

PROCEDURA APERTA PER LA FORNITURA MEPA CONSIP RDO N.2481273 PER LA FORNITURA DI FILTRI ANTIBATTERICI /ANTILEGIONELLA

VERBALE SEDUTA RISERVATA n.1 del 02.03.2020

- In data 02.03.2020 alle ore 11:00:, presso gli Uffici della UOC Provveditorato-Economato di questa AORN ubicati al piano 1° AORN di via Palasciano, Caserta, si costituisce, in seduta riservata, il Seggio di gara composto come segue:
- Dott. Mario Massimo Mensorio – Direttore UOC Organizzazione, Programmazione dei Servizi Ospedalieri e Sanitari-Presidente;
- Arch. Virgilio Patitucci – Direttore UOC Ingegneria Ospedaliera – Componente;
- Dott. Gianfranco Lauria - Consulente Tecnico Supporto al RUP– Componente;
- Sig. Filippo Di Lorenzo - Assistente Amministrativo UOC Provveditorato ed Economato AORN, Segretario;

Premesso che

- in data 20.12.2019 è stata attivata procedura mediante Mepa Consip RDO n.2481273 per la fornitura di filtri antibatterici /antilegionella;
- che entro il termine di scadenza fissato per la presentazione delle offerte ore 12:00 del 17.01.2020 hanno fatto pervenire offerta, le ditte STERIMED S.R.L., ANTONIO SERIO PRODOTTI CHIMICI SRL, PURETECH SRL, CULLIGAN ITALIANA SPA, NGMED , BIOLINK SRL, RENTACS ITALIA S.R.L., MEDICAL EUROPEAN FORNITURE SAS DI CORRADO FELLICO & C., H.E.D. S.R.L. e AIR LIQUIDE SANITÀ SERVICE .

Tanto premesso si dichiara aperta la seduta.

I componenti della Commissione di gara come sopra costituita procedono, quindi, alla valutazione delle schede tecniche presentate valutandone la conformità delle offerte come da prospetto allegato;

Valutate le schede tecniche e ritenute tutte le ditte conformi, i componenti procedono alla valutazione delle offerte economiche presentate.

La fornitura viene, pertanto, aggiudicata a favore della ditta Medical European Forniture sas in quanto migliore offerente per una spesa complessiva pari ad € 4.118,40 iva esclusa comprensiva di filtri, raccordi e adattatori come da offerta allegata.

La seduta viene chiusa alle ore 12:00 Del che è verbale che, letto e confermato, viene sottoscritto.



IL SEGGIO

- Dott. Mario Massimo Mensorio

Mario Massimo Mensorio

- Arch. Virgilio Patitucci

Virgilio Patitucci

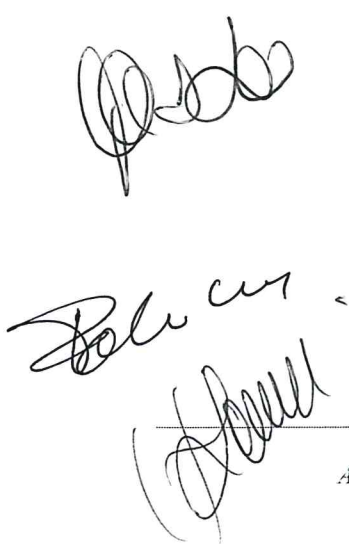
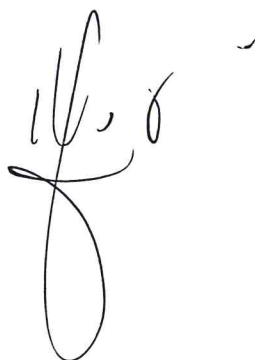
- Dott. Gianfranco Lauria

Gianfranco Lauria

- Sig. Filippo Di Lorenzo

Filippo Di Lorenzo

DITTA	CONFORMITA' SCHEDE TECNICHE	NON CONFORME
MEDICAL EUROPEAN FORNITURE SAS DI CORRADO FELLICO & C.	conforme	
AIR LIQUIDE SANITÀ SERVICE	conforme	
H.E.D. S.R.L.	conforme	
PURETECH SRL	conforme	
STERIMED S.R.L.	conforme	
CULLIGAN ITALIANA SPA	conforme	
BIOLINK SRL	conforme	
RENTACS ITALIA S.R.L.	conforme	
NGMED	conforme	
ANTONIO SERIO PRODOTTI CHIMICI SRL	conforme	

DESCRIZIONE MATERIALE	UNITAR	COMPLESS
Filtri per acqua ad uso medicale PENTAIR, per doccia portatata 9 l/min a pressione 2 bar	36	€ 29,33 € 1.055,88
nella versione standard per la protezione da tutti i batteri		
presenti nelle condutture idrauliche come legionella, ritenzione batteriologica > 7 log per batteri,		
dispositivo medico marcato CE classe I, dotati di un		
modulo a membrana filtrante, grado di filtrazione 0,2 micron		
durata 92 giorni dal primo utilizzo		
Filtri per acqua ad uso medicale PENTAIR, per rubinetti portata 4 l/min a pressione 2 bar	96	€ 29,33 € 2.815,68
nella versione standard per la protezione da tutti i batteri		
presenti nelle condutture idrauliche come legionella, ritenzione batteriologica > 7 log per batteri,		
dispositivo medico marcato CE classe I, dotati di un		
modulo a membrana filtrante, grado di filtrazione 0,2 micron		
durata 92 giorni dal primo utilizzo		
Adattatore per rubinetti	24	€ 2,30 € 55,20
Raccordo per rubinetti	24	€ 5,75 € 138,00
Raccordo per doccia modello telefono (adatto già all'allaccio presente all'estremità del laccio doccia in Vs. possesso quindi non serve adattatore)	9	€ 5,96 € 53,64
Totale Iva Esclusa		€ 4.118,40

Come da Vs. chiarimento del 16/01/2020 si è dedotto che i punti di erogazione da coprire sono: 24 rubinetti e 9 docce. Tale deduzione è scaturita dalla durata di 31 giorni da Voi imputata ad ogni filtro e quindi sono stati da Voi previsti 12 cambi; di conseguenza 396 filtri (totale dei filtri richiesti dato dalla somma di 24 rubinetti X 12 cambi = 288 e 9 docce X 12 cambi = 108) per la durata da noi indicata per la sostituzione (92 giordi dal primo utilizzo) si riducono ad un totale di 132, in quanto le sostituzioni saranno solo 4 (365 giorni annui : 92 giorni durata filtro = 3,97 e cioè 4 cambi).

Raccorderie ed adattatori posso essere tranquillamente acquistati una sola volta se la manutenzione degli impinati viene fatta regolarmente e la sostituzione dei filtri viene effettuata correttamente.

Si precisa che tale offerta riguarda la sola ed esclusiva fornitura dei beni richiesti.

Non potendo modificare la quantità di filtri da Voi indicata all'interno della scheda tecnica da Voi creata per la formulazione dell'offerta economica, il totale da noi offerto è stato diviso per il moltiplicatore 396.

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 di Felice Sorrobbi & C.
 Via Sant'Agata 97 / 00194 ROMA
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DESCRIZIONE MATERIALE	UNITAR	COMPLESS
Filtri per acqua ad uso medicale PENTAIR, per doccia portata 9 l/min a pressione 2 bar	36	€ 1.055,88
Filtri per acqua standard per la protezione da tutti i batteri nella versione standard per la protezione da tutti i batteri presenti nelle condutture idrauliche come legionella, ritenzione batteriologica > 7 log per batteri,		
dispositivo medico marcato CE classe I, dotati di un modulo a membrana filtrante, grado di filtrazione 0,2 micron		
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nella versione standard per la protezione da tutti i batteri presenti nelle condutture idrauliche come legionella, ritenzione batteriologica > 7 log per batteri,		
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 .ITVA 07032250636

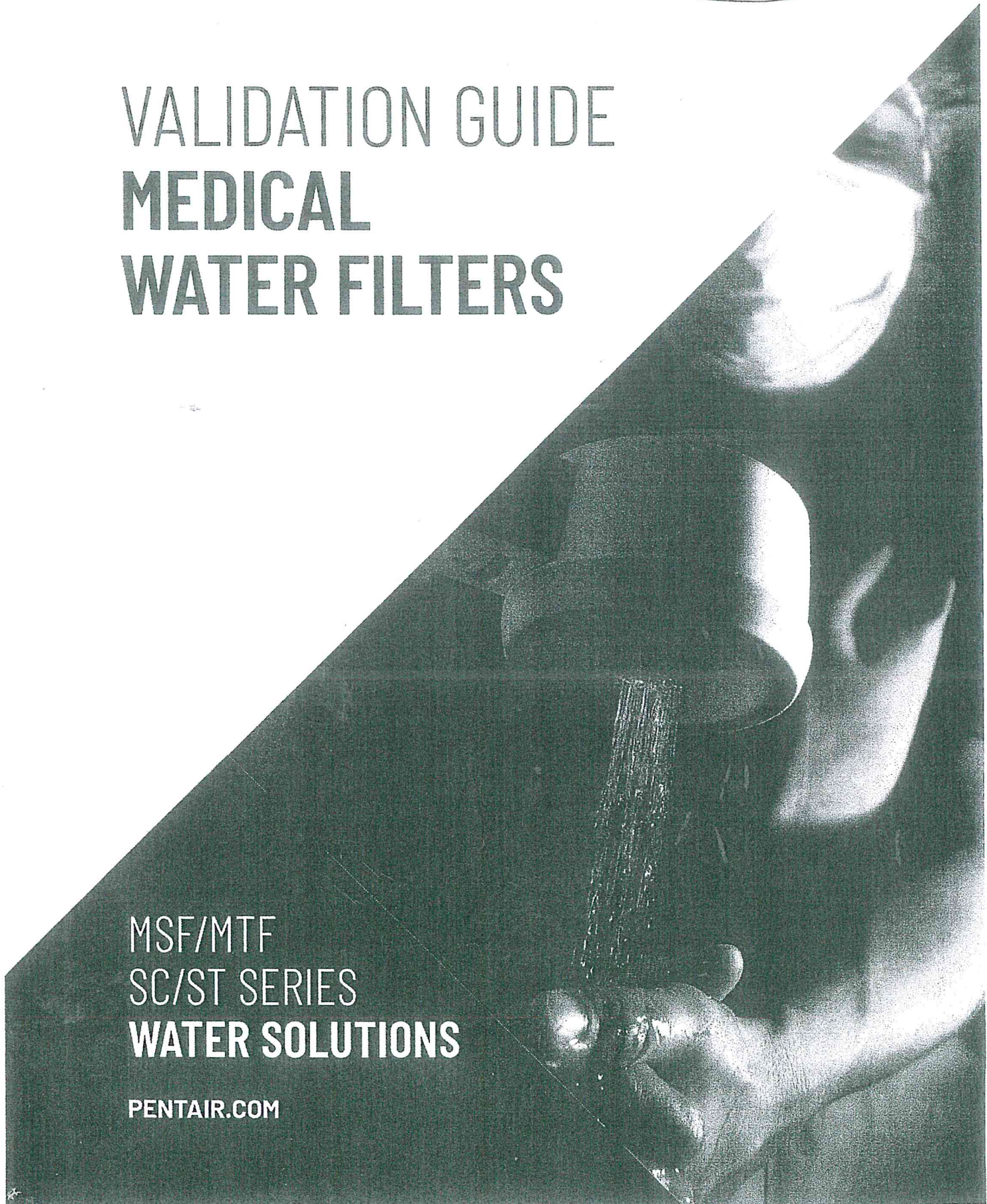


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VALIDATION GUIDE MEDICAL WATER FILTERS

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MEDICAL WATER FILTERS

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Validation guide

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POSTAZIONE EXTRA

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 be 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-shelf sterile products. Sterilization of the product is done by gamma irradiation treatment with a minimum dose of 25 kGy.

