apo norm®
die marke der apotheke

# INSTRUCTIONS FOR USE
# UPPER ARM BLOOD PRESSURE MONITOR
## PROFESSIONAL TOUCH

**The specialist for atrial fibrillation-Recognition with PC connectivity[1]**

- Atrial fibrillation detection[1]
- Triple measurement 15 seconds[2]
- PC connection[3]
- Touch-screen display
- Comfort cuff M-L
- One user with 99 memory spaces
- Blood pressure traffic light
- Keypad lock

Also suitable for:

- Diabetic patients
- Kidney disease
- Pregnant women[4]
- For people 12+[4]

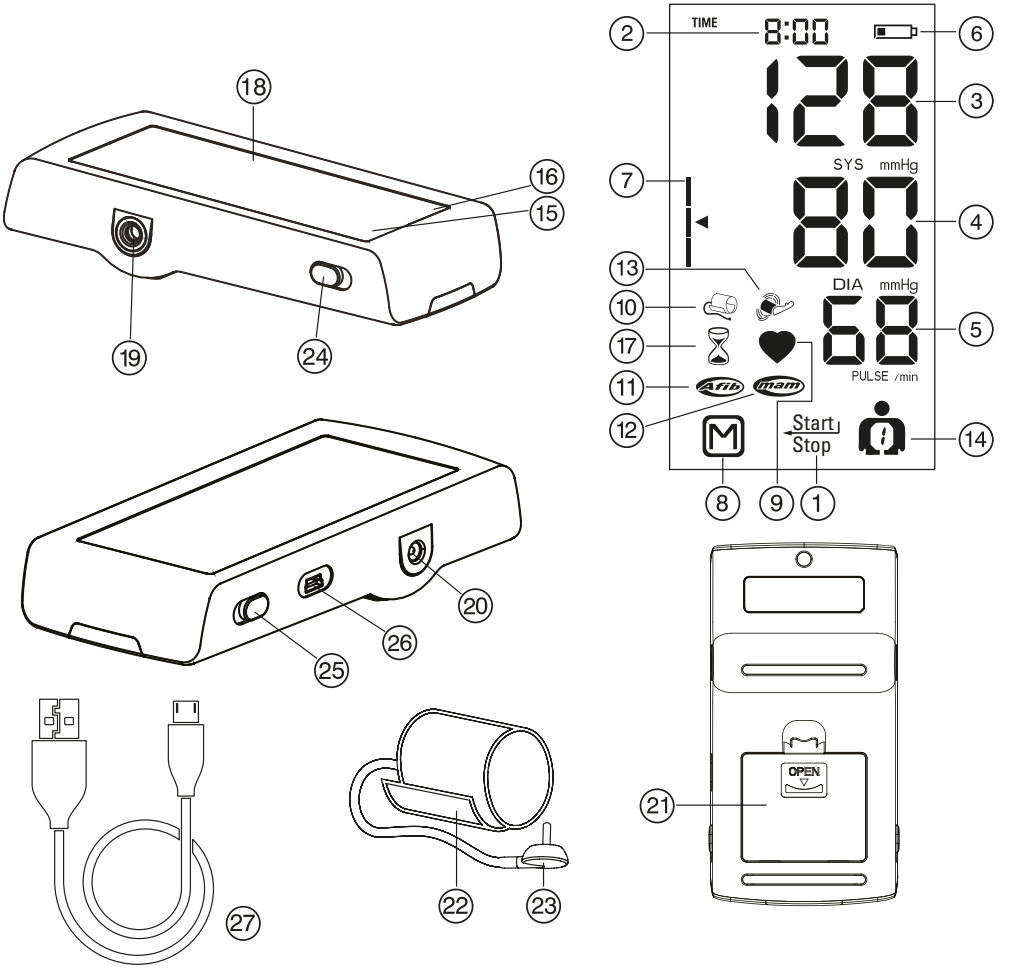

5 Year Warranty[5]

KLINISCH VALIDIERT

Manschetten S-XL verfügbar[6]

[1]Integrated AFIB$_{sens}$ technology can detect atrial fibrillation; overview of studies at www.aponorm.de/studien. [2]Based on the ESC Guidelines 2024; simple measurement mode adjustable as desired. [3]The use of the software is free of charge. System requirements can be found at www.aponorm.de/software. [4]In young people and pregnant women, a measurement is recommended without considering the detection of atrial fibrillation (see page 8 of these instructions for use). [5]The warranty does not cover wear parts, batteries, and accessories (the cuff has a two-year functional warranty). The warranty is granted for consumers residing in Germany and Austria. For further warranty conditions, see page 25 of these instructions for use. [6]Alternative sizes to the included standard cuff available separately (see page 10 ).

