



Wrist digital blood pressure monitor



INSTRUCTION MANUAL

▶ Introduction to SENDO SMART 2

Thank you for purchasing the state-of-the-art **SENDO SMART 2** blood pressure monitor. Designed for ease of use and accuracy, this device will facilitate your daily blood pressure regimen.

SENDO SMART 2 will give you years of accurate measurements if it is used properly. We are always ready to provide help on our telephone line for your country.

Please read this manual carefully before using SENDO SMART 2.

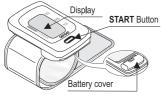
This device fulfils the following provisions

Medical Device Regulations (EU 2017/745).

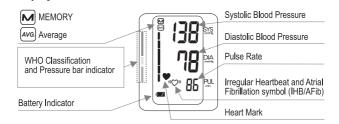
The device is designed for use by people 13 years and older, not newborns and infants.



Display







▶ Intended Purpose

SENDO SMART 2 is intended to be used by patients to measure systolic and diastolic blood pressure and pulse rate in the home environment.

SENDO SMART 2 provides the patient with an indication of an irregular heartbeat allowing further medical attention to be sort.

▶ Clinical Benefit:

Successful assessment of blood pressure reading in accordance with the device's intended purpose.

Symbols

SYMBOLS THAT APPEAR ON THE DISPLAY					
Symbols Function/ Meaning Recommended /					
•	Appears while measurement is in progress. It blinks when the pulse is detected.	Measurement is in progress. Remain as still as possible.			
	Irregular Heartbeat and Atrial Fibrillation symbol (IHB/AFib) appears when an irregular	Apply the cuff correctly, then take another measurement.			
(((\(\)))	heartbeat is detected. It may light up when a very slight vibration like shivering or shaking is detected.	If the "\\" symbol continues to appear, we recommend you to consult with your physician.			
M	Previous measurements stored in MEMORY				
AVG.	Average data				
c Z	FULL BATTERY The battery power indicator during measurement.				
□	LOW BATTERY The battery is low when it blinks.	Replace all batteries with new ones when the indicator blinks.			

▶ Symbols

SYMBOLS THAT APPEAR ON THE DISPLAY					
Symbols	Function/ Meaning	Recommended Action			
E for E	Unstable blood pressure due to movement during the measurement.	Take another measurement. Remain still during measurement.			
101 5	The systolic and diastolic values are within 10 mmHg of each other.				
E	The pressure value did not increase during inflation.	Apply the cuff correctly and take another measurement.			
	The cuff is not applied correctly.				
Ε	PUL DISPLAY ERROR. The pulse is not detected correctly.				
E Device internal error		Remove the batteries and press the START button, and then install the batteries			
E ₉	Device internal error	again. If the error still appears, contact the dealer.			

SYMBOLS THAT ARE PRINTED ON THE DEVICE CASE AND THE PACKAGING				
Symbols	Function/ Meaning	Symbols	Function/ Meaning	
SYS	Systolic blood pressure in mmHg	ш	Manufacturer	
DIA	Diastolic blood pressure in mmHg	2014 كسا	Date of manufacture	
PUL	Pulse per minute	IP	International protection symbol	
⊕(R6(AA))⊖	Battery installation guide	X	WEEE label	
===	Direct current	SN	Serial number	
*	Type BF: Device, cuff and tubing are designed to provide special protection against electrical shocks	③	Refer to instruction manual/ booklet	
C € ₂₇₉₇	CE marking.	⊝-©- ⊕	Polarity of DC jack	
EC REP	EU-representative	*	Keep dry	
MD	Medical Device.	UDI	Unique Device Identifier	
1	Temperature limit	Æ	Humidity limitation.	
9	Atmospheric pressure limitation.	1	Importer	
	Distributer	<u>்</u>	Standby and turn the device on	

▶ Troubleshooting

Problem	Possible Reason	Recommended Action
Nothing appears on the display, even when the device is	Batteries are drained.	Replace all batteries with new ones.
turned on.	Battery terminals are not in the correct position.	Reinstall the batteries with negative and positive terminals matching those indicated on the battery compartment.
The cuff does not inflate.	Battery voltage is too low. (LOW BATTERY mark) blinks. If the batteries are drained completely, the mark does not appear.	Replace all batteries with new ones.
The device does not measure. Readings	The cuff is not applied properly.	Apply the cuff correctly.
are too high or too low.	You moved your arm or body during measurement.	Make sure you remain very still and quiet during measurement.
	The cuff position is not correct.	Sit comfortably and still. Place your arm on a table with your palm facing upward and the cuff at the same level as your heart.
		If you have a very weak or irregular heartbeat, the device may have difficulty in determining your blood pressure.
Other	The value is different from that measured at a clinic or doctor's office.	Refer to "Why Measure Blood Pressure at Home?".
		Remove the batteries. Place them back properly and try the measurement again.

