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Tenso-comfort Blood pressure monitor BPM 105/ BPM 205 User manual

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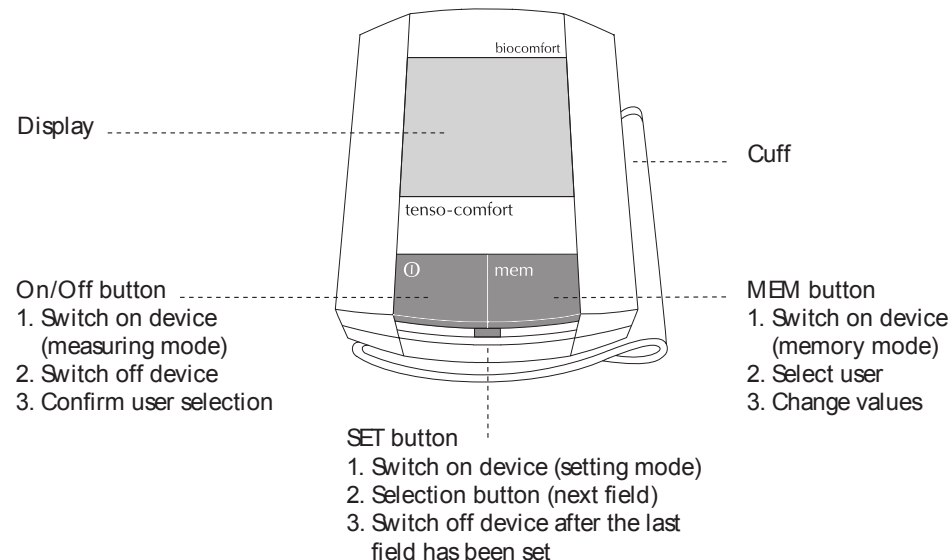
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Warnings	see Chapter 1
Limited Product Warranty	see Chapter 11
Disclaimer of Warranties	see Chapter 12
Limitation of Liability and Exclusion of Certain Damages	see Chapter 13

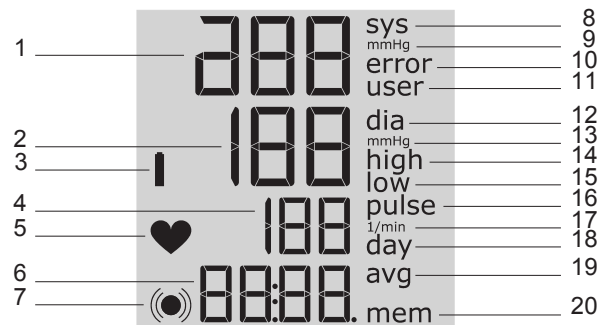
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Control elements



Display elements



- 1 Number field for systolic blood pressure, user no., error code
- 2 Number field for diastolic blood pressure and year
- 3 Battery symbol
– on: weak battery
– blinking: dead battery
- 4 Number field for pulse
- 5 Heart symbol
– blinks with pulse rate during measurement
- 6 Number field for time, date, year, user activated/deactivated, wireless connection activated/deactivated (BPM105 model only)
- 7 Symbol for active wireless connection (BPM105 model only)
- 8 Systolic blood pressure indication
- 9 Blood pressure unit indication
- 10 Error indication
- 11 User no. indication
- 12 Diastolic blood pressure indication
- 13 Blood pressure unit indication
- 14 Indication that measurement is too high (“high”)
- 15 Indication that measurement is too low (“low”)
- 16 Pulse indication
- 17 Pulse unit indication
- 18 Days, e.g. 7, 14, 21, 28, from which the average blood pressure values are to be calculated
- 19 Indication of average measurements for 7, 14, 21, 28 days
- 20 Indication of stored measurement (“memory function”)

Contents of Package

- Blood pressure monitor
- Storage bag
- 2 x 1.5 V alkaline batteries (type AAA / LR03)
- User manual and important safety information
- Biocomfort Limited Product Warranty

Info at www.biocomfort.com

For help getting started or any questions you may have, please do not hesitate to give us a call at 1-866-294-8267 (available from 9 a.m. to 5 p.m. Monday through Friday EST)

1 Introduction; Safety Information

Dear Customer,

We are pleased that you have chosen the Biocomfort blood pressure monitor tenso-comfort. It will be a reliable aid for you in checking your blood pressure. The device is easy to operate and works reliably.

Please read these safety and operation instructions before using this Biocomfort product or any accessories provided with this product or allowing any other person to use this product. When using this Biocomfort product, these basic safety precautions and warnings must be followed to reduce the risk of injury to your person and health, the risk of damage to the Biocomfort products and the risk of injury or damage to other persons or property. Retain all safety, operating and use instructions for future reference.

WARNING: If you allow any other person to use this product, you must ensure that the person has received and read and understands this user manual, including in particular the safety instructions herein.

Keep this user manual in close proximity to the equipment.

All warnings on the product and in the user manual must be strictly adhered to. You are responsible to ensure that any other person using this product adheres to these warnings and instructions.

WARNING: All operating, use and assembly instructions must be followed by you. Failure to do so could result in health injury, bodily harm and/or damage to the equipment or other property.

The product is only intended for use as described in this manual. This product may not be used for medical diagnosis or treatment on any person.

The Biocomfort blood pressure monitor is a compact, fully automatic wrist blood pressure meter. It measures your systolic and diastolic blood pressure and pulse simply and quickly according to the oscillometric principle. It is suitable for making blood pressure measurements yourself and is therefore an aid for monitoring blood pressure at home and in the clinical setting. The Biocomfort blood pressure monitor can be used by several persons. To do this, the measured value memory can be configured so that blood pressure measurements can be stored for up to 8 different users based on a user identity number (1 to 8).

1.1 Intended use

The tenso-comfort BPM 105 / BPM 205 is a non-invasive wrist blood pressure device intended for use in measuring blood pressure and pulse rate by adults

The measuring method is an oscillometric blood pressure measurement with automatic sequence and refers to the auscultatory method as the reference standard.

The model version BPM 105 is equipped with a radio module to transmit the measurement data to a PC or PDA.

1.2 Warnings

The symbols below identify and alert the user to the presence of important safety, operating, and service instructions.

