Validation report

# Baclyser® *neo* S

Safe water hygiene

by point of use sterile filtration

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# 1 Introduction

## 1.1 Aqua *free* – a certified company

Aqua *free* GmbH is a leading manufacturer of membrane filters for the medical sector. In addition to high-quality products for water hygiene, Aqua *free* also offers comprehensive services such as on-time delivery, filter exchange and documentation. Furthermore, Aqua *free* supports educational events, creates water safety plans for clinics and collaborates with numerous clinics and hygiene institutes on developments and solutions.

The Baclyser® *neo* S filters are disposable sterilizing grade filters. This validation report summarises investigations and tests to validate the use of these point of use filters for the provision of sterile filtered water in the medical field.

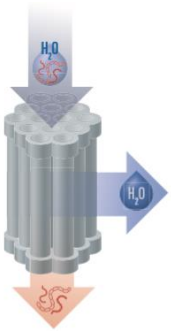
## 1.2 Water hygiene

Wherever drinking water pipes are installed, water can stagnate on the way from the mains house connection to the tapping outlet point, creating ideal living conditions for microorganisms. Stagnation is when water stands in the pipelines for several hours or even days [1]. Water-bound microorganisms, such as *Pseudomonas aeruginosa*, can attach to surfaces of pipes and hoses during this period and initiate biofilm formation. Biofilms provide an ideal habitat for microorganisms. Once the microorganisms have established themselves in the biofilm and multiplied, they are difficult to remove by chemical or thermal means and can reach the consumer when the water is dispensed [2,3]. This poses a health risk especially for immunocompromised and immunosuppressed people. It becomes particularly critical when the water-bound microorganisms are facultatively pathogenic, i.e. potentially disease-causing microorganisms such as legionella or pseudomonads [4]. A wide distribution of resistant phenotypes of *Pseudomonas aeruginosa* has been found in household water treatment systems. This presence of resistant pseudomonads is considered a major public health problem [5]. The transmission of these resistant strains from a contaminated tap to patients has also been documented [6].

With the help of membrane filters, it is possible to retain microorganisms contained in tap water and thus prevent transmission. The use of point of use membrane filters accordingly not only leads to the removal of water-bound pathogens, but also to the prevention of nosocomial hospital infections [7,8,9].

In this respect, the use of point of use membrane filters has established itself as the safest method of protection against water-bound microorganisms, particularly in the medical sector, and represents the current state of the art. Point of use membrane filters are thus used at the last point before water withdrawal (e.g. tap or shower) to provide preventive protection against water-bound microorganisms [10]. This preventive use is also recommended by the Robert Koch Institute (RKI) according to the german Infection Protection Act (IfSG) as a measure to protect against water-bound germs [11].

## 1.3 Principle of the hollow fibre membrane



The Baclyser® *neo* S sterilizing grade filters manufactured by Aqua *free* contain high quality hollow fibre membranes. The hollow fibres are fixed in the filter housing so that water is led to the hollow fibres and filtered through the pores of these fibres. The pore size of 0.2 µm provides reliable protection against water-bound microorganisms and, according to the definition of “sterile filtration”, leads to a reduction of at least 7 log levels of the test organism *Brevundimonas diminuta* (*B. diminuta*) per square centimetre of filter surface [12,13], i.e. a germ reduction of 99.99999 %.

## 1.4 Product presentation

### 1.4.1 Baclyser® *neo* S

The Baclyser® *neo* S is a disposable sterile filter for the shower and is available in 3 different operational lifespans (2M, 3M and 4M). With the help of the G1/2" screw thread, the shower filter can be used in place of the shower head of the existing shower fitting. The high-quality 0.2 µm hollow-fibre membrane used in the filter effectively retains microorganisms from the mains supply and thus offers reliable protection against nosocomial infections caused by legionella or pseudomonads, for example, to immunocompromised and immunosuppressed patients. This protection is guaranteed over the entire service life.

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# 2 Management Summary

## 2.1 Microbial testing

- The Baclyser® *neo* S filters meet the requirements of ASTM F838-20 in terms of a retention capacity of 7 log stages per square centimeter of filter surface for *Brevundimonas diminuta* (test germ of ASTM F838-20). In addition, the Baclyser® neo S filters have a retention capacity of 7 log steps per square centimeter of filter area for *L. pneumophila* and *P. aeruginosa.*

## 2.2 Clinical field study and laboratory study

- The Baclyser® *neo* S 2M provides reliable retention of water-bound bacteria over a period of 62 days.
- The Baclyser® *neo* S 3M provides reliable retention of water-bound bacteria over a period of 93 days.
- The Baclyser® *neo* S 4M provides reliable retention of water-bound bacteria over a period of 124 days.

