EliteVue

Gebrauchsanweisung
Diagnostische Instrumente

Instructions
Diagnostic Instruments

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Диагностические приборы

CE

Riester

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1. Important information to note before commissioning

You have purchased a high-quality Riester diagnostic set, which was manufactured in accordance with Regulation (EU) 2017/745 on medical devices and is subject to the strictest quality controls at all times. The excellent quality guarantees reliable diagnoses. This user manual describes the use of the Riester battery handles, the EliteVue® instrument heads and their accessories. Please read the instructions carefully before use and keep them at hand.

Should you have any questions, please contact us or your Riester representative at any time. Our contact details are listed on the last page of this user manual. We will gladly provide you with the address of our representative upon request.

Please note that all instruments described in this user manual are only suitable for use by appropriately trained persons. Please note that the proper and safe functioning of our instruments is only guaranteed if both the instruments and their accessories are exclusively from Riester.

1.1. Safety symbols

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

1.1. Safety symbols

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

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

1.3 Caution/contraindications
There may be a risk of ignition of gases if the instrument is used in the presence of flammable mixtures or mixtures of pharmaceuticals.
- The instrument heads and battery handles must never be placed in liquids.
- The exposure to intense light during an extended eye examination using the ophthalmoscope may damage the retina.
- The product and ear specula are non-sterile. Do not use on injured tissue.
- Use new or sanitised ear specula to limit the risk of cross-contamination.
- Used ear specula must be disposed of in accordance with current medical practices or local regulations regarding the disposal of infectious, biological medical waste.
- Only use Riester or Riester-approved accessories/consumables.
- Cleaning frequency and sequence must comply with the cleaning regulations of non-sterile products in the respective facility. Note the cleaning/disinfection instructions in the user manual.
- The product may only be used by trained personnel.

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

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

1.6 Required skills/operator training
- Since only doctors use the otoscopes, they have the appropriate qualifications.

1.7 Environmental conditions
- Otoscopes
- The device is intended for use in rooms with a controlled environment.

The device must not be exposed to adverse/harsh environmental conditions.

1.8 Warnings/caution

 **Warning**

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


Do not use in a magnetic resonance environment!


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

Electric shock!
The housing of the EliteVue may only be opened by authorised persons.

Damage to the device due to a fall or strong ESD influence!

If the device is not functioning, it must be returned to the manufacturer for repair.

The device must be used in a controlled environment.

The device must not be exposed to harsh environmental conditions.

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

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

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

Cleaning frequency and sequence must comply with the cleaning regulations of non-sterile products in the respective facility. Cleaning/disinfection instructions in the instructions for use must be observed.

We recommend removing the (rechargeable) batteries from the battery handle before cleaning or disinfecting.

Clean and disinfect the devices carefully so that no liquid penetrates the interior.

Never place the devices in liquids!

The instruments with battery handles are supplied in a non-sterile condition. Do not use ethylene, oxide gas, heat, autoclaves or any other harsh methods to sterilise the device. The devices have not been approved for mechanical reprocessing or sterilisation. This leads to irreparable damage.

The patient is not the intended operator.

The product may only be used by qualified personnel.

Qualified personnel are doctors or nurses in hospitals, medical facilities, clinics and medical practices.

Caution!

User responsibility

It is your responsibility to:

The user must check the integrity and completeness of the instruments before each use. All components must be compatible with each other.

Incompatible components can result in degraded performance.

Never knowingly use a defective device.

Replace parts that are defective, worn, missing or incomplete.

Contact the nearest factory-approved service center if repairs or replacements are required.

In addition, the user of the device bears sole responsibility for malfunctions resulting from improper use, incorrect maintenance, improper repair, damage or changes by persons other than Riester employees or authorised service personnel.

