

RVS-200 Wall Diagnostic Station and
RVS-200 Extension Module for
RVS-100 Vital Signs Monitor
Instructions for use

CE

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1. Introduction

1.1 Important information prior to use

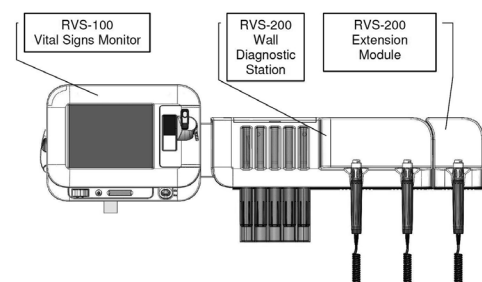
You have purchased a high-quality Riester device, which was manufactured in compliance with Regulation (EU) 2017/745 and is subject to the strictest quality controls at all times. Read through these instructions for use carefully before using the device and keep them in a safe place. If you have any 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 distribution 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.

Intended use

The RVS-200 Wall Diagnostic Station and RVS-200 Extension Module were manufactured for use with multiple ri-scope L instrument heads for non-invasive ENT and ophthalmological diagnoses.

The RVS-200 Wall Diagnostic Station and RVS-200 Extension Module can only be operated in conjunction with the RVS-100 Vital Signs Monitor. The RVS-100 Vital Signs Monitor is the sole power source.

The integrated speculum dispenser serves as a storage container for ear specula of varying sizes, which are easily dispensed. The RVS-100 Vital Signs Monitor, RVS-200 Wall Diagnostic Station, and RVS-200 Extension Module were designed for use in outpatient departments and emergency treatment rooms of hospitals, community clinics, private clinics and other medical institutions. They are not intended for flight transport, ambulance or home use.



Restrictions on use

They are not intended for flight transport, ambulance or home use.

Manufacturer's configuration

The RVS-200 consists primarily of a storage container / dispenser for ear specula. The integrated handles serve as power sources for the interchangeable instrument heads.

Warning: The monitor and the wall unit are intended for use only by clinical professionals or under their guidance. It must only be used by personnel who have received adequate training on its use. Any unauthorized or untrained individual must not operate the device.

1.2 Safety symbols

Symbol	Note on symbol
	The operator is obliged to read the instructions of the operating manual
	Type BF indicates the device is classified as a device with a Type BF applied part
	Regulate light intensity
	Medical device
	Warning! The general warning symbol indicates a potentially dangerous situation that can lead to serious injuries.
	Caution! Read operating instructions before use
	Date of manufacture
	Manufacturer
	Production lot number/batch
	Temperature for transportation and storage
	Relative humidity for transportation and storage
	CE Mark
	The symbol refers to the separate collection of waste electrical and electronic equipment in accordance with Directive 2002/96/EC.
	Non-ionizing radiation
	For single use only

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.
	Stacking layer limit. This indicates the maximum number N of stacking layers of the same package, where N stands for the number of layers. (N is 6).
	„Green Dot“ (country-specific)

1.4 Purpose

The RVS-200 Wall Diagnostic Station and RVS-200 Extension Module were manufactured for use with various instrument heads for non-invasive ENT and ophthalmological diagnoses.

The RVS-200 Wall Diagnostic Station and RVS-200 Extension Module can only be operated in conjunction with the RVS-100 Vital Signs Monitor. The RVS-100 Vital Signs Monitor is the sole power source.

The integrated ear specula dispenser serves as a storage container for ear specula, and various sizes of ear specula can be easily dispensed. RVS-100 Vital Signs Monitor, RVS-200 Wall Diagnostic Station, and the RVS-200 Extension Module

have been designed for use in outpatient departments and emergency treatment rooms in hospitals, health centers, private clinics and other medical institutions. They are not intended for air transport, ambulance or home use.

1.4.1 Indications

Product description/indications

The RVS-200 Wall Diagnostic Station is an optional expansion unit without its own power supply and, when connected, serves as an extension (accessory) of the RVS-100 Vital Signs Monitor. It has 2 handles. The specula dispenser is integrated and serves as a storage box for ear specula, with a mechanism for removing ear specula of various sizes.

An RVS-200 Extension Module with one handle can be installed and connected to the right side of the RVS-200 Wall Diagnostic Station. The handles can be equipped with various instrument heads. Instrument heads are not included and must be purchased separately.

These various instruments aid the trained clinician in the detection, diagnosis, monitoring, treatment or alleviation of illnesses, injuries or disabilities. Their proper use is possible using only the 3.5V ri-scope L instrument heads also manufactured by Riester.

Functions - The RVS-200 Wall Diagnostic Station, and RVS-200 Extension Module, supply the various instrument heads with energy that is drawn from the RVS-100 Vital Signs Monitor.

1.4.2 Contraindications

They are not intended for flight transport, ambulance or home use.

1.4.3 Intended patient population

The device is intended for neonates to geriatric patients.

1.4.4 Intended operator/user

The device is to be operated by a doctor, a nurse or technician in hospitals, medical institutions, clinics, doctor's offices.


1.4.5 Required skills/operator training


The operators should have the appropriate qualifications to operate the RVS-200 Wall Diagnostic Station and RVS-200 Extension Module for the RVS-100 Vital Data Monitor.


1.4.6 Environmental conditions

The device is intended for use in rooms with a controlled environment. The device must not be exposed to adverse/harsh environmental conditions.


1.5 Warnings/caution


 The monitor with wall unit is intended for use only by clinical professionals or under their guidance. It must only be used by personnel who have received adequate training in its use. Any unauthorized or untrained personnel must not operate the device.

-  Please observe the operating instructions for the RVS-100!
- Before the system is put into operation, ensure that the RVS-100, the RVS-200 and the accessories are working flawlessly.
 - If the integrity of the external protective conductor in the installation or its configuration is in question, the device must be operated with its internal power source.
 - To avoid the risk of explosion, the RVS-100 and RVS-200 devices must not be used in the vicinity of flammable anaesthetics or other flammable substances used in combination with air, oxygen-enriched environments, or nitrous oxide.
 - Do not open the RVS-100 and RVS-200 housings; there is danger of electric shock. All servicing and future upgrades must only be carried out by personnel trained and authorized by the manufacturer.
 - When using the monitor with electrosurgical units (ESU), it is essential to ensure the safety of the patient.
 - To avoid the risk of electric shock, this device must only be connected to a mains supply with a grounding connection (included).

