uni® I, II, III
econom®

Gebrauchsanweisung
Diagnostische Instrumente

Instructions
Diagnostic Instruments

Mode d' emploi
Instruments de diagnostiques

Instrucciones para el uso
Instrumentos diagnósticoss

Инструкция по эксплуатации
Диагностические инструменты

Istruzioni per l' uso
Presidi diagnostici

CE

Riester

ENGLISH

Table of contents

1. Introduction

1.1 Please note the following important information before startup

You have purchased a high-quality Riester product, which has been manufactured in compliance with Regulation (EU) 2017/745 and is always subject to the strictest quality controls. The outstanding quality will ensure reliable diagnoses.
This user manual describes the use of the Riester instruments uni® I, II, III and econom® and their accessories.
Read these instructions for use (IFU) carefully before using the device and keep them in a safe place. If you have any questions, we are available at any time, and our contact information is provided at the end of this IFU.. The address of our sales partner can be obtained upon request. Please note all instruments described in these instructions for use may only be used by appropriately trained personnel. The safe functioning of this device is only guaranteed if Riester original parts and accessories are used.

1.2 Safety symbols

Symbol	Note on symbol
	Follow the instructions in the operation manual. The symbol is printed in black colour on the probe cover box.
	Application part type B
	Medical device
	Protection class II
	**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
	Date of manufacture YYYY-MM-DD / (Year-Month-Day)
	Manufacturer
	Manufacturer's serial number
	Lot / batch number
	Temperature for transportation and storage
	Relative humidity for transportation and storage
	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
	Recyclable Li-ion battery
	Date of manufacture/month/year
	**Caution:** (US) federal law restricts this device from being used by or by order of a doctor (licensed physician).

1.3 Packaging symbols

Symbol	Note on symbol
	Fragile. The package should be handled with care.
	Keep the package from getting wet.
	This way up. The symbol indicates the correct positioning for transporting the package.
	Keep away from sunlight
	"Green Dot" (country-specific)

1.4 Purpose
Otoscope and accessories:
The Riester otoscope was manufactured to illuminate and examine the ear canal and tympanic membrane.

-Accessories: battery handles
Battery handles are used to supply the instrument heads with energy (the bulbs are contained in the corresponding instrument heads). Clinicians use the handle to guide and control the device during exams.

-Accessories: ear specula
The shape of the ear specula makes it easier to see into the ear and nose.

-Accessories: nasal speculum:
The nasal speculum was manufactured to illuminate and thus examine the inside of the nose.

May ophthalmoscope:
The Riester May ophthalmoscopes were manufactured to examine the eye and the fundus.

Bent Arm Illuminator and accessories:
The bent arm illuminator was manufactured to provide additional lighting to the oral cavity and the pharynx.

-Accessories: Tongue Depressor Holder
The tongue depressor holder was manufactured to examine the mouth and throat area and can be used with standard wooden or plastic depressors, and the Riester bent arm illuminator.

-Accessories: laryngeal mirror
The laryngeal mirror was made for mirroring and thus for examining the oropharynx in combination with the Riester bent arm illuminator.

1.4.1 Indications
Otoscope and accessories:
It is one of the standard instruments used by all ENT clinicians and is used for the visual examination of the external auditory canal (meatus acusticus externus) and the eardrum. Otoscopy can diagnose diseases (otitis externa), foreign bodies or parasites in the external auditory canal as well as changes in the eardrum. It is usually performed by the ENT physician as the first examination in the event of hearing problems.

-Accessories: battery handles
Battery handles are used to supply the instrument heads with energy (the bulbs are contained in the corresponding instrument heads). Clinicians use the handle to guide and control

the device during exams.

-Accessories: ear specula
The shape of the ear specula makes it easier to see into the ear and nose.

-Accessories: nasal speculum:
The nasal speculum was made to illuminate and thus examine the inside of the nose for inflammation and injuries.

May ophthalmoscope:
With direct ophthalmoscopy, the central parts of the eye such as the optic nerve head, vascular origins, and the yellow spot (macula lutea), as well as the retina, can be viewed.

Bent Arm Illuminator and accessories:
The bent arm illuminator was manufactured for lighting and thus for examining the oral cavity and the pharynx for inflammation and injuries.

