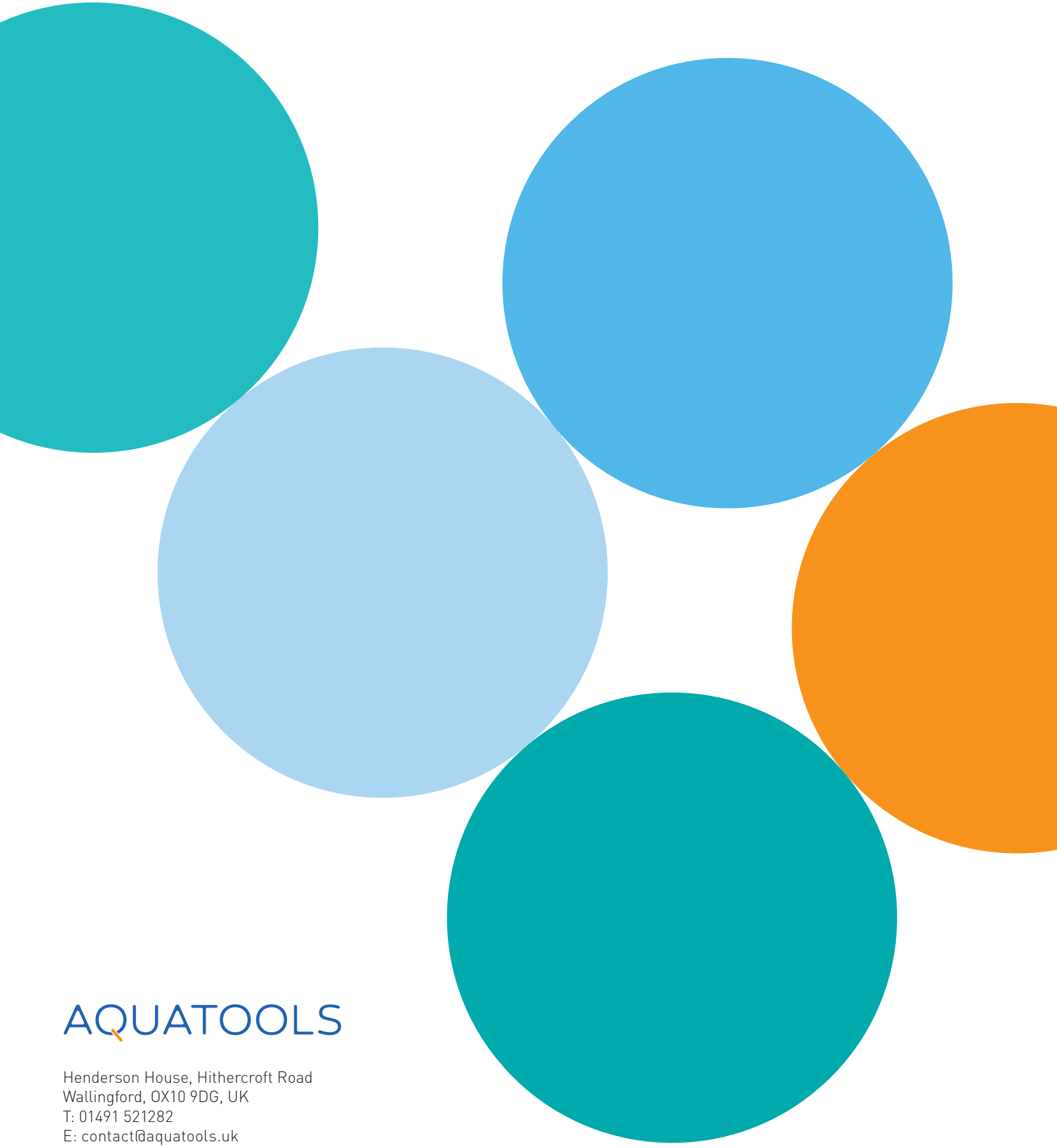
TECHNICAL & SCIENTIFIC VALIDATION GUIDE

FILT'*RAY* Compact sterile and non-sterile point-of-use filters for 1, 2, 3 & 4 months

Screw-on shower head filters; laminar and shower flow tap filters

AQUATOOLS



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1. INTRODUCTION

This technical and scientific validation guide presents all **the safety and performance characteristics of the FILT'*RAY* Compact** single use point-of-use filters developed in France by AQUATOOLS.

The range of FILT'*RAY* Compact single use point-of-use filters is intended to be used to obtain **water free from bacteria** to protect immuno-compromised patients.

Recommended by hygiene professionals in biological risk management and the prevention of nosocomial diseases, they provide an immediate barrier against waterborne germs *(Legionella pneumophila, Pseudomonas aeruginosa, Aspergillus, etc.)*.
FILT'*RAY* Compact single use point-of-use filters are designed to deliver bacteriologically controlled water (type Q.2.1 - Water Guidelines for Healthcare Facilities).

These environmental control measures are used to protect patients and/or residents from waterborne micro-organisms.

FILT'*RAY* Compact single use point-of-use filters are available in sterile and non-sterile versions. They have Sanitary Conformity Certificates (ACS) and International certification, including KTW, WRAS and KIWA*
(*certification pending).

1.1 FILT'*RAY* COMPACT SCREW-ON SHOWER HEAD AND TAP FILTERS PRODUCT OVERVIEW

A range of uniformly designed filters is available in the following formats:
- Hand held shower head filters - screw directly onto a shower hose,
- Tap filters with laminar or shower flow, connect onto the tap/mixer spout or fixed shower head using a push-fit connector.

FILT'*RAY* Compact filters are available in **sterile** or **non-sterile versions.**

All filters in the FILT'*RAY* Compact range demonstrate resistance to premature clogging and ensure high-performance filtration with a comfortable flow rate for users.

The ultra-resistant tubular micro-filtration membrane is sterilising grade and preserves the organoleptic characteristics of the water.

The filter cartridge is located at the end of the filters to minimize the volume of filtered stagnant water after use. All filters in the FILT'*RAY* Compact range are cylindrical and the cartridge is welded using an ultrasonic welding technique. This assembly concept allows the same tests, described below, to be performed on both shower head and tap filters.