A quality brand of WEPA
DIE APOTHEKENMARKE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### Display indications

① Start/stop key (Enter key)
② Date/time display
③ Systolic pressure
④ Diastolic pressure
⑤ Pulse Indicator
⑥ Low battery warning light
⑦ Classification of your blood pressure measurement
⑧ M key (memory display)
⑨ Pulse measurement active
⑩ Cuff check (ERR 3)
⑪ Atrial fibrillation warning symbol $AFIB_{sens}$
⑫ MAM display (triple measurement active)
⑬ Motion alarm (ERR 2)
⑭ User selection
⑮ "Back" button
⑯ "Forward" button
⑰ Pause countdown (only in MAM mode)

### Switches, housings, and accessories

⑱ Touch-screen display
⑲ Cuff socket
⑳ Mains adapter connection
㉑ Battery compartment
㉒ Cuff
㉓ Cuff connector
㉔ Measurement mode selector switch
㉕ Lock switch/keypad lock
㉖ USB socket for computer connection
㉗ USB cable for computer connection

This product is subject to the European Directive 2012/19/EU on waste electrical and electronic equipment and is marked accordingly. Do not dispose of electronic devices with household waste. Please check your local regulations for proper disposal of electrical and electronic products. Proper disposal helps prevent potential harm to the environment and human health.

**Caution! These instructions must be observed to prevent possible damage to the device or error messages.**

Protect against moisture.

Carefully read the instructions before use.

Type BF applied part


Medical device

Manufacturer


EU representative

Importer


Keep out of reach of children aged 0-3 years.

Humidity limit for operation or storage

Temperature limitation for operation or storage

Atmospheric pressure limitation

CE 0044 CE marking

SN Serial number
YYYY-MM-DD-SSSS
Year-Month-Day Serial Number

REF Model designation/factory number

Purpose:
This oscillometric blood pressure monitor is intended for the non-invasive measurement of blood pressure in people aged 12 years and older.

Clinically validated in patients with hypertension, hypotension, diabetes, pregnancy, pre-eclampsia, atherosclerosis, end-stage renal disease, obesity, and in older adults.

The device can detect an irregular pulse indicating atrial fibrillation (AF). Please note that this device cannot diagnose atrial fibrillation. A diagnosis of atrial fibrillation can only be confirmed by a physician using an ECG.

**Available formats for the visually impaired:**
The instructions for use available at www.aponorm.de/bmg-downloads in PDF format can be printed in enlarged form (see QR code below).

www.aponorm.de/bmg-downloads

Dear Customer,

Atrial fibrillation is a major risk factor for stroke and affects approximately 40 million people worldwide.[1, 2] Many cases of atrial fibrillation remain undetected because they are asymptomatic. This increases the risk of serious complications. However, early detection and subsequent appropriate treatment can prevent up to 68% of strokes caused by atrial fibrillation.[3, 4]

The Microlife AFIB$_{sens}$® technology is a leader in the field of atrial fibrillation examination and provides people with a reliable and clinically validated tool for monitoring their heart rhythm. Developed in collaboration with leading medical experts, this patented technology integrates an advanced algorithm into blood pressure monitors, thereby allowing users to be screened for atrial fibrillation and hypertension simultaneously.

An atrial fibrillation diagnosis can be confirmed only by a doctor using an electrocardiogram (ECG). If atrial fibrillation is detected with a blood pressure monitor featuring integrated Microlife AFIB$_{sens}$® technology, you should consult a doctor for further examination.

If you have any questions or problems or need spare parts, please feel free to use the contact form on the product website www.aponorm.de or contact the retailer from which you purchased the product.

On the product website, you will also find a variety of other useful information about this product (e.g. FAQs, troubleshooting aids, digital user manuals).


[1] Giuseppe Lippi, Global epidemiology of atrial fibrillation: An increasing epidemic and public health challenge, International Journal of Stroke, 2021 Feb;16(2):217-221.

[2] Kornej J, Börschel C, Benjamin E, Schnabel R. Epidemiology of atrial fibrillation in the 21st century: novel methods and new insights. Circ Res. 2020;27:4–20.

[3] Van Gelder, Isabelle C., et al. "2024 ESC Guidelines for the management of atrial fibrillation," developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). Eur Heart J, 45, 36, 2024: 3314–414.

[4] Hart RG, Benavente O, McBride R, Pearce LA: Antithrombotic therapy to prevent stroke in patients with atrial fibrillation: a meta-analysis. Ann Intern Med 1999; 131:492–501.

