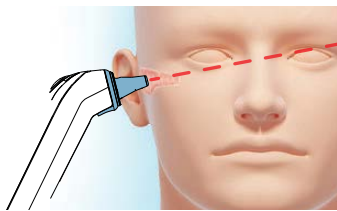




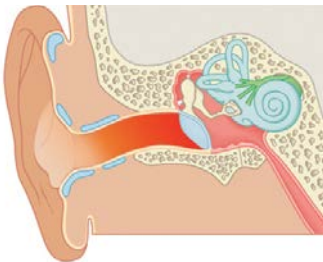
The Secret Behind Welch Allyn Braun ThermoScan® PRO 6000 Ear Thermometer Technology and Its Success



The Gold Standard in IR Ear Temperature Measurement



Temperatures taken in the ear reflect the body's core temperature¹



Ear canal temperature gradient

Regarded as one of the leading technologies used in healthcare facilities around the world and as a benchmark thermometer for several clinical studies, the Braun ThermoScan Thermometer is the gold standard in infrared ear temperature. In this document we provide information on the key features of the Braun ThermoScan PRO 6000 technology and explain the secret behind its unmatched accuracy and repeatability.

Why is the ear an ideal spot to measure the body temperature?

Clinical studies have shown that the ear is an excellent site for temperature measurement because temperatures taken in the ear reflect the body's core temperature¹. Body temperature is regulated by the hypothalamus², which shares the same blood supply as the tympanic membrane². Changes in core body temperature are usually seen sooner at the tympanic membrane than at other sites, such as the rectum, mouth or under the arm. Advantages of taking temperatures in the ear versus traditional sites:

- Axillary temperature measurements reflect skin temperature, which may not reliably indicate the internal body temperature.
- Rectal temperatures often lag significantly behind internal body temperature changes, especially at times of rapidly changing temperatures. Also, there is a risk of cross contamination.
- Oral temperatures are often influenced by eating, drinking, thermometer placement, breathing through the mouth, or the inability of the person to close their mouth completely.

The unique technical features of the Braun ThermoScan PRO 6000



PerfecTemp®



ExacTemp®



Pre-warmed tip



Proprietary algorithm



Unique sensor technology

The Braun PRO 6000 technology reads the infrared energy emitted by the tympanic membrane and surrounding tissues to determine the patient's temperature. To help ensure accurate temperature measurements, the sensor itself is warmed to a temperature close to that of the human body. When the Braun ThermoScan is placed in the ear and a measurement is started, it continuously monitors the infrared energy until a stable temperature is detected and an accurate measurement can be taken.

validated in a clinical study³ by comparing IR measurements with the oral readings from afebrile and febrile patients of various ages. This displayed temperature adjusts for the impact of different ambient temperatures on the skin of the ear canal and adjusts for how well the thermometer is positioned in the ear.

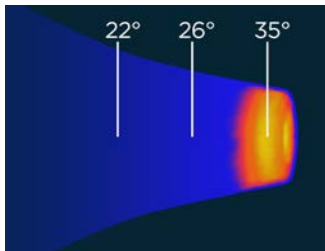
The device offers the possibility to use an Unadjusted Operating Mode for a simple ear temperature measurement. This mode can be accessed by using the Welch Allyn Service Tool.

The thermometer displays a clinically accurate, oral equivalent temperature that has been

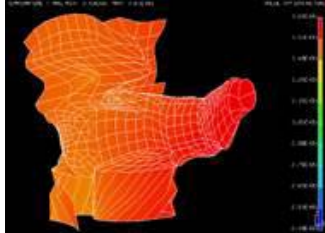
WelchAllyn®

1- Guyton A C, Textbook of medical physiology, W.B. Saunders, Philadelphia, 1996, p 754-5
 2- Netter H F, Atlas of Human Anatomy, Novartis Medical Education, East Hanover, NJ, 1997, pp 63, 95.
 3- Hamilton, P. A., Marcos, L. S. and Secic, M. (2013), Performance of infrared ear and forehead thermometers: a comparative study in 205 febrile and afebrile children. J Clin Nurs, 22: 2509-2518. doi:10.1111/jocn.12060

Braun PRO 6000 pre-heated tip

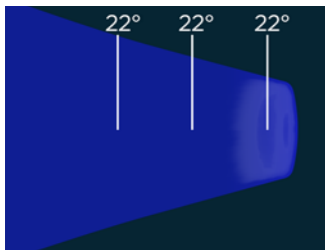


Helps prevent cooling of the ear canal

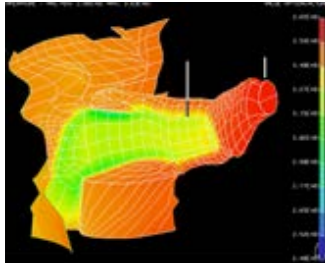


Temperature conditions in the ear canal not affected by the thermometer

Other technologies without pre-heated tip



Cooling down of ear canal due to a "cold" tip



Cooling down (Thermal Draw-down effect) after 0.4 seconds due to a "cold" tip

Taking a temperature reading with Braun ThermoScan PRO 6000

Step 1 Preparation of the device

The Braun PRO 6000 tip and sensor begins to quickly warm to a temperature close to the human body when removed from the device cradle and prior to being inserted into the ear, thereby reducing the temperature difference between the human body temperature in the ear canal and the IR sensor.