-  Please observe the operating instructions for the RVS-100!
- To ensure patient safety, only parts and accessories specified in this manual may be used.
 - At the end of its service life the monitor, as well as its accessories, must be disposed of in compliance with the regulations covering the disposal of such products. Please contact us if you have any questions regarding disposal of the product.
 - Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason you should ensure that all other external devices that are operated in the vicinity of the monitor comply with the relevant EMC requirements.
 - Mobile phones, X-ray equipment or MRI devices are a possible source of interference as they may emit high levels of electromagnetic radiation.
 - Before connecting the monitor to the power line, check that the voltage and frequency of the power line are correct according to the Information on the label of the monitor or in these operating instructions.
 - Always install or carry the monitor properly to avoid damage caused by dropping, impact, strong vibration or other mechanical force.

 The RVS-100 and RVS-200 are neither therapeutic instruments nor devices for use at home.

 Never install the RVS-100 and RVS-200 in an environment where flammable anaesthetic gases are present.

 The RVS-200 does not contain any parts that can be repaired by users. All repairs of the device must always be conducted by a technician authorized by the manufacturer.


Important safety instructions
Please observe the operating instructions for the RVS-100!


- Protection against ingress of liquid
To avoid electric shock or device malfunction, liquids must not be allowed to enter the device. If liquids have entered the device, take it out of service and have it checked by a technician before it is used again.
- Before use
Before putting the system into operation, please visually inspect all connecting cables for signs of damage. Damaged cables and connections must be replaced immediately.
Before using the system, the operator must verify that it is in correct working order and operating condition. At regular intervals and whenever the integrity of the product is in doubt, all functions must be tested.
- Electric cables
Route all cables away from the patient's neck to avoid possible strangulation.
- Disposal of packaging
When disposing of the packaging material, pay attention to the relevant waste regulations. Keep out of the reach of children.
- Explosion hazard
Do not use this equipment in the presence of flammable anaesthetics, vapours or liquids.
- Disposal of accessories and device
Disposable accessories are intended for single use. They should not be reused as their function may be impaired or they may be contaminated. The service life of this RVS-200 station is 5 years. At the end of its service life the RVS-200, as well as its accessories, must be disposed of in compliance with the directives regulating the disposal of such products. If you have questions regarding the disposal of the product, please contact the manufacturer.
- EMC
Magnetic and electrical fields are capable of interfering with the proper performance of


the device. For this reason you should ensure that all other external devices that are operated in the vicinity of the RVS-200 comply with the relevant EMC requirements.

X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation. Also, mobile phones and other telecommunication equipment should not be used in the vicinity of the monitor.

- Instructions for use
To ensure safe use of the monitor, it is necessary to follow these operating instructions carefully. However, the instructions listed in this manual in no way supersede established medical practices regarding patient care.


-  Please ensure that the wall selected for the installation of the RVS-200 has sufficient load-bearing capacity!
- Keep the packing materials out of the reach of children. Disposal of packing materials should conform with applicable waste regulations.
 - Contamination may have occurred during storage of the RVS-200 station. Before use, please check that the packaging, especially of disposable accessories, is still intact. In case of any damage, do not use the RVS-200 with patients.
 - Make sure that the RVS-200 is used under the intended conditions, otherwise the technical specifications given in this instruction manual will not be achieved, possibly resulting in damage to equipment as well as other unexpected results.


-  If a second handle is removed from the handle holder, it switches on and the first handle in use is switched off. Only one handle can ever be operated at a time.

 When replacing the instrument heads, do not touch the patient at the same time, otherwise the patient will receive an electric shock.


Instrument heads

 The temperature of the bulb XL of the L1 otoscope, the human operating otoscope and the veterinary operating otoscope is between 41°C / 105,8°F and 43°C / 109,4°F. Do not touch!


 Because prolonged intense light exposure can damage the retina, the use of the device for eye examination should not be unnecessarily prolonged and the brightness setting should not be higher than needed for a clear view of the target structures.


 The pin of the bulb must be inserted into the guide groove on the ophthalmoscope's instrument head!


- We recommend that before cleaning or disinfection the device is removed from the power supply.
- Never insert the instrument heads and instrument handles into liquids! Take care while cleaning and disinfecting that no liquid enters the instrument!
- The devices are not designed for machine maintenance or sterilisation. This may lead to irretrievable damage!


 Caution!
The caution symbol indicates a potentially dangerous situation that can lead to minor or moderate injuries. The symbol may also indicate unsafe practices.

RVS-200

-  Safety precautions for installation.
Please observe the operating instructions for the RVS-100!
- Connect the power cord to a properly grounded socket. Avoid using the same electrical circuit to which appliances such as air conditioners that are regularly switched on and off are connected.
 - Avoid putting the RVS-100 and RVS-200 in wobbly or unstable locations.
 - Enough space should be left around the devices to ensure normal ventilation.
 - Make sure that the ambient temperature and humidity are stable, and avoid the occurrence of condensation during the operation of the devices.

 Caution: The RVS-200 does not contain any parts that can be repaired by users. Repair of the instrument must be conducted by technical personnel authorised by the manufacturer.

 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.

 Please observe the operating instructions for the RVS-100

2. First use

2.1 Scope of delivery

Item no.:
1961-RRXXE
RVS-200 NIBP (Riester) + SpO2 (Riester) extension module 2 handles, without heads, 1 user manual

1961-RRBXE
RVS-200 NIBP (Riester) + SpO2 (Riester) + Pred. Temp Oral (blue), 1 user manual

1961-RRBPE
RVS-200 NIBP (Riester) + SpO2 (Riester) + Pred. Temp Oral (blue) and printer, 1 user manual

1961-RNXXE
RVS-200 NIBP (Riester) + SpO2 (Nellcor), 1 user manual


1961-RNBXE
RVS-200 NIBP (Riester) + SpO2 (Nellcor) + Pred. Temp Oral (blue), 1 user manual

1961-RNBPE
RVS-200 NIBP (Riester) + SpO2 (Nellcor) + Pred. Temp Oral (blue) and printer, 1 user manual

1961-RMXXE
RVS-200 NIBP (Riester) + Sp02 (Masimo), 1 user manual

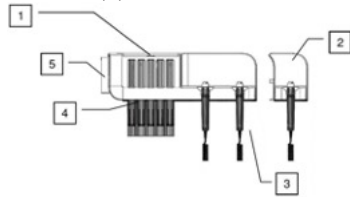
1961-RMBXE
RVS-200 NIBP (Riester) + Sp02 (Masimo) + Pred. Temp Oral (blue), 1 user manual

1961-RMBPE
RVS-200 NIBP (Riester) + Sp02 (Masimo) + Pred. Temp Oral (blue) and printer, 1 user manual

 Remove the RVS-100 and RVS-200 devices from the packaging and check all parts for damage.

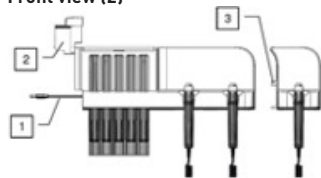
2.2 Device function

Front view (1)



1. The housing of the RVS-200 wall diagnostic station with protective cover for the specula dispenser and with two handles to connect the instrument heads.
2. Optional RVS-200 Extension Module with a handle to which another instrument head can be connected.
3. Handle for instrument head.
4. Specula dispenser.
5. Maintenance cover.