1.2 FILT'*RAY* COMPACT STERILE & NON-STERILE FILTER REFERENCES

References	FILT'*RAY* COMPACT shower flow tap filters
AT20150	1-month - FILT'*RAY* Compact tap filter - sterile
AT20250	2-month - FILT'*RAY* Compact tap filter - sterile
AT20350	3-month - FILT'*RAY* Compact tap filter - sterile
AT20450	4-month - FILT'*RAY* Compact tap filter - sterile
AT30150	1-month - FILT'*RAY* Compact tap filter - non-sterile
AT30250	2-month - FILT'*RAY* Compact tap filter - non-sterile
AT30350	3-month - FILT'*RAY* Compact tap filter - non-sterile
AT30450	4-month - FILT'*RAY* Compact tap filter - non-sterile
References	FILT'*RAY* COMPACT laminar flow tap filters
AT20151	1-month - FILT'*RAY* Compact tap filter - sterile
AT20251	2-month - FILT'*RAY* Compact tap filter - sterile
AT20351	3-month - FILT'*RAY* Compact tap filter - sterile
AT20451	4-month - FILT'*RAY* Compact tap filter - sterile
AT30151	1-month - FILT'*RAY* Compact tap filter - non-sterile
AT30251	2-month - FILT'*RAY* Compact tap filter - non-sterile
AT30351	3-month - FILT'*RAY* Compact tap filter - non-sterile
AT30451	4-month - FILT'*RAY* Compact tap filter - non-sterile
References	FILT'*RAY* COMPACT shower filters
AT20161	1-month - FILT'*RAY* Compact shower filter - sterile
AT20261	2-month - FILT'*RAY* Compact shower filter - sterile
AT20361	3-month - FILT'*RAY* Compact shower filter - sterile
AT20461	4-month - FILT'*RAY* Compact shower filter - sterile
AT30161	1-month - FILT'*RAY* Compact shower filter - non-sterile
AT30261	2-month - FILT'*RAY* Compact shower filter - non-sterile
AT30361	3-month - FILT'*RAY* Compact shower filter - non-sterile
AT30461	4-month - FILT'*RAY* Compact shower filter - non-sterile

The devices are packaged in boxes of 10 units and can be used within 3 years of the date of manufacture (see expiry date).

1.3 FILT'*RAY* COMPACT POINT-OF-USE SCREW-ON SHOWER HEAD AND TAP FILTERS PERFORMANCE CHARACTERISTICS

To optimise the size and the amount of raw materials used, the FILT'*RAY* Compact point-of-use filters' micro-filtration cartridges have been adapted to the length of their lifespan after installation (1, 2, 3, or 4 months).

This does not, however, compromise the clinical, biological, and technical performance of the devices offered compared to the FILT'*RAY* range, since the micro-filtration cartridges also provide tubular membrane filtration with **a porosity of 0.1 µm (nominal-rated)**, while maintaining the same level of permeability and resistance to transient pressure.

FILT'*RAY* Compact filters are designed to operate when the system water pressure is between 1 and 5 bar, and the water temperature is between 5°C and 42°C. The measured flow rate at the outlet for each filter is as follows:

FILT'*RAY* Compact filters					
	Pressure (bar)				
	1	2	3	4	5
Flow rate (lpm) - 1M Tap	2.7	4.0	5.1	6.0	7.0
Flow rate (lpm) - 2M Tap	3.0	4.4	5.5	6.5	7.4
Flow rate (lpm) - 3M Tap	4.6	6.6	7.6	8.6	9.4
Flow rate (lpm) - 4M Tap	4.6	6.5	7.6	8.5	9.4
Flow rate (lpm) - 1M Shower head	6.0	8.8	11.2	12.8	13.0
Flow rate (lpm) - 2M Shower head	6.0	8.8	11.2	12.8	13.0
Flow rate (lpm) - 3M Shower head	6.2	9.2	11.2	12.4	13.2
Flow rate (lpm) - 4M Shower head	6.5	9.6	11.8	13.2	14.1

1.4 DESIGN, MANUFACTURE & MARKET AVAILABILITY

FILT'*RAY* Compact point-of-use filters were **developed in northern France**, in Friville. AQUATOOLS is ISO 14001 certified for its sustainable development approach, which means that during the design phase, a product life cycle analysis is conducted at the beginning and end of the design process.

In 2022, a CSR (Corporate Social Responsibility) initiative was launched, and numerous projects are underway within the company's teams, enabling the company to achieve **a Platinum EcoVadis medal**.

We are constantly launching actions with the support of our partners so that we can continue to improve and advance our EcoVadis certification together.

FILT'*RAY* Compact point-of-use filters are manufactured at a production site that meets **ISO 9001 and ISO 13485 quality standards**.
They follow strict, identical manufacturing processes and are manufactured in a bacteriologically -controlled environment.

To ensure the production environment is controlled, the processes are carried out in an **ISO Class 8 cleanroom environment** (reference standard: ISO 14644-1).

The application of the quality management system involves rigorous controls such as: individual checks of the micro-filtration cartridges; validation of injected thermoplastic parts; physical resistance and sealing integrity of individual packaging sachets; and checks to ensure traceability.

2. SUMMARY & CONCLUSIONS

- **Membrane sterilising grade validation at 0.1µm nominal-rated**
  FILT'*RAY* Compact point-of-use filters retain up to **10^7 CFU** per filtration surface area for *Brevundimonas diminuta, Pseudomonas aeruginosa* and *Legionella pneumophila* bacteria commonly found in drinking water. Test results were obtained following a bacterial challenge using an inoculum to verify the sterilising grade of the micro-filtration membrane at 0.2µm absolute-rated, according to **ASTM F838**.

- **Microbial retention during intermittent use of 1, 2, 3 or 4 month filters**
  FILT'*RAY* Compact point-of-use filters retain up to **10^7 CFU** per filtration surface for *Brevundimonas diminuta, Pseudomonas aeruginosa* and *Legionella pneumophila* bacteria during bacterial retention tests carried out according to the requirements of **ASTM F838** for each of the post-installation lifespans **(1, 2, 3 or 4 months).**

- **Managing the risk of bacterial development**
  FILT'*RAY* Compact point-of-use filters have smooth surfaces (mirror-polished finish), and are constructed in a single piece without any corners where bacteria can accumulate.
  The device must be disinfected in accordance with the procedures in place at the healthcare facility.

- **Flow rates at different water pressures**

FILT'*RAY* Compact filters					
	Pressure (bar)				
	1	2	3	4	5
Flow rate (lpm) - 1M Tap	2.7	4.0	5.1	6.0	7.0
Flow rate (lpm) - 2M Tap	3.0	4.4	5.5	6.5	7.4
Flow rate (lpm) - 3M Tap	4.6	6.6	7.6	8.6	9.4
Flow rate (lpm) - 4M Tap	4.6	6.5	7.6	8.5	9.4
Flow rate (lpm) - 1M Shower head	6.0	8.8	11.2	12.8	13.0
Flow rate (lpm) - 2M Shower head	6.0	8.8	11.2	12.8	13.0
Flow rate (lpm) - 3M Shower head	6.2	9.2	11.2	12.4	13.2
Flow rate (lpm) - 4M Shower head	6.5	9.6	11.8	13.2	14.1

Table 1: *Typical flow rate variation (lpm) depending on the water inlet pressure.*

- **Maximum operating temperature and pressure**
  FILT'*RAY* Compact filters are designed to operate when the system water pressure is between 1 and 5 bar, and the water temperature is between 5°C and 42°C.

