World Health Organization

International Scheme to Evaluate Household Water Treatment Technologies

ORISA®

Product evaluation report

WHO performance classification	Comprehensive protection Three-star (★★★) classification
Manufacturer	Fonto De Vivo 4 Rue de la Vallée 44330 Le Pallet France www.fontodevivo.com
Evaluation procedure	Abbreviated laboratory test
WHO report issue date	Round III, 2021
WHO reference	24/1/2020-R3-25

Summary of evaluation

This report summarizes the evaluation results of a membrane ultrafiltration device known by the tradename 'ORISA®', under Round III of the World Health Organization (WHO) International Scheme to Evaluate Household Water Treatment Technologies (the Scheme). Evaluation of the ORISA® followed the requirements of the WHO protocol for filtration technologies and investigated the ability of the device to reduce bacteria and viruses. Reduction of protozoa was assigned based on the mean bacterial reduction achieved.

Based on the evaluation results, the ORISA® meets WHO performance criteria and is classified as providing three-star (★★★) *comprehensive protection.*

1. Background

Evaluation under the Scheme is based on performance criteria set out in *Evaluating Household Water Treatment Options: Health-based targets and microbiological performance specifications* (WHO, 2011). The criteria were determined by applying the quantitative microbial risk assessment (QMRA) methods outlined in the *Guidelines for Drinking-water Quality* (WHO, 2017) and set $\log_{10}$ reduction targets against bacteria, viruses and protozoa, as shown in Table 1.

Table 1. WHO performance criteria for household water treatment technologies

Performance classification	Bacteria ($\log_{10}$ reduction required)	Viruses ($\log_{10}$ reduction required)	Protozoa ($\log_{10}$ reduction required)	Interpretation (with correct and consistent use)
★★★	≥ 4	≥ 5	≥ 4	Comprehensive protection
★★	≥ 2	≥ 3	≥ 2	
★	Meets at least 2-star (★★) criteria for two classes of pathogens			Targeted protection
—	Fails to meet criteria for 1-star (★)			Little or no protection

Product description

The ORISA® is a membrane ultrafiltration device. It is operated by clamping it to a vessel containing raw water and manually pumping water through it. Forcing water through the hollow fibre membranes removes the microorganisms. The device does not have an integrated clean water receptacle; a separate collection / storage vessel is required.

The full product description, illustrations and use instructions can be found at: www.fontodevivo.com.

2. Evaluation approach

Product-specific test plan: A product-specific test plan was developed based on the manufacturer's instructions for use; the Scheme *Harmonized Testing Protocol: Technology Non-Specific V 2.0* (WHO, 2019); and the *Testing Protocol for Filtration Technologies V 3.2* (WHO, 2020). Testing was conducted at a WHO-designated laboratory, NSF International, in the United States.

Test organisms: Evaluation of the ORISA® investigated its ability to remove bacteria and viruses. The test organisms were *Escherichia coli (E. coli)*, representing bacteria, and coliphages MS2 and phiX174, representing viruses. Based on the available evidence on filtration media on the removal of protozoan cysts, testing against this microbial group was not conducted (WHO, 2019). The protozoan reduction is assigned based on the mean bacterial reduction observed.

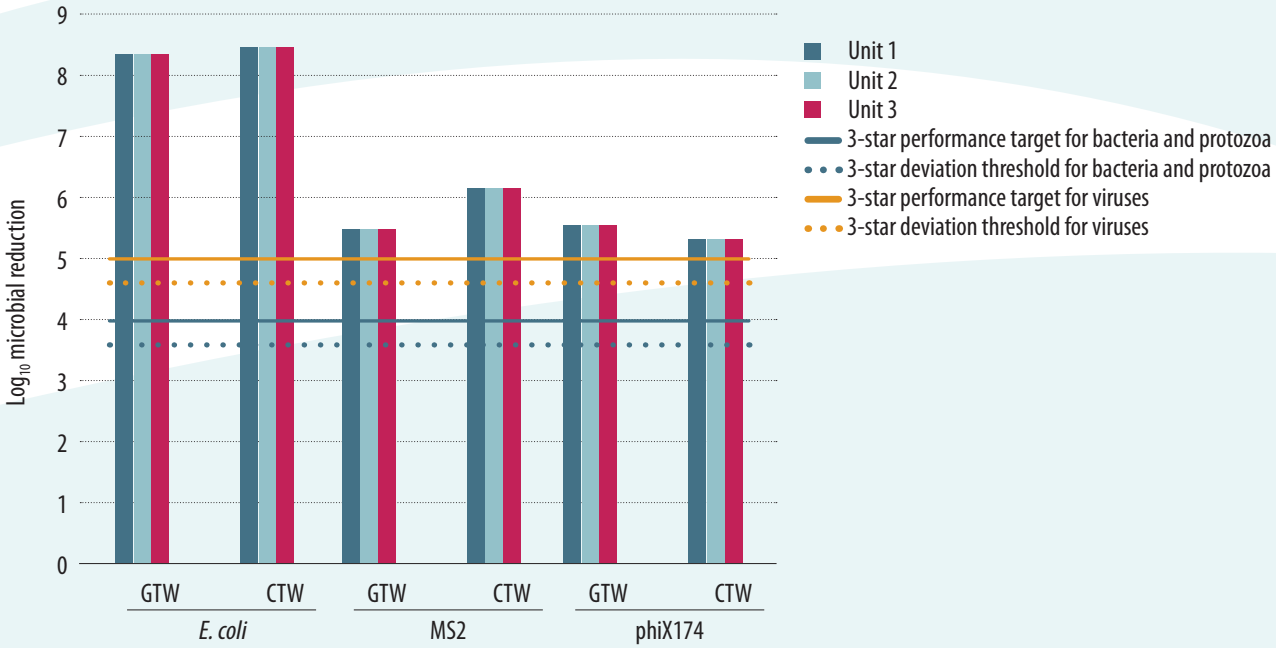
Test waters: The device was tested in two waters: general test water (GTW), simulating high quality groundwater, and challenge test water (CTW), simulating surface water. Refer to the Testing protocol for Filtration Technologies V 3.2 (WHO, 2020) for details on physicochemical characteristics of the test waters.

