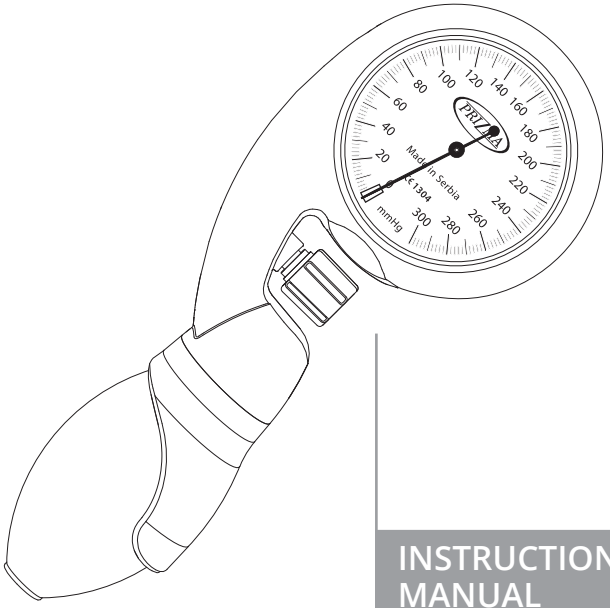
PRIZMA

Aneroid blood pressure measuring device

PA1



INSTRUCTION MANUAL

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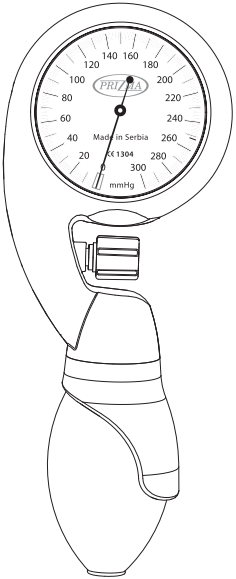
Dear Customer,



About this Manual

This manual contains information necessary for proper use, maintenance, and storage of your aneroid blood pressure measuring device. We recommend that you read this manual carefully, including warnings, contraindications and notes, before using this device.

We wish you good health!

Your PRIZMA Kragujevac

Table of Contents

1. Preface

1.1 About blood pressure

Blood pressure is the mechanical pressure exerted by blood on the inner surface of arterial blood vessels. It is measured in millimeters of mercury. Blood pressure of a human is not constant over 24 hours, but fluctuates within the certain range. There are two components of blood pressure:

Systolic blood pressure is the value of blood pressure that occurs in arteries in the moment of contraction and ejection of blood from the left ventricle into circulation.

Diastolic blood pressure refers to pressure in arteries in the moment of ventricular relaxation.

Classification of arterial hypertension					
ESH/ESC category	Systolic pressure		Diastolic pressure		AHA/ACC category
	mmHg	kPa	mmHg	kPa	
Optimal	< 120	< 15.9	< 80	< 10.5	Normal
Normal	120–129	15.9-16,5	80–84	10.5-10,8	Prehypertension
High normal	130–139	17.0–18.5	85–89	11.0–11.9	Prehypertension
Hypertension	**≥140**	**≥18.7**	**≥90**	**≥12.0**	**Hypertension**
Stage I (mild hypertension)	140–159	18.7–21.2	90–99	12.0–13.2	Stage I
Stage II (moderate hypertension)	≥160-179	≥21.3-24,0	≥100-110	≥13.3-14.3	Stage II
Stage III (severe hypertension)	≥180	≥24.0	≥110	≥14.3	Stage II

Table 1.

1.2 Blood pressure disorders

High blood pressure (Arterial hypertension) is defined as a condition in which either both or one component of blood pressure are elevated above the values referred to as referent ones(Table 1).

A good control of blood pressure requires repeated blood pressure measurements at few days' intervals, which can be performed at your doctor's office or out of it. Elevated blood pressure values are often without symptoms, which can result in a delayed diagnosis. If elevated blood pressure values persist over prolonged period of time, they can cause numerous complications in target organs, such as heart, brain, and kidneys. A better control of blood pressure may reduce the risk form sudden cardiovascular and cerebrovascular events.

Regular measurement of blood pressure is beneficial for diagnosis, as well as for therapy control. High blood pressure in pregnancy represents a particular problem, which requires a regular monitoring with a constant consultation with physician.

