beurer

Model: MD6000

BM 81 easyLock

EN Upper arm blood pressure monitor
Instructions for use

CE 0123

ENGLISH

Read these instructions for use carefully and keep them for later use, be sure to make them accessible to other users and observe the information they contain.

Dear customer,

Thank you for choosing a product from our range. Our name stands for high-quality, thoroughly tested prod ucts for applications in the areas of heat, weight, blood pressure, body temperature, pulse, gentle therapy, massage, beauty, air and baby.

With kind regards
Your Beurer team

Contents

1. Included in delivery

Check that the exterior of the cardboard delivery packaging is intact and make sure that all contents are pre sent. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Service address.

1x upper arm blood pressure monitor with integrated easyLock universal cuff (24 – 40 cm)
1x instructions for use
1x brief instructions
4x 1.5 V AAA LR03 batteries

2. Signs and symbols

The following symbols are used on the device, in these instructions for use, on the packaging and on the type plate for the device:

	WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.
	CAUTION indicates a hazardous situation which, if not avoided, may result in minor or moderate injury.

	Product information Note on important information
	Observe the instructions Read the instructions before starting work and/or operating devices or machines
	Isolation of applied parts, type BF Galvanically isolated application part (F stands for "floating"); meets the requirements for leakage currents for type BF
	Direct current The device is suitable for use with direct current only
	Disposal Disposal in accordance with EC Directive WEEE (Waste Electrical and Electronic Equipment)
	Battery disposal Do not dispose of batteries containing hazardous substances with household waste
	Packaging disposal Dispose of packaging in an environmentally friendly manner
	Manufacturer
EC REP	Authorized representative in the European Community
	Distributor
	Temperature limit The temperature limit values to which the medical device can safely be exposed are indicated.
	Humidity, limit Indicates the humidity range to which the medical device can safely be exposed.
	Atmospheric pressure, limit Indicates the range of atmospheric pressures to which the medical device can be safely ex posed
IP22	IP class Device protected against foreign objects ≥ 12.5 mm and against water dripping at an angle
SN	Serial number
LOT	Batch code
REF	Item number
MD	Medical device

CE 0123	CE labelling This product satisfies the requirements of the applicable European and national directives

3. Intended use

Intended use

The blood pressure monitor is intended for the fully automatic, non-invasive measurement of arterial blood pressure and pulse values on the upper arm.

Target group

It is designed for self-measurement by adults in the home environment and is suitable for users whose upper arm circumference is within the range printed on the cuff.

Indication/clinical benefits

The user can record their blood pressure and pulse values quickly and easily using the device. The recorded values are classified according to internationally applicable guidelines and evaluated graphically. Furthermore, the device can detect any irregular heart beats that occur during measurement and inform the user via a symbol in the display. The device saves the recorded measurements and can also output average values of previous measurements. The recorded data can provide healthcare service providers with support during the diagnosis and treatment of blood pressure problems, and therefore plays a part in the long-term monitoring of the user's health.

4. Warnings and safety notes

⚠ Contraindications

- Do not use the blood pressure monitor on newborns, children or pets.
- People with restricted physical, sensory or mental skills should be supervised by a person responsible for their safety and receive instructions from this person on how to use the device.
- If you have any of the following conditions, it is essential you consult your doctor before using the device: cardiac arrhythmia, circulatory problems, diabetes, pregnancy, pre-eclampsia, hypotension, chills, shaking.
- People with pacemakers or other electrical implants should consult their doctor before using the device.
- The blood pressure monitor must not be used in connection with a high-frequency surgical unit.
- Do not use the cuff on people who have undergone a mastectomy.
- Do not place the cuff over wounds as this may cause further injury.
- Make sure that the cuff is not placed on an arm in which the arteries or veins are undergoing medical treatment, e.g. intravascular access or intravascular therapy, or an arteriovenous (AV) shunt.
- This device is not intended to be used as an Ambulatory Blood Pressure Monitor. Please do not apply the cuff for a long period of time

