
PRODUCT BULLETIN #3189

To: Our Valued Hemodialysis Customers

From: Michael Verguldi, Product Manager - Medical

Date: March 28, 2014

Subject: **FR-4 RO Machines**



Background

The FR-4 units are Reverse Osmosis (RO) machines built for central water treatment systems specifically designed for use in the chronic hemodialysis arena. They were originally designed and manufactured by G.E.M. Water Systems, Int'l offered primarily for the California medical marketplace. After Mar Cor Purification (MCP) acquired the business in 2009, they transitioned the production of this line from Los Angeles to the main manufacturing facility in Plymouth, MN. Since that time, MCP built and sold over 50 of this Class II medical device.

MCP decided to discontinue offering the FR-4 RO with plans to move towards newer technologies. Hundreds of these machines are in the field today and we are confident that they will continue to perform as intended. We will continue to support the chronic dialysis marketplace with our other successful lines of central RO product offerings.

Action

As of the Effective Date, the FR-4 and FR-2 product line of central RO machines is officially discontinued and will no longer be offered or sold anywhere in the world. MCP will not update, modify, or do any other type of improvements on these products unless dictated by safety concerns to the operator or the patient. Be advised that after April 4, 2021, the use of all FR-Series machines needs to be contemplated as technical support, field repair, and service parts will no longer be available.

Support for these devices will continue for the next seven years with parts, technical, and field help. MCP reserves the right to discontinue product support at any time if manufacturing or product availability has been compromised. Customers can continue to receive product assistance on these RO's by contacting Technical Support at Ext. 2904. Technical documentation and information will remain available.

Effective Date

April 4, 2014