POOYANDEGAN RAH SAADAT Co.

Digital Blood Pressure Monitor

bp4

User Manual

CE 2195

D01027-V8

POOYANDEGAN RAH SAADAT CO

No. 4, 1st East St., Ettehad Blvd., Damavand St., TEHRAN, IRAN.

Post box: 1658916599
Tel: +98 21 77960719, +98 21 77962181
Fax: +98 21 77964239

Customer Services:
Tel: +98 21 73098000, +98 21 77798910
Cell: +98 912 1977157
Fax: +98 21 77960761

Legal responsible:
Trionara Technologies AB
Polygonvägen 21. 18766. Täby. Sweden
E-Mail: info@trionara.com
Tel: +46-76-4114418

Web site: www.SAADATco.com
Email: info@SAADATco.com

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Purpose of the user manual

This user manual is intended for both bp4 digital blood pressure monitor models, one equipped with AA batteries and the other equipped with lithium rechargeable battery.
This user manual provides the instructions necessary for proper and safe operation of the device for the patient and the operator. If you have any question about the device, please contact our customer service.

Explanations of the used expressions in this manual

Warning

A WARNING symbol advises against certain actions or situations that could result in personal injury or equipment damage and provides considerations for better device function.

Note

A NOTE message provides useful facts and topics for more information and considerations about device performance.

Version Information

This manual has a version number. The version number changes whenever the manual is updated due to technical specification changes. The version information of this manual is as follows.

Release date	Version number
Feb. 2024	D01027-V8

- Read this manual carefully before you use the device.
- All illustrations in this manual are provided as examples only. They may not necessarily reflect your device setup or data displayed on your device.
- Pooyandegan Rah Saadat Co. reserves the right to make changes to this manual and improvements to the product at any time without notice obligation.
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Symbols

Symbol	Explanation
	The device is IEC60601-1 Type BF equipment.
	Consult user manual of the device and pay attention to the warnings and cautions.
	The equipment shall be disposed of in an environmentally- friendly manner.
	Direct current
	CE mark
SN	Serial number
 yyyy	Date of Manufacture
	Manufacturer information
EC REP	Authorized representative in the European Community

General Warnings

Warning

- Do not use in combination with a hyperbaric oxygen therapy device, or in an environment where combustible gas may be generated.
- Do not use in combination with magnetic resonance imaging (MRI) equipment.
- Do not use with a defibrillator.
- Do not install the unit in the following locations:
    - Locations subject to vibration or shock such as ambulances and emergency helicopters.
    - A location where there is gas, flame or heater.
    - A location where there is water or steam.
    - A location where chemicals are stored.
    - Locations with dust, salt or sulfur.
    - Locations directly exposed to sunlight for extended period. In particular, do not leave in direct sunlight or near a source of ultraviolet (UV) for extended periods, as UV will cause deterioration of the LCD.
- Do not use at extremely high temperature, high humidity, or high altitude. Use only within the required ambient conditions.
- Do not use this unit in a vehicle.
- Do not use the unit near large equipment that uses a switching relay for power ON/OFF.
- Do not use the cuff or AC adapter to lift the unit; it can also cause the unit to malfunction.
- Do not place heavy objects on the AC adapter cable, or allow the unit to sit on the cord.
- Do not use in a location where the unit may easily fall. In the event that the unit falls, verify that it operates normally and safely.
- Do not use an AC adapter or battery pack not specified for this unit.
- Do not use the battery pack of other devices for this unit.
- Do not disassemble the battery pack.
- Do not use a broken power cord or AC adapter.
- Do not plug in or unplug the AC adapter with wet hands.
- Do not use any cuff other than the models exclusive for this unit.
- Do not modify or replace connectors of the NIBP[1] air hose except with company-approved connectors. Use only recommended manufacturer Blood Pressure Cuffs and Hose. The use of other cuffs and hoses has a negative effect on the accuracy of the measurement.
- Unplug the AC adaptor from the electric outlet if this unit is unused for an extended period.
- Unplug the AC adaptor from the electric outlet when installing, removing or cleaning the unit.
- Do not share an electric outlet with another unit or electric appliance.
- After cleaning this unit, dry it well before plugging the AC adapter in the electric outlet.
- If this unit fails to perform as indicated, discontinue use, turn off the unit, unplug the AC adapter from the electric outlet, and contact company's repair department.
- Parts and accessories not approved for use with the device may damage the unit
- Do not connect the air tube or the cuff to other equipment that is connected to an intracorporeal organ. Air embolisms may result.

