

NEPHROS

Instructions for Use Part #: 70-0282

Nephros S100 Shower Handheld Filter

Introduction

Information on this sheet must be read before the use of this device to ensure safe and effective operation.

Sterility: The device is sterilized by ethylene oxide.

Recommended Storage: Between 5°C and 35°C (41°F and 95°F).

Indications

Description: The S100 Shower Handheld Filter is a disposable point-of-use micro-filter used to filter EPA-quality drinking water. The filter retains bacteria. By retaining bacteria in water for washing and drinking, the filter may aid in infection control. The filter produces water that is suitable for cleaning of equipment used in medical procedures and washing of surgeon's hands.

Use: The device is intended for long-term, continuous use. Once it completes its useful life, the filter should be discarded and replaced. Do not attempt to sterilize or re-use it.

Contraindications

Medical: The filter is not intended to provide water that can be used as a substitute for USP sterile water.

Chemical: The S100 retains bacteria. To obtain chemically pure water it is necessary to use the filter in conjunction with other devices such as DI beds or RO systems.

Warnings & Precautions

Pressure: The S100 is intended for a maximum incoming water pressure of 75 psi (5 bar).

Temperature: The S100 is rated for a maximum incoming water temperature of 60°C.

Cyclic Use: The S100 is rated for a maximum of 1,000 on/off cycles.

Replacement: The filter should be replaced when the flow rate begins to noticeably decrease. It is recommended to establish a maintenance schedule of replacing the filter dependent on water quality.

Water Monitoring: After installation of the S100, periodic monitoring of the water for bacteria is recommended.

Installation & Removal

- Remove the old shower head from the end of the shower hose.
- The following steps are recommended prior to attaching the filter.
- Measure the incoming water pressure by attaching a pressure gauge to the adapter and opening the faucet valves.
- Measure the pressure at a time of low facility water usage, hence the highest pressure (e.g. in the evening).
- Remove the filter from its package and thread the end of the shower hose onto the filter.
- If desired a pin mount adapter can be used and threaded between the filter and the shower hose.
- To remove a used filter, simply unscrew it from the shower hose.
- Discard the filter appropriately and replace it with a new one as previously described.

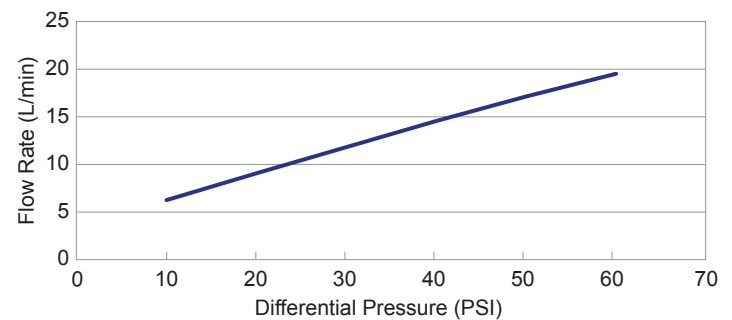
Note: Exposure of the filter to alkyl dimethyl benzyl ammonium chloride (ADBAC) may result in cracks to the external housing. It is recommended not to use ADBAC based cleaners. All S100 filters contain a bacteriostatic additive incorporated into the housing material in order to guard against surface touch contamination.

In cases where the external housing of the filters might be subject to heavy surface contamination (e.g. rinsing of used surgical instruments), it is recommended to wipe down the exterior surface of the filters with 1% bleach. Do not remove the filters or immerse them in cleaning solution.

Operation

After a new S100 is installed, water should be run through the filter for approximately 20 seconds to purge it of trapped air. The pressure drop across the S100 generally reduces the flow rate by about 1/4 of the rate without a filter. The filter should operate for up to 3 months of normal use with minimal degradation in flow. If the flow rate degrades significantly, the filter should be replaced.

