ADC® 6012N Advantage[™]Semi-Automatic Blood Pressure Monitor



Directions for Use



I. A SPECIAL THANK YOU

Congratulations on your purchase of an ADC B Advantage M Automatic Blood Pressure Monitor.

In hospitals and physician's offices throughout the world, where accuracy and dependability are critical, ADC(professional diagnostic products are the instruments of choice.

Now you, too, can enjoy the benefits of ADC® engineering and quality in the home. This feature rich instrument was designed to simplify the measurement of blood pressure and pulse rate at home and deliver consistent, dependable results.

Read this booklet thoroughly before attempting to use your new ADC® Advantage™ Automatic Blood Pressure Monitor.

1. INTRODUCTION AND INTENDED USE

This manual is for Advantage[™] Semi-Automatic Blood Pressure Monitor (6012N).

Your ADC[®] Advantage™ blood pressure monitor is a semi-automatic digital blood pressure measuring device for use on the upper arm. It enables very fast and reliable measurement of the systolic and diastolic blood pressure as well as the pulse by way of the oscillometric method. This device offers clinically proven accuracy and has been designed to be user friendly.

Read this booklet thoroughly before attempting to use your new ADC[∞] Advantage[™] Semi-Automatic Blood Pressure Monitor.

Remember...

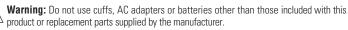
- Only a healthcare professional is qualified to interpret blood pressure measurements. This device is NOT intended to replace regular medical checkups.
- It is recommended that your physician review your procedure for using this device.
- Blood pressure readings obtained by this device should be verified before prescribing or making adjustments to any medications used to control hypertension. Under no circumstances should YOU alter the dosages of any drugs prescribed by your doctor.
- This monitor is intended for use by adults only. Consult with a physician before using this instrument on a child.
- In cases of irregular heartbeat (Arrhythmia), measurements made with this instrument should only be evaluated after consultation with your doctor.
- Familiarize yourself with the section titled "About Blood Pressure". It contains important
 information on the dynamics of blood pressure readings and will help you to obtain the
 best results.

2. WARNINGS AND PRECAUTIONS

Warning: The device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g., mobile telephones, microwave ovens). These can lead to temporary impairment of the measuring accuracy.



Warning: Use of this instrument on patients under dialysis therapy or on anticoagulant, A antiplatelets, or steroids could cause internal bleeding.



Warning: This system may fail to yield specified measurement accuracy if operated or stored in temperature or humidity conditions outside the limits stated in the specifications section of this manual.

Marning: This product may contain a chemical known to the state of California to cause cancer, birth defects, or other reproductive harm.

Caution: The standard material used is latex-free.

Attention: Self-measurement means control, not diagnosis or treatment. Unusual values must always be discussed with your doctor. Under no circumstances should you alter the dosages of any drugs prescribed by your doctor.

Attention: The pulse display is not suitable for checking the frequency of heart pacemakers!

Attention: In cases of irregular heartbeat, measurements made with this instrument should only be evaluated after consultation with your doctor.

NOTE: To obtain the greatest accuracy from your blood pressure instrument, it is recommended that the instrument be used within a temperature range of 50°F (10°C) to 104°F (40°C), with a relative humidity range of 15-85% (non-condensing).

3. ABOUT BLOOD PRESSURE

3.1. What is Blood Pressure?

Simply put, arterial blood pressure is the force of blood exerted against the walls of the arteries. There are two components to blood pressure — systolic and diastolic pressure. Systolic, the higher pressure, occurs during contraction of the heart. Diastolic, the lower pressure, occurs when the heart is at "rest."

Your level of blood pressure is determined in the circulatory center of the brain and adjusts to a variety of situations through feedback from the nervous system. To adjust blood pressure, the strength and frequency of the heart (Pulse), as well as the width of circulatory blood vessels is altered. Blood vessel width is affected by fine muscles in the blood vessel walls. Blood pressure is traditionally measured in millimeters of mercury (mmHg).

It is recorded as systolic/diastolic. For example a systolic of 120 and diastolic of 80 would be recorded 120/80.

Blood pressure is a dynamic vital sign - one that changes constantly throughout the day. A person's "resting" blood pressure is the pressure that exists first thing in the morning while a person is still at rest and before consumption of food or drink.

3.2. What is a Normal Blood Pressure?

A systolic pressure of less than 120mmHg and a diastolic pressure of under 80mmHg are recognized as normal by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, 2003.