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

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

1.9 Scope of delivery

10510 EliteVue head, single, LED, 2.5 V
10511 EliteVue head, single, XL, 2.5 V
10512 EliteVue head, single, LED, 3.5 V
10512-301 EliteVue head, single, LED, 3.5 V, with anti-theft device (for ri-former wall station)
10513 EliteVue head, single, XL, 3.5 V
10513-301 EliteVue head, single, XL, 3.5 V, with anti-theft device (for ri-former wall station)
2200-204 EliteVue otoscope set, LED, 2.5V, with handle C for 2 alkaline batteries
2200-202 EliteVue otoscope set, XL, 2.5V, with handle C for 2 alkaline batteries
2200-203 EliteVue otoscope set, LED, 3.5V, with handle C for 1 rechargeable Li-ion battery
2200-201 EliteVue otoscope set, XL, 3.5V, with handle C for 1 rechargeable Li-ion battery
2210-204 EliteVue otoscope/ophthalmoscope L2 set, LED, 2.5V, with handle C for 2 alkaline batteries
2210-202 EliteVue otoscope/ophthalmoscope L2 set, XL, 2.5V, with handle C for 2 alkaline batteries
2210-203 EliteVue otoscope/ophthalmoscope L2 set, LED, 3.5V, with handle C for 1 rechargeable Li-ion battery
2210-201 EliteVue otoscope/ophthalmoscope L2 set, XL, 3.5V, with handle C for 1 rechargeable Li-ion battery
2211-203 EliteVue otoscope set, LED, 3.5V, with handle C, 1 rechargeable Li-ion battery and plug-in charger
2212-203 EliteVue otoscope/ophthalmoscope set, LED, 3.5V, with 2 handles C, 2 rechargeable Li-ion batteries and desktop charger ri-charger L

Battery handles and charging stations:

Art. no.: 10670
Battery handle type C rheotronic®, black chrome-plated for 2 C batteries or 1 ri-accu®/ri-accu® L

Art. no.: 10686
Alkaline C batteries, 1.5 V, MV 1400 LR14

Art. no.: 10691
Li-ion battery, 3.5 V, ri-accu®L for battery handle type C and ri-charger® L

Art. no.: 10694
Li-ion battery, 3.5 V, ri-accu®L for plug-in charger for battery handle type C

Art. no.: 10670
Battery handle type C rheotronic®, black chrome-plated for 2 C batteries or 1 ri-accu®/ri-accu® L

Art. no.: 10686
2 alkaline C batteries, 1.5 V, MV 1400, LR14

Art. no.: 10691
Li-ion battery, 3.5 V, ri-accu®L for battery handle type C and ri-charger® L

Art. no.: 10694
Li-ion battery, 3.5 V, ri-accu®L for plug-in charger for battery handle type C
Art. no.: 10699
Li-ion battery, 3.5 V, ri-accu®USB for battery handle type C

Art. no.: 10642
Battery handle type AA with rheotronic® for 2 AA batteries or 1 ri-accu®/ri-accu® L

Art. no.: 10685
4 alkaline AA batteries (Mignon), type E 91, alkaline, 1.5 V

Art. no.: 10690
Li-ion battery, 3.5 V, ri-accu®L for battery handle type AA and ri-charger® L

Art. no.: 10705
ri-charger® L 3.5 V/230 V with wall mount

Art. no.: 10706
ri-charger® L 3.5 V/120 V with wall mount

Art. no.: 10707
Plug-in charger for Li-ion battery, 3.5 V, ri-accu®L for battery handle type C, with EU plug

Art. no.: 10708
Plug-in charger with Li-ion battery, 3.5 V, ri-accu®L for battery handle type C, with EU plug

Art. no.: 10704
ri-accu USB with handle type C, charging cable and power supply

2. Battery handles and commissioning
2.1. Purpose/indication
The Riester battery handles described in this manual are used to power the instrument heads (the lamps are incorporated into the corresponding instrument heads). They also serve as a holder. Battery handles in conjunction with plug-in charger for ri-accu® L.

2.2. Battery handles product range
All instrument heads described in this manual fit the following battery handles and can therefore be combined individually. All instrument heads also fit on the handles of the wall model ri-former®.

CAUTION ⚠
LED instrument heads are only compatible with a specific serial number of the ri-former® diagnostic station. Information on the compatibility of your diagnostic station is available upon request.

