SAFETY ALERT

June 21, 2024

Dear Distributor,

Problem Description

Baxter Healthcare Corporation has identified that the **Braun Thermoscan® PRO 6000** ear thermometers listed below may have been shipped with a compact disc (CD) containing an outdated version of the Instructions for Use (IFU). The affected product was shipped to Malaysia on 16 Nov 2022. Please be aware that the current, correct IFU includes an additional warning (shown below) regarding proper cleaning, and the risks associated with the speculum tip potentially overheating due to fluid ingress.

WARNING If cleaning instructions are not followed, the device may be exposed to fluid ingress. If this occurs, there is a risk of the probe tip overheating and potentially causing a burn to the user or the ear canal of the patient. In addition, fluid ingress may cause inaccurate temperature readings.

The IFU can be found at Hillrom.com, by accessing the Braun ThermoScan PRO 6000 products page:

- From the home page at Hillrom.com, choose *Products >> Physical Exam & Diagnostics >> Thermometry*, then scroll down to the pictured results and click on *Braun ThermoScan PRO 6000; or*
- Use the following link: https://www.hillrom.com/en/products/braun-thermoscan-pro-6000

The IFU can be found in the "Education & Documentation" section, under "User Manual."

Affected Product

Product Code	Product Description	Serial Numbers
06000-200	Braun Thermoscan® PRO 6000 Ear Thermometer w/ Small Cradle	10421K60210
06000-200	Braun Thermoscan® PRO 6000 Ear Thermometer w/ Small Cradle	04022K60665

Hazard Involved

If cleaning instructions are not followed, the device may be exposed to excess amounts of cleaning solution, leading to fluid ingress. If this occurs, there is a risk of the probe tip overheating and potentially causing a burn to the user or the ear canal of the patient. The population at greatest risk are patients who are unable to withdraw from the heat source, or those who are unable to effectively communicate pain. To date, Baxter has not received any reports of serious injury related to this issue.

Actions to be taken by Customers

1. **If you received this communication directly from Baxter, please acknowledge receipt of this letter by completing the Customer Reply Form (Enclosed).** Acknowledging receipt of this notification will prevent you from receiving repeat notices.

2. If you purchased this product from a distributor, please note that the Baxter reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to your distributor/wholesaler according to their instructions.

3. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them, informing them of the requirement.

4. If you are a dealer, wholesaler, distributor, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this safety Alert in accordance with customary procedures and **check the associated box on the customer reply form.**

The Medical Device Authority (MDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of this product may be reported via Malaysia_productcomplaint@baxter.com.

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

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Sincerely,

Signature: Anju Shear

Electronically signed by: Anju Shear
Reason: I approve this document
Date: Jun 21, 2024 14:27 GMT+5.5

Email: anju_shear@baxter.com

Anju Shear
QA Manager
Baxter Healthcare Corporation

Enclosure: Baxter Reply Form Instruction Sheet