komprimeter

Gebrauchsanweisung
komprimeter

Instructions
Pneumatic tourniquet

Mode d' emploi
Tourniquet pneumatique

Instrucciones para el uso
Tourniquete neumático

инструкция по эксплуатации
0омприметр 3невматический турникет

Istruzioni per l' uso
Strumento di compressione

CE

Riester

Englisch

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1. Introduction

1.1 Important information prior to use

You have purchased a high-quality Riester product, which was manufactured according to Regulation (EU) 2017/745 for medical devices and is subject to the most stringent quality controls at all times.
If you have any questions, we are available at any time, and our contact information is provided at the end of this IFU. The address of our sales and distribution partners can be obtained upon request. Please note all instruments described in these instructions for use should only be used by appropriately trained personnel. The safe functioning of this device is only guaranteed if Riester original parts and accessories are used.

1.2 Safety symbols

Symbol	Note on Symbol
	Meaning of the symbols on the outer packaging / scale: Caution: Take note of the instructions for use!
	Caution: Follow the instructions for use! The symbol is printed in black.
	Latex-free
	Medical device
	**Warnings** The general warning sign indicates a possibly dangerous situation that can lead to serious injuries.
	**Caution!** The symbol for „Caution": indicates a possibly dangerous situation that can lead to minor to moderate injuries. The symbol may also indicate unsafe practices.
	Date of manufacture YYYY-MM-DD / (Year-Month-Day)
	Manufacturer
	Serial number
	Permissible temperature range in °C and °F for storage and transport
	Permissible humidity for storage and transport
	CE-Mark

1.3 Packaging symbols

Symbol	Note on symbol
	Indicates that the contents of the transport package are fragile and should therefore be handled with care.
	Store in a dry place
	Indicates the correct position for transporting the package.
	Keep away from sunlight
	"Green Dot" (country-specific)

1.4 Purpose
The komprimeter by Riester was produced to generate blood depletion in the limbs during amputations.

1.4.1 Indications
Limb amputation

1.4.2 Contraindications


Injury to skin


Pressure damage and paralysis from the tourniquet


Injury to large and small blood vessels


Bruises or haematomas, painful amputation neuromas (nerve nodules in the area of separation).


A contraindication or counterindication is only present if the chance of preserving the extremeity is too low and the health risks from surgery outweigh the benefits.

1.4.3 Intended patient population
The komprimeters are intended for children to adults.

1.4.4 Intended operators/users
The komprimeters are for use by doctors/trained hospital staff, medical facilities, clinics, medical practices.

1.4.5 Required skills/operator training Operators
The user must have the qualifications of a doctor or other medically trained person (e.g. a nurse).

1.4.6 Environmental conditions
The device is intended for use in a controlled environment (hospitals, medical institutions, clinics).
The device must not be exposed to any adverse/harsh environmental conditions.

1.5 Warnings/caution


Do not connect the compressor to
Pressure-generating devices.


Before each use, the komprimeter with its cuff must be checked by trained personnel (doctor) for function and absence of leaks.


The set pressure shown by the manometer must be continuously monitored by a responsible doctor during use and if necessary can be corrected by further pumping.

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The safe functioning of our Products is only guaranteed if both the products and accessories are exclusively from Riester.

⚠

Never place the komprimeter in liquids!

⚠

The item is not approved for machine reprocessing and sterilisation. This will lead to irreparable damage!

⚠

The cuff cover must not be ironed! Never expose the cuffs to intense sunlight! Do not touch the cuff cover or the pad with a pointed object, as these can be damaged as a result!

⚠

When using 70% isopropyl alcohol, ensure that the room is well ventilated! Do not use in the vicinity of fire-triggering devices or fire.

⚠

All serious incidents occurring in connection with the product must be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is resident.