-Accessories: tongue blade holder:
The tongue blade holder was manufactured to examine the mouth and throat in combination with standard wooden and plastic tongue depressors in conjunction with the Riester bent arm illuminator.

-Accessories: laryngeal mirror
The laryngeal mirror was made for mirroring and thus for examining the oropharynx in combination with the Riester bent arm illuminator.

1.4.2 Contraindications

⚠
Do not exceed the recommended maximum exposure time

1.4.3 Intended patient population
The hand instruments are intended for adult and paediatric patients.

1.4.4 Intended operator/user

⚠
The hand instruments are designed for outpatient ENT and eye examinations and are used by a doctor or a nurse in hospitals, medical institutions, clinics, and doctor's offices.

1.4.5 Required skills/operator training

⚠
The operator must have basic knowledge of ENT/ophthalmology. All functions, connections and links are clearly explained in the user manual.
The user must strictly adhere to the specifications in the user manual.

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

1.5 Warnings/caution

⚠
Do not use in the presence of flammable gases/liquids, or oxygen-rich environments.

⚠
The socket handle must not be charged for more than 24 hours.

⚠
The handle must never be in the socket when replacing the battery!

⚠
Do not shine directly into someone's eyes. Do not stare into the light when in use. May damage the eyes.

⚠
This product should not be immersed in liquids.

⚠
If there is a suspicion that liquid or condensation has penetrated the handle, it must not be charged under any circumstances. This may cause a life-threatening electric shock, especially with plug-in handles.

⚠
Do not disassemble or modify the battery. There are no serviceable components inside the device.

⚠
Do not open, short circuit, or dispose of the battery in a fire.

⚠
Only use original parts and spare parts approved by Riester, otherwise device safety and performance may be impaired.

⚠
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 can be twice as long to reach the maximum limit.
Although no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be reduced to the minimum required for examination/diagnosis. Infants / children, aphasics and people with eye diseases are at higher risk. The risk may be increased if the patient has already been examined with this or another ophthalmological instrument during the last 24 hours. This is especially true when the eye has been exposed to retinal photography.
The light of this instrument may be harmful. The risk of eye damage increases with the duration of irradiation. An irradiation period with this instrument at maximum intensity of longer than >5 min. exceeds the guideline value for hazards.
This instrument does not pose a photobiological hazard according to DIN EN 62471.

⚠
The information in the instructions for use on cleaning and disinfection must be observed.

⚠
• If you do not use the device for a long time or take it with you while travelling, please remove the batteries from the battery compartment.

⚠
• 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.

⚠
Follow the instructions for cleaning and regular maintenance to avoid personal injury, or damage to the device.

⚠
Switch off the device and disconnect it from the power supply before starting cleaning or inspection.

⚠
Do not autoclave or immerse in cleaning fluids.

⚠
Make sure that excess solution does not get into the instrument. Take special care that the cloth is not saturated with solution.

⚠
Please note that the temperature can exceed 41 °C (105,8°F) during intended use!

⚠
Defective bulbs must be replaced immediately.

⚠
The used medical device must be disposed of in accordance with current medical practices or local regulations on the disposal of infectious biological medical waste.

⚠

Batteries and electrical/electronic devices may not be treated as domestic waste and must be disposed of in accordance with local regulations.

⚠

All serious incidents related to the product must be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is resident.

2. First use

2.1 Scope of delivery

uni® I otoscope
Battery handle type C with rheostat

Art. no.: 2010	Vacuum 2.7 V
Art. no.: 2010-201	XL 2.5 V

Plug-In handle type C with rheostat incl. ri-accu® / ri-accu® L

Art. no.: 2011-200	Vacuum 2.7 V / 230 V
Art. no.: 2012-200	Vacuum 2.7 V / 120 V
Art. no.: 2011-201	XL 2.5 V / 230 V
Art. no.: 2012-201	XL 2.5 V / 120 V
Art. no.: 2011-202	XL 3.5 V / 230 V
Art. no.: 2012-202	XL 3.5 V / 120 V

