Baxter

URGENT MEDICAL DEVICE CORRECTION

Follow-up Communication to June 13, 2024, Safety Alert

July 24, 2024

Dear Healthcare Provider or Distributor:

On June 13, 2024, Baxter issued a Safety Alert letter for Braun Thermoscan® PRO 6000 ear thermometers. This letter has been updated to include additional information in the 'Actions to be taken by Customers section on page 2. The updated actions are in bold.

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Braun Thermoscan® PRO 6000 ear thermometers listed below may have been shipped with a compact disc (CD) containing an outdated version of the Instructions for Use (IFU).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 US customers between 9/15/2022 and 2/22/2024. 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

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

Affected Product

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.**
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. If you received this communication directly from Baxter, please acknowledge receipt of this notification by responding on our customer portal at https://BaxterFieldActionCustomerPortal.onprocess.com, even if you do not have any remaining inventory. Log in to the portal using the account number listed in the enclosed reply form instruction sheet. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.
7. If you purchased this product from a distributor or wholesaler, note that responding on the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions.
8. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
9. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please distribute this notification to them and check the associated box on the customer portal.

Further information and support

For general questions regarding this communication, please contact Baxter (legacy Welch Allyn and Hillrom) Technical Support at 800-535-6663, option 2, between the hours of 8:00 am and 8:00 pm Eastern Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of these products may be reported using one of the following options:

- Contacting Baxter Technical Support at 800--535--6663, option 2, then 1 for English or 2 for Spanish, then choose option 1, then option 3. Support is available between the hours of 8:00 am and 8:00 pm Eastern Time, Monday through Friday
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
  - Online: By completing and submitting the report online at: https://www.accessdata.fda.gov/scripts/medwatch/

- Regular mail or Fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178

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

Sincerely,

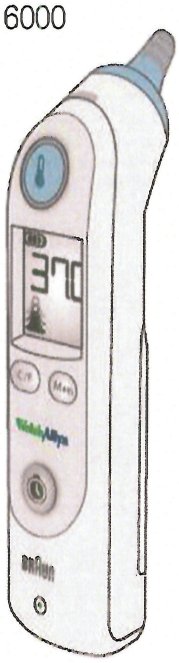
Brian Ray
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Reply Form Instruction Sheet
Cleaning Guide

Hillrom.

BRAUN

ThermoScan®
PRO 6000



Cleaning guide

Thermometer body

NOTE Place a new probe cover on the thermometer before cleaning.

Approved cleaning solutions

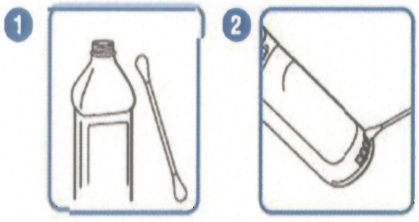
- 70% isopropyl alcohol or ethyl alcohol
- Hydrogen peroxide (Virox, Oxivir)
- Quaternary ammonium compounds (CaviWipes™, Clinell Universal Wipes', Sanicloth)
- 10% Chlorine bleach solution

Wipe dry. Allow 5 minutes drying time.
Make sure thermometer body is dry before use.

Thermometer contacts

Approved cleaning solutions

- 70% isopropyl alcohol or ethyl alcohol

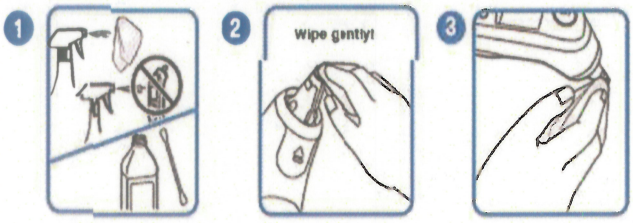


Place the thermometer aside for 1 minute, allowing the contacts to air dry.

Lens window and probe

Approved cleaning solutions

- 70% isopropyl alcohol or ethyl alcohol only!



Wipe dry. Allow 5 minutes drying time.
Make sure probe lens window is dry before use.

hillrom.com

This product is manufactured by Welch Allyn, Inc. under license to the 'Braun' trademark. 'Braun' is a registered trademark of Braun GmbH, Kronberg, Germany. Thermoscan is a registered trademark owned by Helen of Troy Limited.

Hillrom Technical Support
hillrom.com/en-us/about-us/locations/
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