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Version Number:1.0

Fully Automatic Upper Arm Smart Blood Pressure Monitor

Model Number: BPS01

USER'S MANUAL



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1. Introduction and Intended Use

The Medscan Smart BP Monitor enables reliable measurement of systolic and diastolic blood pressure as well as pulse through the oscillometric method.

Before using, please read this instruction manual carefully and then keep it in a safe place.

1.1 Remember...

- Only a health-care professional is qualified to interpret blood pressure measurements.
- This device is NOT intended to replace regular medical checkups.
- Blood pressure readings obtained by this device should be verified before prescribing or making adjustments to any medications used to control hypertension. Under no circumstances should YOU alter the dosages of any drugs prescribed by your physician.
- This monitor is intended for use by adults only. Consult with a physician before using this instrument on a child.
- In cases of irregular heartbeat, measurements made with this instrument should only be evaluated after consultation with a physician.

1.2 Warnings and Precautions

- Warning:** The use of other accessories other than those specified or provided by the equipment manufacturer may cause electromagnetic radiation to increase or decrease electromagnetic immunity resulting in operational failure
- Warning:** This system may fail to yield specified measurement accuracy if operated or stored in temperature or humidity conditions outside the limits stated in the specifications section of this manual.
- Warning:** The user must check that the equipment functions safely and see that it is in proper working condition before being used.
- Warning:** The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- Warning:** The patient is an intended operator, the functions of monitoring blood pressure and pulse rate can be safely used by patient. The routine clean and changing batteries can be performed by the patient.
- Warning:** This device can not be used together with hf surgical equipment.
- Warning:** Use of power adapters
1.Adapter: input 100-240V, 50/60hz output DC 5V 1A
2.Do not position the device in a manner which makes it difficult to operate or disconnect the device while using the adaptor.
3.Do not expose to water, high temperature, moisture, direct sunlight or any corrosive gas environment. Do not use this product in the above environment.
- Warning:** Too frequent measurements can cause injury to the PATIENT due to blood flow interference.
- Warning:** Don't place the cuff over any wound.
- Warning:** Pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring medical equipment on the same limb.
- Caution:** To avoid any possibility of accidental strangulation, keep this unit away from children and do not drape tubing around your neck.

- Caution:** Keep this unit away from children and pets.
- Caution:** The standard material used for the bladder and tubing is latex-free.
- Attention:** Self-measurement is for observation, not diagnosis or treatment. Unusual values must always be discussed with a physician. Under no circumstances should you alter the dosages of any drugs prescribed by your physician.
- Attention:** The pulse display is not suitable for checking the frequency of heart pacemakers!
- Attention:** In cases of irregular heartbeat, measurements made with this instrument should only be evaluated after consultation with a physician.
- Note:** To obtain the greatest accuracy from your blood pressure instrument, it is recommended that the instrument be used within the specified temperature and the relative humidity, please see the Technical Specifications.
- Note:** The cuff is specially designed for the Medscan Smart Blood Pressure Monitor. The user should contact the manufacturer for assistance, if needed, in setting up, using or maintaining the device.
- Note:** This device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens) during use. These can lead to erratic and inaccurate results.
- Note:** Do not attempt to service or repair this device yourself. Should a malfunction occur, refer to local distributor or the manufacturer.

2.Important Information on Blood Pressure and its Measurement

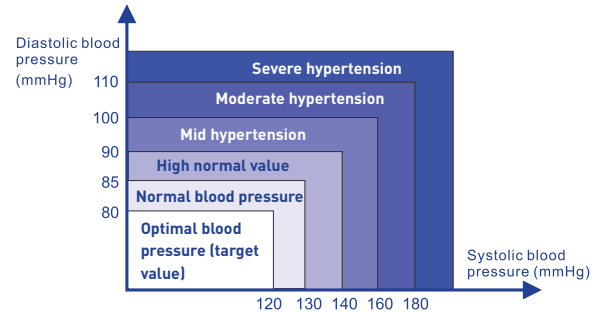
2.1. How does high or low blood pressure arise?

Your level of blood pressure is determined in the circulatory center of the brain and adjusts to a variety of situations through feedback from the nervous system. To adjust blood pressure, the strength and speed of the heart (Pulse), as well as the width of circulatory blood vessels is altered. Blood vessel width is controlled by fine muscles in the blood vessel walls.

