NEPHROS

**Instructions for Use** Part #: **70-0283 / 70-0284**

# Nephros SSU-H

## 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 SSU-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 3 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 SSU-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 SSU-H is designed for a maximum incoming water pressure of 75 psi (5 bar) and a maximum incoming temperature of 60°C (140°F).

**Cyclic Use:** The SSU-H is intended for a maximum of 5,000 on/off cycles in in-line use and 500 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 3 months dependent on water quality.

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

## Installation & Removal

**Note:** If it is the first time a SSU-H is installed in a location, please refer to one of the SSU-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.
- If installing the threaded version of the filter, turn off the water supply valve. For the quick connect version it is not necessary to turn off the water valves before disconnecting the filter as the female quick connectors have internal shut off valves.
- Disconnect the inlet of the used filter followed by the outlet.
- Seal the used filter ports with the caps to minimize water leakage.
- Remove the used filter from its mounting clamp and discard appropriately.
- Place the new filter in the clamp making sure the flow direction arrow points towards the water outlet.
- Connect the outlet line to the filter followed by the inlet line.

**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

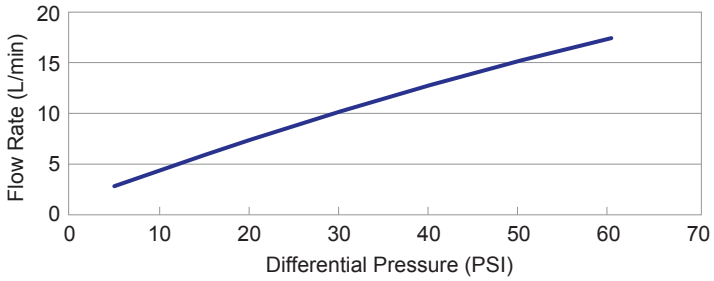
After a new SSU-H is installed, water should be run through the filter for approximately 30 seconds to purge it of trapped air. The pressure drop across the SSU-H generally reduces the flow rate by about 1/4 to 1/3 of the rate without a filter. The filter should operate for up to 3 months of normal use with minimal degradation in flow. If the flow rate degrades significantly, the filter should be replaced.

## Integrity Testing

One can test the integrity of the filter using the following technique

- Disconnect the inlet port connection.
- Disconnect the outlet connection and connect a sterile 60 cc syringe to the outlet port using an adapter.
- With the inlet to drain, pump air into the filter using the 60 cc syringe until water stops flowing out the inlet port (2-3 syringe volumes).
- Attempt to push one final syringe volume of air into the filter. Hold the plunger down for 5 seconds then release it.
- If the plunger rises the filter integrity is assured. If it fails to rise it is recommended to replace the filter.

**Clean Water Flow Rate**




| Specifications | |
|---|---|
| **Sterilization Method** | Ethylene Oxide |
| **Max Inlet Pressure** | 75 psi (5 bar) |
| **Max Inlet Temperature** | 60°C (140°F) |
| **Max # On/Off Cycles** | |
| **In-Line Use** | 5,000 |
| **Open Discharge** | 500 |
| **Filter Membrane**(1) | 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/mlz |
| **Expected Life** | up to 3 months |

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

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| Symbol | Symbol Title | Standard Reference | Standard Title | Explanatory Text |
|---|---|---|---|---|
|  | **Manufacturer** | ISO 15223-1:2021, Clause 5.1.1 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied | Indicates the medical device manufacturer |
| | | ISO 7000:2019, 3082 | Graphical symbols for use on equipment | |
|  | **Use by Date** | ISO 15223-1:2021, Clause 5.1.4 | 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 7000:2019, 2607 | Graphical symbols for use on equipment | |
|  | **Batch Code** | ISO 15223-1:2021, Clause 5.1.5 | 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 7000:2019, 2492 | Graphical symbols for use on equipment | |
|  | **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 | 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 7000:2019, 2501 | Graphical symbols for use on equipment | |
|  | **DO NOT Resterilize** | ISO 15223-1:2021, Clause 5.2.6 | 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 7000:2019, 2608 | Graphical symbols for use on equipment | |
|  | **DO NOT Use if Package Is Damaged and Consult Instructions for Use** | ISO 15223-1:2021, Clause 5.2.8 | 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 7000:2019, 2606 | Graphical symbols for use on equipment | |
|  | **Consult Instructions for Use** | ISO 15223-1, Clause 5.4.3 | 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 7000:2019, 1641 | Graphical symbols for use on equipment | |
|  | **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 | 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 7000:2019, 0621 | Graphical symbols for use on equipment | |
| | | ISO 780:2015, Clause 4.3 | Packaging — Distribution packaging — Graphical symbols for handling and storage of packages | |
|  | **Rain** | ISO 15223-1:2021, Clause 5.3.4 | 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 7000:2019, 0626 | Graphical symbols for use on equipment | |
| | | ISO 780:2015, Clause 4.4 | Packaging — Distribution packaging — Graphical symbols for handling and storage of packages | |
|  | **Keep Away from Sunlight** | ISO 15223-1:2021, Clause 5.3.2 | 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 7000:2019, 0624 | Graphical symbols for use on equipment | |
| | | ISO 780:2015, Clause 4.4 | Packaging — Distribution packaging — Graphical symbols for handling and storage of packages | |
|  | **Temperature** | ISO 15223-1:2021, Clause 5.3.7 | 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 7000:2019, 0632 | Graphical symbols for use on equipment | |
| | | ISO 780:2015, Clause 4.4 | Packaging — Distribution packaging — Graphical symbols for handling and storage of packages | |
|  | **This Way Up** | ISO 780:2015, Clause 4.4 | 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 7000:2019, 0623 | Graphical symbols for use on equipment | |
|  | **Stacking Load** | ISO 780:2015, Clause 4.5 | 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 7000:2019, 0630 | Graphical symbols for use on equipment | |

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