## 2.3 Safety from retrograde protection

- The surface coating of the jet discs of the Baclyser® *neo* S filters with MetalSkin Medical® provides a strong antibacterial effect (reduction by 5 log levels) against *E. coli, P. aeruginosa* and *S. aureus* (ISO 22196 test germs) with the contact time of 24 hours specified in ISO 22196. Already after a contact time of 1 h (according to standard NF S90-700) a reduction of more than 2 log-steps is achieved for *P. aeruginosa* and *E. coli*. This provides a very high level of protection against retrograde contamination in the particularly critical area of the blasting disc.

## 2.4 Chemical influences

- The Baclyser® *neo* S filters can withstand a continuous addition of 10 ppm chlorine over their service life. Short-term dosing (1 h) of a high chlorine dose (400,000 ppm) is also possible.
- The Baclyser® *neo* S filters can withstand a continuous addition of 0.8 mg/l chlorine dioxide over their service life.

## 2.5 Physical influences

- The Baclyser® *neo* S filters can withstand an operating pressure of 5 bar.
- The Baclyser® *neo* S filters can withstand a dynamic load under real conditions with intense pressure surges.
- The Baclyser® *neo* S filters have a flow rate that increases with the pressure. At a line pressure of 1 - 5 bar, the flow rate of the Baclyser® *neo* S is around 6.7 to 17.1 l/min.
- The maximum operating temperatures of the Baclyser® *neo* S filters are 60°C. In the case of thermal disinfection of the piping system, the filters can also be exposed to a water temperature of 70°C for a short time (30 minutes).

## 2.6 Compatibilities

- The Baclyser® *neo* S filters meet the technical requirements for sterilizing grade filters.
- The Baclyser® *neo* S filters are compatible with the common surface disinfectants.

# 3 Microbial testing

For the Baclyser® *neo* S filters, Aqua *free* uses high-quality hollow fibre membranes that have a defined pore size of 0.2 µm and a safe bacteria retention capacity of 7 log levels. The microbiological characterisation of this retention is done with the smallest aquatic bacterium called *Brevundimonas diminuta*. According to the international standard ASTM F838-20, this requires a retention capacity for *B. diminuta* of at least $1\times10^7$ germs per $cm^2$ of effective filter area [12].

In addition, the retention is examined for *P. aeruginosa* and Legionella, which are typical facultative pathogenic water-bound microorganisms.

## 3.1 Bacterial retention of *B. diminuta*

### 3.1.1 Introduction

*B. diminuta*, with a diameter of 0.3 µm, is the smallest aquatic bacterium and is accordingly used by ASTM F838-20 as a surrogate organism for bacteria retention [12].

### 3.1.2 Material and methods

2 l of a bacterial suspension of *B. diminuta* (DSM 1635) with a minimum concentration of $10^7$ CFU/$cm^2$ is filtered through the sterilising grade filter. The filtrate is collected and analysed by quantitative culture. For this purpose, 0.1 ml of the filtrate is spread on blood agar in duplicate and incubated, and a defined volume is filtered using membrane filtration. The retention capacity of the filters is then calculated from the determined bacterial counts in the filtered suspension and the filtrate.

### 3.1.3 Results

Table 1 below shows the test results of the retention capacity of the 7 log levels of *B. diminuta* of the Baclyser® *neo* S filters.

**Table 1: Results of the retention of the 7 Log-levels of *B. diminuta* for Baclyser® *neo* S.**

| **Germ count in the solution to be filtered (2l)** | **$6{,}2 \times 10^{11}$ CFU** | | |
|---|---|---|---|
| **Germ count/$cm^2$ filter area** | **$1{,}44 \times 10^8$ CFU/ $cm^2$** | | |
| | **Cultural result in the filtrate [CFU/ 10 ml]** | | **Germ count 0,1 ml filtrate blood plate [CFU/ 0,1ml]** |
| Baclyser® *neo* S 2M | 0 | 0 | 0 |
| Baclyser® *neo* S 2M | 0 | 0 | 0 |
| Baclyser® *neo* S 2M | 0 | 0 | 0 |
| Baclyser® *neo* S 3M | 0 | 0 | 0 |
| Baclyser® *neo* S 3M | 0 | 0 | 0 |
| Baclyser® *neo* S 3M | 0 | 0 | 0 |
| Baclyser® *neo* S 4M | 0 | 0 | 0 |
| Baclyser® *neo* S 4M | 0 | 0 | 0 |
| Baclyser® *neo* S 4M | 0 | 0 | 0 |

### 3.1.4 Conclusion

The tests on the retention capacity confirm that the Baclyser® *neo* S guarantees a safe **germ retention of > 7 log levels of *B. diminuta* per square centimetre of filter surface**.

