Stethoscopes

Gebrauchsanweisung
Diagnostische Instrumente

Instructions
Diagnostic Instruments

Mode d' emploi
Instruments de diagnostiques

Instrucciones para el uso
Instrumentos diagnósticoss

Istruzioni per l' uso
Presidi diagnostici

Инструкция по эксплуатации
Диагностические инструменты

CE

Riester

ENGLISH

Table of Contents

1. Introduction

1.1 Important information prior to use

You have purchased a high-quality Riester device, which was manufactured in compliance with Regulation (EU) 2017/745 and is subject to the strictest quality controls at all times. Read through these instructions for use carefully before using the device and keep them in a safe place. If you have any questions, we are available at any time, and our contact information is provided at the end of this IFU. Contact information for Riester sales and dsitribution partners can be provided upon request. Please note all instruments described in these instructions for use may 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
	The operator is obliged to read the instructions of the operating manual
	Meaning of the symbol on the outer packaging: The stethoscopes are latex-free.
	Medical device
	Warning! The general warning symbol indicates a potentially dangerous situation that can lead to serious injuries.
	Caution! The caution symbol indicates a potentially dangerous situation that can lead to minor or moderate injuries. The symbol may also indicate unsafe practices.
	Do not use in an MR environment!
	Date of manufacture YYYY-MM-DD / (Year-Month-Day)
	Manufacturer
	Manufacturer's batch number
	Temperature requirements for transport and storage
	Relative humidity for transport and storage
	CE Mark

1.3 Packaging symbols

Symbol	Note on symbol
	Fragile. The package should be handled with care.
	Keep the package from getting wet
	This way up. The symbol indicates the correct positioning for transporting the package.
	Keep away from sunlight
	„Green Dot" (country-specific)

1.4 Purpose

Stethoscopes are sound-conducting devices for listening to body sounds, particularly from the heart and lungs, and for diagnosing diseases of internal organs. In medicine, a stethoscope is used by clinicians to assess tones and sounds that arise in connection with activity of the heart, lungs and intestines. When measuring blood pressure, a stethoscope is used to detect the Korotkov sounds to determine systolic and diastolic blood pressure.

The Riester stethoscope product portfolio offers the full range of options for perfect auscultation in adults, children, infants and newborns.

1.4.1 Indications
In medicine, trained clinicians use a stethoscope to assess tones and sounds that arise in connection with the activity of the heart, lungs and intestines. When measuring blood pressure, a stethoscope is used to detect the Korotkov sounds to determine systolic and diastolic blood pressure.
Riester stethoscopes are used on adults, children, infants and newborns.

The stethoscope is used in cardiology/general medicine to diagnose diseases and assess their course.
Cardiac auscultation is part of the physical examination and is used to record physiological heart tones and to detect pathological heart murmurs that may be present. Indicating pathological changes in heart valves, for example.
When auscultating, it is advisable to simultaneously palpate the pulse at the radial artery, so that a possible pulse deficit (discrepancy between heart rate and pulse rate, e.g. in the context of arrhythmia, cardiac insufficiency or vascular stenosis), as well as the definitive classification of a systolic or a diastolic murmur, can be determined.
Lung auscultation is used to detect breathing sounds and secondary breathing noises that arise in the thoracic region. Auscultation is usually done with a stethoscope. It is part of the physical examination.
Lung auscultation makes it possible to detect pathological changes in the lungs with simple means and thus obtain signs and symptoms leading to further diagnostic measures.

In the stethoscope tube, a column of air is created between the membrane of the chestpiece and the eardrums, which transmits the sound directly from the membrane to the eardrums. The ear tips attached to the head section seal the ear canal and prevent the sound waves from escaping and noise from entering. The sound amplification is achieved by a funnel embedded in the chestpiece. In the case of stethoscopes with a double-headed chestpiece, the chestpiece can be rotated by 180°. In addition to the diaphragm, there is a bell without a diaphragm. It enables better perception of lower frequencies, which can be particularly useful in cardiology.

Special chestpiece construction makes it possible to isolate different frequency ranges by modifying the contact pressure of the membrane. When pressed lightly, the lower frequencies are emphasised; when pressed harder, the higher-frequency sound waves are emphasised.

1.4.2 Contraindications
A different or broader use is not intended. The manufacturer is not liable for any damages resulting from such. The user bears the sole risk.

