

*e-sphyg*TM

Digital Aneroid

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User's Manual

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A Special Thank You...

Thank you for choosing an ADC® Diagnostix™ e-sphyg™ blood pressure instrument. We're proud of the care and quality that goes into the manufacture of each and every item that bears our name.

Only the finest materials are used to assure you of a timeless instrument designed for optimum performance.

You'll quickly appreciate the results; for you now own one of the finest sphygmomanometers that money can buy.

With proper care and maintenance, your ADC blood pressure instrument is sure to provide you with many years of dependable service. Please read the following instructions and general information, which will prove helpful in allowing you to enjoy your ADC product.

Thank you for your patronage. It is indeed our pleasure to serve you.

Sincerely,
American Diagnostic Corp.

To Register Your Product, visit us at
www.adctoday.com and follow the links

FOR QUESTIONS, COMMENTS, OR SUGGESTIONS
CALL TOLL FREE: 1-800-ADC-2670

Limited Warranty

American Diagnostic Corporation (ADC) warrants its products against defects in materials and workmanship under normal use and service as follows:

1. Warranty service extends to the original retail purchaser only and commences with the date of delivery.
2. The entire sphygmomanometer is warranted for one year.
3. The manometer is warranted to function and remain accurate to ± 3 mmHg over its full range when compared to a reference standard for life.

What is Covered: Repair, or replacement of parts, and labor.

What is not covered: Transportation charges to and from ADC. Damages caused by abuse, misuse, accident, or negligence. Incidental, special, or consequential damages. Some states do not allow the exclusion or limitation of incidental, special, or consequential damages, so this limitation may not apply to you.

To Obtain Warranty Service: Send item(s) postage paid to ADC, Attn: Service Dept., 55 Commerce Dr., Hauppauge, NY 11788. Please include your name and address, daytime phone no., proof of purchase, a brief note explaining the problem, and \$2.00 to cover the cost of return shipping and handling.

Implied Warranty: Any implied warranty shall be limited in duration to the terms of this warranty and in no case beyond the original selling price (except where prohibited by law). This warranty gives you specific legal rights and you may have other rights which vary from state to state.

ADC[®] *e-sphyg*[™] (Models 7002, 8002)

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This manual is intended to assist the user in the safe and efficient operation of the *e-sphyg*[™] Sphygmomanometer. The product must be used in accordance with the procedures contained in this manual and must not be used for purposes other than those described herein. It is essential to read and understand the entire manual. It is also important that your patients be acknowledged on blood pressure measurement described in "Measurement Procedure".

Introduction

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the auscultatory method, within the limits prescribed by the American National Standards Institute, ANSI/AAMI SP10: 2002, Manual, Electronic, or Automated Sphygmomanometers.

Your new ADC® e-sphyg™ gauge provides you with all of the functionality of a traditional aneroid gauge, with none of the problems associated with these mechanical devices. Using state of the art technology, your e-sphyg™ gauge will provide you with performance and reliability exceeding the most popular aneroid models. While traditional mechanical gauges can be easily knocked out of calibration when dropped, your digital gauge will remain accurate even when subjected to rough treatment. With its helpful on-screen calibration reminder, you will be able to use your new digital gauge with confidence and with the knowledge that it will remain calibrated beyond the lifespan of a more traditional mechanical gauge.

Your digital e-sphyg™ aneroid also has several features not available in a more traditional mechanical gauge. The systolic assist function will give you a visual alert when you are approaching the patient's estimated systolic pressure, allowing you to focus your attention to detect the beginnings of phase 1 Korotkoff sounds. The digital gauge will also monitor the patient's pulse during the measurement process, and display this information onscreen for you to record.

We hope you enjoy the convenience and accuracy of your new digital e-sphyg™ gauge. Using state-of-the-art technology, your e-sphyg™ will provide digital accuracy with tank-like reliability.

Intended Use

ADC® aneroid, digital aneroid, and mercurial sphygmomanometers are used by professional healthcare providers and individuals trained in auscultatory blood pressure technique to determine systolic and diastolic pressure in humans.

