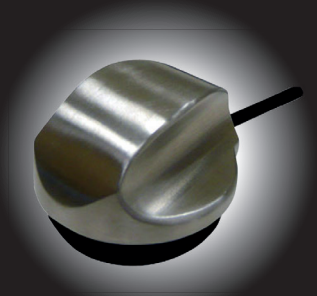
Riester



ri-sonic®

Instructions for use EN

2023-09-25

EN About these Instructions for use

Read these instructions for use before using the device. Keep these instructions for use near the device so that they are easily available when needed. These instructions for use contain all the necessary instructions for using the product safely and as intended. Observance of these instructions for use is a prerequisite for correct product performance and operation and ensures the safety of the patient and operator. For reasons of readability, the masculine form has been chosen for personal designations, but the feminine form is always included.

Version control

Date	Version	Description
2022-04-28	1.0	Initial creation
2023-09-25	2.0	complete revision

Copyright

Regulatory information

The device has been manufactured in accordance with the applicable laws, standards and directives. The manufacturer provides a corresponding list on request and on their website.

Manufacturer

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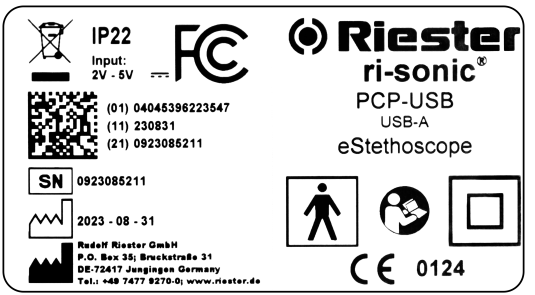
Identification

The type plate allows you to clearly identify the ri-sonic® electronic stethoscope. The symbols are explained on the following page.



Type plate

Symbols

The following symbols are used in this manual, on the device or on the packaging. They have the following meaning:


Danger warning


Consult instructions for use


Date of manufacture

European conformity


Manufacturer

Medical device

Lot number

Serial number

Product number

Unique product identification number

FCC approval

Protection class II

Direct current

Application part type B not defibrillation-proof

UDI

Unique
device identification (2D)
(01) GTIN
(Global Trade Item Number)
(11) Date of manufacture
(21) Serial number

IP22

Protection class, protection against ingress of solid foreign bodies with a diameter > 12.5 mm. Protection against dripping water with 15° slope.

Non-ionizing radiation can occur here

Temperature range for transport and storage

Relative humidity for transport and storage

Air pressure for transport, storage and operation

Symbol for labeling electrical and electronic equipment.
Do not dispose of in household waste.

Fragile.
Handle with care

Keep dry.

This way up.

USB port

Green Dot
(country specific)

Keep away from sunlight.

Abbreviations

Abbreviation	Meaning
EMC	Electromagnetic compatibility
RF	Radio frequency
SOC	Battery charge level (State of charge)

Symbols in these instructions for use

Symbol	Meaning
🕮	Cross-reference to further information or another chapter in the instructions for use.
▶	Start of an instruction
ⓘ	Supplementary or further information
☑	Result of an action

EN Content

EN Instructions for use

Familiarize yourself with the information in this instruction for use so that you can use the device safely.

1. Safety

Failure to follow the safety instructions can result in death, serious injury or wrong diagnoses. Use the device only, if you have understood and are able to follow the following safety information. Report to the manufacturer and the competent authority, if a serious incident has occurred in connection with this product.

1.1. Intended use

This ri-sonic® is an electronic stethoscope. It is used to convert internal body sounds, such as heart and lung sounds, into electronic signals and to transmit them to a suitable PC or mobile device. Only use this device as described in this instruction for use.

1.2. Users

There are two user groups that are allowed to operate the ri-sonic®:

Healthcare professionals

The ri-sonic® is intended for use by medical personnel.

Medical laymen

Medical laymen may only operate the ri-sonic® and use it on themselves or a family member, if they have previously been instructed in its use by medical personnel. Medical personnel must ensure that a medical laymen can use the ri-sonic® can use it appropriately. The ri-sonic® may only be temporarily dispensed to medical laymen.

