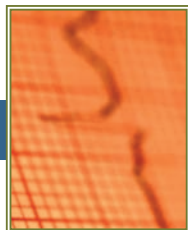


Digital Wrist Blood Pressure Monitor

Automatic Blood Pressure Monitor



6015

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

ADC[®]
AMERICAN DIAGNOSTIC CORPORATION

1. Introduction

1.1. Features of your blood pressure monitor

This blood pressure monitor, with integrated time/date display, is a fully automatic, digital blood pressure measuring device for use on the wrist. It enables very fast and reliable measurement of the systolic and diastolic blood pressure as well as pulse by way of the oscillometric method of measuring. This device offers a very high degree of accuracy demonstrated through clinical studies. It is also very easy to use.

Before using, please read through this instruction manual carefully and then keep it in a safe place. For further questions on the subject of blood pressure and its measurement, please contact your doctor.

Attention!

1.2. Important information about self-measurement

- **Caution: Self measurement of blood pressure helps your health care professional assist in the management of your blood pressure. Unusual values must always be discussed with your doctor. Under no circumstances should you alter the dosages of any drugs prescribed by your doctor.**
- The pulse display is not suitable for checking the functioning of heart pacemakers!
- **In cases of cardiac irregularity, measurements made with this instrument should only be evaluated by your doctor.**

Electromagnetic interference:

The device contains sensitive electronic components (Microcomputer). Therefore, avoid strong electrical or electromagnetic fields in the direct vicinity of the device, such as cellular telephones and microwave ovens. These devices, when in operation close to your blood pressure monitor, can lead to temporary impairment of the measuring accuracy.

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, 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.

Warning: 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 15-90% (non-condensing).

3. Important information on blood pressure and its measurement

3.1. How does high/low blood pressure arise?

Your level of blood pressure is determined in a part of the brain called the circulatory center. This part of your brain responds to a situation through feedback with the nervous system. To adjust the 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 altered by fine muscles in the blood vessel walls.

The level of arterial blood pressure changes periodically during heart activity: During blood ejection from the heart (Systole) the value is maximal (systolic blood pressure value). At the end of the heart's rest period, Diastole or diastolic blood pressure value, blood pressure falls to a low value. Blood pressure values must lie within certain normal ranges in order to prevent particular diseases.

3.2 Which values are normal?

Blood pressure is too high if at rest, your diastolic pressure is above 90mmHg and/or the systolic blood pressure is over 160mmHg. **You should bring these values to the attention of your doctor immediately. Long-term values at this level endanger your health due to the associated advancing damage to the blood vessels in your body.**

Should the systolic blood pressure values lie between 140mmHg and 160mmHg and/or the diastolic blood pressure values between 90mmHg and 95mmHg, please consult your doctor, and check your blood pressure regularly.

With blood pressure values that are too low, i.e. systolic values under 105mmHg and/or diastolic values under 60mmHg, please consult your doctor.

Even with normal blood pressure values, a regular self-check with your blood pressure monitor is recommended. In this way you can detect possible changes in your values early and react appropriately, in consultation with your physician.

If you are undergoing medical treatment to control your blood pressure, please keep a record of your blood pressure levels by carrying out regular self-measurements at specific times of the day. Show these values to your doctor. **Never use the results of your measurements to discontinue or independently alter the drug doses prescribed by your doctor.**

The following standards for assessing high blood pressure in adults have been established by the National Institutes of Health JNC7.

Category	Systolic (mmHg)	Diastolic (mmHg)
Normal Self-Check	<120	<80
Pre-Hypertension	120 - 139	80 - 89
Stage 1 Hypertension	140 - 159	90 - 99
Stage 2 Hypertension	≥160	≥100

Further information

- If your values are mostly standard under resting conditions but exceptionally high under conditions of physical or psychological stress, it is possible that you are suffering from so-called “labile hypertension”. Please consult your doctor if you suspect that this might be the case.

Warning:

- **Diastolic blood pressure values above 120mmHg require immediate medical treatment.**

3.3. What can be done if regular high/low values are obtained?

Please consult your doctor.