NOTE: If the actions described above do not solve the problem, contact the dealer. Do not attempt to open or repair this product, as any attempt to do so will make your warranty invalid.

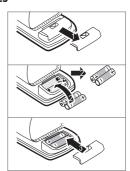
▶ Using SENDO SMART 2

INSTALLING/ CHANGING THE BATTERIES

- 1. Remove the battery cover.
- Remove the used batteries from the battery compartment when changing them.
- Insert new batteries into the battery compartment as shown, taking care that the polarities (+ and -) are correct. Use only LRO3 or AAA batteries.
- 4. Attach the battery cover.

NOTE: Rechargeable batteries are not recommended for use with this monitor.

NOTE: Batteries are not treated as normal household waste and must be disposed of according to the applicable local regulations.



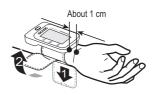
CAUTION

- Insert the batteries as shown in the battery compartment. If installed incorrectly, the device will
 not work.
- When (LOW BATTERY mark) appears on the display, replace all batteries with new ones. Do not mix old and new batteries. It may shorten the battery life or cause the device to malfunction.
- (LOW BATTERY mark) will disappear when the batteries are replaced.
- The battery life varies with the ambient temperature and may be shorter at low temperatures.
 Generally, two new LR03/AAA batteries will last approximately for four months when used twice a day for measurement.
- Use the specified batteries only.
- Remove the batteries if the device is not to be used for a long time. The batteries may leak and
 cause a malfunction.

APPLYING THE CUFF

- Wrap the cuff around your wrist, about 1 cm above your hand, as shown in the figure on the right.
- **2.** Fasten the cuff tightly using the Velcro strip.

NOTE: For accurate measurements, fasten the cuff tightly and measure on a bare wrist.

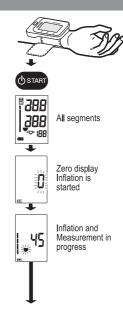


Measurements

- Wrap the cuff around your wrist. Sit comfortably with the cuff at the same level as your heart and relax.
- Press the START button. All the display segments are displayed.
- 3. Zero (0) is displayed blinking briefly. Then the display changes, as measurement begins. The cuff starts to inflate. It is normal for the cuff to feel very tight. The measurement starts automatically when inflation starts, and the (heart mark) blinks.

NOTE: If you wish to stop inflation at any time, press the **START** button again.

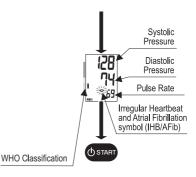
4. When the measurement is complete, the device displays readings (of the systolic and diastolic pressure readings, pulse rate, WHO classification, IHB/AFib symbol). The cuff exhausts the remaining air and deflates automatically.



5. Press the **START** button again to turn the device off. Remove the cuff.

NOTE: SENDO Smart 2 has an automatic power shut-off function which stores the current data in the memory and turns the device off automatically one minute after measurement

NOTE: Allow at least three minutes between measurements on the same person. SENDO SMART 2 will provide an inflation appropriate to the user



HOW TO TAKE PROPER MEASUREMENTS?

- Sit down in a comfortable position. Place your arm on a table with your palm facing upward and the cuff is at the same level as your heart.
- Relax for about five to ten minutes before taking a measurement. If you are
 excited or depressed by emotional stress, the measurement will reflect this
 stress as a higher (or lower) than normal blood pressure reading and the
 pulse reading will usually be faster than normal.
- Your blood pressure varies constantly, depending on what you are doing and what you have eaten. What you drink can have a very strong and rapid effect on your blood pressure.
- Do not measure right after physical exercise or a bath. Rest for twenty or thirty minutes before taking the measurement.
- This device bases its measurements on the heartbeat. If you have a very weak or irregular heartbeat, the device may have difficulty determining your blood pressure.
- Should the device detect a condition that is abnormal, it will stop the measurement and display an error symbol. Refer to section Display Symbols for description of the symbols.
- Try to measure you blood pressure at the same time every day.
- This device is intended for use by adults. Consult with your physician before using this device on a child. A child should not use this device unattended.
- The automatic blood pressure monitor's performance may be affected by excessive temperature, humidity or altitude.
- Remain still and keep quiet during measurement.
- Do not cross your legs. Keep your feet flat on the floor and straighten your back.

