Instruction of use
Electronic Stethoscope

ri-sonic PCP-USB
ri-sonic PCP-1

Riester

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1. Introduction

1.1 Important Information read prior to Start-up

You have purchased a high quality Riester Stethoscope, which has been manufactured according to the Directive 93/42 EEC and is subject to the strictest quality controls at all times. Read these instructions for use carefully before putting the unit into operation and keep them in a safe place. If you should have any questions, we are available to answer queries at all times. Our address can be found in these instructions for use. The address of our sales partner will be given upon request. Please note that all instruments described in these instructions for use are only to be used by suitably trained personnel. The perfect and safe functioning of this device is only guaranteed when original parts and accessories from Riester are used.

1.2 Safety Symbols / Information

Symbol	Note on symbol
	Follow the instructions in the operation manual.
	Protection class II
IP22	Warning! The general warning sign indicates a potentially hazardous situation which could result in serious injury.
	**Warning!** The general warning sign indicates a potentially hazardous situation which could result in serious injury.
	**Attention!** Important note in this instruction use. The attention symbol indicates a potentially hazardous situation which may result in minor or moderate injury. It may also be used to alert against unsafe practices

	Manufacturing date YYYY-MM-DD / (Year-Month-Day)
	Manufacturer
	Lot number
	Relative Luftfeuchtigkeit für Transport- und Lagerbedingungen
	Air pressure for transport and storage Air pressure for Ambient Operating
CE 0124	CE-Kennzeichnung
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.
	Direct current
	Non-ionizing radiation
	USB- Plug

1.3 Packaging Symbols

Symbol	Note on symbol
	Fragile. Show transport package contents fragile, so handling should be handled with care.
	Beware the package from getting wet.
	Upward. It shows the correct position to transport the package.
	Keep away from sunlight
	"Green Dot" (country-specific)

1.4 Intended Use

Electronic stethoscope sensor to convert internal bodysounds, such as heart and lung sounds to electronic Signals and deliver to suitable PC or mobile device.

1.4.1Indication

The instruments serve the trained doctor or specialist as an aid in the detection, diagnosis, monitoring and treatment, the alleviation of illnesses, injuries or disabilities.

1.4.2 Contraindication

There are no contraindications.

1.4.3 Intended patient population

The device is intended for all patients. The electronic stethoscope is in physical contact with the patient‘s body (upper body).

1.4.4 Intended operators / users

A stethoscope is a tool used by clinicians who are trained in the use of a stethoscope for auscultation.

1.4.5 Required skills / training of operators

The user must have the qualifications of a doctor, a medically trained person (e.g. nurse).
The stethoscopes are a common instrument in medicine.

1.4.6 Environmental conditions / Intended Environment

This device is intended for use in a Professional Healthcare Facility Environment.

1.5 Warnings / Attention

This product is not a defibrillation-proof applied part.

This product is not suitable for use in the presence of a flammable anesthetic mixture with air or with continuous oxygen or nitrous oxide.

Allergic reaction to the skin.
Only use the stethoscope when it has been cleaned!

Do not use, store or transport this product in excessively dusty conditions.

There are no modifications to this product that a user can make and they should not attempt to do so. If a unit fails to perform properly, contact Riester Representative from which the unit was purchased for service.

Cables are a strangulation hazard. Keep the ri-sonic PCP-USB / ri-sonic PCP-1 cord out of the reach of infants and small children.

2. First application

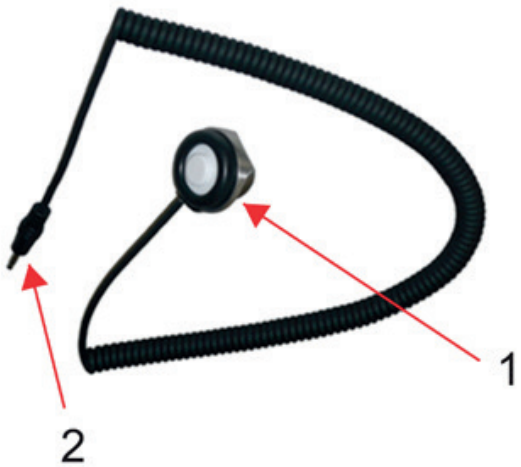
2.1 Scope of Supply

Art.Nr. 4300 ri-sonic PCP-USB - Instruction of use

2.2 Device Function

ri-sonic PCP-USB connector with straight cable

ri-sonic PCP-1 with spiral cable



Chest Piece Top

Chest Piece Bottom

All electronic stethoscopes manufactured by Rudolf Riester have the same basic structure.
The stethoscope consists of two elements:
1. Chest piece
2. Cable with plug (USB plug with straight cable or 3.5mm stereo plug with spiral cable)

3. Operation and Function

3.1 Introduction

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The ri-sonic PCP-USB / ri-sonic PCP-1 chestpiece can be used with a general PC.
The device / PC that supplies power must comply with IEC 60950.