Specifications

Power Source: Two 1.5V DC LR03 (AAA) Alkaline Batteries

MEASUREMENT RANGE

Pressure: 0-299 mmHg
Pulse: 30-240 beats/min Accuracy
Pressure: ±3 mmHg
Pulse: Within ±5% of reading
Pressure Sensor: Semi-conductor
Inflation: Manual
Deflation: Manual Air Release Valve
Auto-shut-off: 1 min. after last key operation
Backlight auto-shut-off: 15 sec. after last key operation

OPERATION ENVIRONMENT

Temperature: 32-115°F (0-46°C)
Humidity: 85% Relative Humidity max

STORAGE ENVIRONMENT

Temperature: -4-131°F (-20-55°C)
Humidity: 90% Relative Humidity max (non condensing)
Dimensions: 3"(L) X 2^{3/8"}(W) X 1^{1/8"}(H)
Weight: 3.14 oz. (G.W.) (w/o Batteries) Type BF
Battery Life: 1500 readings with back light on
3000 readings with back light off

Device and cuff are designed to provide special protection against electrical shocks. Specifications are subject to change without notice.

Standards

ADC's digital aneroid sphygmomanometer is accurate to +/- 3 mmHg and conforms to applicable sections of the following international standards:

EV council directive 93/42/EEC

EMC directive 89/336/EEC

EN 1060-1: 1995, Non-invasive sphygmomanometers - Part 1:
General Requirements

EN 1060-3: 1997, Non-invasive sphygmomanometers - Part 3:
supplementary requirements for electro-mechanical blood pressure measuring systems
ANSI / AAMI SP10: 2002, Manual, Electronic, or Automated Sphygmomanometers

Care and Maintenance

Storage: After measurement, wrap cuff around gauge and bulb and store in zippered carrying case.

Cleaning: Digital Manometer: Your ADC® DIAGNOSTIX™ brand e-sphyg™ gauge requires minimal care and maintenance.

The manometer may be cleaned with a slightly dampened soft cloth, but should not be dismantled under any circumstances.

Cuff: Sponge with a damp cloth or alcohol pad. If necessary, it can be washed in cool water with mild soap or detergent-disinfectant. Remember to remove bladder from cuff prior to washing. After washing, it should be rinsed and allowed to air dry. **NEVER IRON.** Be sure to remove the bladder and all components before cleaning the cuff.

Bladder and Bulb: Remove bladder from cuff and disconnect bulb from tubing and valves. Wipe with a damp cloth. To help preserve it from cracking or discoloring, wipe with a soft cloth moistened with ethanol.

Valves: Clean the surface with a dry fabric such as soft cotton material. Remove dust from filter screen.

Carry Case: Wipe with a damp cloth and dry thoroughly with a dry cloth. If necessary, it can be washed with cool water and mild soap. Do not allow to air dry.

Batteries: If the e-sphyg™ will not be used for an extended period of time, remove batteries.

Disinfection and Sterilization

Disinfecting: Glutaraldehyde-type liquid disinfectant may only be used on the cuff. Follow instructions for use provided with the glutaraldehyde product. Prolonged use of this disinfectant may cause discoloration. DO NOT use glutaraldehyde-type liquid disinfectant on the digital gauge, bulb, valves, or bladder.

Sterilizing: The blood pressure cuff may be gas sterilized. **DO NOT** use steam or heat to sterilize the cuff, bulb, valve, or bladder. **DO NOT** attempt to sterilize the digital gauge.

WARNINGS

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.

NOTE: Systolic Assist and pulse measurement functions are NOT motion tolerant. (Pressure readings ARE). In a dynamic environment, systolic assist and pulse rate display may not operate correctly.

 **Caution:** Federal law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.

 **Caution:** Leaky batteries can damage the unit.

 **Caution:** Remove the batteries when the unit will not be used for an extended period of time.

 **Caution:** Your digital aneroid is a medical device designed for use by trained medical professionals. Keep out of the reach of children.

 **Caution:** Your digital aneroid is not field serviceable.

 **Caution:** You should not use any tool to open the device nor should you attempt to adjust anything inside the device.

 **Caution:** To stop the operation of your digital aneroid at any time, open the air release valve as you would on any mechanical blood pressure instrument, and the air in the cuff will be rapidly exhausted.