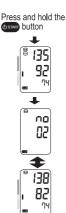
Memory

RECALLING THE MEMORY

SENDO SMART 2 stores up to 60 measurements in memory. Press and hold the START button to recall the data. Stored data is automatically displayed in the order of the newest to the oldest.

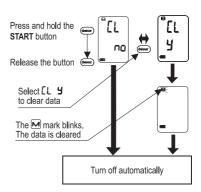
- When nothing is displayed, press and hold the START button to recall the stored data.
- 2. Release the button when displaying the average data.
- The data number and stored data are automatically displayed in order from the last measurement.
- **4.** The display will turn off automatically after all data is displayed.

NOTE: If you press the **START** button while recalling data, the device turns off.



DELETING THE MEMORY

- When turning off the device, press and hold the START button until the LL no is displayed.
- 2. Select [L y to clear data.
- **3.** Data is cleared when the **M** mark blinks.
- The device turns off automatically.



▶ What is the IHB/AFib indicator?

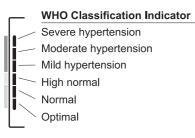
When Sendo Smart 2 detects an irregular rhythm during the measurements, the IHB/AFib indicator (()) will appear on the display with the measurement values.

▶ What is AFib?

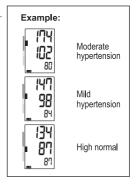
The heart contracts due to electrical signals occurring in heart and sends blood through the body. Atrial fibrillation (AFib) occurs when the electrical signal in the atrium becomes confused and leads to disturbances in the pulse interval. AFib can cause blood to stagnate in the heart, which can easily create clots of blood, a cause of stroke and heart attack.

▶ WHO Classification Indicator

Each segment of the bar indicator corresponds to the WHO blood pressure classification described below.

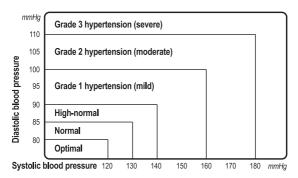


 The indicator displays a segment based on the current data corresponding to the WHO classification.



WHO Blood Pressure Classification

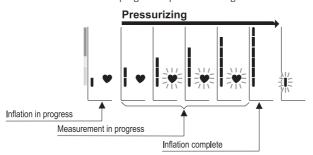
Standards to assess high blood pressure, without regard to age, have been established by the World Health Organization (WHO), as shown in the chart.



Reference Material: Journal of Hypertension 1999, Vol. 17, No. 2

▶ Pressure Bar Indicator

The indicator monitors the progress of pressure during measurement.



▶ About Blood Pressure

WHAT IS BLOOD PRESSURE?

Blood pressure is the force exerted by blood against the walls of the arteries. Systolic pressure occurs when the heart contracts. Diastolic pressure occurs when the heart expands. Blood pressure is measured in millimeters of mercury (mmHg). One's natural blood pressure is represented by the fundamental pressure, which is measured first thing in the morning while one is still at rest and before eating.

WHAT IS HYPERTENSION AND HOW IS IT CONTROLLED?

Hypertension, an abnormally high arterial blood pressure, if left unattended, can cause many health problems including stroke and heart attack. Hypertension can be controlled by altering lifestyle, avoiding stress, and with medication under a doctor's supervision.

To prevent hypertension or keep it under control:

- Do not smoke
- · Exercise regularly
- · Reduce salt and fat intake
- · Have regular physical checkups
- · Maintain proper weight

WHY MEASURE BLOOD PRESSURE AT HOME?

Blood pressure measured at a clinic or doctor's office may cause apprehension and can produce an elevated reading, 25 to 30 mmHg higher than that measured at home. Home measurement reduces the effects of outside influences on blood pressure readings, supplements the doctor's readings and provides a more accurate, complete blood pressure history.

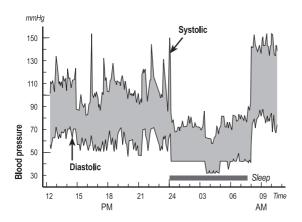
BLOOD PRESSURE VARIATIONS

An individual's blood pressure varies greatly on a daily and seasonal basis. It may vary by 30 to 50 mmHg due to various conditions during the day. In hypertensive individuals, variations are even more pronounced. Normally, the blood pressure rises while at work or play and falls to its lowest levels during sleep. So, do not be overly concerned by the results of one measurement.