⚠ General warnings

- The measured values taken by you are for your information only – they are no substitute for a medical examination. Discuss the measured values with your doctor and never make your own medical decisions based on them (e.g. regarding dosages of medicines).
- The device is only intended for the purpose described in these instructions for use. The manufacturer is not liable for damage resulting from improper or incorrect use.
- Using the blood pressure monitor outside your home environment or whilst on the move (e.g. whilst travelling in a car, ambulance or helicopter, or whilst undertaking physical activity such as playing sport) can influence the measurement accuracy and cause incorrect measurements.
- Cardiovascular diseases may lead to incorrect measurements or have a detrimental effect on measurement accuracy.
- The PATIENT is an intended OPERATOR

- Do not use the device at the same time as other medical electrical devices (ME equipment). This could lead to a malfunction of the device and/or an inaccurate measurement.
- Do not use the device outside of the specified storage and operating conditions. This could lead to incorrect measurements.
- Only use the cuffs included in delivery or cuffs described in these instructions for use for the device. Using another cuff may lead to measurement inaccuracies.
- Please note that when inflating the cuff, the functions of the limb in question may be impaired.
- Do not perform measurements more frequently than necessary. Due to the restriction of blood flow, some bruising may occur.
- During the blood pressure measurement, the blood circulation must not be stopped for an unnecessarily long time. If the device malfunctions remove the cuff from the arm.
- Place the cuff on your upper arm only. Do not place the cuff on other parts of the body.
- Small parts may present a choking hazard for small children if swallowed. They should therefore always be supervised.

⚠ General precautions

- The blood pressure monitor is made from precision and electronic components. The accuracy of the measurements and service life of the device depend on its careful handling.
- Protect the device from impacts, humidity, dirt, marked temperature fluctuations and direct sunlight.
- Ensure the device is at room temperature before measuring. If the measuring device has been stored close to the maximum or minimum storage and transport temperatures and is placed in an environment with a temperature of 20 °C, it is recommended that you wait approx. 2 hours before using the measuring device.
- Do not drop the device.
- Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.
- We recommend that the batteries be removed if the device is not to be used for a prolonged period of time.
- Avoid any mechanical restriction, compression or bending of the cuff line.
- The temperature of cuff may reached to 42.1°C during normal operation at 40.0°C environment

Measures for handling batteries

⚠
- If your skin or eyes come into contact with battery fluid, rinse the affected areas with water and seek medical assistance.
- Choking hazard! Small children may swallow and choke on batteries. Therefore, store batteries out of the reach of small children.
- Risk of explosion! Do not throw batteries into a fire.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- Do not disassemble, open or crush the batteries.

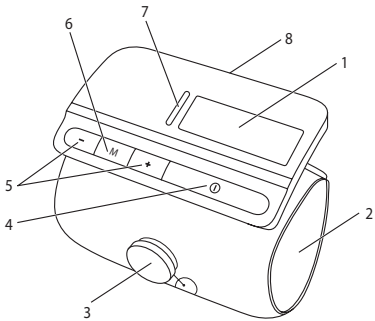
⚠
- Observe the plus (+) and minus (-) polarity signs.
- Protect the batteries from excessive heat.
- Do not charge or short-circuit batteries.
- If the device is not to be used for a relatively long period, take the batteries out of the battery compartment.
- Use identical or equivalent battery types only.
- Always replace all batteries at the same time.
- Do not use rechargeable batteries!

⚠ Notes on electromagnetic compatibility

- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The use of the device may be limited in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/device.
- Avoid using this device directly next to other devices or stacked on top of other devices, as this could lead to faulty operation. If, however, it is necessary to use the device in the manner stated, this device as well as the other devices must be monitored to ensure they are working properly.
- The use of accessories other than those specified or provided by the manufacturer of this device can lead to an increase in electromagnetic emissions or a decrease in the device's electromagnetic immunity; this can result in faulty operation.
- Failure to comply with the above can impair the performance of the device.

