

BRAUN

WelchAllyn®

ThermoScan®

PRO 6000 Ear thermometer
Service documentation



This product is manufactured licensed to the 'Braun' trademark.
'Braun' is a registered trademark of Braun GmbH, Kronberg, Germany.

ThermoScan is a registered trademark of Helen of Troy Limited and its affiliates.

1.0 Scope

The purpose of this document is to provide the necessary information to check the accuracy of the Braun ThermoScan® PRO 6000 Ear thermometer. The document will be used to standardize the procedure of checking the thermometer accuracy.

2.0 Technical specifications

Displayed temperature range:	20-42.2°C (68-108°F)
Operating ambient temperature range:	10-40°C (50-104°F)
Display resolution:	0.1°C or °F
Accuracy for displayed temperature range:	
With probe cover:	
±0.2°C (±0.4°F) (35.0-42°C) (95-107.6°F)	
±0.3°C (±0.5°F) (outside this temperature range)	
Without probe cover:	
±0.1°C (0.2°F) (35.0-42°C) (95-107.6°F)	
±0.2°C (±0.4°F) (outside this temperature range)	
Clinical bias:	0.09 °C (0.16 °F)
Limits of agreement:	0.58 °C (1.0 °F)
Clinical repeatability:	0.19 °C (0.34 °F) (Calculated per ASTM E:1965)
Reference body site:	Oral
Measuring site:	Ear
Warm up time:	initial start-up time: 3-4 seconds
Measurement time:	2-3 seconds
Automatic power down:	10 seconds
Battery life:	6 months/1000 measurements
Battery type:	2*MN 1500 or 1.5V AA (LR6)
Thermometer dimension:	6"x1.7"x1.3" (152mm x 44mm x 33mm)
Thermometer weight:	3.6 oz (100g) without batteries

Long term storage ranges

Storage temperature:	-20 to 50°C (-4 to 122°F)
Storage humidity:	0 to 85% RH non-condensing
Shock:	withstands drops of 1 meter (3 feet)
Pressure:	700-1060hPA (0.7-1.06 atm)
	The thermometer is specified to operate at 0.7-1.06 atmospheric pressure.

2.1 Serial number encoding

Serial number location

To locate the serial number, open the battery door and then remove the batteries and set aside.

Standards and compliance

This device conforms to the following Safety and Performance Standards:

This infrared thermometer meets requirements established in ASTM Standard E 1965–98 (for the thermometer system [thermometer with probe cover]). Full responsibility for the conformance of the product to the standard is assumed by Welch Allyn, Inc. 4341 State Street Road, Skaneateles Falls, NY, USA 13153.

ASTM laboratory accuracy requirements in the display range of 37 °C to 39 °C (98 °F to 102 °F) for infrared thermometers is ± 0.2 °C (± 0.4 °F), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E 667-86 and E 1112-86 is ± 0.1 °C (± 0.2 °F).

This product conforms to the provisions of the EC directive 93/42/EEC (Medical Device Directive).

A clinical summary is available upon request.

ANSI/AAMI STD ES60601-1, UL STD 60601-1, CAN/CSA STD C22.2 No. 60601.1, IEC 60601-1 and EN 60601-1; 2nd and 3.1 Editions.

Medical electrical equipment— Part 1: General requirements for basic safety and essential performance Meets CB Scheme

BS EN 60601-1-2:2015, IEC 60601-1-2:2014

Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and test

IEC/EN 62304:2006 +A1: 2015 Medical device software—Software life cycle processes

IEC/EN 62366-1:2015 (IEC 60601-1-6:2010+A1: 2013) Medical devices—Application of usability engineering to medical devices

ISO 14971:2012 Medical devices—Application of risk management to medical devices

ISO 80601-2-56:2009 (EN 80601-2-56: 2012) Medical electrical equipment—Part 2–56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

ISO 10993-1:2009 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (includes US FDA Blue book memo G95-1-100 Title)

GBT 21417.1:2008

MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC. For detailed description of EMC requirements please contact an authorized local Service Centre.

Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT

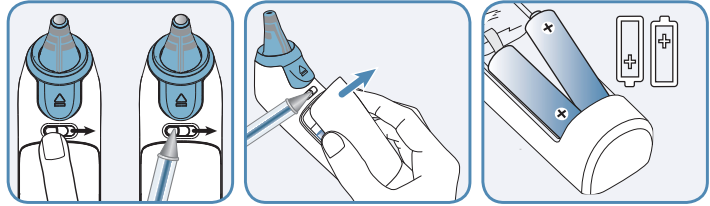
Internally powered ME equipment.

Continuous operation.

Not protected against ingress of water.

 IPX0

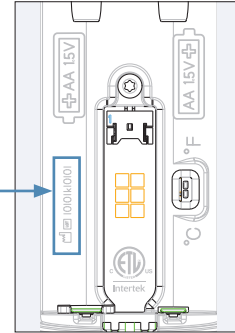
The serial number is located on the left side of the battery compartment.



Interpreting the serial number

00115k10101

A B C



A: Julian manufacture date: Represents the first 5 numerals of the serial number.

Numerals 1 through 3: Represent the day that the product was manufactured, for example 001=January 1st. These numerals will range from 001 to 365.

Numerals 4 and 5: Represent the calendar year the product was manufactured, for example 15=2015

In the above example the Julian date of 00115 is calendar date January 1, 2015

B: Manufacturer: Letter indicates the manufacturer code.

C: Lot serial number: Represents the manufacturer serial number.

A, B and C combined represent a unique serial number for the whole device.

2.2 Inspecting the thermometer

Visual inspection

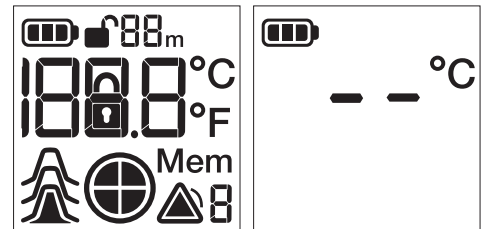
Always start with a visual inspection for any external damage especially the probe and probe lens window.

Initial start up

After removing the thermometer from the cradle the display screen will engage showing all segments followed by two dashes. If the display shows ERR, or other indication of error, refer to the directions for use, section 12.

Accuracy verification

Can only be tested using the 9600 Plus Calibration Tester (black body), which has a precisely defined temperature.



3.0 Frequency of calibration check

In general, the accuracy for the Braun Thermoscan® PRO 6000 Ear thermometer should be checked any time you suspect the unit is not reading correctly.

Some countries, e.g. Germany, have regulations requiring a regular check of the measuring accuracy for all medical devices used by professionals.

For infrared thermometers, this check must be done yearly and it is required to verify the measuring accuracy for the full temperature range. This implies that the thermometer will be tested at 3 different temperatures and the results will be documented via test protocol.

The Welch Allyn 9600 Plus Calibration Tester meets this requirement by testing the accuracy at low, mid, and high points of the temperature range. See the 9600 Plus Calibration Tester user's manual for information on testing the Braun Thermoscan® PRO 6000 Ear thermometer.

Note that the above described test procedure with the BB 3200 is not sufficient for this purpose. The 9600 PLUS Calibration device can test to these parameters.

The Braun Thermoscan® PRO 6000 Ear thermometer cannot be calibrated in the field. The calibration check is only used to determine that the thermometer measurements are accurate within the specified tolerances across the measurement range.

3.1 Service tool

The Welch Allyn Service tool is designed to support the Braun Thermoscan® PRO 6000 Ear thermometer and allows the service technician to view device information, install software upgrades, perform a calibration check, and change configurable settings. The service tool software and service tool installation guide are available through an internet link on the Braun Thermoscan® PRO 6000 Ear thermometer CD or from:
<http://www.welchallyn.com/en/service-support/service-center/service-tool.html>.

After downloading and installing the Welch Allyn Service tool, you can access the Braun Thermoscan® PRO 6000 Ear thermometer help files from the help menu. Here you will find a complete guide on how to use the Welch Allyn Service tool with the Braun Thermoscan® PRO 6000 Ear thermometer.

