

Instructions for use

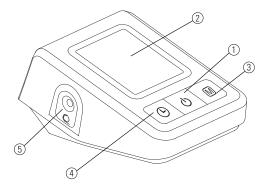


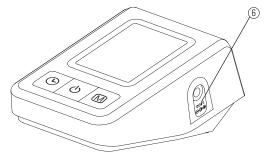
 Top-selling in German pharmacies, IMS Health Pharmatrend Database – digital blood pressure monitor sales, date 02/2019

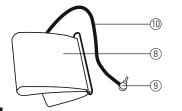
* Warranty of 2 years on blood pressure monitor cuff as a wearing part

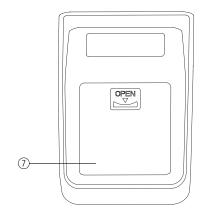
technology by microlife

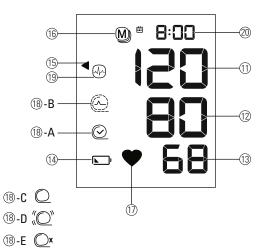
aponorm[®] Basis Control











Switches, housing and accessories

Display

- ① On/off button
- ② Display
- ③ M button (Memory)
- ④ Time button
- ⑤ Cuff socket
- ⁽⁶⁾ Mains adapter connector
- ⑦ Battery compartment
- ⑧ Cuff
- ④ Cuff connector
- 10 Cuff hose

- 1 Systolic value
- Diastolic value
- 13 Pulse indicator
- (1) Battery level indicator
- ⁽¹⁵⁾ Blood pressure evaluation indicator
- (16) Stored value
- 1 Pulse rate measurement active
- 18 Cuff check
 - -A: Optimum cuff position and fit
 - -B: Cuff signal error indicator **«Err 1»**
 - -C: Cuff position/fit not optimal
 - -D: Arm movement error indicator «Err 2»
 - -E: Cuff pressure error indicator **«Err 3»**
- (19) Heart arrhythmia warning symbol (PAD)
- Date/time indicator

\wedge

Important! Please observe the information in this booklet in order to prevent damage to the device and avoid error messages.



Protect from moisture.



Read the instructions carefully before using this monitor.



BF specification part.

aponorm® Basis Control

Designated use:

This oscillometric blood pressure monitor serves for non-invasive measurement of the blood pressure of persons aged 12 years or older.

It is clinically validated for patients suffering from hypertension, diabetes, pregnant women, pregnant women suffering from preeclampsia, atherosclerosis, kidney diseases, obesity and for the elderly. Dear Customer,

This instrument was developed in collaboration with physicians and clinical tests prove its measurement accuracy to be very high.*

If you have any questions or problems or want to order spare parts, please contact the aponorm[®] customer service at the product website <u>www.</u> <u>aponorm.de</u> or the distributor where you purchased the monitor. The product website provides much additional useful information on your product.

Stay healthy - the aponorm® team!

* This device uses the same measuring technology as the award winning «BP 3BTO-A» model tested according to the British Hypertension Society (BHS) protocol.

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1. Using the monitor for the first time

Inserting the batteries

After having unpacked the monitor, insert the batteries. The battery compartment \bigcirc is on the bottom of the monitor. Insert the batteries (4 x size AA 1.5 V), observing the indicated polarity +/-.

Setting the date and time

- 1. After the new batteries are fitted, the year flashes in the display. Press the M button ③ several times to set the year. To confirm the year you want to set, press the time button ④.
- 2. Now you can set the present month in the same way, using the M button ③ and confirm your setting by pressing the time button ④.
- 3. Follow the instructions above to set the day, hour and minutes.
- Once you have set the minutes and confirmed the setting, the date/time setting is complete. When the monitor is not in operation, it displays the time ⁽²⁾. The date, however, is only required for the memory display.
- If you want to change the date and time subsequently, press and hold the time button down for approx. 3 seconds until the year starts to flash. Now you can enter the new values as described above.

Selecting the correct cuff

Microlife offers different cuff sizes. Select the cuff size to match the circumference of your upper arm (measured by close fitting in the centre of the upper arm).

If the cuff ^(®) coming with the monitor does not fit, please contact your local pharmacist who can order an alternative size for you.

Cuff size	for circumference of
	upper arm
S	17 - 22 cm
Μ	22 - 32 cm
M - L	22 - 42 cm

- In addition to the above-mentioned soft cuffs, a preformed comfort cuff is available in M - L, one size fits all.
- Use only aponorm[®] cuffs or cuffs manufactured by Microlife.
- All aponorm[®] cuffs are latex-free.
- Connect the cuff to the monitor by inserting the cuff connector ⁽³⁾ into the cuff socket ⁽⁵⁾ as far as it will go.

