all models

Gebrauchsanweisung

Stirnspiegel und Stirnlampen

Instructions

Head mirrors and head lamps

Mode d'emploi

Miroirs frontaux et lampes frontales

Instrucciones para el uso

Lámpas frontales y espejos frontales

Инструкция по эксплуатации

Налобные зеркала и налобные осветители

Istruzioni per l' uso

Lampade frontali e specchi frontali



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Inhaltsverzeichnis 1. Wichtige Information zur Beachtung vor Inbetriebnahme 2. Stirnlampen und Stirnspiegel 3. Ersatzteile 4. Technische Daten 5. Wartung 6. Entsorgung Garantie	Seite 06 06 11 12 12 12 81
Table of Contents 1. Important information to be observed before operation 2. Headlights and head mirrors 3. Replacement parts 4. Technical data 5. Maintenance 6. Disposal Warranty	Page 19 19 24 25 25 25 81
Sommaire 1. Informations importantes à lire attentivement avant utilisation 2. Lampes frontales et miroirs frontaux 3. Pièces de rechange 4. Caractéristiques techniques 5. Maintenance 6. Elimination Garantie	Page 31 31 36 37 37 37 82
 Índice 1. Información importante que debe tenerse en cuenta antes del uso 2. Lámparas frontales y espejos frontales 3. Accesorios 4. Datos técnicos 5. Mantenimiento 6. Eliminación de residuos Garantía 	Página 44 44 49 50 50 50 82
Содержание 1.Важная информация для прочтения перед использованием 2. Салобные осветители и зеркала 3. Вапасные части 4. Lехнические характеристики 5. Lехническое обслуживание 6. Утилизация Гарантия	стр. 57 57 62 63 63 63 83

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Sommario	Pagina
1. Informazioni importanti da leggere prima dell'uso	70
2. Lampade frontali e specchi frontali	70
3. Pezzi di ricambio	75
4. Dati tecnici	75
5. Manutenzione	76
6. Smaltimento	76
Garanzia	83

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LED Licht Nicht in den Strahl blicken Klasse 2 LED



LED Licht Klasse1 LED



Grüner Punkt" (Länderspezifisch)



Trocken aufbewahren



Chargen-Code



Seriennummer



Temperaturgrenzen in °C für Lagerung und Transport



Temperaturgrenzen in °F für Lagerung und Transport



Zerbrechlich, mit Sorgfalt behandeln



Warnhinweis

 ${\it dieses \ Symbol \ macht \ auf \ eine \ m\"{o}glicherweise \ gef\"{a}hrliche \ Situation \ aufmerksam}.}$

1. Important information to be observed before operation

You have purchased a high quality **Riester** product, which has been manufactured according to the Directive 93/42/EEC for medical devices and is subject to the strictest quality controls at all times. The outstanding quality is a guarantee for reliable diagnosis. Please read the Instructions for Use carefully before operating the unit and keep them in a safe place.

If you should have any questions, we or your responsible **Riester** product representative are available to answer queries at any time. Our address can be found on the last page of these Instructions for Use. The address of our sales representative will be provided upon request.

Please note that the instruments described in these Instructions for Use are only to be used by suitably trained personnel. The user should ensure that the instrument is working safely and is in good condition before use.

Furthermore, please note that the perfect and safe functioning of our instruments is only guaranteed when both the instruments as well as the accessories used are from **Riester**.

Remarks on electromagnetic tolerability

There are currently no indications that electromagnetic interactions with other devices can occur when this device is used correctly. However, interference cannot be completely excluded under the strong influence of unfavourable field strengths, e.g. when operating a cell telephone and from radiological instruments.



The use of other accessories may result in increased electromagnetic emissions or reduced electromagnetic immunity of the device and may lead to incorrect operation.

2. Headlights und head mirrors

2.1. Intended use

The headlights and head mirrors described in these Instructions for Use have been manufactured to illuminate or throw light on the areas of the body to be examined.

2.2. Headlights and head mirrors Preparation prior to operation

Attention!

- Don't use the examination light for eye-examination
- There may be a risk of gas ignition when the light is used in the presence of inflammable drug mixtures such as air and/or oxygen or laughing gas!

2.3 Putting into initial service and function

2.3.1 Adjusting the headband

The adjustment of the headband is the same for all models.

Loosen the aluminium turning knob in a counter-clockwise direction. Adjust the headband and fix it in the required position by turning the knob clockwise.



2.3.2 Adjusting the lamp head ri-focus® LED

Individual adjustment of the lamp head with the flexible light arm: see Picture 1 parallel to the optical path of the eyes.

Individual fine adjustment of the lamp head (during the examination) with the flexible light arm

Caution!

The flexible arm of the light should not be bent in a too small radius in order to prevent premature material fatigue.

 $\operatorname{Don}\xspace^*$ t continue with focussing when you realize the stop as this can damage the lamp.



ri-focus® LED

clar N 55 mm

Loosen the plastic turning knob on the joint, adjust the mirror and tighten the knob again.



clar N 55 mm

2.3.3 Fitting batteries or rechargeable batteries ri-focus® LED und clar N

In order to open the battery compartment, press the two push buttons and pull off the cover of the battery compartment



Polarity of batteries type AAA or rechargeable batteries Type AAA



Polarity of batteries lithium CR 123A

Attention: It is important to ensure that the polarity is correct.





