

Digital Blood Pressure Monitor Semi-Automatic with Manual Inflation

Instructions for Use Model 6012N



This medical instrument must be used according to instructions to ensure accurate readings. Questions? Call ADC at 1-800-232-2670



C€ 0044

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Table of Contents

A 0	
A Special Thank You	
Introduction and Intended Use	
Contraindications	4
Symbol Definitions	4
Warnings and Precautions	5
What's in the Box	6
Display Icons	7
Setting Up Your Monitor	8
Insert the Batteries	8
Assemble the Bulb and Valve	8-9
Connect the Cuff	9
Preparing for a Measurement	9-10
Fitting the D-Bar Cuff	10
Taking a Measurement	
Inflating Further	14
Stopping a Measurement	14
Last-Reading Memory	15
Irregular Heartbeat Detector	16
Understanding Blood Pressure Readings	17
Performing Reliable Measurements	18-19
Error Messages and Troubleshooting	19-20
Care and Maintenance	21
Technical Specifications	22
Warranty	23
Quality Standards	23
How to Contact Us	23

Warranty

This blood pressure monitor is warranted for five 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/support/warranty-registration.

Quality Standards

Device standard:

This device is manufactured to meet the European and United States standards for non-invasive blood pressure monitors: EN 1060-1/-3/-4

Electromagnetic compatibility:

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

How to Contact Us

1-800-ADC-2670 Email: info@adctoday.com www.adctoday.com

Technical Specifications

LCD (Liquid Crystal Display) Display:

Weight: .96 lbs. (436 g) with batteries and cuff

Dimensions: 3.75" (W) x 4.25" (L) x 5.5" (H)

(77mm x 85mm x 140mm)

Including cuff

Operating conditions: 50°F to 104°F (10°C to 40°C)

15 to 90% relative maximum humidity

Storage conditions: -4°F to 131°F (-20°C to 55°C)

Measuring procedure: Oscillometric, corresponding to

Korotkoff method: Phase I systolic.

Phase V diastolic

Measurement range: Sys: 60 - 225 mmHg Dia: 40 - 200 mmHg

Pulse 40-200 beats per minute

Automatically stores the last measurement Memory:

Cuff pressure display range: 0 - 299 mmHg

Measuring resolution: 1 mmHa

Pressure within +3 mmHa or Static accuracy:

2% of reading >=200 mmHg

+5% of the read-out value Pulse accuracy:

Power source: 4 AA batteries

Additional cuff sizes Item No. Size Range are also available for 850-6012N Adult 8.7" - 12.6" (22-32 cm)

the device: 850-6022NX 12.5" - 20.4" (32-52 cm) La. Adult

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

A Special Thank You

Thank you for purchasing an ADC Advantage[™] semi-automatic home blood pressure monitor.

In hospitals and physician 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 instrument was designed to simplify the measurement of blood pressure and pulse rate at home and deliver consistent, dependable results.

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Introduction and Intended Use

This manual covers the Advantage[™] 6012N semi-automatic digital upper-arm blood pressure monitor. To find the model number of your device, see the rating label located on the bottom of the unit.

Your unit uses the oscillometric method to provide systolic pressure, diastolic pressure, and pulse rate. It's semi-automatic, relying on manual cuff inflation. Other features include an easy-to-read LCD display, irregular heartbeat detection, and last-reading memory.

Before getting started, please read this instruction manual carefully and then keep it in a safe place. Additional documentation is available at www.adctoday.com/ADCatHome. Please contact your doctor if you have further questions about blood pressure and its measurement.

Contraindications

This device is contraindicated for any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator.

This blood pressure monitor is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

ARRING: The device is not suitable for use on: pregnant women; users with implanted electric devices; users with preeclampsia, premature ventricular beats, atrial fibrillation, or peripheral arterial disease; users undergoing intravascular therapy or arteriovenous shunt; or people who received a mastectomy. Consult with your physician prior to using this unit if you suffer from any of these illnesses or conditions.

Symbol Definitions

The following symbols are associated with your monitor.

Symbol	Definition
Λ	Important Warning/Caution
<u></u>	Relative humidity limits
LOT	Lot code
XX	Not made with natural rubber latex
\boxtimes	Phthalate free
*	Keep dry
☀	Type BF applied part
***	Manufacturer's information
Ā	Dispose in accordance with regulations
IP20	Protected against solid foreign particles with a diameter of more than 12.5 mm, no protection against water

Symbol	Definition
(3)	Read operating instructions
UDI	UDI number
MD	Medical device
SN	Serial Number
¥.	Temperature limits
REF	Product identifier
0	Limb circumference (Minimum/Maximum)
EC REP	Authorized European representative's information
C€ 0044	Meets essential requirements of European Medical Device Directive 93/42/EEC

Care and Maintenance



Clean the monitor only when necessary. Use a soft, dry cloth with a 70% isopropyl alcohol solution.