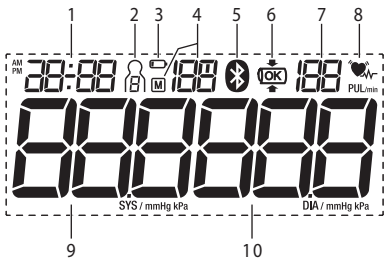
5. Device description

Blood pressure monitor and cuff



1. Display
2. Upper arm cuff
3. easyLock locking button
4. Start/stop button
5. Setting buttons +/-
6. Memory buttons M
7. LED risk indicator
8. Battery compartment lid

Display

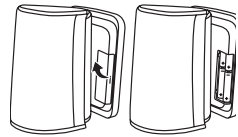


1. Date / time
2. User memory
3. Battery replacement symbol
4. Number of memory space/memory display average value ( ), morning ( ), evening ( )
5. Symbol for Bluetooth® transfer
6. Cuff position control
7. Calculated pulse value incl. unit
8. Pulse symbol
   Cardiac arrhythmia symbol
9. Systolic pressure incl. unit
10. Diastolic pressure incl. unit

6. Initial use

Inserting the batteries

- Remove the battery compartment lid on the rear of the device.
- Insert four 1.5 V AAA (alkaline type LR03) batteries. Make sure that the batteries are inserted the correct way round.
- Close the battery compartment lid again carefully.
- All display elements are briefly displayed, 24 h flashes in the display. Set the date and time as described below.



If the battery replacement symbol is permanently displayed, you can no longer perform any measurements and must replace all batteries. Once the batteries have been removed from the device, the date and time must be set again. Any saved measurements are retained.

Making settings

You must make sure that the device has the correct settings before use in order to be able to make full use of all functions. Only by doing so can your measurements with associated date and time be saved and accessed later by you.

Set the hour format, date, time and Bluetooth ® settings

It is essential to set the date and time. Otherwise, you will not be able to save your measured values correctly with a date and time and access them again later.

ⓘ There are two different ways to access the menu from which you can adjust the settings:

- Before initial use and after each time you replace the battery:
- When inserting batteries into the device, you will be taken to the relevant menu automatically.
- If the batteries have already been inserted:
- Press and hold the memory button M on the device when **switched off** for approx. 5 seconds.

In this menu you can adjust the following settings in succession:

Hour format → Date → Time → Bluetooth ® → User

Hour format

The hour format now flashes on the display.

- Using the +/- setting buttons, select your desired hour format and confirm with the M memory button.

Date

The year flashes on the display .

- Using the +/- setting buttons, select your desired number for the year and confirm with the M memory button.

The month flashes on the display .

- Using the +/- setting buttons, select your desired month and confirm with the M memory button.

The day flashes on the display .

- Using the +/- setting buttons, select your desired day and confirm with the M memory button.

Date

ⓘ If the hour format is set as 12h, the day/month display sequence is reversed.

Time

The hour flashes on the display .

- Using the +/- setting buttons, select your desired number for the hour and confirm with the M memory button.

The minute flashes on the display .

- Using the +/- setting buttons, select your desired number for the minute and confirm with the M memory button.

Bluetooth® settings

The Bluetooth® symbol flashes on the display.

- Using the +/- setting buttons, select whether automatic Bluetooth® data transfer is to be activated (Bluetooth® symbol flashes) or deactivated (Bluetooth® symbol is not shown) and confirm with the M memory button.

ⓘ Bluetooth® transfers will reduce the battery life.

User

The user memory symbol flashes in the display.

- Using the +/- setting buttons, select your desired user and confirm your selection with the M memory button.
- The device then switches off automatically.

7. Usage

General rules when measuring blood pressure yourself

- In order to generate as informative a profile of the progression of your blood pressure as possible and ensure that the measured values can be compared, you should measure your blood pressure regularly and always at the same times of day. It is recommended that you measure your blood pressure twice a day: once in the morning after getting up and once in the evening.
- You should always carry out the measurement when you are sufficiently physically rested. You should therefore avoid taking measurements during stressful periods.
- Do not take a measurement within 30 minutes of eating, drinking, smoking or exercising.
- Before the initial blood pressure measurement, make sure always to rest for 5 minutes.
- Furthermore, if you want to take several measurements in succession, make sure always to wait for at least 1 minute between the individual measurements.
- Repeat the measurement if you are unsure of the measured value.

Attaching the cuff

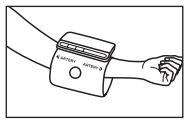
- Fundamentally, blood pressure can be measured on both arms. Certain deviations between the measured blood pressure on the right arm and left arm are due to physiological causes and completely normal. You should always perform the measurement on the arm with the highest blood pressure values. Before starting self-measurement, consult your doctor in this regard. From this point on, always take measurements on the same arm.