1.4.3 Intended patient population
The stethoscopes are intended for all patients. In order to optimally examine different body sizes (neonate, baby, adult), the stethoscopes are available in different sizes.

1.4.4 Intended operator/user
The stethoscopes are designed for outpatient and inpatient examinations and are for use by doctors/trained personnel in hospitals, medical institutions, clinics, and doctor's offices.

1.4.5 Required skills/operator training
The user must have the qualifications of a doctor or a medically trained clinician (e.g. nurse).
Stethoscopes are a common instrument in medicine.

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

1.5 Warnings/caution

Do not use in an MR environment!


Clean the ear tips regularly and check for free passage.


Never place the stethoscope in liquids!

⚠
The item is not approved for machine reprocessing and sterilization. This will lead to irreparable damage!
⚠
Phenol-based disinfectants must not be used to clean and disinfect the stethoscopes.
The pH of the treatment solution used must be between 4.5 and 10.
⚠
Never use stethoscopes without ear tips/diaphragms!
⚠
The ear tips must not penetrate too far into the ear canal!
⚠
All serious incidents related to 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

cardiophon 2.0
No. 4240-01 black
No. 4240-04 burgundy red
No. 4240-03 blue
- User manual
- 2 pairs of spare ear tips
- 1 spare diaphragm Ø 44
- 1 spare diaphragm Ø 32
- 1 name tag

duplex 2.0
stainless steel
No. 4210-01 black
No. 4210-02 white
No. 4210-03 blue
No. 4210-04 red
No. 4210-05 green
Aluminium
No. 4200-01 black
No. 4200-02 white
No. 4200-03 blue
No. 4200-04 red
No. 4200-05 green
No. 4201-01 black edition
- User manual
- 1 pair of spare ear tips
- 1 spare diaphragm
- 1 name tag

duplex® 2.0 baby
No. 4220-02 white
No. 4220-04 red
No. 4220-05 green
No. 4220-01 black
- User manual
- 1 pair of spare ear tips
- 1 spare diaphragm
- 1 name tag

duplex® 2.0 neonatal
No. 4230-02 white
No. 4230-04 red
No. 4230-05 green
No. 4230-01 black
- User manual
-1 pair of spare ear tips
-1 spare diaphragm
-1 name tag
Aluminium chestpiece

duplex®
No. 4001-01 black
No. 4001-02 slate grey
No. 4031-03 blue
No. 4033-05 green
Chromed brass chestpiece
No. 4011-01 black
No. 4011-02 slate grey
No. 4011-03 blue
No. 4011-05 green
- User manual
- 1 pair of spare ear tips
- 1 spare diaphragm

duplex® baby
No. 4041 blue
- User manual
- 1 pair of spare ear tips
- 1 spare diaphragm

duplex® neonatal
No. 4051 blue
- User manual
- 1 pair of spare ear tips
- 1 spare diaphragm

duplex® teaching stethoscope
No. 4002-02 slate grey
- User manual
- 2 pairs of spare ear tips
- 1 spare diaphragm

tristar®
No. 4091 slate grey
No. 4093 blue
- User manual
- 2 pairs of spare ear tips
- 1 spare diaphragm Ø 48
- 1 spare diaphragm Ø 36
- 1 spare diaphragm Ø 28
- 1 name tag

anestophon
No. 4177-01 black
No. 4177-02 slate grey
No. 4177-03 blue
- User manual
- 1 pair of spare ear tips
- 1 spare diaphragm

ri-rap®
Tubing length 40 cm
No. 4150-01 black
No. 4150-03 blue
Tubing length 80 cm
No. 4155-01
- User manual
- 2 pairs of spare ear tips
- Bell Ø 33.5 mm, 27.3 mm, 20.3 mm
- 1 spare diaphragm Ø 45
- 1 spare diaphragm Ø 32

pinard
No. 4190 plastic
No. 4191 aluminium

2.2 Device function
All stethoscopes manufactured by Rudolf Riester have the same basic structure. The stethoscope consists of four elements:

1. Tubing
2. Binaural tubes
3. Ear tips
4. Chestpiece

3. Operation and function
3.1 Symbol identification

cardiophon 2.0, duplex® 2.0, duplex® 2.0 baby, duplex® 2.0 neonatal:
The opened diaphragm outlet can be recognized immediately by the marking on the tubing connection above.

