Gebrauchsanleitung (DE-2 - DE-29) Instructions for use (EN-30 - EN-57) Mode d'emploi (FR-58 - FR-85) Istruzioni per l'uso (IT-86 - IT-113)



visomat® comfort 20/40





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Thank you for choosing the visomat® comfort 20/40 upper arm blood pressure monitor (also referred to in the following as the unit).

This unit is recommended to patients with unstable blood pressure for measuring their blood pressure at home and for therapy support.

Mode of operation:

visomat $^{\!\circ}$ comfort 20/40 uses the oscillometric method for measuring blood pressure and pulse rate on the upper arm.

The cuff is first placed as shown in the illustration on the cuff on the upper arm and then connected to the unit. When the Start/Stop button is pressed, the system starts to build up pressure automatically. Within a very short space of time the unit records the small oscillations within the cuff which occur owing to expansion and contraction of the arteries in the arm (heartbeat). The build-up of pressure stops after systole, diastole and pulse are established, after which the cuff is deflated. The amplitude of each pressure wave is measured in millimetres of mercury (mmHg), converted and displayed in the LCD as a digital value.

As well as indicating systole, diastole and pulse, the unit offers additional displays for determining irregular pulses and pulse pressure. Irregular pulses may be an indication of an irregular heartbeat but also of restlessness during the measurement. Pulse pressure provides an indication of the stretchability of the blood vessels. A memory stores the last 30 measurement results in each case.

Safety instructions

Safety instructions

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These instructions are intended to help the user to use the digital blood pressure monitor safely and efficiently manner and must be kept with the product and forwarded, if applicable.

The unit must be used in accordance with the procedures contained in these instructions and must not be used for other purposes. Please read these instructions carefully before using the unit.

1. Important patient instructions

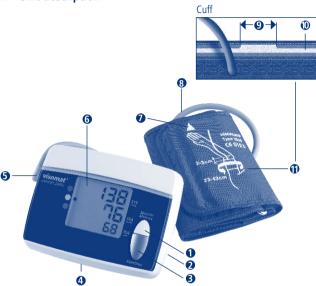
- The unit is designed for non-invasive measurement of the systolic and diastolic blood pressure on the upper arm, as well as measurement of the pulse rate of adults, i.e. 15 years of age and older. Blood pressure measurements on children require specialist knowledge! Please consult your doctor if you wish to measure the blood pressure of a child. Do not under any circumstances use the unit on a baby/infant.
- The cuff has been specially developed for this unit and must not be used with other units. It is designed for an upper arm circumference of 23-43 cm.
- The measurement results of automatically measuring blood pressure monitors may be falsified by pregnancy, irregular heartbeats, or arteriosclerosis. Measure your own blood pressure in cooperation with your doctor.
- Do not under any circumstances place the cuff on or over any critical point, e.g. wound, aneurysm, etc. Risk of injuries! The supply via an intravascular access (infusion) could possibly be interrupted.
- Measuring your own blood pressure does not constitute treatment. Do not modify of you own accord the dosage of drugs/medication prescribed by your doctor.
- Please refer to the chapter "Important instructions for use" (Page EN-36) before conducting any measurements yourself.

2. Important technical details

- A constantly good power supply to the unit is necessary for trouble-free blood pressure measurements.
 - Please use long-life alkaline batteries only (LR6).
 - Always replace all batteries simultaneously during battery replacement.
 - You will need 4 x 1.5 V batteries. Rechargeable batteries have a voltage of only 1.2 V and are thus not suitable.
 - When using the unit with a mains adapter, please use the type A1 mains adapter specially tested for medical devices only.
 - If the unit is not to be operated with batteries for an extended period of time, remove the batteries. Essentially, all batteries can leak.
- The unit must only be operated with original spare parts. The warranty will be invalidated if the unit is damaged by non-approved accessories!
- Using this unit near mobile phones, microwave ovens or other devices with strong electromagnetic fields may lead to malfunctions. See also EMC description from Page EN-51.
- The display of the pulse frequency is not suitable for checking the frequency
 of cardiac pacemakers. Cardiac pacemakers and blood pressure monitors do
 not influence each other regarding their mode of operation.
- Never open or modify the unit or the cuff this is a medical device. (Exception: replacing batteries). If the unit has been opened, it must be subjected to a metrological inspection by an authorised institution.
- The cuff may be inflated on the arm only.
- Please comply with the specified ambient conditions for measurement. See Technical data, Page EN-46.
- The inflating and measuring procedure can be stopped by pressing the Start/Stop button. In this case, the unit stops the inflation procedure and deflates the cuff.

