BRAUN

WelchAllyn®

ThermoScan®

Ear thermometer Instructions for use



BRAUN

ThermoScan®

PRO 6000 Ear thermometer

This manual applies to REF 901054 EarThermometer, REF 901009 Accessory, Thermometry, and REF 901010 Accessory, Thermometry

These instructions for use/directions for use (IFU/DFU) may contain information about products that may or may not be approved for use by a relevant regulatory authority in any particular country or region of the world. Customers and/or End-Users are requested to contact their local sales representative for further information regarding regulatory registration status and availability of products.



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EC REP

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For information about any Welch Allyn product, contact: Welch Allyn Technical Support:

www.welchallyn.com/support

Visit locations:

www.welchallyn.com/about/company/locations.html

Replacement parts

Probe covers: 06000-005, 06000-801, 06000-800 For a complete list of parts, go to www.welchallyn.com

For patent information, visit

www.welchallyn.com/patents © 2021 All rights reserved.

Made in Mexico

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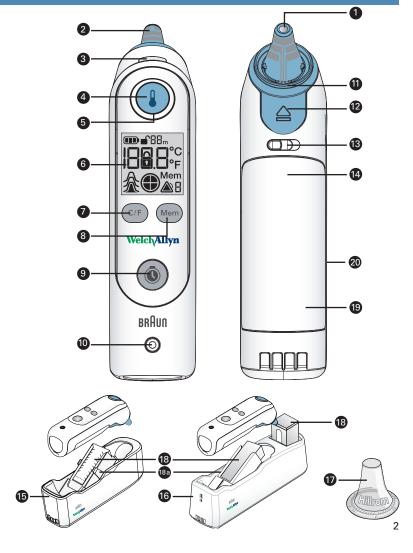
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Use only **Hillrom**probe covers



1. Braun Thermoscan® PRO 6000 Ear thermometer



2. Package components

Braun Thermoscan® PRO 6000 Ear thermometer

Cradle

Probe covers (1 or 2 probe cover boxes, depending on model)

CD containing Instructions for use, Quick reference guide, Welch Allyn ServiceTool software (available via internet link), and ServiceTool installation guide (available via Internet link).

2 (AA) Duracell® alkaline batteries

3. Product description (See Section 1. Braun Thermoscan® PRO 6000 Ear thermometer)

- 1 Probe lens window
- 2 Probe
- 3 ExacTemp™ light
- 4 Measure button
- Measure light
- 6 Display
- 7 C/F button
- 8 Memory button
- 9 Timer button
- Tether mount (Tether sold separately)
- 11 Probe cover detect switch

- 12 Probe cover ejector
- Battery door latch
- 14 Battery door
- 15 Small cradle one storage box
- 16 Large cradle two storage boxes
- Probe cover
- 18 Probe cover box
- 8a Probe cover box carrier
- 19 GTIN code
- Temperature scale switch (inside battery compartment)

Screen elements

Battery



Full battery—indicates battery is between 100 % and 70 % of usable battery capacity



Partial battery-indicates battery is between 70 % and



30 % of usable battery capacity Low battery—indicates battery is between 30 % and 10 % of usable battery capacity



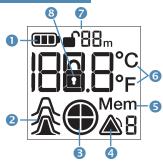
Critically low battery—battery is between 10 % and 1 % of usable battery capacity. When final segment flashes, batteries have low power. The thermometer will take a proper measurement but batteries must be replaced soon. If rechargeable batteries are in use, batteries should be recharged.



Empty battery-battery has 1 % or less of usable battery capacity. When battery outline flashes, the thermometer will not operate. Replace the batteries. If rechargeable batteries are in use, batteries should be recharged. See 14.7 Maintenance and service. Replacing the batteries

Probe cover icon

The icon animates in an upward motion to remove probe cover. The icon animates in a downward motion to apply a probe cover. See 9. Using the Braun Thermoscan® PRO 6000 Ear thermometer



Timer icon

The Braun Thermoscan® PRO 6000 Ear thermometer includes a 60 second timer that features an audible notification and visual indicator at 0. 15, 30, 45, and 60 seconds. The first quadrant begins flashing when timer starts and becomes solid at 15 seconds. This repeats for each 15 second interval. The timer turns off automatically 5 seconds after 60 seconds is completed. See 10.3 Controls, Manual timer

Alert icon

Icon that appears with error message. See 12. Errors and notifications

Memory indicator

Indicates the reading shown on the display is the reading in memory. See 10.1 Controls, Memory

6 C/F scale

Indicates default temperature scale. Either °C or °F will display, depending on setting. See 10.2 Controls, C/F Celsius/Fahrenheit