2. MICROBIOLOGICAL TESTS

2.1 Retention of *Pseudomonas 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 *Pseudomonas 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 10⁷ bacteria per cm² 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/cm². 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.

Filter	Influent			Effluent			
	Total CFU load	CFU/cm ²	CFU/L	After 5L suspension filtrated		Mixed sample from 5L	
				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 92 days (3 months) 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 92 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 reference bacterium *Klebsiella terrigena*, the clinically relevant *Legionella pneumophila* and *Pseudomonas aeruginosa* and the opportunistic fungi *Aspergillus fumigatus* and *Fusarium solani*.

2.2.2 Test results

The log reduction for each microorganism is shown over the duration of the test, over 3 months. Results are shown for the samples taken at the start of the test and for every week. Extended results for all of these 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* (test over 11 weeks)

Filter cartridge	Sample 1	Sample 2	Sample 3
	Log retention in effluent		
Start of the 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 weeks and 4 days	>8.5	>8.5	>8.5
After 2 weeks and 5 days	>7.2	>7.2	>7.2
After 3 weeks	>7.1	>7.1	>7.1
After 3 weeks and 4 days	>7.0	>7.0	>7.0
After 3 weeks and 5 days	>6.9	>6.9	>6.9
After 4 weeks	>7.0	>7.0	>7.0
After 4 weeks and 4 days	>7.1	>7.1	>7.1
After 4 weeks 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 4 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
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

**no data due to an error in sample acquisition

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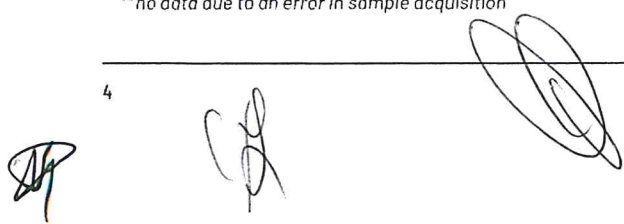


Table 3: Log reduction values for the retention of *L. pneumophila* (test over > 3 months)

Cartridge	Log reduction <i>Klebsiella terrigena</i>			Log reduction <i>Legionella pneumophila</i>		
	1	2	3	1	2	3
After 1 month	>7.5	>6.9	>7.4	>7.2	>7.2	>7.2
After 2 months	>7.5	>7.5	>7.7	>7.2	>7.2	>7.2
After 3 months	>7.6	>7.6	>7.6	>7.1	>7.1	>7.1
After 4 months	>7.8	>7.8	>7.7	>7.2	>7.2	>7.2
After 5 months	>7.7	>7.7	>7.6	>7.5	>7.5	>7.5
After 6 months	>7.7	>7.7	>7.6	>7.2	>7.2	>7.2

Table 4: Log reduction values for the retention of *P. aeruginosa*

Filter cartridge	Sample 1	Sample 2	Sample 3
	Log retention in effluent		
Start of the 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	>6.9	>6.9	>6.9
After 1 week and 3 days	>7.0	>7.0	>7.0
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 week and 1 day	>8.1	>8.1	>8.1
After 5 week 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

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Table 5: Log reduction values for the retention of *F. solani*

Filter cartridge	Log retention from <i>Fusarium solani</i>		
	Sample 1	Sample 2	Sample 3
Start of the test	>3,9	>3,9	>3,9
After 1 day	>3,7	>3,7	>3,7
After 3 days	>3,7	>3,7	>3,7
After 1 week	>4,0	>4,0	>4,0
After 1 week and 1 day	>4,1	>4,1	>4,1
After 1 week and 3 days	>4,0	>4,0	>4,0
After 2 weeks	>4,0	>4,0	>4,0
After 2 weeks and 1 day	>4,2	>4,2	>4,2
After 2 weeks and 3 days	>4,0	>4,0	>4,0
After 3 weeks	>4,0	>4,0	>4,0
After 3 weeks and 1 day	>4,2	>4,2	>4,2
After 3 weeks and 3 days	>4,2	>4,2	>4,2
After 4 weeks	>4,2	>4,2	>4,2
After 4 weeks and 1 day	>4,2	>4,2	>4,2
After 4 weeks and 3 days	>4,3	>4,3	>4,3
After 5 weeks	>4,3	>4,3	>4,3
After 5 weeks and 1 day	>4,4	>4,4	>4,4
After 5 weeks and 3 days	>3,7	>3,7	>3,7
After 6 weeks	>4,1	>4,1	>4,1
After 6 weeks and 1 day	>4,1	>4,1	>4,1
After 6 weeks and 3 days	>4,2	>4,2	>4,2
After 7 weeks	>3,7	>3,7	>3,7
After 7 weeks and 1 day	>4,1	>4,1	>4,1
After 7 weeks and 3 days	>3,8	>3,8	>3,8
After 3 months	>4,1	>4,1	>4,1

✕ 2.2.3 Conclusion

For both *Klebsiella terrigena*, *Legionella pneumophila* and *Pseudomonas aeruginosa* a reduction of more than log 6 was obtained for the entire 3 months, compliant with international standards. Furthermore, no *Aspergillus fumigatus* and *Fusarium solani* was detected in the effluent samples resulting in a minimal retention of log >3.9.

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 taps.

✕ 2.3.1 Test description

The clinical test was performed at the clinic in Nordrhein-Westfalen region in Germany. It concerns an over 100 years old building with regular high *Legionella* counts. For that reason it uses Pentair Medical Water Filters, especially in the high-risk areas. In this clinical trail 4 sample points in 2 stations (neonatology and intensive care) were selected. Weekly samples were taken for a period of 10 weeks. All samples were taken according to DIN EN ISO 19458, Table 1 by ISO 17025 certified Synlab from Berlin, and processed according to DIN EN ISO 11731. The inlet samples were taken directly from the water tap. The outlet samples were taken from the Pentair Water Filters.

2.3.2 Test results

At the Neonatology station both inlet sample points showed high *Legionella* counts at the start of the test. In the course of the test almost all inlet samples continued to show high counts. No *Legionella* bacteria could be found in any of the outlet samples. In some of the samples the *Legionella* count could not be established by cultivation as a result of bacterial overgrowth, which can be explained by recontamination from the environment of the filter.



At the intensive care station the inlet points showed a relatively low Legionella count throughout the test. No Legionella bacteria could be found in any of the outlet samples. Also here the bacterial overgrowth prevented a Legionella count in some of the samples. In two cases this was so strong that not even a direct value could be established.

Table 6: Results of the clinical tests at the neonatology station

Week	Tap nr.	Inlet (Legionella CFU/100 ml)	Outlet (Legionella CFU/100 ml)
0	I	400	0
	II	300	0
1	I	0	0
	II	200	0
2	I	600	0
	II	700	0
3	I	200	0
	II	1400	0
4	I	200	0
	II	0	0
5	I	0	0
	II	100	0
6	I	100	0
	II	100	0
7	I	<100*	0
	II	<100*	<100*
8	I	<100*	0
	II	<100*	<100*
9	I	0	0
	II	<100*	<100*
10	I	100	0
	II	0	0

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*direct Legionella value only, no cultivation of Legionella species possible as a result of bacterial overgrowth

Table 7: Results of the clinical tests at the intensive care station

Week	Tap nr.	Inlet (Legionella CFU/100 ml)	Outlet (Legionella CFU/100 ml)
0	I	0	0
	II	100	0
1	I	0	0
	II	0	0
2	I	0	0
	II	0	0
3	I	0	0
	II	0	0
4	I	0	0
	II	<100*	0
5	I	0	0
	II	0	0
6	I	0	0
	II	100	0
7	I	0	0
	II	0	<100*
8	I	0	0
	II	0	n.a.
9	I	0	0
	II	n.a.	n.a.
10	I	0	0
	II	<100*	<100*

*direct Legionella value only, no cultivation of Legionella species possible as a result of bacterial overgrowth n.a. no value as a result of strong bacterial overgrowth

2.3.3 Conclusion

The clinical test has shown that the Pentair Medical Water Filters are perfectly capable of filtering out Legionella from the hospital water over their lifetime.

2.4 Evaluation of Medical Water Filters with antimicrobial additives

Although all bacteria are retained from the water supply by the membranes, there is still the risk of growth of bacteria on the membrane housing at the effluent side of the membrane. Bacteria from the atmosphere can get into the compartment after the membranes (CAM) and start to grow over time. This is generally known as cross-contamination and needs to be prevented.

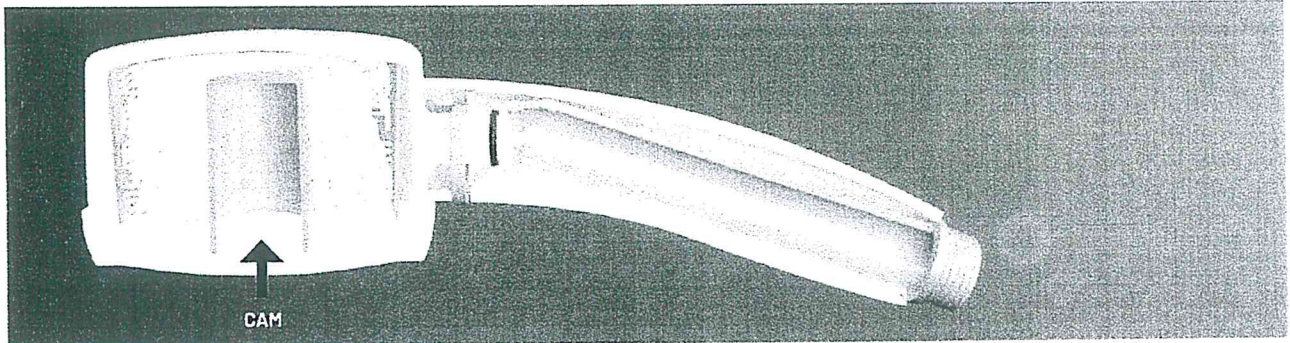


Figure 1: Location of the compartment after membranes that can be affected by bacteria from the environment.

Based on an extensive study with different types of antimicrobials we have introduced antimicrobials to our product line. In these products the plastic of the spray cap is blended with a polymer additive containing silver. The silver released from the plastic is accumulated in the 0.01 L compartment after the membranes but strongly diluted during use of the filter. Different tests have shown that the silver concentration measured in the effluent is always far below the WHO limit of 100 ppb, and therefore causes no harm to the user.