WARNING:

Indicates that non-compliance with the safety instructions may lead to health injury or bodily harm of the user or other persons.

CAUTION:

Indicates that non-compliance with the safety instructions may lead to damage to the product or other property and/or to bodily harm of the user or other persons.

General Warnings:

WARNING:

Please read these safety and operations instructions in their entirety for this device and any of its accompanying accessories and software and all other literature provided in the box prior to using or allowing another person to use

this device or any of its accompanying accessories or software. When using this Biocomfort device, compliance with these basic safety instructions is essential to reducing the risk of personal injury or damage to property. Retain all of these instructions for future reference.

WARNING:

This device is only intended for use as described in this manual. Do not use this device for any other purpose. This device is intended only for measuring blood pressure and pulse rate.

WARNING:

Contact your physician for specific information about your blood pressure. Contact your doctor immediately about any unusually results measured by the device, such as, for example, high or low blood pressure or irregular pulse rate. Self-diagnosis and treatment using measured results may be dangerous.

This device is not intended to provide any diagnosis or treatment. Always follow the instructions of your physician or licensed healthcare provider.

WARNING:

The values measured on this Biocomfort device should only be interpreted by a physician.

WARNING:

Do not take any new medication, cease taking any medication that you are currently taking, or modify or vary the dosage of medication you are currently taking without consulting your physician.

WARNING: This device will not properly measure blood pressure in individuals with severe arteriosclerosis, severe hypertension, severe diabetes, severe kidney disease or cascular disease or other conditions that may compromise circulation. Consult your physician before using

this device if you suffer from any of these conditions.

WARNING:

If you suffer from arrhythmia, you must consult with your physician prior to using this device.

WARNING:

This device has been designed for and is intended for use on persons with normal sinus rhythms only. Consult your physician before using this device if you do not have a normal sinus rhythm

WARNING:

If you have a cardiac pacemaker, this device will indicate your actual pulse rate. This device is not suitable for measuring the frequency of cardiac pacemakers. A cardiac pacemaker will also affect the results of any blood pressure measurements. Please consult your physician.

WARNING:

This device is not suitable for use by children or infants or other persons who cannot express their intentions.

WARNING:

If this device is used on an individual with a contagious diseases, it should only be used on that individual and by no other person.

WARNING:

The cuff of this device may cause allergic skin reactions.

WARNING:

This device may be a choking hazard. Do not allow children or infants to use or play with it.

WARNING:

This product contains one or more chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm

WARNING:

Take three or more consecutive measurements to determine blood pressure with the device. If you experience variations in the measurements, contact your physician. A single measurement may not provide accurate results.

WARNING:

This device is not defibrillator protected.

WARNING:

Any physical activity that you may undertake, including in particular to reduce or manage your blood pressure, is a potentially hazardous activity which may involve physical risks. You assume all risk arising out of such activity. It is your responsibility to consult with a physician to determine your fitness to engage in any and all activities. It is also your responsibility to use equipment, clothing, and techniques appropriate

to these activities. You are solely responsible for your own safety.

Operating the device:

WARNING:

This device should be used only around the wrist.

CAUTION: The wrist circumference (at the measuring location) of the individual using this device should be between 5.31 inches (13.49 cm) and 8.66 inches (22.0 cm).

CAUTION: If the cuff of this device becomes excessively tight or fails to deflate within two and a half minutes, manually remove the Velcro strap.

CAUTION: Do not use mobile phones, microwave ovens or other instruments that emit an electromagnetic field near this device as they may cause this device to malfunction.

CAUTION: Use only with Biocomfort parts and accessories with this device. Parts and accessories not approved by Biocomfort for use with this device may damage the unit.

CAUTION: The cuff contains a sensitive air-tight bubble. Handle the cuff carefully and avoid all types of stress through twisting or buckling.

WARNING:

Make sure you keep the device at heart level during measurement to avoid a user accuracy error.

CAUTION: Operate the device within the following temperature range: 50 F to 104 F at a relative humidity of 20% to 85%.

WARNING:

Carry out measurements in a quite environment. You should be in a relaxed, seated position. Do not talk or move during measurements. Do not carry out measurements in a vehicle or other mode of transportation.

CAUTION: Measurements can be affected by physical exertion, stress. Avoid taking measurements under these conditions.

CAUTION: Measurements can be affected by consumption of food and drinks or a full bladder. To ensure a reliable reading, avoid eating, drinking, alcohol, caffeine, smoking, exercising, and bathing for at least 30 minutes before taking measurements. Rest for at least 15 minutes before taking a measurement.

Care and Maintenance:

CAUTION: Do not submerge the device in water or clean the device with gasoline, paint thinner, or other solvents. The device should be cleaned only with a soft, clean cloth and, if necessary, a mild cleaning solution.

CAUTION: Only use AAA LR03 1.5V batteries in this device. Replace batteries periodically. If the blood pressure monitor is left unused for long periods, remove the batteries from the device.

CAUTION: Ensure that batteries are inserted with the correct polarity. Improper installation is a hazard.

CAUTION: Do not expose the device or any of the components to extreme temperatures, humidity, dust, or direct sunlight.

CAUTION: Do not expose the device to strong shocks. Do not drop the device or treat it roughly in any way. Avoid strong vibrations.

CAUTION: Do not attempt to open or repair the device yourself. This may damage the device or cause personal injury. The monitor does not contain any user serviceable components.

CAUTION: Store and transport the device in and accessories in a safe and clean location within the following temperatures: -4 F to +140 F at a relative humidity of 10% to 95%.

CAUTION: This device should be checked for accuracy at least every two years by Biocomfort. Such a check is also required if there are any signs of malfunction of the device.

WARNING:

Please also note the limitations with regard to the ambient temperature and humidity while the device is stored or used (see Chapter 8, "Technical data"). Temperatures which are too high or too low can especially lead to faulty measurements

WARNING:

Only use the blood pressure meter for measuring blood pressure. It is not a general measuring device for measuring other pressure values.

WARNING:

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

Operation of Device with Wireless Capability (BPM105):

CAUTION: Do not activate or use the wireless device where the use of wireless devices (e.g. phones) is prohibited or when it may cause interference or danger.

