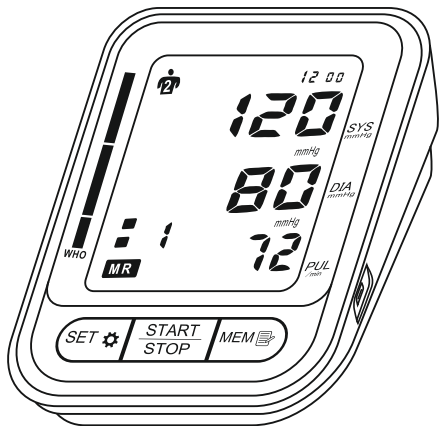


Blood Pressure Monitor NOVACHECK BP-12 BACKLIGHT



INSTRUCTION BOOKLET
&
WARRANTY CARD

IMPORTANT SAFETY PRECAUTIONS

READ THIS BEFORE USE

1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or damaged.
4. Do **NOT** use the equipment where aerosol sprays are being used, or where oxygen is being administered.
5. Do **NOT** use under any circumstances on newborns.
6. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured are for reference only. Always consult your doctor to have the results interpreted.
7. Keep the equipment and its flexible cord away from hot surfaces.
8. Do **NOT** apply the cuff to areas other than the place directed.
9. Do not remove plastic wrapping membrane to ensure the waterproof function.
10. Proper maintenance and periodically calibration are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact local customer service for help.

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1. BEFORE YOU BEGIN

1.1. INTENDED USE

The Blood Pressure Monitor is a system designed to measure people's systolic, diastolic blood pressure and pulse rate at home and in clinical settings by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm.

This system is intended for individuals age 18 or above.

Do not use it for diagnosis of hypertension or testing on newborns, babies, young children or persons who cannot express their consent.

1.2. TEST PRINCIPLE

Blood pressure is measured non-invasively at the arm based on oscillometric method.

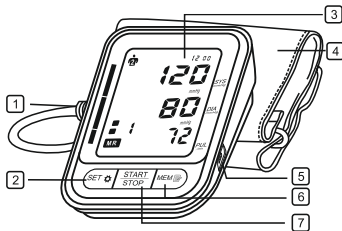
If you have been diagnosed with a severe arrhythmia or irregular heartbeat, atrial or ventricular premature beats or atrial fibrillation, measurements made with this instrument should only be evaluated after consultation with the doctor or your healthcare professionals.

Electromagnetic interference

The device contains sensitive electronic components. Avoid strong electromagnetic fields in the direct vicinity of the device (e.g. mobile phones, microwave ovens. Electrical interference can lead to temporary impairment of the measuring accuracy).

1.3. MONITOR OVERVIEW

a. Device



1. CUFF Connector
2. SET button
3. LCD display
4. CUFF

5. USB socket
6. MEM BUTTON
7. START/STOP button

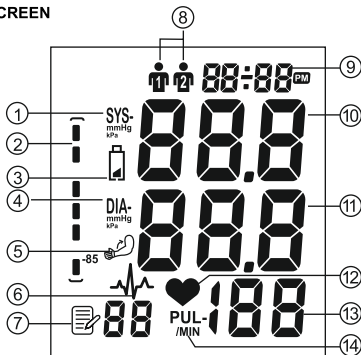
b. Cuff:

We offer a cuff measuring size: 22~42 cm suitable for most of arm circumferences



Do not use accessories or equipment which are not certified by manufacturer, they might increase emissions or decrease immunity of this system.

1.4. DISPLAY SCREEN



1. Systolic Pressure icon and unit Date
2. WHO classification bar
3. Low battery icon
4. Diastolic Pressure icon and unit
5. Arm moving icon Blue tooth icon
6. Irregular heartbeat detector
7. Memory icon and index

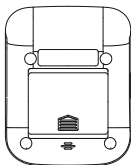
8. User
9. Date/Time
10. Systolic Pressure
11. Diastolic Pressure
12. Heartbeat icon
13. Heartbeat rate
14. Heartbeat rate unit

2. SETTING THE MONITOR


Before using your monitor for the first time, check and update these settings. Make sure you complete the steps below and save the desired settings.

