Proactive
medical products

Protekt® BP Upper Arm Blood Pressure Monitor

INSTRUCTION MANUAL

Model: PMDBPA

English Instruction Guide

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IMPORTANT INFORMATION

- Please read this instruction manual thoroughly so that you completely understand the operations, cautions, performance and limitations with this monitor. After reading this manual, please keep it for future reference.
- You should not use this blood pressure monitor for self-diagnosis, self-treatment or to change medication without consulting your physician or other health care professional. Should you have any doubt or question about your blood pressure measurements, you should consult your physician or other health care professional.
- This device contains high-precision parts; therefore, avoid exposing it to extreme temperature or humidity or to direct sunlight, shock and dust. Proactive guarantees the accuracy of this monitor only when it is stored and used properly.
- Do not attempt to calibrate or repair this monitor. If you have any questions regarding the function or operation of this monitor, please contact our service agent so we can provide you with accurate information.
- Should the monitor or cuff need cleaning, use a dry, soft cloth or a cloth dampened with water and a mild detergent. Never use alcohol, benzene, thinner or other harsh chemicals to clean the monitor or cuff.
- Remove and replace the batteries if the monitor is not used for more than 6 months. Alkaline batteries recommended.

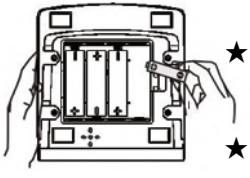
PRECAUTION FOR USE

The Protekt® BP Upper Arm Automatic Blood Pressure Monitor is designed to be operated by anyone who is eighteen years and older or by medical professionals to monitor blood pressure (systolic and diastolic) and pulse rate.

BEFORE YOU START

Please make sure you have installed 4 AAA (1.5 volt) batteries *(alkaline batteries are recommended)* or use the optional AC-DC Adapter. Always attach the cuff to the monitor before turning it on. To install *batteries* or replace them if the "Low Battery" symbol appears on display, proceed as follows:

■ Battery Loading



★ Remove the battery compartment cover by gently pushing down on arrow and sliding cover forward.

★ Place batteries with positive "+" and negative "-" terminals into compartment and make sure they match the indicated terminals in the compartment.

★ Close the battery cover by gently sliding it into the compartment and pressing it into place.

Note：

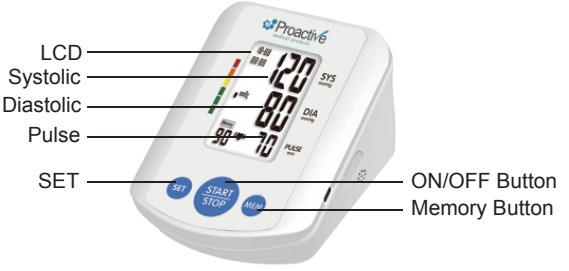
★ When the LCD display shows "Low Battery" signal ,the batteries must be replaced for accurate readings.

★ Do not use rechargeable batteries *(voltage 1.2V)*. They are not suitable for this product, can damage the monitor and will cause inaccurate readings to be obtained.

★ Remove the batteries if the monitor will not be used for six months or longer to avoid damage from the possibility of leaking batteries.

★ All the measurements will remain in the memory should the batteries become drained, removed, or replaced.

MONITOR COMPONENTS



★" **SET** " Button /Clock Setting

★" **M** " Button /Measured Result recall/ Clock Number Adjusting

★ON/OFF Button (For measuring)

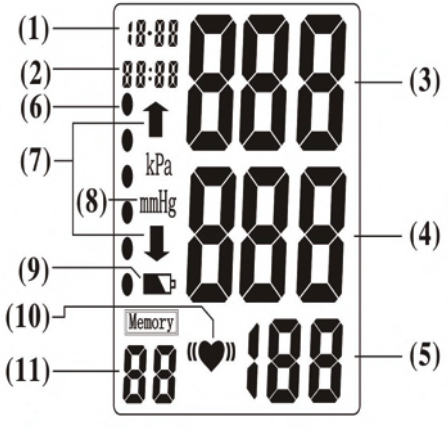
★LCD Display

★Systolic Indicator

★Diastolic Indicator

★Pulse Indicator

DISPLAY OF LCD



Note for LCD display:

