

PRODUCT BULLETIN #3208

To: Our Valued Hemodialysis Customers

From: Michael Verguldi, Product Manager - Medical

Date: September 27, 2016

Subject: **Discontinued Medical Device – Siemens Hemodialysis Water Systems**

INTRODUCTION

This addresses the position of Mar Cor Purification, Inc. (“MCP”) regarding **End of Life** as it relates to ongoing and future support of the Siemens Hemodialysis Water Systems (the “Siemens HWS”).

BACKGROUND

On November 14, 2014, MCP posted Product Bulletin #3196 (the “Bulletin”) on its website noting that all manufacturing of Siemens HWS ended on March 25, 2013. The Bulletin further stated that (i) MCP would continue to support Siemens HWS until December 31, 2017 and (ii) MCP reserved the right to discontinue product support at any time if manufacturing or product availability was compromised prior to December 31, 2017. The Siemens HWS, also known as US Filter and/or Continental water systems for dialysis, impacted by this Bulletin include, but are not limited to, complete hemodialysis water treatment systems, the MED-RO™ Reverse Osmosis (RO) machine and older RO devices (i.e., ROSLM and ROLS), the BICARB50SYS/100SYS bicarbonate mixing and dispensing systems, acid delivery systems, and recessed patient station boxes.

ONGOING AND FUTURE SUPPORT

Effective immediately, please note the following:

1. MCP will honor service on Siemens HWS after December 31, 2017 as required pursuant to an existing annual service or preventative maintenance contract entered into on or prior to January 1, 2017 (“Existing Contract”). After January 1, 2017, MCP will not generate any new quotes or proposals that include service, repair, cleaning or performing any preventative maintenance on Siemens HWS to be performed after December 31, 2017.

MCP will be in contact with each customer under an Existing Contract to discuss how this will impact such Existing Contract.

2. MCP will no longer be able to guarantee dedicated stock, spare parts or replacements items for the Siemens HWS after December 31, 2017. MCP will be in contact with each customer under an Existing Contract to discuss how this will impact such Existing Contract. Please note that certain items and/or parts may not be available today as a result of older technology, manufacturer's (including Original Equipment Manufacturers (OEM)) discontinuance of parts, and/or other circumstances outside of MCP's control.
3. MCP will not take any steps that require changes or improvements to the Siemens HWS due to complaints or other issues surrounding these devices, unless patient and/or user safety is in jeopardy prior to December 31, 2017.
4. Due to the circumstances surrounding all of these systems, it is MCP's position that without OEM and/or validated parts along with ongoing technical support for the Siemens HWS that continuing to operate these devices as intended may expose patients and staff members to undue risk when operated beyond December 31, 2017. If a customer chooses not to make a switch to another system, RO machine, bicarbonate mixer, acid delivery system, and/or recessed patient station box, such customer will assume the risk of operating a device that may need a part that is no longer available, and therefore, it may not have a system in place to produce water or provide solutions for treatments. As a result, there is risk associated with continuing to use any known medical device under those conditions.

MCP understands the End of Life challenge and we stand ready to provide your program with a variety of system options. MCP is committed to assisting you during this process and we are prepared to provide a seamless transition. We thank you for your understanding and value your business. If you have any questions, please contact your local Sales Representative or Product Management at 800-633-3080 or visit our website at www.mcpur.com.