

PRO-35

Automatic Upper Arm
Blood Pressure Monitor



1. INTRODUCTION

Thank you for purchasing the B.Well upper arm blood pressure monitor PRO-35. 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-35 is a fully automatic, digital, upper arm blood pressure measuring device.

Important advantages of PRO-35

- Up-to-date IntellectClassic technology uses oscillometric measurement during deflation for quick, precise and painless result.
- The Pulse Arrhythmia Detection technology.
- Memory of 30 measurements.
- Traffic Light Indication according to European Society of Hypertension (ESH). 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

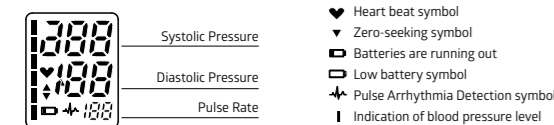
Table for classifying blood pressure values (mmHg) according to European Society of Hypertension (ESH)

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

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-35



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 22 cm-42 cm.

5. CONTRAINDICATION

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

6. PRECAUTIONS

- Read all of the information in the user's manual and any other literature in the box before operating the unit.
- Rest, stay still and calm for 5 minutes before blood pressure measurement.
- The cuff should be placed at the same level as your heart.
- During measurement, neither speak nor move your body and arm.
- Measuring on left arm for each measurement.
- 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.
- Consult your physician if you have any doubt about below cases:
 - The application of the cuff over a wound or inflammation diseases;
 - The application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present;
 - The application of the cuff on the arm on the side of a mastectomy;
 - Simultaneously used with other monitoring medical equipments on the same limb;
 - Need to check the blood circulation of the user.
- △ 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 elder children.
- Do not use this unit in a moving vehicle. This may result in erroneous measurement.
- 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.

- Information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices together with the advice to avoid such interference please see the part ELECTROMAGNETIC COMPATIBILITY INFORMATION.
- Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
- △ 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.
- △ Please do not share the cuff with other infective person to avoid cross-infection.
- 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.
- 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.
- If this complete set did not switch on 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 60601-1-2. You shouldn't use any other adapter model.

7. SETUP AND OPERATING PROCEDURES

7.1. Battery loading

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

- If the LCD displays battery symbol batteries are finishing. Please replace all batteries with new ones.
- After the LCD displays battery symbol the monitor will not turn on. Please replace all batteries 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 the local regulations at the end of their usage.

7.2. Using a mains adapter

- Plug in the mains adaptor into a 100-240 V, 50/60Hz power socket.
- Plug in the DIN plug into the socket at the right side of the instrument.

Batteries power will not be used while the mains adapter is connected to the monitor.

WARNING: If you need mains adapter, You may purchase it separately. Use only the mains adapter AD-155. The use of any other adapters can make your warranty void.

7.3. Connecting the cuff to the monitor

Insert the Air Tube Plug firmly into the Air Tube Socket on the side of the Monitor. Make certain that the Plug is completely inserted in order to prevent air leakage during use.

△ Avoid compression or restriction of the connection tubing during measurement, which may cause inflation error, or harmful injury due to continuous cuff pressure.

7.4. Applying the cuff

- Pulling the cuff end through the medial loop (the cuff is packaged like this already), turn it outward (away from your body) and tighten it and close the Velcro fastener.
- Place a cuff around a naked hand 1-2 cm higher than an elbow pole.
- Being in a sitting position, put a hand palm up before yourself on a plain surface, for example, on a table. Arrange a cuff on a hand so that its bottom edge was apart 1-2 cm above an elbow pole. The red tag (Artery mark) has to be over an elbow pole.
- The cuff has to cover densely a hand, otherwise the result of measurement will not be proper. It is not recommended to dress a cuff over clothes.

7.5. 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 ten minutes before the measurement.
- Remove any garment that fits closely to your upper arm.
- 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.

