

Ophthalmoscope **BX α RCUSBLED** User's Manual



Thank you for purchasing the NEITZ Ophthalmoscope BX α RCUSBLED (hereinafter referred to as “BX α RCUSBLED”). This is a hand-held ophthalmic device (direct ophthalmoscope) using a rechargeable battery to power the LED bulb for examination of the internal areas and fundus of the eye. Please read this User's Manual carefully before use to avoid unexpected accidents and store them in a safe place for future reference.

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	6
3	Operation.....	8
3.1	Charging the BXαRCUSBLED.....	8
3.1.1	Use of the AC Adapter	8
3.1.2	Attaching the AC Adapter to BXαRCUSBLED and how to charge	9
3.1.3	Alarm when charging	10
3.2	Turning Illumination ON/OFF	10
3.3	Correction Lens and Filters.....	11
3.3.1	Rekoss Lens	11
3.3.2	Filter Disc Lever.....	11
3.3.3	Observation Polarizing Filter	11
3.3.4	Illumination Dial	12
3.4	Viewing the Fundus	12
4	Maintenance.....	14
4.1	Cleaning.....	14
4.2	Battery Unit Replacement.....	14
4.3	The LED Bulb.....	14
4.4	Disposal	14
5	Troubleshooting.....	15
6	Specifications	17
7	Contact Information.....	20
	ANNEX A	21
	ANNEX B.....	22

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 BXαRCUSBLED is a hand-held, battery-powered medical device containing an LED 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 BXαRCUSBLED, and to warn and caution you of potential hazards to yourself and others.

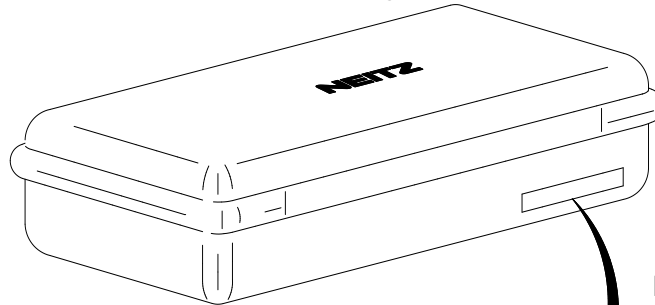
	Potentially hazardous situation which, if not avoided, could result in death or serious injury
	Potentially hazardous situation which, if not avoided may result in minor or moderate injury or property damage
 Prohibited	Prohibited actions (must not be performed)
 Instruction	Required actions (must be performed)
	Consult User's Manual for information on proper use
	Temperature limits (°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
	Manufacturer's name and address
	Symbol of a medical device.
	Serial number



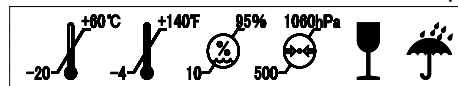
Barcode for traceability purposes (This is a sample.)

1.3 Labeling on Package

The following label has been adhered to the Outer Package of the BXαRCUSBLED 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.

[Safety Information Common to All Components]









⚠ WARNING	
 Prohibited	In case the device is left without turning it off, the temperature of the metal parts may rise. Never fail to turn off the illumination after use.
 Prohibited	When charging, do not detach the BXαLED Head. Otherwise, electric shock, fire, or device failure may occur.
 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	Do not touch the LED bulb immediately after turning off the device with bare hands as the LED bulb may be very hot. This may cause burn injury.
 Prohibited	Do not turn on the LED rechargeable battery handle without the BXαLED Head attached. Touching the electrode carelessly may cause electric shock.
 Prohibited	Never touch liquid which may have leaked from the battery. In case of contact with the eye(s), flush with clean water without rubbing, and consult a physician immediately. Failure to do so may result in serious injury, including loss of eyesight.
 Prohibited	Do not use damaged cables or cords. Doing so may cause electric shock, fire or device failure.
 Prohibited	Do not use accessories such as the AC adapter other than the ones specified by the manufacturer. Use of a foreign accessory may result in electric shock, fire or device failure.
 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, cables, cords or power outlet with wet hands. Doing so may result in electric shock.
 Instruction	Keep the illumination to the patient's eye at minimum.



