# BRAUN

# ThermoScan®

Infrared ear thermometer



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Manufactured by
Kaz Europe Sàrl
Place Chauderon 18
CH-1003 Lausanne
Switzerland
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Patents / 專利:

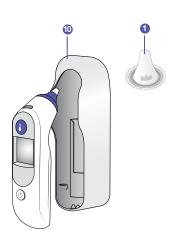
www.kaz.com/patents/braun Designed in Germany, Made in Mexico.

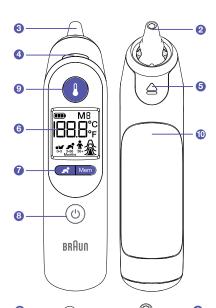
> IRT 6030/6520AP P/N: 31IM65AP192 31AUG15

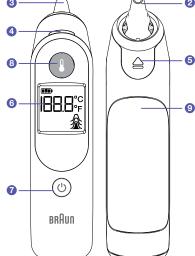
#### **IRT 6520**











#### Product description

#### IRT 6520

- 1 Lens filter (Box of 20)
- Probe tip
- 3 Probe
- ExacTemp light
- 6 Lens filter ejector
- 6 Display
- AgeSmart and Memory buttons
- 8 Power button
- Start button
- Battery door
- Protective case

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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 indicated for intermittent measurement and monitoring of human body temperature for people of all ages. It is intended for household use only.

Use of IRT 6520 along with AgeSmart feature is not intended as a substitute for consultation with your physician.



## **WARNINGS AND PRECAUTIONS**

- 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 any color of the background light or absence of fever.
- Please consult your doctor if the thermometer shows elevated temperature (yellow or red background lights for IRT 6520).

The operating ambient temperature range for this thermometer is  $10-40\,^{\circ}\text{C}$  ( $50-104\,^{\circ}\text{F}$ ). Do not expose the thermometer to temperature extremes (below  $-25\,^{\circ}\text{C}$  /  $-13\,^{\circ}\text{F}$  or over  $55\,^{\circ}\text{C}$  /  $131\,^{\circ}\text{F}$ ) or excessive humidity (>  $95\,^{\circ}\text{M}$  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. This product is not intended to diagnose any disease, but is a useful screening tool for temperature. Use of this thermometer is not intended as a substitute for consultation with your physician.

The AgeSmart feature is not intended for pre-term babies or small-for-gestational age babies. The AgeSmart feature is not intended to interpret hypothermic temperatures. Do not allow children to take their temperatures 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.

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

Temperature elevation as indicated by AgeSmart may signal a serious illness, especially in adults who are old, frail, have a weakened immune system, or neonates and infants. 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 37.4 °C or 99.4 °F)
- · Patients over 60 years of age
- 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)

Fever may be blunted or even absent in elderly patients.

This thermometer contains small parts that can be swallowed or produce a choking hazard to children. Always keep the thermometer out of children's reach.

#### **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 range as additional reference.

#### AgeSmart™ color-coded display

Clinical research shows the definition of fever changes as newborns grow into little kids and little kids grow into adults'.

Braun's AgeSmart color-coded display takes the guess work out of interpreting temperature for the entire family.

Simply use the AgeSmart button to select the appropriate age setting, take a temperature and the color-coded display will glow green, yellow, or red to help you understand the temperature reading. A green screen suggests no fever, a yellow screen suggests moderate fever, and red signals high fever.

1. Herzog L, Phillips S. Addressing Concerns About Fever. Clinical Pediatrics. 2011; 50(#5): 383-390.

#### 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 sooner in the ear than at other sites. Axillary temperatures measure skin temperature and may not be a reliable indicator of core body temperature. Oral 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®





Remove the thermometer from the protective case.



Push the Power button (1)

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



<sup>1.</sup> Guyton A C, Textbook of medical physiology, W.B. Saunders, Philadelphia, 1996, p 919

<sup>2.</sup> Guyton A C, Textbook of medical physiology, W.B. Saunders, Philadelphia, 1996, p 754-5

<sup>3,</sup> Netter H F, Atlas of Human Anatomy, Novartis Medical Education, East Hanover, NJ, 1997, pp 63, 95.

