

Automatic Blood Pressure Monitor

Instructions for Use





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





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Table of Contents

A Special Thank You	4
Introduction and Intended Use	!
Contraindications	
Symbol Definitions	
Warnings and Precautions	
What's in the Box	
Display Icons	
Setting Up Your Monitor	10
Insert the Batteries	10
Using the AC Power Adapter	10
Set the Time and Date	1 ⁻
Connect the Cuff	1 ⁻
Select the User	12
Preparing for a Measurement	13
Fitting the D-Bar Cuff	13
Taking a Measurement	14-1
Stopping a Measurement	1
Using the Memory	15-17
Viewing Stored Readings	16
Clearing the Memory	17
Irregular Heartbeat Detector	18
Understanding Blood Pressure Readings	19
Performing Reliable Measurements	20-2
Error Messages and Troubleshooting	22-23
Care and Maintenance	24
Technical Specifications	2





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.adctodav.com/support/warrantvregistration.

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: IEC 60601-1-2: ANSI/AAMI/IEC 80601-2-30; ANSI/AAMI/ISO 81060-2.

Electromagnetic compatibility:

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

Clinical testing:

BHS A/A Rated. Clinical performance tests were carried out in the U.K. "Association Protocol and British HTP Protocol"

How to Contact Us

1-800-ADC-2670

Email: info@adctodav.com www.adctoday.com

Warranty	26
Quality Standards	26
How to Contact Us	26





A Special Thank You

Thank you for purchasing an ADC Advantage[™] automatic home 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 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 device. Additional documentation is available at www.adctodav.com/ADCatHome.

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Technical Specifications

Display: LCD (Liquid Crystal Display)

Weight: 1.07 lbs. (487 g) with batteries and

wide-range cuff

Dimensions: 5.35" (W) x 3.78" (L) x 2.28" (H)

(136mm x 96mm x 58mm)

Including cuff

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

15 to 90% relative maximum humidity

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

Measuring procedure: Oscillometric, corresponding to

Korotkoff method: Phase I systolic.

Phase V diastolic

Measurement range: 60 - 225 mmHg Sys:

> 40 - 200 mmHa Dia:

Pulse 40-200 beats per minute

Memory: 99 measurements for each user

Cuff pressure display range: 0 - 299 mmHg

Measuring resolution: 1 mmHa

Pressure within ±3 mmHg or Static accuracy: 2% of reading >=200 mmHg

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

4 AA batteries Power source:

or 1.5V AC adapter (sold separately)

Battery lifetime: Approx. 920 measurements

Additional cuff sizes Item No. Size

are also available for 850-6022N Wide Range 8.7" - 16.5" (22-42 cm) these devices: 850-6021NSA Sm. Adult 6.7" - 8.7" (17-22 cm)

850-6022NX Lg. Adult

12.5" - 20.4" (32-52 cm)

Range





Care and Maintenance



Clean the monitor only when necessary. Use a soft, dry cloth with a 70% isopropyl alcohol solution or a 10% chlorine bleach/90% water solution (e.g., standard bleach wipe).



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



Do not drop the monitor.



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



Do not clean with gas, thinners, or similar solvents.



Do not submerge any parts in water.



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



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



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













Introduction and Intended Use

This manual covers the Advantage[™] digital upper-arm automatic blood pressure monitors. 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. Other features include an easy-to-read LCD display and irregular heartbeat detection.

The device accommodates two users, each with 99 reading memory, and offers clinically proven accuracy with a user-friendly design.

Before getting started, please read this instruction manual carefully and then keep it in a safe place. Additional documentation is available at www.adctodav.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.

WARNING: 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.



at the doctor's.

Symbol Definitions

The following symbols are associated with your monitor.

Symbol	Definition
<u>^</u>	Important Warning/Caution
	Relative humidity limits
LOT	Lot code
W	Not made with natural rubber latex
\boxtimes	Phthalate free
Ť	Keep dry
☀	Type BF applied part
***	Manufacturer's information
Ā	Dispose in accordance with regulations
(3)	Read Operating Instructions

Symbol	Definition
UDI	UDI number
MD	Medical device
1	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
IP20	Protected against solid foreign particles with a diameter of more than 12.5 mm, no protection against water

Other possible errors and their solutions

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

Malfunction Remedy 1. Check battery installation/polarity. The display remains blank when the device is 2. Remove the batteries and if the display is unusual, then exchange them for new ones. switched on although the batteries are in place. Check polarity. The pressure does not Check the connection of the cuff tube and rise although the pump connect properly. is running. The device frequently fails 1. Fit the cuff correctly on the arm. to measure, or the values 2. Confirm proper measuring technique as measured are too low or described Preparing for a Measurement high. (page 13) and Performing Reliable Measurements (page 20). Every measurement 1. Confirm proper measuring technique as described in Preparing for a Measurement results in different values. (page 13) and Taking a Measurement (page 14). Blood pressure values 2. Consult our informational document differ from those measured About Blood Pressure, at

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!

www.adctoday.com/ADCatHome.

- 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.





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	If inflation of the cuff takes too long, the cuff is not correctly seated or the hose connection's not tight.
ERR 5	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.
Н	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.

