EN

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EN Instruction for use

PRO-39

Automatic Blood Pressure Monitor

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1. INTRODUCTION

Thank you for purchasing the B.Well Wrist Blood Pressure Monitor PRO-39. Designed for convenient and easy operation, this device provides fast and reliable measurement of systolic and diastolic blood pressure as well as heart rate using the oscillometric measurement method.
The PRO-39 is a fully automatic, digital, wrist blood pressure measuring device.
Intended use: The Blood Pressure Monitor PRO-39 including accessories is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using the oscillometric measurement method.
Application area: for use by medical professionals or at home.

Important advantages of PRO-39:

- Up-to-date IntellectClassic technology uses oscillometric measurement during deflation for quick, precise and painless result.
- The Pulse Arrhythmia Detection technology.
- Last measurement memory.
- This device has been proven in clinical studies to provide excellent accuracy.

2. CLASSIFICATION OF BLOOD PRESSURE VALUES

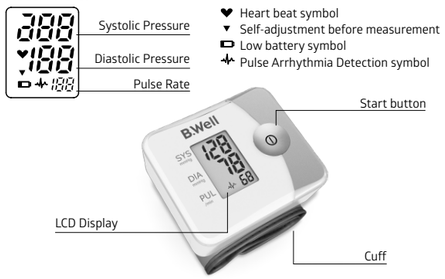
Table for classifying blood pressure values (mmHg) according to European Society of Hypertension (ESH)

Range	Systolic blood pressure	Diastolic blood pressure	Measures
Grade 3: severe hypertension	Higher or equal to 180	Higher or equal to 110	Urgently seek medical advice!
Grade 2: moderate hypertension	160-179	100-109	Consult your doctor immediately
Grade 1: mild hypertension	140-159	90-99	Consult your doctor
High normal	130-139	85-89	Consult your doctor
Normal	Lower than 130	Lower than 85	Self-check
Optimal	Lower than 120	Lower than 80	Self-check

ⓘ **NOTE:** Show the measured values to your doctor. Never use the results of your measurements to change the doses of drugs prescribed by your doctor.

3. CONTENTS AND DISPLAY INDICATORS

Model PRO-39



4. CONTRAINDICATION

Do not use the device if there is a skin surface damage on the wrist. It is inappropriate for people with serious arrhythmia to use this device.

5. PRECAUTIONS

1. Read all of the information in the instruction for use before operating the unit.
2. Stay still, calm and rest for 5 minutes before blood pressure measurement.
3. The cuff should be placed at the same level as your heart.
4. During measurement, neither speak nor move your body and arm.
5. Measuring on both arms for each measurement. Hereafter measurement should be done on the arm where the blood pressure is higher.
6. Please always relax about 5 minutes between measurements to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceed 300 mmHg or maintained above15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your arm.
7. Consult your physician if you have any doubt about below cases:
   1) The application of the cuff over a wound or inflammation diseases;
   2) The application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present;
   3) The application of the cuff on the arm on the side of a mastectomy;
   4) Simultaneously used with other monitoring medical equipments on the same limb;
   5) The usage by a person with a cardiac pacemaker. The device does not affect the cardiac pacemaker. However, if there is a serious arrhythmia or a low pulse, the measurement results may be inaccurate.
8. ⚠ This digital automatic blood pressure monitor is designed for adults and should never be used on infants or young children. Consult your physician or other health care professionals before use on older children.
9. Do not use this unit in a moving vehicle.
10. Blood pressure measurements determined by this monitor are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard Institute, Electronic or automated sphygmomanometers.
11. Information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices together with advice regarding avoidance of such interference please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION.
12. Please do not use the cuff other than supplied by the manufacturer, otherwise it may cause biocompatible hazard and might result in measurement error.
13. ⚠ The monitor might not meet its performance specifications or cause safety hazard if stored or used outside the specified temperature and humidity ranges in specifications.
14. ⚠ Please do not share the cuff with other infective person to avoid cross-infection.
15. Please note that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
16. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
   — Reorient or relocate the receiving antenna.
   — Increase the separation between the equipment and receiver.
   — Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
   — Consult the dealer or an experienced radio/TV technician for help.

6. SETUP AND OPERATING PROCEDURES

6.1. Battery loading

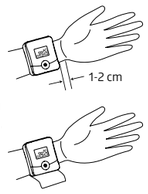
a. Open battery cover at the back of the monitor.
b. Load two "AAA" size batteries. Please pay attention to polarity.
c. Close the battery cover.
d. Once you install the batteries or turn off the monitor, the LCD does not display anything. Now the monitor is in Off.

⚠ If the LCD displays low battery symbol, the batteries are running out and should be replaced with new ones.
⚠ Rechargeable batteries are not suitable for this monitor.
⚠ Remove the batteries if the monitor will not be used for a month or more to avoid relevant damage of battery leakage.
⚠ Avoid the battery fluid to get in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.

The monitor, the batteries and the cuff, must be disposed of according to local regulations at the end of their usage.