Security unlock icon and countdown time

(Requires charging station or compatible Welch Allyn Vital Signs device, sold separately.) If the security function is enabled, it requires the thermometer be returned to the charging station within a pre-selected time interval. Countdown time indicates the amount of time remaining until the thermometer will be locked if not returned to the charging station. See 11.2 Settings, Advanced functions

8 Security lock icon

(Requires charging station or compatible Welch Allyn Vital Signs device, sold separately.) Indicates the thermometer is locked. Return the thermometer to the charging station to reset the countdown and resume normal operation. See 11.2 Settings, Advanced functions

5. About the Braun Thermoscan® PRO 6000 Ear thermometer

5.1 Intended Use

The BraunThermoscan® PRO 6000 Ear thermometer is indicated for the intermittent measurement of human body temperature for patients having ages ranging from normal weight (full term) newborn to geriatric adults in a professional use environment. The probe cover is used as a sanitary barrier between the infrared thermometer and the ear canal.

5.2 How does Braun ThermoScan work?

The BraunThermoscan® PRO 6000 Ear thermometer 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 BraunThermoScan is placed in the ear, it continuously monitors the infrared energy until a temperature equilibrium has been reached and an accurate measurement can be taken. The thermometer displays an actual measured ear temperature or clinically accurate, oral equivalent temperature that has been validated in clinical studies by comparing IR measurements with the oral readings from afebrile and febrile patients of various ages. Unadjusted operating mode ear temperature readings are available via unadjusted mode, which can be accessed using the Welch Allyn Service Tool.



5.3 PerfecTemp™ Sensor System

Speed and ease of access are two key advantages of ear thermometry. Concerns regarding accuracy and reliability have hindered adoption of this technology. In clinical studies, the precision of ear temperature measurement has been shown to be influenced by ear canal anatomy and variability in user technique. Proper probe placement can also be a challenge, particularly with young patients that move around during measurement. Shallow probe placement, coupled with anatomical variabilities such as ear canals with a small circumference and poor visibility of the tympanic membrane, can result in readings that are low compared to core temperature because the thermometer could be focused on the cooler outer ear canal.



Table 1: Ear canal temperature gradient

The BraunThermoscan® PRO 6000 Ear thermometer incorporates a new proprietary sensor system, PerfecTemp™, that overcomes the challenges presented by ear canal anatomy and variations in technique among clinicians. The thermometer collects information about the direction and depth of ear probe placement as it is placed into the ear canal and automatically incorporates this information into the temperature calculation. Incorporating information related to patient specific anatomy and exact ear probe placement in the ear canal increases the accuracy of the measurement as compared to core temperature, especially when probe positioning is not ideal.

5.4 ExacTemp™ technology

The BraunThermoscan® PRO 6000 Ear thermometer also features ExacTemp™ technology which supports temperature measurement reliability by detecting the stability of the probe placement during the measurement. 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. Consistent probe placement helps support accurate temperature measurement.

5.5 Why measure in the ear?

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 temperature'. Body temperature is regulated by the hypothalamus², which shares the same blood supply as the tympanic membrane³. 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 at 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.
- 1. Guyton A C, Textbook of medical physiology, W.B. Saunders, Philadelphia, 1996, p 919
- 2. Guyton A C, Textbook of medical physiology, W.B. Saunders, Philadelphia, 1996, p 754-5
- 3. Netter H F, Atlas of Human Anatomy, Novartis Medical Education, East Hanover, NJ, 1997, pp 63, 95.

5.6 Body temperature



Normal body temperature is a range. The following table shows that this normal range also varies by site. Therefore, measurements from different sites, even if taken at the same time, should not be directly compared.

Normal ranges by site¹:						
Axillary ^{1, 2} :	95.6–99.4 °F	35.3–37.4 °C				
Oral ^{1, 2} :	95.7–99.9 °F	35.4–37.7 °C				
Rectal ^{1, 2} :	96.6–100.8 °F	35.9–38.2 °C				
ThermoScan ^{1, 2} :	95.7–99.9 °F	35.4–37.7 °C				

A person's normal temperature range tends to vary with age. The following table shows normalThermoScan ranges by age.

Normal ThermoScan ranges by age ^{1, 2} :					
< 3 months	96.4–99.4 °F	35.8–37.4 °C			
3–36 months	95.7–99.6 °F	35.4-37.6 °C			
> 36 months	95.7–99.9 °F	35.4-37.7 °C			

The range of normal varies from person to person and can be influenced by many factors such as time of day, level of activity, medications, and gender.