1.3. Indication and contraindication

The ri-sonic® electronic stethoscope is used by trained medical personnel as a medical aid for auscultation (listening of the chest) of patients. It is suitable for all patient groups, provided there are no concerns about physical contact with the device. The device is intended for use in a professional medical environment.
Contraindications are not known.

1.4. Environmental conditions

⚠ WARNING

Danger to life of patient or staff during defibrillation or anesthesia

The device is not defibrillation-proof and not protected against explosion.

- ▶ Never use the device simultaneously with a defibrillator.
- ▶ Never use the device in presence of flammable gases such as nitrous oxide during anesthesia.

1.5. Infection and allergic reaction

⚠CAUTION

Risk of infection due to poor hygiene

Lack of hygiene can lead to the transmission of contagious diseases.

- Disinfect the device after use on a patient. Observe the instructions for cleaning and disinfection.
  4. Cleaning and disinfection, EN-19

Allergic reaction due to irritating substances

Lack of cleanliness and allergenic substances can cause skin reactions.

- Only use the stethoscope after it has been cleaned. The cleaning frequency and procedure must comply with the regulations for cleaning non-sterile products in your facility.
- Do not use, store or transport this product in excessively dusty conditions.

1.6. Usage

⚠ CAUTION

Risk of strangulation and tripping due to cables

Small children can get strangled by the cable while playing. People may stumble, if cables are within reach of feet.

- ▶ Keep the device's cables out of the reach of infants and small children.
- ▶ Ensure that cables do not create a tripping hazard.

Misdiagnosis due to malfunction

Damage to the chest piece or the cable can cause malfunctions.

- ▶ Do not use the stethoscope, if it is not functioning properly or has been damaged.

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2. Product description

The electronic ri-sonic® stethoscopes are used in conjunction with a computer. The versions of the ri-sonic® differ externally only by different plugs and cables of different lengths.

A

B

C

A Chest piece **B** Cable with USB-A plug **C** Cable with connectors TRS, TRRS

The following adapters are also available:

- TRS to TRRS
- USB-A to Lightning Adapter (Apple)

The chest piece contains the sensor and the electronics. The power supply is provided by the connected computer via the cables.

An app or software on the computer is required to operate the ri-sonic®. This app or software is not included in the scope of delivery.

2.1. System requirements

Computers to which a ri-sonic® is to be connected require at least the following features:

- PC with Windows 10 or Apple computer with Mac OS 10.13.6
- complying with IEC 60950 or IEC 62368-1
- Audio support
- Sound card or onboard sound
- USB or microphone port
- Speakers with a frequency range of 20 - 2000 Hz

2.2. Available versions

Product number	Description ri-sonic®
4300	USB-A cable, 1.8 m, Plain Box
4301	USB-A cable, 1.8 m, Retail Box
4303	USB-A cable, 4 m, Plain Box
4305	USB-C cable, 4 m, Retail Box
4307	USB-A cable, 1.8 m, Retail Box, with USB-A - USB-C adapter
4309	USB-A cable, 1.8 m, Retail Box, with A1440 adapter
4310	TRS Audio cable, 1.4 m, Plain Box
4311	TRS Audio cable, 1.4 m, Retail Box
4313	TRS Audio cable, 1.4 m, Retail Box, with TRS - TRRS adapter
4315	TRS Audio cable, 1.4 m, Retail Box, with TRS - USB-C adapter
4317	TRRS Audio cable, 1.4 m, Retail Box, with TRRS - USB-C adapter

3. Operation

An examination with the ri-sonic® is performed by medical personnel. If you are a medical layman, you may only perform an assisted examination, if you have been instructed by your physician and follow their instructions.

▶ Examination procedure

1 Insert the plug of the cable into the appropriate socket on the computer.

2 Launch the software or app and follow the on-screen instructions.

3 Place the chest piece on the patient's skin and perform the auscultatory examination.

4 Clean and disinfect the ri-sonic® after completion of the examination.

4. Cleaning and disinfection

Cleaning and disinfection serve to protect the patient, the user and third parties as well as for preserving the value of the device. The service life of the device is depending on the frequency of use and gentle handling. Therefore, no maximum limit of feasible reprocessing cycles can be determined. Defective devices must have undergone the described cleaning and disinfection before being returned for repair.

