Blood Pressure Monitor

User's manual

EN

SENCOR®

SBP 690

Thank you for choosing the SBP 690 digital blood pressure monitor and we hope that you will be happy with it.

The SBP 690 blood pressure monitor presents the perfect combination of attractive design, simple controls and functionality.

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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.
Blood pressure changes constantly over the course day. Early in the morning it rises and before noon it falls. In the afternoon it rises again and then falls in the evening hours. Blood pressure may also change within an instant and so the subsequent measurement results may vary.

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 2nd level (medium)	160–179	100–109
Hypertension: Grade 3 (heavy)	≥180	≥110
Isolated systolic hypertension	≥140	<90

What is cardiac arrhythmia?

Cardiac arrhythmias are a disorder of the rhythm of the heartbeat. They result from a varied creation or conduction of electrical impulses in the heart. Many cardiac arrhythmias are only temporary in nature. Such types of arrhythmias are considered to be harmless and include the cases where the heart misses or adds a beat. This may be caused by strong emotions or exercise. However, there exist types of arrhythmia, which may be life threatening and require professional treatment.

Symptoms of cardiac arrhythmia

Symptoms of cardiac arrhythmia: strong or accelerated beating of the heart, feeling of tiredness, vertigo, loss of consciousness, lack of breath and chest pain.
Symptoms of bradycardia (slowed down heart activity): feeling of tiredness, lack of breath, vertigo or dizziness.
Symptoms of tachycardia (accelerated heart activity): the heartbeat may be felt in the neck or as a beat in the chest with irregular speed, feeling of unease, weakness, lack of breath, dizziness, sweating and vertigo.

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Can cardiac arrhythmia be treated?

Cardiac arrhythmia can to a certain extent be prevented by eliminating the stimuli (physical exertion, stress, smoking, consumption of alcohol, coffee or other beverages containing caffeine) affecting the nervous system. Many types of cardiac arrhythmias do not require treatment as they are naturally compensated by the immune system. Other types of cardiac arrhythmias must be treated with medication (antiarrhythmic agents), defibrillator implants or pacemakers. The treatment method depends on the type of cardiac arrhythmia, age of the patient and their physical condition.

MEASUREMENT PRINCIPLE

This product uses the Oscillometric Measuring method to detect blood pressure.
Before every measurement, the unit establishes a "zero pressure" equivalent to the air pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

INDICATIONS FOR USE

The Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22 cm to 42 cm (about 8¾˝–16½˝).
It is intended for adult indoor use only.

CONTRAINDICATIONS

1. The device is not suitable for use on may be pregnant women or pregnant women.
2. The device is not suitable for use on patients with implanted,electrical devices, such as cardiac pacemakers, defibrillators.

IMPORTANT INSTRUCTIONS

Prior to using this product, please read the user's manual thoroughly, even in cases, when one has already familiarised themselves with previous use of similar types of products. Use the product 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.

- This device is designed for non-invasive blood pressure measurement.
- The cuff with an adjustable length of 22–42 cm is intended only for adults.
- Do not twist or excessively bend the cuff or the air hose. Take care not to damage the cuff or the air hose by sharp items, such as pins, needles, etc.
- Do not disassemble the device and do not make any alterations to it.
- Use only original accessories supplied with the device.
- Do not use the device if your arm is injured.
- If you suffer from a circulatory system disorder, such as atherosclerosis, diabetes, liver or kidney illness, heavy hypertension, external circulation disorders, etc., consult your doctor or an expert healthcare professional about the suitability of using a blood pressure monitor or similar devices.
- If you are undergoing medical treatment or taking medication, consult the use of this device with a doctor.
- Rest at least 5 to 10 minutes before measuring blood pressure.

