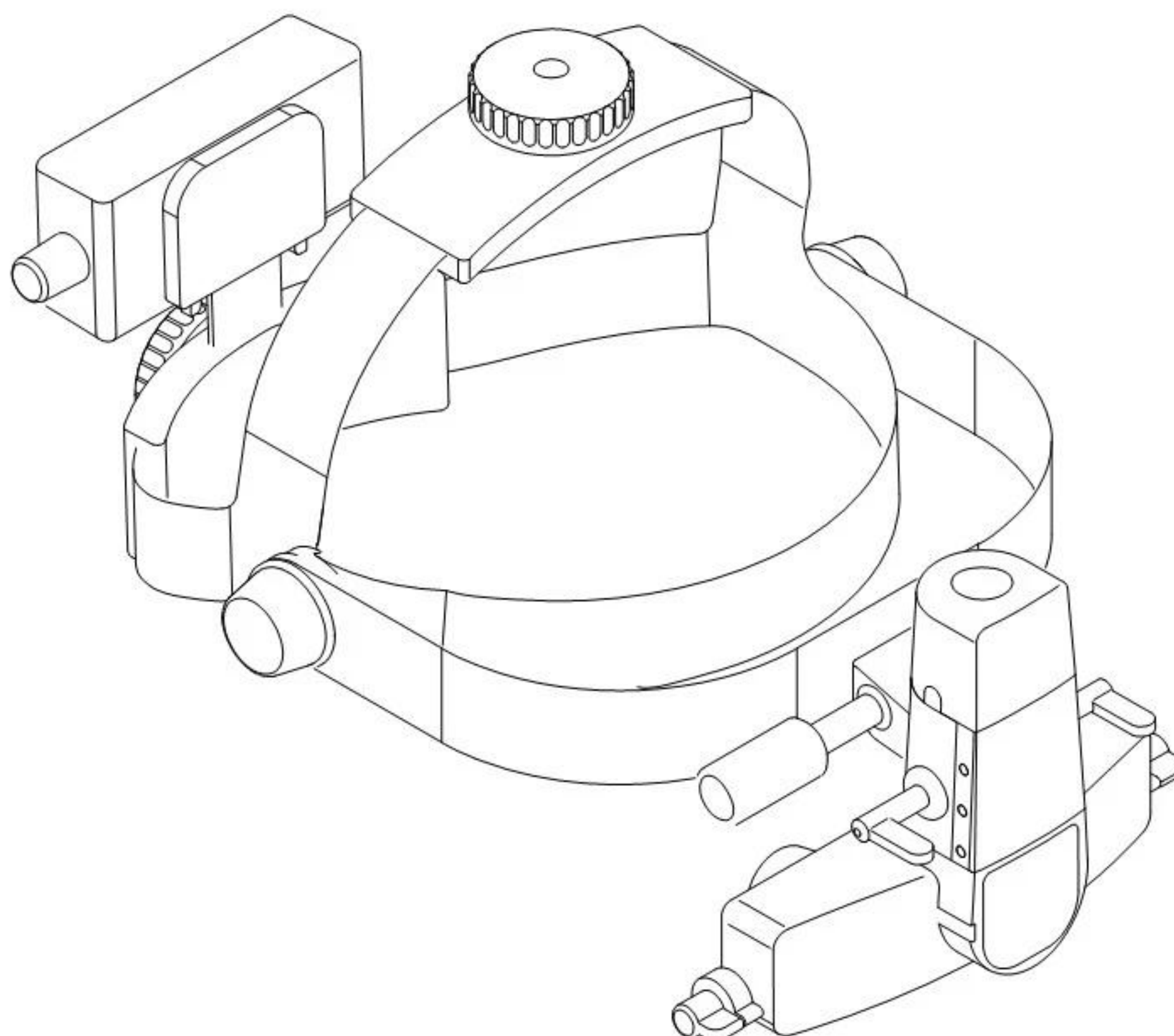


NEITZ

Binocular Indirect Ophthalmoscope **IO-α LED** (Battery-powered Type) **User's Manual**



Thank you for purchasing the NEITZ Binocular Ophthalmoscope IO-α LED (Battery-powered Type). 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 or a belt and the like.

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



TD11-13000002E

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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

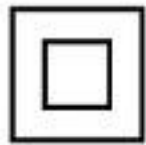
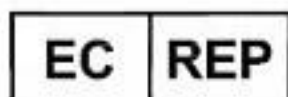
The NEITZ Binocular Indirect Ophthalmoscope IO- α LED (Battery-powered Type) (hereinafter referred to as "IO- α ") is a battery powered medical device containing an LED bulb for illumination and viewing optics intended to examine the media (cornea, aqueous, lens and vitreous) and retina of the eye.

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.

	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 ($^{\circ}\text{C}$) 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
	Certification symbols demonstrating product has passed the corresponding safety tests.
	
	

	
	
	
	
	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
	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)

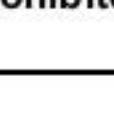
1.3 Safety Information

For your safety, please comply with the following precautions.

 WARNING	
 Prohibited	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.
 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 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	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	Be sure not to loosen the Overband Fixation Knob too much. Doing so may free the knob and cause the Scope Unit to drop.
 Instruction	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.

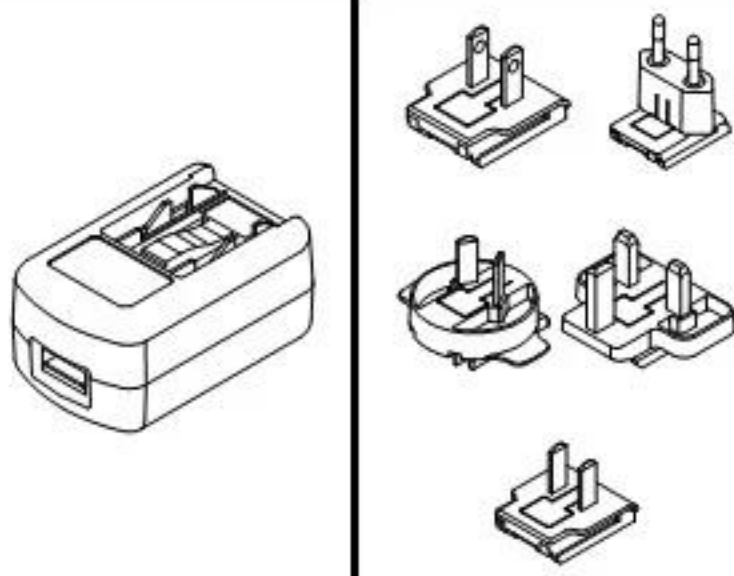
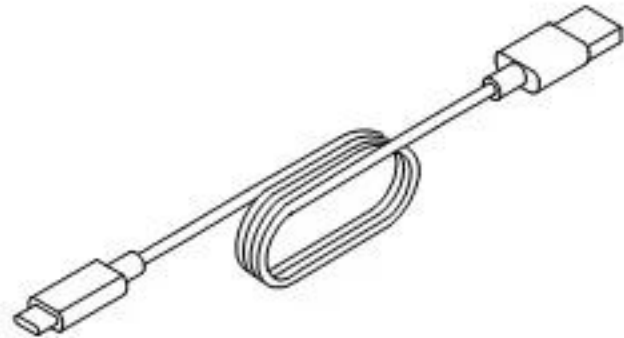
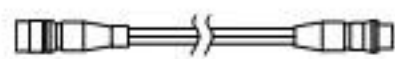
 CAUTION	
 Prohibited	Do not sterilize the device. Doing so may cause device deformation or failure.
 Prohibited	Do not install the device in places where it may be difficult to plug in/out to/from the power outlet or to switch power since the plug-out from the outlet is one of the separation methods 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.

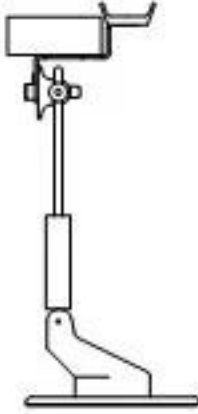
 Prohibited	Do not place heavy objects on, apply excessive tension to, or fold cables, cords and connectors. Doing so may result in damage and electric shock or fire.
 Prohibited	Do not use paint thinners, cleaning agents or boiling water to clean the device. Doing so may cause deformation or device failure.
 Prohibited	Do not immerse in cleaning detergents or rinse with water. Doing so may cause device failure.
 Prohibited	Use of the IO-α LED 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 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	Allow the device to return to room temperature before unpacking. Not doing so may cause condensation and lead to device failure.
 Instruction	Wear a cap or the like when equipping the IO-α LED.
 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

