Digital Blood Pressure Monitor



Semi-Automatic Blood Pressure Monitor

6012

Instruction Manual



PLEASE NOTE:

THIS MEDICAL INSTRUMENT MUST BE USED ACCORDING TO INSTRUCTIONS TO ENSURE ACCURATE READINGS.

Questions? Call ADC toll free at 1-800-232-2670



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1. INTRODUCTION

1. Introduction

Congratulations on your purchase of the Semi-Automatic $\mathsf{ADC}^{\circledast}$ $\mathsf{ADvantage}^{\mathsf{TM}}$ 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.

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 $^{\odot}$ ADvantage $^{\rm TM}$ Digital Blood Pressure Monitor.

Remember...

- Only a health care 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 alterthe 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.

NOTE! This device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens) during use. These can lead to erratic results. Do not attempt to service or repair this device yourself. Should a malfunction occur, refer to the back of this booklet for service information.

2. WARNINGS and PRECAUTIONS \perp

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 measuriong accuracy.

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

Warning: Do not use cuffs, AC adapters or batteries other than those included with thisproduct or replacement parts supplied by the manufacturer.

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.

Warning: This Product May Contain A Chemical Known To The State of California To Cause Cancer, Birth Defects, Or Other Reproductive Harm.

Caution: To avoid any possibility of accidental strangulation, keep this unit away from children and do not tubing around your neck.

Caution: The standard material used for the bladder and tubing 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 15-90% (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 effected 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 and 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 under-going 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?

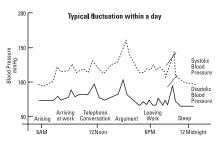
Blood pressure is influenced by many factors including age, weight, physical conditioning, past illness, time of day, altitude, activity, and climate, to name just a few. In general, blood pressure is lower in the morning and increases throughout the day. It is lower in warm weather, and higher in cold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

Important 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?

Health care 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 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 measurements by setting up a simple chart in a spiral bound notebook as shown below, or use the included record book.

Date	Time	Reading	Pulse
4/24/98	7:50AM	128/83	72
4/25/98	8:00AM	135/77	77
4/26/98	7:45AM	130/75	71
4/27/98	2:00PM	153/89	80

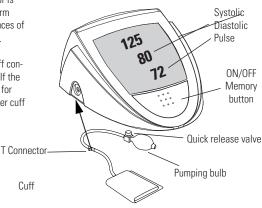
If you like you can add a column for comments about your condition at the time of measurement, or a listing of any factors that may have influenced your readings (such as "had a cold", or "just returned from vacation").

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 blood pressure monitor is model #6012. The upper arm cuff is for arm circumferences of (9"-13" / 22.86 - 33.02cm).

Note: Do not force the cuff connection into the opening. If the cuff is too small, call ADC for further information. A larger cuff is available.



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 from the bottom plate, as illustrated.
- b) Insert the batteries (4 x size AA). Always use AA long life batter-
- ies or alkaline 1.5v batteries. Do not use rechargeable batteries.

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

Attention!

 After the battery warning appears, the device will not operate until the batteries have been replaced.

- If the blood pressure monitor will be left unused for long periods, remove the batteries from the device.
- The use of rechargeable batteries is not recommended.

Functional check: Hold the ON/OFF (0/I) button down to test all the display elements. When the device is functioning correctly, all elements should appear.

5.2. Tube connection

Insert the cuff tube into the opening on the side of the instrument, as shown in the diagram.

6. Taking a Measurement

6.1. Before measuring

- Avoid eating and smoking as well as all forms of exertion directly before a measurement. All these factors influence the measurement result. Relax by sitting in an armchair in a quiet atmosphere for about ten minutes before a measurement.
- Remove clothing from your upper arm.
- Always measure on the same arm (normally left).
- Take measurements at the same time of day, since

blood pressure changes during the course of the day.

6.2. Common sources of error

Note: Comparable blood pressure measurements always require the same conditions! (quiet conditions).

 Supporting your arm can increase blood pressure. Make sure you are in a comfortable, relaxed position and do not flex any of the muscles in the arm during the measurement. Use a cushion for support if necessary.

If the cuff is considerably lower or higher than the heart, an erroneously higher or lower blood pressure will be measured! (Each 15 cm difference in height results in a measurement error of 10 mmHg!)

