![Challis Antibacterial logo with Ag+ symbol]

CHALLIS
ANTIBACTERIAL

VALIDATION GUIDE
MicroFilter Shower Head By Challis Antibacterial

Table of Contents

Part I. General

1. Introduction

This report contains data validation applicable to the Challis Microfilter disposable shower with Legionella incorporated filter. This shower is operating in external / internal filtration with an arrangement of hollow fibres. The Microfilter shower is ready to provide bacteria-free water on the item use shower. It comes under non-sterile packaging.

It has been validated as follows:

- Measuring flow Microfilter various water inlet pressures.
- Retention efficiency with Brevundimonas diminuta bacteria-4 challenges.
- Retention efficiency with Legionella pneumophila bacteria-over 63 days.

2. Presentation of the filtration system

The cut off chosen is 0.10 microns , which is much less than the minimum width of the bacterium Legionella pneumophila and as such conforms to **ASTM F838-05** (Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration) This filtration, low cut off, does not affect the permeability of the Microfilter because it is compensated by the large filter area installed therein .
This new technological choices on the market where we encounter rather flat pleated membranes, lower filter surfaces, less compact, more permeable but at the expense of a larger and often exceeding the limit of 0.2 microns cutoff, is only possible thanks to the particular geometry of the hollow fibre membranes .
The hollow fibre membranes are Polysulfone, which gives their properties very high mechanical and thermal resistance. These fibres can be used on hot water systems and can withstand heavy use without altering the performance. Figure 2 shows a photograph of the Microfilter and Figure 3 its block diagram .

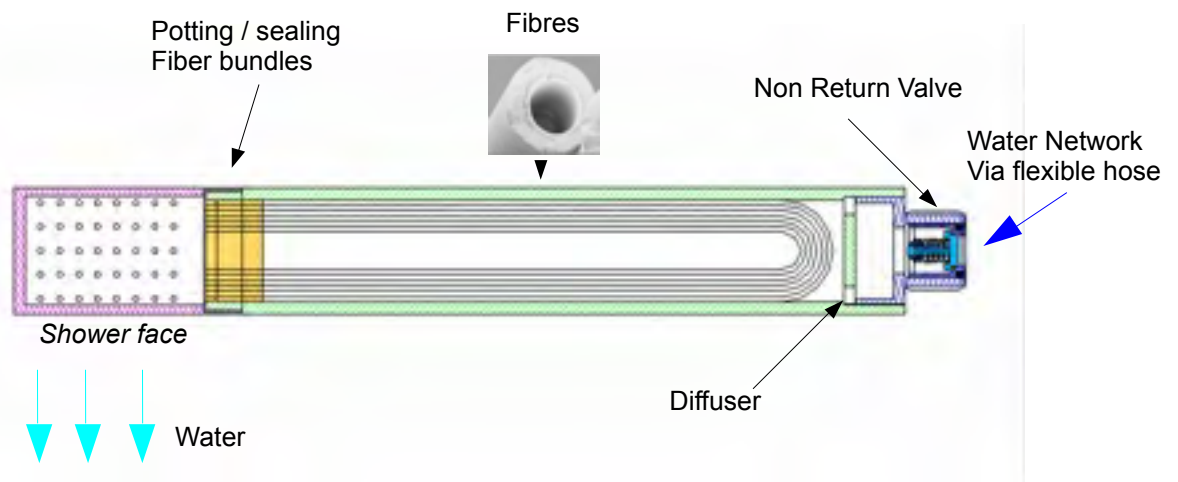*Figure 2: Photograph of the Challis Microfilter shower (front and back)*

Potting / sealing Fiber bundles

Fibres

Non Return Valve

Water Network Via flexible hose

Shower face

Water

Diffuser

Figure 3 : Diagram of the Challis MicroFilter

Note: A check valve is inserted into the connection port / input avoid back-contamination in the water system.

Technical Data

Maximum Operating Pressure	5 bar
Normal Operating Pressure	2-4 bar
Maximum Temperature Peak	70º C for 30 min on the maximum life of the filter
Maximum Operating Temperature	60º C
LOA	Environ 235 mm

Properties :

| Filter Medium		Hollow Fibre
Name of Polymer		Polysulphone
Bacterial Retention Threshold	µm	10
Outer Diameter Fibres	mm	45
Surface Filtration	cm²	2800

Part II. Validation of hydraulic performance

The objective of this test was to establish the typical flow of water at different water inlet pressures. The Microfilter was subjected to different pressures and the filtration rates were measured. The test device is installed on a water network with a pre filtration cartridge of UF-0.01 microns. This test is intended to demonstrate the ability of the flow shower-free water turbidity (NTU).

