

Instructions for use

Upper arm **BASIS CONTROL**

PLUS

apornorm[®]

die marke der apotheke

Automatic multiple measurement
for increased measuring reliability



**CLINICALLY +
VALIDATED**

5 YEARS WARRANTY



Also suitable for:



Kidney disease



Diabetics



Pregnant women

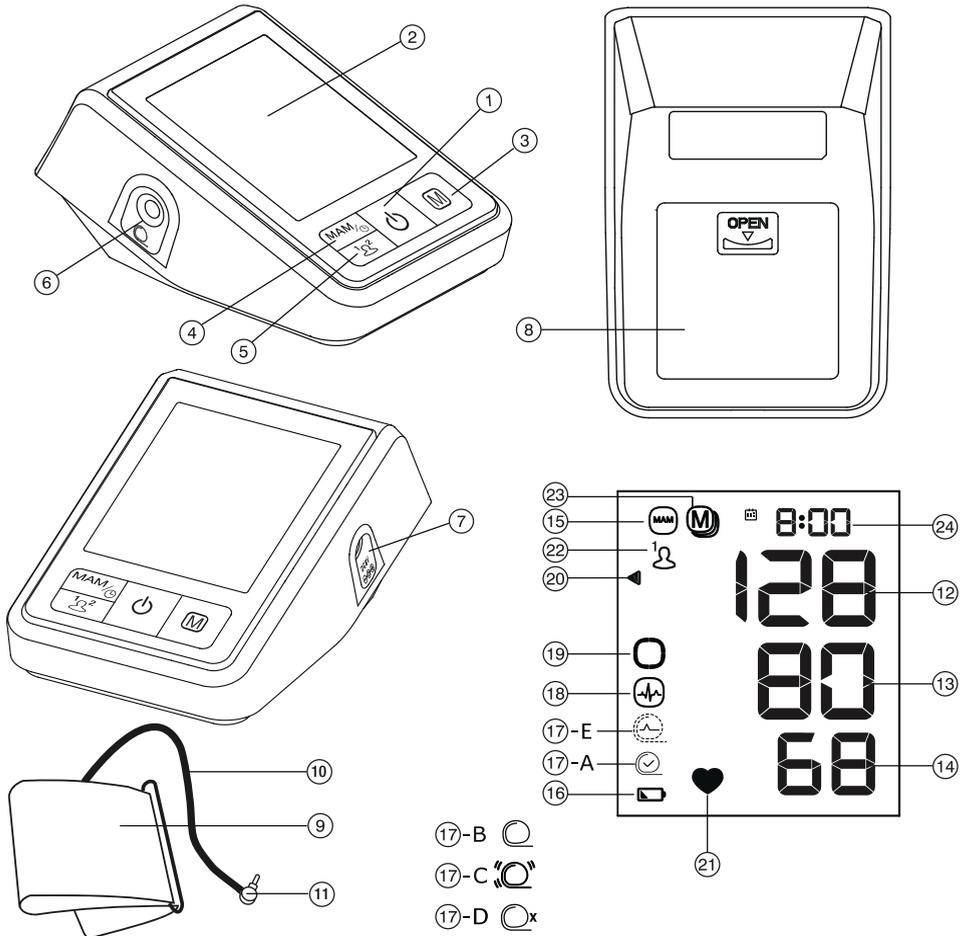
12+

Children

technology by
microlife[®]

* Functional warranty of 2 years on the cuff as a wear part

aponorm® Basis Control PLUS



Switches, housing and accessories

- ① On/off switch
- ② Display
- ③ M button (Memory)
- ④ MAM/Multiple measurements & time selection button
- ⑤ User selection button
- ⑥ Cuff connection
- ⑦ Mains adapter connector
- ⑧ Battery compartment
- ⑨ Cuff
- ⑩ Cuff tube
- ⑪ Cuff connector

Display indication

- ⑫ Systolic value
- ⑬ Diastolic value
- ⑭ Pulse indicator
- ⑮ MAM mode (multiple measurement mode active)
- ⑯ Battery level warning light
- ⑰ Cuff seating check
 - A Optimum cuff seat
 - B Less than optimal cuff seat
 - C Arm movement disturbance indicator «Err 2»
 - D Cuff signal disturbance indicator «Err 1»
 - E Cuff pressure disturbance indicator «Err 3»
- ⑱ Pulse arrhythmia detector (PAD)
- ⑲ MAM waiting time symbol
- ⑳ Blood pressure traffic light indicator
- ㉑ Pulse measurement active
- ㉒ User selection display
- ㉓ Stored value
- ㉔ Date/time display



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



Protect from moisture.



Before use, carefully read the operating instructions.