- The device may only be operated with one of the following cuffs. This should be selected in accordance with your upper arm circumference. The fit should be checked before measurement using the index mark described below.

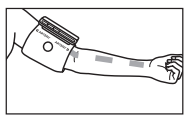
Ref. no.	Designation	Arm c ircumference
164.290*	easyLock- Universal cuff	24-40 cm

* Included in standard delivery

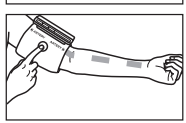
- Pass your bare upper arm through the tube-shaped cuff. The circulation of the arm must not be hindered by tight clothing or similar.



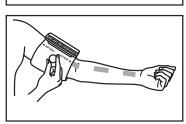
- The device must be placed on the upper arm so that the bottom edge is positioned approx. 2–3 cm above the elbow. Adjust the device so that the "ARTERY ▮▶" mark is directly over the artery.



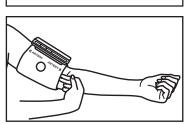
- Now press the easyLock locking button until it clicks into place to activate the locking mechanism.



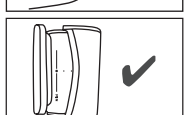
- After it has clicked into place, you can adjust the cuff precisely by turning the easyLock locking button.



- The cuff should be fastened securely but not too tight – so that two fingers fit under the closed cuff.



- The easyLock cuff is suitable for you if parts of the index marking are still visible after attaching and adjusting the cuff and do not disappear in the cuff.

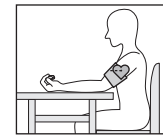


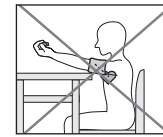
Cuff position control

The device has a cuff position control function. Using this feature, the device automatically checks the correct positioning of the cuff on your upper arm during measurement. If the cuff is correctly positioned, the symbol will appear on the display during inflation. It will remain there until the measurement has been successfully completed and will then be displayed together with the determined measured values.
In the event that the cuff has been positioned incorrectly, the measurement is cancelled and an error message appears in the display. In this case, please observe the information in the section "What if there are problems?".

Adopting the correct posture

- To carry out a blood pressure measurement, make sure you are sitting upright and comfortably. Lean back and place your arm on a surface. Do not cross your legs. Place your feet next to each other flat on the floor.
- Always make sure that the cuff is at heart level.
- To avoid distorting the measurement, you should remain as still as possible during the measurement and not speak.





Selecting the user

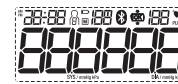
This device has 2 user memories with 120 memory spaces each in order that you can save measurements from 2 different people separately from each other.
If multiple people are using the device, make sure that the relevant user is set before each measurement.
To do so, proceed as follows:

- Press the setting button + or - on the switched-off device. The last selected user appears on the display.
- Using the +/- setting buttons, set the desired user and confirm your selection with the Start/stop button ⏻. The device then switches off automatically.

Performing the blood pressure measurement

Measurement

- To start the blood pressure monitor, press the Start/stop button ⏻. All display elements are briefly displayed.



- The blood pressure monitor will begin the measurement automatically after approx. 3 seconds.
- The cuff inflates automatically while the actual measuring process starts. As soon as a pulse is found, the pulse symbol ♥ is displayed.

ⓘ You can cancel the measurement at any time by pressing the Start/stop button ⏻. The remaining air is released quickly once the measurement is complete. The remaining air is released quickly once the measurement is complete.

- The systolic pressure, diastolic pressure and pulse measurements are displayed, and the LED risk indicator gives you a classification of your measured values using various colours.

- Er_ appears if the measurement could not be performed properly. In this case, please read the section "What if there are problems?".

Measurement

- If the Bluetooth ® function has been activated, the data transfer to the "beurer HealthManager" app starts automatically after the measurement.
- The Bluetooth ® symbol flashes on the display. The device now attempts to connect to the app for approx. 30 seconds.
- The Bluetooth ® symbol stops flashing as soon as the connection is established. All measurement data is transferred to the apps. Once the data transfer is successfully complete, the device switches off automatically.
- If a connection to the app cannot be established after 30 seconds, the Bluetooth ® symbol goes out and the device switches off automatically after 1 minute.
- If you forget to turn off the device, it switches off automatically after approximately 1 minute. In this case too, the value is stored in the selected or most recently used user memory.