2.1. INSERT BATTERIES

After you have unpacked your device, first insert the attached batteries (4 x size AA 1.5V) with the indicated polarity. The battery compartment is located at the side of the device (see illustration).



Note:

- After the warning  appears, device is blocked till the batteries have been replaced.
- Please use 4 pcs "AA" Long-Life Alkaline 1.5V Batteries.
- If the blood-pressure monitor is left unused for long periods, please remove the batteries.

2.2. ENTER THE SETTING MODE

Press SET button for 3 sec then the "2021" flashes on LCD. (The meter comes into Setting mode if supplying power first time)

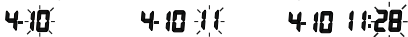


2.2.1. SETTING THE DATE AND TIME

- When the year flashes, press MEM button until the correct year appears.
Press SET button to confirm and change to Month setting.
- When the month flashes, press MEM button until the correct month appears.
Press SET button to confirm and change to date setting.



Set the day, hour and minute in the same way as described above.



NOTE

If the meter is idle for 1.5 minutes during the setting mode, it will switch off automatically.

2.2.2. User selection

- User 1 is the default user and user 1 flashes. Press M-button for selecting the user
Press SET button to confirm.



- The user can be switch when the meter stands by press the SET button shortly.

2.2.2. Unit selection

- Press M-button to choose the unit
- Press SET button to confirm

mmHg
↑↓
kPa

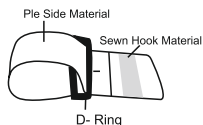
3. TESTING YOUR BLOOD PRESSURE

3.1. BEFORE MEASUREMENT

- Avoid caffeine, tea, alcohol and tobacco for at least 30 minutes before measurement.
- Wait 30 minutes after exercising or bathing before measurement.
- Sit or lie down for at least 10 minutes before measurement.
- Do not measure when feeling anxious or tense.
- Take a 5-10 minutes break between measurements. This break can be longer if necessary, depending on your physical condition
- Keep the records for your doctor as reference.
- Blood pressure naturally varies between each arm. Always measure your blood pressure on the same arm.

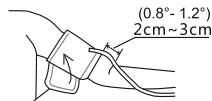
3.1.1. FITTING THE CUFF PROPERLY

- Plug the cuff connector to the cuff socket on the device left side.
- Assemble the cuff as shown below. The smooth surface should be inside of the cuff loop and the metal D-ring should not touch your skin.

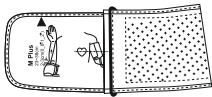


- Stretch your left (right) arm in front of you with your palm facing up. Slide and place the cuff onto your arm to let the air tube and artery mark region toward the lower arm.

Wrap and tighten the cuff above your elbow. The artery mark on the edge of the cuff should be approx. 0.8" to 1.2" (2 cm to 3 cm) above your elbow. Align the tube over the main arteries on the inside.



- d. Leave a little free space between the arm and the cuff: you should be able to fit two fingers between them.
Remove all clothing covering or constricting the measurement arm.
- e. Press the hook material firmly against the pile material. The top and bottom edges of the cuff should be tightened evenly around your upper arm.



3.1.2. PROPER MEASUREMENT POSITION

- a. Sit down for at least 10 minutes before measuring.
- b. Place your elbow on a flat surface. Relax your hand with the palm facing up.
- c. Make sure the cuff is about the same height as the location of your heart.
- d. Press the START/STOP button to switch on the monitor.
- e. Remain still and do not talk or move during the measurement.