## Table of contents

## 1. Display of the AFIB$_{sens}$ symbol for the early detection of atrial fibrillation

**(Only active in triple measurement mode; see Chapter 2 on page 10)**

This device can detect atrial fibrillation. The symbol ⑪ indicates that atrial fibrillation was detected during the measurement.

### Consult a doctor if the AFIB$_{sens}$ symbol appears frequently

This device is an oscillometric blood pressure monitor that also analyses pulse irregularities during measurement. The device has been clinically tested. When the AFIB$_{sens}$ symbol appears on the display of the blood pressure monitor, it indicates the possible presence of atrial fibrillation. If the AFIB$_{sens}$ symbol is displayed after a triple measurement, you are advised to perform another triple measurement. If the AFIB$_{sens}$ symbol appears again, we recommend consulting a doctor. **However, diagnosis of atrial fibrillation must be made by a cardiologist based on ECG interpretation.**

- Keep your arm still during the measurement to prevent inaccurate results.
- This device cannot or may incorrectly detect atrial fibrillation in individuals with pacemakers or defibrillators.
- In the presence of atrial fibrillation, the diastolic blood pressure may not be accurate.
- In the presence of atrial fibrillation, measurement in triple measurement mode (MAM) is recommended for a more reliable blood pressure measurement.

### What is atrial fibrillation (AF)?

Your heart normally contracts and relaxes regularly to the rhythm of your heartbeat. Certain cells in your heart produce electrical signals that cause the heart to contract and transport blood through the body. Atrial fibrillation occurs when rapid, irregular electrical signals in the two upper chambers of the heart (the atria) cause them to contract in an uncoordinated (fibrillating) manner. Atrial fibrillation is the most common form of cardiac arrhythmia. Often you may not feel any symptoms Nevertheless, the risk of having a stroke increases.

### Who should be tested for atrial fibrillation?

Atrial fibrillation screening is recommended for people aged 65 and over, as the risk of stroke increases with age. For people with high blood pressure (e.g. SYS above 159 or DIA above 99), diabetes, coronary heart disease, or a previous stroke, atrial fibrillation screening is recommended from the age of 50. . However, atrial fibrillation screening is not recommended for younger people or during pregnancy, as it may lead to false results and unnecessary anxiety. In addition, young people with AF have a lower risk of stroke than older people.

**Risk factors you can control**

Early diagnosis of atrial fibrillation followed by adequate treatment can considerably reduce the risk of stroke.
The first proactive step against stroke is to know your blood pressure and whether you have AF. For more information, visit www.aponorm.de/bmg-technologien.


## 2. Initial commissioning of the device

**Disposal of batteries**

First, unlock the device using the lock switch ㉕ . Insert the new batteries. The battery compartment ㉑ is located on the underside of the device. Insert the batteries (4 × 1.5 V, size AAA), ensuring correct polarity as indicated on the device.

**Setting the date and time**

1. After inserting new batteries, a year will start flashing on the display. You can now set the current year using the "+" ⑯ and "–" ⑮ buttons. Press the Enter key ↵ ① to confirm the desired year.
2. You can then set the current month in the same way and confirm by pressing the Enter button ① .
3. Next, repeat the process for day, hour, and minutes.
4. Once you have set and confirmed the minutes, the date and time setting is complete. The time is now displayed on the screen when the device is in standby mode ②. The date is required only for the memory display.

   If you want to change the date and time later, press and hold the time display ② until the year starts flashing. Repeat Steps 1–4 to reset the date/time.

**Selecting the right cuff**

aponorm® offers you various cuff sizes to choose from. The circumference of your upper arm is decisive (tightly fitted measured in the middle of the upper arm).

If the supplied cuff ㉒ does not fit, please use one of the alternative sizes available from your pharmacy).

| **Cuff size** | **for upper arm circumference** |
|---|---|
| S arm cuff | 17 - 22 cm |
| M arm cuff | 22 - 32 cm |
| M-L cuff | 22–42 cm |
| L-XL arm cuff | 52–32 cm |

All aponorm® cuff variants are latex-free.

Use only aponorm® cuffs or original Microlife cuffs (overview at www.aponorm.de/bmg-zubehoer).


- Connect the cuff to the device by inserting the cuff connector fully into the socket ㉓ until it clicks into place ⑲.

**Selecting the user**

With this blood pressure monitor, you can save the results for two different users. Additionally, the device features a guestmode. In this mode, the blood pressure values are not stored in the memory.

Before each measurement, select the desired user: "1", "2", or "–" (guest mode):

1. Tap the user icon ⑭ until the number in the symbol starts to blink.
2. You can select the user by tapping the user symbol repeatedly (User "1", "2", or "–" if you do not wish to save the result in guest mode).
3. Wait for about 2–3 s until the symbol stops blinking. The device is now ready for use.