BF part.

aponorm® Basis Control Plus

Use:

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

It is clinically validated for patients suffering from hypertension, diabetes, pregnant women, pregnant women suffering from preeclampsia, patients suffering from atherosclerosis, terminal 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 of a very high standard.*

If you have any questions or problems or want to order spare parts, please contact the aponorm® customer service at the product website www.aponorm.de 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 and Irish 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 ⑧ is on the bottom of the monitor. Insert the batteries (4 x size AAA 1.5 V), observing the polarity +/- indicated on the housing.

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 present year. To confirm the year you want to set, press the MAM & time combination 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 MAM & time button ④.
3. Now repeat the instructions above to set the day, hour and minutes.
4. 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 ⑳. The date, however, is only required for the memory display.



If you want to change the date and time again, press and hold the MAM & time button ④ down for approx. three 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 ⑨ 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
M	22 - 32 cm
M - L	22 - 42 cm
L - XL	32 - 52 cm

- ▶ In addition to the soft cuffs in the above-mentioned sizes, as an alternative, a preformed comfort cuff is available in M - L, one size fits all.
- ▶ Use only aponorm® cuffs manufactured by Microlife.
- ▶ All aponorm® cuffs are latex-free.
- ▶ Connect the cuff to the monitor by inserting the cuff connector ⑪ into the cuff socket ⑥ as far as it will go.

Selecting the users

This monitor stores the data of 2 different users. Before each measurement, ensure that the correct user is selected.

Select the desired user (user 1 or user 2 ②), activating the user button ⑤ by activating the user button. The last selection is always stored for the next measurement.

Selection of multiple/MAM or individual measurement

Please select before each measurement whether you want to perform a normal single measurement (NO MAM symbol ⑮ in the display) or a multiple/MAM measurement (MAM symbol ⑮ visible in the display). In the MAM mode, three measurements are automatically taken one after the other, the result from all measurements is automatically analysed and then displayed. As the blood pressure varies constantly even within a very short time, a result determined in such a way is slightly more reliable than just one single measurement.

To select the MAM mode, press the MAM & time button ④ until the MAM symbol appears in the display. In order to return to the normal mode (individual measurement), press the MAM button again until the MAM symbol is no longer displayed.

- ▶ During the measurement in the MAM mode, the number 1, 2 or 3 at the bottom right of the display shows which of the three measure-

ments is currently taken.

- ▶ Between the individual measurements, there is an automatic pause of 15 seconds each, indicated by the MAM waiting symbol ⑰. A countdown indicates the remaining time.
- ▶ The results of the individual measurements are not shown. Instead, you will be shown the total result from the three measurements on completion of the cycle.
- ▶ Leave the cuff on your arm between the individual measurements.
- ▶ If the monitor detects that one of the individual measurements within the cycle was unsuccessful, a fourth measurement is automatically performed.

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.
 - Make sure that the cuff is positioned 2.5 cm above the crook of the arm.
 - The artery mark on the cuff (approx. 3 cm long bar) must lie over the artery which runs down the inner side of the arm.
 - Support your arm so it is relaxed.
 - Ensure that the cuff is at the same height as your heart.

3. Taking the blood pressure

1. Press the On/off button to start the measurement ①.
2. The cuff will now inflate automatically. Relax, do not move and do not tense your arm muscles until the measurement result is displayed. Breathe normally and do not talk.
3. If after a short while a cuff symbol appears with a check mark (⑰-A), the cuff signal and pressure are optimal for measurement. If there is no mark inside the cuff symbol (⑰-B), 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 ⑰-C, ⑰-D or ⑰-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 ⑫ flashes in the display.
6. The result, comprising the systolic ⑫ and the diastolic ⑬ blood pressure and the pulse rate per minute ⑭ is displayed.
7. When the monitor has finished measuring, remove the cuff.
8. 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 ① (e.g. if you feel uneasy or an unpleasant pressure sensation).

👉 This monitor is specially tested for use in pregnancy and when suffering from pre-eclampsia. 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» ② flashes. Confirm the deletion by pressing the MAM & 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 ⑳ points at the range your blood pressure reading is in. The reading is either in the optimum (green), increased (yellow) or high (red) blood pressure range. The classification corresponds to the following ranges defined by international guidelines (ESH, ESC, JSH) (values in mmHg).

Range	Systolic	Diastolic	Recommendation
1. blood pressure too high	≥ 135	≥ 85	seek medical advice
2. blood pressure elevated	130 -134	80-84	self-check
3. blood pressure optimum	< 130	< 80	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 detector (PAD)

This symbol  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 99 readings for each user.

