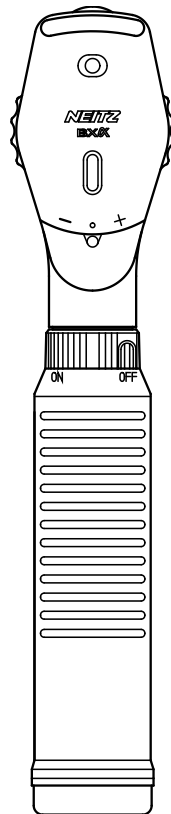


NEITZ

Ophthalmoscope BX α -RC User's Manual



Thank you for purchasing the NEITZ Ophthalmoscope BX α -RC. This is a hand-held ophthalmic device (direct ophthalmoscope) using rechargeable batteries to power a halogen lightbulb for examination of the internal areas and fundus of the eye. The BX α -RC 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
TD11-10750005E-9

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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 Ophthalmoscope BX α -RC (hereinafter referred to as “BX- α RC”) is a hand-held, battery-powered medical device containing a halogen bulb for illumination and viewing optics for examination of the media (cornea, aqueous, lens and vitreous) and fundus of the eye. Do not use this device for any purpose other than its intended use.

1.2 Symbols

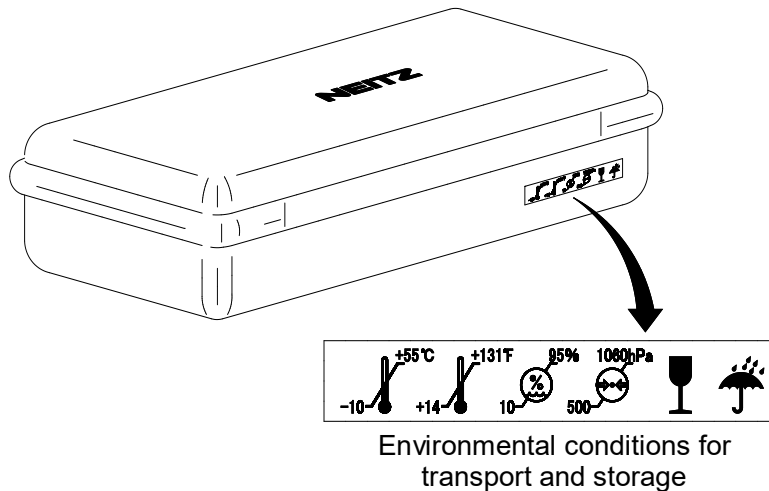
The following symbols are used on this manual and/or package to assist you in proper handling and use of the BX α -RC, and to warn and caution you of potential hazards to yourself and others.

 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 ($^{\circ}$ C) 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
	Symbol of a medical device.
	Barcode for traceability purposes
	Serial number
	Authorized representative in Europe






1.3 Labeling on Package





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

















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 to view the fundus.
 Instruction	Be sure the illumination is turned off when charging. Leaving the illumination on may prevent charging or induce excessive heat.
 Instruction	Use only batteries provided by the manufacturer. Failure to do so may result in device failure.

