DE Gebrauchsanweisung
Aneroid Blutdruckmessgerät und Manschette

EN Instructions
Aneroid Sphygmomanometers and cuffs

FR Mode d'emploi
Tensiomètres anéroïdes et brassards

IT Istruzioni
Sfigmomanometri aneroidi e bracciali

ES Instrucciones para el uso
Esfigmomanómetros aneroides y brazaletes

CE

Riester

Information on the variousmodels of Riester aneroid sphygmomanometers
You have acquired a high-quality **Riester** precision aneroid sphygmomanometer, which has been manufactured in accordance with the ISO 81060-1: 2007 standard (DIN EN ISO 81060-1: 2013) and is subject to the strictest quality controls. The excellent quality will guarantee years of reliable measurements.

Intended purpose: The aneroid sphygmomanometers from **Riester** are used by physicians and persons trained in auscultatory blood pressure measurement to determine the systolic and diastolic blood pressure in humans (adults, children, babies and neonates). **Riester** aneroid sphygmomanometers are intended exclusively for blood pressure measurement on healthy skin on the upper arm or thigh. The product is normally used professionally in a medical practice or a hospital. The sphygmomanometer/aneroid manometer is intended for use as a diagnostic aid.

Product description / indication: All blood pressure measuring devices / aneroid manometers distributed by company **Rudolf Riester GmbH** are of the same basic structure. Blood Pressure measuring devices / aneroid manometers consists of measuring system, cuff and inflation system (consisting of the pump [ball with non-return valve], and the screw valve [air lock or air drain].) All devices work according to the same measuring principle: Indirect blood pressure measurement according to the Korotkoff method.

Warnings / Contraindications:
- If there is overpressure in the cuff, you can reduce the pressure with the quick release.
- For units with air release valve: fully open the air release screw.
- For devices with push-button valve: Press push-button valve completely.
- Use the ball to pump up the cuff up approximately 20 mmHg above the expected systolic blood pressure value (= the upper value). Never inflate higher than 300 mmHg.
- The cuffs are offered with latex-free and latex materials. These are indicated by corresponding symbols on the cuff.
- Pay attention to the paragraph „blood pressure measurement" in the instructions for use, the blood pressure measurement can only done from doctors and persons trained in auscultatory blood pressure measurement.
- Observe the measurement and storage conditions in the instructions for use under „Technical data" and the information on the label.
- Check the pointer zero position as described in „Test of precision".
- For Germany, the Medical Devices Operator Ordinance applies. See also point „metrological control".
- A description of where the LOT No. is located can be found in the cuff table at the end of the instructions for use.

1. **Models** exacta® **and** sphygmotensiophone
   They are equipped with 2-tube cuffs because the pressure gauge is not directly connected to the inflation system.
2. **Models e**-mega**,** R1 **shock-proof®,** minimus® II**,** precisa® N**,** precisa® N shock-proof**,** babyphon® **and ri-**san® **1-tube.**
   They are equipped with 1-tube cuffs. Here the inflation system is directly connected to the manometer.
3. **Models e**-mega**,** minimus® III**,** precisa® N **double-tube**
   They are equipped with double tube cuffs. Here the inflation system is directly connected to the manometer.
4. **Models** sanaphon® **and ri-**san®
   These devices are devices for self-measurement. The manometer and the inflation system form a unit. In the 1-tube cuff, a chestpiece is integrated, which absorbs the Korotkoff sounds and forwards them to the ear via the enclosed stethoscope, which must be screwed into the thread on the outside of the cuff.
5. **Models** big ben **Round / Square desk, wall, mobile and anesthesia and ri-**former® big ben
   This easy-to-read aneroid sphygmomanometer is equipped with a 2-tube cuff. One tube is connected to the inflation system with air release valve, the other tube is connected to the connector on the spiral tube.

Installation instructions for the different models (with the exception of the desk model):

5.1. Wall modell / ri-former® big ben
Remove the wing nut underneath the cuff basket and take off the wall bracket. Hold the bracket against the wall at the desired location and mark the positions of the mounting holes for drilling. Drill the holes and insert screw anchors in them. Now you can fasten down the wall bracket with screws. Place the unit on the wall bracket so that the top part of the wall bracket engages the edge of the cuff basket and the bottom part fits over the screw that protrudes from the underside of the cuff basket. Now replace and tighten the wing nut on the protruding screw. In connection with **ri-**former® big ben, please observe the enclosed drilling plan.