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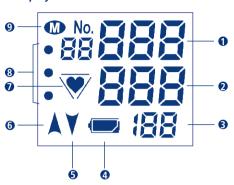
1. Unit description



- Memory button (memory recall button)
- Connecting socket for mains adapter
- 3 Start/Stop button
- 4 Battery compartment
- 6 Air socket
- **6** Display

- Measurement arrow for arm circumference
- 8 Air hose
- Artery marking
- White marking for arm circumference
- Cuff

2. Control displays



- SYS = Systole
- 2 DIA = Diastole
- PUL 1/min = Pulse calculates pulse frequency per minute
- 4 Battery check display

- **5** Deflate cuff
- 6 Inflate cuff
- **7** Pulse signal display or irregular pulse waves
- 8 WHO traffic light
- Memory identifier

Failure and error messages (page EN-44) Err-300, -1, -2 ...



Operating the unit

Operating the unit

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3. Important instructions for use

- Refrain from drinking alcoholic or caffeinated beverages and smoking at least one hour before measuring.
- Please rest at least 5 minutes before measuring. Depending on the previous degree of stress/exertion, this can even require up to one hour.
- Expose the upper arm, the clothes must not impair the blood flow in or from the arm as this influences the blood pressure at the measurement point.
- Body posture must be relaxed:
 - For this purpose, sit at a table (if possible the height of a dining table, not a coffee table!).
 - Rest your back against the backrest of the chair.
 - Lay down your lower arm completely.
 - Place your feet on the floor and do not cross your legs.
- There should be no irregular heartbeats during the measurement! Irregular
 movements, vibrations, speaking, and breathing heavily will also affect the
 measurement.Listen out for regular pulse beep signals during measurement; if
 necessary, repeat the measurement in improved conditions.
- Resting during the measurement is absolutely essential! Talking or moving as well as strong irregular heartbeats will affect the measurement result, the values becoming too high.
- Unusual measurement results are possible with all automatically measuring blood pressure measurement systems from time to time. Check yourself: did you comply with the instructions for use above? If necessary, repeat the measurement after allowing the blood circulation in the arm to recuperate briefly; rest for about 3-5 minutes for this purpose. Tip: Remain seated, your monitor will switch off automatically about 3 minutes after a measurement. Afterwards, we recommend that you repeat the measurement.
- Blood pressure is not a fixed value. It may fluctuate upwards or downwards by more than 20 mmHq on patients within a few minutes.

4. Initial operation of the unit

Insert the supplied batteries into the unit, if these have not been inserted already.

If the unit is to be operated from the mains power supply, the cable plug of the mains adapter (accessory) must be inserted into the connection socket on the right side of the unit. The batteries are switched off automatically.



5. Inserting/replacing batteries:

- Opening the battery compartment
 Remove the cover of the battery compartment on the underside of the unit.
- Inserting batteries
 Remove the old batteries from the unit and insert the new ones. Please
 observe proper polarity (marking in battery compartment).
- Closing the battery compartment
 Close the battery compartment by clipping the battery cover back into the unit.
- Please note:

Replace the batteries

- if the flat battery symbol appears in the display after the segment check.
- if the display remains blank in spite of the Start/ Stop button being pressed.



Operating the unit

Operating the unit

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6. Attaching the cuff

- Expose the upper arm.
- Push the cuff onto the arm until the lower edge of the cuff is 2-3 cm above the crook of the arm.
- When using the unit on the left arm the air hose runs to the unit through the middle of the crook of the arm so that the 4 cm long artery marking is located centrally above the pulse position.
- When using the unit on the right arm the cuff must be rotated to the left until the artery marking is on the pulse position. The air hose then runs along the inner side of the upper arm.
- The cuff should be tightened to such an extent that 2 fingers can still be inserted between arm and cuff. Tip:
 - Angle the arm slightly.
 - The upper arm muscle is tensioned slightly.
 - This increases the circumference of the arm slightly.
- Now pull the free cuff end tight and flip it back tightly above the Velcro fastener.
- Check if the arrow on the cuff is within the marking at the edge of the cuff.
- Insert the air connector of the cuff into the air socket on the unit.
- Now pull the free cuff end tight and flip it back tightly above the Velcro fastener.





