

LED Slit Lamp

XL-1

Instruction for use

The electronic data of the Instruction for use can be viewed on Ohira's web site.

The contents of this Instruction for use may be changed without prior notice.

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Disclaimer

Ohira will not bear any responsibilities on the following matters.

1. The trouble and/or damage caused by the results not observing the Notes on Safety or the operational method mentioned in this Instruction for use.
2. Under the circumstances not within the operating conditions of this unit including the power source or the setting environment mentioned in this Instruction for use.
3. The trouble and/or damage caused by the result(s) of remodeling or improper repair of the device.
4. When a trouble and/or damage occurs caused by the maintenance and/or repair conducted by a person other than Ohira or the dealer specified by Rexxam.
5. The trouble and/or damage of Ohira device caused by the device of other manufacturer not delivered by Ohira.
6. The trouble and/or damage caused by the maintenance and/or repair using the repair parts not specified by Ohira.
7. The trouble and/or damage caused by act of god such as fire, earthquake, flood, or thunders.

1. The contents of this Instruction for use may be changed without prior notice.
2. We have prepared the contents of this Instruction for use with thoroughgoing measures. However, if an inadequate description or error is found, please let us know.
3. It is prohibited to copy a part or an entire part of this Instruction for use without getting Ohira's permission.

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1. Purpose of use

This device (XL-1) is a device used for observation and imaging of eyeballs, etc.

2. Defined intended usage

This device (XL-1) is a stereomicroscope that irradiates a transparent body such as the cornea or crystalline lens of the eyeball with interstitial light from an oblique direction to cut the light, and the light diffused by the tissue highlights slight abnormalities. Make a magnified observation by.

3. Intended user, patient population

This device (XL-1) is a medical electrical device. When using this device, please use it under the guidance of a doctor.

Patients undergoing medical examination with this device (XL-1) should follow the instructions below. Being in a sitting position.

Being able to answer questions from doctors, optometrists, etc.

4. Accessories

Carrying case	: 1 pc	Forehead support	: 1 pc
Eyepiece 10X	: 2 pcs/set	Eyepiece 16X (Option)	: 2 pcs/set
Diopter adjustment bar	: 1 pc	Instruction for use	: 1 pc

Please contact your dealer for details.

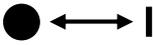
5. Indications and graphic symbols for safe use

Please read the text and follow the instructions after familiarizing yourself with the following indications and symbols.

Display description

 Warning	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
 Caution	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
 NOTE	Useful functions to know. Paying attention to these will prevent the noted problems

Symbol displayed on the outside of the main unit

Symbol	Description
	Degree of protection against electric shock Type B Applied part
	Slit opening and closing
	Illumination light intensity adjustment
	Lighting ON / OFF

Symbol	Description
	Manufacturer
	CE mark
	Serial number
	Authorised Representative in the European Community
	Medical Device
	Separate collection for waste of electrical and electronic equipment
	Consult instruction for use
	「UDI-DI」 4571260230514

Symbol displayed on the packing box

Symbol	Description
	Fragile, handle with care
	This way up
	Stacking limit by number
	Keep away from rain
	The number on the left indicates the lower temperature limit, and the number on the right indicates the upper temperature limit.
	The number on the left indicates the lower limit humidity, and the number on the right indicates the upper limit humidity.

6. Precautions for use



Warning

1. If something goes wrong (abnormal noise, smoke, etc.), immediately remove the battery from the device and contact your dealer. Continued use may cause fire or injury.
2. If you experience any abnormalities such as smoke or a strange odor while charging the battery, stop charging and unplug the power plug from the outlet.
3. Do not disassemble, modify or repair. There is a risk of injury due to electric shock.
4. Do not open the cover. Ask a service person for repair. There is a risk of injury due to electric shock.
5. EMD electromagnetic disturbances
This device complies with the EMD standard IEC60601-1-2: 2014, and the expected electromagnetic environment for the entire life cycle is the home healthcare environment.
If there is electromagnetic interference stronger than the IEC 60601-1 test level, it may not be possible to irradiate gap light (slit light) as a loss / deterioration of basic performance due to electromagnetic interference.
Do not use it near or stacked with other equipment.
If close or stacked use is required, it is necessary to confirm normal operation in that arrangement.
Use of accessories, transducers or cables other than those specified may result in increased emissions or reduced immunity of the device.
Do not use equipment that generates electromagnetic waves within 30 cm (12 inch) from any part of this device. It can result in poor performance.