4

Spots on the cuff can be removed carefully with a damp cloth and soapsuds.



Do not drop the monitor.



V

Do not clean with gas, thinners, or similar solvents



Avoid stress when handling the cuff and tubing. Twisting or buckling can damage the sensitive air-tight bubble. Keep away from sharp edges.



V

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



V

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



Do not submerge any parts in water.



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



Other possible errors and their solutions

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

Malfunction	Remedy
The display remains blank when the device is switched on although the batteries are in place.	Check battery installation/polarity. Remove the batteries and if the display is unusual, then exchange them for new ones. Check polarity.
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. Confirm proper measuring technique as described Preparing for a Measurement (page 9) and Performing Reliable Measurements (page 18).
Every measurement results in different values.	Confirm proper measuring technique as described in Preparing for a Measurement (page 9) and Taking a Measurement
Blood pressure values differ from those measured at the doctor.	(page 11). 2. Consult our informational document About Blood Pressure, at www.adctoday.com/ADCatHome.

- 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!
- If your blood pressure readings regularly fluctuate more than 15 mmHg, or if you repeatedly see the irregular heartbeat icon, consult your doctor.

⚠ If you experience technical malfunctions with the monitor, contact the dealer where you bought the device or ADC. Never attempt to repair the instrument yourself! Unauthorized opening invalidates the warranty.

Warnings and Precautions 🛕

A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately, could lead to patient injury, illness or death.

⚠ 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.

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

 \triangle WARNING: Do not use cuffs or batteries other than those included with this product 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.

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.

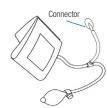
ATTENTION: The pulse display is not suitable for checking the frequency of heart pacemakers!

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 to 104°F (10°C to 40°C), with a 15-90% relative humidity.

What's in the Box





Blood Pressure Cuff

The 6012N includes a soft, nylon, self-adjusting D-bar cuff, with inflation bulb and quick-release valve.

Fits Arm Circumference	
22 cm - 32 cm	
(8.7 in - 12.6 in	

Instructions for Use



4 AA Batteries







- A loose cuff or a sideways protruding air pocket causes false measurements. Ensure that cuff is properly applied.
- With repeated measurements, blood accumulates in the arm, which can lead to false results.
- To learn more about blood pressure, see our informational document About Blood Pressure, at www.adctoday.com/ADCatHome.

Error Messages and Troubleshooting

If an error occurs during a measurement, the measurement is interrupted 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.

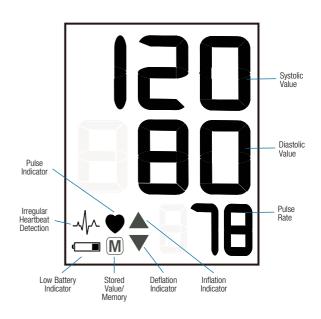
Performing Reliable Measurements

- When taking blood pressure, ensure all steps involved in the process are properly observed. Small variations in technique can cause large variances in measurements. Comparable blood pressure measurements require the same conditions.
- Efforts by the user to support the arm can increase blood pressure. Make sure you are in a comfortable, relaxed position and do not flex any of the muscles in the measurement arm during the measurement. Use a cushion for support if necessary.
- If the arm artery lies considerably lower or higher than the heart, blood pressure may read erroneously higher or lower. Each 15 cm (6 inch) difference in height between your heart and the cuff results in a measurement error of 10 mmHq.
- Cuffs that are too narrow or too short result in false measurement values. Selecting the correct cuff is extremely important. Cuff size is dependent upon the circumference of the arm (measured in the center). Each model has its own cuff:

Model	Cuff Size	Fits Arm Circumference
6012N	Adult	22 cm - 32 cm
	(#850-6012N)	(8.7 in - 12.6 in)

- If the cuff provided with your unit is too small), please call 1-800-232-2670, or consult the cuff sizes chart on page 22. Only use approved ADC cuffs.
- ADC cuffs have specially designed markings to promote the precise and accurate determination of blood pressure. Please review the section on fitting your cuff on page 10.

Display Icons: 6012N



Setting Up Your Monitor

Insert the Batteries

Batteries are packaged with the cuff. The battery compartment is on the bottom of the device.



Remove cover, insert batteries, and replace cover





Press and hold for about five seconds to perform a function check





Low Battery Warning



Expired Battery Warning

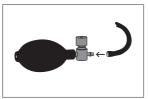
Use AA long-life or alkaline 1.5V batteries. Do not use rechargeable batteries. Remove batteries if monitor will not be used for long periods.

Assemble the Bulb and Valve

If your unit is new, you'll need to assemble the bulb and valve.



Insert quick-release valve stem into the tube end leading from the cuff



Understanding Blood Pressure Readings

The current blood pressure scale and classifications (see chart below) were established by the American Heart Association and American College of Cardiology in 2017.