**Selecting triple or single measurement**

Before each measurement, choose whether you want to perform a normal single measurement or a triple measurement (MAM symbol ⑨ will be shown on the display). In MAM mode, three measurements are automatically performed in succession. The result of all measurements performed is then automatically analysed and displayed. Because blood pressure fluctuates constantly, a result obtained in this way is even more reliable than a single measurement.

To select MAM mode, set the mode selection switch ㉔ on the device to Position 3 ($Afib_{sens}$). To switch back to normal mode (single measurement), slide the switch to Position 1.

- Between measurements, there is an automatic 15-second pause, indicated by a rotating countdown symbol ⑰. For this purpose, the remaining break time is displayed and counted down.
- Keep the cuff on between measurements.
- If the device detects that a single measurement within the triple measurement was faulty, a fourth or fifth measurement will be automatically carried out.
- During the measurement in MAM mode, you will see in the bottom right of the display the numbers (1, 2, 3) indicating which of the three measurements is currently being taken.

- An average value is calculated only after the triple measurement has been completed The results of the individual intermediate measurements are not displayed.

☞ Atrial fibrillation detection (see Chapter 1, page 8) is only active in MAM mode. In single mode, the device screens for simple pulse anomalies only (without limiting to atrial fibrillation).

## 3. Checklist for a reliable measurement

- Always take measurements in a quiet environment.
- The measurement should be taken while seated with back support (e.g. a chair with a backrest) after a five-minute rest period If you have performed intense physical activity immediately before the measurement, extend this rest period accordingly.
- Avoid caffeine, nicotine, and alcohol for at least one hour before the measurement.
- Always measure on the same arm. Unless otherwise directed by your doctor, choose the arm with the weaker muscles (usually the left arm for right-handed individuals). It is recommended that doctors determine the measuring arm once by measuring both sides. In future, the arm with the higher blood pressure value will be used as the measuring arm.
- Remove tight clothing from the upper arm. To avoid constriction, a shirt sleeve should not be rolled up; if it lies smooth and flat under the cuff, it will not interfere. Remove thick clothing completely because it will interfere with the measurement signal.
- Always ensure that the correct cuff size is used (size information can be found directly on the cuff).

☞ Place the cuff snugly – but not too tightly – on the upper arm (two fingers placed side by side should still fit underneath).

☞ Ensure that the lower edge of the cuff is approximately 1–2 cm away from the elbow crease.

☞ Ensure that the cuff is at heart level.

☞ The yellow artery marker on the cuff must be positioned over the artery that runs along the inside of the arm.

☞ Ensure that the measuring arm is resting relaxed on a flat surface. Keep your hand loose (do not clench your fist).

Further guidelines on performing a correct blood pressure measurement can be found at www.aponorm.de/blutdruckmessregeln.

www.aponorm.de/blutdruckmessregeln

## 4. Carrying out a blood pressure measurement

1. Slide the locking switch ㉕ to the "open" position. Start the measurement by tapping the Start key ①.
2. Thecuff is inflated automatically. Remain seated in a relaxed position, breathe normally, and do not speak or move.
3. Once the correct pressure is reached, inflation stops and the pressure gradually decreases. If the pressure was not sufficient, the device automatically pumps until a measurement is possible.
4. A heart symbol ⑨ flashes on the display during the measurement. This indicates that the (pulse) measurement is now taking place.

☞ You can stop the measurement at any time by pressing the Stop button ① (e.g. if you feel unwell or experience uncomfortable pressure).

5. The result, consisting of systolic ③ and diastolic ④ blood pressure as well as the pulse rate per minute ⑤ will be displayed after the measurement (in triple measurement mode only after three measurements have been completed, each with a 15-second interval) pause time between individual measurements; see Chapter 2 on page 10).

☞ This blood pressure monitor has been specifically tested for use during pregnancy and in cases of pre-eclampsia If you measure unusually high values during pregnancy, you should measure again after a short time (e.g. 1 h).

If the value is still too high, consult your doctor.

6. Remove the cuff from the device.
7. Switch off the device using the Start/stop button ①. Otherwise, it will automatically deactivate after approx. one minute of inactivity.

### Do not save a measurement result

As soon as the measurement result appears on the display, press and hold the Start/stop key ① until the M key ⑧ on the display blinks.

Then confirm the deletion process by tapping the M key ⑧ again.

☞ "CL" is displayed when a measurement value has been successfully deleted from the memory.

### How do I assess my blood pressure?

The triangle at the left edge of the display ⑦ indicates the range in which your measured blood pressure value lies. The value will fall within the optimal (green), borderline (yellow), or high (red) range.