- **Expiry date**
  FILT'*RAY* Compact filters can be used within 3 years of the date of manufacture (see expiry date).

  FILT'*RAY* Compact filters have a lifespan of 1, 2, 3 or 4 months after the date of installation, depending on the model chosen.

1. INSTANTANEOUS MICROBIAL CHALLENGE DESIGNED TO VERIFY THE STERILISING GRADE OF THE FILTRATION MEMBRANE AT 0.1µm NOMINAL-RATED

BREVUNDIMONAS DIMINUTA, PSEUDOMONAS AERUGINOSA & LEGIONELLA PNEUMOPHILA

1.1 INTRODUCTION

The microbial challenge is carried out using the **ASTM F838** standard – "*To determine the bacterial retention capability of filter membranes used for filtering liquids*" to verify the sterilising grade of the 0.1µm membrane.
This method determines the bacterial retention characteristics of the micro-filtration membrane using *Brevundimonas diminuta. Pseudomonas aeruginosa* and *Legionella pneumophila* were also used during a liquid challenge conducted at an external laboratory.

1.2 METHODOLOGY

The point-of-use filters are evaluated with a bacterial concentration of 10^7 CFU (log 7) for effective micro-filtration surface area, in accordance with **ASTM F838**.

The bacterial challenge tests are conducted with three strains of bacteria commonly found in drinking water systems.

BREVUNDIMONAS DIMINUTA (CIP 103020) is the smallest known bacterium found in drinking water systems. It is a bacillus measuring 0.2µm. This Gram-negative bacillus does not form spores (non-sporulating). It is frequently found in hospital settings and can cause nosocomial infections in immuno-compromised patients.

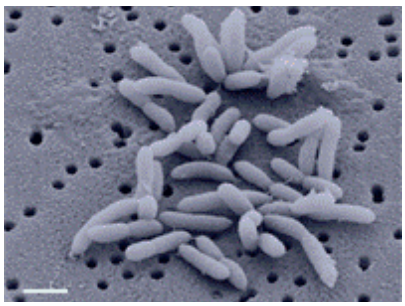


Fig. 1 below demonstrates the test assembly**.**

The filters were tested during the design phase according to the established validation plan, and they are continually tested to ensure the filtration performance remains effective. The laboratory protocol is as follows: A 5-litre pressure vessel is filled with sterile buffered water. An inoculum of *Brevundimonas diminuta* is introduced into the vessel and adjusted to obtain a concentration > 1 x 10^7 CFU. The sample is collected aseptically to confirm the challenge level. The entire inoculum is filtered through the filters at a flow rate of 2 to 4 litres per minute. The filter is collected on a 0.2µm membrane and incubated on agar for at least 48 hours.

Filtration performance is measured using the following formula: Filter performance = Log (N_0) - Log (N). A result greater than log 7 ensures filtration of more than 99.99% of bacteria.

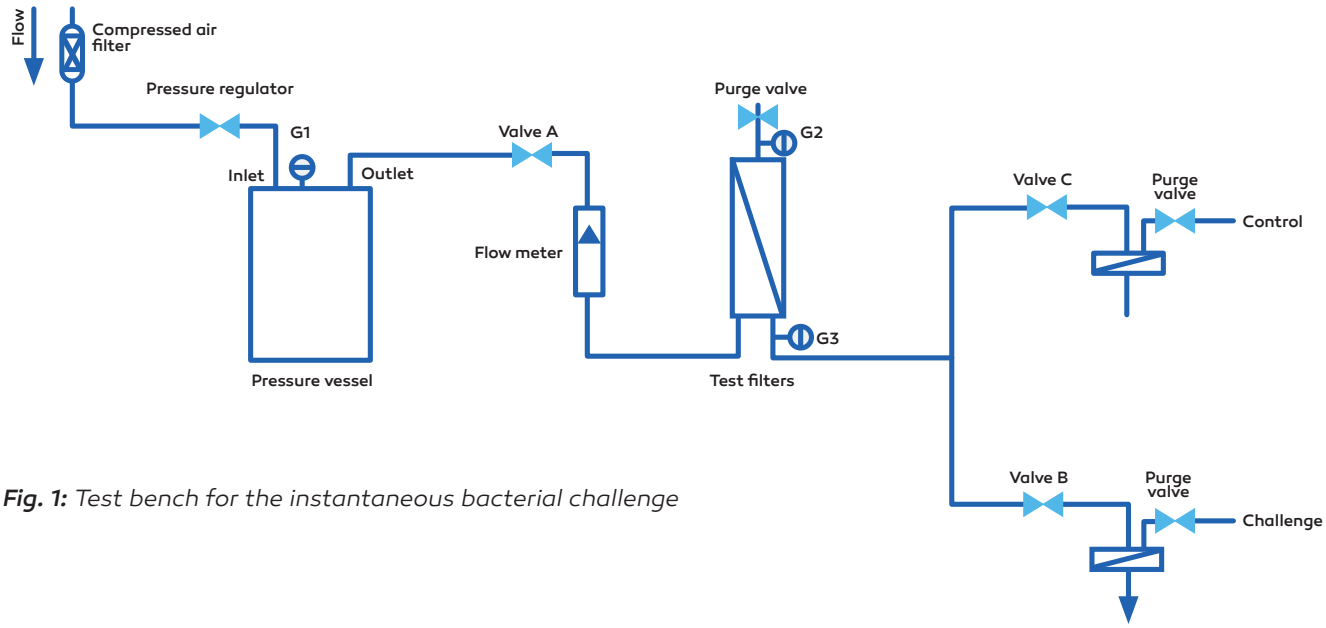
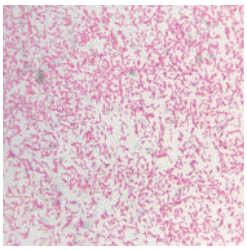


Fig. 1: *Test bench for the instantaneous bacterial challenge*



PSEUDOMONAS AERUGINOSA (CIP 82118) is a Gram-negative bacterium that takes the form of a bacillus with a flagellum; it does not sporulate (non-sporulating). It is often found in hospital environments, particularly in water systems. This bacterium is known to reproduce rapidly, colonising drinking water systems by creating biofilms, which provide a source of nutrients for other bacteria. Like *Brevundimonas diminuta*, it can cause nosocomial infections in immuno-compromised patients.
It is widely accepted that the *Pseudomonas aeruginosa* bacterium is very frequently found in drinking water systems. It reproduces and disperses very easily, providing a breeding ground for other pathogenic bacteria.