2. Check list for performing reliable measurements

- Please read the enclosed flyer on the "8 golden rules of taking the blood pressure".
- Avoid activity, eating or smoking immediately before taking the measurement.
- Sit down on a chair with a backrest and relax for at least 5 minutes. Keep your feet flat on the floor and do not cross your legs.
- Always take your blood pressure on the same arm (normally the left one). It is recommended that doctors perform double arm measurements on a patient's first visit in order to determine which arm to measure in the future. Select the arm where the higher blood pressure was determined.
- Remove close-fitting garments from the upper arm. To avoid constriction, shirt sleeves should not be rolled up - they do not interfere with the cuff if they are laid flat (please take off any heavy clothing, as it interferes with the signal).
- Always ensure that the correct cuff size is used (see on the cuff for size information).
 - · Fit the cuff closely, but not too tight.
 - \cdot Make sure that the cuff is positioned 2.5 cm above the crook of the arm.

- long bar) must lie over the artery which runs down the inner side of the arm.
- \cdot Support your arm so it is relaxed.
- \cdot Ensure that the cuff is at the same height as your heart.

3. Taking the blood pressure

- 1. Press the On/off button ① to start the measurement.
- The cuff will now inflate automatically. Relax, do not move and do not tense your arm muscles until the reading is displayed. Breathe normally and do not talk.
- 3. If after a short while a cuff symbol appears with a check mark (19-A), the cuff signal and pressure are optimal for measurement. If there is no mark inside the cuff symbol (19-C) signal and/or pressure are less than optimal, but still sufficient for proper measurement. If, however, the cuff signal and pressure are absolutely too low for measuring or if there are excessive interferences (e. g. due to the patient moving, tensing their muscles or talking, etc.), an error message «ERR» (Error) will be displayed together with one of the cuff symbols (18-C)
- \cdot The artery mark on the cuff (approx. 3 cm

⁽¹⁾ -D or ⁽¹⁾ -E. In this case re-position the cuff and repeat the measurement. For other error messages, please read chapter 7 on page 12.

- 4. Once the correct pressure is reached, the inflating stops and the pressure gradually falls. If the required pressure was not reached, the monitor will automatically pump some more air into the cuff until the blood pressure can be taken.
- 5. During the measurement, the "pulse rate measurement active" icon ⑦ flashes in the display.
- 6. The result, comprising the systolic ⁽¹⁾ and the diastolic ⁽¹⁾ blood pressures and the pulse rate per minute ⁽¹⁾ is displayed.
- 7. When the monitor has finished measuring, remove the cuff.
- Switch off the monitor. (The monitor does switch off automatically after approx. 1 minute, though).

You can stop the measurement at any time by pressing the On/Off button (e.g. if you feel uneasy or an unpleasant pressure sensation).

This monitor is specially tested for use in pregnancy and preeclampsia. When you detect unusually high readings in pregnancy, take your blood pressure again after a short while (approx. 1 hour). If the reading is still too high in the repeat measurement, please contact your doctor or gynaecologist.

Manual inflation

In case of very high systolic blood pressure (e.g. exceeding 135 mmHg), it can be of use that you determine the pressure yourself. Press the On/ off button after the monitor started inflating and a pressure of approx. 30 mmHg appears in the display. Keep the button pressed until the pressure is about 40 mmHg above your average systolic value – then release the button.

How not to store a reading

As soon as the result appears in the display, press the on/off button 1 and keep it pressed until «M» 1 is flashing. Confirm the deletion by pressing the time button 4.

☞ «CL» is shown after the reading was successfully deleted from the memory.

How do I evaluate my blood pressure?

The triangle at the left edge of the display (15) points at the range your blood pressure reading is in. The reading is either in the optimum (white), increased (cross-hatched in grey) or high (black) blood pressure range. The classification corres-

ponds to the following ranges defined by international guidelines (ESH, ESC, JSK) (values in mmHg).

Range		Systo- lic	Diasto- lic	Recommenda- tion
	Blood pressure too high	≥ 135	≥ 85	Seek medical advice
2.	Blood pressure elevated	130-134	80-84	Self-check

The higher value is the one that determines the evaluation. Example: a blood pressure value of 140/80 mmHg or a value of 130/90 mmHg indicates «blood pressure too high».

