

New Product Information Sheet

Specifications subject to change
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Sales Name: **Gentle Temp 522 PRO**
Item Number: **MC-522-E**

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SWIFT BOTKNL2X
CHAMBER OF COMMERCE NR. 342.10306
BTW/VAT NR. NL8132.86.281.B01

*Infrared Ear Thermometer
Omron Gentle Temp 522 PRO (MC-522-E)*



LEGAL MANUFACTURER

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General description:

Ear Thermometer Omron Gentle Temp 522 PRO is a medical device meant for measurement of temperature. The 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 522 PRO also measures the surface temperature of an item for example baby's milk. The device also shows the room temperature when turned on.

Packaging content:

The manufacturer produces the ear thermometer Omron Gentle Temp 522 PRO with the applicable accessories included, necessary for the application of its intended purpose.

1. Main unit
2. Instruction manual
3. Test battery (lithium button battery CR2032)
4. Probe cover
5. Connection Ring
6. Hard case

The complete set of the medical device is specified in the Instruction Manual in the Technical Data section

List of Harmonized EN Standards

The above mentioned medical device belongs to a IIa (MDD Annex IX Rule 10) potential risk class.

Applicable Directives: Medical Device Directive (MDD) 93/42/EEC

Standards: EN980:2008
EN1041:2008
EN60601-1:2006
EN60601-1-2:2007
EN60601-1-6:2007
EN ISO14971:2012
EN ISO 10993-1:2009
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN62304:2006
EN62366:2008
EN12470-5:2003

Intended Use

Medical product's intended use as determined by the manufacturer.

The device is a professional digital ear thermometer to measure the infrared heat given off by the eardrum and surrounding tissues, and converts this heat into an equivalent ear temperature. The OMRON Gentle Temp 522 PRO offers comfortable, safe, accurate, and quick temperature measurement and is mainly designed for professional use.

Application field:

This device is designed for use in a home environment.

User:

This device is designed be used by an adult on themselves or children/babies.

Intended Use of the Probe Covers (MC-EP3-E)

Medical product's intended use as determined by the manufacturer.

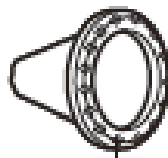
The probe cover MC-EP3-E is designed to be used on the Omron Gentle Temp 522 digital ear thermometer. It protects the sensor from dirt and ear wax to ensure accurate measurements.

Application field:

This device is designed for use in a home environment.

User:

This device is designed be used by an adult on themselves or children/babies.



Particularities of Gentle Temp 522 PRO (MC-522-E)

OMRON is introducing the Gentle Temp 522 PRO ear thermometer. It uses a highly accurate technology and includes some of its advanced features, including selectable centigrade/Fahrenheit readings, probe cover ejector and automatic memory for the last reading. It comes with 1 probe cover included in the sales package. OMRON recommends changing the covers each time to ensure good hygiene and the most accurate measurements.

The Gentle Temp 522 PRO is a supplement to our current EFT portfolio.

Key features

- Fast 1 second measurement
- Selectable Celsius/Fahrenheit
- Probe cover ejector
- Ergonomic design
- Large display
- Extended battery life (more than 6000 readings)

How it works

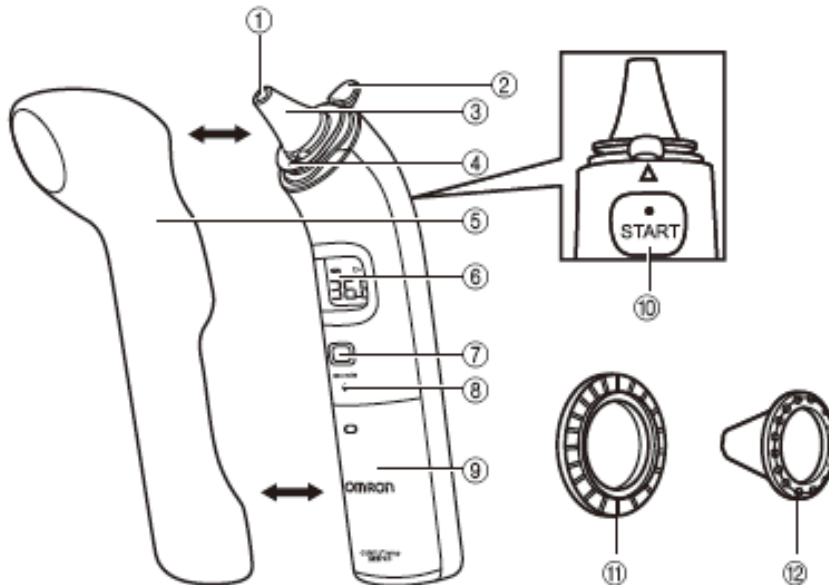
The digital ear thermometer Omron Gentle Temp 522 measures the infrared heat given off by the eardrum and surrounding tissues, and converts this heat into an equivalent ear temperature. For surface and room temperature the device measures the infrared heat given off by the air or surface.