CAUTION: The wireless device may not work properly if it is near a wireless device or equipment that has not been approved by or does not comply with the regulations of the Federal Communications Commission (FCC). Any such device or equipment may interfere with the operation of the Biocomfort wireless device.

CAUTION: Do not use the wireless device in hospitals or near other medical equipment or devices that is not manufactured by Biocomfort. Follow any restrictions imposed by hospitals on the use of wireless devices.

CAUTION: Do not use the wireless device on aircraft. Wireless devices can cause interference in aircraft. Follow instructions by authorized aircraft personnel.

WARNING:

Do not use the wireless device at a refueling point. Do not use near fuel or chemicals.

WARNING:

Do not use the wireless device near blasting. Follow any restrictions. Do not use the device where blasting is in progress.

2 General information for self-measurement of blood pressure

2.1 Before Taking A Measurement

Blood pressure should be measured at least twice daily (morning and evening) when you are relaxed. Since physical exertion, eating, smoking, and drinking (especially alcohol and caffeine) affects blood pressure measurements, you should avoid these activities prior to measuring your blood pressure. Avoid eating, drinking, alcohol, caffeine, smoking, exercising and bathing for at least 30 minutes before taking measurements. Rest for at least 15 minutes before taking a measurement.

In addition, please be aware that stress, a full bladder and other extraneous factors can affect your blood pressure measurements. Stress raises blood pressure. Avoid taking measurements during periods of stress.

In light of these factors and general fluctuations in blood pressure, results may vary even if measurements are taken in close succession. Therefore, single or irregular measurements do not provide a reliable or accurate indication of your true blood pressure. Measurements should be taken over a longer period and under similar conditions. Try to measure your blood pressure at the same times each day for consistency.

Measurements should be taken in a quiet place and you should be in a relaxed, seated position. Remain still and do not talk during the measurements. Make sure you keep the device at heart level during measurement.

Make sure you keep the device at heart level during measurement to avoid a user accuracy error.

Wait 2-3 minutes between measurements. The wait time allows the arteries to return to the condition prior to taking the blood pressure measurement. You may need to

increase the wait time depending on your individual physiological characteristics.

It is important that you document your blood pressure and pulse measurements for your physician. Keep a record of your blood pressure and pulse readings for your physician.

Do not take any new medication, cease taking any medication that you are currently taking or modify the dosage of medication you are currently taking without consulting your physician, even if this device indicates that your blood pressure has temporarily lowered or raised.

Discuss all unusual values resulting from your measurements with your physician.

For most accurate measurements, comply with all instructions in this manual and measure your blood pressure on your left wrist. Most measurement errors result from incorrect device positioning or measurement time.

2.2 Blood Pressure Information

The heart works like a pump which makes the blood circulate through the blood vessels under a certain pressure.

The blood pressure level depends on the beating force of the heart, the elasticity and diameter of the blood vessels, and other factors.

Two values are important for determining blood pressure: the systolic blood pressure (SYS) and the diastolic blood pressure (DIA).

The systolic blood pressure is the pressure created when the heart contracts and pumps blood into the vessels. The systolic blood pressure is therefore the highest pressure in the vascular system. The diastolic blood pressure is the pressure created during the time when the heart rests between two beats. It is therefore the minimum residual pressure in the vascular system.

The unit for blood pressure is mmHg (millimeters of mercury).

Blood pressure does not remain constant. It changes constantly. In the morning it is lower than in the evening. It is lowest during sleep. It can also vary depending on whether physical or mental work is being done. Eating, smoking, fear, stress and other factors influence blood pressure.

Your blood pressure must lie within certain normal ranges in order to prevent particular diseases.

Blood pressure that lies above the normal ranges is referred to as high blood pressure, or hypertension. If high blood pressure is ignored and goes untreated, high blood pressure can lead to serious damage to your health. Therefore, measure your blood pressure and consult your physician regularly regarding your blood pressure. Any diagnosis and any treatment must be performed by your physician.

According to the World Health Organization (WHO), normal values for blood pressure are 140 mmHg for the systolic pressure and 90 mmHg for the diastolic blood pressure.

If your systolic blood pressure values lie between 140 mmHg and 160 mmHg and/or your diastolic blood pressure values lie between 90 mmHg and 95 mmHg while at rest, consult your physician.

Your blood pressure is dangerously high if your diastolic pressure is above 90 mmHg and/or your systolic blood pressure is over 160 mmHg, while at rest. In this case, please consult your physician immediately. Long-term values at this level endanger your health through continual damage to the blood vessels in your body.

Correctly measured diastolic blood pressure values above 100 mmHg require immediate medical treatment.

Bear in mind that you have blood pressure if only one of the values lies over the limit.

A blood pressure which is too low (hypotension) (i.e., systolic values under 105 mmHg and/or diastolic values under 60 mmHg) can cause unpleasant discomfort, such as dizziness and fatigue. Please consult your physician.

A regular self check with the Biocomfort blood pressure monitor will be necessary if your blood pressure lies outside these normal ranges. Regular self checks are strongly recommended even with normal blood pressure values.

If you are undergoing medical treatment to control your blood pressure, keep a record of values along with the time of day and date of when the measurement was taken. Show these values to your physician.

Do not alter the dosage of any medication or cease using any medication prescribed by your physician. Consult your physician.

If your values are mostly under resting conditions but exceptionally high under conditions of physical or psychological stress, you may be

suffering from so-called “labile hypertension”. Consult your physician.

The following standards for assessing high blood pressure (without regard to age) have been established by the U.S. National Institutes of Health in 2003:

Category	Systolic (mmHg)	Diastolic (mmHg)
Normal (Self Check)	<120	<80
Pre-Hypertension	120-139	80-89
Stage 1 Hypertension	140-159	90-99
Stage 2 Hypertension	>160	>100

Consult your physician if you regularly measure high or low blood pressure values. Increased blood pressure values

are associated with considerable health risks. Arterial blood vessels in your body are endangered due to narrowing caused by deposits in the vessel walls (Arteriosclerosis). A deficient supply of blood to important organs (heart, brain, muscles) can result. In addition, the heart will become structurally damaged with increased blood pressure. There are many causes of high blood pressure. For example, blood pressure may be due to specific organ malfunctions. Consult your physician about the possible origins of your high blood pressure and treatment of your high blood pressure.

