



To: Fresenius Kidney Care Clinical Managers, Facility Administrators, Directors of Operation, Area Team Leads, Tactical Care Team, Regional Vice Presidents, Home Therapy Program Managers, Senior Directors Clinical Quality, Senior Managers Clinical Quality, Senior Directors Regulatory Affairs, Senior Regulatory Managers, Senior Managers Clinical Technology, Clinical Technology Managers, Senior Directors of Clinical Education, Senior Managers of Clinical Education, Clinical Educators, Director Clinical Education Learning Strategies Home Therapies, Directors of Clinical Education Development and Initiatives, Senior Directors of Technical, VP of Technical, Regional Technical Operations Managers, Area Technical Operations Managers, Biomedical Technicians

From: Fresenius Kidney Care Nursing and Clinical Services Biomedical Services

Date: December 20, 2024

Re: **Medical Device Correction: 2008® Series Hemodialysis Machines with Blood Pressure Module BPM3**

Fresenius Kidney Care
Clinical Services Dept.
920 Winter Street
Waltham, MA 02451
Phone: 781-699-9000
Fax: 781-699-9709

Purpose This memo informs Fresenius Kidney Care facilities and programs that Fresenius Medical Care Renal Therapies Group, LLC (FMCRTG, LLC) has released a medical device correction for the 2008T BlueStar Hemodialysis Machines equipped with a fix that includes the new BPM3 Blood Pressure Module, firmware version S007, that fixes the previous issue.

Background Fresenius Medical Care Renal Therapies Group, LLC (FMCRTG, LLC) released a medical device correction for the 2008T BlueStar Hemodialysis Machines equipped with Blood Pressure Module BPM3 (Blood pressure monitor TM-2917B with firmware version S005) in August 2024.
[BlueStar 2.5 Blood Pressure Module 08.12.2024](#)

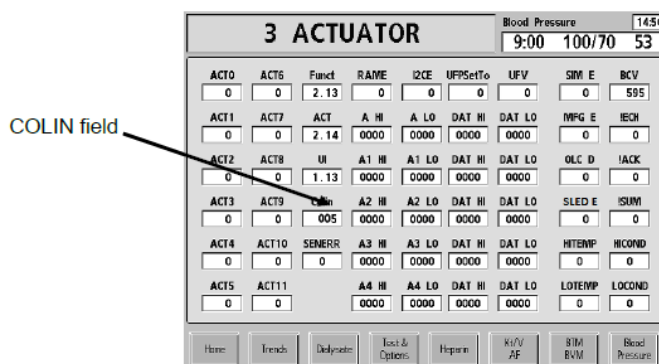
FMCRTG, LLC is informing clinics and facilities there is a new BPM3 Blood Pressure Module, firmware version S007 available that fixes the previous issue.
[Customer-Notification](#)

To determine if you have the affected BPM3 firmware, perform the following steps on your machine. The installed blood pressure module firmware can be identified from one of the debug screens.

Accessing Debug Screens:

- The Debug Screens can be accessed in both Dialysis mode and Rinse Mode by pressing and holding the CTRL key and then pressing the up and down arrow keys at the same time on the keyboard.

- Use the up and down arrow keys individually to scroll through each Debug Screen.
- On Debug screen 3, locate the COLIN field.



The COLIN field shows specific codes based upon which blood pressure module installed:
The applicable BPM3 module type TM-2917 is shown; other modules exist and only 005 is affected by this letter.

Blood Pressure Module	COLIN Module Code: Debug Screen 3	Affected?
TM-2917	005	Yes (return)
TM-2917	007	No (keep)

Note: In rare cases, the COLIN field might be blank or empty. Communication with the blood pressure module was unable to determine the module type. Power cycle the machine and try again.

- If you have any questions regarding the steps above, contact Fresenius Technical Service at 1-800-227-2572.

Facility/ Program Action

Facilities and Programs with the 2008T Hemodialysis Machine with Blood Pressure Module BPM3 should:

Identify what Blood Pressure Module BPM3 (Blood pressure module) is present in clinic machines. For those equipped with the BPM3 (Blood Pressure Monitor TM-2917B) note the firmware version displayed.

A. If Firmware version S005:

Contact Fresenius Medical Care Technical Service at 1-800-227-2572 for replacement.

- Order a replacement part; **PART NUMBER: 191378** (Kit, A&D TM2917B BPM Replacement S007).
- Request a Returned Goods Authorization (RGA) number.
- **Please retain the packaging** from the new BPM3 Module when received and place the affected BPM3 Module (firmware version S005) in the packaging for RGA return.



- **Please note that to receive credit, you must return the affected BPM3 (S005) to the address below:**
 - Fresenius Medical Care
900 W. Zaragoza Dr., Suite D
Pharr, TX 78557
- **Please ensure the assigned RGA number is marked** on the package for return.

B. If firmware version S007:

This is the correct version, and no further actions are required.

Further Guidance:

- Facilities and programs experiencing issues with the 2008T Hemodialysis Machine with Blood Pressure Module BPM3 should submit a Product Complaint.
[Product Complaint Form](#)
- Facilities and Programs should communicate this to all appropriate facility staff, medical directors, and attending physicians.
[Customer-Notification](#)
- Review this communication during your next QAI meeting; document this review in the QAI minutes.
- Complete the reply form.

**Contact
Information**

For questions contact Fresenius Medical Care Technical Service at 1-800-227-2572.