## 3.2 Bacterial retention of *P. aeruginosa*

### 3.2.1 Introduction

One of the most common nosocomial infections is *Pseudomonas aeruginosa* [13]. For this reason, the retention capacity of *P. aeruginosa* was also investigated for the Baclyser® *neo* S filters.

### 3.2.2 Material and methods

The retention determination was carried out according to 3.1.2. Instead of *B. diminuta*, *P. aeruginosa* (ATCC 15442) was used as the test microorganism.

### 3.2.3 Results

Table 2 shows the test results of the retention capacity of the 7 log levels of *P. aeruginosa* of the Baclyser® *neo* S.

**Table 2: Results of the retention of the 7 Log-levels of *P. aeruginosa* for Baclyser® *neo* S.**

| **Germ count in the solution to be filtered (2l)** | **$5{,}0 \times 10^{11}$ CFU** | | |
|---|---|---|---|
| **Germ count/cm² filter area** | **$1{,}16 \times 10^{8}$ CFU/ cm²** | | |
| | **Cultural result in the filtrate [CFU/ 10 ml]** | **Germ count 0,1 ml filtrate blood plate [CFU/0,1ml]** | |
| Baclyser® *neo* S 2M | 0 | 0 | 0 |
| Baclyser® *neo* S 2M | 0 | 0 | 0 |
| Baclyser® *neo* S 3M | 0 | 0 | 0 |
| Baclyser® *neo* S 3M | 0 | 0 | 0 |
| Baclyser® *neo* S 4M | 0 | 0 | 0 |
| Baclyser® *neo* S 4M | 0 | 0 | 0 |

### 3.2.4 Conclusion

These results show that ***Pseudomonas aeruginosa*** is retained by the **7 log levels** of the Baclyser® *neo* S.

## 3.3 Bacterial retention of *L. pneumophila*

### 3.3.1 Introduction

Other facultative pathogenic water germs are legionella, which can cause severe pneumonia. *Legionella pneumophila* is the most common facultative pathogen of Legionella and can cause legionellosis (also known as Legionnaires' disease), which can be fatal [14]. For this reason, the retention capacity of *L. pneumophilia* was also investigated for the Baclyser® *neo* S filters.

### 3.3.2 Material and methods

The retention determination was made in accordance with ASTM F838-20 (see 3.1.2). Instead of *B. diminuta*, *L. pneumophila* (SG 2-14) was used as the test microorganism.

### 3.3.3 Results

Table 3 shows the test results of the retention capacity of the 7 log levels of *L. pneumophila* of the Baclyser® *neo* S filters.

**Table 3: Results of the retention of the 7 Log-levels of *L. pneumophila* for Baclyser® *neo* S.**

| **Germ count in the solution to be filtered (2l)** | **$2{,}4 \times 10^{11}$ CFU** | | |
|---|---|---|---|
| **Germ count/cm² filter area** | **$5{,}58 \times 10^{7}$ CFU/ cm²** | | |
| | **Cultural result in the filtrate [CFU/ 10 ml]** | **Germ count 0,1 ml filtrate blood plate [CFU/ 0,1ml]** | |
| Baclyser® *neo* S 2M | 0 | 0 | 0 |
| Baclyser® *neo* S 2M | 0 | 0 | 0 |
| Baclyser® *neo* S 3M | 0 | 0 | 0 |
| Baclyser® *neo* S 3M | 0 | 0 | 0 |
| Baclyser® *neo* S 4M | 0 | 0 | 0 |
| Baclyser® *neo* S 4M | 0 | 0 | 0 |

### 3.3.4 Conclusion

These results show that ***Legionella pneumophilia*** **is retained** by the Baclyser® *neo* S filters **with 7 log levels.**

# 4 Clinical field study and laboratory study

For the verification of the service life of a water filter, tests of the retention capacity and the retrograde contamination under laboratory conditions as well as the actual behaviour in practice are important. Areas such as retrograde contamination, user behaviour, water quality and hygiene environment play a decisive role here.