Front view (2)



1. Power connection for RVS-100.
2. Opened maintenance cover.
3. Power connection from the RVS-200 Extension Module to the RVS-200 Wall Diagnostic Station.


3. Operation and function


3.1 Symbol identification

 Regulate light intensity

3.2 Startup


3.2.1 Before first use

-  Please observe the operating instructions for the RVS-100!
- Connect the power cord to a properly grounded socket. Avoid using the same electrical circuit to which appliances such as air conditioners that are regularly switched on and off are connected.
 - Avoid putting the RVS-100 and RVS-200 in wobbly or unstable locations.
 - Enough space should be left around the devices to ensure normal ventilation.
 - Make sure the ambient temperature and humidity are stable and avoid the occurrence of condensation during the operation of the devices.

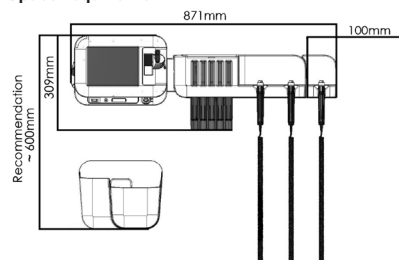
 Never install the RVS-100 and RVS-200 in an environment where flammable anaesthetic gases are present.

3.2.2 Wall mounting

3.2.2.1 Attaching the RVS-100 and RVS-200 Wall Diagnostic Station

 Please make sure that the wall to which the RVS-200 is mounted has sufficient load bearing capacity!

Space requirement



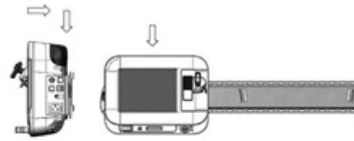
600mm = 23,622 inch
309mm = 12,165 inch
871mm = 34,291 inch
100mm = 3,937 inch

- a.) Drilling instructions for RVS-100 and RVS-200 Wall Diagnostic Station. Follow the instructions when drilling the holes in the wall.
- b.) Attaching the wall mounting plates
After you have drilled the holes, take the dowels supplied and push them into the holes as far they will go. Hold the wall mounting plate against the wall so that the screws can be inserted through the holes in the mounting plate into the dowels. Now tighten the screws with a screwdriver.
We recommend these mounting points!



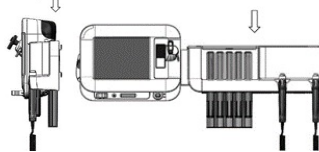
3.2.2.2 Attachment of the RVS-100

When all screws have been screwed in tightly, take the RVS-100 and pass the holder through the openings (1). Then press the RVS-100 downwards until it snaps into place.



3.2.2.3 Attachment of the RVS-200 Wall Diagnostic Station

Take the RVS-200 Wall Diagnostic Station and pass the holder through the openings (1). Then press the RVS-200 Wall Diagnostic Station downwards until it snaps into place.



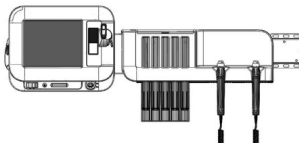
3.2.2.4 Attachment of the RVS-200 Extension Module

Drilling instructions for the RVS-200 Extension Module. Follow the instructions when drilling the holes in the wall.

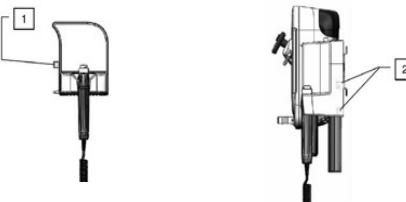
a.) Attaching the wall mounting plates

After you have drilled the holes, take the dowels supplied and push them into the holes as far they will go. Hold the wall mounting plate against the wall so that the screws can be inserted through the holes in the mounting plate into the dowels. Now tighten the screws with a screwdriver.

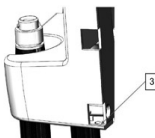
We recommend these mounting points!



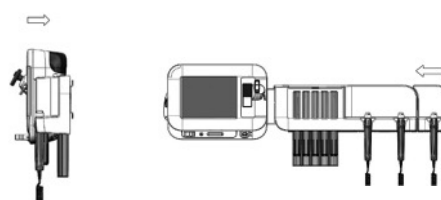
b.) Make sure that the connector is undamaged (1). Also, make sure that the two predetermined breaking points at the RVS-200 Wall Diagnostic Station are broken out with a pair of pliers (2).



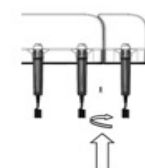
c.) If a burr remains there (3), please remove with a knife.



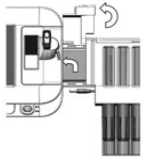
d.) When all screws have been tightened, take the RVS-200 Extension Module and pass the screw head through the openings. Then press the RVS-200 Extension Module to the left until it docks properly.



e.) Connect the RVS-200 Extension Module to the RVS-200 Wall Diagnostic Station with the screw supplied.



f.) Now open the cover as shown and connect the RVS-200 Wall Diagnostic Station to the RVS-100 by connecting the plug. Close the cover again.



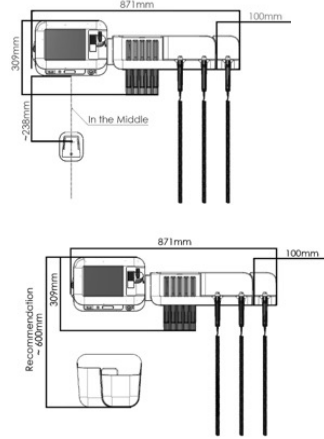
Drilling instructions for the cuff basket.

Follow the instructions when drilling the holes in the wall.

a.) Attaching the cuff basket.

After you have drilled the holes, take the dowels supplied and push them into the holes as far they will go. Hold the cuff basket onto the wall so that the screws can be inserted through the holes in the container into the dowels. Now tighten the screws with a screwdriver.

Insert the cuff basket from above into the guide until it stops.



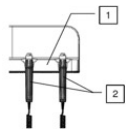
600mm = 23,622 inch
309mm = 12,165 inch
238mm = 9,37 inch
871mm = 34,291 inch
100mm = 3,937 inch

3.3 Startup

3.3.1 Function

The RVS-200 Wall Diagnostic Station is used thus:

a.) Each handle (2) automatically operates at 100% light intensity as soon as it is taken out of the handle holder (1). The handle (2) is automatically switched off when placed back into the handle holder (1).



b.) rheotronic® for light intensity control.

The light intensity is controlled directly via the handle: tap the switching ring clockwise to increase the light intensity; tap it counter-clockwise to decrease the light intensity. Caution!

