INSTRUCTIONS FOR USE

Arm-type Fully Automatic Blood Pressure Monitor

DBP-6191

Contents

1. SAFETY NOTICE

Dear Customer,

thank you for purchasing the DBP-6191 Blood Pressure Monitor. The unit has been constructed using reliable circuitry and durable materials. Used properly, this unit will provide yeas of satisfactory use.

This device is intended for non-invasive measuring adults and adolescents over 12 years of age individual's systolic, diastolic blood pressure and heart rate using the oscillometric method. The device is not intended for use on infants and children. The device is designed for home or clinical use. All functions can be used safely and values can be read out in one LCD DISPLAY. Measurement position is on adult upper arm only.

Please read this manual thoroughly before using the unit. Please retain this manual for future reference. For specific information about your blood pressure, please CONSULT YOUR DOCTOR.

To avoid risk and damage follow all warning precautions. Operate unit only as intended. Read all instructions prior to use.

WARNING SIGNS AND SYMBOLS USED

	Caution	SN	Serial Number		Importer
	Mandatory				Manufacturer
	Prohibited				Keep Dry
	Type BF Equipment				Manufacturing Date
	Instructions For Use MUST be Consulted				Keep off Sunlight
	Discard the used product to the recycling collection point according to local regulations			MD	Medical Device
CE 0123	The product conforms to the requirements of the Regulation (EU) 2017/745 MDR on medical devices				Temperature limitation
EC REP	Authorised Representative in the European Community				Humidity limitation

⚠ **CAUTION:**

❗ Individuals with serious circulation problems may experience discomfort. Consult your physician prior to use.

❗ Contact your physician if test results regularly indicate abnormal readings. Do not attempt to self-treat these symptoms without consulting your physician first.

⊘ Product is designed for its intended use only. Do not misuse in any way.

⊘ Product is not intended for infants or individuals who cannot express their intentions.

⊘ Do not disassemble or attempt to repair.

⊘ Do not use cell phones and other devices, which generate strong electrical or electromagnetic fields, near the device, as they may cause incorrect readings and interference or become interference source to the device.

⊘ Only use a recommended AC adaptor double-insulated complying with EN 60601-1 and EN 60601-1-2 see page 4). An unauthorized adaptor may cause fire and electric shock.

⚠ **CAUTION. Battery Precautions**

Do not mix new and old batteries simultaneously.
Replace batteries when Low Battery Indicator ▭ appears on screen.
Be sure battery polarity is correct.
Do not mix battery types. Long-life alkaline batteries are recommended.
Remove batteries from device when not in operation for more than 3 months.
Dispose batteries properly; observe local laws and regulations.

Important Instructions Before Use

1. Do not confuse self-monitoring with self-diagnosis. Blood pressure measurements should only be interpreted by a health professional who is familiar with your medical history.
2. Contact your physician if test results regularly indicate abnormal readings.
3. If you are taking medication, consult with your physician to determine the most appropriate time to measure your blood pressure. NEVER change a prescribed medication without first consulting with your physician.
4. Individuals with serious circulation problems may experience discomfort. Consult your physician prior to use.
5. For persons with irregular or unstable circulation resulting from diabetes, liver disease, arteriosclerosis or other medical conditions, there may be variations in blood pressure values measured at the wrist versus at the upper arm. Monitoring the trends in your blood pressure taken at either the arm or the wrist is nevertheless useful and important.

6. People suffering from vascular constriction, liver disorders or diabetes, people with cardiac pacemakers or a weak pulse, and women who are pregnant should consult their physician before measuring their blood pressure themselves. Different values may be obtained due to their condition.
7. People suffering from arrhythmias such as atrial or ventricular premature beats or atrial fibrillation only use this blood pressure monitor in consultation with your doctor. In certain cases oscillometric measurement method can produce incorrect readings.
8. Too frequent measurements can cause injury to the patient due to blood flow interference.
9. The cuff should not be applied over a wound as this can cause further injury.
10. **DO NOT** attach the cuff to a limb being used for IV infusions or any other intravascular access, therapy or an arterio-venous (A-V) shunt. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.
11. The cuff should not be placed on the arm on the side of a mastectomy. In the case of a double mastectomy use the side of the least dominant arm.
12. Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.
13. A compressed or kinked connection hose may cause continuous cuff pressure resulting in blood flow interference and potentially harmful injury to the patient.
14. Check that operation of the unit does not result in prolonged impairment of the circulation of the patient.
15. Product is designed for its intended use only. Do not misuse in any way.
16. Product is not intended for infants or individuals who cannot express their intentions.
17. Prolonged over-inflation of the bladder may cause ecchymoma of your arm.
18. Do not disassemble the unit or arm cuff. Do not attempt to repair.
19. Use only the approved arm cuff for this unit. Use of other arm cuffs may result in incorrect measurement results.
20. The system might produce incorrect readings if stored or used outside the manufacturer's specified temperature and humidity ranges.
21. Do not use the device near strong electrical or electromagnetic fields generated by cell phones or other devices, they may cause incorrect readings and interference or become interference source to the device. Do not use the device during patient transport outside healthcare facility for interference source existing as well.
22. Do not mix new and old batteries simultaneously.
23. Replace batteries when Low Battery Indicator  appears on screen. Replace both batteries at the same time.

