

# NEPHROS

Instructions for Use Part #: 70-0285 / 70-0286

## Nephros DSU-H Filter

Read instructions before the use of this device to ensure safe and effective operation

### Device Description

**Device 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 endotoxins.

**Indications for Use:** The Nephros DSU-H Filter 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.

### 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 (6.9 bar) and a maximum incoming temperature of 60°C (140°F).<sup>(1)</sup>

**Cyclic Use:** The DSU-H is intended for a maximum of 10,000 on/off cycles of in-line use and 1,000 cycles of 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.

**Reuse Precaution Statement:** 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.

### Installation & Replacement

For important installation and replacement instruction for the DSU-H, please refer to the applicable *DSU-H Installation Guide(s)*, Doc. No.: 50-3203, 50-3204, and 50-3205.

**Caution:** Some medical grade plastics (e.g. ABS) are more susceptible to cracking under stress as a result of exposure to organic solvents. Alkyl dimethyl benzyl ammonium chloride (ADBAC), glycols, alcohols, ketones, silicones, and acetones are some examples of the leading organic solvents found in cleaning and sanitizing agents. Use of cleaning/sanitizing agents on the filter housings is not required and should be avoided.

**Note:** Plumbing system pressures may fluctuate post install. Follow pressure recommendations outlined in Specification Table Note 1.

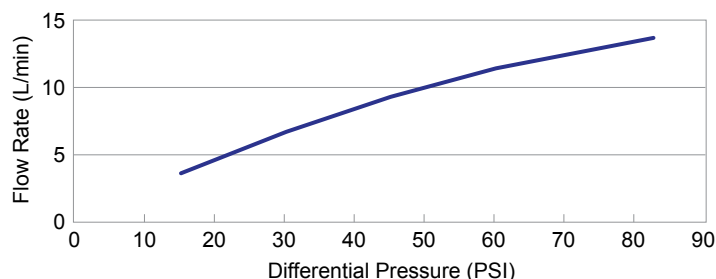
### Operation

After a new DSU-H is installed, water should be run through the filter for approximately 3-5 minutes to flush and purge it of trapped air. The filter should operate for up to 6 months of normal use with minimal degradation in flow. However, if the flow rate degrades significantly, the filter should be replaced. Note: 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.

### 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 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.

















### Clean Water Flow Rate



### Specifications

<b>Sterilization Method</b>	Ethylene Oxide
<b>Max Inlet Pressure<sup>(1)</sup></b>	100 psi (6.8 bar)
<b>Max Inlet Temperature</b>	60°C (140°F)
<b>Max # On/Off Cycles</b>	
<b>In-Line Use</b>	10,000
<b>Open Discharge</b>	1,000
<b>Material</b>	Polysulfone
<b>Pore Size</b>	0.005 micron
<b>Bacterial Retention<sup>(2)</sup></b>	> 10 <sup>11</sup> (B. diminuta)
<b>Virus Retention</b>	> 10 <sup>8</sup> (PhiX-174)
<b>Endotoxin Retention</b>	> 10 <sup>5</sup> EU/ml
<b>Expected Life</b>	Up to 6 months
<b>Recommended Storage</b>	Between 5°C and 35°C (41°F and 95°F)

(1) For inlet pressures above 75 psi, a pressure regulator should be installed ( $\leq 75$  psi) to account for plumbing system pressure fluctuations (typically up to  $\pm 25$  psi). A hammer arrester should be installed in applications where water hammer may be present. (2) DSU-H 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 DSU-H Validation Report: NEP020422. For additional reference see: FDA "Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice," September 2004.

Symbol	Symbol Title	Standard Reference	Standard Title	Explanatory Text
	Manufacturer	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the medical device manufacturer
		ISO 7000	Graphical symbols for use on equipment	
	Use by Date	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the date after which the medical device is not to be used.
		ISO 7000	Graphical symbols for use on equipment	
	Batch Code	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the manufacturer's batch code so that the batch or lot can be identified.
		ISO 7000	Graphical symbols for use on equipment	
	Part Number	ISO 15223-1	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	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that has been sterilized using Ethylene Oxide.
		ISO 7000	Graphical symbols for use on equipment	
	DO NOT Resterilize	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that is not to be resterilized.
		ISO 7000	Graphical symbols for use on equipment	
	DO NOT Use if Package Is Damaged and Consult Instructions for Use	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that should not be used if the package has been damaged or open.
		ISO 7000	Graphical symbols for use on equipment	
	Consult Instructions for Use	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the need for the user to consult the instructions for use.
		ISO 7000	Graphical symbols for use on equipment	
	Medical Device	ISO 15223-1	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	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	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall be handled with care.
		ISO 7000	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	Rain	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall be kept away from rain and be kept in dry conditions.
		ISO 7000	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	Keep Away from Sunlight	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall not be exposed to sunlight.
		ISO 7000	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	Temperature	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the temperature limits in which the medical device can be safely exposed.
		ISO 7000	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	This Way Up	ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates the correct upright position of the distribution packages for transport and/or storage.
		ISO 7000	Graphical symbols for use on equipment	
	Stacking Load	ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates the maximum stacking load which may be stacked on the distribution packages.
		ISO 7000	Graphical symbols for use on equipment	

**MANUFACTURER:**

**Nephros, Inc.**  
380 Lackawanna Place, South Orange, NJ 07079 USA  
(201) 343-5202

**ASSEMBLED AT:**

**MEDICA S.p.A.**  
Via Degli Artigiani, 7  
41036 Medolla (MO), Italy