The lens filter indicator will blink to signal one is

To achieve accurate measurements, make sure a 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.









Select age with AgeSmart button 🚅 as shown below. Press button to togale through each age group.

NOTE: You must select an age in order to take a measurement. >3-36 Months >36 Months-

0-3 Months







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



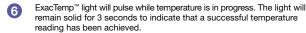




Fit the probe snuggly into the ear canal, then push and release the Start button | ...







**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

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.









Age range	Green	Yellow	Red
	Normal temperature	Moderate fever	High fever
● 0-3 Months	≥35.8 - ≤37.4 °C (≥96.4 - ≤99.4 °F)	$\nearrow$	>37.4 °C (>99.4 °F)
>3-36 Months	≥35.4 - ≤37.6 °C	>37.6 - ≤38.5 °C	>38.5 °C
	(≥95.7 - ≤99.6 °F)	(>99.6 - ≤101.3 °F)	(>101.3 °F)
>36 Months - adult	≥35.4 - ≤37.7 °C	>37.7 - ≤39.4 °C	>39.4 °C
	(≥95.7 - ≤99.9 °F)	(>99.9 - ≤103.0 °F)	(>103.3 °F)

go blank.

Temperature displays.





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

NOTE: Defaults to last age setting used if you do not change.

The Braun ThermoScan® ear thermometer turns off automatically after 60 seconds of inactivity. The thermometer can also be turned off by

NFF pressing the Power button (). The display will briefly flash OFF and it will





#### 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 when an individual has:

Factor	Yes affects
Poor probe placement	<b>✓</b>
Used lens filter	✓
Dirty lens	<b>✓</b>

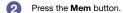
In the cases below, wait 20 minutes prior to taking a temperature.

Factor	Yes affects	
Extreme hot and cold room temperature	<b>✓</b>	
Hearing aid	<b>✓</b>	
Lying on pillow	<u> </u>	

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

#### **Memory mode**

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



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 (eq. M2).

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







050

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





#### Night light feature

The 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

Your Braun ThermoScan® is shipped with the Celsius (° C) temperature scale activated. If you wish to switch to Fahrenheit (° F) and/or back from Fahrenheit to Celsius, proceed as follows:

Make sure the thermometer is turned off.

Press and hold down the Power button (). After about 3 seconds the display will show this sequence: °C/SET/°F/SET...





Release the Power button when the desired temperature scale is shown. There will be a short beep to confirm the new setting, then the thermometer is turned off automatically.

#### Care and cleaning



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:

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.



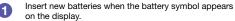
If the probe tip is damaged, please contact the local service center.

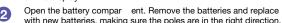
Use a soft, dry cloth to clean the thermometer display and exterior. Do not use abrasive cleaners. Never submerge this thermometer in water or any other liquid. Store thermometer and lens filters in a dry location free from dust and contamination and away from direct sunlight.

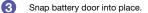
Additional lens filters (LF 40) are available at most stores carrying Braun ThermoScan®.

#### 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.









Only discard empty batteries. To protect the environment, dispose of 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 the temperature measurement, please contact your authorized service center.

Manufacturing date is given by the LOT number located in 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 11614K, this product has been manufactured on the 116th day of the year 2014.

#### **Errors and troubleshooting**

Error Message	Situation	Solution
	No lens filter is attached.	Attach new, clean lens filter.
P05	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 ( $10-40^{\circ}\text{C}$ or $50-104^{\circ}\text{F}$ ).	Allow the thermometer to remain for 30 minutes in a room where the temperature is between 10 and 40 °C or 50 and 104 °F.
HI LO	Temperature taken is not within typical human temperature range (34 – 42.2 °C or 93.2 – 108 °F).  HI = too high  LO = too low	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.
MB MB °C   BB B°F   M € \$\frac{1}{2} \frac{1}{2} \fra	System error – self-check display flashes continuously and will not be followed by the ready beep and the ready symbol.  If error persists,	Wait 1 minute until the thermometer turns off automatically, then turn on again.  reset the thermometer by re-moving the batteries and putting them back in.
·	If error still persists,	please contact the service centre.
	Battery is low, but thermometer will still operate correctly.	Insert new batteries.
	Battery is too low to take correct temperature measurement.	Insert new batteries.

