

September 2023

Use of Generic probe Covers [probe covers that are not branded Hillrom/Baxter¹ are referred to as “Generic probe Covers”].

To ensure adequate safety and performance especially related to thermometer measurement accuracy as well as usability, we highly recommend that health care providers use ONLY Hillrom/Baxter branded probe covers.



Figure1. Pro6000 Thermometer (ThermoScan) and associated probe covers

Hillrom/Baxter¹ branded probe covers are not merely meant as sanitary barriers but plays an integral role in ensuring an accurate temperature reading.

The Hillrom/Baxter branded probe covers are not merely used as a sanitary barrier but contribute up to a maximum of $\pm 0.1^{\circ}\text{C}$ towards the accuracy of the temperature readings in any ambient temperature in which the thermometer works. The thickness of the probe covers is carefully controlled to ensure that the thermometer meets the overall thermometer accuracy specification.

Hillrom/Baxter branded probe covers, which are manufactured in the United States, are subject to a detailed five (5) step quality check (transmissivity, ejection force, attachment, concentricity, dimensional) during production and are required to meet specifications on accuracy, tip thickness, ejection force, and dimensional tolerances to ensure that every cover used results in an accurate and reliable reading regardless of patient or ambient temperature. The probe covers along with the thermometer also undergo rigorous testing using a sophisticated five environmental (5E) chamber that precisely controls five different combinations of temperature and humidity conditions during testing. A simple calibration check using a black body or such

¹ Currently branded Hillrom

ALWAYS READ LABELS AND DIRECTIONS FOR USE. For healthcare professional use only.

Authorized Australian Sponsor: Welch Allyn Australia Pty Limited

1 Baxter Drive, Old Toongabbie NSW 2146

T 1800 445 576

other reference device is not sufficient to validate the probe covers are accurate and compatible and show conformance to the required harmonized and international standards.

Probe covers that do not contain the Hillrom/Baxter logo on packaging and embossed on the cover itself may not be subject to the same five-step quality check tests as well as the five environmental (5E) test conditions. Our testing has indicated that this can seriously affect the accuracy of the thermometer and usability of the probe covers.

To demonstrate an example of potential inaccuracy, testing of a random sampling of generic probe covers from a single batch of 'Product A' samples and 2 batches of 'Product B' samples resulted in a maximum lab accuracy reading error due to the probe cover of 4.7 °C for 'Product A' probe covers (NOT Hillrom/Baxter brand) and 1.2 °C for 'Product B' probe covers (NOT Hillrom/Baxter brand). Refer to table below.

The maximum allowable probe cover error specification for the Hillrom/Baxter branded probe cover is 0.1 °C. The PRO 6000 thermometer does not give a reading within the specification when used with probe covers that are not Hillrom/Baxter branded.

Error caused by Generic probe Covers (Table 1)

Generic probe cover type	Maximum error reading with PRO6000 (Hillrom/Baxter probe cover specification: 0.1 °C)
Product A (Not Hillrom/Baxter brand) (n=50 readings, 1 batch)	4.7 °C
Product B(Not Hillrom/Baxter brand) (n=100 readings, 2 batch)	1.2 °C

In addition to the above probe cover error testing using a **PRO 6000** thermometer, the generic probe covers were inspected using the standard inspection method used to ensure the quality performance of the Hillrom/Baxter probe cover. Only a small percentage of the probe covers that were not Hillrom/Baxter brand passed as shown below.

Inspection results (Table 2)

Generic probe cover group	Inspection Result
Product A (Not Hillrom/Baxter brand)	81% Failed
Product B (Not Hillrom/Baxter brand)	97% Failed

ALWAYS READ LABELS AND DIRECTIONS FOR USE. For healthcare professional use only.

Authorized Australian Sponsor: Welch Allyn Australia Pty Limited

1 Baxter Drive, Old Toongabbie NSW 2146

T 1800 445 576

Probe covers that are not Hillrom/Baxter branded may also have other usability issues.

Along with accuracy, basic usability was also compromised with covers that were not Baxter brand. While Baxter covers are kept to a comfortable ejection force, competitor generic probe covers have been measured that require over 6kg. of force to eject. With repeated use over the course of a user's shift, this may cause fatigue.

Probe covers that are not Hillrom/Baxter branded have no guarantee.

To ensure accuracy, patient safety, and user comfort, it is essential to use only Hillrom/Baxter brand probe covers with the Hillrom/Baxter ThermoScan infrared thermometers. "The Professional Hillrom/Baxter Pro series thermometers use ThermoScan probe covers (Hillrom/Baxter brand) which are distributed worldwide exclusively by Welch Allyn, Inc."

Hillrom/Baxter cannot guarantee the safety and performance of the device used with probe covers that are not Hillrom/Baxter branded. In addition, use of probe covers that are not Hillrom/Baxter branded invalidate the warranty of the thermometer.

Hillrom/Baxter branded probe covers are cleared for sales by regulatory bodies such as U.S. Food and Drug Administration, along with the Therapeutic Goods Administration (TGA) in Australia.

Regards,

Wendy Porter
Product Manager ANZ
Connected Monitoring & Intelligent Diagnostics

ALWAYS READ LABELS AND DIRECTIONS FOR USE. For healthcare professional use only.

Authorized Australian Sponsor: Welch Allyn Australia Pty Limited

1 Baxter Drive, Old Toongabbie NSW 2146

T 1800 445 576