Kowa nonmyd WX 3D

INSTRUCTION MANUAL



KOWA nonmyd WX

Kowa

EU



Introduction

Accept our congratulations on your purchase of KOWA nonmyd WX.

KOWA nonmyd WX is a Non-mydriatic retinal camera for mono and stereo retinal photography.

This manual provides a description of the operation procedures of KOWA nonmyd WX and important precautions to be observed during its use.

Please read this manual carefully to assure that the instrument can demonstrate its full capabilities and work safely.

After you have finished reading, keep this manual in an easily accessible location near the instrument for future reference.

Operational considerations for safety

This manual describes important precautions to be observed when you use this system to assure that the system is used safely without causing any damage to the human body or property of the purchaser and other persons.

The designations and pictorial symbols used in this manual have the following meanings.

These should be fully comprehended before reading the text of this manual.

Meanings of designations



Warning

If the instrument should be operated wrongly, there may incur a risk of causing death or serious injury.



Caution

If the instrument should be operated wrongly, there may result in a bodily injury^{*1} or damage to property^{*2}.

- *1 A bodily injury means an injury, burn, electrical shock and so forth that will not necessitate hospitalization or long-term outpatient treatment.
- *2 Damage to property means an extensive damage to a house and/or household goods as well as a domestic animal and pet.

Meanings of symbols

| Graphical indication of any danger (including warning and caution). What is warned is explicitly and pictorially indicated by a picture or its associated message on or near a pictorial symbol. |
|---|
| Graphical indication of prohibited operation (prohibitive item). What is prohibited is explicitly and pictorially indicated by a picture or its associated message on or near a pictorial symbol. |
| Graphical indication of any mandatory action (obligatory item). What must always be done is explicitly and pictorially indicated by a picture or its associated message on or near a pictorial symbol. |

Disclaimer

Kowa is not responsible for:

- Any damage caused by fire, earthquake, third party's action, any other accident or user's intentional or unintentional error, abuse or use under abnormal conditions.
- Any damage resulting from use of the product or its malfunction (e.g. operating loss, shutdown, change/loss of stored data and so forth).
- · Any damage resulting from disobedience of what is described in this manual.
- · Any damage resulting from, for instance, malfunctioning of instrument caused by a combination of connected devices.

| <u> </u> | | | | |
|---|---|---|--|--|
| | the main po Continued (| rmal smell, sound, overheating or smoke should be detected, be sure to turn OFF ower immediately and then unplug the instrument from the power outlet. Use of the instrument may cause the instrument to malfunction or cause a fire. Control or your Kowa dealer for inspection immediately. | | |
| | | When replacing the flash lamp, make sure the instrument is turned OFF and then unplugged from the power outlet. Otherwise, there may occur electrical shock. | | |
| Unplug | Warning High-Voltage | When replacing the fuse, make sure the instrument is turned OFF and unplugged from the power outlet. If the fuse holder cover is removed with the instrument unplugged, there may occur electrical shock. | | |
| | | This instrument is equipped with a storage capacitor for photography light. Replacing the flash lamp while this capacitor is still not yet fully discharged causes a danger of an electrical shock. Check that the discharge indicator LED is turned OFF before replacing the flash lamp. | | |
| | | olug into the power outlet completely and securely. here may cause a fire or electrical shock. | | |
| • | Use a designated fuse only. Otherwise, the instrument may malfunction or a fire may break out. | | | |
| Obligatory | Make sure that the instrument is properly grounded to protect from bodily injury. Connect the plug into the three-wire grounding type outlet with ground wire. Otherwise, there may occur electrical shock. | | | |
| | Do not place a container or cup containing liquid near the instrument. Spilled liquid entering into the instrument may cause electrical shock. If liquid should be spilled into the instrument, turn OFF the main power and then unplugged from the power outlet. Contact Kowa or your Kowa dealer for inspection. | | | |
| Do not load the power outlet or cable with excess of its rated capacity If the main power cable should share a power outlet with other device is exceeded, there may cause a fire or electrical shock. | | power cable should share a power outlet with other devices and the rated capacity | | |
| | Do not insert any metal object into an air vent or opening of the instrument. It may cause an instrument malfunctioning, fire or electrical shock. | | | |
| Disassembly prohibited | Do not disassemble, modify or repair the instrument yourself. It may cause a fire, electrical shock, instrument malfunctioning or bodily injury. Refer all servicing to Kowa or your Kowa dealer. The product assembled by yourself will not be covered under warranty nor any other service. | | | |

| | <u>A</u> Caution |
|------------|---|
| | The power supply must be provided for the sole use of this instrument. Sharing a same power supply with other devices may cause malfunctioning. |
| Obligatory | When operating the instrument, take good care so that the patient's eye, nose or face does not come in contact with the instrument. |
| | When moving up or down the chin rest to adjust the height of the patient's eyes, carefully manipulate the instrument while checking the position of the patients' head. A patient with the smaller head may get his or her head caught between the components. |
| | Handle the flash lamps and fuses made of glass with good care. |

A Caution

Do not pull the power supply cable when unplugging.

Doing so may damage the cable and cause a fire or electrical shock. Be sure to hold the plug when unplugging.

Do not plug or unplug the power supply cable with wet hand.

Otherwise, there may occur electrical shock.

Do not install the instrument at unstable location such as on a shaky base or a tilting surface. Doing so may cause the instrument to drop or fall over and result in a bodily injury.



Caution High-temperature

Prohibitory

Do not replace the flash lamp immediately after turning the OFF the main power. You could be burned by the lamp heated to a high temperature.

Wait for more than 10 minutes to cool the lamp down before replacing.

Do not touch the flash lamp bulb with your bare hand.

Otherwise, the lamp may reduce the light intensity and longevity.

Do not increase the observation illumination light intensity more than required. Otherwise the eye may be injured.

Do not increase the photography light intensity more than required.

Otherwise the patient may experience pain and his or her eye may be injured.

The air vent must not be obstructed.

Obstructing the air vent may increase the internal temperature resulting in malfunctioning of the instrument or a fire.

Do not insert any metal object into an air vent or opening of the instrument.

It may cause electrical shock and malfunctioning of the instrument.

When operating this instrument, keep your fingers off the gap between the optical head base and the power supply or the chin rest support and the forehead rest support, or the gap underneath the chin rest.

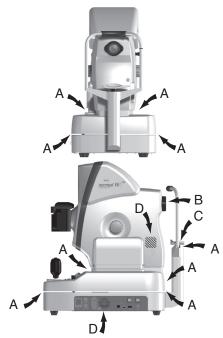
Otherwise, the fingers may be pinched and injured.

Instruct the patient not to place his or her fingers on the instrument.

Do not wipe the outer surface of the instrument with solvents such as benzene, alcohol, organic solvent, ether.

Doing so may cause discoloration or degradation.

Keep your finger off the spaces shown with an arrow. Otherwise you may be injured.



| <u> </u> | | |
|------------|-----|---|
| <u>/i</u> | | |
| <u></u> | 3 | 3 |
| <u></u> | • A | _ |
| <i>/</i> i | | |

| \triangle | Caution |
|-------------|---------|
| | |

- A: Keep your finger off the locations shown with an arrow "A" when operating the instrument.
 - Otherwise, the fingers may be pinched and injured. Instruct the patient not to place his or her fingers on the instrument.
- **Caution**
- B: Take good care so that the patient's eye, nose or face does not come in contact with the locations shown with an arrow "B" when operating the instrument.
- **A** Caution
- C: When moving up or down the chin rest to adjust the height of the patient's eyes, carefully manipulate the instrument while checking the position of the patients' head.

