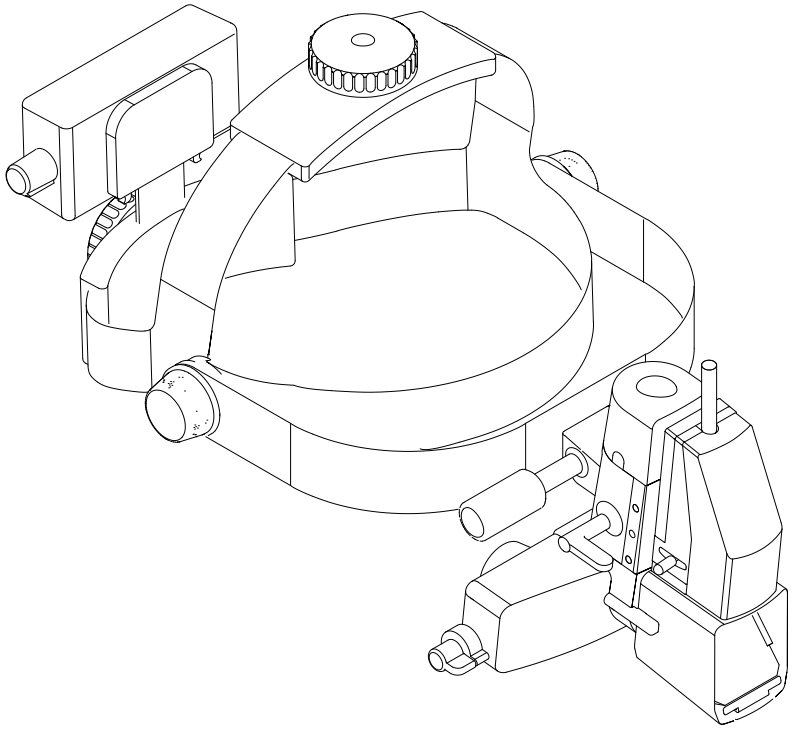
NEITZ

Binocular Indirect Ophthalmoscope

IO-α LED CAMERA

User's Manual



Thank you for purchasing the NEITZ Binocular Ophthalmoscope IO-α LED CAMERA. This is a battery-powered device to examine the inside and fundus of the eyes by illuminating with an LED bulb. The device is powered by the Battery Pack IO-BP3A which can be attached to the Headband.

Please read this User's Manual carefully before use to avoid unexpected accidents and store it in a safe place for future reference.

VIEWLIGHT
POWERED BY INNOVATION

CE

TD11-12850003E-2

Table of Contents

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 Binocular Indirect Ophthalmoscope IO-α LED CAMERA (hereinafter referred to as “IO-α CAMERA”) is a battery-powered medical device containing an LED bulb for illumination and viewing optics intended to examine the media (cornea, aqueous, lens and vitreous) and the retina 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 IO-α, 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 (°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
	Manufacturer’s name and address

	Class II ME equipment
	For indoor use only
	Certification symbols demonstrating product has passed the corresponding safety tests.
	
	
	
	
	
	
 Li-ion	Lithium-ion rechargeable battery (must be recycled)
	Barcode for traceability purposes
	Serial number
	Authorized representative in Europe
	Symbol of the Administrative Measure on the Control of Pollution Caused by Electronic Information Products (China RoHS)
	Symbol of a medical device

1.3 Safety Information

For your safety, please comply with the following precautions.

⚠WARNING	
 Prohibited	Do not connect the power cable to an outlet with too many other devices. Doing so may cause injury or fire.
 Prohibited	Do not use damaged cables or cords. Doing so may cause electric shock, fire or device failure.

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 turned on for prolonged periods or cover the device during illumination. Doing so may cause the device to reach high temperatures.
Prohibited	Never touch liquid which may have leaked from the battery pack. 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 short-circuit connectors or touch them with bare hands. Doing so may cause electric shock 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	Never remove the cover of the battery pack. Attempting to charge commercial batteries so may cause leakage of liquids, heat generation or rupturing during charging.
Prohibited	Do not touch the device with wet hands. Doing so may result in electric shock.
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	In the event of ingress of water or other liquids, unplug from the power outlet immediately. Failure to do so may result in electric shock, fire or device failure.
Instruction	Unplug the power cable from the power outlet prior to cleaning. Failure to do so may result in electric shock
Instruction	Take care to only touch insulated parts when inserting the power plug into the power outlet. Failure to do so may cause electric shock or fire.
Instruction	Do not use if dust or other foreign matter is adhered to the power plug. Doing so may result in fire.

⚠CAUTION	
Prohibited	Do not sterilize the device. Doing so may cause device deformation or failure.
Prohibited	Do not install the device in places where it may be difficult to plug in/out to/from the power outlet or to power on/off since the plug-out from the outlet is one of the separation methods between the device and the power supply
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 attempt to charge the device in temperatures exceeding 35 °C (95 °F). Doing so may prevent the device from charging or result in device failure.
Prohibited	Do not attempt to charge the device when wet. Doing so may cause excessive heating, fire or rupture.

 Prohibited	Do not pull the cables, cords, or plugs strongly. Do not fold them into a small shape. Doing so may result in failure.
 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 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	When handling the USB cable and foot switch cable, avoid the patient and her/his adjacent areas. A contact of the patient with the cables may cause an injury.
 Prohibited	Do not use the foot switch with the converter box hung in midair. The power plug may come off and cause injury.
 Prohibited	Use of the IO-α LED CAMERA adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
 Prohibited	Use of accessories, transducers and cables 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	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 IO-α LED CAMERA including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
 Instruction	Unplug from the power outlet during long periods of disuse. Not doing so may cause fire or device failure.
 Instruction	Connect the IO-α LED CAMERA only to devices conforming to IEC 62368-1.
 Instruction	Connect the IO-α LED CAMERA to your PC outside the patient environment.
 Instruction	Wear a cap or the like when equipping the IO-α LED CAMERA.
 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.
 Instruction	When disconnecting cables, be sure to hold the plug. Never pull the cable.