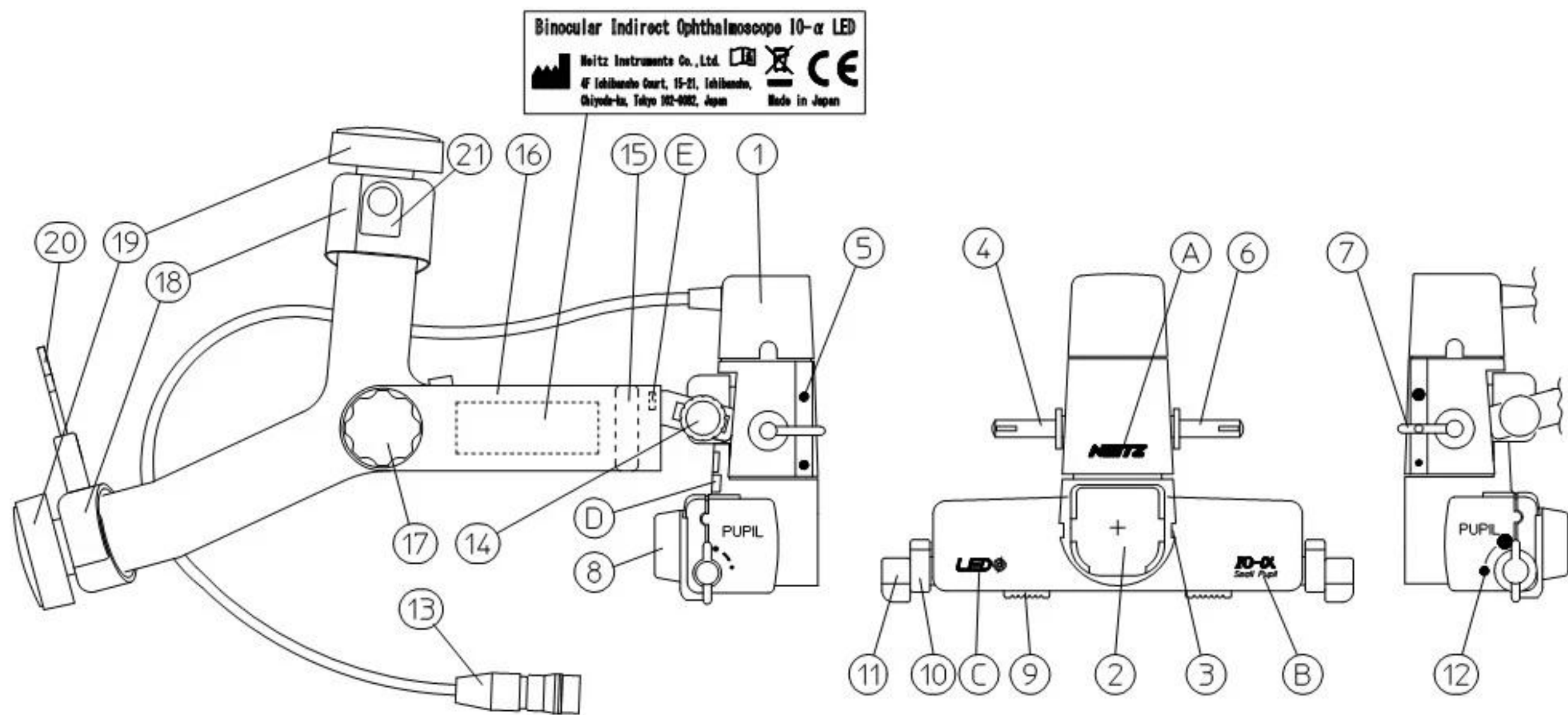
Make sure to match all items in the package with the components shown below and inspect each item for damage. Should any items be missing or damaged, do not use the IO- α and contact your local dealer immediately.

Item		Set Type	Set 4	Set 3	Set 2
IO- α main unit	See 2.2.1		1	1	1
IO-BP3A	See 2.2.2		1	1	1
AC Adapter set			1	1	1
USB cable (Type-C)			1	1	1
Extension cord (1 m)			1	1	1
Belt hook			1	1	1
Wiring ring			1	1	1
Teaching mirror			1	-	-
Detachment chart			1	-	-
User's manual			1	1	1
Carrying case			1	1	-
Aspherical lens			Optional		

Replacement bulb		Optional
IO stand		Optional

2.2 Nomenclature

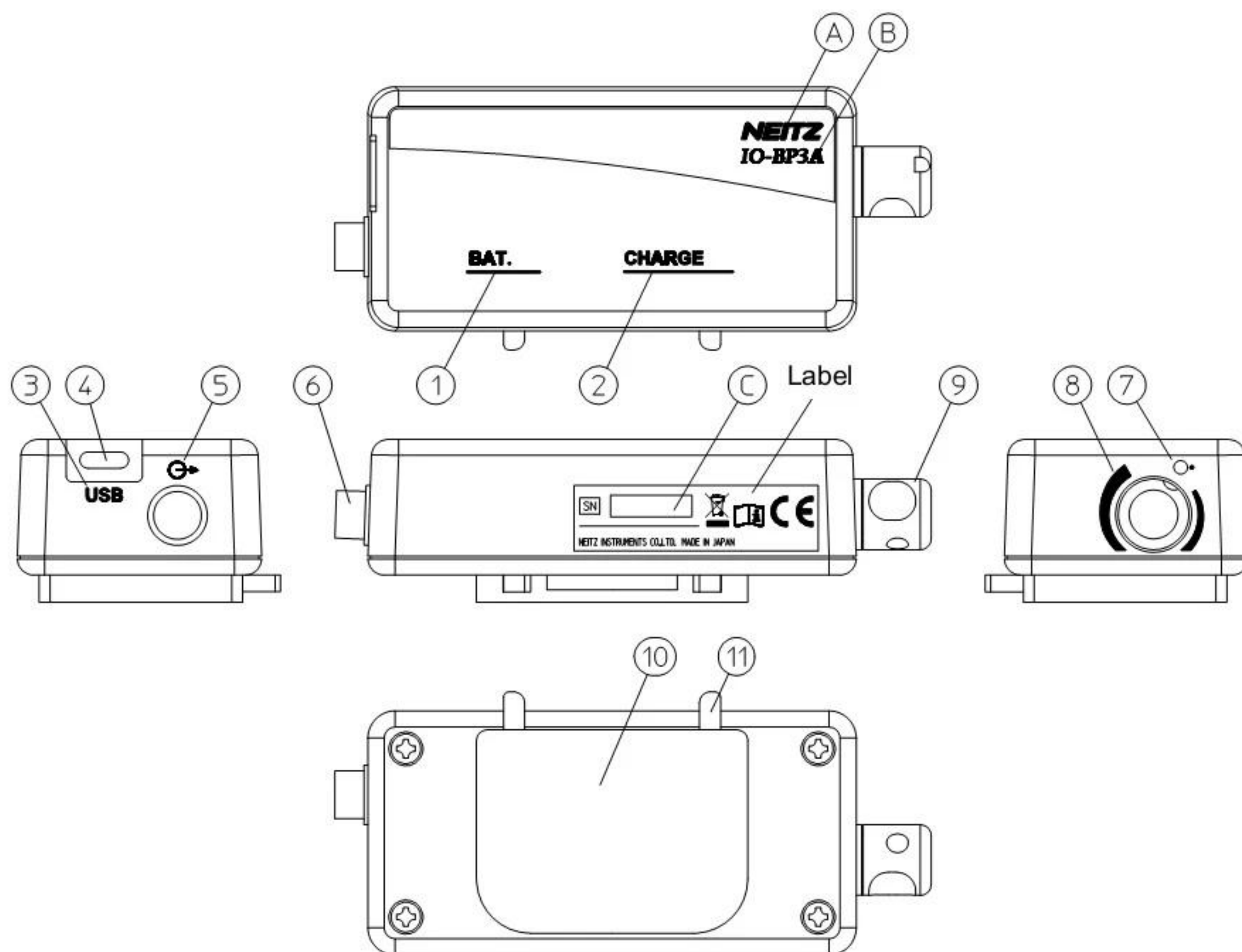
2.2.1 IO-α Main Unit



A		Manufacturer's logo
B		Model logo
C		Uses an LED bulb
D		Serial number of the Scope unit
E		Serial number of the Headband
1	Lamphouse	Holds the LED bulb
2	Front window	Outputs illumination
3	Teaching mirror slot	To insert the Teaching mirror
4	Filter selection lever	Allows for switching between "UV filter (white)", "Red-free filter (green)" and "Cobalt blue filter (blue)"
5		Filter selection marker
6	Aperture selection lever	Switches the area of the illumination field
7		Aperture selection marker
8	Eyepiece	A +2 D (diopter) lens is included

9	PD adjuster	Adjusts the pupil distance (PD). The scale (54 mm to 74 mm) is indicated above the eyepiece
10	Illumination angle adjustment lever	Adjusts the illumination angle. Levers located on both sides of the scope unit are coupled and move in conjunction.
11	Observation angle adjustment lever	Adjusts the observation angle. Levers located on both sides of the scope unit are coupled and move in conjunction.
12		Graphic display of the approximate subject pupil size.
13	Lamp plug	Connects to the Lamp jack of the IO-BP3A
14	Scope unit fixation knob	Loosen to position the Scope unit
15	Headpad	Applied to the forehead to keep the scope unit in place
16	Overband	Holds the scope unit. Can be flipped up.
17	Overband fixation knob	Loosen to flip up the Overband. Tighten to keep the Overband in place
18	Headband cover(s)	Covers the adjustment mechanics of the Headband. For your safety, do not remove.
19	Headband size adjustment knob(s)	Turn clockwise to tighten the Headband. Turn counter-clockwise to loosen the Headband.
20	Battery pack fixation prong	Inserted into the Connector attachment to hold the battery pack
21	Cable fixation strap	Used to fix the Lamp cord to the Headband

2.2.2 IO-BP3A



- | | | |
|---|---|---|
| A | NEITZ | Manufacturer's logo |
| B | IO-BP3A | Model logo |
| C |  | Serial number of the IO-BP3A |
| 1 | <u>BAT.</u> | Battery indicator: The color of the LED in the right of this symbol shows the remaining battery amount. |
| 2 | <u>CHARGE</u> | 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 level 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 belt hook or the Headband of the suitable device.
11	Fixation release	Used to detach the battery pack from the Headband or belt hook.

