



Riester e-scope, e-xam Diagnostic Instruments Instructions

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Instructions

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1. Important information to take note of before taking the product into operation You have acquired a valuable Riester diagnostic set manufactured in compliance with Directive 93/42/EEC for medical products and subject to continuous stringent quality control, whose excellent quality will ensure reliable diagnoses. Please read these Operating Instructions carefully prior to startup and keep in a safe place. Should you have any queries, please contact the Company or your Riester Agent who will be pleased to assist you. For addresses see last page of these Operating Instructions. The address of your authorized Riester Agent will be supplied to you on request. Please note that any instruments described in these Operating Instructions are only suited for application by trained operators. Please also note that correct and safe operation of instruments will only be guaranteed when Riester instruments and accessories are used throughout.



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.




















Caution/Contraindications

- There may be a risk of ignition of gases when 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.
- In the case of a longer eye examination with the ophthalmoscope, the intensive exposure to light can damage the retina.
- The product and the ear specula are non-sterile. Do not use on injured tissue.
- Use new or sanitized specula to limit the risk of cross-contamination.
- The disposal of used ear specula must occur in accordance with current medical practices or local regulations regarding the disposal of infectious, biological medical waste.
- Only use accessories/consumables from Riester or Riester-approved accessories/ consumables.

– Cleaning frequency and sequence must comply with regulations on the cleaning of non-sterile products in their respective facility. Cleaning/disinfection instructions in the operating manual must be observed.

– The product may only be used by trained personnel.

Safety instructions:

	Manufacturer
	CE marking
	Temperature limits in °C for storage and transport
	Temperature limits in °F for storage and transport
	Relative humidity
	Fragile, handle with care
	Store in a dry place
	„Green Dot“ (country-specific)
	Warning, this symbol indicates a potentially dangerous situation.
	Device of protection class II
	Application part type B
	For single use only
	
	
	Attention: Used electrical and electronic equipment should not be treated as normal household waste but should be disposed of separately in accordance with national or EU directives
	
	Batch code
	Serial number
	Please observe the operating instructions

2. Battery handles and start-up

2.1. Purpose

Riester battery handles described in these Instructions for Use supply the instrument heads with power (the lamps are included in appropriate instrument heads), also serving as a bracket.

2.2. Readiness for operation

(insertion and removal of batteries)

Turn off instrument head from handle in counter-clockwise direction. Insert two commercial type "AA" Mignon alkaline batteries of 1.5 V (IEC standard reference LR6) into the case of the handle with the plus poles towards the upper section of the handle.

Warning: 

- Should the unit not be used for an extended period of time or whilst travelling, remove batteries from handle.
- Insert new batteries when light intensity of the unit is reduced, thus affecting examination.
- For maximum light yield it is recommended to always insert new high-quality batteries on replacement.
- Ensure that no fluid or condensation penetrates into the handle.

Disposal:

Please note that batteries are subject to separate disposal. For details ask your local authority and/or your environmental officer.

2.3. Attachment of instrument heads

Turn instrument head in clockwise direction on to the handle.

2.4. Starting and stopping

When pushing the slide up, the unit is switched on, when pushing it down, the unit is off.

2.5 Instructions for care

General information

Cleaning and disinfection of the medical devices serves to protect the patient, the user and third parties and to preserve the value of the medical devices. Due to the product design and the materials used, no defined limit can be specified for the maximum number of reprocessing cycles that can be carried out. The life span of the medical devices is determined by their function and by gentle handling of the devices. Defective products must undergo the reprocessing procedure described before being returned for repair.

Cleaning and disinfection

The battery handles can be cleaned externally with a moist cloth until visually clean. Wipe-disinfection as specified by the disinfectant manufacturer. Only disinfectants with proven efficacy should be used, taking into account the national requirements. After disinfection, wipe the instrument down with a moist cloth to remove possible disinfectant residues.