NOTE: Blood pressure does increase with age, so you must check with your doctor to find out what is "normal" for you! Even with normal blood pressure values, a regular self-check with your blood pressure monitor is recommended. You can detect possible changes in your values early and react appropriately. If you are undergoing medical treatment to control your blood pressure, keep a record of values along with time of day and date. Show these values to your doctor. Never use the results of your measurements to independently alter the drug doses prescribed by your doctor.

3.3. What Influences Blood Pressure?

Blood pressure is influenced by many factors including age, weight, physical conditioning, past illness, time of day, altitude, activity, and climate, to name just a few. In general, blood pressure is lower in the morning and increases throughout the day. It is lower in warm weather, and higher in cold weather.

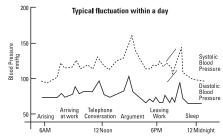
Physical activity can have a significant short term impact on blood pressure. Work, exercise, smoking, eating, drinking - even talking, laughing, or crying will all affect a person's blood pressure.

Your diet, including beverages containing caffeine or alcohol, may affect blood pressure. Emotional stress can have a dramatic impact on your blood pressure.

Even repeated blood pressure measurements taken without adequate rest between readings will alter your blood pressure as the vessels in your arm engorge with blood. Many of these influences are only temporary or short term, though chronic (long term) exposure to some factors may result in permanently elevated blood pressure levels.

3.4. Does Blood Pressure Vary?

Constantly. An individual's blood pressure varies greatly on a daily and seasonal basis. It changes throughout one's lifetime. It is not uncommon for systolic pressure to vary by 40mmHg or more throughout the course of a single day! While generally not as volatile, diastolic pressure can still vary significantly. In hypertensive individuals, variations are even



more pronounced. Normally, blood pressure is at its lowest during sleep and rises in the morning and throughout the day. The chart (page 8) illustrates the fluctuations that could occur in a typical day.

3.5. What is Hypertension?

Hypertension (high blood pressure) is elevated systolic or diastolic levels. In 90 to 95 percent of the diagnosed cases, the specific causes are unknown, although the condition is often linked with family history, and lifestyle. This is referred to as essential hypertension. In the remaining cases, high blood pressure is a symptom of an underlying, often treatable condition, which if corrected, may normalize blood pressure. This less common type is known as secondary hypertension. Hypertension, if left untreated, may contribute to kidney disease, heart attack, stroke, or other debilitating illnesses. The following standards for assessment of high blood pressure in adults have been established by the Joint National Committee, 2003.

Range Classifications	Systolic Blood Pressure	Diastolic Blood Pressure	Precaution Measures
Normal	<120	<80	Monitor regularly
Prehypertension	120 - 139	80 - 99	Contact your physician
	HYPERT	ENSION	
Stage 1 (Moderate)	140 - 159	90 - 99	Contact your physician Immediately
Stage 2 (Severe)	≥160	≥100	Contact your physician URGENTLY

(JNC-7 report: Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure / 2003)

Remember, only a physician is qualified to interpret the readings obtained from your blood pressure monitor. No attempt should ever be made at self-diagnosis or treatment.

3.6. Can Hypertension be Controlled?

Although essential hypertension cannot be cured, it can usually be controlled by altering lifestyle (including diet), adopting a program of exercise, stress management and, where necessary, with medication under a doctor's supervision.

To help reduce the risk of hypertension, or keep it under control, the American Heart Association (AHA) recommends the following:

- Don't smoke
- Reduce salt and fat intake
- Maintain proper weight
- · Exercise regularly
- Have regular physical checkups

3.7. Why Measure Blood Pressure at Home?

Clinical studies have shown improved detection and treatment of hypertension when regular home blood pressure monitoring is done in consultation with a physician.

Blood pressure measured in a doctor's office or hospital setting may cause anxiety and lead to an elevated reading - a condition referred to as "white coat hypertension."

Home measurements generally reduce the "outside" influences on blood pressure readings, and can provide a more comprehensive and meaningful blood pressure history.

Note: While it is important to keep an accurate record of your blood pressure measurements, don't be overly concerned by the results of any one measurement. Individual results may be influenced by spiking of your pressure due to diet, anxiety, or mis-measurement resulting from excessive arm movement, or misapplication of the cuff. Many readings taken at the same time each day give a more comprehensive blood pressure history.

Always be sure to note the date and time when recording blood pressure and pulse measurements. For best results, and with time permitting, 3 successive measurements may be taken daily. Make sure to allow at least 5 minute intervals between measurements. Discard any reading that appears suspect and record the average of the remaining readings.