LEGIONELLA PNEUMOPHILA (CIP103854T) is an intracellular Gram-negative bacillus which does not sporulate (non-sporulating). It is heat-resistant, and it develops in hot water systems where the temperature is below 50°C and in cooling circuits with a cooling tower.
The bacterium is pathogenic to humans and is transmitted through the inhalation of contaminated aerosols under certain environmental conditions.
Legionnaires' disease causes lung infection and pneumonia.
It can be fatal for at-risk individuals, such as immuno-compromised patients, the elderly, or those with breathing difficulties.

CIP: Collection of the Institut Pasteur

1.3 RESULTS

The results obtained, see Table 2, confirm the filters' efficiency in retaining the various micro-organisms under normal use.

Strain	Test report number	Batch number	Product reference	Product type	Filtration performance	Quantity of bacteria found
B. Diminuta	PUB22A00170	1510211	AT30150	1-month tap cartridge	Log 7.65	0
B. Diminuta	PUB22A00172	1510211	AT30150	1-month tap cartridge	Log 7.65	0

Table 2: *Instantaneous microbial challenge retention in accordance with ASTM F838 standard on the smallest micro-filtration cartridges in the range, namely the 1-month tap.*

1.4 CONCLUSION

FILT'*RAY* Compact filters comply with ASTM specifications as they retain sufficient bacteria to confirm a result greater than 10^7 (=log 7) CFU.

These performance tests are periodically reverified to confirm the filtration performance of our products. We recommend disinfecting our filters regularly, following the protocols established by the healthcare facility.

In addition, we have implemented the following features to minimise bacterial development:
- A protective skirt to prevent direct contact between the outlet diffuser and any surface,
- A tilted connector to direct the jet away from the waste to reduce retro-contamination from splashing.

1.5 NORMATIVE REFERENCES

American Standard Test Method (ASTM) F838: *Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration.*

2. INSTANTANEOUS MICROBIAL CHALLENGE AT 1, 2, 3 & 4 MONTHS

2.1 INTRODUCTION

This new series of tests, based on the ASTM F838 test standard described above, aims to confirm the membrane integrity and microbial retention capacity of FILT'*RAY* Compact filters during use for up to 1, 2, 3 and 4 months.

2.2 METHODOLOGY

A volume of water equivalent to normal usage conditions is passed through the filter to determine its effectiveness in terms **of performance, bacterial retention capacity, resistance, and integrity.** Different water volumes are used to simulate lifespans.

FILT'*RAY* Compact filters connected to the test bench **(Fig. 2)** filter volumes of 3,000 to 12,000 litres of water at 3 - 5 bar pressure to simulate maximum usage periods of 1, 2, 3, and 4 months.
The water used for the test is from the distribution system and is then recycled (closed circuit).

In accordance with ASTM F838, the microbial challenge test is performed by an accredited external laboratory to validate the retention capacity of *Brevundimonas diminuta, Legionella pneumophila* and *Pseudomonas aeruginosa*.

ASTM F838 describes the test methods for *B. diminuta* only. We have applied the same methodology to verify the effectiveness of the filters for the target bacteria.

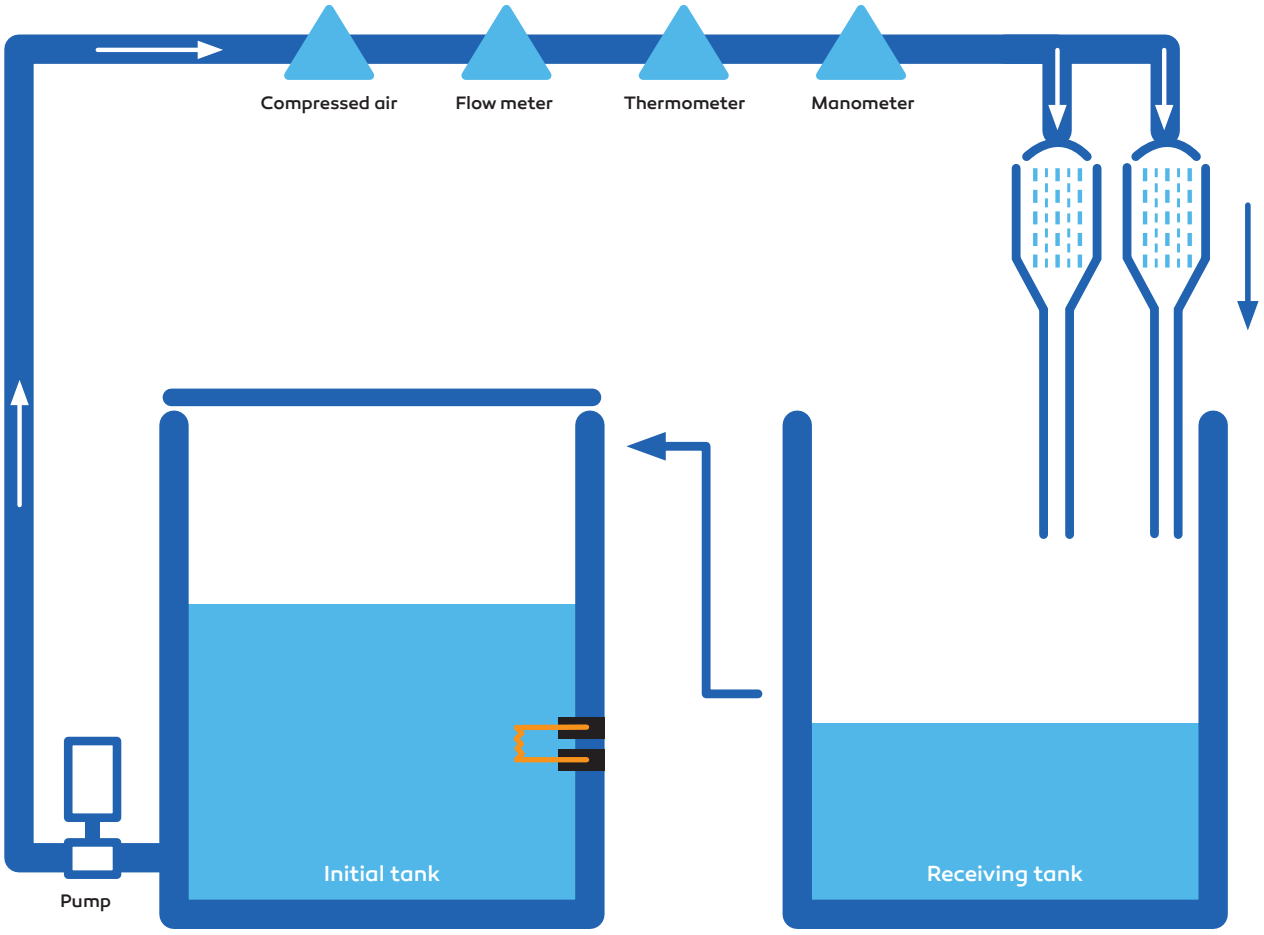


Fig. 2: *Test bench*

2.3 RESULTS

Table 3 shows the results obtained, confirming the high level of effectiveness in retaining various micro-organisms using FILT'*RAY* Compact filters after use.