3 Operation

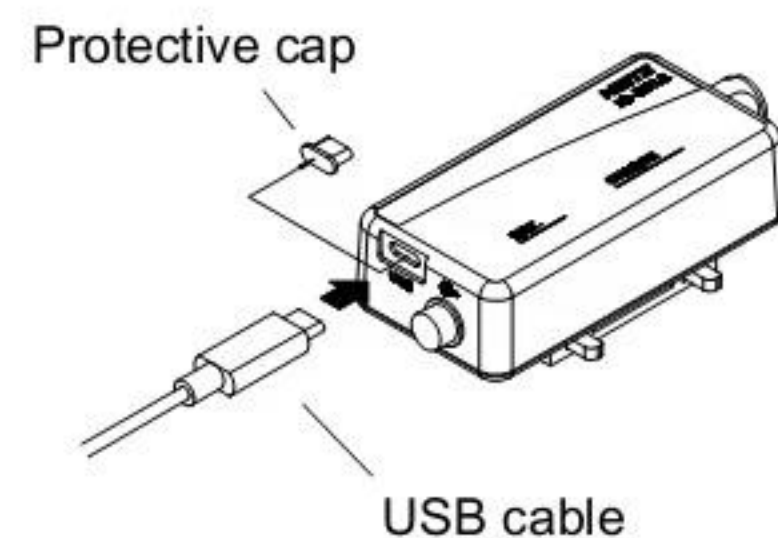
3.1 Preparation

3.1.1 Charging the IO-BP3A



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

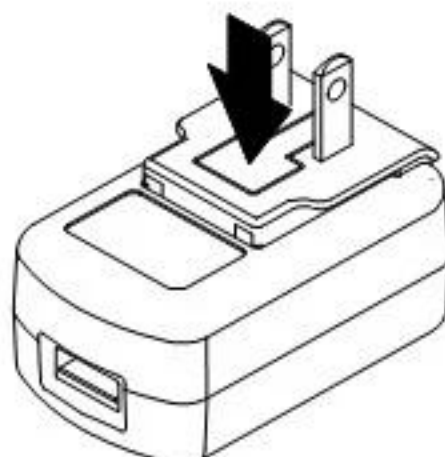
- (1) Attach one of the enclosed power plugs to the AC adapter (See “Attaching / detaching the power plug” below.) Several power plugs are enclosed. Choose the suitable one.
- (2) Connect the AC adaptor and the Type-A terminal of the USB cable. Connect to the AC power outlet.
- (3) Detach the protective 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 cannot be used while charging.
- (5) 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>

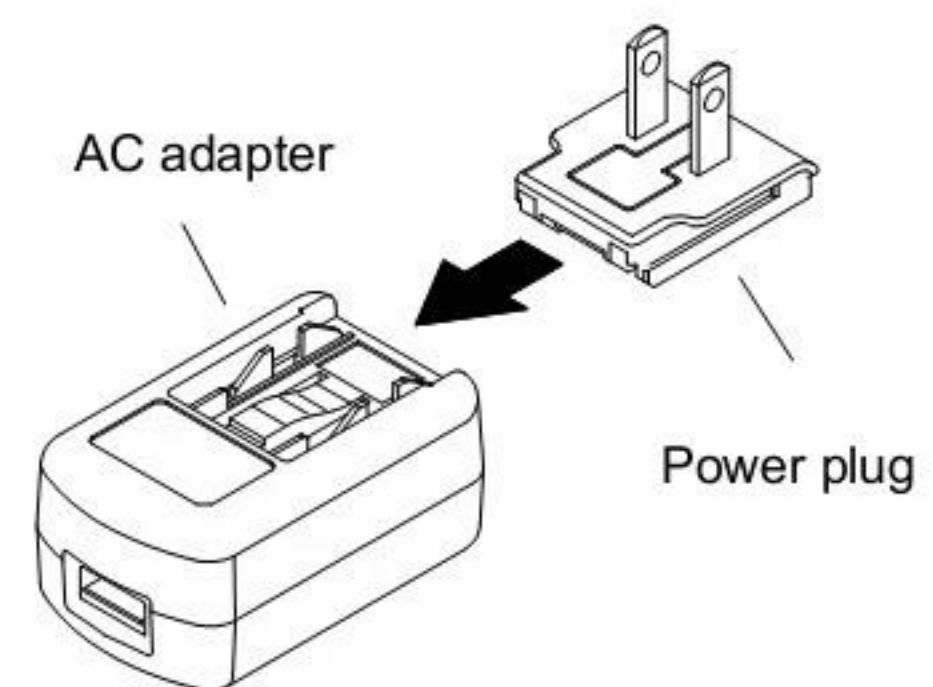
How to attach:

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

The IO-BP3A can be attached to either the Headband using the Headband hook or a belt or the like using the Belt hook.

<Attaching to the Headband>

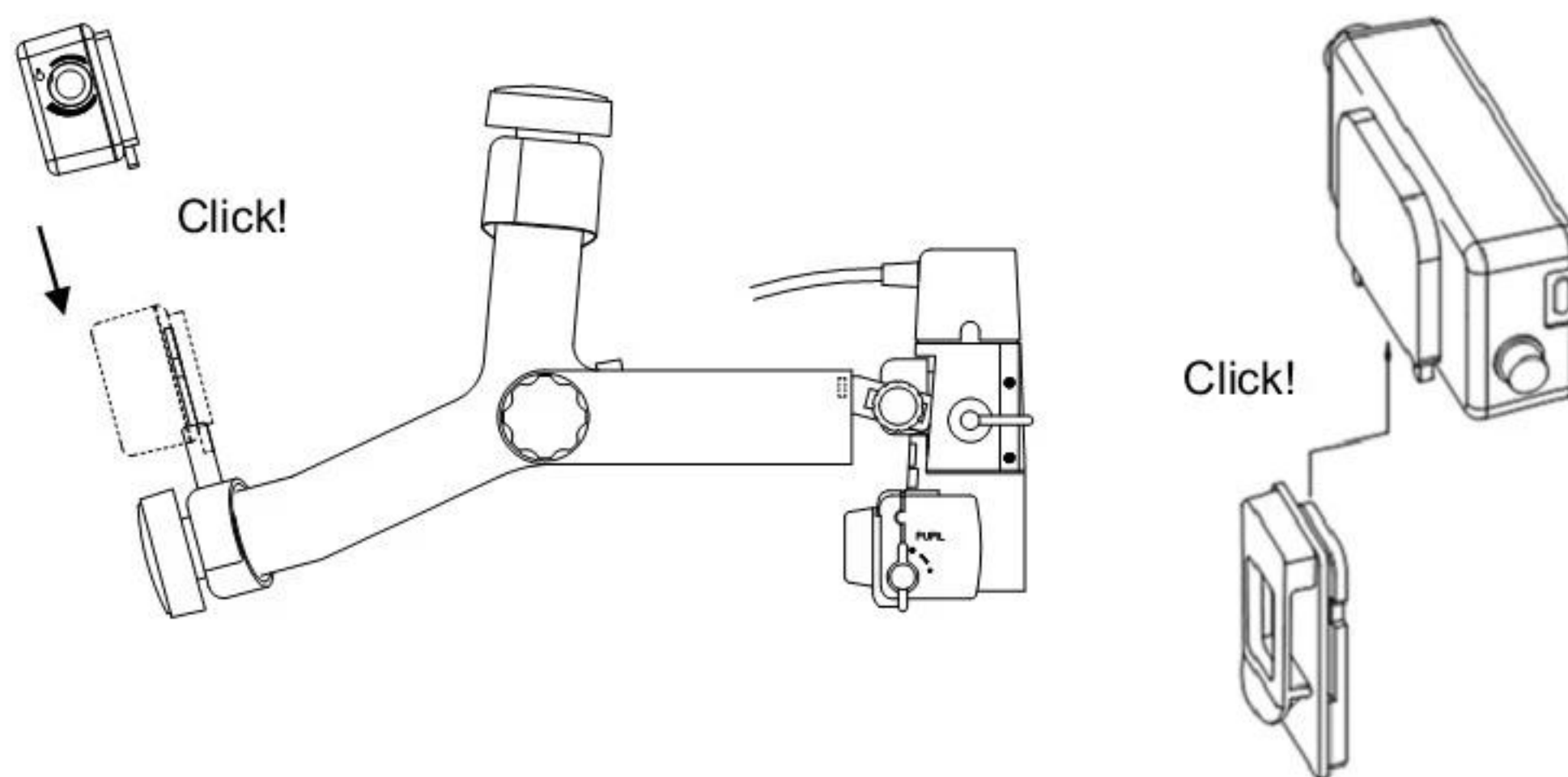
Insert the Connector attachment on the IO-BP3A into the Battery pack fixation prong on the Headband.