The classification for self-measurements is defined by international guidelines (ESH, ESC, JSH; data in mmHg).

| Range | | Systolic pressure | Diastolic pressure | Classification |
|---|---|---|---|---|
| 1. | Red | ≥ **135** | ≥ **85** | Too high |
| 2. | Orange | **130–134** | **80–84** | Elevated |
| 3. | Green | **< 130** | **< 80** | Normal |

The higher value is always used for classification of your blood pressure. Example: In the measurements of **142**/75 mmHg or 125/**90** mmHg, these are classified as high blood pressure (red).

☞ **Note:** The blood pressure classification is a general guideline for blood pressure measurements at home. The diagnosis of high blood pressure must always be made by a healthcare professional based on the patient's individual condition. Always consult your doctor in the event of abnormal or unclear values. Please also note that different threshold values apply to self-measurements than to measurements taken by a doctor or in a pharmacy.

## 5. Measurement memory

This device automatically stores the last 99 measurements in the internal memory (measurement values in the software are unlimited; see Chapter 8 on page 16).

### Display of stored values

First, select the user whose measurement results you want to retrieve from memory using the user icon ⑭. Then briefly tap the M key ⑧. The display now switches to the memory display.

First, the average value of all stored measurements is displayed, indicated by the symbol "A" (for "Average") ) in the lower right above the user icon ⑭. By repeatedly pressing the M key ⑧, you can now cycle through the individual, numbered measurement results (chronologically from the most recent to the oldest value).

Press the Stop button ① to exit memory mode.

☞ The maximum storage capacity is 99 measurements. **When the memory is full, the oldest value is automatically set to 100. Measurement overwritten.** The values should be documented separately, for example via the software (see Chapter 8 on page 16) before the full storage capacity is reached; otherwise, the measurement data will be lost.

### Deleting all values

First, unlock the device (set the locking switch ㉕ to the "open" position). If you are sure that you want to permanently delete all stored values, press and hold the M button ⑧ (the device must be switched off beforehand) until "CL" (for „Clear") appears. ) flashes in the display and then release the key.

To permanently delete the memory, tap the M key again ⑧.

☞ Cancellation of the deletion process:
Tap the Stop button ① while "CL" is flashing to cancel the process.

☞ Individual values cannot be deleted.

## 6. Battery indicator and battery replacement

### Batteries running low

If the batteries are about 3three-quarters depleted, a partially-filled battery symbol will start flashing immediately after switching on the device ⑥ . You can still measure reliably with the device, but you should have new batteries ready as soon as possible.

### Batteries fully discharged/replacement of batteries

When the batteries are completely discharged, a blank battery symbol ⑥ will start blinking immediately after switching on.

You can no longer take a measurement and must replace the batteries immediately.

☞ Values that have already been measured are retained in memory even during a battery change/power failure. However, the date and time must be reset; this is indicated by a flashing year.

To change the batteries and reset the date/time, please proceed as described in Chapter 2 on page 9.

### Which batteries and what to consider?

- Use four new, long-lasting 1.5 V alkaline batteries, size AAA.
- Do not use batteries beyond the specified expiry date.
- Remove the batteries if the device is not going to be used for an extended period.
- Further helpful tips can be found online at www.aponorm.de/bmg-batterien.

www.aponorm.de/bmg-batterien

**Use of rechargeable batteries (accumulators)**

You can also use this device with rechargeable batteries.

- Use only rechargeable "NiMH" batteries.
- When the battery symbol (empty battery) is displayed, the batteries must be removed and recharged. They may not be left in the device because they may be damaged (deep discharge because of the low power consumption of the device even when switched off).
- Always remove rechargeable batteries from the device if you are not using it for a week or longer.
- The batteries cannot be charged in the blood pressure monitor. Charge the batteries in an external charger and observe the notes on charging, care, and shelf life.

## 7. Using the power adapter

You can use this device with the Microlife power adapter (DC 6V, 600 mA) (sold separately; not included).

Use the Microlife mains adapter available as original accessories. This is available from pharmacies.

☞ Ensure that the power adapter and cables are free of damage.

1. Plug the adapter cable into the power adapter socket ⑳ of the blood pressure monitor.
2. Plug the adapter plug into the mains socket.

When the AC adapter is connected, no battery power is consumed. As a safety measure, we recommend that you leave the batteries inserted even during mains operation. This means that the time and date are retained in the event of a power failure and do not need to be entered again.

For further information, please visit www.aponorm.de/bmg-zubehoer.


## 8. Data transfer to the PC

This device can be used together with the "Microlife Blood Pressure Analyser+" (BPA+) software. The stored data can be transferred between the instrument and the computer via a cable connection. For this, you will need the USB cable included (connection via the USB port ㉖ on the device).

