Wrist Blood Pressure Monitor

User's manual

EN

SENCOR®

SBD 1680

Prior to using this appliance, please read the user's manual thoroughly, even in cases, when one has already familiarised themselves with previous use of similar types of appliances. Use the appliance only as described in this manual. Keep this manual for later use.

Caution! Not following the instructions contained in this user's manual may lead to faulty operation of the device or its damage.

We recommend saving the original package, packaging material, receipt and warranty card for the duration of warranty. In the case of transportation, pack the product using the original packaging materials only.

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WHAT YOU SHOULD KNOW ABOUT BLOOD PRESSURE

What is blood pressure?

Blood pressure is defined as the pressure exerted by the blood on the walls of the arteries through which it flows. Blood pressure fluctuates during the course of each heartbeat between the maximum (systolic) and the minimum (diastolic) value. Blood pressure is influenced by many factors, such as physical activity, fear, anger or by a certain time of day.

Why is it important to measure your blood pressure at home?

Many people have increased blood pressure when they visit their doctor, while at home their blood pressure is in the normal range. This is the so-called white coat syndrome and may affect up to 15 % of the population.
Home blood pressure measurement eliminates the white coat syndrome and provides the doctor with a picture of the various blood pressure levels during your natural activity.

Blood pressure classification by the World Health Organisation

The following table shows the blood pressure classification for an adult person according to the World Health Organisation (WHO).

Blood pressure category	Systolic blood pressure (in mmHg)	Diastolic blood pressure (in mmHg)
Optimal	<120	<80
Normal	120–129	80–84
High normal	130–139	85–89
Hypertension: Grade 1 (mild)	140–159	90–99
Hypertension: Grade 2 (moderate)	160–179	100–109
Hypertension: Grade 3 (severe)	≥180	≥110

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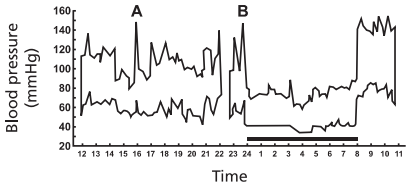
Fluctuation of blood pressure

The fluctuation of blood pressure during the day is normal for every healthy person. Changes in blood pressure may occur completely naturally or as a result of physical activity or psychological stress. Therefore, the results of repeated blood pressure measurements during the course of the day may vary.
The graph below illustrates the fluctuation of blood pressure during the course of the day. The blood pressure values were recorded every five minutes. The thick line indicates sleep. The sudden increase in blood pressure at 4 pm (value A in the graph below) and at 12 midnight (value B in the graph below) resulted from sudden pain.

A



IMPORTANT NOTICES

- This device is designed for non-invasive blood pressure measurement on adults.
- Take care not to damage the cuff by sharp items, such as pins, needles, etc.
- Do not disassemble the device and do not make any alterations to it.
- Do not use the device if your wrist is injured.
- Pregnant women and persons undergoing treatment, taking medication or who suffer from a circulatory system disorder, such as atherosclerosis, diabetes, liver or kidney illness, heavy hypertension, external circulation disorders, etc., should consult their doctor or an expert healthcare professional about the suitability of using a blood pressure monitor or similar devices.
- Rest at least 5 to 10 minutes before measuring blood pressure.
- Wait at least 4 to 5 minutes before measuring again, so that your blood circulation can return to the normal state.
- Do not perform measurement sooner than 30–45 minutes after consuming beverages containing caffeine or after smoking cigarettes.
- Use the cuff only on the wrist. Do not use on another part of the body.
- Do not start measurement until the cuff is attached to the wrist.

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- The device automatically releases air when the pressure in the cuff exceeds 300 mmHg. If this does not occur, press the START/STOP button to release the air from the cuff. Wait at least 4 to 5 minutes before measuring again.
- Remember that blood pressure fluctuates over the course of the day and is also affected by many factors, such as smoking, consumption of alcohol, taking medicines and physical activity.
- The measurement results should be evaluated by a doctor or another expert, who knows your long term health condition. Please, do not make conclusions on the basis of the results yourself.
- By regularly measuring your blood pressure and recording the measurement results, you will provide your doctor with a complete picture of your blood pressure during natural activity.
- Blood pressure values measured using the oscillometric method when using this device are equivalent to the measurement results taken by an experienced observer using the auscultatory (listening) method using a stethoscope and a blood pressure monitor.
- This device is designed for domestic use and does not substitute for professional medical care.
- Keep the device and the batteries out of reach of children.