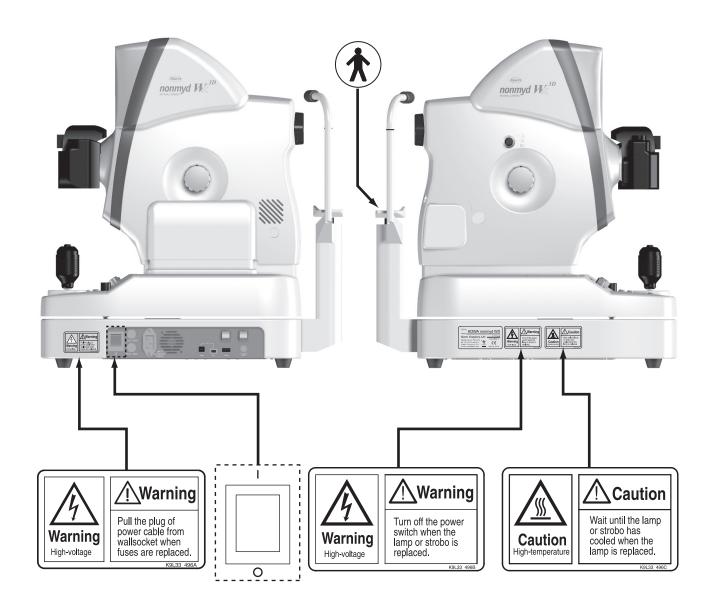
A patient with the smaller head may get his or her head caught between the components.

- D: The air vent must not be obstructed.

 Obstructing the air vent may increase the internal temperature resulting in malfunction of the instrument or
- **Caution**
- **D**: Do not insert any metal object into an air vent or opening of the instrument.

It may cause electrical shock and malfunctioning of the instrument.

Meanings of symbols



| † | Symbol for "Type B applied part". | |
|----------|-----------------------------------|--|
| | Symbol for "Power ON". | |
| 0 | Symbol for "Power OFF". | |

| <u> </u> | Symbol for "Caution". |
|----------|--|
| <u>A</u> | Symbol for "Warning High-voltage". |
| | Symbol for "Warning High-temperature". |
| | Symbol for "MANUFACTURER" |
| EC REP | Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY" |



Operating precautions

1. Operating environment

- 1) Instrument should be operated only by qualified and trained personnel.
- 2) Handle the instrument with care, and do not apply strong shock to the instrument.
- 3) Avoid high temperature and humidity, direct sunlight, and dust when installing and storing the instrument. Strictly observe the following environmental conditions.

| | Operating | Transporting and storing |
|---------------------------|-------------|--------------------------|
| Environmental temperature | 10 to 35 °C | -15 to +55 °C |
| Relative humidity | 30 to 90 % | 10 to 95 % |

- 4) Avoid condensation when using, transporting or storing the instrument.
- 5) Use the designated digital camera only since other camera may adversely affect the safety or performance of this instrument
- 6) Install the instrument in a room where the lighting is 5 lux or less which you may barely manage to read a newspaper.

2. Precautions on electric system

- 1) When the instrument has not been used for a long period of time, inspect the items below. Inspect if the objective lens is free from soils.
 - Inspect if intensity of the lamps appropriately adjustable.
- 2) Install the system in a location where there is little risk of the plug being pulled out while operating. If the plug should be pulled out accidentally, be sure to turn OFF the main power before plugging the system back in.
- 3) Kowa is not liable for malfunctions and/or damages resulting from maintenance and/or repairs performed by the third party other than an agent authorized by Kowa.
- 4) Kowa is not liable for malfunctions and/or damages resulting from maintenance and/or repairs using parts other than repair parts specified by Kowa.
- 5) The input voltage should always be maintained within \pm 10% of the rated voltage.
- 6) Do not turn ON the flash lamp and adjust photography light intensity at the same time.
- 7) Wait for approx. 10 seconds to stabilize the power unit after turning the power ON before using the switches on the operation panel.
- 8) Do not turn the main power ON and OFF in succession. Allow an interval of at least 10 seconds before turning the main power ON and OFF.
- 9) Be sure to turn OFF the main power before connecting an external device.
- 10) Do not touch the patient and connectors at the same time as it may adversely affect the safety.
- 11) Disinfect using alcohol the parts accessible by the patient.
- 12) The power supply must be provided for the sole use of this instrument.

3. Precautions when using a digital camera with this instrument

- 1) Carefully handle the objective lens as soiled or scratched part of the objective lens may be imaged as white spots.
- 2) Always cover this instrument and the digital camera when not in use in order to protect them.
- 3) Do not apply strong shock or force to the objective lens.
- 4) Set a dial or knob with clicking positions to its designated position. The dislocated diopter compensation knob may result in a photograph with a missing part or underexposure.
- Securely install the digital camera. The digital camera installed insecurely may cause distortion of an image or misalignment of focus.
 - The digital camera installed insecurely may fall off and become unusable.
- 6) Never disassemble or adjust this instrument or the digital camera by yourself as it uses precision parts which requires special tool for doing so.

4. Disposal precautions

- 1) LCD monitor of this instrument has a fluorescent lamp that contains mercury. When disposing this instrument, applicable federal, state, and local regulations must be observed.
- 2) When disposing, this instrument and/or its consumables is categorized as industrial waste; therefore, the disposal must be handled by licensed industrial waste disposal contractor.

nonmyd WX^{3D}

Precautions: use of medical electrical system

1. Precautions on use of medical electrical system

- 1) All components of this medical electrical system may be installed within a limited patient environment (a radius of 1.5 m around a patient) when all components are installed in accordance with the installation instructions using "Multi-tap with Isolation Transformer", which is one of the system components.
- 2) As prerequisite for installing to this system, other components (a PC, printer, video capture printer, video monitor, or other devices) which do not comply with IEC60601-1 must be powered from Multi-tap with Isolation Transformer. The electric power to these components supplied from an electric source other than Multi-tap with Isolation Transformer (e.g., wall outlets) may cause increased enclosure leakage current or potential difference between protective grounds resulting in the injury to the patient or operator. Use Multi-tap with Isolation Transformer only for supplying the power to the components other than the system components.
- 3) Any medical electrical equipment that connected to this system to compose a medical system must comply with IEC60601-1.
- 4) Any non-medical electrical equipment that is connected to this system to compose a medical system must comply with safety standards of IEC or ISO provisions applicable to such a non-medical electrical equipment.
- 5) Do not use any additional multi-tap or extension power cable other than those Kowa specified to this system.
- 6) Power supply to this system or "Multi-tap with Isolation Transformer" must be provided individually. (Do not route the power supply through other multi-tap to the system or "Multi-tap with Isolation Transformer".)
- 7) The power cable for an electrical equipment that compose a medical system must have durability that meets IEC60245/IEC60227 or higher standards.
- 8) Assure that the power supply is turned OFF when connecting other device to the system.
- 9) Do not turn ON the power supply until all devices are completely connected.
- 10) Do not place or install the devices and the system components on the unstable or inclined table.

2. Precautions for use of "Multi-tap with Isolation Transformer"

- 1) Do not place "Multi-tap with Isolation Transformer" directly on the floor. Water droplets during room cleaning may enter the multi-tap resulting in the component failure.
- 2) The power supply cable to "Multi-tap with Isolation Transformer" must be connected to a power receptacle with a protective ground terminal equipotential to the protective ground of this instrument.
- 3) When using a multi-tap power receptacle with a protective ground terminal, read the instruction for use attached to the receptacle to familiarize yourself with the correct use before use.

3. Daily maintenance and cleaning

- 1) System components
- Wipe the soiled outer surface with firmly squeezed dampened soft cloth. Use mild detergent to remove excessive soils. Do not use chemicals or solvents such as thinner and benzene. (As the LCD monitor screen cover easily gets scratched, lightly wipe it with soft cloth such as gauze.)
- · Refer to the instruction for use provided with each device for details of device maintenance and cleaning.
- 2) Power cables, connecting cables, and connectors
 - Visually inspect that all cables have no flaw or damage.
- Visually verify that earth leads of all components and protective ground terminals are securely connected.
- Disconnect the power cables from the power supply receptacles when you do not use the system for a long period
 of time.
- 3) Others
- When you add a PC to the system for a filing purpose, captured images are stored in the HDD of the PC. Back up
 the data stored in the HDD regularly since HDDs may have a mechanical or electrical failure.