24. Do not mix battery types. Long-life alkaline batteries are recommended.
25. Remove batteries from device when not in operation for more than 3 months.
26. Do not insert the batteries with their polarities incorrectly aligned.
27. Dispose batteries properly; observe local laws and regulations.
28. Only use a recommended class II AC adaptor double-insulated complying with EN 60601-1 and EN 60601-1-2. An unauthorized adapter may cause fire and electric shock.
29. Advising operator that Instruction manual/ Booklet must be consulted.
30. Essential performance:

Electrosurgery interference recovery	Refer 202.6.2.101	IEC 80601-2-30
Limits of the error of the manometer	Refer. 202.12.1.102	IEC 80601-2-30
Reproducibility of the BLOOD PRESSURE DETERMINATION	Refer 201.12.1.107	IEC 80601-2-30

2. UNIT ILLUSTRATION

Automatic blood pressure monitor

Arm cuff 22–42 cm (M/L)

4 × batteries type AAA 3

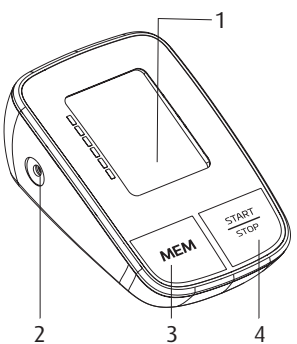
Carrying case

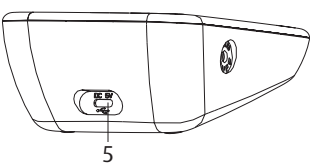
Instruction for use

2MOPP Medical USB-Type C Adapter (DC 5.0 V,1000 mA) (recommended, not provided) (included)

3. BLOOD PRESSURE MONITOR DESIGN

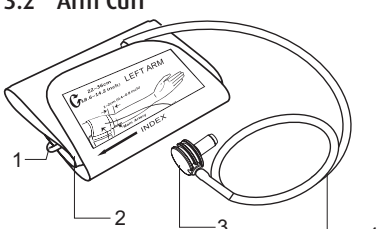
3.1 Monitor Unit





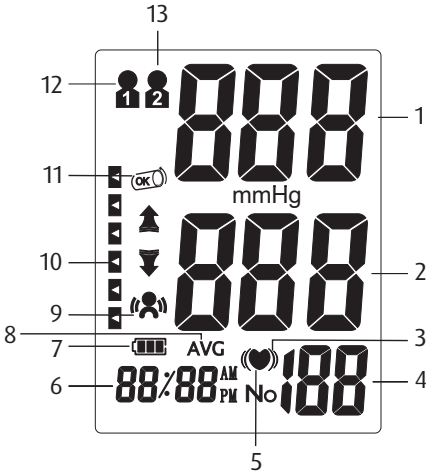
1. LCD Display
2. Cuff Connection Port
3. "MEM" Button
4. "START/STOP" Button
5. USB Adapter Jack

3.2 Arm Cuff



1. Metal buckle
2. Arm Cuff
3. Air Plug
4. Air Tube

3.3 Display



1. Systolic Blood Pressure
2. Diastolic Blood Pressure
3. Irregular Heartbeat Indicator
4. Pulse Rate
5. Heart Rate Indicator
6. Time/Date
7. Low Battery Indicator
8. Last 3 Tests Average
9. Arm Shake Indicator
10. WHO Blood Pressure Classification Indicator
11. Cuff Loose Indicator
12. Group 1
13. Group 2

4. IMPORTANT TESTING GUIDELINES

1. Avoid eating, exercising, and bathing for 30 minutes prior to testing.
2. Sit in a calm environment for at least 5 minutes prior to testing.
3. Do not stand while testing. Sit in a relaxed position while keeping your arm level with your heart.
4. Avoid speaking or moving body parts while testing.
5. While testing, avoid strong electromagnetic interference such as microwave ovens and cell phones.
6. Wait 3 minutes or longer before re-testing.
7. Try to measure your blood pressure at the same time each day for consistency.
8. Test comparisons should only be made when monitor is used on the same arm, in the same position, and at the same time of day.
9. This blood pressure monitor is not recommended for people with severe arrhythmia.
10. Do not use this blood pressure monitor if the device is damaged.

