e-sphyg3™

Digital Blood Pressure Monitor

Instructions for Use

CAUTION: Federal law restricts this device to sale by or on the order of a physician or licensed healthcare provider

AMERICAN DIAGNOSTIC CORPORATION®

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A Special Thank You

Thank you for choosing an ADC blood pressure device. 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 device designed for optimum performance.

You'll quickly appreciate the results, for you now own one of the finest non-invasive blood pressure monitors that money can buy. With proper care and maintenance, your ADC blood pressure device is sure to provide you with many years of dependable service. Please read the following instructions.

Introduction

These instructions will help you understand the capabilities and operation of the e-sphyg 3 digital blood pressure monitor. Read this manual thoroughly before attempting to set up, configure, use, troubleshoot, or maintain the device.

Intended Use

The e-sphyg 3 is a non-invasive digital blood pressure monitor using oscillometric technique and an upper-arm blood pressure cuff to measure systolic and diastolic blood pressures, pulse rate, and mean arterial pressure (MAP). It can be used in pediatric and adult populations with arm cuff circumference sizes ranging from 14 cm to 52 cm.

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected preeclampsia.

The e-sphyg 3 combines the advantages of an automatic blood pressure device and auscultatory sphygmomanometer. It is designed to provide convenient, accurate, and reliable office blood pressure measurements according to guidelines of the European Society of Hypertension (ESH)[1], American Heart Association (AHA)[2], and World Health Organization (WHO)[3], with the only modification that the e-sphyg 3 always performs three repeated measurements, regardless of the result of the first two measurements.

Pregnancy

Approximately 20% of women develop hypertension during pregnancy (preeclampsia or toxemia). Preeclampsia can usually be recognized by a clear increase in blood pressure and high urine protein levels after 20 weeks of gestation. Since many oscillometric devices appeared to be unsuitable for use in pregnancy, preeclampsia health care authorities require that blood pressure monitors used for this vulnerable patient group are specifically tested.

The ADC e-sphyg 3 digital blood pressure monitor has successfully passed this validation and therefore may be recommended for use during pregnancy and preeclampsia.

[1] Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals: Part 1: Blood pressure measurement in humans: a statement for professionals from the subcommittee of professional and public education of the American Heart Association Council on High Blood Pressure Research. Circulation 2005;111:697-716.

[2] Whitworth JA. 2003 World Health Organization (WHO)/International Society of Hypertension (ISH) statement on management of hypertension. J Hypertens 2003;21:1983-92.

[3] O'Brien E, Asmar R, Beilin L, et al. Practice guidelines of the European Society of Hypertension for clinic, ambulatory and self blood pressure measurement. J Hypertens 2005;23:697-701. E, Asmar R, Beilin L, Imai Y, et al. European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. European Society of Hypertension Working Group on Blood Pressure Monitoring. J Hypertens 2005;23:697- 701.2003,21:1983-1992.

Warnings and Cautions

General warnings and cautions

WARNING: The information in these instructions for use provides a comprehensive guide to the operation of the e-sphyg 3. For best results, read thoroughly before using the device.

WARNING: The device is intended for use only in environments with clinician supervision.

WARNING: The device is designed for medical clinician use. Only a trained clinician should use this device.

WARNING: This device is NOT motion tolerant. It is not intended for use during patient transport.

WARNING: Fire and explosion hazard. Do not operate the device in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide, or in oxygen-enriched environments.

WARNING: Periodically inspect the blood pressure cuff and accessories for fraying or other damage. Replace as necessary.

WARNING: Inaccurate measurement risk. Do not use the device on patients who are connected to heart/lung machines.

WARNING: Electric shock hazard. Do not open the device or attempt repairs. There are no user-serviceable parts inside the e-sphyg 3, other than battery replacement. Only perform routine cleaning and maintenance as described in these instructions.

WARNING: The device complies with applicable domestic and international standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using the device in close proximity to other equipment.

WARNING: ADC is not responsible for the integrity of any mounting installation. ADC recommends that customers contact their Biomedical Engineering Department or maintenance service to ensure professional installation for safety and reliability of any mounting accessory.

WARNING: The device may not function properly if dropped or damaged. Do not use the device if you notice any signs of damage. Qualified service personnel must check any device that is dropped or damaged for proper operation before putting the device back in to use.

WARNING: If the battery shows any signs of damage, leakage, or cracking, it must be replaced immediately and only with a battery recommended for or supplied with the device.

WARNING: Improper disposal of batteries may create an explosion or contamination hazard. Never dispose of batteries in refuse containers. Do not incinerate batteries. Always recycle batteries according to local regulations.

WARNING: Improper handling of the battery can lead to heat generation, smoke, bursting, or fire.

WARNING: Do not disassemble, modify, or alter the battery.

WARNING: For proper patient electrical isolation and battery charging, use only the provided external power supply to charge the device.

WARNING: Electric shock hazard. Before cleaning the device, disconnect the power cord from the power source and the device.

WARNING: Take care to prevent water or other fluid from entering any connectors on the device. Should this occur, dry the connectors with warm air and check the accuracy of all operating functions.

WARNING: Avoid simultaneously connecting patients to the device and high-frequency surgical equipment.

CAUTION: The device is not heat-resistant. Do not autoclave.

CAUTION: Use the device within stated operating temperature ranges. The device will not meet performance specifications if used outside these temperatures.

CAUTION: Always unplug the external power source from the outlet before moving the device to a new location.

CAUTION: Use only ADC-approved accessories. Use of unapproved accessories with the device can affect patient and operator safety and can reduce product performance and accuracy.

CAUTION: Federal law restricts this device to sale by or on the order of a physician or licensed health care provider.

NIBP (non-invasive blood pressure) warnings and cautions

WARNING: The e-sphyg 3 is not intended to measure blood pressure on children younger than three years of age.