(1) Date: Month – Day/ Alarm Clock
(2) Time: Hour – Minute
(3) Systolic Blood Pressure (unit: mmHg)
(4) Diastolic Blood Pressure (unit: mmHg)/ Time
(5) Pulse Rate (unit: beat/minute)/Ambient Temperature
(6) WHO Blood Pressure Classification Indicator
(7) Inflation / Deflation Indicator
(8) Blood Pressure Measurement Unit
(9) Battery Symbol
(10) Irregular Heartbeat Indicator
(11) Memory Record Number

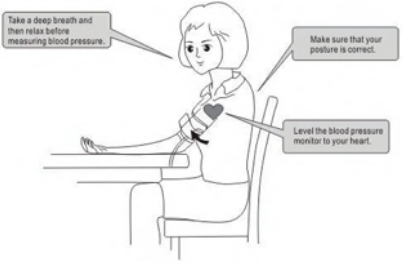
TIPS FOR BLOOD PRESSURE MONITORING

★ Relax for about 5 minutes before measurement.
★ Do not smoke or ingest caffeine at least 30 minutes prior to measurement.
★ Remove any constricting clothing and place the cuff on a bare arm.
★ Keep still and do not talk until the measurement is complete.
★ The cuff must be neither too tight nor too loose. Using a little force, you should be able to place two fingers between the cuff and your arm.

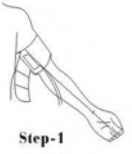
TAKING A MEASUREMENT

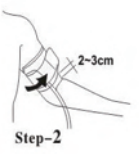
(1) POSTURE FOR TAKING BLOOD PRESSURE MEASUREMENT

★ Make yourself comfortable and sit-up straight.
★ Place your arm with cuff in front of you on the table with your palm facing up.
★ Cuff should be at the same height as your heart.



HOW TO WRAP THE CUFF ON YOUR ARM:





★ Place the cuff around a bare arm ½" to ¾"' above the elbow joint. The pressure tube should be oriented to run down the center of the inside of your arm. *(Refer to diagram on cuff for proper placement.)*

★ Keep the cuff at approximately the same level as your heart.

★ Unless your physician recommends otherwise, always use the left arm to measure your blood pressure.

★ The cuff should be snug but not too tight. You should be able to insert two fingers between the cuff and your arm.

NOTE:

1. **REFER TO THE DIAGRAM PRINTED ON THE CUFF FOR PROPER PLACEMENT.**
2. **FOR ACCURATE READINGS, THE CUFF/PRESSURE MUST BE ORIENTED CORRECTLY AND ALIGNED WITH THE ARTERY.**

LCD DISPLAY FOR TAKING BLOOD PRESSURE

After you are in a comfortable position, press the “ON/OFF” button. The device will verify itself showing all “8s”, then LCD will show “00”.

PROGRAMMING DATE, TIME AND LANGUAGE

YEAR, DATE, TIME SETTING-

★ Press the “SET” button for 5 seconds while the device is in standby status, the number of the YEAR will begin to blink on the LCD display. Press the “ **M** ” button to advance the YEAR displayed. When you have reached the correct date, press the “SET” button and release. (Don't keep on clicking on the 'SET' button without being released during programming.)

When the “SET” button is pressed and released, the YEAR will stop blinking and the MONTH will begin to blink. Press and release either “ **M** ” button to increase or decrease numbers until the desired month is reached. Repeat this process to set the DAY, HOUR, MINUTES.

VOICE ON or OFF SETTING-

★ After you finish the minute setting, you will see “SP OF “or “SP ON “ blink . This will allow you to set voice ON or OFF by pressing Memory Button to switch between “SP ON" “or “SP OF “.

IRREGULAR HEARTBEAT INDICATOR

If an irregular heartbeat is detected, the Irregular Heartbeat symbol ((♥)) will appear and blink in the display window.

READING AN AVERAGE OF THE LATEST THREE MEASUREMENTS (AVg)

★ Press and release the " **M** " button. LCD will display "AVg" in the upper corner of the LCD Display. The result that is first displayed and the result that is first announced – if in "TALKING" mode – is the average of your latest three measurements.