Battery handle type C with rheostat incl. ri-accu® and ri-charger®

Art. no.: 2013-200	Vacuum 2.7 V / 230 V
Art. no.: 2014-200	Vacuum 2.7 V / 120 V
Art. no.: 2013-201	XL 2.5 V / 230 V
Art. no.: 2014-201	XL 2.5 V / 120 V
Art. no.: 2013-202	XL 3.5 V / 230 V
Art. no.: 2014-202	XL 3.5 V / 120 V

uni® II May ophthalmoscope
Battery handle type C with rheostat

Art. no.: 2020	XL 2.5 V
Art. no.: 2020-201	XL 2.5 V

Plug-In handle type C with rheostat incl. ri-accu® / ri-accu® L

Art. no.: 2021-200	XL 2.5 V / 230 V
Art. no.: 2022-200	XL 2.5 V / 120 V
Art. no.: 2021-202	XL 3.5 V / 230 V
Art. no.: 2022-202	XL 3.5 V / 120 V

Battery handle type C with rheostat incl. ri-accu® and ri-charger®

Art. no.: 2023-200	XL 2.5 V / 230 V
Art. no.: 2024-200	XL 2.5 V / 120 V
Art. no.: 2023-202	XL 3.5 V / 230 V
Art. no.: 2024-202	XL 3.5 V / 120 V

uni® III otoscope, May ophthalmoscope
Battery handle type C with rheostat

Art. no.: 2030	Vacuum 2.7 V / XL 2.5 V
Art. no.: 2030-201	XL 2.5 V

Plug-In handle type C with rheostat incl. ri-accu®

Art. no.: 2031-200	Vacuum 2.7 V / XL 2.5 V / 230 V
Art. no.: 2032-200	Vacuum 2.7 V / XL 2.5 V / 120 V
Art. no.: 2031-201	XL 2.5 V / 230 V
Art. no.: 2032-201	XL 2.5 V / 120 V
Art. no.: 2031-202	XL 3.5 V / 230 V
Art. no.: 2032-202	XL 3.5 V / 120 V

Battery handle type C with rheostat incl. ri-accu® and ri-charger®
Art. no.: 2033-200 Vacuum 2.7 V / XL 2.5 V / 230 V
Art. no.: 2034-200 Vacuum 2.7 V / XL 2.5 V / 120 V
Art. no.: 2033-201 XL 2.5 V / 230 V
Art. no.: 2034-201 XL 2.5 V / 120 V
Art. no.: 2033-202 XL 3.5 V / 230 V
Art. no.: 2034-202 XL 3.5 V / 120 V

econom®
Battery handle type C with rheostat
Art. no.: 2050 Vacuum 2.7 V / XL 2.5 V
Art. no.: 2050-201 XL 2.5 V

Plug-In handle type C with rheostat incl. ri-accu® / ri-accu® L
Art. no.: 2051-200 Vacuum 2.7 V / XL 2.5 V / 230 V
Art. no.: 2052-200 Vacuum 2.7 V / XL 2.5 V / 120 V
Art. no.: 2051-201 XL 2.5 V / 230 V
Art. no.: 2052-201 XL 2.5 V / 120 V
Art. no.: 2051-202 XL 3.5 V / 230 V
Art. no.: 2052-202 XL 3.5 V / 120 V

Battery handle type C with rheostat incl. ri-accu® and ri-charger®
Art. no.: 2053-200 Vacuum 2.7 V / XL 2.5 V / 230 V
Art. no.: 2054-200 Vacuum 2.7 V / XL 2.5 V / 120 V
Art. no.: 2053-201 XL 2.5 V / 230 V
Art. no.: 2054-201 XL 2.5 V / 120 V
Art. no.: 2053-202 XL 3.5 V / 230 V
Art. no.: 2054-202 XL 3.5 V / 120 V

econom®
Battery handle type C with rheostat
Art. no.: 2050-525 Vacuum 2.7 V / XL 2.5 V
Art. no.: 2050-525-201 XL 2.5 V

Plug-In handle type C with rheostat incl. ri-accu® / Plug-in handle type C with rheostat, including ri-accu®
Art. no.: 2051-525-200 Vacuum 2.7 V / XL 2.5 V / 230 V
Art. no.: 2052-525-200 Vacuum 2.7 V / XL 2.5 V / 120 V
Art. no.: 2051-525-201 XL 2.5 V / 230 V
Art. no.: 2052-525-201 XL 2.5 V / 120 V
Art. no.: 2051-525-202 XL 3.5 V / 230 V
Art. no.: 2052-525-202 XL 3.5 V / 120 V