That is why Aqua *free* has carried out both a laboratory study and extensive tests directly on a ward at a German university hospital using the Baclyser® *neo* S filters.

## 4.1 Clinical field study

### 4.1.1 Material and methods

The Baclyser® *neo* S filters were installed in patient rooms of a German university hospital and their routine use was accompanied by a weekly microbiological examination of the water before and after the filter.

The filters were not changed during the study period. Water samples were taken at the beginning and at weekly intervals for 9 weeks. Both cold and hot water samples were taken, as well as samples before and after the filter. Sampling was carried out according to the requirements of DIN EN ISO 19458:

- Before the filter according to purpose B
- After the filter according to purpose C

In accordance with the German Drinking Water Ordinance (TrinkwV), the samples were microbiologically tested for the following parameters by a DAkkS-accredited laboratory:

- TVC 20 °C and 36 °C
- *P. aeruginosa*
- Legionella

### 4.1.2 Results

The following tables (see Table 4 to Table 7) show the results of the microbial examination of the clinical field study. Figure 1 shows the flow rate at different pressures of the individual test filters after 9 weeks of use.

**Table 4: Results of the microbial examination of the filtrate as well as the water samples before the filters for the TVC at 20°C in CFU/ml over the examination period of 9 weeks. (B = before the filter, A = after the filter).**

| TVC 20 °C - before & after the filter - CFU/ 1 ml | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Week** | **0** | | **1** | | **2** | | **3** | | **4** | | **5** | | **6** | | **7** | | **8** | | **9** | |
| | Filter serial no. | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A |
| ***neo S*** | 0820NSG1003 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | 0820NSG1002 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 0820NSG1001 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

**Table 5: Results of the microbial examination of the filtrate as well as the water samples before the filters for the TVC at 36°C in CFU/ml over the examination period of 9 weeks. (B = before the filter, A = after the filter).**

| TVC 36 °C - before & after the filter - CFU/ 1ml | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Week** | **0** | | **1** | | **2** | | **3** | | **4** | | **5** | | **6** | | **7** | | **8** | | **9** | |
| | Filter serial no. | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A |
| ***neo S*** | 0820NSG1003 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0820NSG1002 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0820NSG1001 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 11 | 0 |

**Table 6: Results of the microbial examination of the filtrate as well as the water samples before the filters for *P. aerguniosa* in CFU/100ml over the examination period of 9 weeks. (B = before the filter, A = after the filter).**

| ***P. aeruginosa* - before & after the filter - CFU/ 100ml** | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Week** | **0** | | **1** | | **2** | | **3** | | **4** | | **5** | | **6** | | **7** | | **8** | | **9** | |
| ***neo S*** | Filter serial no. | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A |
| | 0820NSG1003 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0820NSG1002 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0820NSG1001 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

**Table 7: Results of the microbial examination of the filtrate as well as the water samples before the filters for Legionella in CFU/100ml over the examination period of 9 weeks. The typing of the legionella showed that it was *L. pneumophila*. (B = before the filter, A = after the filter).**

| **Legionella - before & after the filter - CFU/ 100ml** | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Week** | **0** | | **1** | | **2** | | **3** | | **4** | | **5** | | **6** | | **7** | | **8** | | **9** | |
| ***neo S*** | Filter serial no. | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A |
| | 0820NSG1003 | 12800 | <2 | 1100 | <2 | 100 | <2 | 200 | <2 | 600 | <2 | 700 | <2 | 500 | <2 | 300 | <2 | 3600 | <2 | 2900 | <2 |
| | 0820NSG1002 | 1700 | <2 | 100 | <2 | 700 | <2 | 100 | <2 | 8 | <2 | 6800 | <2 | 200 | <2 | 1100 | <2 | 1000 | <2 | 9400 | <2 |
| | 0820NSG1001 | 600 | <2 | 100 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | 2 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | <2 |

