

## EXTENSION OF STORAGE DURATION FOR PORTABLE RO MACHINES

The current recommendation for storage duration for the Millennium and 700 Series portable reverse osmosis (RO) machines is 24 hours; for example, reference the Millennium RO Operating Manual, page 4-35. It is our recommendation that portable ROs be disinfected with Minncare® HD Disinfectant prior to use if the portable RO has been idle for over 24 hours. This can present a challenge to staff to maintain this criterion and ensure that the portable RO is available for immediate use in the event of an acute requirement for hemodialysis.

This Technical Note provides new operating conditions under which the Millennium and 700 Series portable RO machines storage duration can be extended in two ways. First, if a longer dormant period (i.e., 72 hours) is desired, the operator must establish and maintain documented results demonstrating the portable ROs product water quality and bacteria results as being within acceptable limits. This means that the RO would not require disinfection prior to use if individual RO testing demonstrated acceptable results within an established dormant period of time beyond 24 hours.

The second method will take the portable RO from 24 hours to 120 hours between chemical disinfection by including the addition of the ENX® ultrafilter or the Nephros SSU-D filter to the product water line of the portable RO machine.

The ENX ultrafilter is a 510(k) cleared medical device, uniquely designed to remove bacteria and pyrogens that may be present in product water. Specifically, the ENX ultrafilter has been validated for absolute removal of bacteria, virus, and other contaminants greater than 0.005 micron with an absolute removal of endotoxin to the same micron detection limit at the  $>10^5$  EU/ml challenge level. The Nephros SSU-D filter is a 510(k) cleared medical device and is designed to remove bacterial, viruses, endotoxins and other contaminants greater than 5 nanometers (nm).

Either method is the preferred course of action. Be sure to read and understand each filter's Instruction for Use to learn about precautions, installation and replacement as well as operation and disinfection protocol. Both filters may be suitable for heat disinfection, but the user needs to refer to the ROs hot water disinfectant system's operating guidelines prior to use. The ENX ultrafilter or the Nephros SSU-D filter can also be used as a final polishing filter on the dialysis machine inlet in a chronic central water system environment. All validated performance claims covered in the respective 510(k) remain in effect and either filter will provide absolute assurance that the water entering the dialysis machine is of "ultrapure" quality with respect to bacteria and pyrogen levels.

For more information on the ENX ultrafilter, consult the ENX ultrafilter Instruction for Use, document P/N W3T574819. See P/N W3T575408 and W3T575407 for the Nephros filter brochures and the Nephros Dialysis Instructions for Use.

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Nephros DSU-D and SSU-D Stage Ultrafilters are manufactured by Nephros, Inc.