• Combination of medical electrical equipment and non-medical electrical equipment

IEC 60601-1-1 "Safety requirements for medical electrical systems" describes the components combination grouped into various clinical settings. The brief overview of IEC 60601-1-1 is shown below.

| | | Medically used r | oom | | Feasible solution |
|---------------|--|--------------------------------------|---------------------------------------|--|---|
| Situation No. | | Inside the PATIENT ENVIRONMENT | Outside the PATIENT ENVIRONMENT | Non-medically used room | (See clause 19 in all situations) |
| | 1a Items A and B in PATIENT ENVIRON- MENT | A IEC 60601 BIEC 60601 | | | |
| 1 | 1b Items A and B in PATIENT ENVIRON- MENT | A IEC 60601 BIEC XXXXX | | | For B:Additional protective earth or separating transformer |
| | 1c Item A powerd from specified power supply in item B in PATIENT ENVIRONMENT | A IEC 60601 B IEC XXXXX | | | For B:Additional protective earth or separating transformer |
| 2 | 2a Item A in PATIENT ENVIRONMENT and item B in medically used room | A IEC 60601 | B IEC 60601 | | |
| 2 | 2b Item A in PATIENT ENVIRONMENT and item B in medically used room | A IEC 60601 | B IEC XXXXX | | For B:See 19.201 and its rationale |
| | 3a Item A in PATIENT ENVIRONMENT and item B in non-medically used room 3 | | mon protective ea | B IEC 60601 or IEC XXXXX | For B:See 19.201 and its rationale |
| 3 | | | rth | B IEC 60601 or IEC XXXXX Protective earth with potential difference | For B:Additional protective earth or SEPARATION DEVICE |

KEY TO TABLE

Additional protective earth: If necessary, provide additional protective earthing, which is permanently connected (See also 58.201).

NOTE Equipment modification may be required.

• Separating transformer : If necessary, limit the ENCLOSURE LEAKAGE CURRENT, by using an additional separating transformer according to annex EEE.

NOTE1 No equipment modification is required.

NOTE2 A separating transformer is a transformer with one or more input winding(s) separated from the output winding(s) by at least basic insulation [IEC 60989]

• SEPARATION DEVICE : If necessary, apply SEPARATION DEVICE.

IEC 60601 : MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601.
 IEC XXXXX : Non medical equipment in compliance with relevant IEC safety standards.



Operational considerations for hospital grade electrical instrument (safety and accident prevention)

1. Only qualified personnel should operate this instrument.

2. The following items shall be considered when installing the instrument.

- 1) Install at a location away from water or accidental splashing.
- 2) Install at a location which will not be adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, air containing salt, sulfur and other substances, and the like.
- 3) Take care to guard against tilt, vibration and strong impacts, for instance, during transportation.
- 4) Instrument must not be installed at locations where chemicals are stored or gasses are generated.
- 5) Be careful with the radio frequencies, voltages and allowable amperes (power consumption) of the power supply.
- 6) Properly connect ground wires.

3. The following items shall be considered before using the instrument.

- 1) Make sure that instrument activates properly after checking switch contact, polarity, dial setting and meters and so forth
- 2) Make sure that the instrument is properly grounded.
- 3) Make sure that all cords are properly connected and secured.
- 4) Use of other instruments and appliances on the same power circuit is liable to cause errors and incorrect flash output resulting in incorrect diagnosis or hazards.
- 5) External circuits and connectors that may come in direct contact with the patient must be checked frequently for signs of wear.

4. The following items shall be considered when using the instrument.

- 1) Be sure to minimize the time and quantity required for diagnosis and treatment.
- 2) Always assure that the instrument and patient are in good condition.
- 3) When an abnormality is found on the instrument, take proper measures, for instance, to stop the operation of the instrument while assuring the patient's safety.
- 4) Do not allow the patient to touch any of the instrument controls.

5. The following items shall be considered after using the instrument.

- 1) Turn OFF the instrument after setting control switches, dials and so forth to their initial status following with a specified procedure.
- 2) Do not pull cords for removal because an excessive force is exerted on them.
- 3) The following shall be considered regarding storage location.
 - Store the instrument at locations free from splashes of water.
 - Store at a location which will not be adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, air containing salt, sulfur and other substances, and the like.
 - Take care to guard against tilt, vibration and strong impacts, for instance, during transportation.
 - Instrument must not be stored at locations where chemicals are stored or gasses are generated.
- 4) Clean and rearrange accessories, cords, and the like.
- 5) The instrument must be cleaned prior to use so that there will be no problem when using it again.

6. In case of a problem or malfunction, stop the operation and contact Kowa or your Kowa dealer for repair.

7. Instrument shall not be modified.

8. Maintenance

- 1) Periodically check the instrument and its components for any abnormality.
- 2) When using the instrument that has not been used for a while, it must be checked beforehand to assure that it is in normal condition and operates safely.

9. Be careful of the possibility that incorrect operation may be caused by strong electromagnetic waves.

This instrument is examined based on EN 60601-1-2:2001.

The purpose of this standard is to keep safety against the dangerous obstacle in typical medical facilities.

When this instrument is influenced by other instrument, or when it affects other instrument or when there is such fear, please devise to move this instrument and other apparatus or to make the distance between those instrument. Moreover, if there is an unknown point, please consult our company, or an agency beforehand.



Accessories

| Main body:1 digital camera:1 | | Power supply cable:1(2.5m) | USB cable(Ty | pe A-B):1(3m) |
|--|---------|--------------------------------|---|---------------------------------|
| | | | | |
| | | USB cable(Type A-Mini-B):1(3m) | Chin rest paper:1 | Chin rest paper retaining pin:2 |
| | | | | B |
| Blower:1 | Fuses:2 | Dust cover:1 | Instruction | n manual:1 |
| | | | SON ROLL OF THE STREET OF THE | N MANUAL. |
| Filing software:1 User's guide:1 Installation manual:1 | | | | |
| | | | | |

Optional accessories

| External fixation target:1 K9L-LE57 | Numerical keypad:1 | PC (filing software) :1 |
|--|--------------------|---|
| | 1 | OS: Windows XP/VISTA CPU : Celeron 1.0GHz Memory : 512Mbyte Display : XGA * Comparable or higher performance required |

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System description

1.1 Intended use

KOWA nonmyd WX is intended for use with retinal image capturing without mydriatic.

The retinal image can be stored to an image filing drive through serial interface.

1.2 System overview

This system is an instrument that enables retinal examination and retinal image capturing using infrared rays without requiring the patients to take any mydriatics and uses the normal or stereo light path to capture, record and display images. Also the designated filing software installed in a PC allows you to save, register or print the captured images.

1.3 Features

- 1) One-touch switching Normal, SP and stereo modes.
- 2) Field angles available are 45° with a round mask for normal mode and 34° (20° horizontal and 27° vertical directions) with a square mask for stereo mode.
- 3) Functions that support mosaic mode photography.
- 4) A high resolution digital camera is installed.
- 5) An intuitive operation panel allows you to diagnose effortlessly.
- 6) Anterior segment button enables one-touch switching between anterior segment alignment and retinal alignment screens easily.

