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Digital Ear Thermometer Model Gentle Temp® 521 Instruction Manual

All for Healthcare



Important Safety Information

To assure the correct use of the product basic safety measures should always be followed including the precautions listed below.

Warning:

- Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
- Conducting self-diagnosis based on the measurement results and/or treatment can be dangerous. Please follow the instructions of your doctor. Self-diagnosis may worsen the symptoms.
- A high or prolonged fever requires medical attention, especially for small children. Please contact your doctor.
- Please keep still during measurement.
- Do not forcibly insert the probe in the ear.
- If you feel discomfort such as a pain during the measurement, stop using the unit immediately. It may injure the external auditory canal.
- Do not use this unit if suffering from ear disease such as otitis externa or otitis media. It may worsen the condition.
- Do not use this unit when the external auditory canal is wet such as after swimming or taking a bath. It may injure the external auditory canal.
- Do not use this unit without attaching a probe cover.
- Please ensure that the ear canal is clean and free of earwax.
- If the probe cover becomes dirty with earwax or other substances, replace it with a new one.
- Do not use a probe cover after someone else has used it. This can lead to cross infections such as otitis externa.
- Correct measurement result may not be obtained if dirty probe covers are used.
- Proper installation of the probe cover ensures accurate measurements.
- When the infrared sensor becomes dirty, wipe it lightly with a soft dry cloth or a cotton swab. Do not wipe the infrared sensor with tissue paper or a paper towel.
- Do not use more than one probe cover at a time.
- If there is any temperature difference between the places where the unit is stored and where you are going to measure, leave the unit in the room where you are going to use it for more than 30 minutes to allow it to reach room temperature first, then measure.
- If the ear is cold, wait until the ear is warmed up before taking a temperature measurement. The measured result may indicate low when you use an ice bag or an ice pack or immediately after coming in from the outside in winter.

Important Safety Information

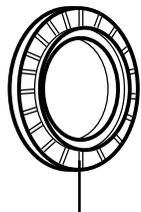
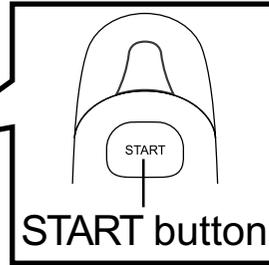
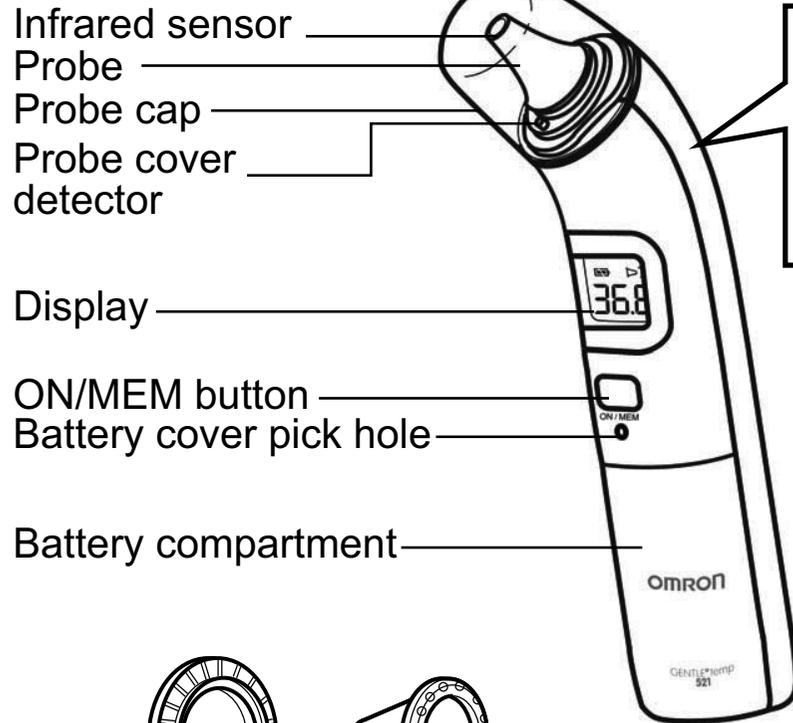
- Do not touch the infrared sensor with a finger or breathe on it.
- Do not attempt measurements when the unit is wet as inaccurate readings may result.
- Check the symbol on the display before and after the measurement so that the measurement is taken in the appropriate mode.
- When taking temperature of the subject with low emissivity such as gold or aluminum inaccurate readings may result.
- Keep the unit out of children's reach.
- Avoid children trying to measure themselves or others as they may damage the ear.
- In an emergency case, if a child swallows a battery or a probe cover, immediately consult with a doctor.
- Do not throw batteries into a fire. The battery may explode.
- Remove the battery when the unit will not be used for 3 months or more. Failure to do so may lead to fluid leakage, heat generation or bursting, resulting in damage to the unit.
- Do not use the unit in places where strong static electricity or electromagnetic fields are present. Doing so may lead to inaccurate readings and may contribute to instrument failure.
- Do not use the unit to measure any item with a temperature higher than 80.0°C (176.0°F).