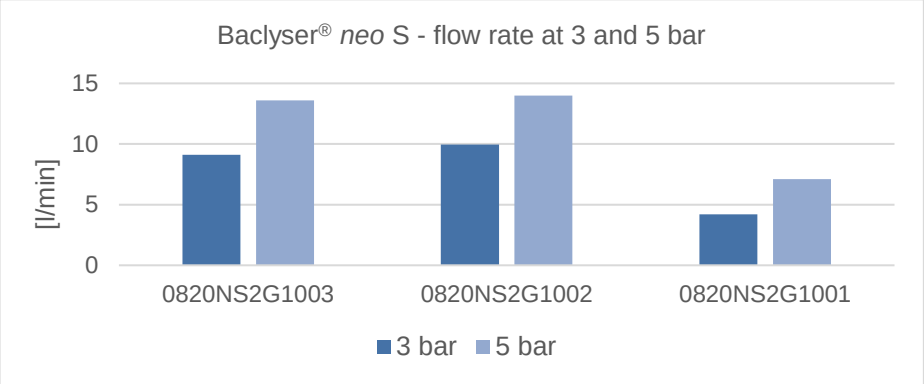


**Figure 1: Baclyser® *neo* S flow rate at different pressures (3 and 5 bar) after 9 weeks of use.**

#### 4.1.3 Conclusion

Over the complete test period of 9 weeks, no findings of legionella were detected in the filtrate of the Baclyser® *neo* S filters, although legionella were present in the incoming water pipe system upstream of the filters, in some cases in considerable quantities (see Table 7).

*P. aeruginosa* could not be detected either before or after the filter during the entire study period (see Table 6).

After operation in the field, the flow of the used filters was checked. The Baclyser® neo S have an average flow volume of 7.75 l/min at 3 bar.

In summary, the field study shows that the Baclyser® *neo* S filters reliably retain water-bound microorganisms over the study period of 9 weeks. The field study confirms a **service life of 2 months** for the Baclyser® *neo* S filters.

## 4.2 Laboratory study

#### 4.2.1 Material and methods

To validate the service life of up to 4 months of the Baclyser® *neo* S filters, a bacteria retention test was carried out in accordance with ASTM F838-20, according to which a volume of water corresponding to the service life flowed through the Baclyser® *neo* S at a threshold load. The flow cycles were 30 minutes each.

#### 4.2.2 Results

Table 8 below shows the results of the laboratory study.

**Table 8: Results of the ASTM F838-20 test after the threshold load with defined flow volumes.**

| Nr. | Filter type | Retention ASTM F838-20 | Filter integrity testing |
|---|---|---|---|
| **1** | Baclyser® *neo* S 2M | >7 log-levels | passed |
| **2** | Baclyser® *neo* S 2M | >7 log-levels | passed |
| **3** | Baclyser® *neo* S 3M | >7 log-levels | passed |
| **4** | Baclyser® *neo* S 3M | >7 log-levels | passed |
| **5** | Baclyser® *neo* S 4M | >7 log-levels | passed |
| **6** | Baclyser® *neo* S 4M | >7 log-levels | passed |

#### 4.2.3 Conclusion

The study confirms a **service life of up to 4 months** for the Baclyser® *neo* S filters.

# 5 Safety from retrograde contamination

Point of use filters are used on taps or as shower filters to protect patients from microorganisms in tap water in hospitals. Nevertheless, microorganisms can sometimes be detected when sampling the filtrate. This is caused by so-called retrograde contamination, i.e. microorganisms that entered the filtered water from the outlet side of the filter [15].

For the safe use of the Baclyser® *neo* S filters, the following points in particular must be observed when handling the filters to avoid retrograde contamination:

- Do not touch the filter if possible
- Avoid dirty water and process water contacting the filters
- Do not clean filters with cleaning agents or rags
- In the case of heavy visible soiling, such as blood, mucus, etc., or visible damage, remove the
- filters immediately.
- Educate patients using facilities with filter equipment on how to handle the medical devices

## 5.1 Antibacterial material

### 5.1.1 Introduction

Baclyser® *neo* S filters have a MetalSkin Medical® jet disc. This is a copper polymer coating that has antimicrobial activity, which can counteract retrograde contamination[1].

### 5.1.2 Material and methods

The tests were carried out in accordance with ISO 22196, considering some requirements of the French standard NF S90-700. In addition to the test organisms *S. aureus* (ATCC 6538) and *E. coli* (ATCC 8739) the antibacterial efficacy on *P. aerugionsa* (ATCC 15442) was also investigated. In addition to a contact time of 24 h, a contact time of 1 h and 3 h was also checked.

0.4 ml of microbial suspension was pipetted onto the jet discs and covered with a film. 3 specimens each were used directly after the inoculation to determine zero time. The remaining specimens were used after an exposure time of 1, 3 and 24 h at 37 °C and 90% relative humidity to recover the test bacteria. Then, the microbial count was determined.

### 5.1.3 Results

Table 9 shows the values of the antibacterial effect of the jet discs with MetalSkin Medical®.

[1] The use of antimicrobial materials does not replace on-site hygiene measures. For recommendations on how to handle filters to avoid retrograde contamination, see chapter 5.