Low blood pressure (Arterial hypotension) is a condition in which either both or one component of blood pressure are lowered bellow expected values. Regular monitoring of blood pressure is beneficial not only for diagnosis of hypertension, but also for diagnosis of hypotension. Hypotension may cause dizziness and loss of consciousness particularly in elderly who experience deterioration of autonomous nervous system functions during standing, after meals, or after having bath.

1.3 Proper measurement of blood pressure

Indirect methods for measurement of blood pressure was introduced by Korotkoff in 1905. It is still used without major modifications.

Blood pressure is measured in sitting position. Cuff should be wrapped around upper arm, so that its edge is positioned 2 cm above the cubital fossa (elbow pit). Palpate radial pulse, inflate the cuff quickly up to 70 mmHg, and later on gradually. Note the level of pressure in which pulse dissapears when blood vessel is completely compressed,

and inflate cuff additionally 30 mmHg above that value. Position the chestpiece on the spot palpated above the brachial artery. Release the air from the cuff at speed of 2-3 mmHg per second. Once the systolic pressure is equalized with the pressure in the cuff, the first sounds are audible (so called Korotkoff sounds). In the moment when they completely disappear, diastolic pressure is equalized with the pressure in the cuff, and blood flow is again uniform. Auscultation of those sounds is conducted in five phases, and occurrence of the first phase that marks appearance of the sounds corresponds to value of systolic pressure, while occurrence of the fifth phase, when sounds disappear, represents the value of diastolic pressure.

Measurement should be repeated after half of an hour, and then mean value of both measurements should be calculated.

Note:

- In children, age 4 to 12, value of diastolic blood pressure is read in the fourth phase. The fourth phase of sounds auscultation marks transition from a clear sound to a muffled one.
- In pregnant women, value of diastolic blood pressure is read in the fifth phase, except in the case when air from the cuff is released and sounds are still audible, and then blood pressure is read in the fourth phase.

1.4 About aneroid blood pressure measuring device

PA1 is an aneroid device for accurate and precise measurement of blood pressure using manometer (pressure gauge) with a pump, cuff and stethoscope. Measured values are read on the large and clearly visible manometer's scale. It is suitable for professional use in hospitals, offices, ambulances, as well as for use in home environment (with an adequate training and provided that instruction for use is carefully read). A special ergonomic design allows a simple and comfortable use with both left and the right hand. PA1 contains a predefined cuff that allows a larger contact area, proper positioning and comfort. Larger contact area allows a higher reliability of the device during blood pressure measurement.

2. Precautions For Safe Use

2.1 Contraindications

- DO NOT PLACE cuff on a patient's arm receiving an intravenous drip, because cuff inflation may cause obstruction of fluid flow and/or injury.
- DO NOT PLACE cuff over wounds, because cuff inflation and pressure may cause additional injury.
- It is not intended to place cuff and to apply pressure on an arm where arterial-venous fistula is placed.

2.2 Warnings

Limitations of use

- Not intended for use in newborns.
- Do not use the device in persons younger than four years or when arm circumference deviates from the recommended 22-42 cm.
- No modification of the device and equipment is allowed.
- Do not repair/maintenance the device while in use.
- The product is not intended for sterilization.
- Modification of this equipment is not allowed.
- It is not intended to inflate the cuff on the side of the body where mastectomy was performed.
- Do not place cuff on the same arm with equipment attached for another medical measurements.

Warnings about proper measurement and safe use

- If you use additional components that were not intended by manufacturer, it may cause a measurement error.
- Make sure that pressure created by cuff inflation is appropriate for the given patient.

- If you notice any abnormalities during measurement, stop measurement immediately and remove cuff from the patient's arm.
- If the cuff does not deflate, remove it properly and safely.
- If the device is exposed to moisture, store it to a well-ventilated place to allow it to dry before the next use.
- Measured blood pressure values should be interpreted only by a qualified physician.
- Please make sure that use of the product does not result in prolonged problems with circulation in patients.
- Store the device in safe place, out of reach of children.

