e-scope®
e-xam

Gebrauchsanweisung
Diagnostische Instrumente

Instructions
Diagnostic Instruments

Mode d' emploi
Instruments diagnostiques

Instrucciones para el uso
Instrumentos diagnósticos

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Strumenti diagnostici

Инструкция по эксплуатации
Диагностические приборы

CE

Riester

ENGLISH

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1. Please note the following important information before startup

You have purchased a high-quality Riester diagnostic set, which was manufactured in accordance with Regulation (EU) 2017/745 on medical devices and is subject to the strictest quality controls at all times. The excellent quality guarantees reliable diagnoses. Please read the instructions carefully before use and keep them at hand. Should you have any questions, please contact us or your Riester representative at any time. Our contact details are listed on the last page of this user manual.
We will gladly provide you with the address of our representative upon request.
Please note that all instruments described in this user manual are only suitable for use by appropriately trained persons. Please note that the proper and safe functioning of our instruments is only guaranteed if both the instruments and their accessories are exclusively from Riester.
Safety instructions:

1.1. Safety symbols

Symbol	Note on symbol
	Follow the instructions in the user manual.
	Type B applied part
MD	Medical device
	Class II protective devices
	**Warning!** The general warning symbol indicates a potentially dangerous situation that can lead to serious injuries.
	**Caution!** Important note in this manual. The caution symbol indicates a potentially dangerous situation that can lead to minor or moderate injuries. It can also be used to warn of unsafe practices.
	Direct current
~	Alternating current
	Manufacturing date YYMMDD (year, month, day)
	Manufacturer
SN	Manufacturer's serial number
LOT	Lot / batch number
REF	Reference number
	Temperature for transportation and storage
	Relative humidity for transportation and storage
	Air pressure for transportation and storage Operating ambient air pressure
CE	CE-marking
	Symbol for the marking of electrical and electronic equipment in accordance with Directive 2002/96/EC. **Caution:** Used electrical and electronic equipment should not be treated as normal household waste, but should be disposed of separately in accordance with national and EU regulations.
	Non-ionizing radiation

1.2 Packaging symbols

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

Warning: 
Please note that the proper and safe functioning of our instruments is only guaranteed if both the instruments and their accessories are exclusively from Riester.
The use of other accessories may result in increased electromagnetic emissions or reduced electromagnetic immunity of the device and may lead to incorrect operation.

1.3. Caution  **/contraindications**
- 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.
- The exposure to intense light during an extended eye examination using the ophthalmoscope may damage the retina.
- The product and ear specula are non-sterile. Do not use on injured tissue.
- Use new or sanitised ear specula to limit the risk of cross-contamination.
- Used ear specula must be disposed of in accordance with current medical practices or local regulations regarding the disposal of infectious, biological medical waste.
- 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.

1.4.Intended patient population
The device is intended for adults and children.

1.5. Intended operators/users
The ophthalmoscopes are intended exclusively for use by doctors in clinics and medical practices.
The otoscopes are intended exclusively for use by doctors in clinics and medical practices.
The diagnostic lamps are intended exclusively for use by doctors in clinics and medical practices.

1.6. Required skills/training
Since only doctors use the ophthalmoscopes, they have the appropriate qualifications.
Since only doctors use the otoscopes, they have the appropriate qualifications.
Since only doctors use the diagnostic lamps, they have the appropriate qualifications.

1.7. Environmental conditions
The instrument is intended to be used in premises with a temperature as specified in point 6.
The Instrument must not be exposed to adverse/harsh environmental conditions.

1.8. Warnings/caution

Warning
The general warning symbol indicates a potentially dangerous situation that can lead to serious injuries.

Do not use in a magnetic resonance environment!

There is a risk of ignition of gases if the device is operated in the presence of flammable mixtures or mixtures of medicinal products and air or oxygen or nitrous oxide! The device must not be operated in rooms in which flammable mixtures or mixtures of pharmaceuticals and air or oxygen or nitrous oxide are present, e.g. operating theatres.

Electric shock!
The housing of the ri-scope L may only be opened by authorised persons.

