

New Product Information Sheet

Specifications subject to change
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Sales Name: **Gentle Temp 720**
Item Number: **MC-720-E**

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OMRON HEALTHCARE EUROPE B.V.
Scorpius 33 2132 LR Hoofddorp The Netherlands
P.O. Box 2050 2130 GL Hoofddorp The Netherlands
Phone: +31 (0)23 55 44 700 fax +31 (0)23 55 44 701
www.omron.healthcare.com

BANKERS BANK OF TOKYO-MITUBISHI (HOLLAND) N.V.
ACC. NR. 063.56.15.320 IBAN NL95BOTK0635615320
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BTW/VAT NR. NL8132.86.281.B01

Infrared Forehead Thermometer Omron Gentle Temp 720 (MC-720-E)



LEGAL MANUFACTURER

Address:

OMRON HEALTHCARE Co., Ltd

53, Kunotsubo, Terado-cho, Muko, Kyoto

617-0002 Japan

Phone/Fax: +31 23 5544700 / +31 23 5544 701

e-mail: info.omronhealthcare@eu.omron.com

PRODUCTION FACILITY

Address:

KunShan Radiant Innovation Co., Ltd. (China).

No. 20, TaiHongRoad, WuSong Jiang Development Zone

YuShan Town, KunShan City, Jiang Su, China

Phone/Fax: +31 23 5544700 / +31 23 5544 701

e-mail: info.omronhealthcare@eu.omron.com

General description

Infrared forehead Thermometer Omron Gentle Temp 720 is a medical device meant for measurement of temperature. The thermometer detects the infrared emission of the skin of the forehead at the measured point, and then calculates the oral-equivalent value using a unique algorithm based on actual body temperature survey data. The Gentle Temp 720 also measures the surface temperature of an item for example baby's milk.

Packaging content

The manufacturer produces the forehead thermometer Omron Gentle Temp 720 with the applicable accessories included, necessary for the application of its intended purpose.

1. Main unit
2. Instruction manual
3. Test battery
4. Probe lens cap

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 an infrared forehead thermometer that measures the temperature at the surface of the forehead by sensing infrared emission of the skin at the measured point, and then converts this heat into an oral-equivalent value using an algorithm based on survey data.

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 720 (MC-720-E)

OMRON is introducing the Gentle Temp 720 as its first forehead thermometer. It uses a highly accurate technology and has advanced features such as one-second measurement, selectable centigrade/Fahrenheit readings and room temperature display before turning off. To assist with readings in the dark (on a ward or in a child's room at night) the device also has backlight function. The 3-in-1 function enables various types of measurement, suitable for forehead, surface and room temperature reading.

The Gentle Temp 720 is an innovative, new supplement to our current EFT portfolio.

Key features

- 3 in 1 measurement (forehead, surface, room temperature measurement)
- Fast 1 second measurement
- Backlight function
- Selectable Celsius/Fahrenheit
- New ergonomic design
- Large display
- Automatic shut-off after 1 minute if no operation is performed

How it works

The infrared forehead thermometer Omron Gentle Temp 720 detects the infrared emission of the skin of the forehead at the measured point, and then calculates the oral-equivalent value using a unique algorithm based on actual body temperature

survey data. For surface and room temperature the device measures the infrared heat given off by the air or surface.

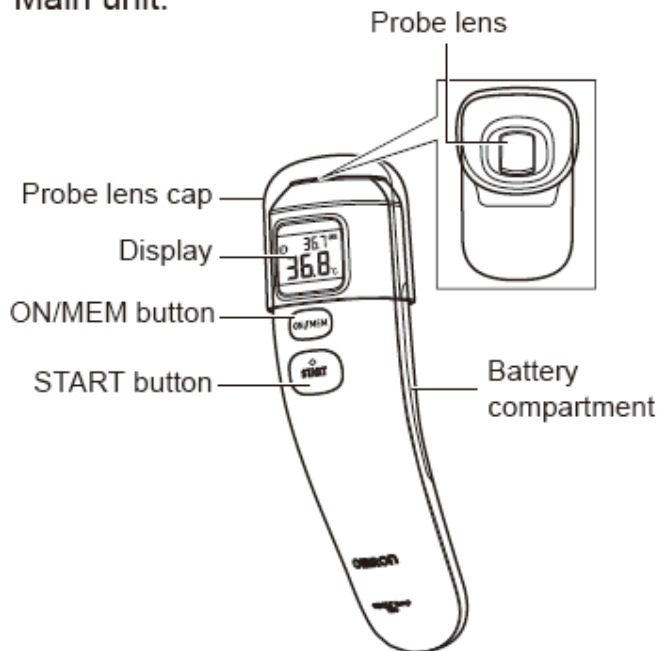
Efficiency of the medical product

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. Infrared method is used for detecting the temperature.