Battery handle type C with rheostat incl. ri-accu® and ri-charger® / Battery handle type C with rheostat, including ri-accu® and ri-charger®
Art. no.: 2053-525-200 Vacuum 2.7 V / XL 2.5 V / 230 V
Art. no.: 2054-525-200 Vacuum 2.7 V / XL 2.5 V / 120 V
Art. no.: 2053-525-201 XL 2.5 V / 230 V
Art. no.: 2054-525-201 XL 2.5 V / 120 V
Art. no.: 2053-525-202 XL 3.5 V / 230 V
Art. no.: 2054-525-202 XL 3.5 V / 120 V

2.2 Device function
1. Switch ON / OFF dimmer

rheostat

ON / OFF
0-100% dimmer

2.3 Battery handles product range
All instrument heads described in this manual fit the following battery handles and can therefore be combined individually.

2.3.1 Battery handle type C with rheostat 2.5 V
To operate this battery handle, you will need:
- 2 commercially available alkaline batteries type C Baby (IEC standard designation LR14) or
-1 rechargeable battery 2.5 V (Art.no. 10681 ri-accu®).
-1 ri-charger® charger (art.no. 10700).

2.3.2 Battery handle type C with rheostat 3.5 V (for ri-charger® L)
To operate this battery handle, you will need:
- 1 rechargeable battery from RIESTER with 3.5 V (art.no. 10691 ri-accu® L).
- 1 ri-charger® L charger (part no. 10705, part no. 10706)

2.3.3 Battery handle type C with rheotronic® 3.5 V for charging in the wall socket 230 V or 120 V.
To operate this plug-in handle, you will need:
- 1 rechargeable battery from RIESTER with 3.5 V (art.no. 10692 ri-accu® L).

2.3.4 Battery handle type C with rheostat 3.5 V (for plug-in charger)
To operate this battery handle, you will need:
- 1 rechargeable RIESTER 3.5 V battery (part no. 10694 ri-accu® L).
-1 plug-in charger (art.no. 10707).

3. Operation and function
3.1 Symbol identification
CE CE mark

ON / OFF
0-100% dimmer

3.2 Startup
3.2.1 Inserting and removing batteries and rechargeable batteries
Use only the combinations described under 2.3 to 2.3.4

3.2.2 Inserting the batteries:
Battery handle (2.3.1) type C with rheostat 2.5 V:
– Unscrew the battery handle cover on the lower part of the handle in a counter-clockwise direction.
– Insert the standard alkaline batteries designated for this battery handle with the plus side in the direction of the handle top into the battery handle.
– Firmly screw the battery handle cover back on.

3.2.3 Removing the batteries:
Battery handle (2.3.1) type C with rheostat 2.5 V:
– Unscrew the battery handle cover on the lower part of the battery handle in a counter-clockwise direction.

– Remove the batteries from the battery handle by holding the opening of the battery handle slightly downwards and shaking it slightly if necessary.
– Firmly screw the battery handle cover back on.

⚠ **CAUTION!**
For all factory-installed or separately supplied batteries, the red safety foil on the plus side must be removed before startup!

⚠ **CAUTION!**
Only applies to battery handle (2.5) type C with rheotronic® 3.5 V for charging at a 230 V or 120 V socket:
When using the new ri-accu® L 10692, make sure that no insulation is attached to the spring of the battery grip cover. When using the old ri-accu® L 10692 insulation must be attached to the spring (risk of short circuit).
⚠

new ri-accu® L

⚠

old ri-accu® L

3.2.4 Inserting the rechargeable batteries:
Battery handles (2.3.1) type C with rheostat 1.5 V (for ri-charger®).
Battery handle (2.3.2) type C with rheostat 3.5 V (for ri-charger® L).
Battery handle (2.3.4) type C with rheostat 3.5 V (for plug-in charger).
Battery handle (2.3.3) type C with rheostat 3.5 V for charging in a 230 V or 120 V socket.

⚠ **CAUTION! Please observe the safety information!**
– Unscrew the battery handle cover on the lower part of the handle in a counter-clockwise direction.
– Remove the red safety foil on the plus side of the battery during initial startup.
– Insert the rechargeable battery approved for your battery grip (see 2.3.1 to 2.3.4) with the plus side in the direction of the upper part of the handle into the battery handle. In addition to the plus symbol, you will also find an arrow that shows you the direction of insertion into the battery grip.
– Firmly screw the battery handle cover back on.

