

Owner's Manual

Wrist-type Fully Automatic Blood Pressure Monitor

Model BP2116



Document No.
Version: REV03.02.22.16

Contact Information

The lay operator or lay responsible organization should contact the manufacturer or the representative of manufacturer.
-for assistance, if needed, in setting up, using or maintaining the product, or
-to report unexpected operation or events.

 Drive Medical
99 Seaview Blvd
Port Washington, NY 11050
Toll-Free 877-224-0946
www.drivemedical.com



Contents

1

Safety Notice	02
Unit Illustration	06
Important Testing Guidelines	09
Quick Start	10
Unit Operation	12
Battery Installation	12
System Settings	13
Applying The Wrist Monitor	15
Testing	17
Power Off	21
Memory Check	22
Memory Deletion	23
Low Battery Indicator	24
Troubleshooting	25
Blood Pressure Information	26
Blood Pressure Q & A	30
Maintenance	32
Specifications	36
Warranty	40

Safety Notice

2

Thank you for purchasing the BP2116 Blood Pressure Monitor. The unit has been constructed using reliable circuitry and durable materials. Used properly, this unit will provide years of satisfactory use.

The device is intended for use by individuals 12 years and older to measure the systolic and diastolic blood pressure and pulse rate. All values can be read out in one LCD DISPLAY.

Blood pressure measurement determined with this device are equivalent to those obtained by a trained observer using the cuff/ stethoscope auscultation method, within the limits prescribed by the American National Standard (ANSI/AAMI Sp10) for electronic sphygmomanometers.

Precautions to Ensure Safe, Reliable Operation

1. Do not drop the unit. Protect it from sudden jars or shocks.
2. Do not insert foreign objects into any openings.
3. Do not attempt to disassemble the unit.
4. Do not crush the pressure cuff.
5. If the unit has been stored at temperatures below 0 °C, leave it in a warm place for about 15 minutes before using it. Otherwise, the cuff may not inflate properly.
6. Do not store the unit in direct sunlight, high humidity or dust.
7. To avoid any possibility of accidental strangulation, keep this unit away from children and do not drape tubing around your neck.
8. Ensure that children do not use the instrument unsupervised; some parts are small enough to be swallowed.
9. Some may get a skin irritation from the cuff taking frequent readings over the course of the day, but this irritation typically goes away on its own after the monitor is removed.

Safety Notice

3

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.



Safety Notice

4

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.

Unit Illustration

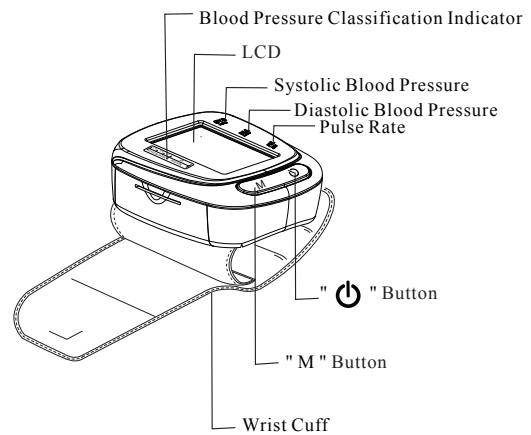
5

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. Any hazards associated with prolonged overinflation of the bladder.
18. Do not disassemble the unit or wrist cuff. Do not attempt to repair.
19. Use only the approved wrist cuff for this unit. Use of other wrist 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 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.
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.  Refer to instruction manual/ booklet symbol.
29.  Refer to keep dry.

