

VEDOFAMILY THERMOMETER TECHNICAL INFORMATION

Definition

- Digital Thermometer.

General features

- Digital thermometer, quick and accurate.
- Handy
- Acoustic sound at the end of the measurement.
- Memory of the last measurement
- Waterproof probe
- Weight 8,6 g.
- Dimension of 120mm * 15mm * 8mm.



Applications

- For checking temperature.
- For general domestic and hospital use.

Medical device according to the directive CEE 93/42

Modified by the directive 2007/47/CE

Implementation with D.L. n°37 del 25-01-2010

CE 0068

Class II A


Conformity

- EN 12470-3:2000; EN ISO 10993-1 [EN12470-3§6.4.2]
- EN 60601-1; EN 60601-1-2
- ASTM E1112-00;
- RAEE 2002/96/CE/WEEE
- 2006/66/EC

Technical specifications

| SPECIFICATIONS | VALUES |
|--------------------------------|--|
| MEASUREMENT FEATURES | |
| Measuring Method | Not predictive |
| Measuring Unit | °C / °F |
| Number of digits | 1 |
| Measuring range [°C] | 32.0 °C – 42.9 °C |
| Tip Type | Rigid – straight |
| Tip dimension | 4 mm * 12 mm |
| DISPLAY | |
| Type | TN type |
| Resolution | (3 DIGITs e ½) ±0.1°C: 35.5°C ≤ T ≤ 42°C ±0.2°C: per T > 42°C e T < 35.5°C |
| Digital Increment | 0.1°C [EN12470-3 §6.2.2] |
| Indicating Unit [mm] | 5.35mm [EN12470-3 §6.4.1.2] |
| Temperature Display Range [°C] | 32.0 °C- 42.9 °C |
| Lower Temperature Mark [°C] | <L> when temperature is < 32.0 °C |
| Higher Temperature Mark [°C] | <H> when temperature is > 42.9 °C |

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| SPECIFICATIONS | VALUES |
|---|--|
| MEMORY | |
| Number of Stored Measurements | Last measure |
| BUZZER | |
| Different Buzzer Sound if Fever has been detected | Yes |
| ELECTRICAL SPECIFICATIONS | |
| Battery Type | L736 - 7.9mm * 3.6mm 1.5V (LR41) |
| Battery Sign Detection | Flat detection Battery  |
| ENVIRONMENT CONDITIONS | |
| Operating Condition Temperature [°C] | MINIMUM RANGE BETWEEN 5 °C e 40 °C |
| Operating Condition Humidity [%] | ≤95%RH, 800-1060hPa WITHOUT CONDENSATION |

| | |
|--|--|
| Sterile Storage instructions | No Store in a cool, dry place, away from heat and direct sunlight |
| Storage & Transportation Temperature [°C] | -25°C ~ 55°C |
| Storage & Temperature Humidity [%] | ≤95%RH WITHOUT CONDENSATION |
| Warranty | unlimited |

Product Cleaning & Disinfection

- The thermometer can be cleaned using a ball of cotton wool soaked in alcohol or a disinfectant solution.
- Do not boil the thermometer and do not place in a dishwasher.
- Do not dip the thermometer in water: not waterproof

Disposal

- In compliance with applicable laws – EU DIRETTIVA 2002/96/EC

Indications for use

- Ensure hands are clean and dry.
- Position correctly the thermometer
- For a oral measurement: Don't eat or drink anything in the 15 minutes before taking the reading.
Position the tip of the thermometer under the tongue towards the base, making sure that the metal sensor is in complete contact with the tissue. Keep the mouth closed during the measurement breathing only through the nose.
- For axillary measurement: Ensure that armpit is dry and that clothes do no prevent the correct positioning of the probe inside the armpit. It requires more time.
- For rectal measurement: It is particularly indicated for children and infants.
Delicately insert the thermometer into the rectum to a depth of no more than 0.5 cm. If you perceive any type of resistance, stop immediately. Hold the thermometer in position while taking the measurement.
- Do not force the probe.



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How to use

- Turn the thermometer on by pressing the ON/OFF button. The display shows "188.8°C
- M" for two seconds, in order to check completeness. Subsequently, the last
- reading and the self-calibration 37.0 °C appear in sequence for two seconds, followed
- by the flashing message "Lo °C" (Lo °F), indicating the start of measurement.
- A beep alerts you when the measurement is finished. If the temperature is ≥ 37.8 °C (\geq
- 100.0 °F), you will hear an alarm sound.
- The scale can be changed from degrees Celsius (°C) to degrees Fahrenheit (°F) by
- pressing the ON/OFF button for a few seconds while the thermometer is off

Quality control

- Artsana S.p.A. defined a check list for the thermometers quality verification, which considers all the requirements of EN 12470-5:2003, and some Artsana's internal requirements, which move beyond the European Standard.

The testing process consists in two phases:

- IN PROCESS CONTROLS: according to the defined check list, 100% of the goods are tested during the production.
- OUT GOING INSPECTION: before release the goods each batch is checked, according to the defined check list and according to an agreed sampling plan.

Packaging

Labels and/or packages have the following:

| |
|---|
| Trade name |
| Instructions and indications for use |
| Manufacturer |
| Lot number indicating production month/year |
| Item bar code |
| Storage instruction |

Packaging material

- Single plastic case.
- Materials used for packaging and the dyes are certified as non-toxic.

Manufacturer

- Artsana S.p.A. Via Saldarini Catelli 1, 22070 Grandate (Como) Italy.



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Assortment

| CODE | DESCRIPTION |
|-------------------|------------------------|
| 00 023030 000 000 | Thermometer VEDOFamily |

Additional information

- Additional information and operating procedures are included in the technical dossiers filed with ARTSANA's Technical/Quality Assurance department.

The Technical Department

ARTSANA S.p.A.
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