5. QUICK START

1. Install batteries. (See Figure A)
2. Insert cuff air plug into the behind side of monitor unit. (See Figure B)

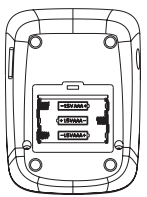


Fig. A

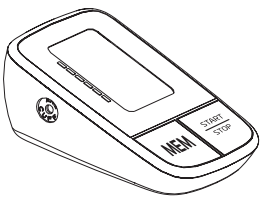


Fig. B

3. Remove thick clothing from the arm area.
4. Rest for several minutes prior to testing. Sit down in a quiet place, preferably at a desk or table, with your arm resting on a firm surface and your feet flat on the floor. (See Figure C)
5. Apply cuff to your left arm and keep level with your heart. Bottom of cuff should be placed approximately 1–2 cm (0.4-0.8") above elbow joint. (See Figures D&E)

Fig. C

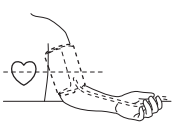


Fig. D

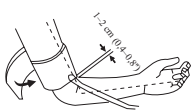


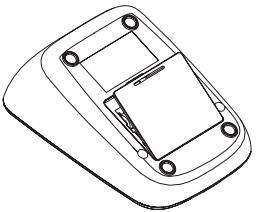
Fig. E

6. Press " START/STOP " Button to start testing.

6. UNIT OPERATION

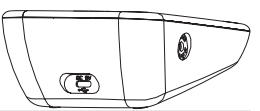
6.1 Battery Installation

Slide battery cover off as indicated by arrow.
Install 3 new AAA alkaline batteries according to polarity.
Close battery cover.



6.2 Medical Adapter

The mains adapter socket is located on the back of the blood pressure monitor. A DC 5.0 V; 1000 mA medical AC adapter (included) can be used with the unit. The power plug should have a USB type C connector.
Do not use any other type of mains adapter as it may harm the unit.



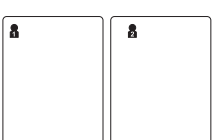
Note: Power supply is specified as part of ME EQUIPMENT.

6.3 System Settings

With power off, press "START/STOP" button about 5 seconds to activate System Settings. The Memory Group icon flashes.

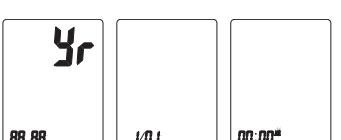
1. Select Memory Group

While in the System Setting mode, you may accumulate test results into 2 different groups. This allows multiple users to save individual test results (up to 150 memories per group.) Press "MEM" button to choose a group setting. Test results will automatically store in each selected group.

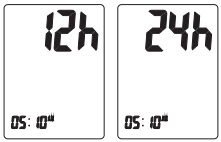


2. Time/Date setting.

Press"START/STOP" button again to set the Time/Date mode. Set the year first by adjusting the "MEM" button.
Press"START/STOP" button again to confirm current month. Continue setting the date, hour and minute in the same way.

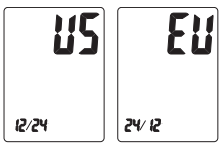


Every time the "START/STOP" button is pressed, it will lock in your selection and continue in succession (month, day, hour, minute, 12/24 hours)



3. Time Format setting

Press "START/STOP" button again to set the time format setting mode. Set the time format by adjusting the "MEM" button. EU means European Time US means U.S Time.



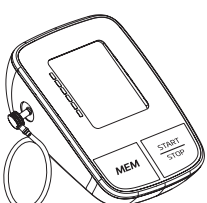
4. Saved Settings

While in any setting mode, press and hold "START/STOP" button to turn the unit off. All information will be saved.

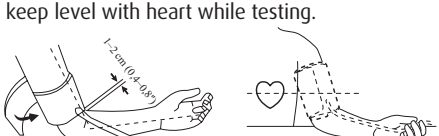
Note: If unit is left on and not in use for 3 minutes, it will automatically save all information and shut off.

6.4 Applying the Arm Cuff

1. Insert the tip of the air hose into the cuff socket on the left side of the blood pressure monitor.



2. Insert the end of the cuff under the metal cuff buckle with the Velcro facing outward.
3. Fasten cuff about 1–2cm (0.4–0.8") above the elbow joint. For best results apply cuff to bare arm and keep level with heart while testing.

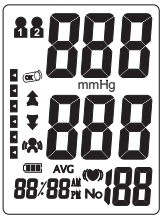


Note: Do not insert the end of the air hose into the hole located at the back of the monitor. This opening is only for connecting the optional power supply.

6.5 Testing

1. Power On

Press "START/STOP" button to turn the unit on. The LCD screen will appear for one second as unit performs a quick diagnosis.



Note: Unit will not function if residual air from previous testing is present in cuff. The LCD will flash until pressure is stabilized.

2. Testing

After cuff inflation, air will slowly rise as indicated by the corresponding cuff pressure value. A flashing ♥ will appear simultaneously on screen signaling heart beat detection. The blood pressure monitor measures pressure while pumping air into the cuff. This method guarantees a short measurement time and optimal selection of cuff pressure, without unnecessary pressure on the arm.