#### **Product specifications**

Displayed temperature range:	34 - 42.2 °C	(93.2 - 108 °F
Operating ambient temperature range:	10 - 40 °C	(50 – 104 °F)
Storage temperature range:	-25 – 55 °C	(-13 – 131 °F)
Operating and storage relative humidity:	10 - 95 %RH (no	on condensing)
Display resolution:	0.1 °C or °F	
Accuracy for displayed temperature range	Maximum Labor	atory Error
35 °C – 42 °C (95 °F – 107.6 °F):	± 0.2 °C	(± 0.4 °F)
outside this range:	± 0.3 °C	(± 0.5 °F)
clinical repeatability:	± 0.14 °C	(± 0.26 °F)
Battery life:	2 years / 350 me	asurements
Service life:	5 years	

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











BF applied parts

Subject to change without notice.

This appliance conforms to the following standards:

Equipment with type See Instruction for use Operating temperature Storage temperature

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 your authorized local service centre (See guarantee card).

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.

#### **Limited warranty**

This product comes with limited warranty commencing on the date of purchase (See warranty card for details). Within the warranty period we will eliminate, free of charge, any defects in the appliance resulting from faults in materials or workmanship, by replacing the complete appliance.

This warranty is applicable only for the appliance supplied by the appointed distributor. This warranty does not cover: damage due to improper use, normal wear or use as well as defects that have a negligible effect on the value or operation of the appliance. The warranty becomes void if repairs are undertaken by unauthorized persons and if original Braun parts are not used.

HK Listing No.: 150181

#### Guidance and manufacturer's declaration - electromagnetic emissions

The IR thermometer equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the IR thermometer should assure 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 it's internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	Complies
Harmonic emissions IEC 61000-3-2	Not Applicable	The ME equipment is
Voltage fluctuations / flicker emissions	Not Applicable	solely battery powered.

#### Guidance and manufacturer's declaration - electromagnetic immunity

The IR thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the IR thermometer should assure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kwww 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%

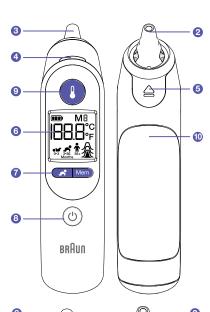
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	Complies	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 V/m.	
			Interference may occur in the vicinity of equipment marked with the following symbol:	
Conducted RF	0)/	Not Applicable	(( <u>^</u> )))	
IEC 61000-4-6	3Vrms 150kHz to 80MHz	(no electrical cabling)	Separation distance calculation provided above. If a known transmitter is present the specific distance can be calculated using the equations.	
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 levels 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.	

## Non-Life Support Equipment Separation Distance Calculation (3Vrms / 3V/m compliance)

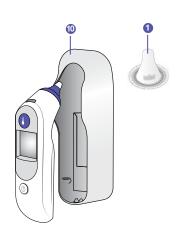
	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz in ISM bands $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.12	0.23
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

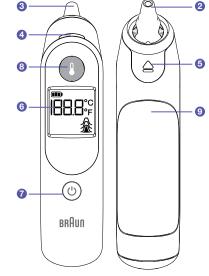
#### **IRT 6520**





**IRT 6030** 





#### 產品說明

#### IRT 6520

- 1 耳套(20個一盒)
- 2 位置偵測器
- ③ 測溫頭
- 4 ExacTemp 正確測量指示燈
- 5 更換耳套按鈕
- 6 顯示幕
- 7 AgeSmart 年齡選擇及記憶功能按鈕
- 8 電源按鈕
- 9 測溫按鈕
- 10 電池蓋
- 1 保護盒