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

<Attaching to the Belt hook>

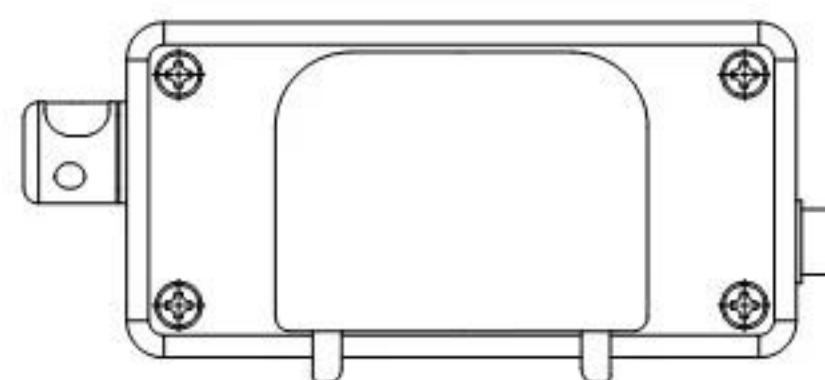
Insert the Battery pack fixation prong on the belt hook into the Connector attachment on the IO-BP3A

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



<Detaching the IO-BP3A>

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

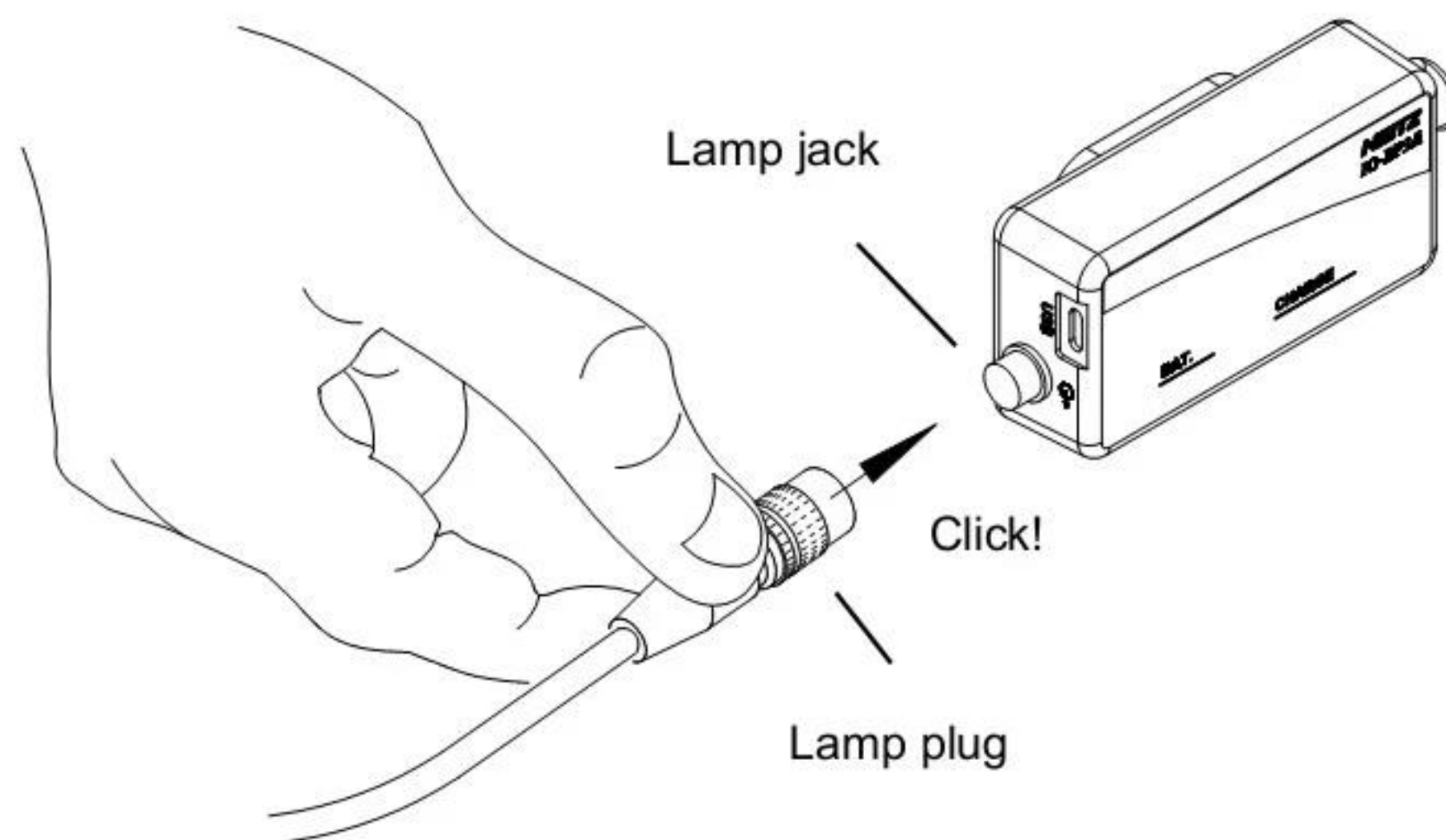


Squeeze inwards

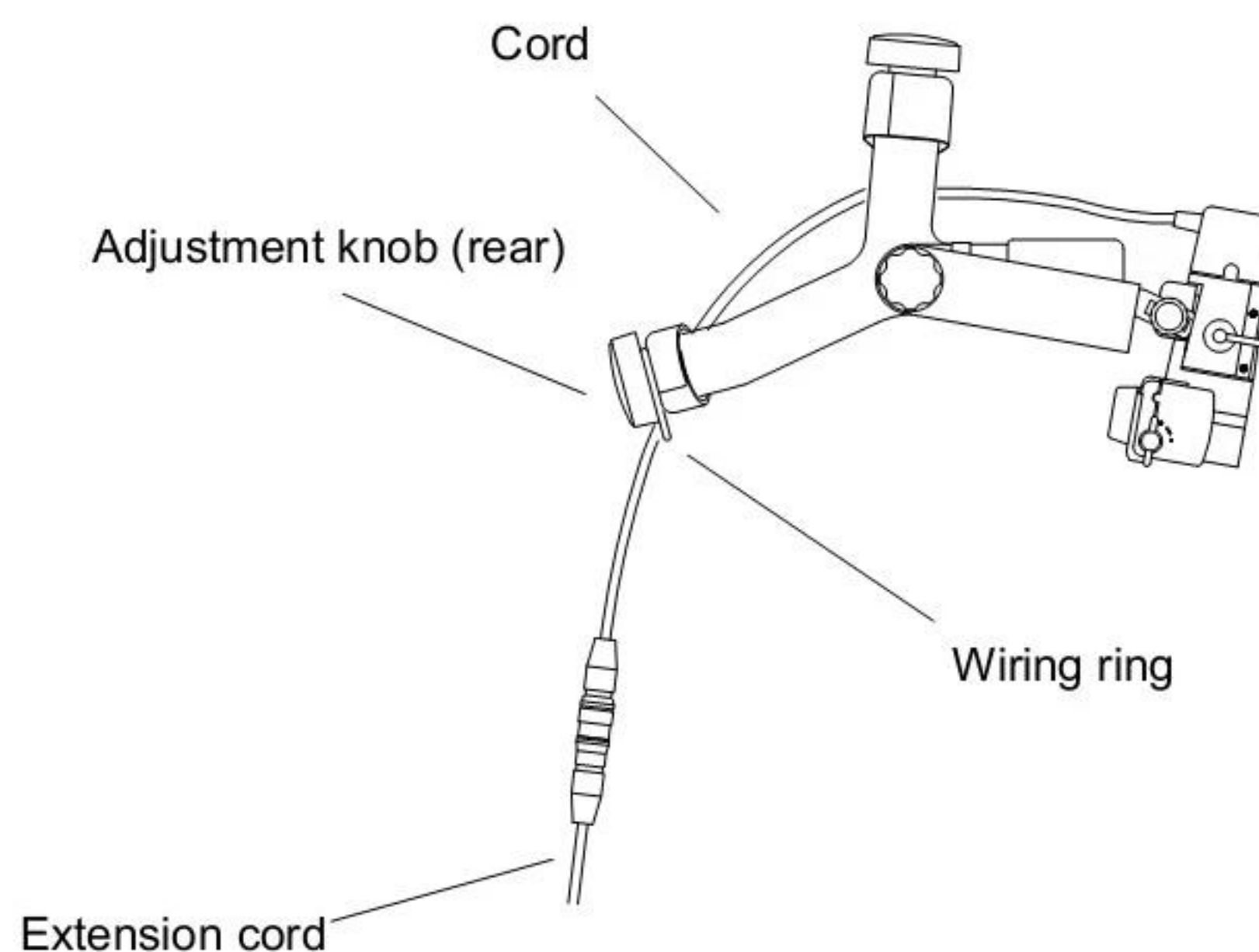
3.1.3 Connecting the IO-BP3A to the Scope Unit

- (1) 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.