Note: Keep relaxed during testing. Avoid speaking or moving body parts.

3. Result Display

The screen will display measurements for systolic and diastolic blood pressure . An indicator representing the current measurement will appear next to the corresponding WHO Classification.

Note: Refer to Page 14 for detail WHO Blood Pressure Classification Information.

6.6 Irregular Heartbeat Indicator

If the monitor detects an irregular heart rhythm two or more times during the measuring process, the Irregular Heartbeat Symbol ((♥)) appears on screen along with measurement results. Irregular heartbeat rhythm is defined as rhythm that is either 25% slower or faster than the average rhythm detected while measuring systolic blood pressure and diastolic blood pressure. Consult your physician if the Irregular Heartbeat Symbol ((♥)) frequently appears with your test results.

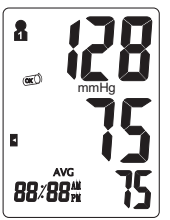
6.7 Power Off

The "START/STOP" button can be pressed to turn off the unit in any mode. The unit can turn off the power itself about 3 minutes no operation in any mode.

Safety Precaution: If pressure in arm cuff becomes too extreme while testing, press the "START/STOP" button to turn power off. The cuff pressure will rapidly dissipate once the unit is off.

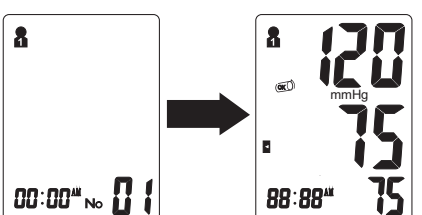
6.8 Last 3 Tests Average

With power off press the "MEM" button to activate screen display. After the unit performs a self-diagnosis ,the screen will display the average test results from the last 3 readings of the last group used. The "AVG" symbol will appear along with the corresponding WHO Blood Pressure Indicator. The Memory Check mode can be accessed by pressing "MEM" button. To check the average results in another user, select the desired Group (User 1 or User 2). (See "Select Memory Group" on Page 8.



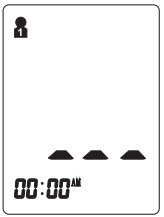
6.9 Memory Check

With power off, you may check past test results by using the "MEM" button. Upon activating test results. you can press the "MEM" button to scroll through all test results stored in memory. The LCD will display the last measurement memory as NO.01 reading.



6.10 Memory Deletion

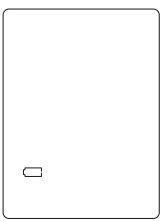
Memory for a selected group may be deleted while in Memory Check mode. Press and hold the "START/STOP" button for approximately 3 seconds to delete all memory records from the selected group. LCD screen display „- - -". Thentransfer into testing mode. Press the "START/STOP " button to turn the unit off.



Note: Memory cannot be recovered once it has been deleted.

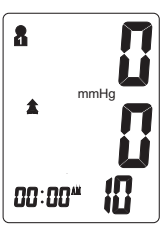
6.11 Low Battery Indicator

When the battery life runs out and you cannot inflate the cuff for measurement the device will display the low battery symbol. No memory loss will occur throughout this process.



6.12 Static Pressure Measurement

In the power down state, press and hold the " START/STOP" button, and then install the batteries. Until the LCD screen is full, release the " START/STOP" button. When the LCD screen displays the double zero, the bloodpressure meter is in static state. Software version is displayed: 10 is a software version in the figure.



Note: Only Service personnel permitted to access to this mode, the mode unavailable in normal use.

6.13 Arm Shake Indicator „"

If the arm moves during the measurement, „" the icon will be displayed, indicating that this may lead to abnormal measurement results, and the LCD screen will be displayed „" after the measurement is finished.

6.14 Cuff loose Indicator

When starting the measurement, „".will be displayed when the cuff is properly wound. When the cuff is too loose, „"will be displayed. At this time, please wear the cuff correctly and start measuring again.

6.15 Troubleshooting

Abnormal phenomenon	Cause analysis	Processing method
Abnormal sphygmomanometer	The armband is tied too tight or too loose, Or the arm strap is tied incorrectly;	Roll the armband correctly
	Move the arm during measurement or Electronic sphygmomanometer	Stay quiet, keep your arm steady, and do not move the monitor
	Speaking, nervous or emotional during measurement	Instead of talking, take deep breaths to calm your mood and relax your body
	Incorrect measurement posture	Adjust posture, see “Blood pressure gauge Wearing”
	There is interference in charging process or improper operation in measuring process	See operation Instructions.

The following table shows the error signs that may occur during measurement, possible causes and handling methods. Please measure again using the correct method.