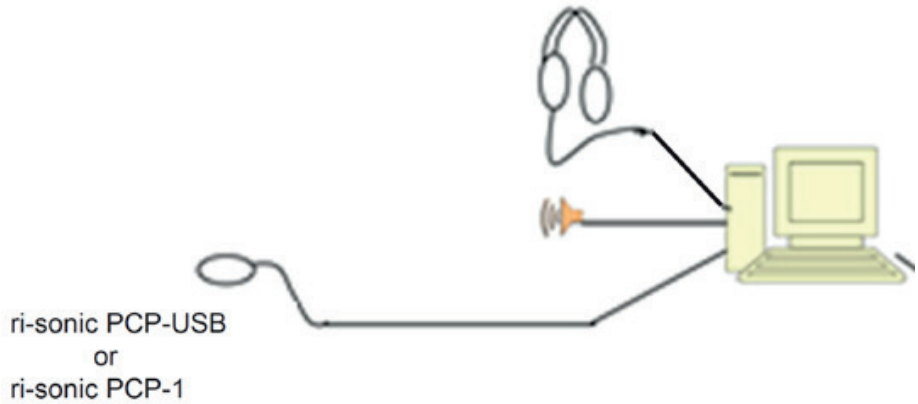
ri-sonic PCP-USB
The ri-sonic PCP-USB stethoscope is intended for use with a standard PC, mobile devices (with USB port) and appropriate app or software, which is not included. The ri-sonic provides sound data as specified. The user must check whether the line data of the sensor matches the requirements of the PC, mobile device, app or software.

The ri-sonic PCP-USB Stethoscope consists of a hardware element, the PCP-Chest Piece. The PCP-USB Chest Piece contains an embedded piezo sensor, audio amplifier Analog to Digital Converter (ADC) and Encoder to create a digitized stream, plus a USB interface to send that data to the PC. The ri-sonic PCP-USB Chest Piece derives its operating voltage from the 5v lead of the USB interface to the PC.

ri-sonic PCP-USB Chest Piece Block Diagram and Assembly. The ri-sonic PCP-USB Chest Piece assembly consists of a Printed Circuit Board Assembly (PCBA), a piezo element (PE), enclosure pieces and a USB cable, which is attached to the PCBA.
The PCBA provides an amplifier and an IC that includes an Analog to Digital Converter (ADC), a Encoder and a USB interface. The operating voltage for the circuitry on the PCBA is obtained from the 5vdc lead of the USB interface to the PC to which the ri-sonic PCP-USB is connected during service. The block diagram for the circuitry on the PCBA is shown in the following figure.
The block before the Amplifier provides impedance matching and protection from external transients.The circuitry is placed on a small round printed circuit board (PCB). The following figure shows a physical representation of components on the PCB.
The cable is attached to the PCBA which is then mounted inside the chest piece assembly along with the piezo element (PE). The following figure shows a cross-section of a physical representation of ri-sonic PCP-USB Chest Piece assembly.

ri-sonic PCP-1
The ri-sonic PCP-1 stethoscope is intended for use with a standard PC, mobile devices (with Microphone port) and appropriate app or software, which is not included . The ri-sonic brings its performance data. The user must check whether the line data of the sensor match the requirement of the PC, mobile devices, app or software.
The only non-generic hardware element in the ri-sonic PCP-1 Stethoscope system is the ri-sonic PCP-1 Chest Piece. High Level Schematic Diagrams of ri-sonic PCP-1
The ri-sonic PCP-1 Chest Piece assembly consists of a Printed Circuit Board Assembly (PCBA), a piezo element (PE), an Enclosure Top piece, an Enclosure Bottom Piece and a cable.
The PCBA provides the amplifier circuitry to bring the signal level from the PE up to the approximate
level that would come from an electret microphone. The gain if the amplifier is not critical since the
amplifier in the PC to which the PCP-1 Chest Piece is attached would have a variable gain amplifier.
Just as an electret microphone gets its operating voltage from the Microphone

input port, so does this
amplifier. A voltage between 2 vdc and 5 vdc is required for operation.
The block diagram for the PCBA is shown in the following figure.