Strain	Batch number	Filter performance	1-month	2-month	3-month	4-month
B. diminuta	1701211	Log 10.45	O			
B. diminuta	2301211	Log 10.59		O		
B. diminuta	37006211	Log 10.72			O	
B. diminuta	43006211	Log 8.71				O
P. aeruginosa	1305211	Log 10.22	O			
P. aeruginosa	2303211	Log 10.11		O		
P. aeruginosa	37006211	Log 10.83			O	
P. aeruginosa	43006211	Log 10.80				O
L. pneumophila	1109211	Log 10.85	O			
L. pneumophila	2108211	Log 10.85		O		
L. pneumophila	43006211	Log 11.34				O

Table 3: *ASTM F838 validation test for FILT'RAY Compact filters with 1, 2, 3 & 4-month lifespans.*

2.4 CONCLUSION

The filters comply with ASTM F838 specifications. Test results demonstrate that the filtration performance meets the normative requirements, i.e., >log 7.

2.5 NORMATIVE REFERENCES

American Standard Test Method (ASTM) F838: *Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration.*

3. MANAGING THE RISK OF BACTERIAL DEVELOPMENT

During the design phase, the following measures were implemented to reduce the risk of bacterial growth as much as possible:

- Smooth surfaces
- "Mirror polished" finish
- No ridges
- Protective skirt around the outlet diffuser
- Tilted connector to adjust the filter position

In addition, a product cleaning protocol is provided by the manufacturer.
Several cleaning products can be used on FILT'*RAY* Compact point-of-use filters.

1. FLOW RATE VARIATIONS AS A FUNCTION OF WATER PRESSURE

1.1 INTRODUCTION

These tests define the water flow rates and the range of use of FILT'*RAY* Compact filters at different water pressures.

1.2 METHODOLOGY

FILT'*RAY* Compact filters are subjected to flow rate/pressure tests. The bench test **(Fig. 3)** allows for the range of filters to be tested. The water pressure is adjusted upstream and downstream of the system using a calibrated digital pressure gauge, and the filters connected to the test bench are pre-wetted.

The flow rate measurement is carried out after the water has flowed for a determined time period.

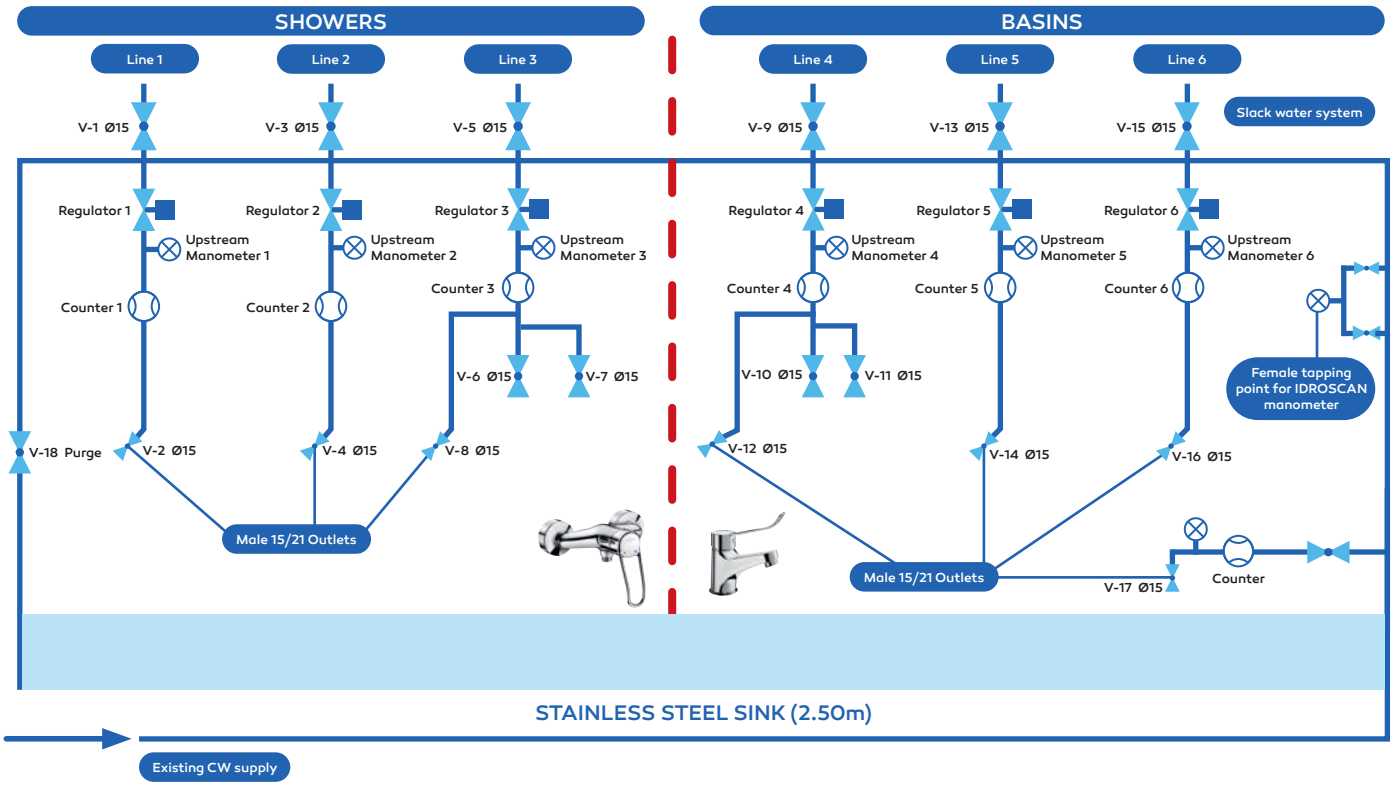


Fig. 3: *Test bench*

1.3 RESULTS

Table 4 indicates the flow rates obtained as a function of the water pressure at the inlet with FILT'*RAY* Compact filters connected to a mixer/tap.