Increased blood pressure values (various forms of hypertension) are associated with considerable health risks. The concern is the arterial blood vessels of your body, which are endangered due to constriction caused by deposits in the vessel walls. (Arteriosclerosis) This can and does cause deficient supply of blood to important organs such as the heart, brain, and muscles. Furthermore, with long-term continuously increased blood pressure values, the heart will become structurally damaged.

There are many different causes of high blood pressure. We differentiate between common primary (essential) hypertension, and secondary hypertension. Secondary hypertension (high) can be related to specific organ malfunctions. Please consult your doctor for information about the possible origins of your own increased blood pressure values.

Lifestyle changes may assist in the reduction of a medically established high blood pressure prevention. These lifestyle changes should be practiced on a continual basis:

1. Eating habits

- Strive for a healthy weight corresponding to your age.
- Avoid excessive consumption of common salt. (Many packed foods contain large amounts of salt.)
- Avoid fatty foods.

2. Previous illnesses

Consistently follow any medical instructions for treating previous illness such as:

- Sugar Diabetes (Diabetes mellitus)
- Fat metabolism disorder
- Gout

3. Habits

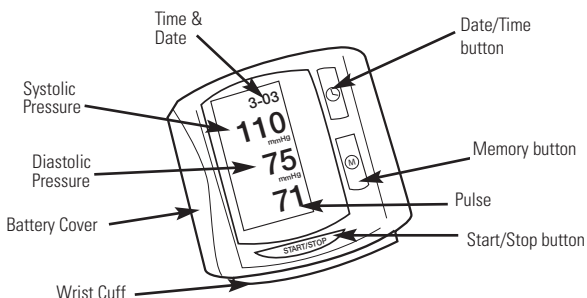
- Smokers should give up smoking completely.
- If you drink alcohol, do so in moderate amounts only.
- Restrict your caffeine consumption (Coffee, coke, tea, chocolate, etc.).

4. Physical constitutioning:

- After a medical examination and clearance from your doctor, exercise regularly.
- Choose sports which require stamina and avoid those which require strength.
- Avoid reaching the limit of your performance.
- **With previous illnesses and/or an age of over 40 years, please consult your doctor before beginning your physical activities. Your doctor will advise you regarding the physical activities that are best for you.**

4. Components of your blood pressure monitor

Your ADC® wrist type blood pressure monitor consists of:

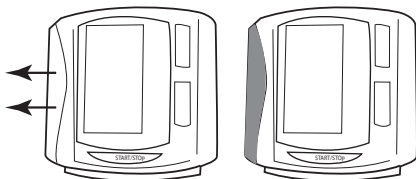


Cuff fits wrist size 5½" to 7¾" inches.

5. Operation of 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 left side of the device (see illustration).



- Remove cover as illustrated.
- Insert the batteries (2 x size AAA 1.5V) following the indicated polarity and replace battery cover.
- If the battery warning appears in the display, the batteries are discharged and must be replaced by new ones.

Attention!

- After the low battery indication warning appears, the device will not function until the batteries have been replaced.
- Please use "AAA" Long Life or Alkaline 1.5V Batteries. Rechargeable batteries are not recommended.
- If the blood pressure monitor is left unused for long periods, remove the batteries from the device.

Functional check:

Press and hold the Start/Stop button to test the unit. When functioning correctly many icons will appear.

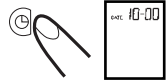
*If the unit is not functioning properly or is not functioning at all after battery insertion, check to

ensure correct placement. See + and - symbols inside battery compartment.

Note: You must set the current time and date after inserting the batteries, and each time you remove the batteries.

5.2. Checking the current time/date/year setting

Press and hold the Date/Time button. The date and time will be displayed.



5.3. Setting the time and date

This blood pressure monitor has an integrated clock with date display. This allows you to store blood pressure values corresponding to time of day and date. A total of 30 measurements with time and day will automatically be stored. After new batteries have been inserted, the clock begins to run from the following setting: 2003-01-01 00:00 o'clock.

You must then set the date and current time. For this, please proceed as follows (Example: Entering 06-15-2008 Time 09:30 A.M.):

1) Press the DATE/TIME button for at least 3 seconds. The display now indicates the set year, during which the characters blink.



