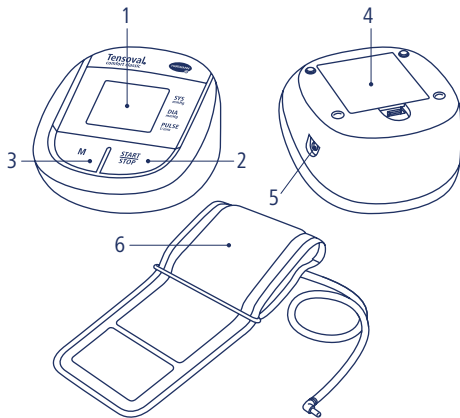


Tensoval® comfort classic

GB Instructions for use

Please read this instruction for use carefully before first use, as correct blood pressure measurement depends on the appropriate use of the device. Use this device according to the information described in the instructions for use and keep these in a safe place.



1. Display
2. START/STOP button
3. Memory button
4. Battery compartment
5. Cuff socket
6. Draw-clamp cuff; for upper arm circumference 22 - 42 cm

General information

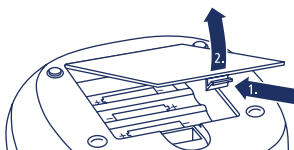
- **SYS** – Systolic (upper) blood pressure: Is produced when the heart contracts and pumps blood into the blood vessels.
- **DIA** – Diastolic (lower) blood pressure: This is the value measured when the heart muscle is dilated and again fills with blood.
- Blood pressure measurement values are expressed in mmHg.

Classification of the blood pressure values according to the World Health Organisation (WHO) and the International Society of Hypertension (ISH):

Assessment	Systolic pressure	Diastolic pressure
Optimal	up to 120 mmHg	up to 80 mmHg
Normal	up to 130 mmHg	up to 85 mmHg
Normal limit values	130 - 139 mmHg	85 - 89 mmHg
Grade 1 hypertension	140 - 159 mmHg	90 - 99 mmHg
Grade 2 hypertension	160 - 179 mmHg	100 - 109 mmHg
Grade 3 hypertension	over 180 mmHg	over 110 mmHg

Please note: Self-measurement of blood pressure does not mean treatment! So do not interpret your measured values by yourself and do not use them for self-prescribed treatment either. Take measurements according to the instructions of your doctor and trust his or her diagnosis.

Inserting / changing the batteries



Open the battery cover on the underside of the device (see fig.). Insert four batteries of the type AA into the battery compartment. Ensure correct polarity ("+" and "-"). Close the battery lid again.

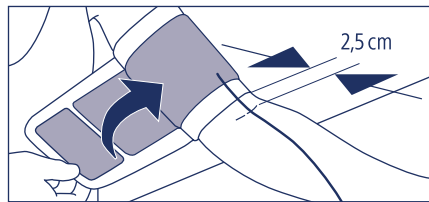
Setting date and time



- After inserting the batteries, you have to set the date and time. On the display, you will see the flashing year first. By pressing the memory button, the year increases. If you want to speed up the process, press down the memory button - thereby the year will increase faster. Next, set the month by pressing the START/STOP button and thereby storing your year setting.
- 17 1 | 12:00
- Next, set the month: The number on the right of the display flashes. Use the memory button as explained above to set the right month. Press the START/STOP button to store the setting. Repeat procedure for storing the day, hour and minute. Each time you change the batteries date and time must be reset.
- You can always reset date and time by pressing the START/STOP button for in between 5 to 10 seconds when the device is switched off. Continue to press down the button when all display segments appear on the display and also when the arrow pointing downwards flashes. Immediately thereafter the date and time setting option appears. Set date and time as described above. Please note that if

you press down the START/STOP button for more than 10 seconds, the device will switch off.

Applying the cuff



- The cuff included with the device is a universal cuff for upper arm circumferences of 22 to 42 cm.
- The cuff should be firm but not too tight. You should be able to push two fingers between the arm and the cuff.
- Insert the cuff connector in the cuff socket on the left side of the device.
- Make sure that the tube is not kinked or damaged.