Efficiency of the medical product

Efficient measurement of the body temperature is one of the most important elements of disease control. The device allows the care giver to easily and accurately measure the patient's body temperature. The infrared method is used for detecting the temperature.

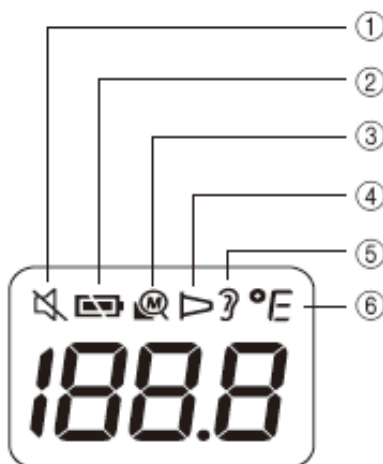
Description of the design and test procedure

Main unit:



- | | |
|-------------------------|----------------------------|
| 1. Probe lens | 7. ON/MEM button |
| 2. Probe cover ejector | 8. Battery cover pick hole |
| 3. Probe | 9. Battery compartment |
| 4. Probe cover detector | 10. START button |
| 5. Hard case | 11. Connection ring |
| 6. Display | 12. Probe cover |

Display:



- | |
|---------------------|
| 1. Buzzer |
| 2. Battery icon |
| 3. Memory icon |
| 4. Probe cover icon |
| 5. Ear icon |
| 6. Temperature mode |

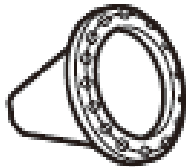
Application:

Review the Instruction Manual for the full details on the application of this product.

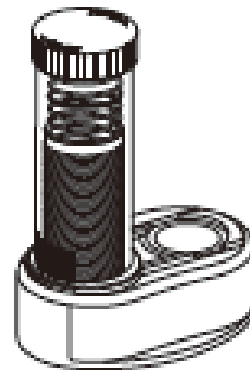
1. Chose which temperature indication (°C and °F)
2. Set the buzzer (to turn the buzzer on or off)
3. Attach the probe cover
4. Press ON/MEM button
5. Insert probe comfortably into the ear in the direction of the eardrum
6. Press START button
7. At the long beep, the thermometer can be removed
8. Read the temperature measurement
9. Press and hold ON/MEM button to shut off

Optional accessories

Probe Cover (MC-EP3-E)



Probe Cover Loader (MC-EPL1-E)



(Within the scope of EC Medical Device Directive 93/42/EEC)

Important Safety Information

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

Warning: The following situations are potentially hazardous for your patients and, if not avoided, could result in death or serious injury.


- Keep still during measurement.
- Do not forcibly insert the probe in the ear.
- If your patients 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 the patient has been swimming or taken a bath. It may injure the external auditory canal.
- Do not use this unit without attaching a probe cover.
- Do not use this unit near an electronic device or magnetic card, such as a computer, credit card, etc. Doing so may damage the device or card.
- Ensure that the ear canal is clean and free of earwax. Correct measurement results may not be obtained if dirty probe covers are used.
- Do not use one probe cover twice. This can lead to cross infections such as external otitis. Always use a clean, undamaged, and new probe cover.
- Proper installation of the probe cover ensures accurate measurements.
- When the probe lens becomes dirty, wipe it lightly with a soft dry cloth or a cotton swab. Do not wipe the probe lens with tissue paper or a paper towel. For details, refer to section 4.2.
- 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 it will be used to measure, leave the unit in the room where it will be used for more than 30 minutes to allow it to reach room temperature first, then measure.
- If the patient's ear is cold, wait until the ear is warmed up before taking a temperature measurement. The measured result may indicate low when the patient uses an ice bag or an ice pack, or immediately after coming in from the outside in winter.
- Do not touch the probe lens with a finger or breathe on it. Doing so may soil or damage the probe lens.
- Do not attempt measurements when the unit is wet as inaccurate readings may result.
- Check the icon on the display before and after the measurement so that the measurement is taken in the appropriate mode.
- Keep the unit out of children's reach.
- 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.

General Precautions

- Do not use this unit other than for measuring the temperature in the human ear.
- 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.