5.2. Mobile stand version / big ben
Assembly:
1. Please assemble the mobile stand first and thereby take note of the installation instruction attached.
2. After assembling the mobile stand, please screw the device (clockwise) onto the mobile stand.

Adjustment:
By opening the retaining screw the desired height can be adjusted. After adjusting the height the mobile stand must be fastened by the retaining screw again.

5.3 anesthesia model / big ben

Remove the wing nut underneath the cuff basket and take off the wall bracket. Affix the wall bracket to the back of universal clamp No. 10384 using the screws included. Place the unit on the wall bracket so that the top part of the wall bracket engages the edge of the cuff basket and the bottom part fits over the screw that protrudes from the underside of the cuff basket. Now replace and tighten the wing nut on the protruding screw.

Selection of suitable cuff sizes

A. Nylon-velcro cuffs, Disinfectable one piece cuff

Our nylon-velcro cuffs, Disinfectable one piece cuff have a tufted strip on one side and hooks on the other. This ensures that the cuffs can be easily opened and closed quickly and repeatedly. On all the models (with the exception of sanaphon®), the cuffs are calibrated, i.e. provided with measurement lines. To make sure that you have chosen the right cuff size, check to see whether the white index line is in the range between the arrows after the cuff has been put on. If the index line fails to reach this range, the cuff is too small. If it is beyond the range, the cuff is too large. Precise blood pressure readings can be obtained only if the correct cuff size is used.

Nylon-Velcro cuffs (Two Piece Reusable Velcro Cuff), The following cuff sizes are available for all models (except sphygmotensiophone**,** sanaphon® **and** exacta®**), see cuff table:**
Disinfectable one piece cuff (One Piece Reusable Velcro Cuff One Tube/Two Tube), The following cuff sizes are available for all models (except sphygmotensiophone**,** sanaphon®**, ri-**san® **self-measurement and** exacta®**), see cuff table:**

sanaphon® **and ri-**san® **(Two Piece Reusable D-Ring Cuff Self-Mesurament):**
Measure your arm circumference to make sure that it lies within the range indicated on the cuff. The following sizes are available: child, adult, large adult and thigh. These sizes correspond to the circumferences given in the above table.

B. Cotton-velcro cuffs self-measurement (Two Piece Reusable Cuff sphygmotensiophone**):**

Our cotton-velcro cuffs have a tufted strip on one side and hooks on the other. This ensures that the cuff can be easily opened and closed quickly and repeatedly. Measure your arm circumference to make sure that it lies within the range indicated on the cuff.
The following cuff sizes are available for the models listed below, see cuff table:
sphygmotensiophone**:**

C. Cotton hook cuffs (Two Piece Reusable Hook Cuff):

On one side of these cuffs, metal bars have been worked into the fabric covering; metal hooks have been riveted to the fabric on the other side. The metal hooks are inserted into the metal bars in the cuff fabric. Measure the circumference of your arm to make sure that it lies within the range indicated on the cuff.
The following cuff sizes are available for the models listed below: R1 **shock-proof®,** minimus® II**,** minimus® III**,** big ben **Round / Square (all versions) and ri-**san®**, siehe cuff table:**

D. Cotton bandage cuffs (Two Piece Reusable Bandage Cuff):

There is a bandage strip and a hook on one side of the bandage cuff. To attach the cuff, simply insert the hook into the bandage strip. Measure the circumference of your arm to make sure that it lies within the range indicated on the cuff.
The following cuff sizes are available for the models listed below: R1 **shock-proof®,** minimus® II**,** minimus® III**,** big ben **Round / Square (all versions) and ri-**san®**, see cuff table:**

Blood pressure measurement

- Patient position for intended use: sit comfortably, legs not crossed, back and arm supported, center of cuff on the upper arm at the level of the right cardiac atrium; the patient should be as relaxed as possible and should refrain from talking during the measuring process; approx. 5 minutes should elapse before the first measurement is taken.
- Close the valve by turning the deflation screw clockwise (except in the case of **ri-**san®).
- Putting on the cuff: Put the cuff on in such a way that the lower edge of the cuff is approx. 2 to 3 cm above the crook of the arm (level of the right cardiac atrium) or approx. 5 cm above the knee joint. Make sure that the marking sign is placed above the artery. The white index strip should be within the marked index range.
- After putting on the cuff, inflate the cuff to approx. 20 mmHg above the expected systolic blood pressure value (= the upper value) with the aid of the ball.
- When measuring blood pressure, the position of the operator is normally in front of the patient or at the patient's side.
- It is recommended to use phase V of the Korotkoff sounds (K5) for auscultatory measurement in adults, to use phase IV of the Korotkoff sounds (K4) for auscultatory measurement in children aged 3 to 12 years, and to use phase V of the Korotkoff sounds (K5) for auscultatory measurement in pregnant female patients, except if the Korotkoff sounds can be heard during deflation of the cuff - if this is the case, K4 is to be used.
- Place the chestpiece of the stethoscope, preferably our model anestophon, catalog no. 4177-01 - 4177-05, above the artery underneath the cuff.

