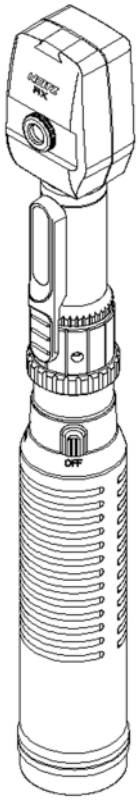
NEITZ

Streak Retinoscope

RX-RC

User's Manual



Thank you for purchasing the NEITZ Streak Retinoscope RX-RC. This is a hand-held ophthalmic device (retinoscope) using rechargeable batteries to power a halogen lightbulb to determine the refractive error of the eye.

This device is only to be charged using the NEITZ Battery Charger RC-II.

Please read this User's Manual and the User's Manual of the RC-II carefully before use to avoid unexpected accidents and store them in a safe place for future reference.

CE

TD11-10890031E-5

Table of Contents

1 Important Information 1
1.1 Intended Use 1
1.2 Symbols 1
1.3 Labeling on Package 2
1.4 Safety Information 2
2 Package Contents and Nomenclature 4
3 Operation 5
3.1 Charging the RX-RC 5
3.2 Turning Illumination ON/OFF 5
3.3 Adjustment of the Streak Light 6
3.4 Screening 7
3.5 Determination of Refractive Power 8
3.6 Examination of the Astigmatic Axis 8
3.7 Accessories 8
4 Maintenance 9
4.1 Cleaning 9
4.2 Replacing Batteries 9
4.3 Replacing the Lightbulb 9
4.4 Disposal 10
5 Troubleshooting 10
6 Specifications 11
7 Contact Information 12
ANNEX 13

1 Important Information

For the U.S. Market;

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

1.1 Intended Use

The NEITZ Streak Retinoscope RX-RC is a hand-held, battery-powered medical device containing a halogen bulb for illumination and viewing optics to determine the refractive error of the eye.
Do not use this device for any purpose other than its intended use.

1.2 Symbols

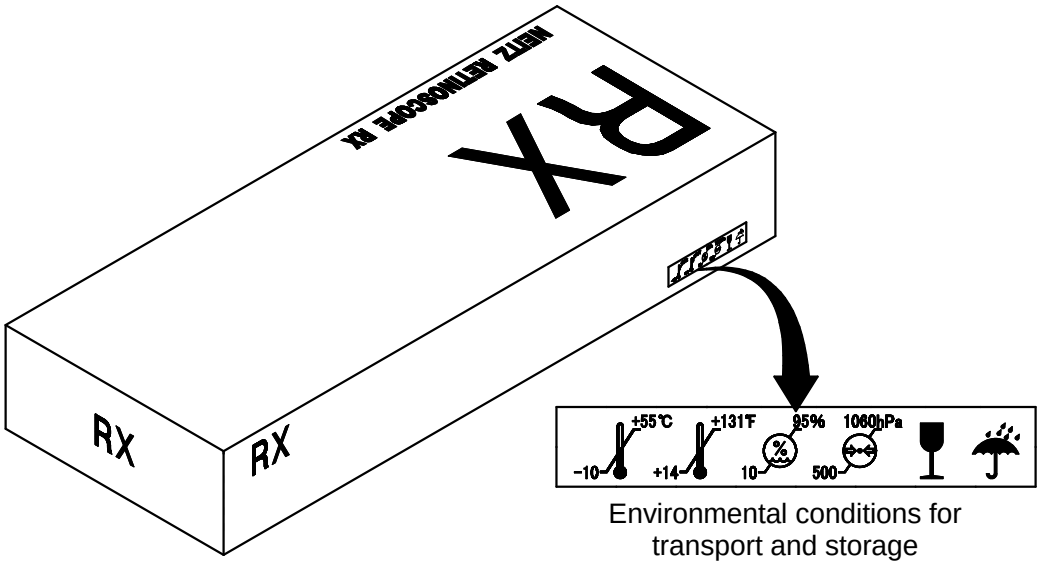
The following symbols are used on this manual and/or package to assist you in proper handling and use of the RX-RC, and to warn and caution you of potential hazards to yourself and others.

