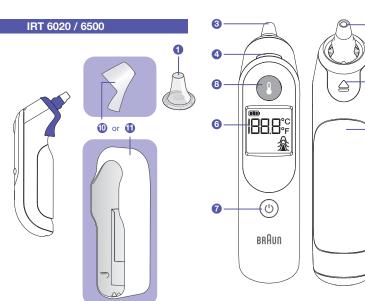
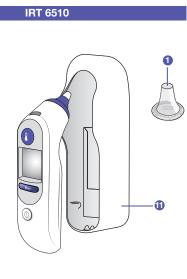
BRAUN ThermoScan® Ear thermometer

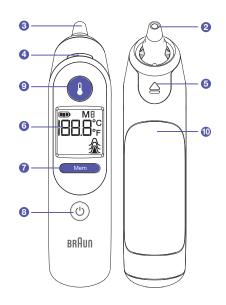




IRT 6020 IRT 6500 IRT 6510







Product description

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IRT 6020/6500 Series IR			F 6510 Series
1	Lens filter (Box of 20)	1	Lens filter (Box of 20)
2	Probe tip	2	Probe tip
3	Probe	3	Probe
4	ExacTemp light	4	ExacTemp light
6	Lens filter ejector	6	Lens filter ejector
6	Display	6	Display
7	Power button	7	Memory button
8	Start button	8	Power button
9	Battery door	9	Start button
10	Protective cap (IRT 6020 only)	10	Battery door
0	Protective case (IRT 6500 only)	1	Protective case

The Braun ThermoScan thermometer has been carefully developed for accurate, safe and fast temperature measurements in the ear.

The shape of the thermometer probe prevents it from being inserted too far into the ear canal which can hurt the eardrum.

However, as with any thermometer, proper technique is critical to obtaining accurate temperatures. Therefore, read the instructions carefully and thoroughly.

The Braun ThermoScan thermometer is intended for intermittent measurement and monitoring of human body temperature for people of all ages. It is intended for household use only.

Use of this thermometer is not intended as a substitute for consultation with your physician.



- Please consult your doctor if you see symptoms such as unexplained irritability, vomiting, diarrhea, dehydration, changes in appetite or activity, seizure, muscle pain, shivering, stiff neck, pain when urinating, etc. in spite of absence of fever.
- Please consult your doctor if the thermometer shows elevated temperature.

The operating ambient temperature range for this thermometer is 50 - 104 °F (10 - 40 °C). Do not expose the thermometer to temperature extremes (below -13 °F / -25 °C or over 131 °F / 55 °C) or excessive humidity (> 95 % RH). This thermometer must only be used with genuine Braun ThermoScan lens filters (LF 40).

To avoid inaccurate measurements always use this thermometer with a new, clean lens filter attached.

If the thermometer is accidentally used without a lens filter attached, clean the lens (see «Care and cleaning» section). Keep lens filters out of reach of children.

This thermometer is intended for household use only. Use of this thermometer is not intended as a substitute for consultation with your physician.

This thermometer is not intended for pre-term babies or small-for-gestational age babies. It is not intended to interpret hypothermic temperatures. Do not allow children under 12 years to take their temperature unattended.

Do not modify this equipment without authorization of the manufacturer.

Parents/guardians should call the pediatrician upon noticing any unusual sign(s) or symptom(s). For example, a child who exhibits irritability, vomiting, diarrhea, dehydration, seizure, changes in appetite or activity, even in the absence of fever, or who exhibits a low temperature, may still need to receive medical attention.

People who are on antibiotics, analgesics, or antipyretics should not be assessed solely on temperature readings to determine the severity of their illness.

Temperature elevation may signal a serious illness, especially in neonates and infants, or in adults who are old, frail, or have a weakened immune system. Please seek professional advice immediately when there is a temperature elevation and if you are taking temperature on:

- Neonates and infants under 3 months (Consult your physician immediately if the temperature exceeds 99.4 °F or 37.4 °C).
- Patients over 60 years of age (Fever may be blunted or absent in older patients).
- Patients having diabetes mellitus or a weakened immune system (e.g., HIV positive, cancer chemotherapy, chronic steroid treatment, splenectomy)
- · Patients who are bedridden (e.g., nursing home patient, stroke, chronic illness, recovering from surgery)
- A transplant patient (e.g., liver, heart, lung, kidney).

