

PRO-33

Automatic Upper Arm
Blood Pressure Monitor



1. INTRODUCTION

Thank you for purchasing the B.Well upper arm blood pressure monitor PRO-33. 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-33 is a fully automatic, digital, upper arm blood pressure measuring device.

Important advantages of PRO-33

- Up-to-date IntellectClassic technology uses oscillometric measurement during deflation for quick, precise and painless result.
- The Pulse Arrhythmia Detection technology.
- Last measurement memory for PRO-33.
- Fan-shape anatomic cuff for arm, washable.
- The possibility to use mains adapter.
- This device is easy to use and has been proven in clinical studies to provide excellent accuracy.

2. CLASSIFICATION OF BLOOD PRESSURE VALUES

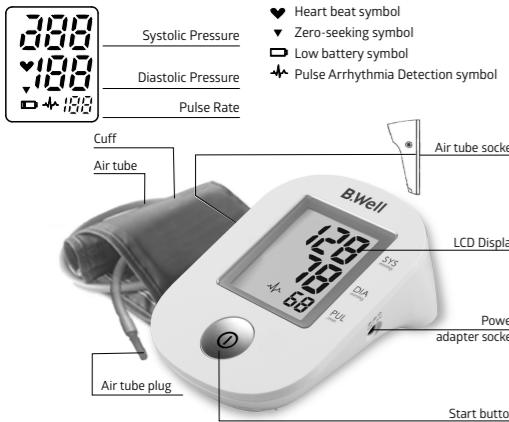
Table for classifying blood pressure values (mmHg) according to European Society of Hypertension (ESH)

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

① 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-33



4. INTENDED USE

The digital automatic blood pressure monitor is intended to be used by medical professionals or at home and is a non-invasive blood pressure measurement system designed to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-42cm.

5. CONTRAINDICATION

It is inappropriate for people with serious arrhythmia to use the digital automatic blood pressure monitor.

6. PRECAUTIONS

1. Read all of the information in the user's manual and any other literature in the box before operating the unit.
2. Rest, stay still and calm 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 left arm for each measurement.
6. Please take a break between measurements for a minimum of 1-1.5 minutes to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceed 300 mmHg or maintained above 15 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) Need to check the blood circulation of the user.
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 medical staff before use on older children.

9. Do not use this unit in a moving vehicle. This may result in erroneous measurement.
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 the advice to avoid such interference please see the part ELECTROMAGNETIC COMPATIBILITY INFORMATION.
12. Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring 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.
17. If this complete set did not include the mains adapter, it can be got separately. Use only the adapter AD-155. The AC adapter which output is DC 6.0V 600mA and complied with IEC 60601-1/EN 60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2/UL 60601-2. You shouldn't use any other adapter model.

7.6. Taking your blood pressure reading (Picture 1, 1-1, 1-2, 1-3, 1-4)
After applying the cuff and your body is in a comfortable position, press the "START" button.
A beep is heard and all display characters are shown for self-test. See picture 1. Please contact the service center if segment is missing.
a. The LCD will momentarily display the last measurement stored in the memory. See picture 1-1. If the monitor has no measurement stored in the memory, the LCD will show "0" for blood pressure and pulse rate. See picture 1-2.

Lying Down Measurement

- b. Place your left arm straight along your side with your palm upside.
- c. The cuff should be placed at the same level as your heart.
- d. Lie on your back.
- e. Place your left arm straight along your side with your palm upside.
- f. The cuff should be placed at the same level as your heart.
5. It is recommended that the performance should be checked every 2 years or after repair. Please contact the service center.
6. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
7. No component can be maintained by the user of the monitor.
8. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is maintained after 1,000 open-close cycles of the fastener.
9. 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 Ethyl alcohol (75-90%), then dry the cuff by airing.
- The cuff cover can be hand-washed at 30°C. Remove the bladder beforehand through the special technological hole in the cover.

⚠ WARNING! Do not wash the bladder! Do not iron the cover!
The technological hole does not need to be sewn up!

9. SPECIFICATIONS

1. Product name: Blood Pressure Monitor, model: PRO-33
2. Classification: Internally powered, Type BF applied part, IPX0, No AP or APG, Continuous operation
3. Machine size: 87mm x 122mm x 53mm (3 7/16" x 4 13/16" x 2 3/32")
4. Cuff circumference: 22cm-42cm (8 21/32"-16 17/32") or 22cm-32cm (8 21/32"-12 19/32") (depends on the set of the device)
5. Weight: approx. 200g (6 3/4 oz.) (excluding batteries and cuff)
6. Measurement method: oscillometric method, automatic air inflation and measurement
7. Memory volume: only the last measurement stored in the memory
8. Power source: DC 6V 600mA, batteries: 4 x 1.5V SIZE AAA Mains adapter (optional)
9. Measurement range:
cuff pressure: 0-300mmHg,
systolic: 60-260mmHg,
diastolic: 40-199mmHg,
pulse rate: 40-180 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-50°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:
M-L size's fan shape cuff (upper arm circumference 22-42 cm)
or M size's fan shape cuff (upper arm circumference 22-32 cm) (depending on picking of the device),
a storage bag,
AAA batteries - 4 pieces,
the mains adapter (if it is included in picking),
the instruction manual.

② Note: Please consult a health care professional for interpretation of pressure measurements.
③ Note: The monitor can memorize the last result. If you change the batteries, the last result will be saved.

7.7. Pulse Arrhythmia Detection

The appearance of the symbol  indicates that a certain pulse irregularity was detected during the measurement. The result can vary from your normal blood pressure. Usually this is not a cause for concern; however, if the symbol  appears more frequently (e.g. several times per week on measurements performed daily) or if it suddenly appears more often than usual, we recommend you inform your doctor.

7.8. 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 SPECIFICATIONS. In this case, you should consult a physician or check if your operation has 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.

7.9. Troubleshooting (1)

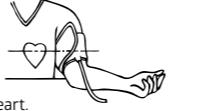
PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD Display shows abnormal result	The cuff position was not correct or it was not properly tightened Body posture was not correct during testing Speaking, arm or body movement, angry, excited or nervous during testing Irregular heartbeat (arrhythmia)	Apply the cuff correctly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

7.10. 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	
LCD shows "Er 1"	Fail to detect systolic pressure	Don't move and try again.
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 300mmHg	
LCD shows "Er 6"	More than 3 minutes with cuff pressure above 15mmHg	Measure again after five minutes. If the monitor is still abnormal, please contact the local distributor or the factory.
LCD shows "Er 7"	EEROM 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.

8. 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 in cold, allow it to acclimate to room temperature before use.
4. Do not attempt to disassemble this monitor.



5. It is recommended that the performance should be checked every 2 years or after repair. Please contact the service center.
6. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
7. No component can be maintained by the user of the monitor.
8. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is maintained after 1,000 open-close cycles of the fastener.
9. 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 Ethyl alcohol (75-90%), then dry the cuff by airing.
- The cuff cover can be hand-washed at 30°C. Remove the bladder beforehand through the special technological hole in the cover.

⚠ WARNING! Do not wash the bladder! Do not iron the cover!
The technological hole does not need to be sewn up!

13. ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1
For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The PRO-33 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PRO-33 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
For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	+ 2 kV for power supply lines + 1 kV for input/ output lines	+ 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be