Blood Pressure Monitor
Instruction Manual
iProvèn BPM-634

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

The BPM-634 measures the blood pressure and the heart rate and saves the results. It also enables transferring the measurement using the Bluetooth connection. The BPM-634 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, so 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**

iProvèn - Professional Care Brought Home
iProvèn is a Masena Invest brand

Intended use of the BPM-634 blood pressure monitor

The BPM-634 is a digital monitor that is used for measuring blood pressure and heart rate by wrapping the cuff around arms of different sizes, within 8¾˝ - 16½˝ (22 cm to 42 cm). The BPM-634 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.

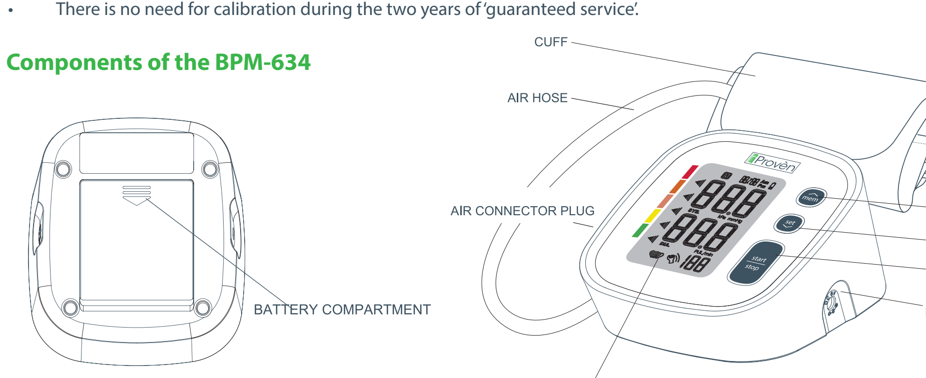
Irregular Heart Beat detection

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 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.

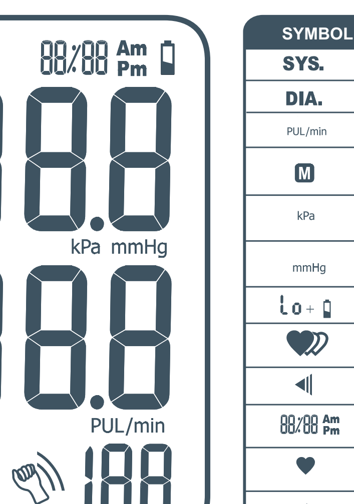
Intended use of the BPM-634 blood pressure monitor

- 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 numbness 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-634



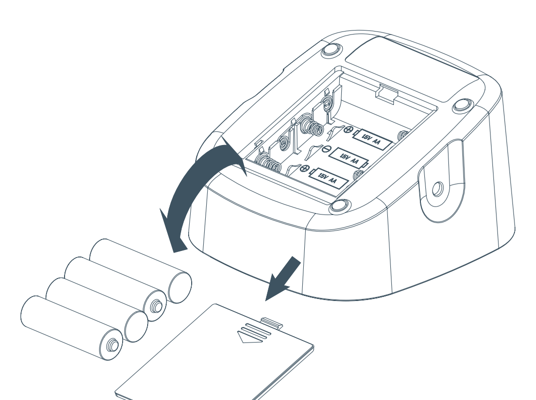
The LCD display and the meanings of the symbols



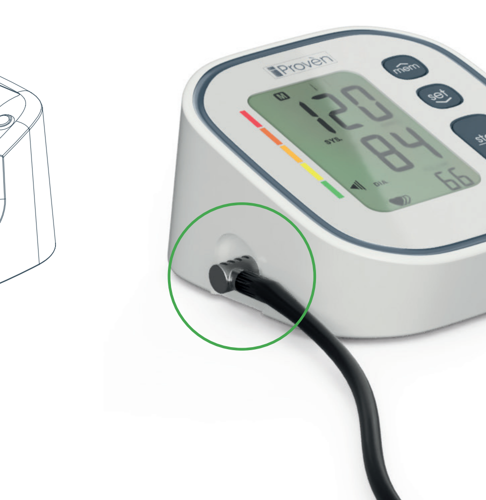
SYMBOL	DESCRIPTION	EXPLANATION
SYS.	Systolic pressure	High blood pressure
DIA.	Diastolic pressure	Low blood pressure
PUL/min	Pulse display	Pulse in beats per minute
M	Memory	Indicates it is in the memory mode and the measurement number
kPa	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
Lo +	Low battery	Batteries are low and need to be replaced
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement
	Blood pressure level indicator	Indicates the blood pressure level
88/88 Am Pm	Current Time	Year/Month/Day, Hour : Minute
	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement
	Motion indicator	Indicates detected motion try to avoid

Preparing the device

- Open the battery cover;
- Insert the four AA batteries conform the right polarity;
- Close the battery cover;



- Connect the cuff by inserting the air plug into the air jack on the left side of the device.