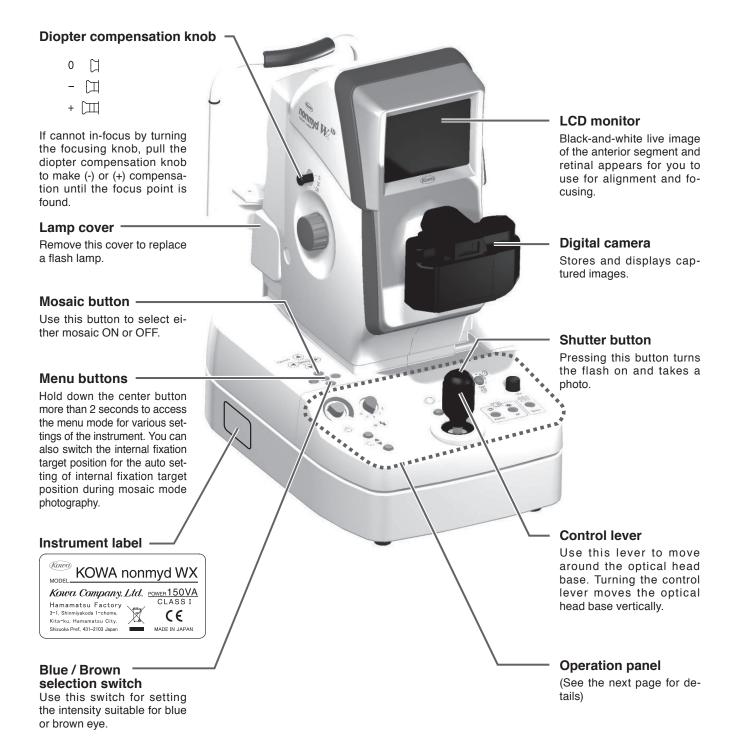
Modes and captured images

| Photography mode | Normal mode | SP (small pupil) mode | Stereo mode |
|-------------------|-------------|-----------------------|---------------|
| Captured image | 45° | | 27° |
| Field angle | 45° | 45° * | 34°(20°× 27°) |

* Some eyes may cause a fiare around their circumference.

1

1.4 Name and function of each component



Operation panel

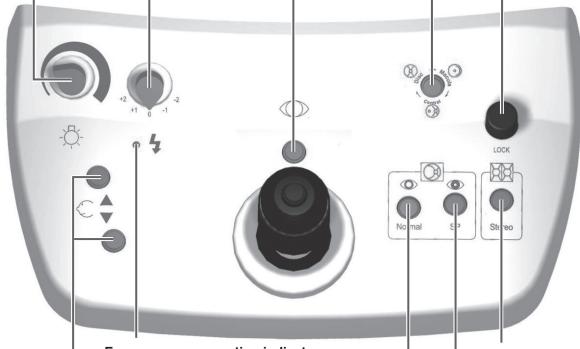
Retinal observation light intensity control knob

Used for adjusting light intensity during retinal observation.

Internal fixation target selection button

Switch the internal fixation target position to posterior, optic disc, and center of macula by pressing this button to go through these selections in normal mode. (In stereo mode, pressing this button goes through optic disc, center of macula and then posterior.) The button turns OFF for posterior, illuminates for optic disc, and flushes for centers of macula. This button turns OFF during mosaic mode photography and the internal fixation target selection function becomes disabled.

Exposure compensation knob Used for adjusting the photography light intensity when photographing. Anterior segment button Pressing this button switches the image shown on the LCD monitor between anterior segment and retinal. The button illuminates when the anterior segment is selected. Moving component fixing screw Tighten the screw when you need to fix the moving component.



Exposure compensation indicator

Illuminates when exposure compensation knob is in any position other than "0" and turns OFF in "0".

Chin rest raising and lowering buttons

Used for raising or lowering the chin rest. The button illuminates normally and flashes when it is in "SLEEP MODE".

Stereo mode button

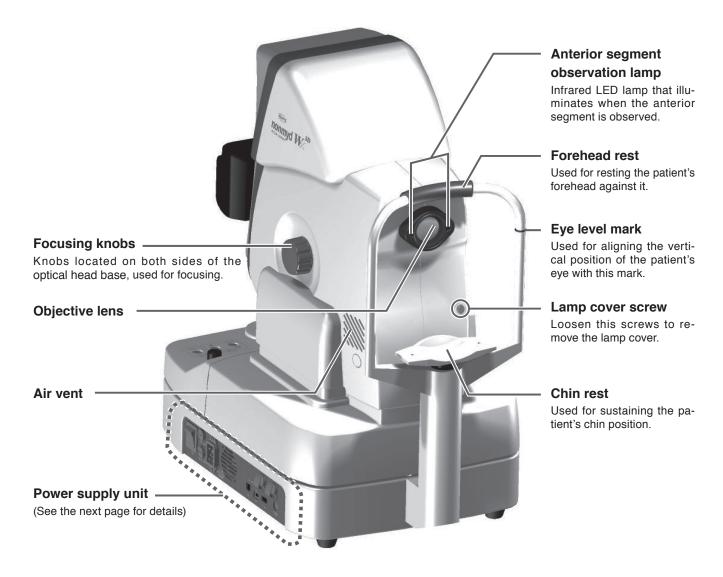
Used for a stereo image with the field angle of 34° (20° horizontal and 27° vertical directions).

SP mode button

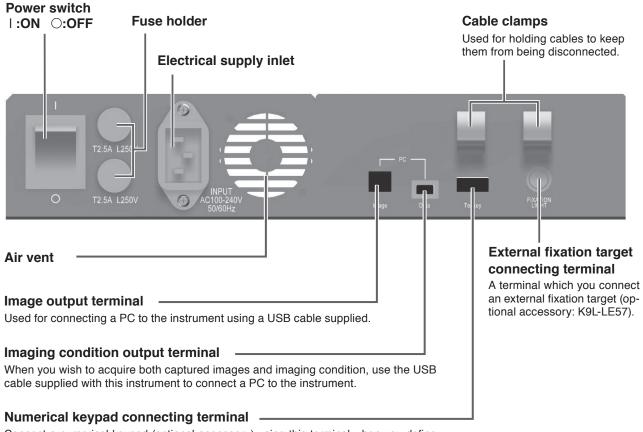
Used for an image with the field angle of 45° for a small pupil diameter.

Normal mode button

Used for an image with the field angle of 45° for a normal pupil diameter.

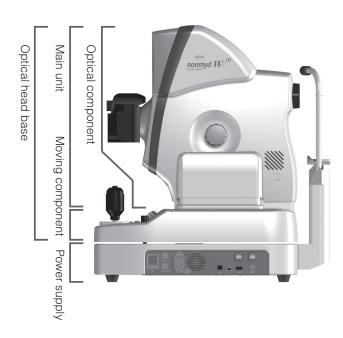


Power supply unit



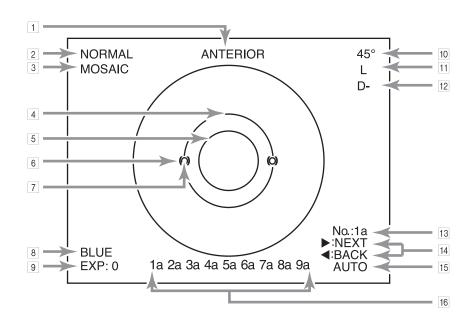
Connect a numerical keypad (optional accessory) using this terminal when you define an internal fixation target position of your choice for mosaic mode photography.

Overall system schematic



Monitor screen indications

Anterior segment observation display



1 Anterior

"ANTERIOR" indicates that the instrument is currently showing the anterior segment observation display.

anterior segment observation: ANTERIOR retinal observation

Photography mode

This indicates the current photography mode.

Normal mode : NORMAL SP mode : SMALL PUPIL Stereo mode : STEREO

3 Mosaic mode photography

ON : MOSAIC **OFF** : none

4 Pupil diameter aid for normal or stereo mode

This aid appears when normal or stereo mode is selected.

5 Pupil diameter aid for SP mode aids

these aids appear when SP mode is selected.

6 Anterior segment working dot position aids

These aids appear during anterior segment observation for you to adjust the working dots.

7 Working dots

The dots are shown optically for you to adjust the distance and position of a patient's eye.

8 Blue eve

This indicates the current Blue / Brown selection switch status.