2.4.1 Test description

Tests were performed according to the JIS Z 2801:2000 protocol. This protocol determines antimicrobial activity by quantifying the survival of bacterial cells on a surface that contains an antimicrobial agent. The test was performed for two bacteria: *Escherichia coli* and methicillin-resistant *Staphylococcus aureus* (MRSA). A cell suspension is placed on the polymer used for our spray cap with the antimicrobial additive. After 24 hours at 35°C the bacteria are counted again and the survival rate is determined.

2.4.2 Test results

In table 8 test results of the antibacterial activity are shown.

Table 8: Determination of antibacterial activity shown as CFU/cm²

	0h	24h	Reduction (%)
<i>E. coli</i>	1.3 x 10 ⁴	56	99.55
MRSA	1.5 x 10 ⁴	79	99.47

2.4.3 Conclusion

The antimicrobial additive to the spray cap of the Medical Water Filters strongly reduces the cross contamination of the filters. The silver release however is far below toxicity levels and does not pose a threat to the users of the filters.

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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. 2). Also tensile strength of the membranes was the same for both hypochlorite exposed and unexposed membranes.

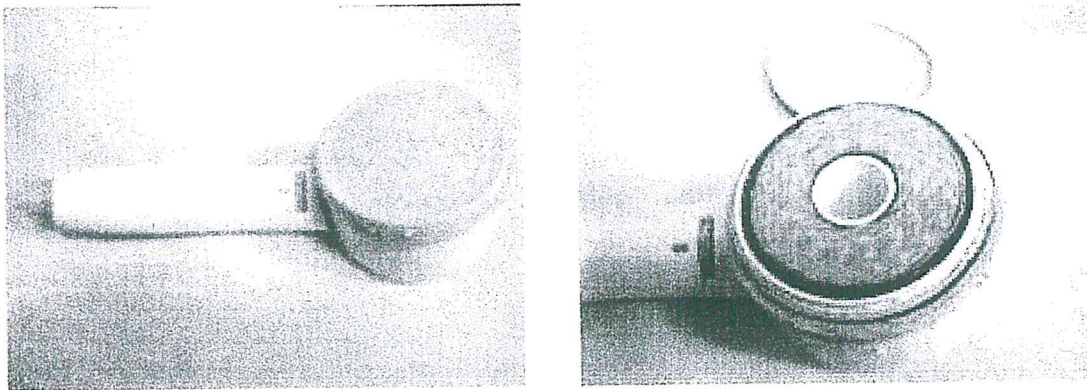


Figure 2: Evaluation of shower filter for defects and discolorations

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 3 and 4 respectively.

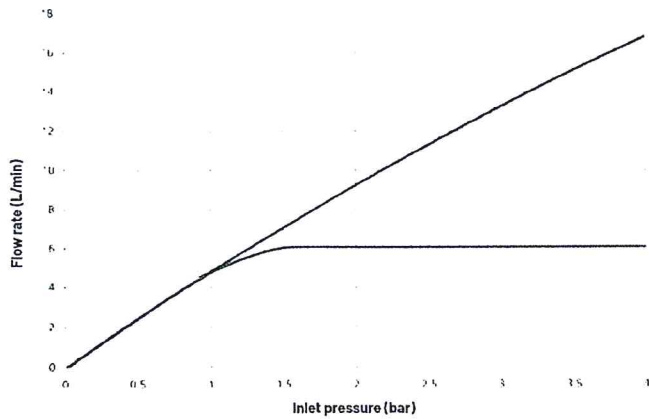


Figure 3: Flow rate-pressure curve of the Medical ShowerFilter with (blue) and without (black) a 6 L/min flow restrictor

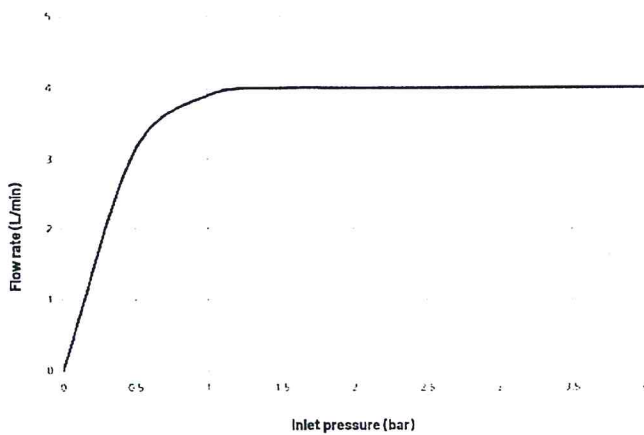
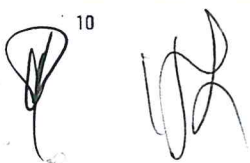


Figure 4: Flow rate-pressure curve of the Medical TapFilter with a 4 L/min flow restrictor

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.

10




5. APPENDICES

MEDICAL EUROPEAN FURNITURE sas
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Via San Rocco 97 - 80070 MARANO (NA)
P.IVA 07032750636

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 and 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	8×10^6	8×10^6	6×10^6	8×10^6	8×10^6	6×10^6
	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 diminuta* challenge experiments, using data from the analytical report of Vitens. The ASTM standard states a challenge of 10^7 bacteria per cm^2 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

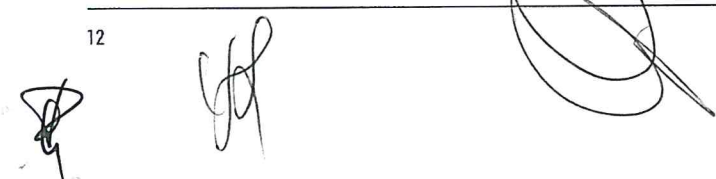
Introduction

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 Laboratorien, Leeuwarden, the Netherlands, an ISO 17025 accredited laboratory. Tests were performed in order to prove that the cartridges have a bacterial retention level of $2 \log_6$ 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 8×10^7 *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 6 weeks followed by a final sample in week 11. The feed and effluent samples taken from the challenge tests were analyzed by Vitens Laboratorien, 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 Virens.

Filter	1	2	3
	Log retention of effluent samples		
Start of test	+6.8	+6.6	+6.8
After 4 days	+7.0	+7.6	+7.9
After 5 days	+7.4	+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
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*.

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 s.r.l. - Via S. Felice 10 - 00100 Roma (RM)
 Via San Rocco, 97 - 00016 MARANO (NA)
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Via Ser. Rec. ... NA;
P.L.A. ...



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.

Cartridge	Log retention of <i>Pseudomonas aeruginosa</i>		
	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
After 4 months	>7.2	>7.2	>7.2
After 5 months	>5.7	>5.7	>5.7
After 6 months	>7.7	>7.7	>7.7


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Conclusion

Almost all samples show a retention performance above the goal of log 6. In one case the influent target level of log 6 wasn't reached due to low influent concentration. In all cases no *Pseudomonas aeruginosa* passed the membrane. It can be concluded that over a period of at least 26 weeks Pentair Medical Water Filters meet the retention requirements for *Pseudomonas aeruginosa*.

5.4 Management Summary *Fusarium solani* retention tests

Management Summary



Fusarium solani 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 $\geq \log 4$ for *Fusarium solani* for a period of 26 weeks.

Methods

Tests were performed on three cartridges from 01st November 2010 under test conditions selected to show the long term performance of microbiological water purifiers. Due to the larger size of fungi a minimum reduction level of $\log 4$ was required in order to determine the capability of fungi reduction. First the cartridges were flushed with 50 L filter sterilized water, followed by a challenge of 5 L water with a minimum concentration of 2×10^6 *Fusarium solani* 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 by once a month over a period of 4 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 *Fusarium solani* challenge experiments, using the data from the analytical reports of Vitens Laboratory.

Cartridge	Log retention of <i>Fusarium solani</i>		
	1	2	3
Start of test	>3.9	>3.9	>3.9
After 1 day	>3.7	>3.7	>3.7
After 3 days	>3.7	>3.7	>3.7
After 1 week	>4.0	>4.0	>4.0
After 1 week and 1 day	>4.1	>4.1	>4.1
After 1 week and 3 days	>4.0	>4.0	>4.0
After 2 weeks	>4.2	>4.2	>4.2
After 2 weeks and 1 day	>4.0	>4.0	>4.0
After 2 weeks and 3 days	>4.2	>4.2	>4.2
After 3 weeks	>4.0	>4.0	>4.0
After 3 weeks and 1 day	>4.2	>4.2	>4.2
After 3 weeks and 3 days	>4.2	>4.2	>4.2
After 4 weeks	>4.2	>4.2	>4.2
After 4 weeks and 1 day	>4.2	>4.2	>4.2
After 4 weeks and 3 days	>4.3	>4.3	>4.3
After 5 weeks	>4.3	>4.3	>4.3
After 5 weeks and 1 day	>4.4	>4.4	>4.4
After 5 weeks and 3 days	>3.7	>3.7	>3.7
After 6 weeks	>4.1	>4.1	>4.1
After 6 weeks and 1 day	>4.1	>4.1	>4.1
After 6 weeks and 3 days	>4.2	>4.2	>4.2
After 7 weeks	>3.7	>3.7	>3.7
After 7 weeks and 1 day	>4.1	>4.1	>4.1
After 7 weeks and 3 days	>3.8	>3.8	>3.8
After 3 months	>4.1	>4.1	>4.1
After 4 months	>4.2	>4.2	>4.2
After 5 months	>4.3	>4.3	>4.3
After 6 months	>4.4	>4.4	>4.4

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 4, rue de la Chapelle 13630
 13630 LAURENTIN (NA)
 04 91 42 10 06 36

Conclusion

Almost all samples show a retention performance above the goal of log 4. In some cases the influent target level of log 4 wasn't reached due to low influent concentration. In all cases no *Fusarium solani* passed the membrane. It can be concluded that over a period of at least 26 weeks Pentair Medical Water Filters meet the retention requirements for *Fusarium solani*.

MOLECULAR MICROBIOLOGY JOURNAL 2003
 VOL. 10, NO. 1, P. 1-10
 DOI: 10.1002/micr.10001

5.5 Product Sheet *Brevundimonas*



Brevundimonas diminuta
 (ATCC® 19146™)

Please read this FIRST

Storage Temp
Frozen: -80°C or colder
Freeze-Dried: 2°C to 8°C
Live Culture: See Propagation Section

Biosafety Level
1

Intended Use

This product is intended for research use only. It is not intended for any animal or human therapeutic or diagnostic use.

Citation of Strain

If use of this culture results in a scientific publication, it should be cited in that manuscript in the following manner: *Brevundimonas diminuta* (ATCC® 19146™)

American Type Culture Collection
 PO Box 1549
 Manassas, VA 20108 USA
www.atcc.org

800.638.6597 or 703.365.2700
 Fax: 703.365.2750
 Email: Tech@atcc.org

Or contact your local distributor

Description

Designation: FDA strain PCI 818 [CCUG 24715, DSM 1635, LMG 10743]
Deposited Name: *Pseudomonas* sp.
Product Description: Formerly *Pseudomonas diminuta*. Used for sterility assurance and membrane filter testing.