Specifications of OMRON Gentle Temp 522 (MC-522-E)


Product Description:	Digital Ear Thermometer
Model:	OMRON Gentle Temp 522 PRO (MC-522-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:	± 0.2°C (± 0.4°F) within 35.0°C to 42.0°C (95.0°F to 107.6°F), ± 0.3°C (± 0.5°F) for other range
Measurement Range:	34.0°C (93.2°F) to 42.2°C (108.0°F)
Power Supply:	3.0V DC, 1 CR2032 Lithium Button Battery
Power Consumption	0.015 W
Battery Life	With a new battery approx. 6,000 measurements or more
Operating environment Temp and Humidity:	10 °C (50°F) to 40°C (104°F), 15 to 85% RH
Storage environment Temperature / Humidity / Air Pressure:	-20 °C (-4°F) to 60°C (140°F) / 10 to 95% / 200 to 1060hPa
Protection against electric shock:	Internally powered ME equipment
Applied Part:	 = Type BF
Weight:	Approx. 63 g (including battery installed)
Outer Dimensions:	36 mm (w) x 154 mm (h) x 48 mm (d)
Package Contents:	Main unit, test battery (lithium button battery CR2032), hard case, probe cover, connection ring, instruction manual.
Options:	Probe cover exclusively for Gentle Temp 522 PRO, MC-EP3-E Probe cover loader exclusively for Gentle Temp 522 PRO, MC-EPL1-E


Materials Used

Component	Material
CAP	Polycarbonates Plastic
Battery Cover	Acrylonitrile - Butadiene - Styrene Plastic
Cosmetic cover	Acrylonitrile - Butadiene - Styrene Plastic
Rear Cover	Acrylonitrile - Butadiene - Styrene Plastic
Action Key	Polypropylene Plastic
Front Cover	Acrylonitrile - Butadiene - Styrene Plastic
Power Button	Silicone Rubber
Probe cover	ZIP Lock Bags_ LLDPE Film + HDPE Ring
Probe cover Detect	Polyoxymethylene, polyacetal

Title page of Instruction Manual

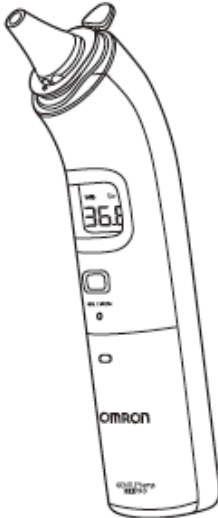
(9 languages – English / French / German / Italian / Spanish / Dutch / Russian / Turkish / Arabic)





**Digital Ear Thermometer
Gentle Temp 522 PRO
Instruction Manual**

All for Healthcare



- English
- Français
- Deutsch
- Italiano
- Español
- Nederlands
- Русский
- Türkçe
- العربية

IM-MC-522-E-01-01/2014
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OMRON Gentle Temp 522 PRO (MC-522-E) Package

Design



Packaging specifications

	Dimensions	Qty	Weight
Main Unit	36 x 48 x 154 mm	1	63g
Package	115 x 59 x 193 mm	1	187g
Master Carton	323 x 252 x 235 mm	10	2.4kg

Operation and Care

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.

Surface cleaning

Wipe the external surface with a soft dry cloth. The probe lens is the most delicate part of the unit. Use care when cleaning the Infrared sensor to avoid damage, wipe it lightly with a soft dry cloth or a cotton swab moistened with 70% alcohol and allow it fully dry.

Storage

- 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.

Servicing

The device requires no routine service other than cleaning, and visually checking for damage.

Repair

In case of malfunction of the device the user must turn to the OMRON retail outlet or distributor to test the device and repair the failure. The user shall not repair the device by themselves.

Disposal

As there is a risk of environmental pollution, follow your applicable national and local legal regulations regarding disposal or recycling of this equipment and batteries. The main constituents of each part are listed in the table "Materials List".

Warranty

Warranty text is included in the Instruction Manual.

This product is guaranteed by OMRON for a period of 3 years after the date of purchase. The proper construction, workmanship and materials of this product are

guaranteed by OMRON. During this period of guarantee, OMRON will, without charge for labor or parts, repair or replace the defect product or any defective parts.

Claimed products will only be replaced when returned together with the original invoice/cash ticket.

The guarantee does not cover battery, packaging and/or damages of any kind due to misusage (such as dropping or physical misuse) caused by the user.

Warranty term for the forehead thermometer: 3 years.

Warranty term for probe cover: none, as this is a single use item.

Lifetime

Lifetime of the ear thermometer: 3 years.

Life of the probe cover: no lifetime, as these are considered disposable items.

Comparison with Previous Product

The Gentle Temp 522 PRO (MC-522-E) with the legal manufacturer of OMRON HEALTHCARE Co., Ltd at the production location of Radiant No. 20, Tai Hong Road, Wu Song Jiang Development Zone, Yu Shan Town, Kun Shan City, Jiang Su, China, is a new product, without direct predecessor.