Take measurements at the same time every day using the procedure described in this manual to get to know your normal blood pressure. Regular readings give a more comprehensive blood pressure history. Be sure to note the date and time when recording your blood pressure.

Consult your doctor to interpret your blood pressure data.

Typical fluctuation within a day (Measured every five minutes)



Maintenance

Do not open the device. It uses delicate electrical components and an intricate air unit that could be damaged. If you cannot fix the problem using the troubleshooting instructions, contact the authorized dealer in your area or our customer service department. The customer service will provide technical information, spare parts and units to authorized dealers.

The device was designed and manufactured for a long service life. However, it is generally recommended to have the device inspected every 2 years to ensure proper functioning and accuracy. Please contact the authorized dealer in your area for maintenance.



DO NOT TRY TO DISASSEMBLE AND FIX THE UNIT BY YOURSELF!

▶ Technical Data

Туре	SENDO SMART 2
Measurement method	Oscillometric measurement
Measurement range	Pressure: 0 – 299 mmHg
	Systolic Blood Pressure: 60 - 279 mmHg
	Diastolic Blood Pressure: 40 - 200 mmHg
	Pulse: 40 – 180 beats/ min
Measurement accuracy	Pressure: ±3 mmHg
	Pulse: ±5%
Power supply	2 x 1.5V alkaline batteries (LR03 or AAA)
Number of measurements	Approx. 250 measurements when AAA alkaline batteries are used, with pressure value of 170 mmHg at room temperature of 23 °C
Wrist circumference	13.5 – 21.5 cm
Classification	Internally powered ME equipment (Continuous operation mode)
Applied part	Cuff: Type BF 🐧
Useful life	Device: 5 years (when used six times a day)
Clinical test	According to ISO 81060-2:2018+A1:2020
EMD	IEC 60601-1-2:2014+A1:2020
Memory	Last 60 measurements
Operating conditions	+10 °C to +40 °C / 15 %RH to 85 %RH 800 to 1060hPa
Transport/ Storage conditions	-20 °C to +60 °C / 10 %RH to 95 %RH 700 to 1060 hPa
Dimensions	Approx. 56 [W] x 88 [H] x 22 [D] mm
Weight	Approx. 90 g, excluding the batteries
Ingress protection	IP22

EMD Technical Data

Battery-operated Blood Pressure Monitor

Medical Electrical Equipment needs special precautions regarding EMD and needs to be installed and put into service according to the EMD information provided in the following.

Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment.

The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit.

ı	Table 1 – Emission Limits				
ſ	Phenomenon	Compliance			
	Conducted and radiated RF emission	CISPR 11	Group 1, Class B		

Table 2 – Immunity Test Levels: Enclosure Port				
Phenomenon	Immunity Test Levels			
Electrostatic discharge IEC 61000-4-2		±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air		
		10 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz		
Proximity fields from RF wireless equipment	See table 3			
Rated power frequency magnetic fields IEC 61000-4-8		30 A/m 50 Hz or 60 Hz		

Table 3 – Test specifications for Enclosure Port Immunity to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 ~ 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 ~ 470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 ~ 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800 ~ 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700 ~ 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 ~ 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 ~ 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

▶ Warranty

As long as the instructions are followed, your SENDO SMART 2 should last for many years. In the event it fails to operate due to manufacturing or materials related defects, we will repair it free of charge during the warranty period. The apparatus has 5 years warranty for its electrical components. The parts made from rubber and textile have 2 years warranty. Any claim for damages covered by the warranty must be accompanied by the purchase receipt (cash register receipt). The warranty does not cover damages when instructions for installing and use are not followed and in the following conditions: if there are discrepancies between the warranty and the product itself; if there are damages caused by unauthorized repair; damages caused by external factors: dust, liquids, exposure to extreme weather conditions or stress on the mechanism, improper use and maintenance of the device or natural abrasion of materials.

Please, check warranty provided by distributor.

Trying to repair the device yourself can cause property damage, additional problems with the product and losing the right to a warranty claim.