⚠ CAUTION	
 Prohibited	Do not attach the existing head of BXα with the halogen bulb to the LED rechargeable battery handle. Doing so may cause device failure.
 Prohibited	Do not attach the BXαLED Head to the existing C-size or AA-size battery handle for halogen bulb head. Doing so may cause device failure.
 Prohibited	Use of accessories other than those specified or provided by the manufacturer of this device may cause device failure.
 Prohibited	Do not pull the spring attached to the tip of the Battery Unit. Doing so may cause device failure.
 Prohibited	Do not apply strong force to the device or handle it roughly. Doing so may result in injury, fire, or device failure such as damage of the LED bulb.
 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. 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 paint thinners, cleaning agents or boiling water to clean the device. Doing so may cause deformation or device failure.
 Prohibited	Do not use the device if the BXαLED Head and the LED rechargeable battery handle are attached loosely or in a backlash.
 Prohibited	Do not use accessories, spare parts, or options other than the ones specified in this manual. Use of foreign parts or accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.
 Prohibited	Do not use the device adjacent to or stacked with other equipment. In cases where adjacent or stacked use is necessary, verify the device operates normally in the actual use conditions 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 device. Otherwise, degradation of the illumination of the device could result.
 Instruction	Do not place the device on unsteady or slanted surfaces. Otherwise, the device may not provide its performance or may roll over and fail.
 Instruction	When the Pilot lamp glows yellow, charge the rechargeable battery immediately. Continuous use without charging may deteriorate the rechargeable battery or cause charging failure.

 Instruction	Unplug the AC adapter from the power outlet during long periods of disuse. Not doing so may cause fire or device failure.
 Instruction	Charge the rechargeable battery fully at least once a year even if it is not used for a long time. Otherwise, charging failure may occur.
 Instruction	When using the AC adapter, make sure no liquid or foreign matters adhere to the Type C terminal of the USB cable or to the USB socket of the Battery Unit. Such matters may cause heat generation or fire due to a short-circuit.
 Instruction	When using the AC adapter, make sure the Type C terminal of the USB cable is fully inserted in the USB socket of the Battery Unit. Otherwise, heat generation or fire may occur due to a poor electrical contact.
 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.
 Instruction	Allow the device to return to room temperature before unpacking. Not doing so may cause condensation and lead to device failure.

[Safety Information for the Power Supply]

 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 connect the power cable to an outlet with too many other devices and do not use at sites where the AC cord could get caught or be pulled. Doing so may cause injury or fire.
 Instruction	In the event of ingress of water or other liquids, unplug the AC adapter from the power outlet immediately. Failure to do so may result in electric shock, fire or device failure.
 Instruction	Heat may be generated if the USB connector is inserted into the USB Type C socket of the Battery Unit when moisture remains near the USB connector. Wipe off any moisture on the USB connector and USB Type C socket of the Battery Unit well before inserting.
 Instruction	Unplug the AC adapter from the power outlet prior to cleaning and maintenance. Failure to do so may result in electric shock.
 Instruction	Do not use the device if some dust or foreign matter adheres to the AC adapter. Otherwise, fires may occur.
 Instruction	Take care to only touch insulated parts when inserting the AC adapter into the power outlet. Failure to do so may cause electric shock or fire.

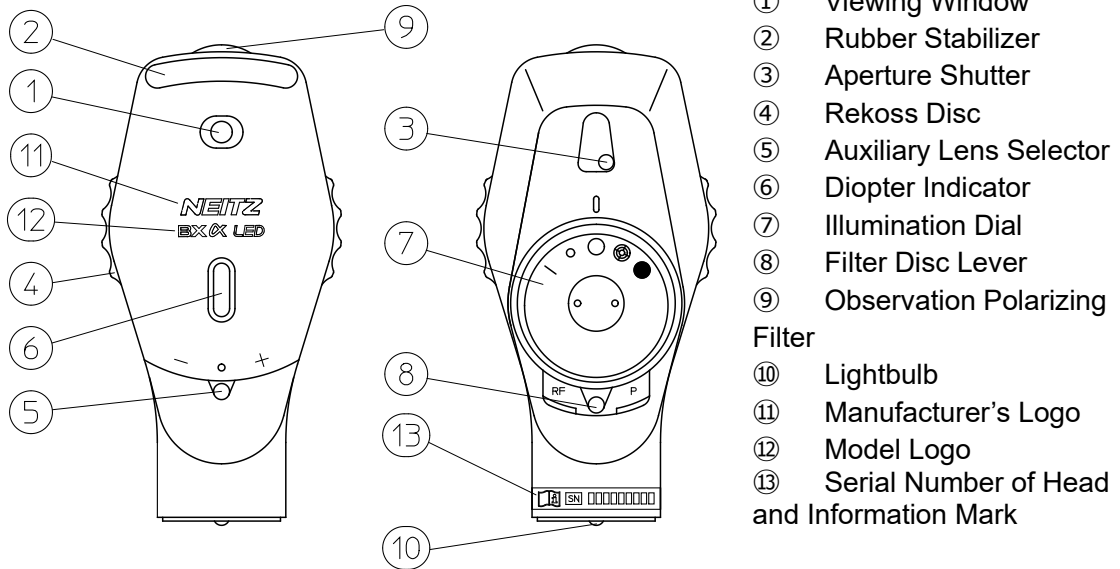
 CAUTION	
 Prohibited	Do not install the device in places where it may be difficult to unplug the AC adapter from the power outlet.
 Prohibited	Do not charge in a condition where the temperature exceeds 35°C. Otherwise, device and/or charging failure may occur.
 Prohibited	Do not strongly pull or fold the cables, cords and plugs into a small shape. This may cause breakages.
 Prohibited	Do not place heavy objects on, apply excessive tension to, or fold cables, cords and connectors. Doing so may result in damage and electric shock or fire.

