

Veroval ECG and blood pressure monitor



Spec.-No.: D9.1722

Department: CMO-PPD

Date: 24.04.2017

1. General Product Description

Veroval ECG and blood pressure monitor is a fully automatic digital blood pressure monitor for the upper arm based on oscillometric measurement technology and a handheld electrocardiograph to measure the electrical activity of the heart using a one-lead ECG signal with three electrodes placed on the product housing. The blood pressure measurement is performed during deflation of the cuff at which inflation and deflation is automatically conducted by a pump and a 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.

With the ECG function it is possible to perform a recording of the electrical heart activity of the user with a duration of 30s each. It detects atrial fibrillation and extrasystoles, an early indication of circulatory disorders and myocardial inflammation. Directly after the recording it provides the average pulse value as well as the automatic classification of the ECG with following symbols: ok, slow, fast, pause, rhythm, wave.

The device features one-button operation for ECG or blood pressure (BP) measurement, automatic switch-off, acoustic alarm reminder for measurement and memory function with capacity of 128 readings (64 each for two users) including date and time and memory delete function separately for each user. Setting of date and time can be made by appropriate operation of the Setting- & Memory button after inserting the batteries or after pressing the Setting button for 5 seconds.

The large and easy to read LCD displays symbols for measurement mode (ECG or BP), pulse (heartbeat), classification of blood pressure values according to the WHO, ECG results, Bluetooth status, data transfer signal, alarm indicator, ECG 30s countdown, stored values, memory/user number and low battery indicator. 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 and ECG results.

The ergonomic shape of the universal upper arm cuff allows an easy handling and correct positioning on the upper arm. The upper arm cuff is easy to fit to all arm sizes and shapes within the given range. With additional strap to pull the cuff over the upper arm and scale for defining individual arm size values. The special section with ear-like shaped contour opposite the strap is for optimum fit to the bend of the elbow as well as for compliance with the required distance at the elbow.

The type and illustrated imprint of the upper arm cuff facilitates simple application and correct positioning at the upper arm. The cuff allows a comfortable adjustment for arm circumferences of 22 – 42 cm and the velcro fastener is also comfortable to open.

The Veroval ECG and blood pressure monitor is only battery-operated (4x size: AAA/LR03). The monitor can be connected to a PC using the included Bluetooth USB-Dongle/Adapter, so the measured values for blood pressure, pulse and ECG including the recorded ECG waveform 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 ECG and blood pressure monitor is a medical device 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 & 11413

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2. Application / Indication

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

3. Presentations

Each Veroval ECG and blood pressure monitor and each upper arm cuff is separately packed inside a plastic bag. The monitor and cuff each are then packed inside a gift box made of cardboard together with the instruction manual, which includes a warranty card, the USB Bluetooth adapter, the batteries and a storage bag. 4 products/gift boxes are packed in one transport carton.

The product is available with one cuff size:

1. Monitor with universal draw-clamp cuff (size: M + L): for 22-42 cm upper arm circumference

(Only the above HARTMANN Veroval ECG and blood pressure universal cuff shall be used for the monitor, otherwise measuring accuracy is not guaranteed.)

The product is available in 12 different language circles:

Article-No.:	Languages:	Packaging:
925341	DE	P1, OK4
925342	DE, FR, IT	P1, OK4
925343	FR	P1, OK4
925344	FR, NL, DE	P1, OK4
925345	ES	P1, OK4
925346	PT, GB	P1, OK4
925347	CZ, SK	P1, OK4
925348	HU, BG	P1, OK4
925349	RU	P1, OK4
925350	RO, GR	P1, OK4
925351	PL, SI	P1, OK4
925352	HK, SR	P1, OK4

4. Conformity

The Veroval ECG and 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"

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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”
DIN EN IEC 60601-2-25	“Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs”
DIN EN IEC 60601-2-47	“Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems”
ESH-IP2 protocol	Validation of clinical accuracy according to the International Protocol (rev. 2010) of the European Society of Hypertension

5. Product Materials

LCD display panel incl. touch buttons	PMMA (Polymethylmethacrylate)
Monitor housing	ABS (Acrylonitrile – Butadiene - Styrene)
Rubber feet	Silicone
Electrodes	Stainless steel
Cuff: outer material	PES (Polyester)
Cuff: velcro fastener	PA (Polyamide)
Cuff: bladder	PVC (Polyvinylchloride)
Cuff: tube	PVC (Polyvinylchloride)
Cuff: metal ring	Metal with chrome plate, rust proof
Storage bag	PU (Polyurethane)
USB Bluetooth Adapter housing	ABS

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 & one lead electrocardiogram
Display range:	0 – 300 mmHg
Display resolution:	1 mmHg
Measuring range:	
Systole (SYS):	60 – 280 mmHg
Diastole (DIA):	30 – 200 mmHg
Pulse:	30 – 180 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:	2-7 mmHg/s (from 160-100 mmHg) and 2-15 mmHg/s (below 100 mmHg)

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Pressure release valve:	linear valve
ECG bandwidth	0,05 – 40 Hz
ECG sampling rate	256 Hz
ECG heart rate detection	5 to 199 min ⁻¹
Display:	LCD liquid crystal display
Display symbols/ -functions:	Sys/Dia/Pulse single readings, traffic light function (WHO classification of values), BP/ECG symbol, heartbeat symbol, memory number, memory „M1/M2“, date / time, low battery indicator, ECG results (ok, slow, fast, pause, rhythm, wave), Bluetooth status, data transfer signal, alarm indicator, ECG 30s countdown
Memory capacity:	2 x 64 measurements (BP, pulse and/or ECG with date and time)
Operating conditions:	Ambient temperature: +10 °C to +40 °C; Relative humidity: 15 - 85%; non-condensing; air pressure 800 - 1050 hPa
Storage / transport conditions:	Ambient temperature: -20°C to +55°C; Relative humidity: 10 - 85%; non-condensing; air pressure 800 - 1050 hPa
Protection against harmful ingress of water or solid materials:	IP22 (not moisture-proof)
Power supply:	4 x 1.5 V Mignon alkaline-manganese (AAA/LR03) batteries
Battery capacity:	approx. 600 measurements (by one transmission per day)
Automatic switch-off:	30 s
Size:	approx. 141 mm (L) x 72 mm (W) x 28 mm (H)
Weight:	approx. 169 g (without batteries / without cuff)
Universal cuff	for upper arm circumferences of 22 – 42 cm
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USB Bluetooth Adapter	Full-Speed USB Interface / with USB Type A connector (Bluetooth 4.0 Single Mode BLE)
Operating conditions:	+10°C to +40°C; 15~85% RH; 700-1060 hPa
Storage / transport conditions:	-22°C to +55°C; 10~85% RH; 700-1060 hPa

(Technical modification subject to change)

8. Labeling

Serial number:

Each device is labelled with a serial number (SN) inside the battery compartment.

Contents of the serial number with 12-digit code:

e.g.:

2017	03	012345
year	week of production	production unit (6 digits)

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Packaging batch:

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

Contents of the LOT-number:

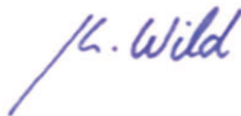
e.g.:

17	03
year	week of production

9. Packaging

One Veroval ECG and 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: 27.04.2017



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