Riester e-scope Diagnostic Instruments Instructions

Contents

Riester e-scope Diagnostic Instruments

Important Information

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 the correct and safe operation of instruments will only be guaranteed when Riester instruments and accessories are used throughout.

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.

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, 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 me-dical 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

Battery handles and start-up

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.

Readiness for operation (insertion and removal of batteries)
Turn off the instrument head from the handle in a 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 traveling, remove batteries from the handle.
- Insert new batteries when the 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.

Attachment of instrument heads
Turn the instrument head in a clockwise direction onto the handle.

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

Instructions for care

General information
Cleaning and disinfection of the medical devices serve 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 the 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.

PLEASE NOTE!
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!

Otoscope and accessories

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.

Insertion and removal of ear speculum
Position the selected speculum on the chromium-plated metal socket of the otoscope. Turn the speculum to the right until resistance is felt. The size of the speculum is marked on the reverse.

Swivel lens for magnification
The swivel lens is fixed to the device and can be swiveled 360°.

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°.

Pneumatic test
In order to perform a pneumatic test (= examination of the ear drum), you will require a bulb that is not included in the normal scope of supply but may be ordered separately (see Spare parts and accessories). Take a metal connector that is not included in the normal scope of supply but may be ordered separately (see Spare parts and accessories) and insert in a recess provided on the side of the otoscope head. Attach the hose of the bulb to the connector. Carefully introduce the required air volume into the auditory canal.

Replacement of lamp
e-scope® otoscope with direct illumination Removes 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 op-tionally 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.

Instructions for care

General information
Cleaning and disinfection of the medical devices serve 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 medical devices is determined by their function and by the 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. Wi-pe-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

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

Single-use
ATTENTION: Repeated use could cause infection

Spare parts and accessories

Reusable ear specula

• 2 mm	Pack of 10 St.	No.: 10775
• 2.5 mm	Pack of 10 St.	No.: 10779

• 4 mm • 5 mm	Pack of 10 St. Pack of 10 St.	No.: 10789 No.: 10795
Reusable ear specula • 2 mm	Pack of 100 St.	No.: 14061-532
• 2.5 mm • 3 mm • 4 mm • 5 mm	Pack of 500 St. Pack of 1.000 St. Pack of 100 St. Pack of 500 St. Pack of 1.000 St. Pack of 100 St. Pack of 500 St. Pack of 1.000 St. Pack of 100 St. Pack of 500 St. Pack of 1.000 St.	No.: 14062-532 No.: 14063-532 No.: 14061-531 No.: 14062-531 No.: 14063-531 No.: 14061-533 No.: 14062-533 No.: 14063-533 No.: 14061-534 No.: 14062-534 No.: 14063-534 No.: 14061-535 No.: 14062-535 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

Ophthalmoscope and accessories

Purpose
Riester ophthalmoscopes described in these Instructions for Use have been designed for the examination of the eye and its background. The examination lamp exam 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 ophthalmo-logical 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 the 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 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.

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.

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.

CAUTION:
The pin of the bulb has to be inserted into the guide slot on the adapter and the adap-ter into the guide slot on the instrument head.

exam
Remove the instrument head from the battery grip. The XL lamp or LED is located in the lamp head.
Turn the white insulation counterclockwise. Remove insulation with contact. The lamp will fall out. Insert a new lamp, and turn contact with insulation clockwise.

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 exam 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

Instructions for care

General information
Cleaning and disinfection of the medical devices serve 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 the 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.

PLEASE NOTE!
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!

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-scoper-pocket-instrments/e-scoper-otos-copes/

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/.

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 authorised Riester dealer in your area. Addresses to be supplied on request.

Notes

- **Ambient temperature:** 0 ° to +40 ° C
- **Relative Humidity:** 30 % to 70 % non-condensing
- **Storage location:** -10° to +55°
- **Relative Humidity:** 10 % to 95 %

CAUTION:
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 the patient vicinity and simultaneously touching the batteries and patient is not allowed.

Electromagnetic compatibility

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

Attention:
Medical electrical equipment is subject to special precautions regarding electromagnetic compatibility (EMC). Portable and mobile radio frequency communication devices can affect medical electrical equipment. The ME device is for operation in an electromagnetic environment for home health care and is 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.

Warning:
The ME device may not be stacked, arranged or used directly next to or with other devices. When the 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.

