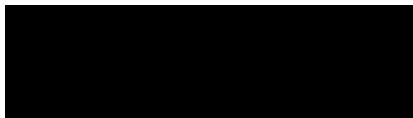


**Urgent Field Safety Notice**

August X, 2021 *(to be adapted locally)*

Dear Healthcare Provider: *(to be adapted locally)*

**Problem  
Description**

Baxter Healthcare Corporation is issuing a Device Correction for the PrisMax System to replace the isolation circuit board. A component on this board was identified that could unexpectedly fail on shutdown and result in the communication ports on the rear of the device to no longer function for the next treatment. This potential failure does not impact all devices, only devices according to the affected product table

- Product code 955558: PrisMax V2 ROW, upgraded with PrisMax V2 TO PrisMax V3 UPGRADE KIT (product code SC8010)
- Any unused PrisMax V2 to V3 Upgrade Kit (product code SC8010).
- New released PrisMax unit product code 955725.

No action is required for other units at your facility.

**Affected  
Product  
(to be adapted)**

Product Code	Product Description	Serial Numbers
955558	PRISMAX, V2 ROW	See Attachment A
955725	PRISMAX V3 CONTROL UNIT-ROW	PX200001
955725	PRISMAX V3 CONTROL UNIT-ROW	PX200002
955725	PRISMAX V3 CONTROL UNIT-ROW	PX200003
955725	PRISMAX V3 CONTROL UNIT-ROW	PX200004
955725	PRISMAX V3 CONTROL UNIT-ROW	PX200005
955725	PRISMAX V3 CONTROL UNIT-ROW	PX200006
955725	PRISMAX V3 CONTROL UNIT-ROW	PX200007
SC8010	PrisMax V2 TO PrisMax V3 UPGRADE KIT	A2210003
SC8010	PrisMax V2 TO PrisMax V3 UPGRADE KIT	A2210004

**Hazard  
Involved**

The potential hazards for this problem are related to the loss of communication with devices connected to the following rear ports:

- 3 Serial Ports (Thermax)
- Ethernet/Wireless
- Remote Alarm (nurse call) connector

These ports are typically used to connect Thermax, EMR systems, or patient monitoring systems and their loss of functionality may result in delay of treatment, the need to use alternative warming methods, or inability to communicate with external patient monitoring systems.

PrisMax can continue to be used without Thermax or with alternative heating options. If TherMax must be used, an alternate PrisMax machine should be used. Patient monitoring and EMR documentation can be accomplished by other means.

**Actions to be  
taken by  
Customers**

1. Operators may continue to safely use the PrisMax Control Unit until the Isolation Board is replaced.
2. A local Baxter service representative will contact your facility to determine the correction plan and schedule the replacement of the Isolation Board within the PrisMax Control Unit or to replace the affected unused spare part kits in your inventory. Your facility will be receiving this replacement from Baxter at no charge.
3. If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form and return it to Baxter by faxing it to (to be adapted locally). Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
4. 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.
5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Device Correction in accordance with your customary procedures.

**Further  
information  
and support**

For general questions regarding this communication, 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 thank you for your attention to this important safety information.

Sincerely,

Name (to be adapted locally)

Title (to be adapted locally)

Baxter Healthcare Corporation (to be adapted locally)

Enclosure: Baxter Customer Reply Form



**Confirmation of receipt of communication**

(DEVICE CORRECTION LETTER DATED **XX (TO BE COMPLETED LOCALLY)**)

**DEVICE NAME** PRISMAX, V2, V3 ROW

**Product code:** 955558, 955725, SC8010 (upgrade kit)

**Serial numbers:** .... **(to be completed locally)**

<p>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. <b>(Can be adapted locally)</b></p>
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Facility Name and Address:	
Reply Confirmation Completed By: (Please print name)	
Title: (Please print)	
Email and/or Telephone Number (including Area Code):	

<b>Signature/Date:</b> REQUIRED FIELD	<hr/>
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We have received the above-mentioned letter, performed the actions outlined in the letter, and have disseminated the information / documentation to our staff, other services/facilities and customers, as applicable.