WARNING: Do not compress the blood pressure hose or cuff during measurement. This may cause system errors or patient safety risks.

WARNING: Inaccurate measurement risk. Do not use the device on patients who are experiencing convulsions or tremors.

WARNING: Use only blood pressure cuffs and hoses listed as approved accessories to ensure safe and accurate blood pressure measurements.

WARNING: Patient injury risk. When several blood pressure measurements are taken on the same patient, regularly check the cuff site and extremity for possible ischemia, purpura, and/or neuropathy.

WARNING: Do not allow a blood pressure cuff to remain on the patient more than five minutes when inflated above 15 mmHg. Excessive cuff tightness may cause venous congestion, peripheral nerve injury, discoloration of the limb, and patient distress.

WARNING: Patient injury risk. Never install luer connectors on ADC blood pressure tubing as it can create the risk of mistakenly connecting the tubing to a patient's intravenous line and introducing air into the patient's circulatory system.

WARNING: NIBP measurements may be inaccurate in the presence of excessive motion artifact. Minimize extremity and cuff motion during blood pressure measurement.

WARNING: The position and physiologic condition of the subject can affect a blood pressure reading.

CAUTION: Measurement arm should be at heart level. If the blood pressure cuff is not at heart level, note the difference in reading due to the hydrostatic effect.

CAUTION: Proper blood pressure cuff size and placement is essential to the accuracy of the blood pressure determination. See the section on Blood Pressure Cuff Selection for sizing information.

CAUTION: The blood pressure cuff must be properly positioned to ensure blood pressure accuracy and patient safety. Be sure to position the artery mark directly over the brachial artery. Wrapping the cuff too loosely (preventing proper inflation) may result in inaccurate blood pressure readings.

CAUTION: The patient should be comfortably seated, legs uncrossed, feet flat on the floor, back and arm supported. The midpoint of the cuff should be at the level of the heart.

CAUTION: For best results, patients should sit and relax for at least five minutes prior to the measurement.

CAUTION: Patients should not talk or move during the measurement procedure.

Symbols

Documentation symbols

WARNING: The warning statements in this manual identify conditions or practices that, if not corrected or discontinued immediately, could lead to illness, injury, or death.

CAUTION: The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.

CAUTION: Consult operating instructions for use (IFU), before using.

Helpful notes

Shipping, storing, and environment symbols

Fragile; handle with care

Recovery/Recyclable

Recycle the product separate from other disposables

Keep dry

Control symbols

On/Off Switch

Start/Stop Button

Memory Button

Adjust measurement interval times

Adjust maximum inflation pressure

Single-Reading Mode

Manual Mode

Three-Reading Average Mode

Miscellaneous symbols

Meets essential requirements of European Medical Device Directive 93/42/EEC

Authorized European Representative

Type BF applied parts

Manufacturer

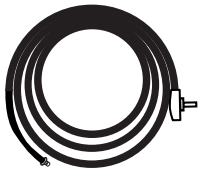
Latex free, not made with natural rubber latex

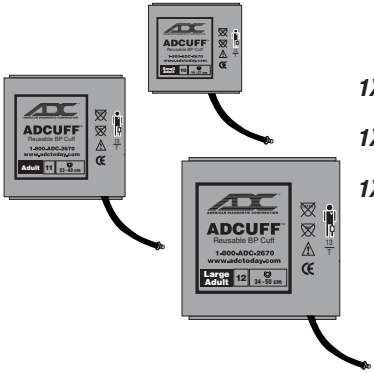
Phthalate free

E-sphyg 3 Components and Accessories

1 X e-sphyg3

Extension Tubing

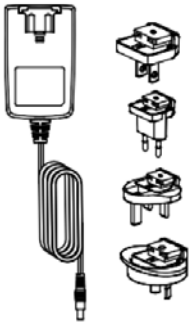




1X Small Adult Cuff (19cm-27cm)

1X Adult Cuff (23cm-40cm)

1X Large Adult Cuff (34cm-50cm)

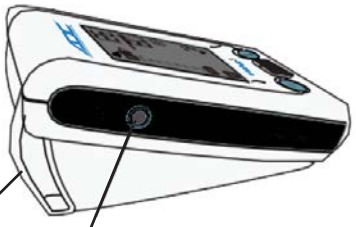


1X Power Adapter

4X Power Plugs
(US, Europe, UK, Australia)

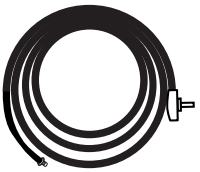
Input: 100-240V - 50/60Hz 0.5A
Output: +7.5V 1.5A