6.2. Applying the cuff

a. Place the cuff around a bare wrist 1-2cm above the wrist joint on the palm side of the wrist.
b. Place the arm with the cuffed wrist in front of your body on a desk or table with the palm up. If the cuff is correctly placed, you can read the LCD display.
c. The cuff must be neither too tight nor too loose. At the same time, there must be no free space between the cuff and the wrist.

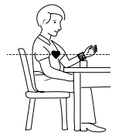


6.3. Carrying out a measurement

Before the measurement:

- Avoid eating, smoking as well as all forms of exertion directly before the measurement. All these factors influence the measurement result. Try and find time to relax by sitting in an armchair in a quiet atmosphere for about five to ten minutes before the measurement.
- Measure always on the same arm.
- Attempt to carry out the measurements regularly at the same time of day, since the blood pressure changes during the course of the day.

Body posture during measurement



Be seated with your feet flat on the floor, and don't cross your legs.

The first way to measure

a. Place palm upside in front of you on a flat surface such as a desk or table.
b. Place something under your arm (for example, the monitor storage bag) so that the middle of the cuff was at the level of the heart. Make sure that the cuff is not pressed by anything.

The second way to measure

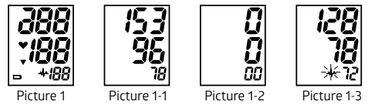
a. Use the free hand to take the elbow of the arm with the blood pressure monitor.
b. Place the arm with the monitor so that the palm of the arm would be next to the opposite shoulder, and the monitor - at the level of the heart.
c. Make sure that you see the display of the monitor. Relax your wrist joint and wrist (do not move your wrist forward or back, do not clench into a fist).

Common sources of error:

- Movement during measurement
- The monitor is not at the level of the heart
- The cuff does not fit you in size
- Loose cuff

6.4. Taking your blood pressure reading

a. After applying the cuff and your body is in a comfortable position, press the "START" button. All display characters are shown for self-test (Picture 1). Please contact the service center if any segment is missing on the display.
b. The LCD will momentarily display the result of last measurement. See picture 1-1. After the new power the LCD will momentarily display 0.See picture 1-2.



Picture 1 Picture 1-1 Picture 1-2 Picture 1-3

c. Then the monitor inflates the cuff until sufficient pressure has built up for a measurement. Then the monitor slowly releases air from the cuff and carries out the measurement. Finally the blood pressure and pulse rate will be calculated and displayed on the LCD screen. Irregular heartbeat symbol (if any) will blink on the screen. See picture 1-3.
d. After measurement, the monitor will turn off automatically after 1 minute of no operation. Alternatively, you can press the "START" button to turn off the monitor manually.
e. During measurement, you can press the "START" button to turn off the monitor manually.

ⓘ **NOTE:** The monitor can memorize the last result. If you change the batteries, the last result will not be saved.

ⓘ **NOTE:** Please consult a health care professional for interpretation of pressure measurements.

6.5. Pulse Arrhythmia Detection

Appearance of the Pulse Arrhythmia Detection

Symbol means that a certain pulse irregularity was detected during the measurement. In this case, the result can vary from your actual blood pressure that's why you should rest for 15 minutes and repeat the measurement.
The appearance of symbol is accompanied by a sound signal. As a rule this is not a cause for concern; however, if the symbol appears more frequently, we recommend you inform your doctor. The monitor does not replace the cardiological examination, but it allows you to detect the arrhythmia even in early stages.

6.6. Technical alarm description

The monitor will show 'HI' or 'Lo' as technical alarm on LCD with no delay if the determined blood pressure (systolic or diastolic) is outside the rated range specified in part SPECIFICACIONS. In this case, you should consult a physician or check if your operation violated the instructions.
The technical alarm condition (outside the rated range) is preset in the factory and cannot be adjusted or inactivated. This alarm condition is assigned as low priority according to IEC 60601-1-8. The technical alarm is non-latching and need no reset. The signal displayed on LCD will disappear automatically after about 8 seconds.

6.7. Troubleshooting (1)

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD Display shows abnormal result	The cuff position was not correct or it was not properly tightened	Apply the cuff correctly and try again
	Body posture was not correct during testing	Review the "BODY POSTURE DURING MEASUREMENT" sections of the instructions and re-test
	Speaking, arm or body movement, angry, excited or nervous during testing	Re-test when calm and without speaking or moving during the test
	Irregular heartbeat (arrhythmia)	It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer

6.8. Troubleshooting (2)

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD shows low battery symbol	Low Battery	Change the batteries
LCD shows "Er 0"	Pressure system is unstable before measurement	Don't move and try again
LCD shows "Er 1"	Fail to detect systolic pressure	
LCD shows "Er 2"	Fail to detect diastolic pressure	
LCD shows "Er 3"	Pneumatic system blocked or cuff is too tight during inflation	Apply the cuff correctly and try again
LCD shows "Er 4"	Pneumatic system leakage or cuff is too loose during inflation	
LCD shows "Er 5"	Cuff pressure above 300 mmHg	Measure again after five minutes. If the monitor is still abnormal, please contact the local distributor or the factory
LCD shows "Er 6"	More than 3 minutes with cuff pressure above 15 mmHg	
LCD shows "Er 7"	EEPROM accessing error	
LCD shows "Er 8"	Device parameter checking error	
LCD shows "Er A"	Pressure sensor parameter error	
No response when you press button or load battery	Incorrect operation or strong electromagnetic interference	Take out batteries for five minutes, and then reinstall all batteries

