NEPHROS

Instructions for Use Part #: **70-0242 / 70-0251**

Nephros SSUmini

Introduction

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

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

Indications

Description: The Nephros SSUmini is intended to be used to filter water or bicarbonate concentrate used in hemodialysis devices. It assists in providing hemodialysis quality water or bicarbonate concentrate. The device is not a complete water treatment system, but serves to remove biological contaminants. Therefore it must be used in conjunction with other water treatment equipment (RO, DI, etc.).

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

Contraindications

Medical: While the SSUmini produces ultrapure water, the water is not intended to be used in medical applications where USP sterile water is normally used.

Chemical: The SSUmini 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

Caution: When used as a medical device, federal law (USA) restricts this device to sale by or on the order of a physician.

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

Replacement: The filter should be replaced if the flow rate begins to noticeably decrease. As long as it is flowing the SSUmini will continue to filter microbiological contaminants. However, it is recommended to establish a regular maintenance schedule for replacing the filter.

Installation & Removal

Note: If it is the first time a SSUmini is installed in a location verify that the correct connections (3/8 BSPP or 1/4 John Guest) are present on the inlet and outlet lines. Prior to handling a new filter it is recommended that one wash their hands and wear disposable gloves.

- Open a new SSUmini blister pack and mark the label with the installation date.
- Turn off the water/bicarbonate source upstream of the filter.
- Disconnect the inlet side of the used filter, then the outlet side.
- Discard the used filter appropriately.
- Mount the new filter in the flow direction indicated on the label.
- Connect the outlet water line to the filter followed by the inlet line.
- After a new SSUmini is installed, prime the filter to drain for a few minutes to purge it of trapped air.
- If connecting to the bicarbonate supply it may be necessary to first prime the filter using the RO water supply. The bicarbonate line pressure alone may not be sufficient to remove air from the filter.
- Verify there are no leaks or flow restrictions.

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 & Disinfection

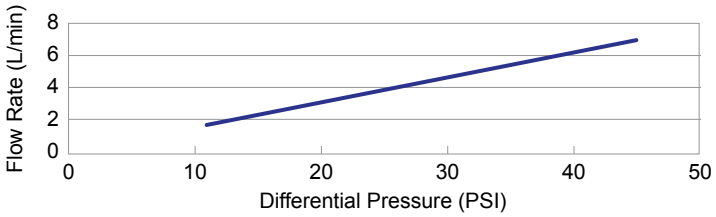
- Following installation, it is recommended to disinfect the lines downstream of the SSUmini as per standard clinic procedure.
- The SSUmini is compatible with most common dialysis disinfection methods. It can be subject to the following disinfectants for 1 year of weekly exposures with no degradation in safety or efficacy.
  - 1% MinnCare
  - 1% Bleach
  - 2% Vinegar
  - 85°C Water (30 PSI Maximum Inlet Pressure)
  - Hydrochloric Acid / Sodium Hydroxide (monthly)
- Disinfection should be carried out as per standard clinic procedures. No special precautions or procedures are required for the SSUmini. It is to be treated simply as an extension of the distribution system.
- Following chemical disinfection the water must be tested for residual disinfectant with test strips or other means. The presence of the SSUmini may require longer rinsing times.
- The pressure drop across the SSUmini generally reduces the flow rate by about 1/4 to 1/3 of the rate without a filter. The filter should operate under normal use with minimal degradation in flow. If the flow rate degrades significantly, replace the filter.

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 does not it is recommended to replace the filter.

Clean Water Flow Rate



Specifications	
Max Inlet Pressure	75 psi (5 bar)
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 1 year

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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	
	**Authorized Representative**	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the authorized representative in the European Country.
	**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	

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