FILT'*RAY* Compact filter					
	Pressure (bar)				
	1	2	3	4	5
Flow rate (lpm) - 1M Tap	2.7	4.0	5.1	6.0	7.0
Flow rate (lpm) - 2M Tap	3.0	4.4	5.5	6.5	7.4
Flow rate (lpm) - 3M Tap	4.6	6.6	7.6	8.6	9.4
Flow rate (lpm) - 4M Tap	4.6	6.5	7.6	8.5	9.4
Flow rate (lpm) - 1M Shower head	6.0	8.8	11.2	12.8	13.0
Flow rate (lpm) - 2M Shower head	6.0	8.8	11.2	12.8	13.0
Flow rate (lpm) - 3M Shower head	6.2	9.2	11.2	12.4	13.2
Flow rate (lpm) - 4M Shower head	6.5	9.6	11.8	13.2	14.1

Table 4: *Flow rate variations as a function of the water pressure at the inlet. The water temperature is approximately 20°C.*

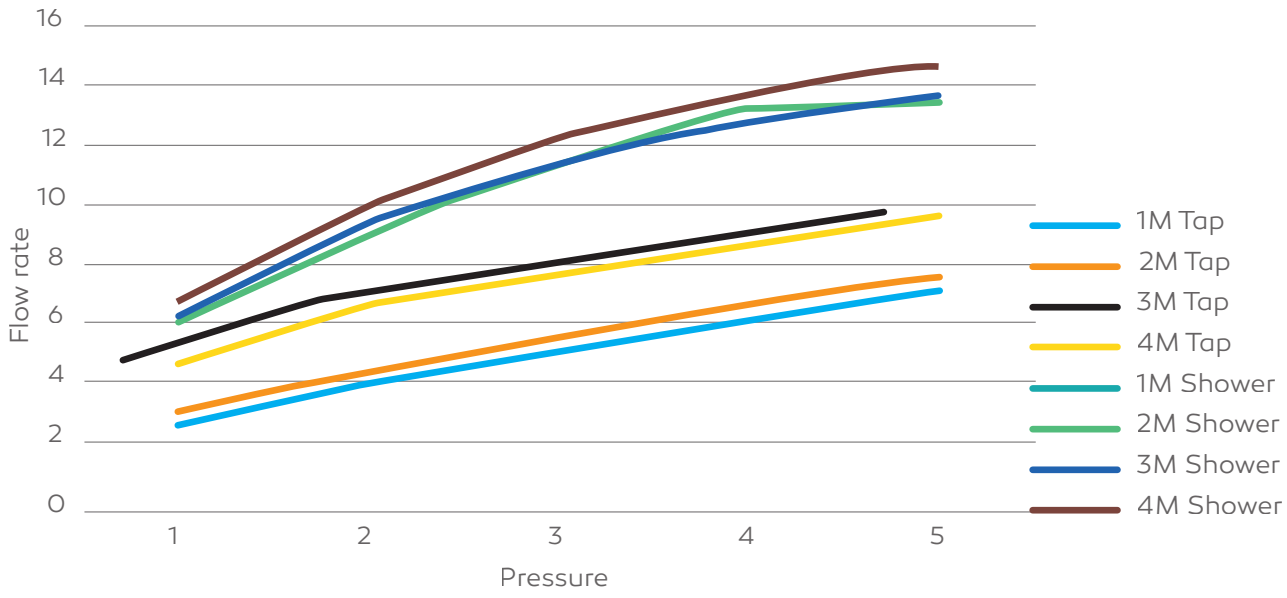


Fig. 4: *Flow rate variations as a function of the water pressure.*

1.4 CONCLUSION

FILT'*RAY* Compact shower head filters deliver water flow rates between **6 and 14.1 lpm**, and the tap filters deliver flow rates between **2.7 and 9.4 lpm** for pressures ranging from **1 - 5 bar**, with low-consumption taps. As part of our environmental strategy, the flow rates have been limited by design to reduce drinking water consumption.

2. MAXIMUM OPERATING TEMPERATURE & THERMAL SHOCKS

2.1 INTRODUCTION

This series of tests aims to confirm that FILT'*RAY* Compact filters can be used at a maximum temperature of **70°C throughout their lifespan.**

2.2 METHODOLOGY

A quantity of water equivalent to normal use is passed through the FILT'*RAY* Compact filter to determine its effectiveness in terms of performance, bacterial retention capacity, lifespan and resistance to extreme temperature conditions.

Thermal resistance test: the products are connected to the test bench ***(Fig. 2)*** and water at a temperature of 70°C is passed through the filter for 30 minutes to simulate a thermal shock. The water used is recycled mains-supply water. This test simultaneously evaluates the micro-filtration cartridge's resistance to temperature and its resistance to clogging during the simulated thermal shock.

A thermal shock is performed with the water temperature raised to 70°C at 3 bar for a period of 30 minutes ***(Fig. 2)***. A cartridge integrity test is performed according to ASTM F838 and verifies the filter's capacity to retain *Brevundimonas diminuta* after the thermal shock (see results table below).

2.3 RESULTS

The results of these tests ***(Table 5)*** confirm the integrity of the filter membrane after simulating a thermal shock at 70°C for 30 minutes.

Strain	Batch number	Filtration performance	1-month	2-month	3-month	4-month
B. diminuta	1703211	Log 10.26	0			
B. diminuta	2303211	Log 10.60		0		
B. diminuta	3510212	Log 11.36			0	
B. diminuta	4110215	Log 10.20				0

Table 5: ASTM F838 bacterial challenge test after 1, 2, 3 & 4 months of re-circulating hot water at 60°C and a thermal shock at 70°C.

2.4 CONCLUSION

The filters can withstand a temperature of 70°C for a cumulative period of 30 minutes during the duration of use.

3. RESISTANCE TO CHLORINE SHOCKS

3.1 INTRODUCTION

This series of tests aims to confirm that FILT'*RAY* Compact filters can withstand a minimum chlorine shock of 100 ppm for a duration of 1 hour for each month of their lifespan.
Example: 1M = 100 ppm / 1 hour
3M = 100 ppm / 3 hours

3.2 METHODOLOGY

A quantity of water equivalent to normal use is passed through the filter to determine its effectiveness in terms of performance, bacterial retention capacity, lifespan, and resistance to extreme operating conditions in contact with chemicals.
The products are connected to the test bench ***(Fig. 2)*** and chlorinated water at 100 ppm of free chlorine, and at a temperature of 38°C at 3 bar is passed through the filter for 1, 2, 3 and 4 hours respectively to simulate the maximum lifespan of 1, 2, 3 and 4 months.

The water used for the test is recycled chlorinated tap water (100 ppm).
This test evaluates the product's resistance to chlorine. A cartridge integrity test is performed according to ASTM F838 to verify the filter's capacity to retain *Brevundimonas diminuta* (see results table below). ***(Test bench Fig. 2)***

3.3 RESULTS

The results of these tests, in **Table 6**, confirm the integrity of the filters after chlorinated water at 100 ppm has passed through.

Strain	Batch number	Filtration performance	1-month	2-month	3-month	4-month
B. diminuta	1701211	Log 10.72	0			
B. diminuta	2303211	Log 10.65		0		
B. diminuta	31007212	Log 10.65			0	
B. diminuta	47006211	Log 11.20				0

Table 6: ASTM F838 bacterial challenge test after chlorine shocks.