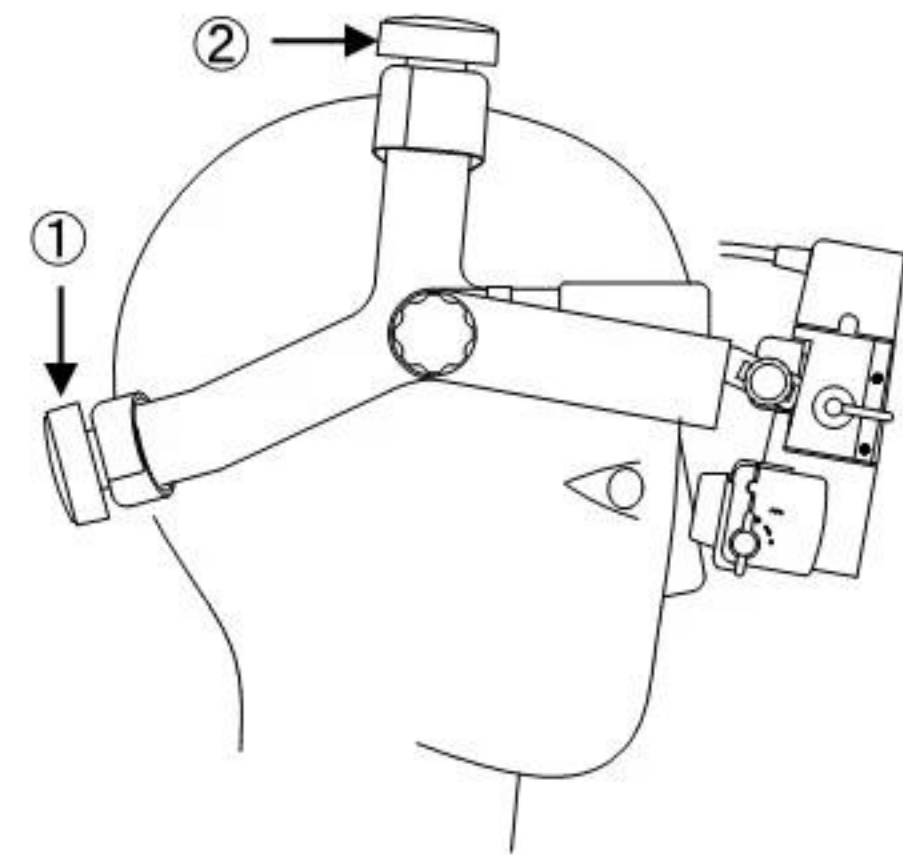
- (2) When using the Belt hook, the Lamp cord attached to the Scope unit is not long enough to connect to the IO-BP3A. In this case, connect the Extension cord provided to the Lamp cord to accommodate. The Wiring ring can be used to keep the wiring from getting in your way.
- (3) Gently pull the **metal ring** on the Lamp plug to disconnect from the IO-BP3A.
 *Note: The cord will not disconnect by simply turning the metal ring.
- (4) When using with IO-BP3A attached to your belt, connect the Extension cord between the Lamp plug and Lamp jack to extend the entire length. In this case, attach the Wiring ring to the rear of the Adjustment knob and pass the cord through the ring to reduce the burden due to the cord hanging down from your back.



3.2 Operation

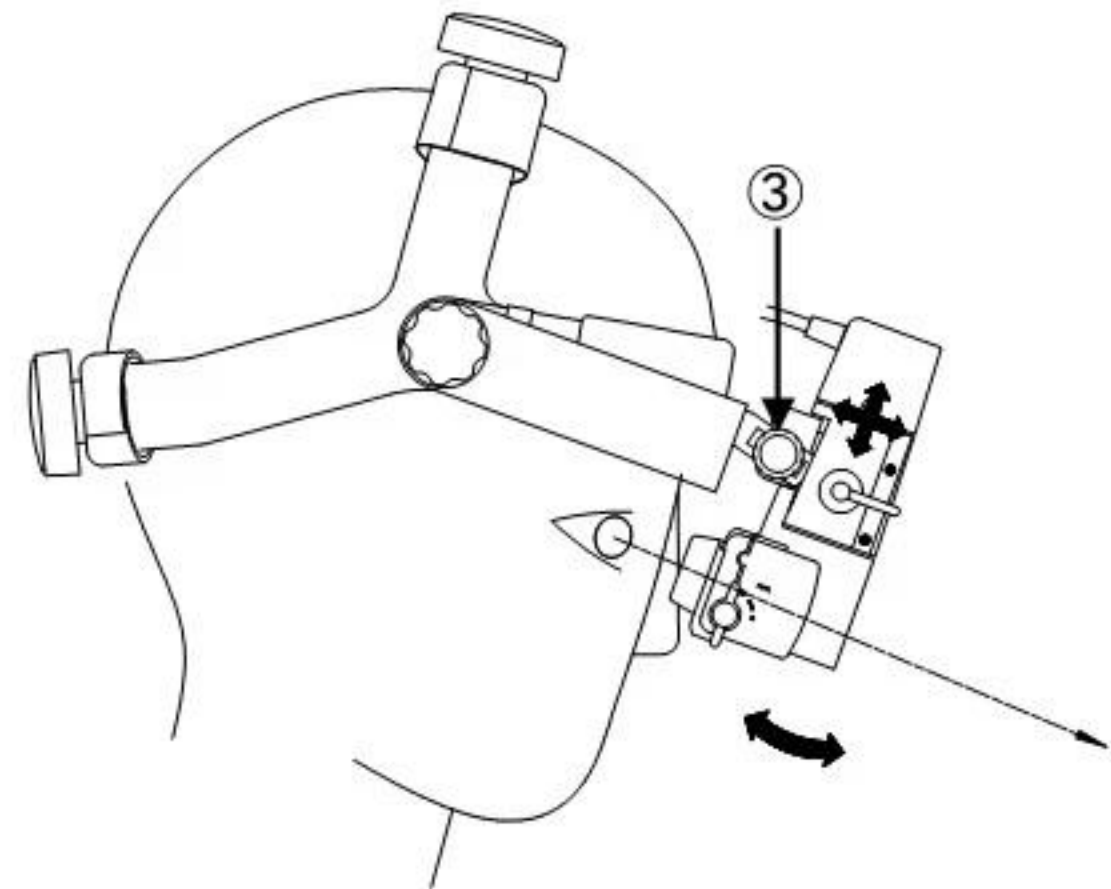
3.2.1 Wearing the IO-α LED

- (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 (①) 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 (②) clockwise to adjust the height.



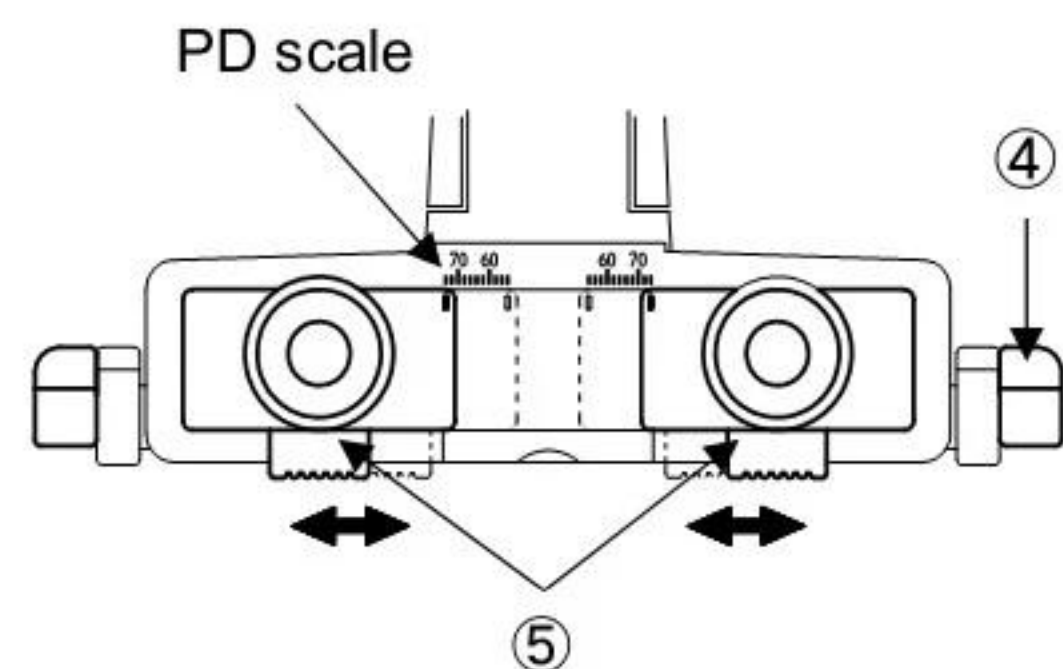
3.2.2 Positioning the Scope Unit

- (1) Loosen the Scope unit fixation knob (③) 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 (④) upward to fully spread the angle of observation.
- (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 (⑤) 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 (a marking to indicate the intensity is shown as ). A clicking sensation indicates the median.
- (2) Choose the desired field of illumination using the Aperture selection lever. The following diameters can be selected.

Marker	Aperture	Diameter at 500 mm distance
	Large	80 mm
	Medium	50 mm
	Small	19 mm

(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 battery power remaining. The Battery lamp will turn orange to indicate that the battery power will last for less than 5 to 10 minutes (at maximum illumination level).

Color	Condition of the 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 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.
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(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.