BLUE BROWN : none

9 Exposure compensation

This indicates the current exposure compensation knob position.

+ 2/ + 1/0/ - 1/ - 2

10 Field angle

This indicates the field angle currently selected.

Normal or SP mode : 45° Stereo mode : 20° x 27°

11 Left or right eve

This indicates which eye you are currently observing.

Left eve : L Right eye: R

12 Diopter compensation

This indicates the diopter compensation knob position. No corrective lens used $(-12 \text{ m}^{-1}(D) \text{ to } +13 \text{ m}^{-1}(D))$: none + compensation $(+10 \text{ m}^{-1}(D) \text{ to } +35 \text{ m}^{-1}(D)): D+$ $(-32 \text{ m}^{-1}(D) \text{ to } -10 \text{ m}^{-1}(D)): D-$ compensation

13 Mosaic mode photography sequence or positions

This indicates the current photographing sequence numbers or photographing positions in mosaic mode photography.

AUTO : No. : 1a to 9a MANUAL : POSITION : 1 to 9

14 Mosaic fixation target switches

They appear when the internal fixation target is set to auto during mosaic mode photography.

: Pressing the right button of the menu but-NEXT tons switches the current photographing

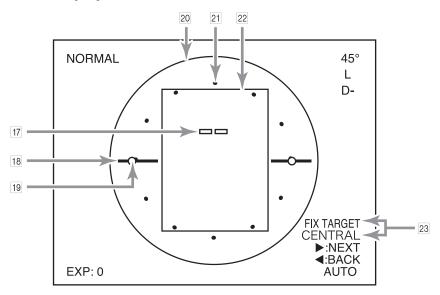
position to the next position.

■BACK : Pressing the left button of the menu but-

tons switches the current photographing

position to the previous position.

Retinal observation display



15 Fixation target position

This indicates the fixation target position currently turned on. Normal, SP, and stereo modes

Posterior : CENTRAL
Optic disc : DISC
Center of macula : MACULA
External fixation target : EXT

Mosaic mode photography

Internal fixation target : AUTO/MANUAL

(this indicates the currently selected position selecting method)

External fixation target : EXT

16 Completed mosaic mode photography

This indicates the completed photographing sequence numbers or photographing positions in mosaic mode photography.

AUTO :1a to 9a MANUAL :1 to 9

17 Focus dots

These dots are shown optically for you to use as reference when focusing.

The dots appear when no diopter compensation is selected. No dot appears when a + compensation or – compensation is selected.

18 Retinal working dot position aids

These aids appear during retinal observation for you to adjust the working dots.

No aid appears in mosaic mode photography.

19 Working dots

These dots are shown optically for you to adjust the distance and position of a patient's eye. No dot appears in mosaic mode photography.

20 Normal mode photographing range

This indicates the photographing range in normal mode.

21 SP mode photographable range

This aid appears when SP mode is selected. It indicates an approximate range where a clear image is captured.

22 Stereo mode photographing range

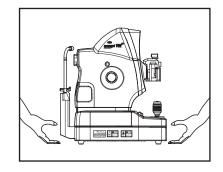
This aid appears when stereo mode is selected and indicates the photographing range in stereo mode.

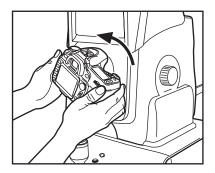
23 Eye fixation direction and mosaic mode photography position

This indicates the guiding or alignment direction when the internal fixation target is used in mosaic mode photography. "FIX TARGET" indicates the direction to which you guide the patient's eye fixation.

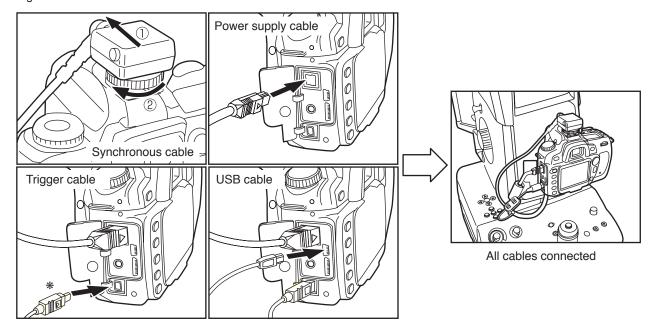
2.1 Installing the system

- ① Place the instrument on a powered optical table (optional accessory). observe the following precautions when moving the instrument.
 - · Fasten the moving component fixing screw.
 - Put your hands under the power supply unit and lift the instrument as shown in the right figure.
 - Do not lift the instrument with holding any parts other than the above.
 - Check the place where you are going to set the instrument is flat with no obstacle that may catch your hand.
 - Be careful not to pinch your hand during installation.
- ② Make sure that the power switch is in OFF ("()") position.
- ③ Install the digital camera in the camera mount.

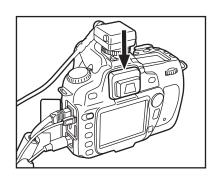




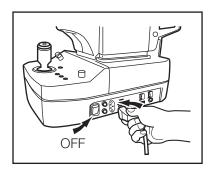
4 Connect the synchronous, power supply, trigger and USB cables to the digital camera.



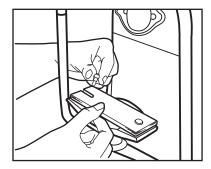
- * Connect the cable with "▷" mark facing towards the LCD monitor of the digital camera.
- ⑤ Ensure that an eye piece cap is attached to the viewfinder of the digital camera.



(6) Make sure that the power switch is in OFF position. Connect the power supply cable to the power supply cable connector. Connect the power supply cable plug to a power outlet.



7 Place the chin rest paper on the chin rest and fix the paper with the chin rest paper retaining pin. Use a sheet of chin rest paper per patient. Remove the top sheet of chin rest paper for the next patient.



🧘 Key ■

- Do not connect a digital camera other than that supplied with this instrument.
- The digital camera is detachable: however, keep detaching/attaching the digital camera to the minimum in order to prevent debris or dust from entering into the instrument and the digital camera.
- The digital camera needs to be disconnected from the instrument when the instrument is to be relocated or the inside of the digital camera is to be cleaned. In such a case arises, contact Kowa or your Kowa dealer in advance for the correct procedures and precautions for detaching the digital camera.

Key ■

- The digital camera supplied with this instrument is set for the retinal camera photography. Do not change the setting.
- Do not detach the eye-piece cap from the digital camera.
- Do not disconnect the cables connected to the digital camera.



Warning



Obligatory

Make sure that the instrument is properly grounded to prevent bodily injuries. Be sure to connect the plug into the three-wire grounding type outlet with ground wire.

Otherwise, there may occur electrical shock.





The power supply must be provided for the sole use of the retinal camera.

Sharing the same power supply with other devices may cause malfunctioning.

2 Installation

2.2 Installing external device (optional PC)

Install a PC by following the PC's instruction manual and turn it on.

Install the application software supplied with the PC. For details of installation, refer to "Installation manual (filing software)".



- When you use a peripheral device and/or other device connected to the peripheral device, it must meet all applicable EN(IEC) standards.
- ☑ Data processing device must meet EN60601-1(IEC60601-1) or IEC60950. The system that combines such data processing device must meet EN60601-1-1(IEC60601-1-1). The system administrator who builds such system bears all responsibility to have the system comply with requirement of EN60601-1-1(IEC60601-1-1). Should you have any question, contact Kowa sales representative or dealership.

2.3 Connecting PC

Connect the image output terminal (PC:Image) of this instrument to an USB terminal of the PC using the USB cable (Type A-B) provided with the instrument.

Connect the imaging condition output terminal (PC: Data) of this instrument to the USB port of the PC using the USB cable (Type A-Mini- B).

* For information on how to connect the instrument to the PC as well as the details of how to use the software, see the attached "Installation manual (filing software)" and "User's guide (filing software)".

