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Date: November 10, 2011

To: Whom It May Concern

Customers often inquire about whether periodic recalibration is required for the Braun ThermoScan® PRO 4000 (referred to as PRO 4000 and distributed by Welch Allyn, Inc for Kaz USA, Inc) thermometer since many competitive devices recommend periodic field calibration. The requirement of periodic calibration is dependent on the design of the sensor and the device. The PRO 4000 thermometer does not require periodic recalibration for two main reasons:

1. The sensor (in the PRO 4000) is a high quality sensor that has been designed for use over many years and is shown to have a high level of reliability over the lifecycle of the product providing extremely stable operating conditions. It is made with a very stable silicone based material and has been engineered for long term stability and reliability.
2. Braun PRO 4000 devices undergo a rigorous five environmental calibration process in special chambers designed to achieve the most accurate readings in all environments per the specified ranges of the device and operating conditions. These conditions cannot be replicated in the field. These conditions make it mandatory for the sensor design to be such that it does not need periodic recalibration.

Hence, once released from the factory, the PRO 4000 thermometer maintains clinical accuracy over many years of continuous and intense use.

The reason other thermometers recommend periodic recalibration is because their devices are designed differently. For example,

- The sensor may contain an inert gas that is different from natural air. Over a period of time, this gas may slowly leak from the sensor enclosure. This leakage can be one of the reasons that the device is required to be recalibrated. However, since the original concentration of the gas can no longer be restored without changing the sensor, the recalibration may no longer be as effective (due to loss in sensitivity) as when it is new.
- Materials used in the design of the Thermometer/Sensor may not be stable.
- The device calibration may not be as tightly controlled requiring periodic re-calibration.

Some competitors might have suggested that infrared thermometers require periodic calibration due to a light beam shift. There is no such phenomenon as "light beam shift" with the Braun PRO 4000 series sensor or device. While the Pro 4000 thermometer does not need periodic recalibration, accuracy can be checked at any time using a 9600 Plus Calibration Tester. Procedures for checking calibration are outlined in the 9600 Plus Calibration Tester (REF 01802-110) directions for use manual.

Welch Allyn recommends checking the calibration (which is different from recalibration) on an annual basis or whenever clinical accuracy of the thermometer is in question due to sensor damage as a result of physical damage or any other such reason. This recommendation does not

supersede any local requirements. If this calibration check shows device accuracy is in question, the unit can be sent to Welch Allyn for verification. Welch Allyn provides a three year warranty on the Braun PRO 4000.

Respectfully Yours,

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