

Nephros DSU™ - 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 30°C (41 and 86°F).

INDICATIONS

Description: The Nephros DSU 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.).

Single 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 produces microbiologically pure water, the water is not intended to be used in medical applications where USP sterile water is normally used.

Chemical: The DSU removes 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 & Temperature: The DSU is designed for a maximum incoming water pressure of 75 psi (5 bar) and a maximum temperature of 60°C (140°F).

Replacement: The filter should be replaced if the flow rate begins to noticeably decrease. As long as it is flowing the DSU will continue to deliver microbiologically pure fluid. However, it is recommended that one establish a regular maintenance schedule for replacing the filter.

INSTALLATION & REMOVAL

Note: If it is the first time a DSU is installed in a location, please refer to the *Nephros DSU 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 blister pack and set aside the two port caps.
- Mark the label with the installation date.
- Disconnect the inlet side of the used filter followed by the outlet side. It is not necessary to turn off the water source to disconnect the filter as the female quick connectors have internal shut off valves.
- Seal the used filter ports with the caps to minimize water leakage.
- Slide the used filter off the mounting pins and discard appropriately.
- Place the new filter on the pins 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 is installed, prime the filter to drain for several minutes to purge it of trapped air.
- Verify there are no leaks or flow restrictions.

OPERATION/ DISINFECTION

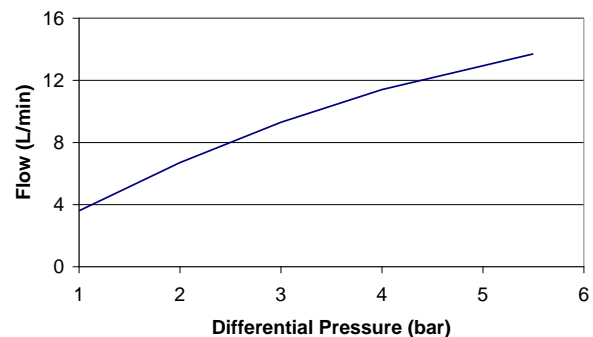
- Following installation, it is recommended to disinfect the lines downstream of the DSU as per standard clinic procedure.
- The DSU is compatible with most common water loop disinfection chemicals. It can be subject to the following chemicals for 1 year of weekly exposures with no degradation in safety or efficacy.
 - 1% Renalin
 - 1% Bleach
 - 2% Vinegar

- Disinfection should be carried out as per standard clinic procedures. No special precautions or procedures are required for the DSU. It is to be treated simply as an extension of the water distribution system.
- Following chemical disinfection the water must be tested for residual disinfectant with test strips or other means. The increase in the water system surface area and volume due to the DSU may require longer rinsing times.
- The pressure drop across the DSU 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 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 - Clean Water Flow Rate



Specifications	Nephros DSU™
Max Inlet Pressure	75 psi (5 bar)
Max Inlet Temperature	60°C (140°F)
<u>Filter Membrane</u>	Medisulfone®
Material	Polysulfone
MW cut-off	15 kDa
Bacterial Retention	> 10 ¹⁰ (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