BASIC FUNCTIONS AND FEATURES OF THE BLOOD PRESSURE MONITOR

- Measurement of the systolic and diastolic blood pressure and pulse frequency
- Adjustable length cuff for wrist circumferences from approx. 13.5 to 19.5 cm
- Automatic inflation and air release of the cuff
- Large LCD display
- 3 × 40 memory positions for three users
- Battery operation
- Travel case

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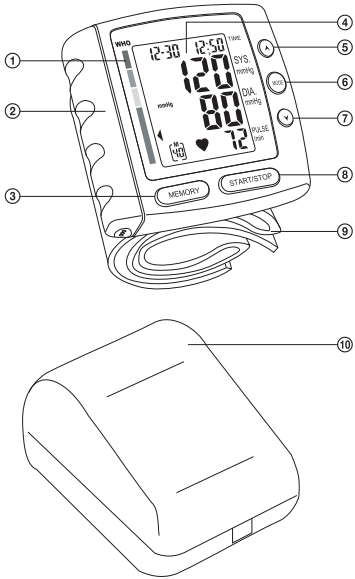
DESCRIPTION OF THE BLOOD PRESSURE MONITOR

B



① WHO risk category indicator (colour scale)
② Battery compartment cover
③ MEMORY button
④ LCD display
⑤ ▲ Button
⑥ MODE button
⑦ ▼ Button
⑧ START/STOP button
⑨ Inflatable cuff
⑩ Travel case

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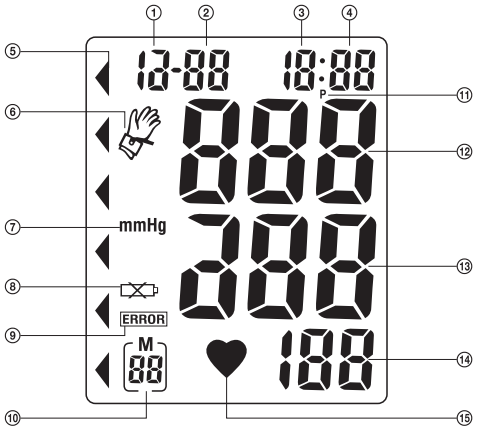
DESCRIPTION OF THE DISPLAY

C



① Month
② Day
③ Hour
④ Minute
⑤ WHO risk category indicator
⑥ Measurement in progress indicator
⑦ Measuring unit
⑧ Flat battery indicator
⑨ Error message
⑩ Display of the sequential number of the record stored in memory
⑪ Afternoon time indicator
⑫ Systolic pressure value
⑬ Diastolic pressure value
⑭ Pulse (number of pulses/minute)
⑮ Pulse detection

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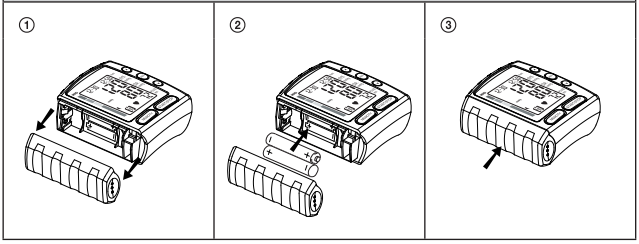
USING THE BLOOD PRESSURE MONITOR

1. Installing and replacing batteries

- To power the device use 2 alkaline batteries type LR03/AAA (2 × 1.5 V).
- Remove the battery compartment cover and insert 2 alkaline batteries type LR03/AAA. When inserting the batteries ensure the correct polarity as shown in the battery compartment. Close the cover.

D



Important: If the polarity is reversed when the batteries are inserted, the device may not only not function but may also heat up. Do not combine used and new batteries or batteries of various types, e.g. alkaline batteries and rechargeable batteries.