WARNING	Potentially hazardous situation which, if not avoided, could result in death or serious injury
CAUTION	Potentially hazardous situation which, if not avoided may result in minor or moderate injury or property damage
 Prohibited	Prohibited actions (must not be performed)
 Instruction	Required actions (must be performed)
	Consult User’s Manual for information on proper use
	Temperature limits for storage and transport
	Relative humidity limits (%) for storage and transport
	Atmospheric pressure limits (hPa) for storage and transport
	Fragile. Handle with care
	Keep dry
	Product complies with the European requirements for safety, health, environment and customer protection.
	Product must not be disposed of with general household waste under the WEEE directive
 Ni-Cd	Nickel-cadmium rechargeable battery

	Manufacturer’s name and address
	Barcode for traceability purposes
SN	Serial number
EC REP	Authorized representative in Europe

1.3 Labeling on Package

The following label has been adhered to the Outer Package of the RX-RC to assist you in the proper transport and storage of the device.



Environmental conditions for transport and storage

1.4 Safety Information

For your safety, please comply with the following precautions.

⚠WARNING	
Prohibited	Do not use in oxygen rich environments, in the presence of propane, gasoline or other combustible gasses, or near dust and debris. Doing so may cause explosion.
Prohibited	Do not leave the illumination on for prolonged periods or cover the device during illumination. Doing so may cause the device to reach high temperatures, resulting in fire, burns or device failure.
Prohibited	Never touch liquid which may have leaked from the batteries. In case of contact with the eye(s), flush with clean water without rubbing, and consult a physician immediately. If leaked liquid gets on skin or clothing, wash with clean water immediately. Failure to do so may result in serious injury, including loss of eyesight.
Prohibited	Do not attempt to disassemble or modify the device. Doing so may result in electric shock, fire or device failure.
Prohibited	Do not touch the device with wet hands. Doing so may result in electric shock.

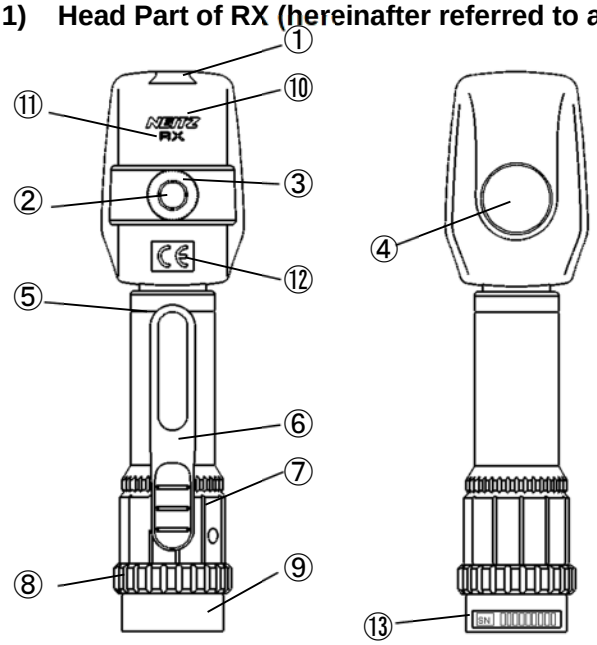
Prohibited	Do not touch the Lightbulb immediately after turning the illumination off, as the bulb may be extremely hot. Doing so may result in burns.
Instruction	Do not illuminate the patient's eye for more than 1 minute per eye and be sure to keep illumination at minimal intensity needed.

⚠CAUTION	
Prohibited	Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
Prohibited	Do not apply strong force to the device or handle it roughly. Doing so may result in injury or device failure.
Prohibited	Do not use in excessively humid or saline environments, or places where the device may be sprayed with water. Doing so may result in electric shock or device failure.
Prohibited	Do not expose the device to direct sunlight or harmful radiation. Doing so may lead to unexpected heating and result in device failure.
Prohibited	Do not sterilize.
Prohibited	Do not use paint thinners, cleaning agents or boiling water to clean the device. Doing so may cause deformation or device failure.
Prohibited	Do not immerse in cleaning detergents or rinse with water. Doing so may cause device failure.
Prohibited	Do not use the RX-RC adjacent to or stacked with other equipment. In cases where adjacent or stacked use is necessary, verify the RX-RC operates normally prior to use.
Prohibited	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RX-RC. Otherwise, degradation of the performance of this equipment could result.
Instruction	Be sure the head and handle are attached firmly before use.
Instruction	Use only alkaline dry-cell batteries.
Instruction	When replacing batteries, replace both at the same time using identical batteries.
Instruction	Remove batteries from the device during prolonged periods of disuse.
Instruction	Allow the device to return to room temperature before unpacking. Not doing so may cause condensation and lead to device failure.
Instruction	Make sure the illumination is turned off during transport or storage and only use the specified casing. Failure to do so may result in deformation, device failure or fire.