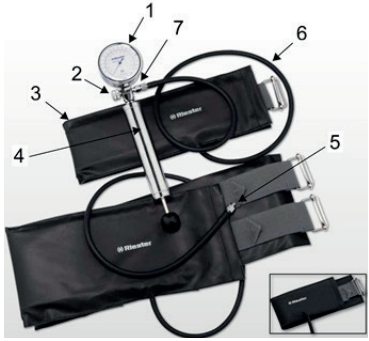
2. First use

2.1 Scope of delivery

No. 5255
1 air pump
1 manometer with release valve
1 upper arm cuff 57 x 9 cm
1 thigh cuff 96 x 13 cm, each with latex-free padding.
1 user manual

2.2 Device function

Components (see illustration)



1. Manometer
2. Air pump release valve
3. Cuff
4. Air pump
5. Tube screw connection part I (male)
6. Tube
7. Tube connection on the manometer

3. Operation and function
3.1 Symbol identification

mm Hg	Millimetres of mercury
kPa	Kilopascals

3.2 Startup
Close the release valve (2) by turning it clockwise.
Screw the tube screw connection at the end of the cuff tube into the designated tube connection on the manometer.
Before each use, the komprimeter with its cuff must be checked by trained personnel (doctor) for function and absence of leaks.

3.2.2 Applying the cuff
Place the cuff around the desired limb and pull the straps attached to the cuff through the metal buckles. The tube outlet should be approximately in the middle of the limb to be treated.

3.2.3 Replacing the pad
Remove the pad via the side opening of the cuff and insert a new pad through the same opening. Pull the tube through the opening on the long side of the cuff.

3.2.4 Operating the pump
Hold the pump (4) securely with one hand and with the other hand, pull carefully on the airpipe of the air pump by the black plastic ball until it stops and push it back again into the pump.
Repeat the pumping process until you have achieved the desired value on the manometer scale.

3.3 Generating blood depletion in the limbs
3.3.1 Generating blood depletion in the limbs
In order to empty blood vessels in the arms, the manometer must be inflated with the pump to approx. 250 mm Hg.

3.3.2 Generating blood depletion in the legs
In order to empty blood vessels in the legs, the manometer must be inflated with the pump to approx. 550 mm Hg.

3.3.3 Pressure control

The set pressure shown by the manometer must be continuously monitored by a responsible doctor during use and if necessary can be corrected by further pumping.

3.4 Deflating the cuff after the procedure

Open the air release valve (2). The air can now escape from the cuff. The cuff can now be removed.

4. Care instructions
4.1 General information
The cleaning and disinfection of the medical devices serves to protect the patient, the user, and third parties, and to maintain the integrity of the devices.

Due to product design and materials used, no defined limit of maximum or realistic reprocessing cycles can be set.
The lifespan of the medical devices is determined by function and by careful handling.
Before being returned for repair, defective products must have gone through the described reprocessing procedure.

For all reusable devices if there are signs of material deterioration, the device should no longer be used and should be disposed of by the procedure described under disposal/warranty.

When using 70% isopropyl alcohol, ensure that the room is well ventilated!
Do not use in the vicinity of fire-triggering devices or fire.

Never place the pressure gauge in liquid!

The item is not approved for machine reprocessing and sterilisation. This will lead to irreparable damage!

4.2 Cleaning and disinfection
4.2.1 Cleaning the manometer/air pump:
The manometer can be wiped with a damp cloth until visual cleanliness is achieved.

4.2.2 Disinfection of the manometer / air pump:
To avoid possible cross-contamination, the equipment must be cleaned and disinfected regularly. The exterior of the devices can be cleaned with a damp cloth (moistened with alcohol if necessary) until visual cleanliness is achieved. Use disinfectants (e.g. Bacillol AF by the company Bode Chemie GmbH / time 30s) only as per the manufacturer's specifications. Only disinfectants with proven effectiveness according to national guidelines should be used. After disinfection, please wipe the devices with a damp cloth to remove any residue. Please make sure that the cloth is moistened, **NOT** wet, so that no moisture penetrates into the openings of the device.
Make sure that the glass cover is only cleaned with a dry and clean cloth.

