

Nephros DSU-D - Dialysis Instructions for Use

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

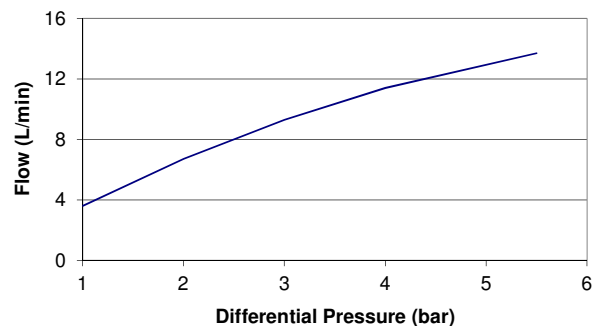
- Following installation, it is recommended to disinfect the lines downstream of the DSU-D as per standard clinic procedure.
- The DSU-D is compatible with most common dialysis disinfection methods. It can be subject to the following disinfectants for 1 year of weekly exposures with no degradation in 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 $\frac{1}{3}$ to $\frac{1}{2}$ 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.

DSU-D - Clean Water Flow Rate



Specifications	Nephros DSU-D
Max Inlet Pressure	75 psi (5 bar)
<u>Filter Membrane</u>	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

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

Assembled at:

Medica S.p.A.
Medolla, Italy

Manufacturer:

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