Unlocking the cuff and removing the device

After the measurement has been taken successfully, you can take off the device again. To do so, proceed as follows:

- Pull the easyLock locking button upwards with your fingers to unlock the cuff.
- You can now slightly expand the tube-shaped cuff and then remove it from your upper arm.

Transfer of measurements via Bluetooth ®

In addition to displaying and saving your measurements locally on the device, you have the option of trans - ferring your measurements to your smartphone using Bluetooth ® low energy technology.
For this you need the "beurer HealthManager Pro" or "beurer HealthManager" app. These apps are available for free in the Apple App Store and from Google Play.

System requirements:

– iOS ≥ 12.0, Android ™ ≥ 8.0
– Bluetooth ® ≥ 4.0

List of compatible devices:

To transfer the measured values, proceed as follows:

Step 1:
Activate the Bluetooth ® function on your device as described in section "Setting the hour format, date, time and Bluetooth ® ".

Step 2: "beurer HealthManager Pro" or "beurer HealthManager" app
In the „beurer HealthManager Pro" or „beurer HealthManager" app, add the BM 81 under Settings / Devices and follow the instructions.

Step 3:
Take a measurement.

Step 4:
(Data transfer immediately following the measurement): If the Bluetooth® function has been activated, the data transfer to the „beurer HealthManager Pro“ or the „beurer HealthManager“ app starts automatically after the measurement.

Step 4:
(Data transfer at a later point in time): Go into the memory recall mode for the desired user memory (see “Saving, accessing and deleting measured values”). The data transfer starts automatically.

ⓘ Also note the following information:

- Ensure that the „beurer HealthManager Pro“ or „beurer HealthManager“ app on your smartphone is always activated and open when you start the data transfer on the device.
- You can tell that the data transfer is in progress by the Bluetooth® symbol shown on the display.
- If your smartphone has a protective cover, remove it to ensure that there is no interference during the transfer.

Evaluating the results

General information about blood pressure

- Blood pressure is the force with which the bloodstream presses against the arterial walls. Arterial blood pressure constantly changes in the course of a cardiac cycle.
- Blood pressure is always stated in the form of two values:
  - The highest pressure in the cycle is called systolic blood pressure. This arises when the heart muscle contracts and blood is pumped into the blood vessels.
  - The lowest is diastolic blood pressure, which is when the heart muscle has completely stretched back out and the heart fills with blood.
- Fluctuations in blood pressure are normal. Even during repeat measurements, considerable differences between the measured values may occur. One-off or irregular measurements therefore do not provide reliable information about the actual blood pressure. Reliable assessment is only possible when you perform the measurement regularly under comparable conditions.

Irregular Heartbeat

This device can identify any Irregular Heartbeat disturbances as part of the analysis of your recorded pulse signal during blood pressure measurement. In this case, after the measurement, the device will indicate any irregularities in your pulse by displaying the symbol in the display. This can be an indicator for Irregular Heartbeat Irregular Heartbeat is an illness in which the heart rhythm is abnormal because of flaws in the bioelectrical system that regulates the heartbeat. The symptoms (skipped or premature heart beats, pulse being slow or too fast) can be caused by factors such as heart disease, age, physical disposition, excess alcohol and tobacco, stress or lack of sleep. If the symbol appears on the display after the measurement, the measurement must be repeated as the measurement accuracy may be impaired. To assess your blood pressure, only use the results that have been recorded without corresponding irregularities in your pulse. If the symbol appears frequently,

please consult your doctor. Only they can establish the existence of Irregular Heartbeat during a checkup, using their means of diagnosis.