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

<table>
<tr><td colspan="3">Guidance and manufacturer’s declaration - electromagnetic emission</td></tr>
<tr><td colspan="3">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</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>RF emissions

HF- emissions pursuant to CISPR 11</td><td>Group 1</td><td>The e-scope® uses RF energy

exclusively for an internal function. Therefore his R F transmission is very low and it is unlikely to be ad jacent

electronic devices are disturbed.</td></tr>
<tr><td>RF emissions

HF- emissions pursuant to CISPR 11</td><td>Class B</td><td rowspan="3">The e-scope® is intended for use in all establishme nts, including residential areas and those directly c onnected to a public supply network that also suppl ies buildings used for residential purposes.</td></tr>
<tr><td>Emissions of harmonics IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Emissions of voltage fluctua tions, flicker

IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

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 - I nstructions
Electrostatic discharge (ESD) IEC 61000-4-2	Con: ±8 kV Air: ±2,4,8,15 kV	Con: ±8 kV Air: ±2,4,8,15 k V	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be a t least 30%.
Fast transient electrical disturbances / bursts I EC 61000-4-4	5/50 ns, 100 kHz , ±2 kV	Not applicable	The quality of the supply voltage should be that of a typical busin ess or hospital environment.
Surge voltage IEC 610 00-4-5	± 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 busin ess or hospital environment.
Voltage dips, short-ter m interruptions and flu ctuations in the supply voltage acc. to IEC 61000-4-11	<0% UT 0.5 period at 0.45, 90, 1 35, 180, 225, 270 and 315 degrees 0% UT 1 period and 70% UT 25/ 30 periods single-phase: at 0 de grees (50/60 Hz)	Not applicable	The quality of the supply voltage should be that of a typical busin ess or hospital environment.
Magnetic field with effi ciency-rated frequenci es IEC 61000-4-8	30A/m 50/60 Hz	30A/m 50/60 Hz	Mains frequency magnetic fields should be at a level characteristi c of a typical location in a typical commercial hospital environmen t.
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 Diturbances acc. to IEC61000-4-6	3 Vrms 0,5 MHz bis 80MHz 6 Vin 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√P 80 MHz to 800 MHz d= 2.3√P 800 MHz to 2.7 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 from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b	
			Interference may occur in the vicinity of equipment marked with the following symbol: 	
Radiated RF	3 V/m	10 V/m		
IEC 61000-4-3	80 MHz to 2.7 GHz			
	380 - 390 MHz 27 V/m;; PM 50%;; 18 Hz 430			

	- 470 MHz 28 V /m;; (FM ± 5 kH z, 1 kHz sine) PM;; 18 H z11	27 V/ m			
	704 - 787 MHz 9 V/ m;; PM 5 0%;; 217 Hz	28 V/ m			
Proximity fields fro m RF wir eless co mmunica tions equ ipment	800 - 960 MHz 28 V /m;; PM 5 0%;; 18 H z	9 V/ m			
	1700 - 199 0 M Hz 28 V /m;; PM 5 0%;; 217 Hz	28 V/ m			
	2400 - 257 0 M Hz 28 V /m;; PM 5 0%;; 217 Hz	9 V/ m			

	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®. 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.				
Rated maximum output power of the transmitter (W)	Separation distance according to the frequency of the transmitter (m)			
	150 KHz to 80 MHz		80 MHz to 800 MHz	800 MHz to 2.7 GHz
0.01	0.12	0.12	0.23	0,23
0.1	0.38	0.38	0.73	0,73
1	1.2	1.2	2.3	2,3
10	3.8	3.8	7.3	7,3
100	12	12	23	23
For transmitters with a maximum output power not listed above, the recommended distance d				
in metres (m) can be estimated using the equation for the transmitter frequency, where P is the				
maximum output power 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. Electromagnetic propagation i s	
affected by the absorption and reflection of structures, objects, and people.	

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 the expiry of the warranty period at a charge. You are also welcome to request a provisional cost estimate from us free of charge.

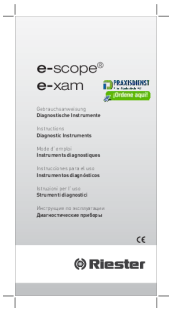
In case of a warranty claim or repair, please return the Riester product with the completed Warranty Card to the following address:

Rudolf Riester GmbH
Dept. Repairs RR Bruckstr. 31
72417 Jungingen
Germany

- Serial number or batch number
- Date, Stamp and signature of the specialist dealer

Rudolf Riester GmbH
Bruckstraße 31 | 72417Jungingen | Germany
Tel.: (+49) 7477-9270-0 | Fax.: (+49) 7477-9270-70
info@riester.de | www.riester.de.

Documents / Resources

	Riester e-scope Diagnostic Instruments [pdf] Instructions e-scope, e-xam, e-scope Diagnostic Instruments, e-scope, Diagnostic Instruments, Instruments , Diagnostic

References

- Rudolf Riester GmbH – Medical devices of the highest standards.