Saving captured images

Save captured images using the methods described in 3.1 or 3.2 below.

3.1 Saving captured images in PC (optional device)

Install the supplied filing software into the PC (optional device).

Use a USB cable supplied to connect a PC to the instrument. Captured images will be stored in the PC after it is connected to the instrument.

About the PC

For details of the specification of the required PC, see the attached "Installation manual (filing software)" and "User's guide (filing software)".

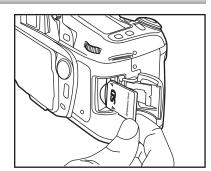


🎝 Key 🚃

- Do not use any USB cable other than the supplied cable.
- Using other USB cable may inhibit normal operation.
- For information on how to connect the PC to the instrument as well as details of how to use the software, see the attached "Installation manual (filing software)" and "User's guide (filing software)".

3.2 Saving captured images in a SD card

Insert a SD card into the digital camera. Captured images will be stored in the SD card.



Captured images saved in a SD card

Captured images saved in a SD card may be displayed on the LCD monitor of the digital camera. The images may be printed out connecting the digital camera to a printer. Contact Kowa or your Kowa dealer for details.



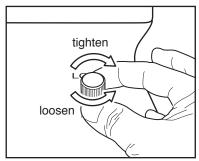
The photographed images are not saved in the SD card when the instrument is connected with the PC.

Basic operation

4.1 Moving component fixing screw

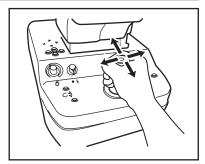
Completely loosen the moving component fixing screw before starting any photography using this instrument.

Completely tighten the moving component fixing screw before moving this instrument to other installation site.



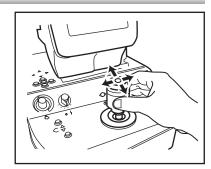
4.2 Coarse motion: moving the optical head base for a long distance

In order to move the optical head base for a slight distance, move the control lever lengthwise or crosswise while holding the lever tightly in upright position.



4.3 Fine motion: moving the optical head base for a short distance

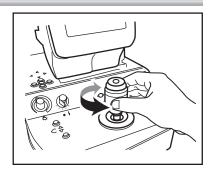
In order to move the optical head base for a very short distance, hold the control lever gently and tilt it lengthwise or crosswise.



4.4 Raising and lowering the optical component

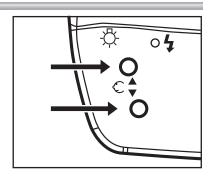
In order to move the optical component up and down, turn the rubber ring of the control lever.

Turning the ring right moves the optical component up and turning left moves the optical component down.



4.5 Raising and lowering the chin rest

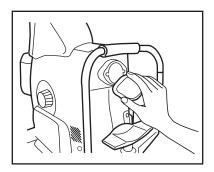
In order to move the chin rest up, press chin rest raising button. In order to move the chin rest down, press chin rest lowering button.



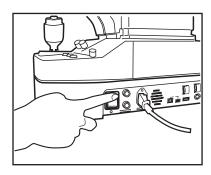
Preparations for photography

5.1 Preparing the instrument

- 1 Make sure that the moving component fixing screw is completely loosened.
- ② Make sure that the instrument is correctly connected to the PC. Make sure that the PC is turned ON and the application software is started.
- ③ Remove objective lens cap.



4 Turn ON the power switch (place it in "I" position).



(5) Make sure that retinal observation light intensity control knob, exposure compensation knob and diopter compensation knob are in their initial position.

The initial positions for the knobs are as below

Retinal observation light intensity control knob : Approx. 10-o'clock position

Exposure compensation knob

: 0 (The indicator under the knob turns OFF at the reference position.

When it is at a position other than the reference position, the indica-

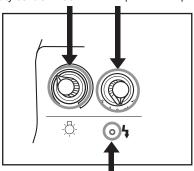
tor illuminates.)

: Pressed position. ("D+" or "D-" does not appear on LCD monitor Diopter compensation knob

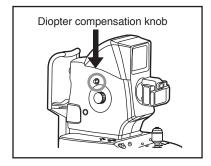
when it is in the initial position.)

Retinal observation light intensity control knob

Exposure compensation knob

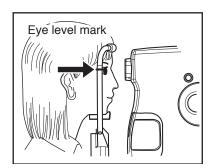


Exposure compensation indicator



5.2 Preparations for patient's eye examination

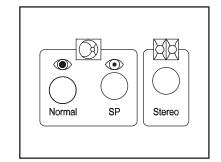
- ① Reduce room's illumination as bright as to make letters on this manual barely readable so that patient's pupil can naturally turn to the size of pupil diameter aid or greater.
- ② Instruct the patient to take off his or her glasses or contact lenses.
- 3 Remove the top sheet of chin rest paper.
- Move and keep optical component as close as possible to you and ask the patient to rest the chin on chin rest.
- ⑤ Adjust chin rest height until the patient's eye level comes to the position of eye level mark.
- (6) Instruct the patient to rest his or her forehead on forehead rest.
- Adjust height of the table which this instrument is installed on so that the patient can place his or her chin on chin rest with ease.
- 8 Adjust optical component height until it comes to the position of eye level mark.



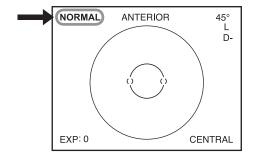
5.3 Selecting a photography mode

This instrument has "Normal mode", "SP mode", and "Stereo mode" for photographing.

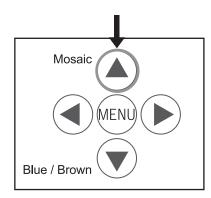
Press "Normal" button for normal photography, "SP" button for small pupil photography, or "Stereo" button for stereo mode.



Upon activation of the instrument, "Normal mode" is selected. The photography mode currently selected is indicated on the upper left corner of LCD monitor.



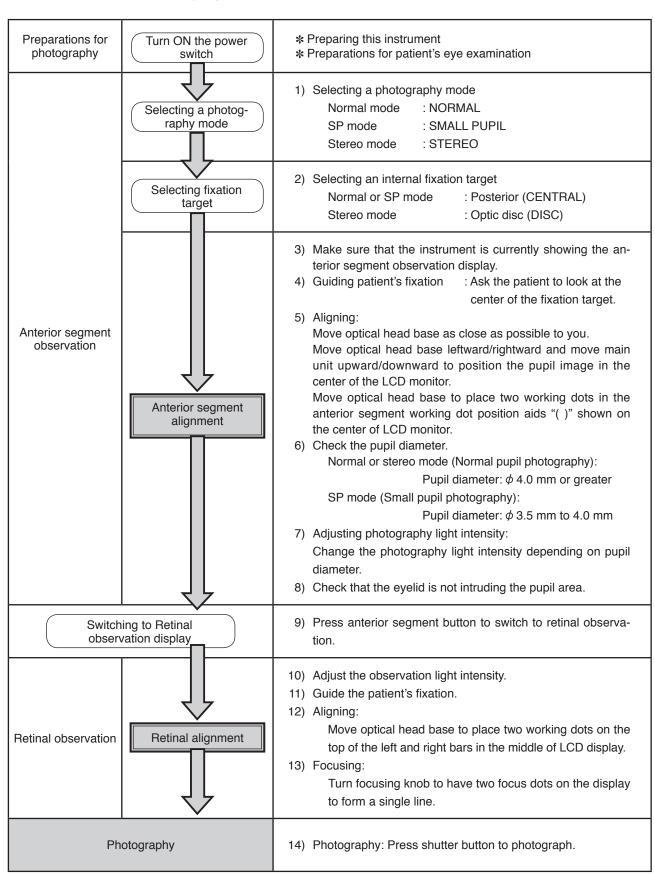
This instrument also has mosaic mode photography for imaging the center of macula and 8 points surrounding the macula. Press "Mosaic" button for mosaic mode photography.