[1] Non-invasive blood pressure

- Never connect intra-arterial or intra-venous lines, or any other incompatible connectors to the NIBP hose. This can cause serious injury or death.
- Do not use the NIBP cuff on a limb with an intravenous infusion, arterial catheter, transfusion in place. When the infusion is slowed or blocked during cuff inflation, tissue damage around the catheter could happen.
- Do not apply cuff on the arm on the side of a mastectomy or lymph node clearance.
- Closing the cuff on the wound may cause further injury.
- Do not wrap the cuff on an arm with a SpO2 sensor or other monitoring equipment attached. The pulse may disappear when the cuff pressurizes, causing a temporary loss of monitoring function.
- Do not measure NIBP on patients with inflammation or on the limb where skin damage has occurred or is expected.
- Continuous cuff pressure due to connection tubing kinking may cause blood flow interference and result in harmful injury to the patient.
- Self-diagnosis of measured results or treatment is dangerous. Please follow the instruction of the doctor or healthcare provider.
- Do not adjust medication based on measurement results from this blood pressure monitor. Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat High or low Blood Pressure.
- Use clinical judgment to determine whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
- NIBP reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition. If you doubt the NIBP measurements, determine the patient's vital signs by alternative means, and then verify that the monitor is working correctly.
- The hospital's clinician staff must decide NIBP diagnostic significance.
- Before use, visually inspect the unit to make sure there are no deformations due to falling, and that there is no dirt or moisture on the unit.
- When the unit has not been used for an extended period of time, always verify that it operates normally and safely before use.
- In order to prevent environmental pollution, disposal of disposable accessories and some parts of the system and its accessories (such as batteries, defective and out-of-service accessories) should be done according to the relevant regulations. To dispose of old batteries, contact your local municipality.
- Do not disassemble or modify this unit.
- If you have any problems with this device, such as setting up, malfunction, maintaining or using, first refer to the Troubleshooting chapter and if the problem is not solved, contact with customer service for assistance.

Note

- Before using the device, verify that none of the following apply to the patient:
  - Poor peripheral circulation, noticeably low blood pressure, or low body temperature (there will be low blood flow to the measurement position)
  - The patient uses an artificial heart and lung (there will be no pulse)
  - The patient has a mastectomy
  - The patient has an aneurysm

- The patient has frequent arrhythmia

Body motions such as convulsions, arterial pulsations, or trembling (cardiac massage in progress, minute continuous vibrations, rheumatism, etc.)

Note

- Only use this device for its intended purpose as described in this user manual.
- When using the unit:
  - Do not inflate cuff without being wrapped over the arm.
  - Do not use a damaged cuff.
- Use this device under the appropriate environmental conditions as indicated in this user manual. If not, this could affect the performance, lifetime of the device and measurement.

Chapter 1: Introduction

General Description

bp4 is a digital monitor intended for non-invasive measurement of systolic and diastolic blood pressure and pulse rate in adults and children of age 3 years and older. The device uses the oscillometric method for measuring Non-Invasive Blood Pressure (NIBP). It is intended to be used by a medical professional in clinical environments.

Intended Purpose

Non-invasive measurement of blood pressure and pulse rate

Indications

The device is a digital pressure monitor intended for non-invasive measurement of systolic and diastolic blood pressures and pulse rate. The measurement is done by wrapping a cuff on the patient's arm.

Contraindications

Do not use this unit on neonates.

Target population

Adults and children of age 3 years and older with arm circumference ranging from 13 cm to 55 cm (from 5 inches to 22 inches).

Intended user

A medical professional should use this device.

Principle of operation

The device uses the oscillometric method for measuring Non-Invasive Blood Pressure (NIBP). NIBP measurement is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall. The oscillometric device uses a blood pressure cuff to sense these oscillations that appear as tiny pulsations in cuff pressure. The oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (MAP[1]) and then diminish. The oscillometric method measures the MAP and determines the systolic and diastolic pressures based on MAP pressure.

Performance characteristics

- Ability to measure in dialysis patients, pregnant women
- Can be used for two users
- Automatic saving of blood pressure measurements (99 records per user)
- Automatic detection of irregular heartbeat
- Simple User-Interface; 4-button operation & large display
- Working with batteries (4 x 1.5V "AA" batteries model or rechargeable lithium battery model) or AC adapter
- Ability to use cuffs in different sizes (13 to 55 cm)
- Cuff holder & handgrip for carrying

Undesired side effects

None.