4.2.3 Cleaning cuff covers:
After removing the pad, the cuff covers may be wiped with a damp cloth or washed with soap in cold water.
Should you choose the latter, rinse the cuff with clean water and allow it to air dry. Wipe the pad and the tubes with a damp cloth.

4.2.4 Disinfection of cuff covers:
After removing the pad, the cuff covers can be washed in cold water with disinfectant and then allowed to air dry. Only agents with proven effectiveness with regard to national requirements should come into consideration. The pads and tubes can be wiped with ethanol on a cotton cloth.

The cuff cover must not be ironed! Never expose the cuffs to intense sunlight!
Do not touch the cuff cover or the pads with a sharp object, as these can be damaged as a result!

5. Technical specifications

Manometer:	Ø 55 mm, CuZn chrome plated
Scale:	Ø 53 mm, aluminium, lacquered and printed
Graduation of the scales in mm Hg:	In steps of 10 mm Hg
Graduation of the scales in kPa:	In steps of 1 kPa
Display range mm Hg:	Up to 700 mm Hg
Display range kPa:	Up to 93 kPa
Pump:	CuZn chrome-plated, polished 1.4305, spring steel
Pressure drop / pressure reduction:	Adjustable release valve
Cuffs:	Vowalon 121-820 nylon
Environmental conditions:	10°C (50°F) to 40°C (104°F) at a relative air humidity of 85% (non-condensing)
Ambient conditions:	10°C (50°F) to 40°C (104°F) at a relative air humidity of 85% (non-condensing)
Storage and transport conditions:	-20 °C (-4 °F) to 70 °C (158 °F) at a relative air humidity of 85% (non-condensing)

6. Spare parts and accessories

Art.no. 11219	Cuff children, 39 x 8 cm 1 tube, black,
Art.no. 11220	Pump
Art.no. 11221	Manometer
Art.no. 11222	Cuff adults, 57 x 9 cm 1 tube, black,
Art.no. 11223	Cuff thigh adults, 96 x 13 cm, black,
Art.no. 11224	Pad adults 46 x 6 cm, 1 tube, latex-free
Art.no. 11225	Pad thigh adults 55 x 10 cm, 1 tube, latex-free,
Art.no. 11227	Cuff cover adults 57 x 9 cm, black,
Art.no. 11228	Adult thigh cuff cover, 96 x 13 cm, black,
Art.no. 11229	Cuff cover children 39 x 8 cm, black,
Art.no.10246	Pad for child cuff

7. Maintenance / accuracy check / calibration / applied standards

The komprimeter and its accessories do not require special maintenance. To check the accuracy, please remove the tube off the manometer and keep the manometer in vertical position. If the pointer stops on the zero indicator of the scale, the device is accurately set. If the pointer is outside of the zero indicator, please return the device to Riester or to an authorized Riester dealer in your area. We are happy to provide all necessary information to you upon request.

8. Disposal

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Caution!

The used medical devices must be disposed of in accordance with the medical practices in place, or local regulations for disposal of infectious biological medical waste.

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Batteries and electrical/electronic equipment must be disposed of in accordance with local regulations, not included with domestic waste.

If you have any questions about the disposal of products, please contact the manufacturer or a manufacturer representative.

9. Warranty

This product was manufactured to the highest quality standards and subjected to a thorough final inspection before leaving our factory. We are pleased to issue a warranty of **2 years from the date of purchase** on all defects traceable to material or manufacturing defects. A warranty claim is excluded from cases of improper handling or use.

Any defective parts will be replaced or repaired free of charge within the warranty period. This excludes wear parts.

A warranty claim can only be made if the product is accompanied by this warranty card, which is filled out in full and stamped by the dealer.

Please note that warranty claims must be made within the warranty period.

We are of course happy to charge for checks or repairs after the expiry of the warranty period. We also offer free, no-obligation quotes.

In case of warranty coverage or repair, we ask you to return the RIESTER product with the completed warranty card to the following address.

Rudolf Riester GmbH
Dept. Repairs RR
Bruckstr. 31
D-72417 Jungingen
Germany

Serial number or batch number, date,
stamp and signature of the dealer