Parts and Assembly

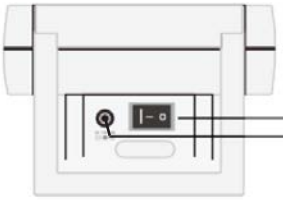


Handle

Cuff Socket



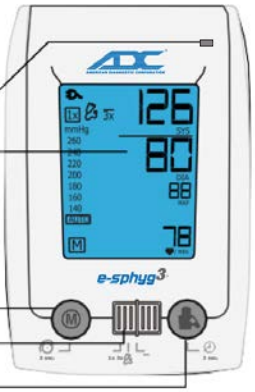
Extension Tubing

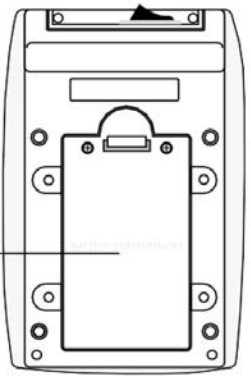


On/Off Switch

Power Adapter Socket

Battery Compartment





Recharge Indicator

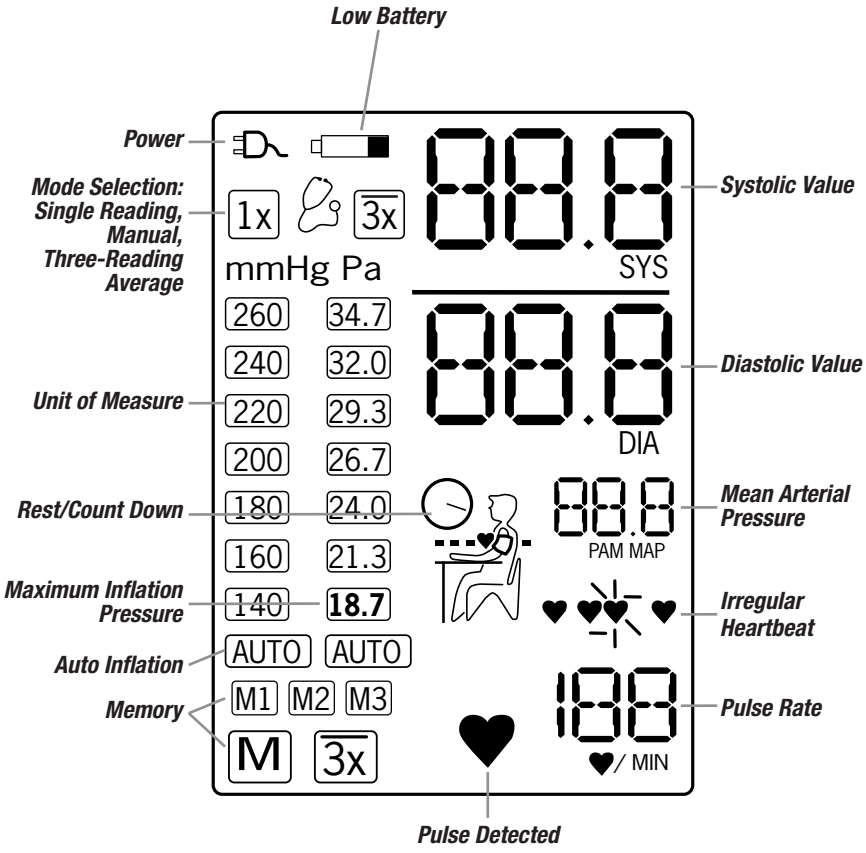
Display

Memory Button

Mode Switch

Start/Stop Button

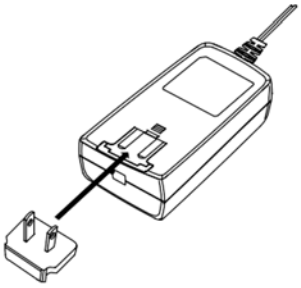
Display


Low Battery
Power
Mode Selection: Single Reading, Manual, Three-Reading Average
Unit of Measure
Rest/Count Down
Maximum Inflation Pressure
Auto Inflation
Memory
Pulse Detected
Systolic Value
Diastolic Value
Mean Arterial Pressure
Irregular Heartbeat
Pulse Rate
1x
3x
mmHg Pa
260
240
220
200
180
160
140
34.7
32.0
29.3
26.7
24.0
21.3
18.7
AUTO
AUTO
M1
M2
M3
M
3x
SYS
DIA
PAM MAP
/ MIN

Initial Setup

Attach power plug to adapter

Select a proper power plug and attach to the power adapter as shown below.



Charge the battery

When using for the first time, charge the battery until the recharge indicator on the device turns to green.

☞ *Refer to page 27 for the section of "Using the power adapter."*

☞ *Refer to page 27 for the section "Rechargeable battery."*

Connect the Extension Tubing

The e-sphyg 3 comes with a 140 cm (4.5 foot) extension tube that allows you to customize the distance between the unit and the patient, depending on your platform type, or mounting location. The blue connector plugs into the cuff socket on the side of the monitor; the metal bayonet connects to the cuff.

The extension tubing length is optimized for use with a wall-mount installation or mobile platform. For desktop use, you may want to shorten the tube. To do so, remove either connector, trim tube to desired length, and reattach connector.

Select the unit of measure

Three measurement unit combinations are available: **mmHg/MAP, mmHg/PAM, and kPa/MAP.**

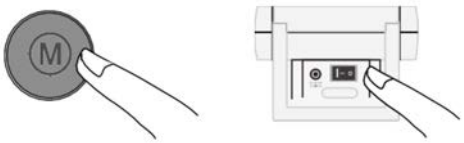
☞ *MAP is the abbreviation of Mean Arterial Pressure.*

☞ *PAM or MAP is chosen depending on language preference.*

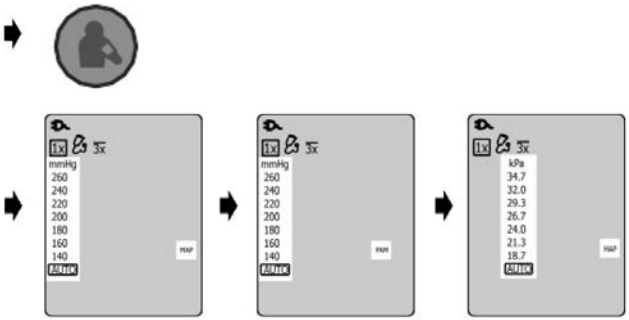
The factory default is mmHg/MAP.

To change the unit of measure:

1) Make sure the device is switched off.
2) Press and hold the Memory Button and then turn on the power with the On/Off Switch.



3) Release the Memory Button when backlight illuminates.
4) Press the Start/Stop Button to select the preferred pressure unit (mmHg or kPa).



5) Press the Memory Button to confirm the selection.