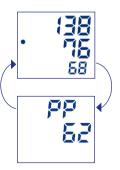


7. Measuring blood pressure

- Switch on the unit by pressing the Start/Stop button. The following display is visible.
- button. The following display is visible.
- The automatically controlled inflation process begins once the unit has completed its calibration against the ambient air pressure.
- The "♥" symbol flashes in the display, beeps sound to denote the pulse, the cuff is inflated and blood pressure and pulse are measured while the cuff is being inflated.
- Inflation stops as soon as the measured values are determined, the cuff is then automatically deflated.
- A long beep denotes the end of measurement.
- The determined values of systole, diastole and pulse and the pulse pressure (PP) are shown alternately in the display.
- The unit switches off automatically after approx.
 3 minutes.







8. WHO traffic light function

The unit categorises the blood pressure readings according to the guidelines of the World Health Organisation (WHO). You can use the coloured fields to read the categorisation of each reading:

- Lower dot (Green) signifies normal value
- Middle dot (Yellow) signifies borderline value*
- Upper dot (Red) signifies high pressure*

WHO 2003 Systolic pressure = Upper value mmHg**		Diastolic pressure = Lower value mmHg**	
Red	Red from 140* from 90*		
Yellow	120 to 139	80 to 89	
Green	below 120	below 80	

- * It is sufficient for one of the values to be raised.
- ** millimetres of mercury

The categorisation according to WHO is stored with the readings and can be called up again together with the readings from the memory.

9. Pulse pressure

The pulse pressure – not to be confused with the pulse beat – provides an indication of the stretchability of the blood vessels. A hard system of vessels can have a negative effect on the cardiovascular system. Studies show that the cardiovascular risk increases if the pulse pressure value is greater than 65 mmHg.

The heart works in two phases, the contraction phase (systole) and the relaxation phase (diastole). The pressure difference between systole and diastole is called the pulse pressure or pulse amplitude. The higher the pulse pressure, the harder the vessels.

Operating the unit

High pulse pressure	above 65 mmHg	
Increased pulse pressure	55 to 65 mmHg	
Normal pulse pressure	below 55 mmHg	

If your pulse pressure is permanently above 55 mmHg, consult your doctor.

10. Irregular pulse waves

If the symbol for irregular pulse waves flashes after a measurement, the unit has recorded irregular pulses during the measurement. This can be set off by an irregular heartbeat (arrhythmia), disturbances caused by movement, talking or even breathing in deeply. The symbol is stored with the respective measurement.



If the symbol appears more frequently, this may be caused by an irregular heartbeat and must be discussed with your doctor! Measurement results accompanied by flashing pulse displays should therefore be viewed as critical and repeated under more favourable conditions.

11. Using the memory

Measured results are automatically stored in the memory. The memory can store up to 30 results and the average value.

When more than 30 measured values have been stored, the oldest value (No. 30) is deleted to allow the latest value (No. 1) to be recorded. Press the Memory button to call up data. The average value of the stored results is displayed with "A", the values for systole, diastole and pulse and the pulse pressure (PP) are shown alternately in the display.

Press the button repeatedly to call up further measured values. If no value is stored, nothing will be displayed (just dashes). The stored data remain visible in the display for around 30 seconds. The unit then switches itself off.

To delete individual measured values, press the Memory button repeatedly to call up the desired measured value. Then press the Memory button again and hold down for 8-10 seconds until the measured value has disappeared.

To delete the entire memory, call up the average value, press the Memory button again and hold down until the average value has disappeared. If the display flashes, the deletion process has not been completed and must be repeated.

If no value is stored, there is no display.

1. Systolic and diastolic blood pressure values

The cardiovascular system has the important function of supplying all organs and tissues in the body with sufficient amounts of blood and of transporting metabolites. For this, the heart contracts and expands at a regular rate of about 60 to 80 times per minute. The pressure of the flowing blood on the artery walls caused by the heart contracting is termed systolic. The pressure in the ensuing relaxation phase, when the heart refills with blood, is termed diastolic. During daily measurement you determine both values.

