Urgent Field Safety Notice

Braun Pro 6000
FA Number: FA-2024-038
Manufacturer: Welch Allyn Inc. (Single Registration Number: US-MF-000013394)
Safety Alert

July DD, 2024 *(To be adapted locally)*

Dear Healthcare Provider or Distributor *(To be adapted locally)*

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Thermoscan® PRO 6000** ear thermometers listed below may have been shipped with a compact disc (CD) containing an outdated version of the Instructions for Use (IFU).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 between 15 September 2022 and 22 February 2024. 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 *(to be adapted locally)*

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

Affected Product *(To be adapted locally)*

Product Code	Product Description	Serial Numbers	Device Identifier
06000-200	**Braun Thermoscan® PRO 6000** Ear Thermometer w/Small Cradle	All	00732094309003
06000-300	**Braun Thermoscan® PRO 6000** Ear Thermometer w/Large Cradle	All	00732094309027

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. Clinicians may continue to use the PRO 6000 ear thermometers according to the current IFU (CD material number 421032). Please discard all versions of the outdated IFU (CD material number 419450). The material number is printed on the CD.
2. **Please share this communication with all potential users in your organization and instruct them to follow cleaning instructions in the IFU Maintenance and Service section for proper cleaning. For convenience, the cleaning instructions are summarized in the enclosed Cleaning Guide.**
3. **Do not use the device if the ring around the measurement button shows a green blinking or flashing light instead of a ready state (solid green light). Contact Baxter Technical Support to report this issue** *(to be adapted locally)***.**
4. **Do not use the device if the device requires multiple power-ups prior to going to ready state (solid green light). Contact Baxter Technical Support to report this issue.**
5. **If you experience an overheating probe tip, do not use the device. Contact Baxter Technical Support to report the issue.**
6. Complete the enclosed customer reply form and return it to Baxter by either faxing it to *(insert local contact information)* or scanning and e-mailing it to *(insert local contact information)* or sending it by post to *(insert local contact information)* 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.
7. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
8. 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.
9. 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 notification in accordance with your customary procedures.

Further information and support

For general questions regarding this communication or any product issue you are experiencing, contact Baxter at *(insert local contact information)*, between the hours of *(insert local information).*

The local Ministry of Health (MOH) has been notified of this action. *(to be adapted locally)*

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

Sincerely,

Name *(to be adapted locally)*
Title *(to be adapted locally)*
Baxter Healthcare Corporation *(to be adapted locally)*

Attachment 1: Customer Reply Form
Attachment 2: Cleaning Guide