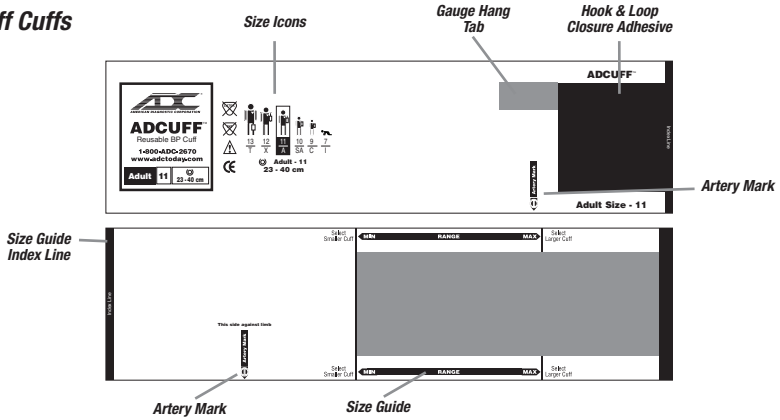
Choosing the Correct Cuff

Your e-sphyg 3 comes standard with three cuffs: ***Small Adult, Adult, and Large Adult.***

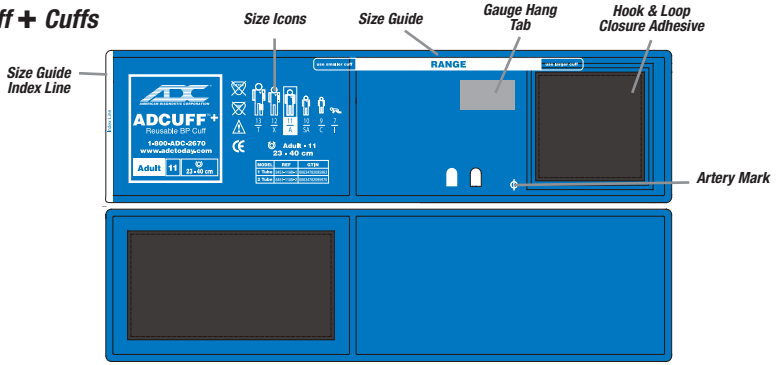
Cuff	Size	Limb Range	
		Inches	CM
Small Adult	**10SA**	**7.4 to 10.6**	**19 to 27**
Adult	**11A**	**9 to 15.7**	**23 to 40**
Large Adult	**12X**	**13.3 to 19.6**	**34 to 50**

ADC's Size Guide marking system assures use of correct cuff size and proper cuff alignment. Printed Index and Range markings and applicable limb range (in/cm) allow easy identification of the correct cuff size. An artery mark indicates bladder midpoint for correct cuff positioning. Hook-and-loop adhesive surface provides a snug, infinitely variable fit and is designed to withstand a minimum of 30,000 open/close cycles.

Adcuff Cuffs



Adcuff + Cuffs



☞ *Each cuff is provided with 50 cm air tube.*

☞ *Use only cuffs provided by ADC!*

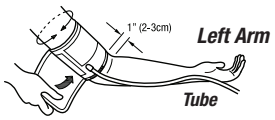
☞ *Contact ADC or an authorized distributor to purchase cuffs.*

Measurement Procedure

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.) When seated, the patient should have their back and arm supported, and their legs should not be crossed. Prior to measurement the patient should relax comfortably for five minutes and should refrain from talking or moving during measurement.

Apply the cuff



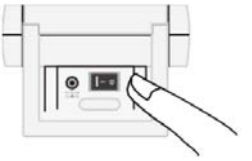
Place the cuff over the bare upper arm with the artery mark positioned directly over the brachial artery. The bottom edge of the cuff should be approximately one inch (2-3 cm) above the antecubital fold. Wrap the opposite end of the cuff around the arm snugly and smoothly and engage adhesive strip.

To verify a correct fit, check that the Index Line falls between the two Range Lines.

Taking Measurements

Turn on the power

Turn on the device by moving the On/Off Switch to the ON position.



Connect the cuff

Connect the cuff to the extension tubing.

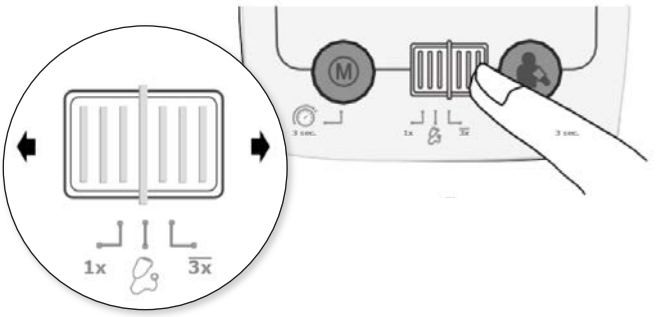
Set maximum inflation pressure

Select desired maximum inflation pressure or choose "AUTO".

☞ *Refer to page 23 for the section on "Set maximum inflation pressure"*

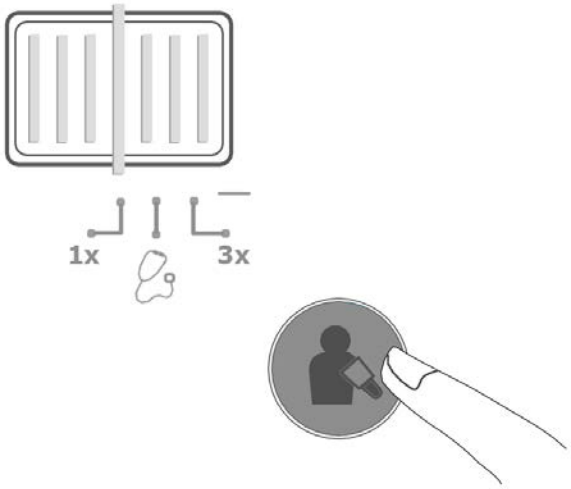
Select an operation mode

There are three measurement modes.
Slide the switch to select ***1x*** (standard single measurement), **Manual,** or ***$\overline{3x}$*** **Mode** (automatic three-reading average).