2. Reasons for measuring different values

Our blood pressure responds to internal and external influences like a sensitive measuring instrument. It can be affected by even slight changes. This explains why often values measured with the doctor or pharmacist are higher than those measured at home in the environment you are used to. Changes in the weather, climate changes, or physical or psychological stress can have effects as well.

3. Why you should measure blood pressure regularly

Even the time of day has an influence on your blood pressure. During the day the values are generally higher than during the periods of rest at night. One-off and irregular measurements therefore say little about your actual blood pressure. A reliable assessment is possible only when measurements are taken regularly. Discuss the measurement values with your doctor.

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Technical information

Technical information

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1. Failure and error messages

Failure encoun- tered	Possible cause	Corrective action	
Display Err - 300 Excessive cuff pressure. inflated to maximum du movement of the arm or		- Repeat measurement - Do not move arm - Do not talk	
ment could not be carried out		- Repeat measurement - Do not move arm - Do not talk	
Display Err - 2	Inflation error, pressure built up too quickly or too slowly.	Check seating of air connector, repeat measurement.	
	Fault was recognised.	- Repeat measurement - Do not move arm - Do not talk	
	Irregular heartbeat, disruptive movements, shaking, wobbling (objects), breathing in deeply, etc. Irregular heartbeat, disruptive movements, shaking, wobbling (objects), breathing in deeply, etc.	Repeat measurement after 3-5 minutes rest. Possible factors (depending on the severity of the arrhythmia) affecting the measurement results must be discussed with your doctor.	
Measured values too high Was the necessary rest observed prior to measurement?		Repeat measurement after a break of approx. 3-5 mins Do not move arm - Do not talk	
Unusual measured values	Movement or talking during measurement, resting time not observed, feet possibly crossed, smoking or coffee cunsumption.	Check conditions and repeat measurement. Observe instructions for use P. EN-38.	

Failure encountered	Possible cause	Corrective action	
Display 0 Start/Stop button accidentally pressed while battery was being changed.		Switch unit off and then on again with Start/Stop button.	
Measurement was interrupted and	Unit detects a fault or that diastolic value is too low.	Unit shows no fault. Repeat measurement.	
cuff first deflated and then inflated	Movement during measure- ment	If necessary, interrupt measure- ment, measure again after a break of 5 minutes.	
No display after	Batteries inserted incorrectly?	Check position of batteries.	
unit is switched on	Batteries flat?	Change batteries.	
	Battery compartment dirty?	Clean battery compartment.	
Dashes in display after Memory but-	No measured values stored.	No display when no measured values are stored.	
ton is pressed	Batteries flat?	Change batteries.	
Measurement interrupted	Batteries flat?	Change batteries.	
Measured values extremely high or low Was the correct measurement position maintained?		Repeat measurement, ensuring correct body posture. Do not move your arm and do not speak.	

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Technical information



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2. Customer service

The unit may only be repaired by the manufacturer or by an expressly authorised organisation.

Please contact: UEBE Medical GmbH Zum Ottersberg 9

D-97877 Wertheim, Germany

Phone: +49 (0) 9342/924040 Fax: +49 (0) 9342/924080 info@uebe.com E-mail: Internet: www.uebe.com

3. Technical data

Unit type:	Digital automatic unit with electric pump for measuring blood pressure on upper arm
Dimensions:	L = 115 mm x W = 150 mm x H = 54 mm
Weight:	330 g not including batteries
Display:	LCD display (liquid crystal display) for measured values and check displays
Memory:	30 measured values (stored automatically) and average value (A)
Measurement procedure:	Oscillometric determination of systole, diastole and pulse
Reference procedure of clinical testing:	Auscultatory measurement
Inflating pressure:	approx. 10-20 mmHg above systolic blood pressure

