

Urgent Medical Device Correction

May 19, 2025

Dear Healthcare Provider,

Vantive is issuing an Urgent Medical Device Correction for the Digital Communication Modules (DCM's) listed below. DCM is a non-medical, separate hardware module that integrates into the PrisMax system and enables the wireless, or wired ethernet communication functionality for the PrisMax device.

Each country has its own wireless regulations, and DCM must obtain country-specific wireless registration approval before it can be installed and used in those countries. This issue does not impact PrisMax system functionality and there is no impact on patients and operators because of this issue. However, as the registration activities are currently ongoing for DCMs in your country, Vantive will be working with customers to uninstall DCMs from Prismax machines until the registration approvals are received.

Affected Product

Product Code	Product Name	Serial Number	Associated PrisMax Product Code	Associated PrisMax Serial Number
SC8080	Digital Communication Module Kit	5002599	955725	PX202977

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. Customers may continue to use PrisMax devices with affected DCMs until the correction is performed.
2. A Vantive representative will contact your facility to schedule the correction.
3. Your facility will be receiving this correction from Vantive at no charge.
4. Complete the enclosed customer reply form and return it to Vantive by either scanning and e-mailing it or sending it by post. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeated notices.
5. 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, please contact gara.malaysia@vantive.com or Vantive Malaysia which can be reached at +603-76616990 between the hours of 9.00 am and 5.30 pm, Monday through Friday. Customers should contact their local Vantive sales representative for account- specific issues.

The Medical Device Authority (MDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of these products may be reported via contacting Vantive Product Surveillance by navigating to the Product Feedback Portal at <https://productfeedback.vantive.com>

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

Sincerely,

Electronically signed by: Wensze Sharon Ding
Reason: I am the author of this document
Date: May 19, 2025 18:00 GMT+8

Sharon Ding
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