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- 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.
- Remove all tight clothing from your arm before taking a blood pressure measurement. Use the cuff only on the arm. Do not use on another part of the body.
- Do not start measurement until the cuff is attached to the arm.
- Perform the measurement in a calm and relaxed position. Do not move the device during measurement.
- The device automatically releases air when the pressure in the cuff reaches 300 mmHg. If the automatic air release does not occur, remove the cuff and press the START/STOP button to end the pressurisation of the cuff.
- 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 blood pressure monitor with a stethoscope.
- This device is not designed for a continuous monitoring of blood pressure during medical treatment, such as for example operations, etc.
- 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.
- 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.
- The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.
- The operator shall not touch output of batteries/ AC adapter and the patient simultaneously.
- Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not start or end the medical treatment without doctor's advice.
- If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.
- Manufacturer will make available on request circuit diagrams, component parts list etc.
- Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
- This device is contraindicated for any female subject who may be suspected of, or is pregnant.
- Besides provided inaccurate readings, the affects of this device on the fetus are unknown.

⚠ **WARNING:**
No modification of this equipment is allowed.

BASIC FUNCTIONS AND FEATURES OF THE BLOOD PRESSURE MONITOR

- Measurement of the systolic and diastolic blood pressure and pulse
- Detection of cardiac arrhythmia
- Adjustable length cuff for arm circumferences from 22 to 42 cm
- Automatic inflation and air release of the cuff
- Large LCD display
- 60 memory positions for storing measurement results including date and time
- Battery or power adapter (not included) operation

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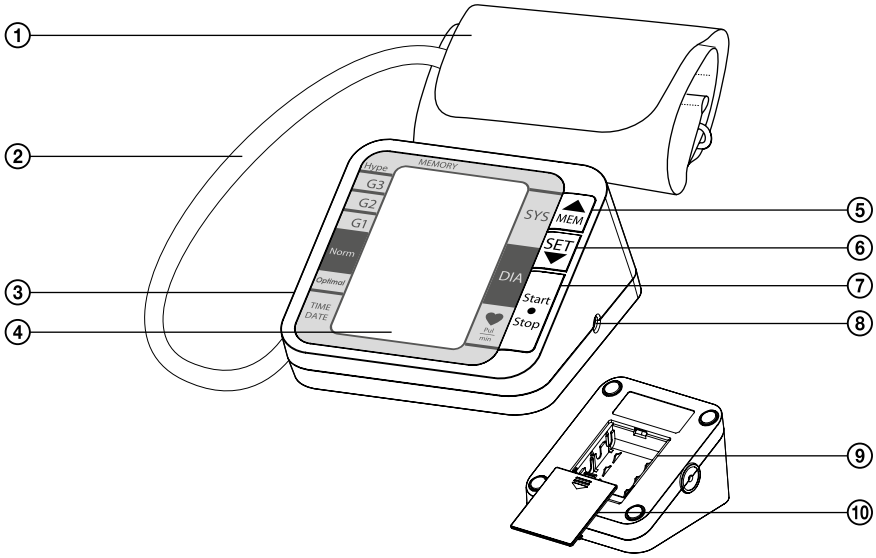
DESCRIPTION OF THE BLOOD PRESSURE MONITOR

A



① Blood pressure cuff
② Air hose
③ Air hose connection socket
④ LCD display
⑤ MEM ▲ button
⑥ SET ▼ button
⑦ START/STOP button
⑧ Power adapter connection socket
⑨ Battery compartment
⑩ Battery compartment cover

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DESCRIPTION OF THE DISPLAY

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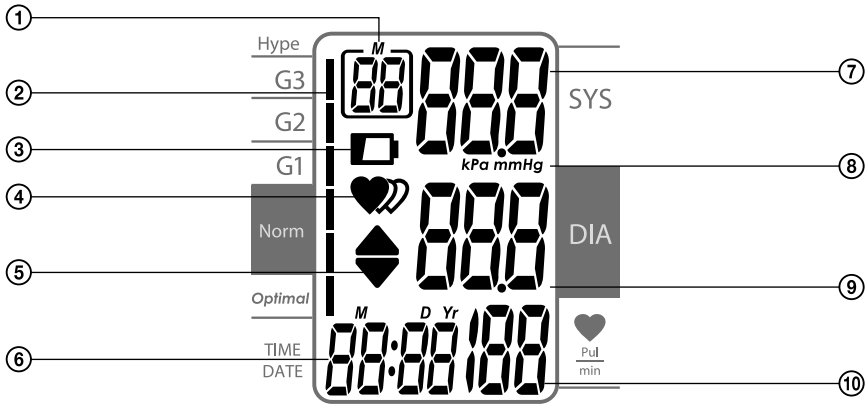