General Precautions

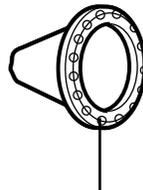
- Do not apply a strong shock to, drop, step on, or vibrate the main unit.
- Do not use a mobile phone near the unit.
- The main unit is not waterproof. Be careful when handling this unit so that no liquid (alcohol, water, or hot water) will get into the main unit. When the unit is wet with vapor, wait until it dries or wipe it lightly with a soft dry cloth.
- Do not disassemble, repair, or modify the unit.
- When you inform your doctor of your temperature, make sure you state that you measured the temperature in the ear.

1. Overview

Main unit:

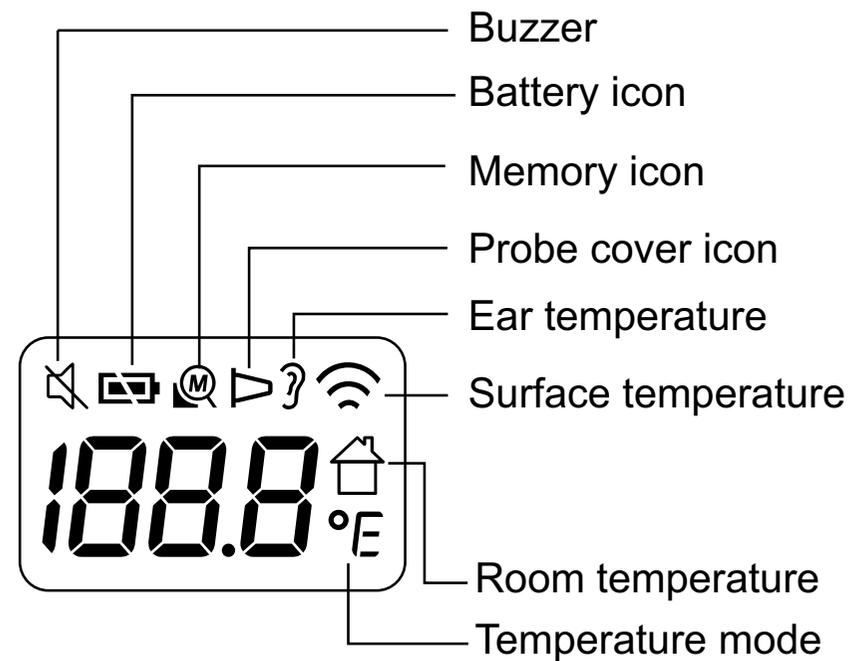


Connection ring



Probe cover

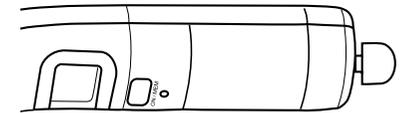
Display:



2. Preparation

2.1 Removing the Insulating Tape

Pull the insulating tape out from the battery compartment by catching the outer part for the first time.



The unit is turned on and after 1 minute the room temperature will appear on the display.



Notes:

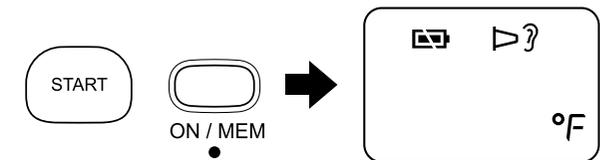
- The room temperature remains on the display even after the unit turns off.
- Place the unit on the table and avoid the direct sunshine or air conditioner flow on for the room temperature.

2.2 Switching between °C and °F

This unit is set in °C as default.

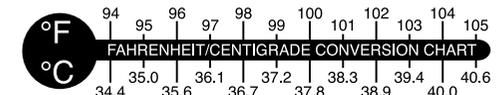
1. While the room temperature is displayed, press and hold the START button.