If you already have the Welch Allyn Service tool installed check the version to see if it supports the Braun Thermoscan® PRO 6000 Ear thermometer, version 1.8 or later is required.

When the Welch Allyn Service tool is used to perform the calibration check the measured temperatures are evaluated by the software and the test results are captured in the service record which may be printed or archived for later reference.

For more information on using the Welch Allyn Service tool to configure the Braun Thermoscan® PRO 6000 Ear thermometer, see Braun Thermoscan® PRO 6000 Ear thermometer directions for use.

4.0 Test equipment for performing a calibration check

In addition to the Braun Thermoscan® PRO 6000 Ear thermometer, the following test equipment and materials are available from Welch Allyn:

Material number	Description
01802-110	Tester, calibration, 9600 Plus
06000-005	Hillrom Ear thermometer probe cover, 5000 ct pkg, (MN)
06000-801	Hillrom Ear thermometer probe cover, 800 ct pkg, (MN)
06000-800	Hillrom Ear thermometer probe cover, 800 ct pkg, (EU)

4.1 Using the Welch Allyn 9600 Plus Calibration Tester

Verify the Welch Allyn 9600 Plus Calibration Tester(s) used to perform this check has been calibrated in the last 12 months.

Follow the procedure described in the 9600 Plus Calibration Tester manual to setup the 9600 plus.

To expedite testing, the following practices are recommended:

- Use three testers set each to different set point to eliminate wait time for the tester to heat to the next set point.
- When using only one tester to test several thermometers at all three temperatures, test all thermometers at one set point before proceeding to the next set point.
- When using only one tester start at the lowest set point to eliminate waiting for the tester to cool, because the tester does not have an internal fan, it requires more time to cool down than to heat up.

To scroll from one set point to the next, press and hold the temperature selection button until a beep sounds. The new set point appears in the upper left corner of the display. The device's current temperature appears, flashes, and continues flashing until the cavity reaches equilibrium at the new set point. The 9600 Plus beeps when the set point is reached.

5.0 To begin calibration verification of the thermometer



Caution: Store thermometers for testing in the same room as the 9600 Plus Calibration Tester for approximately 30 minutes prior to testing to allow for thermal accommodation.



Caution: The ambient temperature must be stable and within the range of 18.3°C (65.0°F) – 26.7°C (80.0°F)

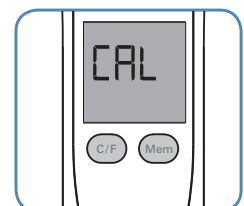
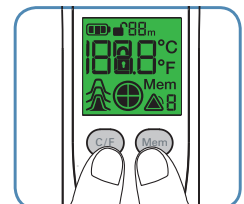
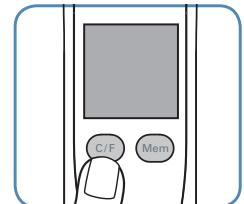
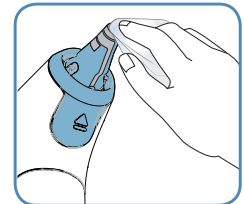
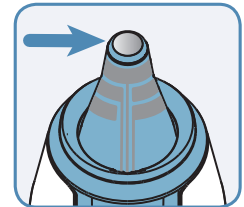


Caution: Set the temperature scales on the 9600 Plus to match the Braun ThermoScan PRO 6000's default temperature scale.



Caution: Setup the 9600 Plus away from sunlight, drafts, and other sources of heat or cold. Fluctuations will impact the calibration check.