Clean Water Flow Rate



















Specifications

Sterilization Method	Ethylene Oxide
Max Inlet Pressure	75 psi (5 bar)
Max Inlet Temperature	60°C (140°F)
Material	Polysulfone
Pore Size	0.1 micron
Bacterial Retention⁽¹⁾	> 10 ⁹ (B. diminuta)
Expected Life	Up to 3 months

(1) S100 filters have been validated by a 3rd-party certified laboratory, in accordance with ASTM F838-20 "Standard Test Method for Determining Bacteria Retention of Membrane Filters Utilized for Liquid Filtration," with total bacteria retention as defined by "Sterilizing Grade" filter. Nephros S100 Validation Report: NEPH061521. For additional reference see: FDA "Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice," September 2004.

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Symbol	Symbol Title	Standard Reference	Standard Title	Explanatory Text
	Manufacturer	ISO 15223-1:2021, Clause 5.1.1 ISO 7000:2019, 3082	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Graphical symbols for use on equipment	Indicates the medical device manufacturer
	Use by Date	ISO 15223-1:2021, Clause 5.1.4 ISO 7000:2019, 2607	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Graphical symbols for use on equipment	Indicates the date after which the medical device is not to be used.
	Batch Code	ISO 15223-1:2021, Clause 5.1.5 ISO 7000:2019, 2492	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Graphical symbols for use on equipment	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Part Number	ISO 15223-1:2021, Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the manufacturer's part number, so that the medical device can be identified.
	Sterilization by Ethylene Oxide	ISO 15223-1:2021, Clause 5.2.3 ISO 7000:2019, 2501	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Graphical symbols for use on equipment	Indicates a medical device that has been sterilized using Ethylene Oxide.
	DO NOT Resterilize	ISO 15223-1:2021, Clause 5.2.6 ISO 7000:2019, 2608	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Graphical symbols for use on equipment	Indicates a medical device that is not to be resterilized.
	DO NOT Use if Package Is Damaged and Consult Instructions for Use	ISO 15223-1:2021, Clause 5.2.8 ISO 7000:2019, 2606	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Graphical symbols for use on equipment	Indicates a medical device that should not be used if the package has been damaged or open.
	Consult Instructions for Use	ISO 15223-1, Clause 5.4.3 ISO 7000:2019, 1641	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Graphical symbols for use on equipment	Indicates the need for the user to consult the instructions for use.
	Medical Device	ISO 15223-1:2021, Clause 5.7.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the item is a medical device.
	Unique Device Identifier	ISO 15223-1:2021, Clause 5.7.10	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the medical device contains a Unique Device Identifier.
	Fragile, Handle with Care	ISO 15223-1:2021, Clause 5.3.1 ISO 7000:2019, 0621 ISO 780:2015, Clause 4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Graphical symbols for use on equipment Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates that the device shall be handled with care.
	Rain	ISO 15223-1:2021, Clause 5.3.4 ISO 7000:2019, 0626 ISO 780:2015, Clause 4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Graphical symbols for use on equipment Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates that the device shall be kept away from rain and be kept in dry conditions.
	Keep Away from Sunlight	ISO 15223-1:2021, Clause 5.3.2 ISO 7000:2019, 0624 ISO 780:2015, Clause 4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Graphical symbols for use on equipment Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates that the device shall not be exposed to sunlight.
	Temperature	ISO 15223-1:2021, Clause 5.3.7 ISO 7000:2019, 0632 ISO 780:2015, Clause 4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Graphical symbols for use on equipment Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates the temperature limits in which the medical device can be safely exposed.
	This Way Up	ISO 780:2015, Clause 4.4 ISO 7000:2019, 0623	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages Graphical symbols for use on equipment	Indicates the correct upright position of the distribution packages for transport and/or storage.
	Stacking Load	ISO 780:2015, Clause 4.5 ISO 7000:2019, 0630	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages Graphical symbols for use on equipment	Indicates the maximum stacking load which may be stacked on the distribution packages.

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