- After inserting the batteries all the elements will be momentarily shown on the display. Then the display will show the date 1-1 (month – day), time 12:00 and "no. 1" (user record database no. 1). After one minute the device will switch to the stand-by mode and the display will show the date and time.
- The batteries need to be replaced when:
  - the display shows the symbol ⌧.
  - the display does not turn on.

2. Setting the date and time

2.1 Before taking the first measurement, set the current date, time. The measured blood pressure values will be stored in memory together with the date and time of measurement.

2.2 Press the MODE button twice. The month will start to flash on the display. To set the current month use the buttons ▲▼. Confirm the setting by pressing the MODE button. The device will automatically switch to the day setting mode.

2.3 To set the current day use the buttons ▲▼. Confirm the setting by pressing the MODE button. The device will automatically switch to the hour setting mode.

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2.4 To set the current hours use the buttons ▲▼. Confirm the setting by pressing the MODE button. The device will automatically switch to the minute setting mode.

Note:
Time can be set in the 12-hour format. The afternoon time is signalled by the "P" indicator on the display.

2.5 To set the current minutes use the buttons ▲▼. Confirm the setting by pressing the MODE button. The setup of the date and time is complete.

2.6 After one minute the device will switch to the stand-by mode and the display will show the date and time. Now the device is ready for measurement.

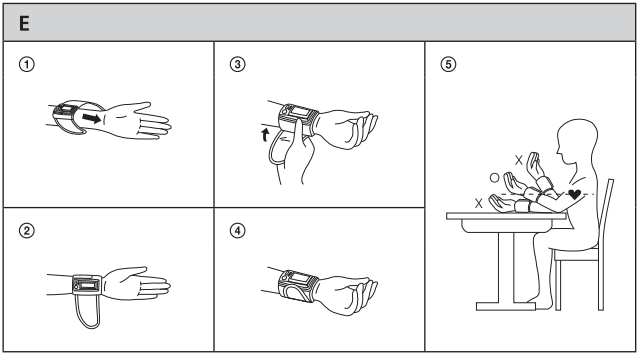
3. Measurement

3.1 Basic instructions for achieving the most accurate measurement results

- Always take measurements at the same time of day, ideally in the morning, at noon and in the evening under the same conditions or according to the recommendations of your doctor.
- Do not perform measurement sooner than 30–45 minutes after consuming coffee, tea or smoking a cigarette.
- Wait at least 20 minutes after taking a hot shower or bath.
- Wait approximately 4 to 5 minutes before measuring again.

3.2 Attaching the cuff and correct posture of the body and hand during measurement

- Remove any clothing, watches, bracelets from the left wrist, etc. before attaching the cuff.
- Attach the cuff to the left wrist so that the display of the blood pressure monitor is on the same side as your palm. The top edge of the cuff should be located approximately 1 cm under the wrist joint. Wind the cuff around the wrist and tighten. There should be no space between the cuff and the wrist.
- Seat yourself comfortably on a chair and rest your left elbow on a table. The palm faces upwards (towards the face) and the blood pressure monitor is located level with the heart. Slightly open the palm and relax the fingers. If the blood pressure monitor is located above or below the level of the heart the measurement results may not be accurate.
- During measurement sit calmly, relaxed and don't talk. Do not move the hand to which the cuff is attached.



3.3 Measuring blood pressure

3.3.1 Using buttons ▲▼ select a database (no 1 – database of user no. 1, no 2 – database of user no. 2, no 3 – database of user no. 3), where measurement results will be stored.

Note:
For repeated measurements ensure that you have selected the correct database in which your previous measurement results are stored.

3.3.2 Start measurement by pressing the START/STOP button. The display will show the symbol and will remain lit until the measurement is completed. The device will automatically pressurise the cuff.

3.3.3 Then a gradual release of pressure from the cuff follows and pulse rate is measured. This is indicated by the flashing ♥ symbol on the LCD display. The systolic (SYS), diastolic (DIA), pulse and blood pressure category will be determined automatically.
The WHO risk category indicator is defined in the following table.