⚠ **Caution:** Make sure that the date/time is set on your blood pressure monitor (even after changing the batteries or disconnecting the power supply) so that your saved values can be correctly assigned later in the analysis program.

If no date/time has been set on the device beforehand, it is not possible to correctly transfer/display the saved values from the device to the software. For information on setting the date/time, see Chapter 2 on page 9.

**Installing, setting up, and synchronising the software**

Download the latest software version free of charge at www.aponorm.de/software.


[1]The use of the software is free of charge. System requirements can be found at www.aponorm.de/software; the app is provided by Microlife Corporation.

To install and set up the program as well as to carry out the data transfer, please use the instructions provided there.

☞ While connected, the device is completely controlled by the computer. It is not possible to activate or change the blood pressure monitor during this time.

## 9. Error messages

If an error occurs during a measurement, the measurement is aborted, and an error message (e.g. "Err 3") is displayed.

☞ If no error message is displayed but the measurement results seem unusual, please check that you have followed all the points in the checklist in Chapter 3 on Page 11.

☞ More detailed troubleshooting information for the device can be found in the download section of the product website at www.aponorm.de/bmg-downloads.


| Error | Designation | Possible cause and remedy |
|---|---|---|
| **"ERR 1"** | Signal too weak | The pulse signals on the cuff are too weak. Reapply the cuff and repeat the measurement.[1] |

| Error | Designation | Possible cause and remedy |
|---|---|---|
| **"ERR 2"** ⑬ | Interference signal detected | During the measurement, interference signals were detected at the cuff (e.g. because of movement or muscle tension). Make sure that you hold your arm still during the measurement and repeat the measurement. |
| **"ERR 3"** ⑩ | Abnormal cuff pressure | The cuff pressure cannot be built up sufficiently. There may be a leak. Check that the cuff is properly connected and not too loose. If necessary, replace the batteries. Then repeat the measurement. |
| **"ERR 5"** | Abnormal result | The measurement signals are inaccurate and therefore no result can be displayed. Please refer to the checklist for reliable measurements (see Chapter 3, page 11), and repeat the measurement.[1] |
| **"ERR 6"** | MAM mode | There were too many errors during the measurement in MAM mode so that no final result can be determined. Please refer to the checklist for carrying out reliable measurements (see Chapter 3 on page 11) and repeat the measurements.[1] |
| **"HI"** | Pulse or cuff pressure too high | The cuff pressure is too high (over 299 mmHg) or the pulse is too high (over 200 beats per minute). Relax for at least 5 minutes before the measurement and repeat the measurement.[1] |
| **"LO"** | Pulse too low | The heart rate is too low (below 40 beats per minute). Repeat the measurement process.[1] |

[1]It is advisable to see a doctor if these or other problems occur repeatedly.

## 10. Safety, maintenance, metrological verification, and disposal

### ⚠ Safety and protection

- Please follow these instructions for use. This document contains important information about the operation and safety of this device. Please carefully read this document before using the device and keep it for future reference.
- This device may be used only for the purpose described in this manual. The manufacturer is not liable for damage resulting from improper handling.
- This device consists of sensitive components and must be handled with care. Please refer to the storage and operating instructions in Chapter 13 on Page 24.
- Protect the device from:
  - Water and moisture
  - Extreme temperatures
  - Bumps and falls
  - Dirt and dust
  - Strong sunlight
  - Heat and cold
- The cuff is delicate and must be handled with care.
- Do not use any other cuffs or cuff connectors for measurement with this device.
- Inflate the cuff only once it is in place.
- Do not use the device near strong electromagnetic fields such as mobile phones or radio equipment. Keep a minimum distance of 3.3 m from such devices when using this device.
- Do not use the device if you notice any damage or anything unusual.
- Never open the device.
- Remove the batteries if the device is not going to be used for an extended period.
- Please refer to the additional safety instructions in the individual chapters of this manual.
- **The pulse display is not suitable for monitoring the frequency of pacemakers.**

⚠ **WARNING:** If you suffer from an arrhythmia, consult your doctor before using the device (see also Chapter 1 on Page 8 for displaying atrial fibrillation).

- **Prolonged high blood pressure can lead to health issues and must therefore be treated by your doctor.**
- Always discuss your values, any particular concerns or uncertainties with your doctor. **Never rely solely on the blood pressure measurements.**
- **Under no circumstances should you change the dosage of medications or start any treat-**

**ment without consulting your doctor.**

- The measurement result displayed by this device is not a medical diagnosis. It does not replace the need for a professional assessment by a doctor, especially if the result does not correspond to the specific condition. Do not rely solely on the measurement result. All potentially occurring symptoms and the specific condition must be considered. Consult a doctor or seek emergency medical assistance.
- Differences between measurements taken at the doctor's or in the pharmacy and at home are normal because you are in completely different situations.
- During pregnancy, you should regularly monitor your blood pressure.