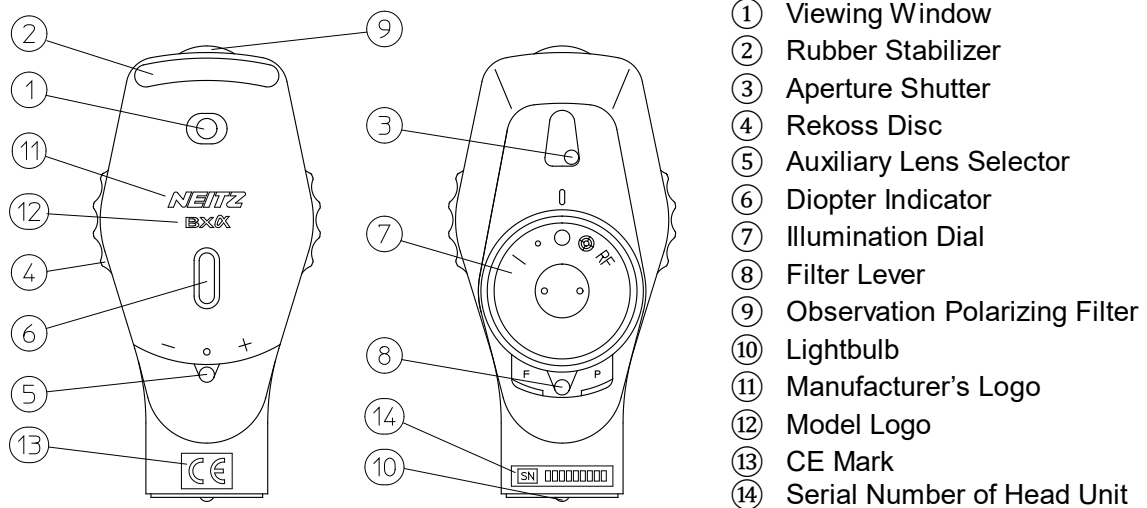
CAUTION

 Prohibited	Use of accessories other than those specified or provided by NEITZ can result in increased electromagnetic emissions or decreased electromagnetic immunity of the BX α -RC 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 BX α -RC adjacent to or stacked with other equipment. In cases where adjacent or stacked use is necessary, verify the BX α -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 BX α -RC. Otherwise, degradation of the performance of this equipment could result.
 Prohibited	Do not bring metallic objects (e.g. paper clips) in proximity of the charging port or wet the charging port.
 Instruction	Be sure the head and handle are attached firmly before use.
 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.

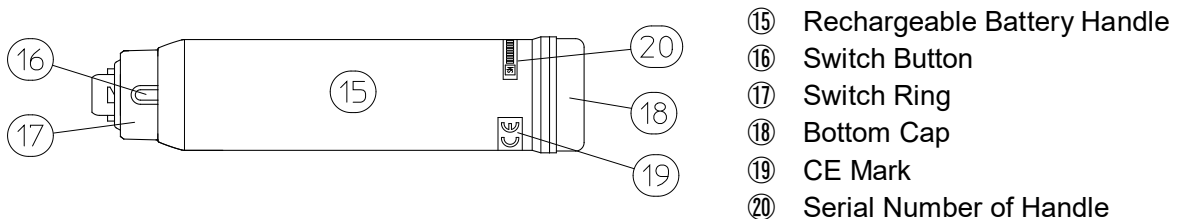
2 Package Contents and Nomenclature

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 BX α -RC and immediately contact your local dealer.

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



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



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

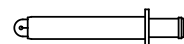
Model: 1000RS (1 pc.)

Voltage: 3.6 V

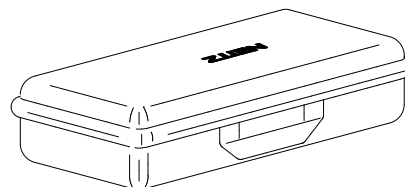


4) Spare Bulb

Type L-29 (1 pc.)




5) Carrying Case



6) User's Manual

3 Operation

3.1 Charging the BX-α RC

 WARNING	<p>Be sure the illumination is turned off when charging. Leaving the illumination on may prevent charging or induce excessive heat.</p>
---	---

Charge the BXα-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 BXα-RC into the Charging Port of the RC-II (see Fig. 3.1)

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

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

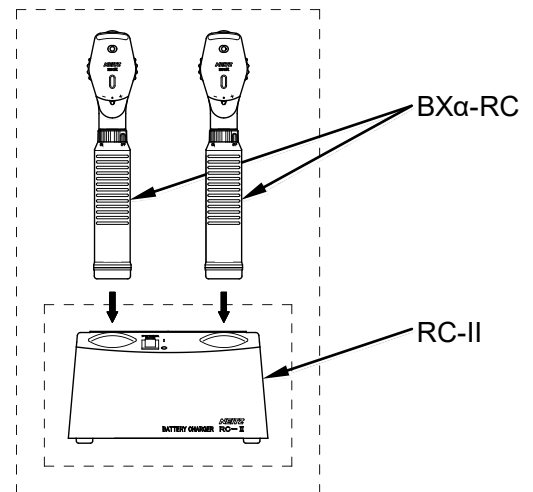


Fig. 3.1

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.

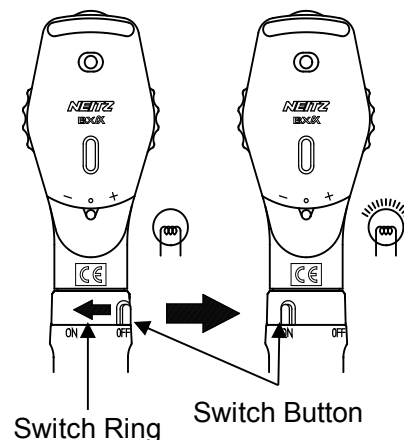


Fig. 3.2

3.3 Correction Lens and Filters

3.3.1 Rekoss Lens

The Rekoss Lens is used to adjust the diopter between the examiner and patient to bring the fundus image into focus. Use the “+” lens to correct hyperopia and “-” lens to correct myopia.