3.4 CONCLUSION

FILT'*RAY* Compact can withstand repetitive chlorine shocks of 100 ppm/hour/month for the duration of use. The integrity of the filter is maintained throughout the simulated lifetime.

4. FILT'*RAY* COMPACT FILTER STERILISATION

FILT'*RAY* Compact filters are sterilised by gamma radiation.
The process is carried out by a certified supplier.

4.1 DETERMINING THE STERILISATION DOSE

The gamma irradiation dose is considered sterilising at a Sterility Assurance Level (SAL) of 10^{-6}. This means that the probability of the presence of a micro-organism after irradiation of the device must be 10^{-6}. The sterilising dose is established according to the VDmax 25 method to comply with ISO 11137:2.

The bacterial load, called bioburden, was determined on 10 FILT'*RAY* Compact from 3 different batches. Based on the average or highest load on the 10 filters, the validation dose is established using the ISO 11137:2 correspondence table.

10 FILT'*RAY* Compact filters from the same batch number were irradiated with the defined validation dose and then subjected to a sterility test.
An inoculate from the sterilised product was then placed in a culture medium and incubated for 14 days.

Results: **no bacterial colonies grew during the 14 days.**
The validation dose is therefore the sterilising dose.

4.2 RADIATION DOSE DISTRIBUTION MAPS

The pre-determined sterilisation dose is valid for one filter. When sterilising several filters simultaneously (e.g. a pallet) radiation dose distribution mapping is required.

Its purpose is to establish that all filters or boxes on the pallet receive the defined sterilisation dose. To do this, dosimeters are placed at various points on the pallet. These dosimeters measure the dose received in KGy to obtain a comprehensive map of the radiation distribution. This, therefore, defines the maximum and minimum dose required to irradiate the pallet while ensuring compliance with the sterilisation dose for each filter.
This validation is repeated three times for each type of load; this is the triple validation.

FILT'*RAY* Compact filters can then be sterilised routinely in accordance with the VDmax25 methodology in compliance with ISO 11137-2.

4.3 ROUTINE MONITORING

Once the sterilisation dose has been established, dose checks called "dose audits" are carried out every 3 months. The audit verifies that the filter's bacterial load is equivalent to that initially measured, and that the sterilisation dose is still sufficient to maintain the SAL at 10^{-6}.

Dose audits are carried out in accordance with **ISO 11137:1.**
A bioburden test is performed on 10 filters from the same batch number to verify that the bacterial load of the filter has not changed.

Ten additional filters from the same batch number are irradiated with the validation dose.
A sterility test is performed on these 10 irradiated filters. This test confirms the sterility of the filters and the sterilisation dose.

Continuously monitoring the microbiological contamination of the filters (bioburden) means that the sterilisation dose is constantly verified and ensures that the batches released are sterile.

5. EXPIRY DATE VALIDATION

To verify the **3-year expiry date of FILT'*RAY* Compact filters,** the filters undergo accelerated ageing. This test is performed in a temperature and humidity-controlled chamber.
The temperature and humidity of the chamber are monitored and regulated throughout the test.

- The integrity of the FILT'*RAY* Compact filter packaging is then tested.

6. PERFORMANCE RATING OF INDIVIDUAL PACKAGING

The purpose of this evaluation is to confirm that the packaging used for FILT'*RAY* Compact filters maintains the sterility of the devices in accordance with ISO 11607. A transport test is performed to simulate the transport conditions to the end customer. Various tests are then carried out to verify the integrity of the pouch using verified methods.

- Seal integrity verified by visual inspection of the bag
- Peel-ability test
- Seal strength test
- Leak test using injected air
- Leak test using injected ink

7. MEMBRANE INTEGRITY TEST

In addition to accelerated ageing tests, real-time ageing tests have been conducted since 2021. Every year, samples are sent to an accredited laboratory to verify the effectiveness of FILT'*RAY* Compact filters in producing germ-free water after three years of storage.
The accredited laboratory conducts bacterial retention tests for *Brevundimonas diminuta* in accordance with ASTM F838.

Conclusion :

- Three-year old FILT'*RAY* Compact filters are **completely effective at retaining *Brevundimonas diminuta*** during the ATSM F838 bacterial challenge, delivering water free from bacteria.
  Real-time ageing tests will continue to confirm these results.
- The individual packaging is intact and **maintains the sterility of the filter.**
- **The expiry date of** FILT'*RAY* Compact filters is **3 years.**

International regulations require materials in contact with drinking water intended for human consumption to be verified. FILT'*RAY* Compact filters are certified as compliant with regulatory microbiological and physicochemical requirements.

1. ACS CERTIFICATION - FRANCE: "ATTESTATION OF SANITARY CONFORMITY"

FILT'*RAY* Compact filters were subjected to **inertness tests.** These tests determine if **extractable substances are likely to be released into the water.** The filters were sent to an accredited laboratory. The evaluation was carried out according to the method described in standard XP P 41-280 "The effect of materials and articles on the quality of water intended for human consumption" by immersing the filter in water.

This assessment is carried out as part of the validation of sanitary conformity for materials that come into contact with water intended for human consumption (ACS).

A control device was used to measure several parameters:

- Organoleptic properties: smell and taste
- Chlorine demand: free and total chlorine consumption
- Physicochemical: conductivity and pH
- Total organic carbon
- Organic micro-pollutants: highly volatile halogenated hydrocarbons, volatile organic compounds.

Results: The permissible levels of extractable materials **were not exceeded**.
The results comply with the requirements **of Circular DGS/SD7A 2002 no. 571** dated 25 November 2002.

Conclusion :

- The FILT'*RAY* Compact range of filters has a certificate of sanitary conformity for materials for its micro-filtration tubular membrane.
- These certificates are valid for 5 years and are renewed with each cycle.
  Certificates are available on request from AQUATOOLS.

2. WRAS CERTIFICATION - UNITED KINGDOM: "WATER REGULATION ADVISORY SCHEME"

FILT'*RAY* Compact filters were tested according to **BS 6920** for the assessment of the suitability of non-metallic products exposed to drinking water and their effect on water quality. This standard requires a microbial inertness test, an extraction test, and hot water tests (45°C).

To comply with **BS 6920 part 2**, the following parameters were measured:

- **Growth of micro-organisms** over a period of one-and-a-half months: calculation of oxygen consumption indicating the presence of bacteria in chlorinated and non-chlorinated water
- **Smell and taste** of cold water at 23°C and hot water at 45°C in chlorinated and non-chlorinated water
- **Appearance of water** at 45°C: analysis of its colour and turbidity
- **Cytotoxicity** over a period of two days at 23°C and 45°C: extraction of harmful substances
- **Metal extraction** over a period of one day in water at 45°C

Results: The objective of these tests is to verify that the tap fitting will not alter the potability of the water. FILT'*RAY* Compact filters meet the conformity criteria set out in **BS 6920 parts 1 and 2** and are suitable for use with cold and hot water up to 45°C.