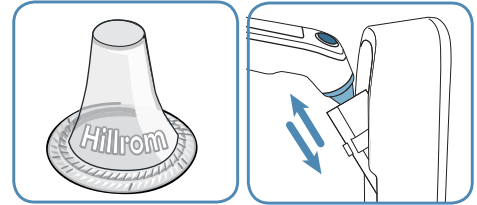
- 1 Check the probe tip lens window for displacement. There shouldn't be any gap in the seam formed between bezel and the lens window. If a gap exists the unit is damaged and must be replaced.
- 2 Gently wipe the probe tip with a cotton swab slightly moistened with Isopropyl or Ethyl alcohol using care not to displace the lens window; remove excess alcohol with a clean cotton swab, and let air dry for 5 minutes. Do not use any chemical other than alcohol to clean the probe window.
- 3 Place the Braun ThermoScan® PRO 6000 Ear thermometer in calibration mode using the following steps:
 - a. With the thermometer in sleep mode, press and release the C/F button
 - b. **Immediately** (while all segments of the LCD are illuminated during self-test) press and hold the C/F button and the Mem button.
 - c. After 5 seconds the thermometer will begin a long beep. During the beep release the Mem button and the C/F button. The thermometer is now in Calibration check mode, indicated by "CAL" flashing on the screen for 0.25 seconds every second.



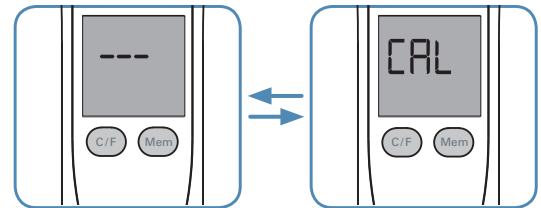
- 4 After entering calibration mode (CAL), wait for 1 minute before taking the first temperature.
Note: Do not hold the thermometer while waiting in order to allow the thermometer to remain at ambient room temperature.



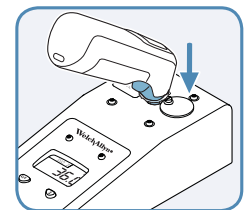
- 5 **If testing with a probe cover** apply a new probe cover, **if testing without a probe cover** go to the next step. If the probe cover is applied properly a short beep will sound and the flashing probe cover icon will disappear from the display.



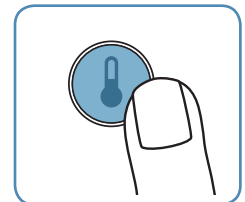
- 6 Wait for the screen to flash three dashes (---) alternating with "CAL"



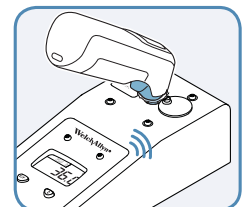
- 7 Place the probe firmly into the ear device port. It is important to ensure that the device is perpendicular in the port, directly aligned with the calibration tester sensor and not at an angle or tilted. Firmly push the device down into the well to ensure perpendicularity, that the probe is fully seated in the device port, and visually check to insure proper alignment. Do not apply too much pressure once the device is firmly seated, as this may cause your hand to waver and tilt or move the device during testing.



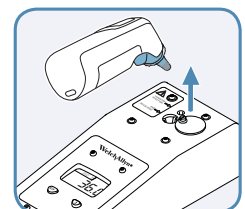
- 8 Wait 5 seconds. Press the thermometer **measure** button, and watch for the green ExacTemp™ light to flash.



- 9 Leave the thermometer in the 9600 Plus Calibration Tester until the ExacTemp light stops flashing and you hear a beep.



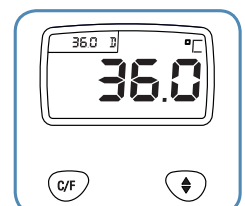
- 10 Remove the Braun Thermoscan® PRO 6000 Ear thermometer from the 9600 Plus Calibration Tester and compare the temperature displayed on the tester with the temperature in the thermometer's display. If the temperatures are within $\pm 0.2^\circ\text{C}$ ($\pm 0.4^\circ\text{F}$), when testing with a probe cover installed or $\pm 0.1^\circ\text{C}$ ($\pm 0.2^\circ\text{F}$) if a probe cover is not installed, the thermometer is within calibration Note: it is recommended that all calibration testing be performed with a probe cover installed.