★ To review the results that are in memory – PRESS the " **M** " button to scroll through previous measurements. Each time you press and release the " **M** " button the next oldest result will be displayed. If the "TALKING" function is turned "ON" each result will be verbally announced.

2-PERSON MEASUREMENT SETTING FUNCTION

This model has 2-Person memory banks and 90 memories storage for each. Press and release 'SET' button can prompt to P1 (Person 1) or P2 (Person 2) as your ID to access the measurement for the first time operation when the device is turned off. Each time, before taking measurement or check memory from the storage, please be sure you have advanced to the correct ID (P1 or P2) which you already set forth prior to starting measuring.

DELETING MEASUREMENT FROM THE MEMORY

Press and hold the " **M** " BUTTON until all numbers change to "ZERO".

ACCESSING BLOOD PRESSURE FOR ADULTS

The following standards for assessing high blood pressure (without regard to age or gender) have been established as a guide according to American College of Cardiology (ACC)/American Heart Association (AHA). Please note that other risk factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration and may affect these figures. Always consult with your physician or other health care professional for accurate assessment.

Blood pressure categories in the new guideline are:

- Normal: Less than 120/80 mmHg;
- Elevated: Systolic between 120-129 and diastolic less than 80;
- Stage 1: Systolic between 130-139 or diastolic between 80-89;
- Stage 2: Systolic at least 140 or diastolic at least 90 mmHg;
- Hypertensive crisis: Systolic over 180 and/or diastolic over 120, with patients needing prompt changes in medication if there are no other indications of problems, or immediate hospitalization if there are signs of organ damage.

ACC/AHA CLASSIFICATION OF BLOOD PRESSURE

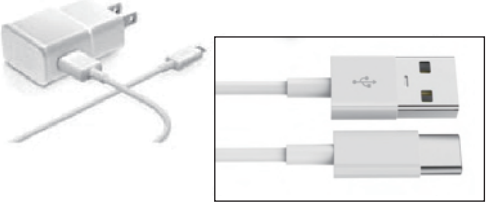
Blood Pressure Classification	Systolic (mmHg)		DBP (mmHg)	COLOR INDICATOR
Normal	<120	and	<80	GREEN
Elevated	120-129	and	<80	YELLOW
Stage 1 Hypertension	130-139	or	80-89	ORANGE
Stage 2 Hypertension	140 or higher	or	90 or higher	RED
Hypertensive Crisis	Higher than 180	And/ or	Higher than 120	RUST

Instructions for using the optional Protekt power supply or your own USB power supply:

In place of batteries, you can power your Protekt® PMDBPA arm blood pressure monitor (BPM) with the optional A/C power supply with TYPE-C USB connector (Figure A). Alternately you can power your arm BPM with a USB power supply with a USB - to TYPE-C USB connector (Figure B). With either option, power your arm BPM by inserting the TYPE-C USB connector into the TYPE-C USB slot (port) on the arm BPM and plugging the power supply into an electrical outlet.

Figure A: Optional A/C power supply With a TYPE-C USB connection*

Figure B: Any USB power supply with a TYPE-C USB connection/cable



* Both the optional AC power supply and the USB power supply are only for powering your arm BPM - not charging it.

Your arm BPM can be operated in 3 ways: using the optional A/C power supply (Figure A), a standard USB power supply with a USB-to TYPE-C USB cable (Figure B) or with 4 AAA batteries.

SPECIFICATIONS

Model No.:	PMDBPA	**Operation Environment:**	Temperature: 5~40°C Humidity: <90%RH
Type:	Oscillometric; Automatic air inflation by air pump and automatic deflation	**Storage Environment:**	Temperature: -20~55°C Humidity: < 95%RH
		Classification:	Class II, type B
Measurement Range:	Pressure: 0~280mmHg Pulse: 30~160 times/minute	**Cuff Circumference:**	8.7" ~ 14.2"
Accuracy:	Pressure: within ±3mmHg Pulse: within ±5%	**Memory:**	90 x 2 memory banks measurements including date and time
Power Supply:	6V DC (4 "AAA" batteries)	**Dimensions:**	128.2 mm (5.05 inches)------(L) 102.2 mm (4.02 inches) -----(W) 64.2 mm (2.53 inches) -----(H)
Battery Life:	Approx. 250 times (180mmHg, once /day, 22°C)	**Voice Processor:**	English announcement
		Weight:	222g (0.490 LBS)