LED risk indicator

The World Health Organization (WHO) has defined the internationally recognised classification for the evaluation of measured blood pressure values listed in the table below:

Measured blood pressure value range		Classification	Colour of the risk indicator
Systole (in mmHg)	Diastole (in mmHg)		
≥ 180	≥ 110	High blood pressure stage 3 (severe)	Red
160 – 179	100 – 109	High blood pressure stage 2 (moderate)	Orange
140 – 159	90 – 99	High blood pressure stage 1 (mild)	Yellow
130 – 139	85 – 89	High normal	Green
120 – 129	80 – 84	Normal	Green
< 120	< 80	Optimal	Green

Source: WHO, 1999 (World Health Organization)

The LED risk indicator (coloured LED on the device to the left of the display) shows which category the recorded blood pressure falls into. If the measured values are in two different classifications (e.g. systole in the high normal category and diastole in the normal category), the risk indicator then always shows you the higher category – "high normal" in the example described.

Please be aware that these standard values can only serve as a general guideline, as the individual blood pressure varies in different people and different age groups, etc.

Furthermore, it must be noted that measurements taken yourself while at home are generally lower than those that are taken by the doctor. For this reason, it is important that you regularly consult your doctor for advice. Only they are able to give you your personal target values for controlled blood pressure – in particular if you receive medicinal therapy.

Displaying and deleting measurements

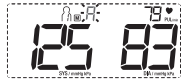
User memory

The results of every successful measurement are stored together with the date and time. If there are more than 120 measurements, the oldest measurements are lost.

- First select the desired user memory that you want to view the data for as described in the chapter on selecting a user.
- Then press the memory button M on the switched-off device.

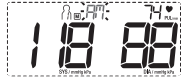
Average values

A flashes on the display.
The average value of all saved measured values in this user memory is displayed.



- Press the memory button M.

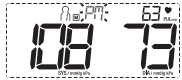
AM flashes on the display.
The average value of the morning measurements for the last 7 days is displayed (morning: 5.00 a.m. – 9.00 a.m.).



- Press the memory button M.

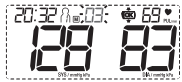
Average values

PM flashes on the display.
The average value of the evening measurements for the last 7 days is displayed (evening: 6.00 p.m. – 08.00 p.m.).



Individual measured values

- When you press the memory button M again, the last individual measurement is displayed (in this example, measurement 03).



- When the memory button M is pressed again, you can view your individual measured values.
- To switch the device off again, press the Start/stop button ⏻ or wait 30 sec.

ⓘ You can exit the menu at any time by pressing the Start/stop button ⏻.

Deleting measured values

- In order to delete all saved measurements from a user, first select it as described.
- **A** flashes on the display and the average value of all saved measured values in this user memory is displayed.
- Press and hold both setting buttons + and - at the same time for approx. 5 seconds.
- **CL 00** appears on the display. All the values in the current user memory are deleted. Das Gerät schaltet sich im Anschluss automatisch ab.

8. Cleaning and maintenance

- Clean the device and cuff carefully using a slightly damp cloth only.
- Do not use any cleaning agents or solvents.
- Under no circumstances hold the device and cuff under water, as this can cause liquid to enter and dam - age the device and cuff.
- If you store the device and cuff, do not place heavy objects on the device and cuff. Remove the batteries. The cuff line should not be bent sharply .

9. Accessories and replacement parts

Accessories and replacement parts are available from the corresponding service address (according to the service address list). Please state the corresponding order number.

Designation	Item number and/or order number
easyLock- Universal cuff (24-40 cm)	164.290

10. What if there are problems?

Error message	Possible cause	Solution
Er1	Unable to record a pulse.	Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the measurement.
Er2	You moved or spoke during the measurement.	
Er3	The cuff is not attached correctly.	Please observe the information in chapter „Attaching the cuff“ and take another measurement after one minute.
Er4	The measured values are outside the specified measurement range.	Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the measurement. If the error occurs repeatedly, consult a doctor to check you are healthy.
	An error occurred during the measurement.	
Er5	The inflation pressure is higher than 300 mmHg.	Please take another measurement to check whether the cuff can be correctly inflated. Make sure that neither your arm nor other heavy objects are pressing on the line, and that the line is not bent.
Er6	The batteries are almost empty.	Insert new batteries into the device.
ER7	Unable to transfer the data via Bluetooth®.	Please observe the information in chapter “Transfer of measurements via Bluetooth®”.