Your level of arterial blood pressure changes periodically during heart activity: During the "blood ejection" (Systole) the value is highest (systolic blood pressure value). At the end of the heart's "rest period" (Diastole) pressure is lowest (diastolic blood pressure value).

2.2. Which values are normal?

Please refer to the diagram below (Picture-01)



Picture-01

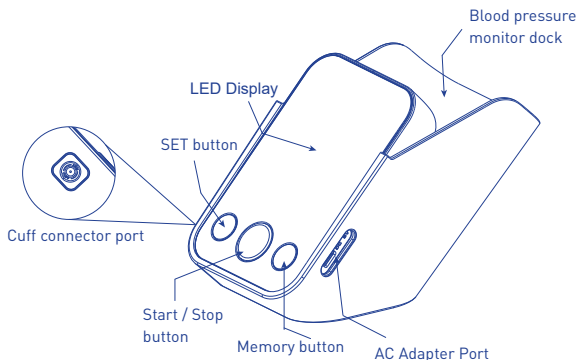
There are six levels graded and shown on the display of device. Please refer to the table below. Different levels represent different interval scales according to the WHO.

Blood pressure value	WHO grids in device	WHO Classification
DIA < 80 & SYS < 120	1	Optimal blood pressure
DIA < 85 & SYS < 130	2	Normal blood pressure
DIA < 90 & SYS < 140	3	High normal value
DIA < 100 & SYS < 160	4	Mild hypertension
DIA < 110 & SYS < 180	5	Moderate hypertension
DIA > 110 or SYS > 180	6	Severe hypertension

picture-01-01

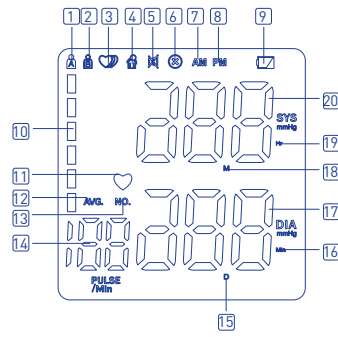
3. Components of your blood pressure monitor

3.1 Blood Pressure Monitor



Picture-02

3.2 Identifying what You See on your LED Display



Picture-03

3.2 The symbols on the LED display

- | | |
|---|---------------------------------|
| 1. User A | 2. User B |
| 3. Irregular heartbeat symbol | 4. Movement error symbol |
| 5. Mute symbol | 6. Cuff self-detecting function |
| 7. AM symbol | 8. PM symbol |
| 9. Low battery symbol | 10. WHO function symbol |
| 11. Heartbeat symbol (Flashes during measurement) | 12. Average value symbol |
| 13. Memory reading number | 14. Pulse symbol |
| 15. Date symbol | 16. Minute symbol |
| 17. Diastolic blood pressure | 18. Month symbol |
| 19. Hour symbol | 20. Systolic blood pressure |

3.3 Features

- | | |
|-----------------------------------|--------------------------------------|
| 1. Cuff self-checking function | 2. Double users: 2 x 120 sets memory |
| 3. Average value function | 4. Irregular heartbeat checking |
| 5. WHO function | 6. Low battery display |
| 7. External power adapter support | 8. Auto power-off |
| 9. Cuff storage | 10. Led display |
| 11. Acrylic lens | 12. Time & data display |

4. Using your Monitor for the First Time

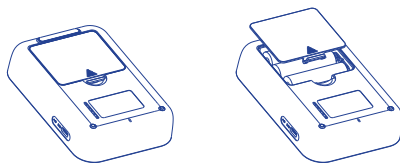
4.1 Using batteries for power

Battery Installation

Use only 1.5V "AA" alkaline batteries with this device.

1. Press the hook on the bottom of the battery cover and lift the cover off in the direction of the arrow (Picture-04).

2. Install 3 "AA" size batteries and make sure the + (positive) and - (negative) polarities match the polarities of the battery compartment, then close the battery cover. Make sure that the battery cover is securely in position.



Picture-04

Battery replacement

1. When the Low Battery Indicator appears on the display, turn the monitor off and remove all the batteries. Replace with 3 new batteries at the same time. Long-life alkaline batteries are recommended.

2. To prevent the damage of monitor from leaked battery fluid, please take the batteries out of the monitor if it will be unused for a long time (generally more than 3 months). If battery fluid get in your eyes, immediately rinse with plenty of clean water. Contact a physician immediately.

3. Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

4.2. System Settings

After you load the battery or connect power for the monitor, long press the SET button for more than 3s, and then you can start to set.

Setting the Year:

When the year display is flashing, press the MEM button continuously and the year will increase by 1 until 2099, and then return the initial year (2020).

Once the desired year is reached, press SET button to confirm.

Setting Month / Day:

Initial Month/Date is 1/01, when the Month display is flashing, press the MEM button, and the month will increase by 1 with each press. Once the desired month is reached, press SET button to confirm.

With the day is flashing, press the MEM button, the day will increase by 1 with each press. Once the desired day is reached, press SET to confirm.

Setting Time :

When the hour display is flashing, press the MEM button, and the hour will increase 1 with each press. Press SET button to confirm desired hour.

When the minute display is flashing, press the MEM button, and the minutes will increase 1 with each press. Press SET button to confirm desired minute.

Setting the User:

Press the MEM button to select User A or User B. When display A (/B) on the screen, press the MEM button to switch to user B (/A). Press the SET button to confirm.

Record Delete:

When you checking the memory data, long press MEM button to delete existing user measurement data.

Note:

You can't delete all measurement record from the monitor storage at one time, if you decide to delete the all record, please keep the record in another way, in case you need it some days later. Take the battery out won't lead to a record missing.

5. Measurement Procedure

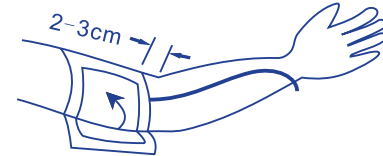
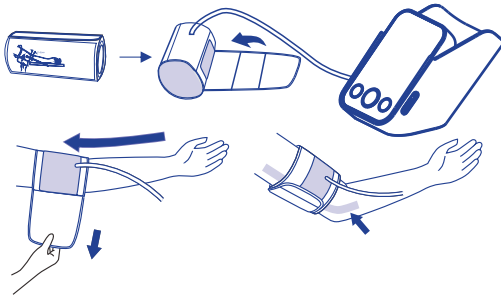
5.1. Before measurement:

- Avoid eating and smoking as well as all forms of exertion directly before measurement. These factors may influence the measurement result. Please relax and be calm for approximately 10 minutes before the measurement.
- Remove any garment that fits tightly to your upper arm.
- Always measure on the same arm (normally left).

5.2. Fitting the Cuff

Please refer to picture-05

- a) Wrap the cuff around your upper left arm. The rubber tube should be on the inside of your arm extending downward to your hand. Make certain the cuff lies approximately 2 to 3 cm above the elbow. Important! The **D** on the edge of the cuff (Artery Mark) must lie over the artery which runs down the inner side of the arm.
- b) To secure the cuff, wrap it around your arm and press the hook and loop closure together.
- c) There should be little free space between your arm and the cuff. You should be able to fit 2 fingers between your arm and the cuff. Cuffs that don't fit properly result in false measurement values. Measure your arm circumference if you are not sure of proper fit.
- d) Lay your arm on a table (palm upward) so the cuff is at the same height as your heart. Make sure the tube is not kinked.



Picture-05

5.3. Measuring your Blood Pressure

Refer to picture-06

1. Sit comfortably in a chair with your feet flat on the floor.
2. Select your User ID (A or B).
3. Stretch your arm forward on the desk and keep relaxing, make sure the palm of hand is upturned. Make sure arm is in correct position, to avoid body movement. Sit still and do not talk or move during the measurement.

After the cuff has been appropriately positioned on the arm and connected to the blood pressure monitor, the measurement can begin:

- a) Press the START/STOP button. The pump begins to inflate the cuff. In the display, the increasing cuff pressure is continually displayed.
- b) After automatically reaching an individual pressure, the pump stops and the pressure slowly falls. The cuff pressure is displayed during the measurement.
- c) When the device has detected your pulse, the heart symbol in the display begins to blink.
- d) When the measurement has been concluded, the measured systolic and diastolic blood pressure values, as well as the pulse will be displayed.
- e) The measurement results are displayed until you switch the device off. If no button is pressed for 60 seconds, the device switches off automatically.
- f) Cuff self-checking symbol (⊗)

The cuff incorrect symbol (⊗) will be displayed if the cuff wrapping too loose to detect enough pressure.