Since forehead temperature measurement involves no bodily support of the thermometer, the resulting measured temperature is typically lower than that of the armpit or mouth. However, as the forehead has blood vessels that are much less prone to vascular constriction (a natural function of body temperature adjustment), it is supposedly a better measurement area for determining core body temperature, even in a lower temperature environment.

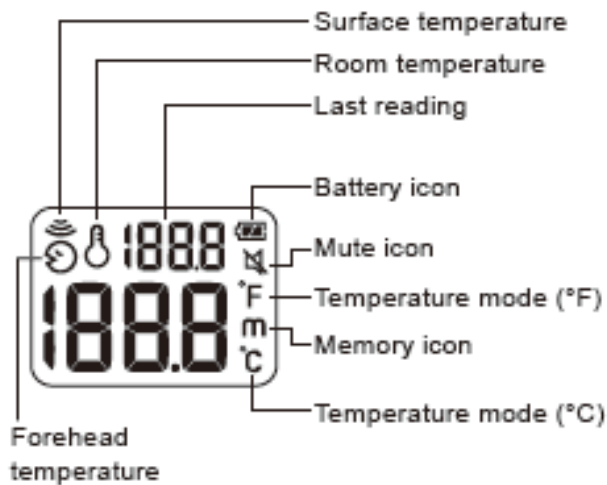
Description of the design and test procedure

Main unit:



- Probe lens
- Probe lens cap
- Display
- ON/MEM button
- START button
- Battery compartment

Display:



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. Pull off the probe lens cap
4. Press the ON/MEM button
5. Hold the probe lens 1-3 cm away from the center of the forehead
6. Press START button
7. At the long beep, the thermometer can be removed
8. Read the temperature measurement
9. Press and hold the ON/MEM button to turn the device off

Important Safety Information

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


- 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.
- Keep the unit out of children's reach.

- If a child swallows the battery, 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 three 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 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 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.
 - 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 forehead is cold, wait until the forehead 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.
 - Do not use the unit when wet after swimming, bathing, or through sweating after physical exercise, as skin temperature may have fallen. Wipe away moisture and allow 30 minutes for the body to acclimatize to room temperature before measuring.
 - Do not touch the probe lens with a finger or breathe on it.
 - 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.
 - When taking the temperature of an object with low emissivity such as gold or aluminum, inaccurate readings may result.
 - When taking the temperature of something with low emissivity (such as milk) in surface measurement mode, slightly lower readings may result.
 - 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.
 - When you inform your doctor of your temperature, make sure you state that you measured the temperature from the forehead.

Specifications of OMRON Gentle Temp 720 (MC-720-E)

