Baxter

URGENT DEVICE CORRECTION

AGMAR d.o.o.
Jakuševečka cesta 4b
10000 Zagreb
CROATIA

May 15, 2019

Dear Agmar colleagues,

Affected Product

All series of Prismaflex 8.10 devices.

Problem Description

Baxter Healthcare has received reports of Prismaflex 8.10 devices with inactive syringe pump during Continuous Renal Replacement Therapy (CRRT) treatment while using RCA (Regional Citrate Anticoagulation). It was determined that there is a potential for the calcium syringe pump to be inactive without the device alarming after completed change syringe procedure.

Baxter will be upgrading all Prismaflex devices with software version 8.10 to software version 8.20. The new software version will include an enhancement to ensure alarm generation when the issue occurs while performing therapy using Regional Citrate Anticoagulation (RCA)

Hazard Involved

An inactive pump may result in under delivery of calcium leading to hypocalcemia. Hypocalcemia may potentially result in serious adverse health consequences. There have been two reports of serious injury associated with this issue.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Clinicians may continue to safely use the Prismaflex devices while utilizing additional caution to ensure that the syringe pump operates as intended after the change syringe procedure, until the software upgrade can be performed.

2. Clinicians should use appropriate syringes when using the Prismaflex device per the operator's manual, see section 15.6.2 Citrate – calcium method.

3. A local Baxter service representative will contact your facility to arrange for the software upgrade for all Prismaflex devices with current 8.10 software. Your facility will be receiving this software upgrade from Baxter at no charge.

4. If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form and return it to Baxter by e-mailing it to agi_zag@baxter.com, 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.

5. 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 per their instructions.

6. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

7. 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 Urgent Medical Device Correction in accordance with your customary procedures.

Further information and support

If you have additional questions, please contact your Baxter sales representative or technical service.

We apologize for any inconvenience this may cause you and your staff. Baxter's software version update will take additional measures to further ensure patient safety. Baxter is committed to ensuring our products and services consistently meet the highest standards of quality and safety for our patients and healthcare providers.

The Local MOH has been informed about this action on May 15, 2019.

Sincerely,

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Enclosure: Baxter Customer Reply Form