Damage to the device due to a fall or strong ESD influence!
If the device is not functioning, it must be returned to the manufacturer for repair.

The device must be used in a controlled environment.
The device must not be exposed to harsh environmental conditions.

 Caution!:
The caution symbol indicates a potentially dangerous situation that can lead to minor or moderate injuries. It can also be used to warn of unsafe practices.

The faultless and safe functioning of the ri-scope L instruments can only be guaranteed if Riester original parts and accessories are used.

Old electronic devices must be disposed of in accordance with the institutional guidelines for the disposal of expired devices.

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.

We recommend removing the (rechargeable) batteries from the battery handle before cleaning or disinfecting.
Clean and disinfect the Instruments carefully so that no liquid penetrates the interior. Never place the Instrument in liquids!
The instruments with battery handles are supplied in a non-sterile condition. Do not use ethylene, oxide gas, heat, autoclaves, or other methods that place undue stress on the material to sterilize the device. The devices have not been approved for mechanical reprocessing or sterilisation. This leads to irreparable damage!

The patient is not the intended operator.
The product may only be used by qualified personnel.
Qualified personnel are doctors or nurses in hospitals, medical facilities, clinics and medical practices.

⚠
Caution!
User Responsibility
It is your responsibility to:
The user must check the integrity and completeness of the instruments before each use. All components must be compatible with each other.
Incompatible components can result in degraded performance.
Never knowingly use a defective device.
Replace parts that are defective, worn, missing or incomplete.
Contact the nearest factory-approved service centre if repairs or replacements are required.
In addition, the user of the device bears sole responsibility for malfunctions resulting from improper use, incorrect maintenance, improper repair, damage or changes by persons other than Riester employees or authorised service personnel.

⚠ 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 established.

If there are any problems with the product or use of the product, please contact your doctor immediately.

1.9. Scope of delivery

	e-scope® otoscope with direct illumination
Art. no.: 2100-200	• 2.7 V vacuum, in white bag
Art. no.: 2101-200	• 2.7 V vacuum, in black bag
Art. no.: 2100-201	• XL 2.5 V, in white bag
Art. no.: 2101-201	• XL 2.5 V, in black bag
	e-scope® F.O. otoscope
Art. no.: 2110-202	• XL 2.5 V, in white case
Art. no.: 2111-202	• XL 2.5 V, in black case
Art. no.: 2110-203	• 3.7 V LED, in white case
Art. no.: 2111-203	• LED 3.7 V, in black case
	e-scope® ophthalmoscope
Art. no.: 2120-200	• 2.7 V vacuum, in white bag
Art. no.: 2121-200	• 2.7 V vacuum, in black bag
Art. no.: 2122-201	• XL 2.5 V, in white case
Art. no.: 2123-201	• XL 2.5 V, in black case
Art. no.: 2122-203	• 3.7 V LED, in white case
Art. no.: 2123-203	• LED 3.7 V, in black case
	e-scope® otoscope with direct illumination/ ophthalmoscope
Art. no.: 2130-200	• 2.7 V vacuum, in white bag
Art. no.: 2131-200	• 2.7 V vacuum, in black bag
	e-scope® F.O. otoscope/ophthalmoscope
Art. no.: 2130-202	• XL 2.5 V, in white case
Art. no.: 2131-202	• XL 2.5 V, in black case
Art. no.: 2130-203	• 3.7 V LED, in white case
Art. no.: 2131-203	• LED 3.7 V, in black case
	e-xam® diagnostic lamp with tongue depressor holder
Art. no. 5130-01	e-xam, black, XL, 2.5V
Art. no. 5130-02	e-xam, white, XL, 2.5V
Art. no. 5131-01	e-xam, black, 2.5V LED
Art. no. 5131-02	e-xam, white, 2.5 V LED

2. Battery handles and commissioning
2.1. Purpose

The Riester battery handles described in this manual are used to power the instrument heads (the lamps are incorporated into the corresponding instrument heads). They also serve as a holder.

2.2. Operational readiness

(Inserting and removing Batteries)
Turn the instrument head anticlockwise to remove it from the handle. Insert 2 standard AA (Mignon) 1.5 V alkaline batteries (IEC standard designation LR6) into the handle sleeve so that the positive terminals point towards the upper part of the handle.