Precautions

- This device is designed to measure blood pressure and pulse rate of people for diagnosis.
- Environment for use: The device is intended for use to operate by yourself in the home healthcare environment.
- The device is designed for use on adults, not newborns or infants.
- This device conforms to the Medical Device Regulations (EU 2017/745) for Medical Products. This is made evident by the C € 2007 mark of conformity.
- Precision components are used in the construction of this device. Extremes in temperature, humidity, direct sunlight, shock or dust should be avoided.
- Clean the device and cuff with a dry, soft cloth or a cloth dampened with water and a neutral detergent. Never use alcohol, benzene, thinner or other harsh chemicals to clean the device or cuff.
- Avoid tightly folding the cuff for long periods, as such treatment may shorten the life of the components.
- The device and cuff are not water resistant. Prevent rain, sweat and water from soiling the device and cuff.
- Measurements may be distorted if the device is used close to televisions, microwave ovens, cellular telephones, X-ray or other deices with strong magnetic fields.
- Do not use a mobile phone or other devices that emit electromagnetic fields near the device. This might result in incorrect operation of the device.

- When reusing the device, make sure that the device is clean.
- Used equipment, parts and batteries are not treated as ordinary household waste, and must be disposed of according to the applicable local regulations.
- Do not modify the device. It may cause accidents or damage to the device.
- To measure blood pressure, the wrist must be squeezed by the cuff hard enough to temporarily stop blood flow through the artery. This may cause pain, numbness or a temporary red mark to the wrist. This condition will appear especially when measurement is repeated successively. Any pain, numbness, or red marks will disappear with time.
- Measuring blood pressure too frequently may cause harm due to blood flow interference. Check that the operation of the device does not result in prolonged impairment of blood circulation, when using the device repeatedly.
- If you have had a mastectomy, please consult a doctor before using the device.
- Do not drop the monitor to strong shocks or vibrations
- Keep away from children and infants to avoid accidental strangulation or injury to them.
- Do not let children use the device by themselves and do not use the device in a place within the reach of infants. It may cause accidents or damage.
- There are small parts that may cause a choking hazard if swallowed by mistake by infants.
- Use of accessories not detailed in this manual may compromise safety.
- Should the battery short-circuit, it may become hot and potentially cause burns.
- Allow the device to adapt to the surrounding environment before use (about one hour).
- Clinical testing has not been conducted on newborn infants and pregnant women. Do not use on newborn infants or pregnant women.
- Do not touch the batteries, and the patient at the same time. That may result in electrical shock.
- In case of single component failure, the cuff might become hot and potentially cause malfunction.
- Do not inflate without wrapping the cuff around your wrist.
- Wireless communication devices such as home networking devices, mobile phones, cordless phones and their base stations, walkie-talkies can affect this blood pressure monitor. A minimum distance of 30 centimeters should be kept from such devices.
- This is a medical device for use by lay person. Please consult your healthcare provider with any questions or concerns you may have regarding your condition.
- When any serious incident occurs in relation to this device, report to its manufacturer and the competent authority in your country.
- Confirm for proper operation before use, if the packaging is damaged, unintentionally opened and exposed to environmental conditions outside of those specified.

- Digital Blood Pressure Monitor is not intended to diagnose heart arrhythmias. If the Irregular Heart Beat indicator illuminates frequently and is unrelated to patient movement during blood pressure measurement, further medical attention must be sort.
- This is a medical device for use by lay person. Please consult your healthcare provider with any questions or concerns you may have regarding your condition.
- When any serious incident occurs in relation to this device, report to its manufacturer and the competent authority in your country.
- Confirm for proper operation before use, if the packaging is damaged, unintentionally opened and exposed to environmental conditions outside of those specified.

Contraindications

The following are precautions for proper use of the device.

- Do not apply the cuff on a wrist with another medical electrical equipment attached. The equipment may not function properly.
- People who have a severe circulatory deficit in the arm must consult a doctor before using the device to avoid medical problems.
- Do not self-diagnose the measurement results and start treatment by yourself. Always consult your doctor for evaluation of the results and treatment.
- Do not apply the cuff on a wrist with an unhealed wound.
- Do not apply the cuff on an arm receiving an intravenous drip or blood transfusion. It may cause injury or accidents.
- Do not use the device where flammable gases such as anesthetic gases are present. It may cause an explosion.
- Do not use the device in highly concentrated oxygen environments, such as a high-pressure oxygen chamber or an oxygen tent. It may cause a fire or explosion.
- Do not provide any servicing and perform maintenance while the medical device is in use.

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Date	Systolic blood pressure	Diastolic blood pressure	Pulse

Date	Systolic blood pressure	Diastolic blood pressure	Pulse

Date	Systolic blood pressure	Diastolic blood pressure	Pulse



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