

**Urgent Field Safety Notice**

**WRO 300H Water Purification System**

**FA-2020-037**

**Device Correction**

August, 2020

Dear Sir, Madam,

**Problem Description** Baxter Healthcare 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.

**Affected Product**

<b>Product Code</b>	<b>Product Description</b>	<b>Serial Numbers</b>
955686	WRO 300H Water Purification System	WR030566
955686	WRO 300H Water Purification System	WR030631
955686	WRO 300H Water Purification System	WR030635
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. 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.
2. If you purchased this product directly from Baxter, complete the enclosed Baxter customer reply form and return it to Baxter by faxing it, or scanning and e-mailing it, even if you do not have any inventory. 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.

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

Sincerely,

Baxter Healthcare Corporation