Unit Illustration

6

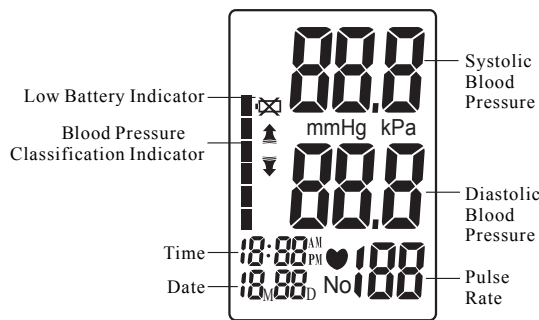
Monitor Unit



Unit Illustration

7

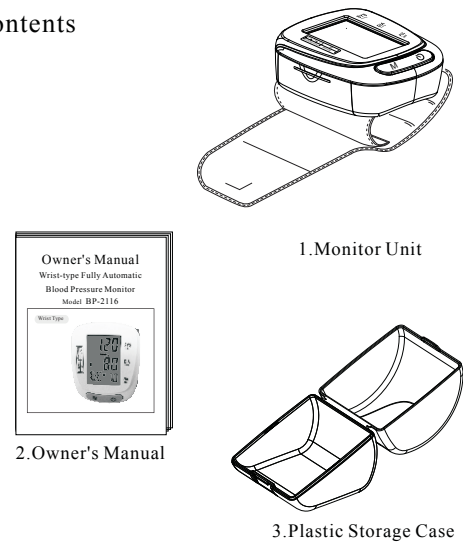
Display



Unit Illustration

8

Contents



Important Testing Guidelines

9

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 wrist 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 wrist, in the same position, and at the same time of day.
9. This blood pressure monitor is not recommended for people with severe arrhythmia.

Any blood pressure recording can be affected by the following factors:

1. The position of the subject, his or her physiologic condition;
2. The performance and accuracy of the device;
3. Cuff size: too small cuff (bladder) will produce a higher blood pressure value than usual, too big cuff (bladder) will produce a lower blood pressure value;
4. Measuring position does not keep level with your heart;
5. Speaking or moving body parts while testing;
6. Not relaxing for about 5 minutes before taking the measurement.

Quick Start

10

1. Install batteries. (See Figure A)



2. Remove clothing from the wrist area. (See Figure B)
3. Rest for several minutes prior to testing. Wrap cuff around left wrist. (See Figure C)

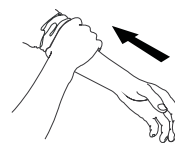


Figure B

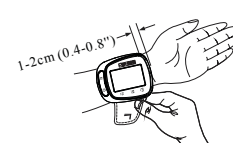


Figure C

Quick Start

11

4. Sit in a comfortable position and place wrist level with heart.
(See Figure D)
5. Press "⏻" button to start testing. (See Figure E)



Figure D

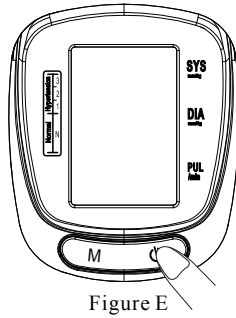


Figure E

Unit Operation

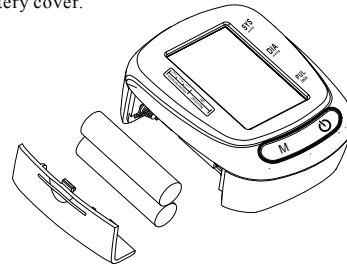
12

Battery Installation

Slide battery cover off as indicated by arrow.

Install 2 new AAA alkaline batteries according to polarity.

Close battery cover.



Note:

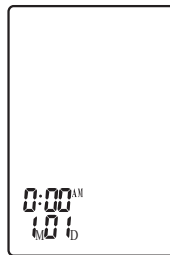
- 1) Replace batteries when Low Battery Indicator "⊗" appears on screen.
- 2) Batteries should be removed from device when not in operation for an extended period of time.

Unit Operation

13

1. Time /Date Setting

With power off, Press "⏻" button 3 seconds to set the Time/Date mode. Set the month first by adjusting the "M" button. Press "⏻" button again to confirm current month. Continue setting the day, hour and minute in the same way. Every time the "⏻" button is pressed, it will lock in your selection and continue in succession (month, day, hour, minute.)