2. While holding it down, press and hold the ON/MEM button until °F appears on the display with 2 beeps.



Notes:

- To select the °C mode, start from step 1.
- When the unit is switched between °C and °F, all the readings stored in the memory are deleted.



2. Preparation

2.3 Setting the Buzzer

The buzzer is only available in the Ear Measurement Mode.
The buzzer is set on as default.

1. Press the ON/MEM button to turn on the unit.

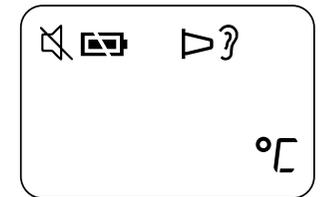
2. Press and hold the ON/MEM button for 3 seconds.

The “” symbol flashes on the display.



3. Release the ON/MEM button.

The “” symbol remains lit and the buzzer is set to off.



Notes:

- If the ON/MEM button is pressed down for more than 5 seconds after the “” flashing, the unit turns off without setting the buzzer.
- To turn the buzzer on, start from step1.

2. Preparation

2.4 Attaching a Probe Cover

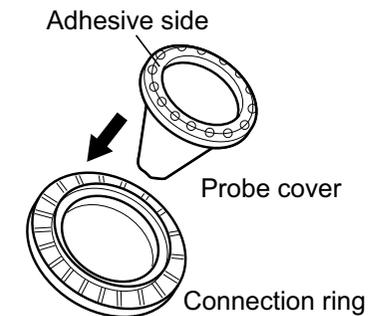
Always use a new and undamaged OMRON MC-EP2 probe cover.

1. Gently twist off the probe cap.

Note: Do not forcibly remove the probe cap.

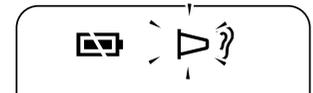
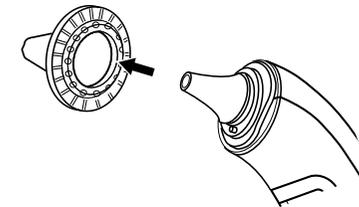
2. Place a new probe cover on the connection ring.

Note: The adhesive side of probe cover should be upward.



3. Insert the probe into the probe cover on the connection ring until it clicks.

Note: When the probe cover is not attached correctly, the probe cover symbol “▷?” will flash on the display and a measurement can’t be taken.



3. Using the Unit

3.1 Taking a Reading

Notes:

- Make sure the probe cover is attached correctly.
- It is recommended that you measure 3 times with the same ear. If the 3 measurements are different, select the highest temperature.

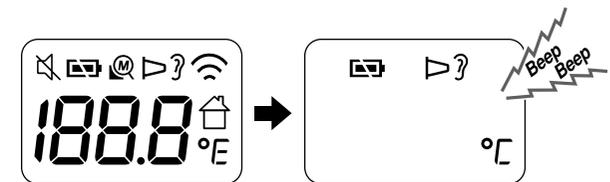
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Ear Measurement Mode

1. Press the ON/MEM button.

All symbols appear on the display.

Then the display shown at the right will appear with 2 beeps.



2. Insert the probe into the ear as far as it comfortably goes in the direction of the eardrum.

Notes:

- Gently pull the ear back to straighten the ear canal and position the probe into the ear so it is snug, aiming towards the membrane of the eardrum to obtain an accurate reading.
- Holding the unit too long may cause a higher ambient temperature reading of the probe. This could make the body temperature measurement lower than usual.



3. Using the Unit

Measuring the temperature of an infant

Measuring on a lying baby.



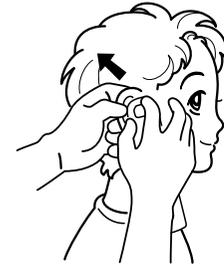
Lightly support the child's body.

Measuring on a sitting baby.



Lightly support the child's body and slightly pull the ear towards the back.

The ear is too small to insert the probe.



While slightly pulling the ear back, cover the external auditory canal with the probe without forcibly trying to insert the probe.

3. Using the Unit

3. Press the START button.

The measurement is complete in 1 second with a long beep.

The display will light up and the “?” symbol will flash for 5 seconds.

Note: You can take another measurement after the display light turns off with 2 beeps. Make sure “?” symbol remains lit.



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4. Remove the unit from the ear and check the measurement result.