This thermometer contains small parts that can be swallowed or produce a choking hazard to children. Keep out of reach of children under 12 years.

Body temperature

Normal body temperature is a range. It varies by site of measurement, and it tends to decrease with age. It also varies from person to person and fluctuates throughout the day. Therefore, it is important to determine normal temperature ranges. This is easily done using Braun ThermoScan. Practice taking temperatures on yourself and healthy family members to determine the normal temperature range.



Note: When consulting your physician, communicate that the ThermoScan temperature is a temperature measured in the ear and if possible, note the individual's normal ThermoScan temperature rance as additional reference.

How does Braun ThermoScan work?

Braun ThermoScan measures the infrared heat generated by the eardrum and surrounding tissues. To help avoid inaccurate temperature measurements, the probe tip is warmed to a temperature close to that of the human body. When the Braun ThermoScan is placed in the ear, it continuously monitors the infrared energy. The measurement is finished and the result displayed when the thermometer detects that an accurate temperature measurement has been taken.



Why measure in the ear?

The goal of thermometry is to measure core body temperature¹ which is the temperature of the vital organs. Ear temperatures accurately reflect core body temperature², since the eardrum shares blood supply with the temperature control center in the brain³, the hypothalamus. Therefore, changes in body temperature are reflected sconer in the ear than at other sites. Axillary temperatures measure skin temperatures are influenced by drinking, eating and mouth breathing. Rectal temperatures often lag behind changes in core body temperature and there is a risk of cross-contamination.

How to use your Braun ThermoScan



IRT 6020

Remove protective cap.



(3)

Push the Power button ()

During an internal self-check, the display shows all segments. Then the last temperature taken will be displayed for 5 seconds.



The lens filter indicator will blink to signal one is needed.

To achieve accurate measurements, make sure a new, clean lens filter is in place before each measurement.

new, clean lens filter is in place before each measurement. Attach a new lens filter by pushing the thermometer probe straight into the lens filter inside the box and then pulling out.

Note: The Braun ThermoScan will not work unless a lens filter is attached.

The thermometer is ready to take a temperature when the display looks like the images below.



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.



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Fit the probe snuggly into the ear canal, then push and release the Start button ($\)$.



5 ExacTemp light will pulse while temperature is in progress. The light will remain solid for 3 seconds to indicate that a successful temperature reading has been achieved.

NOTE: If the probe has been properly inserted into the ear canal during the measurement, a long beep will sound to signal the completed measurement.

If the probe has NOT been constantly placed in a stable position in the ear canal, a sequence of short beeps will sound, the ExacTemp light will go out and the display will show an error message (POS = position error).

See «Errors and troubleshooting» section for more information



The confirmation beep indicates that an accurate temperature measurement has been taken. The result is shown on the display.



For the next measurement, press Eject button to to remove and discard used lens filter, and put on a new, clean lens filter.

The Braun ThermoScan ear thermometer turns off automatically after 60 seconds of inactivity. The thermometer can also be turned off by pressing the Power button \bigcirc .

The display will briefly flash OFF and it will go blank.



Temperature taking hints

Always replace disposable lens filters 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 earwax build-up to take an accurate reading.

External factors may influence ear temperatures, including:

Factor	Yes affects		
Poor probe placement	✓		
Used lens filter			
Dirty lens	 Image: A start of the start of		

In the cases below, wait 20 minutes prior to taking a temperature.

Factor	Yes affects
Extreme hot and cold room temperature	✓
Hearing aid	
Lying on pillow	

Use the untreated ear if ear drops or other ear medications have been placed in the ear canal.

Merr

Memory mode

The last temperature taken is stored in the memory and will be automatically displayed for 5 seconds when it is turned on again.