Measuring blood pressure

- We recommend that you measure your blood pressure while sitting with your back supported by the back of the chair. Place both feet flat on the floor and the legs next to each other. Your legs should not be crossed. Place your forearm with the palm relaxed upwards on a support and make sure the cuff is at the level of the heart.
- Do not switch the device on until the cuff has been applied, otherwise the cuff can become damaged through the resulting excess pressure.
- Press the START/STOP button. The appearance of all display segments followed by a flashing arrow pointing downwards shows that the device is checking itself automatically and is ready for use. Subsequently, the cuff rapidly inflates to a cuff pressure of 30 mmHg. Then the cuff proceeds to inflate at a slower pace. This is when the measurement is performed. The heart symbol flashes as soon as the device reads your pulse rate. The inflation stops automatically as soon as the measurement is completed. The cuff pressure will then be released at once.
- The systolic and diastolic blood pressure value, as well as the pulse rate can be read off the display. The time of the measurement appears on the left of the pulse rate. The device stores your measurement automatically.
- In order to switch off the device, press the START/STOP button. Otherwise the device will automatically switch off after 3 minutes.
- If you wish to cancel the measuring procedure for any reason, simply press the START/STOP button. The inflation or measuring procedure is cancelled and an automatic fall in pressure occurs.

10 golden rules for blood pressure measurement

1. Rest for approx. 5 minutes before measurement. Even deskwork increases blood pressure.
2. Do not consume any nicotine or coffee up to one hour before measurement.
3. Do not measure with a full bladder.
4. Take measurements from the naked upper arm and while sitting upright.
5. In the case of using a wrist monitor, hold the wrist and the device at the level of the heart during the measuring procedure. The cuff of an upper arm monitor automatically finds the correct level at the arm.
6. Please do not talk or move during the measuring procedure.
7. Wait at least one minute between two measurements, so that the vessels are relieved from pressure in preparation for a new measurement.
8. Enter the values in the blood pressure diary: Note down the measured values, always together with any drugs taken, date and time.
9. Take measurements regularly. Even if your values have improved, you should continue to check them for monitoring purposes.
10. Always take measurements at the same time of day. Because a person has approx. 100,000 different blood pressure values every day, individual measurements have no significance. Only regular measurements at the same time each day over a longer period of time allow a meaningful evaluation of blood pressure values.

Memory function



- The memory recall is activated by pressing the memory button, when the device is switched off. First, the average value of all stored data will be shown. The "A" symbol appears on the display and the number of measurements, from which the average value was calculated (see fig.), is displayed next to it. Press the memory button to show memory position 1.
- This blood pressure monitor can store up to 60 measurements. The most recent measured value is always at memory position 1 and all older stored values shift down one memory position. When all memory positions are occupied, the oldest value will be deleted each time.
- By repeatedly pressing the memory button all stored values can be recalled one by one. The number of the measurement, date and time alternately appear below the measured values in 2 - 3 second intervals.
- You can cancel the memory recall at any time by pressing the START/STOP button. Otherwise, the device will switch off automatically after a few seconds.
- Even if the power supply fails, e.g. when changing the batteries, the stored values will still be available.
- Deleting the stored values: You can only delete all measured values at once. To do this, press the memory button. The average value

will then appear on the display. Press the memory button again and press it down for a long period. After four seconds, the display will flash and four seconds after the display started to flash all data are deleted. If you release the button ahead of time, no data will be deleted.

Explanation of symbols

- ♥ The heart symbol flashes when the device is measuring and the pulse is being taken.
- ☀ The flashing battery symbol indicates that the battery is low.
- ☀ The permanently illuminated battery symbol indicates that the batteries are empty and have to be replaced.
- ⬇ The arrow pointing upwards appears during rapid inflation at the start of measurement.
- ⬆ The arrow pointing downwards appears during automatic system check.
- M The memory symbol appears if a stored value is called.

Explanation of error indications

Error which has occurred	Possible causes	Remedy
Err -1	The measuring signals could not, or not correctly, be read. This can be caused by incorrect application of the cuff, moving, talking or by a very weak pulse.	Check the correct position of the cuff. Do not talk or move during the measuring procedure. Also observe the 10 golden rules.
Err -2	Cuff does not inflate or does not inflate fast enough. This can, among other things, be due to a too loosely applied cuff or to movement during the measuring procedure.	Apply the cuff so that you are able to push about two fingers between the cuff and the upper arm. Air tube is not correctly inserted into the device. Check the correct position of the cuff connector.
Err 300	The pressure in the cuff exceeds 300 mmHg. Therefore, an automatic fall in pressure occurs.	Please rest for at least a minute and take the measurement again.
Implausible measured values	Implausible measured values often occur due to inappropriate use of the device or mistakes during the measurement procedure.	Please observe the 10 golden rules of blood pressure measurement and the safety information below. Then repeat the measurement.