Note:

- If your measurement result is over 37.5°C (99.5°F), the buzzer will beep three times after a long beep.
- After each Ear Measurement, the unit needs 5 seconds to be ready for next measurement. During this 5 seconds waiting time, the ear icon will be flashing and Backlight will light.



5. Press and hold the ON/MEM button until “OFF” appears on the display to turn off the unit.

The unit automatically stores the measurement in its memory. It will automatically turn off after 1 minute.

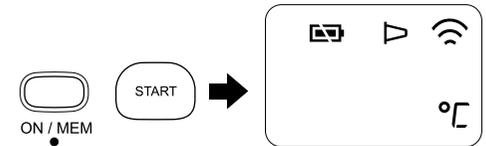
3. Using the Unit

Surface Mode

The unit is set in the Ear Measurement Mode as default. The Surface Measurement mode is not intended for the body temperature measurement.

The surface mode shows the actual and unadjusted surface temperature which is different from the body temperature. It can help you monitor if the object temperature is suitable for the baby or patient, for example the baby's milk.

- 1. Press the ON/MEM button to turn on the unit.**
- 2. Press and hold the ON/MEM button. While holding it down, press the START button then the “” symbol appears on the display.**



- 3. Move the unit close to the subject and press the START button.**

It measures continuously until the START button is released.

Notes:

- Move the Infrared sensor as close to the subject as possible when using in the surface mode (1 cm apart is recommended). Do not apply the Infrared sensor to the subject directly.
- The surface mode shows the surface result. The surface and internal temperature may be different. Make sure it is safe when measuring the subject with extremely high or low temperature.
- The Surface Mode is not intended for medical use.
- The display will not light up in the Surface Mode.
- The buzzer is off in the Surface Mode.
- To select the Ear Measurement Mode, start from step 2.
- The unit will automatically turn off after 1 minute.
- When the power is off, the surface mode will disappear. And the unit will display the room temperature.



⚠ Caution: You cannot turn off the unit by pressing and holding the ON/MEM button in Surface Mode.

3. Using the Unit

3.2 Using the Memory Function

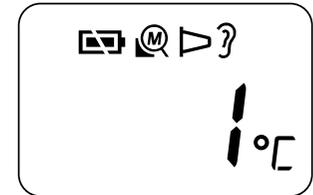
This unit automatically stores the results up to 25 sets after each measurement.

Note: If the memory is full, the unit will delete the oldest reading.

1. Press the ON/MEM button to turn on the unit.

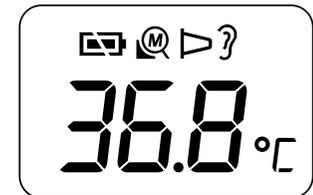
2. Press the ON/MEM button again.

The memory number appears on the display.



3. Release the ON/MEM button.

The most recent result will appear on the display.
Press the ON/MEM button repeatedly to view the older results.

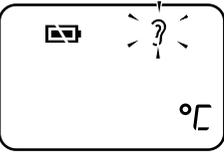
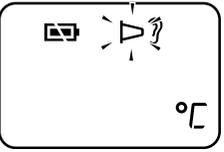
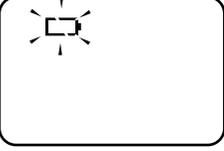


4. Press and hold the ON/MEM button until “OFF” appears on the display to turn off the unit.

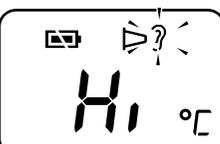
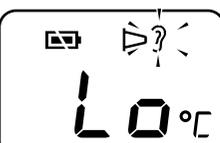
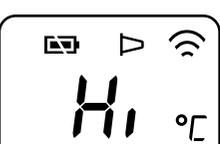
It will automatically turn off after 1 minute.

4. Troubleshooting and Maintenance

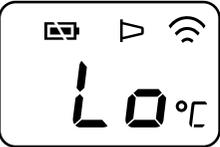
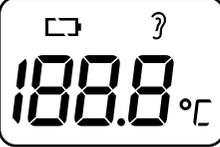
4.1 The Icons and Error Messages

Error Display	Cause	Remedy
	Device stabilization in process.	Wait until ? stops flashing.
	Probe cover is not attached correctly.	Attach the probe cover again until ▷ stops flashing.
	Battery is low.	Replace the battery. (Refer to section 4.3)
	Measurement before device stabilization.	Wait until ? stops flashing.
	The device is showing a rapid ambient temperature change.	Allow the thermometer to rest in a room for at least 30 minutes at room temperature: 10°C and 40°C (50°F - 104°F).