Water flow in l / min the following pressures in bar for Challis Microfilter Shower

reference pressure	0 bar	1 bar	2 bar	**3 bar**	4 bar	5 bar
Flow in l / min	0	7.1	14.2	**21.25**	28.4	35.5

The typical change in filtration rate as a function of the operating pressure is:
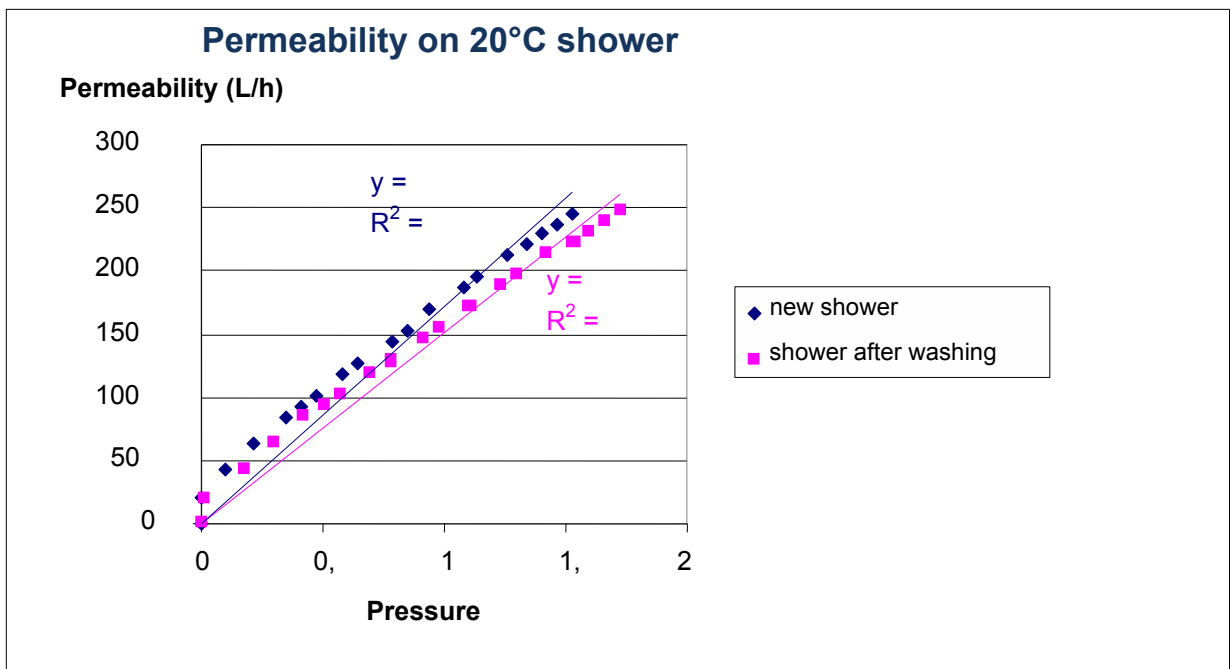
Part III. Retention test on strain-Brevundimonas diminuta

1. Objective

The test was used to evaluate the retention capacity for Challis Microfilter showers, suitable for in line filtration of the water network, with respect to Brevundimonas diminuta CIP 103020, under those conditions representative of the practice.

2. Test conditions

Strain test Brevundimonas diminuta CIP 103020
Maintenance medium and counting TS agar (Biomerieux)
Incubation conditions: 37 ° C under aerobic
Period: 04/12/06 to 12/12/06.

