

Urgent Medical Device Correction

Subject: Potential risk of probe tip overheating associated with Welch Allyn® Braun® ThermoScan® PRO 6000 Ear Thermometer.

FSCA-identifier: FA-2021-05-001-SKF-004

Type of action: Device Correction

Date: 29-JUL-2021

To: Chief Executive; Facility Administrator; Facility Engineer; Vigilance Manager; Biomedical Engineering; Medical Device Liaison Officer; Distributor

Description of the problem:

Welch Allyn, Inc. (a Hillrom company) is issuing this letter to notify you of the potential risk associated with overheating of the Braun ThermoScan PRO 6000 probe tip due to fluid ingress. This issue potentially impacts all PRO 6000 in the field.

Potential Risk:

If the device is exposed to fluid ingress and is used before the cleaning fluid has completely dried, there is a risk of the device overheating potentially causing a burn to the user or the ear canal of the patient. Population at greatest risk are patients that are unable to communicate or react to heat exposure.

Background:

Hillrom has received 116 reports of complaints regarding overheating of the Braun ThermoScan PRO 6000 probe tip out of more than 1.1 million units sold. To date, we are aware of one reported moderate injury associated with this issue.

Our investigation has confirmed that the probe tip overheating is the result of fluid ingress. Fluid ingress causes the sensor to behave inconsistently, which does not allow the built-in safety mitigation (turn off the heating element) to work correctly. The majority of the devices which experience overheating of the probe tip show one of two behaviors at time of power up:

1. The ring around the measurement button will show a green blinking or flashing light instead of a ready state (solid green light).

2. The device requires multiple power-ups prior to going to ready state (solid green light). See Figure 1.

Internal testing has confirmed that once dried, a device that had previously overheated would not further exhibit this issue if cleaned following the instructions for use recommendations.

Fig 1:



This Field Safety Notice is intended to:

1. Remind users of the correct cleaning procedures for the device. Hillrom is including a Cleaning Guide which summarizes the correct cleaning protocol to minimize potential for liquid ingress.
2. Inform users of the potential safety risk of inappropriate cleaning practices.
3. Inform users of what visual signals to look for to minimize the potential exposure to overheating probe tips.

Actions to be taken by the User:

1. Please share this communication with all potential users in your organization and instruct them to follow the provided Cleaning Guide for proper cleaning.
2. 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) and contact Hillrom Customer Service to report this issue.
3. Do not use the device if the device requires multiple power-ups prior to going to "ready state" (solid green light) and contact Hillrom Customer Service to report this issue.
4. If you experience an overheating probe tip, do not use the device and contact Hillrom Customer Service to report the issue.
5. Complete the attached response form and return to HillromSKF004@stericycle.com within one month.

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.