3.3 Charging the battery handles that have rechargeable batteries:
3.3.1 Battery handle (2.3.1) type C with rheostat 2.5 V (for ri-charger®).
– Can only be used in the ri-charger® L charger (art.no. 10700, art.no. 10701) by RIESTER.
– The ri-charger® charger comes with an additional user manual that must be observed.

3.3.1.1 Battery handle (2.3.2) type C with rheostat 3.5 V (for ri-charger® L)
⚠
– Can only be used in the ri-charger® L charger (art.no. 10705, part no. 10706) by RIESTER.
– The ri-charger® L charger comes with an additional user manual that must be observed.

3.3.2 Battery handle (2.3.4) type C with rheostat 3.5 V (for plug-in charger)
⚠
– It can only be charged with the plug-in charger (art.no. 10707) by RIESTER.
For this purpose, the small round plug at the bottom of the battery handle is plugged into

the rechargeable battery at the opening in the battery handle cover (part no. 10694 ri-accu® L). Now connect the power plug of the plug-in charger to the power supply. The charge status of the battery is indicated via the LED on the plug-in charger.
Red light means charging, green light means the battery is fully charged.

3.3.3 Battery handle (2.3.3) type C with rheostat 3.5 V for charging in a 230 V or 120 V socket.

– Remove the base of the socket handle by turning it counter-clockwise. The plug contacts become visible. Round contacts are for 230 V mains operation (see type label), flat contacts are for 120 V mains operation (see type label). Now plug the handle base into the socket for charging.

⚠ **CAUTION!**
Before using the plug-in handle for the first time, it should be plugged into the socket up to a max. of 24 hours.

⚠ **Warning!**
The plug-in handle must not be charged for more than 24 hours.

⚠ **Warning!**
The handle must never be in the socket when replacing the battery!

⚠ **CAUTION!**

- Should you not use the device for a long time, or take it with you while travelling, please remove the batteries from the battery compartment.
- New batteries should be inserted when the light intensity of the instrument becomes weaker and could impair the examination.
- In order to obtain the best possible light output, we recommend that you always replace the batteries with 2 new, high-quality batteries (as described in 3.2.2 and 3.2.3).

Disposal:
Please note that batteries must be disposed of in a special manner. Information about this can be obtained from your municipality or from your environmental consultant.

⚠
If there is a suspicion that liquid or condensation has penetrated the handle, it must not be charged under any circumstances. This may cause a life-threatening electric shock, especially with plug-in handles.

3.3.4 Attaching instrument heads
Make sure that the knurled screw on the battery handle is turned up so far that the screw tip can no longer be seen inside the holder.
Place the desired instrument head on the holder on the battery handle so that the indentation points in the direction of the knurled screw. Fix it with the locking screw.

3.3.5 Switching on and off
Switch the instrument on by pressing the red on/off switch on the black knurled plastic ring (rheostat) and turning it to the left away from the „0". Switch off the instrument by pressing the red on/off switch and turning it to the right to position „0".

3.3.6 Rheostat to regulate light intensity
The rheostat makes it possible to adjust the light intensity. Depending on how far you turn the switch with the black knurled ring counter-clockwise or clockwise, the light intensity is weaker or stronger. The marking below the rheostat serves as a guide for this.

3.4 Otoscope

1. Ear specula
2. Connection for pneumatic otoscopy
3. Swivel lens
4. Cover glass
5. Replacing the lightbulb

3.4.1 Attaching and removing ear specula
Place the desired ear speculum on the otoscope head so that the recess on the metal part of the ear speculum fits into the guide pin of the head. Fasten the speculum firmly by turning it clockwise.
To remove the funnel, first turn it firmly in the opposite direction and then remove it from the otoscope head.

3.4.2 Pneumatic otoscopy
⚠
Pneumatic otoscopy (an examination of the eardrum), requires a bulb which is not included in the normal scope of delivery but may be ordered separately (see 6. Parts and accessories).
There is a black cover ring with a connector on the otoscope head. Connect the tube end of the bulb to the connector. You can now carefully introduce the necessary amount of air into the ear canal.

3.4.3 Swivel lens for magnification
Swivel lens for magnification
There is a 360° swivel magnifying lens on the otoscope head with a magnification power of about 4 times. The swivel lens can be easily removed by pulling it out if desired.