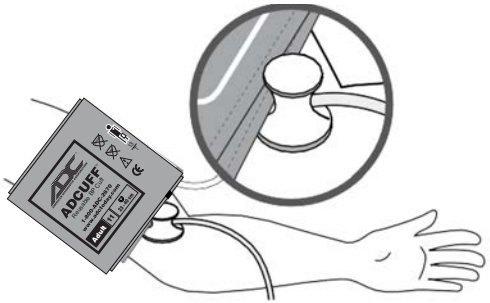
1x Mode (standard single measurement)

Select «***1x***» Mode then press the Start/Stop Button to perform a single blood pressure measurement. The measurement reading is displayed and saved after the measurement.

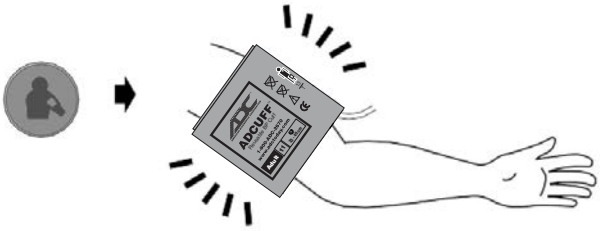


«Manual» Mode

Select **Manual** Mode if auscultatory blood pressure measurement is preferred above using the oscillometric method. In «***Manual***» Mode, the device serves only as a pressure gauge. No oscillometric measurements will be taken. The user can hear the systolic and diastolic Korotkoff sounds by means of a stethoscope placed over the brachial artery.



Start inflation – Press the Start/Stop Button to begin inflation. When maximum inflation pressure is reached, the e-sphyg 3 will automatically begin linear deflation at a rate of 3 mmHg/sec.



Re-inflate – Push and Hold the Memory Button during deflation to re-inflate for as long as the button is held (up to a max of 299 mmHg). Release the button to continue deflation.

Exceeding 299 mmHg will result in an immediate release of cuff pressure and a '**HI**' error message.

When the cuff pressure reaches 20 mmHg during the deflation cycle, the remaining pressure is vented and the e-sphyg 3 goes into standby mode.

Push the Start/Stop Button at any time to start fast deflation and set the e-sphyg 3 to standby.

Take note of the systolic and diastolic values in the same manner as performed with sphygmomanometer measurements.

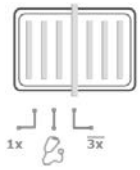
Set to standby – The device can be set to standby while a reading is displayed by pressing the Start/Stop Button. The device will automatically switch to standby if there is no operation for one minute.

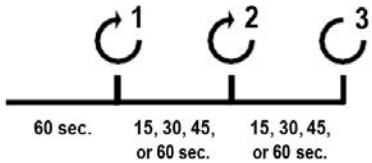
«$\overline{3x}$» Mode (automatic three-reading average)

Select «$\overline{3x}$» Mode then press the Start/Stop Button to perform on automatic three-reading average.

The countdown time before the first measurement is set at 60 seconds.

The interval times between measurements is user adjustable to 15, 30, 45, or 60 seconds. The average measurement reading is displayed and saved after all three measurements are complete.





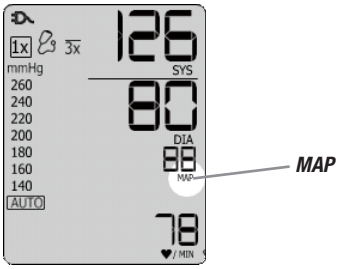
☞ *The user can manually select measurement interval times of 15, 30, 45 or 60 seconds in «$\overline{3x}$» Mode. (Please refer to "Setting measurement interval times" on page 25).*

☞ *The 60-second wait period before the first measurement is not adjustable but may be bypassed by pressing the Start/Stop Button a second time. This will start the first reading immediately.*

Special Features

MAP (mean arterial pressure)

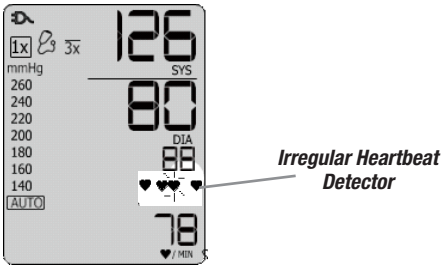
The e-sphyg 3 measures the patient's true mean arterial pressure (MAP). Each measurement includes a single MAP value. The MAP value will always be displayed together with the systolic and diastolic blood pressure value.



☞ *MAP is determined from the maximum peak of the oscillometric envelope curve.*

Irregular heartbeat detector in «*1x*» Mode

The device detects irregular heartbeat in *«**1x**»* Mode. The irregular heartbeat symbol shows up if, during the blood pressure measurement, the heart rate has varied by more than 25%. An irregular heartbeat can affect the blood pressure measurement. It is recommended to repeat the measurement or to choose *«**Manual**»* Mode for verification.

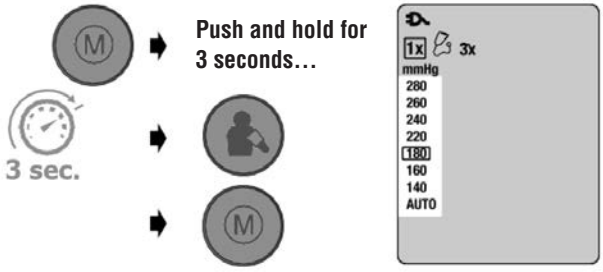


Setting maximum inflation pressure

1) Press and hold the Memory Button for three seconds until the column with pressure values flashes.