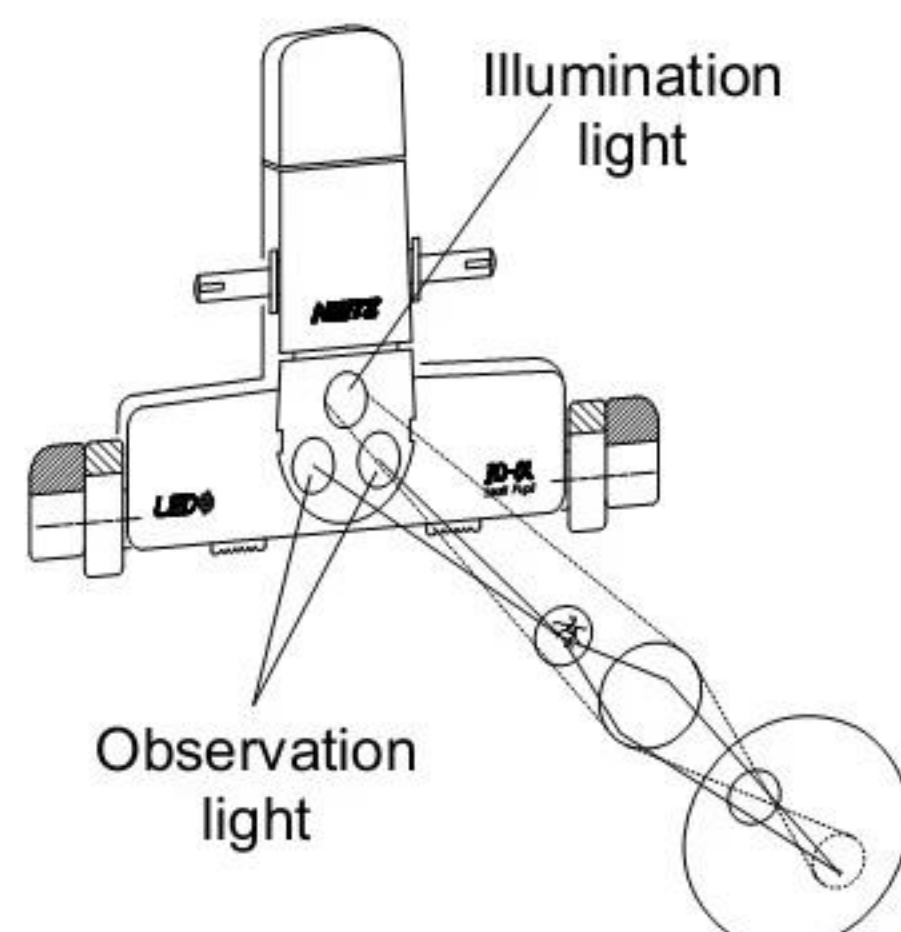
*Note: The distance between the patient eye and aspherical lens is dependent on the optical power (diopter, $1 \text{ D} = 1 / \text{focal distance in meters}$) of the aspherical lens.

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

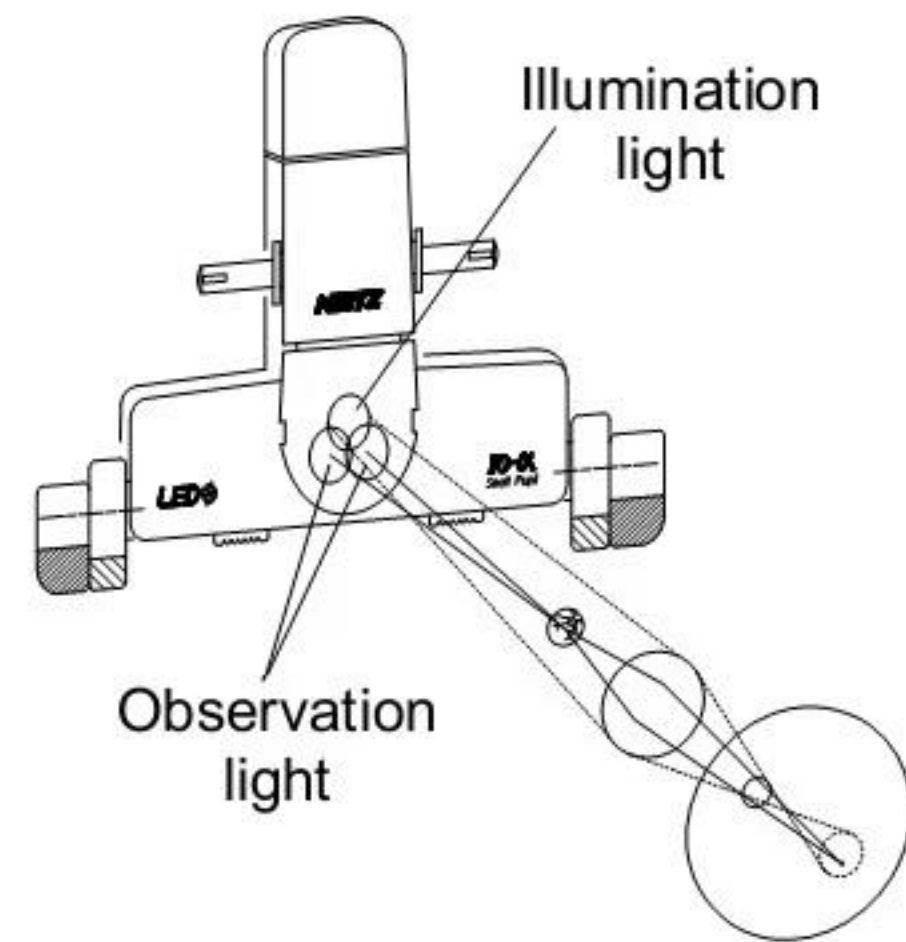
<Examining large pupils>

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.



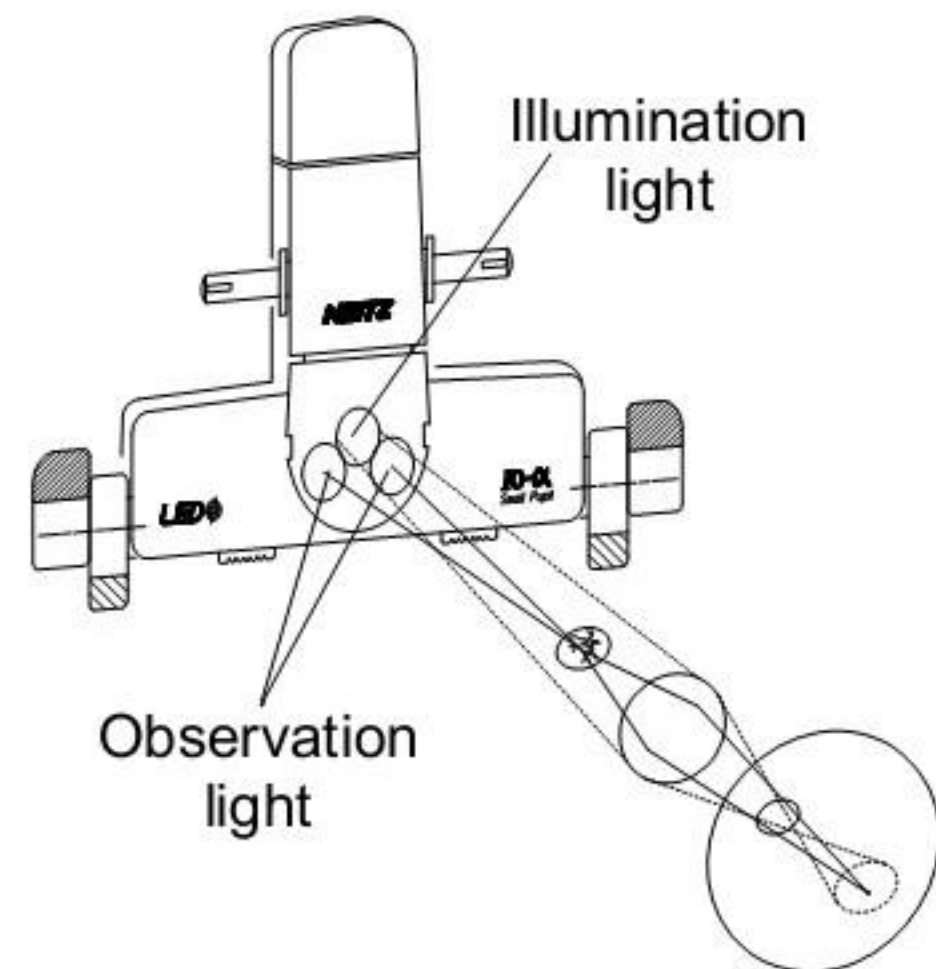
<Examining small pupils>

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.