3.8. How is Blood Pressure Measured?

Healthcare professionals traditionally use a device known as a sphygmomanometer along with a stethoscope - essentially a professional version of the very same instrument you have purchased. The sphygmomanometer is a system consisting of an inflatable bladder contained within a cuff, inflation bulb with air control valve, and pressure measuring manometer (gauge). The gauge may be mechanical, digital, or mercurial. The cuff is wrapped around the limb and inflated to constrict blood flow to the artery. As pressure is released from the cuff through the deflation valve, blood flow returns to the artery producing pulse beats known as Korotkoff sounds, which are detected with the stethoscope. Systolic pressure is recorded at the onset of these sounds. Diastolic pressure is generally recorded when the sounds disappear (when blood flow to the artery returns to normal).

3.9. How should I record my blood pressure?

Record your blood pressure by setting up a simple chart in a spiral-bound notebook as shown below, or use the included record book.

Date	Time	Reading	Pulse
4/24	7:50AM	128/83	72
4/25	8:00AM	135/77	77
4/26	7:45AM	130/75	71
4/27	2:00PM	153/89	80

If you like you can add a column for comments about your condition at the time of measurement, or a listing of any factors that may have influenced your readings (such as "had a cold", or "just returned from vacation").

For best results, and with time permitting, 3 successive measurements may be taken daily. Make sure to allow at least 5 minute intervals between measurements. Discard any reading that appears suspect and record the average of the remaining readings. If this method is used, be sure to note that the readings are averaged.

4. COMPONENTS OF YOUR BLOOD PRESSURE MONITOR



The illustration shows your blood pressure monitor, consisting of:

Fits limb range: 8.7-12.6" (22-32 cm)

5. SETTING UP YOUR BLOOD PRESSURE MONITOR

5.1. Inserting the batteries

After you have unpacked your device, insert the batteries. The battery compartment is located on the back side of the device (see illustration).



- a) Remove cover as illustrated.
- b) Insert the batteries (4 x AA, 1.5V), observing the indicated polarity.
- c) Reinstall battery cover.

Attention!

 If a battery warning = appears in the display, the batteries are almost discharged and must be replaced.



- After battery warning appears, the device will not work until the batteries have been replaced.
- If the blood pressure monitor is not used for long periods, remove the batteries from the device.
- Use "AA" Long-Life or Alkaline 1.5V batteries. Do not use rechargeable batteries.
- Functional check: Press and hold the «ON/OFF» button down to test all the display elements. When functioning correctly many icons will appear.

5.2. Cuff Connection

Insert the cuff connector into the opening provided on the side of the device as shown in the picture.

6. MEASUREMENT PROCEDURE

Attention!

- Find time to relax by sitting in a quiet atmosphere for some time before measurement.
- Efforts by the patient to support the arm can increase the blood pressure. Make sure you
 are in a comfortable, relaxed position and do not activate any muscles in the arm during
 measurement.
- · Always measure on the same arm (normally left).
- Remove any garment that fits closely to your upper arm. Do not roll the sleeve since it can squeeze your arm and this can lead to false results.
- Use only clinically approved ADC[®] cuffs.
- If you want to follow the results of your blood pressure measurements, always perform
 measurements at the same time of day, since blood pressure changes during the course of the day.
- Measurements should be done after 5 minute rest to ensure accuracy.

6.1. Fitting the Cuff

- Position the cuff flat on the table with hook and loop adhesive side down. Pass the end of the cuff through the flat metal ring so that a loop is formed. (Ignore this step if cuff is already prepared.)
- b) Place the cuff over the left upper arm so that tube is closer to your lower arm.
- Lay the cuff on the arm so that the lower edge of the cuff lies approximately 2 to 3 cm above the elbow.

Important! The small white Φ (Artery Mark) on the cuff must lie exactly over the artery which runs down the inner side of the arm.

- d) Tighten the cuff by pulling the end and close the cuff by affixing the hook and loop closure.
- e) There should be little free space between the arm and the cuff. You should be able to fit 2 fingers between your arm and the cuff. Clothing must not restrict the arm. Any piece of clothing which does, must be removed. Cuffs that don't fit properly result in false measurement values. Measure your arm circumference if you are not sure of proper fit. Other size cuffs are available (Page 21).
- f) Lay your arm on a table (palm upward) so the cuff is at the same height as your heart. Make sure the tube is not kinked.
- g) Remain seated quietly for at least two minutes before you begin the measurement.