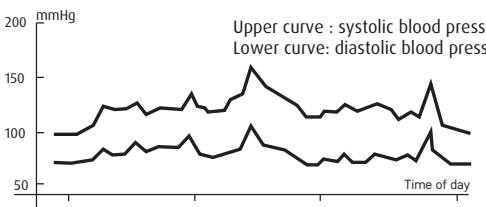
Error display	The cause of the problem	The solution
Er1	Can’t detect high and low pressure	Please fasten the cuff before measuring
Er2	Cuff too loose or loose	Please fasten the cuff before measuring
Er3	Improper compression caused by arm or body movement	Measure again. If you cannot solve the problem, please contact the authorised service centre.
Er4	The pressure exceeds 300 mmHg	Please fasten the cuff before measuring
Er5	The pressure exceeds 15 mmHg for 3 minutes	Check whether the cuff is knotted or the vent valve is blocked. If the problem persists, contact the authorised service centre
Er6	Blood pressure measurements were out of range	Take another measurement following the instructions exactly. If you cannot solve the problem, contact an authorised service centre.
	Battery dead	Replace the battery or connect the power adapter (if any).

Note: If you cannot solve the abnormal situation by yourself, you can consult the manufacturer or the manufacturer’s designated unit by phone. It is forbidden to disassemble and repair without permission. If necessary, professional maintenance personnel can ask the manufacturer for the list of components and circuit schematic diagram.

7. BLOOD PRESSURE INFORMATION

7.1 Blood Pressure

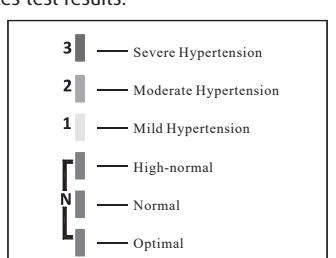
Blood pressure is the force of blood pushing against the walls of arteries. It is typically measured in millimeters of mercury (mmHg.) Systolic blood pressure is the maximum force exerted against blood vessel walls each time the heart beats. Diastolic blood pressure is the force exerted on blood vessels when the heart is resting between beats. An individual's blood pressure frequently changes throughout the course of a day. Excitement and tension can cause blood pressure to rise, while drinking alcohol and bathing can lower blood pressure. Certain hormones like adrenaline (which your body releases under stress) can cause blood vessels to constrict, leading to a rise in blood pressure. If these measuring numbers become too high, it means the heart is working harder than it should.

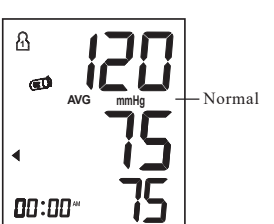


Example: fluctuation within a day (male, 35 years old)

7.2 WHO Blood Pressure Classification Indicator

The DBP-6191 is equipped with a classification indicator based on established guidelines from the World Health Organization. The chart below (color coded on monitor unit) indicates test results.

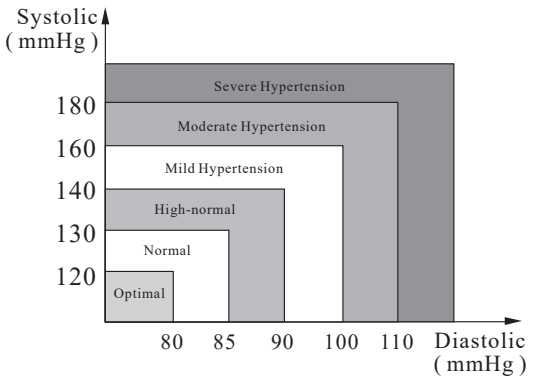




: Blood Pressure Classification Indicator

7.3 Health Reminder

Hypertension is a dangerous disease that can affect the quality of life. It can lead to a lot of problems including heart failure, kidney failure, and cerebral hemorrhaging. By maintaining a healthy lifestyle and visiting your physician on a regular basis, hypertension and relative diseases are much easier to control when diagnosed in their early stages.



Note: Do not be alarmed if an abnormal reading occurs. Better indication of an individual's blood pressure occurs after 2–3 readings are taken at the same time each day over an extended period of time. Consult your physician if test results remain abnormal.

8. BLOOD PRESSURE Q&A

Q: What is the difference between measuring blood pressure at home or at a professional healthcare clinic?

A: Blood pressure readings taken at home are now seen to give a more accurate account as they better reflect your daily life. Readings can be elevated when taken in a clinical or medical environment. This is known as White Coat Hypertension and may be caused by feeling anxious or nervous.

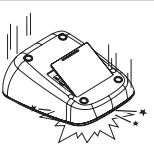
Note: Abnormal test results may be caused by:

1. Improper cuff placement
   Make sure cuff is snug-not too tight or too loose.
   Make sure bottom of the cuff is approximately 1–2cm (1/2") above the elbow joint.
2. Improper body position
   Make sure to keep your body in an upright position.
3. Feeling anxious or nervous
   Take 2–3 deep breaths, wait a few minutes and resume testing.

