

March 27, 2020

Dear Healthcare Professional,

Given the dramatic increase in thermometry probe cover demand globally resulting from the COVID-19 pandemic, we have received multiple inquiries regarding alternatives to the single use of *SureTemp* and *Braun* probe covers. For this reason, we are providing the following relevant information.

This document does not constitute a change in the current product labeling; instead, it is an attempt to provide you with appropriate knowledge to help expand the availability of probe covers during this public health emergency.

Re-use of probe covers

Disposable probe covers provide both a sanitary barrier and ensure accuracy, which can be affected by build-up of cerumen and any other contaminant from re-use. The probe covers are made of polypropylene and have not been designed for cleaning and disinfecting; consequently, the transmissivity of the probe cover material may be affected. We have not assessed the impact on performance of the measurement algorithm using re-used probe covers.

If a clinician chooses to re-use a probe cover, clinical considerations should include limiting the cover to a single patient (to minimize cross contamination), inspecting the cover for cerumen/contaminants between uses, and storing the cover in a manner to reduce contact with foreign material.

Operation of the thermometer without a probe cover

The *SureTemp* thermometer prediction algorithm requires the mass of the probe cover to accurately calculate temperature. While the *SureTemp* will display a temperature reading, use without a probe cover will display a higher temperature than actual.

The *Braun PRO 6000* or *PRO 4000* thermometers can only take a patient's temperature with a probe cover on. Because the transmissivity of the probe cover is calculated within the device algorithm, the device is designed to detect the presence of a probe cover to function and will not give a reading. If any alternative materials are used to simulate a probe cover, the reading will be inaccurate.

Use of Generic Probe Covers

Braun® certified probe covers manufactured by Hillrom or Kaz follow a manufacturing and quality assessment process to ensure proper fit and that every probe cover used results in an accurate and reliable reading. We do not have data that support the use of generic probe covers for this product. Differences in the material or design of the probe cover may also lead to inaccuracy of measurement.



Use outside operating/ambient temperature range (10C/50F-40C/104F)

The *SureTemp* and *Braun Device Family* was designed to be used in operating/ambient temperatures between 10°C/50°F and 40°C/104°F. Below or above these temperatures, units will either display “ERR” or provide a reading that may not be accurate, depending on the ambient temperature of the device.

Please do not hesitate to contact me if I can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. Urrea', with a stylized flourish at the end.

Carlos A. Urrea, MD, MPH

Vice President Medical Affairs & Informatics

+1 312.819.7224 office

+1 215.327.5500 mobile

Carlos.Urrea@Hillrom.com