[Example]

For an examiner with myopia and a patient with hyperopia:

$$\begin{array}{ccccccc}
 -5 \text{ D} & + & +3 \text{ D} & + & -2 \text{ D} & = & -4 \text{ D} \\
 \text{Examiner's Myopia} & & \text{Patient's Hyperopia} & & \text{Accommodation Power} & &
 \end{array}$$

In the above example, it would be necessary to set the Rekoss Disc to -4 D.

However, in practice, the Rekoss Disc is rotated while observing the fundus to find the appropriate diopter.

In cases of extreme myopia or hyperopia, where the image cannot be focused by using only the ReKoss Disc, it is also possible to insert an auxiliary lens for accommodation. The following ranges may be covered depending on the position of the Auxiliary Lens Selector:

Position	Range
-	-36 D to -13 D
•	-12 D to +11 D
+	+12 D to +35 D

3.3.2 4000 K and Polarizing Filters

It is possible to insert the following filters in the illumination system using the Filter Lever:

Position	Filter	Function
O	Open	No filter is inserted in the center position
F	4000 K	A 4000 K filter is inserted into the illumination system. Use for observation with light resembling natural light (daylight).
P	Polarizing	A polarizing filter is inserted into the illumination system. Use in combination with the Observation Polarizing Filter.

3.3.3 Observation Polarizing Filter

The Observation Polarizing Filter is used when light reflected from the cornea interferes with examination.


Rotate the disc to insert a polarizing filter into the observation system. When the white mark on the disc faces up, the Observation Polarizing Filter is aligned perpendicular to the Polarizing Filter mentioned in 3.3.2, for minimum reflection.

Rotating the disc further will rotate the polarizing axis to allow for a brighter image. Adjust the disc to obtain the optimum image.


The disc will stop with a click to indicate that the Observation Polarizing Filter has been disengaged.

3.3.4 Illumination Dial

The Illumination Dial can be used to adjust the illumination entering the patient's eye as follows:

Position	Aperture/Filter	Function
○	Normal Aperture	Used for typical fundus examinations
◦	Small Aperture	Used when examining small pupils. In particular, when examining through constricted pupils such as during examination of the macula.
RF	Red-Free Filter	Red tissue such as blood vessels appear black, facilitating detection of minute fundal hemorrhages.
	Concentric Scale	While observing the patient's fundus, instruct the patient to fixate on the center of the concentric scale. It is possible to determine the presence of eccentric fixation from the relation between the center of the concentric scale and the patient's foveola.
	Slit	Using a slit illumination facilitates recognition of roughness on the surface of the fundus.

3.4 Viewing the Fundus

 WARNING	When observing the fundus, use only illumination with the least intensity necessary for visualization, and do not illuminate the patient eye for more than one minute per eye.
---	--

- (1) Open the Aperture Shutter until it clicks and turn on the illumination.
- (2) To examine the patient's right eye, hold the ophthalmoscope in your right hand and observe using your right eye. To examine the left eye, use your left hand and eye.
- (3) Place your index finger on the edge of the Rekoss Disc and grip the Handle with the remaining 4 fingers. Use your index finger to rotate the Rekoss Disc as needed.
- (4) Place the upper part of the ophthalmoscope against the side of your nose and position it so that you have a clear view when looking through the Viewing Window (see Fig. 3.3).



Fig. 3.3

- (5) While looking at a distant target, rotate the Rekoss Disc to correct your refractive error.
- (6) Sit the patient down away from ambient light and instruct the patient to focus on a distant target.
- (7) To examine the right eye, stand to the right of the patient. Placing the ophthalmoscope firmly against your face, direct the light into the patient's pupil from a distance of about 15 cm to check for the presence of a red reflex.
- (8) Paying attention not to lose sight of this red reflex, slowly move closer, with the ophthalmoscope, to the patient's face. The fundus image should become visible at a distance of about 2 cm to 3 cm (see Fig. 3.4).



Fig. 3.4

- (9) Rotate the Rekoss Disc as necessary to bring the fundus image into focus.
- (10) To examine other regions of the fundus, move both the ophthalmoscope and your face in unison. Move in an arc with the patient's pupil as the center of rotation so as to keep directing illumination into the pupil.
- (11) Turn off the illumination and close the Aperture Shutter once you are finished with the examination.