 Prohibited	Do not attempt to charge a device when it is wet. Otherwise, fire, heat generation, or device failure may occur.
 Instruction	Unplug the AC adapter from the power outlet during long periods of disuse. Not doing so may cause fire or device failure.

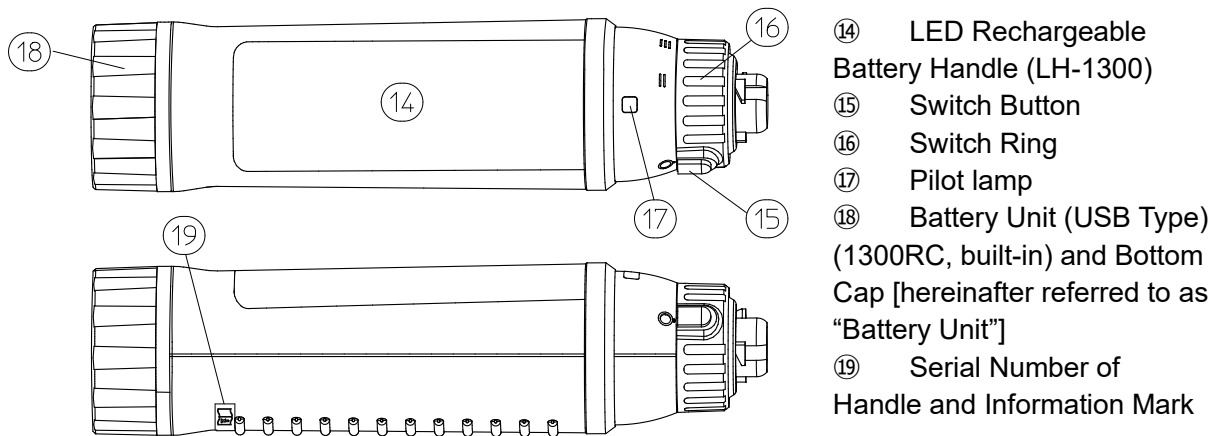
2 Package Contents and Nomenclature

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 BXαRCUSBLEd and immediately contact your local dealer.

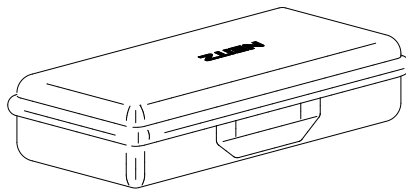
1) LED Ophthalmoscope BXαLED Head (hereinafter referred to as “Head”)



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



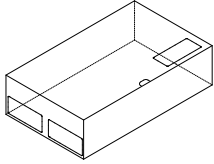
3) Carrying Case



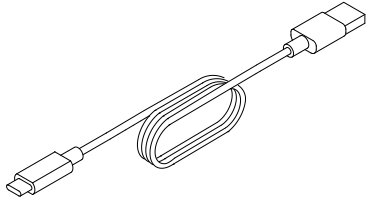
4) User's Manual



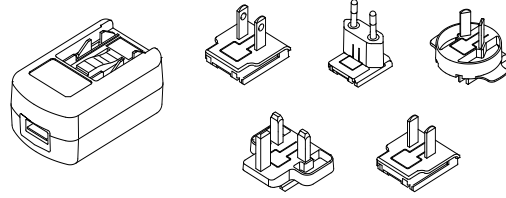
Outer Package






USB Cable (Type A ↔ Type C)












AC Adapter Set



3 Operation

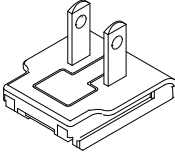
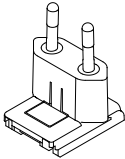
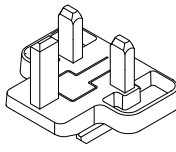
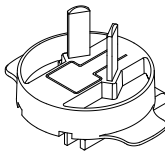
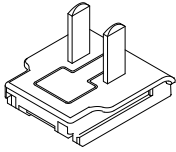
 Prohibited	Do not attach the existing head of BXα with the halogen bulb to the LED rechargeable battery handle. Doing so may cause device failure.
 Prohibited	Do not attach the BXαLED Head to the existing C-size or AA-size battery handle for halogen bulb head. Doing so may cause device failure.
 WARNING	In case the device is left without turning it off, the temperature of the metal parts may rise. Never fail to turn off the illumination after use.