The handle switches off automatically after approx. 3 minutes. If a second handle is removed from the handle holder, it switches on and the first handle in use is switched off. Only one handle can ever be operated at a time.



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If a second handle is removed from the handle holder, it switches on and the first handle in use is switched off. Only one handle can ever be operated at a time.

4. Care instructions

The cleaning and disinfecting of the medical devices serves to protect the patient, the user and third parties and to maintain the value of the medical devices.

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 careful handling.

Before return for repair, defective products must have undergone the prescribed reprocessing procedure.

4.1 General information



If a reusable device shows signs of material deterioration, it should no longer be used and should be disposed of according to the procedures described in the disposal/warranty sections.

4.2 Cleaning and disinfection

In order to avoid possible cross-contamination, the devices must be cleaned and disinfected regularly.

The outside of the devices can be cleaned with a damp cloth (if necessary, moistened with alcohol) until they are visually clean. Use disinfectant (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 directives should be used. After disinfecting, wipe the instruments with a damp cloth to remove any disinfectant residue. Please make sure that the cloth is moistened but NOT wet, so that no moisture penetrates

the openings of the devices.

Make sure that the glass cover is only cleaned with a dry and clean cloth.



- We recommend that before cleaning or disinfection the device is removed from the power supply.
- Never insert the instrument heads and instrument handles into liquids! Take care while cleaning and disinfecting that no liquid enters the instrument!
- The item is not approved for machine reprocessing and sterilisation. This can lead to irreparable damage!

5. Technical specifications

Medical device Medical device for powering instrument heads.

Protection class Protection class II

Classification Application part type
BF non-defibrillation protected

Model:
RVS-200 Wall Diagnostic Station
and

Input 1: 15 VDC / 1.2 A
Output 1: 2 x 3.5 VDC / 2 x 750 mA;
Output 2: 4.5 VDC / 1 A

Model:
RVS-200 Extension Module for

Input 1: 4.5 VDC / 1 A
Output 1: 4.5 VDC / 1 A

Operating temperature: +5°C / 41°F to +40°C / 104°F, 15% to 85% relative humidity (non-condensing)

Operating atmospheric pressure: 700 hPa to 1060 hPa

Transportation and storage location: -20°C / -4 to +55°C / 131°F, 10% up to 93% relative humidity (non-condensing)

Atmospheric pressure during transportation and storage: 500 hPa to 1060 hPa

6. Instrument heads

6.1 Attaching instrument heads

Attach the required instrument head to the mount on the upper part of the handle so that the two recesses on the lower part of the instrument head align with the two protruding guide pins of the battery handle. Gently press the instrument head onto the battery handle and turn the handle clockwise until it stops. The head is removed by turning it counter-clockwise.

⚠ - Otosopes

The temperature of the bulb XL of the L1 otoscope, the human operating otoscope and the veterinary operating otoscope is between 41°C / 105,8°F and 43°C / 109,4°F. Do not touch!

⚠ Retinoscopes/ophthalmoscopes

Because prolonged intense exposure to light can damage the retina, the use of the eye exam device should not be unnecessarily prolonged, and the brightness setting should not be set higher than needed for a clear representation of the target structures.

The irradiation dose of the photochemical exposure to the retina is the product of irradiance and duration of irradiation. If the irradiance is reduced by half, the irradiation time may be twice as long to reach the maximum limit.

Although no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be reduced to the minimum required for examination/diagnosis. Infants / children, aphasics and people with eye diseases are at higher risk. The risk may be increased if the patient has already been examined with this or another ophthalmological instrument during the last 24 hours. This is especially true when the eye has been exposed to retinal photography.

The light of this instrument may be harmful. The risk of eye damage increases with the duration of irradiation. An irradiation period with this instrument at maximum intensity of longer than >5 min. exceeds the guideline value for hazards.

This instrument does not pose a photobiological hazard according to DIN EN 62471 but still features a safety shutdown after 2 - 3 minutes.

Contraindications:

All instrument heads

There may be a risk of ignition of gases if the instrument is used in the presence of flammable mixtures or mixtures of pharmaceuticals.

The instrument heads and battery handles must never be placed in liquids.

Retinoscope/ophthalmoscope

The exposure to intense light during an extended eye examination using the ophthalmoscope may damage the retina.

The product is non-sterile. Do not use on injured tissue.

Only use Riester or Riester-approved accessories/consumables.

Cleaning frequency and sequence must comply with the cleaning regulations of non-sterile products in the respective facility. Cleaning/disinfection instructions in the instructions for use must be observed.

The product may only be used by trained personnel.

Intended patient population:

-The instruments are intended for adults and children.

Intended operators/users:

- The otoscopes are intended exclusively for use by doctors in clinics and medical practices.

Required skills/operator training:

- Only licensed professionals and clinicians should use the otoscopes, as they have the required qualifications.

Environmental conditions:

-The instruments are intended for use in premises with a controlled environment. The instruments must not be exposed to adverse/harsh environmental conditions.

6.1.1 ri-scope® L otoscope



- 1) Ear speculum
- 2) Bayonet mount
- 3) Swivel lens, 3x magnification
- 4) Operation lens
- 5) Push button for ear speculum ejection (L3 only)

Purpose/indications

The Riester otoscope described in these operating instructions is produced for illumination and examination of the auditory canal in combination with Riester ear specula.

Attaching and removing ear specula

The otoscope head can take either disposable Riester ear specula (in black) or reusable Riester ear specula (in black). The size of the ear speculum is marked at the back of the speculum.

Otoscope L1 and L2

Turn the speculum clockwise until you feel resistance. To remove the speculum, turn it counter-clockwise.

Otoscope L3, EliteVue Fibre Optic Macro Otoscope

Place the selected speculum on the chromed metal fitting of the otoscope until it clicks into place. To remove the speculum, press the blue eject button. The speculum will detach automatically.

Swivel lens for magnification

The swivel lens is fixed to the device and can be swivelled 360°.

Inserting external instruments into the ear.

If you wish to insert external instruments into the ear (e.g. forceps), you have to turn the swivel lens (approx. 3x magnification) located on the otoscope head by 180°. You can now insert the operating lens.

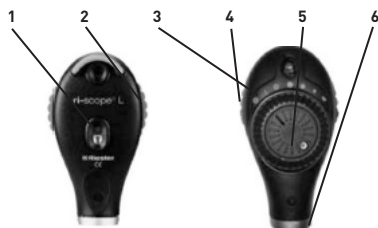
Pneumatic otoscopy

Pneumatic otoscopy (an examination of the eardrum), requires an insufflator bulb which is not included but may be ordered separately. The hose of the bulb is put on the connection. You can now carefully introduce the necessary amount of air into the ear canal.