Sund-Levander M, Forsberg C, Wahren LK. Normal oral, rectal, tympanic and axillary body temperature in adult men and women: a systematic literature review. Scand J Caring Sci 2002 June;16(2):122–8.

^{2.} Herzog L, Phillips SG. Addressing concerns about fever. Clin Pediatr (Phila) 2011 May;50(5):383-90.

6. Contraindications

None

6.1 What affects accuracy

Always use a new disposable probe cover for each measurement to maintain accuracy and hygiene. The right ear measurement may differ from the measurement taken in the left ear. Therefore, always take the temperature in the same ear. The ear must be free from obstructions or excess earway build-up to take an accurate reading.

External factors that may influence ear temperatures include:

Factor	Affected	Not affected
Used probe cover	/	
Ambient temperature		~
Wet / dirty / damaged lens	/	
Hearing aid	/	
Lying on pillow	/	
Moderate cerumen (ear wax)		~
Otitis media (ear infections)		~
Tympanostomy tubes		~

In the event the patient is lying on a pillow or wearing ear plugs or a hearing aid, remove the individual from the situation and wait 30 minutes prior to taking a temperature.

7. Warnings and cautions





WARNING This thermometer is for professional use only.



WARNING This thermometer must only be used with genuine Hillrom probe covers.



WARNING Do not use any cleaning agent other than isopropyl or ethyl alcohol for cleaning the probe lens window and probe as specified in the cleaning section of this manual.



WARNING If cleaning instructions are not followed, the device may be exposed to fluid ingress. If this occurs, there is a risk of the probe tip overheating and potentially causing a burn to the user or the ear canal of the patient. In addition, fluid ingress may cause inaccurate temperature readings.



CAUTION Do not use any cleaning agent other than those on the approved list of cleaners for cleaning the body of the thermometer.



WARNING To avoid inaccurate measurements, always attach a new, clean probe cover for each temperature measurement.



WARNING The probe lens window must be kept clean, dry, and undamaged at all times to ensure accurate measurements. To protect the probe lens window, always keep the thermometer in the storage cradle while transporting or when not in use.



WARNING This thermometer is not intended for pre-term babies or small-for-gestational age babies.



WARNING Do not modify this equipment without authorization of manufacturer



CAUTION Never use the thermometer for purposes other than those it has been intended for. Please follow the general safety precautions.



CAUTION Do not expose the thermometer to temperature extremes (below –25 °C / –13 °F or over 55 °C / 131 °F) nor excessive humidity (> 95 % RH).



CAUTION This thermometer complies with current required standards for electromagnetic interference and should not present a problem to other equipment nor is it affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.



WARNING Do not use an ear thermometer if there is blood or drainage in the external ear canal.



WARNING An ear thermometer should not be used on a patient who exhibits symptoms of an acute or chronic inflammatory condition of the external ear canal.



WARNING Common situations like the presence of moderate amounts of cerumen (ear wax) in the ear canal, otitis media, and tympanostomy tubes do not significantly impact temperature readings. However, complete ear canal occlusion due to cerumen (ear wax) can result in lower temperature readings.



WARNING If prescription ear drops or other medications have been placed in the ear canal, use the untreated ear to take a measurement.



WARNING Patients who have deformities of the face and/or ear may not be able to have a temperature taken with an ear thermometer.

8. Setup

8.1 Battery installation

Your Braun Thermoscan® PRO 6000 Ear thermometer ships with two (AA) alkaline batteries. See 14.7 Maintenance and service, Replacing the batteries.

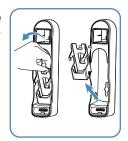
The BraunThermoscan® Charging station (sold separately) ships with one rechargeable battery pack.

8.2 Mounting instructions (Large cradle only)

Mounting hardware not included.

The large cradle (2 box storage) can be mounted as an easily removable wall hanger or a permanent wall mount. All mounting must be done into a wall stud. To mount the cradle the following items are needed:

- 2 #8 wood or sheet metal, pan head screws, 3.2 cm (1.25") long
- Ruler (or tape measure can be substituted)
- · Screwdriver to match drive of screws
- Remove probe cover box carrier from the cradle by rotating the probe cover box carrier forward.



- Mount to wall:
 - · Removable wall hanger:

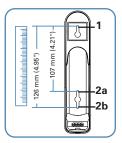
Locate the stud on the wall. Mount the 1st screw in position 1 and the 2nd screw in position 2a.

Permanent wall mounting:

Locate the stud on the wall. Mount the 1st screw in position 1 and the 2nd screw in position 2b. Tighten screws.



