iProvèn BPM-337

Blood Pressure Monitor

Instruction Manual

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iProvèn

Thank you for making iProvèn your top choice. Please read the instructions carefully in order to accurately and safely utilize this equipment.

The BPM-337 measures the blood pressure and the heart rate and saves the results. The BPM-337 offers real time and accurate readings that are as convenient as possible thanks to the Oscillometric Measuring method. Blood pressure measurements may not be valid or accurate if they are not performed in accordance with the instructions provided in this manual. Please keep these instructions handy for future reference. You can also find the digital version of this manual on **www.iproven.com**

It is our passion to develop high quality products for home use. Our products are manufactured at the highest technical standards of professional quality, durability, and consistency. They are also designed with elegant simplicity in mind, making them easy to use at home.

To help you get the most from our products, we provide clear instructions with each device. The manual also includes helpful information that contributes to your overall health awareness.

In order to make sure that our products are tailored to your needs, we welcome your feedback. If you have any issues, questions or recommendations, please share your thoughts with us at **www.iproven.com**

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Intended use of the BPM-337 blood pressure monitor

The BPM-337 is a digital monitor that is used for measuring blood pressure and heart rate by cuffing the device around wrists of different sizes from 5½˝-8½˝ (13.5cm to 21.5 cm). The BPM-337 is intended for home use and for adults only.

How this device works

The product uses the Oscillometric Measuring method to detect blood pressure. When the measurement is started, it calibrates to "zero pressure" which is the natural air pressure. As soon as it starts inflating the wrist cuff, the device detects the pressure oscillations according to the beat-to-beat pulsatile and so it determines the systolic, diastolic pressure and the heart rate.

Irregular Heart Beat detection

The device is equipped with irregular heart beat detection, IHB. The algorithm of the device compares the longest and shortest intervals of registered pulse waves (the time interval) and calculates the standard deviation. If the differences in the time intervals are more than 25% you have an irregular heartbeat and the IHB sign will appear in the display. If the device detects irregular heartbeat during consecutive measurements and you are following the correct procedure, please consult your doctor.

⚠ CAUTIONS

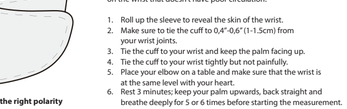
- Adult-use ONLY;
- Non-invasive measuring and monitoring of arterial blood pressure;
- Use only on the WRIST!
- Consult your doctor about the use of this device;
- When the pressure on the cuff exceeds 40 kPa (300 mmHg), the unit will automatically deflate;
- If the unit doesn't deflate when exceeding the 40 kPa (300 mmHg), detach the cuff from the wrist and press the START/STOP button to stop inflation;
- Do not use the monitor under conditions of strong electromagnetic fields;
- Electromagnetic fields will interfere with the signal and electrically fast transient/burst signal;
- The maximum temperature that the applied part can achieve is 42.5 ºC while the environmental temperature is 40 ºC;
- The device is not AP/APG equipment;
- It is not suitable for use in the presence of a flammable anesthetic mixture with air (or oxygen, nitrous oxide);
- Keep the Unit OUT OF REACH of infants, children or pets since inhalation or swallowing of small parts is dangerous or even fatal;
- Use only accessories or detachable parts specified and authorized by the Manufacturer;
- This Device should NOT be used on females suspected of pregnancy or pregnant! It may provide inaccurate readings and can have effects on the fetus.
- If you are suffering from arrhythmias such as atrial or ventricular premature heartbeats or atrial fibrillation the measurement results can be incoherent. In this case please consult your physician about the results.

Extra notes on the device

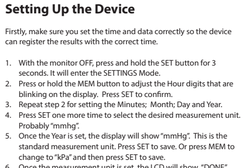
- The unit should not be used for prolonged monitoring during medical emergencies or operations.
- The cuff being inflated for a prolonged time will lead to numb ness of wrist and fingers, causing anesthesia, pain and ecchymosis.
- Use the device according to the instructions of this manual to guarantee an efficient performance and durability of the device.
- The cuff complies with the requirements of ISO 10993-5:2009 and ISO 10993-10:2010.
- The cuff does not cause any potential allergic reaction or contact injury.
- There is no need for calibration during the two years of ' guaranteed service.

Components of the BPM-337

The Monitor Components



The LCD Display

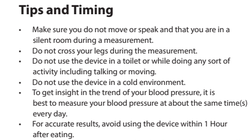


SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic Blood Pressure	High blood pressure level
DIA	Diastolic Blood Pressure	Low blood pressure level
Pul /min	Pulse	Pulse in beats per minute
+Lo	Low battery	Low battery, please replace the batteries
	AHA indicator	Indicating the AHA category of the measurement
	IHB Detector	Blood pressure monitor is detecting an irregular heartbeat during measurement
E	Error	See Error Messages and FAQ section
88	Memory	Indicating the memory mode and the number of the measurement
8888	Time	Hour: Minute (Month/Day/Year)
mmHg kPa	Measurement units	Measurement unit of blood pressure (1 mmHg=0.133kPa)

The Cuff Components

Component List:
1. PCBA;
2. Air Pipe;
3. Pump;
4. Valve;
5. Cuff.

