

## Veroval wrist blood pressure monitor



Spec.-No.: D9.1721  
Department: COH-PPD  
Date: 13.09.2018

### 1. General Product Description

Veroval wrist blood pressure monitor is a fully automatic digital blood pressure monitor for the wrist based on oscillometric measurement technology. The measurement is performed during deflation of the cuff at which inflation and deflation is automatically conducted by a pump and a linear valve. The inflation pressure depends on the systolic value (Comfort Air Technology) and is adjusted individually based on previously measured blood pressure values, except for the first measurement which requires an inflation to 190 mmHg. As a result of measurement the systolic and diastolic blood pressure values as well as the pulse rate are displayed on the large LCD screen.

The device features one-button operation for measurement, automatic switch-off, irregular heartbeat (IHB), position check indication (for correct positioning at heart level) and memory function with capacity for a total of 100 readings each for two users including date and time. In addition, the mean values for a) all memory readings, b) for morning readings and c) for evening readings of the last 7 days each are calculated and displayed separately for each user. Date and time are also automatically stored together with each blood pressure measurement and clearly indicated.

Large, easy to read LCD display with further symbols for date & time, start of inflation, pulse (heartbeat), IHB, memory with memory number, user number, mean values, WHO classification and weak battery status. With memory delete function separately for each user.

Setting of date and time can be made by appropriate operation of the Start/Stop & Memory buttons after inserting the batteries.

The position check indicator, for the right positioning of the monitor at heart level, and the design of the device allow simple handling and operation as well as convenient reading off the blood pressure results. The type and illustrated imprint of the universal wrist cuff of the Veroval wrist blood pressure monitor facilitates simple application and correct positioning at the wrist. The universal cuff allows a comfortable adjustment for all wrist sizes within the peripheral range of 12.5-21.0 cm and has an additional marker bar for correct adjustment of the cuff. The velcro fastener is also comfortable to open.

The Veroval wrist blood pressure monitor is battery-operated (2x size: AAA/LR03). The blood pressure monitor can be connected to a PC via USB cable, so the measured values can be transferred on PC using the "Veroval medi.connect" software.

Cleaning of the product is possible with a slightly moistened cloth with water and a mild detergent.

Veroval wrist blood pressure monitor 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.: 16-173

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### 2. Application / Indication

For external measurement of human blood pressure at the wrist of adult persons.  
For clinical and home use.

### 3. Presentations

Each Veroval wrist blood pressure monitor 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 monitor, USB cable and batteries.  
4 pieces/gift boxes are packed in one transport carton.

The product is available in 6 different language circles:

Article-No.:	Languages:	Packaging:
925321	DE, IT, FR	P1, OK4
925322	FR, AE, NL, DE	P1, OK4
925323	ES, PT, GB	P1, OK4
925324	CZ, SK, HU, BG	P1, OK4
925325	RU, RO, GR	P1, OK4
925326	PL, SI, HR, RS	P1, OK4
925327	EN, TR, HK, AR	P1, OK4

### 4. Conformity

The Veroval wrist blood pressure monitor complies amongst others with the requirements of the following standards/protocols:

DIN EN IEC 60601-1	"Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
DIN EN IEC 60601-1-2	"Medical electrical equipment - Part 1-2: Collateral standard: Electro-magnetic disturbances - Requirements and tests"
DIN EN 1060-3	"Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems"
DIN EN IEC 80601-2-30	"Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers"
DIN EN ISO 81060-1	"Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type"
DIN EN ISO 81060-2	"Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type"
ESH-IP2 protocol	Validation of clinical accuracy according to the International Protocol (rev. 2010) of the European Society of Hypertension

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### 5. Product Materials

LCD display panel	PC (Polycarbonate)
Start/Stop, M1, M2 buttons	PC (Polycarbonate)
Monitor housing	ABS (Acrylonitrile - Butadiene – Styrene)
Cuff outer material	PES (Polyester)
Cuff velcro fastener	Blended plastic
Cuff bladder	PVC (Polyvinylchloride)
Cuff metal clip	Nickel-plated steel
Storage box	PP (Polypropylen)

### 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

Measuring method:	oscillometric
Display range:	0 – 300 mmHg
Display resolution:	1 mmHg
Measuring range:	
Systole (SYS):	50 – 280 mmHg
Diastole (DIA):	30 – 200 mmHg
Pulse:	40 – 199 min <sup>-1</sup>
Technical measuring accuracy:	Cuff pressure: ± 3 mmHg Pulse: ± 5 % of displayed pulse rate
Inflation pressure:	approx. to 190 mmHg (for the first measurement)
Deflation rate	2 – 8 mmHg/sec
Pressure release valve:	Linear valve
Display:	LCD liquid crystal display
Display symbols/ -functions:	Sys/Dia/Pulse single readings & mean values, irregular heartbeat symbol (IHB), traffic light function (WHO classification of values with coloured scale), position check indicator, heartbeat symbol, memory number, memory „M1/M2“, date / time, low battery indicator
Memory capacity:	2 x 100 measurements with average of all measurements and morning / evening average of the last 7 days
Operating conditions:	Ambient temperature: + 10 °C to + 40 °C; Relative humidity: 0 - 85 %; non-condensing; air pressure 800 hPa – 1050 hPa
Storage / transport conditions:	Ambient temperature: -20 °C to +50 °C; Relative humidity: 0 - 85 %; non-condensing;
Protection against harmful ingress of water or solid materials:	IP22 (not protected against moisture)
Power supply:	2 x 1,5 V Mignon alkaline-manganese (AAA/LR03) batteries

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Battery capacity:	approx. 1000 measurements
Automatic switch-off:	1 minute after end of measurement; 10 seconds after end of PC connection, otherwise 30 seconds
Size:	approx. 72 mm (L) x 100 mm (W) x 24 mm (H)
Weight:	approx. 143 g (without batteries)
Universal cuff	for wrist circumferences of 12.5 – 21.0 cm

(Technical modification subject to change)

### 8. Labeling

#### 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.:

2017  
year

03  
week of production

012345  
production unit (6 digits)

#### Packaging batch:

The gift box and all other transport cartons are labeled with.

Contents of the LOT-number:

e.g.:

17  
year

03  
week of production

### 9. Packaging

One Veroval wrist blood pressure monitor (incl. cuff and accessories) is packed in a gift box (folding box) and 4 pieces are packed in a master/transport carton. The transport cartons are sealed with special HARTMANN adhesive tapes and packed onto europallet.

Date: 2018-09-13



PAUL HARTMANN AG  
Product Development Personal Health Care