Pulse arrhythmia indicator (PAD)

This symbol ⁽¹⁹⁾ indicates that certain pulse irregularities were detected during the measurement. If the result deviates from your normal blood pressure repeat the measurement. In most cases, this is no cause for concern. However, if the symbol appears on a regular basis (e.g. several times a week with measurements taken daily) we advise you to tell your doctor.

4. Data memory

This monitor automatically stores the last 30 readings.

Viewing the stored values

Press the M-button 3 briefly, when the monitor is switched off. Now the display changes over to the data memory display, indicated by «M» 1 (= Memory).

First, the average value of all measurement stored in the memory is shown, as indicated by the «A» to the right of the value (A = Average).

Pressing the M button again displays the last value. Pressing the M button repeatedly allows you to move from one stored value to another (from the last to the first entry in the memory).

- Blood pressure readings with the cuff position and fit ⁽¹⁾-C being not optimal are not included in the average.
- Pay attention that the maximum memory capacity of 30 values is not exceeded. Once the memory is full, the oldest value is automatically overwritten with the 31st value. The values should be evaluated by a doctor before the full memory capacity is reached - otherwise data will be lost.

Clearing all values

If you are sure that you want to permanently remove all stored values, hold down the M button (the monitor must have been switched off beforehand) until «CL ALL» (= Clear all) appears and then release the button. To permanently clear the memory, press the M button while «CL ALL» is flashing.

- Simply press the On/off button ① again while «CL ALL» is flashing to abort the deletion.
- The second secon

5. Battery indicator and battery change

Batteries almost flat

When the <u>batteries are approx. 3/4 empty</u> the partly filled battery symbol ⁽¹⁾ will flash as soon as the device is switched on. Although the monitor will continue to measure reliably, you should obtain replacement batteries.

Batteries flat - replacement

When the <u>batteries are flat</u> an <u>empty battery</u> <u>symbol</u> ⁽¹⁾ will flash as soon as the monitor is switched on. You cannot take any further measurements and must replace the batteries. In the event of a battery change or power failure, the memory retains all values measured; the date and time must, however, be reset. This is indicated by the year indicator flashing.

For changing the batteries and resetting the date/ time please follow the instructions in Section 1 on page 6.

Which batteries and which procedure?

- Please use 4 new, long-life 1.5 V, size AA alkaline batteries.
- Do not use batteries beyond their date of expiry.
- If the monitor is not going to be used for a prolonged period of time, the batteries must be removed.

Using rechargeable batteries

You can also operate this monitor with rechargeable batteries.

- Only use «NiMH» type reusable batteries.
- When the flat battery symbol appears, remove the batteries and recharge them. They must not remain in the monitor as they may become destroyed (exhaustive discharge due to low consumption of the monitor even when switched off).

- Always remove the rechargeable batteries if you do not intend to use the monitor for a week or more.
- The batteries canNOT be charged while inserted in the blood pressure monitor. Recharge the batteries in an external charger and observe the information regarding charging, handling and durability.

6. Using a mains adapter

You can operate this monitor using the Microlife mains adapter (DC 6 V, 600 mA).

- Only use the aponorm[®] mains adapter available as an original accessory appropriate for your supply voltage. You can purchase the mains adapter in your local pharmacy.
- Ensure that neither mains adapter nor cable are damaged.
- 1. Plug the adapter cable into the mains adapter socket ⁽⁶⁾ of the blood pressure monitor.
- 2. Plug the adapter plug into the wall socket.

When the mains adapter is connected, no battery current is consumed. We recommend to have batteries in the monitor even with mains operation, just as a back-up. They ensure that in the event of a power failure date and time are retained and do not have to be entered manually again.

7. Error messages

When an error occurs during a measurement, the measurement is interrupted and an error message displayed, e.g. «Err 3».

- If you do not receive an error message, but if the results seem unusual to you, please check whether you observed all points of the check list on page 7 and in the enclosed flyer "8 golden rules of taking the blood pressure".
- For more detailed help in troubleshooting the monitor, please refer to the download section of the <u>www.aponorm.de</u> product website.