Comment: If it is not possible to fit the cuff to your left arm, it can also be placed on your right arm. However, all measurements should be made using the same arm. Comparable blood pressure measurements always require the same conditions (Relax for several minutes before taking a measurement).

6.2. Measurement Procedure:

After the cuff has been appropriately positioned and connected to the monitor, the measurement can begin:

- Press the «ON/OFF» button to turn the device on. You will see a flashing upward triangle ▲.
- 2. You will hear 3 short beeps, and a steady "0" will be displayed.
- Grasp the bulb with your free hand and inflate the cuff to a pressure at least 30 mmHg higher than the expected systolic pressure, during which an upward triangle will begin flashing. If you do not know the value of this pressure, inflate to a value between 160–180 mmHg.
- 4. Stop pumping when the upward triangle stops flashing. The device then starts to deflate.
- Lay down the bulb and remain in a quiet and relaxed sitting position. The measurement now proceeds on its own and is taken automatically.

If no measurement takes place and all that appears in the display is a flashing, upwards pointing arrow, pump the bulb again and inflate to a higher pressure (see "Inflating Further" in section 6.4). When the device detects a pulse, a heart symbol in the display starts to flash and a beep is heard for every heartbeat.

6.3. Reading Measurement Results:

When the measurement has been concluded, a long beep tone sounds. The measured systolic and diastolic blood pressure values, as well as the pulse are now displayed. A downward triangle will flash, indicating the rest of air pressure in the cuff can be released.

The cuff pressure can now be quickly released by pressing the quick release valve on the bulb.

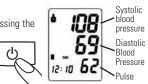
Note: To prolong the batteries' life the device switches off automatically if no button is pressed for 3 minutes. Otherwise you can switch it off by pressing the **«ON/OFF**» button.

6.4. Inflating Further:

If the cuff is not inflated sufficiently, the measurement is stopped after a few seconds and a flashing arrow pointing upwards ▲ appears in the display. It is then necessary to inflate at least 20 mmHg higher than the previous value until cuff pressure displays again on the LCD. The instruction to inflate further can appear several times if the pressure is still not sufficient.

Attention!

If the cuff is inflated too far (over 300 mmHg), HI appears in the display and a warning signal is sounded. The cuff pressure must then be immediately released using the quick-release valve on the inflation bulb!











6.5. Discontinuing Measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell), press and hold the quick-release valve on the bulb at any time. The device then immediately lowers the cuff pressure automatically.

6.6. Irregular Heartbeat Detector

This function indicates an irregular heart beat. If the symbol of IHD $\sqrt{-1}$ appears on the display that means that certain abnormalities in the heartbeat frequency were detected during the measurement. In this case, the result may deviate from your normal blood pressure - repeat the measurement. In most cases, this is no cause for concern. However, if the symbol $\mathcal{M}_{\mathcal{A}}$ appears on a regular basis (e.g. several times a week with measurements taken daily) we advise you to tell your doctor. Please show your doctor the following explanation:

Information for the doctor on frequent appearance of the Irregular Heartbeat Detector

This instrument is an oscillometric blood pressure monitor that also analyses pulse frequency during measurement. The instrument is clinically tested. The symbol -M is displayed after the measurement. if pulse irregularities occur during measurement. If the symbol appears more frequently (e.g. several times per week on measurements performed daily) we recommend the patient to seek medical advice. The instrument does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

7. MEMORY FUNCTION

This semi-automatic blood pressure monitor automatically stores the last result measured.

When the unit is off, press and hold the «ON/OFF» button and the last measurement will be displayed.

8. ERROR MESSAGES/TROUBLESHOOTING

If an error occurs during a measurement, the measurement is discontinued and a corresponding error code is displayed (Example: Err 2).

Error No.	Possible Cause(s)/Solutions	
ERR 1	The systolic pressure was determined, but then the pressure in the cuff went down to less than 20 mmHg (diastolic blood pressure can't be measured). The tube may have loosened after the systolic pressure has been determined. Further possible reason: pulse could not be detected.	
ERR 2	Unnatural pressure impulses influence the measurement result. Reason: the arm was moved during the measurement.	
ERR 3	The difference between systolic and diastolic is excessive. Measure again carefully following proper procedures. Consult your doctor if you still get unusual results of measurements.	
ERR 5	The measuring signals are inaccurate and no result can be displayed. Read through the checklist for performing reliable measurements and then repeat the measurement.	