Propagation

Medium
 ATCC® Medium 2495: 10mM Phosphate Buffer
 ATCC® Medium 3: Nutrient agar or nutrient broth

Growth Conditions
Temperature: 30°C
Atmosphere: Aerobic

Propagation Procedure

1. Open vial according to enclosed instructions or visit www.atcc.org for instructions.
2. Rehydrate the entire pellet with approximately 0.5 mL of #2495 broth. Aseptically transfer the entire contents to a 5-6 mL tube of #2495 broth. Additional test tubes can be inoculated by transferring 0.5 mL of the primary broth tube to these secondary tubes.
3. Use several drops of the primary broth tube to inoculate a #3 plate and/or #3 agar slant.
4. Incubate at 30°C for 48 to 72 hours.

Notes

Phosphate buffer is for rehydration and transfer only, not for growth.
 Two colony types may be found in this strain if it is passed through Nutrient Broth (BD 234000). To prevent proliferation of the second colony type, rehydrate the vial as above and maintain the culture by transferring from agar to agar.
 Purified genomic DNA of this strain is available as ATCC® 19146D-5™.
 Additional information on this culture is available on the ATCC® web site at www.atcc.org.

References

References and other information relating to this product are available online at www.atcc.org.

Biosafety Level: 1

Appropriate safety procedures should always be used with this material. Laboratory safety is discussed in the current publication of the *Biosafety in Microbiological and Biomedical Laboratories* from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes for Health.

ATCC Warranty

ATCC® products are warranted for 30 days from the date of shipment, and this warranty is valid only if the product is stored and handled according to the information included on this product information sheet. If the ATCC® product is a living cell or microorganism, ATCC lists the media formulation that has been found to be effective for this product. While other, unspecified media may also produce satisfactory results, a change in media or the absence of an additive from the ATCC recommended media may affect recovery, growth and/or function of this product. If an alternative medium formulation is used, the ATCC warranty for viability is no longer valid.

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This product is intended for laboratory research purposes only. It is not intended for use in humans. While ATCC uses reasonable efforts to include accurate and up-to-date information on this product sheet, ATCC makes no warranties or representations as to its accuracy. Citations from scientific literature and patents are provided for informational purposes only. ATCC does not warrant that such information has been confirmed to be accurate.
 This product is sent with the condition that you are responsible for its safe storage, handling, and use. ATCC

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ATCC 19146

Brevundimonas diminuta
(ATCC® 19146™)


is not liable for any damages or injuries arising from receipt and/or use of this product. While reasonable effort is made to insure authenticity and reliability of materials on deposit, ATCC is not liable for damages arising from the misidentification or misrepresentation of such materials.

Please see the enclosed Material Transfer Agreement (MTA) for further details regarding the use of this product. The MTA is also available on our Web site at www.atcc.org


Additional information on this culture is available on the ATCC web site at www.atcc.org

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Please read this FIRST



Storage Temp.
Frozen: -80°C or colder
Freeze-Dried: 2°C to 8°C
Live Culture: See Propagation Section



Biosafety Level
1

Intended Use

This product is intended for research use only. It is not intended for any animal or human therapeutic or diagnostic use.

Citation of Strain

If use of this culture results in a scientific publication, it should be cited in that manuscript in the following manner: *Brevundimonas diminuta* (ATCC® 19146™)

American Type Culture Collection
PO Box 1546
Manassas, VA 20108 USA
www.atcc.org

800.638.6597 or 703.365.2700
Fax: 703.365.2750
Email: Tech@atcc.org

Or contact your local distributor

INDUSTRIAL EQUIPMENT CORPORATION S.A.S.
Via ...
Tel. ...
Fax. ...



Pentair Medical Water Filters are worldwide exclusively distributed by
Fealter BV The Netherlands
For more information please visit our website fealter.com



X-FLOW BV | P.O. Box 739 | NL-7500 AS Enschede | Netherlands | xflow.pentair.com

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MEDICAL WATER FILTERS

STANDARD SERIES ST92

Patient and staff safety in hospitals is of vital importance. Not only in high-risk areas such as critical wards, intensive care units and operating theaters, but also in the medium-risk areas like kitchens, changing and patient rooms.

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. The pathogens can then be transmitted to patients when the water is used for their care. Pentair, a specialist in water purification solutions, offers a complete range of point-of-use membrane filters for shower heads and taps/faucets. These are specifically designed for use in healthcare facilities.

BENEFITS

- ◀ Protects from waterborne bacteria like legionella
- ◀ CE Medical Class I marked device
- ◀ For medium risk areas like kitchens, changing and patient rooms
- ◀ Relief in outbreak situations or permanent infection control

APPLICATIONS

Pentair Medical Filters standard version offers protection in medium risk (non-sterile) areas where there

is risk of waterborne infection. It provides reliable and easy protection at the last possible moment before patient and staff contact.

MATERIALS AND OPERATING SPECIFICATIONS

Filter Media

Capillary microfiltration membranes

Micron Rating

0.2 µm

Max. operating pressure

5 bar (72.5 psi)

Operating temperature

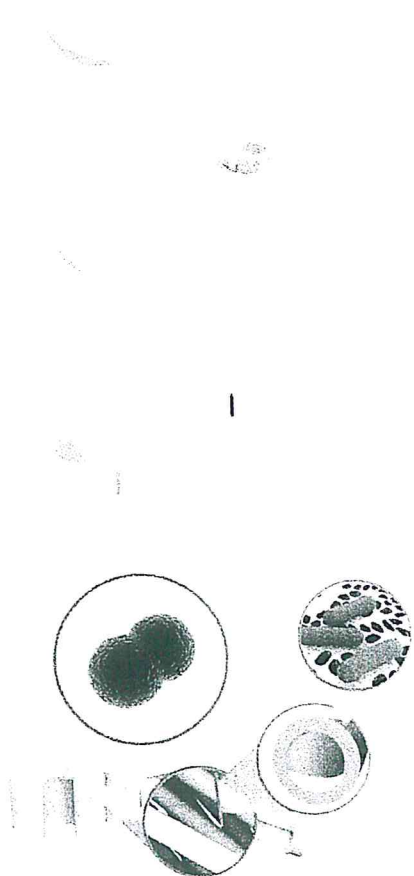
Continually 0 - 60 °C @ 5 bar inlet pressure
70 °C for 60 min. cumulative over the lifetime of the filter cartridge (compliant with thermal disinfection procedures)

Chlorine exposure

1.200 ppm for 10 hours cumulative over the lifetime of the filter cartridge

Storage & Handling

- Validated shelf life: 2 years
- Keep dry during storage; protect against freezing after first use
- Handle with care; do not expose to shocks
- Disposable product; discard as regular waste



FILTER CARTRIDGE SPECIFICATIONS & PERFORMANCE DATA

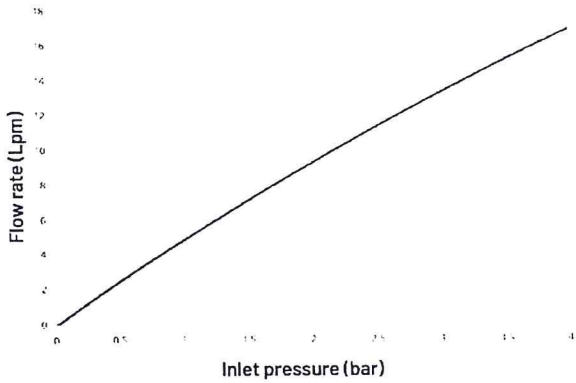
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MODEL NUMBER	MSE-STSS	MSE-STRC	MTEW-STSS	MTEW-STRC	MTFD-STSS	MTFD-STRC
Model name	Medical Shower Filter Starter	Medical Shower Filter Replacement Cartridge	Medical Tap Filter Washing Standard Starter	Medical Tap Filter Washing Replacement Cartridge	Medical Tap Filter Drinking Standard Starter	Medical Tap Filter Drinking Replacement Cartridge
Max. Dimensions	156 x 63 mm	88 x 63 mm	156 x 63 mm	88 x 63 mm	156 x 63 mm	88 x 61 mm
Weight	240 g	50 g	240 g	50 g	240 g	150 g
Connection	1/2 inch BSPP ¹	proprietary quick release	22 mm inner thread	proprietary quick release	22 mm inner thread	proprietary quick release
inlet flowrate at 1 bar	9 l/min (2.4 Gpm) ²	9 l/min (2.4 Gpm) ²	4 l/min (1 Gpm) ²	4 l/min (1 Gpm) ²	4 l/min (1 Gpm) ²	4 l/min (1 Gpm) ²
validated lifetime	30 days (3 months) ³					
Biological Retention	Bacteria Log 7.0 (up to 10 ⁶) ⁴					
<small>¹ adapter to 24 mm 1/2" outer & inner thread available</small>	<small>² flow restriction recommended</small>		<small>³ flow restriction required</small>		<small>⁴ Refer to the validation guide for information</small>	

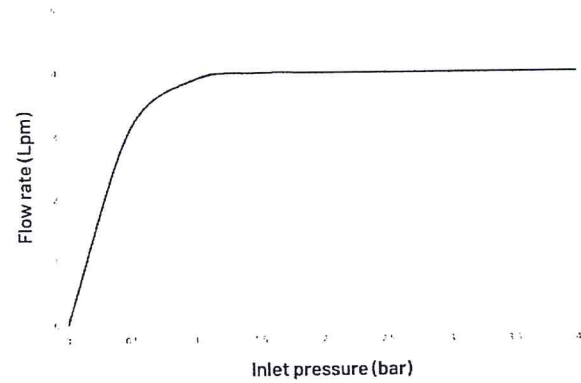
Product Certification: The Medical Water Filters Standard series comply to the requirements of the Medical Device Directive 93/42/EEC, Annex VII and are registered a Class I, rule I products.