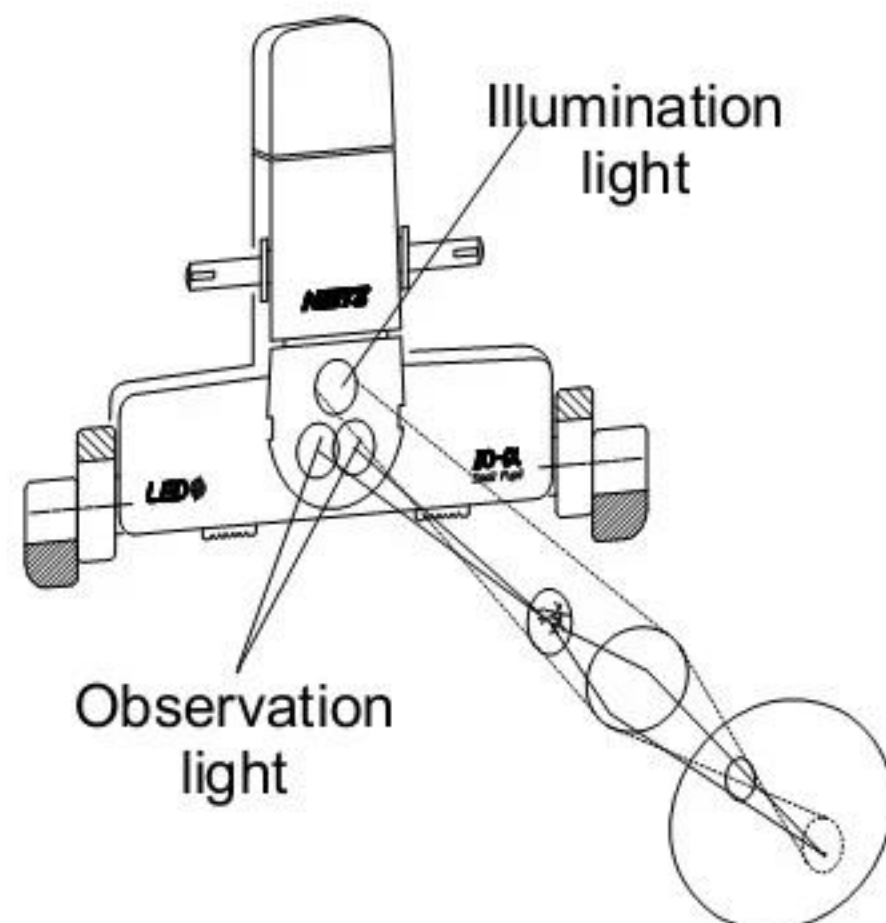
<Examining horizontally elliptical pupils>

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.

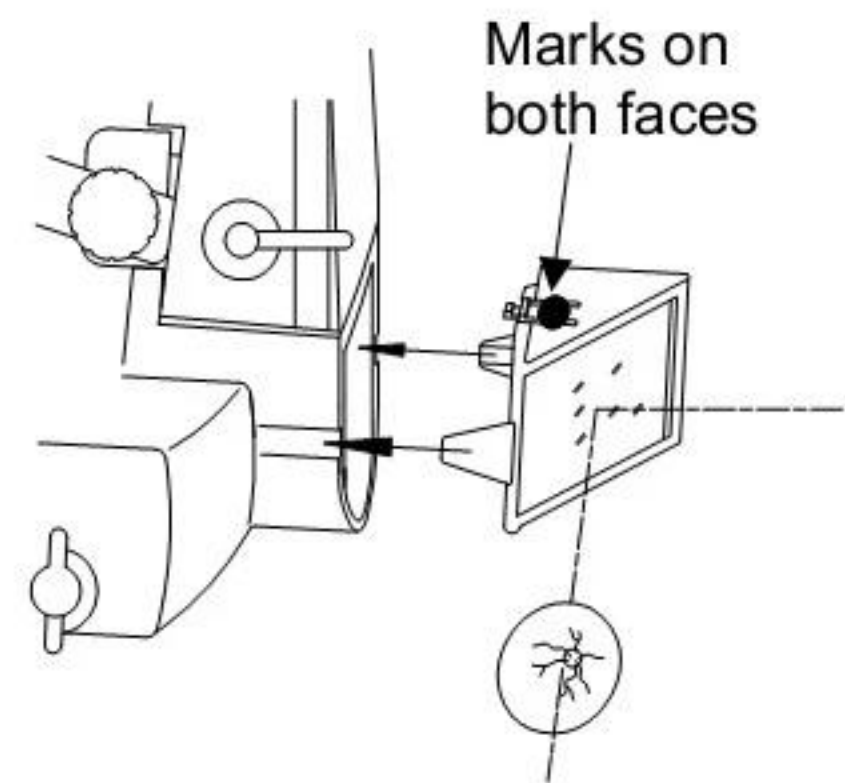
3.2.6 Using the Teaching Mirror

It is also possible to view the fundus image from the side by inserting the Teaching mirror into the Teaching mirror slot on the Scope unit.

The Teaching mirror may be attached to face either the left or right of the examiner.

When detaching the Teaching mirror from the Scope unit, depress the ● mark on both the upper and lower faces of the Teaching mirror and pull gently.

*Note: Do not attempt to detach the Teaching mirror forcefully as the Teaching mirror may break.