How to Install and Replace Batteries:



1. Open the battery cover
2. Insert the two AAA batteries conform the right polarity
3. Close the battery cover

Setting Up the Device

Firstly, make sure you set the time and data correctly so the device can register the results with the correct time.

1. With the monitor OFF, press and hold the SET button for 3 seconds. It will enter the SETTINGS Mode.
2. Press or hold the MEM button to adjust the Hour digits that are blinking on the display. Press SET to confirm.
3. Repeat step 2 for setting the Minutes; Month; Day and Year.
4. Press SET one more time to select the desired measurement unit. Probably "mmhg".
5. Once the Year is set, the display will show "mmHg". This is the standard measurement unit. Press SET to save. Or press MEM to change to "kPa" and then press SET to save.
6. Once the measurement unit is set, the LCD will show "DONE" and the device will shut off.

Preparing the measurement

Before tying the cuff to your wrist, make sure you remove all accessories from the wrist (bracelets, watch, etc.). Use the device on the wrist that doesn't have poor circulation.

1. Roll up the sleeve to reveal the skin of the wrist.
2. Make sure to tie the cuff to 0.4"-0.6" (1-1.5cm) from your wrist joints.
3. Tie the cuff to your wrist and keep the palm facing up.
4. Tie the cuff to your wrist tightly but not painfully.
5. Place your elbow on a table and make sure that the wrist is at the same level with your heart.
6. Rest 3 minutes; keep your palm upwards, back straight and breathe deeply for 5 or 6 times before starting the measurement.

Taking a measurement

1. After resting press the Start Button and the measuring procedure will start.
2. First the measured air pressure will calibrate to zero and then the device will inflate and start reading the blood pressure and heart rate.
3. When the measurement is completed the results will appear in the screen. The measurement is also saved in the memory.

Tips and Timing

- Make sure you do not move or speak and that you are in a silent room during a measurement.
- Do not cross your legs during the measurement.
- Do not use the device in a toilet or while doing any sort of activity including talking or moving.
- Do not use the device in a cold environment.
- To get insight in the trend of your blood pressure, it is best to measure your blood pressure at about the same time(s) every day.
- For accurate results, avoid using the device within 1 Hour after eating.
- You shouldn't measure immediately after drinking tea or coffee and after smoking.
- Avoid measuring after 30 minutes of taking a shower or bath.
- For an accurate and clear result, please measure the same wrist every time. Blood circulation may differ from wrist to wrist so you can get a different result when you change wrists.

Using the memory function

- Make sure that the date and time is set correctly.
- Every measurement is automatically saved in the memory, with a maximum capacity of 60 measurements;
- To view the recorded data press the MEM button while the monitor is inactive. If the monitor is not yet inactive, first deactivate it by pressing the start/stop button.
- Use the buttons MEM for Up and Set for Down to read through the records.

Deleting the records

In case you want to delete your recorded measurements, please follow these steps:

1. Make sure the monitor is inactive; press START/STOP if needed.
2. Press MEM to go to Memory.
3. Press and hold the MEM button for 3 seconds.
4. "DEL ALL" will start blinking. Press SET to confirm.
5. "DEL DONE" will show, meaning the stored data is deleted. The device will shut off.

Keeping the device safe

Please make sure to place the device away from the sun. Store it in a dry place. When you want to clean the device, you should use a dry cloth. Do not place it in water or clean it with wet cloths. Also, be careful not to shake or throw the device. For a better performance, keep it in a room with stable temperature and away from dust. The cuff should not be cleaned as it may affect the accuracy of the reading.

Basic info about Blood Pressure

Systolic pressure means that the ventricles contract and pump out blood, increasing the blood pressure. The diastolic pressure means that the ventricles relax so the blood pressure decreases.

AHA indicator

After each measurement an arrow indicates the corresponding category color on the left of the display. The colors represent the different categories of the American Heart Association blood pressure classification as depicted in the chart below.

Blood Pressure Category	Systolic mm HG (upper#)		Diastolic mm Hg (lower#)
Normal	less than **120**	and	less than **80**
Prehypertension	**120-139**	or	**80-89**
High Blood Pressure (hypertension) **Stage 1**	**140-159**	or	**90-99**
High Blood Pressure (hypertension) **Stage 2**	**160** or higher	or	**100** or higher
Hypertensive Crisis (Emergency care needed)	Higher than **180**	or	Higher than **100**

Changes in blood pressure

There are many factors that cause the blood pressure to change. Weather, emotions, stress, food, physical activities; all these influence the variations in the blood pressure. Bear in mind that measuring in clinical settings tend to cause the blood pressure to increase. This is called "white coat effect".