For ri-scope®L otoscopes, ri-scope®L ophthalmoscopes, perfect, H.N.O, praktikant, de luxe®, vet, slit and spot retinoscopes, ri-vision® and EliteVue:

2.3. Battery handle type C with rheotronic®, 2.5 V
To operate these battery handles, you need 2 standard type C Baby (IEC Standard LR14) alkaline batteries or a ri-accu® 2.5 V. The handle of the Riester ri-accu® can only be charged in the Riester ri-charger®.

2.4 Battery handle type C with rheotronic®, 3.5 V (for ri-charger® L)
To operate this battery handle you need:
- 1 Riester rechargeable battery, 3.5 V (art.no.10691 ri-accu® L).
- 1 ri-charger® L charger (art.no. 10705, art.no. 10706)

2.5 Battery handle type C with rheotronic®, 3.5 V
For charging at a 230 V or 120 V socket To operate this socket handle you need:
- 1 Riester rechargeable battery, 3.5 V (art.no. 10692 ri-accu® L).

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

New  **ri-accu® USB**
2.6.1 Art.no. 10704
Battery handle type C with rheotronic® 3.5 V and with ri-accu® USB charging technology contains:
- 1 Riester rechargeable battery, 3.5 V (art.no.10699 ri-accu® USB)
- 1 handle type C rheotronic®
- 1 USB cable type C to charge the battery using any USB power supply/power source without patient contact approved by DIN EN 60950/DIN EN 62368-1 (2 MOOP). Riester offers an optional medically approved power supply under art.no. 10709.

Function:
Instrument head with battery handle type C and ri-accu® USB is ready for use while charging. This allows for it to be used in a patient examination while charging.

CAUTION! ⚠
If a patient examination is done while charging (battery handle type C with USB charging technology, art.no. 10704), only the Riester medical power supply (art.no. 10709) may be used, since this ME system was tested in accordance with standard IEC 60601-1: 2005 (Third Edition) + CORR.1: 2006 + CORR.2: 2007 + A1: 2012 and is medically approved.
This ri-accu® USB has a charge status indicator.
LED is green: battery is fully charged.
LED flashes green: battery is being charged.
LED is orange: battery is too weak and must be charged.

- Specifications:
18650 Li-ion battery, 3.6 V, 2600 mAh, 9.62 Wh

Ambient temperature:	0 ° t + 40 °C
Relative humidity:	30% to 70% non-condensing
Transport and storage temperature:	-10 ° to +55 °C
Relative humidity:	10% to 95% non-condensing
Air pressure:	800 hPa - 1100 hPa

Operating environment:
The ri-accu® USB is used exclusively by professionals in clinics and medical practices.

2.7 Battery handle type AA with rheotronic®, 2.5 V
To operate these battery handles, you need 2 standard alkaline AA batteries (IEC standard LR6)

2.8 Battery handle type AA with rheotronic®, 3.5 V (for ri-charger® L) To operate this battery handle you need:
– 1 Riester rechargeable battery, 3.5 V (art.no.10690 ri-accu® L)
– 1 ri-charger® L charger (art.no. 10705, art.no. 10706)

3. Operation (inserting and removing batteries and rechargeable batteries)

CAUTION! ⚠
Use only the combinations described under 2.3 to 2.8!

3.1 Inserting the batteries:
Battery handles (2.3 and 2.7) type C and AA with rheotronic® 2.5 V:
– Unscrew the battery handle cover on the lower part of the handle in an anticlockwise 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 Removing the batteries:
– Battery handles (2.3 and 2.7) type C and AA with rheotronic® 2.5 V:
– Unscrew the battery handle cover on the lower part of the battery handle in an anticlockwise 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, art.no. 10692, ensure that the spring of the battery handle cover is not insulated. When using the old ri-accu® L, art.no. 10692, the spring must be insulated (short circuit hazard).


neuer **ri-**accu® L


alter **ri-**accu® L

3.3 Inserting the batteries:
Battery handles (2.4 and 2.8) type C and AA with rheotronic® 3.5 V (for ri-charger® L).
Battery handle (2.6) type C with rheotronic® 3.5 V (for plug-in charger). Battery handle (2.5) type C with rheotronic® 3.5 V for charging at 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 an anticlockwise direction.
- Remove the red safety foil on the plus side of the battery during initial startup.
- Insert the battery appropriate for your battery handle (see 2.2) into the battery handle with the plus side pointing towards the top of the 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.

