UPDATE TO OCTOBER 2016 FIELD SAFETY CORRECTIVE ACTION

Formula® Hemodialysis Machines:
Formula®, Formula® 2000, Formula® PLUS, Formula® 2000 PLUS, Formula® Therapy, and Formula® Domus.

XX January, 2017

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

Dear Valued Customer:

This is an update to Medtronic's October, 2016 notification titled "Urgent Field Safety Notice – Formula® Hemodialysis Machines" (the "Notice") describing thermal events that led to fire (Attachment A). Please refer to the Section(s) applicable to the Formula machine configuration in your facility.

Section 1: Formula Machines with Battery Backup:

In Formula hemodialysis machines that are equipped with battery backup, we will make the following changes to correct the issue described in the Notice. First, a coating has been applied to the battery charge board to protect the electrical components from environmental contamination such as chemicals and moisture. Second, a battery cover will be installed to minimize the likelihood of potential contaminants from the battery. Finally, a 15 amp fuse was added to the battery connection cable located on the battery charge board. These changes have been validated to have no negative impact on the existing operation or performance of the Formula machine and will restore battery backup functionality.

In order to perform this correction, you will need a correction kit, which includes a coated battery charge board, a battery cover and a battery. There are no indications that the battery was associated with the reported thermal events. However, a new battery is being provided to simplify implementation of this field action. Production of correction kits has commenced and with the first shipments being available in January 2017. We anticipate that it may take up to four months to produce a sufficient number of correction kits to restore battery backup functionality in the field.

To facilitate shipment of the correction kits to your facility, please complete and return Attachment B as directed by the form. Once we receive that completed form (and depending on the availability of correction kit inventory), we will ship the requested number of correction kits to your facility. We recognize that customers with a large number of Formula hemodialysis machines may be unable to implement the corrective action all at once. Accordingly, we intend to stagger the shipment of kits based

on our customers' ability to implement the corrective action (given the information provided in response to Attachment B). Therefore, we expect the implementation of the correction to take several months. Please refer to Attachment C for instructions on how to implement this correction once you receive your correction kits. If your facility has Formula hemodialysis machines without battery backup, please refer to Section 2 below.

Section 2: Formula Machines without Battery Backup:

In Formula hemodialysis machines that were not equipped with battery backup, we have determined the appropriate corrective action for this machine configuration is to permanently remove the battery charge board from the unit (which should have been disconnected pursuant to the Notice). This action will ensure that no battery charge boards of the original design implicated in the field action remain in the field. Please refer to Attachment D for further instruction on how to implement this correction if you haven't already done so.

Section 3: Implementation of Correction:

Trained service technicians in your facility can perform these corrections as outlined in Attachments C and D. If you encounter difficulty in performing any of these operations or require assistance, Bellco/Medtronic personnel will be available to assist you and your staff.

Section 4: Acknowledgement of Correction:

Finally, Bellco/Medtronic is requesting acknowledgement that the corrections have been applied to Formula machines both with and without battery backup. Please refer to and complete Attachment E: Correction Acknowledgement Form after implementation of the corrective actions and return according to the instructions on the form.

Please forward this communication to all personnel in your organization who use or support the use of the Formula machines. Additionally, if your facility has distributed Formula machines to other persons or facilities, please promptly forward a copy of this notification to those recipients.

This notification is being issued with the knowledge of [*insert local Competent Authority*] and other global regulatory agencies.

Thank you for your attention to this notification. We appreciate your cooperation during the implementation of this corrective action, and sincerely apologize for any inconvenience this situation may cause you, your patients, staff and facility. We remain committed to ensuring unsurpassed product quality and are working diligently to provide your facility with correction kits to resolve this issue in a timely manner.

Sincerely,

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Attachments:

Attachment A: October 2016 Field Safety Notice
Attachment B: Correction Kit Request Form
Attachment C: Correction Instructions for Formula Machines with Battery Backup
Attachment D: Correction Instructions for Formula Machines without Battery Backup
Attachment E: Correction Acknowledgement Form