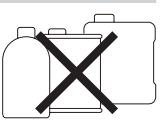
Q: What causes different readings?
A: Blood pressure varies throughout the course of a day. Many factors including diet, stress, cuff placement, etc. may affect an individual's blood pressure.
Q: Should I apply the cuff to the left or right arm? What is the difference?
A: Either arm can be used when testing, however, when comparing results, the same arm should be used. Testing on your left arm may provide more accurate results as it is located closer to your heart.
Q: What is the best time of day for testing?
A: Morning time or any time you feel relaxed and stress free.

9. MAINTENANCE

1. Avoid dropping, slamming, or throwing the unit.

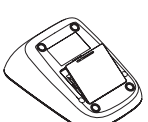


2. Do not use petrol, thinners or similar solvents.



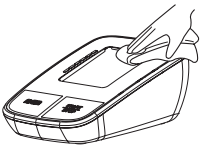
3. Avoid extreme temperatures. Do not expose unit directly under sunshine.

4. Remove batteries when not in operation for an extended period of time.



5. Do not disassemble product.

6. When cleaning the unit, use a soft fabric and lightly wipe with mild detergent. Use a damp cloth to remove dirt and excess detergent.



7. Cuff Cleaning: Do not soak cuff in water! Apply a small amount of rubbing alcohol to a soft cloth to clean cuff's surface. Use a damp cloth (water-based) to wipe clean. Allow cuff to dry naturally at room temperature. The cuff must be cleaned and disinfected before use between different users.
8. It is recommended the performance should be checked every 2 years.
9. Expected service life: Approximately three years at 10 tests per day.
10. No service and maintenance while it is in use and maintenance only be performed by service personnel. Service and maintenance require parts, repair, technical support will be provided.

10. SPECIFICATIONS

Product Description	Arm-type Fully Automatic Blood Pressure Monitor	
Model	DBP-6191	
Display	LCD Digital Display Size: 46×62,1 mm (1.81"×2.44")	
Measurement Method	Oscillometric Method	
Measurement Range	Systolic Pressure	60–260 mmHg
	Diastolic Pressure	40–200 mmHg
	Pressure	0–299 mmHg
	Pressure	±3 mmHg
	Pulse	30–180 Beats/Minute
	Pulse	±5%
Pressurization	Automatic Pressurization	
Memory	2×150 Memories in Two Groups with Date and Time	
Function	Irregular Heartbeat Detection	
	WHO Classification Indicator	
	Last 3 Tests Average	
	Low Battery Detection	
	Automatic Power-Off	
	Backlight display	

Power Source	3 AAA batteries or Medical USB Type-C Adapter (DC 5.0 V; 1000 mA) (included)	
Battery Life	Approximately 2 months at 3 tests per day	
Unit Weight	Approx.188 g (6.63 oz) (excluding battery)	
Unit Dimensions	Approx. 136×95,3×57 mm (5.35"×3.75"×2.24")(L×W×H)	
Cuff Circumference	Approx. 135×485 mm (W×L) (Cuff size M/L: fits arm circumference 22-42 cm)	
Operating Environment	Temperature	10-40°C (50-104°F)
	Humidity	15-93% RH
	Pressure	800-1060 hPa
Storage Environment	Temperature	-25-55°C (-13-131°F)
	Humidity	≤93% RH
Classification:	Internal Powered Equipment, Type BF , Cuff is the Applied Part	
Ingress Protection Rating:	IP21, Indoor Use Only	

Specifications are subject to change without notice.

This Blood Pressure Monitor complies with the European regulations and bears the CE mark"CE 0123".This blood pressure monitor also complies with mainly following standards (included but not limited):

Safety standard:

EN 60601-1 Medical electrical equipment part 1: General requirements for safety

EMC standard:

EN 60601-1-2 Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances – Requirements And Tests.

Performance standards:

IEC 81060-2-30, Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

EN 1060-3 Non-invasive sphygmomanometers – Supplementary requirements for electromechanical blood pressure measuring systems.

EN 1060-4 Non-invasive sphygmomanometers – Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.

ISO 81060-2, non-invasive sphygmomanometers – part 2: clinical validation of automated measurement type.

Correct Disposal of This Product (Waste Electrical & Electronic Equipment)
This marking shown on the product indicates that it should not be disposed with other household waste at the end of its life. To prevent potential harm to the environment or to human health, please separate this product from other types of wastes and recycle it responsibly. When disposing this type of product, contact the retailer where product was purchased or contact your local government office for details regarding how this item can be disposed in an environmentally safe recycling center.
Business users should contact their supplier and check the terms and conditions of the purchasing agreement. This product should not be mixed with other commercial wastes for disposal. This product is free of hazardous materials.