Never immerse the handles in liquids! Take care to ensure that no liquids get inside the casing! This item is not approved for automated reprocessing and sterilization. These procedures cause irreparable damage!

3. Otoscope and accessories

3.1. Purpose

Riester otoscopes described in these Instructions for Use have been produced for lighting and examination of the auditory canal, combined with a Riester ear speculum.

3.2. Insertion and removal of ear speculum

Position the selected speculum on the chromium plated metal socket of the otoscope. Turn speculum to the right until a resistance is felt. The size of the speculum is marked on the reverse.

3.3. Swivel lens for magnification

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

3.4. Insertion of external instruments into the ear

If you wish to insert external instruments into the ear (e.g. tweezers), you have to rotate the swivel lens (approx. 3-fold magnification) located on the otoscope head by 180°.

3.5. Pneumatic test

In order to perform a pneumatic test (= examination of the ear drum), you will require a bulb which is not included

in the normal scope of supply but may be ordered separately (see Spare parts and accessories). Take metal connector which is not included in the normal scope of supply but may be ordered separately (see Spare parts and accessories) and insert in recess provided on the side of the otoscope head. Attach hose of bulb to connector. Carefully introduce the required air volume into the auditory canal.

3.6. Replacement of lamp

e-scope® otoscope with direct illumination Remove the speculum socket by turning it to the left with your thumb and index finger until it stops. Pull the speculum socket forward to remove it. Unscrew the bulb counterclockwise. Screw the new bulb in clockwise and reattach the speculum socket.

e-scope® otoscope with fiber optics

Unscrew the instrument head from the battery handle. The LED/bulb is located in the lower part of the instrument head. Pull the bulb out of the instrument head using your thumb and index finger or a suitable tool. When replacing an LED with a bulb, the optionally available adapter is additionally required; when replacing a bulb with an LED, the adapter must first be removed from the bulb unit. Firmly insert the new LED/bulb.

3.7 Instructions for care General information

Cleaning and disinfection of the medical devices serves to protect the patient, the user and third parties and to preserve the value of the medical devices. Due to the product design and the materials used, no defined limit can be specified for the maximum number of reprocessing cycles that can be carried out. The life span of the medical devices is determined by their function and by gentle handling of the devices. Defective products must undergo the reprocessing procedure described before being returned for repair.

Cleaning and disinfection

The otoscope can be cleaned externally with a moist cloth until visually clean. Wipe-disinfection as specified by the disinfectant manufacturer. Only disinfectants with proven efficacy should be used, taking into account the national requirements. After disinfection, wipe the instrument down with a moist cloth to remove possible disinfectant residues.

PLEASE NOTE!

Never immerse the otoscope in liquids! Take care to ensure that no liquids get inside the casing! This item is not approved for automated reprocessing and sterilization. These procedures cause irreparable damage!

Sterilization

a) Reusable ear specula

The ear specula can be sterilized in the steam sterilizer at 134°C with 10 minutes hold time.

Single use

ATTENTION: Repeated use could cause infection

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

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

for e-scope® F.O. 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 and accessories

4.1. Purpose

Riester ophthalmoscopes described in these Instructions for Use have been designed for the examination of the eye and its background. The examination lamp e-xam was produced for the purpose of examining body orifices. Furthermore, it can also be used for pupil reaction examination. (Photobiological test report EN 62471:2008)

ATTENTION!

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 but still features a safety shutdown after 2/3 minutes.

4.2. Lens wheel and correcting lenses

The correcting lenses may be adjusted on the lens wheel. The following correcting lenses are available:

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

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

Readings will be displayed on a lit panel. Plus values are displayed in black digits, minus values in red digits.

4.3. Diaphragms and filters

The following apertures and/or filters may be selected by the aperture and filter wheel:

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.