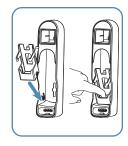
NOTE Permanent mounting is not recommended if using the charging station to access the security function, other advanced functions or charge the rechargeable battery.



Place probe cover box carrier back in cradle by lining up the brackets and pushing down.



NOTE For a mounting template please reference the Braun Thermoscan® PRO 6000 Ear thermometer CD.



8.3 Tether installation

A kit to tether the thermometer to the cradle is available separately. Installation instructions are provided with the tethering kit. Contact Welch Allyn for details.

9. Using the Braun Thermoscan® PRO 6000 Ear thermometer

Temperature measurement

 Remove thermometer from cradle by gripping thermometer at base and pivoting up.

Thermometer will turn on automatically. Probe cover icon in will flash on display indicating a new probe cover is needed.



Attach new probe cover by pushing probe tip straight into box, then pulling thermometer out.





3 Wait for the ready indication. Ring around measure button turns green, thermometer will beep once and three lines on display indicate thermometer is ready.



Place probe snugly in ear canal and direct toward opposite temple. Keep thermometer probe steady in the ear canal. Correct probe placement is essential for accurate measurements.





5 Press and release measure ▮ button.



The thermometer will beep once, running dashes will appear on the display then the green ExacTemp light will flash, indicating consistent probe position.



NOTE Always press the measure button before taking a measurement.



Temperature measurement. A long beep and steady green ExacTemp light will signal the end of the measuring process.



The temperature will show on the display.



If the thermometer is unstable or patient is moving during the measuring process, the device will beep, the green ExacTemp light will flash and POS (Position Error) will flash on the display. Be sure the device is stable and restrict patient movement for the next measurement. Change the probe cover to reset.

* See 12. Errors and notifications



Remove used probe cover by pressing Probe Cover Ejector button ▲.

To achieve accurate measurements, use a new, clean probe cover for each measurement.

To take another measurement, place a new, clean probe cover on the thermometer. If no action is taken the thermometer will enter **sleep** mode after 10 seconds or upon return to the thermometer cradle or host device.





10. Controls

10.1 Memory

Press **MEM** (the memory button) to reveal the last completed temperature. The temperature will show with a Mem indicator until **MEM** (the memory button) is pushed again, a new probe cover is applied, or the thermometer enters sleep state. Memory can also be accessed from the thermometer sleep mode and will display for 5 seconds before returning to sleep.



10.2 C/F (Celsius/Fahrenheit)

Once the temperature scale has been set (See 11.1 Default temperature scale), the alternative scale can be quickly referenced at any time while a temperature is displayed.

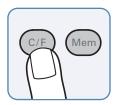
If the temperature scale is set to Celsius, press and release C/F (the C/F button) to view the temperature in Fahrenheit.

If the temperature scale is set to Fahrenheit, press and release **C/F** to view the temperature in Celsius.

Press and release C/F again to revert back to default scale



NOTE If temperature conversion is disabled, refer to the Service Manual for more information.



10.3 Manual timer

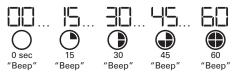
The BraunThermoscan® PRO 6000 Ear thermometer includes a 60 second timer that features an audible notification and visual indicator at 0, 15, 30, 45, and 60 seconds. The timer turns off automatically 5 seconds after 60 seconds is completed. The timer can be stopped at any time by pressing the Timer button or applying a probe cover. This feature can be used to time pulse, respirations, etc. To use this feature:

Press and hold timer button (a) for one second to activate timer. A beep is heard at initiation of the timer.

The display will show timer counting up in seconds.

The display will show an icon that has four 15 second quadrants.

The timer will beep at the completion of each 15 second interval to provide audible notification. Then the current segment will become solid and the next segment will flash. At 60 seconds a long beep will sound, all quadrants will appear solid ending the timer function. The thermometer will exit the timer mode after an additional 5 seconds.







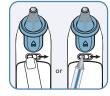
To stop the timer at any time, press the timer button.

11. Settings

11.1 Default temperature scale

To set the default temperature scale:

Open battery door by sliding spring latch to the right using your finger or a pointed object such as a pen. While holding the latch in the open position, grasp the battery door and remove it. Remove batteries and set aside. Once batteries are removed, the C/F switch is accessible





- Slide switch to C or F using a pen or pointed object.
- Place batteries back into thermometer. Snap the battery door back into place and ensure the latch returns to the original latched position. Celsius or Fahrenheit symbol will appear on the display.



