

Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	URGENT: Field Safety Notice	FA-2021-05-001-SKF-004
---	------------------------------------	------------------------

Date

Customer name Customer Street Address Customer Country,

Commercial name of affected product:

Braun® ThermoScan® Pro 6000 Ear Thermometer

Subject:

Potential risk of probe tip overheating

Affected Devices: All Braun PRO 6000 Ear Thermometers in distribution.

Production Dates: From 2015 to date

Type of action: **Field Safety Notice**

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

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 reports of complaints regarding overheating of the Braun ThermoScan PRO 6000 probe tip. 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).

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.



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.

Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	URGENT: Field Safety Notice	FA-2021-05-001-SKF-004
---	------------------------------------	------------------------

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 HillromSKF004OUS@hillrom.com within one month.

Actions to be taken by the distributor:

Please share with end users and/or your accounts and complete the attached response form and return to HillromSKF004OUS@hillrom.com within one month.

Contact HillromSKF004OUS@hillrom.com to receive an electronic copy of this notification, response form, and further instructions for notifying your accounts.

Actions being taken by Hillrom:

Hillrom is in the process of updating the Braun ThermoScan Pro 6000 Instructions for Use (IFU) to include additional fluid ingress warnings.

The IFU and Cleaning Guide can be found on the Hillrom website, Hillrom.com, under the Education & Documentation section of the Braun ThermoScan PRO 6000 Products page.

The updated IFU will be available on the website once released.

Contact Reference Person:

Should you have any questions regarding this notification, please contact Hillrom/Welch Allyn Technical Support, using email or number below.

Region/Country	Technical Support Phone	Technical Support Email
CZECH REPUBLIC	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
GERMANY	+49 6950 985 132, Option 3	eme.techsupport@hillrom.com
ITALY	+39 0269682425, Option 3	eme.techsupport@hillrom.com
NETHERLANDS	+31 (0) 20 206 13 60, Option 3	eme.techsupport@hillrom.com
BELGIUM	+31 20 206 13 60, Option 3	eme.techsupport@hillrom.com
SLOVENIA	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com

Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	URGENT: Field Safety Notice	FA-2021-05-001-SKF-004
---	------------------------------------	------------------------

RUSSIA	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
POLAND	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
FRANCE	+33 1 57 32 49 94, Option 3	eme.techsupport@hillrom.com
LATVIA	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
TURKEY	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
MOROCCO	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
CROATIA	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
PORTUGAL	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
UNITED KINGDOM	+41 44 6545315	eme.techsupport@hillrom.com
SWITZERLAND	+44 207 365 6780, Option 3	eme.techsupport@hillrom.com

Transmission of this Field Safety Notice:

Please ensure this notice is circulated to all appropriate personnel. This may include, but is not limited to:

• A&E departments	• In-house maintenance staff
• Adult intensive care units	• IV nurse specialists
• All wards & Clinics	• Medical directors
• Biomedical engineering staff	• Nursing executive directors
• Clinical governance leads	• Oncology units
• Day case theatres	• Pediatric intensive care units
• EBME departments	• Risk managers
• Equipment stores & Libraries	• Supplies managers
• Health and safety managers	• Theatres

The undersign confirms that this notice has been communicated to your local Regulatory Agency.

Sincerely,

Joel Roth
Director, Quality Assurance

Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	URGENT: Field Safety Notice	FA-2021-05-001-SKF-004
---	------------------------------------	------------------------

Response Form / Receipt

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

(FA-2021-05-001-SKF-004)

It is important that you return this form/receipt as acknowledgement of your receipt and provide us with the necessary information.

Please complete the following with the correct information and **return this Response Form** within one month.

Hillrom account number (if known): _____

Name of the facility: _____

Address of the facility: _____

City: _____ Zip: _____ Country: _____

Facility Contact Person Name: (print)

Signature: _____ Date: ____/____/____

Title: _____ Phone: _____

Email: _____

Check actions taken by end users:

We have reviewed and understand the attached Urgent Medical Device Correction and have shared with potential users in our organization.

Yes No

Check actions taken by distributors:

We have distributed the product further and notified our customers of the attached Urgent Medical Device Safety Notice per the instructions noted above.

Yes No

Response form shall be returned to HillromSKF004OUS@hillrom.com within one month.