Sitting Comfortably Measurement

- Be seated with your feet flat on the floor, and don't cross your legs.
- Place palm upside in front of you on a flat surface such as a desk or table.
- The middle of the cuff should be at the level of the heart.

Lying Down Measurement

- Lie on your back.
- Place your left arm straight along your side with your palm upside.
- The cuff should be placed at the same level as your heart.

Common sources of error:

- Movement during measurement.
- The arm artery lies considerably lower (higher) than the heart.
- The cuff does not fit you in size.
- Loose cuff or a sideways protruding air-pocket.

NOTE:

- With repeated measurements, blood accumulates in the respective arm, which can lead to false results. Correctly executed blood pressure measurements should therefore first be repeated after a 1 minute pause.

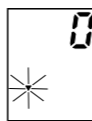
7.6. Taking your blood pressure reading (Picture 1, 1-1, 1-2)

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.

- Then the monitor starts to seek zero pressure. See Picture 1-1.



Picture 1



Picture 1-1



Picture 1-2

- 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. See picture Picture 1-2.
- The monitor will turn Off automatically if not being disturbed for 1 minute after measurement. Alternatively, you can press the "START" button to turn off the monitor manually.
- During measurement, you can press the "START" button to turn off the monitor manually.

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

NOTE: The monitor can memorize 30 results. If you change the batteries, the results will be saved.

7.7. Pulse Arrhythmia Detection

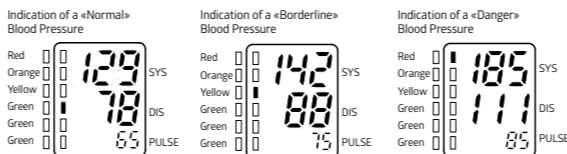
The appearance of the symbol signifies that a certain pulse irregularity was detected during the measurement. The result can vary from your normal blood pressure. Usually this is not a cause for concern; however, if the symbol appears more frequently (e.g. several times per week on measurements performed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

7.8. Traffic Light Indication

The coloured bars on the left-hand edge of the display show you the range within which the indicated blood pressure values lies. Depending on the height of the bar, the readout value is either within the normal (green), borderline (yellow and orange) or danger (red) range.

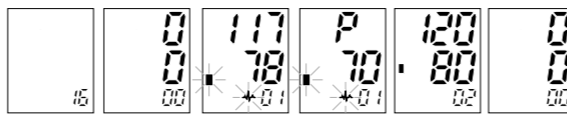
The classification corresponds to the 6 ranges in the Table as defined by the ESH and described on the table of the point 2.

The recommendations of the European Society of Hypertension (ESH) allow to diagnose and treat the hypertension more effectively and do not contradict World Health Organization recommendations.



7.9. Displaying stored results

a. After the measurement, you can review the measurements in the current memory bank by pressing button "MEM". Now the LCD displays the amount of the results in the current bank. See picture 2. If no result stored, LCD will show zero like Picture 2-1.



Picture 2

Picture 2-1

Picture 2-2

Picture 2-3

Picture 2-4

Picture 3

- Then most recent result will be displayed. See picture 2-2. Followed by, the blood pressure and pulse rate will be shown separately. Irregular heartbeat symbol (if any) will blink. See picture 2-2&3. Press "MEM" button again to review the next result. See picture 2-4. In this way, repeatedly pressing the "MEM" button displays the respective results measured previously. When displaying the stored results, the monitor will turn off automatically after 1 minute of no operation. You can also press the button "START" to turn off the monitor manually.

7.10. Deleting measurements from the memory

When any result (except average reading of the last three results) is displaying, keeping on pressing button "MEM" for three seconds, all results in the current memory bank will be deleted after three "beep". LCD will show picture 3, press the button "MEM" or "START", the monitor will turn off.

7.11. Technical alarm description

The monitor will show "H" 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.