[1] Mean Arterial Pressure

Intended environment

Physicians' offices, hospitals, clinics and other medical facilities

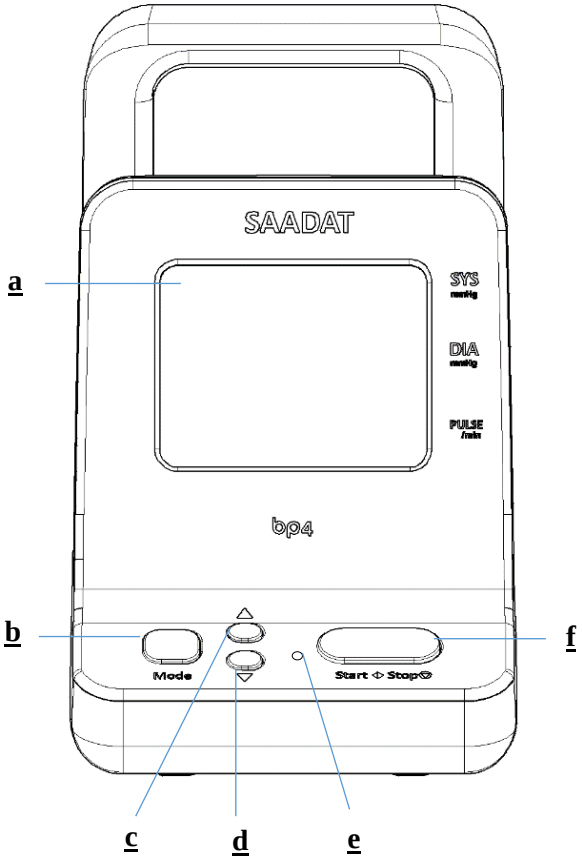
Components of the package

Device with rechargeable lithium battery	Device with AA battery
bp4 blood pressure monitor	
M5134 cuff	
Lithium battery	4 non-rechargeable AA batteries
AC adapter	AC adapter (Optional)

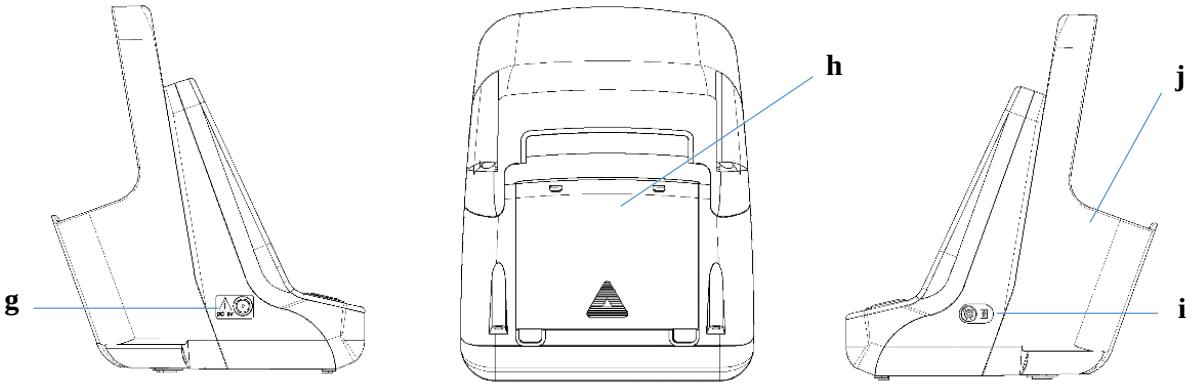
Know your Monitor

Front view

- **a)** Display
- **b)** Mode button
- **c)** Next/Increase button
- **d)** Previous / Decrease button
- **e)** Charging LED (only in devices equipped with rechargeable batteries)
- **f)** START / STOP button

