

# Thermoval® standard

## General Product Description/Intended Purpose

The Thermoval® standard thermometer is a reusable, digital thermometer for rectal, oral or axillary measurement that is intended for temporary monitoring of the body temperature of humans and can be used by laypersons and healthcare professionals in clinical and domestic settings.

Thermoval® standard is a digital maximum thermometer in direct measuring mode (non-extrapolating) and therefore is a real measuring and not a predictive measuring device.

## Application/Indication

Thermoval® standard is applicable for the determination and monitoring of human body temperature in the rectum, the mouth or the armpit.

The digital pen-type thermometer is equipped with a rigid measuring tip, on/off button, removable battery cap and is delivered with a transparent protective case. It displays the measured temperature in °C, has battery sign, beeper signal, acoustic fever signal, automatic switch-off function and single memory function. It is battery powered using a replaceable long-life battery and is free of Latex, PVC (polyvinyl chloride), DEHP (diethylhexyl phthalate) and Mercury (Hg).

The device can be switched on by pressing the on/off button and a 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.

Thermoval® standard measures the body temperature within following times:

- rectal: approx. 40-60 sec
- oral: at least 60 sec
- axillary: at least 90 sec

(The above measurement periods are average experience values in dependence of the correct placement of the measurement tip and of individual conditions.)

The device is not waterproof. Make sure no liquid can penetrate the inside of the thermometer and never immerse the device in water or other cleaning agents. (Only the thermometer tip is waterproof.) Cleaning of the product is possible with a slightly moistened cloth with water and a mild detergent or by applying 70 % Isopropyl alcohol with a damp cloth. Disinfection of the product is recommended to perform by wipe disinfection applying a suitable disinfectant which is compatible with the product materials.

The housing colour of Thermoval® standard is white. The colour of on/off button is blue.

## Reference Numbers

The product is available in four different language circles:

Article-No.:	Product name:	Languages:	Packaging:
925021	Thermoval® standard	DE,FR,IT,NL,HU	P12, OK4
925022	Thermoval® standard	ES,PT,EL,AR,EN	P12, OK4
925023	Thermoval® standard	CS,SK,RO,BG	P12, OK4
925024	Thermoval® standard	SI,HR,TR,ZH,EN	P12, OK4

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

Each fever thermometer device includes an installed battery, is delivered inside a protective case and packed inside a folding box made of cardboard. The folding box also contains the instructions manual leaflet.

12 products/folding boxes are packed in one display box.

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## Warnings



For information on important safety instructions, please refer to the sections marked with the “Caution” symbol in the Thermoval<sup>®</sup> standard instructions for use.

## Product Disposal



This product is subject to the European Directive 2012/19/EU on Used Electrical and Electronic Equipment and is marked accordingly. Never dispose of electronic equipment in your household waste. Please obtain information about local regulations on the proper disposal of electrical and electronic products.

Proper disposal protects the environment and human health.

## Packaging Materials

All packing materials and packing components conform to the relevant essential requirements (specific to manufacturing and composition, reusable nature and recoverable nature of packing) of the Packaging and Packaging Waste Directive 94/62/EC and amended directive 2004/12/EC respectively.

## Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.



## Material Characteristics

### Thermoval<sup>®</sup> standard

Product component:	Material composition
Housing incl. battery cover:	ABS (Acrylonitrile-Butadiene-Styrene)
LCD display:	Top layer of LCD: TAC (tri-acetyl cellulose)
Sensor tip:	SUS304 (Stainless steel with part of Nickel: 8.0 - 10.5 %)
On/Off button:	Silicone rubber
Protective cover:	AS (Acrylonitrile-Styrene), transparent

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## Product Characteristics

Thermoval® standard	
Property	Characteristics
Product description:	Compact clinical electrical thermometer with maximum device
Measurement range:	32.0 to 42.9 °C
Smallest display unit:	0.1°C
Measurement unit:	Degrees Celsius
Display:	3-digit LCD display
Measurement accuracy:	± 0.1°C at 35.5 to 42.0°C ± 0.2°C for the remaining range
Operating mode:	Measurement in direct mode, intermittent (non-extrapolating)
Acoustic signal:	Switching on, switching off, end of measurement
Memory capacity:	1 reading (autom. saving of the last reading)
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
Acoustic fever signal:	≥ 37.8°C (10x3 short signal tones)
Operating conditions:	Ambient temperature: +10 to +40°C; Relative humidity: 15 to 90%, non-condensing
Storage/transport conditions:	Ambient temperature: -25 to +55°C; Relative humidity: 15 to 90%, non-condensing
Automatic switch off function:	Approx. 10 minutes after end of measurement (approx. 3 minutes if no measurement is performed)
Voltage limit indication:	 Battery symbol when battery is empty
Self check function:	 “Err” symbol if device or sensor is defective
Battery type:	1.5 V alkaline manganese button cell (LR41)
Battery capacity:	Approx. 3000 measurements
Protection against harmful ingress of water or solid materials:	IP20: not protected against moisture, protected against solid objects ≥ 12.5mm
Service life (operating life):	5 years
Device dimensions:	approx. 129.5 x 22.5 x 11.5 mm (L x W x H)
Device weight:	approx. 11g (incl. battery / without protective cover)
Reference to standard:	DIN EN ISO 80601-2-56:2020; ASTM E1112-00; DIN EN 60601-1:2013; DIN EN 60601-1-2:2016
(Technical modification subject to change)	

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## Labelling

LOT number with 4-digit code:

e.g.: 2101



21

01

year of production

week of production

Manufacturing Date with 8-digit code:

e.g.: 2021-01-01



2021

-

01

-

01

year

month

day

Medical Device:



Thermoval<sup>®</sup> standard is a class IIa active medical device with measuring function in accordance with the (MDR) Medical Device Regulation (EU) 2017/745 and bears the CE-mark.



UMDNS Code: 14-032

GMDN Code: 14035

CND Code: V03010102

Unique Device Identifier (UDI):



Each device and all higher levels of packaging are labeled with an UDI code. (implementation date according to Regulation 2017/745/EU on Medical Devices)

**Latest Date of Revision:** 2020-09-04