2 Package Contents and Nomenclature

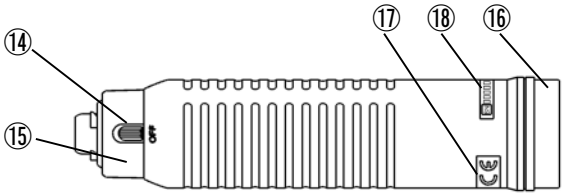
Make sure to match all items in the package with the components shown below and inspect each item for damage. Should any items be missing or damaged, do not use the RX-RC and immediately contact your local dealer.

1) Head Part of RX (hereinafter referred to as “Head”)



① Head Attachment Mount
② Viewing Window
③ Viewing Window Rim
④ Illumination Opening
⑤ Reference Line
⑥ Streak Adjustment Lever
⑦ Head Rotation Ring
⑧ Streak Rotation Ring
⑨ Head Joint
⑩ Manufacturer’s Logo
⑪ Model Logo
⑫ CE Mark
⑬ Serial Number

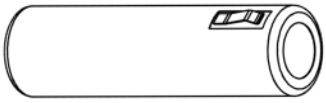
2) Battery Handle (hereinafter referred to as “Handle”)



⑭ Switch Button
⑮ Switch Ring
⑯ Bottom Cap
⑰ CE Mark
⑱ Serial Number of Handle

3) Rechargeable Battery (Preassembled with the Head and Handle prior to shipping)

Model: 1000RS (1 pc.)
Voltage: 3.6 V



4) Head Attachment



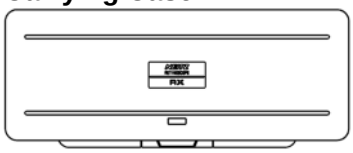
5) Presbyopic Lens (+2 D)



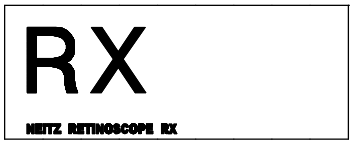
6) Spare Bulb
Type L-27 (1 pc.)



7) Carrying Case



8) Outer Package



9) User’s Manual

3 Operation

3.1 Charging the RX-RC

⚠ **WARNING**	Be sure the illumination is turned off when charging. Leaving the illumination on may prevent charging or induce excessive heat.

Charge the RX-RC using the NEITZ Battery Charger RC-II (hereinafter referred to as “RC-II”), sold separately. Up to two Handles can be recharged simultaneously.

1) Connect the RC-II to the AC supply mains using the provided AC adaptor.
2) Insert the Handle of the unlit RX-RC into the Charging Port of the RC-II (see Fig. 3.1)

Charging takes approximately 15 hours.
When fully charged, the RX-RC can be lit for approximately 80 minutes at maximum intensity.

※ Refer to the User’s Manual of the RC-II for further details.