System requirements:
PC with- Windows 10
Apple Computer with- Apple macOS 10.13.6

The are no additional hardware requirements to any Computer which covers the minimum requirement of the Operating System

- Audio support
- Sound card or onboard sound
- USB or/ Microphone port
- Speaker Frequency coverage (20 – 2000 Hz)

3.2 Commissioning

3.2.1 Installation ri-sonic PCP-USB

Installation of the ri-sonic PCP-USB Stethoscope is comprised of plugging the USB connector of the ri-sonic PCP-USB Chest Piece into the USB port of the PC. For usage with PC only no additional software ist required. For use with specialized software follow the instructions of the Software.

3.2.2 Installation ri-sonic PCP-1

Installation of the ri-sonic PCP-1 Stethoscope is comprised of plugging the 3.5mm stereo plug of the ri-sonic PCP-1 Chest Piece into the Microphone port of the PC.
For usage with PC only no additional software ist required. For use with speciali-

zed software follow the instructions of the Software.

3.23 Auscultation Sessions (Examination of the patient)

A typical operation consists of connecting the stethoscope to the PC before an auscultation session begins and all doctors present can hear the body noises.
The chest piece will be positioned on the patient to satisfy the clinical objectives of the exam.

4. Care instructions

4.1 General Information

Cleaning and disinfection of medical products protects patients, users and third parties, lead to value retention of medical products. Due to product design and materials used there is no possibility to define the maximum limit of re-processing cycles. The lifetime of a medical product is determined by its function and how it is used. Before sending back defective products for repair, the following instructions should be followed.

4.2 Cleaning and Disinfection

In order to avoid possible cross-contamination, the stethoscope must be cleaned and disinfected regularly before each use.
The stethoscopes can be cleaned on the outside using a damp cloth (if necessary moistened with alcohol) until optical cleanliness is achieved. Use disinfection products (e.g. Disinfectant Bacillol AF from Bode Chemie GmbH / time 30s) only according to the manufacturer's instructions. Only disinfectants with proven effectiveness according to national guidelines should be used. After disinfection, please wipe the instruments using a damp cloth in order to eliminate any remnants of the disinfectant.

The ri-sonic PCP-USB / ri-sonic PCP-1 Chest Piece is not a sterile device and does not require sterilization

Do never put stethoscopes into liquids!

Stethoscopes are not meant to undergo machine-processed maintenance and sterilization. It may lead to irretrievable damages!

5. Technical Data

Mode of operation:	This product may be used in continuous operation.
Electrical protection:	Class II protection against electrical shock:
Model	ri-sonic PCP-USB ri-sonic PCP-1
Voltage:	Input: 2V- 5V VDC (From PC)
Auscultation bandwidth:	
Frequency range:	20 Hz to 2.000 Hz.
Classification:	Type BF applied part
Weight:	ri-sonic PCP-USB with cable: 180g ri-sonic PCP-1 with cable: 145g
Operating conditions: 50mbar a	5°C to 40°C at a water vapor pressure up to relative humidity range of 30% to 75%
Storage and transport conditions:	-25°C bis 35°C,→ 35° C to 70° C at a water vapor pressure up to 50mbar a relative humidity range of 0% to 90%
Airpressure:	700hPa to 1060hPa

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There is no minimum time required for the unit to warm up from minimum storage temperature or to cool down from maximum storage temperature before use.

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If a unit is exposed to environmental conditions outside these ranges, it should be checked for proper operation before being put back into service.

6. Accessories

Art.No.75042 Instructions of use ri-sonic PCP-USB / ri-sonic PCP-1 Stethoscope

7. Maintenance / Accuracy check / Calibration

The ri-sonic PCP-USB / ri-sonic PCP-1 Chest Piece requires no preventive inspection, no preventive or routine maintenance, and it does not have to be calibrated.

8. Disposal

Batteries and electrical/electronic devices must be disposed in accordance with locally applicable regulations, not with domestic waste.

If you have any questions regarding disposal of products, please contact the manufacturer or its representatives.