3.1 Charging the BXαRCUSBLED

 WARNING	When charging, do not detach the BXαLED Head. Otherwise, electric shock, fire, or device failure may occur. *Hereinafter “BXαRCUSBLED“ means the BXαLED Head with the LED rechargeable battery handle attached.
 WARNING	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.
 WARNING	Do not charge in a high temperature condition. Doing so may result in fire, burns or device failure.
 WARNING	Do not use accessories such as the AC adapter other than the ones specified by the manufacturer. Use of a foreign accessory may result in fire or device failure.
 WARNING	Heat may be generated if the USB connector is inserted into the USB Type C socket of the Battery Unit when moisture remains near the USB connector. Wipe off any moisture on the USB connector and USB Type C socket of the Battery Unit well before inserting.
 WARNING	When charging, make sure no liquid or foreign matters adhere to the Type C terminal of the USB cable or to the USB socket of the Battery Unit. Such matters may cause heat generation or fire due to a short-circuit.
 WARNING	When charging, make sure the Type C terminal of the USB cable is fully inserted in the USB socket of the Battery Unit. Otherwise, heat generation or fire may occur due to a poor electrical contact.
 WARNING	Use the attached original AC adapter for the attached USB cable. Use of a non-original AC adapter may result in insufficient charging. Connecting the USB cable to a USB multiport hub may damage your PC. Also, the battery may be not charged due to a low voltage by doing this.
 WARNING	Use the attached AC adapter with the power plug suitable for your area. When using the AC adapter at a different voltage, refer to “3.1.1 Use of the AC Adapter” below.

3.1.1 Use of the AC Adapter

- 1) Attach one of power plugs to the AC adapter. (See below.) Five power plugs are included. Use the one suitable for your power outlet.

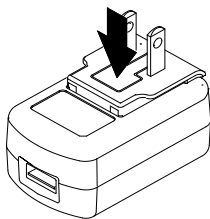
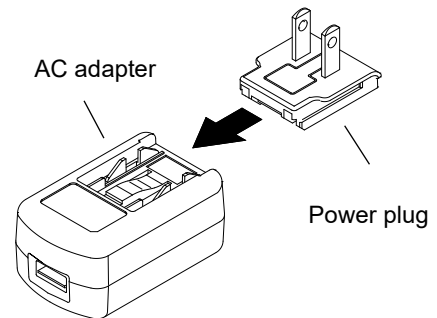
Japan and North America	European Union	United Kingdom	Australia	China
				

2) Connect the AC adapter and USB cable (Type A end). Connect the AC adapter to your power outlet.

<Attaching / detaching the power plug>

How to attach:

Align the tabs of the AC adapter and grooves of the power plug. Slide the power plug in the direction of the arrow in the illustration to attach. It has a locking mechanism. Slide the power plug until you hear a clicking sound.



How to detach:

To release the lock, depress the power plug as the arrow in the illustration shows. Keep the power plug depressed and slide it to detach.

3.1.2 Attaching the AC Adapter to BXαRCUSBLED and how to charge

1) Connect the charging USB cable (Type A) and AC adapter. Insert the AC adapter to your power outlet.

2) Insert the charging USB cable (Type C) in the USB Type C socket of the Battery Unit of BXαRCUSBLED. Charging will start automatically.

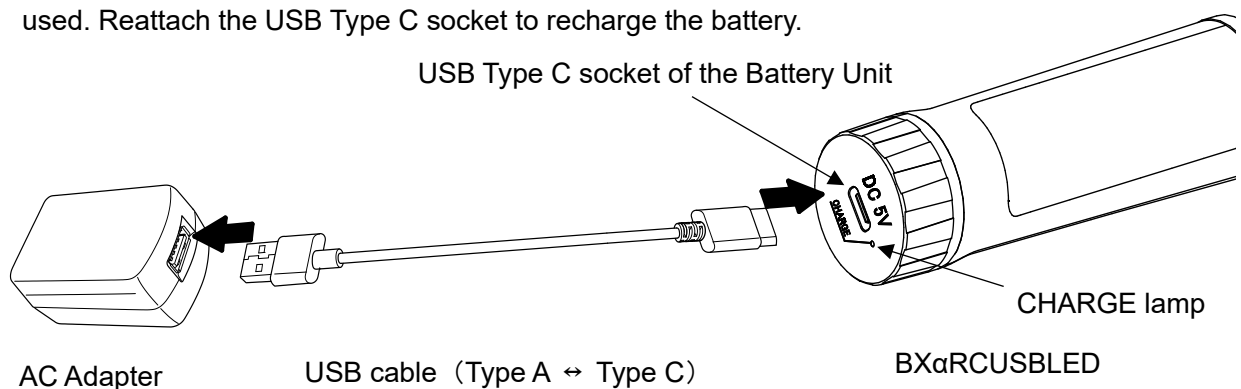
* If charging starts while the illumination is on, it is turned off automatically. The illumination will turn on again when the USB cable (Type C) and the USB Type C socket are disconnected.

3) The CHARGE lamp on the bottom cap glows blue while charging.

* To charge the battery fully will take approximately 5 hours if it is empty.

4) When charging is completed, the color of the lamp on the bottom cap will change to green.