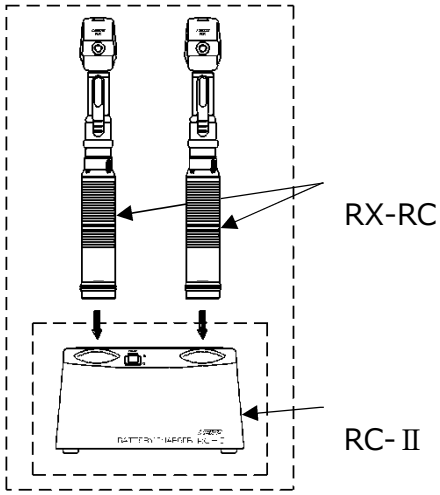


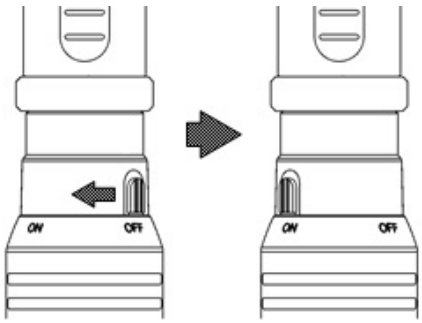
Fig. 3.1

3.2 Turning Illumination ON/OFF

While pressing the Switch Button on the Handle, rotate the Switch Ring to the left (towards ON) to turn the illumination on (see Fig. 3.2).

The device is equipped with a built-in illumination adjustment function. The further left the ring is rotated, the brighter the illumination.

To turn the illumination off, rotate the Switch Ring to the right until the Switch Button returns to the OFF position.



Illumination OFF Illumination ON
Fig. 3.2

3.3 Adjustment of the Streak Light

The streak light can be adjusted by moving the Streak Adjustment Lever vertically. The characteristic of the streak light is dependent on the position of the top of the Streak Adjustment Lever (hereinafter referred to as “Reference Point”) and the Reference Line (see Fig. 3.3).

(a) Reference Point above the Reference Line:
Convergent Streak

(b) Reference Point on the Reference Line:
Parallel Streak

(c) Reference Point below the Reference Line:
Divergent Streak

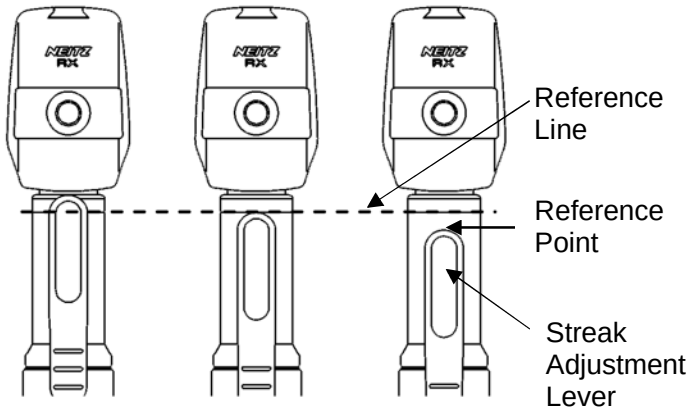


Fig. 3.3a Fig. 3.3b Fig. 3.3c

3.4 Screening

⚠ **WARNING**	When examining the eye, use only illumination with the least intensity necessary and do not illuminate the patient eye for more than one minute per eye.

(1) Turn on the illumination and fully lower the Streak Adjustment Lever to produce a divergent streak. (The following procedures are for screening using a divergent streak.
(2) Instruct the patient to focus on a distance target to simulate optical infinity.
(3) Direct the streak light into the patient's eye from a distance of 50 cm.
(4) While looking through the Viewing Window, slowly sweep the streak light horizontally across the pupil ("scan") to observe the reflex off the patient's retina.
(5) The patient's refractive condition can be determined from the relationship between the streak light and the reflex.
  (a) "With" reflex (direction of reflex is the same as the scanning direction)
  Myopia of less than -2 D, normal vision, hyperopia
  (b) Neutralized reflex
  Myopia of -2 D
  (c) "Against" reflex (direction of reflex is opposite the scanning direction)
  Myopia of more than -2 D

*Note 1: The aforementioned principle (see Fig. 3.4) applies only to scanning with a divergent beam. Scanning with a convergent beam will give reverse results.

*Note 2: The refractive power -2 D above is inversely dependent on the distance between the examiner and the patient, where 1 D = 1 / (distance in meters).