3.4 Removing the batteries:
Battery handles (2.4 and 2.8) type C and AA with rheotronic® 3.5 V (for ri-charger® L).
Battery handle (2.6) type C with rheotronic® 3.5 V (for plug-in charger). Battery handle (2.5) type C with rheotronic® 3.5 V for charging at a 230 V or 120 V socket.

CAUTION! ⚠
Please observe the safety information
- Unscrew the battery handle cover on the lower part of the battery handle in an anticlockwise 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.

4. Charging battery handles with rechargeable batteries:
4.1 Battery handles (2.4 and 2.8) type C and AA with rheotronic® 3.5 V (for ri-charger® L).
- Can only be charged in the ri-charger® L charger (art.no. 10705, art.no. 10706) from Riester.
- The ri-charger® L charger comes with an additional user manual that must be observed.

4.2 Battery handle (2.6) type C with rheotronic® 3.5 V (for plug-in charger).
- It can only be charged with the plug-in charger (art.no. 10707) from 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 (art.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.

4.3 Battery handle (2.5) type C with rheotronic® 3.5 V for charging at a 230 V or 120 V socket.
Remove the base of the socket handle by turning it anti-clockwise. The plug contacts become visible. Round contacts are for 230 V mains operation, flat contacts are for 120 V mains operation. Now plug the handle base into the socket for charging.

CAUTION! ⚠
Before using the socket handle for the first time, it should be charged in the socket for a maximum of 24 hours.

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

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

Specifications: 230 V or 120 V version options

CAUTION! ⚠
- If you do not use the device for a long time or take it with you while traveling, please remove the batteries and rechargeable batteries from the handle.
- New batteries should be inserted when the light intensity of the instrument becomes weaker.
- In order to obtain an optimal light yield, we recommend that you always insert new high-quality batteries when changing the battery (as described in 3.1 and 3.2).
- 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.
- To extend the battery life, the battery should not be charged until the light intensity of the instrument becomes weaker.

4.4 Disposal:
Please note that (rechargeable) batteries must be disposed of specially. Information about this can be obtained from your municipality or from your responsible environmental consultant.

5. Attaching instrument heads
Attach the required instrument head to the mount on the upper part of the handle so that the two recesses on the lower part of the instrument head align with the two protruding guide pins of the battery handle. Gently press the instrument head onto the battery handle and turn the handle clockwise until it stops. The head is removed by turning it anti-clockwise.

5.1. Switching on and off
With battery handles type C and AA, switch on the instrument by tapping the switching ring on the upper part of the handle in a clockwise direction. To turn the instrument off, turn the ring anti-clockwise until the device turns off.

5.2. rheotronic® to regulate light intensity
The rheotronic® allows for the light intensity to be adjusted on the type C and AA battery handles. The light intensity will be weaker or stronger depending on how often you move the switch ring in the clockwise or anti-clockwise direction.

CAUTION! ⚠
The light intensity is at 100%, every time the battery handle is turned on. Automatic safety shutdown after 180 seconds.
Explanation of the symbol on the socket handle:

CAUTION! ⚠
Observe the instructions for use!

6. EliteVue® otoscope
Device function:

1) Ear specula
2) Bayonet mount
3) Focusing wheel
4) Lens system, 5.5x magnification
5) Push button for ear specula ejection

6.1. Purpose/indication
The Riester EliteVue otoscope described in these operating instructions is produced for illumination and examination of the auditory canal in combination with a Riester ear specula.

6.2. Attaching and removing ear specula
The otoscope head can take either disposable Riester ear specula (in black) or reusable Riester ear specula (in black). The size of the ear speculum is marked at the back of the speculum. Welch Allyn specula can also be used.

L1 and L2 specula
Turn the speculum clockwise until you feel resistance. To remove the speculum, turn it anti-clockwise.
L3 specula
Place the selected speculum on the chromed metal fitting of the otoscope until it clicks into place. To be able to remove the speculum, press the blue eject button. The speculum will be ejected automatically.