3.2 Startup
3.2.1 Low/high frequencies:

duplex®, duplex® baby, duplex® neonatal, tristar®, ri-rap®:
Rotating the chest piece selects the diaphragm side (high frequencies) or the bell side (low frequencies).
It is essential to ensure good surface adaptation during auscultation. When measuring blood pressure, the chestpiece can be partially pushed under the cuff with the diaphragm side down. You can immediately see which side is active from the closed/open bell outlet. After putting on the Binaural tubes, you can recognize acoustically whether the diaphragm is active by gently tapping the diaphragm. With the ri-rap® model, the small diaphragm side can optionally be converted into an open bell. The different bell sizes can be found in the enclosed spare parts list.

3.2.2 Adjusting/putting on the Binaural tubes
duplex®, duplex® baby, duplex® neonatal, tristar®, anestophon®, ri-rap®:

Fig. A.
Please ensure that the Binaural tubes are set to the anatomically correct angle, i.e. they are to be worn so that they point slightly forward (see Fig.A).

Fig. B
The angle can be adjusted individually by rotating the Binaural tubes. The ear tips are correctly positioned when they are perfectly aligned with the external auditory canal which optimally prevent distracting external noise. The soft Riester ear

tips are particularly suitable for this. If the contact pressure of the Binaural tubes is too strong or too weak, proceed as follows:
If the contact pressure is too weak, press the two Binaural tubes together, as shown in Fig. B. If the contact pressure is too strong, spread the two Binaural tubes apart, as shown in Fig.C.

3.2.3 cardiophon 2.0, duplex® 2.0, duplex® 2.0 baby, duplex® 2.0 neonatal

Fig. C

The Binaural tubes are anatomically correctly set at the factory; their contact pressure is individually adjustable (Figs. B and C), the ear tips are rotatable and made of an extra-soft material. Overall, this achieves a perfect seal of the ear canal against external noises, and prevents noise from the ear tips rubbing against the ear, even while the stethoscope is moving.

⚠ The ear tips must not penetrate too far into the ear canal!

3.3 Replacing diaphragms
3.3.1 duplex®, duplex® baby, duplex® neonatal, tristar®, anestophon®, ri-rap®:
duplex®, duplex® baby, duplex® neonatal, tristar®, anestophon®, ri-rap®:
To change the diaphragm, take the non-chill rim between your thumb and forefinger and pull it off the chestpiece. Place the non-chill rim with the flat side down on a flat surface and insert the diaphragm into the non-chill rim with the printed side facing up. Take the non-chill rim with the diaphragm and press it onto the chestpiece.
With the ri-rap® chestpiece, the diaphragm is inserted into the threaded ring and the threaded ring is screwed back on. In the case of diaphragms with a curvature, this should point outwards, away from the ri-rap® chestpiece.

3.3.2 cardiophon 2.0, duplex® 2.0, duplex® 2.0 baby, duplex® 2.0 neonatal
To change the diaphragm, take the non-chill rim between your thumb and forefinger and pull it off the chestpiece. Place the new diaphragm with the printed side up centered in the opening of the chestpiece, then place the non-chill rim in the centered position and press it back onto the chestpiece with your thumbs in a semicircular movement. Please ensure that the diaphragm remains centered in the opening and is not shifted.

4. Care Instructions
4.1 General Information
The cleaning and disinfecting of medical devices serves to protect the patient, user, and third parties, and to maintain the value and function of the medical device.
The product design and materials used make it impossible to define an upper limit on max. feasible treatment cycles. The service life of medical devices is determined by their function and proper handling.
Before return for repair, defective products must have undergone the prescribed reprocessing procedure.
⚠
If a reusable device shows signs of material deterioration, it should no longer be used and should be disposed of/claimed according to the procedures described in the disposal/warranty sections.

4.2 Cleaning and disinfection
To avoid possible cross-contamination, the stethoscope must be cleaned and disinfected regularly.
The outside of the device can be cleaned with a damp cloth (if necessary, moistened with alcohol) until they are visually clean. Use
disinfectants (e.g. disinfectant 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 directives should be used. After disinfection, please wipe the devices with a
damp cloth to remove any residual disinfectant.
Please make sure that the cloth is moistened,
NOT wet, to prevent moisture from entering the device openings.

For this, the non-chill rims and membrane(s) must be removed from the chestpiece.
Take the non-chill rim between your thumb and forefinger and pull it off the chestpiece. The loose membrane can then be removed from the chestpiece.
With the ri-rap® chestpiece, the threaded rings are unscrewed for this.
For thorough cleaning and disinfection of the ear tips, these can be pulled off (unscrewed in the case of the ri-rap).

