Nephros SSU-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 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.
- 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.

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.

SSU-D - Clean Water Flow

![Graph](SSU_D_Clean_Water_Flow.png)

- Specifications
  - Nephros SSU-D
  - Max Inlet Pressure: 75 psi (5 bar)
  - Filter Membrane: Medisulfone®
  - Material: Polysulfone
  - MW cut-off: 15 kDa
  - Bacterial Retention: >10¹¹ (B. diminuta)
  - Virus Retention: >10⁶ (PhiX-174)
  - Endotoxin Retention: >10⁵ 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:
Nephros, Inc.
380 Lackawanna Place South
Orange, NJ 07047 USA
833-NEPHROS