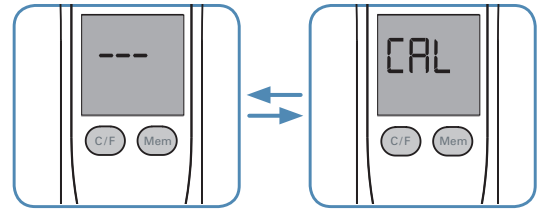
If temperatures are outside $\pm 0.2^\circ\text{C}$, verify the test procedure was strictly observed; if so, then the thermometer is outside calibration and is considered a "fail."

To perform the calibration check in high resolution mode see section 8, part 8.1.

- 11 **If testing with a probe cover** replace the probe cover to reset, **if testing without a probe cover**, press the measure button to reset. Wait for the thermometer screen to flash three



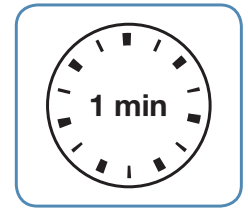
dashes (---) alternating with "CAL"



Note: The probe cover must be replaced with a new probe cover before each reading, to remove any residual heat absorbed from the 9600 Plus Calibration Tester.

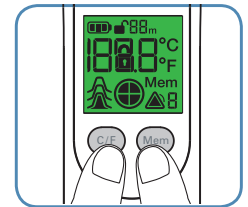


- 12** Wait one full minute before taking another reading with the same thermometer. Repeated measurements in short sequence may cause higher readings.
Note: Do not hold the thermometer while waiting in order to allow the thermometer to remain at ambient room temperature.



- 13** Test all available thermometers for calibration verification at the **current calibration set point temperature** before proceeding to the next calibration set point temperature. See "Using the Welch Allyn 9600 Plus Calibration Tester" in section 4.1 to change the set point temperature.

- 14** The device will exit CAL mode after ten minutes of inactivity, or may be forced to exit by holding both the C/F button and Mem button for 5 seconds. Upon exiting calibration check mode the thermometer will return to sleep mode.



Test record Braun ThermoScan® PRO 6000 Ear thermometer manual calibration test

Device model:	Serial number:
----------------------	-----------------------

9600 Plus Calibration tester(s)					
ID No:		ID No:		ID No:	
Calibration date:		Calibration date:		Calibration date:	
Calibration due date:		Calibration due date:		Calibration due date:	

Service tool version:	Thermometer software version:
------------------------------	--------------------------------------

Temperature tested specification ± 0.4 °F (± 0.2 °C) with probe cover

Temperature	°F or °C	Actual reading	Pass	Fail
96.8 °F (36.0 °C) 96.4 °F to 97.2 °F 35.8 °C to 36.2 °C				
101.3 °F (38.5 °C) 100.9 °F to 101.7 °F 38.3 °C to 38.7 °C				
105.8 °F (41.0 °C) 105.4 °F to 106.2 °F 40.8 °C to 41.2 °C				

Date:	Time:
Technician:	

6.0 Interpreting results

6.1 The thermometer is within calibration range if the measured values are at:

Tenth degree

Accuracy range with probe cover
36.0°C ±0.2°C (96.8°F ±0.4°F)
38.5°C ±0.2°C (101.3°F ±0.4°F)
41°C ±0.2°C (105.8°F ±0.4°F)

Hundredth degree (high resolution)

The smallest significant digit is the tenths digit (0.X), therefore when interpreting data at the hundredths digit (0.XX) the reading must be rounded to the nearest tenth prior to interpretation. As such, the accuracy ranges are as follows:

Accuracy range with probe cover
36.0°C ±0.24°C (96.8°F ±0.44°F)
38.5°C ±0.24°C (101.3°F ±0.44°F)
41°C ±0.24°C (105.8°F ±0.44°F)

6.2 If results are outside the allowable tolerances, contact your local Welch Allyn Customer Care Representative:

Go to www.welchallyn.com to find the contact information for technical support in your region.

Complaints or concerns:

Welch Allyn encourages all service centers to report customer complaints. This information is valuable for the improvements of products.

All complaints where it is alleged that our product has caused or contributed to a death or a serious deterioration in the state of health of a patient, user or other person, must be reported immediately to your local Welch Allyn Organization.

