September 2018 Volume 72 Number 8
www.iheem.org.uk

IHEEM 75th Anniversary

health estate journal

IHEEM

hej

JOURNAL OF THE INSTITUTE OF HEALTHCARE ENGINEERING AND ESTATE MANAGEMENT

Aiming for clarity on water filtration

Aiming for clarity on water filtration

Due to its crucial role in hygiene and infection control in healthcare facilities, but equally hospital water systems' vulnerability to bacteria which can put the health of patients at risk, water hygiene and safety are key and – on large estates – often constant concerns for healthcare estates professionals. The problem of selecting the most suitable water hygiene solutions can, however, be compounded by the complex terms that surround them. Here, Mike Hemingway, UK sales director for ISO 13485-certified medical water hygiene specialist, Aqua free, 'cuts through the jargon' to address the key guidance and standards relating to point-of-use filtration.

A hospital's Water Safety Group brings together expertise from Estates, Infection Control, and often a specialist external Authorising Engineer. Working together, they aim to ensure that water hygiene is dealt with effectively. However, even within such a group, is it actually possible to provide expertise about every type of technology available on the market? As our understanding of waterborne diseases (and preventing them) develops all the time, even the most qualified and experienced among us may struggle to keep up with best practice. The following sections aim to offer some clarity on the subject, providing a glossary and breakdown of the key guidance and standards relating to water filtration and healthcare water system safety, and explanation of some of the terminology, to help in selecting a suitable point-of-use filter for clinical environments.

The guidance

Health Technical Memorandum (HTM) 04-01: *Safe water in healthcare premises*, provides (among other things) a definition of a point-of-use (POU) filter as 'a filter with a maximal pore size of 0.2 µm applied at the outlet, which removes bacteria from the water flow'. Part A (*Design, Installation and Commissioning*) advocates the use of 'sterilising-grade' POU filters, where necessary, and references American Standard Test Method (ASTM) F838-05.

The 'basics'

Pore size

The guidance raises important points for industry standards. Most POU filters will have a pore size of 0.2 µm, or a little smaller. The 0.2 µm pore size is used as the standard for bacteria removal, since it is smaller than the smallest known bacteria.

An important consideration when selecting a POU tap filter is the operating space available between outlet and sink.

'Sterilising grade' filter

For a POU filter to be deemed 'sterilising-grade', it must be capable of retaining a defined amount of a specific bacteria. The ASTM F838-05 protocol uses the US Food and Drug Administration (FDA) definition of sterilising-grade, that being: the complete retention of 10^7 (7 log steps) CFU/cm^2 *Brevundimonas diminuta*, at a differential pressure of 2 bar.

> HTM 04-01: *Safe water in healthcare premises*, provides a definition of a POU filter as 'a filter with a maximal pore size of 0.2 µm applied at the outlet, which removes bacteria from the water flow'

Brevundimonas diminuta

Brevundimonas diminuta is the smallest water bacterium, and is therefore used as the reference microorganism when testing the bacteriological effectiveness of POU filters. It is accepted that if the filter can retain the required level of *B. diminuta* throughout its lifecycle, it will also be able to retain all other waterborne bacteria, such as *Legionella* and *Pseudomonas aeruginosa*.

ASTM F838-05

American Standard Test Method (ASTM) F838-05: *Determining bacteria retention of membrane filters utilised for liquid filtration,* is the accepted global standard for measuring the bacterial retention of membrane filters – the results of which demonstrate whether a POU filter will be capable of delivering sterile filtered water for the entirety of its expected lifecycle. In contrast to WRAS approval or CE marking (see below), the basis of ASTM F838-05 is to establish the microbiological performance of the filter. For this reason, it should be considered to be as important as WRAS approval.