11. ELECTROMAGNETIC COMPATIBILITY INFORMATION

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the unit in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

Table 1

Guidance and declaration of manufacturer-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**
Radiated emission CISPR 11	Group 1, class B.	The device uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emission CISPR 11	Group 1, 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	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and declaration of manufacturer-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 ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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%.
Electrostatic transient/burst IEC 61000-4-4	±2 kV, 100 kHz, for AC power port	± 2 kV, 100 kHz, for AC power port	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV (differential mode)	±0.5 kV, ±1 kV (differential mode)	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% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° 0% UT; 250/300 cycle	0% UT; 0,5 cycle At 0°, 45°, 90°,135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz or 60Hz	30 A/m; 50Hz or 60Hz	Power frequency magnetic fields should be at levels charactertic of a typical location in a typical commercial or hospital environment.

Table 2

Guidance and declaration of manufacturer-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 EM fields IEC 61000-4-3	3 V/m or 10 V/m 80MHz-2.7 Ghz 80%AM at 1kHz	3 V/m or 10 V/m 80MHz-2.7 Ghz 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 applicable to the frequency of the transmitter. Recommended separation distance 80 MHz to 800 MHz 800 MHz to 2.7 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. Interference may occur in the vicinity of equipment marked with the following symbol:  .
Conducted disturbances Induced by RF fields IEC 61000-4-6	3 V in 0.15 MHz- 80 MHz 6 V in ISM and/or amateur radio bands between 0,15 MHz and 80 MHz 80 %AM at 1kHz	3 V w 0,15 MHz- 80 MHz 6 V w ISM and/or amateur radio bands between 0,15 MHz and 80 MHz 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 applicable to the frequency of the transmitter. Recommended separation distance 80 MHz to 800 MHz 800 MHz to 2.7 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. Interference may occur in the vicinity of equipment marked with the following symbol: .

Table 3

Guidance and declaration of manufacturer-electromagnetic immunity						
Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. Arm-type Fully Automatic Digital Blood Pressure Monitor has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this medical equipment and/or systems as recommended below.						
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380–390	TETRA 400	Pulse modulation 18Hz	1,8	0,3	27
450	430–470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0,3	28
710	704–787	LTE Band 13, 17	Pulse modulation 217Hz	0,2	0,3	9
745						
780						
810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0,3	28
870						
930						
1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0,3	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0,2	0,3	9
5500						
5785						

Table 4

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 therefore 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 (transmitters) 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]	
	80 MHz do 800 MHz $d=\left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz do 2,7 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0,01	0,12	0,23
0,1	0,38	0,73
1	1,2	2,3
10	3,8	7,3
100	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.

12. ADDITIONAL NOTES

Important Instructions Before Use

1. **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
2. **WARNING:** PORTABLE RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Arm-type Fully Automatic Digital Blood Pressure Monitor, including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment could result.

3. The software identifier refer to the software evaluation report , and the file code is **JYRJ201012001**.
4. Verify manometer pressure accuracy:
   In the power down state, press and hold the " START/STOP" button, and theninstall the batteries. Until the LCD screen is full, release the " START/STOP" button. When the LCD screen displays the double zero, the bloodpressure meter is in static state. At this point, 500ml gas capacity, calibrated standard pressure gauge and manual pressure device can be connected to the sphygmomanometer through the sleeve interface of the sphygmomanometer, and manual pressure can be applied to the effective display range of the sphygmomanometer, and then the difference between the reading of the sphygmomanometer and that of the standard pressure gauge can be compared. This mode can be used to verify manometer pressure accuracy.
5. **Contraindications**: Product is not intended for infants or individuals who cannot express their intentions.
6. **Intended Use:** The digital blood pressure monitor are reusable for clinical and home use and are non-invasive blood pressure measurement systems designed to measure the systolic and diastolic blood pressure and pulse rate of adolescents and adults individual by using a non-invasive technique, which is a well-known technique in the market called the "oscillometric method". it can measure the systolic blood pressure, diastolic blood pressure and pulse rated on up-arm,and the device is reusable for clinical or home use.
7. The patient is the operator:
   The PATIENT is an intended OPERATOR.
   The PATIENT Do not carry out other maintenance operations except to replace the battery.
8. **WARNING:** Do not modify this equipment without authorization of the manufacturer.
9. ESSENTIAL PERFORMANCE Maintenance advice:
   Pressure calibration will be carried out when this product leaves the factory. Patients can use the method described in the section "Verify Manometer Pressure Accuracy" to verify the accuracy. If the accuracy deviation is large, please contact the manufacturer to recalibration.
10. Mechanical strength and resistance to heat. The resistance to heat will be retained by device during the EXPECTED SERVICE LIFE of the ME EQUIPMENT
11. Do not place the blood pressure monitor and cuff at will. It will cause asphyxiation if the child swallows or twine around his neck.