The blood pressure measurements determined with this device are substantially equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, with the limits prescribed by the American National Standard manual, electronic, or automated sphygmomanometers.

3 How to start up your blood pressure meter

Preliminary note:

This operating manual refers to the blood pressure monitor model BPM105 with a wireless interface and model BPM205 without a wireless interface.

The measured value memory for the BPM105 device with a wireless interface is directly configured via the Health Manager software. Chapter 3.5 does not apply to the BPM105 model.

3.1 Inserting / exchanging batteries

The Biocomfort blood pressure meter is delivered with two 1.5 V alkaline batteries (type AAA/ LR03) which must be inserted before the first measurement is taken.

If the battery symbol appears on the display, the batteries are low and must be exchanged as soon as possible, but measurements can still be made. When the battery symbol on the display starts to blink, the bat-

teries are already so weak, that measurement is no longer possible.

Low batteries are to be exchanged to ensure proper operation of the device.

When batteries are exchanged, all settings which have been made on the device are retained, as well as the stored measurements.

WARNING:

If battery fluid should get in your eye, immediately rinse with clean water and contact your physician.

CAUTION: Dispose of this device, all components, accessories, software storage medium and batteries in accordance with all applicable laws and regulations. Unlawful disposal may cause environmental pollution.

Please follow the following steps for inserting/exchanging batteries:

Step 1

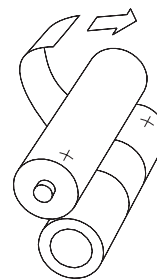
Please always switch off the device before exchanging the batteries.

Step 2

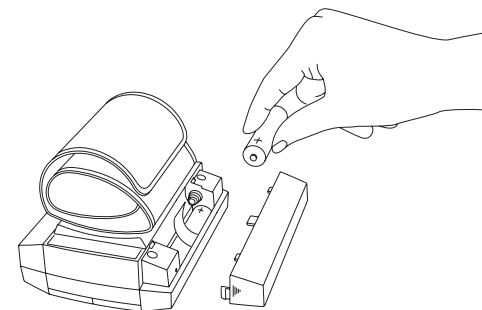
Pull the battery compartment cover on the back side of the device in the direction of the arrow and remove.

Step 3

Remove any used batteries. To make it easier to remove the used batteries, you can pull on the plastic band looped around the batteries in the direction of the arrow.



Insert both batteries according to the symbols in the battery compartment. Please make sure that the plastic band is looped around the batteries as shown in the figure.



Step 4

Push the battery compartment cover back on until you feel it click into place.

Step 5

Afterwards, check whether the batteries have been correctly inserted by briefly pressing the On/Off button. If this is the case, all display elements appear for about 2 seconds as a function test.

Note:

Please make sure that you have replacement batteries on hand. New batteries (1.5 V alkaline batteries) have a lifetime of circa 300 measurements.

When batteries are removed, the internal clock of the measuring device doesn't continue to run, so when the device is used again after exchanging the batteries or after storing the device without batteries, the date and time may have to be reset (see Section 3.4).

3.2 Switching on

Switch on your blood pressure meter by pressing the On/Off button. Every time you turn it on, all display elements appear for about 2 seconds as a function test. Please make sure that the display elements can actually be seen completely, as shown in the figure on page 4. If a segment is missing, this could lead to a false display of later measurements.

Note:

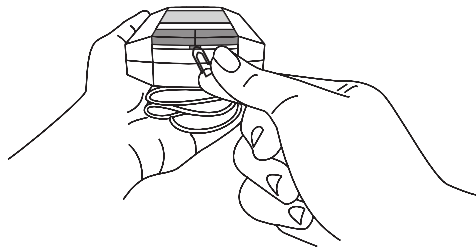
If no measurement is started or no button is pushed within 2 minutes, the blood pressure meter switches off automatically.

Caution:

Only switch the device on once the cuff has already been applied and the measuring process can begin.

3.3 Configuring the device

Before using the blood pressure meter for the first time, or if you would like to adapt the device to your needs, you must make a few settings in the settings menu, whereby the SET, MEM and On/Off buttons are pressed as described in the following sections.

**Pressing the SET button:**

The SET button can be found underneath the On/Off and MEM buttons and is covered by these two buttons to avoid pressing it by mistake. It's easiest to press the SET button with a small, flat object (e.g. paperclip).

While you are in the settings menu, the buttons have the following tasks:

SET button:

When you press the SET button with the device switched off, you enter the settings menu, whereby the first setting which can be made is the year of the present date. You can tell which parameter can be set at any given time by its blinking. If you press SET again, you proceed to the next settable parameter.

MEM button:

By pressing the MEM button, you can change the currently blinking parameter until it takes on a value you desire. Once this is the case, you can go to the next

parameter by pressing the SET button, or you can exit the settings menu by pressing the On/Off button.

Note:

If you keep the MEM button pressed, you can change the currently active parameter faster.

On/Off button:

By pressing the On/Off button, you exit the settings menu and the set parameters are saved.

3.4 Setting the date and time

Note:

The measured blood pressure and pulse values are stored with the date and time. The correct setting of the date and time makes it easier for you to make a correct time allocation of your measurements.

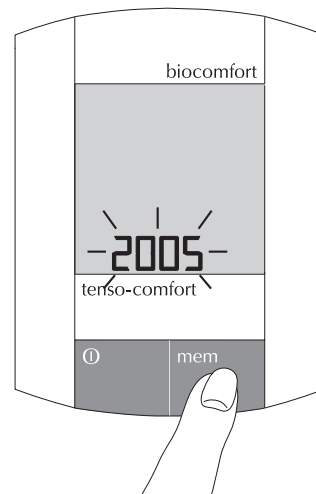
In order to set the correct date and time in your measuring device, please proceed as follows:

Step 1:

With the device switched off, first press the SET button with a small, flat object (e.g. paper clip).

Step 2:

As soon as the year starts blinking on the display, press the MEM button until the correct year appears.



Step 3:

Press the SET button again: Now the display for the month starts blinking.