Types of membrane

There are two types of membrane commonly used in POU filters: flat sheet/pleated, or hollow fibre. Each has its advantages and disadvantages. Some suggest that hollow fibre filters only operate with a single layer of membrane, and others that that the pleating of flat sheet filters builds stresses into the membrane, thus requiring a dual layer. The reality is that both types of membrane filter are only as good as the quality standards which surround

their design, manufacture, and testing. The proof of performance is in the tests carried out to validate the filters' performance for their intended applications.

Validation testing

Validation of performance

To validate the performance of a POU filter for clinical use, its operating life performance must be judged on the potential worst-case operating conditions. Filter membranes can be impacted by all sorts of stresses during normal day-to-day use. Variations in pressure, temperature, and flow, can cause stresses to build up in the membrane, and, in extreme conditions, cause it to break. Typically, validation testing should be a combination of both laboratory tests and field trials.

Laboratory testing

Laboratory tests allow filters to be thoroughly and repeatedly pushed to the extremes of their performance – something not achievable or easily measurable in field trials. Laboratory testing should establish the bacterial retention of the filter over its whole lifespan, but also tests can be carried out to simulate extremes of operating conditions and the effects of extreme pressure, temperature, and chemical loading, on the filter.

Laboratory testing can also examine the impact of using antibacterial materials, which are used by many filter manufacturers to mitigate the potential for retrograde contamination of the filter. However, when considering how to mitigate against retrograde contamination, it is important to consider that an isolated test of the effectiveness of antibacterial materials is not sufficient. Retrograde contamination of a filter can occur from many sources, and the effectiveness of antibacterial materials varies considerably depending on the level of surface contamination, and even whether the surface is wet or dry. A filter manufacturer should thus also consider other, mechanical means, of protecting the filter. The effectiveness of such measures is best demonstrated in field trials.

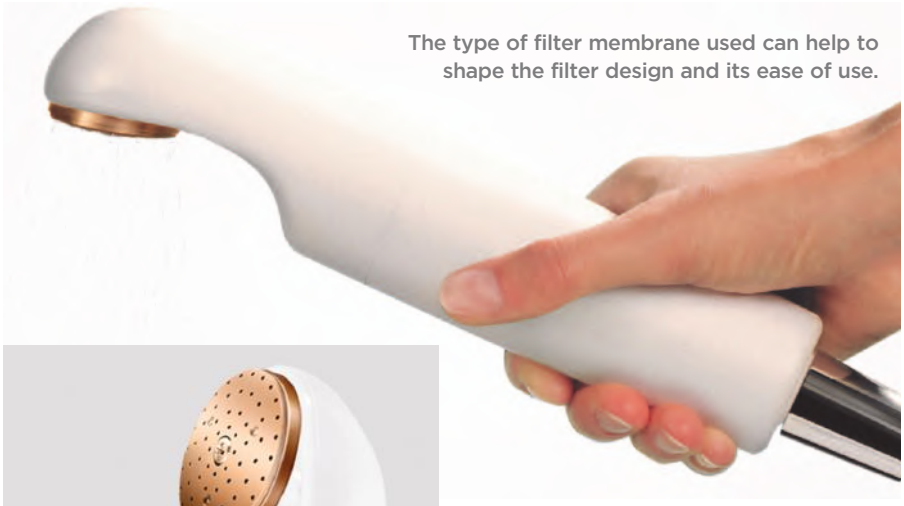
Field trials

Field trials demonstrate the use of the filter in a real-world scenario, and therefore consider how the filter is used and handled by patients and staff as part of the intended application. They are therefore useful to assess the impact of varying water quality, and the potential for retrograde contamination.

Local field trials

In reality, validation of filter performance is a complicated process. It requires some depth of knowledge to understand the validation report and the body of testing which supports that report. It also requires some trust in the supplier, and the assurance that the testing has been conducted following the necessary quality standards. It is not surprising, therefore, that some NHS Trusts or Health Boards decide to carry out local field trials to assess filter performance before committing to a new supplier. Although not strictly necessary, local field trials do have their advantages. For example, frequency of use and local water quality can have a bearing on a product's performance. Certainly, a high sediment content in the local water supply has the potential to impact the achievable operating time. Furthermore, poor handling procedures can exponentially increase the potential for retrograde contamination. Carrying out local field trials allows a client to supplement the guidance provided by a filter manufacturer, and establish a realistic operating time for the filters.