**Table 9: Value of the antibacterial effect of MetalSkin Medical® jet discs on *E. coli*, *P. aeruginosa* and *S. aureus* at different exposure times.**

| Contact time | Value of antibacterial effect: A | | |
|---|---|---|---|
| | ***E. coli*** | ***P. aeruginosa*** | ***S. aureus*** |
| **1 h** | 2,59 | 2,86 | 1,7 |
| **3 h** | 2,29 | 3,75 | 2,86 |
| **24 h** | 5,18 | 5,95 | 5,00 |

### 5.1.4 Conclusion

The surface coating of the blasting discs of the Baclyser® *neo* S filters with MetalSkin Medical® provides a **strong antibacterial effect** (**reduction by 5 log levels**) against *E. coli, P. aeruginosa* and *S. aureus* with the contact time of 24 hours specified in ISO 22196.

The material properties of the MetalSkin Medical® jet discs thus contribute to protection against retrograde contamination [16].

# 6 Chemical influences

## 6.1 Chlorine test

### 6.1.1 Introduction

Water is exposed to chemical influences, whether through treatment within the framework of the Drinking Water Ordinance or through disinfection and sanitation measures of pipe systems. Therefore, it is important that filter systems are resistant to these substances (mostly chlorine). The maximum permissible addition, according to §11 of the Drinking Water Ordinance (as of December 2019) is 1.2 mg/l to max. 6mg/l (1.2 ppm-6 ppm) free $Cl_2$.

### 6.1.2 Material and methods

To test the chlorine resistance at a continuous dosage of 10 ppm, chlorinated water was pumped through the Baclyser® *neo* S filters by means of a centrifugal pump in a circuit over a defined period of time. The Baclyser® *neo* S filters were also soaked in a chlorine solution with a minimum concentration of 2 ppm chlorine. The integrity of the filters was then checked by means of a pressure drop test.

To test a high chlorine concentration over a short exposure time (400.000 ppm for 1 h), the Baclyser® *neo* S filters were placed in a chlorine solution with a chlorine content of 130.000 ppm over a period of 4 hours. The filters were subsequently also tested for integrity by a pressure drop test.

### 6.1.3 Results

The pressure drop test was passed by all Baclyser® *neo* S filters.

### 6.1.4 Conclusion

It was shown that both the **short-term (1 h) very high chlorine doses (400.000 ppm)** and a **continuous addition of 10 ppm** over the service life had no effect on the full functionality of the filters.

## 6.2 Chlorine dioxide test

### 6.2.1 Introduction

In addition to chlorine, there are other substances that are used for the disinfection and sanitation of pipe systems. According to the Drinking Water Ordinance, chlorine dioxide is also included here. The maximum permissible addition, according to §11 of the Drinking Water Ordinance (as of December 2020) is 0.4 mg/l $ClO_2$.

### 6.2.2 Material and methods

To test the chlorine dioxide resistance, water containing chlorine dioxide $\geq 0.8\ \frac{mg}{l}$ was pumped through several Baclyser® *neo* S filters over a volume corresponding to the service life. The integrity of the filters was then checked by means of a pressure drop test.

### 6.2.3 Results

. The pressure drop test was passed by all Baclyser® *neo* S filters.

### 6.2.4 Conclusion

It was shown that a **continuous addition of** $0.8\frac{mg}{l}$ **chlorine dioxide** over the service life had no effect on the full functionality of the filters.

# 7 Physical influences

## 7.1 Pressure load

### 7.1.1 Introduction

Depending on local conditions, the water pressure may vary. A certain water pressure is necessary, for example, so that the water also flows on higher floors. This pressure also has an effect on filter performance. For this reason, the integrity of the Baclyser® *neo* S filters was tested at a line pressure of 5 bar, in accordance with the requirements of German twin no. 12.

### 7.1.2 Material and methods

The Baclyser® *neo* S filters are sequentially subjected to a load of 5 bar line pressure in a flow test at a water temperature of 50 °C and then tested for their integrity by a pressure drop test.

### 7.1.3 Results

All Baclyser® *neo* S filters passed the pressure drop test.