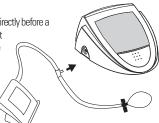
• Selecting the correct cuff size is of extraordinary importance. The cuff size is dependent upon the circumference of the arm (measured in the center). The permissible range is printed on the cuff. If your cuff does not fit properly, contact ADC.

Note: Only use clinically approved ADC cuffs!

• A loose cuff or a protruding air-pocket causes false measurement values.

• With repeated measurements, blood accumulates in the arm, which can lead to false results. Correctly executed blood pressure measurements should be repeated after a **5 minute** pause.

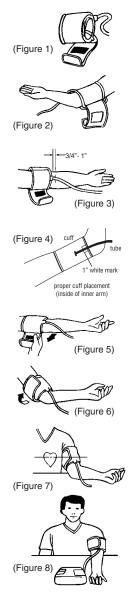




6.3. Fitting the cuff

- a) Position the cuff flat on a table with the hook and loop adhesive side down. Pass the end of the cuff through the metal ring so that a loop is formed. The hook & loop closure must be facing outward. (Ignore this step if the cuff has already been prepared - Figure 1).
- b) Place the cuff over the left upper arm so that the tube points in the direction of the lower arm (Figure 2).
- c) Lay the cuff on the arm as illustrated. Make certain that the lower edge of the cuff lies approximately 3/4 to 1"
 (2 to 3 cm) above the elbow and that the tube is closer to the inner side of the arm (Figure 3).
 Important! The 1" Artery Mark " (¹)" on the cuff must lie exactly over the brachial artery, which runs down the inner side of the arm (Figure 4).
- d) Tighten the cuff by pulling on the free end and close the cuff by affixing the hook and loop closure (Figure 5).
- e) The cuff should be snug on the upper arm and there should be enough space to fit 2 fingers between the arm and the cuff. Clothing must not restrict the arm; any piece of clothing that 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. A larger size cuff is available (Figure 6).
- f) Lay the arm on a table (palm upward) so that the cuff is at the same height as the heart (Figure 7). Make sure that the tube is not kinked (Figure 8).
- 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 the left arm, it can also be placed on the right arm. However, all future measurments should be made using the same arm. Comparable blood pressure measurements always require the same conditions.



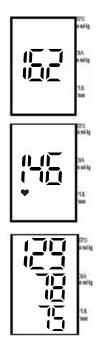
6.4. Measuring procedure

After the cuff has been appropriately positioned, the measurement can begin:

- a) Turn on the instrument by pressing the On/Off/Memory button. Many icons will appear in the display for 2 seconds. 3 short beeps follow to indicate that the instrument is ready. A blinking «O» is shown in the display.
- b) Grasp the bulb with your right hand, (if cuff is on right arm, use your left hand) and inflate the cuff to a pressure at least 30 mmHg higher than the expected systolic pressure. If you do not know the value of this pressure, inflate to a value of approximately 160–180 mmHg. The cuff pressure is shown continuously on the display.
- c) After the inflation process, lay down the bulb and remain in a quiet and relaxed sitting position. The measurement now proceeds on its own. 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. When the instrument detects a pulse, a heart symbol in the display starts to flash and a beep is heard for every heartbeat.
- d) 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. The cuff pressure can now be quickly released by pressing the release valve on the bulb.







6.5. 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. 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 3 beeps will sound. The cuff pressure must then be immediately released using the

quick-release valve on the bulb! As soon as the cuff is inflated sufficiently and the measurement is proceeding, continue as described under points 5.4 - d.

6.6. Discontinuing a measurement

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

6.7. Memory – displaying the last measurement

This blood pressure monitor automatically stores the last measurement value. When the unit is OFF press the MEMORY button for at least 3 seconds, and the last measurement will be displayed.

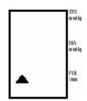
Further information

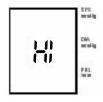
To ensure accurate readings, measurements should not occur soon after each other.

Wait at least 5 minutes in a relaxed position, sitting or

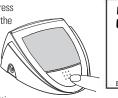
lying down, before you repeat a measurement.

*If taking BP lying down, make sure to support your arm with a towel or cushion. (according to AHA)





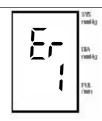






7. ERROR MESSAGES/TROUBLESHOOTING

If an error occurs during a measurement, the measurement is discontinued and a corresponding error code is displayed. (example: Er 1)



Error No.	Possible Cause(s)	
Er 1	The systolic pressure was determined but afterwards the cuff pressure fell below 20 mmHg. The tube may have become unplugged. Further possible cause: No pulse was detected.	
Er 2	The pressure dropped below 20 mmHg without a measurement taking place. The release valve was pressed during the measurement.	