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- 9 電池蓋
- 保護盒

百靈耳溫槍是為提供準確、安全和快速的耳道測溫而精心研製的。本耳溫槍的測溫頭設計能避免測溫頭插入耳道過深,以避免損傷耳膜。然而,無論是哪一種耳溫槍,都需要正確的操作技巧才能夠測得準確的溫度。因此,請仔細閱讀本說明書。百靈ThermoScan®耳溫槍用於間歇性測量和觀察不同年齡人士的體溫,且僅供家庭使用。使用百靈耳溫槍並不能代替醫生的診斷。

### 警告和注意事項

- 如身體出現原因不明的煩躁不安、嘔吐、腹瀉、脱水、食慾或行為模式出現變化、癲癇、肌肉疼痛、顫抖、脖子僵硬、小便疼痛等症狀,無論背景燈顯示何種顏色,以及即使沒有發燒跡象,亦應儘快求醫。
- 如耳溫槍顯示體溫過高 (IRT 6520 顯示黃色或紅色背燈) ,請求醫。

本耳溫槍的操作環境溫度為10-40°C (50-104°F)。切勿將本耳溫槍放置於極端溫度(-25°C /-13°F以下或55°C /131°F以上)或高濕度(95% RH以上)環境。本耳溫槍只能配合原裝百靈ThermoScan®耳套(LF40)使用。

為免影響測量的準確度,使用本耳溫槍時必須套上潔淨的新耳套。

若在沒有套上耳套的情況下不慎使用了本耳溫槍,請清潔測溫頭(參閱「保養和清潔」部分)。切勿讓兒童接觸耳套。

本耳溫槍只適合家居使用。本產品並非用於診斷疾病,但能有效反映體溫狀況。本耳溫槍不能 代替醫生的診斷。

AgeSmart 年齡選擇功能不適用於早產嬰兒或胎齡不足的嬰兒,亦不適用於測量低體溫。切勿讓兒童在無人監管的情況下自行測量體溫。

未經製造商授權,切勿改裝本耳溫槍。

如家長/監護人發現嬰幼兒有任何不良狀況或症狀,應與兒科醫生聯絡。例如,若兒童出現煩躁不安、嘔吐、腹瀉、脱水、癲癇發作等症狀,或食慾或行為發生變化等,即使沒有發燒或出現體溫偏低,仍可能需要就醫。若兒童正在服用抗生素、止痛藥或退燒藥,不宜只憑體溫讀數判斷其病情的輕重。

若AgeSmart年齡選擇功能顯示體溫讀數上升,可能是出現嚴重疾病的徵兆,尤其是年老體弱、免疫力低下的成年人,或新生兒和嬰兒。若測量到以下人士體溫上升,請立即就醫:

- ●新生兒及不足三個月的嬰兒(如體溫超過37.4°C或99.4°F,請立即求醫)
- 60歳以上長者
- 糖尿病患者或免疫力低下的人士(例如愛滋病毒測試結果呈陽性的人士、接受癌症化療、慢性類固醇治療或脾切除術的人士)
- 長期臥床的病人(例如療養院病人、中風、慢性病患者,以及處於術後康復期的病人)
- 接受過器官移植的患者(例如肝臟、心臟、肺或腎臟移植)

年長患者的發燒症狀可能會較為不明顯,甚至完全沒有症狀。 本耳溫槍含有細小零件,若兒童不慎吞下,可能會造成窒息。切勿讓兒童接觸本耳溫槍。

#### 體溫

人體的正常體溫是一個範圍。正常體溫範圍會因不同測量部位而有所不同, 亦會隨 著年齡的增長而下降。

每個人均有自己的正常體溫範圍, 而人體於一天內的體溫會在該範圍內浮動。因此, 確定自己的正常體溫範圍很重要。這一點, 百靈ThermoScan®耳溫槍能讓您輕易達成此目標, 請利用本產品測量自己及家人的體溫, 以確定大家的正常體溫 節圍。