WHO Risk Category Indicator

Colour scale on the device	Blood pressure category according to the WHO	Systolic blood pressure (in mmHg)	Diastolic blood pressure (in mmHg)
Red segment	Hypertension: Grade 3 (severe)	≥180	≥110
Orange segment	Hypertension: Grade 2 (moderate)	160–179	100–109
Yellow segment	Hypertension: Grade 1 (mild)	140–159	90–99
Green segment	High normal	130–139	85–89
Green segment	Normal	120–129	80–84
Green segment	Optimal	<120	<80

Recommendations by SIGN 49: Hypertension in older people

Hypertension: Grade 3 – Confirm immediately and repeat BP in one day and again within one week depending on clinical situation.
Hypertension: Grade 2 – Serial blood pressures repeated within one month.
Hypertension: Grade 1 – Provide advice about lifestyle modification and confirm within two months.
High normal – Provide advice about lifestyle modification and recheck in one year.
Normal and Optimal – Recheck in 2–5 years. (Patients aged above 75 years offered annual health check.)

Note:
The above table is not exact for classification of blood pressure and it's intended to be used as a guide in understanding non-invasive blood pressure measurements.
Usually this is not a cause for concern; however we recommend you consult with your physician for proper diagnosis or seek medical advice according to our recommendation mentioned above. Please note that the device should not be used to diagnose hypertension, and it is only for user reference on blood pressure monitoring.

Note:
If the measured values of systolic and diastolic blood pressure fall into different categories, the higher value will determine the outcome.
Example no. 1
Measured values: SYS (systolic pressure) – 181 mmHg, DIA (diastolic pressure) – 99 mmHg. The device will evaluate the blood pressure condition as hypertension level 3 and the blood pressure category indicator will appear in the red segment of the colour scale.

Example no. 2
Measured values: SYS – 110 mmHg , DIA – 95 mmHg. The device will evaluate the blood pressure condition as hypertension level 1 and the blood pressure category indicator will appear in the yellow segment of the colour scale.

Note:
The measuring process can be interrupted at any time by pressing the START/STOP button. Air will be released from the cuff immediately after the START/STOP button is pressed.

3.3.4 To turn off the device to the stand-by mode press the START/STOP button. If you do not turn off the device, it will turn itself off automatically 1 minute after the last measurement. Remove the cuff from your wrist after completing the measurement.

4. Recalling memory

4.1 Use the buttons ▲▼ to select the user database, the stored values of which you wish to display. To display the records press the MEMORY button. The display will show the last stored record.

Note:
The maximum capacity of each user's database is 40 measurements. As soon as the maximum memory capacity is achieved, every new measurement will delete the oldest measurement.
If there is no record stored in the respective database, the display will show the number of the database after the MEMORY button is pressed.

4.2 To scroll through the individual records use the buttons ▲▼. For each record the month, day and time it was taken will be displayed. If the first or last record stored in the database is shown on the display and you press the ▲ or ▼ button, the display will automatically switch to the database selection mode.
4.3 To turn off the device to the stand-by mode press the START/STOP button.

5. Deleting memory

5.1 Use the buttons ▲▼ to select the user database, the stored values of which you wish to delete.
5.2 Press the MEMORY button.
5.3 To delete the records stored in the respective database press the MODE and ▲ buttons simultaneously. The display will show "CLR" (deletion of memory).
5.4 When the memory is subsequently recalled using the MEMORY button, the display will only show the number of the database.

TROUBLESHOOTING

In this chapter you will find solutions to problems that you may encounter when using this device.
If you were unable to remedy the problem according to the following instructions, contact an authorised service centre.