2) Press the Start/Stop Button to select the preferred pressure value (after value “260” has been reached the selector will return to “AUTO” at the bottom of the list).

3) Press the Memory Button to confirm the selected value.



☞ *The inflation pressure selection (mmHg/kPa) can be done in «**1x**», «**3x**», or Manual Mode. The default setting is “AUTO.”*

☞ *When set to AUTO, the e-sphyg 3 will automatically determine the maximum inflation pressure as it inflates the cuff.*

If the maximum inflation pressure selected (or the maximum inflation pressure as determined while in AUTO mode) is not adequate to determine systolic pressure, the device will reinflate to a pressure 30 mmHg higher than the previous inflation pressure and attempt another cycle. This can be repeated increasing the maximum inflation by 30 mmHg each time. If a maximum inflation pressure of 280 mmHg is reached, and the e-sphyg 3 is unable to determine a blood pressure, an error code will be displayed.

It is recommended at this point to switch to the manual mode and determine blood pressure with a stethoscope using traditional Korotkoff method (see *«**Manual**»* Mode, page 19*).*

Taking fewer than three measurements in «$\overline{3x}$» Mode

The measurement sequence can be stopped at any time by pressing the Start/Stop Button. The device enters standby and remaining measurements are cancelled. Data from the measured blood pressure can be viewed by pushing the Memory Button.

Cancel remaining measurements at any time during the measurement sequence.

Skipping countdown time in «$\overline{3x}$» Mode

The countdown before and between measurements in «$\overline{3x}$» Mode can be skipped by pressing the Start/Stop Button. When the Start/Stop Button is pressed during countdown, the device will immediately begin the next measurement.

Skip the countdown time and begin the measurement.

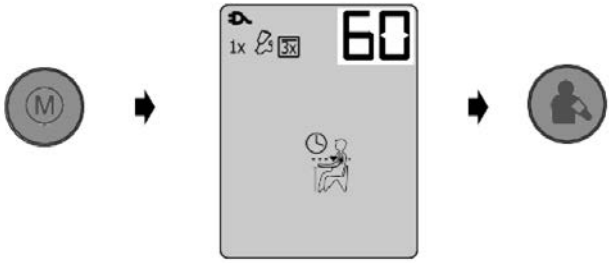
☞ *The device can be set to standby while a reading result is displayed by pressing the Start/Stop Button. The device will automatically switch to standby if there is no operation for one minute.*

Setting measurement interval times in «$\overline{3x}$» Mode

The default measurement interval time is 60 seconds. The interval times can be set as 15, 30, 45, or 60 seconds.

1) Press and hold the Start/Stop Button for three seconds.

2) Press the Memory Button to adjust the measurement interval time, then press the Start/Stop Button to confirm. The device will go back to standby.

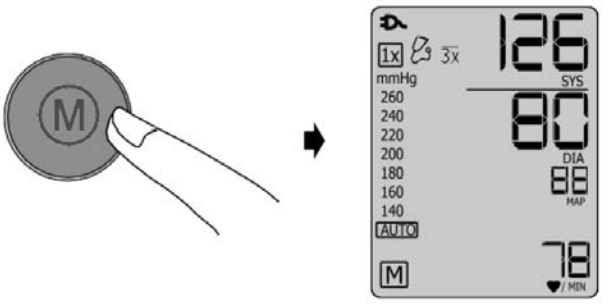


☞ *Interval times can be set to 15, 30, 45, or 60 seconds.*

Viewing the stored values

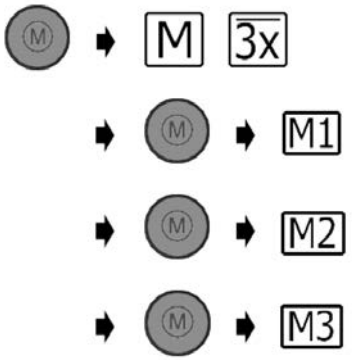
*The device stores blood pressure values of the last measurement procedure in **«1x»** and **«3x»** Mode. Press the Memory Button to review the stored readings when the device is in standby mode.*

In «1x» Mode



In «3x» Mode

Press the Memory Button to reveal the average of the triple measurements. Continue pressing the Memory Button to review individual measurements.



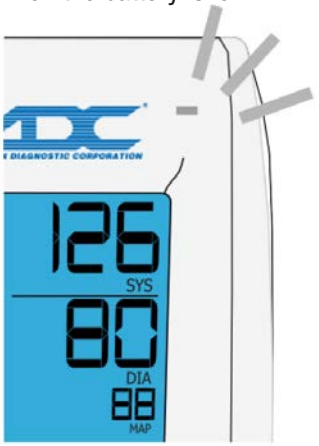
☞ *The device stores only the last measurement completed in «**1x**» Mode and the last three measurements completed in « **3x**» Mode.*

☞ *Stored values are erased when the unit is powered off.*

Rechargeable Battery and Power Adapter

Rechargeable battery

The e-sphyg 3 features a built-in, rechargeable Ni-MH battery pack that provides up to 1200 measurement cycles on a full charge. The battery can be recharged with the power adapter provided. The empty battery indicator is displayed when the battery is low.



☞ *When using for the first time, charge the battery until the recharge indicator turns to green.*

☞ *The orange recharge indicator means that the recharge is in progress.*

☞ *A green recharge indicator means that the recharge is completed.*

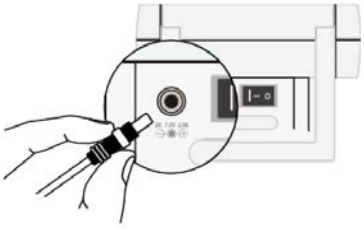
Using the power adapter

Use only the adapter supplied with e-sphyg 3 to recharge the device.