As soon as the sensor and tip are pre-warmed and a new probe cover has been attached, the device is ready to use. The ring around the *Measure* button will turn green, the thermometer will beep once and three lines on the display indicate that a measurement can be taken. A pre-warmed tip helps prevent cooling of the ear canal by inhibiting a transfer of heat from the body to the thermometer probe, a process referred to as "Thermal Draw-Down." This improves accuracy, repeatability and precision.

Infrared sensors work by measuring the difference between their own temperature and the temperature of whatever they are looking at by measuring the nature of the IR energy being emitted from the target. Because of the pre-warmed sensor—close to the body temperature and well controlled—the portion of the reading coming from the measurement of the IR energy is much smaller, improving overall accuracy.

Unlike other IR thermometers, the Braun PRO 6000 scans a tighter bandwidth of energy than other brands, resulting in less error due to incorrect probe placement, patient movement, dirty lenses and other variables.

Step 2 Positioning in the ear

PerfecTemp technology is another unique feature compensating for a shallow probe placement. PerfecTemp works through three patented capacitive sensing rings on the outside of the tip to analyze the measured temperatures of the ear canal itself as the thermometer is inserted into the ear and throughout placement.

The electrical capacitance of these rings gives an indication of the depth of insertion and fit of the probe in the ear canal. This information, along with the ambient temperature and readings of the temperature of the ear tissues as the thermometer is brought into final position, are part of the proprietary technology to compensate for any error caused by suboptimal positioning of probe in the ear canal.

The highest plateau of reading determined between this algorithm and the classic Braun algorithm is the temperature that is displayed on the device. As a result, a lower reading that might have previously been caused by suboptimal placement of the sensor in the ear canal is compensated to give a more accurate reading.

The Braun PRO 6000 Ear Thermometer also features ExacTemp technology, which supports temperature measurement reliability by detecting the stability of the probe placement during the measurement. A light on the device will initially flash during the measuring process; this indicates that ExacTemp technology is active. A reading is performed and the light remains illuminated upon recognizing that the probe was held steady and near optimally placed to ensure that a reading is taken only during the best available placement of the probe.

If the thermometer is unstable or patient is moving during the measurement process, the device will beep, the green ExacTemp light will flash and POS (*Position Error*) will appear on the display.

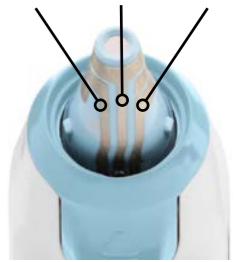
Step 3 Obtaining a temperature reading

The Braun ThermoScan PRO 6000 continuously monitors the infrared energy emanating from the tympanic membrane and surrounding tissue. After the *Start* button is pressed, up to 62 temperature readings are taken and analyzed multiple times in the seconds it takes to capture. The sensor is read 10 times per second—more than enough to detect a stability and appropriate aiming/a plateau. Other technologies, instead of detecting a stability and a correct placement, use a peak detection method that takes a single reading of the highest temperature measured.

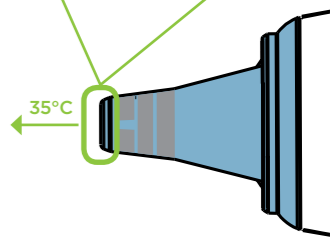
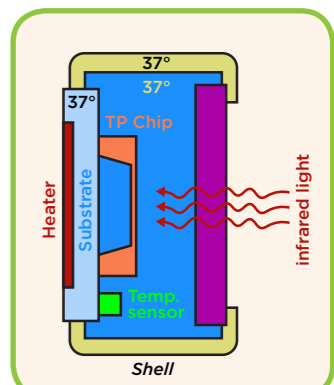
Once the thermometer is steady and pointed correctly, and all the accuracy algorithms are satisfied, a final measurement is taken. The PRO 6000 has the capability to display either an oral equivalent or actual raw ear temperature, using *Unadjusted Operating Mode*, when an ear temperature reading is desired without applied algorithms.

The temperature reading itself can be displayed as a raw unadjusted ear temperature or a clinically accurate, oral equivalent temperature using a **variable offset** to account for body site correlation (between ear canal and oral) and ambient temperature, as well as actual outer ear canal temperature and the position of the probe in the ear canal when the measurement is taken. This is a more advanced way to determine an equivalent temperature when compared to a simple static offset. The offset algorithm was developed through multiple internal clinical studies by comparing the infrared ear temperature measurements and the oral temperature measurements taken in a well sampled dataset consisting of afebrile and febrile patients of all ages.