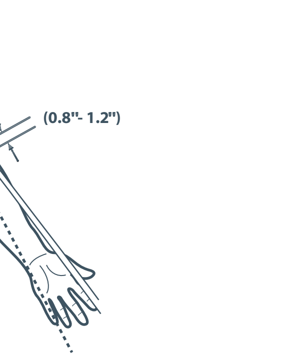


Setting up the device

1. First make sure you set the time and data correctly so the device can register the results with the correct time;
2. With the monitor OFF, press SET. The time will now show in the display;
3. Hold the SET button for 3 seconds until the "Year" starts blinking;
4. Press or hold MEM to adjust the Year digits that are blinking on the display. Press SET to confirm;
5. Repeat step 2 for setting the Month & Day, Hour & Minutes;
6. Once the Minutes are 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;
7. Once the measurement unit is set, the LCD will show "DONE". Then the device will show the settings and then shut off.

Preparing the measurement

Wrapping the cuff
When wrapping the cuff around your upper arm, make sure that:
- The ART sign of the cuff is close to the artery;
- The cuff is positioned around an inch from the bent of your arm;
- The cuff is snug but not too tight. You have to be able to insert one finger between the cuff and the arm.



Taking a measurement
1. Be seated in a quiet and comfortable room, with your arm resting on a flat surface;
2. After wrapping the cuff (see "wrapping the cuff" section), rest 3 minutes, keep your the palm of your hand upwards, your back straight and breathe deeply for 5 or 6 times before starting the measurement;
3. Press START to begin the measurement;
4. The monitor will first calibrate to zero air pressure and then inflate the cuff. While inflating the measurements are made;
5. When the measurement is completed the results will appear in the screen. The measurement is also saved in the memory.

Tips for better accuracy

- During the measurement do not move or speak and be seated in a silent room;
- 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 arm every time;
- As a rule of thumb: when you measure your left arm, position the hose in line with the index finger. For even higher accuracy, make sure the ART sign on the cuff is closest to the artery. You can locate the artery by pressing 2 fingers 1 inch above the bend of your elbow on the inside of your arm. The artery is where you can feel the pulse the strongest.

Using the memory function

- Every measurement is automatically saved in the memory, with a maximum capacity of 60 measurements;
- Make sure that the date and time are set correctly;
- 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 STOP;
- 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. If the monitor is not yet inactive, first deactivate it by pressing STOP;
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. (Or press STOP to cancel);
5. "DEL DONE" will show, meaning the stored data is deleted. The device will shut off.

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 AHA 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#)
Green	Normal	less than **120**	and	less than **80**
Yellow	**Prehypertension**	**120-129**	and	less than **80**
Orange	**High Blood Pressure** (hypertension) **Stage 1**	**130-139**	or	**80-89**
Dark Orange	**High Blood Pressure** (hypertension) **Stage 2**	**140** or higher	or	**90** or higher
Red	**Hypertensive Crisis** (Emergency care needed)	Higher than **180**	and/or	Higher than **120**

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 show [battery] +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 while measuring.	Movement can affect the measurement.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 arm and then measure again.
	E 04 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	EExx,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.
Warning message	"out " shows	Out of measurement range	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician.

Power supply	Battery powered mode: 6VDC 4×AA alkaline batteries AC adaptor powered mode: 6V ⎓ 1A (Please only use the recommended AC adaptor model).(Not included)
Display mode	Digital LCD V.A.73mm×49mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg(0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Accuracy	Pressure: 5℃-40℃ within±3mmHg(0.4kPa) Pulse value:±5%
Normal working condition	A temperature range of :+5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of : 700 hPa to 1060 hPa
Storage & transportation condition	Temperature:-20°C to +60°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the upper arm	About 22cm~42cm
Weight	Approx.260g(Excluding the dry cells and cuff)
External dimensions	Approx.118mm×126mm×72mm
Attachment	4×AA batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 It means the device could protected against solid foreign objects of 12.5mm and greater, and protect against vertically falling water drops.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
Software Version	A01

Important symbols on the monitor

	Symbol for "THE OPERATION GUIDE MUST BE READ"		Symbol for "TYPE BF APPLIED PARTS"
	Symbol for "MANUFACTURER"		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"
SN	Symbol for "SERIAL NUMBER"		
	Symbol for "DIRECT CURRENT"		
	Symbol for "MANUFACTURE DATE"		Symbol for "Recycle"
	The Green Dot is the license symbol of a European network of industry-funded systems for recycling the packaging materials of consumer goods.		Caution: These notes must be observed to prevent any damage to the device.