Step 4:

Press the MEM button until the correct month is displayed.



Step 5:
Press the SET button again: Now the display for the day starts blinking.

Step 6:
Press the MEM button until the correct day is displayed.



Step 7:
Press the SET button again: Now the display for the hours starts blinking.

Step 8:
Press the MEM button until the correct hour is displayed.



Step 9:
Press the SET button again: Now the display for the minutes starts blinking.

Step 10:
Press the MEM button until the correct minute is displayed.

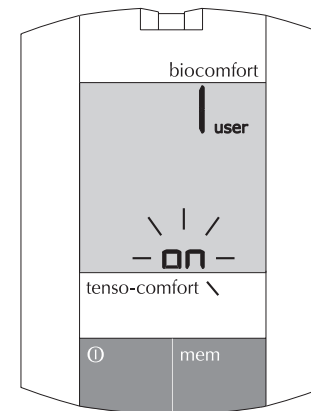


Step 11:
If you do not wish to make any further settings, exit the settings menu by pressing the On/Off button. Otherwise, continue with the settings by pressing the SET button.

3.5 Configuring the measured value memory (applies only for the BPM205 device (without wireless interface))

Note:
The blood pressure meter stores the measured blood pressure and pulse values. The measured value memory can be set so that the measurements can be allocated to 8 different users. To do this, the measured value memory must be enabled for the individual users in the settings menu.

- In its delivered condition, the measured value memory is only enabled for one user ("User 1").



The configuration of the measured value memory can be found after the time setting in the settings menu sequence.

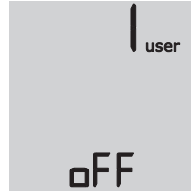
Step 1:

To enable (or block) the measured value memory, press the SET button until the word “user” appears on the display in the upper right-hand corner, and to the left of the word “user”, the number “1” appears (see figure). In the lower area of the display, either the word “on” or “off” is blinking. This is an indication of whether the measured value memory for user “1” is enabled or blocked at this time.

“on” means: The measured value memory is enabled for user “1”.



“off” means: The measured value memory is blocked for user “1”.



Step 2:

To change the measured value memory state for user “1” from “off” to “on” or vice versa, press the MEM button.

Step 3:

After you have set the measured value memory to the status you wish, you can set the status of the measured value memory for user “2” by pressing the SET button again.

Remark:

If, for example, you (only) want to change the measured value memory status for user “5”, press the SET button until the number “5” appears to the left next to the word “user” and carry out step 2.

Step 4:

If you do not wish to make any further settings, exit the settings menu by pressing the On/Off button. Otherwise, continue with the settings by pressing the SET button.

Note:

- If measured value memories are enabled for several users, each user must know his own user identity number. Before each measurement, it must be made sure that the correct user identity number has been selected (see Section 4.2 “Carrying out the blood pressure measurement”, steps 3 to 5).

- The procedure for clearing the measured value memory is described in Section 3.7.

3.6 Resetting the wireless connection (only applies for the BPM105 model)

Note:

The BPM105 model is equipped with a wireless interface. With this, you can transfer the measured blood pressure measurements wirelessly for further processing (e.g. statistical evaluation) or archiving to a PC which is equipped with a Biocomfort wireless module (USB105) or to a PDA (equipped with wireless module CFC105). The values are then analyzed and stored by the Biocomfort Health Manager software. The wireless connection should only be reset manually when it is not possible to reset it with the Health Manager software. Details can be found in the software instructions.

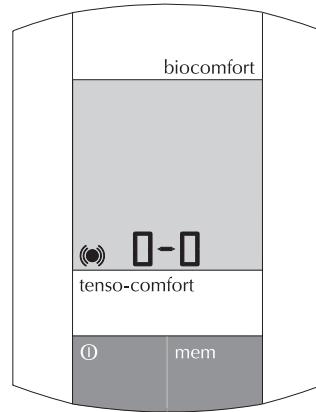
The onfiguration of the wireless interface can be found after the measured value memory configuration in the settings menu sequence.

Step 1:

To reset the wireless interface, press the SET button until the radio symbol (= fat black dot in double parentheses) appears in the bottom left-hand corner of the display.

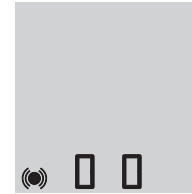
To the right of the radio symbol appear two "0"s.

- If there is a dash between the two "0"s, this means that the wireless connection is being maintained.
- If there is no dash between the two "0"s, this means that the wireless connection is reset.



Step 2:

To switch between maintaining and resetting the wireless connection, press the MEM button.



Step 3:

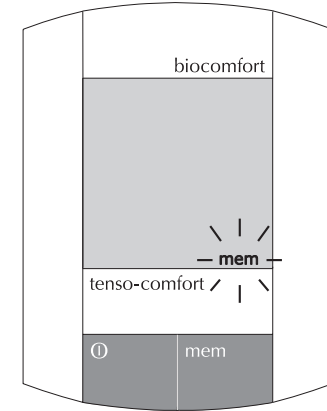
If you do not wish to make any further settings, exit the settings menu by pressing the On/Off button. Otherwise, continue with the settings by pressing the SET button.

3.7 Clearing the measured value memory

The operation for clearing the measured value memory can be found after the configuration of the wireless interface in the settings menu sequence.

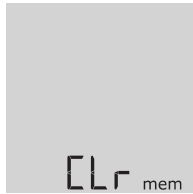
Step 1:

In order to clear the stored blood pressure values from the measured value memory, press the SET button until the word "mem" starts blinking on the right side of the display.



Step 2:

When you press the MEM button, "CLr" (clear) appears at the bottom of the display, which means that the memory will be cleared.



Remark:

When the abbreviation "CLr" appears on the display and you switch off the device via the On/Off button or continue by pressing the SET button, the entire measured value memory is cleared. If you do not wish to clear the values, press the MEM button again to make

"CLr" disappear. If you now carry out step 3, the contents in memory will be retained.

Step 3:

If you do not wish to make any further settings, exit the settings menu by pressing the On/Off button. Otherwise, continue with the settings by pressing the SET button.