5) After completion of charging, the battery level decreases even if BXαRCUSBLED is not used. Reattach the USB Type C socket to recharge the battery.



Note: When the USB cable is detached while charging, charging stops. Charging will resume by inserting the USB cable in the USB socket. If charging is right before the completion, the CHARGE lamp might glow green (showing completion of charging) due to the nature of the battery. However, this is not an anomaly.

3.1.3 Alarm when charging

The CHARGE lamp lights up usually blue or green. The displays below show alarms.

Alarm display	Possible cause	Solution
Blinking orange	Heat generation inside prevents charging.	Stop charging immediately and recharge after cooling. Do not charge in a condition where the temperature exceeds 35°C. If blinking orange reappears after recharging, there is a possibility of malfunction. Contact your dealer.
Yellow glow	Decreased input voltage prevents charging.	Use the original AC adapter. Connecting to a USB multiport hub may lower the voltage.

3.2 Turning Illumination ON/OFF

While pressing the Switch Button on the Handle, rotate the Switch Ring to the left (towards the = mark) to turn on the illumination on (see Fig. 3.1). The pilot lamp turns on at the same time. While rotating the Switch Ring, the illumination gets brighter. You will feel a light click at the position of =. Turning the ring further, it will stop at the position of ≡ mark.).

The Normal mode is intended for normal examination and the brightness change is modest. The Boost mode is intended for fluorescein examination using the cobalt blue filter, for example, and the brightness change of is sharp (see Fig. 3.2).

To turn off the illumination, rotate the Switch Ring fully to the right until the Switch Button returns to the O position. The pilot lamp will turn off when the device is turned off.

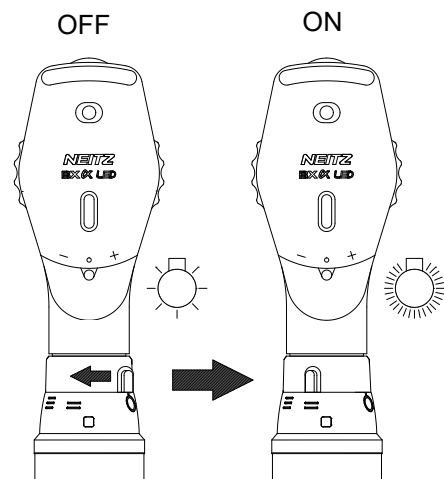


Fig. 3.1

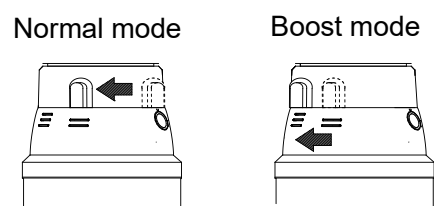


Fig. 3.2

When the level of the rechargeable battery is low, the Pilot lamp may glow green or yellow depending on the position of the Switch Ring. In such case, insert the USB cable (Type C) into the USB Type C socket of the Battery Unit to recharge the battery.

- *1. The boost effect decreases when the battery voltage is lowered (Pilot lamp glows yellow).
- *2 When the battery is fully charged, the operation duration in boost mode is approx. 5 hours.
- *3 Leaving the power of the device on will exhaust the battery. The illumination and yellow Pilot lamp will turn off when the battery is exhausted.
- *4. In case the brightness needed for use is not obtained or the Pilot lamp does not turn on, insert the USB cable (Type C) into the USB Type C socket of the Battery Unit to recharge.
- *5. The Pilot lamp glows usually green, however, the display below means an alarm.

Alarm display	Possible cause	Solution
Blinking yellow	Heat generation in the LED rechargeable battery handle.	Use in a condition of high temperature may be the cause of the heat. Turn off the device and let it cool. Then turn it on again.
Yellow glow	Low rechargeable battery voltage. (The illumination and pilot lamp will turn off when the voltage is below working voltage.)	Charge immediately. When the voltage exceeds the detectable level, the pilot lamp will glow green.

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:

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

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 Filter Disc Lever

It is possible to insert the filters below in the illumination system by the Filter Disc Lever:

Position	Filter	Function
O	Open	No filter is inserted in the center position
RF	Red-free	Red tissue such as blood vessels appear black, facilitating detection of minute fundal hemorrhages.
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 adjusts the illumination entering the patient's eye as follows:

Position	Aperture/Filter	Function
●	Cobalt blue filter	Used for fluorescein examination to observe damage on the cornea, for example.
○	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.
⊙	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	<p>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.</p>
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- (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).
- (5) While looking at a distant target, rotate the Rekoss Disc to correct your refractive error.



Fig. 3.3

- (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).
- (9) Rotate the Rekos 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.



Fig. 3.4

4 Maintenance

4.1 Cleaning

If the device becomes dirty, wipe clean with a dry, lint-free cloth.