- For the units intended for home use, no separate stethoscope is needed, since the chestpiece is integrated in the cuff. If a unit intended for home use is used, the membrane of the chestpiece installed in the cuff must be placed above the artery. The cuff is put on by pulling the free end of the cuff through the metal retainer and closing the cuff with the aid of the hook-and-loop fastener.

A. Nylon-velcro cuffs: Close the cuff using the Velcro hook-and-loop fastener.
B. Bandage cuffs: Fasten the bandage cuff by hooking the hook onto the bandage strap.
C. Hook cuffs: In the case of a hook cuff, the metal hook is hooked onto the small metal rods of the cuff cover.

- To enable blood pressure measurement, open the deflation screw by turning it counterclockwise. The deflation rate should ideally range between 2 and 3 mmHg/s and can be set by delicate adjustment of the screw. Visual check of the deflation rate: The needle must move through 1 to 1.5 scale marks per second on the scale. After completion of the measurement, open the valve completely for rapid deflation of the cuff.
- The **ri-san**® model is equipped with a push-button valve. Activate this valve in such a way that the ideal deflation rate between 2 and 3 mmHg/s is achieved. To completely deflate the cuff, press the button all the way to the stop position.
- When the upper blood pressure value (systole) has been reached, rhythmic beats can be heard.
  Systole = The upper blood pressure value is the value that results when the heart contracts and the blood is pressed into the blood vessels.
- When the lower blood pressure value (diastole) has been reached, the beats fall silent.
  Diastole = The lower blood pressure value which prevails when the heart muscle has expanded and is once again filling up with blood.
- The blood pressure measurement has been completed.
- We would like to point out to you that a unit intended for home use does not replace regular visits to the doctor and that only the doctor can accurately analyze your measured values.

How to care for the aneroid sphygmomanometer
General information
The goal of cleaning and disinfection of medical products is the protection of patients, users and third persons and conserving the value of the medical products. On account of the product design and the used material, no defined limit of maximum processing cycles can be fixed. The lifetime of the medical products depends on their
function and on a appropriate treatment of the devices. Before returning faulty products for repair they must have gone through the described reprocessing process.

1. Manometer and bulb
Manometer and bulb can be cleaned outside with a humid cloth until optical cleanness is given.

ATTENTION!
Never place the manometer in liquid! This item is not approved for automated reprocessing and sterilization. These procedures cause irreparable damage!

2. Cuffs
Cotton and Nylon velcro cuff (latex and latex free)
Cleaning:
After removing the bladder, wipe the nylon-velcro covers with a damp cloth. Alternatively, these can be washed with soap and cold water like all the other cuffs. If you decide on the latter course, rinse the cuffs with clear water afterwards and let them air dry. Wipe the bladder and tubes with a damp cloth.

Disinfection:
After removing the bladder, wash the cuff covers in cold water to which disinfectant has been added. Afterwards, let them air dry. Only disinfectants with approved efficiency and in accordance with the national sta dards can be used. The bladder and tubes can be wiped with a cotton cloth moistened with ethanol.

Disinfectable one piece cuff
Cleaning:
The cuff can be wiped with a damp cloth. Alternatively, it can be washed with soap and cold water like all the other cuffs. Please rinse the cuff with clear water afterwards. In addition this cuff can be washed at up to 60 °C in the washing machine. Before next use, please ensure that no liquid is remaining in the cuff. This can affect the measurement results negatively and it can damage the manometer technology.

Disinfection:
The cuff can be completely inserted into liquid disinfectant. Only disinfectants with approved efficiency and in accordance with the national standards can be used. Before next use, please ensure that no liquid is remaining in the cuff. This can affect the measurement results negatively and it can damage the manometer technology.

IMPORTANT!
Do not iron nylon-velcro cuffs, Disinfectable one piece cuff. Never expose the cuffs to intensive solar radiation! Never touch the cuff covers or bladders with a sharp instrument, since this could cause damage!

Maintenance The product does not require any maintenance.