Caution

1. Do not illuminate the patient's eyes for long periods of time.
Classified as Group 1 for ISO 10939 and ISO 15004-2 requirements.
2. If fingerprints, dust, etc. adhere to optical parts such as lenses, the observation image or slit image will bleed or blur, affecting the observation. Never touch it with your fingers and be careful not to get dust on it.
3. Do not install near wireless devices such as TVs and radios. There may be noise on the TV / radio.
4. If the device gets wet with liquid or foreign matter gets inside, remove the battery immediately and contact the distributor.
5. Do not short the positive and negative terminals of the battery.
6. If you do not use the device for a long time, remove the battery from the device and store it. There is a possibility of the battery leakage.
7. Be sure to observe from the side of the instrument during observation.
The main unit may come into contact with the eye or nose of the examinee.
8. When disposing of the lithium-ion battery, dispose of it according to the regulations of the local government.



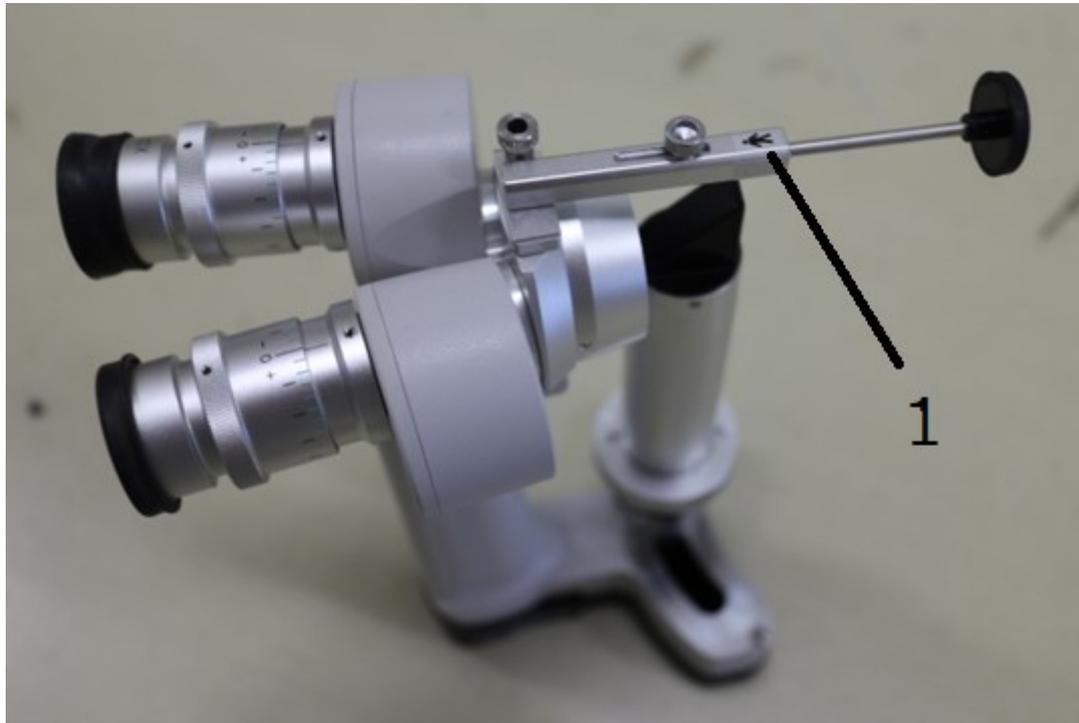
NOTE

1. Report any serious accidents related to your device to the manufacturer and the competent authority.

7. Warning display and position

For safety reasons, warnings are indicated.

Please follow the instructions on the label to use the device properly. If the following labels are not found on the device, please contact your distributor.



No.	Label	Meaning
1		Caution Degree of protection against electric shock: Type B applied part.