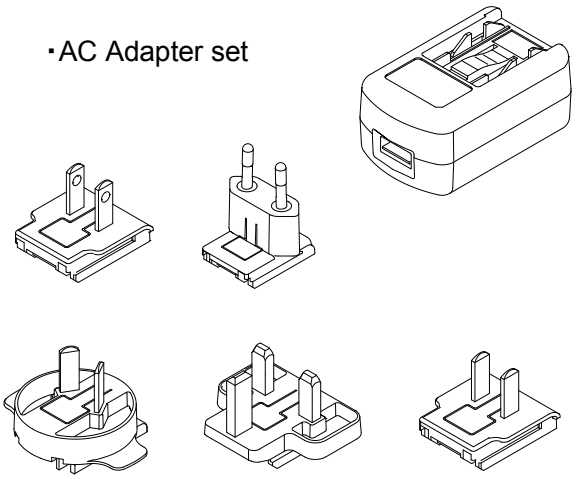
2 Checking Package Contents

2.1 Composition

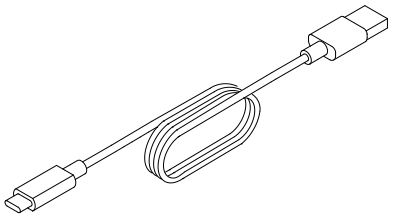
Make sure to match all items in the package with the components shown below and inspect each item for damage. Should any items be missing or damaged, do not use the IO-α LED CAMERA and contact your local dealer immediately.

- ◆ IO-α LED CAMERA (See 2.2) x1
- ◆ Battery Pack IO-BP3A (See 2.2) x1
- ◆ AC Adapter set x1
- ◆ USB Cable (Type-C).....x1
- ◆ Foot Switch.....x1
- ◆ User's Manual (this manual) x1
- ◆ Capture Software User's Manual ...x1
- ◆ Carrying Case x1

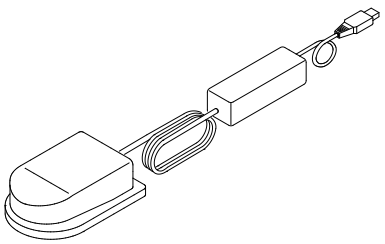
・AC Adapter set



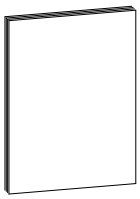
・USB Cable (Type-C）



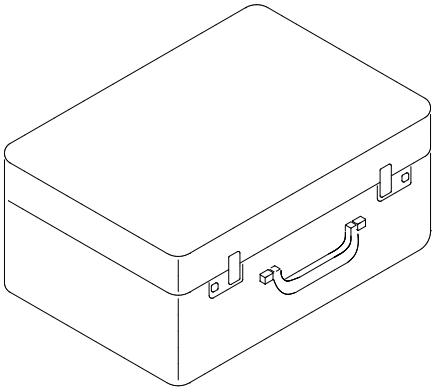
・Foot Switch



・User's Manuals
(for IO-α LED CAMERA and
for Capture Software)

