



# Technical Data Sheet

## Thermoval standard®



Spec.-No.: D 9.1507

Department: CMO-PPD

Date: 2015-01-23

### 1. General Product Description:

Thermoval standard® is a digital pen-type electronic fever thermometer (non-predictive) with maximum device for self-measurement of human body temperature.

The product is equipped with a rigid measuring tip, large LCD display, on/off button, removable battery cap and stored inside a transparent protective case. It displays the measured temperature in °C, has battery sign, beeper signal, fever alarm, automatic switch-off function, single memory function and is battery powered using a replaceable long-life battery.

The device can be switched on by pressing the on/off button and a short signal tone confirms that the thermometer is operational. The flashing of the "°C" symbol indicates when the thermometer is ready for temperature measurement and an acoustic beeper signal indicates when the measurement is completed. At a temperature of 37.8 °C or higher the signal tone beeps rapidly.

Cleaning of the product at the measurement tip is possible with a slightly moistened cloth with water and a mild detergent or by applying e.g. 70 % Isopropyl alcohol with a damp cloth (except LCD, button and battery cap).

Disinfection of the product at the measurement tip is recommended to perform by wipe disinfection applying a suitable disinfectant which is compatible with the product materials (except LCD, button and battery cap).

It is possible to use Thermoval protective covers (art.-no. 925037) with Thermoval standard® thereby decreasing possible microbial contamination and infection of the patient or user.

Thermoval standard® is a class II a active medical device with measuring function in accordance with Directive 93/42/EEC on Medical Devices (MDD) and bears the CE-mark.

UMDNS (Universal Medical Device Nomenclature System) No.: 14-032

### 2. Application / Indication:

Thermoval standard® is applicable for oral, axillar and rectal self-measurement of human body temperature.

### 3. Presentations:

Each fever thermometer device includes an installed battery, is stored inside a protective case and packed inside a folding box made of cardboard. The folding box also contains the instruction manual leaflet. 12 products/folding boxes are packed in one display box.

The product is available in four different language circles:

Article-No.:	Languages:	Packaging:
925021	DE, FR, IT, NL, HU	P12, OK4
925022	ES, PT, GR, AE, GB	P12, OK4
925023	RU, PL, CZ, SK, RO	P12, OK4
925024	SI, HR, TR, HK, EN	P12, OK4

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The Thermoval standard® thermometer device is identical for all different language circles.

### 4. Product Materials:

Housing:	ABS (Acrylonitrile-Butadiene-Styrene), white
Display:	LCD display with top layer of TAC (Tri-Acetyl cellulose)
Measurement tip:	Stainless Steel (SUS304)
On/Off button:	Silica rubber, blue
Protective case:	AS (Acrylonitrile Styrene), transparent

### 5. Product Characteristics:

Type:	maximum thermometer
Device dimensions:	approx. 130 x 23 x 12 mm (L x W x H)
Device weight:	approx. 11g (incl. battery)
Measurement range:	32.0 °C - 42.9 °C
Measurement accuracy:	± 0.1 °C (in the range of 35.5 °C - 42.0 °C) ± 0.2 °C (for the remaining measurement range)
Display:	3-digit LCD display
Temperature scale:	degree Celsius (°C)
Digital increment:	0.1 °C
Operating conditions:	+10 °C to +35 °C, ≤80 % rel. hum., non-condensing
Storage/transport conditions:	-25 °C to +55 °C, ≤95 % rel. hum., non-condensing
Low temperature indication:	“Lo °C” symbol if detected temperature is < 32.0°C
High temperature indication:	“Hi °C” symbol if detected temperature is > 42.9°C
Protection against harmful ingress of water or solid materials:	IP 20 (not moisture proof)
Measuring time:	typically 40-60 sec. at rectal measurement
Fever alarm:	rapid acoustic signal at temperatures ≥37.8 °C
Memory:	1 memory: display of last measured value
Automatic switch off:	after approx. 7 minutes
Battery type:	alkaline manganese, LR41, 1.5V or 1.55V
Battery life:	approx. 3.000 measurements
Voltage limit indication:	visual warning when battery is low
Self check function:	“Err” symbol if device or sensor is defective
Shelf life:	typically 5 years
(Water resistance only for the measuring tip. LCD and battery cap are not water resistant.)	
(Technical modification subject to change)	

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Thermoval standard® is compliant, among others, with the requirements of the following standards:  
DIN EN 12470-3, DIN EN 60601-1 and DIN EN 60601-1-2.

### 6. Labelling:

LOT-No. with 4-digit code on rating label of the product and on all packaging units:

Contents of the LOT-number:

e.g.:

13	26
year	week of production

example: LOT 1326

### 7. Packaging:

One Thermoval standard® (incl. transparent protective case) is packed in a single unit folding box. 12 pcs of folding boxes are packed in a display box, 4 display boxes are packed in a master carton. 6 master cartons are packed into one transport carton. Master/transport carton according DIN, sealed with special HARTMANN adhesive tape, packed onto Europallet.

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