2 This model stores the last 9 temperature measurements. To display the stored measurement, the thermometer must be turned on.



Available only in IRT 6510

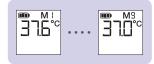
(4)

The display shows the temperature, and when releasing the **Mem** button, the stored temperature for that memory number is displayed, together with "M".

Each time the **Mem** button is pushed, the stored reading and an M is displayed to indicate each temperature measurement (eg. M2).

Memory mode is automatically exited by not pressing the memory button for 5 seconds.





Night light feature

This thermometer includes a convenient night light to illuminate the display in a dim environment.

The light will turn on when you press any button. It will stay on until the thermometer is inactive for up to 15 seconds even after temperature is taken.



Changing the temperature scale

If you wish to change the temperature scale of your thermometer:

Make sure the thermometer is turned off. 1

is turned off automatically.

- Release the Power button () when the desired temperature scale is shown. 00 There will be a short beep to confirm the new setting, then the thermometer
- Care and cleaning



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The probe tip is the most delicate part of the thermometer. It must be clean and intact to ensure accurate readings. If the thermometer is ever accidentally used without a lens filter, clean the probe tip as follows:

Press and hold down the Power button (). After about 3 seconds

the display will show this sequence: ° C / SET / ° F / SET ...



Very gently wipe the surface with a cotton swab or soft cloth moistened with alcohol. After the alcohol has completely dried out, you can put a new lens filter on and take a temperature measurement.

If the probe tip is damaged, please contact Consumer Relations.

Use a soft, dry cloth to clean the thermometer display and exterior. Do not use abrasive cleaners. Never submerge this thermometer in water or any other liquid. Store thermometer and lens filters in a dry location free from dust and contamination and away from direct sunlight.

Additional lens filters (LF 40) are available at most stores carrying Braun ThermoScan.

Replacing the batteries

The thermometer is supplied with two 1.5 V type AA (LR 06) batteries. For best performance, we recommend Duracell® alkaline batteries.



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Insert new batteries when the battery symbol appears on the display.

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

Snap battery door into place.

To protect the environment, dispose of the product and empty batteries at your retail store or at appropriate collection sites according to national or local regulations.



Calibration

The thermometer is initially calibrated at the time of manufacture. If this thermometer is used according to the use instructions, periodic re-adjustment is not required. If at any time you question the accuracy of temperature measurements, please contact Consumer Relations.

Manufacturing date is given by the LOT number located inside the battery compartment. The first three (3) digits after LOT represent the Julian date that the product was manufactured and the next two (2) digits represent the last two numbers of the calendar year the product was manufactured. The last identifiers are the letters that represent the manufacturer.

An example: LOT 11614KTC, this product has been manufactured on the 116th day of the year 2014.

Errors and tro	oubleshooting	
Error Message	Situation	Solution
	No lens filter is attached.	Attach new, clean lens filter.
POS	The thermometer probe was not positioned securely in the ear. An accurate measurement was not possible. POS = position error	Take care that the positioning of the probe is correct and remains stable. Replace lens filter and reposition. Press Start button to begin a new measurement.
Err	Ambient temperature is not within the allowed operating range $(50 - 104 ^{\circ}\text{F} \text{ or } 10 - 40 ^{\circ}\text{C}).$	Allow the thermometer to remain for 30 minutes in a room where the temperature is between 50 and 104 °F or 10 and 40 °C.
H	Temperature taken is not within typical human temperature range (93.2 – 108 °F or 34 – 42.2 °C). HI = too high	Make sure the probe tip and lens are clean and a new, clean lens filter is attached. Make sure the thermometer is properly inserted. Then, take a new temperature.
LO	LO = too low	
	System error – self-check display flashes continuously and will not be followed by the ready beep and the ready symbol.	Wait 1 minute until the thermometer turns off automatically, then turn on again.
	If error persists,	reset the thermometer by removing the batteries and putting them back in.
-715	If error still persists,	please contact Customer Service.
	Battery is low, but thermometer will still operate correctly.	Insert new batteries.
	Battery is too low to take correct	Insert new batteries.

temperature measurement.