7. MAINTENANCE

1. ⚠ Do not drop this monitor or subject it to strong impact.
2. ⚠ Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.
3. If this monitor is stored near freezing, allow it to acclimate to room temperature before use.
4. ⚠ Do not attempt to disassemble this monitor and do not disconnect the cuff from the monitor.
5. If you do not use the moitor for a long time, please remove the batteries.
6. It is recommended the performance should be checked every 2 years or after it has been dropped. Please contact the service center.
7. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water or diluted detergent.
8. Keep the cuff clean. It is recommended the cuff should be disinfected 2 times every week if needed (For example, in hospital or in clinic). Wipe the inner side (the side contacts skin) of the cuff by a soft cloth squeezed after moistened with a 3 % solution of hydrogen peroxide, then dry the cuff by airing.
9. No component can be maintained by user in the monitor.
10. The external surfaces of the blood pressure monitors and the cuff are resistant to disinfection with a 3% solution of hydrogen peroxide.

8. SPECIFICATIONS

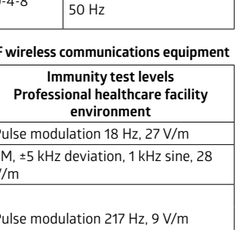
1. Product name: Wrist Blood Pressure Monitor, model: PRO-39
2. Classification: Internally powered, Type BF applied part, IP22, No AP or APG, Continuous operation
3. Machine size: Approx. 73 mm×62 mm×28,5 mm (2 7/8"x 2 1/2"x 1 1/8")
4. Wrist cuff circumference: 14cm-19.5cm(approx.5 1/2"-7 11/16")
5. Weight: not more than 69,3 g ± 10% (exclude batteries)
6. Measuring method: Oscillometric method, automatic inflation and measurement
7. Memory Capacity: The last measurement is saved.
8. Power source: batteries: 2 ×1.5V ⎓ SIZE AAA
9. Measurement range: Cuff pressure: 0-300 mmHg, systolic: 60-280 mmHg, diastolic: 20-199 mmHg, pulse rate: 40-200 beats/minute.
10. Accuracy: pressure: ±3mmHg, pulse rate: ±5%.
11. Environmental temperature for operation: 10°C~40°C (50°F~104°F).
12. Environmental humidity for operation: ≤85% RH.
13. Environmental temperature for storage and transport: -20°C~70°C (-4°F~122°F).
14. Environmental humidity for storage and transport: ≤85% RH.
15. Environmental pressure: 80kPa-105kPa.
16. Battery life: Approx 270 times.
17. Blood pressure monitor set: blood pressure monitor – 1 piece, wrist cuff – 1 piece, bladder – 1 piece, AAA batteries – 2 pieces, the instruction manual – 1 piece, box – 1 piece, a storage bag – 1 piece.

ⓘ **NOTE:** These specifications are subject to change without notice.

9. APPLIED STANDARDS

The digital automatic blood pressure monitor corresponds to the below standards:
IEC 60601-1:2005/EN 60601-1:2006/AC:2010 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance),
IEC60601-1-2:2007/EN 60601-1-2:2007 /AC:2010 (Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests),
IEC 80601-2-30 : 2009+Cor.2010 (Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers),
EN 1060-1: 1995 + A1: 2002 + A2: 2009 (Non-invasive sphygmomanometers – Part 1: General requirements),
EN 1060-3: 1997 + A1: 2005 + A2: 2009 (Non-invasive sphygmomanometers – Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems).

10. SYMBOL INFORMATION



11. WARRANTY INFORMATION

Warranty period is 3 years from the date of purchase for monitor and 1 year for cuff. This warranty doesn't cover any damages caused by improper using, and also battery, and packaging. When a manufacturing defect is revealed during the warranty period a faulty unit would be repaired or, if repairing is impossible, replaced with another one.
Manufacturing date is in a serial number: WWYYXXXXX.
The manufacturer may change units partially or completely if necessary, without prior notice.

12. ELECTROMAGNETIC COMPATIBILITY INFORMATION

For all ME EQUIPMENT and ME SYSTEMS

Table 1 – Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Home healthcare environment

Table 2 – Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM field	IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1k Hz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels Professional healthcare facility environment
385	380-390	Pulse modulation 18 Hz, 27 V/m
450	430-470	FM, ±5 kHz deviation, 1 kHz sine, 28 V/m
710	704-787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800-960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700-1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217 Hz, 28 V/m
5240	5100-5800	Pulse modulation 217 Hz, 28 V/m
5500		
5785		

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