Problem / error message	Possible cause	Possible solution
After pressing the START/ STOP button the display does not turn on.	The batteries are inserted incorrectly.	Insert the batteries according to the instructions in chapter Installation and replacement of batteries.
	Batteries are flat.	Replace the batteries according to the instructions in chapter Installation and replacement of batteries.
The symbol ⌧ is shown on the display.	Batteries are almost flat.	Replace the flat batteries for new ones according to the instructions in chapter Installation and replacement of batteries.
The symbol ERROR is shown on the display.	Measurement error.	Check that the cuff is attached to the wrist according to the instructions in chapter Attaching the cuff and correct posture of the body and hand during measurement. Rest for 4 to 5 minutes and then repeat the measurement.
		Incorrect hand posture may affect the measurement result. Follow the instructions included in chapter Attaching the cuff and correct posture of the body and hand during measurement. Rest for 4 to 5 minutes and then repeat the measurement.
		Hand movement may affect the measurement result. Rest for 4 to 5 minutes and then repeat the measurement.
EP appears on the display.		Contact your vendor or authorised service centre.

MAINTENANCE AND CLEANING

- Keep the device clean. Wipe off dust using a lightly damp cloth.
- Do not wash the device or the pressurising cuff under running water or submerge it in water.
- Do not use abrasive cleaning products or petrol for cleaning. Otherwise the device may be damaged.

STORAGE

- If you will not be using the device for an extended period of time, remove the batteries.
- Protect the device against impacts and falls.
- Store the device in a clean, dry place out of reach of children. Do not expose the device to direct sunlight or extreme temperature changes.

CALIBRATION

Recommendation: To ensure accurate measurement results we recommend the device is calibrated after two years of operation. All costs associated with the calibration are borne by the customer.

ELECTROMAGNETIC INTERFERENCE

To prevent measurement inaccuracies caused by electromagnetic interference, do not use this device in the vicinity of mobile telephones or microwave ovens.

CE 0197 This device meets the requirements of the European directive 93/42/EEC.

COMPLIANCE WITH STANDARDS

This device complies with European standards:
EN 60601-1 Medical electrical devices – Part 1: General basic safety and necessary functionality requirements
EN 60601-1-2 Medical electrical devices – Part 1-2: General basic safety and necessary functionality requirements – Group norm: Electromagnetic compatibility – Requirements and tests
EN 1060-1 Non-invasive blood pressure monitors – Part 1: General requirements
EN 1060-3 Non-invasive blood pressure monitors – Part 3: Specific requirements for electromechanical systems for the measurement of blood pressure
EN 1060-4 Non-invasive blood pressure monitors – Part 4: Testing procedures for determining the overall accuracy of automatic non-invasive blood pressure monitor systems.

The manufacturing date is marked on the rating label of the device.

LOT The production batch number (lot number) is marked on the rating label of the device.

Manufacturer: Health & Life Co., Ltd., 9F, No. 186, Jian Yi Road, Zhonghe District, New Taipei City, Taiwan

EC REP **Authorised EC Representative:** Emergo Europe, Molenstraat 15, 2513 BH, The Hague, The Netherlands

TECHNICAL SPECIFICATIONS

Measuring method	Oscillometric
Display	LCD
Memory capacity	3 × 40 records
Measuring range	Pressure: 0–300 mmHg Pulse: 40–199 pulses/minute
Measurement accuracy	Pressure: ±3 mmHg Pulse: ±5 %
Adjustable size of the cuff	13.5–19.5 cm
Power source	2 × LR03/AAA alkaline batteries
Safety class for electric shock protection	Applied part type BF
Electric shock protection type	Powered by an internal power source
Degree of protection against the intrusion of water	IPX0 – The device is not protected against water penetration (no special protection).
Safety of use in the presence of anaesthetic combustible mixtures	The device is not suitable for use in the presence of combustible anaesthetic and air mixtures or combustible anaesthetic and oxygen mixtures, or mixtures containing oxides of nitrogen.
Operating mode	Continuous operation with short term loading
Operating conditions	Ambient temperature: 10 °C to 40 °C, ≦ 85% R.H.
Storage conditions	Ambient temperature: –20 °C to 70 °C, ≦ 85% R.H.
Battery lifetime	approx. 250 measurements
Accessories	2 × alkaline batteries type LR03/AAA, travel case, user's manual

We reserve the right to change text and technical specifications.

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INSTRUCTIONS AND INFORMATION REGARDING THE DISPOSAL OF USED PACKAGING MATERIALS

Dispose of used packaging material at a site designated for waste in your municipality.