11. Disposal

Repairing and disposing of the device

- Do not repair or adjust the device yourself. Proper operation can no longer be guaranteed in this case.
- Do not open the device. Failure to comply will invalidate the warranty.
- Repairs must only be carried out by Customer Services or authorised retailers. Before making a claim, please check the batteries first and replace them if necessary.
- For environmental reasons, do not dispose of the device in household waste at the end of its service life. Dispose of the device at a suitable local collection or recycling point in your country. Dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal.

Disposing of the batteries

- The empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.

- The codes below are printed on batteries containing harmful substances:
  Pb = Battery contains lead,
  Cd = Battery contains cadmium,
  Hg = Battery contains mercury.

12. Specifications

Device	
Model no.	MD6000
Type	BM 81
Measurement method	Oscillometric, non-invasive blood pressure measurement on the upper arm
Measurement range	Cuff pressure 0 – 300 mmHg, systolic 50 – 250 mmHg, diastolic 30 – 200 mmHg, Pulse 40 – 180 beats/minute
Display accuracy	Systolic ± 3 mmHg, diastolic ± 3 mmHg, pulse ± 5 % of the value shown
Measurement inaccuracy	Max. permissible standard deviation according to clinical testing: systolic 8 mmHg /diastolic 8 mmHg
Memory	2 x 120 memory spaces
Dimensions	L 175 mm x W 117 mm x H 50 mm
Weight	Approx. 518 g (without batteries, with cuff)
Cuff size	24 to 40 cm
Permissible operating conditions	+5 °C to + 40 °C, 15 % – 90 % relative air humidity (non-condensing)
Permissible storage and transport conditions	-25 °C to + 70 °C, up to 90%, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa
Power supply	4 x 1,5 V ⎓ AAA batteries
Battery life	For approx. 120 measurements, depending on the blood pressure level and/or pump pressure
Service life	10,000 measurement at least.
Classification	Internal supply, IP22 , no AP or APG, continuous operation, applica - tion part type BF
Data transfer via Bluetooth® wireless technology	The blood pressure monitor uses Bluetooth® low energy techno - logy, 2402MHz – 2480MHz frequency band, Transmission power max. 4 dBm, Compatible with Bluetooth® 4.2 smartphones/tablets

The serial number is located on the device or in the battery compartment.

Technical information is subject to change without notification to allow for updates.

- This unit is in line with European Standard EN 60601-1-2 (i n accordance with CISPR 11, IEC61000-3-3, IEC61000-4-2, IEC61000-4-3, IEC61000-4-4, IEC61000-4-5, IEC61000-4-6, IEC61000-4-8, IEC61000-4-11) and is subject to particular precautions with regard to electromagnetic compatibility (EEC). Please note that portable and mobile HF communication systems may interfere with this unit.
- This device is in line with the EU Medical Devices Directive 93/42/EEC, the "Medizinproduktegesetz" (German Medical Devices Act) and the standards EN 1060-1 (non-invasive sphygmomanometers, Part 1: General requirements), EN 1060-3 (non-invasive sphygmomanometers, Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems) and IEC 80601-2-30 (Medical electrical equipment – Part 2 – 30: Particular requirements for the safety and essential performance of automated non-invasive blood pressure monitors).
- The accuracy of this blood pressure monitor has been carefully checked and developed with regard to a long useful life. If using the device for commercial medical purposes, it must be regularly tested for accuracy by appropriate means. Precise instructions for checking accuracy may be requested from the service address.
- We hereby confirm that this product complies with the European RED Directive 2014/53/EU. The CE Declaration of Conformity for this product can be found under:

13. Warranty / service

Beurer GmbH, Söflinger Straße 218, 89077 Ulm, Germany (hereinafter referred to as "Beurer") provides a warranty for this product, subject to the requirements below and to the extent described as follows.

The warranty conditions below shall not affect the seller's statutory warranty obligations which ensue from the sales agreement with the buyer.
The warranty shall apply without prejudice to any mandatory statutory provisions on liability.

Beurer guarantees the perfect functionality and completeness of this product.

The worldwide warranty period is 5 years, commencing from the purchase of the new, unused product from the seller.

The warranty only applies to products purchased by the buyer as a consumer and used exclusively for personal purposes in the context of domestic use.
German law shall apply.