2.3. CAUTION: ⚠

- If you do not use the device for a long time or take it with you while travelling, please remove the batteries from the handle.
- New batteries should be inserted when the light intensity of the instrument becomes weaker and could impair the examination.
- For optimal light output, we recommend that you always use new high-quality batteries when changing the battery.
- Make sure that no liquid or moisture penetrates the handle.

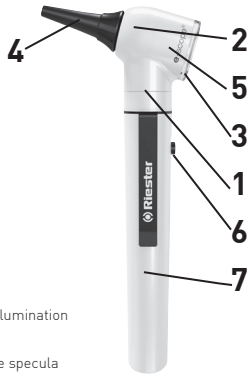
2.4. Disposal:

Please note that batteries must be disposed of specially. Information about this can be obtained from your municipality or from your responsible environmental consultant.

Attaching instrument heads

Twist the instrument head clockwise onto the handle.
Switching on and off
There is an on/off slide switch on the handle. If the slide switch is pushed up, the device is switched on; if it is pushed down, the device is switched off.

3. Otoscope and accessories
3.1. Device function:



1) 3.7 V LED, 2.5 V xenon or vacuum illumination
2) Internal fibre optics
3) Swivel lens with 3x magnification
4) Ear specula, reusable or disposable specula
5) Connection for pneumatic otoscopy
6) On/off slide switch
7) Battery compartment for 2 x AA batteries, housing made of ABS plastic

3.2. Purpose
The Riester otoscopes described in these operating instructions were produced for illumination and examination of the auditory canal in combination with a Riester ear specula.

3.3. Attaching and removing ear specula
Place the selected speculum on the metal frame of the otoscope. Turn the speculum to the right until you feel resistance. The size of the ear speculum is marked at the

back of the speculum.

3.4. Swivel lens for magnification

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

3.5. 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°.

3.6. Pneumatic otoscopy

Pneumatic otoscopy (= an examination of the eardrum), requires a ball which is not included in normal delivery but may be ordered separately (see Spare parts and accessories). Take the metal connector, which is not included in the normal scope of delivery, but can be ordered separately (see spare parts and accessories) and insert it into the recess provided on the side of the otoscope head. The tube of the ball is fitted on the connector. You can now carefully fill the necessary amount of air into the ear canal.

3.7. Replacing the bulb

Otoscope e-scope® with direct illumination

Remove the speculum receptacle from the otoscope. To do so, use your index finger and thumb to turn it to the left until it stops. You can then pull the speculum receptacle forwards to remove it. The bulb can be unscrewed anticlockwise. Tighten the new bulb clockwise and reattach the specula receptacle.

e-scope® otoscopes with fibre optics

Unscrew the instrument head from the battery handle. The LED/incandescent 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. When switching from an LED to an incandescent bulb, an optionally available adapter must also be used; when changing from an incandescent bulb to an LED, this must be removed from the lamp compartment. Insert the new LED/incandescent bulb firmly.

3.8. Spare parts and accessories

Reusable ear specula

• 2 mm	Pack of 10 St.	No.: 10775
• 2.5 mm	Pack of 10 St.	No.: 10779
• 3 mm	Pack of 10 St.	No.: 10783
• 4 mm	Pack of 10 St.	No.: 10789
• 5 mm	Pack of 10 St.	No.: 10795

Reusable ear specula

• 2 mm	Pack of 100 St.	No.: 14061-532
	Pack of 500 St.	No.: 14062-532
	Pack of 1.000 St.	No.: 14063-532
• 2.5 mm	Pack of 100 St.	No.: 14061-531
	Pack of 500 St.	No.: 14062-531
	Pack of 1.000 St.	No.: 14063-531
• 3 mm	Pack of 100 St.	No.: 14061-533
	Pack of 500 St.	No.: 14062-533
	Pack of 1.000 St.	No.: 14063-533
• 4 mm	Pack of 100 St.	No.: 14061-534
	Pack of 500 St.	No.: 14062-534
	Pack of 1.000 St.	No.: 14063-534
• 5 mm	Pack of 100 St.	No.: 14061-535
	Pack of 500 St.	No.: 14062-535
	Pack of 1.000 St.	No.: 14063-535