Unit Operation

14

2. Save Settings

While in any setting mode, press "⏻" button about 3seconds to turn the unit off. All information will be saved.

Note: Unit will automatically save all information and shut off if left it for 3 minutes.

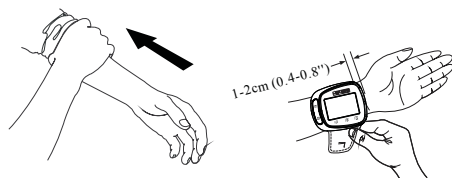
Unit Operation

15

Applying The Wrist Monitor

Do not apply over clothing. If wearing a long sleeved shirt, be sure to roll sleeve back to forearm.

Apply monitor to wrist as illustrated. Tighten cuff firmly as not to wiggle.



Unit Operation

16

Do not stand while testing. Sit in a comfortable position and place wrist level with heart.



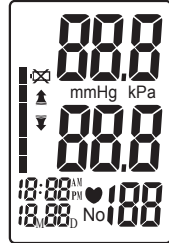
Unit Operation

17

Testing

1. Power On

Press and hold "⏻" button until a beep sounds. The LCD screen will appear for one second as unit performs a quick diagnosis. A long tone indicates device is ready for testing.



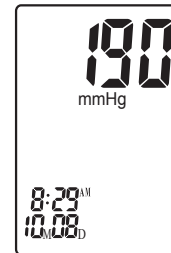
Note: Unit will not function if residual air from previous testing is present in cuff. The LCD will flash "▼" until pressure is stabilized.

Unit Operation

18

2. Pressurization

Initial pressure is first pumped to 190mmHg. If the current user's systolic blood pressure is over 190mmHg, the unit will automatically re-inflate to the proper shelf.



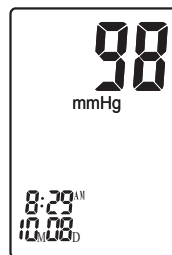
Note: Pressurization will gradually subside and ultimately stop when cuff is not properly applied to the wrist. If this occurs, pressing the "⏻" button to turn the unit off.

Unit Operation

19

3. Testing

After cuff inflation, air will slowly subside as indicated by the corresponding cuff pressure value. A flashing "♥" will appear simultaneously on screen signaling heart beat detection.



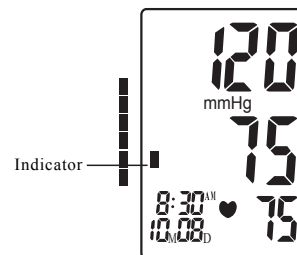
Note: Remain relaxed during testing. Avoid speaking or moving body parts.

Unit Operation

20

4. Result Display

Three short beeps sound when testing is complete. The screen will display measurements for systolic and diastolic blood pressure. An indicator representing the current measurement will appear.



Unit Operation

21

Power Off

The "⏻" button can be pressed to turn off the unit in any mode.

The unit can turn off the power itself in about 3 minutes with no operation in any mode.

⚠ Safety Precaution: If pressure in cuff becomes too extreme while testing, press the "⏻" button to turn power off.

The cuff pressure will rapidly dissipate once the unit is off.

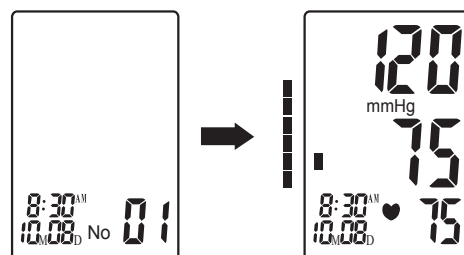
Unit Operation

22

Memory Check

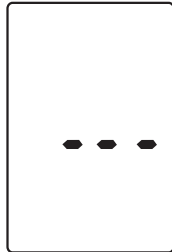
With power off, you may check past test results by using the "M" button.

Upon activating test results, you can press the "M" button to scroll through all test results stored in memory. The LCD will display the last measurement memory as NO 01 reading.