Error Messages and FAQ

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
Low batteries	Display is dim or display ▭ +Lo	Batteries are low.	Replace with new batteries
Error message	E 01 shows	The cuff is too tight or too loose.	Refasten the cuff and then measure again.
	E 02 shows	The monitor detected motion,talking or the pulse is too poor while measuring.	Relax for a moment and then measure again.
	E 03 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the wrist and then measure again.
	E 04 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	EE XX,shows on the display.	A calibration error occurred.(XX can be some digital symbol,such as 01, 02,etc., if this similar situation appear, all belong to calibration error.)	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance.Refer to the warranty for contact information and return instructions.
	"oUt " shows	Out of measurement range.	Follow the instructions in user manual and measure again.

Power supply	2×AAA batteries,3V ⎓
Display mode	Digital LCD V.A.36mmx41mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~300mmHg (0kPa - 40kPa) Measurement pressure: 40mmHg-230mmHg (5.3kPa-30.7kPa) Pulse value: (40-199) beat/minute
Accuracy	Pressure: 5℃-40℃within±3mmHg(0.4kPa) Pulse value:±5%
Normal working condition	Temperature:5℃-40℃ Relative humidity: ≤85%RH Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20℃ to 60℃ Relative Humidity: 10% RH to 93% RH Atmospheric pressure: 50PA to 106kPa
Measurement perimeter of the wrist	About 13.5cm-21.5cm
Net Weight	Approx.120g(Excluding the dry cells)
External dimensions	Approx.80mm×65mm×22mm
Attachment	2×AAA batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP22: The first number 2: Protected against solid foreign objects of 12,5mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure titled up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is titled at any angle up to 15° on either side of the vertical
Software version	V01
Device classification	Internally Powered ME Equipment

Important Symbols on the Monitor

	Symbol for "THE OPERATION GUIDE MUST BE READ"		Symbol for "TYPE BF APPLIED PARTS"
	Symbol for "MANUFACTURE DATE"		Symbol for "ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice"
	Caution: These notes must be observed to prevent any damage to the device.		
SN	Symbol for Serial Number	⎓	Symbol for "DIRECT CURRENT"

Complied European Standards List

Risk management	ISO 14971:2007 Medical devices — Application of risk management to medical devices
Labeling	ISO 15223-1:2012 Symbols for use in the labelling of medical devices
User manual	EN 1041:2008 Information supplied by the manufacturer of medical devices
General Requirements for Safety	IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-11:2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	IEC 60601-1-2: 2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard:Electromagnetic compatibility - Requirements and tests
Performance requirements	IEC80601-2-30: 2009 Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
Clinical investigation	ISO 81060-2:2009 Automatic Blood Pressure Monitor overall system Interventional accuracy of the testing process
Usability	IEC60601-1-6:2010 2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability IEC 62366:2007 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	IEC 62304:2006 Medical device software - Software life cycle processes

Electromagnetic Compatibility Measures

Please pay attention to the precautions of EMC (Electromagnetic Compatibility) of this Monitor. The Blood Pressure Monitor must be installed and used according to the EMC information shown in this manual. The device can be affected by portable and mobile RF communication equipment.

Remove any devices that emit electromagnetic fields such as mobile phones from nearby the device.

The Blood Pressure Monitor has been tested and inspected to guarantee a proper performance.

Do not store or use this Monitor with other electric equipment.

Manufacturer's declaration on Electromagnetic Emissions for all ME Equipments and Sytem

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device 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 device 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration on Electromagnetic Immunity for all ME Equipments and Systems

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 floors are covered with synthetic material, the relative humidity should be at least 30%.
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 line(s) to line(s) ±2 kV line(s) to earth	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% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) 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 U_T is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration on Electromagnetic Immunity for all ME Equipments and Systems that do not provide LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Not applicable 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 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 metres (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 broad-cast 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

The safe distances between portable and mobile RF communications equipment, ME Equipments and Systems that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmittters) and the device 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 $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 80MHz and 800MHz, 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.

FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Warranty

This Limited Warranty covers any defects in materials or workmanship under normal use during the Warranty Period. iProvèn will either replace the product or repair the product at no charge, using new or refurbished replacement parts. The Warranty Period of this iProvèn product is 2 years from the date of purchase. A replacement product or product part assumes the remaining warranty of the original product purchase. This Limited Warranty does not cover batteries and packaging, nor any problem that is caused by conditions, malfunctions, or damage not resulting from defects in material or workmanship.

To obtain warranty service, contact our customer support at www.iproven.com to determine the problem and the most appropriate solution for your situation.

iProvèn

DISTRIBUTED BY
NETDIRECT DISTRIBUTION, LLC
9360 Federal Blvd
Denver , CO 80260

Phone: 1-503-974-0913

HEADQUARTERS
Ebweg 12D
2991 LT Barendrecht
The Netherlands

Phone: +31 (0)84-8838876