Technical data for the bulb

Otoscope XL 2.5 V, 2.5 V, 750 mA, averagelifespan 15 h
Otoscope XL 3.5 V, 3.5 V, 720 mA, averagelifespan 15 h
Otoscope LED 2.5 V, 2.5 V, 280 mA, averagelifespan 10,000 h
Otoscope LED 3.5 V, 2.5 V, 280 mA, averagelifespan 10,000 h

6.1.2 ri-scope® L ophthalmoscope



- 1) Dioptre display
- 2) Dioptre wheel
- 3) Aperture symbols
- 4) Aperture wheel
- 5) Filter wheel
- 6) Bayonet head

Purpose/indications

The Riester ophthalmoscope described in these instructions for use is produced for examination of the eye and fundus.



Because prolonged intense exposure to light can damage the retina, the use of the eye exam device should not be unnecessarily prolonged, and the brightness setting should not be set higher than needed for a clear representation of the target structures.

The irradiation dose of the photochemical exposure to the retina is the product of irradiance and duration of irradiation. If the irradiance is reduced by half, the irradiation time may be twice as long to reach the maximum limit.

Although no acute optical radiation hazards have been identified for direct or indirect opt-

thalmoscopes, it is recommended that the intensity of light directed into the patient's eye be reduced to the minimum required for examination/diagnosis. Infants / children, aphasics and people with eye diseases are at higher risk. The risk may be increased if the patient has already been examined with this or another ophthalmological instrument during the last 24 hours. This is especially true when the eye has been exposed to retinal photography. The light of this instrument may be harmful. The risk of eye damage increases with the duration of irradiation. An irradiation period with this instrument at maximum intensity of longer than >5 min. exceeds the guideline value for hazards. This instrument does not pose a photobiological hazard according to DIN EN 62471 but still features a safety shutdown after 2 - 3 minutes.

Lens wheel with correction lenses

The correction lenses can be adjusted using the lens wheel. The following correction lenses are available:

Ophthalmoscope L1 and L2

Plus: 1-10, 12, 15, 20, 40.

Minus: 1-10, 15, 20, 25, 30, 35.

Ophthalmoscope L3

Plus: 1-45 in single steps

Minus: 1-44 in single steps

The values can be read off in the illuminated field of view. Plus values are indicated by green numbers, minus values by red numbers.

Apertures

The following apertures can be selected using the aperture setting wheel:

Ophthalmoscope L1








Semi-circle, small/medium/large circular aperture, fixation star, slit.

Ophthalmoscope L2

Semi-circle, small/medium/large circular aperture, fixation star and slit.

Ophthalmoscope L3

Semi-circle, small/medium/large circular aperture, fixation star, slit and grid.

Aperture	function
	Semi-circle: for examination of cloudy lenses
	Small circle: for reflex reduction in small pupils
	Medium circle: for reflex reduction in small pupils
	Large circle: for normal fundus examinations
	Diamond: for topographical determination of retinal changes
	Slit: to determine differences in level
	Fixation star: for determination of central or eccentric fixation

Filters

The following filters can be applied to each aperture using the filter wheel:

Ophthalmoscope L1 red-free filter

Ophthalmoscope L2 red-free filter, blue filter and polarization filter.

Ophthalmoscope L3 red-free filter, blue filter and polarization filter.

Filter	function
Red-free filter:	contrast-enhancing to assess fine vascular changes e.g. retinal haemorrhages
Polarizing filter:	for precise assessment of tissue colours and to reduce corneal reflections
Blue filter:	for better detection of vascular anomalies or haemorrhages, for fluorescence ophthalmology

With L2 + L3 every filter can be applied to every aperture.

Focusing device (L3 only)

By turning the focusing wheel, you can quickly fine-tune the examination area to be viewed at various distances.

Magnifying glass

A magnifying glass with 5x magnification is supplied with the ophthalmoscope set. This can be held between the instrument head and the examination area as required. The examination area is enlarged accordingly.

Technical data for the bulb

Ophthalmoscope 2.5 V XL 2.5 V 750 mA, average lifespan 15 h

Ophthalmoscope 3.5 V XL 3.5 V 690 mA, average lifespan 15 h

Ophthalmoscope 3.5 V LED 3.5 V 290 mA, average lifespan 10,000 h

6.1.3 Slit and spot retinoscopes

ri-scope® retinoscope (skiascope)



- 1) 360° scale
- 2) Examination window
- 3) Bayonet mount
- 4) Examination window (patient side)
- 5) Focusing wheel

Purpose/indications

The slit/spot retinoscopes described in these instructions for use [aka skiascopes] were manufactured to determine the refraction [ametropia] of the eye.

Startup and function

Attach the required instrument head to the mount on the upper part of the handle so that the two recesses on the lower part of the instrument head align with the two protruding guide pins of the battery handle. Gently press the instrument head onto the battery handle and turn the handle clockwise until it stops. The head is removed by turning it anti-clockwise. You can now use the knurled screw to rotate the slit image and focus the slit or spot image.

Rotation

The slit image can be rotated 360° using the control element. The respective angle can be read directly from the scale on the retinoscope.

Fixation card

For dynamic retinoscopy, the fixation cards are hung and fixed in the holder on the object side of the retinoscope.

Technical data for the bulb

Slit retinoscope HL 2.5 V 2.5 V 440 mA, avg.lifespan 15 h
 Line retinoscope XL 3.5 V 3.5 V 690 mA avg.lifespan 50 h
 Point retinoscope HL 2.5 V 2.5 V 450 mA avg.lifespan 15 h
 Point retinoscope XL 3.5 V 3.5 V 640 mA avg.lifespan 40 h

6.1.4 ri-scope® F.O. Light Conductor



- 1) Light Conductor with internal fibre optics
- 2) Bayonet mount

Purpose/indications

The Light Conductor described in these instructions for use is made to illuminate the oral cavity and the pharynx.

Technical data for the bulb

Light Conductor XL 2.5 V 2.5 V 750 mA avg.lifespan 15 h
 Light Conductor XL 3.5 V 3.5 V 690 mA avg.lifespan 15 h
 Light Conductor LED 2.5 V 2.5 V 280 mA avg.lifespan 10,000 h
 Light Conductor LED 3.5 V 3.5 V 280 mA avg.lifespan 10,000 h

6.1.5 ri-scope® dermatoscope



- 1) Skin-friendly contact plate with scale
- 2) Metal housing
- 3) Focusing wheel
- 4) Bayonet mount
- 5) Magnifying lens, 10x

Purpose/indications

The ri-derma dermatoscope described in these instructions for use is produced for the early detection of pigmented skin changes (malignant melanomas).

Focusing

Turn the ocular ring to focus the magnifying glass.

Skin-friendly contact plates

2 skin-friendly contact plates are included:

- 1) With a scale of 0-10 mm for the measurement of pigmented lesions such as malignant melanoma.
- 2) Without scale.

Both skin-friendly contact plates are easily removable and replaceable.

