

## Thermoval duo scan



Techn. Data **D 9.1510**  
 Sheet No.:  
 Department: **SM-PDP**  
 Date: 3.3.2011

### CHANGE PROTOCOL

Page /Edition	replaces Page/Edition	Reason for Change
1-2 from 3.03.2011	-----	New Technical Data Sheet

Department	Date	Signature
Product Development SM-PDP	3.3.2011	<i>Wolfgang Schmidt</i>

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### 1. General Product Description

Thermoval duo scan is an electronic dual-mode infrared thermometer for self-measurement of human body temperature. The device is usable for ear measurement and forehead measurement. For forehead measurement the forehead cap is removable. The thermometer has a large digital display. The temperature in °C, battery sign; automatic switch-off function; memory function; replaceable long-life batteries operated. An acoustic signal indicates when the thermometer is ready for operation and when measurement is completed. The tip of the thermometer contains a capacitive sensor to detect the condition of insertion into the ear. The device can be switched on by pressing the O/I button. After flashing the °C symbol the SCAN button can be pressed to start a measurement.

For the cleaning of the measurement tip it is recommended to perform a wipe cleaning by applying a disinfectant (e.g. 70% ethyl alcohol) with a damp cloth, eg. Soft Zellin.

The housing colour of the rigid part is white and the battery cap and on/off switch is blue. The forehead cap is blue.

\* Thermoval duo scan measures the body temperature in following time:

- Ear Mode: 1 sec
- Forehead Mode: 3 sec

These measurement times are average experience values in dependence of the correct placement of the measurement tip and of individual conditions.

Thermoval duo scan is a class IIa active medical device according to the Medical Device Directive EEC 93/42 and will be delivered with the CE-mark.

### 2. Application / Indication

For ear and forehead measurement of human body temperature.

### 3. Product Materials


- |                  |  |
|------------------|--|
| - housing        | ABS(707) (Acrylonitrile-Butadiene-Styrene) |
| - battery cap    | ABS(707) (Acrylonitrile-Butadiene-Styrene) |
| - forehead cap   | ABS(758) + TPR                             |
| - display panel: | PMMA                                       |
| - storing case:  | PP   |
| - I / O button:  | TPE (Thermoplastic Elastomere)             |
| - scan button:   | TPE (Thermoplastic Elastomere)             |

## Thermoval duo scan

### 4. Packaging materials

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.

### 5. Product Requirements

dimensions:	Approx. 150 x 3,5 x 3 cm Tip bended
measuring range:	32,0 °C – 42,2 °C
Measuring accuracy (ear mode)	±0.2°C at 35.5°C ~ 42.0°C ±0.3°C at 32.0°C ~ 35.4°C and 42.1°C ~ 42.2°C
Measuring accuracy (forehead mode)	±0.2°C at 35.5°C ~ 42.0°C ±0.3°C at 34.0°C ~ 35.4°C and 42.1~ 42.2°C
Display	Liquid Crystal Display (LCD) with blue backlight
	LED lit bar over START button, light is on during the whole measuring process
operating condition	10°C to 45°C; 15% to 95% R.H.
storage / transportation condition	-25°C to 55°C; 15% to 95 % R.H.
Display indication	-Symbols: memory, battery sign, blinking °C, L and H -Ear and forehead, ready sign
Memory display time	max.3 [min]
°C mark flashing time	1 [sec]
Digital increment	0,1 [°C] in full range of 32,0 °C– 42,2 °C
Control / Auto detection of measuring place	Capacitive technology, to detect human skin touching the measurement tip ( Ear mode). Non touching the sensor tip ( Forehead mode)
Out-of-range indication	IR mode :Displays “L” when measured Temperature is lower than 32.0° C and “H” when higher than 42.2 °C FR mode: Display “L” when measured temp. is lower than 34.0° C and “H” when higher than 42.2° C
Memory function	• One set memory: The unit displays the last reading automatically for 2 seconds when the unit is switched ON.
Auto off function	Around 60 seconds after the last measurement is completed.
Temperature Scale	°C fixed
Self-test function	Displays "Err" when system malfunctions
Battery sign detection	“  ” Displays when the battery is low. The unit will not work until the battery is replaced
Battery life	Minimum 1.000 measurements

Thermoval duo scan conforms to the requirements of EN 12470-5, EN 60601-1, EN 60601-1-2, and EN 1441. Additional vertical and horizontal standards (national and international) may apply.

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### 6. Serial number

The serial number is printed on a sticker which is fixed inside the battery compartment.

Contents of the serial number SN:

2011	22	000001
year	week of manufacture	production unit (6 digits)

example: SN2011-22 - 000001

### 7. Labelling

Lot-No. with 4-digit code:

Contents of the LOT-number:

2011	22
Year	week of production

example: LOT 1122

### 8. Packaging

Thermoval duo scan is packed with a transparent hard case in a single unit box. 4 pcs of single unit box are packed into a master carton. The master cartons are sealed with an HARTMANN-tape and packed on an Euro pallet.

3. March 2011

A handwritten signature in black ink, appearing to read "Nico Schmidt".

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- Development Department SM-PDP