TROUBLE SHOOTING (1)

Abnormality	Probable Reason	Corrective action
LCD shows Low Battery symbol 	Batteries are low.	Install new batteries.
The unit does not measure. Readings are too high or too low.	Pneumatic system blocked or cuff is too tightly wrapped.	Make certain the cuff is wrapped around your arm correctly and re-measure.
	Pressure system was unstable before measurement.	Measure again. Stay calm. Do not move or speak during measurement.
	The cuff position is not correct.	Sit comfortably and still. Make sure the cuff is at the same level as your heart.
An irregular heartbeat symbol occurs. 	Irregular heartbeat.	Relax for about 5 minutes and measure again. If the symbol appears again, consult your physician or other health care professional.
Voice processor	Unclear announcement by voice processor.	Batteries may be low. Please install new batteries and then take a measurement again.
Incorrect operation	Some interference in inflation or wrong operation during measuring.	Refer to the inflation step in “Taking blood pressure” and process again.

TROUBLE SHOOTING (2)

Abnormality	Reason	Checkout
LCD shows "Er U"	Insufficient inflation	Wait for 5 minutes and re-measure. If operation is still abnormal, contact manufacturer or agent (see the last page)
LCD shows "Er H"	Inflation over 305 mmHg	
LCD shows "Er 1"	Undetectable pulse	
LCD shows "Er 2"	Radiation interference	Move away the radiation source
LCD shows "Er 3"	Measured result appears wrong	Measure again

LIMITED WARRANTY

The Protekt® BP Blood Pressure Monitor has been carefully manufactured and inspected and is guaranteed for 2-years from the date of purchase. If the Blood Pressure Monitor does not function properly due to defective components, please contact Proactive Medical or an authorized Proactive distributor. The warranty does not cover damages to your Blood Pressure Monitor due to abuse, improper handling, negligence, unauthorized repairs or any operation other than the intended use of this product as outlined in the manual.

Proactive medical products

Protekt® BP Upper Arm Blood Pressure Monitor

Name: Age: Weight:
Nambre: Edad: Peso:

Date:	AM	SYS/DIA	PULSE		PM	SYS/DIA	PULSE
Fecha:	AM	SIS/DIA	PULSO		PM	SIS/DIA	PULSO

Note: By monitoring and controlling high blood pressure, you can lower your risk of stroke, heart attack, heart failure and kidney disease.

STATEMENTS AND DECLARATIONS:

1. Arm Blood Pressure Monitor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.

2. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d = 3,3 m away from the equipment.
(Note. As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3,3 m at an IMMUNITY LEVEL of 3 V/m)

3. The manufacturer is available for request of circuit diagrams, component part lists,
descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of the device.

4. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-- Reorient or relocate the receiving antenna.
-- Increase the separation between the equipment and receiver.
-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. -
-- Consult the dealer or an experienced radio/TV technician for help.

Guidance and manufacturer's declaration

Guidance and manufacture's declaration – electromagnetic emission		
The Arm Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer of the user of the Arm Blood Pressure Monitor should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Arm Blood Pressure Monitor use 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 emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration – electromagnetic immunity			
The Arm Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Arm Blood Pressure Monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode. ±2 kV common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TL-100Drequires continued operation during power mains interruptions, it is recommended that the TL-100Dbe powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The Arm Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Arm Blood Pressure Monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Arm Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Arm Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Arm Blood Pressure Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Arm Blood Pressure Monitor.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between
portable and mobile RF communications equipment and the Arm Blood Pressure Monitor.

The Arm Blood Pressure Monitor i*s* intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Arm Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Arm Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.333\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Explanation of Symbols:

Symbol for batch code

Symbol for manufacturer

IP 21 Symbol for “the IP classification”

Symbol for “ RF transmitters”

Symbol for “ENVIRONMENT PROTECTION - Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice”

Symbol for “TYPE BF APPLIED PART”

Symbol for “Follow operating instructions”

Software Version: V1.3
Manual Version: V2.0
Issue data: Aug. 21 2020