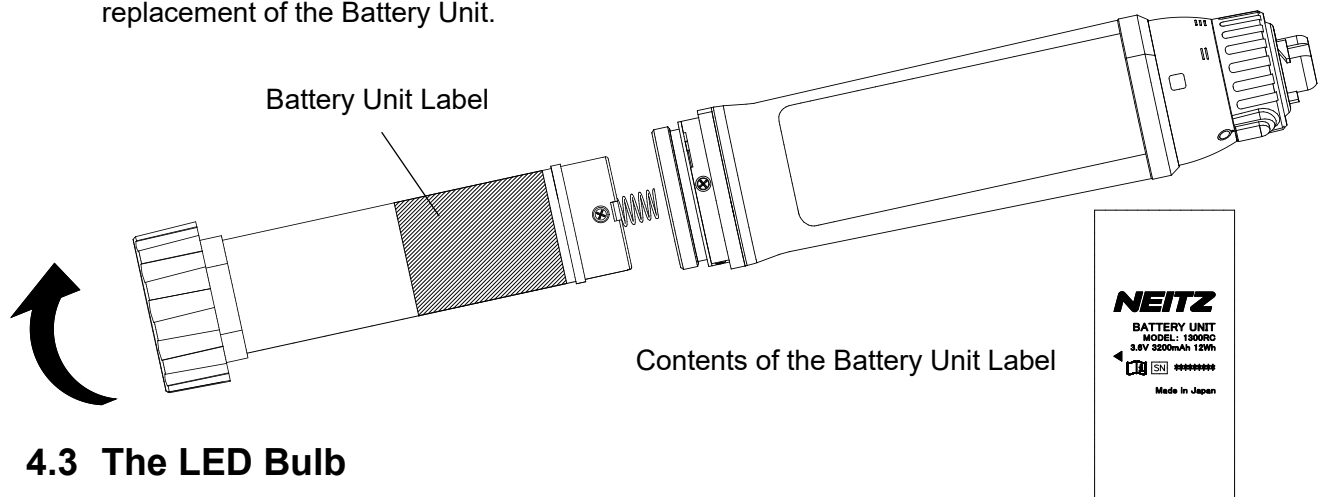
Should dirt remain, moisten with diluted neutral detergent and wipe clean. Then, wipe dry.

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 and from the USB Type C socket of the Battery Unit.

4.2 Battery Unit Replacement

The Battery Unit will degrade through repeated cycles of charging and discharging. Use of a considerably deteriorated rechargeable battery will cause much shorter illumination time. Further, the power output will be blocked by a safeguard device peculiar to a Li-ion battery. It is the lifetime end of the Li-ion battery. In such case, contact your local dealer for replacement of the Battery Unit.



4.3 The LED Bulb

 WARNING	Do not touch the LED bulb immediately after turning off the device with bare hands as the LED bulb may be very hot. This may cause burn injury.
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The BXαRCUSBLED uses an LED bulb as the light source. It does not go out as frequently as a halogen lightbulb and need to be replaced through normal use. In case the LED bulb goes out and does not light for some reason, please contact your local dealer. The LED bulb is not available as a spare part.

4.4 Disposal

Dispose of the BXαRCUSBLED and its accessories including the Battery Unit in accordance with your local regulations and/or environmental guidelines.

The symbol on the right is the recycle mark of lithium-ion rechargeable batteries.



5 Troubleshooting

If you experience any problems while using the BXαRCUSBLED, 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
Illumination does not turn on (Diopter Indicator is dark)	The Battery Unit is not inserted.	Insert the Battery Unit.
	Broken or loose LED bulb.	Contact your local dealer.
	The illumination is turned off by a drop or strong impact while the device power is on.	Turn off the device and turn it on again. In case the illumination still does not turn on, contact your local dealer.
Pilot lamp does not turn on when the Switch ring is turned.	The remaining level of the Battery Unit is insufficient.	Recharge the Battery Unit.
Illumination blocked (Diopter Indicator lights up)	Illumination Dial mispositioned.	Rotate the Illumination Dial until it stops with a click.
	Filter Disc Lever mispositioned.	Swing the Filter Disc Lever until it stops with a click.
	Aperture Shutter shut.	Open the Aperture Shutter until it stops with a click.
Poor illumination	Low battery level.	Recharge the Battery Unit.
	Unintentional use of filters.	Disengage filters.
	Disturbance by portable RF communications equipment.	Stop using the portable RF communications equipment or keep the device away from it.
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.	

Problem	Possible Cause	Solution
Charging impossible	The USB socket of Battery Unit is not properly inserted in BXαRCUSBLED.	Check the connection and insert again.
	Some foreign matter adheres to the USB socket of Battery Unit in the LED rechargeable battery handle.	Remove the foreign matter.
	In case the problem is not solved, the inside rechargeable battery may be damaged or deteriorated. Please send both BXαRCUSBLED and the USB cable for repair via your local dealer.	

