

## **URGENT FIELD SAFETY NOTICE** **Formula® Hemodialysis Machines:**

**Formula®, Formula® 2000, Formula® PLUS, Formula® 2000 PLUS, Formula® Therapy, and Formula® Domus.**

**DD OCT 2016**

To: Medical Directors, Risk Managers, Dialysis Center/Program Mangers, Distributors, Hospital Biomedical Managers:

The purpose of this letter is to inform you that Bellco, now a part of Medtronic, is conducting a Field Safety Corrective Action (FSCA) on the Formula® hemodialysis machine. To date, three thermal events that led to fire have been reported in three separate machines; one during a disinfection cycle, and two prior to patient use when the machines were switched ON. While there was damage to each of these machines, no patients or healthcare providers were injured as a result of these events. The occurrence of such events is low, with a rate of approximately 0.01% of Formula machines manufactured since 1998.

Based on our internal investigations, we determined the battery charge board to be the source of two of the events. The source of the third event could not be conclusively confirmed due to the extent of the damage to the board, but the available evidence is consistent with the other two events. We have determined that disconnecting the battery charge board will eliminate the possibility of the failure mode while a permanent solution is implemented.

Disconnecting the battery charge board will disable battery backup in Formula machines equipped with this functionality. In the event of an extended power failure, the absence of back-up battery power would require manual operation of the blood pump to return blood from the extracorporeal circuit to the patient. Accordingly, customers are urged to take into account the unique elements related to their practice, such as numbers of patients simultaneously undergoing treatment, staffing ratios of nurses and technicians and availability of backup power sources, in determining the potential impact on patients in following the recommended actions described in this notice.

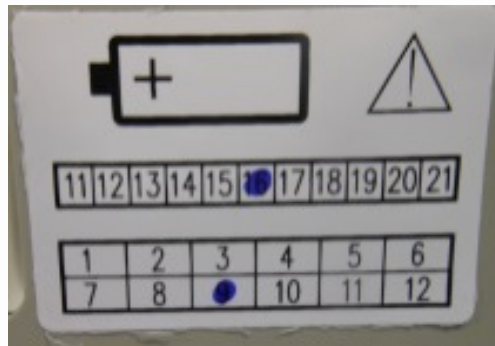
This notification serves to describe the steps necessary to implement the mitigation measures which will disable battery backup functionality by disconnecting the battery charge board.

1. Locate all the Formula hemodialysis machines you manage (e.g., clinic, hospital, home). Note that the scope of this issue and associated mitigation includes only the Formula family of hemodialysis machines\*.

\* Formula family of hemodialysis machines includes the following models; Formula®, Formula® 2000, Formula® PLUS, Formula® 2000 PLUS, Formula® Therapy, and Formula® Domus.

Page 1 of 3

2. Identify whether or not the Formula hemodialysis machine has battery backup. If your machine has battery backup, you will see this label in the rear panel of the machine.



- For those machines with battery backup, refer to **Attachment A**. This attachment will describe the procedure to disconnect the battery charge board in Formula machines with battery backup by a trained technician.
    - Also, review **Attachment B** for existing instructions on machine operation during power failures. Please note that in cases of power failure or interruption without battery backup, the Formula machine will enter a power failure mode and the blood pump will stop. Please read the instructions for use for manual blood return to ensure safe operation during an extended power outage.
  - For machines without battery backup, refer to **Attachment C**. This attachment will describe the procedure to disconnect the battery charge board in Formula machines without battery backup by a trained technician.
3. In all cases, complete and return the Acknowledgement and Receipt Form, **Attachment D**, by fax or email.

Trained service technicians in your facility can perform the actions outlined in the Attachments. However, if you encounter any difficulty in performing these operations, Bellco/Medtronic personnel will be available via telephone to assist you and your staff. Please contact [formulaservice@bellco.net](mailto:formulaservice@bellco.net) for more information.

Our engineering team is diligently working on determining a permanent solution to restore battery backup functionality and to correct this issue. As soon as a solution is finalized, your Bellco/Medtronic or local sales representative will contact you to schedule time for implementation. If the battery backup was disabled on your machines as a result of this temporary mitigation, the correction once implemented, will restore this functionality.

Thank you for your attention to this notification. We are committed to ensuring unsurpassed product quality, reliability and patient safety and correcting this issue is our top priority. We sincerely apologize for any inconvenience this has caused you, your patients, staff and facility. Please do not hesitate to contact me with any questions.

Sincerely,



Asim Nigam  
Sr. Quality Systems Director  
Medtronic Plc.  
Renal Care Solutions  
+00.1.320.761.4477  
asim.nigam@medtronic.com

**Attachments:**

- Attachment A: Procedure for Formula Machines with Battery Backup
- Attachment B: Formula Machine Operation during Power Failure without Backup Battery
- Attachment C: Procedure for Formula Machines without Battery Backup
- Attachment D: Acknowledgement and Receipt Form