

Blood Pressure Monitor

Instruction Manual

iProvèn BPM-634



Provèn

Manual Version: 2.0
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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

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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.

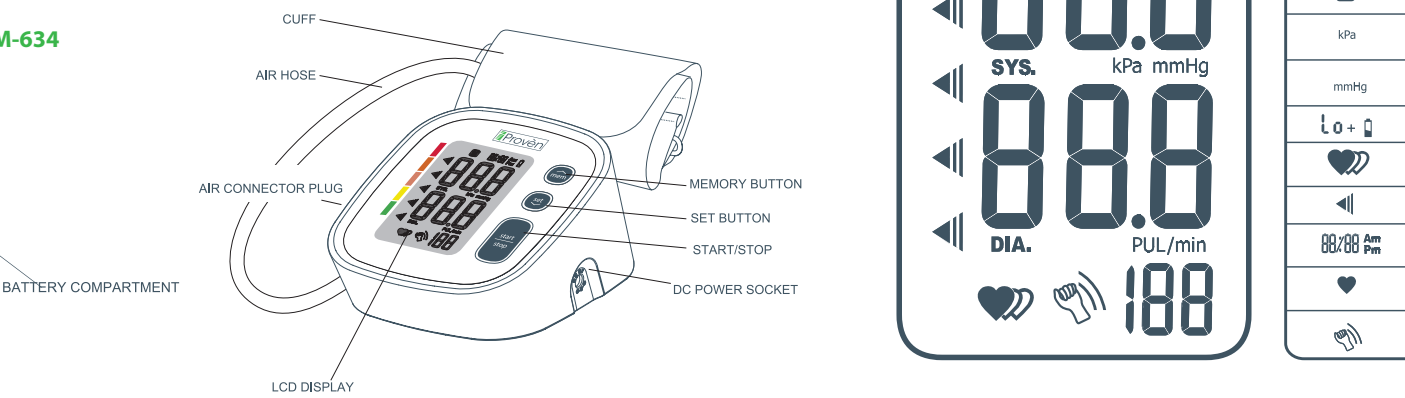
Irregular Heart Beat detection

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

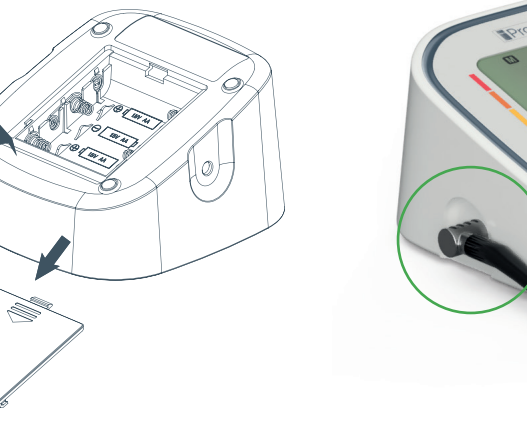


The LCD display and the meanings of the symbols

SYMBOL	DESCRIPTION	EXPLANATION
	Systolic pressure	High blood pressure
	Diastolic pressure	Low blood pressure
	Pulse display	Pulse in beats per minute
	Memory	Indicates it is in the memory mode and the measurement number
	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
	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
	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

When wrapping the cuff around your upper arm, make sure that:

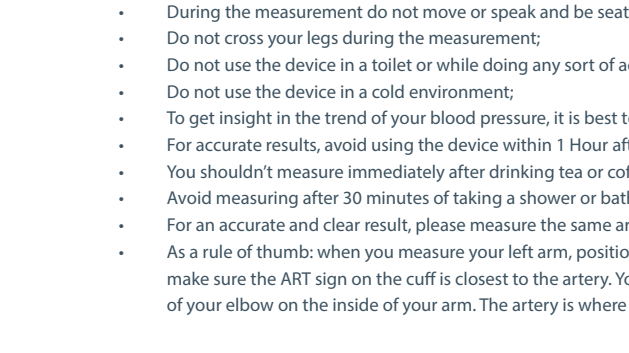
- The ART sign of the cuff is close to the artery;
- The cuff is positioned around an inch from the bent of your arm;
- The cuff is snug but not too tight. You have to be able to insert one finger between the cuff and the arm.

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 shows	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.
	EEEx 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	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, 7.3mm x 49mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~260mmHg(0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) and smaller DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40~199)beats/minute
Accuracy	Pressure: 5~40 °C 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 1050 hPa Temperature: 20°C to +60°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Storage & transportation condition	About 22cm x 42cm
Measurement perimeter of the upper arm	Approx. 260g (Excluding the dry cells and cuff)
Weight	Approx. 118mm x 126mm x 72mm
External dimensions	4-AA batteries, user manual
Attachment	Continuous operation
Mode of operation	Type BF applied part
Degree of protection	IP21 It means the device could be protected against solid foreign objects of 12.5mm and greater, and protect against vertically falling water drops.
Protection against ingress of water	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
Device Classification	
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"
	Symbol for "DIRECT CURRENT 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	

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Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	power supply lines: ±1 kV input/output lines: ±1 kV	power supply lines: ±2 kV input/output lines: ±2 kV
Surge IEC 61000-4-5	(line(s) to line(s): ±1 kV (line(s) to earth): ±2 kV 100 kHz repetition frequency	(line(s) to line(s): ±1 kV (line(s) to earth): ±2 kV 100 kHz repetition frequency
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 non-condensing, at 0% 300 cycle	0% 0.5 cycle At 0°: 45° 90° 135° 180° 225° 270° and 315° 0% 1 cycle and 70% 25/50 cycles Single phase, at 0% 300 cycle
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50/60Hz	30 A/m 50/60Hz
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NOTE 1 A 180 MHz and 800 MHz, the higher frequency range applies.		
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a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, 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 reconfiguring the device, b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.		

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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 non-condensing, at 0% 300 cycle	0% 0.5 cycle At 0°: 45° 90° 135° 180° 225° 270° and 315° 0% 1 cycle and 70% 25/50 cycles Single phase, at 0% 300 cycle
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50/60Hz	30 A/m 50/60Hz
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50/60Hz	30 A/m 50/60Hz
NOTE 1 A 180 MHz and 800 MHz, the higher frequency range applies.		
NOTE 2 If these guidelines may not apply in all situations, the manufacturer's declaration is affected by the electromagnetic propagation is affected by the environment - Software cycle processes		
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, 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 reconfiguring the device, b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.		

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
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	power supply lines: ±1 kV input/output lines: ±1 kV	power supply lines: ±2 kV input/output lines: ±2 kV
Surge IEC 61000-4-5	(line(s) to line(s): ±1 kV (line(s) to earth): ±2 kV 100 kHz repetition frequency	(line(s) to line(s): ±1 kV (line(s) to earth): ±2 kV 100 kHz repetition frequency
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 non-condensing, at 0% 300 cycle	0% 0.5 cycle At 0°: 45° 90° 135° 180° 225° 270° and 315° 0% 1 cycle and 70% 25/50 cycles Single phase, at 0% 300 cycle
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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
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV	



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 or 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 sensitization 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/adaptor 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 /adaptor 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 calculated 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 parts 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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