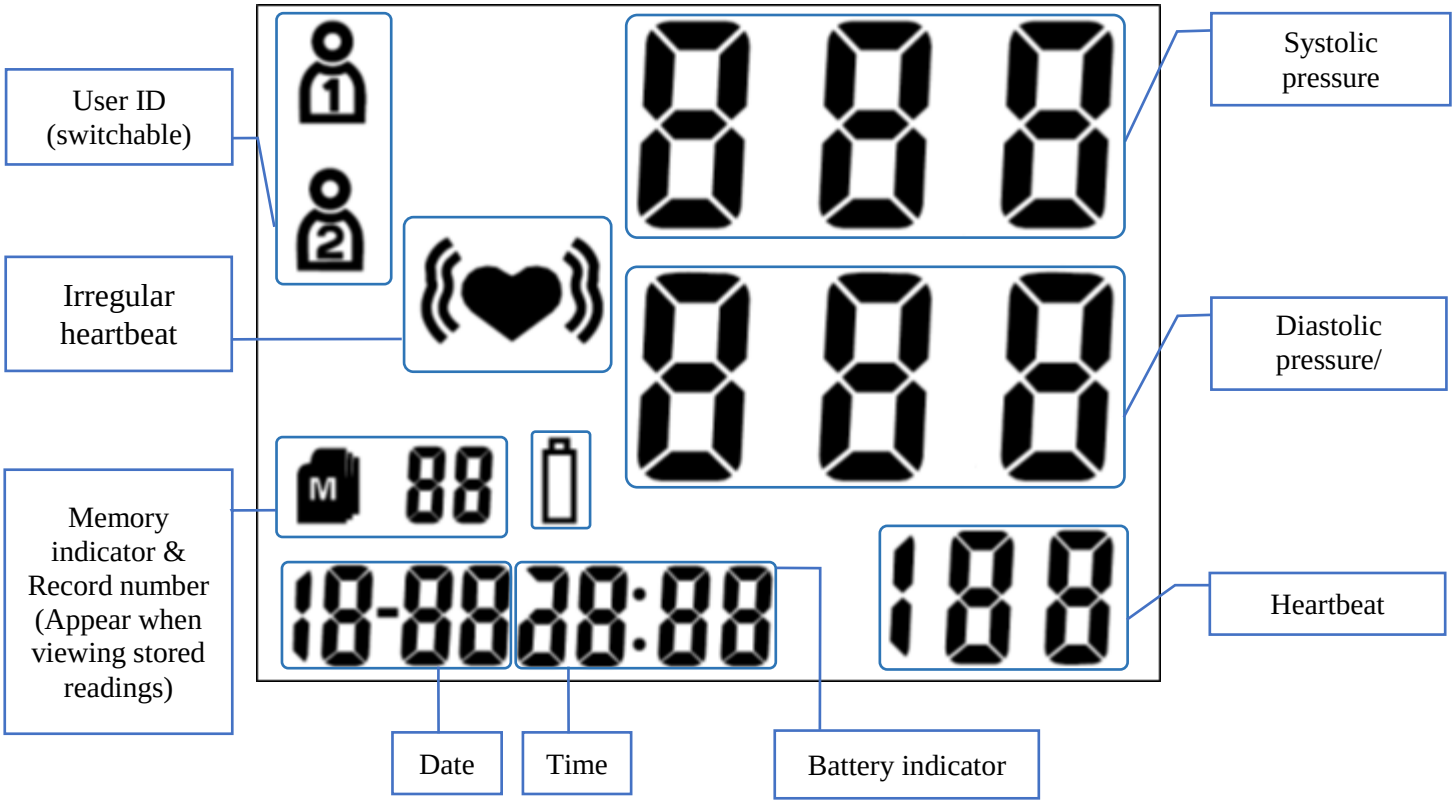


Bottom and side views of the monitor



- **g)** AC adapter jack (left side)
- **h)** Battery compartment (bottom)
- **i)** NIBP connector (right side)
- **j)** Cuff holder

Symbols of Display



Power Supply

Device with “AA” (LR6) batteries

Battery installation

1. Push down the hook of the battery cover and open it.
2. Insert four “AA” alkaline batteries as indicated in the battery compartment.
3. Close the battery cover.

Note

- To replace batteries, turn your device off and remove all batteries. Then replace with four new batteries.
- Replacing batteries will not delete previous readings.

Using the AC Adapter

1. Insert the AC adapter plug into the AC adapter jack on the device.
2. Plug the AC adapter in to an electrical outlet.

To unplug the AC adapter, unplug the AC adapter from the electrical outlet and then remove the AC adapter plug from the monitor.

Note

- Make sure not to place your monitor in a location where it is difficult to plug and unplug the AC adapter.
- We recommend keeping batteries in your monitor at all times, even if you choose to use the AC adapter. If only the AC adapter is used without keeping batteries in your monitor, you may need to reset the date and time each time you unplug and plug back the AC adapter. The readings will not be deleted.
- The symbol "▯" indicates that the battery charge is getting low and the batteries need to be replaced.
- When the symbol "▯" flashes, it means that the battery charge has reached a critical state and is running out. You need to change the batteries immediately. Do not measure in this state. If the battery charge is too low, the device will not be able to perform the measurement and turns off.

Battery life

- If the device has new "AA" alkaline batteries, you can perform more than 500 measurements.

Device with rechargeable lithium Batteries

Battery installation

1. Push down the hook of the battery cover and open it.
2. Connect the battery pack to the connector.
3. Place the battery in the compartment.
4. Close the battery cover.
5. Connect the main unit to the AC adapter to charge the new battery. The battery is not charged when you purchase the monitor. When you use the battery for the first time, charge it for more than 5 hours before use.

Warning

- Never use an unapproved battery. Contact service personnel in order to change the battery.

Charging time

- The battery can be completely charged in approximately five hours.
- While the battery is being charged, the charging LED turns red. When it is fully charged, the LED turns green.

Using the AC Adapter

1. Insert the AC adapter plug into the AC adapter jack on the right side of your monitor.
2. Plug the AC adapter in to an electrical outlet.

To unplug the AC adapter, unplug the AC adapter from the electrical outlet and then remove the AC adapter plug from the monitor.

Note

- When the AC adapter is connected, it charges the installed rechargeable battery.
- Make sure not to place your monitor in a location where it is difficult to plug and unplug the AC adapter.
- The symbol "" indicates that the battery charge is getting low and needs to be recharged.
- When the symbol "" flashes, it means that the battery charge has reached a critical state and is running out. You need to charge the battery immediately. Do not measure in this state. If the battery charge is too low, the device will not be able to perform the measurement and turns off.

