

**Re:** Use of Generic Probe Covers [Probe covers that are not Braun® Certified are referred to as “Generic Probe Covers”.]

**Date:** June 4, 2012

**From:** Kaz USA, Inc

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**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 Braun® certified probe covers.**



**Figure1. Pro 4000 Thermometer and associated Probe Covers**

**Braun® Certified probe covers are not merely meant as sanitary barriers but play an integral role in ensuring an accurate temperature reading.**

The Braun® Certified 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 as a whole meets the overall thermometer accuracy specification.

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

**Braun® Certified probe covers are cleared for marketing by the regulatory bodies such as the notified bodies (such as TUV, DQS or BSI in the EU as an example) or the Food and Drug Administration (in the US) , whereas the generic probe covers may not be approved.**

All models of the Braun® infrared thermometers and Braun® certified probe covers are cleared by the notified bodies (for CE certification) as class IIa medical devices (since they

enter the ear canal and hence are considered as invasive) or by the FDA in the US as class II medical devices as part of the thermometer, not as individual devices. This certification is obtained based on submission of the validation data on the five step quality check data outlined above. This is designated by a 4 digit notified body number next to the CE marking. Absence of this 4 digit notified body number would constitute a misrepresentation of the certification process.

The generic probe covers may not be cleared or approved by notified bodies, especially if they do not carry the 4 digit notified body number next to the CE marking.

**Generic probe covers not subject to these controlled conditions of production and testing have been shown to have significant accuracy issues.**

Probe covers that are NOT Braun<sup>®</sup> certified (that do not contain the Braun<sup>®</sup> logo on packaging) are most likely not subject to these same five-step quality check tests as well as the five environmental (5E) test conditions, and our testing has indicated that this can seriously affect the accuracy of the thermometer and usability of the probe covers.

Specifically, a random sampling of generic probe covers from a single batch of Tempscan samples and 2 batches of Medisense samples resulted in a maximum lab accuracy reading error due to the probe cover of 4.7°C for Tempscan probe covers (NOT Braun certified) and 1.2°C for Medisense probe covers (NOT Braun certified). Refer to table below.

The maximum allowable probe cover error specification for the Braun certified probe cover is 0.1°C. The PRO 4000 thermometer does not give a reading within the specification when used with these probe covers that are not Braun certified.

**Error caused by Generic Probe Covers**

<b>Generic probe cover type</b>	<b>Maximum error reading with PRO4000 (Braun probe cover specification: 0.1°C)</b>
Tempscan (Not Braun certified) (n=50 readings, 1 batch)	4.7 °C
Medisense (Not Braun certified) (n=100 readings, 2 batch)	1.2 °C

In addition to the above probe cover error testing using a PRO4000 thermometer, the generic probe covers were inspected using the standard inspection method used to ensure the quality performance of the Braun probe cover. Only a small percentage of the probe covers that were not Braun certified passed as shown below.

### Inspection results of Error caused by Generic Probe Covers

Generic probe cover group	Inspection Result
Tempscan (Not Braun certified)	81% Failed
Medisense (Not Braun certified)	97% Failed

Based on the inspection results, a majority of such generic probe covers that are not Braun certified should have been rejected prior to leaving the factory and not allowed for use on Braun® Thermoscan® thermometers.

#### **Probe covers that are not Braun® Certified also have other usability issues.**

Along with accuracy, basic usability was also compromised with covers that were not Braun certified. While Braun® covers are kept to a comfortable ejection force, competitor generic probe covers have been measured that require over 13 lbs of force to eject. With repeated use over the course of a user's shift, this may cause fatigue.

#### **Probe covers that are not Braun® Certified have no guarantee**

To ensure accuracy, patient safety, and user comfort, it is absolutely essential to use only Braun certified probe covers with the Braun® Thermoscan® infrared thermometers. "The professional Braun PRO series thermometers use Welch Allyn Braun ThermoScan probe covers (Braun Certified) which are distributed worldwide exclusively by Welch Allyn, Inc. and are manufactured in the USA by Kaz, USA Inc."

Kaz cannot guarantee the safety and performance of the device use with probe covers that are not Braun® certified. In addition, use of probe covers that are not Braun® certified invalidate the warranty of the thermometer.

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