Under these guidelines, a systolic pressure of less than 120mmHg and a diastolic pressure of under 80mmHg are recognized as normal.

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.

Blood Pressure Category	Systolic mm Hg (upper number)	and/or	Diastolic mm Hg (lower number)
HYPERTENSIVE CRISIS Consult your doctor immediately	Higher Than 180	and/or	Higher Than 120
HIGH BLOOD PRESSURE HYPERTENSION Stage 2	140 or Higher		90 or Higher
HIGH BLOOD PRESSURE HYPERTENSION Stage 1	130 - 139	or	80 - 89
ELEVATED	120 - 129	and	Less than 80
NORMAL	Less Than 120	and	Less than 80

- Only a physician is qualified to interpret the readings obtained from blood pressure monitor. No attempt should ever be made at self-diagnosis or treatment.
- Readings below 90 (sys) and/or 60 (dia) may be considered hypotensive. Consult your physician.

Irregular Heartbeat Detector



The appearance of this icon means allorhythmia, or irregular. heartbeat was detected. If the symbol appears, then certain abnormalities in heartbeat frequency were detected during the measurement. This indicator is only a caution.

1 It is important that you are relaxed, remain still, and do not talk during measurement

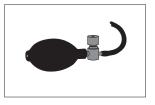
In most cases, the appearance of an irregular heartbeat is no cause for concern. However, if the symbol appears on a regular basis (e.g., several times a week with measurements taken daily) we advise you to speak with your doctor.

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

This device is an oscillometric blood pressure monitor that also analyzes pulse irregularity during measurement. The device is clinically tested. The arrhythmia symbol is displayed after the 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. This device does not replace a cardiac examination but serves to detect pulse irregularities at an early stage.



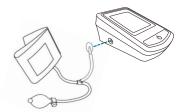
Push until fully seated



Connect the Cuff



Insert the cuff connector into the port on the left side of the unit



Make sure cuff connector is fully inserted before taking a reading.

Preparing for a Measurement

Find time to relax by sitting in an armchair in a quiet atmosphere for about ten minutes before taking a measurement. Avoid eating and smoking as well as all forms of exertion directly before measurement.

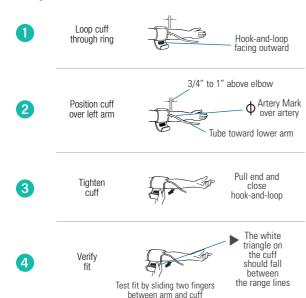
Measure on a bare arm, if possible,

Always measure on the same arm (normally left).

Try to take measurements around the same time each day.

For additional tips and information on obtaining accurate readings, see page 17.

Fitting the D-Bar Cuff



If the cuff provided with your unit is too small, please call 1-800-232-2670 or consult the cuff sizes chart on page 22. Only use approved ADC cuffs.

Last-Reading Memory

M

The monitor automatically stores the last reading in memory.



The irregular heartbeat icon will appear if it was detected during that reading.

Inflating Further

If cuff inflation is not high enough for an accurate reading, the measurement will pause and the inflation indicator will flash on the display.





Pump the bulb again to inflate at least 20 mmHg higher



The instruction to inflate further can appear several times.

Repeat, if necessary, until pressure is sufficient for measurement.

Stopping a Measurement

You can stop a measurement at any time.





guick-release valve



Cuff will deflate

If you experience any discomfort, such as pain in the arm, stop the measurement immediately and remove the cuff.

Taking a Measurement

Lay your arm on a table, palm up, so the cuff is at the same height as your heart. Make sure the tube is not kinked.







The unit will turn on and you'll see a 0 on the display



Three beeps will sound and the inflation indicator will begin flashing



Grasp the bulb with your free hand and begin pumping

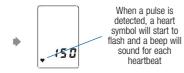




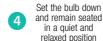
Keep pumping until the cuff is inflated to a pressure that's about 30 mmHg higher than your typical systolic pressure



- If you don't know your typical systolic value, inflate to around 160-180 mmHg.
- If you stop pumping the bulb for more than a few seconds, some air may start releasing through the connector.



- (i) If measurement does not begin or if the inflation indicator reappears, pump the bulb again to inflate to a higher pressure.
- If the cuff is inflated over 300 mmHg, a warning beep will sound and HI will appear on the display. Use the quick-release valve on the bulb to deflate cuff pressure, then start the reading again.





The measurement proceeds on its own, automatically





A long beep sounds when measurement is complete and the systolic pressure, diastolic pressure, and pulse rate are displayed

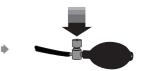




The deflation indicator will begin flashing to signal that remaining cuff pressure can be released



Press and hold the quick-release valve until cuff is fully deflated







f no button is pressed for 90 seconds the instrument will turn itself off.