For thorough cleaning and disinfection, you can use 70% isopropyl alcohol or soapy water to wipe the chestpiece, the non-chill rims the membrane(s), the ear tips and Binaural tubes with tubing.

After cleaning and disinfection, the parts must be dried thoroughly before assembly. Then attach or screw the ear tips back onto the Binaural tubes.

duplex®, duplex® baby, duplex® neonatal, tristar®, anestophon®, ri-rap®:

Place the non-chill rim with the flat side down on a flat surface and insert the diaphragm into the non-chill rim with the printed side facing up. Take the non-chill rim with the diaphragm and press it onto the chestpiece.
With the ri-rap® chestpiece, the diaphragm is inserted into the threaded ring and the threaded ring is screwed back on.
In the case of diaphragms with a curvature, this should point outwards, away from the ri-rap® chestpiece.

cardiophon 2.0, duplex® 2.0, duplex® 2.0 baby, duplex® 2.0 neonatal:

Place the diaphragm with the printed side up centered in the opening of the chest piece, position the non-chill rim correctly, and press it back onto the chestpiece with your thumbs, each in a semicircular motion. Please ensure that the diaphragm remains in its opening and is not off-center.

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

⚠
Regularly clean and disinfect the ear tips and check for free passage.

⚠
Never place the stethoscope in liquids!

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

⚠
Phenol-based disinfectants must not be used to clean and disinfect the stethoscopes.
The pH of the treatment solution used must be between 4.5 and 10.

⚠
Never use stethoscopes without ear tips/diaphragms!

5. Technical specifications

Operating conditions:	10°C / 50°F to 40°C / 104°F with a relative humidity of 30% to 70% (non-condensing) 700 hPa to 1060 hPa
Storage conditions:	-10°C / 14°F to 55°C / 131°F with a relative humidity of 85% (non-condensing)

6. Spare parts and accessories

Item no. 13216	Binaural tubes with ear tips and tubing, burgundy, cardiophon 2.0
Item no. 13220	Binaural tubes with ear tips and tubing, black, cardiophon 2.0
Item no. 13222	Binaural tubes with ear tips and tubing, blue, cardiophon 2.0
Item no. 13223	Binaural tubes with ear tips and tubing, black, duplex® 2.0
Item no. 13224	Binaural tubes with ear tips and tubing, white, duplex® 2.0
Item no. 13225	Binaural tubes with ear tips and tubing, blue, duplex® 2.0
Item no. 13226	Binaural tubes with ear tips and tubing, red, duplex® 2.0
Item no. 13227	Binaural tubes with ear tips and tubing, green, duplex® 2.0
Item no. 13228	Binaural tubes with ear tips and tubing, black, duplex® 2.0
Item no 11065-01	Binaural tubes with Y-tubing, black, duplex®, anestophon
Item no. 11065-02	Binaural tubes with Y-tubing, slate grey, duplex®, anestophon
Item no. 11060-03	Binaural tubes with Y-tubing, blue, duplex®, anestophon
Item no. 11061-01	Binaural tubes with Y-tubing, green, duplex®, anestophon

Item no. 11068-02 Binaural tubes with Y-tubing, slate grey, tubing connector, tristar
Item no. 11068-03 Binaural tubes with Y-tubing, blue, tubing connector, tristar
Item no. 11070-01 Binaural tubes with double tubing, black, ri-rap 40 cm
Item no. 11070-03 Binaural tubes with double tubing, blue, ri-rap 40 cm
Item no. 11071-01 Binaural tubes with double tubing, black, ri-rap 80 cm
Item no. 11071-03 Binaural tubes with double tubing, blue, ri-rap 80 cm

Binaural tubes with ear tips, without tubing
Item no. 11080 Binaural tubes duplex®, anestophon
Item no. 11083 Binaural tubes ri-rap