Operational procedure in photography

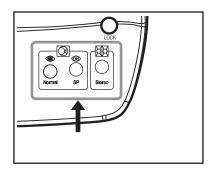
6.1 Normal, SP, and stereo modes

The chart shown blow describes the operation procedure in normal, SP, and stereo modes. Details of items shown in the chart are described on the following pages.

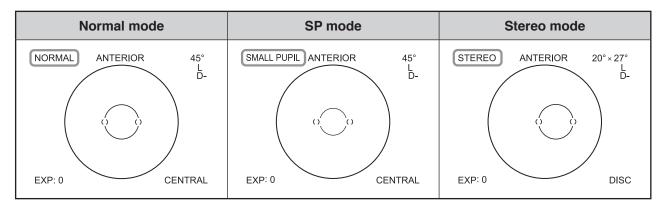


6.1.1 Selecting a photography mode

Select a photography mode by pressing "Normal", "SP", or "Stereo" button.



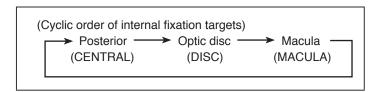
Check that the mode you have selected is shown on the upper left corner of LCD monitor.

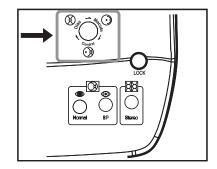


6.1.2 Selecting an internal fixation target

Use internal fixation target selection button to select an internal fixation target that you use for retinal observation.

Continuously pressing the button cycles through the targets as shown in the figure below.



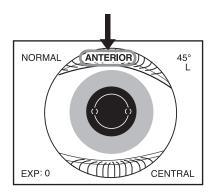


Check

When the photography mode is switched, "CENTRAL" is selected for normal or SP mode while "DISC" is selected for stereo mode. The internal fixation target you have selected appears on the lower right corner of LCD monitor. (See the figures of normal, SP, and stereo modes shown in "6.1.1 Selecting a photography mode".)

6.1.3 Checking anterior segment observation display

Make sure that "ANTERIOR" is shown in the upper part of LCD monitor. Press anterior segment button when "ANTERIOR" is not shown.



6.1.4 Guiding patient's fixation

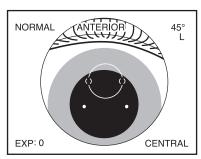
Instruct the patient to look straight ahead.

Perform the step described in "6.1.5 Alignment". Ask the patient to look straight ahead at the green illuminating spot when the patient's pupil becomes shown in the center of LCD monitor.

When failed to complete the patient's fixation by using the internal fixation target, use the external fixation target (optional accessory: K9L-LE57). Refer to "7.2 external fixation target" for details of connecting and operating the external fixation target.

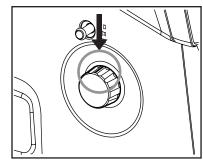
6.1.5 Aligning

Pull the optical component as close as possible to you and move the optical head base leftward/rightward or upward/downward in order to capture the pupil at the center of the LCD monitor.



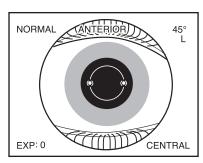
Beginning of alignment

Rotate focusing knob until the black line engraved on the knob faces upwards.



Focusing knob position

After the pupil image is captured successfully, move the optical head base forward until two working dots come in two pairs of round brackets "()".



Alignment completed

6.1.6 Checking pupil diameter

Check the condition of dilation by comparing the patient's pupil diameter against the pupil diameter aid.

Change the photography light intensity as required depending on the mydriatic state.

If the patient's pupil diameter is smaller than that shown by the pupil diameter aid, press SP mode button to proceed to small pupil photography.

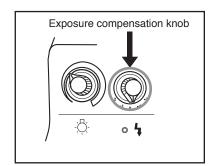
| Photography light intensity | 0 | +1 | Insufficient for photography |
|---|---|----|------------------------------|
| Normal mode Stereo mode Pupil diameter: ϕ 4 mm or greater | | | |
| SP mode Pupil diameter: ϕ 3.5 mm to 4 mm | | | |



- In case of the above insufficient for photography, make the room darker, or take more time to get accustomed to darkness so that the pupil's dilation can be facilitated.
- It would be difficult to capture a clear image when the pupil diameter is insufficient. However it may not be applicable to some patients.

6.1.7 Adjusting photography light intensity

Change the photography light intensity by the exposure compensation knob as needed depending on the condition of dilation.



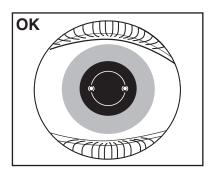
Key

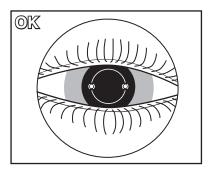
The photography light intensity is automatically set to the standard level sufficient for each photographing procedure. However, each patient's mydriatic state and iris color may cause excessive or insufficient light intensity. When excessive or insufficient light intensity occurs, use exposure compensation knob to compensate the intensity. The LCD monitor shows the current light intensity setting as a guideline. Rotating exposure compensation knob to one step up or down changes 1/2 step of exposure value.

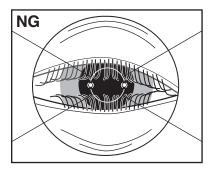
6.1.8 Checking eyelids and eyelashes

The eyelids or eyelashes intruding the pupil area interferes photography. In such a case,

- · Instruct the patient to widely open his or her eyes, or
- · You or your assistant help the patient keep the eye wide open.



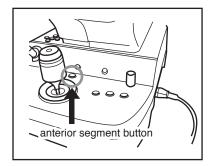




6.1.9 Switching from anterior segment observation to retinal observation

After alignment of the anterior segment is completed, press anterior segment button to switch to retinal observation.

When you want to go back to anterior segment observation, press the button again.



"ANTERIOR" and the pupil diameter aid of the LCD monitor disappear during retinal observation. Anterior segment working dot position aids " (O) " changes to retinal working dot position aids " — ", and the focus dots appears.

| Normal mode | SP mode | Stereo mode | |
|-------------------------|--------------------------------|--------------------------|--|
| NORMAL 45° L D- CENTRAL | SMALL PUPIL 45° L D- CENTRAL | STEREO 20°×27° L D- DISC | |

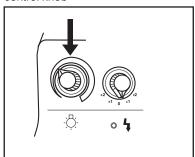


For stereo mode observation, move the photography target to the center of the LCD monitor.

6.1.10 Adjusting observation light intensity

Adjust the image brightness by retinal observation light intensity control knob when the retinal image, focus dots, and working dots are not clearly shown. For details of LCD monitor brightness and contrast adjustment, refer to "9.4.6" MONITOR BRIGHTNESS / CONTRAST".

Retinal observation light intensity control knob



6.1.11 **Guiding patient's fixation**

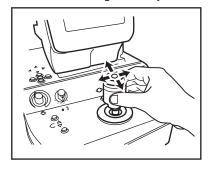
The fixation target position changes when anterior segment observation is switched to retinal observation. In order for the patient to stare at the selected internal fixation target, guide the patient's fixation to the internal fixation target by asking the patient to look at the green light.

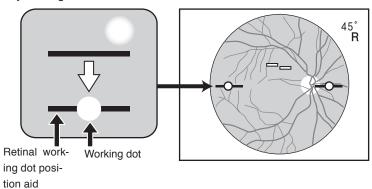
Patients would recognize the fixation target at the locations shown in the right table depending on whether the right or left eye is examined and which fixation target position is selected.

| | Right eye | Left eye |
|------------------|-------------|----------|
| Posterior | Near center | |
| Optic disc | Left | Right |
| Center of macula | Center | |

6.1.12 **Aligning**

Move the optical head base slightly until the sizes of the two working dots become the smallest and the dots are aligned on the top of the left and right retinal working dot position aids " —— " in the LCD monitor as shown in the figure below. The focus of the two working dots may be fine tuned by moving the control lever forward/backward.