2.3 Caution during measurement

- During blood pressure measurement, cuff should be placed at the heart level, the person should be still, should not move his/her arm, and it is preferable that person is not talking.
- If the arm, where the cuff is placed, is bent, keep it in that position, do not stretch the arm or touch the cuff. Otherwise, sudden changes of pressure within the cuff may occur, which interfere with measurement.
- If the patient feels pain or discomfort during inflation of the cuff, remove the cuff. Excessive inflation may block blod flow in the patient's arm.
- Use and storage of the device that are not in accordance with the conditions provided in this manual may cause damages.

2.4 Environmental preservation and protection

- Please handle discarded cuffs, components or main device in accordance with local regulations governing environmental protection.

- Contaminated equipment must be dispose of in accordance with local regulations governing environmental protection, in order not to endanger customers' health.

2.5 Maintenance

- Please use only equipment supplied by Prizma in order to avoid measurement errors.
- Maintenance procedure should be entrusted only to trained personnel or to personnel authorized by company Prizma.
- Documentation required for service activities by trained personnel or by personnel authorized by company Prizma, is available at...
- In the event of malfunctioning, refer to Section 5. Troubleshooting.

Note:

- Technical details are intended for trained personnel or personnel authorized by company Prizma.
- Certain governmental institutions may request additional qualifications for personnel in charge of service activities.

In order to protect the device from damages, please adhere to the following:

- Store the device and components in a clean and safe place.
- Do not disassemble the device, and do not attempt to repair device and equipment, because that will void the warranty. Changes or modification not approved by manufacturer will void the warranty.
- Accuracy of this blood pressure measuring device was carefully tested and device was designed to have a long service life. It is generally recommended to inspect the device every six months in order to ensure its proper operation and accuracy. Consult the vendor or distributor for company PRIZMA.

- Referent manometer for accuracy check must be traceable to the national or international standard.

2.6 Cleaning

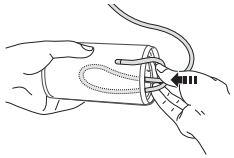
- Do not use any abrasive or volatile agents.
- Do not wash the device or any component or immerse them into water. Do not use benzine, diluting agents or similar solvents for cleaning of the device.
- Use soft, dry cloth or soft cloth moistened with a neutral detergent for cleaning of the device, its components, stethoscope and arm cuff.

2.7 Storage

When the device is not in use, keep it in its carrying case.

1. Remove the air hose from the air hose connector on the manometer.
2. Carefully fold air hose inside the arm cuff.

   Note: Do not excessively fold or bend the air hose.



3. Put the device, arm cuff and stethoscope in the carrying case.

Do note store the device in the following situations:

- If the device is wet.
- In environment with exposure to excessively high temperatures, humidity, direct sunlight, dust or corrosive vapours.
- In places exposed to vibration and shocks.

3. Product Overview

3.1 Introduction

PA1 aneroid blood pressure measuring device is used for measurement of blood pressure, which includes measurements of patient's systolic and diastolic pressure. It is adapted for both left and right hand operation.

3.2 Package contents

Before use, please verify that all components are present, and in the case of any damage to the device or accessories, or existence of any of the above mentioned issues, please contact Prizma.

PA1 Components list	
Component name	**Pcs.**
Blood pressure measuring device	1
Carryng case	1
Cuff (27.5 - 36.5 cm)	1
Instruction Manual	1

* Product package should contain the above listed components. In the case that any component is missing, please contact company Prizma immediately.

Optional components
Component name
Cuff small (13.8 - 21.5 cm)
Cuff large (35.5 - 46 cm)