SHOWERFILTER



TAPFILTER



Pentair Medical Water Filters are worldwide exclusively distributed by Fealler BV The Netherlands. For more information please visit our website fealler.com

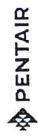


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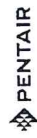


MEDICAL WATER FILTERS

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PEN-2-PURGE-WATER-FILTERS



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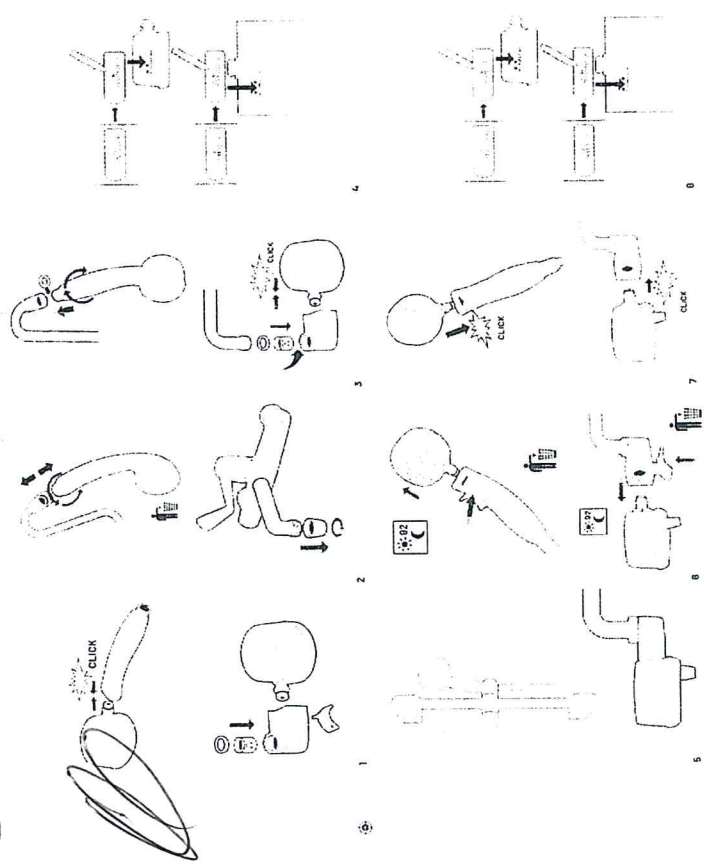
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MEDICAL WATER FILTERS

MSF/MTF ST92 SERIES

APPLICABLE REGULATIONS: MDR 2017/745
CE MARKING: CE 0389

Installations- und Bedienungsanleitung

EINFÜHRUNG




Vielen Dank, dass Sie sich für einen Pentair Medical Filter entschieden haben. Die Pentair Medical Filter sind mit einem Membranmodul ausgestattet, das für die Beseitigung aller im Leitungsnetz vorhandenen Bakterien geeignet ist. Die Filter können im Rahmen der persönlichen Hygiene in Krankenhäusern eingesetzt werden, beispielsweise an Duschen und Wasserhähnen. Der Filter ist 92 Tage nach der ersten Benutzung auszutauschen. Die Lebensdauer des Filters verlängert sich durch eine vorübergehende Nichtbenutzung nicht. Der Filter kann nach der Nutzung nicht mittels eines Autoklaven oder einer anderen Sterilisationstechnik sterilisiert werden. Weitere Einzelheiten zu den Leistungsmerkmalen und den Nutzungs- und Lagerungsbedingungen finden Sie in dem entsprechenden Datenblatt auf unserer Webseite www.xflow.pentair.com.

WICHTIGE VORSICHTSMASSNAHMEN UND HINWEISE

Das Produkt ist ausschließlich für den Anschluss an die Kalt- und Mischwasserversorgung geeignet. Die maximal zulässige Betriebs-temperatur beträgt 60 °C. Der maximale Betriebsdruck des Filtersystems beträgt 5 bar. Informationen zum anliegenden Wasserdruck erfragen Sie bei Ihrem Wasserlieferanten oder bei Ihrer technischen Abteilung. Sorgen Sie dafür, dass das Filtersystem korrekt angeschlossen wird, indem Sie sich genau an die Hinweise in vorliegender Bedienungsanleitung halten. Produkt bei

Beschädigung oder nach Ablauf des äußersten Haltbarkeitsdatums nicht mehr verwenden. Vor der Installation des Filters wird sorgfältiges Händewaschen empfohlen. Vermeiden Sie dabei möglichst den Kontakt mit der Ausflussöffnung des Filters, um eine bakterielle Infektion zu verhindern. Der Filter sollte nach der ersten Verwendung Temperaturen von unter 0 °C nicht ausgesetzt werden. Filter mit Vorsicht behandeln, keinen Erschütterungen aussetzen. Dadurch kann das Material beschädigt werden. Im Zweifelsfall Filterpatrone austauschen.

INSTALLATION DES BRAUSEFILTERS



Befolgen Sie den Stufenplan auf der inneren Umschlagseite dieser Bedienungsanleitung für die Installation des Brausefilters (Abbildung 1-5).

Bei Bedarf den vorhandenen Duschkopf demontieren. Nehmen Sie den Brausefilter aus der Verpackung. Der Brausefilter ist serienmäßig mit einem 1/2-Zoll Anschlussstück (Aussengewinde) ausgerüstet. Achten Sie auf einen korrekten Sitz der Flachdichtung der Duschschlauch-Kupplung. Befestigen Sie das mitgelieferte wasserdichte, zweiteilige Datumsetikett am Filter und notieren Sie das Inbetriebnahmedatum und das Austauschdatum (nach 92 Tagen) auf beiden Etikettabschnitten. Das obere Etikett ist für Ihre eigenen Unterlagen bestimmt. Das untere Etikett ist am Filter zu befestigen. Wenn Sie über Instrumenten-Management-Software verfügen, kann der Filter mit dem Strichcode eingelesen werden. Der Brausefilter kann nun in Betrieb genommen werden.

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INSTALLATION DES TAPFILTERS

Befolgen Sie den Stufenplan auf der inneren Umschlagseite dieser Bedienungsanleitung für die Installation des TapFilters (Abbildung 1-5).

Bei Bedarf den Hahnauslauf entfernen. Nehmen Sie den TapFilter aus der Verpackung. Setzen Sie den Durchflussregler in die dafür vorgesehene Aussparung ein. Der Pfeil auf dem Durchflussregler zeigt die Strömungsrichtung an. Drücken Sie den Durchflussregler an und setzen Sie anschließend die Flachdichtung ein. Schrauben Sie den TapFilter auf die Hahnöffnung. Der TapFilter ist serienmäßig mit einem 22 mm Anschlussstück (Innengewinde) ausgerüstet. Ein Adapter für andere Größen ist erhältlich. Achten Sie auf die richtige Position der Flachdichtung des Anschlussstücks. Befestigen Sie das mitgelieferte wasserdichte, zweiteilige Datumsetikett am Filter und notieren Sie das Inbetriebnahmedatum und das Austauschdatum (nach 92 Tagen) auf beiden Etikettabschnitten. Das obere Etikett ist für Ihre eigenen Unterlagen bestimmt. Das untere Etikett ist am Filter zu befestigen. Wenn Sie über Instrumenten-Management-Software verfügen, kann der Filter mit dem Strichcode eingelesen werden. Der TapFilter kann nun in Betrieb genommen werden.

AUSTAUSCH DER FILTERPATRONE

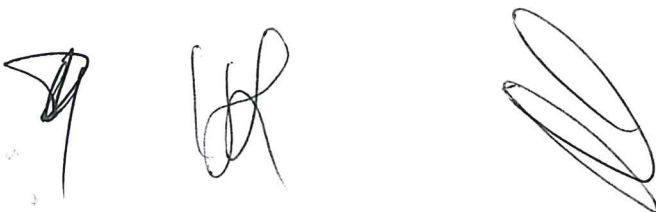
Spätestens 92 Tage nach der ersten Inbetriebnahme ist die Filterpatrone auszutauschen. Tauschen Sie die Filterpatrone in jedem Falle dann, wenn Sie eine deutliche Verringerung des Wasserdrucks

feststellen. Die Notwendigkeit eines vorzeitigen Austausches tritt in der Regel nicht als Folge eines defekten Filtersystems auf, sondern ist eher ein Hinweis auf die geringere Qualität des Versorgungswassers oder eine überdurchschnittliche Nutzungsfrequenz dieses Abnahmepunktes. Befolgen Sie den Stufenplan auf der inneren Umschlagseite dieser Bedienungsanleitung für den Austausch der Filterpatrone (Abbildung 6-7).

Vor der Installation des Filters wird sorgfältiges Händewaschen empfohlen. Vermeiden Sie dabei möglichst einen Kontakt mit der Ausflussöffnung des Filters. Entfernen Sie die Patrone vom Anschlussstück mit Hilfe des beiliegenden grauen Werkzeugs. Das Rückschlagventil verhindert, dass eventuell verunreinigtes Wasser aus der Patrone fließt. Aus dem Anschlussstück kann eine kleine Leitungswassermenge auslaufen. Die gebrauchte Filterpatrone ist verschlossen und kann im Hausmüll entsorgt werden. Nehmen Sie die Filterpatrone aus der sterilen Verpackung. Befestigen Sie das mitgelieferte wasserdichte, zweiteilige Datumsetikett am Filter und notieren Sie das Inbetriebnahmedatum und das Austauschdatum (nach 92 Tagen) auf beiden Etiketten. Das obere Etikett ist für Ihre eigenen Unterlagen bestimmt. Das untere Etikett ist am Filter zu befestigen. Wenn Sie über Instrumenten-Management-Software verfügen, kann der Filter mit dem Strichcode eingelesen werden. Drücken Sie die neue Patrone auf die Schnellkupplung, bis sie einrastet (Klick-Geräusch) und richtig anschließt.

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GARANTIEBEDINGUNGEN UND HAFTUNG

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MEDICAL WATER FILTERS

MSF/MTF ST92 SERIES

Installation and operating instructions

INTRODUCTION

Thank you for choosing a Pentair Medical Filter. The Pentair Medical Filters come with a membrane module that has been validated for the removal of specific bacteria that occur in the water supply system. The filters can be used for personal hygiene in hospitals, such as showers, and for washing your hands. The filter must be replaced 92 days after its first use. The service life of the filter cannot be extended by not using it temporarily. After use the filter cannot be sterilised in an autoclave or by means of any other sterilisation technique. For more details about performance and the usage and storage conditions, please refer to the relevant product data sheet on our website www.xflow.pentair.com.

IMPORTANT PRECAUTIONS AND INSTRUCTIONS

The product is suitable only for connection to a cold-water or mixing-water facility. The maximum allowable operating temperature is 60 °C (140 °F). The maximum allowable operating pressure of the filter system is 5 bar (72.5 psi). Contact your water supplier or your technical department for information about the current water pressure. Make sure that the filter system is connected correctly by carefully following these operating instructions. Do not use if the package has been damaged, or after the expiry date has passed. We recommend washing your hands thoroughly before installation. Avoid contact with the outlet opening of the filter as much as possible to prevent bacterial contamination. During periodic disinfection of the water supply system, the filter

basically does not have to be removed. Depending on the disinfection method used, the filter may have to be replaced afterwards. Please refer to the filter data sheet for this. Avoid exposure to temperatures below 0 °C after first use. Handle with care, do not expose to shocks. This may damage the filter material. When in doubt, we recommend placing a new filter cartridge.

INSTALLATION OF THE SHOWERFILTER

Follow the step-by-step plan on the fold-out page of these instructions to install the ShowerFilter (picture 1-5).

Where required, remove the existing shower head. Remove the ShowerFilter from the packaging. Place the ShowerFilter on the end of the shower hose. The ShowerFilter comes standard with a ½" G (BSP) coupling (male). Make sure that the flat seal of the shower hose coupling is in the correct position. Attach the watertight 2-part date label supplied to the filter and write down the date of first use and the replacement date (92 days later) on both labels. The top label is for your own administration. Attach the bottom label to the filter. If you have instrument management software the filter can be registered via the barcode. The ShowerFilter can now be put into use.

INSTALLATION OF THE TAPFILTER

Follow the step-by-step plan on the fold-out page of these instructions to install the TapFilter (picture 1-5).