Attention: There is no possibility to clear the memory for only one or two users

4 Carrying out the blood pressure measurement

4.1 Applying the cuff

Note:

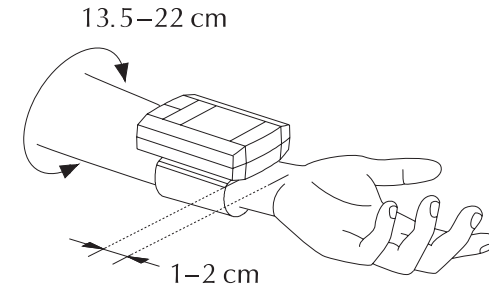
- Usually, measurements should be made on the left wrist. If the blood pressure differs in the two arms, however, the arm with the higher blood pressure should be used. Further reasons for measuring on the right arm:
 - Pain or scars on the left arm
 - Water retention in tissue (oedema, e.g. after operation)
 - IV infusion lines in the left arm or a shunt for dialysis
- The cuff is suitable for a wrist circumference of 5.31 inch to 8.66 inch.
- Only switch the device on after the cuff has been applied.

CAUTION: This device is intended for use in measuring blood pressure and pulse rate in adult population. Do not use this device on infants or children or other persons who cannot express their intentions.

CAUTION:
Read all the information in this instruction manual or any other literature before operating the device

Step 1:

Push your sleeve up without constricting your arm.
The cuff is closed with a velcro closure and should not be too tight or too loose. The device should sit about 0.4-0.8 inch away from the heel of your hand (see figure).



Note:

If the cuff is too tight or too loose, this can lead to faulty measurements.

WARNING: Operate the device only as intended. Do not use the device for any other purpose.

The wrist circumference at the point of measurement must be at least 5.31inch.

4.2 Carrying out the blood pressure measurement

Please note the following when carrying out blood pressure measurements:

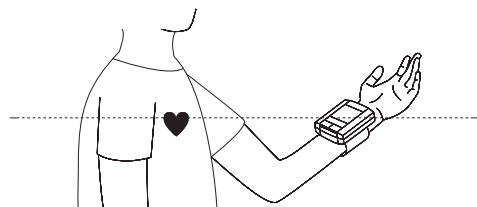
- Make sure there is at least a 3-minute interval between two consecutive measurements.
- Set comfortably and up straight. Place both feet firmly on the floor and relax.
- When the device is held above or below the heart, this leads to faulty measurements. For this reason, hold your wrist with the

blood pressure meter, if possible, exactly at heart level (see figure below).

- You can stop the measuring process at any time by pressing the On/Off button.

Step 2:

Switch the device on with the On/Off button. All display elements will appear for about 2 seconds.



Step 3:

The user identity number blinks on the display, in the measured value memory in which the result of the last blood pressure measurement was stored (see Section 4.3 “Use by multiple persons” and Section 3.5 “Configuring the measured value memory”).

Step 4:

If the user identity number doesn't agree with your measured value memory, press the MEM button until the identity number of your measured value memory appears.

Step 5:

Confirm the measured value memory selection by pressing the On/Off button. This is acknowledged by the measuring device with an acoustical signal. The device now begins by automatically pumping up the cuff.

Attention:

The pumping up of the cuff can be terminated at any time by pressing the On/Off button

WARNING:

If the cuff causes pain, or if you feel that the pressure is too high, pressure can be relieved quickly by pressing the On/Off button. If the pressure is not relieved fast enough, simply open the velcro closure of the cuff in the event of an emergency.

Step 6:

After reaching the pumped up pressure, the pump switches off and the air slowly escapes from the cuff. The slowly falling cuff pressure is shown on the display now. In addition, as soon as a pulse signal is detected, a heart symbol appears which blinks at the same rate as the pulse.

Step 7:

After the measuring operation is complete, the installed valve opens automatically to quickly let the air out of the cuff.

The end of measurement is signalled by a short beep and the measured systolic and diastolic blood pressures, the pulse, and the date and time of the measurement now appear on the display.

The data is stored in the measured value memory of the user.



Step 8:

Press the On/Off button to switch off the device.

Note:

The device switches off automatically no later than 2 minutes after the end of the measurement.

WARNING:

Hypertension warning

According to the World Health Organization (WHO), normal values for blood pressure are 140 mmHg for the systolic pressure and 90 mmHg for the diastolic pressure. These thresholds may not be directly applicable to any specific patient.

If the result of your blood pressure measurement has a systolic blood pressure value higher than 139 mmHg and/or has a diastolic value higher than 89 mmHg, the warning symbol “high” appears to the right next to the diastolic blood pressure value.

Please repeat the measurement to confirm the result.

If the measurements do not change, consult your physician immediately!

4.3 Use by multiple persons

When the blood pressure meter is shared by several persons, the measured value memory can be configured so that the measured blood pressure measurements can be allocated to up to 8 different users based on the user identity number (1 to 8). In this case, the measured value memory for the individual user identity numbers is to be enabled according to the procedure in Section 3.5 “Configuring the measured value memory”.

To make sure that the measured values are allocated to the correct measured value memory, the user is prompted after switching off the device and before starting the measuring operation to confirm the displayed user identity number or to select the correct user

identity number (see Section 4.2 “Carrying out the blood pressure measurement”, steps 3 to 5).

5 Measured value memory

5.1 Storing the measured values

For every user identity number (1 to 8), the blood pressure meter automatically stores the last 110 measured blood pressure measurements together with the date and time of the measurement. If the memory is full, the oldest result is overwritten by the result of the next measurement.

The measured values are retained in the measured value memory even when the batteries are removed.

5.2 Recalling the stored measured values

For every user identity number, the stored blood pressure and pulse measurements can be called up from the last to the oldest stored measurement. Furthermore, the average blood pressure

values for 7, 14, 21 and 28 days can be displayed.

To display the memory contents, proceed as follows:

Step 1:

In order to access the measured value memory, press the MEM button to switch on the device.

Step 2:

The user identity number blinks on the display, in the measured value memory of which the result of the last blood pressure measurement was stored.

Step 3:

In order to look at the contents of the measured value memory of a certain user, press the MEM button until the desired user identity number appears.

Step 4:

Confirm the selection by pressing the On/Off button.

