



Document Description: CSB – Probe Cover Requirement	Document Number: 80026535 Version: B
	
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Customer Service Bulletin

Product: SureTemp / Braun	Date: 2020-03-25
Subject: Off Label Use Questions during Covid-19 Pandemic	
HW Version(s) Affected: ALL	SW Version(s) Affected: ALL
Serial Numbers Affected: ALL	Lot or Date Code Affected: ALL

Classification: As Needed
Distribution: <input checked="" type="checkbox"/> Customer Care <input checked="" type="checkbox"/> Product Service <input checked="" type="checkbox"/> Field Service <input type="checkbox"/> ASPs <input type="checkbox"/> Distributors <input checked="" type="checkbox"/> Customers <input type="checkbox"/> Company Confidential

Training Required: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Summary: <p>Hillrom is aware of shortages in probe cover supply globally as a result of increased need during the COVID 19 Pandemic. The following guidance is issued by our VP of Medical Affairs and Informatics as supplemental guidance for limited reuse of probe covers in healthcare settings.</p> <ul style="list-style-type: none"> • With the higher demand for SureTemp and Braun units and probe covers, there have been an increase in customer questions regarding off-label usage of the SureTemp and Braun products. This CSB details Hillrom’s (HRC) response to the questions. • Use without probe covers will cause temperature inaccuracies. • Hillrom does not recommend re-use of probe covers. • Generic probe covers have been shown to have accuracy issues. • The Braun Device Family is designed to be used in operating/ambient temperatures between 10°C/50°F and 40°C/104°F.

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Detailed explanations:

1. Use without probe covers with the Welch Allyn Braun Pro4000/Braun Pro6000 Ear and SureTemp 690/692 Oral Thermometers

Use without a probe cover will cause temperature inaccuracies. The Braun family can only operate in a clinical mode with a probe cover. The transmissivity of the probe cover is calculated within the device algorithm and alternative materials or having no probe cover in place will have a substantial impact on the measurement accuracy. Furthermore, the Braun family probes are not designed to come into direct contact with human tissue also impacting accuracy.

The SureTemp family prediction algorithm requires the mass of the probe to accurately calculate temperature. Use without a probe cover will display a higher temperature than actual-creating false positives.

2. Re-use of probe covers

HRC does not recommend 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.


Can probe covers be cleaned? HRC has not conducted testing regarding cleaning a used probe cover. Additionally, probe cover material was not intended to be cleaned as the transmissivity of the probe cover could be changed reducing accuracy. We do not guarantee the results of any reading post cleaning a probe cover.

Any considered re-use should include limiting the cover to same patient (to minimize cross contamination), inspecting the cover for cerumen/contaminants between uses, and storing the cover in a manner to reduce foreign material contact. HRC makes no claim of accuracy of the Braun or SureTemp Devices if probe covers are re-used though limited reuse at this time can be considered based on clinical judgement and local need.

3. Use of Generic Probe Covers on the Welch Allyn Braun Pro4000 and Pro6000 Ear Thermometers

Generic probe covers (not Braun® certified and manufactured by Kaz or Hillrom) have been shown to have accuracy issues as high as 4 degrees Celsius in testing.

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Generic probe covers will not fit adequately on the Pro6000 Ear Thermometer which can lead to inaccuracy.

The Braun® certified probe covers manufactured by Hillrom provide both a sanitary barrier and ensure an accurate temperature reading. Braun® certified probe covers undergo a very rigorous and stringent manufacturing and quality assessment process to ensure that every probe cover used results in an accurate and reliable reading.

4. Braun Pro 4000 and 6000 Family device use outside operating/ambient temperature range (10C/50F-40C/104F)

The 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. HRC makes no claims on the accuracy of temperatures displayed above or below the operating range stated above.

Version	Sec, Pg, Para Changed	Change Made	Date Version Created	Version Created By (initials)
A	N/A	Initial Release	2020-03-23	MRP
B	All	Language clarifications throughout	2020-03-25	MRP