1) Plug the adapter cable into the power socket on the back of the device.

2) Plug the adapter plug into an AC wall socket. After the battery is fully recharged, the charging will stop. No battery power will be used while the adapter is plugged in, though the battery must remain in the e-sphyg 3 when using AC power.

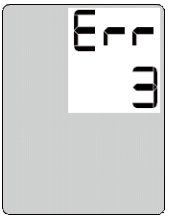
3) If the battery starts losing capacity, contact your local dealer for a replacement battery. The battery is user replaceable.



Troubleshooting

Problem	Possible cause	Solutions
No power (No LCD display)	Power supply is not properly plugged in.	Plug the power supply into the wall socket.
	Battery is fully discharged.	Recharge the battery by plugging in the power supply.
Cuff does not inflate properly	Loose connection of the tube.	Make sure the tube of the cuff is securely connected to the device.
	Leakage of the tube / bladder.	Check for cracks on the tube or the bladder. Replace the blood pressure cuff if necessary.
No result displayed after measurements	Device is in Manual Mode.	Switch to «***1x***» or «$\overline{3x}$» Mode and repeat the measurements.

Error Messages



If an error occurs during a measurement, the measurement is interrupted and an error message «Err» is displayed.

Error	Description	Potential cause and remedy
«Err 1»	**Signal too weak**	The pulse signals on the cuff are too weak. Reposition the cuff and repeat the measurement.
«Err 2»	**Error signal**	During the measurement, error signals were detected by the cuff (caused, for instance, by movement or muscle tension). Repeat the measurement keeping patient's arm still.

«Err 3»	**No pressure in the cuff**	An adequate pressure cannot be generated in the cuff. A leak may have occurred. Replace the blood pressure cuff if necessary. Repeat the measurement.
«Err 5»	**No valid results**	The measuring signals are inaccurate therefore no result can be displayed. Switch to Manual Mode and determine blood pressure with a stethoscope using traditional Korotkoff method.
«HI»	**Pulse rate or cuff pressure too high**	The pressure in the cuff is too high (over 300 mmHg) OR the pulse is too high (over 200 beats per minute). Have the patient relax for 5 minutes and repeat the measurement.
«LO»	**Pulse too low**	The pulse is too low (less than 40 beats per minute). Repeat the measurement.

Safety and Protection

This device may be used only for the purpose described in this manual. The device contains sensitive components and must be treated with care. The manufacturer cannot be held liable for damage caused by incorrect application.

- Only activate the pump when the cuff is connected to the device.
- Do not use the device if you think it is damaged or if anything appears unusual.
- Read further safety instructions in the individual sections of the instruction manual.

☞ Observe the storage and operating conditions described in the “Technical Specifications” on page 33.

- Protect the device from water and moisture
- Protect the device from direct sunlight
- Protect the device from extreme heat and cold
- Never open device
- Avoid proximity to electromagnetic fields, such as those produced by mobile phones
- Protect device from impact and drops

Cleaning the Unit

Use a soft cloth with one of the following recommended cleaning solutions to wipe the exterior of the device:

1) Mild soap and water
2) Hydrogen peroxide solution (3% diluted with water)
3) Sodium hypochlorite solution (1:10 dilution of household chloride bleach in water)

Cleaning the Cuff

Adcuff (Two-piece design):

Remove the bladder. Fold and place the cuff cover inside a washing bag. Wash the cuff cover with warm water (43°C; 110°F) and a mild detergent in the washing machine.

Pasteurization: Wash the cuff cover in 75°C (167°F) hot water for 30 minutes.

Air dry the cuff. DO NOT iron the cuff cover.

Adcuff+ (One-piece design):

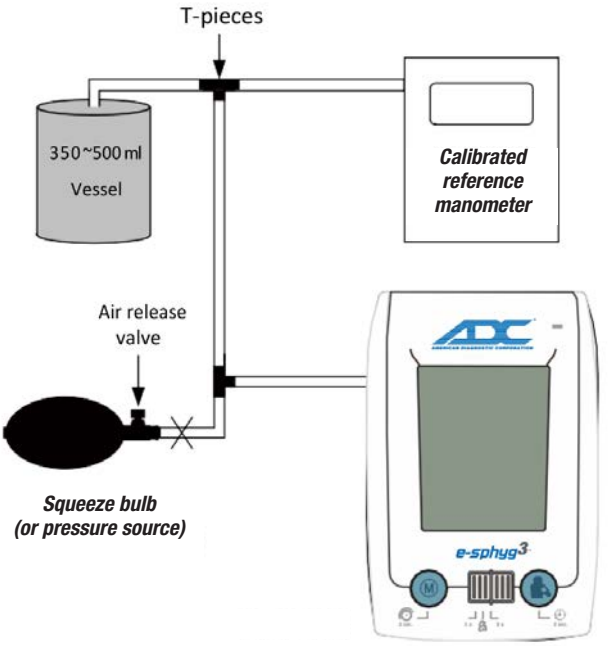
Throughly saturate all surfaces of the cuff and accessories with germicidal cleaner. Use a soft brush to remove visible soil. Rinse with water, then damp dry.

To disinfect, throughly re-saturate all surfaces of the cuff with germicidal cleaner. Use a soft brush to clean. Allow a five-minute wet contact time (or as directed by the cleaner manufacturer). Do not exceed 10 minutes of wet contact time.

