

Veroval® DS 22

Dual Mode infrared fever thermometer



Spec.-No.: D9.1760
Department: COH-PPD
Date: 2018-09-13

1. General Product Description

The Veroval® DS22 is an electronic fever thermometer using infrared technology for self-measurement of human body temperature. The device features "2 in 1" measurement functionality and detects the human body temperature on the forehead and in the ear with a measuring range of 34 °C – 43 °C.

The thermometer offers a fast and accurate measurement of body temperature in a smooth way.

For forehead measurements the blue colored and removable forehead-cap is used.

By using the included single-use protective covers a hygienic ear measurement can be achieved as the risk of cross-contamination or infections by transmission of bacteria or viruses is minimized.

The measurement tip contains a non-contact infrared sensor as well as a tactile sensor to detect if the protective cover is attached.

Veroval® DS 22 is ideally suited for children from 6 months, but can also be used for adults.

The device can be switched on by pressing the SCAN/Ø button. An acoustic signal indicates when the infrared thermometer is ready for operation. The mode switch on the side shows the selected measurement mode.

By pressing the SCAN/Ø button again, the device starts the measurement.

The temperature scan inside the ear takes only 1 second.

For a forehead measurement the SCAN/Ø button is pressed and held while scanning slowly from the left to the right temple in a recommended time of approx. 5 seconds.

The device is turned off by pressing the SCAN/Ø button for 10 seconds.

The M-button shows the last 10 measured values in the memory, the S-button de-/activates the buzzer.

The Veroval® DS 22 features a hygienic fever measurement by using disposable protective caps, a large and easy to read display with backlight, degree Celsius as unit, a mode switch for ear or forehead, automatic protective cover detection, error indication in case of application or device errors, memory function with capacity for a total of 10 readings including date and time, no touch protective cover ejection, deactivatable buzzer (silent mode), optical fever alarm (green / red indication light), automatic switch-off function, and replaceable long-life batteries.

Large, easy-to-read LCD display with symbols for measurement mode (ear / forehead), protective cover, date & time, temperature value, Celsius sign °C, memory with memory number, buzzer symbol, and weak battery status. Setting of date and time can be made by appropriate operation of the SCAN buttons after inserting the batteries.

As a result of measurement, the temperature value to one decimal place, the measurement mode and the date and time are displayed on the LCD screen. The optical fever alarm shows green light indicating normal body temperature (< 37,6 °C) or red light indicating increased temperature or fever (≥ 37,6 °C).

For the cleaning of the measurement tip or the housing, it is recommended to use a slightly moistened cloth with water and a mild detergent or a suitable disinfectant (e.g. 70 % Isopropyl alcohol).

The Veroval® DS22 is battery-operated (2x size: AAA/LR03).

The product is delivered together with a practical storage box and 10 disposable protective covers.

Veroval® DS22 thermometer is a class IIa 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

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2. Application / Indication

For ear and forehead measurement of human body temperature.
For clinical and home use.

3. Presentations

Each Veroval® DS fever thermometer (with batteries) is separately packed in a gift box made of cardboard. The gift box also contains an instruction manual which includes a warranty card, a practical plastic hardbox for storage of the device and 10 single-use protective covers.
4 pieces/gift boxes are packed in one master carton.

The product is available in 5 different language circles:

Article-No.:	Languages:	Packaging:
925461	DE, NL, FR, IT	P1, OK4
925462	FR, ES, PT, AR	P1, OK4
925463	CZ, SK, HR, SI	P1, OK4
925464	RO, GR	P1, OK4
925465	PL, HU, BG	P1, OK4
925466	EN, TR, HK, AR	P1, OK4

4. Conformity

The Veroval® DS22 fever thermometer complies amongst others with the requirements of the following standards/protocols:

DIN EN ISO 80601-2-56	"Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement"
DIN EN IEC 60601-1	"Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
DIN EN 60601-1-2	"Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests"

5. Product Materials

Housing body & cap	ABS (Acrylonitrile - Butadiene – Styrene)
Measuring probe	ABS (Acrylonitrile - Butadiene – Styrene)
Buttons & mode switch	ABS (Acrylonitrile - Butadiene – Styrene)
Display lens	PMMA (Polymethylmethacrylate)
Protective covers	PE (Polyethylene)
Storage box	PP (Polypropylen)

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6. Packaging Materials

All packing materials and packing components are 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.

7. Product Characteristics

Model:	Veroval® DS 22
Type:	DS 22
Measuring method:	Infrared technology
Measuring unit:	°Celsius (°C)
Measuring range:	34 °C – 43 °C (ear and forehead mode)
Display resolution:	0,1°C in full range of 34 °C – 43 °C
Technical measuring accuracy:	Ear mode: ±0,2 °C (inside range 35,5 °C – 42 °C; outside range: ±0,3 °C) Forehead mode: ±0,3 °C (inside range 35 °C – 42 °C)
Measuring time:	1 second (or scan duration of forehead measurement)
Time between 2 measurements:	minimum 5 seconds
Display:	LCD liquid crystal display with blue backlight
Display symbols/-functions:	measurement mode (ear / forehead), protective cover detection sign, date & time, temperature value, Celsius sign °C, memory with memory number, buzzer/sound sign, low battery indicator
Optical fever alarm:	red indication light: ≥ 37,6 °C green indication light: < 37,6 °C
Memory:	displays the last reading automatically
Memory capacity:	10 measurements with date and time
Out of range indicator:	displays "Hi" for temperatures >43°C; "Lo" for temperatures <34°C
Protective cover indicator:	displays "P" symbol when a protective cover is detected
Error indication:	"Er1", "Er2", "Er3" when malfunction of device or application error; CAP: protective cover detection is active while forehead mode is selected
Operating conditions:	Ambient temperature: + 10 °C to + 40 °C; Relative humidity: 15 - 85 %; non-condensing; air pressure 700 hPa – 1050 hPa
Storage / transport conditions:	Ambient temperature: - 25 °C to +55°C; Relative humidity: 15 – 95 %; non-condensing;
Protection against harmful ingress of water or solid materials:	IP22 (not protected against moisture)
Power supply:	2 x 1.5 V (AAA/LR03) batteries
Battery capacity:	approx. 1000 measurements
Expected service life:	10.000 measurements
Automatic switch-off:	approx. 1 minute
Size:	approx. 155 mm (L) 42 mm (W) x 35 mm (H)
Weight:	approx. 60 g (without batteries)
Protective cover:	Veroval® PC 22 (certified protective covers for Veroval® DS 22 only)
Serial number:	see rating label

(Technical modification subject to change)

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8. Labelling

Serial number:

Each device is labeled with a serial number (SN) on the rating label.

Contents of the serial number with 12-digit code:

e.g.:

2018
year

01
week of production

012345
production unit (6 digits)

Packaging batch:

The gift box and all other cartons are labeled with a 4-digit LOT code.

Contents of the LOT-number:

e.g.:

18
year

01
week of production

9. Packaging

One Veroval® DS22 (incl. accessories) is packed in a gift box (folding box) and 4 pieces are packed in a master carton. All cartons are sealed with special HARTMANN adhesive tapes and packed onto europallet.

Date: 2018-09-13

A handwritten signature in blue ink, appearing to read "M. Völz".

PAUL HARTMANN AG
Product Development Personal Health Care