Switch the device off if an error symbol appears. Check the possible causes and also go through the 10 golden rules of blood pressure measurement again. Relax for a minute and then take the measurement again.

Safety information concerning your health

- Consult your doctor before carrying out self-measurement of blood pressure if
- you are pregnant.
 - you suffer from diabetes, hepatic disorders or narrowed blood vessels (for example, arteriosclerosis, peripheral arterial occlusive diseases (PAOD), because altered measured values may occur in such cases.
 - you suffer from certain blood diseases (e.g. haemophilia) or severely impaired blood flow, or if you take blood-thinning drugs.
 - you have severe heart rhythm disorders (arrhythmias): Due to the oscillometric measuring method of the device, in these cases, it may be that incorrect measured values are determined or no measurement result is obtained at all.
 - you wear a cardiac pacemaker. In this case, altered measured values may occur. The blood pressure monitor itself has no impact on the cardiac pacemaker. Please note that the displayed pulse rate is not suitable for checking the rate of cardiac pacemakers.
 - you tend to bruise and/or are sensitive to pain on pressure.
- Use the device exclusively for taking blood pressure measurements on the human upper arm.
 - Do not take your blood pressure after taking a bath or exercising.
 - Do not leave the device unattended near toddlers or persons who cannot operate it themselves. There is a risk of strangulation through getting caught in the cuff tube. Swallowing small parts that have come off the device can also result in attacks of suffocation.
 - Do not under any circumstances carry out blood pressure measurements on babies or toddlers.
 - Please do not apply the cuff over a wound, as this may result in further injuries.
 - If you have had a mastectomy, do not carry out the measurement on the arm on the affected side of the body.
 - Please note that the pressure built up by the cuff can lead to temporary disruption to medical devices being simultaneously used on the same arm.
 - If an intravenous treatment is being carried out or a venous catheter is present on the arm, blood pressure measurements can lead to injury. Please never use the cuff on the arm on which these

conditions apply.

- If you are carrying out the measurement on another person, please ensure that the use of the blood pressure monitor does not result in persistent impairment of the blood circulation.

Safety information concerning the device

- This blood pressure monitor is not waterproof!
- This blood pressure monitor consists of high-quality electronic precision components. Protect the device from hard knocks or vibrations and do not drop it to the floor.
- Do not excessively bend or fold cuff and air tube.
- Never open the device. The device must not be altered, dismantled, or repaired by the user. Repairs may only be carried out by authorized professionals.
- Never inflate the cuff when it is not properly applied to the upper arm.
- Use the device only with the approved upper arm cuff; otherwise the device can be damaged externally or internally.
- The cuff tube may only be removed from the device by pulling on the black connector. Never pull on the tube itself.
- Do not expose the device neither to extreme temperatures nor to humidity, dust, or direct sunlight, as this may lead to malfunction.
- Only use a soft, moistened cloth to clean the device. Do not use any detergents or solvents.
- The cuff can be cleaned carefully with a lightly moistened cloth and mild soap solution. Do not completely immerse the cuff in water.

Batteries


- We recommend the use of high-quality batteries as other batteries or accumulators may result in a reduction in the measuring performance. Never mix old and new batteries or batteries made by different manufacturers.
- If the battery symbol is permanently displayed, the batteries are dead and have to be replaced.
- Remove the batteries from the device if it is not being used for a longer period.




Disposal

- In the interests of environmental protection, exhausted batteries may not be disposed of in household waste. Please observe the applicable waste disposal regulations or use public collecting bins.
- This product is covered by European Directive 2002/96/EC and/or 2012/19/EU on waste electrical and electronic equipment and is marked accordingly. Never dispose of electronic devices in household waste. Please inform you about the local regulations for the proper disposal of electrical and electronic products. Proper disposal helps to protect the environment and human health.

Symbols

 Pay attention to the operating instructions.

 Please note.

 Protection from electric shock (type BF).

