



**Hillrom™**

July 23<sup>rd</sup>, 2020

**Attention:** Phuntsok Namgyal  
Manager, Operational effectiveness and excellence  
Runnymede Healthcare Centre  
625 Runnymede Rd  
Toronto, ON, M6S 3A3  
Canada

Subject: Investigation of Braun ThermoScan PRO6000 returned from Runnymede Hospital for failure analysis

Thank you for taking the time to report the product issue that you have experienced using the Braun ThermoScan PRO6000 thermometer. Hillrom is dedicated to product quality and committed to safe and reliable usage of our products at your facility.

Our global quality team has performed investigations on the most common defects experienced with our Braun PRO6000. Results of investigation have shown that fluid may enter the device around the measurement button, measure light, C/F and Memory button, or through the battery door. After ingress, the liquid can impact the internal electronics which may result in a permanent or intermittent malfunction.

We received over 220 Braun PRO6000 units from your site. Our global quality team conducted this analysis and documented their findings related with the failures encountered by your Braun PRO6000 devices at your facility.

A representative cross section of ten (10) Braun PRO 6000 units were analyzed. The devices received had been reported with failures including failure to turn on, inaccurate, High/Low, POS (positioning) Error.

### **Overview of Analysis/Findings**

Four (4) of the devices were made prior to October 2019 when rubber buttons to provide additional ingress protection were introduced and six (6) of the devices had the rubber buttons

1. Two of the devices had displays which were not working.
2. Residue from liquid ingress was seen on some units (main printed circuit boards, buttons, and in the display).
3. Seven of the devices had dried residue (most likely from cleaners) on and inside the display.
4. Nine units had corrosion, mainly on the metal tether screw.



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5. Two devices which were made prior to implementation of rubber buttons had residue (most likely from cleaners) on the buttons making them sticky to operate.
6. Devices with rubber buttons did not show evidence of ingress through buttons.

Conclusions:

1. 70% of the devices showed clear signs of fluid ingress which frequently causes the failures reported.
2. 90% of the devices showed some evidence of corrosion on exposed metal parts due to fluid ingress.
3. The rubber buttons added to product shipped as of October 2019 does appear to prevent fluid ingress, however the unit itself is unsealed (device has an IPX0 rating) and susceptible to liquid ingress through seams in the unit (including through the battery cover).

Because your Braun thermometers are still under warranty, we will replace your current defective thermometers at no charge to Runnymede Hospital. Due to supply / demand we are unable to replace your defective Braun PRO6000 with the same device. Due in part to COVID device shortage we will replace your defective Braun units with our comparable SureTemp device (with 2 years warranty).

Your Account Manager Danya Fenech will communicate with you the official action plan to support the Braun Pro6000 warranty replacement and timing of replacement.

Please let us know if you have any questions or require further information.

Thank you,

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