3.3 Product description

1 Sphygmomanometer (main unit)

2 Air pump

3 Air exhaust valve

4 Manometer scale

5 Air hose connector

6 Arm cuff (main unit accessory)

7 Air hose

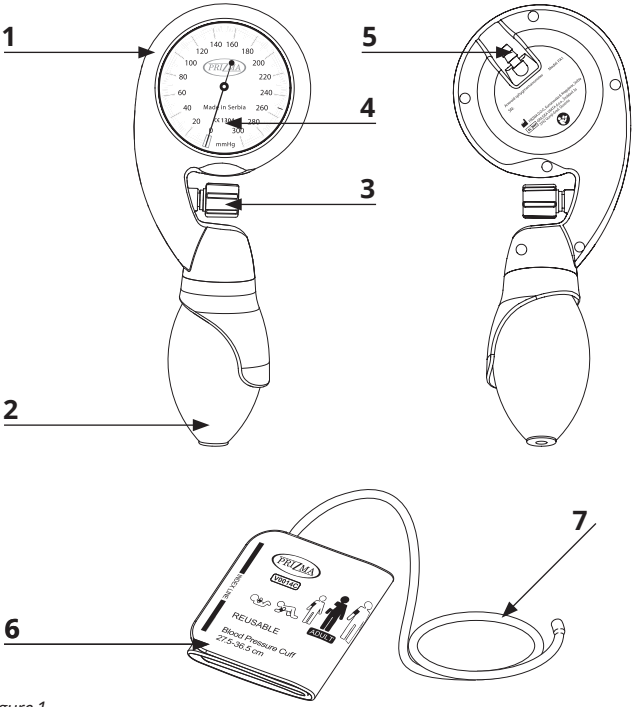


Figure 1

4. Using The Product

4.1 Preparation

In order to meet conditions for proper measurement of blood pressure, avoid physical activity, alcohol, caffeine, cigarettes, and do not take a bath or eat for 30 minutes before taking a measurement.

Prepare the PA1 device. Attach the air hose from the cuff to air hose connector on manometer (Figure 1).

4.2 Body position during measurement

Proper body position during measurement is necessary in order to obtain accurate results (Figure 2).

Note:

- Measurements should be taken in a quiet place, in relaxed, sitting position. Take a measurement at room temperature.
- Do not move or talk during measurement.

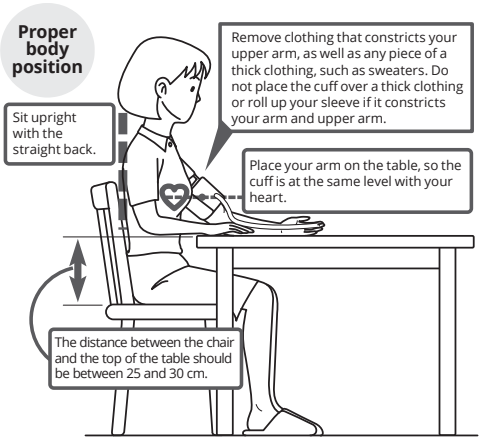
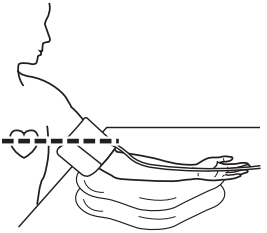


Figure 2

Measurements can be taken on the left or the right arm. Blood pressure may be different between the left and the right arm, hence, blood pressure measurement readings may differ between arms. It is recommended to take measurements on the same arm, in order for results to be comparable. If measurement values between arms are significantly different, consult your doctor to verify which arm should be used for measurements.

Incorrect body position:

- Hunched back (bent forward)
- Sitting with your legs crossed
- Sitting on a sofa or a low table, leaning forward.



Such situations may cause high blood pressure values due to strain or the cuff being positioned billow your heart level. If the cuff is positioned bellow your heart level, use pillows and adjust the height of your arm.

4.3 Placing the cuff

Bare your upper arm.

Caution: If you roll up your sleeve, ensure that it is not too tight because it may disrupt the blood circulation.

During blood pressure measurements, cuff has to be wrapped around upper arm, so that its lower edge is positioned 2 cm above the cubital fossa (elbow pit). PA1 has a preformed cuff that follows the shape of

your arm, so it is sufficient to wrap the cuff around your upper arm and slightly tighten it. Place the cuff positioning the mark for artery in the middle of your upper arm. Air hose should lay along the inner side of the forearm. It is also possible to measure blood pressure on the right upper arm.

Note:

- When you take measurements on your right arm, air hose will be located on the outer side of your upper arm. Be careful not to lower your arm on the air hose during measurement.
- Blood pressure may be different between the left and the right arm, and that is why measured blood pressure values may differ between arms. PRIZMA recommends that you always use the same arm to take measurements.