⚠ CAUTION

Risk of infection due to carryover of germs.

Insufficient cleanliness and hygiene can lead to the transmission of diseases.

▶ Regularly clean and disinfect all surfaces of the device.

NOTICE

Incorrect cleaning and disinfection can damage or destroy the device.

Observe the following advice:

- ▶ Never sterilize the ri-sonic®.
- ▶ Never immerse the ri-sonic® in liquid.
- ▶ If you notice any signs of material deterioration, stop using the device. Inform the service or dispose of the device according to the manufacturer's instructions.

You will need the following materials for cleaning and disinfection:

- Lint-free cloths
- Alcohol for cleaning purposes
- Disinfectant (e.g. Bacillol AF by Bode Chemie GmbH)

▶ Clean and disinfect the device

1 Wipe the device including the cable and plug with a damp cloth until no more contamination is visible. Use alcohol for cleaning purposes if necessary.

2 Moisten the device with disinfectant and let it act for 30 seconds.

3 Wipe-off the device with a damp cloth and remove any residual disinfectant.

5. Technical data

Operating mode	ri-sonic® can be used in continuous operation.
Electrical protection	Protection class II against electric shock
Models	ri-sonic® PCP-USB and ri-sonic® PCP-1
Voltage	Input: 2 V - 5 V VDC (from PC)
Auscultation bandwidth	Frequency range: 20 Hz - 2,000 Hz
Classification	Applied part type BF
Weight	ri-sonic® PCP-USB with cable: 180 g ri-sonic® PCP-1 with cable: 145 g
Operating conditions	5 °C - 40 °C at a water vapor pressure of up to 50 mbar and a relative humidity of 30% - 75%
Storage and transport conditions	-25 °C - 35 °C, 35 °C - 70 °C at a water vapor pressure of up to 50 mbar and a relative humidity range of 0% - 90%
Air pressure	700 hPa - 1060 hPa

No specific time is required for the unit to warm up from the minimum storage temperature or cool down from the maximum storage temperature before use.
If a device is exposed to environmental conditions outside these ranges, it should be checked for proper operation before recommissioning.

6. Maintenance

The ri-sonic® is maintenance-free and does not need to be calibrated.

7. Interference

When no stethoscope sounds are heard on the PC:

- Check if the ri-sonic® was recognized when connected to the PC.
- Check the system settings of the PC whether the audio output is set to speakers or headphones.
- Check the set volume.
- Check if the chest piece has failed by connecting a replacement unit.

NOTICE

Repair attempts damage the device

If the device does not work properly, you must not perform any repairs.

- ▶ Contact the manufacturer or your dealer for appropriate service.
- ▶ Do not try to fix the problem yourself.

8. Disposal

Do not dispose of the device with household waste but in accordance with local regulations for electronic devices. If you have any questions about disposal, contact the manufacturer or dealer.

9. Electromagnetic compatibility

The ri-sonic® is subject to the electromagnetic compatibility (EMC) regulations for medical products and is manufactured and tested in accordance with the requirements of DIN EN 60601. Mobile communication devices such as cell phones can affect medical devices. If you use other cables or non-approved accessories, the ri-sonic® may cause interference or be disturbed. Avoid using the ri-sonic® in the immediate vicinity to or together with other devices. If this is unavoidable, observe the equipment and check if it is working appropriately.

You can *download* the technical data for EMC.

10. Warranty

This product has been manufactured under strictest quality standards and has undergone a thorough final quality inspection before leaving our factory. We are therefore pleased to offer a warranty of 2 years from the date of purchase on all defects that have evidently caused by material or manufacturing faults. There is no warranty claim in case of improper handling.
Within the warranty period, all defective parts of the product will be replaced or repaired free of charge. This does not apply to wear parts. A warranty claim can only be granted, if this warranty card is filled out and stamped by the dealer and enclosed with the product. Please remember that all warranty claims must be made within the warranty period. Of course, we will be happy to perform inspections or repairs at the owner's expense after the warranty period has expired. You are also welcome to request a preliminary cost estimate from us free of charge. In case of warranty claims or repairs, please send the product to the manufacturer enclosing the completed warranty card.

Warranty card

Serial number or batch number

Date, stamp and signature of the distributor

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