Replacement lamps for e-scope® otoscope with direct illumination

Vacuum, 2.7 V, pack of 6	No.: 10488
XL, 2.5 V, pack of 6	No.: 10489

for e-scope® F.O. Otoscope

XL 2.5 V, Packung à 6 Stück	No.: 10600
LED 3.7 V	No.: 14041

3.9. Technical data of the lamp for e-scope® otoscope with direct illumination

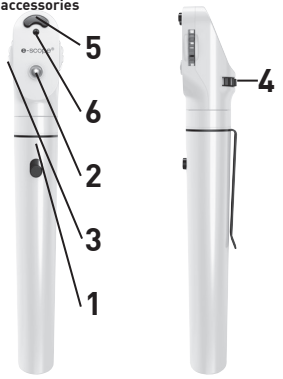
Vacuum, 2.5 V	300 mA	mean life span 15 h
XL, 2.5 V	750 mA	mean life span 16.5 h

3.9.1. Technical data of the lamp for e-scope® F.0. Otoscope

XL 2.5 V	750 mA	mean life span 15 h
LED 3.7 V	52 mA	mean life span 20.000 h

Other spare parts
No.: 10960 Bulb for pneumatic test
No.: 10961 Connector for pneumatic test

4. Ophthalmoscope/ e-xam and accessories
4.1. Device function:



1) 3.7 V LED, 2.5 V xenon or vacuum illumination
2) Dioptre display
3) Dioptre adjustment wheel
4) Aperture wheel
5) Glasses protection
6) Dust-proof housing

1) Battery handle
2) Lamp head with LED

4.2. Purpose
The Riester ophthalmoscopes described in these instructions for use were produced for examination of the eye and fundus.

CAUTION! ⚠
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 a 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.

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

D+ 1 | 2 | 3 | 4 | 6 | 8 | 10 | 15 | 20
D- 1 | 2 | 3 | 4 | 6 | 8 | 10 | 15 | 20

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

4.4. Aperture wheel
Using the aperture wheel and filter wheel, the following apertures or filters can be selected:

	Aperture	Function
	Semi circle:	For examinations with turbid lenses.
●	Small circle	For reduction of reflexes of small pupils.
⊕	Large circle:	For standard fundus examination.
	Fixation star:	For definition of central and eccentric fixation.

Filter Function

Red-free filter: To increase contrast for assessment of (green filter) changes in fine vessels, i.e. retinal haemorrhages.

Blue filter: for improved recognition of vascular abnormalities or bleeding, for fluorescence ophthalmology.

4.5. Replacing the bulb
e-scope® **ophthalmoscopes**
Remove the instrument head from the battery handle. The LED/incandescent bulb is located at the bottom of the instrument head. Remove the lamp from the instrument head using your thumb and forefinger or a suitable tool. When switching from an LED to an incandescent bulb, an optionally available adapter must also be used; when changing from an incandescent bulb to an LED, this must be removed from the lamp compartment. Insert the new LED/incandescent bulb firmly.

CAUTION! ⚠
The pin of the lamp must be inserted into the guide groove on the adapter and the adapter must be inserted into the guide groove on the instrument head.

e-xam
Remove the instrument head from the battery handle. The XL or LED lamp is located in the lamp head.
Turn white insulation counter clockwise. Remove insulation with contact.
Lamp will fall out. Insert new lamp, turn contact with insulation clockwise.

4.6. Technical data of the ophthalmoscope lamp
XL 2.5 V, 750 mA, average lifespan 16.5 h
LED 3.7 V 38 mA avg. lifespan 20,000 h
Technical data for the e-xam lamp
XL 2.5 V, 750 mA, average lifespan 16.5 h
LED 2.5 V 120 mA 5,000-5,500 Kelvin, CRI 72 avg. lifespan 20,000 h

4.7. Care instructions
General note
The cleaning and disinfecting of the medical devices serve to protect the patient, the user and third parties and to maintain the value of the medical devices. Due to the product design and the materials used, a defined limit for the maximum possible number of reprocessing cycles cannot be determined. The service life of medical devices is defined by their function and careful handling.
Before return for repair, defective products must have undergone the prescribed re-

conditioning process.