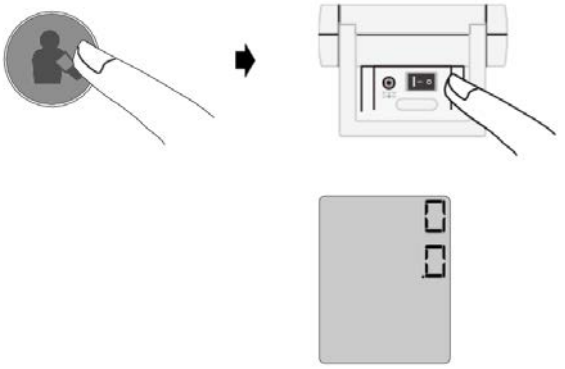
Calibration

We recommend the device be tested for accuracy every two years or after mechanical impact (e.g., been dropped).

1) Set up for accuracy test:



2) Push and hold Start/Stop Button, turn the power on, then release the Start/Stop Button. A series of codes will flash on screen, then “0.0” will display.

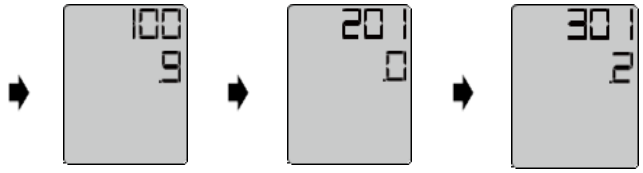


3) Pump the pressure to nearly 100 mmHg. Compare the pressure displayed on the screens of the device and the reference manometer. For example, the “100 .9” displayed on the device stands for “100.9 mmHg.”

4) Pump the pressure to nearly 200 mmHg. Compare the pressure displayed on the screens of the device and the reference manometer. For example, the “201.0” displayed on the device stands for “201.0 mmHg.”

5) Pump the pressure to nearly 300 mmHg. Compare the pressure displayed on the screens of the device and the reference manometer. For example, the “301.2” displayed on the device stands for “301.2 mmHg.”

6) If the difference between the device and the reference manometer at any calibration point exceeds ±3 mmHg plus the stated accuracy of the reference manometer, contact ADC to obtain calibration service.



Technical Specifications

Operation temperature/humidity:
50°F to 104°F (10°C to 40°C)
15 - 90% relative maximum humidity

Storage temperature/humidity:
-4°F to 131°F (-20°C to 55°C)
15 - 90% relative maximum humidity

Weight: 2.08 lbs (942 g) (including rechargeable battery pack)

Dimensions: 7.87'' x 4.92'' x 3.54'' (20 x 12.5 x 9 cm)

Measuring method: Oscillometric
Systolic blood pressure = K1
Diastolic blood pressure = K5

Measurement range:
60 - 255 mmHg - systolic blood pressure
30 - 200 mmHg - diastolic blood pressure
40 - 200 beats per minute - pulse

Cuff pressure display:
Range: 0 - 299 mmHg
Resolution: 1 mmHg
Static accuracy: pressure within ± 3 mmHg
Pulse accuracy: ±5% of the readout value

Power source: Rechargeable battery pack
4.8V 3500 mAh
Mains power supply DC 7.5V, 1.5 A

ADC reserves the right to alter technical specifications without prior written notice.

Reference to standards:
IEC 60601-1: 2005+A1:2012
IEC 60601-1-2: 2014
IEC 60601-1-6
ANSI/AAMI/ISO 81060-2
ANSI/AAMI/ISO/IEC 80601-2-30

Electromagnetic compatibility:
Device fulfills the stipulations of the standard IEC 60601-1-2.

CE 0044 The stipulations of the EU Directive 93/42/EEC for Medical Devices Class IIa have been fulfilled.

Type BF applied part

Intertek 5000497 ETL Classified

Annex of Report

Manufacturer's Declaration of the EUT

Report No.: TRE14120020 A 2 Issued: 2014-12-15

Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

1	**Guidelines and manufacturer's declaration - electromagnetic emissions**		
2	The e-sphyg 3 Digital Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of e-sphyg 3 Blood Pressure Monitor should assure that it is used in such an environment.		
3	**Emissions Test**	**Compliance**	**Electromagnetic Environment - Guidance**
4	RF emissions CISPR 11	Group 1	The e-sphyg 3 Digital Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	The e-sphyg 3 Digital Blood Pressure Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The e-sphyg 3 Digital Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the e-sphyg 3 Digital Blood Pressure Monitor should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the e-sphyg 3 Digital Blood Pressure Monitor requires continued operation during power mains interruptions, it is recommended that the e-sphyg 3 Digital Blood Pressure Monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note - UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity

The e-sphyg 3 Digital Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the e-sphyg 3 Digital Blood Pressure Monitor should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the e-sphyg 3 Digital Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d [3.5] P V 1 d [3.5] P 80 MHz to 800 MHz E1 d [7] P 800 MHz to 2.5 GHz E1 where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the e-sphyg 3 Digital Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the e-sphyg 3 Digital Blood Pressure Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the e-sphyg 3 Digital Blood Pressure Monitor .b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - or EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the e-sphyg 3 Digital Blood Pressure Monitor

The e-sphyg 3 Digital Blood Pressure Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the e-sphyg 3 Digital Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the e-sphyg 3 Digital Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d [3.5] P V 1	80 MHz to 800 MHz d [3.5] P E1	800 MHz to 2.5GHz d [7] P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Warranty

Please register your e-sphyg 3 online at: **http://www.adctoday.com/register**.

ADC warrants its products against defects in materials and workmanship under normal use and service as follows:

Your e-sphyg 3 and Adcuffs are warranted for three years. The battery is warranted for one year. Accessories are warranted for one year. Warranty service extends to the original retail purchaser only and commences with the date of delivery.

What Is Covered: Replacement of parts and labor.

What Is Not Covered: Transportation charges to 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: Repair Dept., 55 Commerce Dr., Hauppauge, NY 11788. Please include your name and address, phone no., proof of purchase, and a brief note explaining the problem.

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.

For Australian Consumers: Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonable foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

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IFU p/n: 93-9003EIFU-00 REV 0 (12/9/2019)