
EXTENSION OF STORAGE DURATION FOR PORTABLE RO MACHINES

The current recommendation for storage duration for the Millenium, F-801, and 700 Series portable reverse osmosis (RO) machines is 24 hours; for example, reference Mar Cor Purification (MCP) Millenium Operating Manual, (P/N 1236572 Rev. K), page 4-35. It is MCP's recommendation that portable RO's be disinfected with Minncare® Cold Sterilant 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 insure 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 Millenium, F-801, and 700 Series portable RO machine 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 RO's 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 demonstrates 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 POSICLEAR™ capsule filter to the product water line of the portable RO machine. The POSICLEAR™ capsule filter is a 510(k) cleared medical device (reference K061782), uniquely designed to remove bacteria and pyrogens that may be present in product water. Specifically, the POSICLEAR™ has been validated for absolute removal of bacteria at the 1 by 10⁷ challenge level and to absolute removal of pyrogen to a 0.03 detection limit at the 5 EU/ml challenge level. This method is the preferred course of action.

The POSICLEAR™ 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 510(k) remain in effect and the filter will provide absolute assurance that the water entering the kidney machine is of "ultrapure" quality with respect to bacteria and pyrogen levels.

For more information on the POSICLEAR™ capsule filter, consult the POSICLEAR™ Capsule Filter Instruction for Use document P/N 3025824.