Lithium battery life

- If the device is fully charged, you can perform more than 1000 measurements with rechargeable lithium batteries.
- Approximate life of battery is two years. However, the battery life from each charging may be shortened depending on the state of using. If the interval between charging becomes short and the battery low icon appears frequently, contact service personnel to replace it.

Chapter 2: Device settings

Keys’ function

Start/Stop button

If the device is off, pressing this key will turn on the device. When the device is on and when the measurement is not taken, the device switches off if the key is held down for 3 seconds.
By pressing and releasing this key in less than three seconds, the measurement process starts or stops. This key is also used to exit the setting modes (User, Date and Time) and review the memory (put the device in standby mode).

Note

- The device automatically shuts down if not used for 3 minutes.

Up and down buttons

These buttons are used to decrease or increase settable parameters and to move between records.

Mode button

Pressing this key activates the various features as follows:

- With the first press of the key, the selection of user 1 or user 2 is done. In this case, the user symbol on the screen starts blinking. By pressing the up or down key, user 1 or 2 is selected.
- Pressing the key again activates the mode of displaying the saved information (archive mode). The memory icon flashes and the last saved measurement of the selected user is displayed immediately. By pressing the up or down keys, other measurements are displayed with the date and time of measurement. If the measurement was performed incorrectly, the error code is displayed. The last measurement is always displayed at first.
- By pressing the key again, the year number setting mode is activated. The year number is displayed as a blink and changes by pressing the up or down keys.
- Pressing the key again activates the month number setting mode. The month number is displayed as a blink and changes by pressing the up or down keys.
- By pressing the key again, the day number setting mode is activated. The day number is displayed as a blink and changes by pressing the up or down keys.
- Pressing the key again activates the hour number setting mode. The hour number is displayed as a blink and changes by pressing the up or down keys.
- By pressing the key again, the minute number setting mode is activated. The minute number is displayed as a blink and changes by pressing the up or down keys.
- By pressing the key again, the above procedure is repeated.

Note

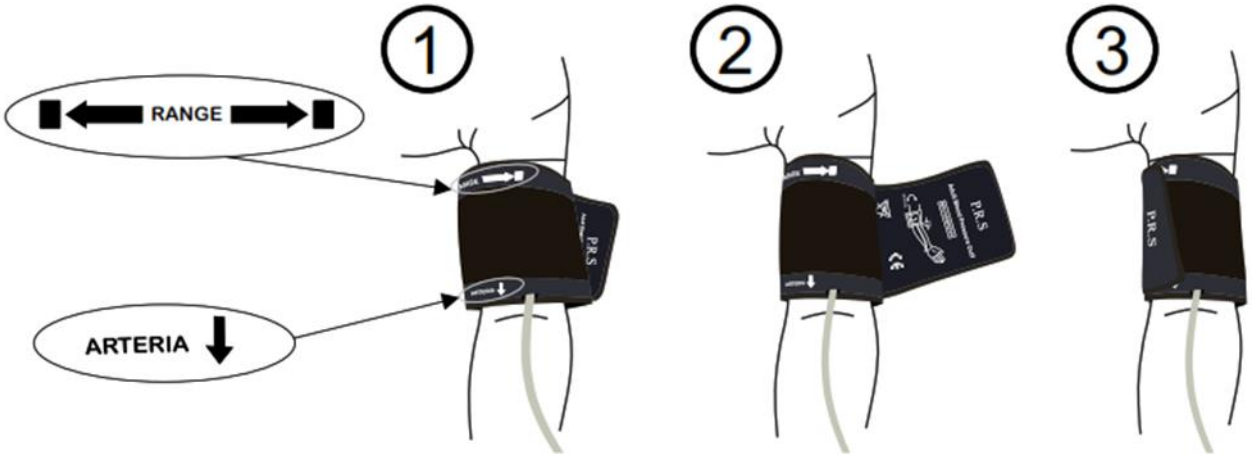
- The set numbers are for setting the time and date controller only and has no other use.
- At each step of the adjustment, pressing the **START / STOP** key saves the changes and puts the device in standby mode.
- The saved records are shown and sorted by their date. (The last record is on top of the list with number 1).
- The adjusted user number is saved and will not change with each record or power off.
- In case of unsuccessful records, the corresponding error code will be displayed and saved in archive. (For more information refer to **Chapter 5: Error Messages & Troubleshooting**).
- If the device is being used for the first time, adjust date and time after installing the battery.

Chapter 3: Blood Pressure Measurement

Attaching the cuff

1. Connect the cuff tube to the NIBP connector on the unit.
2. Make sure the cuff tube is not bent.
3. Wrap the cuff so that the 

sign is directly over the brachial artery.
    - The brachial artery is on the inner side of the patient's upper arm.