Test procedure: TOf the four new production units provided, three were randomly selected for testing. All units were operated according to the manufacturer's instructions. Pretreatment and posttreatment water grab samples were analysed using methods identified in the product-specific test plan. Testing was conducted over four days, in GTW on Days 1 and 2 and in CTW on Days 3 and 4, resulting in a total of 12 sample points for each organism (i.e. 2 days x 2 test waters x 3 test units).

3. Results

Fig. 1 presents the results of the bacterial and viral testing for the three units in GTW and CTW. All test water characteristics were within specifications.

Fig. 1. Performance across test units[1]



CTW: challenge test water; *E. coli: Escherichia coli*; GTW: general test water.

The ORISA® achieved mean $\log_{10}$ reductions of greater than 8.53 for *E. coli*; greater than 5.81 for MS2; and greater than 5.42 for phiX174. Performance was consistent across all three units.

4. Interpretation and application of results

As shown in Table 1, performance is classified in three ascending tiers: ★ (one-star); ★★ (two-star); and ★★★ (three-star). Both three- and two-star products provide *comprehensive protection* against all three microbial groups. One-star products meet performance targets for only two of the three microbial groups, providing *targeted protection.*

Each production unit should consistently meet or exceed the performance target for each microbial group in both test waters (GTW and CTW). A maximum deviation of 0.2 $\log_{10}$ is acceptable for 25% of sample points at the two-star performance tier and 0.4 $\log_{10}$ at the three-star performance tier[2]. This means that for classification as a two-star product, up to three of the 12 sample points can achieve a minimum reduction of 1.8 $\log_{10}$ for bacteria or protozoan cysts (instead of 2 $\log_{10}$) or 2.8 $\log_{10}$ for viruses (instead of 3 $\log_{10}$). Each phage is treated separately for evaluating acceptable allowance, and the overall claim for viruses is based on the lower performing phage.

[1] The maximum microbial reduction that can be demonstrated is limited by the pretreatment challenge concentration delivered. For each organism tested, the pretreatment concentration must be sufficient to allow for the demonstration of the performance targets shown in Table 1. Due to the complexity of using viable organisms, these pretreatment concentrations may be above what is sufficient, which may lead to demonstrated reductions that far exceed the performance targets. However, the emphasis is on whether the performance target has been met and not the extent by which the target was exceeded.

[2] These cut-off values were determined using QMRA modelling and selecting ranges that still result in appreciable health gains within a specific performance tier

Performance classification

The ORISA® met all performance targets for bacteria and viruses. For the protozoan reduction, a value of greater than 8.53 $\log_{10}$ was assigned based on the mean bacterial reduction achieved. As such, the ORISA® is classified as providing three-star (★★★) *comprehensive protection.*

Considerations for product selection

	**Microbial conditions**	Effective against bacteria, viruses and protozoa; can be used under all microbial water quality conditions
	**Physico-chemical water characteristics**	Can be used to treat turbid water
	**Product information and labelling**	Check that the product is appropriately labelled and has clear instructions for use

References

WHO (2011). Evaluating household water treatment options: health-based targets and microbiological performance specifications. Geneva: World Health Organization (https://apps.who.int/iris/bitstream/handle/10665/44693/9789241548229_eng.pdf?sequence=1&isAllowed=y).

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