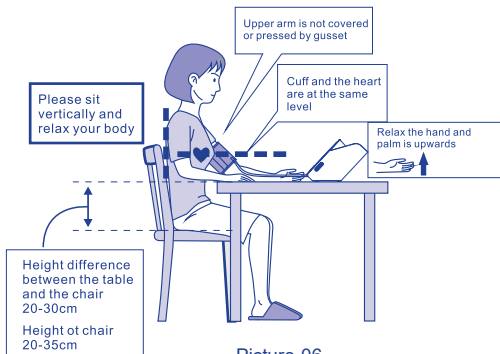
- g) Movement error symbol (⏸)

The Movement Error Symbol (⏸) is displayed if you move your body during the measurement. Please remove the cuff, and wait 2-3 minutes. Reapply the cuff and take another measurement.

NOTE:


Patient Position:

- 1) Comfortably seated
- 2) Legs uncrossed
- 3) Feet flat on the floor
- 4) Position with back and arm supported
- 5) Middle of the CUFF at the level of the right atrium of the heart



Picture-06

5.4. Irregular Heartbeat Detector

 This symbol - indicates that certain pulse irregularities were detected during the measurement. In this case, the result may deviate from your normal blood pressure – repeat the measurement.

Consult your physician on frequent appearance of the Irregular Heartbeat Symbol.

This instrument is an oscillometric blood pressure monitor device that also analyzes pulse frequency during measurement. The instrument is clinically tested.


If pulse irregularities occur during measurement, the irregular heartbeat symbol is displayed after the measurement. If the symbol appears more frequently [e.g. several times per week on measurements performed daily] or if it suddenly appears more often than usual, we recommend the patient to seek medical advice. The instrument does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

5.5. Error Messages

The following message will appear on the display indicating:









SYMBOL	CAUSE	CORRECTION
No display appears	Weak battery or improper placement	Replace both batteries with new ones. Check the battery installation for proper placement of the battery polarities.
Er 1	Sensor abnormality	Check if the pump is working or not. If it is working, then the problem is sensor abnormality. Please contact customer service for advice.
Er 2	Monitor could not detect pulse wave or cannot calculate the blood pressure data	Check if the air releasing is too slow or not. If it is too slow, please check if there is any dust in the tube plug of the cuff and the cuff port in the device. If yes, please clean and start the measurement again. If no, please contact customer service for advice.
Er 3	Measurement result is abnormal (SYS \geq 35mmHg, DIA \geq 23mmHg)	Occurs once. Please repeat measurement. Occurs continuously, contact Medescan customer service
Er 4	Too loose cuff or air leakage (Cannot inflate to 30mmHg within 15s)	Readjust the cuff correctly and make sure the air plug is properly inserted in the unit
Er 5	The air tube is crimped	Correct it and take the measurement again
Er 6	The sensor is sensing great fluctuation in the pressure	Please keep quiet and don't move
Er 7	The pressure that the sensor sensing is over the limit	Please contact Medescan Customer service
Er 8	The calibration is incorrect or the device has not been calibrated	Please contact Medescan Customer service








Troubleshooting

Problem	Check	Cause and solution
No power	Check the battery power	Replace the batteries
	Check the polarity position	Install the batteries in the correct position and polarity
Not inflating	Check the cuff is plugged correctly	Insert the cuff into the air socket
	Check for tears or breaks of air plug	Change to a new cuff
Err and Not working	Possibly moved the arm during inflation	Please stay still
	Possible talking during measurement	Please remain silent
Cuff leaking	Check if cuff is loose on arm	Wrap cuff tightly
	Check if cuff is broken / ripped	Change to new cuff
 Please contact Medescan Customer Service team on 1300 736 330 for any queries or unresolved issues.		

SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the Medescan Smart Blood Pressure Monitor, or on its accessories. Some of the symbols represent standards and compliances associated with the Medescan Smart Blood Pressure Monitor and its use.

	Authorized Representative in the European Community
	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Date of manufacture.
	Manufacturer
SN	Specifies serial number
	Type BF applied part
	Direct current
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
	Follow instructions for use

	Face up
	Fragile
	Avoid water
	Avoid direct sunlight
	Class II equipment
	Handle with care
	Temperature range
No Sterile requirements	
Not category AP / APG equipment	
Mode of operation: continuous	

5.6. Memory

Each unit stores 120 sets measurements for 2 users, totally 240 memory sets (User A and B) .