① Display of the memory sequence number
② Measured blood pressure category
③ Flat battery indicator
④ Detection of cardiac arrhythmia
⑤ Cuff air release indicator
⑥ Display of date and time
⑦ Systolic pressure value
⑧ Measuring unit
⑨ Diastolic pressure value
⑩ Pulse rate (number of pulses/minute)

USING THE BLOOD PRESSURE MONITOR

1. Selecting a power source

1.1 Using an internal power source

- To power the device using an internal power source use four LR6/AA type batteries (4 × 1.5 V).
- Remove the battery compartment cover and insert four LR6/AA type batteries. When inserting the batteries ensure the correct polarity as shown in the battery compartment. Close the cover.
- The batteries need to be replaced when:
  – the display shows the symbol ▭.
  – the display is dim.
  – the display does not turn on.

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1.2 Using an external power source

- A power adapter Sencor SBX 001 (BLJ06L060100P-V, output 6 V ⎓, 1 A) can be purchased. To purchase the power adapter, please contact your vendor.
- Connect the power adapter connector to the socket on the right side of the device. Insert the power supply plug into the an electrical power socket.
- Only use the adapter designed for this device.

Note:
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.
Do not use the adapter and batteries at the same time.
Saved records will remain stored in the memory even after the batteries are replaced.

- The old battery is harmful to the environment, so please do not dispose with other daily trash.
- Remove the old battery from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.

2. Setting the date, time and measuring units

2.1 Before taking measurements, set the current date, time and measuring unit. The measured values will be stored in memory together with the date and time of measurement.

2.2 Check that the device is turned off (the LCD display is off) or turn it off using the START/STOP button. Hold down the SET ▼ button for 3 seconds. "Year" will start to flash on the display.

2.3 Use the MEM ▲ button to set the current year. Confirm the setting by pressing the SET ▼ button. The device will automatically switch to the month setting mode.

2.4 Use the MEM ▲ button to set the current month. Confirm the setting by pressing the SET ▼ button. The device will automatically switch to the day setting mode.

2.5 Set the current day of the month using the MEM ▲ button. Confirm the setting by pressing the SET ▼ button. The device will automatically switch to the hour setting mode.

2.6 Use the MEM ▲ button to set the current hour. Confirm the setting by pressing the SET ▼ button. The device will automatically switch to the minute setting mode.

2.7 Use the MEM ▲ button to set the current minutes. Confirm the setting by pressing the SET ▼ button. The device will automatically switch to the measuring unit selection mode.

2.8 Select the measuring unit mmHg or kPa using the MEM ▲ button. Confirm the setting by pressing the SET ▼ button.

Note:
The standard measuring unit for the measurement of blood pressure is mmHg (millimetres of a mercury column).

2.9 After completing the setup, "done" will appear on the display. Setup of the date, time and measuring units is complete. Then the device turns itself off automatically.

Note:
Setting range: year 2000–2050, time format: 24 hour

3. Measurement

3.1 Basic instructions for achieving the most accurate measuring 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.
- During measurement sit calmly, relaxed and don't talk. Do not move the arm to which the cuff is attached.
- Wait approximately 4–5 minutes before measuring again.

