

Urgent Field Safety Notice

**WRO 300H Water Purification System
FA-2020-037
Device Correction**

**Urgent Field
Safety Notice**

14 September 2020

Dear Chief Renal Technician:

Problem Description Baxter Healthcare Limited has identified that power supply code K80732001 was installed on certain WRO 300H Water Purification System devices (product code 955686) instead of power supply code K79786001. To comply with IEC 60601-1 Ed. 3.1 b:2012 certification standards, Baxter will be replacing power supply code K80732001 with code K79786001. The affected devices were distributed between 05 June 2020 and 08 July 2020

Affected Product

Product Code	Product Description	Serial Numbers
955686	WRO 300H Water Purification System	WR030566
955686	WRO 300H Water Purification System	WR030631
955686	WRO 300H Water Purification System	WR030649
955686	WRO 300H Water Purification System	WR030650

Hazard Involved

The usage of the PSU K80732001 in WRO 300 H does not introduce any new hazard or hazardous situation or change any existing hazard /hazardous situation to the patient/operator/environment. The usage of power supply unit K80732001 in WRO 300 H device 955686 does not affect the safety, effectiveness and the performance of the device. Therefore, no adverse health consequences are expected. No complaints associated with this issue was received by Baxter.

Actions to be Taken by Customers

1. Operators may continue to safely use the affected Water Purification System devices until the power supply replacement is performed.
2. A Baxter service representative will contact your facility to determine the correction plan and schedule the power supply replacement. Your facility will be receiving this correction from Baxter at no charge.
3. **Please complete the enclosed Baxter Customer Reply Form and return it to Baxter by emailing to uk_shs_fca@baxter.com.** Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

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

**Further
information
and support**

For general questions regarding this communication, contact Baxter at uk_shs_fca@baxter.com

Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

Reporting product quality complaints:

• Call: 01604 704 603

• Email: uk_shs_ga_complaints@baxter.com

Reporting adverse events with drugs:

• Call: 01635 206 360

• Email: vigilanceuk@baxter.com

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

Sincerely,



Lucia Cardone
Senior Product Manager HD | Renal Care
Baxter Healthcare Ltd

Enclosure: Baxter Customer Reply Form

Customer Reply Form

DEVICE CORRECTION LETTER DATED 14 SEP 2020

PRODUCT NAME: WRO 300H WATER PURIFICATION SYSTEM

PRODUCT CODE: 955686

SERIAL NUMBERS: WR030566, WR030631, WR030649 & WR030650

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

Facility Name and Address: <i>(Please Print)</i>	
Reply Confirmation Completed By: <i>(Please Print Name)</i>	
Title: <i>(Please Print)</i>	
Email and/or Telephone Number <i>(Including Area Code):</i>	
Current Location of the Device and Serial Numbers	

Signature/Date: REQUIRED FIELD	<hr/>
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Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.