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

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

4.4. Replacement of lamp e-scope® ophthalmoscope

Remove the instrument head from the battery handle. The LED/bulb is located in the lower part of the instrument head. Remove the bulb from the instrument head using your thumb and index finger or a suitable tool. When replacing an LED with a bulb, the optionally available adapter is additionally required; when replacing a bulb with an LED, the adapter must first be removed from the bulb unit. Firmly insert the new LED/bulb.



The pin of the bulb has to be inserted into the guide slot on the adapter and the adapter into the guide slot on the instrument head.

e-xam

Remove the instrument head from the battery grip. The XL lamp or LED 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.

4.5 Technical data for the ophthalmoscope lamp

XL 2.5 V 750 mA avg. life 16.5 h

LED 3.7 V 38 mA avg. life 20.000 h

Technical data for the e-xam lamp

XL 2.5 V 750 mA avg. life 16.5 h

LED 2.5 V 120 mA 5.000 – 5.500 Kelvin, CRI 72 avg. life 20.000 h

4.6 Instructions for care

General information

Cleaning and disinfection of the medical devices serves to protect the patient, the user and third parties and to preserve the value of the medical devices. Due to the product design and the materials used, no defined limit can be specified for the maximum number of reprocessing cycles that can be carried out. The life span of the medical devices is determined by their function and by gentle handling of the devices. Defective products must undergo the reprocessing procedure described before being returned for repair.

Cleaning and disinfection

The ophthalmoscope can be cleaned externally with a moist cloth until visually clean. Wipe-disinfection as specified by the disinfectant manufacturer. Only disinfectants with proven efficacy should be used, taking into account the national requirements. After disinfection, wipe the instrument down with a moist cloth to remove possible disinfectant residues.



Never immerse the ophthalmoscope in liquids! Take care to ensure that no liquids get inside the casing! This item is not approved for automated reprocessing and sterilization. These procedures cause irreparable damage!

4.7 Spare parts Replacement lamps

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-scooper-pocket-instrments/e-scooper-otoscopes/>

for e-xam

XL 2,5 V, Pack of 6, Art.-No.: 11178

5. Maintenance

These instruments and their accessories do not require any specific maintenance. Should an instrument have to be examined for any specific reason whatsoever, please return it to the Company or an authorized Riester dealer in your area. Addresses to be supplied on request.

6. Notes

Ambient temperature: 0 ° to +40 ° C

Relative Humidity: 30 % to 70 % noncondensing

Storage location: -10° to +55°

Relative Humidity: 10 % to 95 %



There is possibly a risk of ignition if the equipment is operated in the presence of flammable mixtures of substances with air or with oxygen, nitrous oxide and anesthetic gases. Safety information according to the international safety standard IEC 60601-1 Electrical safety of medical devices: Opening of the handle in patient vicinity and simultaneously touching the batteries and patient is not allowed.

7. Electromagnetic compatibility

Accompanying documents according to IEC 60601-1-2, 2014, Ed. 4.0



Medical electrical equipment is subject to special precautions regarding electromagnetic compatibility (EMC). Portable and mobile radio frequency communication devices can affect medical electrical equipment. The ME device is for operation in an electromagnetic environment for home health care and intended for professional facilities such as industrial areas and hospitals.

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



The ME device may not be stacked, arranged or used directly next to or with other devices. When operation is required to be close to or stacked with other devices, the ME device and the other ME devices must be observed in order to ensure proper operation within this arrangement. This ME device is intended for use by medical professionals only. This device may cause radio interference or interfere with the operation of nearby devices. It may become necessary to take appropriate corrective measures, such as redirecting or rearranging the ME device or shield.

The rated ME device does not exhibit any basic performance features in the sense of EN60601-1, which would present an unacceptable risk to patients, operators or third parties should the power supply fail or malfunction.



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 hand grips specified by the manufacturer. Failure to comply may result in a reduction in the device's performance features.