 **Caution:** Your digital aneroid is designed for normal blood pressure measurement at the upper arm or thigh on healthy skin. Proper use of this device is essential for accurate measurement.

 **Caution:** Do not inflate your digital aneroid unit to more than 300 mmHg.

Warning: If luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel. Immediately consult a physician if this occurs.

Warning: Do not allow a blood pressure cuff to remain on patient for more than 10 minutes when inflated above 10 mmHg. This may cause patient distress, disturb blood circulation, and contribute to the injury of peripheral nerves.

Warning: Safety and effectiveness with neonate cuff sizes 1 through 5 is not established.

Assembly

Your ADC DIAGNOSTIX™ e-sphyg™ digital aneroid sphygmomanometer consists of a digital manometer (gauge), complete inflation system (ADCUFF™ calibrated nylon cuff, latex inflation bladder (latex-free bladder optional), squeeze bulb, and the ADFLOW™ valve), a zippered carrying case, and operating instructions.

Parts and Features

- Extra large LCD is easier to read
- Virtually indestructible
- Backlight display for viewing in any light condition
- Splash resistant housing for use in harsh environments
- Manometer works with virtually any cuff



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ERROR DISPLAYS and TROUBLESHOOTING

Error Message:	Description:	Solution:
Err	Heartbeat rate detection error.	The cuff was deflated too rapidly. Keep the deflation rate at about 2-3 mmHg per second.
EE	A Pressure of over 15mmHg remaining for more than 3 minutes is detected.	Press the "⏏" button to switch the unit off, or the unit will automatically switch off after 60 seconds.
E3	Data Error.	Remove and reinsert the batteries. If this error keeps occurring, return the device to your local distributor or service center.
01	The cuff was inflated to a pressure over 300 mmHg.	Open the valve immediately to rapidly exhaust the air in the cuff.

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Calibration of Digital Gauge

Gauge accuracy can be checked visually whenever it is switched on. If the unit is used more than 10,000 times, a calibration reminder message (CAL) will appear on the digital display. Any digital gauge that displays this message should be returned for re-calibration to ADC's Service Department. Only ADC or an authorized service technician is qualified to perform this calibration service.

Do not attempt to recalibrate the gauge yourself.

In addition to the visual inspection indicated above, we also recommend you perform the following calibration check on an annual basis:

- Connect your gauge to a high-quality, known pressure standard using ADC's "Y" Test Kit (part number 991)
- Pressurize the gauge to 300 mmHg
- Reduce the pressure at a rate no greater than 10 mmHg per second, and stop to check at the following test points: 300mmHg, 240 mmHg, 160 mmHg, 120 mmHg, and 80 mmHg. Your gauge should be within +/-3 mmHg of your reference standard.

ADC recommends using the most sensitive pressure standard possible when performing this calibration check, as your ability to measure the accuracy of a gauge depends on the sensitivity of the pressure standard. If you are using a reference pressure standard that is only calibrated to +/- 3 mmHg (such as a mercury column or aneroid gauge), then you will only be able to determine the accuracy of the test gauge to within +/- 6 mmHg. If you use a reference pressure standard that is +/- .01 mmHg (such as a digital pressure standard), you will be able to determine the accuracy of the gauge being tested to within +/- 3.1 mmHg.

In the event that the gauge is ever in need of calibration, simply return to ADC. Damaged or broken parts will be replaced as needed at a minimum charge. Refer to the warranty for specific details of warranty coverage.

Display Explanations

1. Pressure:
Deflation Rate (During Measurement) /
Heartbeat Rate (After Measurement)
2. Heartbeat Mark
3. Deflation Rate
4. Calibration Reminder
5. Weak Battery Mark



Installing and Replacing Batteries

1. Rotate the clip 180°.
2. Loosen the screw on the battery cover using a coin or screwdriver.
3. Install the batteries with the polarities facing in the correct direction.
4. Replace the battery cover and tighten the screw.
5. Rotate the clip back.

Note: You should replace the batteries if:

- The weak battery mark appears in the display.
- Nothing appears in the display when the power is switched on. The supplied batteries may be discharged earlier than store-bought batteries. Always replace both batteries together.