WARNING:

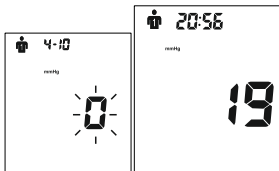
- If the cuff is relatively lower (higher) than the heart, the obtained blood pressure value could be higher (lower) than the actual value. A 15 cm difference in height may result in an error around 10 mmHg.

3.2. TAKING MEASUREMENTS

3.2.1. TAKING A SINGLE MEASUREMENT

Always apply the pressure cuff before turning on the monitor.

- Press START button, pump begins to inflate the cuff. The rising pressure in the cuff is shown on the display.



- Pressure in cuff increases to working pressure. Then pump stops and pressure falls.


Note: In case the inflation pressure is not sufficient to determine measurement result, the monitor automatically re-inflates to a higher level.

- The heart symbol "♥" starts to flash every heart beat once pulse is detected.



- After the measurement, systolic pressure, diastolic pressure, pulse rate and color bars classified from ESH (European Society of Hypertension) standards shows on the display.



- e. If irregular heartbeat was detected during the measurement, LCD displays the “” icon to remind users of heartbeat irregularity. Please consult your doctor if it appears often.



4. MONITOR MEMORY

4.1. AVERAGE OF ALL STORED MEMORIES

Press MEM button, LCD shows a set of values averaged from all the stored memories, accompanied by an icon “AV”.



4.2. MEMORY RECALL

The device stores 90 most recent blood pressure test results along with respective dates and times in the monitor memory.

Reviewing Test Results

- a. Press MEM button again after you see the average of all stored memories, the single memory reading appears.



- b. Per the setting, the first reading you see is the last blood pressure result. Presses MEM button again, the next measurement e.g. M90, as well as the previous 90 measurements (M88 M87... M1) can be displayed one after the other.

4.3. DELETE ALL STORED MEMORIES

Hold down SET button for 9 times until “CL” flashes on LCD, press START button, all the stored memories inside is removed.



Before you delete all the readings stored in the memory, please make sure you will not need to use them any more at a later time.

5. MAINTENANCE

5.1. CARING FOR YOUR MONITOR

To avoid the monitor attracting dirt, dust or other contaminants, wash and dry your hands thoroughly before use.

Cleaning

- To clean the monitor exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT flush with water.
- Do NOT use organic solvents to clean the monitor.
- Do NOT wash the pressure cuff.
- Do NOT iron the pressure cuff.

Monitor Storage

- Storage condition: -20°C to 55°C (-4°F to 131°F), below 95% relative humidity.
- Always store or transport the monitor in its original storage case.
- Avoid dropping or heavy impact.
- Avoid direct sunlight and high humidity.

6. DETAILED INFORMATION

6.1. Reference Values

Clinical studies show that adult diabetes is often accompanied by elevated blood pressure. People with diabetes can reduce their heart risk by managing their blood pressure along with diabetes treatment*1.

Monitoring your routine blood pressure trend helps you to know your body condition. Human blood pressure naturally increases after reaching middle age.

This symptom is a result of continuous ageing of the blood vessels. Further causes include obesity, lack of exercise and cholesterol (LDL) adhering to the blood vessels, diabetes. Rising blood pressure accelerates hardening of the arteries, and the body becomes more susceptible to apoplexy and coronary infarction.

Definitions and Classification of blood pressure levels according to 2007 ESH-ESC Practice Guidelines for the Management of Arterial Hypertension: Data in mmHg

| Category | Systolic (mmHg) | | Diastolic (mmHg) |
|--------------------------------|-----------------|--------|------------------|
| Optimal | < 120 | and | < 80 |
| Normal*3 | 120–129 | and/or | 80–84 |
| High normal | 130–139 | and/or | 85–89 |
| Grade 1 hypertension | 140 – 159 | and/or | 90 – 90 |
| Grade 2 hypertension | 160–179 | and/or | 100–109 |
| Grade 3 hypertension | ≥ 180 | and/or | ≥ 110 |
| Isolated systolic hypertension | ≥ 140 | and | < 90 |

Isolated systolic hypertension should be graded (1, 2, 3) according to systolic blood pressure values in the ranges indicated, provided that diastolic values are < 90mmHg.