4. Make sure that the tail of the cuff is within the 

. If outside the range, there will be greater error in the blood pressure value. Use an appropriate cuff.
    - Attach the cuff so that the bottom edge is 1 to 2 cm from the inner side of the elbow joint.
    - The cuff should be wrapped to a tightness that roughly allows two fingers to be inserted under the cuff.
5. During measurement, keep the brachial artery on which the cuff is wrapped at the same height as the heart.

Note

- The device can be either used on the right or left arm. Wrap the cuff on a bare arm or over thin clothing. Thick clothing or a rolled-up sleeve will cause inaccurate blood pressure measurements.
- Approximate life of cuff is 5 years. However, if the cuff develops a problem such as a hole or leak, replace the cuff.

Tips for proper measurement

Note

- NIBP measurement should be performed on the upper arm.
- During NIBP, stop excessive body movement by the patient and minimize trembling.
- The cuff provided with the device is suitable for an arm circumference range between 13 and 55 cm. If the arm circumference is much smaller/larger than the acceptable range, the measured value will be lower/higher than the actual pressure value.

- The measurement should be done on the upper arm.
- The patient must remain without motion and vibration.
- The cuff delivered in the package is suitable for an arm circumference in range of 25 to 35 cm. If the cuff is too large/small, the measured blood pressure will be less/more than the actual value.
- Before and during measurement, verify that none of the following apply to the patient:
    - The size of the cuff is unsuitable for the circumference of the person's limb.
    - The part where the cuff is wrapped is at a different height than the heart. (A difference of 10 cm (4 inches) in height may cause a variation in the blood pressure value of up to 7 or 8 mmHg.)
    - Body movement or conversing during measurement.
    - Cuff wrapped over thick clothing.
    - Pressure on the arm due to a rolled-up sleeve.
- Do not use the cuff if it is damaged or has holes.
- Only company-approved CUFF can be used with this device. The use of any other cuff may result in incorrect measurement.
- To measure correctly, it is recommended that the patient relax and not talk during measurement.
- To measure correctly, it is recommended that the patient rest quietly for 5 minutes before measurement
- Before using the unit, make sure that no accessories are missing and that the unit and accessories are not damaged. If an accessory is missing or there is damage, please contact your local representative.

Note

The measurement may be inaccurate or impossible in the following situations:

- Regular arterial pressure pulses are hard to detect.
- Excessive and continuous patient movement such as shivering or convulsions.
- Cardiac arrhythmias.
- Rapid blood pressure changes.
- Severe shock or hypothermia that reduces blood flow to the peripheries.
- On an edematous extremity.
- Obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery.
- For people who have low peripheral blood flow, significantly low blood pressure, or significantly low body temperature, measurement may not be possible (an error will occur) or the measurement result may not be reliable due to insufficient blood flow in the measurement location.
- Measurement reliability will decrease if the user moves or speaks during measurement, or the body position is not correct.
- Measurement reliability will decrease if the arm is compressed because a garment with thick sleeves is worn or the sleeves are rolled up.

Note

- The performance of NIBP module in dialysis patients was evaluated and the results showed a reliable measurement of the NIBP module in theses patient.
- The performance of NIBP module in pregnant women was evaluated and the results showed a reliable measurement of the NIBP module in theses patient.

Start measurement

1. Press the **START/STOP** button once, to switch on the device.
2. Attach the cuff to the patient's arm (see "Attaching the cuff") and make sure their posture is correct (see "Tips for proper measurement").
3. Press the **START/STOP** button to start the measurement. Inflation of the cuff starts automatically.
    - If changing the user is needed, press the **Mode** button, select the user with the **up and down** buttons and then start measurement.
    - During inflation and deflation, the unit determines the systolic pressure and diastolic pressure as well as heart rate.
    - The movement may result in inaccurate measurement results.
4. When the measurement is finished, the cuff deflates and the measurement results are shown on the display.
5. Press and hold the **START/STOP** button for 3 seconds to switch off the device.

Note

- During the measurement, the procedure will stop by pressing the **START/STOP** button at any time.
- The device can store 99 results for each user. However, only your current measurement will be visible on the device display. Other measurements are available in the archive mode.
- If the device detects irregular heartbeat, the  sign on the screen will turn on.

Chapter 4: Care and Cleaning

Cleaning and disinfecting should be performed in accordance with your facility's infection control practice.
Wipe with a cloth moistened with warm soapy water or mild detergent and for disinfection use alcohol 70%, isopropyl alcohol or N-propanol.
Do not wipe the Power connector or allow it to become wet. Use a moistened cotton bud to remove dust that has accumulated on the vent ports. The device requires no routine service other than cleaning, and visually checking the cuffs, tubing, etc.

