathogens can accumulate in biofilm located within the plumbing system, even if a hospital disinfects water at the point-of-entry (POE). The pathogens can then be transmitted to patients when the water is used for their care.

Pentair, a specialist in water purification solutions, developed a new generation of point-of-use (POU) membrane filters for shower heads and water faucets designed specifically for use in medical facilities. The ShowerFilter and the TapFilter provide easy and reliable protection at the last possible moment before patient contact.

POWERFUL PROTECTION

Pentair Medical Water Filters use proven membrane technology as a solution to solve the challenge of water purification in hospitals. Pentair Medical Water Filters are equipped with an unique replaceable filter cartridge. This cartridge contains hollow fiber microfiltration membranes with billions of microscopic pores.

The pores form an ultra-fine filter which retains any bacteria or fungi present in the water resulting in clean and safe water for patients. Placing TapFilters on washroom taps and ShowerFilters on shower heads will minimize the risk of infection and ensure patient and staff safety.

FEATURES & BENEFITS

- 0.2 micron microfiltration membranes
- > log 7 reduction of bacteria
- > log 4 reduction of fungi
- Sterile-class edition for high-risk areas/ all bacteria
- Standard edition for medium-risk areas/ legionella prevention
- CE Medical Class I (s) marked
- Tracking and tracing label for easy replacement administration
- Non-return valve prevents contamination during replacement
- Easy to filter replacement,
- Special key prevents unwanted change-outs
- Less waste, and therefore more environmentally-friendly
- Extended service life – up to 40 % longer than the market standard
- Ergonomical design

EXTENDED VALIDATED SERVICE LIFE

Pentair Medical Water Filters provide bacteriological safe water for a validated service life in many cases much longer than the market standard. To support this, Pentair Medical Filters have been extensively tested in accordance with all the relevant microbiological test protocols both in independent laboratories as well as clinically in hospitals.

DESIGNED FOR EASY USE

The ShowerFilter looks and feels like an ordinary handheld shower unit and the balance and grip of the product make it easy to use for both hospital staff and patients.

The TapFilter mounts to the existing water faucet and is positioned off to the side rather than directly underneath the faucet which provides more room for hand washing.

A SUSTAINABLE SOLUTION

Pentair Medical Filters offer an important waste reduction benefit. The ShowerFilter and the TapFilter are each made up of two independent components, which means the filter head is the only piece that needs to be replaced. This creates up to 50 percent less waste than other solutions on the market. Pentair Medical Filters are not only good for your patients' and staffs health, but also a much more sustainable option in the long run!

VALIDATION GUIDE
SHOWERFILTER DELUXE

ICF DL 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.

The Pentair ShowerFilter Deluxe contains 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 ShowerFilter Deluxe provides easy and reliable protection at the last possible moment before patient contact.

This validation guide summarizes tests that have been performed for validation and qualification of the Pentair 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 10^7 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 Water Filters performed in triplo according to the ASTM F838-05 protocol.

	Influent			Effluent			
				After 5L 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 x 10^{10}	3.33 x 10^7	8 x 10^9	<100	>7.2	<100	>7.2
2	4 x 10^{10}	3.33 x 10^7	8 x 10^9	<100	>7.2	<100	>7.2
3	3 x 10^{10}	2.5 x 10^7	6 x 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

3. CHEMICAL RESISTANCE

3.1 Test description

In order to test the chemical resistance of the ShowerFilter Deluxe it was 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 ShowerFilter Deluxe 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 ShowerFilter Deluxe. Therefore it can be concluded that the ShowerFilter Deluxe is compatible with this chemical treatment.

4. FLOW RATE AND PRESSURE TESTS

4.1 Test description

In order to evaluate the flow rate, the ShowerFilter Deluxe was flushed with tap water at increasing pressure. Tests on the ShowerFilter Deluxe were performed with and a 6 l/min flow restrictor, that is included in the product for water saving purposes.

4.2 Test results

Results of the ShowerFilter Deluxe is shown in Figure 2.

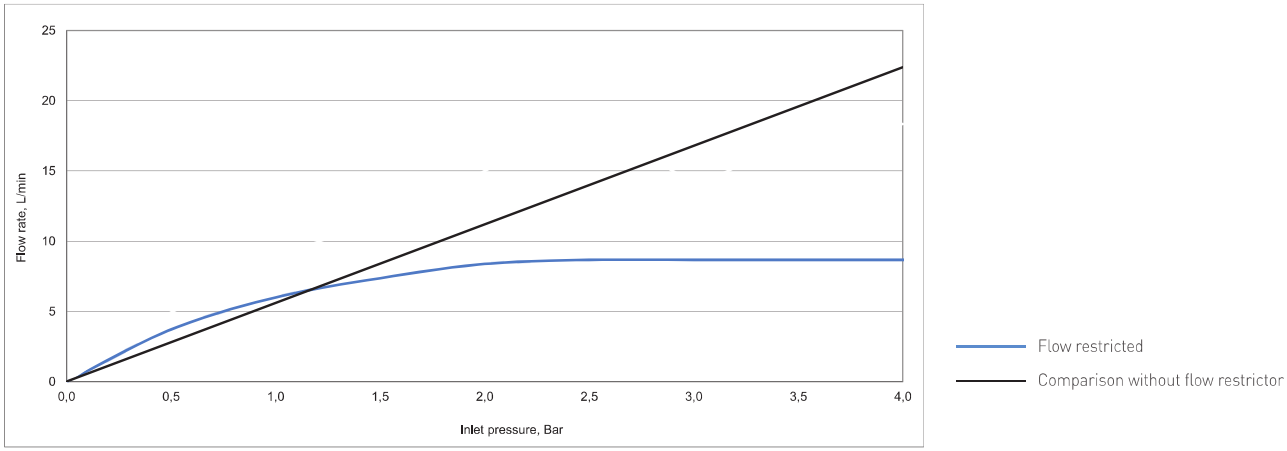


Figure 2: Flow rate-pressure curve of the Pentair Water Filters with (blue) and without (black) a 6 L/min flow restrictor

4.3 Conclusions

The ShowerFilter Deluxe shows 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.

5.2 Management Summary Legionella pneumophila retention tests

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.

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.

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*.

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.

CEpartner4U

Certificate number: 2009-MDD/CE070

Certificate of MDD-Annex VII assessment

This is to certify that, in relation to the Medical Device Directive 93/42/EEC, **CEpartner4U BV** acts as independent regulatory affairs consultant for

Filtrix BV
Siliciumweg 28
3812 SX Amersfoort
The Netherlands

The manufacturer has registered with the Dutch Competent Authorities the products as listed on the manufacture's Declaration of Conformity:

Medical Device Directive	*Medical Devices*	*Risk class/rule*	*Registration date*
L 169; 93/42/EEC	ShowerFilter and Tapfilter	Class I, rule 1	2009-09-28

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity dated 2007-04-12. CEpartner4U declares that based on their assessment the medical devices fulfil adequately the requirements of Directive 93/42/EEC, Annex VII.

2009-10-06

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