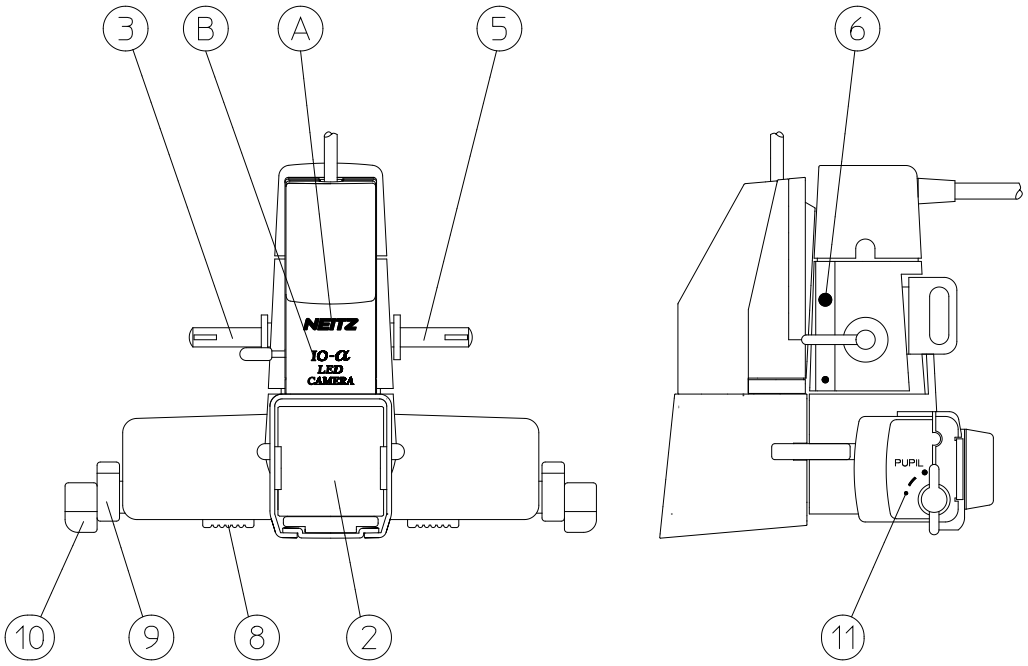


・Carrying Case

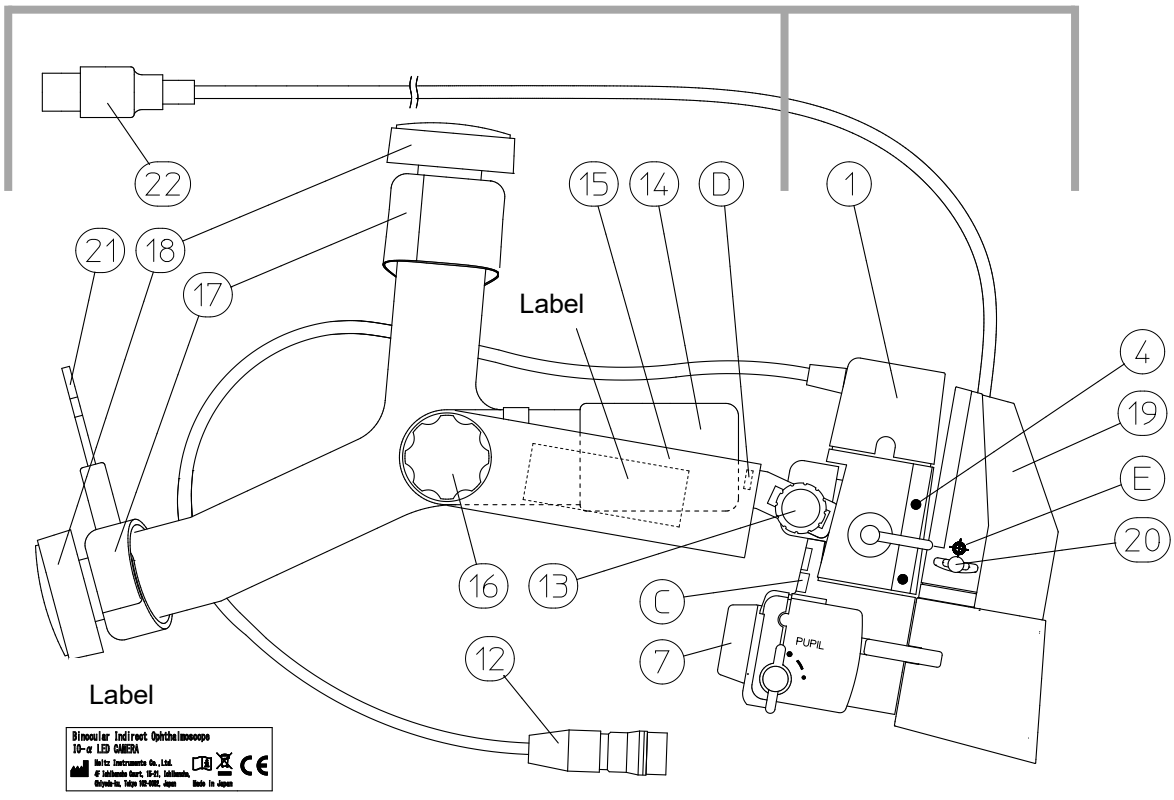


2.2 Nomenclature

2.2.1 IO-α LED CAMERA Scope Unit with Headband



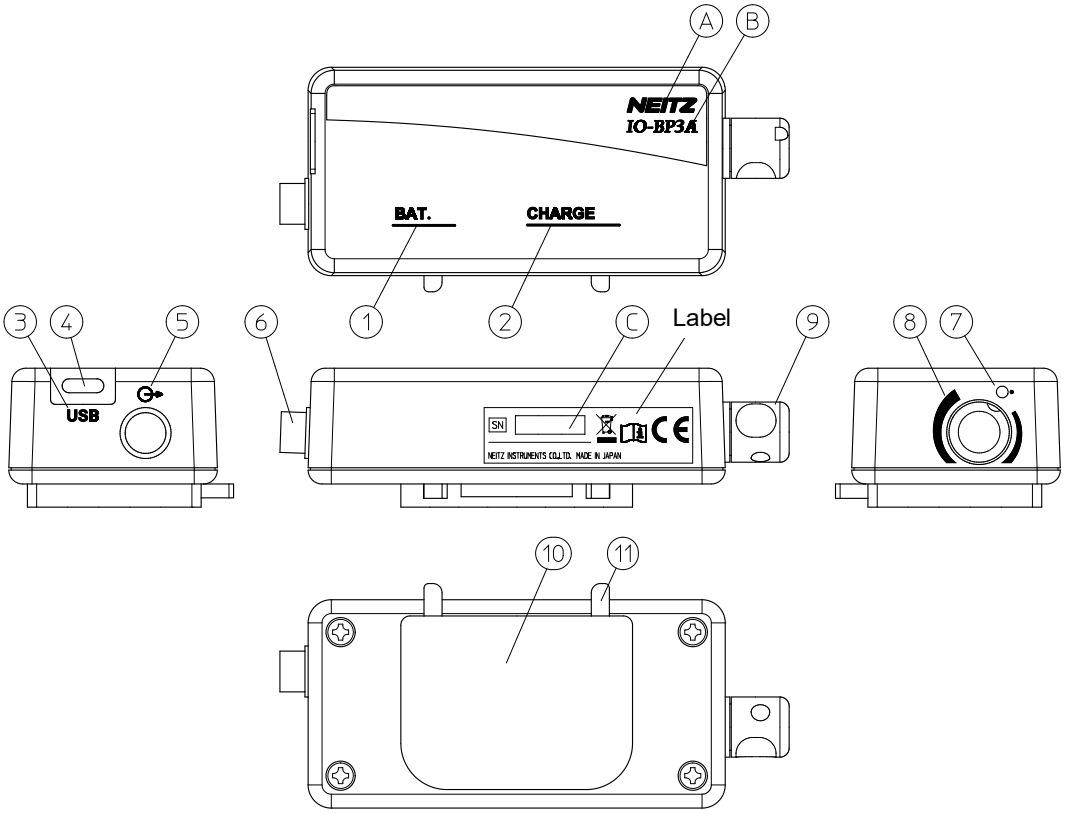
Headband **Scope Unit**



A	NEITZ	Manufacturer's logo
B	IO-α LED CAMERA	Model logo
C	SN *********	Serial number of the Scope unit
D	SN *********	Serial number of the Headband
E		Camera focus mark
1	Lamphouse	Holds the LED bulb
2	Half mirror	Makes the shooting axis and the observation axis nearly coaxial.
3	Filter selection lever	Allows for switching between "UV filter (white)", "Red-free filter (green)" and "Cobalt blue filter (blue)"
4		Filter selection marker
5	Aperture selection lever	Switches the area of the illumination field
6		Aperture selection marker
7	Eyepiece	A +2 D (diopter) lens is included
8	PD adjuster	Adjusts the pupil distance (PD). The scale (54 mm to 74 mm) is indicated above the eyepiece
9	Illumination angle adjustment lever	Adjusts the illumination angle. Levers located on both sides of the scope unit are coupled and move in conjunction.
10	Observation angle adjustment lever	Adjusts the observation angle. Levers located on both sides of the scope unit are coupled and move in conjunction.
11		Graphic display of the approximate subject pupil size.
12	Lamp plug	Connects to the Lamp jack of the IO-BP3A
13	Scope unit fixation knob	Loosen to position the Scope unit
14	Headpad	Applied to the forehead to keep the scope unit in place
15	Overband	Holds the scope unit. Can be flipped up.
16	Overband fixation knob	Loosen to flip up the Overband. Tighten to keep the Overband in place
17	Headband cover(s)	Covers the adjustment mechanics of the Headband. For your safety, do not remove.

18	Headband size adjustment knob(s)	Turn clockwise to tighten the Headband. Turn counter-clockwise to loosen the Headband.
19	Camera unit	Holds the CMOS camera
20	Focus lever	Adjusts the focus of the CMOS camera
21	Battery pack fixation prong	Inserted into the Connector attachment to hold the battery pack
22	Camera USB cable	Outputs the camera image to the PC connected

2.2.2 IO-BP3A



A	NEITZ	Manufacturer's logo
B	IO-BP3A	Model logo
C	SN *********	Serial number of the IO-BP3A
1	BAT.	Battery indicator: The color of the LED in the right of this symbol shows the remaining battery amount.
2	CHARGE	Charge lamp: The color of the LED in the right of this symbol shows the status of the battery charging.
3	USB	Symbol showing the charging input port of the battery pack.
4	Charging input port	Charging input port of the battery pack with a protective cap. Accepts a USB Type-C connector.
5		Symbol showing the output port (power supply) from the battery pack.
6	Output connector	Output connector from the battery pack. It supplies the power when connected to a suitable device.
7		Symbol for the ON / OFF position of the output from the battery pack.
8		Symbol showing the output kevel from the battery pack. The thicker line shows the higher output level.

