Digital Communication Module Kit
FA-2022-034
Device Correction

26th July 2022

Dear Healthcare Provider

Problem Description

Baxter Healthcare is issuing a Device Correction communication for the Digital Communication Modules (DCM's) listed below. DCM code SC8080 is an optional spare part upgrade for the PrisMax System monitor, which provides wireless communication functionality in addition to the current cable (serial or ethernet) connection as part of the TrueVue offering. The DCM is configured to use wireless settings which do not take into account global power limits and transmission power controls required in all countries. This impacts DCM's installed on PrisMax conforming to CE mark and installed in countries that recognize the CE mark, where wireless communication is enabled. The DCM functions correctly but is incorrectly configured to meet wireless regulations. There are no new or increased therapy risks when using the PrisMax System. Please note that DCM's using a wired configuration are not affected by this issue.

Baxter will be working with customers to convert the affected DCM's to a wired configuration until a software update with the proper wireless configuration is available.

Affected Product

Product Code	Product Description	Lot Numbers
SC8080	Digital Communication Module Kit	All DCM's with the potential for wireless communication to be enabled

Hazard Involved

This issue does not have the potential for adverse health consequences and there have been no associated complaints or serious injuries reported.

Actions to be taken by Customers

1. Operators may continue to use PrisMax Systems with affected DCM devices installed until the wired reconfiguration is performed.
2. A Baxter representative will contact your facility to determine the correction plan for the DCM reconfiguration.
3. Once a software update is available with the proper wireless configuration, a Baxter representative will contact your facility to schedule an upgrade.
4. Your facility will be receiving these corrections from Baxter at no charge.
5. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form and return it to Baxter** by scanning and e-mailing it to QA_Dublin@baxter.com 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.
6. 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.
7. 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

For general questions regarding this communication or any product issue you are experiencing, contact Baxter at shs_customer_services_dublin@baxter.com or phone 01 206 5500.

The HPRA has been notified of this action.

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

Sincerely,

Andrew Warburton
Business Unit Head, Acute Therapies
Baxter Healthcare Ltd

Baxter

Confirmation of receipt of communication

(DEVICE CORRECTION LETTER DATED 26TH JULY 2022)

DEVICE NAME

Product code: SC8080

Serial numbers : All DCM's with the potential for wireless communication to be enabled

Please complete and return one copy of this form per facility by e-mail (QA_Dublin@baxter.com) as confirmation that you have received this notification.
A fax cover sheet is not required.

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

Signature/Date: REQUIRED FIELD	

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.