3.4.4 Inserting external instruments into the ear
If you want to insert external instruments into the ear (e.g. tweezers), you can remove the cover glass with the black ring and the connector for the pneumatic test by turning it counter-clockwise and pulling it out.
Put the glass back on. Make sure that the notch on the black plastic ring fits into the guide pin on the otoscope head. Fasten the ring firmly by turning it clockwise.

3.4.5 Replacing the lightbulb
Remove the ear speculum from the otoscope (see 3.4.1). Unscrew the lightbulb counter-clockwise.
Screw the new bulb in tightly in a clockwise direction and put the desired ear speculum back on (see 3.4.1) Defective bulbs must be replaced immediately.
Please note that the temperature can exceed 41 °C (105,8°F) during intended use!

3.5 Ophthalmoscope

1. Lens wheel with correction lenses
2. Use with lamp

3.5.1 Lens wheel with correction lenses
The correction lenses can be adjusted using the lens wheel. The following correction lenses are available:
0 to +20 and 0 to -20 dioptres. The values can be read off in the illuminated field of view.
Plus values are displayed with a black background, minus values with a red background.

3.5.2 Aperture
A permanently installed aperture (round circle for normal fundus examinations) is available.

3.5.3 Replacing the lightbulb
⚠
Turn the knurled screw on the ophthalmoscope head counter-clockwise and pull out the insert with the bulb. Unscrew the lightbulb counter-clockwise.
Screw a new bulb in tightly clockwise, fit the insert into the ophthalmoscope so that the screw fits into the recess provided below the knurled screw and tighten the knurled screw.
Defective bulbs must be replaced immediately.
⚠
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 can be twice as long to reach the maximum limit.
Although no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be reduced to the minimum required for examination/diagnosis. Infants / children, aphasics and people with eye diseases are at higher risk. The risk may be increased if the patient has already been examined with this or another ophthalmological instrument during the last 24 hours. This is especially true when the eye has been exposed to retinal photography. The light of this instrument may be harmful. The risk of eye damage increases with the duration of irradiation. An irradiation period with this instrument at maximum intensity of longer than >5 min. exceeds the guideline value for hazards.
This instrument does not pose a photobiological hazard according to DIN EN 62471.
⚠
Please note that the temperature can exceed 41 °C during intended use!

3.6 Bent Arm Illuminator

1. Lightbulb

3.6.1 Replacing the lightbulb
⚠
Unscrew the bulb at the front of the lamp holder counterclockwise and screw a new bulb clockwise back onto the lamp holder.
Defective bulbs must be replaced immediately.
⚠
Please note that the temperature can exceed 41 °C during intended use!

3.7 Nasal speculum
3.7.1 Startup and function

1.Nasal speculum closed

The nasal speculum is only intended for use with the otoscope head, in order to ensure optimal lighting. Remove the ear speculum from the otoscope head (see 3.4.1) and place the nasal speculum on the otoscope head so that the notch on the metal part of the nasal speculum fits into the guide pin of the head. Spread and close the legs of the nasal speculum by turning the knurled screw on the speculum back and forth.
⚠
Please note that the temperature can exceed 41 °C (105,8°F) during intended use!

3.8 Tongue Blade Holder
3.8.1 Startup and function

1. Place the tongue blade holder on the bent arm illuminator.

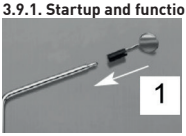
The tongue blade holder is intended to function with the bent arm illumination, since the light source of the bent arm illuminator can also be used for the tongue blade holder or for

the depressor.
Take the tongue blade holder and place it on the front of the bent arm illuminator.
Take standard wooden or plastic depressors and push them into the opening provided in the tongue blade holder.

⚠

Please note that the temperature can exceed 41 °C (105,8°F) during intended use!

3.9 Laryngeal mirror
3.9.1. Startup and function



1. Place the laryngeal mirror on the lamp holder.

The laryngeal mirrors can only be used in combination with the bent arm illuminator.
This ensures optimal illumination. Take one of the 2 laryngeal mirrors and attach it to the front of the bent arm illuminator.

⚠

Please note that the temperature can exceed 41 °C (105,8°F) during intended use!