Technical data for the bulb

ri-derma XL 2.5 V 750 mA avg.lifespan 15 h
 ri-derma XL 3.5 V 690 mA avg.lifespan 15 h
 ri-derma LED 2.5 V 280 mA avg.lifespan 10,000 h
 ri-derma LED 3.5 V 280 mA avg.lifespan 10,000 h

6.1.6 ri-scope® F.O. tongue blade holder



- 1) Light guide
- 2) Plastic housing
- 3) Sliding mechanism for tongue depressor
- 4) Internal fibre optics
- 5) Bayonet mount

Purpose/indications

The tongue depressor holder described in these instructions for use is manufactured for the examination of the mouth and throat area in combination with standard wooden and plastic tongue depressors.

Startup

Insert a standard wooden or plastic tongue depressor into the aperture below the light opening to the stop. The tongue depressor is easy to remove after examination by actuating the ejector.

Technical data for the bulb

F.O. tongue blade holder XL 2.5 V 2.5 V 750 mA avg.lifespan 15 h
 F.O. tongue blade holder XL 3.5 V 3.5 V 720 mA avg.lifespan 15 h
 F.O. tongue blade holder XL 2.5 V 2.5 V 280 mA avg.lifespan 10,000 h
 F.O. tongue blade holder LED 3.5 V 3.5 V 280 mA avg.lifespan 10,000 h



- 1) Mirror
- 2) Bracket for lamp holder

Purpose/indications

The laryngeal mirrors described in these instructions for use are manufactured for mirroring examination of the mouth and throat area in combination with a Riester lamp holder.

Startup

The laryngeal mirrors can only be used in combination with the light conductor. This ensures optimal illumination. Take one of the 2 laryngeal mirrors and attach it to the front of the light conductor in the desired direction.

6.1.7 ri-scope® nasal speculum



- 1) Screw for expanding the speculum
- 2) Swivel lens, 2.5x magnification
- 3) Expandable speculum
- 4) Internal fibre optics
- 5) Bayonet mount

Purpose/indications

The nasal speculum described in these instructions for use is produced for illumination and thereby examination of the inside of the nose.

Two modes of operation are possible:

- a) Quick spreading
Push the set screw on the instrument head down with your thumb. In this adjustment, the position of the shank of the speculum cannot be changed.
- b) Individual expansion
Turn the adjusting screw clockwise until you reach the desired expansion width. The shanks close again when the screw is turned counter-clockwise.

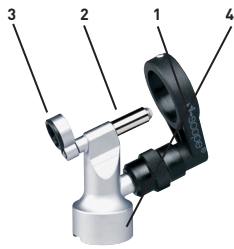
Swivel lens

On the nasal speculum there is a swivel lens with a magnification of around 2.5x, which can be simply pulled out or reinserted into the opening provided on the nasal speculum, as required.

Technical data for the bulb

Nasal speculum XL 2.5V, 2.5V 750 mA avg.lifespan 15 h
 Nasal speculum XL 3.5V, 3.5V 720 mA avg.lifespan 15 h
 Nasal speculum LED 2.5V, 2.5V 280 mA avg.lifespan 10,000 h
 Nasal speculum LED 3.5V, 3.5V 280 mA avg.lifespan 10,000 h

6.1.8 ri-scope® human operating otoscope without speculum



- 1) Ear speculum holder
- 2) Bulb
- 3) Magnifying glass
- 4) Bayonet mount

Purpose/indications

The Riester operating otoscope described in these operating Instructions is produced for illumination and examination of the auditory canal and for insertion of external instruments into the auditory canal.

Attaching and removing ear specula for human medicine.

Place the desired speculum on the black holder on the operating otoscope so that the notch on the speculum fits into the guide in the holder. Fasten the speculum by turning it clockwise.

Inserting external instruments into the ear

The operating otoscope is designed so that external instruments can be inserted into the ear.

Technical data for the bulb

Operating otoscope HL 2.5 V 2.5 V 680 mA avg.lifespan 20 h
 Operating otoscope XL 3.5 V 3.5 V 700 mA avg.lifespan 20 h

6.1.9 ri-scope® veterinary operating otoscope without speculum



- 1) Ear speculum holder
- 2) Bulb
- 3) Magnifying glass
- 4) Bayonet mount

Purpose/indications

The Riester operating otoscope described in this user manual is produced exclusively for use on animals or for veterinary medicine and therefore has no CE marking. It can be used for illumination and examination of the auditory canal, as well as for minor operations in the auditory canal.

Attaching and removing ear specula for veterinary medicine

Place the desired speculum on the black holder on the operating otoscope so that the notch on the speculum fits into the guide in the holder. Fasten the speculum by turning it clockwise.

Swivel magnifying lens for enlarging

There is a small 360° swivel magnifying lens on the operating otoscope with a magnification power of about 2.5 times.

Inserting external instruments into the ear

The operating otoscope has an open design so that external instruments can be inserted into the ear.

Technical data for the bulb

Operating otoscope HL 2.5 V 2.5 V 680 mA avg.lifespan 20 h
 Operating otoscope XL 3.5 V 3.5 V 700 mA avg.lifespan 20 h

6.2 Replacing the light bulb

Otoscope L1

Remove the speculum receptacle from the otoscope. Unscrew the bulb anticlockwise. Tighten the new bulb clockwise and reattach the speculum holder.

Otosopes L2, L3, EliteVue Fibre Optic Macro Otoscope, ri-derma, lamp holder, nasal speculum and depressor holder

Unscrew the instrument head from the battery handle. The bulb is located at the bottom of the instrument head. Using your thumb and forefinger or a suitable tool, pull the bulb out of the instrument head. Insert the new bulb firmly.

Ophthalmoscopes/retinoscopes

Remove the instrument head from the battery handle. The bulb is located at the bottom of the instrument head. Remove the bulb from the instrument head using your thumb and forefinger or a suitable tool. Insert the new bulb firmly.



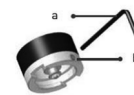
The pin of the bulb must be inserted into the guide groove on the instrument head.

Operating otoscopes veterinary/human

Unscrew the bulb from the socket in the operating otoscope and firmly screw in a new bulb.

6.3 Setting up the anti-theft device

6.3.1 Function



Place the desired instrument head onto the attachment on the handle so that the two recesses on the lower part of the instrument head sit on top of the two projecting guide cams on the upper part of the battery handle. Press the instrument head lightly onto the handle and turn the handle in a clockwise direction until it stops.

In order to activate the anti-theft function, turn the Allen screw (b) using the Allen key (a) (included with the instrument head) until it stops. The instrument head can now no longer be removed from the handle. In order to deactivate the anti-theft function, the Allen screw (b) should be unscrewed again using the Allen key (a).

⚠ Attention!