6.3 Focusing wheel
The focusing wheel gives you the option to set the focus in the ear canal (eardrum). The high quality lens system offers 5.5x magnification and a field of view of 11 mm in diameter at a distance of about 20mm.

6.4 Pneumatic otoscopy
Pneumatic otoscopy (= an examination of the eardrum), requires a ball which is not included in normal delivery but may be ordered separately. The hose of the ball is put on the connection. You can now carefully fill the ear canal with the necessary amount of air.

6.5 Technical data for the lamp
Otoscope XL 2.5 V, 2.5 V, 750 mA, averagelifespan 15 h
Otoscope XL 3.5 V, 3.5 V, 720 mA, averagelifespan 15 h
Otoscope LED 2.5 V, 2.5 V, 280 mA, averagelifespan 10,000 h
Otoscope LED 3.5 V, 2.5 V, 280 mA, averagelifespan 10.0

6.6 Replacing the EliteVue lamp
Unscrew the instrument head from the battery handle. The bulb is located at the bottom of the instrument head. Using your thumb and forefinger or a suitable tool, pull the bulb out of the instrument head. Insert the new lamp firmly.

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

7.2. Cleaning and disinfection
To avoid possible cross-contamination, the diagnostic instruments and their handles must be cleaned and disinfected regularly.

The diagnostic instruments together with their handles can be cleaned on the outside using a damp cloth (if necessary, moistened with alcohol) until they are visually clean. Wipe with disinfectant (e.g. disinfectant Bacillol AF from Bode Chemie GmbH (time 30s)) only according to the instructions of use of the respective manufacturer of disinfectant. Only disinfectants with proven effectiveness according to national guidelines should be used. After disinfecting, wipe the instruments with a damp cloth to remove potential residue.

Make sure that the cloth is moistened but **NOT** saturated so that no moisture penetrates the openings in the diagnostic instrument or its handle.

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

Caution! ⚠
The diagnostic instruments are not sterile devices; they cannot be sterilized.

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

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

7.3. Reprocessing of reusable ear specula
Cleaning: manual
Required equipment: mild 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 at least drinking water quality, tub/basin for cleaner, lint-free cloths (Braun Wipes Eco 19726 have been validated).
1. The cleaning solution is produced according to the manufacturer's instructions for the cleaning agent (neodisher Mediclean 0.5% has been validated).
2. Completely immerse the medical devices in the cleaning solution.
3. Make sure that all surfaces are completely wetted with cleaning solution.
4. Carry out all subsequent steps below the liquid level to prevent the contaminated liquid from splashing.
5. Brush the hard-to-reach areas of the immersed ear specula with a soft brush during the exposure time. Pay attention to the critical, hard-to-reach places where a visual assessment of the cleaning effect is not possible.
6. The total exposure time in the cleaning solution is at least 10 minutes (10 minutes has been validated).
7. Remove the medical devices from the cleaning solution.
8. Rinse the medical devices under running tap water (at least drinking water quality) for at least 1 minute (1 minute has been validated) to completely remove any supernatant or residual cleaning solution. Check that the device is clean; if soiling is visible, repeat the above steps.
9. Dry with a lint-free cloth.

Disinfection: manual

Required equipment: Disinfectant (e.g. CIDEX OPA, Johnson & Johnson 20391 has been validated), demineralised water (demineralised water, free of facultative pathogenic microorganisms according to the KRINKO/BfArM recommendation) 20 ± 2 °C, sterile, lint-free cloths.

1. Prepare the disinfectant solution according to the manufacturer's instructions (CIDEX OPA is a ready-to-use solution; the concentration must be checked using test strips, see manufacturer's instructions) (CIDEX OPA has been validated).
2. Completely immerse the ear specula in the disinfectant solution.
3. Exposure time of the disinfectant solution according to the manufacturer's instructions for high-level disinfection (CIDEX OPA for 12 minutes has been validated).
4. Remove the ear specula from the disinfectant solution and place them in a tub/basin containing demineralised water for at least 1 minute (1 minute has been validated).
5. Repeat the step twice with fresh demineralised water.
6. Place the ear specula on a clean, dry cloth and allow to dry.

Further information for the user:
For information on cleaning and disinfection, refer to the current standard **DIN EN ISO 17664**.

