MEDICAL DEVICE CORRECTION

November 15, 2019

Dear Healthcare Provider:

Problem Description

Baxter Healthcare has identified the TherMax Blood Warmers listed below may not be in compliance with an electrical safety standard, which requires a protective earth connection that can sustain a current of 25 amps for 10 seconds. The affected units may not have an adequate ground path, which could cause the units to become damaged if used with improperly grounded outlets. The damage could cause the TherMax Blood Warmer units to be nonfunctional during clinical use. If the TherMax units are used with a properly grounded outlet, no issues are expected.

To address this issue, Baxter will be repairing affected TherMax Blood Warmers at your facility.

Affected Product

Product Code	Product Description	Serial Numbers
955515	TherMax, Blood Warmer Unit, ROW	101270

Hazard Involved

A nonfunctional TherMax blood warmer may result in a delay of therapy or inability to use the device for blood warming; however, adverse health consequences are not likely, since alternative means of patient warming may be used. There have been no reports of serious injury associated with this issue.

Actions to be Taken by Customers

1. Operators may continue to safely use affected devices with a properly grounded outlet.
2. A local Baxter service representative will contact your facility to determine the correction plan and schedule the device repair.
3. 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 the sales representative**.** 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 Urgent Medical Device Correction in accordance with your customary procedures.

The Health Sciences Authority has been notified of this action. If you have questions regarding this communication or if you have any other questions, please call your Baxter Sales Representative.

Please kindly report any quality problems or any adverse events associated with the product to the following personnel:

- Please report Product Complaints to singapore_productcomplaint@baxter.com
- Please report Adverse Events to singapore_patientsafety@baxter.com

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

Sincerely,

[redacted]

Corynn Tan
Senior QA Manager
Baxter Healthcare (Asia) Pte Ltd
cc: Director of Pharmacy, Chairman Medical Board and relevant Head of Departments