More information about

ri-scope®L

ri-scope

is in the user manual item no. 99220

7. Spare parts and accessories

Reusable ear specula for L1/L2

Item no.:

- 10775 2 mm/10 pcs
- 10779 2.5 mm/10 pcs
- 10783 3 mm/10 pcs
- 10789 4 mm/10 pcs
- 10795 5 mm/10 pcs

Disposable specula for L1/L2

Item no.:

- 10772-532 2 mm, 100 pcs
- 10773-532 2 mm, 500 pcs
- 10774-532 2 mm, 1,000 pcs
- 10772-531 2.5 mm, 100 pcs
- 10773-531 2.5 mm, 500 pcs
- 10774-531 2.5 mm, 1,000 pcs
- 10772-533 3 mm, 100 pcs
- 10773-533 3 mm, 500 pcs
- 10774-533 3 mm, 1,000 pcs
- 10772-534 4 mm, 100 pcs
- 10773-534 4 mm, 500 pcs
- 10774-534 4 mm, 1,000 pcs
- 10772-535 5 mm, 100 pcs
- 10773-535 5 mm, 500 pcs
- 10774-535 5 mm, 1,000 pcs

Reusable ear specula for L3, EliteVue Fibre Optic Macro Otoscope

Item no.:

- 10800-532 2 mm, 10 pcs
- 10800-533 3 mm, 10 pcs
- 10800-534 4 mm, 10 pcs
- 10800-535 5 mm, 10 pcs
- 10800-539 6 mm, 10 pcs

Disposable specula for L3, EliteVue Fibre Optic Macro Otoscope

Item no.:

- 10801-532 2 mm, 100 pcs
- 10802-532 2 mm, 500 pcs
- 10803-532 2 mm, 1,000 pcs
- 10801-533 3 mm, 100 pcs
- 10802-533 3 mm, 500 pcs
- 10803-533 3 mm, 1,000 pcs
- 10801-534 4 mm, 100 pcs
- 10802-534 4 mm, 500 pcs
- 10803-534 4 mm, 1,000 pcs
- 10801-535 5 mm, 100 pcs
- 10802-535 5 mm, 500 pcs
- 10803-535 5 mm, 1,000 pcs
- 10801-539 9 mm, 100 pcs
- 10802-539 9 mm, 500 pcs
- 10803-539 9 mm, 1,000 pcs

Operating lens

Item no.: 11449

Insufflator Bulb for pneumatic otoscopy

Item no.: 10960

pack of 6 XL 2.5 V bulbs for pen-scope, ri-scope® L1, e-scope® otoscopes

Item no.: 10489

pack of 6 XL 2.5 V bulbs, for ri-mini/ri-scope® L1, L2, L3, e-scope® & ri-derma®

Item no.: 10605

LED 2.5 V for ri-scope®L otoscope L2/L3 Kelvin = 4000, CRI = 92

Item no.: 10626

LED 2.5 V for ri-scope®L ophthalmoscope L1/L2/L3 Kelvin = 4000, CRI = 92

Item no.: 10624

LED 3.5 V for ri-scope ophth. L1/L2/L3 Kelvin = 4000, CRI = 92

Item no.: 10627

LED 3.5 V for ri-scope® L otoscopes L2/L3/EliteVue Kelvin = 4000, CRI = 92
Item no.: 10625

pack of 6 XL bulbs, 3.5 V, ri-scope® L1 otoscope
Item no.: 10487

pack of 6 XL bulbs, 3.5 V, ri-scope® otoscope L2/L3
Item no.: 10607

pack of 6 XL 3.5 V bulbs, ri-scope® ophthalmoscope L1, L2, L3
Item no.: 10608

Spare parts and accessories

A detailed list can be found in „Instruments for ENT,“ Ophthal-mologic Instruments, which you can find at www.riester.de
<https://www.riester.de/en/productdetails/d/ri-scooper-l-premium-ent-and-ophthalmic-instruments/other-ri-scope-l-accessories/>

8. Maintenance/accuracy check/calibration/applied standards

The instruments and their accessories require no special maintenance. If an instrument needs to be tested for any reason, please send it to us or an authorised Riester dealer in your area, the details of which we will provide you with upon request.
Making changes to the device is not allowed!

8.1 Applied standards

Reference to d. standards:

- IEC 60601-1
- IEC 60601-1-2

9. Care instructions

9.1 General information



The cleaning and disinfecting of the medical devices serves to protect the patient, the user and third parties and to maintain the value of the medical devices.

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 careful handling.

Before return for repair, defective products must have undergone the prescribed reprocessing procedure.

Warning:

- We recommend that before cleaning or disinfection the device is removed from the power supply.
 - The diagnostic instruments are not sterile devices; they cannot be sterilised
 - Never place the instrument heads and handles in liquids!
 - Make sure that no liquids penetrate the housing interior!
 - The article is not approved for machine reprocessing and sterilisation. This will lead to irreparable damage!



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.

9.2 Cleaning and disinfection



To avoid possible cross-contamination, the diagnostic instruments and their handles must be cleaned and disinfected regularly.

The diagnostic instruments together with their handles can be cleaned on the outside using a damp cloth (if necessary, moistened with alcohol) until they are visually clean. Use disinfectant (e.g. disinfectant Bacillol AF from Bode Chemie GmbH (time 30s)) only according to the instructions of use of the respective manufacturer of disinfectant. Only disinfectants with proven effectiveness according to national directives should be used. After disinfecting, wipe the instruments with a damp cloth to remove potential residue.

Please make sure that the cloth is moistened but NOT wet, so that no moisture penetrates the openings in the diagnostic instrument or its handle.

Make sure that all glass and lenses are only cleaned with a dry and clean cloth.

9.3 Processing of reusable ear specula

Cleaning: manual

Required equipment: mildly alkaline cleaner (e.g. neodisher Mediclean, Dr. Weigert 404333 has been validated) 15°C / 59°F -50°C / 122°F, cleaning brush (Interlock 09098 and 09050 have been validated), tap water/running water 20±2°C / 68±35,6°F of at least drinking water quality, tub/basin for cleaning agent, lint-free cloths (Braun Wipes Eco 19726 have been validated).

1. The cleaning solution is prepared according to the manufacturer's instructions for the cleaning agent (neodisher Mediclean 0.5% has been validated).
2. Completely immerse the medical devices in the cleaning solution.
3. Make sure that all surfaces are completely wetted with cleaning solution.
4. Carry out all subsequent steps below the liquid level to prevent the contaminated liquid from splashing.
5. Brush the hard-to-reach areas of the immersed ear specula with a soft brush during the exposure time. Pay attention to the critical, hard-to-reach places where a visual assessment of the cleaning effect is not possible.
6. The total exposure time in the cleaning solution is at least 10 minutes (10 minutes has been validated).
7. Remove the medical devices from the cleaning solution.
8. Rinse the medical devices under running tap water (at least drinking water quality) for at least 1 minute (1 minute has been validated) to completely remove any supernatant or residual cleaning solution. Check that the device is clean; if soiling is visible, repeat the above steps.
9. Dry with a lint-free cloth.