The homepage of **RKI Guideline – KRINKO/BfArM** also regularly provides information about developments regarding cleaning and disinfection for the reprocessing of medical devices.

Single use ear specula

For one-time use only

Caution: Repeated use can lead to infection.

7.4 Spare parts and accessories
Reusable ear specula
Article no.:
10775 2 mm/10 pcs
10779 2.5 mm/10 pcs
10783 3 mm/10 pcs
10789 4 mm/10 pcs
10795 5 mm/10 pcs

Disposable specula for

10772-532 2 mm, 100 pcs
10773-532 2 mm, 500 pcs
10774-532 2 mm, 1000 pcs
10772-531 2.5 mm, 100 pcs
10773-531 2.5 mm, 500 pcs
10774-531 2.5 mm, 1000 pcs
10772-533 3 mm, 100 pcs
10773-533 3 mm, 500 pcs
10774-533 3 mm, 1000 pcs
10772-534 4 mm, 100 pcs
10773-534 4 mm, 500 pcs
10774-534 4 mm, 1000 pcs
10772-535 5 mm, 100 pcs
10773-535 5 mm, 500 pcs
10774-535 5 mm, 1000 pcs

Reusable ear specula

10800-532 2 mm, 10 pcs
10800-533 3 mm, 10 pcs
10800-534 4 mm, 10 pcs
10800-535 5 mm, 10 pcs
10800-539 6 mm, 10 pcs

Disposable specula

10800-532 2 mm, 100 pcs
10802-532 2 mm, 500 pcs
10803-532 2 mm, 1000 pcs
10801-533 3 mm, 100 pcs
10802-533 3 mm, 500 pcs
10803-533 3 mm, 1000 pcs
10801-534 4 mm, 100 pcs

10802-534 4 mm, 500 pcs
10803-534 4 mm, 1000 pcs
10801-535 5 mm, 100 pcs
10802-535 5 mm, 500 pcs
10803-535 5 mm, 1000 pcs
10801-539 9 mm, 100 pcs
10802-539 9 mm, 500 pcs
10803-539 9 mm, 1000 pcs

10960 Ball for pneumatic otoscopy

Bulbs:

Art. no.: 10626 2.5 V LED for EliteVue Kelvin = 4000, CRI = 92
Art. no.: 10625 3.5 V LED for EliteVue Kelvin = 4000, CRI = 92
Art. no.: 10600 XL 2.5 V xenon bulb for EliteVue
Art. no.: 10607 XL 3.5 V xenon bulb for EliteVue

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

7.6.Instructions

Ambient temperature:	0 ° to +40 °
Relative humidity:	30% to 70% non-condensing
Transport and storage temperature:	-10 ° to +55 °C
Relative humidity:	10% to 95% non-condensing
Air pressure:	800 hPa - 1100 hPa

7.7 ELECTROMAGNETIC COMPATIBILITY
ACCOMPANYING DOCUMENTS ACCORDING TO IEC 60601-1-2, 2014, Ed.4.0

Caution: ⚠
Medical electrical equipment is subject to special precautions in terms of electromagnetic compatibility (EMC). Portable and mobile radio frequency communication devices can affect medical electrical equipment. The ME device is intended for operation in a home health¬ care electromagnetic environment and for professional facilities such as industrial areas and ¬hospitals. The user of the device should ensure that it is being operated within such an environment.

Warning: ⚠
The ME device may not be stacked, arranged or used directly next to or with other devices. When use close to or stacked with other devices is required, the ME device and the other ME devices must be monitored to ensure intended operation within this configuration. This ME device is intended for use by medical professionals only. This device may cause radio frequency interference or interfere with the operation of nearby devices. It may become necessary to take appropriate corrective measures, such as redirecting or rearranging the ME device or shield.
The ME device assessed does not exhibit any essential performance characteristics in the sense of EN60601-1, which would present an unacceptable risk to patients, operators or third parties should the power supply fail or malfunction.

Warning: ⚠
Portable RF communications equipment (radios) including accessories, such as antenna cables and external antennas should not be used within less than 30 cm (12 inches) to parts and wiring of the EliteVue instrument head with handles, as specified by the manufacturer. Failure to comply may result in a reduction of the device's performance features.

