

VEDOCLEAR 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
- Fever alarm
- Maxi display
- Flexible Waterproof probe
- Weight 10,5 g.
- Dimension of 135mm * 22mm * 10mm.



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	Flexible
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]	9.8mm [EN12470-3 §6.4.1.2]
Temperature Display Range [°C]	32.0 °C- 42.9 °C



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Lower Temperature Mark [°C]	<L> when temperature is < 32.0 °C
Higher Temperature Mark [°C]	<H> when temperature is > 42.9 °C

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 and 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 the thermometer

- 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 023032 000 000	VEDOClear Thermometer

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.
Dr. MAURO CASSANI
Medical Devices Department
Technical Director

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