HI	The pressure in the cuff is too high (over 300mmHg) or the pulse is too high (over 200 beats per minute). Relax for 5 minutes and repeat the measurement.
LO	The pulse is too low (less than 40 beats per minute). Relax for 5 minutes and repeat the measurement.

Other possible errors and their solutions

If problems occur when using this device, the following points should be checked.

Malfunction	Remedy	
The display remains blank when the device is switched on though the batteries are in place.	 Check battery installation/ polarity. Remove the batteries and if the display is unusual, then exchange them for new ones. 	
The pressure does not rise although the inflation bulb is being pumped.	Check the connection of the cuff tube and connect properly.	
The device frequently fails to measure, or the values measured are too low or high.	 Fit the cuff correctly on the arm. Before starting measurement make sure that clothing is not exerting pressure on the arm. Take articles of clothing off if necessary. Measure blood pressure again in complete peace and quiet. 	
Every measurement results in different values, although the device functions normally and normal values are displayed.	Refer to Section 3. About Blood Pressure.	
Blood pressure values differ from those measured at the doctor's.	Refer to Section 3.7. Why Measure Blood Pressure at Home?	

NOTE: Blood pressure is subject to fluctuations even in healthy people. Please remember that **comparable blood pressure measurements always require the same time and the same conditions!** These are normally quiet conditions. If you follow the procedure described earlier and still get fluctuations of blood pressure of greater than 15 mmHg and/or you repeatedly hear irregular pulse tones, consult your doctor.

Attention!

Should any technical malfunctions arise with the blood pressure monitor, please contact the dealer where you bought the device or ADC. **Never attempt to repair the instrument yourself!** Any unauthorized opening of the instrument invalidates all warranty claims.

9. CARE AND MAINTENANCE

Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.

Handle the cuff carefully and avoid all types of stress through twisting or buckling in order not to damage the sensitive air-tight bubble.

Clean the device with a soft, dry cloth. Do not use gas, thinners or similar solvents. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. Do not submerge the cuff in water!

Handle the tubing carefully. Keep the tube away from sharp edges.

Do not drop the monitor or treat it roughly in any way.

Never open the monitor! This invalidates the manufacturer's warranty.

Note: According to international standards, your monitor should be checked for calibration every 2 years. Contact ADC for an accuracy check.

10. TECHNICAL SPECIFICATIONS

.96 lbs. (436 g) (with batteries + cuff)		
3.75" x 4.25" x 5.5" 85mm x 77mm x 140mm (including cuff)		
23°F–122°F (–5°C– +50°C)		
15 to 85% relative humidity maximum		
50°F–104°F (10°C–40°C)		
LCD (Liquid Crystal Display)		
Oscillometric		
Capacitive		
SYS/DIA: 30 to 280 mmHg		
40 to 200 beats per minute		
0-299 mmHg		
Automatically stores the last measurement.		
1 mmHg		
Pressure within \pm 3 mmHg or 2% of the reading \geq 200mmHg Pulse \pm 5 % of the reading		

 Power Source: Includes:
 4 "AA" batteries Semi-automatic Blood Pressure Monitor Model 6012N, Adult cuff with tubing and bulb, 4 AA batteries, Instruction Book, and Record Book.

 A large adult cuff is also available as a special accessory:
 as a special accessory:

 Item No
 Size
 Range 850-6012N

 850-6012N
 Adult
 8.7-12.6" (22-32 cm) 850-6022NX

11. WARRANTY

This blood pressure monitor is warranted for 5 years from date of purchase. This warranty includes the instrument and the cuff. The warranty does not apply to damage caused by improper handling, accidents, improper use, or alterations made to the instrument by third parties. The warranty is only valid after the product is registered online at **www.adctoday.com**.

12. QUALITY STANDARDS

Device standard:

This device is manufactured to meet the European and United States standards for noninvasive blood pressure monitors:

EN1060-1 / 1995 • EN1060-3 / 1997 • EN1060-4 / 2004

Electromagnetic compatibility:

Device fulfills the stipulations of the International standard IEC60601-1-2

13. SYMBOL DEFINITIONS

Symbol	Definition	Symbol	Definition
Â	Important Warning/Caution	EC REP	Authorized European Represenative's Information
\odot	Latex-Free		Manufacturer's Information
0	Circumference Size	Ĩ.	Temperature Limit
Œ	Conforms to EU Standards	ø	Humidity Limitation



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