11.2 Advanced functions

The Welch Allyn Service tool software is required to modify the thermometer's configuration. A charging station and rechargeable batteries or compatible Welch Allyn Device is required to connect to the PC running the Welch Allyn Service Tool. (See 11.3 Advanced function settings and 11.4 Service tools)

Item	Description	Settings	Default setting
PerfecTemp™	Improves reading accuracy by detecting placement of probe in ear canal	On/Off	On
C/F button	Use the C/F button to view measurements in the non-default (alternate) temperature scale. When off (disabled) only the default scale is available.	On/Off	On
Default C/F manual switch	When on (enabled), the default scale can be set using the manual switch in the battery compartment. When the control is off (disabled), the radio buttons for Celsius and Fahrenheit are enabled allowing the service tool to set the default scale.	On/Off	On
Security function	Sets countdown time after removal from charging dock to lock	1 through 12 hours	Off
Timer icon	Displays an icon along with the timer counter	On/Off	On
Unadjusted operating mode	Places thermometer in mode to detect raw ear temperature only	Allows user to set device to unadjusted operating mode	Off

11.3 Advanced function settings

The Welch Allyn Service tool software is required to modify the thermometer's configuration.

A charging station and rechargeable batteries or compatible Welch Allyn Device is required to connect to the PC running the Welch Allyn ServiceTool.

Follow the instructions to access BraunThermoscan® PRO 6000 Ear thermometer advanced settings using the Welch Allyn ServiceTool.

 Dock the BraunThermoscan® PRO 6000 Ear thermometer in the Charging Station



The recommended action is to use the USB cable that connects to the wall adapter—unplug it from the wall adapter and plug it into your computer.



- a. Launch the Welch Allyn Service Tool.
 - b. If the startup screen with the "Add new features" and "Service" button appears click "Service".
 - Log in as ADMIN with no password or use any account you previously created.



NOTE If the log on prompt does not appear click the Log on button. You must be logged on to access the configuration dialog.



Click the Braun Thermoscan® PRO 6000 Ear thermometer from the Device list (Device list) to highlight, then click the select button.



The device tab opens.



6 Click the Configure tab to the right of the device information tab.



Click the Change button in the current settings box. The configuration settings dialog box opens.



8

Select the setting you wish to enable or disable by clicking the check box next to the setting. A check mark indicates the setting will be enabled, an empty check box indicates the setting will be disabled. To select the Security function click the drop down menu and click the desired time or Off to disable. To restore the factory default settings click Restore Defaults. Once the desired settings are selected click the Save button to send the settings to the Braun Thermoscan® PRO 6000 Ear thermometer and close the box.



To close the box without changing the settings click the Cancel button.

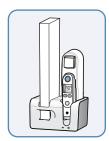
11.4 Service tools

For more information on the ServiceTool and ServiceTool installation guide go to www.hillrom.com/en/services/welch-allyn-service-tool/ and download the service tool found under the Services & SupportTab/Service Centers/Download service tool.

11.5 Charging station for storage, charging, and security function (optional)

A charging station is available for the BraunThermoscan® PRO 6000 Ear thermometer. The charging station automatically recharges the thermometer when using the rechargeable battery which is included. Use of alkaline batteries in the thermometer while using the charging station is permitted but the alkaline batteries will not be charged.

The charging station has an electronic, individually adjustable security function which requires the thermometer to be returned to the station within an individually pre-selected time or the thermometer will be locked. The charging station serves as a convenient storage base which can also be wall mounted. Contact Welch Allyn for details.



Welch Allyn Technical Support:

www.welchallyn.com/support

Visit locations:

www.welchallyn.com/about/company/locations.html

12. Errors and notifications

Error message	Situation	Solution
	No probe cover is attached (animates ON).	Attach new, clean probe cover.
3 7.0°°	Used probe cover is attached (animates OFF).	Discard probe cover that is on and attach new, clean probe cover if taking another temperature measurement.
P05,	(POS = position error) The infrared monitor cannot find a temperature equilibrium and allows no measurement.	Change the probe cover to reset. Restrict patient movement and ensure that the positioning of the probe is correct and remains stable while taking new temperature.
Err	Ambient temperature is not within the allowed operating range (10–40 °C or 50–104 °F) or changing too rapidly.	Wait 20 sec. until thermometer turns off automatically, then turn on again. Ensure thermometer and patient are in an environment for 30 minutes where the temperature is between 10 °C and 40 °C or 50 °F and 104 °F prior to measurement.
H	Temperature taken is not within typical human temperature range. HI will be displayed when temperature is higher than 42.2 °C (108 °F).	Change probe cover to reset. Then, make sure thermometer is properly inserted and take a new temperature.
LO	LO will be displayed when temperature is lower than 20 °C (68 °F).	