They are inert with respect to drinking water and do not alter its organoleptic characteristics (smell and taste); stimulate bacterial growth; or release harmful substances that could cause public health problems according to **BS 6920.**

These tests enable the application to be submitted to a committee which approved the WRAS certification. The certificates are available on request from AQUATOOLS.

3. KTW CERTIFICATION - GERMANY: "KUNSTSTOFFE UND TRINKWASSER - PLASTIC & DRINKING WATER"

KTW-BWGL

FILT'*RAY* Compact filters were tested **according to the KTW guidelines and the DIN EN1622** standard for assessing the conformity of polymers exposed to hot and cold drinking water. This approval process includes an extraction test, a taste test, and a register of permitted components.

Formulation phase: Study of the composition of all components used in the manufacture of FILT'*RAY* Compact filters and validation of their conformity.

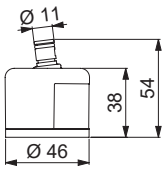
Test phase: To comply with the requirements of the **KTW guidelines and the DIN EN1622 standard**, the following parameters were measured:

- **Smell and taste** of water at 23°C and 60°C
- **Appearance of water** at 23°C and 60°C (colour and turbidity)
- **Growth of micro-organisms in the water** over 3 months by measuring the biomass of circulating water per unit of contaminated surface area - according to standard W270
- **Organic carbon** at 23°C and 60°C

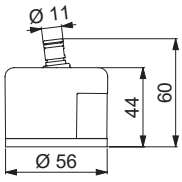
Results: FILT'*RAY* Compact filters meet the conformity criteria set out in **the KTW guideline** and the **DIN EN1622** standard, and are suitable for use with cold and hot water up to 70°C. They are inert with respect to drinking water and do not: cause any change in its organoleptic characteristics (smell and taste); stimulate bacterial growth; or release harmful substances that could cause public health problems.

4. FILT'*RAY* COMPACT FILTER DIMENSIONS

Sterile:



AT20150 - AT20151



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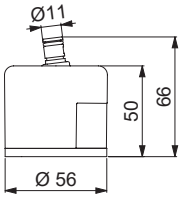

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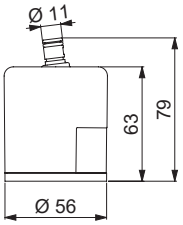

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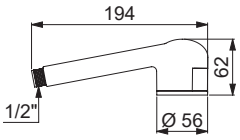
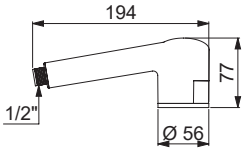


AT20161 - AT20261



AT20361-AT20461

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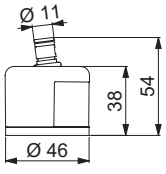

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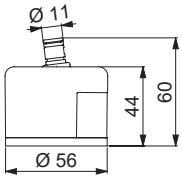
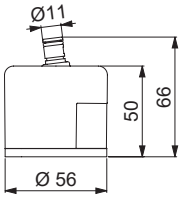


AT30250 - AT30251



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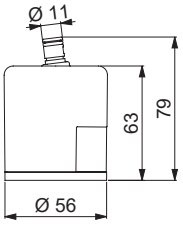

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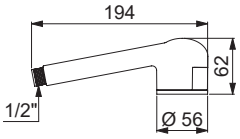

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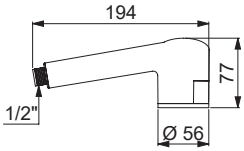
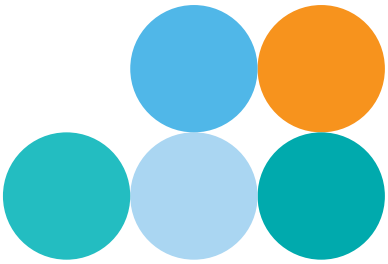


AT30361 - AT30461

5. APPENDIX : INTERNATIONAL VALIDATION TABLE FOR FILT'*RAY* COMPACT FILTERS DRINKING WATER AND BACTERIAL RETENTION PERFORMANCE

Type of test	ACS (France)	KTW (Germany)	WRAS (United Kingdom)
Formulation test	Yes	Yes	
Smell and taste of water - cold water	Standard: NF EN 1622 Yes at 23°C	Standard: DIN EN 1622 Yes 23°C	Standard: BS6920: suitability of non-metallic products in contact with water intended for human consumption - assessment of water quality (Part 2: Section 2.2.1) at 23°C. Tests performed on chlorinated and non-chlorinated water
Smell and taste of water - hot water		Standard: DIN EN 1622 Yes at 60°C	Standard: BS 6920: Part 2: Section 2.2.1. Tests performed on chlorinated and non-chlorinated water at 70°C
Appearance of water	Standard: ISO 7393-1 Yes, measures the consumption of chlorine and conductivity at 25°C	Standard: in accordance with KTW guidelines Yes, measures the colour and turbidity at 23°C and 60°C	Standard: BS 6920: Part 2: Section 2.3 Yes, measures the colour and turbidity at 70°C
Growth of micro-organisms		Standard: W270 Yes, circulating water between 9-15°C, measures the bioburden every 3 months (biofilm formation). Measures per unit of contaminated surface area	Standard: (BS 6920: Part 2: Section 2.4) Yes at 30°C for more than 1.5 months. Measures oxygen consumption T- MDOD (Mean dissolved oxygen difference)
Cytotoxicity	Standards: (XP P 41-250-3 and NF P 41-290) Yes at 20°C		Standard: (BS 6920: Part 2: Section 2.5). Yes, 2 days at 23°C and 70°C
Metal extraction	Standard: (XP P 41-250-2) Yes - mineral, organic, VOCs		Standard: (BS 6920: Part 2: Section 2.6) Yes at 70°C for heavy metals
TOC (Total organic carbon)	Standard: (NF EN 1484)	Standard: (DIN EN 1484) at 23°C/60°C	
Tests	Examination of the formulation of the material in contact with water at more than 50%: filtration membrane. Testing of the filtration membrane and the filter as a finished product	Examination of the formulation of the micro-filtration cartridge compound and its accessories (raw materials, dyes, etc.)	Migration test on the micro-filtration cartridge and its accessories (raw materials, dyes, etc.)
Test results	The migration test revealed no anomalies. The results comply with the requirements of Circular DGS/SD7A 2002 No. 571 dated 25 November, 2002	Certification obtained for 5 years	This product meets the criteria defined in BS 6920: Part 1: 2014"Specification" and is therefore suitable for use with hot water (up to 70°C) and cold water

AQUATOOLS



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