Where required, remove the outlet piece of the tap. Remove the TapFilter from the packaging. Fit the flow regulator in the designated opening. The arrow on the regulator indicates the flow direction. Press the regulator into place, and then fit the flat gasket. Screw the TapFilter onto the tap opening. The TapFilter comes standard with a 22-mm coupling (inner thread). An adapter for other sizes is available. Make sure that the flat seal of the coupling is in the correct position. Attach the watertight 2-part date label supplied to the filter and write down the date of first use and the replacement date (92 days later) on both labels. The top label is for your own administration. Attach the bottom label to the filter. If you have instrument management software the filter can be registered via the barcode. The TapFilter can now be put into use.



REPLACING THE FILTER CARTRIDGE

The filter must be replaced no later than 92 days after it was used for the first time. Replace the cartridge in any case if the water pressure is noticeably reduced. If the filter needs to be replaced early, this is generally not a result of a defect in the filter system, but rather an indication that the quality of the incoming water is inferior or that this tap is being used more than average. Follow the step-by-step plan on the fold-out page of these instructions to replace the cartridge (picture 6-7).

We recommend washing your hands thoroughly before replacement. Avoid contact with the outlet opening of the filter as much as possible. Remove the cartridge from the coupling using the little grey

tool supplied. The non-return valve ensures that no contaminated water can flow out of the cartridge. A small amount of mains water may flow out of the coupling. The used cartridge is sealed and can be disposed of as regular waste. Remove the filter cartridge from the packaging. Attach the watertight 2-part date label supplied to the filter and write down the date of first use and the replacement date (92 days later) on both labels. The top label is for your own administration. Attach the bottom label to the filter. If you have instrument management software the filter can be registered via the barcode. Place the new cartridge by pushing it onto the quick-connect coupling until you hear a click and the cartridge is firmly connected.

LIMITATION OF WARRANTY AND LIABILITY

X-Flow BV represents and warrants for the warranty period of one year that its products are free from substantial defects in materials and workmanship and conform to the specifications. X-Flow BV's warranties do not cover defects or deficiencies due to or arising from (1) normal wear and tear or improper, abnormal, or negligent handling, operation, maintenance, overloading, or use; (2) tampering, alteration, or repair by buyer or third parties without the prior written consent of X-Flow BV. The warranties specifically contained in this section are the only warranties provided and are expressly in lieu of all other warranties, express or implied, including - without limiting the generality of the foregoing - implied warranties of merchantability and fitness for a particular purpose, which are hereby disclaimed. In no event shall



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MEDICAL WATER FILTERS

MSF/MTF ST92 SERIES

Installatie en gebruiksaanwijzing

INTRODUCTIE

Hartelijk dank voor uw keuze voor een Pentair Medical Filter. De Pentair Medical Filters zijn voorzien van een membraanmodule die is gevalideerd voor de verwijdering van alle in het waterleidingnet voorkomende bacteriën. De filters kunnen worden gebruikt voor persoonlijke hygiëne in ziekenhuizen, zoals douchen en het wassen van handen. Het filter dient na 92 dagen na de eerste ingebruikname te worden vervangen. De levensduur van het filter kan niet worden verlengd door het tijdelijk niet te gebruiken. Het filter kan na gebruik niet worden gesteriliseerd door middel van een autoclaaf of door enig andere sterilisatietechniek. Voor meer details over de prestaties en de gebruik- en opslagcondities verwijzen wij u naar het desbetreffende product datablad op onze website www.xflow.pentair.com.

BELANGRIJKE VOORZORGSMAATREGELEN EN AANWIJZINGEN

Het product is uitsluitend geschikt voor aansluiting op de koudwater- of mengwater-voorziening. De maximaal toelaatbare gebruikstemperatuur bedraagt 60 °C. De maximaal toelaatbare gebruiksdruk van het filtersysteem bedraagt 5 bar. Raadpleeg het waterbedrijf of uw technische dienst voor informatie over de geldende waterdruk. Zorg ervoor dat het filtersysteem juist wordt aangesloten door de aanwijzingen in deze gebruiksaanwijzing nauw-keurig op te volgen. Niet gebruiken indien de verpakking beschadigd is of na het verstrijken van de uiterste houdbaarheidsdatum. Het verdient

aanbeveling voor de installatie de handen zorgvuldig te wassen. Vermijdt daarbij zoveel mogelijk het contact met de uitstroomopening van het filter om bacteriële besmetting te voorkomen. Tijdens periodieke desinfectie van het waterleidingsysteem hoeft het filter in principe niet te worden verwijderd. Afhankelijk van de toegepaste desinfectie methode dient het filter hierna mogelijk vervangen te worden. Raadpleeg hiervoor het datasheet van het filter. Voorkom blootstelling aan temperaturen onder de 0 °C na het eerste gebruik. Voorzichtig behandelen, niet blootstellen aan schokken. Het filter materiaal kan hierdoor beschadigen. Bij twijfel raden wij u aan een nieuwe filtercartridge te plaatsen.

INSTALLATIE VAN DE SHOWERFILTER

Volg het stappenplan op de uitklappagina van deze handleiding voor het installeren van de ShowerFilter (afbeelding 1 - 5).

Verwijder zo nodig de aanwezige douchekop. Haal de ShowerFilter uit de verpakking. Plaats de ShowerFilter op het uiteinde van de doucheslang. De ShowerFilter is standaard voorzien van een 1/2" G (BSP) koppeling (buitendraad). Let er op dat de vlakke pakking van de doucheslang koppeling juist is gepositioneerd. Voorzie het filter van het bijgeleverde watervaste 2-delige datumlabel en noteer de datum van ingebruikname en de vervangingsdatum (92 dagen later) op beide labels. Het bovenste label is voor uw eigen administratie. Het onderste label plaats u op het filter. Indien u beschikt over instrument management software

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kan het filter met behulp van de barcode worden ingelezen. De ShowerFilter kan nu in gebruik worden genomen.

INSTALLATIE VAN DE TAPFILTER

Volg het stappenplan op de uitklappagina van deze handleiding voor het installeren van de TapFilter (afbeelding 1-5).

Verwijder zo nodig het uitloopstuk van de kraan. Haal de TapFilter uit de verpakking. Plaats de doorstroom-begrenzer in de daarvoor bestemde holte. De pijl op de begrenzer geeft de stromingsrichting aan. Druk de begrenzer aan. Plaats vervolgens de vlakke pakking. Draai de TapFilter op de kraanmond. De TapFilter is standaard voorzien van een 22 mm koppeling (binnendraad). Een adapter naar andere maten is verkrijgbaar. Let er op dat de vlakke pakking van de koppeling juist is gepositioneerd. Voorzie het filter van het bijgeleverde watervaste 2-delige datumlabel en noteer de datum van ingebruikname en de vervangingsdatum (92 dagen later) op beide labels. Het bovenste label is voor uw eigen administratie. Het onderste label plaatst u op het filter. Indien u beschikt over instrument management software kan het filter met behulp van de barcode worden ingelezen. De TapFilter kan nu in gebruik worden genomen.

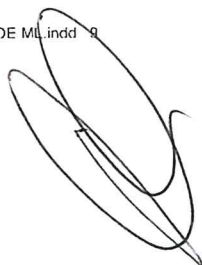


VERVANGEN VAN DE FILTERCARTRIDGE

Maximaal 92 dagen na de eerste ingebruikname dient de filtercartridge te worden vervangen.

Vervang de cartridge in ieder geval als er een duidelijke afname van de waterdruk merkbaar is. De noodzaak van een voortijdige vervanging is in de regel geen gevolg van een defect van het filtersysteem, maar eerder een indicatie van een mindere kwaliteit van het inkomende water of van een bovengemiddeld gebruik van dit tappunt. Volg het stappenplan op de uitklappagina van deze handleiding voor het vervangen van de cartridge (afbeelding 6-7).

Het verdient aanbeveling voor de vervanging de handen zorgvuldig schoon te maken. Vermijd zoveel mogelijk het contact met de uitstroomopening van het filter. Verwijder de cartridge van het aansluitstuk met behulp van het meegeleverde grijze tooltje. De keerklep zorgt ervoor dat mogelijk verontreinigd water niet uit de cartridge stroomt. Uit de douchegreep kan een kleine hoeveelheid leidingwater stromen. De gebruikte cartridge is afgesloten en kan als gewoon afval worden verwijderd. Haal de filtercartridge uit de verpakking. Voorzie het filter van het bijgeleverde watervaste 2-delige datumlabel en noteer de datum van ingebruikname en de vervangingsdatum (92 dagen later) op beide labels. Het bovenste label is voor uw eigen administratie. Het onderste label plaatst u op het filter. Indien u beschikt over instrument management software kan het filter met behulp van de barcode worden ingelezen. Plaats de nieuwe cartridge door deze op de snelkoppeling te duwen tot er een klik hoorbaar is en de cartridge goed aansluit op de douchegreep.





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BEPERKTE GARANTIE EN AANSPRAKELIJKHEID

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MEDICAL WATER FILTERS

MSF/MTF ST92 SERIES

Instalación e instrucciones de uso

INTRODUCCIÓN

¡Gracias por escoger el Pentair Medical Filter! Los Pentair Medical Filters disponen de un módulo de membrana apto para eliminar bacterias específicas que puedan hallarse en la red de las tuberías del agua. Los filtros pueden utilizarse para la higiene personal en hospitales, en las duchas y en los lavamanos. El filtro debe ser reemplazado 92 días después de su primer uso. Detener el uso del filtro no prolongará su vida útil. Una vez usado, el filtro no puede ser esterilizado mediante autoclave o cualquier otra técnica de esterilización. Para más detalles sobre el rendimiento y las condiciones de uso y almacenamiento, consulte la ficha de datos del producto correspondiente, en nuestro sitio web www.xflow.pentair.com.

MEDIDAS PREVENTIVAS E INDICACIONES IMPORTANTES

El producto es únicamente apto para su conexión en el grifo de agua fría o en el grifo mezclador. La máxima temperatura de uso permitida es de 60 °C. La máxima presión de uso permitida, del sistema de filtrado, es de 5 bar. Solicite información sobre el suministro de presión de agua a la compañía del agua o su servicio técnico. Procure que el sistema de filtrado esté correctamente instalado siguiendo atentamente las instrucciones de uso descritas en este manual. No lo utilice si el envoltorio está dañado o si ha expirado la fecha de caducidad. Es recomendable lavarse bien las manos antes de instalar el producto. Durante la instalación, evite al máximo el contacto con la boca de salida del filtro

para evitar la contaminación bacteriana. Durante la desinfección periódica del sistema de tuberías del agua, no es necesario, en principio, desmontar el filtro. Según el método aplicado de desinfección, debe reemplazarse el filtro tras la desinfección. Consulte para ello la ficha de datos del filtro. Tras el primer uso evite exponer el filtro a temperaturas por debajo de 0 grados centígrados. Trate el producto con cuidado evitando golpes y sacudidas, pues podría dañar el material del filtro. En caso de duda, es aconsejable utilizar un nuevo cartucho de filtración.

INSTALACIÓN DEL SHOWERFILTER

Siga los pasos descritos en la página desplegable de este manual para instalar el ShowerFilter (figura 1-5).