Error message	Situation	Solution
® 6 88 _m 1 1 1 0 °C 1 1 1 1 0 °F	System error (All icons display or display is blank)	Wait 20 seconds until the thermometer turns off automatically, then turn on again.
Mem or B or	If error persists,	reset the thermometer by removing the batteries and putting them back in.
	If error still persists,	batteries are dead. Insert new batteries.
	If error still persists,	contact local Welch Allyn Service Center or representative.
	Battery is low, but thermometer will still operate correctly.	Insert new batteries.
	Battery is too low to allow temperature measurement.	Insert new batteries.
	Do you have any further questions?	contact local Welch Allyn Service Center or representative.

13. PerfecTemp™ status

Error message Situation PerfecTemp™ sensor system is not functioning or disabled. ... contact local Welch Allyn Service Center or representative. U is "Unadjusted Operating See 11.3 Advanced function



U is "Unadjusted Operating Mode". Mode used for raw temperature measurement. Requires service tool access to enable.

See 11.3 Advanced function settings and adjust settings via ServiceTool or contact local Welch Allyn Service Center or representative.

14. Maintenance and service

14.1 Cleaning the probe lens window, probe, and contacts



WARNING Only use Hillrom Thermometer disposable probe covers.



WARNING Do not use damaged, perforated, soiled or poor fitting probe covers. Do not reuse probe covers.



WARNING Dirty probe lens window = lower readings. Fingerprints, cerumen, dust, and other soiling components reduce transparency of the tip and result in lower temperature measurements. If thermometer is placed in ear without a probe cover, clean immediately.



WARNING Do not damage probe lens window. Avoid touching probe lens window except when cleaning. If probe lens window is damaged return to Welch Allyn for service.



WARNING If cleaning instructions are not followed, the device may be exposed to fluid ingress. If this occurs, there is a risk of the probe tip overheating and potentially causing a burn to the user or the ear canal of the patient. In addition, fluid ingress may cause inaccurate temperature readings.



CAUTION Do not modify, change or adjust probe lens window. These changes will affect calibration and accuracy of the thermometer. If probe lens window is damaged return to Welch Allyn for service.



CAUTION Do not use a cleaning solution other than isopropyl or ethyl alcohol to clean probe lens window and probe. Bleach and other cleaning agents will cause permanent damage to the probe and probe lens window.



CAUTION Cleaning the probe lens window and probe

The thermometer probe and probe lens window should be cleaned when there are fingerprints, cerumen, dust, or other soiling components present, following the directions below:



Remove probe cover and discard.



Moisten cotton swab or cloth slightly with isopropyl or ethyl alcohol. Do not saturate.



- Gently wipe surface of probe lens window with cotton swab or cloth slightly moistened with isopropyl or ethyl alcohol only.
 - NOTE Use gentle pressure when cleaning the sensor to prevent damaging the unit by accidently changing the position of the sensor.



- With probe facing down, wipe the probe with a damp cloth or cleaning wipe moistened with isopropyl or ethyl alcohol.
- Gently wipe with dry, clean cotton swab or cloth immediately.



6 Allow at least 5 minutes drying time before taking temperature. Make sure probe lens window is clean and dry prior to use.



Cleaning the contacts

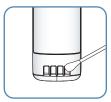


CAUTION Do not use bleach solutions of any kind when cleaning metal electrical contacts. It will damage the device.

1 Slightly dampen a cotton swab with 70% isopropyl alcohol.



Remove the thermometer from the dock and clean the metal electrical contacts on the thermometer.



Place the thermometer aside for 1 minute, allowing the contacts to air dry.



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NOTE If any cleaning agent, other than isopropyl or ethyl alcohol, comes into contact with the probe, probe lens window, or contacts immediately wipe dry. Then clean the probe, probe lens window, and contacts with isopropyl or ethyl alcohol.

14.2 Cleaning the thermometer body and cradle



CAUTION Do not submerge the thermometer. Excess liquid may cause damage to the thermometer.

Wipes should be moist, not saturated.



CAUTION Do not use any chemical other than those listed in the Approved Cleaning Solution Table to clean the thermometer body and cradle. Other cleaning agents could cause damage to the thermometer.

When cleaning the probe lens window or probe ONLY use isopropyl or ethyl alcohol.



CAUTION Do not use abrasives pads or cleaners.