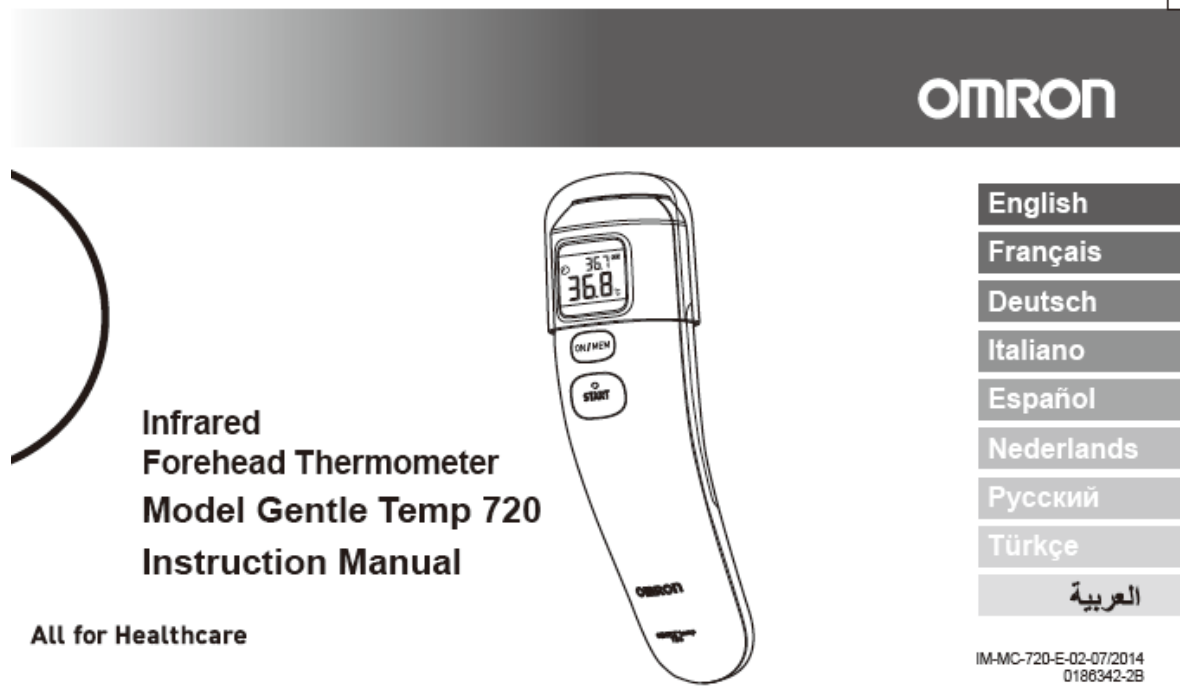
Product Description:	Infrared forehead Thermometer
Model:	OMRON Gentle Temp720 (MC-720-E)
Sensing Unit:	Thermopile
Temperature Display:	4-digit, °F display in 0.1 degree increments 3-digit, °C display in 0.1 degree increments
Measurement Accuracy:	Forehead Measurement Mode: ± 0.2°C (± 0.4°F) within 35.0°C to 42.0°C (95.0°F to 107.6°F), ± 0.3°C (± 0.5°F) for other range Surface Mode: ± 0.3°C (± 0.5°F) within 22.0°C to 42.2°C (71.6°F to 108.0°F). Outside this range it is ±2°C (± 3.6°F) or 4% (of actual temperature) whichever is greater. Room temperature mode: ± 0.2°C (± 3.6°F) within 10°C to 40°C (50°F to 104°F). Out of this range, the measurement result can't meet the accuracy aforementioned.
Measurement Range:	Forehead measurement mode: 34.0°C (93.2°F) to 42.2°C (108.0°F) Surface measurement mode: -22.0°C (7.6°F) to 80.0°C (176.0°F) Room temperature mode: 10°C (50°F) to 40°C (104°F)
Power Supply:	3.0V DC, 1 CR2032 Lithium Button Battery
Power Consumption	0.018 W
Battery Life	With a new battery approx. 2,500 measurements or more
Operating environment Temp and Humidity:	10 °C (50°F) to 40°C (104°F), 15 ≤ RH ≤ 85%
Storage environment Temp and Humidity:	-20 °C (-4°F) to 60°C (140°F), 10 ≤ RH ≤ 95%
Protection against electric shock:	Internally powered ME equipment
Applied Part:	 = Type BF
Weight:	Approx. 90 g (including battery installed)
Outer Dimensions:	45 mm (w) x 155 mm (h) x 39 mm (d)
Package Contents:	Main unit, test battery (lithium button battery CR2032), probe lens cap, instruction manual

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

Title page of Instruction Manual

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



OMRON Gentle Temp 720 (MC-720-E) Package

Design



Packaging specifications

	Dimensions	Qty	Weight
Main Unit	45 x 39 x 155 mm	1	90 g
Package	118.5 x 68 x 204 mm	1	338 g
Master Carton	490 x 420 x 365 mm	40	14.79 kg

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.

Lifetime

Lifetime of the ear thermometer: 5 years.

Comparison with Previous Product

The Gentle Temp 720 (MC-720-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 device, without a direct predecessor in OMRON's portfolio.