

Urgent Field Safety Notice

AK 98
FA-2018-040
Device Correction

Follow-Up Communication: AK 98

March 17th, 2020

Dear Healthcare Provider:

On September 2018, Baxter issued the enclosed important safety information regarding the potential for AK 98 Hemodialysis Devices to generate excessive ultrafiltration (UF) in certain situations where treatment-related alarms occur, or where there is an ultrafilter leak.

Baxter released software version V3.0 for the AK 98 device that mitigates cases of excessive fluid loss in patients. Baxter is in the process of upgrading all AK 98 devices to software version V3.0.

The purpose of this communication is to inform you that Baxter has identified an unintended scenario in the upgraded AK 98 V3.0 devices in which the UF measurement may be incorrectly displayed on the screen and minor back filtration or excessive UF may occur. These events may happen during the time of the Conductivity Alarm which occurs when the B-concentrate or Bicart runs out during therapy. This scenario should be minimized by starting with a new B-Concentrate canister or BiCart cartridge or having a new canister or cartridge readily available for prompt replacement.

Baxter has not received complaints related to this issue.

- **Baxter will be developing an additional software upgrade to address this issue. If you have already received a V3.0 device or the V3.0 upgrade, a Baxter Service Technician will contact you to schedule this additional upgrade when it becomes available.**
- **If you have not yet received the V3.0 upgrade, please note that Baxter is continuing to upgrade all devices to V3.0 as this version has many important safety improvements that benefit patients. Once this additional software is available, Baxter will contact you to schedule the upgrade.**



If you have questions regarding the content of the attached communication, please contact Baxter at +971 45196346, between the hours of 9:00 am and 6:00 pm, Sunday through Thursday.

Please return the attached Customer Reply Form to acknowledge the receipt of this communication.

We apologize for any inconvenience this may cause you and your staff and look forward to continuing to serve your needs.

Sincerely, ;



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Attachment 1: Baxter Customer Reply Form



Attachment 1: Customer Reply Form

Confirmation of receipt of communication
(DEVICE CORRECTION LETTER DATED **17 MAR 2020**)

AK 98

Product codes: 115244, 115248, 115249, 115250, 955106, 955403, 955404, 955406
Serial numbers : All Software V.3.0

Please complete and return one copy of this form per facility by e-mail to ziad_awadallah@baxter.com as confirmation that you have received this notification.

Facility Name and Address:	
Reply Confirmation Completed By: <i>(Please print name)</i>	
Title: <i>(Please print)</i>	
Email and/or Telephone Number (including Area Code):	

Signature/Date: REQUIRED FIELD	_____ / ____ / ____
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We have received the above-mentioned letter, performed the actions outlined in the letter, and have disseminated the information / documentation to our staff, other services/facilities and customers, as applicable.