注意:就醫時,請告知醫生您提供的是耳溫。如可能,提供個人的ThermoScan®正常體溫範圍作為參考。

#### AgeSmart™年齡選擇功能顏色背光顯示

臨床研究顯示,發燒的界定會隨著不同的年齡階段而變化,因此嬰兒、小童及成年人 的發燒界定均有所不同'。

百靈AgeSmart年齡選擇功能以不同顏色顯示 體溫狀況,讓您輕易掌握家庭成員的體溫狀況,而毋須胡亂猜測。

您只需使用AgeSmart按鈕選擇相對應的年齡設定,然後測量體溫。 綠色顯示幕表示 體溫正常,黃色顯示幕表示輕度發燒,紅色則表示高燒。

1. Herzog L, Phillips S. Addressing Concerns About Fever. Clinical Pediatrics. 2011; 50(#5): 383-390.

#### 百靈ThermoScan◎耳溫槍的操作模式

百靈ThermoScan®耳溫槍透過探測耳鼓及周圍組織輻射的紅外線能量測量體溫。為避免測溫不準確,耳溫槍會先將測溫頭預熱至接近人體溫度。測溫頭插入耳朵後,ThermoScan®耳溫槍便會持續探測紅外線能量,並在測得準確讀數後完成操作,將結果顯示出來。



#### 為什麼要測量耳溫?

測量體溫的目的是要測量中樞軀幹的溫度',也就是身體內重要器官的溫度。因為耳膜和大腦體溫控制中心<sup>2</sup>---下視丘有著相同的血液供應,所以耳溫能夠準確地反映中樞軀幹的體溫'。因此,耳朵會比身體其他部位更能快速而準確地反映體溫的變化。



腋溫只是體表溫度,因此並不能可靠地反映中樞軀幹的溫度;口腔溫度則會 受飲食及呼吸影響;直腸溫度的變化通常比中樞軀幹體溫的變化延遲,而且 有可能造成交叉感染。

#### 如何使用百靈ThermoScan® 耳溫槍





從保護盒上取出耳溫槍。

2

按下電源按鈕 Ů。

耳溫槍進行自我檢查,顯示幕顯示各項內容,然後顯示最後一次體溫讀數5秒。



<sup>1.</sup> Guyton A C, Textbook of medical physiology, W.B. Saunders, Philadelphia, 1996, p 919

<sup>2.</sup> Guyton A C, Textbook of medical physiology, W.B. Saunders, Philadelphia, 1996, p 754-5

<sup>3.</sup> Netter H F, Atlas of Human Anatomy, Novartis Medical Education, East Hanover, NJ, 1997, pp 63, 95.

更換耳套標誌閃爍,提醒您裝上耳套。

為獲得準確讀數,每次測量體溫前均應裝上潔 淨的新耳套。

將耳溫槍測溫頭插入耳套盒,然後拉出,便可 套上新的耳套。

注意:若未裝上耳套,百靈ThermoScan®將無 法操作。







利用AgeSmart年齡選擇功能按鈕 🖍 選擇年齡,如下圖所示。 按下按鈕可切換年齡組別。

注意:測溫前必須先選擇年齡組別。

6520

0-3 個月

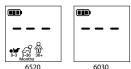
**₩**£\$

>3-36 個月

**□** 



耳溫槍顯示幕顯示如下畫面時,便可開始測量體溫。



把測溫頭伸入耳道,然後按下並鬆開測 溫按鈕 ↓





ExacTemp 正確測量指示燈會在測量過程中閃爍,成功測量體溫後, 便會持續發亮3秒。

注意:如在測量過程中,測溫頭正確插入耳道,耳溫槍會發出一聲長鳴,以示完成測量體溫。

若測溫頭在耳道中放置不穩,耳溫槍會發出一連串鳴響,ExacTemp 正確測量指示燈熄滅,顯示幕則會顯示 POS (POS=放置不當)。

詳情請參閱「故障排除 | 部分。





耳溫槍發出確認鳴響,代表已準確測量體溫,體溫顯示於顯示幕。









6520

紅色 高燒 緑色 體溫正常 年齡組別 ≥35.8 - ≤37.4 °C ● 10-3 個月 >37.4 °C (≥96.4 - ≤99.4 °F) (>99.4 °F) ≥35.4 - ≤37.6 °C >37.6 - ≤38.5 °C >38.5 °C >3-36 個月 (≥95.7 - ≤99.6 °F) (>99.6 - ≤101.3 °F) (>101.3 °F) >39.4 °C → >36 個月以 上一成年人 >35.4 - <37.7 °C >37.7 - <39.4 °C (>103.3 °F) (>99.9 - ≤103.0 °F) (≥95.7 - ≤99.9 °F)