9. Trouble Shooting

If no stethoscope sounds are heard from the PC:

Check for a failed ri-sonic PCP-USB / ri-sonic PCP-1 Chest Piece by testing the local loop back through the PC Control Panel

Check for a failed ri-sonic PCP-USB / ri-sonic PCP-1 Chest Piece by substituting it with a replacement ri-sonic PCP-USB / ri-sonic PCP-1 Chest Piece.

10. Electromagnetic Compatibility
EMC (electromagnetic compatibility)

- During installation and operation of the device, observe the following instructions:
- Do not use the device simultaneously with other electronic equipment to avoid electromagnetic interference with the operation of the device.
- Do not use or stack the device near, on, or under other electronic equipment to avoid electromagnetic interference with the operation of the device.
- Do not use the device in the same room as other electronic equipment, such as life-support equipment that has major effects on the life of the patient and results of treatment, or any other measurement or treatment equipment that involves small electric current.
- Do not use cables or accessories that are not specified for the device because that may increase the emission of electromagnetic waves from the device and decrease the immunity of the device to electromagnetic disturbance.

⚠ Attention!
Medical electrical equipment is subject to special precautions regarding electromagnetic compatibility (EMC).
Portable and mobile radio frequency communication devices can affect medical electrical equipment. The ME device is for operation in an electromagnetic environment and intended for professional facilities such as industrial areas and hospitals.
The user of the device should ensure that it is operated within such an en¬vironment.

⚠ Warning!
The ME device may not be stacked, arranged or used directly next to or with other devices. When operation is required to be close to or stacked with other devices, the ME device and the other ME devices must be observed in order to ensure proper operation within this arrangement. This ME device is intended for use by medical professionals only. This device may cause radio interference or interfere with the operation of nearby devices. It may become necessary to take appropriate corrective measures, such as redirecting or rearranging the ME device or shield.
The rated ME device does not exhibit any basic performance features in the sense of IEC 60601-1, which would present an unacceptable risk to patients, operators or third parties should the power supply fail or malfunction.

⚠ Warning!
Portable / stationare RF communications equipment (radios) including accessories, such as antenna cables and external antennas, should not be used in closer proximity than 30 cm (12 inches) to parts and cables of the Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 specified by the manufacturer. Failure to comply may result in a reduction in the device‘s performance features.
Directives and manufacturer‘s declaration - Electromagnetic emissions
The Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 are intended for use in the electromagnetic environ¬ment specified below. The customer or user of the Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 should ensure that it is used in such an environment.

Guidelines and manufacturer's declaration - electromagnetic emissions		
The Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 intended for use in the electromagnetic environment specified below. The customer of the user of the Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 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.
RF emissions CISPR 11	Class B	The Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 is intended for use in all establishments, including residential areas and those directly connected to a public supply network that also supplies buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Emissions of voltage fluctuations, flicker IEC 61000-3-3	Not applicable	

Guidelines and manufacturer's declaration – electromagnetic immunity			
The Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 should assure that it is used in such an environment.			
Immunity testing	**IEC 60601 Testlevel**	**Com-pliance**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 Proximity fields from RF wireless com-muni-cations equipment	Pass 10 V/m 80 MHz to 2.7 GHz	Pass 10 V/m	Portable and mobile RF commu-nications equipment should not be used closer to any part of the Electronic Stethoscopes ri-so-nic PCP-USB / ri-sonic PCP-1, including the cables, than the recommended distance, which is calculated using the equation applicable to the transmitter fre-quency. Recommended separation dis-tance d= 1.2√P 150 KHz to 80 MHz d= 1.2√P 80 MHz to 800 MHz d= 2.3√P 800 MHz to 2.7 GHz Where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufac¬turer and the recom-mended distance is given in me-ters (m). Field strengths from fixed RF transmitters determined by an electromagnetic site survey a, should be less than the compliance level in each frequen-cy range b. Interference may occur in the vi-cinity of devices 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 propagation 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 landmobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoreticallywith accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic sitesurvey should be considered. If the measured field strength in the location in which the Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 is used exceeds the applicable RF compliance level above, the Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1
b.) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1.

The Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Electronic Stethoscopes ri-sonic PCP-USB / ri-sonic PCP-1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter (W)	**Separation distance according to the frequency of the transmitte (m)**		
	150 kHz - 80 MHz	**80 MHz - 800 MHz**	**800 MHz - 2,7 GHz**
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 inmetres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is themaximum 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 andreflection from structures, objects and people.

11. 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. 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 must 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

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