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 Immunity for all ME Equipments and Systems

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, other than domestic 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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	±8 kV contact ±15 kV air	±8 kV contact ±15 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	power supply lines: ±2 kV input/output lines: ±1 kV	power supply lines: ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	line(s) to line(s): ±1 kV line(s) to earth: ±2 kV 100 kHz repetition frequency	line(s) to line(s): ±1 kV 100 kHz repetition frequency	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	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°,225°,270° and 315° 0% 1 cycle and 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°,225°,270° and 315° 0% 1 cycle and 70% 25/30 cycles Single phase: at 0 0% 300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	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	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	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 appropriate for the frequency of the transmitter. Recommended separation distances: d=0.35; d=1.2	
Radiated RF IEC 61000-4-3	10V/m, 80% Am at 1kHz	10V/m, 80% Am at 1kHz	80 MHz to 800 MHz: d=1.2 800 MHz to 2.7 GHz: d=2.3	where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. 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 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 8 $d = 3.5$	0 MHz to 800 MHz $d = 1.2$	800 MHz to 2.7 GHz $d = 2.3$
0.01	0.12	0.12	0.23
0.1	0.37	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 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.

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.

Complied European Standards List

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labeling	EN 980:2008 Symbols for use in the labelling of medical devices ISO 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements
User manual	EN 1041:2008 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2010/ IEC 60601-1-11:2015 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	EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems IEC 80601-2-30:2013 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	EN 60601-1-6:2010/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability EN 62366:2008/ IEC 62366-1:2015 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304:2006 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Guidance and manufactures - 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.

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.32	7
	450	380-390	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	20	.3	28
	710 745 780	704-787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.20	.3	9
	810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.32	8
	1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	2	0.32	8
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.32	8
	5240 5240 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.39	

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

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

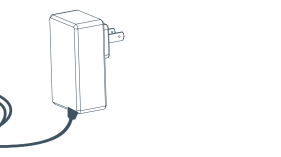
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

E=

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

Authorized Component

1. Please use the iProvèn authorized adapter. (not included)



Adapter
Model: KH0601000UW
Input: AC 100-240V
50/60Hz 0.4A Max
Output: ⎓6V 1000mA

CAUTIONS

- When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: connection tubing kinking too frequent and consecutive multiple measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.
- Warning: Do not apply the cuff over a wound;otherwise it can cause further injury.
- Do not inflate the cuff on the samb limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.
- On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately.
- Prolonged high pressure (cuff pressure > 300mmHg or constant pressure > 15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.
- Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
- When measurement, please avoid compression or restriction of the connection tubing.
- The device cannot be used with HF surgical equipment at the same time.
- The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.
- To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
- This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
- Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries. This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's arm and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
- When not in use, store the device with the adapter in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
- This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.

CAUTIONS

- This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.
- The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.
- Warning: No servicing/maintenance while the ME equipment is in use.
- The patient is an intended operator.
- The patient can measure data under normal circumstances and maintain the device and its accessories according to the user manual.
- To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
- The blood pressure monitor, its adaptor, and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
- During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensization or irritation reaction.
- Adaptor is specified as a part of ME EQUIPMENT.
- If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
- If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures reaches 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
- Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
- Do not wash the cuff in a washing machine or dishwasher!
- The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
- It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
- Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
- Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions,etc., to assist to service personnel in parts repair.

CAUTIONS

- The plug/adapter plug pins insulates the device from the main supply. Do not position the device in a position where it is difficult to disconnect from the supply mains to safely terminate operation of ME equipment.
- The operator shall not touch output of batteries /adapter and the patient simultaneously.
- Cleaning :Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
- The device doesn't need to be calibrated within two years of reliable service.
- If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of iProvèn. Don't open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
- Please report to iProvèn if any unexpected operation or events occur.
- Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
- Be careful to strangulation due to cables and hoses, particularly due to excessive length.
- At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
- This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
- 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 away from the equipment. The distance d is caculated by the MANUFACTURER from the 80 MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.
- Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
- There is no luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
- Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

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.

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