

K 964605

510(k) SUMMARY

MAY 16 1997

Submitter's Name: Thermoscan, Inc.

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Date of Summary: 11/15/96

Name of Device: Braun ThermoScan® pro-2000 Instant Thermometer

Predicate Device: THERMOSCAN Instant Thermometer, Model IR-2000
THERMOSCAN Instant Thermometer, Model IR-5000
THERMOSCAN Instant Thermometer, Model IR-6000

Device Description: The Braun ThermoScan pro-2000 Instant Thermometer, is a hand held instrument that measures temperature through the opening of the auditory canal. Operation is based on measuring the natural thermal radiation emitted from the tympanic membrane and adjacent surfaces

Intended Use: The Braun ThermoScan pro-2000 Instant Thermometer is intended for the intermittent measurement and monitoring of human body temperature by medical professionals. It is intended for use on people of all ages.

Technological Characteristics: The Braun ThermoScan Instant Thermometers, Model PRO-2000, IR-2000, IR-5000 and IR-6000 have the same general design and incorporate similar technologies, materials and components.

The primary function of the Braun ThermoScan pro-2000 Instant Thermometer is the same as the ThermoScan Instant Thermometer, Models IR-2000, IR-5000 and IR-6000 for the measurement of body temperature and raise no new questions of safety and effectiveness. ThermoScan Inc. concludes that the Braun ThermoScan pro-2000 Instant Thermometer, is substantially equivalent to the ThermoScan IR-2000, IR-5000 and IR-6000.

PRODUCT SPECIFICATIONS:

Model Number PRO-2000

Temperature Ranges

Patient temperature range 80.0 to 108.0°F (26.6 to 42.2°C)
 Ambient temperature operating range 60.8 to 104°F (16.0 to 40.0°C)
 Temperature scales (user selectable) °F or °C
 Storage temperature range -4.0 to 122.0°F (-20.0 to 50.0°C)
 Display modes EAR (The displayed EAR temperature is the actual measured ear canal temperature plus a mathematical adjustment to approximate the familiar oral range. However, this is not necessarily the same as an oral temperature measured at the same time.)

Humidity Range

15 - 95% Noncondensing

Resolution

0.1°F or C

Shock

Withstands one meter drop in thermometer storage cover

Accuracy: Meets American Society for Testing and Materials (ASTM) Standard E1112-86 as it pertains to IR thermometers

Applicable patient ages All ages

Patient temperature range	Error °F	Error °C
<96.4°F (<35.8°C)	±0.5	±0.3
96.4 to <98.0°F (35.8 to <37.0°C)	±0.3	±0.2
98.0 to 102.0°F (37.0 to 39.0°C)	±0.2	±0.1
>102.0 to 106.0°F (>39.0 to 41.0°C)	±0.3	±0.2
>106.0°F (>41.0°C)	±0.5	±0.3

Time

Measurement time 1 second
 Minimum time between readings 8 seconds
 Automatic "power down" 60 seconds

Weight 7 oz (195 gm)

SUMMARY OF TESTING:

Clinical Results

A comparison study and clinical repeatability testing was performed on the following four age groups; 0-3 yrs, 4-10 yrs, 11-65 yrs, and >65 yrs. The comparison study demonstrated that the Braun ThermoScan pro-2000 Instant Thermometer measured ear temperature equivalently to the IR-2000 in all age groups. The clinical repeatability for each age group met ASTM standards.