Warning: Remove batteries when the unit is not in use for extended periods of time. Batteries are hazardous waste; please dispose of them properly.



Assembling your Sphygmomanometer

Your inflation system is pre-assembled and ready for use. You will need to simply connect your digital gauge to the complete inflation system by inserting the twist lock connector (pre-assembled on a bladder tube) into the air port at the bottom of the digital gauge, twist to lock.

If you will be hanging the gauge from the cuff gauge holder, it is recommended that the bladder tubing connecting the gauge be trimmed to a length of 6" to 9" for convenience. (Note: Be sure to retain the twist lock connector needed to attach the digital gauge to the tubing.)

Measurement Procedure (Auscultatory Method)

1. Patient Position: The patient should sit or lie comfortably. The arm should be fully supported on a flat surface at heart level. (If the arm's position varies, or is not level with the heart, measurement values obtained will not be consistent with the patient's true blood pressure.)

2. Apply the cuff: To attach the digital gauge, plug the connector into the gauge and twist clockwise to ensure a secure connection. The e-sphyg™ gauge can be either clipped on the gauge hang tab, or held in your hand during use. ADCUFF™ nylon cuffs are specially designed to promote the accurate determination of blood pressure. Index and range markings ensure use of the correct cuff size. The artery mark indicates proper cuff positioning.

Place the cuff over the bare upper arm with the artery mark positioned directly over the brachial artery. The bottom edge of the cuff should be positioned approximately one inch above the antecubital fold. Wrap the end of the cuff not containing the bladder around the arm snugly and smoothly and engage adhesive strips. To verify a correct fit, check that the Index Line falls between the two Range Lines.

3. Activate the digital aneroid and inflate the cuff: Press the "Ⓚ" On/Off button to activate your digital gauge. After zeroing, your digital gauge is ready to measure. Close the ADFLOW™ valve by turning thumbscrew clockwise. Palpate the radial artery while inflating the cuff. Be sure to inflate cuff quickly by squeezing bulb rapidly. Inflate cuff 20-30 mmHg above the point at which the radial pulse disappears.

4. Position the Stethoscope: Position the chestpiece in the antecubital space below the cuff, distal to the brachium. Do not place the chestpiece underneath the cuff, as this impedes accurate measurement. Use the bell side of a combination stethoscope for clearest detection of the low pitched Korotkoff (pulse) sounds.

5. Systolic Assist Function and Pulse Rate Display: Your digital e-sphyg™ gauge is equipped with a systolic assist function to help you more easily determine the onset of systolic blood pressure. As you deflate the cuff, a heart symbol will flash when the pressure is within about 20 mmHg of systolic pressure. Once you see the flashing symbol, pay close attention for the start of phase 1 Korotkoff sounds. The digital gauge will also measure the patient's pulse while you are measuring blood pressure, and display this information on the LCD screen once the cuff has been deflated.

Note: Systolic assist and pulse display features are NOT motion tolerant. Excessive movement may interfere with accurate display of these features. Excessive movement will NOT interfere with accurate determination of blood pressure using the e-sphyg™.

6. Deflate the cuff: Open the valve to deflate the cuff gradually at a rate of 2-5 mmHg per second (2-3 is preferred). The display will show the average deflation rate in the lower right corner of the LCD screen.

Caution: Excessive deflation rates (in excess of 7mmHg) will lead to inaccurate measurement and will make it difficult to pinpoint the readings on the display.

7. Measurement: Record the onset of Korotkoff sounds as the systolic pressure, and the disappearance of these sounds as diastolic pressure. (Some healthcare professionals recommend recording diastolic 1 and diastolic 2. Diastolic 1 occurs at phase 4).

After measurement is completed, open valve fully to release any remaining air in the cuff. The digital gauge will now display the patient's pulse. Remove cuff.

Backlight Control

The default setting on your digital gauge is to have the back light on once the pressure is inflated over 30 mmHg, and throughout the measurement process. To switch the backlight off at any time, press the "Ⓚ" button on the left side. You will need to deactivate the backlight each time you power on the instrument.