2) The correct year can be entered by pressing the MEMORY button. (Example: Pressing 6 times changes to 2008).



3) Press the DATE/TIME button again. The display now switches to the date, during which the first character (month) blinks.



4) The current month can now be entered by pressing the MEMORY button.



5) Press the DATE/TIME button again. The last two characters (day) are now blinking.



6) The corresponding day can now be entered by pressing the MEMORY button.



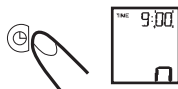
7) Press the DATE/TIME button again. The display now switches to the current time, during which the first character (hour) blinks.



8) The corresponding hour can now be entered by pressing the MEMORY button.



9) Press the DATE/TIME button again. The last two characters (minutes) now blink.



10) The exact time (minutes) can now be entered pressing the MEMORY button.



11) Now after all settings have been made, press the TIME button once again. The input is now complete and the clock begins to run. You can check the time and date settings by pushing the time button.



6. Measurement Procedure

6.1. Before the measurement:

- Avoid eating, smoking, and all forms of exertion before taking your blood pressure.
- All these factors influence the measurement result. Try to find time to relax by sitting in an armchair in a quiet atmosphere for about ten minutes before measurement.
- Always measure on the same wrist (normally left).
- Attempt to measure regularly at the same time of day, since your 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! Taking pressure when relaxed in a quiet environment is important.
- All efforts to hold your arm up can increase blood pressure. Make sure you are in a comfortable, relaxed position and do not activate any of the muscles in the measurement arm during the measurement. Use a cushion for support if necessary.
- **It is very important to have your blood pressure monitor at heart level.**
- Support your arm with a pillow. Taking your pressure with the monitor lower than heart level results in a false high reading.
- If the monitor is higher than heart level, a false low reading will result.
- A variation of 6 inches between monitor and heart level can result in a reading error of + or - 10 mmHg.
- A loose cuff causes false measurement values.
- With repeated measurements, blood accumulates in the measurement arm, which can lead to false results. Correctly executed blood pressure measurements should be repeated after a 5 minute pause, and after the arm has been held up in order to allow the accumulated blood to flow away for at least 3 minutes.

6.3. Fitting the cuff

- a) Remove all jewelry and watches. The palm of your hand should be facing you. Apply the cuff so that the display is facing you.
- b) The distance between the cuff and the hand should be 1/4" to 1/2" inch.

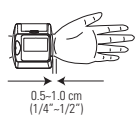
c) Secure the cuff with the hook and loop adhesive so that it lies comfortably and **not too tight**. It should be comfortable.

d) Lay your arm on a table with your palm upwards. Support your arm with a cushion so that the cuff rests at about the same height as the heart. Remain still for 2 minutes, sitting quietly, before beginning a measurement.



6.4. Measuring procedure (Measure in a seated position only. Stay still.)

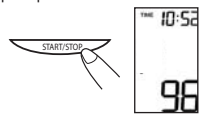
After the cuff has been appropriately positioned, and your arm is supported at heart level, the measurement can begin:



a) Press the Start/Stop button. The pump begins to inflate the cuff. In the display, the increasing cuff pressure is continually displayed.



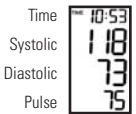
b) After automatically reaching the correct inflation pressure, the pump stops and the pressure slowly falls. The cuff pressure (large characters) is displayed during the measurement. When the device has detected the pulse, the heart symbol in the display begins to blink and a beep tone is audible for every pulse beat.



c) When the measurement is complete, a long beep tone sounds. The measured systolic and diastolic blood pressure values as well as the pulse are displayed.



The measurement results are displayed until you switch the device off by pressing the START/STOP button. If no button is pressed for 5 minutes, the device switches off automatically to save the batteries.

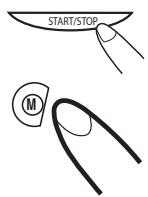


6.5. Discontinuing a measurement

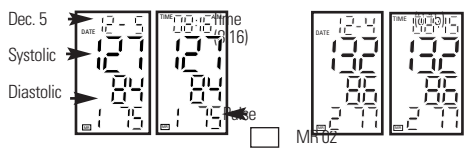
If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell), the Start/Stop button should be pressed at any time. The device then immediately lowers the cuff pressure automatically.