Approved cleaning solutions						
Family	Solution or brand	Probe lens window	Probe	Contacts	Thermometer body & cradle	Tether
Chlorine and chlorine compounds	10 % Chlorine bleach solution	No	No	No	Yes	Yes
Quaternary ammonium compounds	CaviWipes™ Clinell® Universal Wipes SaniCloth	No	No	No	Yes	Yes
Hydrogen peroxide	Virox Oxivir	No	No	No	Yes	Yes
Alcohol	70 % isopropyl or ethyl alcohol	Yes	Yes	Yes	Yes	Yes

Additional cleaning agents may be periodically evaluated for compatibility. If your cleaning agent is not listed, contact Welch Allyn to determine if additional cleaning agents are approved for use.

As needed, clean the thermometer body and cradle following the below directions.



NOTE If any cleaning agent, other than isopropyl or ethyl alcohol, comes into contact with the probe, probe lens window or contacts immediately wipe dry. Then clean the probe, probe lens window, and contacts with isopropyl or ethyl alcohol.

1 For additional protection, we recommend placing a new probe cover on the thermometer probe to protect this area when cleaning the body of the thermometer.



Use a damp cloth or cleaning wipe with cleaning solution from the Approved Cleaning Solutions Table. To clean the body, ensure that the wipe is moist, not saturated. Wipe the body with the display facing up.



Remove probe cover box carrier from the cradle by rotating the probe cover box carrier forward. See 14.5 Removing and installing probe cover box carrier.



Wipe the cradle and probe cover carrier with a damp cloth or cleaning wipe with cleaning solution from the Approved Cleaning Solutions Table.



Allow at least 5 minutes drying time before taking temperature. Make sure probe, body, and cradle are clean and dry prior to use.



14.3 Cleaning the tether (sold separately)

1 To clean the tether, ensure that the wipe is moist, not saturated. Wipe the tether with a damp cloth or cleaning wipe with cleaning solution from the Approved Cleaning Solutions Table.



14.4 Installing new probe cover box



Keep out of reach of children.

 Remove empty probe cover box from probe cover box carrier by pulling up.



Open the new probe cover box. Pull down on the perforated strip. Discard perforated strips.



Insert new probe cover box into probe cover carrier by placing inside brackets and pushing down.



14.5 Removing and installing probe cover box carrier

 Remove thermometer from cradle by gripping thermometer at base and pivoting up.



Remove probe cover box carrier from the cradle by rotating the probe cover box carrier forward.



Place probe cover box carrier back in cradle by lining up the brackets and pushing down.



14.6 Storage environment

Store thermometer and probe covers in a dry location (the thermometer is not protected against ingress of water), free from dust and contamination and away from direct sunlight.

Storage temperature: -20 to 50 °C (-4 to 122 °F)

Storage humidity: 0 % to 85 % non condensing

Replacing the batteries

The thermometer is supplied with two 1.5 V batteries type AA (LR 6). For best performance, Duracell® alkaline batteries are recommended.



NOTE The battery life performance testing was based on the Duracell® alkaline batteries. Batteries other than these are not guaranteed to provide the same life performance results.

- Insert new batteries when the battery symbol begins to flash on the display (See 12. Errors and notifications).
- Open battery door by sliding spring latch to the right using your finger or a pointed object such as a pen. While holding the latch in the open position, grasp the battery door and remove it.





Remove the batteries and replace with new batteries, making sure the poles are in the right direction.



Snap battery door back into place and ensure the latch returns to original latch position.





This product contains batteries and recyclable electronic waste. To protect the environment, do not dispose of it in the trash, but take it to appropriate local collection points according to national or local regulations.

14.7 Calibration testing

The thermometer is initially calibrated at the time of manufacture. If the thermometer is used according to the instructions for use, periodic readjustment is not required. However, Welch Allyn recommends checking calibration on an annual basis or whenever clinical accuracy of the thermometer is in question. Procedures for checking calibration are outlined in the 9600 Plus Calibration Tester (REF 01802-110) directions for use manual.

The above recommendations do not supersede the legal requirements. The user must always comply with legal requirements for the control of the measurement, functionality, and accuracy of the device which are required by the scope of relevant laws, directives or ordinances where the device is used.