Viewing the stored values

With the unit off, press the Memory button. The display first shows "A", then shows an average of all measurements stored in the unit. Please note: Measurements for each user are averaged and stored separately. Be certain that you are viewing the measurements for the correct user. Pressing the Memory button again displays the previous value. To view a particular stored memory, press and hold the Memory button to scroll to that stored reading.

5.7. Discontinuing a Measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g the patient feels unwell), the Start/Stop button can be pressed at any time. The device then immediately lowers the cuff pressure automatically.

5.8. Using the AC Adapter

You may also operate this monitor using the AC adapter (output 5V DC1A with Type-C connector).

Use only the approved AC adapter to avoid damaging the unit.

- a) Ensure that the AC adapter and cable are not damaged.
- b) Plug the adapter cable into the AC adapter port on the right side of the blood pressure monitor.
- c) Plug the adapter into your electrical outlet. When the AC adapter is connected, no battery current is consumed.

Note: No power is taken from the batteries while the AC adapter is connected to the monitor. If electrical power is interrupted, (e.g., by accidental removal of the AC adapter from the outlet) the monitor must be reset by removing the plug from the socket and reinserting the AC adapter connection.

6. Care and Maintenance

Wash hands after each time measurement.

If one device is used by different patients, wash hands before and after each use.

- a) Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.
- b) The cuff contains a sensitive air-tight bubble. Handle this cuff carefully and avoid all types of stress through twisting or buckling.
- c) Clean the device with a soft, dry cloth. Do not use gas, thinners or similar solvents. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff with bladder must not be washed in a dishwasher, clothes washer, or submerged in water.
- d) Handle the tube carefully. Do not pull on it. Do not allow the tubing to kink and keep it away from sharp edges.
- e) Do not drop the monitor or damage it in any way. Avoid strong vibrations.
- f) Never open the monitor! This voids the manufacturer's warranty.
- g) Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

6.1. Accuracy test

Sensitive measuring devices may need to be checked for accuracy from time to time. Please contact Medescan customer service if you have doubt about the measurements obtained.

7. Warranty/Service

Your blood pressure monitor is guaranteed for 1 year against manufacturers' defects from date of purchase. The warranty does not apply to damage caused by improper handling, accidents, professional use, not following the operating instructions or alterations made to the instrument by third parties. Warranty only applies to the main device and its cuff. All other accessories are not covered by warranty. There are no user serviceable parts inside. Batteries or damage from old batteries is not covered by the warranty.

8. Certifications

Device standard:

This device is manufactured to meet the European blood pressure monitors: EN1060-3 / IEC 80601-2-30 / ISO81060-1 / IEC60601-1-11 / IEC60601-1

Electromagnetic compatibility:

Device fulfills the stipulations of the International standard IEC60601-1-2

TGA ARTG listing 228211

9. Technical Specifications

Model: BPS01

Weight: 256g (Batteries and AC adapter are optional and may not be included)

Display: 62.5*63.5mm 【2.46"x2.5"】 LED Digital Display

Size: 118 (W) x 110 (L) x 52 (H) mm

Accessories: 1xMain Device, 1xCuff, 1xUsers manual

Operating Conditions: Temperature: 5°C to 40°C; Humidity : 15% to 93% RH;

Storage And Shipping Conditions: Temperature: -25°C to +70°C;

Humidity: ≤ 93% RH;

Atmospheric pressure range: 70kPa-106kPa

Measuring method: Oscillometric

Pressure sensor: Resistive

Measuring range: DIA: 40-130mmHg; SYS: 60-230mmHg

Pulse: 40 to 170 per minute

Cuff pressure display range: <300mmHg

Memory: Automatically stores the last 120 measurements for 2 users (total 240)

Measuring resolution: 1 mmHg

Accuracy: Pressure within ± 3 mmHg / pulse ± 5 % of the reading

Power source:

a) 3*AA batteries, 1.5 V

b) AC adapter INPUT: 100-240VAC 50/60HZ

OUTPUT: 5V DC 1A

Accessories: Wide range rigid cuff 8.7" – 15.7" (22 - 40 cm)

Automatically power off : 60 seconds

Users: Adult

Technical alterations reserved!

10. EMC Declaration

- 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.