En caso necesario, desmonte el cabezal de la ducha. Extraiga el ShowerFilter del envoltorio. Monte el ShowerFilter en el extremo de la manguera de la ducha. El modelo estándar del ShowerFilter dispone de un empalme macho de 1/2" G (BSP). Asegúrese de que la parte plana de la manguera de la ducha esté en la posición adecuada. Adjunte al filtro la etiqueta resistente al agua de dos piezas que acompaña al producto e indica la fecha. Anote, en ambas etiquetas, la fecha del primer uso y la fecha para su recambio (al cabo de 92 días). Conserve la etiqueta superior para su propia administración. Adhiera la etiqueta inferior al filtro. Si utiliza software de gestión de instrumental, puede leer el código de barras del filtro. Ahora ya puede utilizar el ShowerFilter.



INSTALACIÓN DEL TAPFILTER

Siga los pasos descritos en la página desplegable de este manual para instalar el TapFilter (figura 1-5).

En caso necesario, desmonte la boca de salida del grifo. Extraiga el TapFilter del envoltorio. Coloque el restrictor de flujo en la toma correspondiente. La flecha en el restrictor indica el sentido del flujo. Encaje el restrictor y coloque, a continuación, la junta plana. Rosque el TapFilter en la boca del grifo. El modelo estándar del TapFilter dispone de un empalme hembra de 22 mm (rosca interior). También es posible adquirir un adaptador de otros tamaños. Asegúrese de que la parte plana del empalme esté en la posición adecuada. Adjunte al filtro la etiqueta resistente al agua de dos piezas que acompaña al producto e indica la fecha. Anote, en ambas etiquetas, la fecha del primer uso y la fecha para su recambio (al cabo de 92 días). Conserve la etiqueta superior para su propia administración. Adhiera la etiqueta inferior al filtro. Si utiliza software de gestión de instrumental, puede leer el código de barras del filtro. Ahora ya puede utilizar el TapFilter.

RECAMBIO DEL CARTUCHO DE FILTRACIÓN

El cartucho de filtración debe ser reemplazado a los 92 días, como máximo, después de su primer uso. En cualquier caso, deberá cambiar el cartucho cuando advierta una clara reducción de la presión del agua. Generalmente, la necesidad de cambiar el cartucho en su debido momento no

representa un defecto del sistema de filtración, sino una indicación de menor calidad del agua suministrada o del uso promedio de este punto de suministro. Siga los pasos descritos en la página desplegable de este manual para cambiar el cartucho (figura 6-7).

Es recomendable lavarse bien las manos antes de cambiar el producto. Evite al máximo el contacto con la boca de salida del filtro. Desmonte el cartucho del empalme mediante la herramienta gris incluida. La válvula de retorno evita que el agua, posiblemente sucia, salga del cartucho. Es posible que salga algo de agua corriente del empalme. El cartucho usado es hermético y puede ser desechado como residuo doméstico. Extraiga el cartucho de filtración del envoltorio. Adjunte al filtro la etiqueta resistente al agua de dos piezas que acompaña al producto e indica la fecha. Anote, en ambos lados de la etiqueta, la fecha del primer uso y la fecha para su recambio (al cabo de 92 días). Conserve la etiqueta superior para su propia administración. Adhiera la etiqueta inferior al filtro. Si utiliza software de gestión de instrumental, puede leer el código de barras del filtro. Coloque el nuevo cartucho encajándolo en el empalme hasta que oiga un clic y conéctelo bien.

LIMITACIÓN DE GARANTÍA Y RESPONSABILIDAD

X-Flow BV declara y garantiza durante el periodo de garantía de un año que sus productos no tienen defectos sustanciales de materiales y mano de obra y cumplen con las especificaciones. Las garantías de X-Flow BV no amparan defectos o deficiencias

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debido o a consecuencia de (1) desgaste normal o el manejo, operación, mantenimiento, sobrecarga, o uso inadecuado, anormal o negligente; (2) adulteración, alteración, o reparación por parte del comprador o terceros sin el consentimiento previo por escrito de X-Flow BV. Las garantías específicamente contenidas en esta sección son las únicas garantías proporcionadas y están expresamente en lugar de toda otra garantía, expresada o implícita, incluyendo sin limitación, la generalidad de las garantías anteriores implícitas de la comerciabilidad y aptitud para un fin particular, que son deslindadas por este medio. En ningún caso X-Flow BV o sus Afiliadas serán responsables de algún daño indirecto. X-Flow BV reparará o reemplazará productos que no cumplan con las garantías ya estipuladas. Cualquier queja acerca de los defectos o el incumplimiento de los productos deberá ser entregada por el comprador a X-Flow BV por escrito especificando el defecto o incumplimiento incluyendo un nivel razonable de detalle, dentro de un plazo de diez (10) días laborales a partir de la recepción de los artículos correspondientes. El incumplimiento con este plazo significará que se pierde el derecho de queja, salvo en relación con los defectos que el comprador no podría haber descubierto razonablemente dentro de este periodo de tiempo. La información y los datos contenidos en este documento están basados en nuestra experiencia general y son considerados correctos. Son proporcionados de buena fe y tienen la intención de brindar un lineamiento para la selección y el uso de nuestros productos. Ya que las condiciones en las cuales pueden usarse nuestros productos están fuera de

nuestro control, esta información no implica ninguna garantía de desempeño final del producto y no podemos aceptar ninguna responsabilidad respecto al uso de nuestros productos. La calidad de nuestros productos está garantizada bajo nuestras condiciones de venta. Deberán respetarse los derechos de propiedad industrial existentes.

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MEDICAL WATER FILTERS

MSF/MTF ST92 SERIES

Installazione e istruzioni per l'uso

INTRODUZIONE

Grazie per avere acquistato il Pentair Medical Filter. I Pentair Medical Filters sono dotati di un modulo a membrana in grado di eliminare tutti i batteri presenti nelle condutture idrauliche. I filtri possono essere utilizzati per l'igiene personale negli ospedali, ad esempio per la doccia e per il lavaggio delle mani. Il filtro deve essere sostituito dopo 92 giorni dal primo utilizzo. La durata del filtro non può essere prolungata evitando di utilizzarlo temporaneamente. Dopo l'uso il filtro non può essere sterilizzato in autoclave o mediante altre tecniche di sterilizzazione. Per ulteriori dettagli sulle prestazioni e sulle condizioni di utilizzo e di conservazione si prega di consultare la scheda dati del prodotto sul nostro sito web www.xflow.pentair.com.

PRECAUZIONI E ISTRUZIONI DI RILIEVO

Il prodotto è adatto esclusivamente per il collegamento all'alimentazione di acqua fredda o miscelata. La temperatura massima di utilizzo è di 60 °C. La pressione di utilizzo massima ammessa del sistema filtrante è pari a 5 bar. Consultare l'acquedotto o il proprio servizio tecnico per informazioni sulla pressione idraulica effettiva. Accertarsi che il sistema filtrante sia installato correttamente attenendosi rigorosamente alle presenti istruzioni per l'uso. Non utilizzare se la confezione è danneggiata o dopo la scadenza indicata. Prima dell'installazione si raccomanda di lavarsi accuratamente le mani. Evitare il più possibile il contatto con l'apertura di uscita del filtro per prevenire la contaminazione batterica.

Durante la disinfezione periodica del sistema di condutture idrauliche, in linea di principio non è necessario smontare il filtro. A seconda del metodo di disinfezione, al termine potrebbe essere necessario sostituire il filtro. A questo proposito, consultare la scheda dati del filtro. Evitare l'esposizione a temperature inferiori a 0 gradi Centigradi dopo il primo utilizzo. Maneggiare con cura e non esporre a urti che potrebbero danneggiare il materiale filtrante. In caso di dubbio, consigliamo di installare una nuova cartuccia filtrante.

INSTALLAZIONE DEL SHOWERFILTER

Per l'installazione del ShowerFilter (figura 1-5) seguire lo schema a passi riportato sulla pagina pieghevole delle presenti istruzioni.

Se necessario, smontare la testa della doccia. Estrarre il ShowerFilter dalla confezione. Montare il ShowerFilter all'estremità del tubo della doccia. Il ShowerFilter è dotato di serie di un raccordo (maschio) da 1/2" G (BSP). Accertarsi che la guarnizione piatta del tubo della doccia sia posizionata correttamente. Applicare sul filtro la doppia etichetta impermeabile per la data fornita in dotazione e annotare la data del primo utilizzo e quella di sostituzione (92 giorni dopo) su entrambe le etichette. L'etichetta superiore è per vostro uso amministrativo. L'etichetta inferiore deve essere applicata sul filtro. Se si dispone del software di gestione degli strumenti, il filtro può essere registrato grazie al codice a barre. Il ShowerFilter può ora essere utilizzato.

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X INSTALLAZIONE DEL TAPFILTER

Per l'installazione del TapFilter (figura 1-5) seguire lo schema a passi riportato sulla pagina pieghevole delle presenti istruzioni.

Se necessario, smontare il becco di uscita del rubinetto. Estrarre il TapFilter dalla confezione. Disporre il limitatore di flusso nell'apposito vano. La freccia sul limitatore indica la direzione del flusso. Premere il limitatore nella sede, quindi montare la guarnizione piatta. Avvitare il TapFilter sulla base del rubinetto. Il TapFilter è dotato di serie di un raccordo (filettatura interna) da 22 mm. È disponibile su richiesta un adattatore per misure diverse. Accertarsi che la guarnizione piatta del raccordo sia posizionata correttamente. Applicare sul filtro la doppia etichetta impermeabile per la data fornita in dotazione e annotare la data del primo utilizzo e quella di sostituzione (92 giorni dopo) su entrambe le etichette. L'etichetta superiore è per vostro uso amministrativo. L'etichetta inferiore deve essere applicata sul filtro. Se si dispone del software di gestione degli strumenti, il filtro può essere registrato grazie al codice a barre. Il TapFilter può ora essere utilizzato.

X SOSTITUZIONE DELLA CARTUCCIA FILTRANTE

La cartuccia filtrante deve essere sostituita entro 92 giorni dal primo utilizzo. Sostituire in ogni caso la cartuccia se si nota un'evidente riduzione della pressione idraulica. Generalmente, la necessità di sostituirla precocemente non è conseguenza di un difetto del sistema filtrante, ma piuttosto indica una






qualità scadente dell'acqua in ingresso o un utilizzo superiore alla media del rubinetto. Per sostituire la cartuccia (figura 6-7) seguire lo schema a passi riportato sulla pagina pieghevole delle presenti istruzioni.

Prima della sostituzione, si raccomanda di lavarsi le mani con cura. Evitare il più possibile il contatto con l'apertura di uscita del filtro. Smontare la cartuccia dal raccordo utilizzando l'attrezzo grigio in dotazione. La valvola girevole impedisce all'acqua eventualmente contaminata di fuoriuscire dalla cartuccia. Dal raccordo può fuoriuscire una piccola quantità di acqua di conduttura. La cartuccia usata è sigillata e può essere smaltita come un normale rifiuto. Estrarre la cartuccia filtrante dalla confezione. Applicare sul filtro la doppia etichetta impermeabile per la data fornita in dotazione e annotare la data del primo utilizzo e quella di sostituzione (92 giorni dopo) su entrambe le etichette. L'etichetta superiore è per vostro uso amministrativo. L'etichetta inferiore deve essere applicata sul filtro. Se si dispone del software di gestione degli strumenti, il filtro può essere registrato grazie al codice a barre. Applicare la cartuccia nuova premendola sul raccordo rapido fino a udire uno scatto e controllare che la cartuccia sia montata correttamente.