Push the battery compartment cover back into the tracks of the battery compartment and push downwards until it snaps into place.

2.3.4 Switching on and off ri-focus® LED und clar N

Simple on-off switch located on the battery compartment.



2.3.5 Battery case cover

Battery case cover 1 is for batteries/accus type AAA (4 pieces)



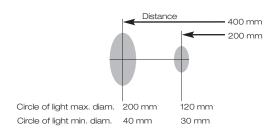
Battery case cover 2 is for batteries/accus type Lithium CR123A 2 pieces]



Attention! Please take care that there is no function if the wrong battery case cover is used.

2.3.6 Focussing ri-focus® LED

Focus by turning the front lamp head.





clar N 55

Manually moving the lamp fixture towards and away from the mirror.

2.3.7 Attaching the headlight / the head mirror ri-focus® LED

The lamp head is firmly fixed to the headband and can only be exchanged together with the headband.

clar N

By opening the plastic screw, the clamping unit located on the headband is opened up until the ball-and-socket joint on the mirror fits. Attach the mirror by turning the plastic screw tightly on the headband.

Attention!

Before exchanging the complete mirror, the electric plug located on the joint of the lamp has to be pulled out. After the mirror has been exchanged, the plug can be pushed back in again.

If the lamp does not function after plugging the cable back in again, the plug has to be rotated 180° and plugged in again.

Attention!

- Never touch the lamps during use.
 - They can get very hot!
- In the case of model ri-focus® LED only touch the ring at the front of the lamp head or the grip at the rear
- of the lamp head during operation. All other parts can heat up considerably.
- In the case of **clar N** model, you can touch the following parts during operation: the plastic shell on the mirror, the adjusting knob and the swivel arm.



2.3.8 Lamps Exchanging the lamp

clar N 55

Turn the lamp away from the mirror with the help of the adjustable lamp joint (enlarge the clearance). The lamp can then be unscrewed and a new lamp screwed back into place.

Atention! Allow the lamp to cool down first before exchanging the lamp!

2.3.9 Operation of the battery charger ri-focus® LED and clar N 55

Plug the charger into the mains socket and then connect it to the battery compartment. As soon as a connection to the battery compartment has been made, the charging indicator of the unit lights up and the rechargeable batteries will be charged up. If the LED on the charger is red, the batteries must be charged. If the LED on the charger is green, the batteries are fully charged.

Battery charger specifications:

Input: AC 100 - 240 V

50/60 Hz 0.3A Output: DC 5.8 V/0.25 A

Caution: For use with 3.6 - 4.8 V

NiMH Pack only Indoor use only

Charging time: First charge minimum 24 hours.

Following charges are possible over night or as required.

Battery mode:

Approx. 90 min. with fully charged batteries.

If the battery voltage falls below the minimum voltage, the LED will switch off.

If the LED does not light up when the power is on, the battery voltage is too low. Batteries must be charged.

Atention:

- Only commercially available rechargeable batteries Type AAA may be charged with this charging device.
- Charging non-rechargeable batteries may lead to the destruction of the batteries or the charging device.
- The charging device may only be used in closed rooms.
- · Remove the device from the mains point when not in use.
- Do not operate, if either the case or the mains plug is damaged.
- · Do not open the device.
- If the device is not used for a longer period of time or is to be taken with when travelling, please remove the batteries or the rechargeable batteries from the battery compartment
- New batteries should be used or the rechargeable batteries should be charged up, if the light intensity of the
 instrument becomes weaker and could compromise examination results.
- In order to obtain an optimal light yield, we recommend the use of new, high quality batteries when exchanging batteries.





2.3.10 Technical data

Description	Voltage	Amperage	Average service life
Lamp for clar N vacuum 55 mm	6 V	0.4 A	approx. 200 hours
Lamp for clar N LED 55 mm	6 V	0.35 A	approx. 15.000 hours
LED for ri-focus® LED	6 V	0.525 A	approx. 50.000 hours

2.3.11 Exchanging the headband padding

The foam padding can be simply removed from the Velcro and replaced by new foam padding.



2.3.12 Instruction for care

General information

The goal of cleaning and disinfection of medical products is the protection of patients, users and third persons and conserving the value of the medical products. On account of the product design and the used material, no defined limit of maximum processing cycles can be fixed. The lifetime of the medical products depends on their function and on a appropriate treatment of the devices. Before returning faulty products for repair they must have gone through the described reprocessing process.

Cleaning and disinfection

Head mirrors and headlights can be cleaned outside with a humid cloth until optical cleanness is given.

Wipe disinfection according to the regulations given by the disinfectant manufacturer. Only disinfectants with approved efficiency and in accordance with the national standards can be used.

After disinfection the device must be cleaned with a humid cloth to remove all possible deposits of disinfectants.

Caution!

Never place the head mirror and headlights in liquid!