Test of precision
Remove the tube from the manometer and hold the manometer in a vertical position. When the pointer stands still at 0 on the scale, the instrument has been adjusted properly. If the pointer is below or above 0, the instrument must be recalibrated. Either take it to an authorised **Riester** dealer or send it to us.

Monitoring of instruments
All countries except for Germany:
The respective legal provisions apply for all countries, except for Germany. The reference manometer, which is used for calibration, must be traceable to national and international measurement standards.

Warning: It is not allowed to make changes to the device.

Technical Data
Minimal environmental conditions under which the error tolerance of +/- 3 mmHg must be satisfied:

Measurement conditions:	10 °C (50 °F) to 40 °C (104 °F) at a relative air humidity of 85 % (non-condensing)
Storage conditions:	-20 °C (-4 °F) to 70 °C (158 °F) at a relative air humidity of 85 % (non-condensing)
Versions:	Aneroid, desk, wall, stand and anaesthetic model
Type of indication:	Round scale
Scale graduation:	Increments of 2 mmHg
Range shown on scale:	0 to 300 mmHg
Measurement range:	0 to 300 mmHg
Pointer movement:	No stop pin
Tube adapter:	1 or 2, depending on the particular model
Pressure generation:	Bulb
Pressure reduction:	Air-release valve that can be regulated

Disposal: You can obtain information on disposal from your appropriate local facility or from your local environmental advisor.

Explanation of the symbols used

The following symbols are depicted on the packaging:

		
		
Two Piece Reusable Velcro Cuff		
LOT Inside the Cover		
Newborn	5 – 7,5 cm	5 – 8 cm
Infant	7,5 – 13 cm	8 – 13 cm
Child	13 – 20 cm	13 – 17 cm
Adult small	17 – 26 cm	17 – 24 cm
Adult	24 – 32 cm	24 – 34 cm
Adult XXL	32 – 48 cm	34 – 48 cm
Thigh	42 – 50 cm	32 – 48 cm
Thigh XL	50 – 70 cm	50 – 70 cm
One Piece Reusable Velcro Cuff 1 Tube / 2 Tube		
LOT On the Cover		
Newborn	–	5 – 8 cm
Infant	–	8 – 13 cm
Child	–	13 – 17 cm
Adult small	–	17 – 24 cm
Adult	–	24 – 32 cm
Adult XXL	–	32 – 41 cm
Two Piece Reusable Velcro Cuff Sphygmotensiophone		
LOT Inside the Cover		
Infant	7,5 – 13 cm	
Child	13 – 20 cm	
Adult	24 – 32 cm	
Two Piece Reusable Hook Cuff		
LOT Inside the Cover		
Adult	24 – 32 cm	
Two Piece Reusable Bandage Cuff		
LOT Inside the Cover		
Adult	24 – 32 cm	

Symbol	Explanation
	Follow the instructions set out in these instructions for use
	Temperature for transport and storage conditions
	Relative humidity for transport and storage conditions
SN	Manufacturer's serial number
LOT	LOT number / Batch number
REF	Reference number
UDI	Product Identification Number
	Manufacturer
	Date of manufacture YY.MM.DD. / (Year, Month, Day) CC: Country of Origin
CE	CE marking
	Arm circumference
	Symbol for artery position
	Product contains latex
	Latex free
	Fragile The symbol indicates that the contents of the transport packaging are fragile, so handling should be carried out with care
	The package should be protected from moisture
	"Green Dot" (country-specific)

WARRANTY

This product has been manufactured under the strictest quality standards and has undergone a thorough final quality check before leaving our factory. We are therefore pleased to be able to provide a warranty of 2 years from the date of purchase on all defects, which can verifiably be shown to be due to material or manufacturing faults. A warranty claim does not apply in the case of improper handling. All defective parts of the product will be replaced or repaired free of charge within the warranty period. This does not apply to wearing parts. For R1 shock-proof, we grant 5 years, for precisa N shock-proof, 3 years for the calibration, which is required by CE-certification. A warranty claim can only be granted if this Warranty Card has been completed and stamped by the dealer and is enclosed with the product. Please remember that all warranty claims have to be made during the warranty period. We will, of course, be pleased to carry out checks or repairs after expiry of the warranty period at a charge. You are also welcome to request a provisional cost estimate fromus free of charge. In case of a warranty claim or repair, please return the **Riester** product with the completed Warranty Card to the following address:

Warranty card / Return card:

Serial number or batch number:

Date, signature and stamp of the specialist retailer:

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