Product specifications

Displayed temperature range:	93.2 – 108 °F	(34 – 42.2 °C)	
Operating ambient temperature range:	50 – 104 °F	(10-40 °C)	
Display resolution:	0.1 °F or °C		
Accuracy for displayed temperature range	Maximum Laborate	ory Error	
95 °F – 107.6 °F (35 °C – 42 °C):	± 0.4 °F	± 0.2 °C	
outside this range:	± 0.5 °F	± 0.3 °C	
clinical repeatability:	± 0.26 °F	± 0.14 °C	
Long term storage ranges			
Storage/transport temperature:	-13 °F to 131 °F	(-25 °C to 55 °C)	
Humidity:	15-95% non conde	ensing	
Battery life:	2 years / 600 meas	urements	
Service life:	5 years		

This thermometer is specified to operate at 1 atmospheric pressure (700-1060hPA) or at altitudes with an atmospheric pressure up to 1 atmospheric pressure (700-1060hPA).





Equipment with type See instruction for use Operating temperature BF applied parts

ACCOMPANYING DOCUMENTS

Subject to change without notice.

This appliance conforms to the following standards:

Standard Reference Edition Title:

EN 12470-5: 2003 Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device).

EN 60601-1: 2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

EN ISO 14971: 2012 Medical devices - Application of risk management to medical devices.

EN ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1: Evaluation and Testing within a risk management process.

EN 60601-1-2: 2007 Medical electrical equipment - part 1-2: General requirements for basic safety and essential performance

- Collateral standard: electromagnetic compatibility

- Requirements and tests

EN 980: 2008 Symbols for use in labeling of medical devices.

EN 1041: 2008 Information supplied by the manufacturer of medical devices.

EN 60601-1-11: 2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

This product conforms to the provisions of the EC directive 93/42/EEC.

MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC. For detailed description of EMC requirements please contact Customer Service.

Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.



Please do not dispose of the product in the household waste at the end of it useful life. To protect the environment, dispose of empty batteries at appropriate collection sites according to

national or local regulations.

Guidance and manufacturer's declaration – electromagnetic emissions			
The ME equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME equipment should ensure that it is used in such an environment.			
Emissions Test Compliance Electromagnetic environment – guidance			
RF Emissions CISPR 11	Group 1	The ME equipment uses RF energy only for its internal function. Therefore, its RF emissi very low and are not likely to cause any interference in nearby electronic equipme	
RF Emissions CISPR 11	Class B	Complies	
Harmonic emissions IEC 61000-3-2	Not Applicable	The ME equipment is	
Voltage fluctuations / flicker emissions			

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Non-Life Support Equipment Separation Distance Calculation (3Vrms / 3V/m compliance)					
	Separation distance according to frequency of transmitter (m)				
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz in ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$		
0.01	0.12	0.12	0.23		
0.1	0.37	0.37	0.74		
1	1.17	1.17	2.33		
10	3.69	3.69	7.38		
100	11.67	11.67	23.33		

Guidance and manufacturer's declaration - electromagnetic immunity

The ME equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME equipment should ensure that it is used in such an environment.					
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance		
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV Air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.		
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	Complies	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 Vm. Interference may occur in the vicinity of equipment marked with the following symbol: ((*)) Separation distance calculation provided above. If a known transmitter is present the specific distance can be calculated using the equations.		
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	Not Applicable (no electrical cabling)			
Electrical fast transient IEC 61000-4-4	±2kV power line ±1kV I/O lines	Not Applicable	The ME equipment is solely battery powered.		
Surge IEC 61000-4-5	±1kV differential ±2kV common	Not Applicable			
Power frequency magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at level characteristic of a typical location in a typical commercial or hospital environment.		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% dip 0.5 cycle 60% dip 5 cycles 70% dip 25 cycles 95% dip 5 sec.	Not Applicable	The ME equipment is solely battery powered.		