Baxter

Urgent Field Safety Notice

HD Monitors
FA-2020-047

23rd November 2020

Dear Customer,

Problem Description

Baxter is communicating important safety information regarding the use of connectors between the patient's blood access device and the Baxter blood set used with the Baxter dialysis machines listed below. Baxter has not validated the use of any connectors placed between the blood set and the patient's blood access with Baxter dialysis machines. The use of connectors with potentially incompatible material may increase the risk for leakage in the extracorporeal circuit and may prevent a secure connection between the blood set and the patient's blood access device. Furthermore, introducing additional components in the blood circuit may cause additional pressure drops and may affect the pressure measurement in the blood circuit.

To ensure a proper connection, users must follow the warnings and cautions listed in the product-specific Operator's Manuals in the enclosed Attachment A.

Affected Product

Product Family	Product Code	Serial Numbers
Artis	107108 955403 955404 955603 955604 115248 110635 115323 115962 955412 955680 107107	All
AK 200 S		
AK 98		
AK 200 ULTRA S		

Hazard Involved

Baxter cannot guarantee connectors will establish and maintain secure connections with Baxter blood sets. Additionally, use of connecting devices with Baxter dialysis machines could interfere with the ability of the device to accurately detect pressure drops in the blood circuit. As a result, vascular access disconnects may go undetected, leading to clinically significant blood loss and fatal exsanguination. Within the last two years, Baxter has received two reports of serious injury as a result of blood loss related to the use of a connecting device between the return line and the blood access device.

Actions to be Taken by Customers

1. Operators may continue to safely use Baxter dialysis machines according to the instructions, warnings, and cautions in the product-specific Operator's Manual.

2. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form and return it to Baxter by emailing qa_dublin@baxter.com.** Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

3. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

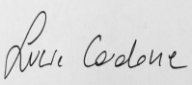
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please distribute this notification to customers and **check the associated box on the reply form.**

Further information and support

For general questions regarding this communication, contact Baxter Dublin Customer Services at shs_customer_services_dublin@baxter.com or phone 01 206 5500.

We thank you for your attention to this important safety information.

Sincerely,



Lucia Cordone
Senior Product Manager
Renal Care Marketing

Enclosure: Baxter Customer Reply Form
Attachment A: Baxter Dialysis Machines – Operator's Manual Excerpts

Baxter

CUSTOMER REPLY FORM

URGENT FIELD SAFETY NOTICE 23RD NOVEMBER 2020

Product Name:

ARTIS, AK 98, AK 200 S, AK 200 Ultra S

Product code:

107108, 955403, 955404, 955603, 955604, 115248, 110635, 115323, 115962, 955412, 955680 & 107107

Batch Number:

All serial numbers

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

Facility Name and Address: *(Please Print)*	
Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Email and/or Telephone Number (Including Area Code):	

We have received the above mentioned letter and have disseminated this information to our staff, other services and facilities.

We have received the above mentioned letter and have disseminated this information to customers/Home Patients.

Signature/Date: REQUIRED FIELD		_____

Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.