9	Output switch	Turns on and off the output from the battery pack. By turning the switch, the output level will be adjusted steplessly.
10	Connector attachment	Used to attach the battery pack to the Headband.
11	Fixation release	Used to detach the battery pack from the Headband.

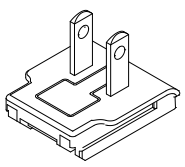
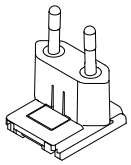
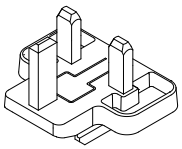
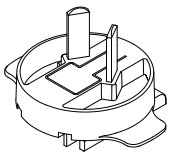
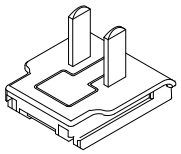
3 Operation

3.1 Preparation

3.1.1 Charging the IO-BP3A

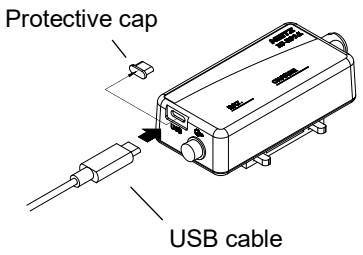
⚠ WARNING	Never remove the cover of the battery pack. Attempting to charge commercial batteries may cause leakage of liquids, heat generation or explosion during charging.

(1) Attach one of the enclosed power plugs to the AC adapter (See “Attaching / detaching the power plug” below.) Several power plugs are enclosed. Choose the suitable one.

Japan, North America	European Union	United Kingdom	Australia	China
				

(2) Connect the AC adaptor and the Type-A terminal of the USB cable. Connect it to the AC power outlet.

(3) Detach the protective cap from the charging input port of the battery pack and connect the Type-C terminal of the USB cable. The charge lamp will light orange and charging will start.



(4) Once the battery pack is fully charged, the charge lamp will light green. The charging time is approximately 2 hours if the battery pack is fully discharged. Please note the battery pack does not output while charging.

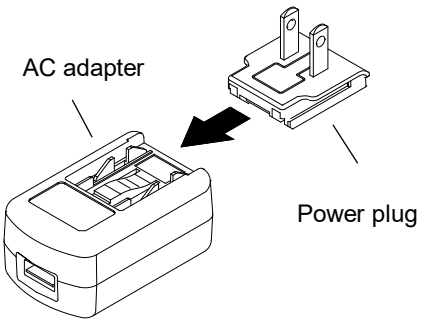
(5) When charging is completed, unplug the AC adapter power plug from the AC power outlet. Detach the USB cable from the battery pack.

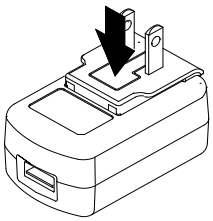
(6) To prevent ingress of foreign matters, cover the charging input port with the protective cap when the battery pack is not charged.

<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.

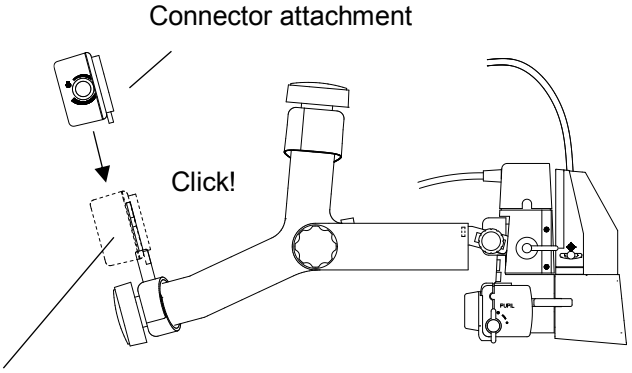
3.1.2 Attaching the IO-BP3A

(1) The battery pack can be attached to and detached from the Headband as follows.

<Attaching the IO-BP3A>

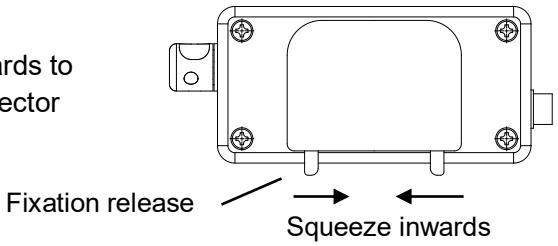
Insert the Connector attachment on the IO-BP3A into the Battery pack fixation prong on the Headband.

*Note: Be sure to insert the prong properly until the Fixation prong releases click.



<Detaching the IO-BP3A>

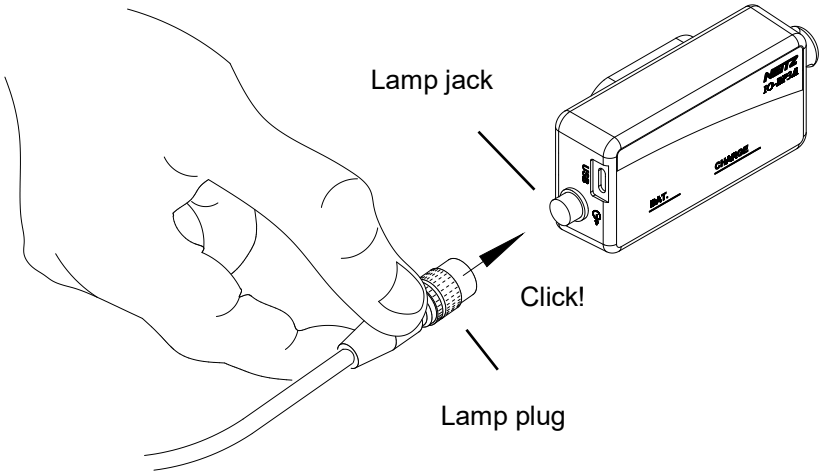
Squeeze the two Fixation releases inwards to release the Battery pack from the Connector attachment.



(2) Connecting the IO-BP3A to the Scope unit

A) Holding the **black rubber** portion, insert the Lamp plug into the Lamp jack. Make sure metal rings on the plug and jack interlock with a click.

*Note: The plug and jack interlock at a single configuration. Rotate the plug as needed to connect smoothly.



