



## Urgent Field Safety Notice

Artis Physio Plus, Artis Physio 230V, Artis AFB.K Physio Plus

FA Number : FAV-2024-003

Manufacturer: Gambro Dasco S.p.A (Single Registration Number: IT-MF-000011224)

Type of Action: Correction

July XX, 2024 (to be adapted locally)

Dear Sir/Madam (to be adapted locally),

**Problem Description** Baxter Healthcare Corporation is issuing a Correction for the product listed below due to the Antibacterial Air Filter (FAIR 2) not being replaced as scheduled during the Preventive Maintenance activities of certain **Artis Physio Plus** Dialysis System machines. FAIR 2 is a mechanical filter for **Artis Physio Plus** which filters the air entering the hydraulic circuit to prevent contamination when draining the machine. This filter should be replaced within 24 months of its installation.

**Affected Product**  
(to be adapted locally – Remove the country column, this is for your reference only)

Product Code	Description	Serial Number	Country
955412	Artis Physio 230V	FX026911	FR
955412	Artis Physio 230V	FX026436	FR
955680	Artis Physio Plus	FX032759	FR
955683	Artis AFB.K Physio Plus	FX034279	IT
955680	Artis Physio Plus	FX032545	NL
955680	Artis Physio Plus	FX032548	NL
955680	Artis Physio Plus	FX032549	NL
955680	Artis Physio Plus	FX032554	NL
955680	Artis Physio Plus	FX031322	NO
955680	Artis Physio Plus	FX034964	NO
955680	Artis Physio Plus	FX034965	NO
955680	Artis Physio Plus	FX034967	NO
955680	Artis Physio Plus	FX035010	NO
955680	Artis Physio Plus	FX035797	NO
955412	Artis Physio 230V	FX029546	SE

**Hazard Involved** Failure to replace the filter may compromise its integrity. This could potentially lead to entry of non-sterile air and subsequent bacterial contamination of the hydraulic



circuit. Patients may be predisposed to a blood stream infection when using the online priming or therapies. Baxter has not received any complaints associated with this issue.

**Action to be taken by the user**

Baxter is kindly asking that you take the following actions:

1. Customers with impacted machines should avoid using online therapies and online priming until the Antibacterial Air Filter in their affected Artis Physio Plus machines has been replaced. The product code and serial number can be located on the side panel of the machine. In the meantime, customers may continue to use the affected machines for therapies with saline priming.
2. A Baxter representative will contact your facility to schedule the filter replacement.
3. Complete the enclosed customer reply form and return it to Baxter by either faxing it to [\(insert local contact information\)](#) or scanning and e-mailing it to [\(insert local contact information\)](#) or sending it by post to [\(insert local contact information\)](#), even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

**Further information and support (to be adapted locally)**

For general questions regarding this communication or any product issue you are experiencing, contact Baxter at [\(insert local contact information\)](#), between the hours of [\(insert local information\)](#).

The local Ministry of Health (MOH) has been notified of this action. [\(to be adapted locally\)](#)

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Name [\(to be adapted locally\)](#)

Title [\(to be adapted locally\)](#)

Baxter Healthcare Corporation [\(to be adapted locally\)](#)





CUSTOMER REPLY FORM related to Product Correction letter dated XXXXXX (to be completed locally)

Product Name: Artis Physio 230V, Artis Physio Plus, Artis AFB.K Physio Plus  
(to be adapted locally)

Product code: 955412, 955680, 955683 (to be adapted locally)

Serial Number: (to be adapted locally)

Please complete and return one copy of this form per facility either by fax (Fax : \_\_\_\_\_) or by e-mail ( \_\_\_\_\_) as confirmation that you have received this notification. A fax cover sheet is not required. (Can be adapted locally).

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

Please list the specific products and serial numbers in your facility below:

Product Code	Serial/Lot number

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date:	<hr style="border: 0; border-top: 1px solid black; width: 100%;"/>
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REQUIRED FIELD	
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