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.

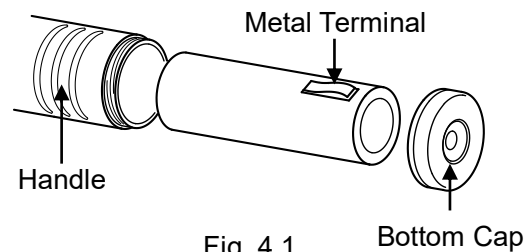



Fig. 4.1

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 BX α -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 in one hand and the Handle in the other, turn the Handle counter-clockwise to detach from the Head (see Fig. 4.2).
- (2) Remove the Lightbulb from the Head by pulling the tip which can be found at the bottom of the Head.
- (3) Check the Lightbulb, and if the filament has blown out, replace with a new bulb.
- (4) Insert the new Lightbulb until it comes to a stop. When inserting the bulb, align the protrusion on the bulb with either of the grooves located at the bottom of the Head (see Fig. 4.3). Pay close attention so as not to touch the glass part of the bulb.
- (5) Attach the Head and Handle by screwing the Handle clockwise.

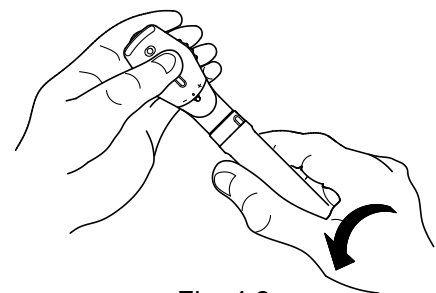


Fig. 4.2

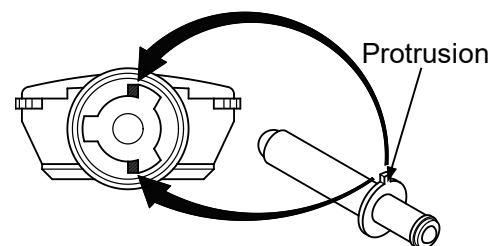


Fig. 4.3

4.4 Disposal

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

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



5 Troubleshooting

If you experience any problems using the BX α -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 (Diopter Indicator is dark)	Battery not inserted.	Insert battery.
	Battery not oriented correctly.	Re-insert battery in the correct orientation.
	Battery degraded.	Replace with new battery.
	Lightbulb blown out.	Replace with new Lightbulb.
Illumination blocked (Diopter Indicator lights up)	Illumination Dial mispositioned.	Rotate the Illumination Dial until it stops with a click.
	Filter Lever mispositioned.	Swing the Filter Lever until it stops with a click.
	Aperture Shutter shut.	Open the Aperture Shutter until it stops with a click.
Poor illumination	Battery degraded.	Replace with new batteries.
	Unintentional use of filters.	Disengage filters.
Narrow field of view	Aperture Shutter partially shut.	Open the Aperture Shutter until it stops with a click.
	Rekoss Disc mispositioned.	Rotate the Rekoss Disc until it stops with a click.
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-29 Halogen Bulb (4 V, 2.5 W)
Correction Range	-36 D to +35 D (in 1 D increments)
Filter Lever (Illumination system)	Polarizing filter, 4000 K filter
Observation Polarizing Filter	ON/OFF
Illumination Dial	Normal Aperture, Small Aperture, Slit, Concentric Scale, Red-Free filter
Battery	1000RS (Nickel-cadmium rechargeable battery)
Illumination Time	Approximately 80 min.
Dimensions and weight *1 *2	ϕ 32 mm × 223 mm Approximately 330 g

*1: Dimensions exclude protrusions.

*2: Weight includes battery.

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
Light hazard protection	Group 1

Safety Standards

Electric Safety	IEC 60601-1:2005+AMD1:2012
Electromagnetic Disturbances	IEC 60601-1-2:2014
Ophthalmic Instruments	ISO 15004-1:2006
Light Hazard	ISO 15004-2:2007
Direct Ophthalmoscopes	ISO 10942:2006

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.

In the event of any serious incident that has occurred in relation to this product, please report the incident to the manufacturer, its authorized representative in Europe shown below and to the competent authority of your country of residence.

[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/>



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

ANNEX EMC Guidance

The BX α -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 BX α -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 BX α -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

Notes:



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/>

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TD11-10750005E-9
202211
Printed in Japan