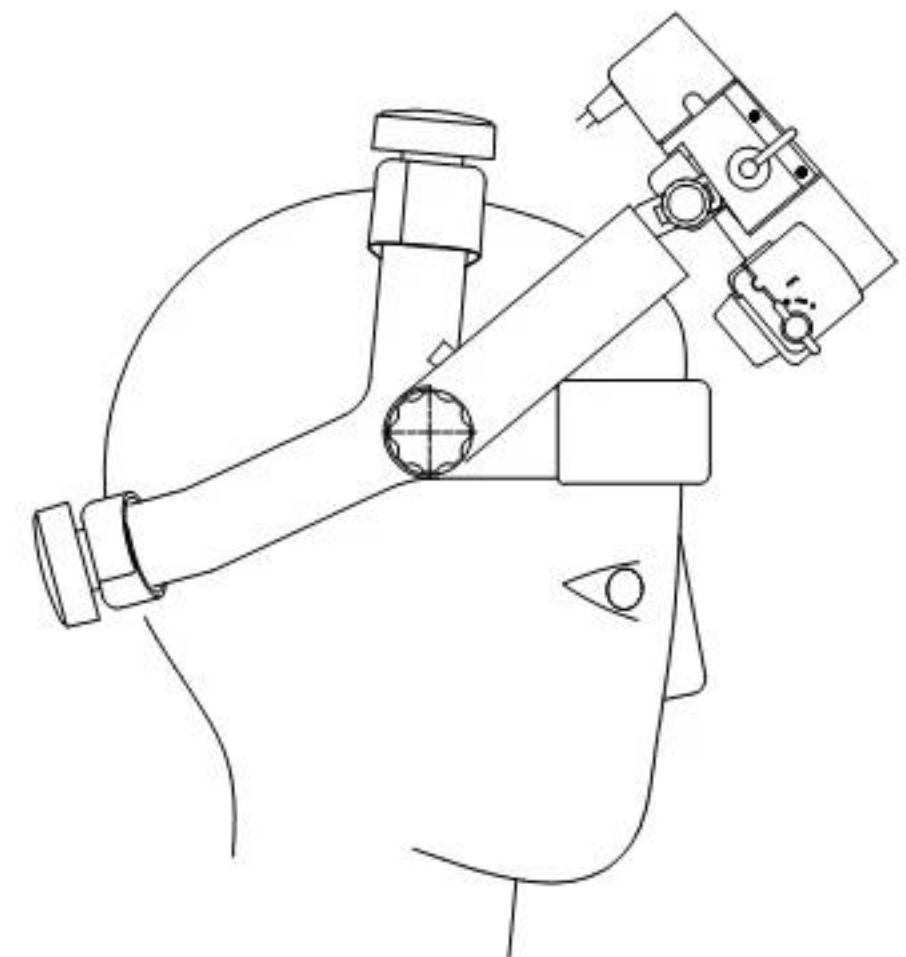
3.2.7 Turning Illumination Off

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

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

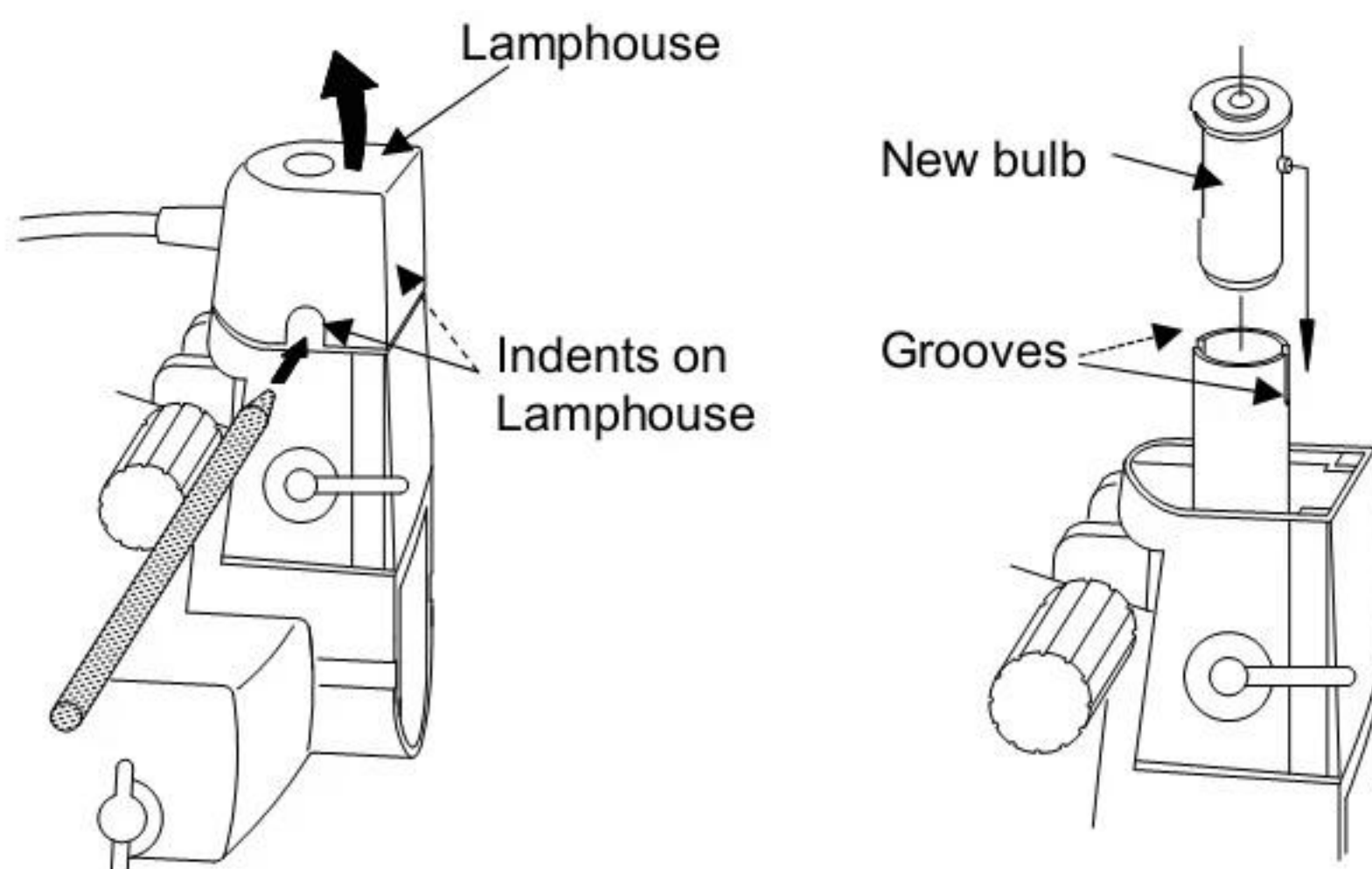
4.1.3 Cleaning Other Exterior Parts

Wipe the surface using a dry lint-free cloth or cloth moistened with diluted neutral detergent and then wipe dry. Use a cloth moistened with alcohol 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.
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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 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 , 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
Illumination does not light	Incorrect cable connection	Correct the connection
	Battery empty	Charge the battery pack
	The USB cable 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 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 front window	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 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

<i>Binocular Indirect Ophthalmoscope</i>		
Illumination Source		Warm white LED
Filters		UV, Red-free, Cobalt Blue
Illumination Field Diameter ^{*1}		19 mm / 50 mm / 80 mm
Maximum Illuminance ^{*1}		Approximately 600 lx (when using the UV filter)
PD Adjustment Range		54 mm to 74 mm
Minimum Pupil Diameter		2 mm
Continuous Illumination Time ^{*2, 3}		Approximately 5 hours at maximum intensity
Incorporated Rechargeable Battery		Rechargeable lithium-ion batteries (3.7V)
Charging Time ^{*3}		Approximately 2 hours
Dimensions	Scope unit ^{*4}	164 mm x 111.5 mm x 58 mm Approximately 480 g
	Headband circumference	Approximately 520 mm to 640 mm
	Battery pack ^{*5}	90 mm x 45 mm x 30 mm Approximately 90 g
<i>AC Adaptor</i>		
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 ME equipment
Applied parts	No applied parts
Degree of protection against harmful ingress of water or particulate matter	IPX20
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 adaptor 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

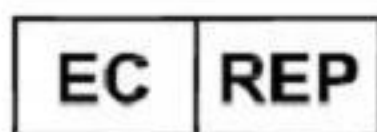
If you have any questions or need technical support, contact your local dealer or Neitz located at the following address.

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/>



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

ANNEX A

Protection from Optical Hazards

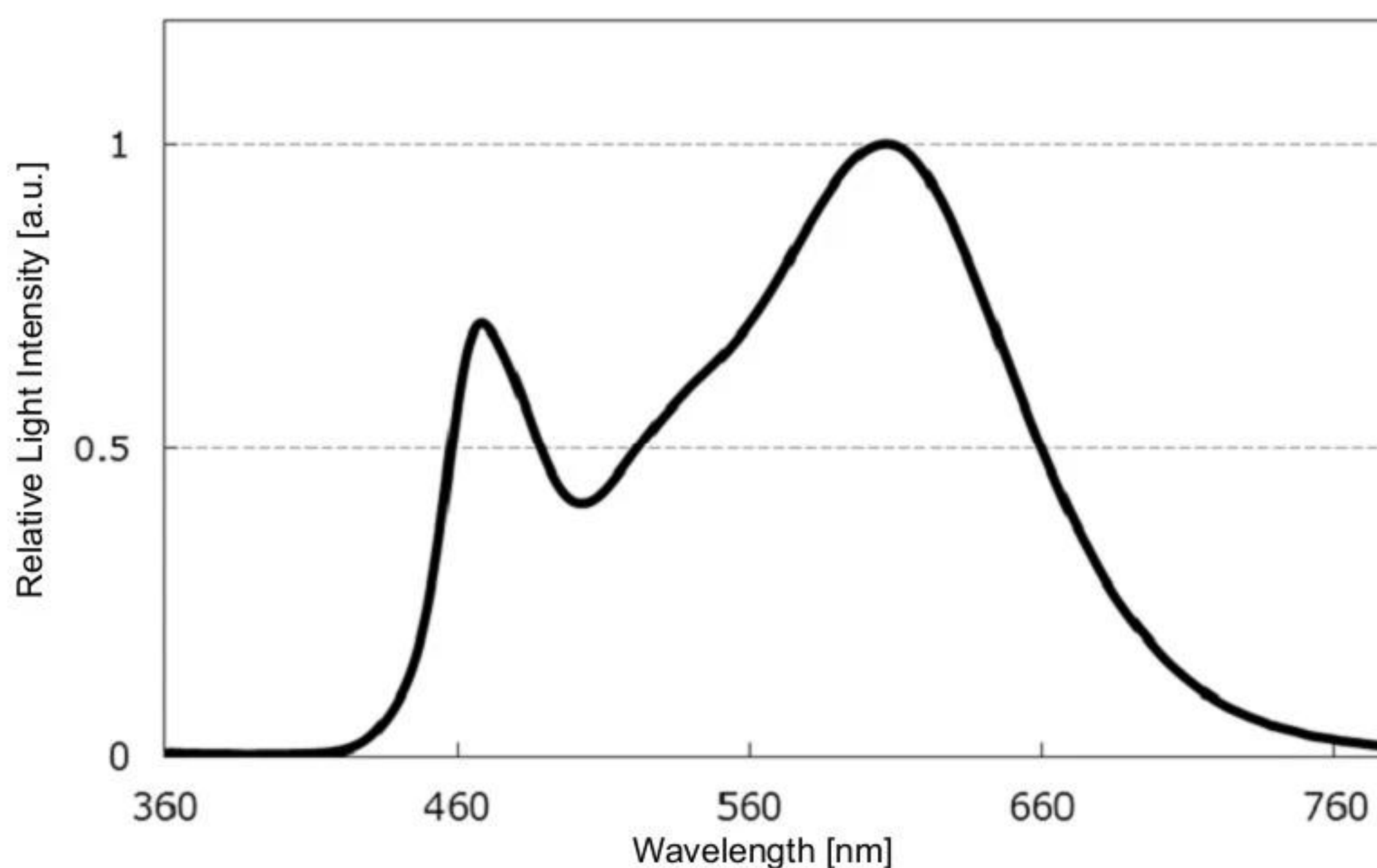
	The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 7 minutes.
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The 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 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 (battery-powered type) is a medical device and requires special precautions regarding EC. 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 (battery-powered type), 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 IO-α LED (battery-powered type) with the applied EMC Standard:
U2C-AC20NBK
- (3) Applied EMC Standard: IEC 60601-1-2: 2014
Applicable port(s): Enclosure port, Input AC power port

Electromagnetic Emissions		
Phenomenon	Applied Standard	Emission Test Levels
Conducted and radiated RF emissions	CISPR 11	Class B Group 1
Voltage changes, voltage fluctuations and flicker emissions	IEC 61000-3-3	230 V 50 Hz

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
Electrical fast transients / bursts	IEC 61000-4-4	Input AC power: ± 2 kV (100 kHz)
Surges	IEC 61000-4-5	Line-to-line: ± 0.5 kV, ± 1 kV Line-to-ground: ± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

Electromagnetic Immunity		
Phenomenon	Applied Standard	Immunity Test Levels
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		

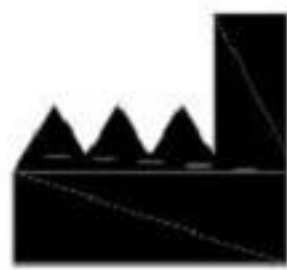
(4) Essential Performance of the IO-α LED

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

Notes:

Notes:

Notes:



Manufactured by

NEITZ INSTRUMENTS CO., LTD.

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