Source: The European Society of Hypertension and European Society of Cardiology Task Force Members. 2007 ESH-ESC Practice Guidelines for the Management of Arterial Hypertension. J Hyper tens 2007; 25: 1751-1762.

7. SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to repair by yourself and never try to disassemble the monitor under any circumstances.

7.1. Error Messages

Airway leakage

1. pressure > 300mmHg, or
2. inflation >53 second, or
3. re-pumping>20 second, or
4. inflation >11 second but pressure < 15mmHg

Wild readings


1. SYS-DIA < 12mmHg, or
2. SYS-DIA > 154mmHg

Artifact

Improper movement detected during measurement.

No pulse detected

1. pressure < 13 mmHg, but no signal can be detected, or
2. pressure < 41 mmHg, signal not sufficient for SYS, DIA, and/or MAP calculation

| MESSAGE | CAUSE | WHAT TO DO |
|---|--|---|
| E-1 | Blood pressure measurement error | Refit cuff tightly and correctly. Relax and repeat the measurement. If error still remains, contact customer service for help. |
| E-2 | External disturbance signal is too big | Please make sure the monitor should be far away from the strong interference devices during measuring, such as mobile, motor. And please do not talk and walk during measuring. If error still remains, contact customer service for help. |
| E-3 | The pressure too high or air leakage too big | Refit cuff tightly and correctly. If error still remains, contact customer service for help. |
| E-5 | Abnormal reading. | Retry and if error still remains, contact customer service for help. |
|  | Low battery | Please connect the charger. If error still remains, contact customer service for help. |

7.2. Troubleshooting

1. If no display appears after pressing START button:

| POSSIBLE CAUSE | WHAT TO DO |
|--|---|
| Batteries exhausted. | Replace the batteries. |
| Batteries incorrectly installed or absent. | Check that the batteries are correctly installed. |

2. If the heart rate is higher/lower than user's average:

| POSSIBLE CAUSE | WHAT TO DO |
|---------------------------------------|-------------------------------------|
| Movement during measurement | Repeat measurement |
| Measurement taken just after exercise | Rest at least 30 minutes beforehand |








3. If the result is higher/lower than user's average measurement:

| POSSIBLE CAUSE | WHAT TO DO |
|--|--|
| May not be in correct position while measuring. | Adjust to the correct position to measure. |
| Blood pressure naturally varies from time to time. | Keep in mind for next measurement. |

4. If the cuff inflates again while measuring:

| POSSIBLE CAUSE | WHAT TO DO |
|--|------------------------|
| Cuff is not fastened. | Fasten the cuff again. |
| If user's blood pressure is higher than the pressure the device has inflated, the device will automatically increase the pressure and start to inflate again. Stay relaxed and wait for the measurement. | |

8. SYMBOL INFORMATION

| Symbol | Referent |
|---|---|
|  | Consult instructions for use |
|  | Manufacturer |
|  | Serial number |
|  | Caution, consult accompanying documents |
|  | Do not use if package is damaged |
|  | Type BF |
|  | Dispose of in accordance with the requirements of your country. |