3.2 Attaching and securing the cuff

- Remove all tight clothing from the arm before attaching the cuff.
- Attach the cuff 2–3 cm above the elbow cavity and ensure that the air hose is located above the brachial artery, as illustrated on the cuff label.
- The cuff must not be too loose or too tight. Verify the correct tightness by easily inserting one finger between the cuff and the arm.
- Place the forearm on an even table surface

Note:
Blood pressure can be measured both on the left and the right arm. However, the measurement results from the left and right arm may differ, and for this reason it is necessary to perform repeated measurements always on the same arm.

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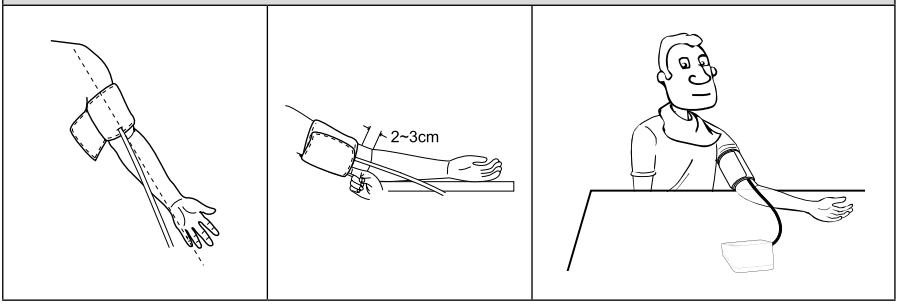

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3.3 Measuring blood pressure

3.3.1 Turn on the device by pressing the START/STOP button. In a short time all the elements will light up on the LCD display.

3.3.2 If residual air remains in the cuff, the symbol ▼ will appear on the display for a short time and the air will be released. The value 0 mmHg (or kPa) and the time of measurement will appear on the display.

3.3.3 The device will automatically pressurise the cuff. While the cuff is being pressurised the pulse rate is being detected. This is indicated by the flashing ♥ symbol on the LCD display.

3.3.4 Then the pressure in the cuff is continuously released and the values of the systolic (SYS) and diastolic (DIA) pressure, pulse rate and the blood pressure are automatically determined. The blood pressure categories are defined in the following table.

Measured blood pressure value in mmHg	Blood pressure category					
	Optimal	Normal	Normal (high)	G1 Mild hypertension	G2 Medium hypertension	G3 Heavy hypertension
SYS (systolic value)	<120	120–129	130–139	140–159	160–179	≥180
DIA (diastolic value)	<80	80–84	85–89	90–99	100–109	≥110

Note:
If the symbol ♥ appears on the display, the device has detected cardiac arrhythmia.

3.3.5 Turn off the device by pressing the START/STOP button. If you do not turn off the device, it will turn itself off automatically within 1 minute of the last measurement. Remove the cuff from your arm after completing the measurement.

4. Recalling memory

4.1 To show the last measurement record press the MEM ▲ button.

4.2 To scroll through the individual measurements in memory, use the MEM ▲ and SET ▼ buttons.

4.3 For each measurement the month/day and the time the measurement was taken will be shown in the bottom left hand part of the display.

4.4 The most recent measurement stored in memory always has the sequence number of 1. The maximum memory capacity is 60 measurements. As soon as the maximum memory capacity is achieved, every new measurement will delete the oldest measurement.

5. Deleting memory

5.1 Check that the device is turned off (the LCD display is off) or turn it off using the START/STOP button. Hold down the MEM ▲ button with your finger for 3 seconds. The message "del all" (delete all) will appear on the display.

5.2 Press the SET ▼ button to confirm the deletion of all measurements in memory. The display will show the message "del" (delete) and "done" (completed). The device will automatically turn itself off.

Note:
If you wish to interrupt the deletion process, press the START/STOP button.