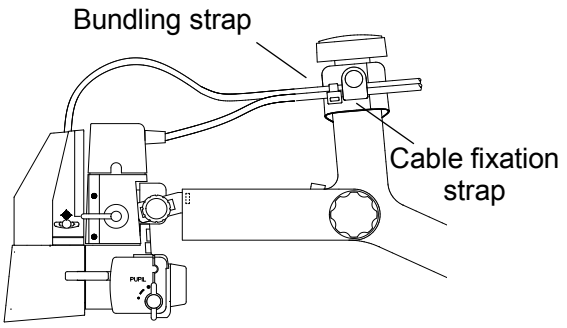
B) Gently pull the **metal ring** on the Lamp plug to disconnect from the IO-BP3A.
*Note: The cord will not disconnect by simply turning the metal ring.

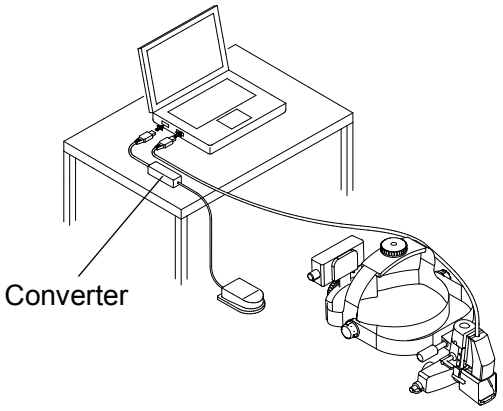
3.1.3 Connecting to the PC

⚠ WARNING	Connect the IO-α LED CAMERA only to devices conforming to IEC 62368-1.
⚠ WARNING	Do not connect the IO-α LED CAMERA to the PC within the patient environment (1.5 m from the patient)

Make sure to install the “Capture Software for NEITZ” (hereinafter referred to as “Capture Software”) beforehand. Refer to the Capture Software User’s Manual for further information concerning installation and use.

(1) Start up the computer with Capture Software installed
(2) Connect the Camera unit to the computer using the Camera USB Cable.
To reduce tension on the cables, fixate the cables with the Cable fixation strap on the Headband. Be sure the Bundling strap comes in front of the Cable fixation strap

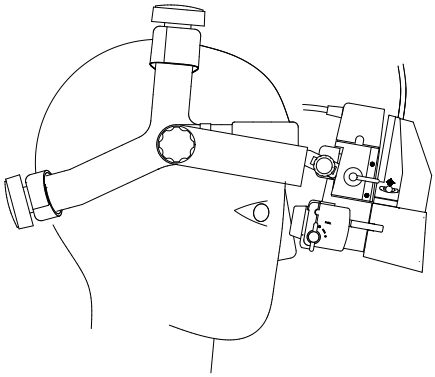




(3) When using the Foot switch, connect the Foot switch to the PC using its USB cable.
*Note: Make sure the Converter is stably mounted on the table.
(4) To record sound, connect a microphone to the computer.
If your computer has a built-in microphone, you can use it to record sound.
(5) Run the Capture Software.
*Note: Make sure to connect the IO-α LED CAMERA to the PC prior to running the Capture Software.
(6) Configure settings in accordance with the Capture Software User’s Manual.

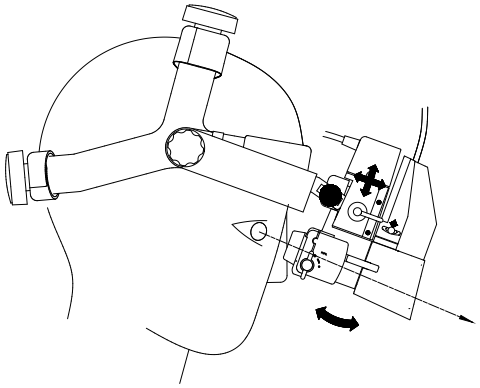
3.2 Operation

3.2.1 Wearing the IO-α LED CAMERA



(1) Loosen the Headband by turning the Headband size adjustment knobs located at the top and rear of the Headband counter-clockwise and position the Headband so that it comes into contact with the forehead.
(2) Turn the rear Headband size adjustment knob clockwise to tighten and keep the Headband in place. It is advised to lower the rear portion of the Headband to increase stability.
(3) Turn the top Headband size adjustment knob clockwise to adjust the height.

3.2.2 Positioning the Scope Unit



(1) Loosen the Scope unit fixation knob by turning counter-clockwise. Be sure to keep hold of the Scope unit while loosening, as the Scope unit may suddenly tilt.
(2) Move the Scope unit and tighten the Scope unit fixation knob to fix in the position with the best view when observed through the eyepieces

3.2.3 PD Adjustment

(1) Turn the Observation angle adjustment lever upward to fully spread the angle of observation (symbol on the device ● → ●).
(2) Focusing on an object (such as a thumb) approximately 400 mm from the Scope unit, move each eyepiece one at a time by sliding the PD adjuster so that the object is centered in the field of view.

3.2.4 Illumination

(1) Turn the Illumination switch (○) clockwise from the OFF position to turn the illumination on. Illumination intensity will increase as the switch is turned.
(2) Choose the desired field of illumination using the Aperture selection lever. Illumination field diameters of 19 mm, 39 mm or 60 mm at 500 mm can be selected.
(3) Rotate the Filter selection lever to choose between the 3 available filters below:

Marker	Filter	Use
White	UV	Normal use. Filter will not alter the color tone
Green	Red-free	Blood will appear dark, facilitating recognition of blood vessels or hemorrhages.
Blue	Cobalt Blue	Used in conjunction with fluorescein

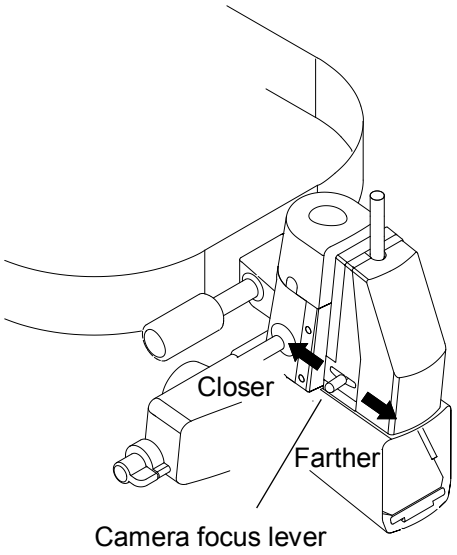
The color of the Battery lamp will change according to the amount of the remaining battery power as in the table below.