DISPOSAL OF USED BATTERIES

Batteries contain environmentally damaging compounds and therefore do not belong in standard household waste. Take the batteries to an appropriate collection point, which will provide for their ecological disposal. You can obtain the contact for the nearest collection point from you town council or from your retailer.

DISPOSAL OF USED ELECTRICAL AND ELECTRONIC EQUIPMENT

This symbol on products or original documents means that used electric or electronic products must not be added to ordinary municipal waste. For proper disposal, renewal and recycling hand over these products to determined collection points. Or as an alternative in some European Union states or other European countries you may return your products to the local retailer when buying an equivalent new product. Correct disposal of this product helps save valuable natural resources and prevents damage to the environment caused by improper waste disposal. Ask your local authorities or collection facility for more details. In accordance with national regulations penalties may be imposed for the incorrect disposal of this type of waste.

For business entities in European Union states
If you want to dispose of electric or electronic devices, ask your retailer or supplier for the necessary information.

Disposal in other countries outside the European Union.
This symbol is valid in the European Union. If you wish to dispose of this appliance, request the necessary information about the correct disposal method from the local council or from your retailer.

The EMC declaration issued according to the requirement of the EN 60601-1-2 Standard.

The user of medical electrical equipment (MEE) must observe particular safety instructions related to the electromagnetic compatibility. MEE must be installed and operated in compliance with the guidance as mentioned below.

The SBD 1680 Blood Pressure Monitor can only be used with the original accessories and components supplied by the manufacturer. The use of other accessories or components may result in increased electromagnetic emissions or decreased immunity of MEE to electromagnetic disturbance.

TABLE 201

Guidance and manufacturer's declaration – Electromagnetic compatibility: Electromagnetic emissions test		
The SBD 1680 Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the SBD 1680 Blood Pressure Monitor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – Guidance**
Standard CISPR 11 Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics	Group 1	The SBD 1680 Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Standard CISPR 11 Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics	Class B	The SBD 1680 Blood Pressure Monitor is suitable for use in all establishments, including domestic establishments.
Standard IEC 61000-3-2 Limits for harmonic current emissions (equipment input current up to 16 A per phase)	Not applicable	
Standard IEC 61000-3-3 Limits for voltage fluctuations and flicker for equipment with rated current 16 A	Not applicable	

TABLE 202

Guidance and manufacturer's declaration – Electromagnetic compatibility: Electromagnetic immunity test			
The SBD 1680 Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the SBD 1680 Blood Pressure Monitor should assure that it is used in such an environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment – Guidance**
Standard IEC 61000-4-2 Electrostatic discharge	±6 kV contact discharge method ±8 kV air discharge method	±6 kV contact discharge method ±8 kV air discharge method	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Standard IEC 61000-4-8 Power frequency magnetic field	3 A/m (magnetic field strength)	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

TABLE 204

Guidance and manufacturer's declaration – Electromagnetic compatibility: Electromagnetic immunity test			
The SBD 1680 Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the SBD 1680 Blood Pressure Monitor should assure that it is used in such an environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment – Guidance**
Standard IEC 61000-4-6 Immunity to conducted disturbances, induced by radio-frequency fields	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the SBD 1680 Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ *80 MHz to 800 MHz* $d = 2,3 \sqrt{P}$ *800 MHz to 2,5 GHz* where P is the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya should be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of the equipment marked with the following symbol:  .
Standard IEC 61000-4-3 Radiated, radio-frequency, electromagnetic field	3 V/m 80 MHz to 2,5 GHz	3 V/m	
Note 1: At 80 MHz and 800 MHz, 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.			

[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 SBD 1680 Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the SBD 1680 Blood Pressure Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SBD 1680 Blood Pressure Monitor.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TABLE 206

Recommended separation distances between portable and mobile RF communications equipment and the SBD 1680 Blood Pressure Monitor.

The SBD 1680 Blood Pressure Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SBD 1680 Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SBD 1680 Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter (W)	Separation distance according to the frequency of the transmitter (m)		
Standard IEC 61000-4-4 Electrical fast transient/burst	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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum rated output power 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.