12. The cuff and the case of the blood pressure monitor have been tested for biocompatibility and do not contain allergenic or harmful materials. Please stop using it if allergy occurs during use.
13. **WARNING:** Non-professionals do not modify the equipment, otherwise it will make the equipment measurement is not accurate.
14. **WARNING:** Do not expose the equipment for a long time, otherwise it will reduce the performance of the equipment.
15. **WARNING:** This device is not used for children and pets.
16. **Clean:** The equipment can be cleaned by lay operator according to the cleaning procedures in the instructions
17. **WARNING:** Do not use a damaged cuff for blood pressure measurement.
18. **WARNING:** When measuring with the cuff, if the tester feels seriously uncomfortable, press the "START/STOP" button of the blood pressure monitor to deflate the cuff, or remove the cuff directly from the arm.
19. **WARNING:** If an unexpected reading occurs, the operator can take several more measurements and consult a doctor.
20. **WARNING:** This equipment is used outside the specified environment, may damage the equipment, and may be inaccurate measurement.
21. ME equipment not intended for use in conjunction with flammable agents "ME equipment not intended for use in oxygen rich environment"

MAIN SERVICE Diagnosis S.A.
ul. Przemysłowa 8,
16-010 Wasilków, Poland
tel.: 85 874 60 45
serwis@diagnosis.pl

store stamp and signature of salesperson

DEVICE NAME:
Arm-type Fully Automatic Digital Blood Pressure Monitor
MODEL: **DBP-6191**
SERIAL NUMBER:.....
DATE OF SALE:.....

WARRANTY CARD

WARRANTY TERMS

1. Diagnosis S.A. grants a warranty:
- 2 years for blood pressure monitor DBP-6191
- 2 years for cuffs
- 1 year for power adapter

Hardware defects revealed during the warranty period will be rectified free of charge within 21 days. The term runs from the date of delivery of the equipment to the service center.

2. The purchaser shall be entitled to replace the equipment for a new one, free of defects, when:
- the repair has not been made within the time limit set in item 1
- an authorized service center found an irreparable manufacturing defect
- during the warranty period, 4 repairs were effected, and the equipment still shows defects that prevent its use in accordance with its intended purpose.

The concept of repair shall not include operations related to equipment check and cleaning.

3. The warranty shall not cover: batteries, products with illegible or damaged serial number, damage due to the operation and storage inconsistent with the user manual, ingress of liquids or foreign bodies, overvoltage of mains, repairs by unauthorized persons and random events.
4. Faulty equipment should be delivered by the buyer to the address of the main service center or one of the Authorized Service Centers (listed in the appendix).
5. The warranty for the sold consumer goods shall not exclude, restrict, or suspend the powers of the buyer resulting from non-conformity of the goods with the contract.
6. The only basis for the warranty rights shall be the warranty card with the date of sale, stamp and signature of the salesperson. If the card is not completed, filled in wrongly, with traces of corrections and entries made by unauthorized persons, illegible as a result of damage – it shall be invalid.

NOTE: Before sending the device for repair, please clean it first from all kinds of dirt.

DOOR TO DOOR WARRANTY INFORMATION

This warranty applies to products labelled "DOOR TO DOOR WARRANTY"

1. The warranty, under the terms and conditions set out in this card, is provided by Diagnosis S.A., with registered office under the address: ul. Gen. W. Andersa 38A, 15-113 Białystok, Poland (hereinafter referred to as the "Warrantor").
2. This card sets out the terms and conditions of the DOOR TO DOOR WARRANTY, which is an additional warranty that in no way limits or waives the basic warranty provided by Guarantor.
3. This warranty applies to individual customers - Consumers.
4. The warranty is valid only in the territory of the Republic of Poland.
5. This warranty for the consumer goods sold does not exclude, limit or suspend the purchaser's rights arising from the non-conformity of the goods with the contract.

How to get warranty service?

- if your **warranty product** is defective, please contact us at **800 70 30 11** or our service centre at **85 874 60 45** or fill out the **online form** at **www.diagnosis.pl** with a detailed description of the problem
- the service technician will determine whether the entire unit needs to be replaced or just the defective component
- provide the service technician with the necessary details for the courier to collect your equipment (name and surname, address for collection, telephone number)
- **prepare the parcel** – pack and secure the faulty unit together with the **warranty card, proof of purchase and a hand-written description of the fault**.

IMPORTANT: do not return any items or accessories that are not the subject of the complaint, e.g. batteries, masks, mouthpieces, mains adapters, etc. The device in question should be clean and odourless – otherwise it may not be repaired.

- equipment received will be repaired and returned to the same address within 21 days.

NOTES ON INSPECTIONS AND REPAIRS

Pos.	Notification date	Repair date	Warranty extended to	Description of activities	Contractor's stamp and signature

Document No. : JDBP-9104-002
Version: A
Date of Issue: 2023.01

CE 0123

The product is in compliance with the requirements of the Regulation (EU) 2017/745 MDR on medical device, „0123" is the identification number of notify body.

Manufacturing address

JOYTECH Healthcare Co., Ltd.
No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, China

European Authorized Representative

EC REP
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Importer and after-sales service

Diagnosis S.A.
ul. Gen. W. Andersa 38A
15-113 Białystok, Poland
www.diagnosis.pl

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