溫度顯示



 如要進行下一次測量體溫,請按下更換鈕 ▲ 取下並丟棄用過的耳套,然後換上潔淨的新耳套。 注意:若沒有使用AgeSmart年齡選擇功能按鈕轉換年齡組別,耳溫槍將維持上次測溫的年齡組別。

若連續60秒沒有操作,百靈ThermoScan®耳溫槍會自動關機。您也可按下電源按鈕 ( ) 關機。





顯示幕會短時間閃爍顯示OFF後熄滅。



#### 測量體溫技巧

為確保衛生及準確地測量體溫,請務必每次更換新的一次性耳套。左右兩耳所測量的 讀數亦可能存在差異,因此請固定在同一邊耳朵測量體溫。為能準確測量體溫,請確 保耳內無堵塞物或耳垢。

以下外部因素會影響耳朵的溫度:

因素	
測溫頭放置不當	<b>✓</b>
使用舊耳套	<b>✓</b>
測溫頭不乾淨	<b>✓</b>

對於以下狀況,請等待20分鐘後再測量體溫。

 因素
 會受到影響

 室溫太熱或太冷
 ✓

 戴助聽器
 ✓

 躺在枕頭上
 ✓

若耳道內滴了耳藥水或其他藥物,請利用另一隻未經用藥的耳朵測量。

#### 記憶模式

本耳溫槍可記憶最近9次體溫讀數。如要顯示所儲存的讀數,必須 先開機。

2 按下 Mem 記憶功能按鈕。

顯示幕顯示溫度。鬆開**Mem** 記憶功能按鈕時,顯示幕顯示"M"及該記憶編號所儲存的溫度。



3 每次按下 **Mem** 鈕,顯示幕都會顯示已儲存的溫度 及其 M 記憶編號(例如: M2).

若連續5秒未按下Mem記憶功能按鈕,耳溫槍會自動退出記憶模式。



**1** 最後一次測量的體溫會儲存於記憶體中,並在 下次開機時自動顯示5秒。





#### 夜光功能

6030

本耳溫槍配備夜光功能,方便在昏暗環境下觀看顯示幕。

按下任何按鈕, 夜光就會自動啟動, 即使完成測量也會繼續保持發亮。若耳溫槍連續15秒沒有任何操作, 夜光就會熄滅。



#### 切換溫度計量單位

您的百靈ThermoScan。耳溫槍的預設計量單位為攝氏度 (° C)。如要切換為華氏度 (° F),或從華氏度切換為攝氏度,請按如下指示操作:

確保耳溫槍處於關機狀態。

② 持續按住電源按鈕 
① 約3秒,顯示幕依次顯示。C/SET/。F/SET... 
☐SET



在顯示幕顯示您所需的計量單位時,鬆開電源按鈕 ① 耳溫槍發出一聲短鳴以示確認,然後便會自動關機。

#### 保養與清潔



測溫頭是耳溫槍中最精密的部份。為確保讀數準確,測溫頭必須 保持清潔及完好無損。若不慎在沒有套上耳套的情況下使用了耳 溫槍,請按以下步驟清潔測溫頭:

使用沾濕酒精的棉棒或軟布輕輕擦拭測溫頭表面,當酒精完全蒸發後,便可套上新的耳套並再次測量。

如測溫頭損壞,請聯絡售後服務熱線。

用乾燥的軟布清潔顯示幕與機身。切勿使用腐蝕性清潔劑。切勿將耳溫槍浸入水或其他液體中。請將耳溫槍存放於乾燥、無塵、無污染,以及不會受到陽光直曬的地方。 大部份出售百靈ThermoScan。耳溫槍的商店均有出售耳套(LF40)。