4. Troubleshooting and Maintenance

Error Display	Cause	Remedy
	The ambient temperature is not within the range between 10°C and 40°C (50°F - 104°F).	Allow the thermometer to rest in a room for at least 30 minutes at room temperature: 10°C and 40°C (50°F - 104°F).
	Error 5-9, the system is not functioning properly.	Remove the battery, wait for 1 minute and repower it. If the message reappears, please contact the OMRON retail outlet or distributor for having the device checked.
	Ear measurement mode: Temperature taken is higher than 42.2°C (108.0°F).	Check the integrity of the probe cover and take a new temperature measurement.
	Ear measurement mode: Temperature taken is lower than 34.0°C (93.2°F).	Check the integrity of the probe cover and take a new temperature measurement.
	Surface mode: Temperature taken is higher than 80.0°C (176.0°F).	Check the integrity of the probe cover and take a new temperature measurement.

4. Troubleshooting and Maintenance

Error Display	Cause	Remedy
	Surface mode: Temperature taken is lower than -22.1°C (-7.8°F).	Check the integrity of the probe cover and take a new temperature measurement.
	Device can not be powered on to the ready stage.	Change to a new battery. (Refer to section 4.3)

4.2 Maintenance

- Please check the device if damaged after it is dropped. If unsure, please contact the OMRON retail outlet or distributor for having the device checked.
- The probe is the most delicate part of the unit. Use care when cleaning the Infrared sensor to avoid damage.
- Do not store the unit in the following types of places. Doing so may damage the unit.
 - Wet locations.
 - Locations with high heat and humidity or those that are exposed to direct sunlight. Areas close to heating equipment, dusty locations, or environments where there are high salt concentrations in the air.
 - Locations where the unit will be subjected to leaning over, falling, shock or vibration.
 - Pharmaceutical storage areas or locations where corrosive gases are present.

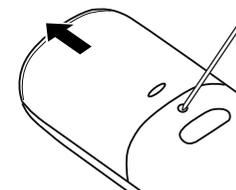
4. Troubleshooting and Maintenance

4.3 Replacing the Battery

Battery: CR2032 Lithium Button Battery

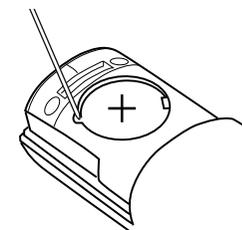
Note: To protect the environment, discard the used batteries in accordance with the local regulations regarding waste disposal procedure. Disposal can be done at your retail store or at appropriate collection sites.

1. **Insert a pointed object into the battery cover pick hole. Slide and remove the battery cover with your thumb.**



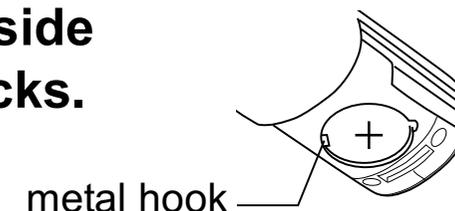
2. **Remove the battery with a pointed object.**

Note: Do not use metal tweezers or a screwdriver.



3. **Insert the new battery under the metal hook on the left side and press the right side of the battery down until it clicks.**

Note: Replace the new battery with the plus (+) side on the top.