Viewing the stored values

Press the M button  briefly while the monitor is switched off. Now the display changes over to the data memory display, indicated by «M»  (M) = 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 measured. 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 -B being not optimal are not included in the average.
-  Pay attention that the maximum memory capacity of 99 values for either user is not exceeded. When the memory is full, the oldest value is automatically overwritten with the 100th value. The values should be evaluated by a doctor or documented in a blood pressure diary 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» («CL ALL» = Clear All) appears and then release the button. To permanently clear the memory, press the M button while «CL ALL» is flashing.

Aborting the deletion:

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

 It is not possible to clear individual readings.

5. Battery indicator and battery change

Batteries almost flat

When the batteries are approximately 3/4 empty, the partly filled battery symbol  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 batteries are flat, the empty battery symbol  will flash as soon as the device 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 can NOT be charged while inserted in the blood pressure monitor. Recharge the batteries in an external charger and observe the information regarding charging, handling and service life.

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 from your local pharmacy.
 -  Ensure that neither the mains adapter nor the cable are damaged.
1. Plug the adapter cable into the mains adapter socket ⑦ 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 8 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 www.aponorm.de product website.

Error	Designation	Potential cause and remedy
«ERR 1» ⑰ -E 	Signal too weak	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.*

Error	Designation	Potential cause and remedy
«ERR 2» ⑰ -C 	Interference signal	During the measurement, interference signals were detected at the cuff, caused for instance by movement or muscle tension. Repeat the measurement, keeping your arm still.
«ERR 3» ⑰ -D 	Irregular cuff pressure	It is not possible to build up sufficient pressure in the cuff. A leak may have occurred. Check that the cuff connection is correct and that the cuff is not too loose around your arm. Replace the batteries if necessary. Repeat the measurement.
«ERR 5»	Irregular measuring result	The measuring signals are inaccurate and no result can therefore be displayed. Read through the check list for performing reliable measurements and repeat the measurement.*

Error	Designation	Potential cause and remedy
«ERR 6»	MAM mode	Too many errors occurred during the measurement in the MAM mode so that no final result can be determined. Read through the check list for performing reliable measurements and then repeat the measurements.*
«HI»	Pulse 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.*
«LO»	Pulse too low	The pulse rate is too low (less than 40 beats per minute). Repeat the measurement.*

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

8. Safety, care, accuracy check 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 18.
- Protect the monitor from:
 - ▶ water and moisture
 - ▶ extreme temperatures
 - ▶ impacts 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 to your arm.
- 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 the monitor if you think it is damaged or 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.
- Please observe the additional safety information in the different 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 physician, 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 contact 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 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 with a soft, dry cloth only.

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. e.g. the device dropped to the floor). Please contact the aponorm® customer service on the website www.aponorm.de.

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 Apothekenbedarf 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 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 term

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 Apothekenbedarf GmbH & Co. KG 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. In this case, 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. Customers 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: 02/2019

10. Technical data

Operating conditions:	10 - 40 °C / 50 - 104 °F 15 - 95 % relative maximal humidity of air
Storage conditions:	-20 - +55 °C / -4 - +131 °F 15 - 95 % relative maximum humidity of air
Weight:	402 g (incl. batteries)
Dimensions:	138 x 94.5 x 62.5 mm

Measuring method:	oszillometric, validated by the Korotkoff method: phase I systolic, phase V diastolic
Measuring range:	20 - 280 mmHg – blood pressure 40 - 200 beats per minute - pulse
Cuff pressure display range:	0 - 299 mmHg
Measuring resolution:	1 mmHg
Static accuracy:	pressure within ± 3 mmHg
Pulse accuracy:	$\pm 5\%$ of meas. value
Voltage source:	· 4 x 1.5 V alkaline batteries, size AA · Mains adapter DC 6V, 600 mA (optional)
Battery life:	ca. 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

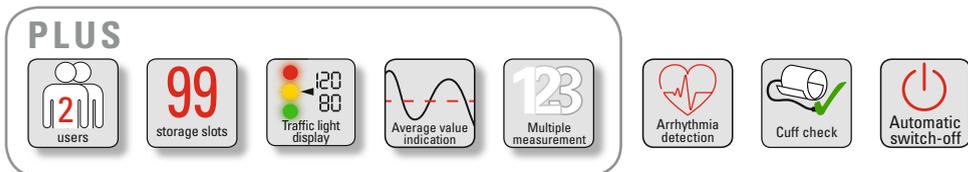
**Average
life:**

monitor: 5 years or
10.000 measurements;
accessories: 2 years

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

Technical alterations reserved!

Functional overview



PLUS = Enhanced functionality compared with basic model aponorm® Basis Control

Important advice:



Homepage

In the download area of www.aponorm.de you find these instructions with updates also in digital form for download, also in German, Turkish, French and Russian.



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