Guidelines and manufacturer's declaration - electromagnetic emissions		
The ri-scope® L and EliteVue instruments are intended for use in the electromagnetic environment specified below. The customer or user of the ri-scope® L/EliteVue should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions RF emissions pursuant to CISPR 11	Group 1	The ri-scope® L/EliteVue uses RF energy exclusively for internal functions. Therefore, its RF emissions are very low and unlikely to disturb nearby electronic devices.
RF emissions RF emissions according to CISPR 11	Class B	The ri-scope® L/EliteVue is intended for use in all establishments, including residential areas and those directly connected to a public supply network that also supplies buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Emissions of voltage fluctuations, flicker IEC 61000-3-3	Not applicable	

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

Guidelines and manufacturer's declaration – electromagnetic immunity			
The ri-scope® L/EliteVue instruments are intended for use in the electromagnetic environment specified below. The customer or user of the ri-scope® L/EliteVue should ensure that it is used in such an environment.			
Immunity testing	**IEC 60601 Testlevel**	**Compliance**	**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-pen, including the cables, than the recommended distance, which is calculated using the equation applicable to the transmitter frequency. Recommended separation distance: d = 1.2 x P 80 MHz to 800 MHz d = 2.3 x P 800 MHz to 2.7 GHz Where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended distance in metres (m). Field strengths of fixed RF transmitters, determined by an electromagnetic site survey, should be lower than the compliance standard in each frequency range. Interference may occur in the vicinity of devices marked with the following symbol: 
Emitted RF IEC 61000-4-3 Proximity fields of wireless RF communications equipment	3 V/m 80 MHz bis 2,7 GHz 380 – 390 MHz 27 V/m, PM 50%, 18 Hz 430 – 470 MHZ 28 V/m, (FM ± 5 kHz, 1 kHz sine) PM, 18 Hz11 704 – 787 MHz 9 V/m, PM 50%, 217 Hz 800 – 960 MHz 28 V/m, PM 50%, 18 Hz 1700 – 1990 MHz 28 V/m, PM 50%, 217 Hz 2400-2570 MHz 28 V/m, PM 50%, 217 Hz 5100-5800 MHz 9 V/m, PM 50%, 217 Hz	10 V/m 27 V/m 28 V/m 9 V/m 28 V/m 28 V/m 9 V/m	

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

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

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

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

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

Rated maximum output power of the transmitter (W)	**Separation distance according to the frequency of the transmitter (m)**		
	150 kHz - 80 MHz	**80 MHz - 800 MHz**	**800 MHz - 2,7 GHz**
0,01	**0,12**	**0,12**	**0,23**
0,1	**0,38**	**0,38**	**0,73**
1	**1,2**	**1,2**	**2,3**
10	**3,8**	**3,8**	**7,3**
100	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance applies to the higher frequency range.

Note 2: These guidelines may not apply in all situations. The electromagnetic propagation is affected by absorption and reflection by structures,objects and people.

7.8 Disposal

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

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

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

7.9 WARRANTY

This product was produced to the highest quality standards and subjected to a thorough final inspection before leaving our factory.
Therefore we are pleased to issue a warranty of **2 years from the date of purchase** on all defects traceable to material or manufacturing defects. A warranty claim is excluded in the case of improper handling.
All defective parts of the product will be replaced or repaired free of charge within the warranty period. This excludes wear parts.
In addition, we offer a 5-year warranty on the R1 shock-proof calibration, as required for the CE certification.
A warranty claim can only be made if the product is accompanied by this warranty card, which is filled out in full and stamped by the dealer. Please note that warranty claims must be made within the warranty period.
We are of course happy to charge for checks or repairs after the expiry of the warranty period. We also offer free, no-obligation quotes.
In case of warranty coverage or repair, we ask you to return the Riester product with the completed warranty card to the following address:

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

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

99360 Rev. D 2021-11 · Änderungen vorbehalten · Subject to alterations · Sous réserve de modifications · Sujeto a modificaciones · Con riserva di apportare modifiche · возможны изменения

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