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Instructions for Use Part #: **70-0243D**

Nephros SSU-D — Dialysis

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 SSU-D 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 SSU-D produces ultrapure water, the water is not intended to be used in medical applications where USP sterile water is normally used.

Chemical: The SSU-D 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 SSU-D 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 SSU-D 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 SSU-D is installed in a location, please refer to the *Nephros SSU-D Dialysis Installation Instructions.* Prior to handling a new filter it is recommended that one wash their hands and wear disposable gloves.

- Open a new SSU-D blister pack and set aside the port caps.
- Mark the label with the installation date.
- Turn off the water source upstream of the filter.
- Disconnect the inlet side of the used filter, then the outlet side.
- Seal the used filter ports with the caps to minimize water leakage.
- Remove the used filter from its clamp and discard appropriately.
- Mount the new filter in the same direction of flow as before.
- Connect the outlet water line to the filter followed by the inlet line.
- After a new SSU-D is installed, prime the filter to drain for several 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.

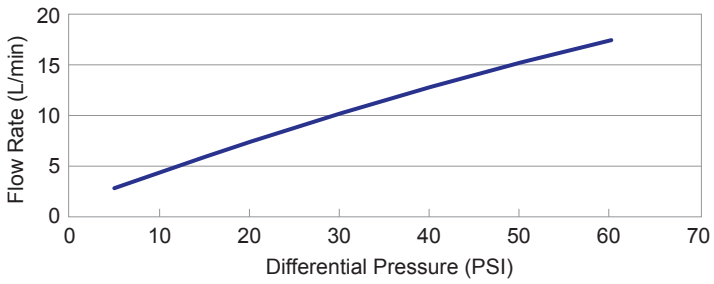
Operation & Disinfection

- Following installation, it is recommended to disinfect the lines downstream of the SSU-D as per standard clinic procedure.
- The SSU-D 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(1)
  - Hydrochloric Acid / Sodium Hydroxide (monthly)
- Disinfection should be carried out as per standard clinic procedures. No special precautions or procedures are required for the SSU-D. 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 SSU-D may require longer rinsing times.
- The pressure drop across the SSU-D generally reduces the flow rate by about ¼ 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

- Connect a sterile 60 cc syringe to the sample port post filter.
- Disconnect the inlet port from the source and close off flow downstream of the sample port.
- 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 passes. If it does not the filter fails.

Clean Water Flow Rate



Specifications

Max Inlet Pressure	75 psi (5 bar)
Filter Membrane(2)	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 1 year

(1) Maximum inlet pressure of 30psi AND flow rate of 1 L/min. Typical pressure drop across the filter at 85°C and 1 L/min is 2psi.

(2) 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	
	**Authorized Representative**	ISO 15223-1:2021, Clause 5.1.2	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 15223-1:2021, 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	
	**CE Marking**	EU MDR 2017/745, Annex V and XII	EU Medical Device Regulation 2017/745	Indicates European Technical Conformity.

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