4. Care instructions
4.1 General information

⚠

Cleaning and disinfecting the medical devices serves to protect the patient, user, third parties, and maintain the integrity of the devices.
The product design and materials used make it impossible to define an upper limit on max. feasible treatment cycles. The service life of medical devices is determined by their function and careful handling.
Before return for repair, defective products must have undergone the prescribed reprocessing procedure.

⚠

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

4.2 Cleaning and disinfection

⚠

To avoid possible cross-contamination, 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 visibly 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 wet, 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.

⚠

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

⚠

Never place the instrument heads and handles in liquids!
Make sure that no liquids penetrate the housing interior!

4.3 Processing of reusable ear specula
Cleaning: manual
Required equipment: mildly alkaline cleaner (e.g. neodisher Mediclean, Dr. Weigert 404333 has been validated) 15°C-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 prepared according to the manufacturer's instructions for the cleaning agent (neodisher Mediclean 0.5% has been validated).
2. Completely immerse the medical devices in the cleaning solution.
3. Make sure that all surfaces are completely wetted with cleaning solution.
4. Carry out all subsequent steps below the liquid level to prevent the contaminated liquid from splashing.
5. Brush the hard-to-reach areas of the immersed ear specula with a soft brush during the exposure time. Pay attention to the critical, hard-to-reach places where a visual assessment of the cleaning effect is not possible.
6. The total exposure time in the cleaning solution is 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 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.

⚠ CAUTION!
The article is not approved for machine reprocessing and sterilization. This can lead to irreparable damage!

5. Technical specifications

Vacuum 2.7 V (2.5 V is specified)	300 mA
Xenon 2.5 V	700 mA
Xenon 3.5 V	700 mA
Lifespan:	Approx. 15 hours
Socket handle:	
Power supply:	Optional 230 V or 120 V version
Operation	Continuous operation
Degree of protection	Protection class II
Classification	Application part type B
Ambient temperature:	0° to + 40° 30% to 70% non-condensing
Transport:	-10° to + 55° 10% to 95% RH
Air pressure:	800 hPa - 1100 hPa

6. Spare parts and accessories
OTOSCOPE
No. 11504 Cover glass for otoscope
No. 10448 Swivel lens for otoscope
Specula for otoscope

No. 10460 2 mm
No. 10461 3 mm
No. 10462 4 mm
No. 10463 4 mm
No. 10464 9 mm (Nasal speculum)
No. 10960 Bulb for pneumatic otoscopy

BATTERY HANDLE
No. 10426 Upper part of the handle with rheostat and plug cap
No. 10440 NASAL SPECULUM

BENT ARM ILLUMINATOR

No. 10447 Laryngeal mirror No. 3 (Ø 20 mm) and No. 4 (Ø 22 mm)
No. 10445 TONGUE BLADE HOLDER

LIGHTBULBS
No. 10421 2.7 V vacuum bulbs
-for otoscope and lamp holder, pack of 6

XL 2.5 V xenon bulbs
No. 10590 - for otoscope and lamp holder, pack of 6
No. 10424 - for May ophthalmoscope, pack of 6

XL 3.5 V xenon bulbs
No. 10592 - for otoscope and lamp holder, pack of 6
No. 10593 - for May ophthalmoscope, pack of 6

Battery handle type C with rheostat
without batteries, handle diameter: 28 mm
No. 10425 - with cover, without hole for two type C batteries
No. 10429 - with cover, with hole for rechargeable NiMH battery ri-accu®
No. 10686 - Alkaline battery 1.5 V type C, pack of 2

Rechargeable NiMH battery ri-accu®
No. 10681 - 2.5 V
No. 10682 - 3.5 V

Battery handle cover
No. 10679 - without hole
No. 10682 - with hole

Plug-in handle with rheostat incl. rechargeable NiMH battery ri-accu®
No. 10430 - 2.5 V / 230 V
No. 10431 - 2.5 V / 120 V

Rechargeable NiMH battery ri-accu®
No. 10683 - 2.5 V

Plug-in handle with rheostat incl. rechargeable Li-ion battery ri-accu® L
No. 10432 - 3.5 V / 230 V
No. 10433 - 3.5 V / 120 V
No. 10692 - rechargeable Li-ion battery ri-accu® L

Combi handles with rheostat with rechargeable NiMH battery ri-accu® for socket handle sleeve.
No. 10668 - 230 V
No. 10669 - 120 V

Rechargeable NiMH battery ri-accu®
No. 10683 2.5 V

Rechargeable NiMH battery ri-accu®
No. 10681 2.5 V

No. 10686 Alkaline battery 1.5 V type C

7. Maintenance / accuracy check / calibration / applied standards

The instruments and their accessories require no special maintenance.
If an instrument needs to be tested for any reason, please send it to us or an authorized Riester dealer in your area, the details of which we will provide you with upon request.