Levy Upstream sample - **T**

Levy Downstream sample - **ET**
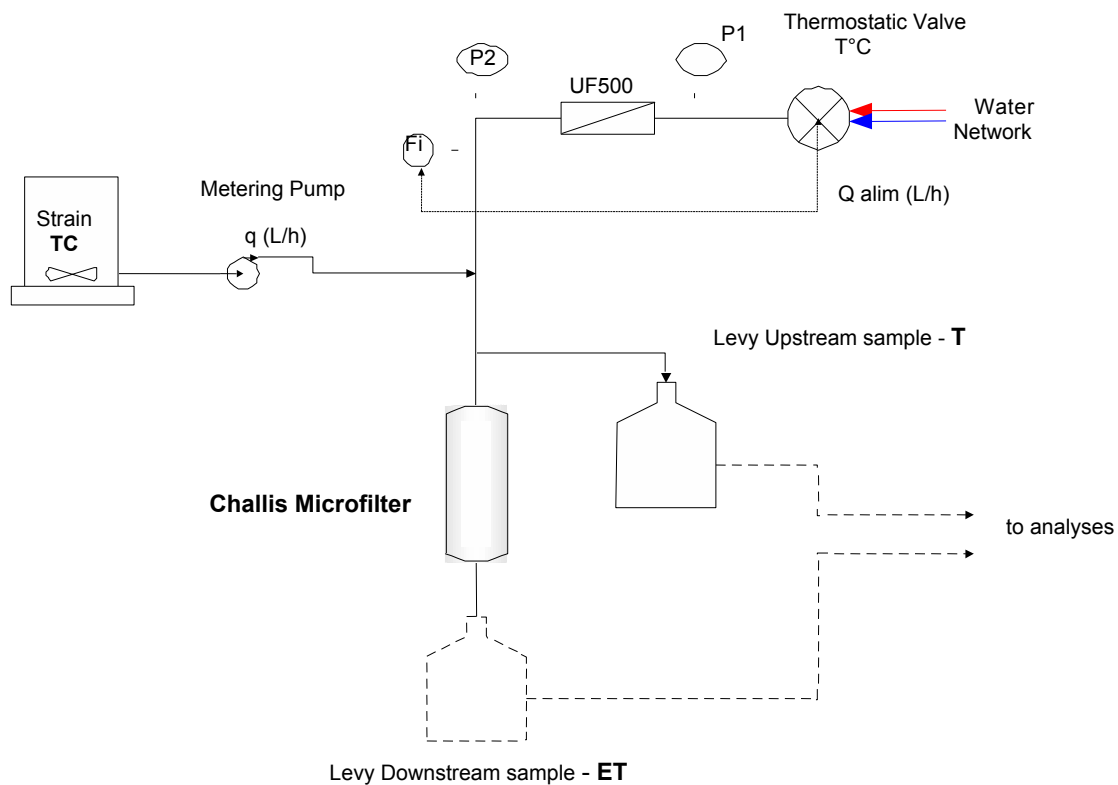
3. Method

Mains water is mixed with a thermostatic valve. Prefilter ultrafiltration UF500 can deliver the perfectly clear and free of suspended solids to the Microfilter test water.

The Challis shower, with a filter area of 2800 cm ², is positioned on a rack equipped with a mixer set at 18 to 20 ° C. The shower is then disinfected externally . Upstream of the spray, an injection system for the bacterial suspension is connected.

A suspension of Brevundimonas diminuta - measuring at least 2.108 bacteria / m is prepared extemporaneously, in order to obtain, during injection, a minimum load of 105/ml . The control suspension is analysed.

The water inlet valve is opened and the flow adjusted to 250 l / h. The water temperature is 25 ° C. At the end of the previous step the timer is started , which corresponds to time T0 . The solution is then Brevundimonas diminuta - injected at t0 10 min and at a flow rate of 0.25 l / h .

A T0 +30 min , a sample before the Challis Microfilter (T) and a sample after the Challis Microfilter (E) are carried out. The injection was stopped after 60 min and T0 thermostatic valve is closed. 3 identical tests were then performed in the same day.

An equal or greater bacterial count of 107UFC/cm ² of filter surface is observed in accordance with the standard ASTM F838-05.

4. Results

The following table shows the count results for all the tests Tc, T and E on the 4 challenges

	Challenge 1	Challenge 2	Challenge 3	Challenge 4
T : UFC/ml Upstream of the counting microfilter	1,9.10	3,1.10	3,8.10	3,6.10
Tc : UFC/ml Counting strain	5,0.10	3,8.10	5,0.10	4,4.10
Challenge total UFC	6,86.10	1,16.10	1,79.10	2,34.10
Challenge total CFU / cm ² filter area	2,75.10	4,64.10	7,16.10	9,36.10
E : Counting downstream microfilter permeate and 1000ml	**< 1 UFC/1000ml**	**< 1 UFC/1000ml**	**< 1 UFC/1000ml**	**< 1 UFC/1000ml**
log reduction	**>8,7**	**>8,6**	**>8,7**	**>8,6**

5. Conclusions

The results indicate, in test conditions, a complete retention of the strain-test-Brevundimonas diminuta on all samples and the four challenges made on the Challis Microfilter Shower.