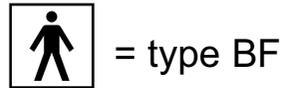
4. **Replace the battery cover.**

5. Technical Data

Product Description:	Digital Ear Thermometer
Model:	Gentle Temp 521 (MC-521-E)
Sensing Unit:	Thermopile
Temperature Display:	4-digit, °F display in 0.1 degree increments 3-digit, °C display in 0.1 degree increments
Measurement Accuracy:	Ear Measurement Mode $\pm 0.2^{\circ}\text{C}$ ($\pm 0.4^{\circ}\text{F}$) within 35.5°C to 42.0°C (95.9°F to 107.6°F), $\pm 0.3^{\circ}\text{C}$ ($\pm 0.5^{\circ}\text{F}$) for other range Surface Mode $\pm 0.3^{\circ}\text{C}$ ($\pm 0.5^{\circ}\text{F}$) within 22.0°C to 42.2°C (71.6°F to 108.0°F), for other range it is $\pm 2^{\circ}\text{C}$ ($\pm 3.6^{\circ}\text{F}$) or 4% whichever is greater.
Measurement Range:	Ear Measurement Mode 34.0°C (93.2°F) to 42.2°C (108.0°F) Surface Mode -22.0°C (-7.6°F) to 80.0°C (176.0°F)
Power Supply:	3.0V DC, 1 CR2032 Lithium Button Battery
Power Consumption:	0.015 W
Battery Life:	With a new battery approx. 2,500 measurements or more (Ambient environment $25\pm 15^{\circ}\text{C}$, $50\pm 40\%\text{RH}$)
Operating Environment Temp and Humidity:	10°C (50°F) to 40°C (104°F), $0 \leq \text{RH} \leq 85\%$
Storage Environment Temp and Humidity:	-20°C (-4°F) to 50°C (122°F), $0 \leq \text{RH} \leq 85\%$
Protection against electric shock:	Internally powered ME equipment

5. Technical Data

Applied Part:



Weight:

Approx. 85g (with battery installed)

Outer Dimensions:

36 mm (w) × 161 mm (h) × 56 mm (d)

Package Content:

Test Battery (Lithium Button Battery CR2032), probe cap, 21 probe covers, connection ring, instruction manual.

Options:

Probe cover exclusively for Gentle Temp 521, MC-EP2.

Notes:

- The specification may be changed without prior notice.
- This OMRON product is produced under the strict quality system of OMRON HEALTHCARE Co. Ltd., Japan.
- This device fulfills the provisions of the EC directive 93/42/EEC (Medical Device Directive) and the European Standard EN12470:2003, Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device)

CE0197

5. Technical Data

OMRON Digital Ear Thermometer

Model: Gentle Temp 521 (MC-521-E)

Information for accompanying documents in the scope of IEC60601-1-2:2007

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

This medical device manufactured by OMRON Healthcare conforms to this EN60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- Do not use mobile (cellular) telephones and other devices, which generate strong electrical or electromagnetic fields, near the medical device. This may result in incorrect operation of the unit and create a potentially unsafe situation. Recommendation is to keep a minimum distance of 7 m. Verify correct operation of the device in case the distance is shorter.

Further documentation in accordance with EN60601-1-2:2007 is available at OMRON HEALTHCARE EUROPE at the address mentioned in this instruction manual.

Documentation is also available at www.omron-healthcare.com.

Correct Disposal of This Product (Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take this item for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial wastes for disposal.

This product does not contain any hazardous substances. Disposal of used batteries should be carried out in accordance with the national regulations for the disposal of batteries.



6. Some Useful Information

6.1 Temperature measurements taken within the ear

The Gentle Temp 521 Digital Ear Thermometer detects the infrared heat given off by the eardrum and surrounding tissues, and it converts this heat into an equivalent ear temperature.

The Gentle Temp 521 is less threatening to a child than a rectal thermometer. It's faster, safer and easier to use than an oral thermometer.

Being digital, there's no worry about the hazard of broken glass or mercury ingestion. Measurements can even be taken while a child is sleeping.

For adults, the Gentle Temp 521 Digital Ear Thermometer offers fast, convenient and accurate readings without the delay of a conventional thermometer.

Clinical research has shown that the ear is an ideal site for taking body temperature. The eardrum shares blood vessels with the hypothalamus, the part of the brain that controls body temperature. Therefore, the ear is an accurate indicator of internal (core) body temperature. An ear temperature, unlike an oral temperature, is unaffected by factors such as talking, drinking, and smoking.

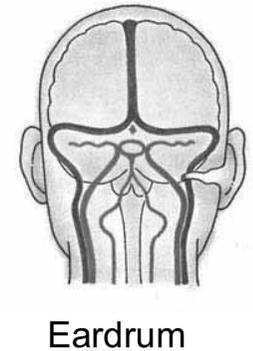
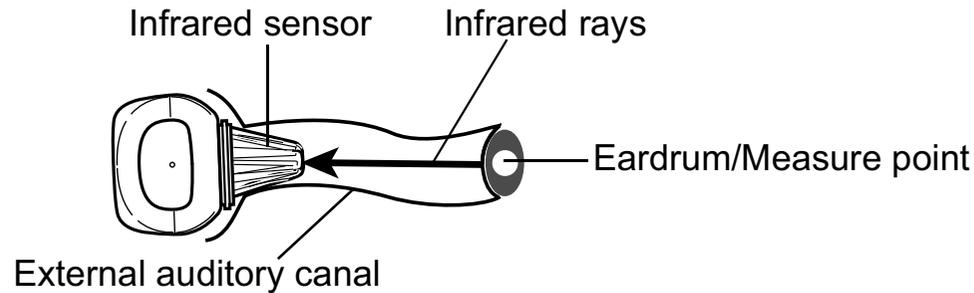
6.2 Normal and raised temperature

We recommend that you practice with the Gentle Temp 521 on yourself and family members.