### 7.1.4 Conclusion

The Baclyser® *neo* S filters can withstand an **operating pressure of 5 bar.**

## 7.2 Dynamic load – as a simulation of loading in use

### 7.2.1 Introduction

In use, the Baclyser® *neo* S filters are exposed to different loads. Depending on whether the water supply is open or closed, there is pressure or no pressure. To qualify the loads arising in the field for development purposes, Aqua *free* GmbH developed testing under threshold loads. The aim is to measure the filter performance under simulation of realistic stress

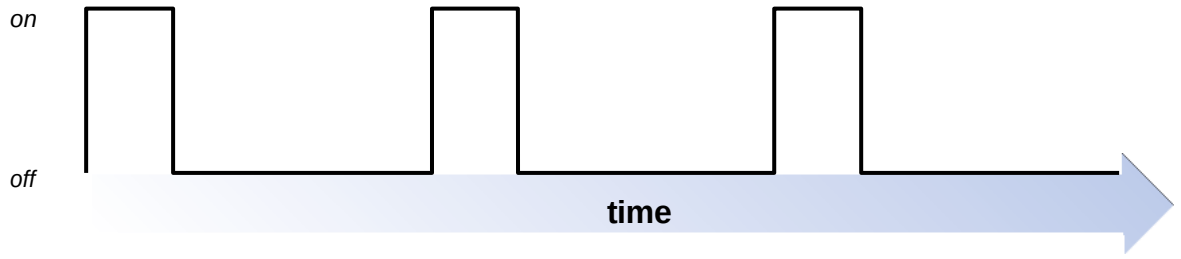


**Figure 2: Threshold load for simulation of load in use**

### 7.2.2 Material and methods

Dynamic loading test show the filter behaves under defined alternation between pressure and non-pressure. This simulates the opening and closing of a valve, for example a shower or water tap, with a particularly intensive impact load. For this purpose, the filters are subjected to 500 x flow cycles at a temperature of 20°C, a pressure of 5 bar and a cycle time of 30 s. After the test position has been performed, the filters are checked for integrity by means of a pressure drop test.

### 7.2.3 Results

The results of the testing are summarised in Table 10. The main criteria considered in the evaluation were the tightness of the housing and the integrity of the membrane after the test.

**Table 10: Results of the pressure drop test.**

| No. | No. of Cycles | Filter integrity testing | Tightness of the jet disc in the housing |
|---|---|---|---|
| **1** | 500 | Passed | OK |
| **3** | 500 | Passed | OK |
| **5** | 500 | Passed | OK |

### 7.2.4 Conclusion

Baclyser® *neo* S filters can withstand a **dynamic load** under real conditions with intense pressure surges.

## 7.3 Flow as a function of pressure

### 7.3.1 Introduction

. The flow varies depending on the applied pressure. The flow pressure test determines how the flow of the Baclyser® *neo* S filters behaves depending on the line pressure.

### 7.3.2 Material and methods

To record the flow-pressure curve, the flow rates of the Baclyser® *neo* S filters were determined with tap water at different pressures.

### 7.3.3 Results

Figure 3 shows the averaged results of the flow pressure test.

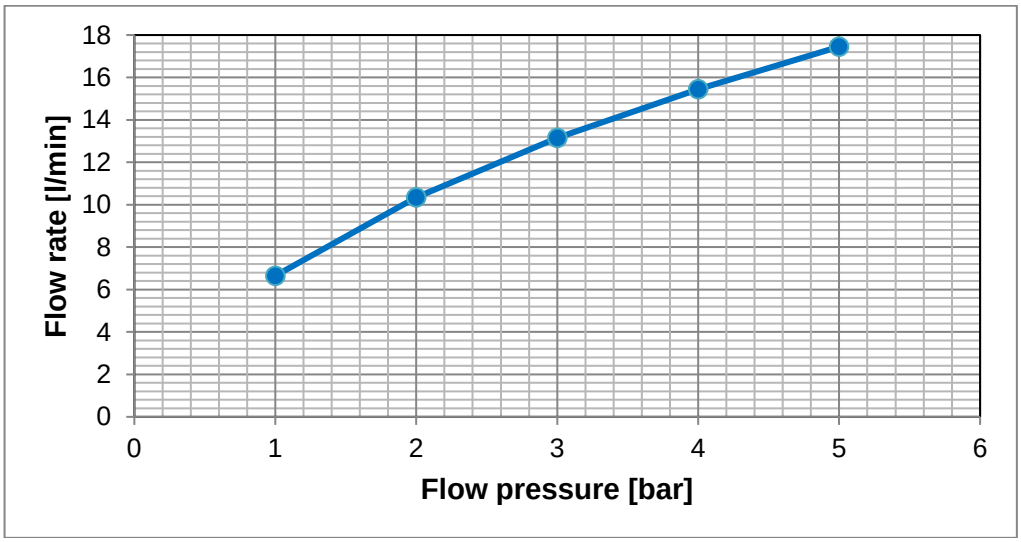


**Figure 3: Flow-pressure curve of the Baclyser® *neo* S**

### 7.3.4 Conclusion

The Baclyser® *neo* S filters have a flow rate that increases with the pressure. At a **line pressure of 1 - 5 bar**, the **flow rate** of the Baclyser® *neo* S **is around 6.7 to 17.1 l/min.**

