

Veroval® compact BPU 22 upper arm blood pressure monitor



Spec.-No.: D9.1723
Department: COH-PPD
Date: 2018-09-13

1. General Product Description

The Veroval® compact BPU22 is a fully automatic digital blood pressure monitor for the upper arm 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 a large LCD screen.

The device features one-button operation for measurement, automatic switch-off, irregular heartbeat (IHB) detection, cuff-fitting check function 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 are clearly indicated.

Large, easy-to-read LCD display with symbols for date & time, pulse (heartbeat), IHB, memory with memory number, user number, mean values, WHO classification, cuff-fitting symbol 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 design of the device allows easy connection with the cuff hose, simple handling and operation as well as convenient reading off the blood pressure results.

The type and illustrated imprint of the universal upper arm cuff facilitates simple application and correct positioning at the upper arm. The universal upper arm cuff allows a comfortable adjustment for all arm sizes within the extended peripheral range of 22-42cm and has an additional scale for defining individual arm size values. The Velcro fastener is also comfortable to open.

The Veroval® BPU22 is battery-operated (4x size: AA/LR06).

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

Veroval® BPU22 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

2. Application / Indication

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

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3. Presentations

Each Veroval[®] BPU22 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 bag for storage of the monitor, universal size cuff and batteries.

4 pieces/gift boxes are packed in one master carton.

1. Monitor with universal size draw-clamp cuff for 22-42 cm upper arm circumference:

(Only the above HARTMANN Veroval[®] BPU22 universal cuff shall be used for the monitor, otherwise measuring accuracy is not guaranteed.)

The product is available in 4 different language circles:

Article-No.:	Languages:	Packaging:
925421	DE, IT, HU	P1, OK4
925422	FR, PT, AR	P1, OK4
925423	CZ, SK, SI, HR	P1, OK4
925424	RO, PL, BG, GR	P1, OK4
925425	EN, TR, HK, AR	P1, OK4

4. Conformity

The Veroval[®] BPU22 upper arm 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
DHL protocol	Validation of clinical accuracy according to the Protocol of the German Hypertension League

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5. Product Materials

Lens foil	PC foil (Polycarbonate)
Monitor housing	ABS (Acrylonitrile – Butadiene - Styrene)
Cuff outer material	PES (Polyester)
Cuff velcro fastener	Nylon + PES (Polyester)
Cuff bladder	PVC (Polyvinylchloride)
Cuff tube	Silicone
Cuff metal ring	Low carbon steel
Storage bag	Nylon

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® BPU 22
Type:	GCE 606
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 ⁻¹
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), cuff-fitting check symbol, 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 - 90 %; non-condensing; air pressure 800 hPa – 1050 hPa
Storage / transport conditions:	Ambient temperature: -20 °C to +55°C; Relative humidity: 0 - 90 %; non-condensing;
Protection against harmful ingress of water or solid materials:	IP21 (not protected against moisture)

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Power supply:	4 x 1.5 V Mignon alkaline-manganese (AA/LR6) batteries
Battery capacity:	approx. 1000 measurements
Expected service life:	20.000 measurements
Automatic switch-off:	1 minute after end of measurement; otherwise 30 seconds
Size:	approx. 134 mm (L) x 48 mm (W) x 91 mm (H)
Weight:	approx. 220 g (without batteries / without cuff)
Universal cuff:	for upper arm circumferences of 22 – 42 cm
Serial number:	see battery compartment

(Technical modification subject to change)

8. 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.:

2018	01	012345
year	week of production	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	01
year	week of production

9. Packaging

One Veroval[®] BPU22 (incl. universal size cuff and 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.

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PAUL HARTMANN AG
Product Development Personal Health Care