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Pressure display range:	0-300 mmHg	
Measurement range	Systolic: 50-250 mmHg Diastolic: 40-150 mmHg Pulse measurement: 40-160 pulses/min	
Error limits:	Blood pressure measurement: corresponds to EN 1060 Part 3 Pressure measurement: ± 3 mmHg Pulse measurement: ± 5%	
Serial number:	The unit bears a serial number SN which provides clear identification.	
Power supply:	Battery type: 4 x 1.5 V round cells alkali manganese (LR 6) lithium (FR 6) Durability: over 800 measurements in 2 years	
	Optionally stabilised type A1 mains adapter, output 6 VDC, min 600 mA	
Cuff:	Metal ring cuff for arm circumferences of 23-43 cm, type 2040	
Operating conditions:	Ambient temperature 10 to 40 °C Relative humidity up to 85%, non-condensing	
Storage and transport conditions:	Ambient temperature -5 to +50 °C Relative humidity up to 85% Protect against moisture, non-condensing	
Automatic switch-off	approx. 3 minutes after end of measurement	

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Technical information

Technical information



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Original spare parts and accessories:

The following original spare parts and accessories are available from specialist dealers:

 Universal cuff 23-43 cm Type 2040 Part. no. 2404001 P7N 1021375

 Mains adapter type A1 Part. no. 2401020 PZN 3558547

Subject to technical modifications.

4. Applicable standards

- DIN EN 1060-1: 1995
 + A1:2002 + prA2:2008 Non-invasive sphygmomanometers Part 1: General requirements
- DIN EN 1060-3: 1997
 + A1:2005 + prA2:2008 Non-invasive sphygmomanometers Part 3:
 Supplementary requirements for electro-mechanical blood pressure measuring systems
- IEC 60601-1:2005 Medical electrical equipment Part 1: General requirements for basic safety
- IEC 60601-1-2: 2007 Medical electrical equipment Electromagnetic compatibility
- DIN EN 1060-4:2004 Non-invasive sphygmomanometers Part 4: Test procedures to determine the overall system accuracy

ESH (European Society of Hypertension) The unit complies with the requirements of the clinical test of the "International Protocol for validation of blood pressure measuring devices in adults. 2002".

- DIN EN ISO 10993-1:2009 Biological evaluation of medical devices Part 1: Evaluation and testing
- This product complies with the Council Directive 93/42/EC from 5 September 2007 regarding medical devices, which became effective on 21 March 2010.

Manufacturer:

UEBE Medical GmbH Zum Ottersberg 9 D-97877 Wertheim, Germany

5. Metrological inspection (previously calibration)

Basically, a metrological inspection is recommended at intervals of 2 years. However, professional users in Germany have to comply with the aforementioned according to "Regulation for Operators of Medical Devices".

This can be implemented either by UEBE Medical GmbH, an authority responsible for metrology, or authorised maintenance services. For this, please observe your national provisions.

Upon request, responsible authorities or authorised maintenance services receive a "Test instruction for metrological inspection" from the manufacturer.

Important: No modifications, e.g. opening the unit (except to replace the batteries) may be made to this unit without the manufacturer's prior permission.

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1. Explanation of symbols

€0123 This product complies with the Council Directive 93/42/EC from 5 September 2007 regarding medical devices, which became effective on 21 March 2010 and bears the mark CE 0123 (TÜV SÜD Product Service GmbH). Units with CE marks are subject to quality inspections in accordance with this Directive and provide a higher level of accuracy than previous calibration.



Degree of protection against electric shock: TYP BF



Please observe operating instructions



Storage and transportation conditions Ambient temperature -5 to +50 °C



Protect against moisture/humidity Rel. air humidity up to 85%



Keep dry



Manufacturer

2. Disposal



Batteries and technical appliances must not be disposed of with domestic waste, but should be handed in at the appropriate collection and disposal points.

General provisions

3. Electromagnetic compatibility (EMC)

Technical description

The unit satisfies the EMC requirements of the international standard IEC60601-1-2. The requirements are satisfied under the conditions described in the tables below. The unit is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the unit. Use of the unit in conjunction with non-approved accessories can affect the unit negatively and alter the electromagnetic compatibility. The unit should not be used directly adjacent to or between other electrical equipment.

Guidance and manufacturer's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ansure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all
Harmonic emissions IEC 61000-3-2	N/A	establishments, including domestic estab- lishments and those directly connected to the public low-voltage power supply
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	network that supplies buildings used for domestic purposes.