9. SPECIFICATIONS

| PARAMETER | SPECIFICATION | |
|---|--|------------------------------|
| Display | LCD digital display | |
| Measuring principle | Oscillometric method | |
| Measuring localization | Upper arm | |
| Measurement range | Pressure | 0~299mmHg (0~39.9kPa) |
| | Pulse | 40~199 pulses/min |
| Accuracy | Pressure | ±3mmHg (±0.4kPa) |
| | Pulse | ±5% of reading |
| LCD indication | Pressure | 3 digits display of mmHg |
| | Pulse | 3 digits display |
| | Symbol | Memory/Heartbeat/Low battery |
| Memory function | 2X90 sets memory of measurement values | |
| Power source | 4pcs AA alkaline battery or 5.0V USB power supply | |
| Automatic power off | In 1.5 minutes | |
| Main unit weight | Approx.240g (batteries not included) | |
| Main unit size | L138mm x W98mm x H41mm | |
| Main unit lifetime | 10,000 times under normal use | |
| Battery life | Could be used for 300 times for normal condition | |
| Accessories | Cuff, instruction manual | |
| Operating environment | Temperature | 5~40℃ |
| | Humidity | 15%~85%RH |
| | Air pressure | 86kPa~106kPa |
| Storage environment/transportation environment | Temperature -20℃~55℃ ,Humidity :10% ~85% Air pressure: 86kPa~106kPa avoid crash, sun burn or rain during transportation. | |
| Note: the product cannot be operated at an altitude of 2000m. | | |

This device has been tested to meet the electrical and safety requirements of:
IEC/EN 60601-1,

Warranty conditions

NOVACHECK BP-12 BACKLIGHT Blood Pressure Monitor is made under strict quality control & utmost care is taken to ensure long, trouble free service.

- This unit is warranted for a period of 24 month from the date of purchase.
- This Card must be dully filled in stamped & signed by the dealer.
- This card & relevant invoice must be preserved and presented to the dealer when the unit is sent for repairs.
- We undertake to repair or replace at our discretion any part which was originally defective, provided the unit was not tampered with or mishandled.
- It shall be customer's responsibility to deliver the unit to the authorized service station; freight prepaid & collect the unit from service station after repairs.
- The warranty is only against manufacturing defects & shall not be applicable in case of damage due to accident, acts of nature, loss of components, intentional damage, and improper installation or if it was opened or service by authorized persons.
- The warranty is void, if the set is not operated according to instructions given in the "Instruction manual booklet", if any repair work is carried out by persons other than authorized company personnel, defects are caused by improper or reckless use, which shall be determined by company personnel.
- The warranty shall not extend towards the payment of compensation to anyone or entitle the customers to replacement of the products as a whole.
- The warranty expressly excludes every condition or warranty whether statutory or otherwise, or any claim for consequential loss or damage.
- Warranty does not cover accessories external to the equipment, defects caused due to causes beyond control like lighting, abnormal voltage, acts of God or while in transit to service centre or to purchasers/premises.
- In the event of a defect being noticed in the equipment during the warranty period, the company or its authorized customer care centre/ service dealer reserves the right to retain any parts / or components replace at its discretion.
- **IMPORTANT:** Warranty is not applicable for cuff and accessories components. Cuff and accessories should be replaced from time to time as needed.



Caring for life

**NOVACHECK BP-12
BACKLIGHT**

WARRANTY CARD

Subject to Mumbai Jurisdiction only

No.

Model

Serial No.

Invoice No. Date:

**Stamp and Signature
of Dealer**

**Name and Address
of Dealer**



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Mfg. By

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Valsad, Gujarat-396185



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ARTWORK SHEET

Format No. FOR/4.2/08

Rev No. 00

Rev Date 00

| | |
|-------------|---|
| Size | 110 (W) X 140 (H) mm |
| Product | S0BB21-3 Blood Pressure Meter Fully Auto Arm Type BP-12 Backlight |
| Location | Product Manual |
| Artwork No. | AR01471 |

140 MM

Blood Pressure Monitor NOVACHECK BP-12 BACKLIGHT



INSTRUCTION BOOKLET & WARRANTY CARD

110 MM

Rupali

lexly

Aravind

Prepared by: IC MKT/OFFICER MKT

Reviewed By: IC QA/Executive QA

Approved By: Head Operation/MD

REVISION TABLE:

| Rev No. | Rev Date | Revision Details |
|---------|------------|---|
| 00 | 09-10-2023 | New Design |
| 01 | 15-11-2023 | Removed EC REP Details, Removed Equipment Word From Type BF |