Guidance and manufacturer's declaration - electromagnetic emission		
The e-scope® instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the e-scope® should ensure that it is used in such an environment		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions HF- emissions pursuant to CISPR 11	Group 1	The e-scope® uses RF energy exclusively for an internal function. Therefore his RF transmission is very low and it is unlikely to be adjacent electronic devices are disturbed.
RF emissions HF- emissions pursuant 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.
Emissions of harmonics IEC 61000-3-2	Not applicable	
Emissions of voltage fluctuations, flicker IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration – electromagnetic immunity
The e-scope® instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the e-scope® should ensure that it is used in such an environment

Immunity testing	IEC 60601 test level	Compliance	Electromagnetic environment - Instructions
Electrostatic discharge (ESD) IEC 61000-4-2	Con: ± 8 kV Air: $\pm 2, 4, 8, 15$ kV	Con: ± 8 kV Air: $\pm 2, 4, 8, 15$ kV	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should 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 business or hospital environment.
Surge voltage IEC 61000-4-5	± 0.5 kV voltage Phase-to-phase conductor ± 2 kV voltage Line-to-earth	Not applicable	The quality of the supply voltage should be that of a typical business or hospital environment.
Voltage dips, short-term interruptions and fluctuations in the supply voltage acc. to IEC 61000-4-11	<0% UT 0.5 period at 0.45, 90, 135, 180, 225, 270 and 315 degrees 0% UT 1 period and 70% UT 25/30 periods single-phase: at 0 degrees (50/60 Hz)	Not applicable	The quality of the supply voltage should be that of a typical business or hospital environment.
Magnetic field with efficiency-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 UT is the AC source. Mains voltage before the application of the test level.			

Directives and manufacturer's declaration - Electromagnetic immunity

The e-scope® instruments are 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 - Instructions
Guided RF Disturbances acc. to IEC61000-4-6	3 Vrms 0,5 MHz bis 80MHz z 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 e-scope®, including the cables, than the recommended distance, which is calculated using the equation applicable to the transmitter frequency.

Recommended separation distance

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

Radiated RF IEC 61000-4-3 Proximity fields from RF wireless communications equipment	3 V/m	10	d = $2.3\sqrt{P}$ 800 MHz to 2.7 GHz
	80 MHz to 2.7 GHz	V / m	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).
	380 - 390 MHz	27 V/m;; PM 50%; ; 18 Hz 430 - 470 MHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
	27 V/m;; PM 50%; ; 18 Hz 430 - 470 MHz	28 V/m;; (FM ± 5 kHz, 1 kHz sine)	Interference may occur in the vicinity of equipment marked with the following symbol:
	28 V/m;; (FM ± 5 kHz, 1 kHz sine)	PM;; 18 Hz	
	PM;; 18 Hz	704 - 787 MHz	
	704 - 787 MHz	9 V/m;; PM 50%; 217 Hz 800 - 960 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%; ; 18 Hz 1700 - 1990 MHz	28 V/m;; PM 50%; ; 217 Hz	
	28 V/m;; PM 50%; ; 217 Hz	2400 - 2570 MHz	
	2400 - 2570 MHz	28 V/m;; PM 50%; ; 217 Hz	
	28 V/m;; PM 50%; ; 217 Hz	5100 - 5800 MHz	
	5100 - 5800 MHz	9 V/m;; PM 50%; 217 Hz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

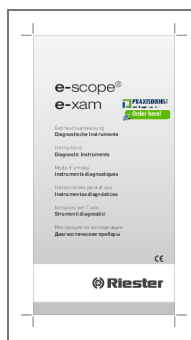
a. field strengths of fixed transmitters, such. B. Base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM broadcasting and television broadcasting can not be predicted theoretically accurately. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic examination should be considered. If the measured field strength at the location where the e-scope® is used exceeds the above RF compliance level, the e-scope® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or shifting the e-scope®.

b With a frequency range over 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 e-scope®

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.

Documents / Resources



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References

- [Rudolf Riester GmbH – Medical devices of the highest standards.](#)