General provisions

General	provisions

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Guidance and manufacturer's declaration - electromagnetic immunity				
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.	
Electrical fast transient/burst IEC 61000- 4-4	±2 kV for power supply lines ±1 kV for input/out- put lines	±2 kV for power supply lines ±1 kV for input/out- put lines	Mains power quality should be that of a typical commercial or hospital environment.	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$\begin{array}{l} <5\% \ U_{_{T}} \ (>95\% \\ dip \ in \ U_{_{J}} \) \ for \ 0.5 \\ cycle \\ 40\% \ U_{_{T}} \ (60\% \\ dip \ in \ U_{_{J}} \) \ for \ 5 \\ cycles \\ 70\% \ U_{_{T}} \ (30\% \\ dip \ in \ U_{_{J}} \) \ for \ 25 \\ cycles \\ <5\% \ U_{_{T}} \ (>95\% \\ dip \ in \ U_{_{J}} \) \ for \ 5 \ sec \end{array}$	$\begin{array}{l} <5\% \ U_{_{T}} (>95\% \\ \text{dip in } U_{_{1}}) \ \text{for } 0.5 \\ \text{cycle} \\ 40\% \ U_{_{T}} (60\% \\ \text{dip in } U_{_{1}}) \ \text{for } 5 \\ \text{cycles} \\ 70\% \ U_{_{T}} (30\% \\ \text{dip in } U_{_{1}}) \ \text{for } 25 \\ \text{cycles} \\ <5\% \ U_{_{T}} (>95\% \\ \text{dip in } U_{_{1}}) \ \text{for } 5 \ \text{sec} \end{array}$	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.	
Power frequency (50/60 Hz) magnetic field IEC 61000- 4-8	3 A/m	0.3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical com- mercial or hospital environment.	
NOTE U_T is the AC mains voltage prior to application of the test level.				

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Guidance and manufacturer's declaration - electromagnetic immunity				
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guid- ance	
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000- 4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	N/A 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. d=1.2√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with (***)	

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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^a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radios broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
W	150 kHz to 80 MHz N/A	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P
0.01	N/A	0.12	0.23
0.1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 To calculate the recommended separation distance of transmitters in the frequency range of 80 MHz and 800 MHz to 2.5 GHz, an additional factor of 10/3 has been used in order to reduce the probability of a mobile/portable communications device unintentionally introduced into the patient area causing a fault.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- The unit contains sensitive parts and must be protected against strong variations in temperature, air humidity, dust and direct sunlight.
- The unit is neither impact-resistant nor shock-proof. We recommend that you
 have the intactness and accuracy of the display checked after heavier falls or
 impacts.
- The unit is not water-proof.
- Please use a soft, dry cloth to clean the unit only. Do not use benzene, thinners or other strong solvents.
- Do not scrub or machine-wash the cuff. Please use synthetic cleaners and softly rub the surface.
- If the unit has been opened, it must be subjected to a metrological inspection conducted by an authorised organisation.
- Make sure that liquid cannot get into the air hose. Dry thoroughly.

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Warranty

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Warranty furnished

The blood pressure monitor has been manufactured and tested with great care. However, in the unlikely event of a defect being detected after delivery, we provide warranty in accordance with the following terms and conditions:

- During the warranty period of 3 years from the date of purchase we reserve the right either to repair any such defect at our expense (upon return of the unit to our factory) or to supply a perfect replacement unit.
- Excluded from the warranty are parts subject to normal wear and tear as well as damage caused by non-compliance with the instructions for use, improper handling (e.g. unsuitable power sources, breakages, leaking batteries) and/or disassembly of the unit by the purchaser. Furthermore, no claims for damages against us are substantiated by the warranty.
- 3. Warranty claims can only be advanced in the warranty period and by presenting proof of purchase. In the event of a warranty claim, the unit must be sent to the following address together with the proof of purchase and a description of the complaint:

UEBE Medical GmbH Service-Center Zum Ottersberg 9 D-97877 Wertheim

 In the case of defectiveness of the goods, the contractual rights of the purchaser to claim against the seller in accordance with § 437 German Civil Code are not limited by the warranty.

Please note:

In the event of a warranty claim it is essential to attach the proof of purchase.

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comfort 20/40

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UFBF Medical GmbH Zum Ottersberg 9 97877 Wertheim Germany

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