Warning

- Do not sterilize by autoclave or gas sterilization (EOG, formaldehyde gas, high-concentration ozone, etc.). Refer to accessory instructions for sterilizing accessories.
- If using an antiseptic solution for cleaning, follow the instructions of the manufacturer.
- This device is not washable. Never immerse the device in water and do not rinse it under running water.
- Never use compressed air, scouring pads, abrasive cleaning agents or aggressive liquids such as petrol, acetone, gasoline, paint thinner or high concentration alcohol to clean the device.

Display screen care

In-between patients and as required use clean and soft cloth with screen cleaner or mild soapy water and with Isopropyl alcohol may be used for disinfection.

Warning

- Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing.
- Do not spray a liquid directly on the screen.

Accessory care: Cuff/cuff tube

Wipe clean on the surface of the cuff with a cloth moistened with alcohol 70% or isopropyl alcohol. Do not allow any liquids inside the cuff. If a liquid gets in the cuff, dry it.

Warranty

The device has 1 year warranty from the date of purchase.

Chapter 5: Error Messages & Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the equipment or accessories, check the table below before requesting for services. If the problem persists, contact your service personnel.

Error	Possible Cause	Solution
Err 6	**LOOSE CUFF** Cuff is not completely wrapped or no cuff attached.	Check cuff for proper fit on patient.
Err 7	**AIR LEAK** Air leak in cuff, tube or connector	Check that the cuff/hose connection is secure. Check cuff for leaks. DO NOT use a known leaky cuff.
Err 8	**AIR PRESSURE ERROR** Unstable pressure value (e.g., kinked hoses)	Make sure the hose is not kinked. Repeat the measurement. If this error repeatedly occurs during normal use, call after-sale service
Err 9	**SIGNAL WEAK** Very weak patient signal due to a loosely wrapped cuff or extremely weak pulse from patient.	Check the fitness of the cuff. Repeat measurement.
Err 10	**RANGE EXCEEDED** Measuring pressure is more than upper limit (255mmHg)	Repeat measurement. If the error is displayed again, use another method to measure the patient's blood pressure.
Err 11	**EXCESSIVE MOTION** Arm movement, noisy signal or irregular pulse (e.g. arrhythmia)	Limit patient activity; the arm must be still and/or relaxed.
Err 12	**OVER PRESSURE** Measured pressure exceeds safe software limit, 290 mmHg	Very rapid squeezing of the cuff can cause this error. Repeat the measurement. If this error repeatedly occurs during normal use, call after-sale service.
Err 14	**PNEUMATIC LEAK** Leakage during leak test	Check that the cuff/hose connection is secure. Check cuff for leaks. If this error repeatedly occurs during normal use, call after-sale service.
Err 15	**SYSTEM FAILURE** Error occurs in pump, A/D sampling, pressure transducer or software.	Measure again. If the problem persists, call after-sale service.
Err 19	**TIME OUT** Measurement time exceeds 3 minutes	An extremely long measurement can be due to a loose cuff, high blood pressure, or device re-pumps. Try measurement again. If error consistently reappears, call after-sale service.
Err 99	**LOW BATTERY** Low battery charge	The battery charge is low for the system to continue working, and you need to replace or charge the battery.
Err 49	**MODE ERROR** Inappropriate user	The neonate's blood pressure was measured by mistake. This device is not suitable for measuring the pressure of neonates.

Chapter 6: Technical Specifications

Item	Specification	
Model	bp4	
Display	Segment LCD	
Protection class	Class II (Optional AC adapter) Internal powered equipment (when operating with battery only)	
Operation Mode	Continuous Operation	
Degree of protection	Type BF (Applied part): Arm cuff	
Measurement Method	Oscillometric method	
Heart rate range	30 to 240 bpm	
Heart rate accuracy	±2%	
Cuff pressure range	0-290 mmHg	
Initial cuff pressure	160 mmHg	
Measurement range	SYS	30 ~ 255 mmHg
	DIA	15 ~ 220 mmHg
NIBP Accuracy	Maximum mean error within ±5 mmHg Maximum standard deviation within 8 mmHg	
Software overpressure protection	290 ± 3 mmHg	
Power	Standard AA Battery	4 x 1.5V “AA” (LR6) Alkaline Batteries or optional AC adapter (INPUT: 100 ~240 VAC, 50-60 Hz, OUTPUT: 5VDC, 1A)
	Lithium-Ion Battery	Rechargeable lithium-Ion 7.4V 2200mAh battery or optional AC adapter (INPUT: 100~240 VAC 50-60 Hz, OUTPUT: 12VDC ,2A)
Current consumption	Standard AA Battery	Idle ~ 50mA at 6v Measurement ~ 200mA at 6v
	Lithium-Ion Battery	Idle ~ 35mA at 7.4v Measurement ~ 150mA at 7.4v
Max measurement time	180 seconds	
Memory	99 records per user	
Physical specification	Width: 128 mm Length: 163 mm Height: 190 mm Weight: Approx. 600 g	
Operating Conditions	Temperature: 5°C to 40°C Humidity: 15% to 90% Atmospheric pressure: 50 to 106KPa	
Storage Conditions	Temperature: -25°C to 60°C Humidity: 10% to 90% Atmospheric pressure: 50 to 106KPa	
Safety, Performance & Regulatory Standards	IEC 60601-1, EN 60601-1-2, IEC 80601-2-30, ISO 81060-2, EN 1060-3, ISO 10993-5, ISO 10993-10	