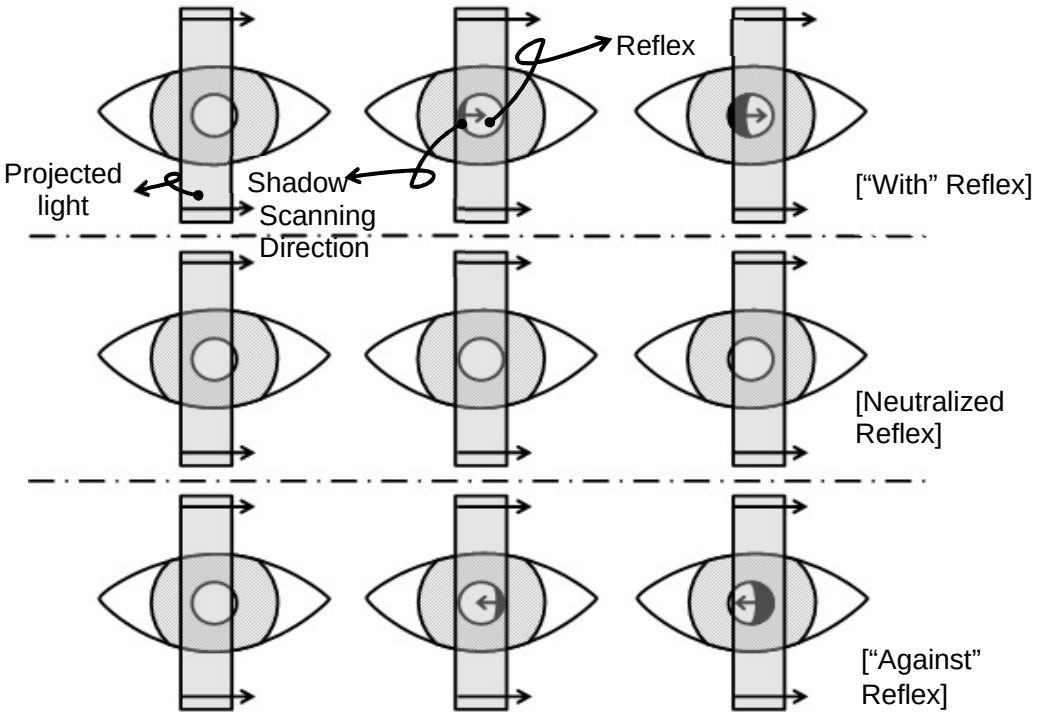


Fig. 3.4

3.5 Determination of Refractive Power

(1) Scan the naked eye and insert a (+) lens for a “with” reflex or a (-) lens for an “against” reflex 12 mm in front of the patient’s eye.
(2) Change the optical power of the lens in increments of 0.5 D to 1 D to find the power where the reflex is neutralized.
*Note: As “against” reflex is harder to detect than “with” reflex, the neutralization point may be determined with greater accuracy by first inserting a lens which induces a “with” reflex and gradually lowering the optical power.
(3) The refractive power of the patient eye can be determined as follows:

< (refractive power) = (optical power of the lens) – (1 / (examination distance in meters)) >

3.6 Examination of the Astigmatic Axis

Presence of astigmatism can be detected when the reflex moves in a direction different from the scanning direction. Rotate the Streak Rotation Ring to align the streak light with the reflex. This angle indicates the main meridian. Rotate the streak light 90° to examine the refractive power along the other meridian. These meridians compose the astigmatic axes.

The streak light can be rotated 360° continuously by turning the Streak Rotation Ring (see Fig. 3.5).

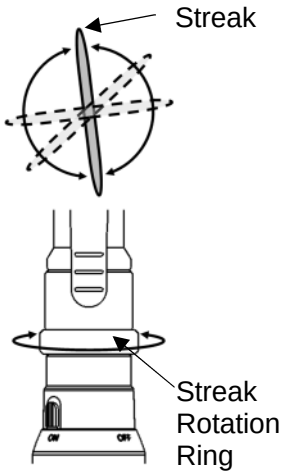


Fig. 3.5

3.7 Accessories

(1) Head Attachment
The Head Attachment can be used when the examiner wishes to wear glasses during examination to protect the glasses. Remove the cover of the Head Attachment Mount and insert the Head Attachment (see Fig. 3.6). The Head Attachment should provide for space to allow operation of the RX-RC without making contact with your glasses.

