

## **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.



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

### <u>Medical device according to the directive CEE 93/42</u> <u>Modified by the directive 2007/47/CE</u> <u>Implementation with D.L. n°37 del 25-01-2010</u>

### Class II A

## <u>ConformitY</u>

- > 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**

Sterile	No
Storage instructions	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	unlimeted

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Codice Fiscale, Partita IVA e Numero d'iscrizione al Registro imprese di Como 03690650134 - Iscritta al R.E.A. della C.C.I.A.A. di Como n.327993



SPECIFICATIONS	VALUES	
MEAS	UREMENT FEATURES	
Measuring Method	Not predictive	
Measuring Unit	°C / °F	
Number of digits	1	
Measuring range [°C]	32.0 °C – 42.9 °C	
Тір Туре	Rigid – straight	
Tip dimension	4 mm * 12 mm	
DISPLAY		
Туре	TN type	
Resolution	(3 DIGITs e ½)	
	±0.1°C: 35.5°C ≤ T ≤42°C	
Disited to succeed	±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] 32.0 °C- 42.9 °C	
Temperature Display Range [°C] Lower Temperature Mark [°C]	<pre><s2.0 42.9="" pre="" °c="" °c<=""><l> when temperature is &lt; 32.0 °C</l></s2.0></pre>	
Higher Temperature Mark [°C]	<pre><!--</td--></pre>	
	MEMORY	
Number of Stored Measurements	Last measure	
BUZZER		
Different Buzzer Sound if Fever has been	Yes	
detected		
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	

#### **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

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#### 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.

#### How to use

Turn the thermometer on by pressing the ON/OFF button. The display shows "188.8°E 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  $\geq$  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**

Pikdare S.p.A. defined a check list for the thermometers quality verification, which considers all the requirements of EN 12470-3:2000, and some 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.

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## **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**

> Pikdare S.p.A. - Via Saldarini Catelli 10 - 22070 Casnate con Bernate (Como) - Italy

## <u>Assortment</u>

CODE	DESCRIPTION
02 023030 000 000	Thermometer VEDOFamily

## Additional information

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

**Technical Director** IKDARE S.D.A SANI tment

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