4.4 Taking a Measurement

During blood pressure measurement with an aneroid device, after proper body positioning and cuff placement, take the following steps:

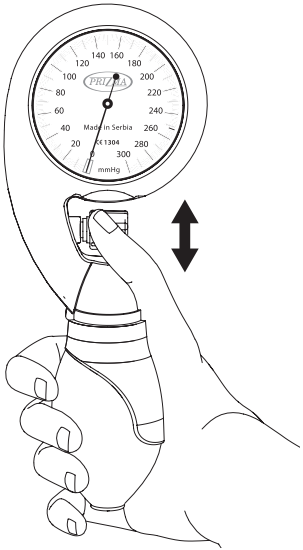
- Verify that arrow on the manometer scale is located within the framed field while the air exhaust valve is opened (Figure 3)
- Palpate the radial pulse
- Close the air exhaust valve by moving your thumb up, towards manometer (Figure 3)
- Inflate the cuff by pressing the rubber bulb (pump) up to value that is 30 mmHg higher than expected one
- Place the chestpiece of the stethoscope on the palpated spot, and insert eartips into your ear canals
- Slowly open air exhaust valve by moving your thumb towards the air pump (Figure 3), so that speed of air release is 23 mmHg per second, which could be verified by monitoring arrow on the manometer scale

- Listen for sounds appearance and monitor values indicated by arrow on the manometer scale
- Once the first sound appears, check the value indicated by arrow on the manometer scale. That sound corresponds to systolic blood pressure
- While sounds disappear, check the value indicated by arrow on the manometer scale at the moment when the last sound is barely audible That sound corresponds to diastolic blood pressure

Measured blood pressure values should be interpreted only by a qualified physician.

Note:

- Take a break of at least 5 minutes between repeated blood pressure measurements.



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5. Troubleshooting

Description	Possible cause	Solution
Measurement result is extremely high or low.	Cuff is too loose.	Place the cuff firmly. Refer to Section 4.3.
	Movement or talking during measurement.	Remain still and do not talk during measurement. Refer to Section 4.2.
	Clothing is interfering with the cuff.	Remove any clothing interfering with the cuff. Refer to Section 4.2.
Pressure in the cuff is not rising.	Air hose is not firmly fastened to connector for air hose.	Make sure that air hose is firmly fastened. Refer to Section 4.1.
	Air is leaking from the cuff.	Replace the cuff with a new one or contact Prizma service.
	Air hose is bent.	Straighten the air hose.
	Exhaust valve is not closed	Close the exhaust valve.
Cuff deflates too quickly.	Cuff is releasing air.	Replace the cuff with a new one or contact Prizma service.
Measurement is not possible or readings are too low or too high.	Is the cuff sufficiently inflated?	Inflate the cuff so the value is 30 to 40 mm Hg above the result of the previous measurement . Refer to Section 4.3.
	Is the exhaust valve open during inflation?	Make sure that exhaust valve is closed during measurement .
Arrow on manometer scale is not moving.	Air is leaking may be from the valve or from air hose connector.	Close the exhaust valve and connect air hose of the cuff. If leakage is not solved yet, contact Prizma service..
	Scale (arrow) is not functioning.	Contact Prizma service.
	Air pump is not functioning.	Contact Prizma service.

6. Product Specification

Name	Aneroid blood pressure measuring device
Model	PA1
Inflation	Manual
Blood pressure measurement range	0-300 mmHg
Accuracy	Static accuracy: ±3 mmHg
Accuracy checking	Every 6 months
Operation Environment	Temperature: 10°C do 40°C; RH: 15% do 85%; Atmospheric pressure: 70 KPa do 106 KPa
Storage conditions	Store at temperatures between -20 °C and +60 °C, RH not higher than 95%, and atmospheric pressure between 70 KPa and 106 Kpa, away from corrosive gasses and in well-ventilated place.
Service life	5 years
* There shall be no further notice required if the product specification should chang	

7. Symbols Description

Symbol	Description
	Manufacturer
	Keep dry
	Fragile
	Temperature limitation
SN	Serial number
	Follow Instructions for Use

Notes

Manufacturer
PRIZMA Kragujevac d.o.o.
Kumanovska 8, 34000 Kragujevac, Serbia
E-mail: prizma@prizma.rs
Web: www.prizma.rs

European Authorized Representative
GRAJSKA VRATA d.o.o
Šmiklavž 3a, 3324 Gornji Grad, Slovenija

EC REP

Information about version
PRIZMA reserves the right to amend or change the content of this Instruction Manual without notice.
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