During the warranty period, should this product prove to be incomplete or defective in functionality in accordance with the following provisions, Beurer shall carry out a repair or a replacement delivery free of charge, in accordance with these warranty conditions.

If the buyer wishes to make a warranty claim, they should approach their local retailer in the first instance: see the attached "International Service" list of service addresses.

The buyer will then receive further information about the processing of the warranty claim, e.g. where they can send the product and what documentation is required.

A warranty claim shall only be considered if the buyer can provide Beurer, or an authorised Beurer partner, with
– a copy of the invoice/purchase receipt, and
– the original product.

The following are explicitly excluded from this warranty:

- deterioration due to normal use or consumption of the product;
- accessories supplied with this product which are worn out or used up through proper use (e.g. batteries, rechargeable batteries, cuffs, seals, electrodes, light sources, attachments and nebuliser accessories);
- products that are used, cleaned, stored or maintained improperly and/or contrary to the provisions of the instructions for use, as well as products that have been opened, repaired or modified by the buyer or by a service centre not authorised by Beurer;
- damage that arises during transport between manufacturer and customer, or between service centre and customer;
- products purchased as seconds or as used goods;
- consequential damage arising from a fault in this product (however, in this case, claims may exist arising from product liability or other compulsory statutory liability provisions).

Repairs or an exchange in full do not extend the warranty period under any circumstances.

Appendix I

Guidance and manufacturer's declaration - electromagnetic emissions	
The Sphygmomanometer (MD6000) is intended for use in the electromagnetic environment specified below. The customer or the user of the Sphygmomanometer (MD6000) should assure that it is used in such an environment.	
Emissions test	**Compliance**
RF emissions CISPR11	Group 1
RF emissions CISPR11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliance

Appendix II

Guidance and manufacturer's declaration - electromagnetic Immunity

The Sphygmomanometer (**MD6000**) is intended for use in the electromagnetic environment specified below. The customer or the user of the Sphygmomanometer (**MD6000**) should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV	Power supply lines: ±2 kV
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV 100 kHz repetition frequency	line(s) to line(s): ±1 kV 100 kHz repetition frequency
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚ and 315˚ 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚ and 315˚ 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC 61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz

NOTE U_T is the a.c. mians voltage prior to application of the test level.

Appendix III

Guidance and manufacturer's declaration - electromagnetic Immunity

The Sphygmomanometer (MD6000) is intended for use in the electromagnetic environment specified below. The customer or the user of the Sphygmomanometer (MD6000) should assure that it is used in such an environment.

	Test Frequency (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Modulation** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communica-tions equipment)	385	380-390	TETRA 400	Pulse modulation 18Hz	1,8	0.3	27
	450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5500						
	5785						

Appendix IV

Recommended separation distances between portable and mobile RF communications equipment and the Sphygmomanometer (MD6000)

The Sphygmomanometer (MD6000) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sphygmomanometer (MD6000) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sphygmomanometer (MD6000) as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**	
	3 V_{rms}	10 V/m
0.01	0.200	0.060
0.1	0.632	0.190
1	2.000	0.600
10	6.33	1.90
100	20.0	6.00

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

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

Appendix V

This device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received,
including interference that may cause undesired operation.
NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications to the product not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

IC Regulations:

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions: 1. This device may not cause interference. 2. This device must accept any interference, including interference that may cause undesired operation of the device.
CAN ICES-3 (B)/NMB-3(B).
The Country Code Selection feature is disabled for products marketed in the US/Canada.

Réglementations de l'IC : cet appareil contient un ou plusieurs émetteurs/récepteur exempts de licence conformes aux normes CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. Son exploitation est soumise aux deux conditions suivantes : 1. Cet appareil ne doit pas produire d'interférences. 2. Cet appareil doit accepter toutes les interférences qu'il reçoit, y compris celles susceptibles de perturber son fonctionnement.
CAN ICES-3 (B)/NMB-3(B).
La fonction Sélection du code pays est désactivée pour les produits disponibles sur les marchés américain/canadien.

Appendix VI

Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

Warning：Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning： Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

Warning：Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Digital Automatic Blood Pressure Monitor (model: MD6000), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any：a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any：the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.
The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.

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