6.6. Memory – storage and recall of the measurements

This blood pressure monitor automatically stores each of the last 30 measurement values. By pressing the MEMORY button, the last measurement ([MR]01) as well as the last 29 measurements ([MR]02, [MR]03, ..., [MR]30) can be displayed, one after the other. Continue to press the Memory button to see other stored measurements.



Understanding memory readings



[MR]01: Values of the last measurement (Alternating display) [MR]02- MR 30: Values of the measurements before MR 01

Clearing the Memory

Press and hold the Memory button until a "CL" is displayed. Audible tone will signal when the memory has been cleared.

Further information

Repeating measurements without resting in between results in inaccurate readings. Wait several minutes in a relaxed position, sitting or lying, before you repeat a measurement.

7. 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)
Err 1	No pulse has been detected. Cuff may be positioned incorrectly.
Err 2	The arm was moved during the measurement.
Err 3	Inflation of the cuff took too long. The cuff is not positioned correctly.

Other possible errors and their solutions

Situation	Solution
The display remains blank when the unit is switched on although the batteries are in place.	<ol style="list-style-type: none">1. Check batteries for correct polarity and if necessary re-insert.2. If the display functions erratically re-insert batteries or exchange them.
The device frequently fails to measure the blood pressure values, or the values measured are too low or too high.	<ol style="list-style-type: none">1. Check the positioning of the cuff.2. Measure the blood pressure again while resting in a quiet environment. See 5.1 and 5.2
Every measurement results in different values, although the device functions normally and expected values are displayed.	<ol style="list-style-type: none">1. Your blood pressure changes minute to minute within a narrow range. Slight variations are not abnormal.
Blood pressure values differ from those measured by your doctor.	<ol style="list-style-type: none">1. Record your daily values and consult your doctor. Often measurements at the doctor's office are high due to anxiety.

Further Information

Your blood pressure is subject to fluctuations even in healthy people. Comparable measurements always require the same conditions. (Quiet conditions)! If you are carefully following the directions in this booklet and the fluctuations in your readings are larger than 15mmHg, and/or you hear irregular pulse tones on several occasions, please consult your doctor.

Consult ADC® if your monitor seems to be defective. **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 through 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 must not be washed!
- d) Do not drop the instrument or treat it roughly in any way. Avoid strong vibrations.
- e) Never open the device! This will invalidate the manufacturers warranty!

9. Warranty

Your ADC® blood pressure monitor is **guaranteed for 5 years** against manufacturers' defects for the original purchaser only, from date of purchase. The warranty does not apply to damage caused by improper handling, accidents, professional use, not following the operating instructions or alterations made to the instrument by third parties.

There are no user serviceable parts inside. Batteries or damage from old batteries is not covered by the warranty. The warranty is honored only after the unit has been registered at **www.adctoday.com** and follow the links.

10. Certifications

Device standard:

This device is manufactured to meet United States standards for non-invasive blood pressure monitors:

EN1060-1

EN1060-3

EN1060-4

AAMI/ANSI SP10

Electromagnetic compatibility:

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

11. Technical specifications:

Weight:	4.8oz. (137g) (with batteries + cuff)
Size:	3.27" x 2.9" x 2.6" (83 x 76 x 66mm) (including cuff)
Storage temperature:	-4°F to 131°F (-20°C to 55°C)
Operating humidity:	15 to 90% relative humidity maximum
Operation temperature:	50°F to 104°F (10°C to 40°C)
Display:	LCD (Liquid Crystal Display)
Measuring method:	Oscillometric
Pressure sensor:	Capacitive
Measuring range:	
SYS/DIA:	30 to 280 mmHg
Pulse:	40 to 200 beats per minute
Cuff pressure display range:	0-299 mmHg
Memory:	Stores 30 measurements
Measuring resolution:	1 mmHg
Accuracy:	Pressure within ± 3 mmHg Pulse ± 5 %
Power source:	2 size AAA, 1.5V batteries
Accessories:	storage case

Technical alterations reserved



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