Disinfection: manual

Required equipment: Disinfectant (e.g. CIDEX OPA, Johnson & Johnson 20391 has been validated), demineralised water (demineralised water free of facultative pathogenic microorganisms according to the KRINKO/BfArM recommendation) 20±2°C, sterile, lint-free cloths.

1. Prepare the disinfectant solution according to the manufacturer's instructions (CIDEX OPA is a ready-to-use solution; the concentration must be checked using test strips, see manufacturer's instructions) (CIDEX OPA has been validated).
2. Completely immerse the ear specula in the disinfectant solution.
3. Exposure time of the disinfectant solution according to the manufacturer's instructions for high-level disinfection (CIDEX OPA for 12 minutes has been validated).
4. Remove the ear specula from the disinfectant solution and place them in a tub/basin containing demineralised water for at least 1 minute (1 minute has been validated).
5. Repeat the step twice with fresh demineralised water.
6. Place the ear specula on a clean, dry cloth and allow to dry.

Further information for the user:

For information on cleaning and disinfection, refer to the current DIN EN ISO 17664 standard.

The homepage of RKI Guideline – KRINKO/BfArM also regularly provides information about developments regarding cleaning and disinfection for the reprocessing of medical devices.

⚠ Single use ear specula

⊗ For single use only

Caution: Repeated use can lead to infection.

10. 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 any questions about the disposal of products, please contact the manufacturer or their representative.

11. Electromagnetic compatibility

The instrument satisfies the requirements for electromagnetic compatibility. Please note that under the influence of unfavourable field strengths, e.g. when operating cell phones or radiological instruments, malfunctions cannot be ruled out.

In accordance with the requirements of IEC60601-1-2:2014, the electromagnetic compatibility of this device has been verified in a test.

- During installation and operation of the device, observe the following instructions:
- To avoid electromagnetic interference with the device's operation, do not use it simultaneously with other electronic equipment.
- Do not use or stack the device near, on or under other electronic equipment to avoid electromagnetic interference when operating the device.
- Do not use the device in the same room as other electronic devices, such as e.g. life-saving equipment that can have a major impact on a patient's life and treatment outcomes, or any other measuring or treatment device that uses weak electrical currents.
- 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 interference.
- Do not touch the pins connecting the control unit to the lenses or the signal pad on the lenses without special precautions.



Medical electrical equipment is subject to special precautions in terms of electromagnetic compatibility (EMC).

Portable and mobile radio frequency communication devices can affect medical electrical equipment. The ME device is intended for operation in a home health care electromagnetic environment and for professional facilities such as industrial areas and hospitals.

The user of the device should ensure that it is operated within such an environment.



Warning:

The ME device may not be stacked, situated or used directly next to or with other devices. When use close to or stacked with other devices is required, the ME device and the other ME devices must be monitored to ensure intended operation within this configuration. This ME device is intended for use by medical professionals only. This device may cause radio frequency 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 ME device assessed does not exhibit any essential performance characteristics in the sense of EN60601-1, which would present an unacceptable risk to patients, operators or third parties should the power supply fail or malfunction.




Warning:

Portable 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 ri-scope L instrument head specified by the manufacturer. Failure to comply may result in a reduction of the device's performance characteristics.

Manufacturer's guidance and declaration on electromagnetic emissions		
The RVS-100 is intended for use in the electromagnetic environments specified below. The user of the RVS-100 should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidelines
RF emissions CISPR 11	Groupe 1	The RVS-100 uses RF energy only for its internal function. Hence, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The RVS-100 is suitable for use in all establishments other than residential premises and those premises directly connected to the public low-voltage power supply network and used for residential purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Manufacturer's guidance and declaration on immunity to electromagnetic interference			
The RVS-100 is intended for use in the electromagnetic environments specified below. The user of the RVS-100 should ensure that it is used in such an environment.			
RF immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical high-speed signal/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	The quality of the supply voltage should be that of a typical business or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	The quality of the supply voltage should be that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% drop in UT) for 0.5 cycle 40% UT (60% drop in UT) for 5 cycles 70% UT (30% drop in UT) for 25 cycles <5% UT (>95% drop in UT) for 5 seconds	<5% UT (>95% drop in UT) for 0.5 cycle 40% UT (60% drop in UT) for 5 cycles 70% UT (30% drop in UT) for 25 cycles <5% UT (>95% drop in UT) for 5 seconds	The quality of the supply voltage should be that of a typical business or hospital environment. If continued operation during mains power interruptions is required, it is recommended that the RVS-100 be powered from an uninterruptible power supply or a battery.
Mains frequency (50 Hz/60 Hz) IEC magnetic field 61000-4-8	3 A/m	3 A/m	Mains frequency magnetic fields should be at the normal level under typical conditions in a typical business or hospital environment.
NOTE: U_T corresponds to the mains voltage before application of the test level.			

Manufacturer's guidance and declaration on immunity to electromagnetic interference			
The RVS-100 is intended for use in the electromagnetic environments specified below. The user of the RVS-100 should ensure that it is used in such an environment.			
RF immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Veff 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the RVS-100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1,2\sqrt{P}$ 80 MHz - 800 MHz $d=2,3\sqrt{P}$ 800MHz - 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths of fixed RF transmitters, as determined by electromagnetic testing (see a), should be less than the compliance level in each frequency range (see b), Interference may occur in the vicinity of devices marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz		
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 influenced by absorption and reflection from buildings, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio telephones (mobile phones/cordless phones) and land mobile radios, amateur radio, AM and FM radios as well as TV transmitters, cannot be predicted with accuracy. To assess the electromagnetic environment with regard to fixed RF transmitters, an on-site electromagnetic survey should be considered. If the measured field strength at the location where the RVS-100 is used exceeds the RF compliance levels, the unit should be monitored to confirm normal operation. If anything unusual is noticed about the device's operation, additional measures may be required, such as changing the orientation or positioning of the RVS-100.			
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended distances between portable and mobile RF communications equipment and the RVS-100			
The RVS-100 is intended for use in an electromagnetic environment where RF interference is controlled. The customer or the user of the RVS-100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RVS-100 as recommended below, according to the maximum output power of the communications equipment.			
Maximum nominal output power of the sender (W)	The separation distance depends on the frequency of transmission (m)		
	150 kHz to 80 MHz $d=1,2\sqrt{P}$	80 MHz to 800 MHz $d=1,2\sqrt{P}$	800 MHz to 2,7 GHz $d=2,3\sqrt{P}$
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 in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum 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 influenced by absorption and reflection from buildings, objects and people.

12. 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.