e-scope®

Gebrauchsanweisung
Diagnostische Instrumente

Instructions
Diagnostic Instruments

Mode d' emploi
Instruments diagnostiques

Instrucciones para el uso
Instrumentos diagnósticos

Инструкция по эксплуатации
Диагностические приборы

Istruzioni per l' uso
Strumenti diagnostici

CE

Riester

ENGLISH

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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 authorised **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.

Classification

Type-B applied part - otoscope head with speculum

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.

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!

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

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

Reusable ear specula

• 2mm	Pack of 100 St.	No.: 14061-532
	Pack of 500 St.	No.: 14062-532
	Pack of 1000 St.	No.: 14063-532
• 2,5mm	Pack of 100 St.	No.: 14061-531
	Pack of 500 St.	No.: 14062-531
	Pack of 1000 St.	No.: 14063-531
• 3mm	Pack of 100 St.	No.: 14061-533
	Pack of 500 St.	No.: 14062-533
	Pack of 1000 St.	No.: 14063-533
• 4mm	Pack of 100 St.	No.: 14061-534
	Pack of 500 St.	No.: 14062-534
	Pack of 1000 St.	No.: 14063-534
• 5mm	Pack of 100 St.	No.: 14061-535
	Pack of 500 St.	No.: 14062-535
	Pack of 1000 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 15h
XL, 2.5 V	750 mA	mean life span 16.5h

for e-scope® F.O. Otoscope

XL 2,5 V	750 mA	mean life span 15h
LED 3,7 V	52 mA	mean life span 20,000h

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.

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 haemorrhages.

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.

CAUTION: 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.

4.5 Technical data of the lamp

Vacuum, 2.5 V	300 mA	mean life span 15h
XL, 2.5 V	750 mA	mean life span 16.5h
LED, 3.7 V	38 mA	mean life span 20000h

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.

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!

4.7 Spare parts and accessories
Spare lamps for e-scope® ophthalmoscope

Vacuum, 2.7 V, pack of 6	No.: 14050
XL, 2.5 V, pack of 6	No.: 10605
LED, 3.7 V	No.: 14051

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 authorised **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%

CAUTION: There is possibly a risk of ignition if the equipment is operated in the pre-

sence 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

Medical electrical equipment is subject to special precautionary measures with regard to electromagnetic compatibility (EMC). Portable and mobile high-frequency communication equipment can influence medical electrical equipment. This ME device is intended for operation in an electromagnetic environment as specified below. The user of the device should ensure that it is operated in such an environment. The ME device must not be used directly next to or arranged in a stack with other devices. If the device has to be operated near to or in a stacked arrangement with other devices, then the ME device should be monitored in order to verify that it operates as intended in this arrangement. This ME device is intended exclusively for use by professional medical staff. This device can cause radio interference and can disrupt the operation of equipment nearby. Suitable remedial measures, such as for instance re-alignment, re-arrangement of the ME device or shielding, can become necessary.

Guidelines and manufacturer's declaration - electromagnetic emissions		
The e-scope is intended for operation in an electromagnetic environment as specified below. The customer or the user of the e-scope should ensure that it is used in such an environment.		
Emission measurements	**Compliance**	**Electromagnetic environment - guidelines**
HF emissions according to CISPR 11	Group 1	The e-scope employs HF energy solely for an internal function. Its HF emission is therefore very low and it is unlikely that neighboring electronic devices will be affected by interference.
HF emissions according to CISPR 11	Class B	The e-scope is intended for use in all facilities, including living quarters and such as are directly connected to a public power supply that also supplies buildings that are used for residential purposes.
Harmonics emissions according to EC61000-3-2	Not applicable	
Voltage fluctuation / flicker emissions according to IEC61000-3-3	Not applicable	

Fast transient electrical interference/bursts according to IEC61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges IEC61000-4-5	± 1 kV voltage phase-to-phase ± 2 kV voltage phase-to-earth	Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, short-time interruptions and fluctuations in the supply voltage according to IEC61000-4-11	<5% U_T (>95 % drop in U_T) for 0.5 cycles 40% U_T (60 % drop in U_T) for 5 cycles 70 % U_T (30 % drop in U_T) for 25 cycles <5% U_T (>95 % drop in U_T) for 5 s	Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment
Magnetic field at the mains frequency (50Hz) according to IEC61000-4-8	3 A/m	3 A/m	If image disturbances occur, the e-scope may have to be placed further away from the sources of mains-frequency magnetic fields, or magnetic shielding may have to be installed: the mains-frequency magnetic field should be measured at the intended set-up site in order to ensure that it is small enough.
Note - U_T is the alternating supply voltage prior to application of the test level.			

Guidelines and manufacturer's declaration - electromagnetic immunity			
The e-scope model is intended for operation 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 test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidelines**
			Portable and mobile radio equipment should not be used within a distance from the e-scope, including cables, that is less than the recommended safety distance as calculated by the equation that is appropriate for the transmission frequency. **Recommended safety distance:**
Conducted HF interference according to IEC61000-4-6	3 Vrms 150 kHz to 80MHz	Not applicable	$d = 1.2\sqrt{P}$
Radiated HF interference according to IEC61000-4-3	3 V/m 80 MHz to 2.5GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 1000 MHz $d = 2.3\sqrt{P}$ 1400 MHz to 2.5 GHz where P is the nominal power of the transmitter in Watts (W) as specified by the manufacturer of the transmitter, and d is the recommended safety distance in meters (m). The field strength of stationary radio transmitters should be less than the compliance level[b] at all frequencies as verified by an on-site test[a] Interference is possible in the vicinity of equipment marked with the following symbol 
		3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher value applies.

Note 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by reflection and absorption by buildings, objects and people.

[a] The field strength of stationary transmitters, such as base stations of wireless telephones and mobile field radio services, amateur radio stations, AM and FM radio and television transmitters cannot be precisely determined theoretically in advance. In order to determine the electromagnetic environment due to stationary HF transmitters, an investigation of the location is advisable. If the field strength determined at the location of the e-scope exceeds the compliance level indicated above, then the e-scope must be monitored with regard to its normal operation at each place where it is used. If unusual performance characteristics are observed, additional measures such as re-alignment of the e-scope or its removal to another place may be necessary.

[b] In the frequency range of 150 kHz to 80 MHz, the field strength should be smaller than 3 V/m.

Recommended safety distances between portable and mobile HF communication devices and e-scope
The e-scope is intended for operation in an electromagnetic environment in which the radiated interference is monitored. The customer or user of the e-scope can help prevent electromagne interference by observing minimum distances between portable and mobile HF communicatio equipment (transmitters) and the e-scope as recommended below, depending on the maximun output power of the communication equipment.

Nominal power of the transmitter **W**	**Safety distance that applies to the transmitter frequency m**		
	150 kHz to 80 MHz Not applicable	**80 MHz to 1000 MHz** $d = 1.2\sqrt{P}$	**1400 MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0.01		0.12	0.23
0.1		0.38	0.73
1		1.2	2.3
10		3.8	7.3
100		12	23

For transmitters whose nominal power is not indicated in the table above, the distance can be determined using the equation belonging to the respective column, where P is the nominal power of the transmitter in Watts (W) as specified by the manufacturer of the transmitter.

Note 1: At 80 MHz and 1400 MHz, the distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by reflection and absorption by buildings, objects and people.

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Rudolf Riester GmbH
P.O. Box 35 | Bruckstraße 31 | DE - 72417 Jungingen | Germany
Tel.: (+49) +7477-9270-0 | Fax.: (+49) +7477-9270-70
E-Mail: info@riester.de | www.riester.de