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August 20, 2021

URGENT MEDICAL DEVICE SAFETY NOTICE
HILLROM Braun® Thermoscan® PRO 6000 Ear Thermometer

R2117
1st Attempt

Hillrom (formerly Welch Allyn) has advised The Stevens Company of a Type III safety notice for the following products:

Product Name	Stevens Catalog #	Manufacturer #	Serial
THERMOMETER EAR PRO-6000 W/SMALL CRADLE	111-06000-200	06000-200	ALL
THERMOMETER EAR PRO-6000 W/LARGE CRADLE	111-06000-300	06000-300	ALL

Reason for Advisory

Welch Allyn has identified a potential safety risk due to fluid ingress for all PRO 6000 thermometer devices. 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 ear canal of the patient. The population at greatest risk are patients that are unable to communicate or react to heat exposure.

One moderate injury has been associated with this issue.

The probe tip overheating has been confirmed to be due to fluid ingress. The fluid ingress causes the sensor to behave inconsistently, which does not allow the built-in safety mitigation (shut off the heating element) to work correctly. The majority of the devices which experience overheating of the probe tip show one of the two behaviours when turned on:

1. The ring around the measurement button will show a green blinking or flashing light instead of a solid green light (ready state.)
2. The device requires multiple power-ups prior to getting a ready state (solid green light.)

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

This notice includes a Cleaning Guide which summarizes the correct cleaning protocol to minimize potential liquid ingress.

No return is necessary – device can continue to be used safely following the instructions for use and cleaning guide.

1. Do not use the device if the ring around the measurement button shows a green blinking or flashing light instead of a solid green light (ready state.)
2. Do not use the device if it requires multiple power-ups prior to getting a solid green light.
3. If you experience overheating of a probe tip, do not use the device and contact Stevens or Welch Allyn.

Thank you,
Steve Baker, CQIA
Regulatory Affairs & Quality Assurance Manager

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