Part IV. Retention test on-Legionella pneumophila strain

1. Objective of the test

The test aims to assess the ability of bacterial retention of the 0.10 μ microfilter and if the Challis MicroFilter single use shower is suitable for in-line filtration of tap water for showers, in relation to Legionella pneumophila-in conditions representative of those in practice.

2. Test conditions

Strain-test-Legionella pneumophila serogroup 2-14
Maintenance medium and counting: BCYE agar / agar GVPC
Incubation conditions: 37 ° C under aerobic
Period: 23 March 2010-25 May 2010

Conservation of the strain is carried out as specified in the standard NF EN 12353 September 2006.

3. Method

The mains water is mixed with a thermostatic mixer at 37 ° C. Mains water is pre-filtered on a 0.01 micron ultrafiltration cartridge to prevent any risk of external contamination which could disrupt the counting of Legionella bacteria. The strain is injected via a dosing pump (downstream of the pre-filter) in the water flow to the Challis Microfilter Shower.

A suspension of Legionella pneumophila-measuring at least 108 bacteria / ml is prepared extemporaneously in each test. The validation test covered a period of 63 days.

A challenge retention Legionella pneumophila, was made at the beginning of the test J +1 followed by 8 other challenges, the last having been made to J +63. For each challenge the injection duration of Legionella bacteria was 1 hour.

To simulate a normal use of the shower, sequences stopping filtration were controlled by a programmable controller for the duration of the test. By test day, 10 filtration time 5 min to 250 l / h (4.2 l / min) were programmed.

About 200 litres a day have been filtered, a total of about 12.5 m3. Test period was 63 days for a filtration area of 2800 cm ².
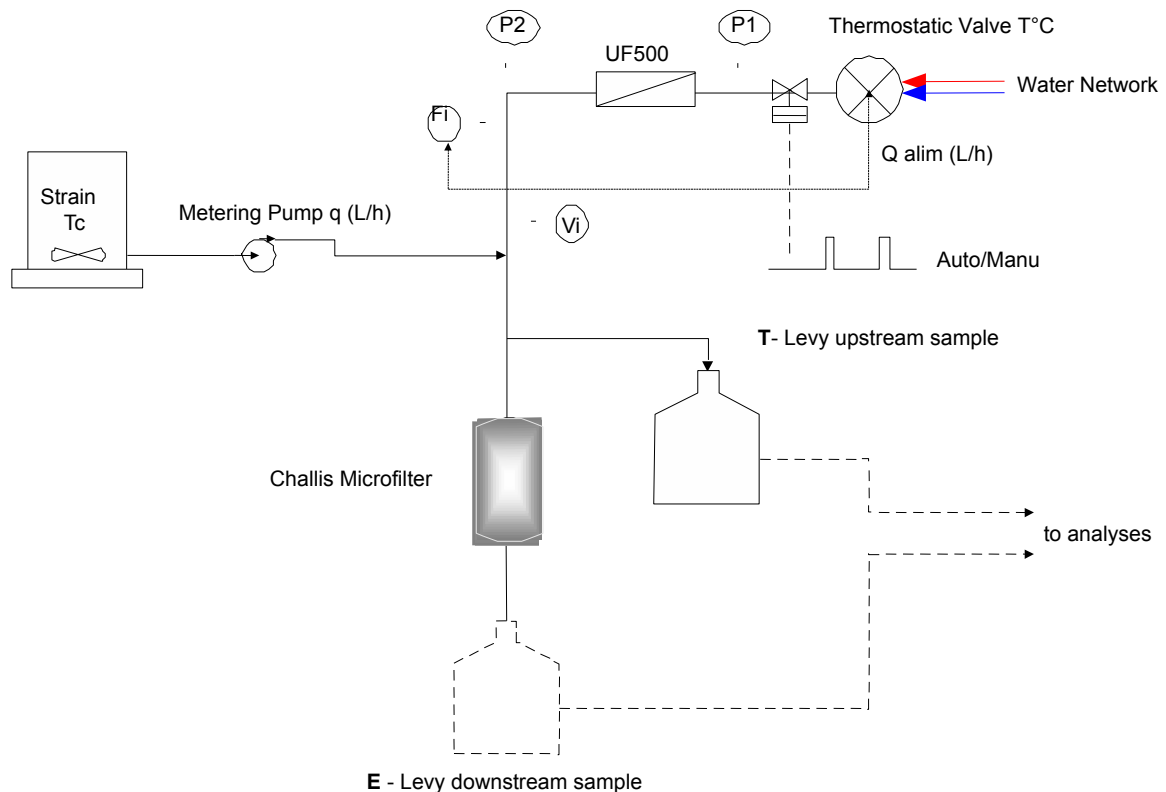
For each challenge, the minimum load of bacteria brought on the membrane filter surface was observed. It is at least ≥107 CFU / cm ² of filter surface in accordance with the standard **ASTM F838-05**.

