

## Veroval® duo control DC3-18



Spec.-No.: D9.1710  
Department: COH-PPD  
Date: 23.07.2018

### 1. General Product Description

Veroval duo control is a fully automatic digital blood pressure monitor for the upper arm based on combined auscultatory ('Korotkoff') and oscillometric measurement (Duo Sensor Technology®).

The inflation adjusts automatically to the patient's individual systolic blood pressure by fuzzy logic inflation (Comfort Air Technology®) and provides a more comfortable measurement. Deflation is also automatically done. The cuff pressure is released by an electronic valve at pulse synchronized deflation speed. Systolic, diastolic blood pressure and pulse rate are displayed as well as measurement progress on the LCD display.

The device features an automatically switch-off, irregular heartbeat (IHB), cuff-fitting check function, rest indicator, display of irregular ambient temperatures and memory function with capacity for a total of 100 readings each for two users including date and time and guest mode. 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 displayed alternately.

Large, simple to read LCD display including backlight with further symbols for date & time, pulse (heartbeat), Duo Sensor Technology, IHB, memory with memory number, user number, mean values, WHO traffic light system for the analysis of measured values, cuff-fitting symbol, rest indicator, OK-symbol, indication of too high or too low ambient temperature and low battery indicator. With memory delete function separately for each user and for single memory data.

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

The device is easy to use. The pull-up system of patented Secure-Fit cuff makes application easier and safer. Lower arm opening for correct and secure fit. The special section with ear-like shaped contour opposite the strap is for better fit to the bend of the elbow as well as for compliance with the required distance at the elbow. The cuff is available in different sizes for different upper arm circumferences.

The Veroval duo control monitor is battery-operated (4x size: AA/LR06) or optionally by supplementary HARTMANN mains adapter. 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.

Veroval duo control 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

The Veroval duo control is a re-usable, non-invasive fully automatic blood pressure monitor for the upper arm that is intended for temporary monitoring of the systolic and diastolic blood pressure and the pulse rate of adults and which can be used by laypersons and healthcare professionals in clinical and domestic settings.

### 3. Presentations

Each blood pressure monitor with upper arm cuff is stored inside a softcase and packed inside a gift box made of cardboard.

The gift box also contains an instruction manual which includes a warranty card, USB cable and batteries for the monitor, packed in a translucent plastic film.

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

The product is available with two different cuff sizes:

1. Monitor with normal/standard size (M-size) fan-shaped cuff \*)
2. Monitor with large size (L-size) fan-shaped cuff \*\*).

The Veroval duo control monitor is identical for all different sizes and types of Veroval duo control cuffs which can be exchanged in order to fit different arm sizes of the user.

Two different cuff-sizes are available with the following configuration:

	upper arm circumference
▶ Normal (M) size with preformed cuff	22 – 32 cm
▶ *) Normal (M) size with fan-shaped cuff	22 – 32 cm
▶ **) Large (L) size with fan-shaped cuff	32 – 42 cm

(Only the above HARTMANN Veroval duo control cuffs shall be used for the monitor, otherwise measuring accuracy is not guaranteed.)

Cuff products are individually sealed in film bags and packed in a folding box made of cardboard.

The product is available in 6 different language circles:

Article-No.:	Size of cuff included	Languages:	Packaging:
925501	M	DE, IT, FR	P1, OK4
925521	L		
925502	M	FR, AR, NL, DE	P1, OK4
925522	L		
925503	M	ES, PT	P1, OK4
925523	L		
925504	M	CZ, SK, HU, BG	P1, OK4
925524	L		
925505	M	RU, RO, PL, GR	P1, OK4
925525	L		
925506	M	EN, TR, AR, CN	P1, OK4
925526	L		

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### 4. Conformity

The Veroval duo control 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 IEC 60601-1-11	“Medical electrical equipment - Part 1-11: Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
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 81060-2	“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
BHS protocol	Validation of clinical accuracy according to the clinical protocol of the British Hypertension Society
DHL Prüfsiegelprotokoll	Validation of clinical accuracy according to the protocol of the German Hypertension League (Deutsche Hochdruckliga e.V.)

### 5. Product Materials

LCD display panel	PMMA (Polymethylmethacrylate)
Start/Stop, M1, M2 buttons	PMMA (Polymethylmethacrylate)
Monitor housing	ABS (Acrylonitrile – Butadiene - Styrene)
Cuff outer material	PA (Polyamide)
Cuff velcro fastener	PA (Polyamide)
Cuff bladder	PVC (Polyvinylchloride)
Cuff tube	PVC (Polyvinylchloride)
Cuff metal ring	Steel & Chrome plating
Storage bag	Polyester (Polyurethane coated)

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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

Measuring method:	oscillometric and auscultatory (Korotkoff principle)
Display range:	0 – 300 mmHg
Display resolution:	1 mmHg
Measuring range:	
Systole (SYS):	50 – 250 mmHg
Diastole (DIA):	40 – 180 mmHg
Pulse:	30 – 199 min <sup>-1</sup>
Technical measuring accuracy:	Cuff pressure: ± 3 mmHg Pulse: ± 5 % of displayed pulse rate
Inflation pressure:	individually according to Fuzzy Logic inflation principle (typically SYS value +30mmHg)
Pressure release valve:	electronically controlled 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, body rest indicator, measurement OK-symbol, ambient temperature limit indication, memory number, memory „M1/M2“, date / time, low battery indicator, inflation/deflation progress bar indicator, heartbeat symbol, Duo Sensor Technology® symbol
Memory capacity:	2 x 100 measurements with average of all measurements and morning / evening average of the last 7 days, plus guest mode
Operating conditions:	Ambient temperature: +10 °C to +40 °C; Relative humidity: 15 - 85 %; non-condensing; air pressure 700 hPa – 1060 hPa
Storage / transport conditions:	Ambient temperature: -20 °C to +50°C; Relative humidity: 15 – 85 %; non-condensing;
Protection against harmful ingress of water or solid materials:	IP20 (not protected against liquids)
Power supply:	4 x 1.5 V Mignon alkaline-manganese (AA/LR06) batteries or optional HARTMANN Veroval mains adapter
Battery capacity:	approx. 950 measurements
Automatic switch-off:	3 minutes (after measurement or if not operated otherwise)
Size:	approx. 158 mm (W) x 90 mm (L) x 53 mm (H)
Weight:	approx. 325 g (without batteries / without cuff)

(Technical modification subject to change)

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### 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.:

2018	03	012345
year	week of production	production unit (6 digits)

#### Packaging batch:

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

Contents of the LOT-number:

e.g.:

18	03
year	week of production

### 9. Packaging

One Veroval duo control 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.

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Product Development Personal Health Care