

Thermoval baby®



Spec.-No.: D 9.1511

Department: CMO-PPD

Date: 2015-12-08

1. General Product Description:

Thermoval baby® is an electronic fever thermometer for self-measurement of body temperature, which uses infrared technology. The device features "3 in 1" measurement functionality and detects the human body temperature on the forehead, the surface temperature of an object as well as the ambient room temperature. All measurements can be performed without contact.

Thermoval baby® operates in two modes: Forehead mode with a measuring range of 34.0 °C to 42.2 °C and object mode with the extended measuring range of 0 °C to 100 °C. Thus, in addition to measuring the body temperature (forehead mode), the surface temperature such as the temperature of baby bottles or the room temperature can be measured in object mode.

The ergonomically shaped product is equipped with a large, easy to read and illuminated, two-colored LCD display, on/off button, scan button and a comfortable to open battery cover. The measurement head contains the non-contact infrared sensor as well as the blue positioning light aside, which also indicates the measurement duration.

The LCD displays the temperature in °C and the symbols for body mode, object mode, memory, memory number and battery status.

The device features intuitive operation for fever/object/ambient measurement, guidance for the measurement scan and the distance via a blue positioning light pattern, automatic display of the last value measured, optical fever alarm, automatic switch-off and memory function with capacity for a total of 10 readings.

Changing between forehead and object mode can be performed by sliding the mode switch on the side of the device. The last 10 measured values can be called up by pressing the scan button.

The device can be switched on by pressing the on/off button and after the LCD display check the flashing of the "°C" symbol indicates when the thermometer is ready for temperature measurement. The temperature scan of the forehead or object takes 3 seconds. At a forehead temperature of 37.6 °C or higher the LCD display will light up red as a fever alarm.

Thermoval baby® is battery-operated (type: AAA/LR03).

Cleaning and disinfection of the housing is also possible with a slightly moistened cloth with water and a mild detergent or a suitable disinfectant (e.g. 70 % Isopropyl alcohol).

Thermoval baby® 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.: 14-036

2. Application / Indication:

For non-contact, external measurement of human body temperature at the forehead.
(In separate non-clinical mode also measurement of object surface or room temperature possible.)

3. Presentations:

Each infrared fever thermometer device includes installed batteries and is packed inside a folding box made of cardboard. The folding box also contains a storage box and the instruction manual leaflet.
4 products/folding boxes are packed in one master carton.

The product is available in four different language circles:

| Article-No.: | Languages: | Packaging: |
|--------------|------------------------|------------|
| 925091 | DE, FR, IT, NL, HU, GB | P1, OK4 |
| 925092 | ES, PT, GR, AE, GB, FR | P1, OK4 |
| 925093 | RU, PL, CZ, SK, RO, GB | P1, OK4 |
| 925094 | SI, HR, TR, BG, HK, GB | P1, OK4 |

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

4. Product Materials:

| | |
|-------------------|--|
| - Housing body | ABS (Acrylonitrile - Butadiene – Styrene), white |
| - Housing probe | ABS, blue |
| - Battery cover | ABS, blue |
| - O/I button | TPE (Thermoplastic Elastomer, TPR: Thermoplastic Rubber) |
| - SCAN / M button | TPE |
| - Display panel | PMMA (Polymethylmethacrylate) |
| - Slide button | ABS, white |
| - Storage case | PP (Polypropylene) |

5. Product Characteristics:

| | |
|---|---|
| Type: | clinical non-contact infrared thermometer |
| Measurement: | scanning |
| Scan duration / measurement time: | 3 sec. |
| Measuring distance: | 3 – 5 cm |
| Device dimensions: | approx. 140 mm (L) x 39 mm (W) x 35 mm (H) |
| Device weight: | approx. 56g (w/o batteries) |
| Measurement range: | Forehead mode: 34.0 °C – 42.2 °C Object mode: 0 °C – 100 °C |
| Technical measurement accuracy forehead mode: | ±0.2 °C at 35.0 °C – 42.0 °C ±0.3 °C at 34.0 °C – 34.9 °C and 42.1 °C – 42.2 °C |
| Technical measuring accuracy object mode: | ±1.0 °C at 0 °C – 100 °C |
| Operating mode: | Clinical thermometer in adjusted mode (oral reference) |
| Display: | 4-digit LCD display, plus special symbols |
| Temperature scale: | degree Celsius (°C) |
| Digital increment: | 0.1 °C |
| Operating conditions: | Forehead mode: ambient temperature: +15 °C to + 40 °C Object mode: ambient temperature: +5 °C to + 40 °C relative humidity: 15 % to 95 %, non-condensing |
| Storage/transport conditions: | ambient temperature: -25 °C to + 55 °C relative humidity: 15 % to 95 %, non-condensing |
| Protection against harmful ingress of water or solid materials: | IP 21 (not moisture proof) |
| Fever alarm: | red optical signal/background light at temperatures ≥37.6 °C |
| Acoustic signal: | no acoustic signal |
| Memory capacity: | 10 measured values |
| Automatic switch off: | approx. 1 minute after end of measurement |
| Battery type: | 2 x 1.5 V alkaline-manganese (AAA/LR03) |
| Battery life: | at least 1000 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)

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Thermoval baby® is compliant, among others, with the requirements of the following standards: DIN EN ISO 80601-2-56, DIN EN 60601-1, DIN EN 60601-1-2 and the relevant requirements of DIN EN 12470-5.

6. Labelling:

Serial number:

Each device is labeled with a serial number (SN) inside the battery compartment.
 Contents of the serial number with 12-digit code:

e.g.:

| | | |
|------|--------------------|----------------------------|
| 2015 | 21 | 012345 |
| year | week of production | production unit (6 digits) |

example: SN 2015-21-012345

Packaging batch:

The folding box and all other cartons are labeled with a 4-digit LOT code.
 Contents of the LOT-number:

e.g.:

| | |
|------|--------------------|
| 15 | 21 |
| year | week of production |

example: LOT 1521

7. Packaging:

One Thermoval baby® (incl. storage box) is packed in a single unit folding box. 4 pcs of folding boxes are packed in a master carton, 4 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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PAUL HARTMANN AG
 Product Development Personal Health Care