Urgent Field Safety Notice

HD Monitors
FA-2020-047
Safety Alert

November 22, 2020

Dear healthcare provider:

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	All Codes	All
Artis Physio		
Artis Physio Plus		
AK 95 S		
AK 96		
AK 98		
AK 200 S		
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. **Complete the enclosed Baxter Customer Reply Form and return it to Baxter by scanning and emailing to** Ahmed_albalaasi@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 distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
4. 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 at +966551048777 between the hours of 8:00 AM – 05:00 PM

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

Sincerely,

Ahmed Albalaasi

Digitally signed by: Ahmed Albalaasi
DN: CN = Ahmed Albalaasi OU = EU, Saudi Arabia, Users, Riyadh
Date: 2020.11.22 23:39:50 +03'00'

Attachment A: Baxter Customer Reply Form

Attachment B: Baxter Dialysis Machines – Operator's Manual Excerpts

Baxter

ATTACHEMENT A

CUSTOMER REPLY FORM

(SAFETY ALERT NOVEMBER 22, 2020)

Product Name:

ARTIS, ARTIS PHYSIO, ARTIS PHYSIO PLUS, AK 95 S, AK 96, AK 98, AK 200 S, AK 200 Ultra S.

Product code:

ALL

Batch Number:

All serial numbers

Please complete and return one copy of this form per facility either by e-mail (Ahmed_albalaasi@Baxter.cm) 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 and we 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.