Memory Deletion

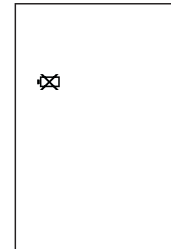
Memory may be deleted while in Memory Check mode. Press and hold the "⏻" button for approximately 3 seconds to delete all memory records. The monitor will beep indicating successful deletion and then transfer into testing mode. Then press the "⏻" button to turn the unit off.



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

Low Battery Indicator

4 short warning beeps sound when battery life is depleting and unable to inflate cuff for testing. The "⊗" appears simultaneously for approximately 5 seconds prior to shutting down. Replace batteries at this time. No memory loss will occur throughout this process.



Troubleshooting

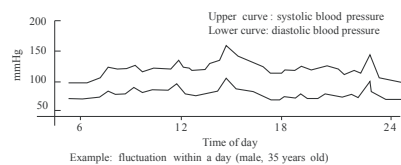
Problem	Possible Cause	Solution
Blood pressure results are not within typical range	Cuff is too tight or not properly positioned on the wrist	Firmly reposition cuff on wrist making sure no wiggle is present. (See Page 15)
	Inaccurate test results due to body movement or monitor movement	Sit in a relaxed position placing wrist level with heart. Avoid speaking or moving body parts while testing. (See Page 8)
"Err" displayed	Cuff fails to inflate properly	Make sure hose is properly fastened to cuff and monitor unit
	Improper operation	Read user manual carefully and re-test properly.
	Pressurization is over 300mmHg	Read user manual carefully and re-test properly.

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.

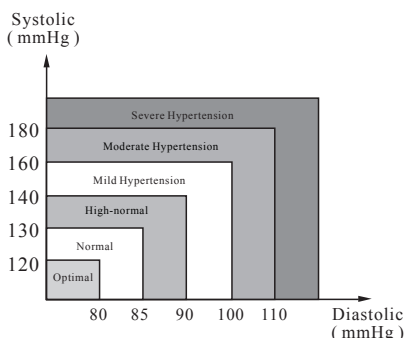
An individual's blood pressure frequently changes throughout the course of a day. Excitement and tension can cause blood pressure to rise, while drinking alcohol and bathing can lower blood pressure. Certain hormones like adrenaline (which your body releases under stress) can cause blood vessels to constrict, leading to a rise in blood pressure.

If these measuring numbers become too high, it means the heart is working harder than it should.



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 the early stages.



Note: Do not be alarmed if an abnormal reading occurs. A 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.

Blood Pressure Q & A

29

- 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.
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.

Blood Pressure Q & A

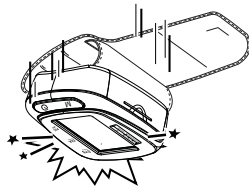
30

- 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 wrist? What is the difference?
- A: Either wrist can be used when testing, however, when comparing results, the same wrist should be used. Testing on your left wrist 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.

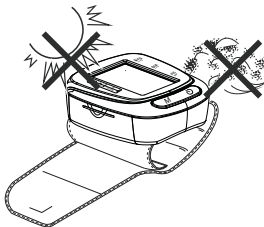
Maintenance

31

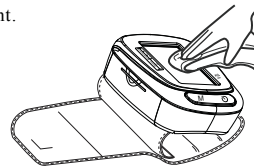
1. Avoid dropping, slamming, or throwing the unit.



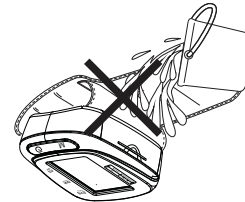
2. Avoid extreme temperatures. Do not use outdoors.



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



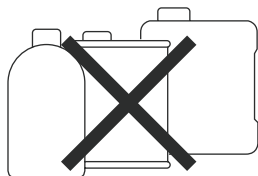
4. Cuff Cleaning: Do not soak cuff in water! Apply a small amount of rubbing alcohol to a soft cloth to clean cuff's surface. Use a damp cloth (water-based) to wipe clean. Allow cuff to dry naturally at room temperature.