A serious deterioration in the state of health can include a life-threatening illness or a condition necessitating medical intervention to prevent permanent damage.

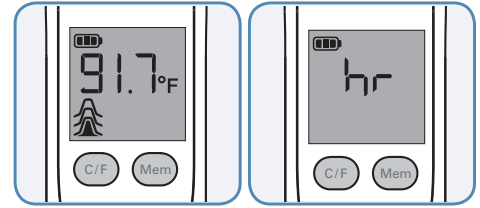
Also all cases should be reported where the circumstances indicate, that the incident was such that, if it occurred again, it may lead to death or serious deterioration in health.

7.0 Additional display screens in calibration mode

7.1 High resolution reading:

The normal resolution of the thermometer is shown to the tenth of a degree (Celsius or Fahrenheit). If resolution to the hundredth of a degree is desired, upon completion of a reading press and release the **timer** button. The "CAL" display will change to "hr" and the temperature reading will show the last 3 digits of the reading to the hundredth of a degree. A reading such as 99.2°F would, in high resolution, be shown as 924 (99.24) or 917 (99.17) as applicable.

To return to the calibration check mode ready state and prepare the thermometer to take a second reading, press and release the **measure** button.

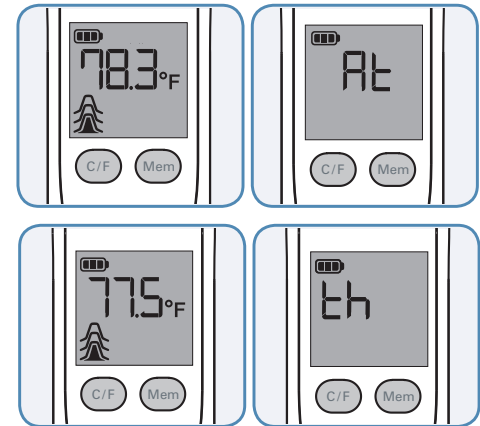


7.2 Ambient temperature reading:

The ambient temperature as read by the thermometer can be displayed next. Press and release the **Timer** button to display the ambient temperature reading. The "hr" display will change to "At" and display the ambient temperature to a tenth of a degree.

To return to the calibration check mode ready state and prepare the thermometer to take a second reading, press and release the **measure** button.

A second ambient sensor (thermistor) is also used (the lower of the two ambient temperatures is used by the thermometer) and can be accessed by pressing the **Timer** button once more. The screen will display "th" alternating with the display.

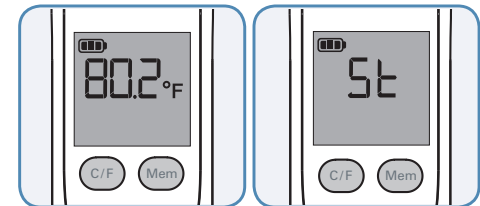


7.3 Sensor temperature reading:

The temperature of the thermopile sensor of the thermometer can be displayed next. Press and release the **Timer** button to change from the ambient temperature reading to the temperature of the thermopile sensor. The display will change "th" to "St" and display the temperature of the sensor to a tenth of a degree.

NOTE: Dependent upon the actions taken prior to entering this display, the temperature may remain steady at the heated level or may decrease until equilibrium with ambient is reached.

To return to the calibration check mode ready state and prepare the thermometer to take a second reading, press and release the **measure** button.



7.4 Target temperature reading prior to measure button press:

The target temperature reading immediately prior to pressing the **measure** button can be displayed next. Press and release the **timer** button from the sensor temperature reading to display the pre-button press target temperature reading, this will change the "St" display to "Pb" and show the target temperature reading prior to **measure** button was pressed.

Note: this reading is taken with the sensor heater activated and **does not** maintain or achieve the same accuracy as the reading following the **Measure** button press. **Do not** evaluate the calibration of the thermometer using this display.

To return to the calibration check mode ready state and prepare the thermometer to take a second reading, press and release the **measure** button or the **timer** button.