## 7.4 Temperature stability

### 7.4.1 Introduction

To meet the hygiene requirements of the Federal Environment Agency (UBA) and to prevent microbial growth, hot water in the entire pipe system should have a temperature of at least 55 °C [17]. The water temperature may also vary depending on use. For thermal disinfection, the water temperature must be at least 70 °C [15,17].

In order to check the resistance of the Baclyser® *neo* S filters against these thermal influences, a hot water test was carried out.

### 7.4.2 Material and methods

To check an operating temperature of 60 °C, water (min. 60 °C) was directed through 4 filters over a period of 6 h at a pressure of 4 bar. To simulate a thermal load, two filter cartridges had 70 °C hot water (5 bar) directed through them for a total duration of 30 minutes. The filters were subsequently tested for integrity by a pressure drop test.

### 7.4.3 Results

Baclyser® *neo* S filters are stable after a flow through with 70°C hot tap water for a total duration of 30 minutes as well as a flow through with min. 60°C water over 6 h.

### 7.4.4 Conclusion

The **maximum operating temperature** of the Baclyser® *neo* S filters is **60 °C**. In the case of thermal disinfection of the piping system, the Baclyser® *neo* S filters can also be exposed to a **water temperature of 70°C for a short time (30 minutes).**

# 8 Compatibilities

## 8.1 Compatibility with technical requirements

Sterile filters should meet certain technical requirements in order to be used in microbially contaminated drinking water installations.

In the following table, the technical requirements and their implementation in the Baclyser® *neo* S are explained.

**Table 11: technical requirements of sterile filters and their implementation in the Baclyser® *neo* S.**

| Technical requirements | Baclyser® *neo* S filter |
|---|---|
| **Designed for temperatures of min. 60 °C** | See 7.4 temperature stability |
| **Designed for a pressure of min. 5 bar** | s. 7.1 Pressure load |
| **Compatibility with treatment substances and disinfection processes** | s. 6.1 Chlorine test and 6.2. Chlorine dioxide test |
| **Individual testing for suitability and tightness** | The filters are 100% tested for suitability and tightness |
| **Permanent marking with serial number and manufacturer's name** | The filters have a filter label which takes this information into account |
| **Ability to mark the installation and removal date** | The filters are provided with a change date sticker after installation. A note on this is given in the instructions for use |
| **Limited service life proven under practical conditions** | s. 4. Clinical field study and laboratory study |
| **Instructions for connection as well as use of the filter must be available** | Instructions for use are enclosed with each filter. |

## 8.2 Disinfectant compatibility

To test the compatibility and resistance of the water filter housings to common surface disinfection agents the water filters were tested by way of example on various disinfection solutions.

For this purpose, a classification was made according to the active substance basis. For each group of active ingredients, one disinfectant was selected as an example. The groups of active ingredients and the selected disinfectants are shown in Table 12.

**Table 12: Active substance groups and disinfectants and the associated test filters.**

| No. | Active substance group | Disinfectant |
|---|---|---|
| **1** | Alcohols | Bode Chemie Bacillol AF |
| **2** | Biguanide | Ecolab Incidin Plus |
| **3** | Chlorine, organic or anorganic substances with active chlorine | Lysoform Trichlorol |
| **4** | Formaldehyde | Dr. Schumacher Ultrasol F |
| **5** | Per connections | Bode Chemie Dismozon plus |
| **6** | Phenol or Phenol derivates | B Braun Helipur |

The experimental setup is based on realistic assumptions regarding the frequency and duration of wipe disinfection. Based on these parameters and the promised service life of the Baclyser® *neo* S filters, an assumed disinfection duration over the complete service life is determined.

One container per group is filled with the disinfectant. After the assumed total disinfection time has elapsed, the filter is rinsed with sterile filtered water. A visual inspection of the water filters then takes place.

The results show that the tested disinfectants of the agent groups 1-5 have no influence on the sterilising grade filters. No visual change of the sterile filter could be detected. When using Helipur (B. Braun), a slight optical change of the housing may occur.

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