Keep out of reach of children; some parts are small enough to be swallowed. Be aware of the risk of strangulation if this device is equipped with cables or hoses.

### Maintenance of the device

Clean the device only with a soft, dry cloth.

### Cleaning the cuff

Carefully remove stains on the cuff with a damp cloth, soapy water or commercially available disinfectant.

**WARNING:** Never wash the cuffs in a washing machine or in a dishwasher

**WARNING:** Do not tumble dry the cuff

**WARNING:** The inner bladder may never be washed

### Calibration, metrological verification and service

The device is calibrated during manufacture.

For devices used in professional settings (e.g. medical practices), metrological verification must be carried out every two years by December 31. year. Metrological verification is not required for privately purchased devices. We recommend carrying out a check in any case after considerable mechanical stress (e.g. if the device has been dropped, if there is liquid ingress, or if malfunctions occur frequently). Metrological verification is not covered by the warranty.

If you have any questions about the device's measurement accuracy or about metrological verification/device testing, please contact your local pharmacy or visit www.aponorm.de/kontakt.

**Caution:** Do not attempt to service or calibrate the device or its accessories yourself.

### Disposal

This device is a medical electrical device. Dispose of this device and the batteries in accordance with the Waste Electrical and Electronic Equipment Directive (WEEE), the German Electrical and Electronic Equipment Act (ElektroG),

the Battery Act (BattG), and applicable local regulations. Do not dispose of the device or batteries with household or commercial waste.

## 11. Warranty conditions

We, WEPA Apothekenbedarf GmbH & Co. KG, voluntarily grant consumers residing in Germany and Austria a five-year warranty on all aponorm® Mobil Basis blood pressure monitors according to the following terms and conditions:

### Scope of the warranty

The warranty applies to all aponorm® Mobil Basis blood pressure monitors of consumers residing in Germany and Austria. WEPA Apothekenbedarf GmbH & Co. KG guarantees that the product is free from material and manufacturing defects. If, despite proper use, a defect occurs within the five-year warranty period, WEPA Apothekenbedarf GmbH & Co. KG will, at its discretion, repair the product free of charge or replace it entirely (excluding shipping costs for returning the device).

### Warranty exclusions

This warranty does not cover damage caused by the purchaser or third parties, e.g. due to falls, accidents, or improper handling. The same applies to damage caused by leaking batteries or failure to follow the instructions for use.

A warranty coverage by WEPA Apothekenbedarf GmbH & Co. KG is also excluded if a defect/damage is attributable to improper repair or other interventions by third parties.

The warranty does not cover wear parts, accessories (e.g. cables), batteries, or the cuff supplied with the product. We offer a two-year functional warranty on the cuff with regard to the correct functioning of the cuff.

### Term of the warranty

The warranty is valid for five years from the date of purchase. The decisive date is that on the purchase receipt or the warranty card completed by the dealer.

The warranty period is not extended by any services provided under this warranty, in particular not in the case of repair or replacement of the product. The warranty period does not start over again in these cases either.

### Assertion of warranty claims

The customer may exercise their warranty rights by presenting the defective product and proof of purchase, or a warranty card completed by the dealer, either to WEPA Apothekenbedarf GmbH & Co. KG or to the dealer from whom the product was purchased, within the warranty period.

In the event of a warranty claim, WEPA Apotheken-

bedarf GmbH & Co. KG will repair the product free of charge or replace it at its discretion (excluding shipping costs for returning the device).

If it is determined that no warranty claim exists, the product can be repaired by WEPA Apothekenbedarf GmbH & Co. KG at the purchaser's expense. In this case, WEPA Apothekenbedarf GmbH & Co. KG shall provide the customer with a cost estimate before carrying out the repair. The customer may choose to have the product repaired at their own expense or request the return of the unrepaired product. WEPA does not cover any transport costs in this case.

**Further rights of the purchaser**

WEPA Apothekenbedarf GmbH & Co. KG provides the warranty under the stated conditions. In addition, the customer may be entitled to further legal rights. The purchaser's contractual and statutory rights, in particular statutory warranty rights against the seller, remain unaffected by this warranty.

The warranty is governed by the laws of the Federal Republic of Germany.

## 12. Reporting serious incidents

If serious incidents occur during use of the product (e.g. deterioration in a person's health or other significant events), please report them to WEPA Apothekenbedarf GmbH & Co. KG or to the manufacturer Microlife (contact details can be found on the back of the instructions for use).