8. Assembly procedure

- 1) Take out the carrying case from the outer box.
- 2) Remove the XL-1 device, diopter adjustment bar, forehead support, battery, etc. from the carrying case.
- 3) Attach the forehead support to the binocular microscope.
- 4) Insert the battery firmly into the battery compartment at the bottom of the main unit.
- 5) Make sure that the 10x eyepiece is firmly mounted on the eyepiece tube.
- 6) Turn the slit opening / closing ring clockwise to open the slit to the maximum.

9. Maintenance

Periodic inspection: Check before use

- 1) Slide the illumination tube left and right and check that it works smoothly.
- 2) Change the slit width and check the slit operation.
- 3) Move the filter switching lever and check that the filter is switched.
- 4) Open and close the eye width of the microscope to check the operation.
- 5) Turning the diopter of the eyepiece and check that the diopter can be adjusted.
- 6) Adjust the volume and check that the amount of light changes.

Daily care

- 1) Remove the battery and store it when it will not be used for a long time.
- 2) If the battery level indicator flashes, remove the battery from the unit and charge the battery. Make sure it is ready for use the next time you use it.
- 3) When not in use, store it in a carrying case, etc.

- 4) If the forehead support becomes dirty, wipe it with a neutral detergent.
- 5) When reusing, disinfect the forehead support that the subject comes in contact with rubbing alcohol.
- 6) If fingerprints, dust, etc. adhere to optical parts such as lenses, it will affect the observation. If it gets dirty, wipe it gently with a soft cloth. In this case, handle it with care and be careful not to damage it. If you do not see any recovery after taking the procedure, please contact your dealer immediately.
- 7) If the slide plate of the lighting unit becomes dirty, move the lighting axis to the left or right and clean it with a dry cloth.

Replacement of consumables

- 1) Battery replacement
If the battery cannot be charged, replace it with a new rechargeable battery.
Replacement battery model: NB-2LH

10. Specifications

1. MICROSCOPE	
(1) Eyepiece	10X, 16X (Option)
(2) Objective lens magnifications	1X
(3) Total magnifications	10X (at eyepiece 10X) 16X (at eyepiece 16X)
(4) Diopter adjustment	±5D (at eyepiece 10X) ±7D (at eyepiece 16X)
(5) Visual field	φ10mm
(6) PD adjustment range	50-75mm (at eyepiece 10X) 55-70mm (at eyepiece 16X)
(7) Working distance	78mm
2. Illumination	
(1) Slit width	0-11mm (Stepless adjustment is possible.)
(2) Slit length	11mm
(3) Filters	Cobalt blue, Green, Color temperature conversion filter
(4) Illumination angle	On the level circumference±30degrees
(5) Light source	LED
3. Battery	
(1) Voltage	7.4V/1000mAh
(2) Operation time	Approx. 2 hours (in full charged state with maximum illumination)
4. Dimension and weight	
(1) Dimension	159 [mm] (W) 107 [mm] (D) 231 [mm] (H)
(2) Weight	About 700 [g] (including a battery)

11. Environmental conditions

Environmental conditions of use

Temperature : 10°C to 35°C

Humidity : 30% to 90% (No condensation)

Storage conditions

Temperature : -10°C to 55°C

Humidity : 10% to 95% (No condensation)

Transport conditions

Temperature : -40°C to 70°C

Humidity : 10% to 95% (No condensation)

12. Discard

To prevent possible damage to the environment and possible health, the device must be disposed of as follows:



(i) For EU countries, follow the WEEE Directive or

(ii) All other countries are subject to local disposal and recycling laws. Packing materials, accessories, etc.

Classify by material and dispose of according to the instructions of the local government.

13. Operation method

- 1) Attach the diopter adjustment bar to the microscope section.
- 2) Adjust the diopter and the eye width.
- 3) Turn on the lighting switch, adjust the brightness of the lighting, slit width, filter, etc., and observe.
- 4) Remove the diopter adjustment bar and attach the forehead support to the microscope section.
- 5) Turn on the lighting switch and observe the eye.
- 6) If you want to change the magnification, replace the eyepiece. (10 X or 16X)
- 7) After observing, clean and store the equipment.

14. Connecting to other devices

This device is not connected to other devices.

15. Device standard information

This device complies with ISO 10939: 2017

Distributor:



Rexxam Co., Ltd.

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