This way you can improve your technique and feel more confident of the measurements you take when a family member is ill. You will also be able to tell when a reading is higher than normal.

6. Some Useful Information

As ambient temperature, sweat, or saliva easily affects body temperature measured under the arm or the tongue, readings may be lower than the core temperature. Tympanic temperature measurement accurately reflects the brain temperature and can lead to a quicker detection of fever.



In order to make a correct judgement of suspected fever conditions, it is important to learn the normal temperatures of family members by measuring their temperatures when they are in good physical condition.

The temperature measured in the ear is different to that measured rectally.

Please use the normal as the standard for understanding the temperature difference during fever.

One speaks of normal body temperature if the measurement value lies within a certain range. Body temperature varies however according to age.

Age	Normal ear temperature in °C and °F	
Babies	36.4°C - 37.5°C	97.5°F - 99.5°F
Children	36.1°C - 37.5°C	97°F - 99.5°F
Teens/Adults	35.9°C - 37.5°C	96.6°F - 99.5°F
Elderly	35.8°C - 37.5°C	96.4°F - 99.5°F

6. Some Useful Information

6.3 Ear temperature compared to other types of body temperature

The normal temperature varies according to different locations on the body.

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6.4 Questions and answers

How many times can I measure consecutively?

You can measure consecutively up to three times. The main unit will then be warmed up and may not be able to measure correctly. If you are going to measure more than three times, wait for 10 minutes, then measure again.

The temperature indicated is rather high.

- 1 The probe cover may be faulty.
- 2 You may have used the thermometer that has been stored in a cool or cold place. Measure the temperature after leaving the unit in the room where you are going to use it for more than 30 minutes. If you store the unit in the room where you are going to measure the temperature, you can promptly use the thermometer.

6. Some Useful Information

Is the temperature measured in the right ear different from that measured in the left ear?

Among healthy people, there should be no significant difference in the measurement results. Differences may be caused by the following reasons:

- 1) The infrared sensor is not inserted in the same way.
- 2) Measurement is not conducted by inserting the unit in a stable manner in the same angle. Try to measure in the ear that consistently shows a higher measurement.

The temperature shown is rather low.

- 1 The probe cover is dirty.
- 2 The infrared sensor is dirty.
- 3 You removed the unit from the ear before the measurement is finished.
- 4 The ear is cold. The temperature tends to indicate low when you use an ice bag or an ice pack, or immediately after coming in from the cold in winter.
- 5 The thermometer is not inserted deep enough in the ear.

Manufacturer 	OMRON HEALTHCARE Co., Ltd. 53, Kunotsubo, Terado-cho, Muko, Kyoto, 617-0002 JAPAN		
EU-representative <table border="1" data-bbox="85 400 293 485"> <tr> <td>EC</td> <td>REP</td> </tr> </table>	EC	REP	OMRON HEALTHCARE EUROPE B.V. Scorpius 33, 2132 LR Hoofddorp, THE NETHERLANDS www.omron-healthcare.com
EC	REP		
Subsidiary Succursale Niederlassung Consociata Empresa filial Dochteronderneming Филиал Yan Kuruluş الشركات التابعة	OMRON HEALTHCARE UK LTD. Opal Drive, Fox Milne, Milton Keynes, MK15 0DG, U.K. <hr/> OMRON MEDIZINTECHNIK HANDELSGESELLSCHAFT mbH Gottlieb-Daimler-Strasse 10, 68165 Mannheim, GERMANY www.omron-medizintechnik.de <hr/> OMRON SANTÉ FRANCE SAS 14, rue de Lisbonne, 93561 Rosny-sous-Bois Cedex, FRANCE Uniquement pour le marché français: OMRON Service Après Vente N° Vert 0 800 91 43 14 consommateurs@omron-sante.fr www.omron-sante.fr/contact		

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