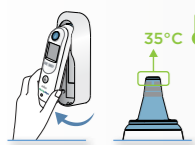
The PerfecTemp Difference
Three capacitive sensing rings provide important information on ear and ambient temperature and well as depth and position of the probe



Braun PRO 6000 Unique Sensor Technology

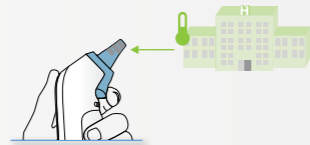


Step 1 PREPARATION OF THE DEVICES



PRE-HEATED PROBE

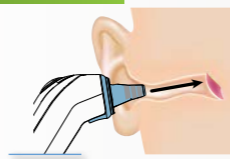
When removed from the cradle, the device's tip and sensor warms to a temperature close to that of the human body, resulting in a more accurate measurement and better patient comfort.



AMBIENT TEMPERATURE

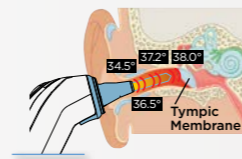
When removed from the cradle, the PRO 6000 starts to analyze the ambient temperature.

Step 2 POSITIONING IN THE EAR



PLACEMENT AND STABILITY OF THE PROBE

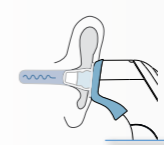
When inserted into the ear canal and throughout placement, the PRO 6000 collects information about the direction and depth of ear probe placement as well as the stability of the probe.



SURROUNDING TISSUES TEMPERATURE

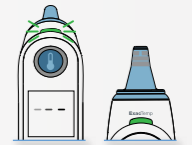
It also reads the infrared energy emitted by surrounding tissues when placed into the ear to determine the patient's temperature.

Step 3 OBTAINING A TEMPERATURE READING



TYMPANIC MEMBRANE TEMPERATURE



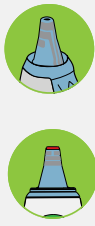

The PRO 6000 continuously monitors the infrared energy until the thermometer is aimed at the hottest area, stability has been detected and an accurate measurement can be taken.



CONSISTENT PLACEMENT

The ExacTemp light flashes during the measuring process and remains illuminated when the measurement is complete, indicating consistent placement of the probe during the measurement process.

Technology Exclusive to Braun ThermoScan Thermometers

Technology	Features	Benefits that help improve accuracy, repeatability and precision	Exclusive to Braun ThermoScan
 PerfectTemp®	Collects information about the direction and depth of ear probe placement	Overcome challenges presented by ear canal anatomy and variability in probe placement	✓
	Collects information about the ear canal and ambient temperature	Uses this information to compensate for any error caused by suboptimal positioning of probe in the ear canal	✓
 ExacTemp®	Probe placement feedback system during the measurement	Helps ensure stable probe placement that is aimed correctly	✓
 Braun ThermoScan® Tip and Sensor	IR thermopile able to detect stability	Continuously monitors (10 readings per second) the IR energy until ExacTemp conditions are met	✓
	Pre-warmed tip	Prevent "Thermal Drawdown" (Cooling of the ear canal by cold probe)	✓
	Pre-warmed sensor	Smaller IR signals variation to contribute little to the overall patient temperature computation	✓
 Braun Algorithm	Variable oral offset (no fixed value) based off of ear temperature and ambient temperature	Offers a more advanced way to determine an equivalent oral temperature when compared to a simple static offset	✓

Braun ThermoScan PRO 6000 Clinical Thermometer

MODELS AND ACCESSORIES



Explore the entire Welch Allyn thermometry portfolio at <http://emeai.welchallyn.com/thermometry> or call us at **+353 46 906 7700**.

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The Braun ThermoScan PRO 6000 thermometer is a clinical grade ear thermometer indicated for the intermittent measurement of human body temperature in patients of all ages in a professional use environment.

Medical device (93/42/EEC); Class IIa

Notified Body: DQS Medizinprodukte GmbH (CE0297)

Manufacturer: Kaz USA, Inc. 250 Turnpike Rd. Southborough, MA 01772, USA

EC Rep.: Kaz Europe Sàrl. Place Chauderon 18. CH 1003 Lausanne - Switzerland

This medical device is a regulated health product which, pursuant to such regulation bears a CE mark. Welch Allyn recommends that you carefully read the detailed instructions for safe and proper use included in the documents accompanying the medical devices. The personnel of healthcare establishments are responsible for the proper use and maintenance of these medical devices. Welch Allyn reserves the right to make changes without notice in design, specifications and models. The only warranty Welch Allyn makes is the express written warranty extended on the sale its products.