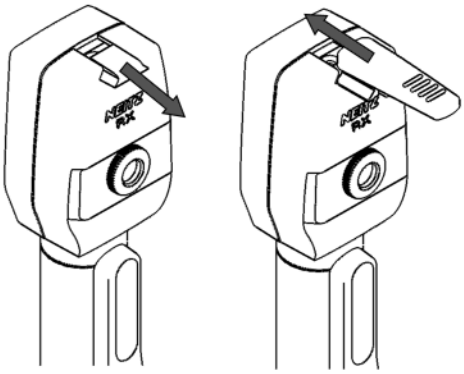


Fig. 3.6

(2) Presbyopic Lens
Turn the Viewing Window Rim counter-clockwise to remove from the Head. Replace with the Presbyopic Lens included in the package and screw clockwise to tighten.

4 Maintenance

4.1 Cleaning

If the device becomes dirty, wipe clean with a dry, lint-free cloth.
Should dirt remain, moisten with diluted neutral detergent and wipe clean. Then, wipe dry.
To disinfect the device, only wipe with alcohol, and DO NOT STERILIZE.
Use an air blower or the like to remove dust and debris from the Viewing Window.

4.2 Replacing Batteries

⚠ **WARNING**	Use only batteries provided by the manufacturer. Failure to do so may result in device failure.

Batteries degrade through repeated cycles of charging and discharging. It is recommended to change the rechargeable battery once every 2 years.

(1) Remove the Bottom Cap from the Handle by turning counter-clockwise.
(2) Remove old battery.
(3) Insert the new battery with the Metal Terminal toward the Bottom Cap (see Fig. 4.1).
(4) Screw the Bottom Cap shut by turning clockwise.

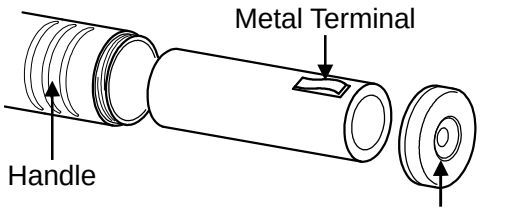


Fig. 4.1

4.3 Replacing the Lightbulb

⚠ **WARNING**	Do not touch the Lightbulb immediately after turning the illumination off, as the bulb may be extremely hot. Doing so may result in burns.

If the RX-RC does not light, the Lightbulb may have blown out. Follow the directions below to check if the Lightbulb has blown out, and if so, to replace the Lightbulb.

(1) Holding the Head Tip in one hand and the Head Base in the other, turn the Head Base counter-clockwise to detach from the Head Tip (see Fig. 4.2).
(2) Remove the Lightbulb from the Head Base by turning counter-clockwise.
(3) Check the Lightbulb, and if the filament has blown out, replace with a new bulb.
(4) Insert the new Lightbulb and screw clockwise until it comes to a stop (see Fig. 4.3). Pay close attention so as not to touch the glass part of the bulb.
(5) Attach the Head Tip and Head Base by screwing the Head Base clockwise.

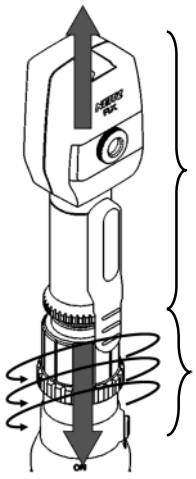


Fig. 4.2

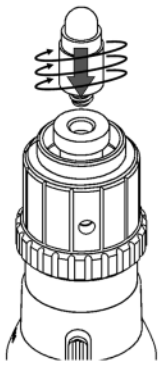


Fig. 4.3

4.4 Disposal

Dispose of the RX-RC and its accessories in accordance with your local regulations and/or environmental guidelines.

The figure to the right demonstrates that the RX-RC utilizes Nickel-cadmium rechargeable batteries which should be recycled.



5 Troubleshooting

If you experience any problems using the RX-RC, refer to the table below for possible solutions. If the problem persists, stop using the device and immediately contact your local dealer or Neitz directly.

Problem	Possible Cause	Solution
Light does not turn on	Batteries not inserted.	Insert batteries.
	Batteries not oriented correctly.	Re-insert batteries in the correct orientation.
	Batteries depleted.	Replace with new batteries.
	Lightbulb blown out.	Replace with new Lightbulb.
Streak distorted	Lightbulb filament bent.	Replace with new Lightbulb.
	Lightbulb loose	Tighten Lightbulb.
Poor illumination	Batteries low.	Replace with new batteries.
Head becomes hot	It is normal for heat to be generated during illumination. The Head may reach temperatures where it feels warm or hot to the touch.	