 Disposal note

Technical data

Measuring method:	Oscillometric
Display range:	0 - 300 mmHg
Measuring range:	Systole (SYS): 50 - 250 mmHg Diastole (DIA): 40 - 180 mmHg Pulse: 40 - 160 beats / minute The displaying of values outside the measuring range cannot be guaranteed.
Technical measuring accuracy:	Cuff pressure: +/- 3 mmHg Pulse: +/- 5 % of displayed pulse rate
Clinical measuring accuracy:	Complies with the requirements of European Standard EN 1060, Part 3.
Power supply:	4 x 1.5 V Mignon alkaline-manganese (AA/LR06) batteries or optional HARTMANN mains adapter
Battery capacity:	> 1,000 measurements
Protection from electric shock:	Medical electrical equipment with an internal power supply (when using batteries). Applied part: Type BF
Protection against harmful penetration of water or solid materials:	IP20 (not moisture-proof)
Operating mode:	Continuous operation
Automatic switch-off function:	3 minutes after end of measurement
Cuff:	Universal draw-clamp cuff, 22 - 42 cm
Pressure release valve:	Electronically controlled linear valve
Memory capacity:	60 measurements and average value
Operating conditions:	Ambient temperature: + 10 °C to + 40 °C (+ 50 °F to + 104 °F) Relative humidity: 15 - 85 %

Storage / transport conditions: Ambient temperature:
- 20 °C to + 50 °C (- 4 °F to + 122 °F)
Relative humidity: 15 - 85 %

Serial number: In battery compartment



PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 HEIDENHEIM
GERMANY



Legal requirements and guidelines

Tensoval comfort complies with the European regulations which are based on the 93/42/EEC Medical Device Directive (MDD) and bears the CE mark. The device complies, for example, with the European Standard EN 1060: Non-invasive blood pressure measuring devices - Part 1: General requirements and Part 3: Additional requirements for electro-mechanical blood pressure measuring systems.

Clinical testing of measuring accuracy was performed according to the European Standard EN 1060-4. The requirements according to the ANSI/AAMI test protocol SP10-1992 are also fulfilled.

Portable and mobile high-frequency and communication devices, such as telephone and mobile phone, can impair the functional capability of electronic medical devices and should therefore be kept at a distance of 3 m from the blood pressure monitor. In compliance with European Standard EN 60601-1-2 further information can be supplied by HARTMANN on request.

Over and beyond the legal requirements, the device has been validated by the ESH (European Society of Hypertension) in accordance with the ESH-IP2 protocol.

Instructions for the calibration check

We recommend a calibration check at intervals of 2 years in the case of professionally used devices, e.g. in pharmacies, medical practices, or hospitals. You should also observe the national regulations determined by the legislator, such as, in Germany, the "Medizinprodukte-Betreiberverordnung" (Medical Device Operating Regulation). Calibration checks can be carried out either by competent authorities or authorized maintenance providers against compensation.

Instructions for the calibration mode

Remove the batteries in order to switch to calibration mode. Press down the START/STOP button and insert the batteries again. Release the button after a few seconds and, after a few moments, two zeros will appear one above each other on the display. Instructions on the calibration check will be supplied on request to competent authorities or authorised maintenance providers by HARTMANN.

Contact information for customer queries

AE - PAUL HARTMANN
Middle East FZE
Dubai

AU - PAUL HARTMANN Pty. Ltd.
Level 6, 5 Ryder Boulevard
Rhodes, NSW 2138 Australia

CN - PAUL HARTMANN (Shanghai) Trade Co., Ltd.
Shanghai 200233, P.R.China

GB - PAUL HARTMANN Ltd.
Heywood/Lancashire OL10 2T

HK - PAUL HARTMANN
Asia-Pacific Ltd.
Hong Kong

ZA - HARTMANN South Africa
2194 Johannesburg

Warranty conditions

We give a 3-year warranty on this high-quality blood pressure monitor from the day of purchase and in accordance with the following conditions. Claims must be made during the warranty period. The date of purchase has to be documented by the proof of purchase. Within the warranty period, HARTMANN shall replace or repair any faulty device components free of charge which were caused by material or manufacturing errors. This does not extend the warranty period.

This warranty is not applicable to damage caused by improper use or unauthorized interference. Accessory parts that are subject to wear and tear (batteries, cuffs etc.) are excluded from the warranty. Claims for compensation are limited to the value of the goods; compensation for subsequent damages is expressly excluded. In warranty cases please send the device with the cuff together with the proof of purchase direct, or via your dealer to the Customer Service department competent for your country.

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