Color	Condition of Battery Pack and Necessary Actions
Green	Battery operational. Continue use
Orange	Little battery power remaining. Charge immediately
Unlit	Battery fully discharged. Charge immediately

3.2.5 Adjusting Camera Focus

Slide the Camera focus lever while viewing the PC display to adjust the camera focus. It is recommended to seek the aid of an assistant, however, in cases where that may be difficult, adjust the focus simulating the working distance beforehand.

Pull the lever closer to your body to bring focus closer; push the lever away from your body to bring focus farther.



3.2.6 Examination

⚠ WARNING	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.

(1) Holding an aspherical lens in one hand, direct the illumination into the patient eye. It is recommended to place the unoccupied fingers of the hand holding the aspherical lens on the patient's face for stability.

(2) Bring the aspherical lens close to the patient eye and gradually move away from the eye until a clear image of the fundus is obtained.

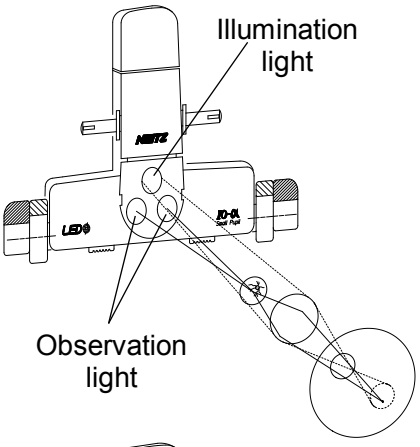
*Note: The distance between the patient eye and aspherical lens is dependent on the optical power (diopter, 1 D = 1 / focal distance in meters) of the aspherical lens.

Optical power	Description of the image
14 D to 16 D	High magnification, bright image, narrow field of view
20 D	Typically used in standard examinations
28 D to 30 D	Low magnification, dim image, wide field of view

The illumination system and observation system can be configured as follows to optimize examination

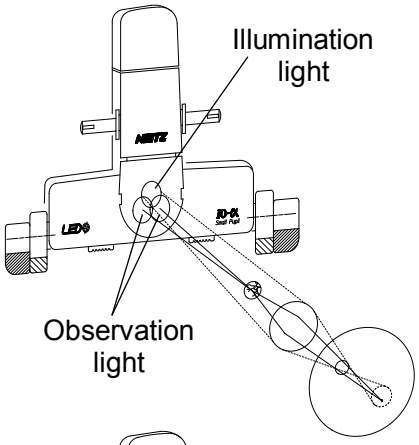
<Examining large pupils>

When examining the fundus through large pupils, raise both the Illumination angle adjustment lever and Observation angle adjustment lever. The illumination axis and observation axes are distanced, allowing for better stereoscopic vision with reduced glare.



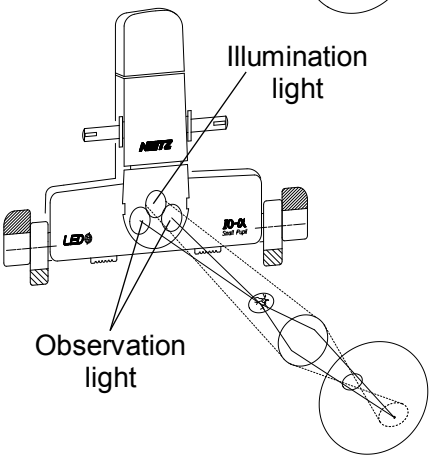
<Examining small pupils>

When examining the fundus through small pupils, lower both the Illumination angle adjustment lever and Observation angle adjustment lever. The illumination axis and observation axes come closer, allowing for easier concentration of light into the pupil.



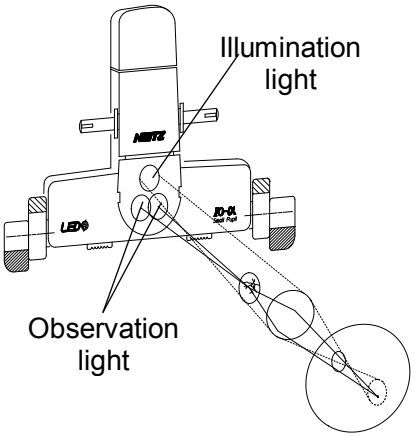
<Examining horizontally elliptical pupils>

When examining the fundus through horizontally elliptical pupils, lower the Illumination angle adjustment lever and raise the Observation angle adjustment lever. The illumination axis will come closer the observation axes while the observation axes remain apart.



<Examining vertically elliptical pupils>

When examining the fundus through vertically elliptical pupils, raise the Illumination angle adjustment lever and lower the Observation angle adjustment lever. The illumination axis will remain apart while the observation axes come closer.



(3) Reflection off the cornea or front or back side of the aspherical lens may interfere during examination. In such cases, tilt the lens slightly to offset the reflection for better observation of the fundus.
(4) Use a scleral depressor to depress the eye for examination of the peripheral retina.

3.2.7 Image Capturing and Recording

Refer to the User's Manual of the Capture Software for instructions on image capturing and recording.

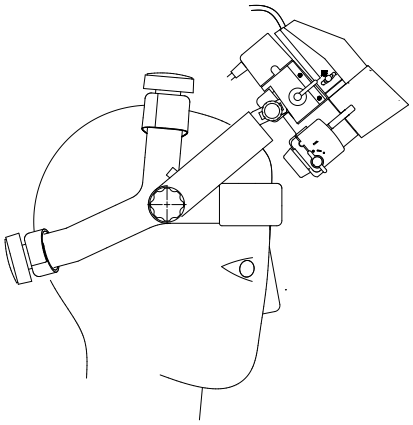
3.2.8 Turning Illumination Off

Turn the Illumination switch to the OFF position ( ) to turn the illumination off.
Make sure the device is turned off by checking that the Battery lamp is unlit.

3.2.9 Flipping the Overband Up

⚠ **WARNING**	Be sure not to loosen the Overband fixation knob too much. Doing so may free the knob and cause the Scope unit to drop.
⚠ **WARNING**	Be sure to tighten the Overband fixation knob firmly after flipping the Overband up. Failure to do so may cause the Scope unit to fall down.

(1) Turn the Overband fixation knobs on both sides of the Headband counter-clockwise to loosen and flip the Headband up.
(2) Turn the Overband fixation knobs clockwise to tighten the knobs to keep the Scope unit fixed in a position where it is out of the line of sight.



4 Maintenance

⚠ WARNING	Unplug the power cable from the power outlet prior to cleaning. Failure to do so may result in electric shock
⚠ WARNING	Do not short-circuit connectors or touch them with bare hands. Doing so may cause electric shock or device failure.