5.3 No values will appear on the display when the memory is subsequently retrieved.

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.	Batteries are flat.	Replace the batteries.
	The batteries are inserted incorrectly.	Insert the batteries with the correct polarity direction as shown in the battery compartment.
	The adapter is not connected to a power socket.	Connect the adapter to a power socket.
The symbol ▭ is shown on the display.	Batteries are almost flat.	Replace the old batteries with new ones.
E1	The cuff is not attached to the arm or is attached to the arm too tight.	Turn off the device using the START/STOP button. Attach the cuff to you arm according to the instructions in chapter Attaching and securing the cuff and repeat the measurement.
E3	The pressure in the cuff was exceeded.	Rest for 4 to 5 minutes and then repeat the measurement.
E10 or E11	The device detected movement during the measurement.	Movement may affect the measurement result. Rest for 4 to 5 minutes and then repeat the measurement.
E20	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
E21	Measurement error.	Rest for 4 to 5 minutes and then repeat the measurement.
EExx shows on the display	A calibration error occured.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions.

If a different error message in the format E + number code or Ee + number code appears on the screen that is not included in the table, turn off the device, take the batteries out of it or disconnect the power adapter from the electrical power socket. Wait a while and then reinsert the batteries or reconnect the power adapter to the electrical power socket. After a few minutes repeat the measurement. If the problem persists, contact your vendor or an 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.

COMPLIED STANDARDS LIST

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labeling	EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements
User manual	EN 1041:2008 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015/ IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems IEC 80601-2-30:2009+A1:2013 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

CE 0123 This device meets the requirements of the European directive 93/42/EEC.

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

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EC REP **Authorised representative for the EU:** MDSS – Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany

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TECHNICAL SPECIFICATIONS

Measuring method	Oscillometric
Display	LCD, display size 93 × 61 mm
Memory capacity	60 records
Measuring range	Rated cuff pressure: 0mmHg~299mmHg(0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Measurement accuracy	Pressure: 5°C–40°C within ±0.4kPa (3mmHg) Pulse: ±5 %
Adjustable size of the cuff	22–42 cm
Power source	4 × type LR6/AA battery (6 V ⎓) or a power adapter Sencor SBX 001 (BLJ06L060100P-V) (not included), Input: 100–240V~50/60Hz 0.2Amax Output: 6V ⎓ 1000mA
Protection against injury by electric shock	Medical electrical device with an internal power supply (only when batteries are used) Sencor SBX 001 power adapter (not included) – Class II protection Applied part type BF 
Degree of protection against the intrusion of water	IP21
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	A temperature range of :+5 °C to +40 °C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of: 700 hPa to 1060 hPa
Storage conditions	Temperature: –20 °C to +60 °C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Dimensions of the device	140 x 120 x 70 mm
Weight of the device	280 g (without cuff and batteries)
Accessories	Blood pressure cuff, 4 × LR6/AA type battery, user's manual
Mode of operation	Continuous operation
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
Software version	A01

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EMC GUIDANCE

1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2)* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) **Caution:** This unit has been thoroughly tested and inspected to assure proper performance and operation!
4)* **Caution:** This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device 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 electronicequipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, other than domestic 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	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete 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	power supply lines: ±2 kV input/output lines: ±1 kV	power supply lines: ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	line(s) to line(s): ±1 kV line(s) to earth: ±2 kV 100 kHz repetition frequency	line(s) to line(s): ±1 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply inputlines IEC 61000-4-11	0%U_T;0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0%U_T; 1 cycle and 70%U_T; 25/30 cycles Single phase: at 0° 0% U_T; 300 cycle	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T;300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity				
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.				
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance	
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d=0.35\sqrt{P}$; $d=1.2\sqrt{P}$	
Radiated RF IEC 61000-4-3	10V/m, 80% Am at 1kHz	10V/m, 80% Am at 1kHz	80 MHz to 800 MHz: $d=1.2\sqrt{P}$ 800 MHz to 2.7 GHz: $d=2.3\sqrt{P}$	where, ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, ***d*** is the recommended separation distance in meters (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) Interference may occur in the vicinity of equipment marked with the following symbol:
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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.				

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the device.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmittters) and the device 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)		
	150 kHz to 80 MHz $d = 3.5\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 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.			