Step 5:

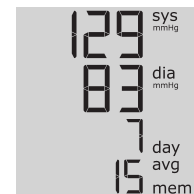
The last stored measurement for the selected user appears on the display with date and time. The date and time are shown alternately on the bottom line, each for 2 seconds.



23.12. = 23rd of December
10:28 = 10:28 a.m.

Step 6:

If you now press the MEM button again, the average value calculated by the device for the last 7 days appears. Here, the number of days selected for the average value is shown to the left of the word "day". To the left next to the abbreviation "avg" (average), the number of measurements appears which were taken into account in the calculation of the average value.



Step 7:
After pressing the MEM button again, the average value of the measurements of the last 14 days is displayed.
Here, the number 14 is displayed to the left of the word "day":



Remark:
When the MEM button continues to be pressed, first the average value of the last 21 days is shown, and then that of the last 28 days.
Afterwards, all stored individual values can be looked at, from the second-to-last stored one to the oldest available measurement.

Once the end of the measured value memory has been reached, or if there are no other measured values available, the following is displayed:



Note:
Press the MEM button and hold to quickly scroll through the results.

Step 8:
To exit memory mode, switch the device off again with the On/Off button.

6 Checking and taking care of the blood pressure meter

6.1 Function control of the display

Every time you turn on the blood pressure meter, all display elements appear for about 2 seconds.

This gives you the opportunity to determine whether all display elements are working properly, since a faulty display can lead to false interpretations of the measured values.

6.2 Cleaning the device

If needed, clean the outside of the switched-off device with a soft, clean cloth, if necessary with a mild cleaning solution. Stains on the cuff can be carefully removed with a moist cloth and soapsuds.
Do not wash!

Caution:
Never submerge the measuring device in water or any liquid.
Do not clean the device with gasoline, paint thinner or other solvents.

6.3 Maintenance and storage

The blood pressure meter does not contain any parts which require regular maintenance.
It is recommended to have the device checked every two years for proper functioning and continued accuracy.
Proper calibration is necessary when the device has been opened (exception: battery exchange).
Please contact Biocomfort for this purpose..

Caution:

Use only Biocomfort parts and accessories with this device. Parts and accessories not approved by Biocomfort for use with this device may damage the unit.

Caution:

Do not attempt to open or repair the device yourself. This may damage the device or cause personal injury. The monitor does not contain any user serviceable components.

Operating and Storage Temperatures and Environmental Conditions

Store the device in a safe and dry location. Make sure that no dirt, dust or water can get into the inside of the blood pressure meter.

Protect your device from extreme humidity, hot or cold temperature and direct sunlight.

Make sure that the cuff is not damaged by sharp objects (needles, scissors, etc.) and do not fold the cuff tightly. Handle the device carefully and store it in the storage bag when not in use. The storage bag is for protecting the measuring device.

Avoid subjecting the monitor to strong shocks or vibrations, such as dropping the unit on the floor.

Remove the batteries if you don't use the device for a longer period of time (more than 3 months). Always replace all the batteries with new ones at the same time.

7 Error messages/causes of error and measures to take

The messages which are displayed on your blood pressure meter

- guide you through the measuring process
- inform you about results stored in the measuring device
- call your attention to any occurring problems

The following error messages may appear on the display if problems occur:

Error messages	Causes	Measures	Remarks
0 error	Weak pulse signal	Switch the device off, re-apply the cuff and repeat the measurement.	
1 error	Pump-up operation too slow or cuff is losing air	Switch the device off, re-apply the cuff and repeat the measurement.	If this error message appears repeatedly, have the device checked by the manufacturer.
2 error	Systolic blood pressure cannot be determined.	Switch the device off, re-apply the cuff and repeat the measurement.	If this error message appears repeatedly, have the device checked by the manufacturer.
3 error	Cuff pressure is too high (higher than 300 mmHg).	Switch the device off, re-apply the cuff and repeat the measurement.	If this error message appears repeatedly, have the device checked by the manufacturer.
4 error	Diastolic blood pressure cannot be determined or is outside of the measuring range.	Switch the device off, re-apply the cuff and repeat the measurement.	If this error message appears repeatedly, have the device checked by the manufacturer.

Error messages	Causes	Measures	Remarks
5 error	Air released too quickly	Switch the device off, reapply the cuff and repeat the measurement.	If this error message appears repeatedly, have the device checked by the manufacturer.
6 error	Air released too slowly	Switch the device off, reapply the cuff and repeat the measurement.	If this error message appears repeatedly, have the device checked by the manufacturer.
7 error	Systolic blood pressure is outside of the measuring range.	If the measured value does not correspond with the way you feel, repeat the measurement.	
8 error	Average blood pressure lies outside of the measuring range.	If the measured value does not correspond with the way you feel, repeat the measurement.	
9 error	Cuff pressure is too low	Switch the device off, reapply the cuff and repeat the measurement.	If this error message appears repeatedly, have the device checked by the manufacturer.

Error messages	Causes	Measures	Remarks
10 error	Internal read error	Switch off the device and restart.	If this error message appears repeatedly, have the device checked by the manufacturer.
11 error	Internal write error	Switch off the device and restart.	If this error message appears repeatedly, have the device checked by the manufacturer.
12 error	Function test of the system was not completed successfully.	Switch off the device and restart.	If this error message appears repeatedly, have the device checked by the manufacturer.
15 error	Internal memory error	Switch off the device and restart.	If this error message appears repeatedly, have the device checked by the manufacturer.
19 error (BPM105)	No user has yet been created with the Health Manager software.	Configure the device with the Health Manager software and enable at least one user.	The first time the device is put into operation, at least one user must be registered.

Error messages	Causes	Measures	Remarks
21 error (BPM105)	No wireless module found	Switch off the device and restart.	If this error message appears repeatedly, have the device checked by the manufacturer.
23 error (BPM105)	The wireless connection could not be cut.	Switch off the device and restart.	Measurement cannot be carried out.
24 error (BPM105)	Communication error		This only occurs with the software, which is available as an accessory.
error and blinking battery symbol	Batteries are too weak.	Switch off the device and exchange the batteries.	When the battery symbol is blinking, measurement is no longer possible.