Chestpieces
Item no. 13229 Double chestpiece stainless steel, cardiophon 2.0
Item no. 13230 Double chestpiece aluminium silver, duplex® 2.0
Item no.1 3231 Double chestpiece stainless steel, duplex® 2.0
Item no. 13232 Double chestpiece aluminium black, duplex® 2.0
Item no. 13233 Double chestpiece stainless steel, duplex® 2.0 baby
Item no. 13234 Double chestpiece stainless steel, duplex® 2.0 neonatal
Item no. 11008 Double chestpiece aluminium, duplex®
Item no. 11010 Double chestpiece chromed, duplex®
Item no. 11015 Double chestpiece aluminium, duplex® baby
Item no. 11018 Double chestpiece aluminium, duplex® neonatal
Item no. 11035 Double chestpiece aluminium adult, tristar
Item no. 11036 Double chestpiece aluminium children, tristar
Item no. 11038 Double chestpiece aluminium infants, tristar
Item no. 11027 Double chestpiece chromed, ri-rap
Item no. 11032 Single chestpiece aluminium, anestophon

Ear tips
Item no. 11139 10 pairs of ear tips soft, grey, cardiophon, duplex® (de luxe), anestophon, tristar
Item no. 13235 10 pairs of ear tips, soft, black, cardiophon 2.0, duplex® 2.0
Item no. 11110 10 pairs of ear tips hard, white, duplex® (de luxe), anestophon, tristar
Item no. 11107 10 pairs of ear tips large, black, hard, ri-rap
Item no. 11106 10 pairs of ear tips small, black, soft, ri-rap
Item no. 111018 10 pairs of ear tips large, clear, soft ri-rap

Printed diaphragms
Item no. 11042 Pack of 10 diaphragms Ø 45 mm, cardiophon, duplex® (de luxe), anestophon, tristar
Item no.11050 Pack of 10 diaphragms Ø 34 mm with hole, cardiophon®, duplex® de luxe
Item no. 11052 Pack of 10 diaphragms Ø 34 mm, duplex® (de luxe) baby, tristar
Item no. 13236 Pack of 10 diaphrams Ø 44 mm, cardiophon 2.0, duplex® 2.0
Item no. 13237 Pack of 10 diaphragms Ø 32 mm, drilled out cardiophon 2.0,
Item no. 11051 Pack of 10 diaphragms Ø 26 mm, duplex® (de luxe) neonatal, tristar
Item no. 13238 Pack of 10 diaphragms Ø 32 mm, duplex® 2.0 baby
Item no. 13239 Pack of 10 diaphragms Ø 24 mm, duplex® 2.0 neonatal
Item no. 11048 Pack of 10 diaphragms Ø 27.5 mm, ri-rap
Item no. 11049 Pack of 10 diaphragms large Ø 40.5 mm, ri-rap

Non Chill Rims
Item no. 13240 Non Chill Rims Ø 52 mm black, cardiophon 2.0, duplex 2.0
Item no. 13241 Non Chill Rims Ø 38 mm black, cardiophon 2.0, duplex 2.0
Item no. 11140 Non Chill Rims Ø 48 mm grey, duplex® (de luxe), tristar
Item no. 11141 Non Chill Rims Cold protection ring Ø 35.8 mm grey, cardiophon, duplex® (de luxe) and baby, tristar
Item no. 11143 Non Chill Rims Ø 28 mm grey, duplex® (de luxe) baby, neonatal, tristar
Item no. 11144 Non Chill Rims Ø 22 mm grey, duplex® (de luxe) neonatal, tristar

Other accessories
Item no. 11120 Spare parts box complete, ri-rap
Item no. 11122 Pack of 10 bell attachments large, ri-rap
Item no. 11124 Pack of 10 bell attachments medium, ri-rap
Item no. 11123 Pack of 10 bell attachments small, ri-rap

Name plate

Item no. 11147 Pack of 10 name plates

Product user manual
Instructions for use for all stethoscopes except pinard
Item no. 99209 User manual, stethoscopes

7. Maintenance/accuracy check/calibration
Riester stethoscopes and accessories do not require special maintenance. If the stethoscope needs to be checked for any reason, please send it to us or an authorized Riester dealer in your area, the details of which we will provide upon request.

8. Disposal
⚠ **Caution!**
The used medical device must be disposed of in accordance with current medical practices or local regulations on the disposal of infectious biological medical waste.
⚠
Batteries and electrical/electronic devices may not be treated as domestic waste and must be disposed of in accordance with local regulations.
⚠
If you have questions about the disposal of products, please contact the manufacturer or their representative.

9. 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 an additional warranty of 5 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 from us 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:

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

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

99209 Rev.G 2021-04 · Änderungen vorbehalten · Subject to alterations · Sous réserve de modifications · Sujeto a modificaciones · Con riserva di apportare modifiche · возможны изменения

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