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

AWARNING: 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, antiplatelets, or steroids could cause internal bleeding.

★ WARNING: Do not use cuffs, AC adapters, 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 Monitor



Blood Pressure Cuff

All models include a soft, nylon D-bar cuff.

Cuff size varies depending on monitor model.		
Model(s)	Cuff Size	Fits Arm Circumference
6021N	Extended Wide Range (#850-6022N)	22 cm - 42 cm (8.7 in - 16.5 in)
6021NX	Large Adult (#850-6022NX)	32 cm - 52 cm (12.5 in - 20.4 in)
6021NSA	Small Adult (#850-6022NSA)	17 cm - 24 cm (6.7 in - 8.7 in)
	Model(s) 6021N 6021NX	Model(s) Cuff Size 6021N Extended Wide Range (#850-6022N) 6021NX Large Adult (#850-6022NX) 6021NSA Small Adult

4 AA Batteries

Instructions for





the cuff.



Carry Case



- 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 13.
- 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.









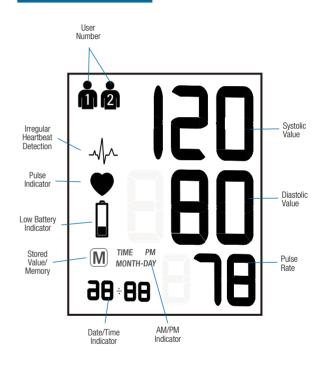
Performing Reliable Measurements

- 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 mmHg.
- 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(s)	Cuff Size	Fits Arm Circumference
6021N	Extended Wide Range (#850-6022N)	22 cm - 42 cm (8.7 in - 16.5 in)
6021NX	Large Adult (#850-6022NX)	32 cm - 52 cm (12.5 in - 20.4 in)
6021NSA	Small Adult (#850-6022NSA)	17 cm - 24 cm (6.7 in - 8.7 in)

If the cuff provided with your unit is not suitable for your use (i.e., too big or too small), please call 1-800-232-2670. Only use approved ADC cuffs.

Display Icons: 6021N







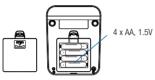
Setting Up Your Monitor

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 release 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.

Using the AC Power Adapter

An optional AC adapter is available for purchase from ADC. To use, plug the adapter into the port on the right side of the device.



No power is taken from the batteries while the AC adapter is connected to the device. Use only the AC adapter provided by ADC.

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.

Set the Time and Date

The device will prompt you to reset the date and time each time you replace the hatteries

When the year is flashing...



M Press until vou reach the current year









Unit will accept the year and continue to month setting

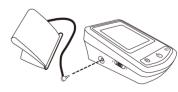


Repeat Steps 1 and 2 to enter current month, date, hour, and minutes. Note the AM and PM icons when setting the hour.

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.





Select the User

The monitor can store 99 measurements for each of two users. Before taking a measurement, check the intended user is selected.

6021N





With the unit off, press and hold for about five seconds. The user number will flash





Press to toggle user number, then press On/Off to confirm selection.

Clearing the Memory

Measurements cannot be individually deleted once in the monitor's memory, but you can clear a user's entire measurement history.

Before proceeding, be certain you won't need to refer to the data in the future. Keep a written record if needed.





Confirm that the monitor is set for the correct user. For more information on changing the user, see page 12.





Press and hold for about 10 seconds



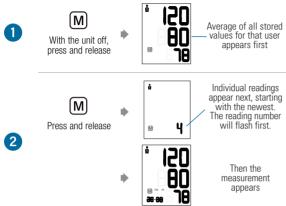




Press to confirm. Monitor will beep and memory will be cleared.



Viewing Stored Readings



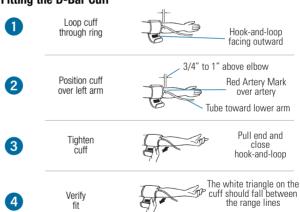
The irregular heartbeat icon will appear if it was detected during that reading.

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 19.

Fitting the D-Bar Cuff



Test fit by sliding two fingers between arm and cuff

If the cuff provided with your unit is too big or small, please call 1-800-232-2670 or consult the Blood Pressure Cuff chart on page 8. Only use approved ADC cuffs.

Taking a Measurement





release



The unit will turn on



The cuff will begin to inflate

If you get an "Err 3" message, consult the Error Messages and Troubleshooting chart on page 22.



Cuff pressure and pulse detection is noted on the display



When sufficient pressure is reached, inflation stops and cuff begins to deflate



When measurement has concluded, a long beep sounds and the systolic pressure, diastolic pressure, and pulse rate appear on display





Press and release to turn off

f no button is pressed for one minute the instrument will turn itself off.

Stopping a Measurement

You can stop a measurement at any time.







Press and release

Unit will turn off and cuff will deflate

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

Using the Memory



Each measurement is stored in memory with the date and time it was taken.



Up to 99 readings are stored for each of two users. Be sure you are viewing the measurements for the correct user.

Once the maximum memory capacity of 99 is reached, the next new reading will overwrite the oldest value currently in memory.