4.8. 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. Wipe with 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 guidelines 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 saturated, so that no moisture penetrates the openings in the diagnostic instrument or its handle.

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

Caution! ⚠

The diagnostic sets are not sterile devices; they cannot be sterilized

Caution! ⚠

Never place the instrument heads and handles in liquids! Make sure that no liquids penetrate the housing interior! The device is not approved for machine reprocessing and sterilisation. It can lead to irreparable damage!

If a reusable device shows signs of material deterioration, it should no longer be reused and should be disposed of/claimed according to the procedures described in the Disposal/Warranty sections

4.8.1. Reprocessing of reusable ear specula

Required equipment: mildly alkaline cleaner (e.g. neodisher Mediclean, Dr. Weigert 404333 has been validated) 15°C-50°C, cleaning brush (Interlock 09098 and 09050 have been validated), tap water/running water 20±2°C 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 produced 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 one-time use only

Caution: Repeated use can lead to infection.

4.9. Spare parts and replacement light bulbs

for e-scope® ophthalmoscope
XL 2.5 V, pack of 6, art.no. 10605
LED 3.7 V, art.no. 14051
https://www.riester.de/productdetails/d/e-scoper-pocket-instrments/e-scoper-otoscopes/

for e-xam
XL 2.5 V, pack of 6, art.no. 11178
LED 2.5 V, art.no. 12320
https://www.riester.de/en/productdetails/d/penlights/e-xam-penlight/

5. Maintenance
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.

6. Instructions
Ambient temperature: 0° to +40°C
Relative humidity: 30% to 70% non-condensing
Transport and storage temperature: -10°C to +55°C
Relative humidity: 10% to 95% non-condensing

CAUTION!
There may be a risk of ignition if the device is operated in the presence of flammable mixtures of pharmaceuticals and air, oxygen, nitrous oxide or anaesthetic gases. Safety information according to international standard IEC 60601-1 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance": It is not permitted to open the battery handle in the vicinity of the patient or to touch batteries and the patient simultaneously.

7. Electromagnetic compatibility
according to IEC 60601-1-2, 2014, Ed. 4.0

Caution:
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, arranged 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 e-scope® instrument head with handles specified by the manufacturer. Failure to comply may result in a reduction of the de-

vice's performance features.

Guidelines and manufacturer's declaration - electromagnetic emissions		
The e-scope instrument is intended for use in the electromagnetic environment specified below. The customer or user of the e-scope should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions RF emissions pursuant to CISPR 11	Group 1	The e-scope uses RF energy exclusively for internal functions. Therefore, its RF emissions are very low and unlikely to interfere with nearby electronic devices.
RF emissions RF emissions according to CISPR 11	Class B	The e-scope 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 e-scope instrument is intended for use in the electromagnetic environment specified below. The customer or user of the e-scope should ensure that it is used in such an environment.			
Immunity testing	**IEC 60601 test level**	**Compliance**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Con: ±8 kV Air: ±2, 4, 8, 15 kV	Con: ±8 kV Air: ±2, 4, 8, 15 kV	Floors should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbances / bursts IEC 61000-4-4	5/50 ns, 100 kHz, ±2 kV	Not applicable	The quality of the supply voltage should be that of a typical commercial or hospital environment.
Impulse voltage IEC 61000-4-5	±0.5 kV voltage Phase-to-phase conductor ± 2 kV voltage Line-to-earth ± 0.5 kV voltage Phase-to-phase conductor ± 2 kV voltage Outer conductor to earth	Not applicable	The quality of the supply voltage should be that of a typical commercial or hospital environment.
IEC 61000-4-11 Voltage dips, short interruptions and voltage variations according to IEC 61000-1-11	<0% UT 0.5 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT 25/30 periods Single phase: at 0 degrees (50/60 Hz)	Not applicabled	The quality of the supply voltage should be that of a typical commercial or hospital environment.
Magnetic field with energy-efficient rated frequencies IEC 61000-4-8	30A/m 50/60 Hz	30A/m 50/60 Hz	Mains frequency magnetic fields should be at a level characteristic of a typical location in a typical commercial hospital environment.
Note: U_T is the AC source. Mains voltage before the application of the test level.			