Other possible malfunctions and possible solutions:

Malfunction	Remedy	
The display remains blank when the instrument is switched on al- though the batteries are in place.	 Check battery polarity and correct if necessary. If the display is unusual, remove the batteries and insert 	
The pressure does not rise although you are pumping the inflation bulb.	 new batteries. Check the connection of the cuff tube and connect properly if necessary. 	

The device frequently fails to measure the blood the blood pressure values or the values measured are too low or too high.	 Fit the cuff correctly on the arm. Before starting a measurement, make sure that the cuff is not fitted too tightly. Ensure clothing is not exerting pressure on the arm above the measuring position. Take off articles of clothing 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.	 Blood pressure changes continually. Your readings may be accurate. Consult your doctor. 	
The blood pressure values measured differ from those measured by your doctor.	 Record the daily development of the values and consult your doctor about them. Anxiety during a doctor visit can result in higher readings. 	

Further information

Even for healthy people, blood pressure is subject to fluctuations. Comparable measurements always require the same conditions (Quiet conditions)!

If fluctuations are larger than 15 mmHg, and/or you hear irregular pulse tones on several occasions, consult your doctor.

Contact ADC[®] if there are technical problems with your blood pressure monitor. Never attempt to repair the instrument yourself!

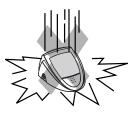
Any unauthorized opening of the instrument invalidates all warranty claims!

8. CARE AND MAINTENANCE

- a) Do not expose the device to extreme temperatures, humidity, dust, or direct sunlight.
- b) The cuff contains a sensitive air-tight bladder. Handle this carefully and avoid all types of straining, twisting, or buckling.
- c) Clean the device with a soft, dry cloth. Do not use gasoline, thinners, or similar solvent. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff is not waterproof.
- d) Handle the tube carefully. Do not pull on it, allow it to twist, or lay it over sharp edges.
- e) Do not drop the instrument or treat it roughly in any way. Avoid strong vibrations.
- f) Never open the device! This will invalidate the manufacturer warranty.









Periodic recalibration

Sensitive measuring devices must from time to time be checked for accuracy. We recommend a periodic inspection of your monitor every 2 years.

Contact ADC® about the need for an accuracy check.

9. WARRANTY

The blood pressure monitor (6012) is warranted for 5 years from date of purchase. This guarantee 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.

10. QUALITY STANDARDS	
Device standard:	This device corresponds to the requirements of the U.S. standards for non-invasive blood pressure monitor
	EN1060–1 EN1060–3
	DIN 58130 ANSI / AAMI SP10
Electromagnetic compatibility:	This device fulfills the stipulations of the European standard EN 60601–1–2
Clinical testing:	Clinical performance testing was carried out in Ger- many according to the DIN 58130/1997 procedure N6 (sequential).

Weight: Size: Storage temperature: Humidity: **Operation temperature:** Display: **Measuring method:** Pressure sensor: Measuring range: SYS/DIA: Pulse: Cuff pressure display range: Memory: Measuring resolution: Accuracy: Pressure Pulse Power source: Accessories:

284 g (with batteries) / 1.37lbs. 3.5" (W) x 6.5" (L) x 8" (H) 119mm (W) x 146mm (L) x 60mm (H) -20° C to +50°C 15% to 90% relative humidity maximum 10°C to 40°C LCD (Liquid Crystal Display) Oscillometric Capacitive

30 to 280 mmHg 40 to 200 per minute 0–299 mmHg Automatically stores the last measurement 1 mmHg

Within ± 3 mmHg, 2% of reading >200mmHg ± 5 % of the reading 4 AA (batteries) 1.5 V Includes an adult cuff for arm circumferences 23–33 cm (9"-13") Large adult cuff for arm circumferences 33–43 cm (13"-17") available as a special accessory.

12. ACCESSORIES

Optional Accessories:

Cuff Sizes:

Adult Large Adult 850-6013 (9" - 13" / 22.86 - 33.02cm) 850-6013X (13" - 17" / 33.02 - 43.18cm)

13. HOW TO CONTACT US

To register your product and obtain further detailed user information about our products and services visit us at:

www.adctoday.com

and follow the links.

For questions, comments, or suggestions call us toll free at:

1-800-232-2670



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