8. Disposal

⚠ **Caution!**

The used medical device must be disposed of in accordance with current medical practices or local regulations on the disposal of infectious biological medical waste.

⚠

Batteries and electrical/electronic devices may not be treated as domestic waste and must be disposed of in accordance with local regulations.

⚠

If you have any questions about the disposal of products, please contact the manufacturer or their representative.

9. Electromagnetic compatibility

⚠

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 for operation
in an electromagnetic environment of 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.

⚠ **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, e.g. re-positioning, re-configuring or shielding the ME device.

The ME device evaluated does not have any significant performance characteristics as defined by EN60601-1, the failure of which or the failure of its power supply would result in an unacceptable risk to the patient, the operator or third parties.

⚠ **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 Diagnostische Instrumente uni® I, II, III / econom® head specified by the manufacturer. Failure to comply may result in a reduction of the device's performance characteristics.

Directives and manufacturer's declaration - Electromagnetic emissions		
The diagnostic instruments uni® I, II, III /econom® are intended for use in the electromagnetic environment specified below. The customer or user of the diagnostic instruments uni® I, II, III / econom® with accessories should ensure that they are used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions RF emissions pursuant to CISPR 11	Group 1	The diagnostic instruments uni® I, II, III / econom® with accessories use RF energy exclusively for an internal function. Therefore, their RF emissions are very low and unlikely to disturb nearby electronic devices.
RF emissions RF emissions according to CISPR 11	Class B	The uni® I, II, III /econom® diagnostic instruments with accessories are intended for use in all facilities, including residential areas and those directly connected to a public utility 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 emissions			
The diagnostic instruments uni® I, II, III / econom® with accessories are intended for use in an electromagnetic environment as specified below. The customer or user of the diagnostic instruments uni® I, II, III / econom® with accessories should ensure that these are 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 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 1 period and 70% 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 diagnostic instruments uni® I, II, III / econom® with accessories are intended for use in an electromagnetic environment as specified below. The customer or user of the diagnostic instruments uni® I, II, III / econom® with accessories should ensure that these are used in such an environment.			
Immunity testing	**IEC 60601 Testlevel**	**Compli-ance**	**Electromagnetic environment - guidance**
IEC 61000-4-6 Conducted RF disturbances according 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-scope® L, 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 the recommended distance is 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 communications equipment	3 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, e.g. base stations for radio (cellular/wireless) telephones and land mobile radios, amateur radio, AM and FM broadcast and television transmissions, 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 diagnostic instruments uni® I, II, III / econom® is used exceeds the abovementioned RF compliance level, the diagnostic instruments uni® I, II, III / econom® with accessories should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or moving the diagnostic instruments uni® I, II, III / econom®.
b) Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended distances between portable and mobile RF communications equipment and the ri-scope® L.

The diagnostic instruments uni® I, II, III / econom® with accessories are intended for use in an electromagnetic environment in which RF interference radiation is controlled. The customer or user of the diagnostic instruments uni® I, II, III / econom® can help to avoid electromagnetic interference by observing the minimum distance between portable and mobile RF communications equipment (transmitters) and the diagnostic instruments uni® I, II, III / econom® 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 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. The electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

10. Warranty

This product was manufactured to the highest quality standards and subjected to a thorough final inspection before leaving our factory. 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 from cases of improper handling or use. All defective parts will be replaced or repaired free of charge within the warranty period. This excludes wear parts.

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 coverage or repair, we ask you to return the RIESTER product with the completed warranty card to the following address:

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

Serial number or batch number, date,
stamp and signature of the specialist dealer

99200 Rev. G 2021-11 · Änderungen vorbehalten · Subject to alterations · Sous réserve de modifications · Sujeto a modificaciones · Con riserva di apportare modifiche · возможны изменения

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