Guidelines and manufacturer's declaration – electromagnetic immunity			
The e-scope instrument is intended for use in the electromagnetic environment specified below. The customer or user of the e-scope should ensure that it is used in such an environment.			
Immunity testing	**IEC 60601 Testlevel**	**Compli-ance**	**Electromagnetic en-vironment - guidance**
Conducted RF disturbances pursuant to IEC 61000-4-6	3 Vrms 0.5 MHz to 80 MHz 6 V in ISM frequency bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Not applicable	Portable and mobile RF communications equipment should not be used closer to any part of the non-contact ri-pen, including the cables, than the recommended distance, which is calculated using the equation applicable to the transmitter frequency. Recommended separation distance: d = 1.2 x P 80 MHz to 800 MHz d = 2.3 x P 800 MHz to 2.7 GHz Where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended distance in metres (m). Field strengths of fixed RF transmitters, determined by an electromagnetic site survey, should be lower than the compliance standard in each frequency range. Interference may occur in the vicinity of devices marked with the following symbol: 
Emitted RF IEC 61000-4-3 Proximity fields of wireless RF commu-nications equipment	33 V/m 80 MHz to 2.7 GHz 380 – 390 MHz 27 V/m, PM 50%, 18 Hz 430 – 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM, 18 Hz11 704 – 787 MHz 9 V/m, PM 50%, 217 Hz 800 – 960 MHz 28 V/m, PM 50%, 18 Hz 1700 – 1990 MHz 28 V/m, PM 50%, 217 Hz 2400 - 2570 MHz 28 V/m, PM 50%, 217 Hz 5100 - 5800 MHz 9 V/m, PM 50%, 217 Hz	10 V/m 27 V/m 28 V/m 9 V/m 28 V/m 28 V/m 9 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. The electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

a: Field strengths of fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast and television transmission cannot be theoretically predicted with accuracy. To evaluate the electromagnetic environment based on fixed RF transmitters, an electromagnetic assessment should be considered. If the measured field strength at the location where the e-scope is used exceeds the above-mentioned RF degree of compliance, the e-scope should be observed to ensure normal operation.
If abnormal performance is observed, additional measures may be required, such as reorienting or moving the e-scope.

b: With a frequency range of 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended distances between portable and mobile RF communications equipment and the ri-pen.

The e-scope is intended for use in an electromagnetic environment in which RF emissions are controlled. The customer or user of the e-scope can help to avoid electromagnetic interference by observing the minimum distance between portable and mobile RF communications equipment (transmitters) and the e-scope in accordance with the maximum output power of the communication equipment.

Rated maximum output power of the transmitter (W)	**Separation distance according to the frequency of the transmitter (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 distance 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 applies to the higher frequency range.
Note 2: These guidelines may not apply in all situations. The electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

7.1. Disposal

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 household 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.

8. WARRANTY

This product was produced to the highest quality standards and subjected to a thorough final inspection before leaving our factory.
Therefore we are pleased to issue a warranty of 2 years from the date of purchase on all defects traceable to material or manufacturing defects. A warranty claim is excluded 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 excludes wear parts.
In addition, we offer a 5-year warranty on the r1 shock-proof calibration, as required for the CE certification.
A warranty claim can only be made if the product is accompanied by this warranty card, which is filled out in full and stamped by the dealer. Please note that warranty claims must be made within the warranty period.
We are of course happy to charge for checks or repairs after the expiry of the warranty period. We also offer free, no-obligation quotes.
In case of warranty service or repair, we ask you to return the Riester product with the completed warranty card to the following address:
Serial number or batch number:

Rudolf Riester GmbH
Repairs dept. RR
Bruckstr. 31
D-72471 Jungingen
Germany

Date, stamp and signature of the specialist dealer

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