The Pilot lamp blinks yellow	Heat generation in the LED rechargeable battery handle.	Use in a condition of high temperature may be the cause of the heat. Turn off the BXRUSBLED and let it cool. Then turn it on again.
The Pilot lamp glows yellow.	Low rechargeable battery voltage. (The illumination and Pilot lamp will turn off when the voltage is below working voltage.)	Charge immediately. When the voltage exceeds the detectable level, the Pilot lamp will glow green.
The CHARGE lamp is blinking orange.	Heat generation inside prevents charging.	Stop charging immediately and recharge after cooling. Do not charge in a condition where the temperature exceeds 35°C. If blinking orange reappears after recharging, there is a possibility of malfunction. Contact your dealer.
The CHARGE lamp glows yellow.	Decreased input voltage prevents charging.	Use the original AC adapter. Connecting to a USB multiport hub may lower the voltage.

6 Specifications

BXαRCUSBLED Specifications

Illumination Source	L-101 (Special LED bulb)
Correction Range	-36 D to +35 D (in increments of 1D)
Filter Disc Lever (Illumination system)	Polarizing filter, Red-free filter
Observation Polarizing Filter	ON/OFF
Illumination Dial	Normal aperture, Small aperture, Slit, Concentric scale, Cobalt blue filter
Battery	1 Lithium-ion battery (rated voltage 3.6 V, 3200 mAh)
Maximum power consumption	Below 2 W (with the head attached)
Dimensions and weight *1 *2	45 mm x 34 mm x 223 mm, Approximately 235 g

*1: Dimensions exclude protrusions. *2: Weight includes the rechargeable battery.

BXαRCUSBLED 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 (ISO 15004-2)	Group 1 (No potential light hazard exists.)

Charging Specifications

Connection	Input from public mains network: AC 100-240V / 50-60Hz, 0.3A (AC adapter)
USB cable	Type A to C, 1.5m
Voltage	DC 5V
Indicators	While charging: Blue. Charging completed: Green.
Electric power	Below 2.25W.

Standards Applied














Electric Safety	IEC 60601-1:2020
Electromagnetic Disturbances	IEC 60601-1-2:2020
Usability Engineering	IEC 62366-1:2020
Alarm System	IEC 60601-1-8:2020
Biological Evaluation	ISO 10993-1:2018
Ophthalmic Instruments	ISO 15004-1:2020
	ISO 15004-2:2024
Direct Ophthalmoscopes	ISO 10942:2022
Medical Device Software	IEC 62304:2015
Battery Regulation	2023/1542/EU
Hazardous Substances	2011/65/EU, 2015/863/EU

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)	-20 °C to +60 °C (4 °F to 140 °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

ME system (AC adapter)

(1) Symbols

	Product satisfying the safety standards in accordance with the Japanese Electrical Appliance and Material Safety Act.
	Product approved by the US Federal Communications Commission
	Product obtained the China Compulsory Certificate
	Product conforming to the UL Safety Standards (UL listed product)
	Product conforming to the safety requirements of the Australian Electrical Regulatory Authorities Council
	Product conforming to the Administrative Measure on the Control of Pollution Caused by Electronic Information Products (China RoHS)
	Product complies with the European requirements for safety, health, environment and customer protection (for the AC adapter only).
	Product complies with the applicable medical device regulations of the United Kingdom (for the AC adapter only)
	Alternating current
	Direct current
	Class II ME equipment
	Product must not be disposed of with general household waste under the WEEE directive of the European Union.
	For indoor use only

(2) Specifications of the AC adapter

1) Range of input power supply	AC100-240V / 50-60Hz 0.3A
2) Protection against electrical hazards	Class II equipment (double insulation)
3) Model and manufacturer	SMI-10-5-V-I38 by CUI Devices
4) Rated output	DC 5V / 2A
5) Output connector	USB-A receptacle
6) Weight and dimensions	60.9 x 38 x 29.2 mm / 40 g

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/>

ANNEX A About the Alarms

The LED direct ophthalmoscope BXαRCUSBLED conforms to the international alarm system standard. Grasp the meaning of the alarms of each module and of the interactions below for use.

[LED Rechargeable Battery Handle LH-1300]

Alarm category	Alarm behavior	Specifications	How to reset
Medium priority	Blinking yellow	1. Exterior temperature is 49°C or higher. 2. Inside temperature is 80°C or higher.	Turn the Switch ring to the OFF position.
Low priority	Blinking yellow	When the battery voltage is below 3.2V. (The indicator and illumination will turn off if the battery voltage falls below 3.0V.)	Charge the rechargeable battery to reset.

[Charging]

Alarm category	Alarm behavior	Specifications	How to reset
Medium priority	Blinking orange	1. The battery temperature is above 50°C. 2. The charging circuit temperature is above 70°C.	Detach the USB cable.
Low priority	Yellow glow	Low power supply voltage (below 4.2V).	Detach the USB cable.

