

Nephros DSU-H - Instructions for Use

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 and 35°C (41 and 95°F).

INDICATIONS

Description: The Nephros DSU-H is a disposable in-line water ultrafilter used to filter EPA quality drinking water. The filter retains bacteria, viruses and endotoxin. By providing ultrapure water for washing and drinking, the filters aid in infection control. The filter produces water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of surgeon's hands.

Single Use: The device is intended for single use. Once installed the filter is intended to be used for up to 6 months. After such time the unit should be replaced and discarded. Do not attempt to sanitize or re-sterilize it.

CONTRAINDICATIONS

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

Chemical: The DSU-H retains biological contaminants. 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 & Temperature: The DSU-H is designed for a maximum incoming water pressure of 100 psi (6.8 bar) and a maximum incoming temperature of 60°C (140°F).

Cyclic Use: The DSU-H is intended for a maximum of 10,000 on/off cycles in in-line use and 1000 cycles in open discharge use.

Replacement: The filter should be replaced when the flow rate begins to noticeably decrease. It is recommended that one establish a maintenance schedule of replacing the filter at least every 6 months dependent on water quality.

Water Monitoring: After installation of the DSU-H, periodic monitoring of the water is recommended.

INSTALLATION & REMOVAL

Note: If it is the first time a DSU-H is installed in a location, please refer to one of the *DSU-H Installation Guides*. Prior to handling a new filter it is recommended that one wash their hands and wear disposable gloves.

- Open a new filter blister pack and remove the port caps.
- Mark the label with the installation date.
- Disconnect the inlet side of the used filter followed by the outlet side. It is not necessary to turn off the water valves before disconnecting the filter as the female quick connectors have internal shut off valves.
- Seal the used filter ports with the caps to minimize water leakage.
- Remove the used filter from its mounting clamps and discard appropriately.
- Place the new filter in the clamps making sure the flow direction arrows point towards the water outlet.
- Connect the outlet water line to the filter followed by the inlet line using the quick connectors.

Note: Prolonged 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.

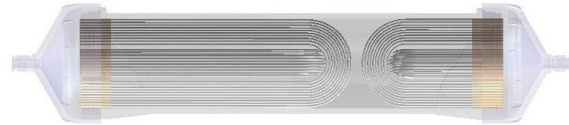
OPERATION

After a new DSU-H is installed, water should be run through the filter for approximately 1 minute to purge it of trapped air. The pressure drop across the DSU-H generally reduces the flow rate by about 1/3 to 1/2 of the rate without a filter. The filter should operate

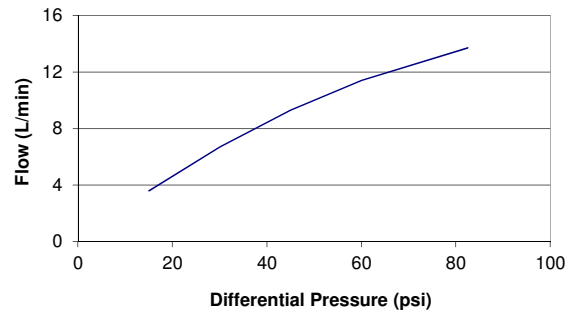
for up to 6 months of normal use with minimal degradation in flow. If the flow rate degrades significantly, the filter should be replaced.

SAFETY

The DSU-H has a unique double ultrafiltration design such that all the filtration occurs in the front section of the filter while the back section serves as a redundant safety filter. During the course of operation the front section of the filter is likely to become fouled with particulate from the incoming water while the back section remains clean. In the unlikely event there is a small breach in the first filter stage, water is still completely filtered by the second (redundant) filter stage.



DSU-H - Clean Water Flow



Specifications	Nephros DSU-H
Sterilization Method	Ethylene Oxide
Max Inlet Pressure	100 psi (6.8 bar)
Max Inlet Temperature	60°C (140°F)
<u>Max # On/Off Cycles</u>	
In-Line Use	10,000
Open Discharge	1,000
<u>Filter Membrane</u>	Medisulfone®
Material	Polysulfone
MW cut-off	15 kDa
Bacterial Retention	> 10 ¹¹ (B. diminuta)
Virus Retention	>10 ⁸ (PhiX-174)
Endotoxin Retention	> 10 ⁵ EU/ml
Expected Life	up to 6 months

Medisulfone® is a registered trademark of Medica S.p.A.

Assembled at:

Medica S.p.A.
Medolla, Italy

Manufacturer:

Nephros Inc.
41 Grand Ave
River Edge, NJ 07661 USA