#### 更換電池

本耳溫槍附送兩粒1.5伏 AA(LR 06)電池。為保持最佳性能, 我們建議使用金霸王®/金頂®鹼性電池。

- 顯示幕出現電池標誌時,請更換電池。
- ② 打開電池蓋取出舊電池, 換上新電池,並確保電池的正負極方 向正確。
- 蓋緊電池蓋。



請只棄置已用完的電池。 為保護環境,請遵照國家或 當地法規,將舊電池 棄置於合適的回收點。



#### 校正

本耳溫槍在製造時已校正過; 若確實遵照本使用説明操作本產品, 無需再作定期校正。若你懷疑測量值的準確性. 請聯絡售後服務熟線。

製造日期請參見電池糟的產品編號。 LOT後第一、二、三碼表示該年份的製造日, 第四、五碼表示製造年份, 最後的字母是製造商的代號。

舉例:LOT11614K代表產品於2014年第116日製造。



故障排除		
錯誤訊息	狀況	— 解決方法
	沒有套上耳套。	套上潔淨的新耳套。
POS	測溫頭在耳道中放置不穩,無法獲得 準確讀數。 POS = 放置不當	正確放置測溫頭並保持穩定。 更換耳套並重新放置。按下測溫按鈕 重新測量。
Err	環境溫度超出正常操作範圍 (10 - 40 °C or 50 - 104 °F) 。	將耳溫槍留在溫度介於 10 - 40 °C 或 50 -104 °F 的房間30分鐘。
HI LO	所測量溫度超出人體溫度範圍 (34 - 42.2 °C 或 93.2 - 108 °F)。 HI = 太高溫 LO = 太低溫	確保位置偵測器和測溫頭清潔,並套上潔淨的新耳套。確保將耳溫槍準確插入耳道,然後重新測量。
M8 M8 °C ***	系統故障—自檢顯示持續閃爍,而且 之後不會發出代表就緒的鳴響及標 誌。 如故障持續, 如故障仍然持續,	等待1分鐘,待耳溫槍自動關機,然後重新開機。 拆下電池再重新裝上,以重置耳溫槍。 請聯絡售後服務熱線。
	電池電量偏低,但耳溫槍仍能正常操	換上新電池。

#### 產品規格

憲命·

顯示溫度範圍: 34 - 42.2 °C (93.2 - 108 °F) 操作環境溫度範圍: 10 - 40 °C (50 – 104 °F) 存放溫度範圍: -25-55 °C (-13 - 131 °F) 操作及存放相對濕度: 10-95% (無凝結) 顯示精確位數: 0.1 °C or °F 顯示溫度範圍的精確度: 實驗室最大誤差 35 °C - 42 °C (95 °F - 107.6 °F): ± 0.2 °C (± 0.4 °F) 此節圍以外: ± 0.3 °C (± 0.5 °F) 臨床測量可重複性: ± 0.14 °C (± 0.26 °F) 電池壽命: 2年/350次測量

本耳溫槍的使用環境為1個大氣壓或不超過1個大氣壓力之海拔高度 (700 - 1060 hPa)。







5年



含BF類應用部件 的設備

請參考操作指示

操作温度

存放溫度範圍

保持乾燥

手冊內容如有更改, 恕不另行通知。

本設備符合以下標準:

標準參考版本標題:

EN 12470-5: 2003《醫療臨床用體溫計》第五部分: 紅外線耳溫槍效能(最大的機器)。

EN 60601-1: 2006《電子醫療器械》第一部分:基本安全及效能的一般要求。

EN ISO 14971: 2012《醫療器械》:醫療器械風險管理的應用。

EN ISO 10993-1: 2009《醫療器械的生物評估》第一部分:

包括風險管理的評估和測試。

EN 60601-1-2: 2007《醫療器械》第一及二部分:基本安全及效能的一般要求。

- 一相關標準:電磁相容性
- 要求及測試

EN 980: 2008 —用於醫療器械的標籤符號。

EN 1041: 2008醫療器械製造商提供的資訊。

EN 60601-1-11:《醫療器械》第一至十一部分:基本安全及效能的一般要求。 — 附屬標 準:用於家庭保健環境的醫療電子設備及醫療電子系統的要求。

本產品符合EC指引93/42/EEC的規定。

醫療電子設備需要特別留意電磁相容性。有關電磁相容性要求的詳情,請聯絡售後服務熱線 (請參考保養書)。

手提式及可懈式射頻通訊設備會影響醫療電子設備



為保護環境,本產品使用壽命完結時,切勿將其連同家居垃圾一起丟棄。請根據國家或地方法規, 將舊電池交給相應的回收點。

22

作。

電池電量太低,耳溫槍無法測量體

換上新電池。

#### 有限保養

本產品保養期為自購買日起計, 詳細內容請見保養卡。在產品保養期內, 我們會就因產品用料或工藝導致的故障提供免費保養, 並會視情況作出維修或更換。本保養適用於授權分銷商銷售本產品的國家。

本保養並不涵蓋:因不當操作、正常磨損或使用造成的損壞,以及對本設備的數值或操作無明 顯影響的瑕疵。若經非授權人士維修,或維修時不使用原廠百靈零件,保養將即時失效。

香港表列號碼: 150181

#### 指南及製造商聲明 — 電磁輻射

本醫療電子設備適合在以下電磁環境使用。顧客或用戶應確保在此等環境下使用本設備。

輻射測試	遵循	電磁環境一指南
射頻輻射 CISPR 11	第1組	本醫療電子設備只利用射頻能量實現其內部功能,因 此其射頻輻射相當輕微,不會對附近的電子設備造成 任何干擾。
射頻輻射 CISPR 11	B類	符合
諧波輻射 IEC 61000-3-2	不適用	★ SS 床帶 フ 汕 井 口
電壓波動 / 閃變 輻射	不適用	· 本醫療電子設備只使用電池供電。 

#### 指南及製造商聲明 — 電磁抗擾性

本醫療電子設備適合在以下電磁環境使用。顧客或用戶應確保在此等環境下使用本設備。

抗擾測試	IEC60601 測試 水平	遵循水平	電磁環境一指南
靜電放電 (ESD) IEC 61000-4-2	±6kV 接觸 ±8kwww 空氣	符合	地板材料應為木、混凝土或 瓷磚。若在地板上鋪上合 成材料,相對濕度至少要 達到 30%

射頻輻射耐受性 IEC 61000-4-3	3 V/m 80MHz 至 2.5GHz	符合	以電磁現場勘察測定、來 自固定射頻發射器的遮罩 位置外的磁場強度應低於 3 V/m。	
射頻傳導耐受性 IEC 61000-4-6	3Vrms 150kHz 至 80MHz	不適用(不含導線)	若鄰近帶有以下標誌的設備,可能會產生干擾: (((金))) 上文列出了分隔距離的計算方法。若存在已知的發射器,可用這些方程式計算具體距離。	
快速瞬變電 IEC 61000-4-4	±2kV 輸電線 ±1kV I/O 線	不適用	本醫療電子設備只使用電	
電湧 IEC 61000-4-5	±1kV 差模 ±2kV 共模	不適用	池供電。	
工頻磁場 IEC 61000-4-8	3 A/m	符合	工頻磁場水平應為典型商業或醫院環境場所的水平。	
電源輸入線的電壓暫降、短時中斷和電壓 漸變 IEC 61000-4-11	>95% 暫降 0.5 週期 60% 暫降 5 週期 70% 暫降 25 週期 95% 暫降 5 秒	不適用	本醫療電子設備只使用電池供電。	

#### 非生命支援設備的分隔距離計算 (遵循 3Vrms / 3V/m)

	按發射器頻率計算的分隔距離 (m)			
發射器的額定最大輸出 功率 (W)	150 kHz 至 80 MHz ,ISM 頻段內 $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz 至 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz 至 2.5 GHz $d = \lfloor \frac{7}{E_1} \rfloor \sqrt{P}$	
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	