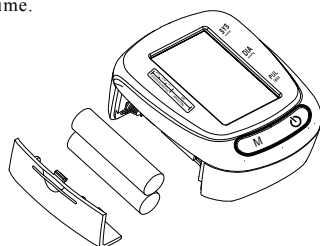
Maintenance

33

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



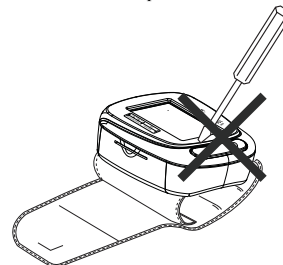
6. Remove batteries when not in operation for an extended period of time.



Maintenance

34

7. Do not disassemble product.



8. It is recommended the performance should be checked every 2 years.
9. Expected service life: Approximately three years at 10 tests per day.


Maintenance

35

Product Description	Wrist-type Fully Automatic Blood Pressure Monitor	
Model	BP-2116	
Display	LCD Digital Display Size:45mmx30mm	
Measurement Method	Oscillometric Method	
Measurement Range	Pressure	0mmHg ~ 300mmHg
	Pulse	30 to 180 Beats/Minute
Measurement Accuracy	Pressure	±3mmHg or ±2% of the reading above 200 mmHg
	Pulse	±5%
Pressurization	Automatic Pressurization	
Memory	120 Memories with Date and Time	
Function	Low Battery Detection	
	Automatic Power-Off	

Specifications

36

Power Source	2 Alkaline Batteries Size AAA	
Battery Life	Approximately 2 months at 3 tests per day	
Unit Weight	Approx. 228g (8 oz.)(Excluding Battery)	
Unit Dimensions	Approx. 79 x 66 x 28mm	
Cuff Circumference	Approx. 75 (W)×300(L) mm	
	Fits wrist circumference 13.5-21.5 cm(5.3"-8.5")	
Operating Environment	Temperature	10°C ~ 40°C (50ℳ ~104ℳ)
	Humidity	15% ~ 90% RH
Storage Environment	Temperature	-20°C~55°C (-4ℳ ~131ℳ)
	Humidity	15% ~ 90% RH
Classification	Internal Powered Equipment, Type BF 	

Specifications are subject to change without notice.

Specifications

37

International Standards:
 AAMI / ANSI SP10:2002/(R) 2008 & 2002/A1:2003/(R)2008 & 2002/A2:2006/(R)2008
 Manual, electronic, or automated sphygmomanometers
 European Directive 93/42 EEC for Medical Products Act
 EN 60601-1 Medical electrical equipment part 1: General requirements for safety
 EN 60601-1-2 Medical electrical equipment part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility- Requirements and tests
 EN 1060-1 Non-invasive sphygmomanometers - General requirements
 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.

Specifications

38

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.

Warranty

40

The Blood Pressure Monitor has been carefully manufactured and inspected and is warranted to be free from defectives in workmanship and materials. Under this warranty, Drive Medical's obligation shall be limited to the replacement or repair of any such units which prove, by Drive Medical's inspection, to be defective within two years from the original purchase date. This warranty is not transferrable or assignable to any subsequent purchaser or owner. Any abuse, operation other than the intended use of this product as outlined in the manual, negligence, accident, or repairs by someone other than a Drive Medical Authorized Service Professional, shall immediately void this warranty.

Drive Medical will not accept damages or charges for labor, parts, or expenses incurred in making field repairs.

The foregoing warranty is exclusive and in lieu of all other expressed warranties. Implied warranties, if any, including but not limited to the implied warranties of merchantability and fitness for a particular purpose, shall not extend beyond the duration of the express warranty provided herein. In no event shall Drive Medical or its subsidiaries be liable for loss of use or profit or other collateral, special or consequential damages.

41