4.1 Cleaning

4.1.1 Cleaning the Optics

If dust or other foreign matter should adhere to the optical glass such as the half mirror or eyepiece, remove with an air blower or the like. If the foreign matter cannot be removed with an air blower, wipe gently using diluted neutral detergent and then wipe dry.

4.1.2 Cleaning the Headpad

When the Headpads of the Headband become dirty, detach from the Headband and hand-wash with diluted neutral detergent and then dry completely.

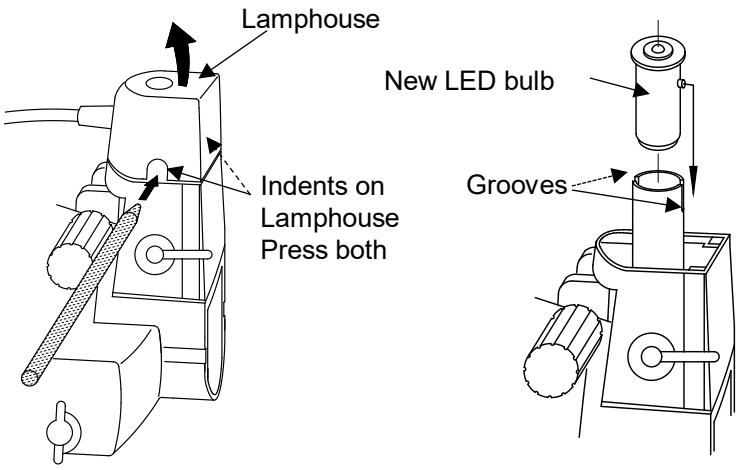
4.1.3 Cleaning Other Exterior Parts

Wipe the surface using a dry lint-free cloth or cloth moistened with diluted neutral detergent and then wipe dry. Use a soft cloth moistened with ethanol to disinfect.

4.2 Replacing the LED Bulb

As LED bulbs have a long lifetime, replacement is generally not necessary. However, should the need arise, follow the directions below to replace the LED bulb.

(1) Confirm the illumination is turned OFF and disconnect the battery pack.
(2) Using a thin stick such as the tip of a pencil, press the indented tabs located on each side of the Lamphouse to remove the Lamphouse cover.
(3) Remove the old LED bulb and replace with a new one. When inserting the LED bulb, be sure to align the protrusion on the side of the bulb with either groove on the socket.
(4) Shut the cover of the Lamphouse until it shuts with a click
(5) Turn the illumination on for confirmation.



4.3 Replacing the IO-BP3A

⚠ WARNING	Never remove the cover of the battery pack. Attempting to charge commercial batteries so may cause leakage of liquids, heat generation or rupturing during charging.

Rechargeable batteries degrade through repeated charging and discharging cycles. Degraded batteries experience shortened illumination times and eventually will cease to operate. If such events should occur, contact your local dealer to purchase a new battery pack.

4.4 Disposal

Dispose of the IO-α LED CAMERA and its accessories (excluding the IO-BP3A) in accordance with your local regulations and/or environmental guidelines.

The IO-BP3A incorporates rechargeable batteries which contain precious resources that can be reused. Recycle used rechargeable batteries in accordance with your local rules, regulations and guidelines.
The symbol shown to the right means “This product can be recycled” with text to indicate the material used, lithium-ion.

5 Troubleshooting

If you experience any problems using the IO-α LED CAMERA, refer to the chart below for possible solutions. If the problem cannot be solved, stop using and immediately contact your local dealer or Neitz directly.

Problem	Possible Cause	Solution
Capture Software does not recognize the camera.	The camera is not connected to your PC.	Connect the USB cable of the camera to the PC.
No image displayed	Some PCs may supply no or insufficient electric power.	Use a PC with sufficient power supplying capability.
Low image tracking	Insufficient light	Increase light intensity
Camera image blurry or distorted	Foreign matter is adhered to the half mirror	Clean in accordance with 4.1.1
Illumination does not light	Incorrect cable connection	Correct the connection
	Battery empty	Charge the battery pack
	The USB cable for battery pack charging is inserted	Remove the USB cable.
	LED bulb degraded	Replace with a new bulb in accordance with **4.2**
Illumination dark	Improper Illumination switch position	Adjust the Illumination switch
	Insufficient charging	Charge the battery pack
	LED bulb degraded	Replace with a new bulb in accordance with **4.2**
Illumination flickers	Insufficient battery power	Charge the battery pack
Non-uniform illumination	Foreign matter is adhered to the half mirror	Clean in accordance with **4.1.1**
	Aperture selection lever or Filter selection lever is mispositioned	Move the lever(s) until you feel a click
Observation image blurry	Foreign matter is adhered to the eyepiece or observation system	Clean in accordance with **4.1.1**
	Foreign matter is adhered to the aspherical lens	Clean aspherical lens
Cannot charge	The USB cable for battery pack charging is not fully plugged in	Plug in all the way
	The battery pack degraded	Replace the battery pack in accordance with **4.3**
Cannot charge despite AC adapter properly connected	Ambient temperature too high (a sensor is incorporated to detect high temperature)	Charge under the conditions specified in Section **6**
Reduced illumination time when fully charged	The battery pack degraded	Replace the battery pack in accordance with **4.3**
The battery pack becomes hot during charging	Heat occurring during charging is normal. The temperature of the battery pack may rise to temperatures which may feel slightly hot to the touch.	
Headband size loosens	Wear of the Headband size adjustment knob	Tighten the screw in the center of the knob.
Headband size fixation is loose	If the Headband size adjustment knob feels loose, tighten the screw in the center of the knob.	