The items are not permitted for machine cleaning and sterilisation as they will damaged!

3. Replacement parts

LED illumination

Art. No. 11302 Lamps 6 V for clar N LED

Standard illumination:

Art. No. 11301 Pack of 6 lamps à 6 V for **clar N** vacuum

4. Technical data

Models: **clar N** vacuum 55 mm. **clar N** LED 55 mm

ri-focus® LED

Energy sources: See remarks on the respective mains device or on the batteries, rechargeable batteries

Initial values: According to the details on the mains devices or the batteries used Working temperature: ± 10 to $\pm 40^{\circ}$, relative air humidity between 30 and 75% (non-condensing)

Storage location: -5°C to 50°C, up to 85% relative air humidity, non-condensing

5. Maintenance

The instruments and their accessories do not require any special maintenance. If an instrument has to be checked for any reason, send it to us or to an authorised **Riester** dealer near you, whom we shall be pleased to name upon request.

6. Disposal

Please note that batteries and electrical appliances have to be disposed of in a special way. You can obtain information about this from municipal collection points.

Manufacturer: see last page of these Instructions for Use.

7. Disposal of the packaging

Observe the appropriate waste material regulations when disposing the packaging material. Please keep out of reach of children.

Danger of explosion

Do not use this device around flammable anaesthetic gases, vapours or liquids.

Disposal of accessories and device

Disposable accessories are intended for single use. They should not be reused as their function could be restricted or they could be contaminated. The operating life of this head lamps is 10 years. At the end of its life, the head lamp and its accessories must be properly disposed in accordance with the regulations of such products. If you have questions regarding product disposal, please contact the manufacturer.

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



Medical electrical equipment is subject to special precautions regarding electromagnetic compatibility (EMC).

Portable and mobile radio frequency communication devices can affect medical electrical equipment. The ME device is for operation in an electromagnetic environment for home health care and intended for professional facilities such as industrial areas and hospitals.

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



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

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

Warning: 1

IEC 61000-3-3

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

		claration – electromagnetic emission or use in the electromagnetic environment specified below. The
customer of the user of the Head	lamps ri-focus and Forehead mir	ror Clar N should assure that it is used in such an environment.
Emission test Emissionsprüfung	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Headlamps ri-focus and Forehead mirror Clar N RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Headlamps ri-focus and Forehead mirror Clar N is suitable for use in all establishments, other than domestic and those directly
Harmonic emissions IEC 61000-3-2	Not applicable	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions	Not applicable	

The Headlamps ri-focus and Forehead mirror Clar N is intended for use in the electromagnetic environment specified below. The customer or the user of Headlamps ri-focus and Forehead mirror Clar N should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	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 floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	Mains power quality should be that on a typical commercial or hospital environment.
Surge IEC 61000-4-5	Not applicable	Not applicable	Mains power quality should be that on a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacture's declaration - electromagnetic immunity

The headlamps ri-focus and Forehead mirror Clar N is intended for use in the electromagnetic environment specified below. The customer or the user of the Headlamps ri-focus and Forehead mirror Clar N should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the ri-focus and clar N, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d= 1.2VP 80 MHz to 800 MHz d= 2.3VP 800 MHz to 2.7 GHz
Conducted RF IEC 61000-4-6	Not applicable	Not applicable	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Radiated RF IEC 61000-4-3 Proximity fields from RF wireless communications equipment	10 V/m 80 MHz to 2.7 GHz	10 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. B Interference may occur in the vicinity of equipment marked with the following symbol:

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

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and landmobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoreticallywith accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic sitesurvey should be considered. If the measured field strength in the location in which the Headlamps ri-focus and Forehead mirror Clar N is used exceeds the applicable RF compliance level above, the Headlamps ri-focus and Forehead mirror Clar N should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Headlamps ri-focus and Forehead mirror Clar N.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ri-focus LED, clar N LED.

Theri-focus and clar N is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ri-focus and clar N can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ri-focus, clar N as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation d	listance according to frequer (m)	ncy of transmitter]
(W)	150 KHz	to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
0.01	0.12	0.12	0.23	
0.1	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 separation distance d inmetres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is themaximum 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 for the higher frequency range applies.

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

~	Fabricant
C€	Marquage CE
	Veuillez respecter les instructions d'utilisation
	Dispositif de protection de classe II
*	Attention: ne pas regarder directement dans la lumière
	Attention: Les dispositifs électriques et électroniques usagés ne doivent pas être éliminés avec les déchets domestiques non triés et doiventêtre collectés séparément conformément à la réglementation nationale/eropéenne en vigueur.
	Ne peut pas utiliser à l'exterieur
90%	Humidité relative
~	courant alternatif



LED lumière Ne pas regarder directement dans la lumière Class 2 LED

courant direct



LED lumière Class 1 LED



« Point Vert » (spécifique au pays)



Conservez dans un endroit des



Code de lot



Numéro de série



Limites de température en °C for pour le stockage et le transport



Limites de température en °F for pour le stockage et le transport



Fragile, manipulez avec soin



Attention, ce symbol indique une situation potentiellerment dangereuse.

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