You may also report the incident to the competent authority of the respective EU Member State. In the Federal Republic of Germany, this is:

Federal Institute for Medicines and Medical Devices, Dept. Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany, www.bfarm.de.

Incidents are considered serious if they have directly or indirectly caused, could have caused, or might cause

a) the death of a person,

b) a temporary or permanent serious deterioration in a person's state of health, or

c) a serious risk to public health.

For any other questions about the product or for technical support, please use the contact form on the product website www.aponorm.de/kontakt to contact aponorm® customer service.

www.aponorm.de/kontakt

## 13. Technical data

| | |
|---|---|
| **Operating conditions:** | 10–40°C/50–104°F<br>15–90% relative, maximum humidity |
| **Storage conditions:** | –20–55°C/–4–131°F<br>15–90% relative, max. humidity |
| **Weight:** | 312 g (with batteries) |
| **Size:** | 160 × 82 × 35 mm |
| **Measurement method:** | oscillometric, validated according to the Korotkoff method: Phase I systolic, Phase V diastolic |
| **Measuring range:** | SYS: 60–255 mmHg systolic<br>DIA: 40–200 mmHg diastolic<br>Pulse: 40–200 beats/minute |
| **Display area cuff pressure:** | 0–299 mmHg |
| **Resolution:** | 1 mmHg |
| **Static Accuracy:** | Pressure within ± 3 mmHg |
| **Pulse accuracy:** | ± 5% of the measured value |
| **Compatibility:** | System requirements www.aponorm.de/software |
| **Power supply:** | 4 × 1.5 V alkaline batteries, size AAA<br>6V DC power adapter, 600 mA (optional) |
| **Battery life:** (with new batteries) | ca. 400 individual measurements |
| **IP classification:** | IP 20 |
| **Reference to Standards:** | IEC 80601-2-30<br>IEC 60601-1; IEC 60601-1-2; (EMC); IEC 60601-1-11 |
| **Average lifespan:** | device: five years or more<br>10,000 measurements Accessories: two years |

This device complies with the requirements of the Medical Device Directive 93/42/EEC.

We reserve the right to make technical changes.



IB_BPA7Touch_WEPA_048216_ProfessionalTouch3G_5025
Revision date: 2025-12-19

## Notes

## Product features

**Identifies risk factors for stroke prevention**
Alerts you thanks to patented technologies upon detection of dangerous atrial fibrillation, one of the most common causes of a stroke[1] (in triple measurement mode) or in the case of irregular heartbeat (in single measurement mode).

[1] Integrated AFIB$_{sens}$-technology can detect atrial fibrillation, study overview at www.aponorm.de/studien.

**Additional measurement reliability thanks to triple measurement**
Can automatically perform three consecutive measurements based on recommendations from professional associations and doctors and calculate an even more accurate average value from them.[4]

[2] Based on the ESC Guidelines 2024; Simple measurement mode adjustable as desired

**Blood pressure evaluation on the computer**
Document your blood pressure values clearly on your home computer. You can easily export your data via software and take it with you to your doctor appointments.[3]

[3] The use of the software is free of charge; system requirements at www.aponorm.de/software

**Blood pressure documentation for dual and guest mode**
Records up to 99 measured values for up to two people so that you can easily track them later (unlimited memory space in the software). You can also take measurements in guest mode; these will not be stored.

**Simple blood pressure classification**
Classifies your blood pressure values on a scale according to international guidelines and automatically calculates the average value of all your measurements stored in the memory.

**Illuminated XXL touch display**
The illuminated touch display in XXL format is not only easy to operate but also particularly easy to read. Even in the dark.

**Especially easy to fit cuff**
The pre-shaped comfort shell cuff fits your arm like by itself with no braces or tightening.

**Energy-efficient operation**
Prevents accidental activation of the device by means of a key lock, thus conserving the batteries.

**Suitable for risk groups and persons aged 12 and over**
This blood pressure monitor is suitable for patients with pre-existing conditions (e.g. diabetes or kidney disease), for blood pressure monitoring during pregnancy, and for persons aged 12 years and older.[4]

[4] In young people and pregnant women, a measurement without consideration of atrial fibrillation detection is recommended (see page 8 of these instructions for use).

**Meets the highest quality standards**
This device has been validated according to ISO81060-2:2013 as well as the globally recognised protocol of the British and Irish Hypertension Society BIHS with Bestnote A/A for systole/diastole. We offer a five-year warranty on this device[1]

[5] The warranty does not cover wear parts, batteries, and accessories (the cuff has a two-year functional warranty). The warranty is granted for consumers residing in Germany and Austria. For further warranty conditions, see page 21 of these instructions for use.

www.aponorm.de

technology by microlife

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