The strain is injected via a dosing pump (downstream of the pre-filter) in the water flow to the Microfilter. The Water flow upstream Microfilter test is measured. The total flow is summed filtered with a water meter (Vi).

At each challenge, the nozzle connected to the pump is immersed in the vial containing 500 ml of bacterial suspension under magnetic stirring. The injection system is started in order to spread the bacterial suspension on the inside of the circuit (0.25L / h). A count of the suspension control (Tc) is made.

The steps of the challenge are:

Clean the head of the shower with a disinfectant wipe.

A. At t = t0: Put the system in manual mode (open the valve and stop sequencing).
B. At t = t1, the bacterial solution injected with the metering pump to the injection set speed.
C. At t = t2, at the same time perform a sampling of the upstream water (T) and a sample of the water downstream of the microfilter (E) in sterile vials.
D. At t = t3, stop the injection of bacteria.
E. At t = t4, return the system to automatic position.

The table below lists all the parameters of the challenge.

Settings	Units	Values
Feed Rate	Q l/h	250
Injection Speed	q (l/h)	0,25
Legionella strain concentration	[C_s	10
Inlet concentration microfilter	[C_e	10
Total number of CFU during (t2-t1) challenge	UFC	2.10
Minimum number of PDUs for each challenge and per cm ² of filter surface	UFC/cm²	**≥10**
t_1	min	10«
t_2	min	70«
t_3	min	71«
t_4	min	100
Temp	T °C	25

The micro filter shower has never been disinfected by back washing of the membrane during the test period.
At the end of 63 days, the amount equivalent to 9 challenges had therefore accumulated on the membrane surface.
The table on page 12 reports the results of the 9 challenges made during these 63 days. At the end of the tests the Microfilter kept an apparent permeability greater than 75% of the initial permeability.

4. Results

Sequence Challenges (from J-0)	J+1	J+7	J+14	J+21	J+31	J+35	J+49	J+56	J+63
Tc: UFC/ml (Enumeration of the suspension)	$2,9.10_8$	$6,5.10_7$	3.10_8	$2,6.10_8$	$3,1.10_8$	$3,3.10_8$	$5,2.10_8$	$4,1.10_8$	$3,9.10_8$
Counting upstream microfilter T:UFC/ml	25.1_5	$1,10_5$	$4,5.10_5$	$5,5.10_5$	$9,3.10_5$	$2,3.10_5$	$1,3.10_5$	$1,6.10_6$	$1,6.10_6$
Feed rate (at the beginning of the challenge)	250 L/h								
Challenge total (UFC)	$6.3.10^{10}$	$2,5.10^{10}$	$1,1.10^{11}$	$1,4.10^{11}$	$2,3.10^{11}$	$5,8.10^{10}$	$3,3.10^{11}$	$4,0.10^{11}$	$4,0.10^{11}$
Challenge total UFC/cm²	$2,5.10_7$	1.10_7	$4,5.10_7$	$5,5.10_7$	$9,3.10_8$	$2,3.10_7$	$1,3.10_8$	$1,6.10_8$	$1,6.10_8$
Enumeration of Legionella pneumophila in downstream microfilter permeate per 100 ml E:UFC/100ml	1 UFC/100 ml								
Log reduction Legionella pneumophila (Log T/E)	>7,4	>7,0	>7,6	>7,7	>8,0	>7,4	>8,1	>8,2	>8,2

5. Conclusions

The results indicate, in test conditions, a complete retention of the strain-pneumophila Legionella test for all periods levies on the Challis MicroFilter Shower until D +63.

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