Appendix 1: Accessories

PART Number	Accessory	
	Lithium battery model	AA battery model
P48028	NIBP Reusable Cuff– Adult – Single M5134- Tube Length: 50 cm – Limb Circumference: 25-35cm	
-	AC Adapter 12V	AC Adapter 5V (optional)
-	Lithium-Ion Battery	4 AA (LR6) alkaline batteries

Optional:

NIBP Accessory
NIBP Reusable Cuff– Pediatric – Single M5543- Tube Length: 50 cm – Limb Circumference: 13-21cm
NIBP Reusable Cuff– Adult – Single M5133- Tube Length: 50 cm – Limb Circumference: 18-26cm
NIBP Reusable Cuff– Adult – Single M5135- Tube Length: 50 cm – Limb Circumference: 35-44cm
NIBP Reusable Cuff– Adult – Single M5547- Tube Length: 50 cm – Limb Circumference: 44-55cm

Appendix 2: Materials used

Materials used for main device

Item	Material
Housing	ABS (acrylonitrile butadiene styrene)
Battery Cover	ABS (acrylonitrile butadiene styrene)
Front Panel	ABS (acrylonitrile butadiene styrene)
Tube	PVC (polyvinyl chloride)
Package	Cardboard

Materials used for accessories

Cuff

Item	Material
Outside cloth	Nylon / Polyester
Inner cloth	Polyester
Air bag	Flexible urethane sheet
Velcro tape hook	Nylon
Velcro tape loop	Nylon
Sewing cotton	Polyester
Air Tube	PU (polyurethane)
Air plug to device	ABS (acrylonitrile butadiene styrene)
Air plug to cuff	PVC (polyvinyl chloride)

AC Adapter

Item	Material
Cable	PVC (polyvinyl chloride)
Adapter plug	Copper
Housing	PPE (polyphenylenether)

Appendix 3: EMC compliance

In this section you can find information regarding Electro Magnetic Compatibility (EMC) for Digital blood pressure monitor.
With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices. For conformity with the requirements for EMC (Electro Magnetic Compatibility), with the aim to prevent unsafe situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices. Our products conform to this EN60601-1-2 standard for both immunity and emissions.
Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by manufacturer, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- During use (or measurement), portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device. Otherwise, degradation of the performance of the device could result.

Refer to next pages for EMC Guidance and manufacturer's declaration.

Guidance and manufacturer's declaration –Digital Blood Pressure Monitor		
The BP4 digital blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the patient monitor, should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Digital Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Digital Blood Pressure Monitor is suitable for use in all establishments, including domestic establishments 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	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – Electromagnetic Immunity			
The BP4 digital blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the patient monitor should assure that it is used in such an environment.			
Immunity Test	Port	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Enclosure	±8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	Patient coupling	± 2 kV, ± 4 kV, ±8 kV, ±15 kV air	
	Signal I/O parts	N/A	
Electrical fast transient/burst IEC 61000-4-4	Input a.c. power	N/A	
	Signal I/O parts	N/A	
Surge IEC 61000-4-5	Input a.c. power	N/A	
	Signal I/O parts	N/A	
Voltage dips, IEC 61000-4-11	Input a.c. power	N/A	
Voltage interruptions IEC 61000-4-11	Input a.c. power	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 or 60 Hz	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 test level.			

Guidance and manufacturer's declaration – Electromagnetic Immunity			
The BP4 digital Blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the patient monitor should assure that it is used in such an environment.			
Immunity Test	Port	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	Input a.c. power	N/A	
	Patient coupling		
	Signal I/O parts		
Radiated RF IEC 61000-4-3	Enclosure	10 V/m 80 MHz –2,7 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Enclosure	Refer to the following table (table 9 of EN 60601-1-2: 2015)	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment.						
Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Max power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [C] ±5 KHz deviation 1 KHz sine	2	0.3	28
710	704-787	LTE Band 13,17	Pulse modulation [b] 217 Hz	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] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; DECT; LTE Band 1,3,4 25; UMTS	Pulse modulation [b] 217 Hz	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
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
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 worst case.