ANNEX B

Guidance of Electromagnetic Disturbances

The BXαRCUSBLED is ME equipment requiring special precautions of electromagnetic disturbances. Refer to the following information for appropriate installation and putting into service.

- (1) Environments of intended use:
 - Professional healthcare facility environments and home healthcare environments
- (2) Designated cable: U2C-AC15NBK
- (3) Applied EMC Standard: IEC 60601-1-2:2020
 - a) Connection to the public mains network: AC 100V (50- 60Hz)
 - b) Applicable ports: Enclosure port, power port

Electromagnetic Emissions / Conforming Standard	
CISPR 11 (Conducted and radiated RF emissions)	Group 1 / Class B
	IEC 61000-3-3 (Voltage changes, voltage fluctuations and flicker emissions)

Applied Standards of Electromagnetic Immunity, Conforming Test Levels		
IEC 61000-4-2	Electrostatic discharge	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
IEC 61000-4-3	Radiated RF EM fields	10 V/m, 80 MHz – 2.7 GHz, 80 % AM at 1 kHz
IEC 61000-4-3	Proximity fields from RF wireless communications equipment	385 MHz Pulse, 18Hz 27V/m 450MHz FM modulation ±5 KHz Deviation 1 KHz sine 28V/m 710MHz Pulse, 217Hz 9V/m 733MHz Pulse, 217Hz 9V/m 745MHz Pulse, 217Hz 9V/m 780MHz Pulse, 217Hz 9V/m 810MHz Pulse, 18Hz 28V/m 830MHz Pulse, 217Hz 28V/m 870MHz Pulse, 18Hz 28V/m 907.5MHz Pulse, 217Hz 28V/m 922.5MHz Pulse, 217Hz 28V/m 930MHz Pulse, 18Hz 28V/m 1445.4MHz Pulse, 217Hz 28V/m 1720MHz Pulse, 217Hz 28V/m 1747.5MHz Pulse, 217Hz 28V/m 1845MHz Pulse, 217Hz 28V/m 1899.8MHz Pulse, 217Hz 28V/m 1950MHz Pulse, 217Hz 28V/m 1970MHz Pulse, 217Hz 28V/m 2350MHz Pulse, 217Hz 28V/m 2441.75MHz Pulse, 217Hz 28V/m

IEC 61000-4-3	Proximity fields from RF wireless communications equipment (continued)	2448.5MHz Pulse, 217Hz 28V/m 2450MHz Pulse, 217Hz 28V/m 2610MHz Pulse, 217Hz 28V/m 3400MHz Pulse, 217Hz 9V/m 3750MHz Pulse, 217Hz 9V/m 4100MHz Pulse, 217Hz 9V/m 4700MHz Pulse, 217Hz 9V/m 5240MHz Pulse, 217Hz 9V/m 5250MHz Pulse, 217Hz 9V/m 5500MHz Pulse, 217Hz 9V/m 5600MHz Pulse, 217Hz 9V/m 5785MHz Pulse, 217Hz 9V/m 6175MHz Pulse, 217Hz 9V/m 27000MHz Pulse, 217Hz 9V/m 28250MHz Pulse, 217Hz 9V/m 29500MHz Pulse, 217Hz 9V/m
IEC 61000-4-4	Electrical fast transients / bursts	± 2kV (LN in combination), repeated frequency 100 kHz
IEC 61000-4-5	Surges	Between L and N: ± 0.5 kV, ± 1 kV
IEC 61000-4-6	Conducted disturbances induced by RF fields	0.15 to 80MHz: 3V, 80 % AM at 1kHz
		ISM and amateur radio bands between 0.15 and 80 MHz: 6V, 80% AM at 1kHz
IEC 61000-4-8	Rated power frequency magnetic fields	30 A/m 50 Hz / 60 Hz
IEC 61000-4-11	Voltage dips	0 % U_T : 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°
		0 % U_T : 1 cycle and 70 % U_T : 25/30 cycles single phase: at 0°
IEC 61000-4-11	Short interruptions and voltage variations	0 % U_T : 250/300 cycles (50/60 Hz)
IEC 61000-4-39	Radiated fields in close proximity - Immunity test	30 kHz CW 8 A/m 134.2 kHz PM 2.1 kHz 65 A/m 13.56 MHz PM50 kHz 7.5 A/m

(4) Effect of electromagnetic disturbances on essential performance

Essential Performance	Outcome if Essential Performance is Lost or Degraded
Emitting the illumination light needed for the fundus examination without flickering.	Flickering illumination or no illumination.
The current consumption in the standby state is less than 40µA.	Rapid depletion of the battery.
Charging is done without problem.	Charging stops and malfunction occurs.

(5) For electromagnetic disturbances, the device has no necessary matter to keep the basic safety and maintain the essential performance during its expected lifetime.

Notes:

Notes:



**Manufactured by
NEITZ INSTRUMENTS CO., LTD.**

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