6 Specifications

Product Specifications

Illumination Source	L-27 Halogen Bulb (4 V, 2.6 W)
Streak Variations	Divergent streak, parallel streak, convergent streak
Streak Rotation	360° continuous rotation
Head Attachment	To prevent contact between the retinoscope and the examiner's glasses
Presbyopic Lens power	+2 D
Battery	1000RS (Nickel-cadmium rechargeable battery)
Illumination Time	Approximately 80 min.
Dimensions[*1,*2]	34 mm x 32 mm x 269 mm Approximately 580 g
Options (sold separately)	Presbyopic Lens (+1 D, +2 D, +3 D)

*1: Excluding protrusions
*2: Weight including batteries

Classification

Degree of protection against electric shock	Internally powered ME equipment
Applied parts	No applied parts
Degree of protection against harmful ingress of water or particulate matter	IPX0
Method(s) of sterilization	Do not sterilize
Suitability for use in an oxygen rich environment	Do not use in oxygen rich environments
Mode of operation	Continuous operation

Safety Standards

Electric Safety	IEC 60601-1:2005+AMD1:2012
Electromagnetic Disturbances	IEC 60601-1-2:2014
Ophthalmic Instruments	ISO 15004-1:2006
Retinoscopes	ISO 12865:2006

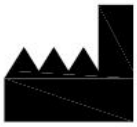
Environmental Conditions

	Use	Storage	Transport
Temperature	+10 °C to +35 °C (50 °F to 90 °F)	-10 °C to +55 °C (14 °F to 131 °F)	-10 °C to +55 °C (14 °F to 131 °F)
Relative Humidity	30 % to 90 % (no condensation)	10 % to 95 % (no condensation)	10 % to 95 % (no condensation)
Atmospheric Pressure	800 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa

7 Contact Information

If you have any questions or need technical support, contact your local dealer or Neitz located at the following address.

[LOCAL DEALER]



Neitz Instruments Co., Ltd.
4F Ichibancho Court, 15-21, Ichibancho, Chiyoda-ku
Tokyo 102-0082, Japan
Phone: +81-3-3237-0552 Fax: +81-3-3237-0554
E-mail: neitz-global@neitz.co.jp
URL: https://www.neitz.co.jp/en/

EC REP

Medical Device Safety Service GmbH
Schiffgraben 41, D-30175 Hannover, Germany

ANNEX
EMC Guidance

The RX-RC is a medical device and requires special precautions regarding EMC. Refer to the following EMC information for appropriate installation and putting into service.
Take care when using portable and mobile RF communications equipment in proximity of the RX-RC, as they can affect performance.

(1) Environments of intended use:
Professional healthcare facility environments and home healthcare environments

(2) Replaceable cables, transducers or accessories likely to affect compliance of the RX-RC with the applied EMC Standard:
N/A

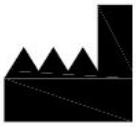
(3) Applied EMC Standard:
IEC 60601-1-2:2014
(a) Connection to the public mains network: None
(b) Applicable port(s): Enclosure Port

Electromagnetic Emissions		
Phenomenon	**Applied Standard**	**Emission Test Levels**
Conducted and radiated RF emissions	CISPR 11	Class B Group 1

Electromagnetic Immunity		
Phenomenon	**Applied Standard**	**Immunity Test Levels**
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	385 MHz – 5785 MHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

(4) Effect of electromagnetic disturbances on essential performance

Essential Performance	**Outcome if Essential Performance is Lost or Degraded**
Continuous steady illumination	Flickering illumination



Manufactured by
NEITZ INSTRUMENTS CO., LTD.
4F Ichibancho Court, 15-21, Ichibancho, Chiyoda-ku,
Tokyo 102-0082, Japan
Phone: +81-3-3237-0552 FAX: +81-3-3237-0554
E-mail: neitz-global@neitz.co.jp
URL: https://www.neitz.co.jp/en/

Distributed by

As part of our policy of continued product improvement, we reserve the right
to alter and/or amend specifications at any time without prior notice.

TD11-10890031E-5
202010
Printed in Japan