7.12. Troubleshooting (1)

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 300mmHg	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	Take out batteries for five minutes, and then reinstall all batteries
No response when you press button or load battery	Incorrect operation or strong electromagnetic interference	

7.13. Troubleshooting (2)

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 blood pressure monitor

8. MAINTENANCE

- Do not drop this monitor or subject it to strong impact.
- Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.
- If this monitor is stored in cold, allow it to acclimate to room temperature before use.
- Do not attempt to disassemble this monitor.
- It is recommended that the performance should be checked every 2 years or after repair. Please contact the service center.
- Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
- No component can be maintained by the user of the monitor.
- 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.
- 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 technical 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

- Product name: Blood Pressure Monitor, model: PRO-35
- Classification: Internally powered, Type BF applied part, IPX0, No AP or APG, Continuous operation
- Machine size: 87 mm × 122 mm × 53 mm (3 7/16" × 4 13/16" × 2 3/32")
- Cuff circumference: 22 cm–42 cm (8 21/32"–16 17/32") or 22 cm–32 cm (8 21/32"– 12 19/32") (depends on the set of the device)
- Weight: approx. 200g (6 3/4 oz.) (excluding batteries and cuff)
- Measurement method: oscillometric method, automatic air inflation and measurement
- Memory volume: 30 results
- Power source: DC 6V 600mA, batteries: 4×1.5V SIZE AAA Mains adapter (optional)
- Measurement range: cuff pressure: 0-300 mmHg, systolic: 60-260 mmHg, diastolic: 40-199 mmHg, pulse rate: 40-180 beats/minute
- Accuracy: pressure: ±3 mmHg, pulse rate: ±5%
- Environmental temperature for operation: 10°C–40°C (50°F–104°F)
- Environmental humidity for operation: ±85% RH
- Environmental temperature for storage and transport: -20°C–50°C (-4°F–122°F)
- Environmental humidity for storage and transport: ±85% RH
- Environmental pressure: 80KPa–105KPa
- Battery life: Approx. 270 times
- 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.

NOTE: These specifications are subject to change without notice.

10. 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).

11. SYMBOL INFORMATION

	THE OPERATIONAL GUIDE MUST BE READ (The sign background colour: blue The sign graphic symbol:white)		NAME ARTICLE NUMBER
	WARNING		SERIAL NUMBER
	TYPE BF APPLIED PARTS (The cuff is type BF applied part)		CE mark (0044) COMPILS WITH MD039/42/EEC REQUIREMENTS
	ENVIRONMENT PROTECTION – Electrical product wastes should not be disposed of with household wastes. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice.		POLARITY OF D.C. POWER CONNECTOR
	OPERATING CONDITION: TEMPERATURE 10°C - 40°C		STORAGE CONDITION: TEMPERATURE -20°C - 50°C
	MANUFACTURER'S NAME		KEEP DRY
	HOUSING INGRESS PROTECTION RATE		UNIQUE DEVICE IDENTIFICATION
	MEDICAL DEVICE		EC REPRESENTATIVE

12. WARRANTY INFORMATION

Warranty period is 3 years from the date of purchase for monitor and 1 year for cuff and adapter. This warranty doesn't cover any damages caused by improper using. The warranty does not apply to components subject to wear and tear, as well as to batteries, purse and packaging of the device. 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: WWWWXXXXX. The manufacturer may change units partially or completely if necessary, without prior notice.*

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-35 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-35 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 earth) + 2 kV (line(s) to earth)	+ 1 kV (line(s) to line(s) + 2 kV (line(s) to earth)	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	-5% U _T (>95 % dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles -5% U _T (>95 % dip in U _T) for 5 s	-5% U _T (>95 % dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles -5% U _T (>95 % dip in U _T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PRO-35 requires continued operation during power mains interruptions, it is recommended that the PRO-35 be powered from an uninterruptible power supply or a battery
Power frequency magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Table 3
For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the PRO-35, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2√P d=1.2√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.5 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, should be less than the compliance level in each frequency range ^a . Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range ^a . Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, 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.			
a. Field strengths from fixed			