6 Specifications

Product Specifications

Binocular Indirect Ophthalmoscope		
Illumination Source		Warm White LED
Filters		UV, Red-free, Cobalt Blue
Illumination Field Diameter[*1]		19 mm / 39 mm / 60 mm
Maximum Illuminance[*1]		Approximately 600 lx (using the UV filter)
PD Adjustment Range		54 mm to 74 mm
Minimum Pupil Diameter		2 mm
Continuous Illumination Time[*2]		Approximately 5 hours at maximum intensity (reference value)
Incorporated Rechargeable Battery		Rechargeable lithium-ion batteries (3.7V)
Charging Time[*2, *3]		Approximately 2 hours (reference value)
Dimensions	Scope Unit[*4]	164 mm x 116.5 mm x 102.5 mm Approximately 730 g
	Headband Circumference	Approximately 520 mm to 640 mm
	Battery Pack[*5]	90 mm x 45 mm x 30 mm Approximately 90 g
Camera Unit		
Sensor		2.13 mega pixels 1945 (H) x 1097 (V) pixels CMOS sensor
Shooting range		Approximately 250 mm to 550 mm from front of the Scope unit
Transfer method		Progressive
Shutter system		Rolling shutter
Output image format and maximum frame rate		MJPEG / 30 fps
Sensitivity		1300 mV at 30 fps (standard value: F5.6)
Driver		Not needed. USB Video Class (UVC) compatible
Interface		USB 2.0 Mini B
Main IPS functions		Adjustment: exposure (auto & manual), color temperature (auto & manual), gain, saturation, sharpness, and gamma correction
Power supply		Power supply voltage 5.0 V (USB bus power) Maximum power consumption approximately 200 mA
Camera properties		Brightness, contrast, hue, vividness, definition, gamma, gain, white balance, backlight correction
AC Adaptor		
Model		SMI10-5-V-I38
Power Input	Voltage	AC 100 V to 240 V
	Current	0.3 A
	Frequency	50 Hz to 60 Hz
Power Output	Voltage	DC 5 V
	Current	2..0 A

*1: Measured at 500 mm distance
*2: The time until the illumination goes out when using new batteries.
*3: Reference values for new rechargeable batteries. The values may vary depending on the use conditions.
*4: Excluding Headband
*5: Excluding protrusions

Classification

Degree of protection against electric shock	Internally powered equipment
Applied parts	No applied parts
Degree of protection against harmful ingress of water or particulate matter	IPX0 (The foot switch is IP28 excluding control box)
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
ME system	When the AC adapter is connected, the charging mode will start and no illumination will turn up.

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

Environmental Conditions

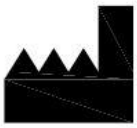
	Use	Storage	Transport
Temperature	+10 °C to +35 °C (50 °F to 90 °F)	-10 °C to +55 °C (14 °F to 131 °F)	-10 °C to +55 °C (14 °F to 131 °F)
Relative Humidity	30 % to 90 % (no condensation)	10 % to 95 % (no condensation)	10 % to 95 % (no condensation)
Atmospheric Pressure	800 hPa to 1060 hPa	500 hPa to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

EC REP

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

ANNEX A
Protection from Optical Hazards

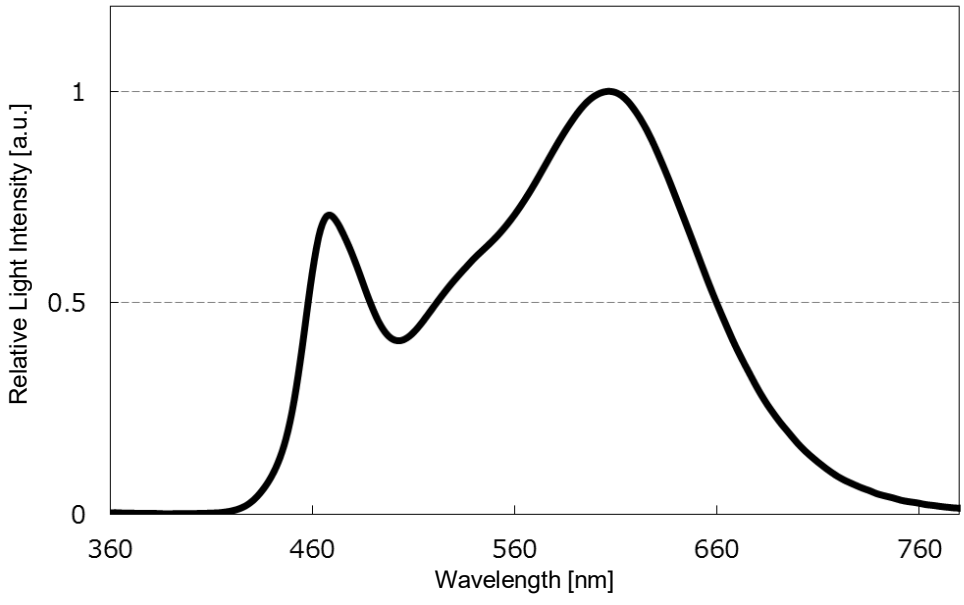
⚠CAUTION	**The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 7 minutes.**

The figure below shows the relative optical output when the device is operated at maximum light intensity at the largest aperture. The figure represents wavelengths from 360 nm to 780 nm, as the LED light source does not emit radiation in the infrared or ultraviolet range.

*The results of evaluation according to ISO 15004-2 “Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection” indicates that the IO-α LED CAMERA is classified to be Group 2 (and ophthalmic instrument for which a potential light hazard exists). Therefore, an indicator that shows that latent optical hazards could arise in relation to the ophthalmic instruments used by the operator is shown. However, this does not determine usage threshold values.

*The above-mentioned optical exposure time means the cumulative time over one day for one eye and this is inversely proportionate to the light intensity applied to the eye. Accordingly, if, for example, half of the maximum light intensity is used, the exposure time to reach latent optical hazard level is twice (approximately 14 minutes) that of when maximum intensity is used.

*Evaluations were taken using a 20 D aspherical lens with a diameter of approximately 49 mm. Results may vary depending on the actual condensing lens used during use of the device.



ANNEX B
EMC Guidance

The IO-α LED CAMERA 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 IO-α LED CAMERA, as they can affect performance.

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

(2) Designated cable: U2C-AC20NBK

(3) Applied EMC Standard: IEC 60601-1-2: 2014

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	Contact: ± 8 kV Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV
Radiated RF EM fields	IEC 61000-4-3	10 V/m, 80 MHz to 2.7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	385 MHz to 5785 MHz
Electrical fast transients / bursts	IEC 61000-4-4	AC power supply: ± 1 kV, ± 2 kV (100 kHz)
Surges	IEC 61000-4-5	Line-to-line: ± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	0.15 MHz to 80 MHz: 3 V ISM and amateur radio bands between 0.15 MHz and 80 MHz: 6 V 80 % AM at 1 kHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Voltage dips, short interruptions and voltage variations	IEC 61000-4-11	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°
		0 % U_T: 250/300 cycles (50/60 Hz)
Note: U_T is the AC mains voltage prior to application of the test level		

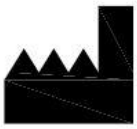
(4) Essential Performance of the IO-α LED CAMERA

No.	Essential Performance	Outcome if essential performance is lost or degraded
1	Uninterrupted charging	Battery lamp remains orange
2	Continuous steady illumination	Flickering illumination
3	Uninterrupted image output	Interrupted image

Notes:

Notes:

Notes:



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