Table 5

Guidance and manufacturer's declaration – electromagnetic immunity							
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device, should assure that it is used in such an environment.							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380–390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
	450	380–390	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710	704–787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.2	0.3	9
	745						
	780						
	810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	870						
	930						
	1720	1700–1990	GSM 1800; CDMA1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
	1845						
	1970						
	2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n,RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
	5240	5100–5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
	5240						
	5785						
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a) For some services, only the uplink frequencies areincluded. b) The carrier shall be modulated using a 50% duty cycle square wavesignal. c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worstcase.							
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the followingequation: $E=\frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.							

IRREGULAR HEARTBEAT DETECTOR

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure.During each measurement, the monitor records all the pulse intervals and calculate the average ; if there are two or more pulse intervals ,the difference between each interval and the average is more than the average value of ±25% , or there are four or more pulse intervals ,the difference between each interval and the average is more than the average value of ±15%,the irregular heartbeat symbol appears on the display when the measurement results are appeared.

CAUTION:
The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

CAUTION:

* This device is intended for adult use in homes only.
* The device is not suitable for use on neonatal patients, pregnant women,patients with implanted, electronical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses.
* The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
* The device is not intended for patient transport outside a healthcare facility.
* The device is not intended for public use.
* This device is intended for no-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure.Do not begin or end medical treatment without asking a physician for treatment advice.
* If you are taking medication,consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.
* Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
* When the device was used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result.
* Don't kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.
* When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient:

connection tubing kinking too frequent and consecutive multiple measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.

* **Warning**: Do not apply the cuff over a wound; otherwise it can cause further injury.
* Do not inflate the cuff on the same limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.
* On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure 300mmHg or constant pressure 15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.
* Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measurement, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.
* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.
* To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
* This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
* Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
* This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's arm and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
* When not in use, store the device with the adapter in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
* This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
* This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.
* The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.
* **Warning**: No servicing/maintenance while the ME equipment is in use.
* The patient is an intended operator.
* The patient can measure data and change batteries under normal circumstances and maintain the device and its accessories according to the user manual.
* To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* The blood pressure monitor, its adaptor, and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
* During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensization or irritation reaction.
* Adaptor is specified as a part of ME EQUIPMENT.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures reaches 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
* Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.

* Do not wash the cuff in a washing machine or dishwasher!
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
* Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions,etc., to assist to service personnel in parts repair.
* The plug/adapter plug pins insulates the device from the main supply. Do not position the device in a position where it is difficult to disconnect from the supply mains to safely terminate operation of ME equipment.
* The operator shall not touch output of batteries /adapter and the patient simultaneously.
* Cleaning :Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
* The device doesn't need to be calibrated within two years of reliable service.
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of SENCOR. Don't open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
* Please report to SENCOR if any unexpected operation or events occur.
* Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.
* At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
* This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
* Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the MANUFACTURER from the 80 MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.
* Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
* There is no luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
* Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

We reserve the right to change text and technical specifications.

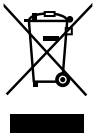
INSTRUCTIONS AND INFORMATION REGARDING THE DISPOSAL OF USED PACKAGING MATERIALS

Dispose of packaging material at a public waste disposal site.

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



The meaning of the symbol on the product, its accessory or packaging indicates that this product shall not be treated as household waste. Please, dispose of this product at your applicable collection point for the recycling of electrical & electronic equipment waste. Alternatively in some states of the European Union or other European states you may return your products to your local retailer when buying an equivalent new product. The correct disposal of this product will help save valuable natural resources and help in preventing the potential negative impact on the environment and human health, which could be caused as a result of improper liquidation of waste. Please ask your local authorities or the nearest waste collection centre for further details. The improper disposal of this type of waste may fall subject to national regulations for fines.

For business entities in the European Union
If you wish to dispose of an electrical or electronic device, request the necessary information from your seller or supplier.

Disposal in other countries outside the European Union
If you wish to dispose of this product, request the necessary information about the correct disposal method from local government departments or from your seller.

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