



Technical Data Sheet

Thermoval rapid®



Spec.-No.: D 9.1500b

Department: CMO-PPD

Date: 2015-03-16

1. General Product Description:

Thermoval rapid® 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, very large LCD display, on/off button, removable battery cap and with a plug-on transparent protective cover. It displays the measured temperature in °C, has battery sign, beeper signal, automatic switch-off function and single memory function. It is battery powered using a replaceable long-life battery and is waterproof.

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

Thermoval rapid® takes the measurement much faster than the existing standard digital electronic thermometers^{*)}.

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.

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

^{*)}Thermoval rapid® measures the body temperature within following times:

- rectal: 10-15 sec
- oral: 10-30 sec
- axillary: 10-40 sec

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

Thermoval rapid® has a direct measuring mode (non-extrapolating) and therefore is a real measuring and *not* a predictive measuring device.

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

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

2. Application / Indication:

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

3. Presentations:

Each fever thermometer device includes an installed battery, is equipped with a plug-on protective cover 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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The product is available in four different language circles:

Article-No.	Languages:	Packaging:
925031	DE, FR, IT, NL, HU	P12, OK4
925032	ES, PT, GR, AE, GB	P12, OK4
925033	RU, PL, CZ, SK, RO	P12, OK4
925034	SI, HR, TR, HK, EN	P12, OK4

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

4. Product Characteristics:

Housing	ABS (Acrylonitrile-Butadiene-Styrene)
Display:	LCD display with top layer of SAN (Styrene-Acrylonitrile-Copolymere)
Measurement tip:	Stainless steel AISI 304 with part of Nickel (8.54%)
On/Off button:	TPE (Thermoplastic Elastomere)
Protective cover:	SAN (Styrene-Acrylonitrile-Copolymere), transparent

5. Product Requirements:

Type:	Clinical digital maximum thermometer
Operating mode:	Direct measuring mode (non-extrapolating)
Device dimensions:	approx. 131 x 22 x 13 mm (L x W x H)
Device weight:	approx. 15g (incl. battery)
Measurement range:	32.0 °C - 43.9 °C
Measurement accuracy:	± 0.1 °C (for the entire measurement range)
Display:	3-digit LCD display
Temperature scale:	degree Celsius (°C)
Digital increment:	0.1 °C
Operating conditions:	+10 °C to +45 °C, 15 to 95 % rel. hum., non-condensing
Storage/transport conditions:	-25 °C to +55 °C, 15 to 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 > 43.9°C
Protection against harmful ingress of water or solid materials:	IP 67 (waterproof)
Measuring time:	typically 10-15 sec. at rectal measurement
Fever alarm:	no fever alarm
Memory:	1 memory: display of last measured value
Automatic switch off:	after approx. 7 minutes

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Battery type:	1.5 V or 1.55 V alkaline-manganese button cell (LR41)
Battery capacity:	approx. 4,000 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
(Technical modification subject to change)	

Thermoval rapid® 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.:

14	26
year	week of production

example: LOT 1426

7. Packaging:

One Thermoval rapid® (incl. transparent protective cover) 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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