LIMITAZIONE DELLA GARANZIA E DELLA RESPONSABILITÀ

X-Flow BV assicura e garantisce, per un periodo di garanzia di un anno, che i suoi prodotti sono esenti da difetti sostanziali dei materiali e di produzione e





che sono conformi alle specifiche. Le garanzie di X-Flow BV non coprono i difetti o le mancanze derivanti (1) dalla normale usura o dalla manipolazione, dal funzionamento, dalla manutenzione o dall'utilizzo impropri, anomali o negligenti, o dal sovraccarico; (2) dalla manomissione, dall'alterazione o da riparazioni eseguite dall'acquirente o da terzi senza la previa autorizzazione scritta di X-Flow BV. Le garanzie indicate specificamente in questa sezione sono le uniche garanzie fornite e sostituiscono esplicitamente le altre garanzie esplicite o implicite, comprese (senza limitazioni del senso generale di quando sopra) le garanzie implicite di commerciabilità e di idoneità per un particolare scopo, da cui si declina con il presente documento. X-Flow BV o le sue controllate non possono in nessun caso essere ritenute responsabili per eventuali danni indiretti. X-Flow BV si impegna a riparare o a sostituire i prodotti non conformi secondo le garanzie descritte sopra. Gli eventuali reclami relativi a difetti o alla non conformità dei prodotti devono essere presentati dall'acquirente per iscritto a X-Flow BV, specificando il difetto o la non conformità con un ragionevole livello di dettaglio, entro dieci (10) giorni lavorativi dal ricevimento del prodotto in questione; in mancanza di ciò, il diritto di reclamo decade, ad eccezione dei difetti che l'acquirente non può ragionevolmente identificare entro questo periodo di tempo. Le informazioni e i dati contenuti in questo documento si basano sulla nostra esperienza generale e sono ritenuti corretti. Essi sono forniti in buona fede e hanno lo scopo di guidare la scelta e l'uso dei nostri prodotti. Poiché le condizioni di utilizzo dei nostri

prodotti sono al di fuori del nostro controllo, queste informazioni non comportano alcuna garanzia sulle prestazioni finali dei prodotti e decliniamo quindi qualunque responsabilità in relazione all'utilizzo dei nostri prodotti. La qualità dei nostri prodotti è garantita alle nostre condizioni di vendita. Devono essere osservati i diritti di proprietà industriale esistenti.

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MEDICAL WATER FILTERS

MSF/MTF ST92 SERIES

Installation et mode d'emploi

INTRODUCTION

Nous vous remercions pour votre choix d'un Pentair Medical Filter. Les Pentair Medical Filters sont munis d'un module à membrane qui est validé pour l'élimination de toutes les bactéries présentes dans le réseau de distribution d'eau. Les filtres peuvent être utilisés pour l'hygiène personnelle dans les hôpitaux, pour les douches ou le lavage des mains par exemple. Le filtre doit être remplacé 92 jours après la première mise en service. Le fait de ne pas utiliser le filtre temporairement ne permet pas de prolonger la durée de vie du filtre. Après utilisation, le filtre ne peut pas être stérilisé au moyen d'un autoclave ou par toute autre technique de stérilisation. Pour plus d'informations sur les performances et les conditions d'utilisation et de stockage, nous vous renvoyons à la fiche technique correspondante du produit sur notre site web www.xflow.pentair.com.

MESURES DE PRÉCAUTION ET CONSIGNES IMPORTANTES

Le produit est destiné exclusivement à un raccordement sur l'alimentation en eau froide ou en eau mitigée. La température de service maximale admissible est de 60 °C. La pression de service maximale admissible pour le système de filtration est de 5 bars. Consultez la société de distribution d'eau ou votre service technique pour des informations sur la pression d'eau du réseau. Veillez à ce que le système de filtration soit raccordé en suivant rigoureusement les consignes de ce mode d'emploi. N'utilisez pas le filtre lorsque

l'emballage est endommagé ou en cas de dépassement de la date limite d'utilisation. Avant l'installation, il est recommandé de bien se laver les mains. En outre, évitez le plus possible tout contact avec l'orifice d'écoulement du filtre afin d'éviter une contamination bactérienne. Durant la désinfection périodique du système de distribution d'eau, il est en principe inutile de retirer le filtre. Suivant la méthode de désinfection appliquée, le filtre doit éventuellement être ensuite remplacé. Consultez à cet effet la fiche technique du filtre. Évitez toute exposition à des températures inférieures à 0 °C après la première mise en service. Manipulez le filtre avec précaution et ne l'exposez pas aux chocs. Ceci peut endommager le matériau du filtre. En cas de doute, nous vous conseillons de placer une nouvelle cartouche filtrante.

INSTALLATION DU SHOWERFILTER

Suivez les étapes figurant sur la page centrale de ce mode d'emploi pour l'installation du ShowerFilter (illustration 1-5).

Retirez le cas échéant le pommeau de douche présent. Retirez le ShowerFilter de l'emballage. Placez le ShowerFilter à l'extrémité du tuyau de douche. Le ShowerFilter est muni de manière standard d'un raccord 1/2" G (BSP) mâle. Assurez-vous que le joint plat du raccord du tuyau de douche est bien positionné. Munissez le filtre de l'étiquette de date imperméable en 2 parties accompagnant le produit et notez la date de mise en service et la date de remplacement (92 jours



92

plus tard) sur les deux parties de l'étiquette. L'étiquette supérieure est destinée à votre propre administration. Placez l'étiquette inférieure sur le filtre. Si vous disposez d'un logiciel de gestion d'instruments, le filtre peut être enregistré à l'aide du code-barres. À présent, le ShowerFilter est prêt à l'emploi.

INSTALLATION DU TAPFILTER

Suivez les étapes figurant sur la page centrale de ce mode d'emploi pour l'installation du TapFilter (illustration 1-5).

Retirez le cas échéant le bec du robinet. Retirez le TapFilter de l'emballage. Placez le limiteur de débit dans le creux prévu à cet effet. La flèche sur le limiteur de débit indique le sens de l'écoulement. Serrez le limiteur de débit. Placez ensuite le joint plat. Vissez le TapFilter sur l'embouchure du robinet. Le TapFilter est muni de manière standard d'un raccord de 22 mm (filetage intérieur). Un adaptateur est disponible pour d'autres tailles. Assurez-vous que le joint plat du raccord est bien positionné. Munissez le filtre de l'étiquette de date imperméable en 2 parties accompagnant le produit et notez la date de mise en service et la date de remplacement (92 jours plus tard) sur les deux parties de l'étiquette. L'étiquette supérieure est destinée à votre propre administration. Placez l'étiquette inférieure sur le filtre. Si vous disposez d'un logiciel de gestion d'instruments, le filtre peut être enregistré à l'aide du code-barres. À présent, le TapFilter est prêt à l'emploi.

REPLACEMENT DE LA CARTOUCHE FILTRANTE

La cartouche filtrante doit être remplacée au maximum 92 jours après la première mise en service. Remplacez en tout cas la cartouche lorsque vous constatez une nette baisse de la pression d'eau. En règle générale, la nécessité de remplacer prématurément le filtre n'est pas une conséquence d'un défaut du système de filtrage, mais plutôt une indication d'une qualité moindre de l'eau d'alimentation ou d'une utilisation de ce point de soutirage supérieure à la moyenne. Suivez les étapes figurant sur la page centrale de ce mode d'emploi pour le remplacement de la cartouche (illustration 6-7).

Avant de remplacer la cartouche, il est recommandé de bien se laver les mains. Évitez le plus possible tout contact avec l'orifice d'écoulement du filtre. Retirez la cartouche du raccord à l'aide de l'outil gris accompagnant le produit. Le clapet antiretour fait en sorte que l'eau potentiellement contaminée ne puisse s'écouler de la cartouche. Une petite quantité d'eau courante peut s'écouler du raccord. La cartouche usagée est fermée et peut être éliminée en tant que déchet domestique ordinaire. Retirez la cartouche filtrante de son emballage. Munissez le filtre de l'étiquette de date imperméable en 2 parties accompagnant le produit et notez la date de mise en service et la date de remplacement (92 jours plus tard) sur les deux parties de l'étiquette. L'étiquette supérieure est destinée à votre propre administration. Placez l'étiquette inférieure sur le filtre. Si vous disposez d'un logiciel de gestion d'instruments, le filtre peut

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être enregistré à l'aide du code-barres. Placez la nouvelle cartouche en l'enfonçant sur le raccord rapide jusqu'à ce que vous entendiez un déclic et que la cartouche soit bien fixée sur la poignée de douche.

LIMITES DE GARANTIE ET DE RESPONSABILITE

X-Flow BV garantit que ses produits sont exempts de vices de fabrication et de matériau pendant la période de validité de la garantie de 1 an et qu'ils sont conformes aux spécifications. Les garanties de X-Flow BV ne sont pas applicables à des défauts ou à des manquements qui sont la conséquence ou qui découlent de (1) l'usure normale et/ou d'un traitement, application, entretien, surcharge ou utilisation inappropriés, anormaux ou entachés de négligence ; (2) d'une modification, adaptation ou réparation non autorisées apportées par l'acheteur ou des tiers sans l'autorisation écrite préalable de X-Flow BV. Les garanties spécifiques stipulées dans le présent document sont les seules garanties fournies et prévalent formellement sur toutes les autres garanties tacites ou expresse, y compris - et sans préjudice du caractère général de ce qui précède - les garanties tacites relatives à la valeur marchande et au caractère adapté à une finalité déterminée, qui sont rejetées par les présentes. Ni X-Flow BV ni ses entreprises affiliées ne sont responsables des dommages indirects. X-Flow BV assurera la réparation ou le remplacement des produits qui ne sont pas conformes aux garanties stipulées dans les présentes. Les réclamations relatives aux défauts et/ou à la non conformité des produits doivent être envoyées par écrit à X-Flow

BV par l'acheteur dans un délai de 10 (dix) jours à compter de la réception des marchandises correspondantes, avec une description détaillée raisonnable du défaut ou de la non-conformité en question. Si une réclamation n'a pas été soumise dans le délai stipulé, l'acheteur est déchu de son droit de réclamation, à l'exception des réclamations relatives à des défauts que l'acheteur n'était pas raisonnablement en mesure de découvrir dans le délai prescrit. Les informations et les données contenues dans le présent document sont basées sur notre expérience et, d'après notre conviction, celles-ci sont exactes. Celles-ci sont fournies de bonne foi et sont destinées à servir de directive pour aider à faire un choix parmi nos produits et à les utiliser. Etant donné que nous ne sommes pas en mesure de contrôler les circonstances dans lesquelles nos produits sont utilisés, les présentes informations ne doivent pas être interprétées comme garantie de la performance de nos produits et nous déclinons toute responsabilité en relation avec l'utilisation de nos produits. La qualité de nos produits est garantie conformément à nos conditions de vente. Les droits de propriété industrielle existants doivent être respectés.

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