Local field trials should not be relied upon in isolation, however. It would be rare indeed that any field trial – however intense – could prove filter performance at the worst case operating conditions of pressure and temperature. Therefore, it is important to consider the certifications and quality standards operated by the filter manufacturer to gain assurance of its suitability to supply such a medical device.



The type of filter membrane used can help to shape the filter design and its ease of use.

Filter design and the use of antibacterial materials can be used to mitigate against retrograde contamination.

Certification – what to look for

There are several types of certification which accompany POU filters. Some demonstrate mandatory compliance with regulations, while others are optional, but offer useful indicators of performance. It should be noted that certification is not a substitute for testing, and should never be used or viewed as such. The three classes of certification listed below should be used to underpin performance testing.

CE Mark, Class I

Medical Device CE Marking is a manufacturer's declaration that its product complies with the requirements of the relevant European legislation. This European legislation concerns health, safety, and environmental protection. Class I is the minimum standard available, and requires the manufacturer to make a self-declaration that its product complies with all the relevant essential requirements of the Directive.

WRAS certification

In the UK, any water fitting which carries or receives water from the public mains water supply must comply with the Water Supply (Water-Fittings) Regulations or Scottish Byelaws. This is to ensure that the product will not cause waste, undue consumption, or contamination of the water supply. WRAS approval is the easiest way to demonstrate compliance, because it is accepted by every water supplier in the UK. For this reason, it tends to be one of the first things that clients look for in a POU filter.

Products such as POU filters undergo mechanical and water quality testing. This type of approval demonstrates full compliance with the requirements of the regulations and byelaws, provided, of course, that they are installed according to any conditions given with the approval.

Physical attributes and materials

WRAS approval relates specifically to the physical characteristics of the unit, i.e. its physical attributes and the materials

used in manufacture. However, it gives no indication of the bacterial retention performance of a filter. Care should be taken to read the WRAS approval for a product thoroughly, as details are provided on limitations of the approval, such as installation requirements, or the maximum allowed operating temperature.

EN ISO 13485

The International Organisation for Standardisation (ISO) is an independent body which develops global standards for safety and innovation. EN ISO 13485 acts as the framework for all medical device compliance across the world, and provides audited Quality Assurance for products used in a healthcare setting. Manufacturers who carry this mark have demonstrated that they have put detailed and externally audited processes in place, in order to ensure the quality, safety, and effectiveness, of their products.

Conclusions

On the face of it, POU filtration seems simple – 'a filter with a maximal pore size of 0.2 µm applied at the outlet, which removes bacteria from the water flow'. However, the reality is far more complex, especially in the healthcare sector, where staff, visitors, and vulnerable patients, can be most at risk. Although there is still plenty to be done to delve deeper into this subject, there are, at least, several quality marks to look out for. By ensuring that decision-makers are kept up to date with these requirements, we can provide a platform of knowledge to build on, thus ensuring that the highest safety standards are met across the board. Water safety must be paramount. hej

Aqua free and Mike Hemingway

Aqua free is an ISO 13485-certified medical water hygiene specialist delivering a wide range of solutions, mainly centering around the point of use. Mike Hemingway was instrumental in establishing the Aqua free business in the UK, and continues to promote the Aqua free name and products, and the importance of selecting correctly tested and certified products for medical applications, to ensure protection from infection for vulnerable patients.

He has over 20 years' water treatment experience. After leaving university, he started his career as a UV system design engineer, then progressing through Project Engineering and Project Department manager roles, before stepping up to general management, and eventually managing the UK Sales and Marketing teams for one of the largest pumping and water treatment equipment suppliers in the world, before moving to Aqua free in 2016.