Error	Designa- tion	Potential cuase and remedy	Error	Designa- tion	Potential cuase and remedy
«ERR 1» ® -B	Signal too weak	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the mea-sure-ment.* When «ERR 1» is indicated, the mo- nitor performs a 15 second countdown and then repeats the measurement.	«ERR 3» (18) -E	Irregular cuff pres- sure	It is not possible to build up sufficient pressure in the cuff. A leak may have oc- curred. Check that the cuff connection is correct and that the cuff is not too loose around your arm. Replace the batte- ries if necessary. Repeat he measurement.
«ERR 2» 1® -D (())	Interference signal	During the measurement, interference signals were detected by the cuff, caused for instance by movement or muscle tension. Repeat the measurement, keeping your arm still.	«ERR 5»	Irregular measuring result	The measuring signals are inaccurate and no result can therefore be displayed. Read through the check list for per- forming reliable measu- rements and repeat the measurement.*
			 «HI»	Pulse rate or cuff pressure too high	The pressure in the cuff is too high (over 299 mmHg) or your pulse rate is too high (over 200 beats per minute). Relax for 5 minutes and repeat the measurement.*

Error	Designa- tion	Potential cuase and remedy
«LO»	Pulse too Iow	The pulse rate is too low (less than 40 beats per minute). Repeat the measurement.*

*Please consult your doctor, if this or any other problem occurs repeatedly

8. Safety, care, accuracy test and disposal

Safety and protection

 Carefully follow these instructions. This document gives important information on the operation and safety of this monitor. Before using the monitor, please read these instructions carefully and retain them for future reference.

This device may only be used for the purposes described in these instructions. The manufacturer will not accept any liability for damage caused by improper use.

This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in Section 10 on page 17.

- Protect the monitor from:
 - water and moisture
 - extreme temperatures
 - impact and falls
 - contamination and dust
 - direct sunlight
 - heat and cold

The cuffs are rather delicate and must be handled with care.

Do not use any other cuffs or cuff connectors for measurements with this monitor.

Only inflate the cuff once fitted.

Do not use this monitor close to strong electromagnetic fields such as mobile telephones or radio installations. We recommend observing a minimum distance of 3.3 m from such devices when using this monitor.

- Do not use this monitor if you think it is damaged or if you notice anything unusual.
- Never open the monitor.
- If the monitor is not going to be used for a prolonged period of time, the batteries must be removed.
- Read the additional safety information in the individual sections of these instructions.
- The measuring result shown by this monitor is NOT a diagnosis. It is not a substitute for a professional evaluation by a physicist, in particular not if the result does not correspond to the patient's physical condition. Never rely on blood pressure measurements alone. All potential symptoms and the patient's statements must be taken into consideration. If necessary, call an ambulance or a physician.
- Permanently high blood pressure values can damage your health and must be treated by your doctor!
- Always discuss your values with your doctor and tell them if you have noticed anything unusual or feel unsure. **Never rely on blood pressure readings alone.**
- Under no circumstances should you alter the dosages of any drugs prescribed or start medication without consultation with your doctor.

Deviations between measurements taken by your doctor or in the pharmacy and those taken at home are quite normal, as these situations are completely different.

The pulse rate display is not suitable for checking the frequency of heart pacemakers!

If you are pregnant, you should monitor your blood pressure very closely as it can change drastically during this time!



Do not let unsupervised children use the monitor. Some of the components are so small that children can swallow them or choke on them. Beware of the risk of strangulations in case this monitor is fitted with cables or tubes.

Monitor care

Clean the monitor only with a soft, dry cloth.

Cleaning the cuff

Remove stains on the cuff carefully with a damp cloth and soapsuds or a commercial disinfectant.



WARNING: Do not wash the cuff in a washing machine or a dishwasher!



WARNING: Do not dry the cuff in a tumble dryer!

Accuracy test

We recommend to have this monitor tested for accuracy every 2 years or after severe mechanical impact (e.g. the device dropped to the floor). Please contact the aponorm[®] customer service on the website <u>www.aponorm.de</u>.

Disposal

Batteries and electronic devices must not be disposed of as normal domestic trash. They must be disposed of in accordance with the applicable local provisions.

9. Warranty terms

We are confident in the quality of our aponorm[®] blood pressure monitors. Therefore we, WEPA Apothekenbedarg GmbH & Co. KG, grant end customers who are private consumers, a voluntary 5 year warranty for all aponorm[®] blood pressure monitors purchased in Germany, subject to the following terms:

Subject matter and scope of the warranty

The warranty applies to all aponorm[®] blood pressure monitors which customers in their capacity as consumers purchased in Germany. WEPA Apothekenbedarf GmbH & Co. KG warrants the customer that the product is free from defects in material and workmanship. Should, despite proper handling of the product, a defect occur within the 5-year warranty period, WEPA Apothekenbedarf GmbH & Co. KG will repair the product free of charge (except for the transport costs for returning the monitor to WEPA) or fully replace it at its discretion.