15. Specifications

Displayed temperature range: 20-42.2 °C (68-108 °F) Operating ambient temperature range: 10-40 °C (50-104 °F) 0.1 °C or 0.1 °F

Display resolution

Accuracy for displayed temperature ± 0.2 °C ± (0.4 °F) (35.0 °C-42 °C) (95 °F-107.6 °F) \pm 0.3 °C \pm (0.5 °F) (outside this temperature range) range:

Clinical bias:

limits of agreement: For a copy of the clinical validation study, please

contact customer care. clinical repeatability:

Reference body site: Oral measuring

Site: Ear

Long term storage ranges

Storage temperature: -20 to 50 °C (-4 to 122 °F) Storage humidity: 0 % to 85 % non condensing Shock: Withstands drop of 3 feet (91.44 cm) 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 x MN 1500 or 1.5 V AA (LR6)

Thermometer dimension: 6" × 1.7" × 1.3" (152 mm × 44 mm × 33 mm)

Thermometer weight: 3.6 oz (100 g) without batteries Pressure: 700-1060 hPA (0.7-1.06 atm)

The thermometer is specified to operate at 0.7-

1.06 Atmospheric Pressure.



CAUTION Do not use this device in the presence of electromagnetic or other interference outside the normal range specified in IEC 60601-1-2.





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 \pm 0.2 °C (\pm 0.4 °F), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E 667-86 and E 1112-86 is \pm 0.1 °C (\pm 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.



Symbol definitions:



Type BF Applied Part



Measure icon



Caution

The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.



Timer icon



Warning

The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. Warning symbols will appear with a grey background in a black and white document.



Calibration date



Separate collection of Electrical and ElectronicEquipment. Do not dispose as unsorted municipal waste.



Consult instructions for use (IFU or DFU). A copy of the IFU is available on this website. A printed copy of the IFU can be ordered from Welch Allyn for delivery within 7 calendar days.



Storage temperature



Storage humidity

16. Warranty

For Model Braun Thermoscan® PRO 6000 Ear thermometer

Welch Allyn (an affiliate of Hill-Rom®) warrants the product to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for the period of three years from the date of purchase from Welch Allyn or its authorized distributors or agents.

The date of purchase is: 1) the invoiced ship date if the device was purchased directly from Welch Allyn, 2) the date specified during product registration, or 3) the date of purchase of the product from a Welch Allyn authorized distributor as documented from a receipt from said distributor, whichever date is earlier.

This warranty does not cover damage caused by 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by Welch Allyn, or 4) accidents. This warranty does not cover batteries, damage to the probe window, or damage to the instrument caused by misuse, negligence or accident, and extends to only to the first purchaser of the product. Replaced units under warranty will have the remainder of the replaced unit's warranty length. Additionally, this warranty becomes void if the thermometer is operated with anything other than genuine Hillrom™ probe covers.

Guidance and manufacturer's declaration – RF wireless communication equipment immunity						
Test frequency	Band ^{a)}	Service a)	Modulation b)	Maximum power	Distance	IMMUNITY TEST LEVEL
(MHz)	(MHz)			(W)	(m)	(V/m)
385	380 –390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0,3	28
710			Pulse			
745	704 – 787	LTE Band 13, 17	modulation b)	0,2	0,3	9
780			217 Hz			
810		GSM 800/900, TETRA 800,	Pulse			
870	800 – 960	iDEN 820,	modulation b)	2	0,3	28
930		CDMA 850, LTE Band 5	18 Hz			
1 720		GSM 1800;				
1 845	1 700 –	CDMA 1900; GSM 1900;	Pulse modulation b)	2	0.3	28
1 970	1 990	1 990 DECT; LTE Band 1, 3, 4, 25; UMTS	217 Hz	-	0,0	20
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28
5 240			Pulse			
5 500	5 100 – 5 800	WLAN 802.11 a/n	modulation b)	0,2	0,3	9
5 785	1		217 Hz			

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Guidance and manufacturer's declaration – RF wireless communication equipment immunity							
Test frequency	Band ^{a)}	Service a)	Modulation b)	Maximum power	Distance	IMMUNITY TEST LEVEL	
(MHz)	(MHz)			(W)	(m)	(V/m)	
385	380 –390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1,8	0,3	27	
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0,3	28	
710			Pulse				
745	704 – 787	LTE Band 13, 17	modulation b)	0,2	0,3	9	
780		217 Hz					
810			GSM 800/900, TETRA 800.	Pulse			
870	800 – 960	iDEN 820,	modulation b)	2	0,3	28	
930		CDMA 850, LTE Band 5	18 Hz				
1 720		GSM 1800;					
1 845	1 700 –	CDMA 1900; GSM 1900;	Pulse modulation b)	2	0.3	28	
1 970	1 990	90 DECT; LTE Band 1, 3, 4, 25; UMTS	217 Hz	-	0,0	20	
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28	
5 240			Pulse				
5 500	5 100 – 5 800	WLAN 802.11 a/n	modulation ^{b)}	0,2	0,3	9	
5 785			217 Hz				

a) For some services, only the uplink frequencies are included.

 $^{^{\}rm b)}$ The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.