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Instructions for Use Part #: **70-0235D**

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

Chemical: The DSU-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 DSU-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 DSU-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 DSU-D is installed in a location, please refer to the Nephros DSU-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 DSU-D blister pack and set aside the two port caps.
- Mark the label with the installation date.
- Turn off the water source upstream of the filter.
- 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 the mounting clamps and discard appropriately.
- Place the new filter in the clamps making sure the direction of flow and label arrows are the same.
- Connect the outlet water line to the filter followed by the inlet line.
- After a new DSU-D is installed, prime the filter to drain for several minutes to purge it of trapped air.
- 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.

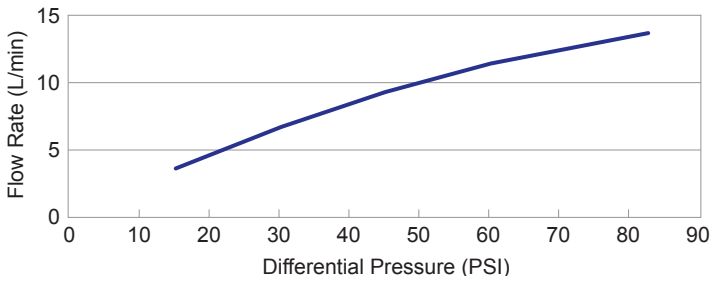
Operation & Disinfection

- Following installation, it is recommended to disinfect the lines downstream of the DSU-D as per standard clinic procedure.
- The DSU-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
- Hydrochloric Acid / Sodium Hydroxide (monthly)
- Disinfection should be carried out as per standard clinic procedures. No special precautions or procedures are required for the DSU-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 DSU-D may require longer rinsing times.
- The pressure drop across the DSU-D generally reduces the flow rate by about 1/3 to 1/2 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.

Safety

The DSU-D 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 contaminants 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 purified by the second (redundant) filter stage.

Clean Water Flow Rate



Specifications

Max Inlet Pressure	75 psi (5 bar)
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/ml
Expected Life	Up to 1 year

(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	
	**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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