Note:

If you can't solve an occurring problem, contact Biocomfort Inc.

8 Technical data

8 Technical data				Measuring accuracy		Transport and storage conditions:		Technical data 8
Device type:	Wrist blood pressure meter	Pulse signal:	optical	– Pressure:	±3 mmHg		–4°F to + 140°F at a relative humidity of 10% to 95%	
Model:	tenso-comfort BPM105 tenso-comfort BPM205	Measuring period:	circa 30 seconds	– Pulse:	±5% of the displayed value			
Serial no.:	Specified on the type plate (bottom of measuring device)			Air release:	Automatic fast air release	Dimensions:	2.75 x 3.54 x 1.02 W x B x H (inch)	
Measuring method:	Oscillometric blood pressure measurement with automatic measuring sequence	Measured value memory:	110 measurements per user (all values with time and date)	Power supply:	2 x 1.5-V alkaline batteries Type AAA/LR03	Weight:	circa 4.5 oz (without batteries)	
		User management:	1 to 8 users	Battery lifetime:	circa 300 measurements	Wrist circumference:	5.31 inch to 8.66 inch	
Display:	LCD			Wireless technology:	IEEE 802.15.4, 2.4 GHz ISM Band (BPM105 model only)	Protection class:	II	
Measuring range		Average values:	7-, 14-, 21-, and 28-day average				The device does not have any touchable metal parts which can conduct electricity in the event of an error. There is no protective earthing conductor.	
– Pressure:	0–300 mmHg	Pressure build-up:	Automatic by means of electric pump	Operating conditions:	+50°F to +104°F at a relative humidity of 20% to 85%			
– Pulse:	40–199 beats per minute							
Emergency off function:	By pressing the On/Off button during measurement, the measuring process is							

Type BF: Device is not protected against the effects of defibrillators

Classification: Europe: Class 2a (EC directive 93/42/EWG, Medical devices)
USA: Device class 2

This device meets the regulations of EC directive 93/42/EWG (directive for medical devices) and is developed and manufactured according to the regulations of the 21CFR 820.

The requirements of the following standards are met:

- IEC 60601-1 Medical electrical devices – General safety regulations
- IEC 60601-1-2 General safety regulations – Standard supplement: Electromagnetic compatibility – Requirements and tests
- EN 1060 : 1995 Non-invasive blood pressure meters Part 1: General requirements

- EN 1060 : 1997 Non-invasive blood pressure meters Part 3: Supplementary requirements for electromechanical blood pressure meters
- ANSI/AAMI SP10:2002 /A1:2003

The wireless module integrated in this device (BPM105 only) fulfills the regulations of EC directive 1999/5/EC (Radio and telecommunication terminal equipment, R&TTE).

The requirements of the following standards are met:

- ETSI EN 301 489-17 Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 17: Specific Conditions for 2,4 GHz Wideband Transmission Systems
- EN 300328-2 V1.2.1 Electromagnetic compatibility and radio spectrum
- FCC Class B Part 15

9 EMC Information (Electromagnetic Compatibility)

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.

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 manufacturer's instructions, may cause interference harmful to radio communications. There is no

guarantee, however, 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 to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio or TV technician for help.


Not authorized changes or modifications could void authority to use this equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The BPM105/BPM205 is intended for use in the electromagnetic environment specified below. The customer or the user of the BPM105/BPM205 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 2	The BPM105/BPM205 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The BPM105/BPM205 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

For Details of essential performance: please refer to section 1.1 Intended Use

Guidance and manufacturer's declaration – electromagnetic immunity			
The BPM105/BPM205 is intended for use in the electromagnetic environment specified below. The customer or the user of the BPM105/BPM205 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, oncrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	-
Surge IEC 61000-4-5	Not applicable	Not applicable	-
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	-
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The BPM105/BPM205 is intended for use in the electromagnetic environment specified below. The customer or the user of the BPM105/BPM205 should assure that it is used in such an environment.			
Electromagnetic environment – guidance Portable and mobile RF communications equipment should be used no closer to any part of the BPM105/BPM205, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity test	IEC 60601 test level	Compliance level	Recommended separation distance:
Conducted RF IEC 61000-4-6	Not applicable	Not applicable	-
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz

<p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BPM105/BPM205 is used exceeds the applicable RF compliance level above, the BPM105/BPM205 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BPM105/BPM205.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>

**Recommended separation distances between portable
and mobile RF communications equipment and the BPM105/BPM205**

The BPM105/BPM205 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BPM105/BPM205 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BPM105/BPM205 as recommended below, according to the maximum output power of the communicationsequipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

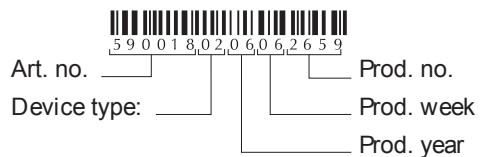
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

10 Symbols and abbreviation

You will find the symbols shown below with the following meanings on the device, the packaging materials and the operating manual:

The serial number of the device is composed as follows and can be found under the barcode.



Please follow the operating manual.

REF

Article or order number



The device contains an HF transmitter (radio transmitter).
(BPM 105 model only)



Symbol for separate collection of electric and electronic devices



⁰¹⁹⁷ The identification number 0197 behind the CE marking identifies the notified body who is responsible for monitoring the manufacturer.

The blood pressure meter is a medical product for personal use.



FCC, Class B Part 15

SN

Serial number

11 Limited Product Warranty Information

This product is subject to the Biocomfort One-Year Limited Warranty separately included in this box and also available from Biocomfort or any authorized Biocomfort dealer or from Biocomfort's website at <http://www.biocomfort.com/support>.

If you do not agree with, and do not want to be bound by, the terms of the Biocomfort one-year limited warranty, return the box and its contents, including the hardware and accessories unused, to Biocomfort, or to the authorized Biocomfort dealer where you purchased the product, within fourteen (14) days of purchase, together with proof of purchase, and your full purchase price will be refunded. By using this product or letting the 14-day period lapse, you agree to the terms of the Biocomfort one-year limited warranty.

12 Disclaimer of Warranties

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13 Limitation of Liability and Exclusion of Certain Damages

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