Exclusion of warranty

No claims can be derived from this warranty in case of damage caused by the customer's or third parties' negligence such as drop, accident or improper handling. The same applies to damage caused by leaking batteries or failure to observe the operating instructions.

Warranty by WEPA Apothekenbedarf GmbH & Co. KG is also excluded if a defect/damage was caused by an improper repair or other third party interventions.

The warranty does not cover wear parts, accessories (e.g. pouches, cables, etc.), batteries and the cuff forming part of the product. We grant a functional guarantee of 2 years on the cuff (tightness of the inner chamber).

Warranty period

The warranty covers a period of 5 years from the date of purchase (warranty period). The relevant

proof is the date of the proof of purchase or of the warranty card with purchase date filled in by the distributor.

The warranty period is not extended by the fact that benefits under this warranty were granted, in particular not in the event of a repair or exchange of the product. In such cases, the warranty does not recommence.

Assertion of warranty claims

Within the warranty period, the customer can claim his/her rights under this warranty by presenting the faulty product and the proof of purchase or the warranty card filled in by the distributor directly to WEPA Apothekenbedarf GmbH & Co. KG or the distributor where the customer had purchased the product.

If the fault/damage is covered by the warranty, WEPA Apothekenbedarf GmbH & Co. KG will repair the product free of charge (except for the transport costs for returning the monitor to WEPA) or fully replace it at its discretion.

If it is found that the fault/damage is not covered by the warranty, the product can be repaired by WEPA Appthekenbedarf GmbH & Co. K at the customer's expenses. In this case, WEPA Apothekenbedarf GmbH & Co. KG informs the customer of the estimated costs in a cost estimate before starting the repair work. The customer is free to commission the repair of the product with costs or to request the return of the unrepaired product.

Further customer rights

WEPA Apothekenbedarf GmbH & Co. KG grants the warranty subject to the terms and conditions stated. Customer can have further statutory rights. The contractual and statutory rights of customers, in particular the statutory warranty rights against the seller of the product, shall not be affected by the warranty.

The warranty is governed by the legislation of the Federal Republic of Germany. Date: 10/2018

10. Technical data

Operating conditions:	10 - 40 °C / 50 - 104 °F 15 - 95% relative maximum air humidity
Storage conditions:	-20 - +55 °C / -4 - +131 °F 15 - 95 % relative maximal air humidity
Weight:	277 g /with batteries)
Size:	131 x 90 x 60.5 mm
Measuring method:	oscillometric, validated by the Korotkoff method: phase I systolic, phase V diastolic

Measuring range:	20 - 280 mmHg – blood pressure 40 - 200 beats per minute - pulse rate	This monitor complies with the requirements of the Medical Device Directive 93/42/EEC. Technical alterations reserved.
Cuff pressure display range:	0 - 299 mmHg	
Measuring resolution	on: 1 mmHg	
Static accuracy:	pressure within ± 3 mmHg	
Pulse rate accuracy	r: ± 5% of the reading	
Soltage source:	· 4 x 1.,5 V alkaline bBatte- ries, size AA	
	· Mains adapter DC 6 V, 600 mA (optional)	
Battery life:	approx. 920 measurements (with new batteries)	
IP class:	IP 20	
Reference to standards:	EN 1060-1 /-3 /-4; IEC 60601-1; IEC 60601-1-2 (EMC); IEC 60601-1-11	
Áverage service life:	Monitor: 5 years or 10,000 measurements; Accessories: 2 years	

Name of customer

Serial number of monitor (SN)



Date of purchase

Pharmacy stamp and signature

aponorm[®] by microlife

Warranty card

To be on the safe side: the aponorm[®] warranty.



Your new blood pressure monitor is a top-class precision medical device. We warrant this with our name and our warranty. Please refer to p. 16 of the instructions for the terms of warranty in detail.

Tips:



In case you lost the instructions for use with the terms of warranty during your period of use of the monitor, you can at any time download them on the Download site at <u>www.aponorm.de.</u>

Here you also find the instructions for use in German, Turkish, French and Russian for download.





Sold by: WEPA Apothekenbedarf GmbH & Co KG Am Fichtenstrauch 6-10 D-56204 Hillscheid www.aponorm.de www.wepa-dieapothekenmarke.de

microlife

Manufactured by: Microlife AG Espenstrasse 139 CH-9443 Widnau www.microlife.ch



Assistive appliances No.: 21.28.01.2103 Order No. 047290

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