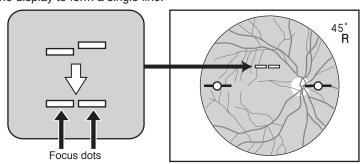




6.1.13 **Focusing**

Turn focusing knob to have two focus dots " == " on the display to form a single line.





6.1.14 **Photography**

After alignment and focusing are completed, photograph by pressing shutter button.

Pictures will be stored in the connected PC. For viewing and analyzing the pictures using a PC, refer to "Installation manual (filing software)".

6.2 Precautions for continuous photography

Please note that the LCD monitor automatically switches back to anterior segment observation. *3 When you continue photographing, note the precautions described below.

*3 You may disable the anterior segment observation auto-return function by changing the setting.
For details of the setting, refer to "9.4.4 EXTERNAL ALIGNMENT:NORMAL" and "9.4.5 EXTERNAL ALIGNMENT: MOSAIC"

6.2.1 Pupil diameter

When you continuously photograph, the pupil is constricted due to the flash light in the previous photography. In such a case, wait for a while and make sure that the pupil diameter is sufficient for photography.

6.2.2 Photographing the other side of eye

When continuously photographing the other side of the eye, pull optical head base toward you so that it will not contact the patient's eye or nose and then move the digital camera toward the other side.



Do not increase the photography light intensity more than required.
 Otherwise the patient may experience pain and his or her eye may be injured.

6.3 Terminating photography

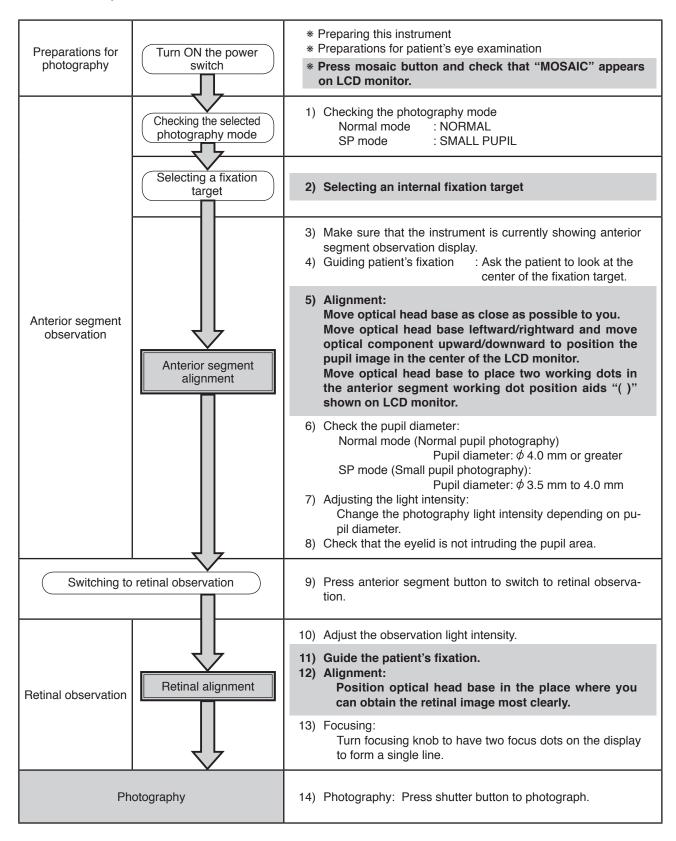
- Turn OFF the power switch of this instrument (place it in "O" position), exit the filing software, and turn OFF the PC. Refer to "Instruction manual (filing software)" or the PC's "Instruction manual" for how to terminate the PC.
- Place the lens cap on the objective lens.
- Move optical head base back to initial position where optical head base is positioned just above the power supply and
 fix it there by tightening the moving component fixing screw.
- Place the dust cover over the instrument.

Advanced photography

7.1 Mosaic mode photography

Mosaic mode photography has its own internal fixation target selection and positioning different form that of Normal or SP mode.

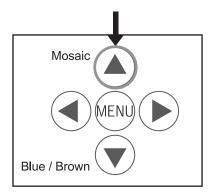
In this section only these differences are described.



7.1.1 Selecting mosaic mode photography

Press mosaic button (the button above "MENU" button).

You can switch between Normal mode and SP mode during mosaic mode photography.



7.1.2 Selecting an internal fixation target

Internal fixation target selection button becomes disabled during mosaic mode photography. Mosaic mode photography has two types of internal fixation target setting methods, "AUTO" and "MANUAL" settings.

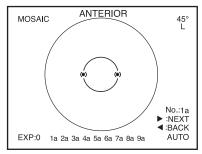
In "Auto mode setting", one of the internal fixation targets is sequentially selected in the predefined order.

In "Manual setting", an internal fixation target is selected manually by pressing one of the keys corresponding to the photographing parts of the eye.

The default setting is "Auto mode setting".

For changing the setting, refer to "9.3 Mosaic internal fixation target setting (Switching internal fixation target in mosaic mode photography)".

■ Switching the internal fixation target in mosaic mode photography – Use in auto mode





MOSAIC

Anterior segment observation display

Retinal observation display

TX TARGET

CENTRAL ▶:NEXT

AUTO

The position of the anterior segment working dot position aids on anterior segment observation display changes depending on the photographing part of the eye.

In auto setting, one internal fixation target is automatically switched to another after completing each photography and the corresponding photographing part of the eye is also changed consequently.

When you want to photograph again because of poor photo quality, press the left key of the menu buttons.

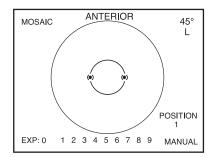
The internal fixation target that corresponds to the last photographing part illuminates.

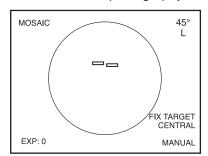
When you do not need to photograph the area currently selected, press the right side button of the menu button. This switches the current part to the next photographing part and the internal fixation target that correspond to the next photographing part illuminates.

1a to 9a shown on the bottom of LCD monitor indicate the mosaic mode photography sequence selected in menu mode. When a photograph is taken, the corresponding number becomes highlighted. Pressing shutter button by mistake while observing anterior segment does not allow the next photographing part to appear since an image capturing must be repeated again.

For details of the mosaic mode photography sequence setting, refer to "9.3.2 Setting of auto mode".

■ Switching the internal fixation target in mosaic mode photography – Use in manual mode



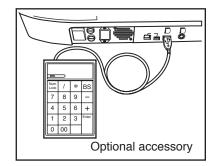


Anterior segment observation display

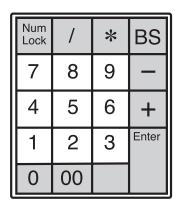
Retinal observation display

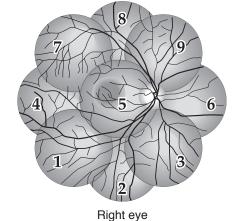
Select manual mode in order to select the photographing parts of your choice in mosaic mode photography.

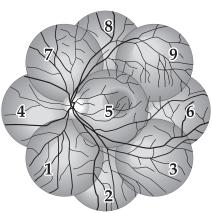
* For details of the setting, refer to "9.3 Mosaic internal fixation target setting (Switching internal fixation target in mosaic mode photography)". Connect a numerical keypad (optional accessory) that allows you to select internal fixation target positions of your choice. Turn ON num lock of the connected numerical keypad.



Keys of a numerical keypad are used to select internal fixation target positions in manual setting. Relationship between the keys and the internal fixation target positions is shown below.







Left eye

Keys of numerical keypad (Shaded keys are invalid.)

The numbers from 1 to 9 that appear on the bottom of the display indicate photographing parts of the eye (and keys

The highlighting is cleared when the optical head base is moved to switch the eye to be examined to the other side of eye.

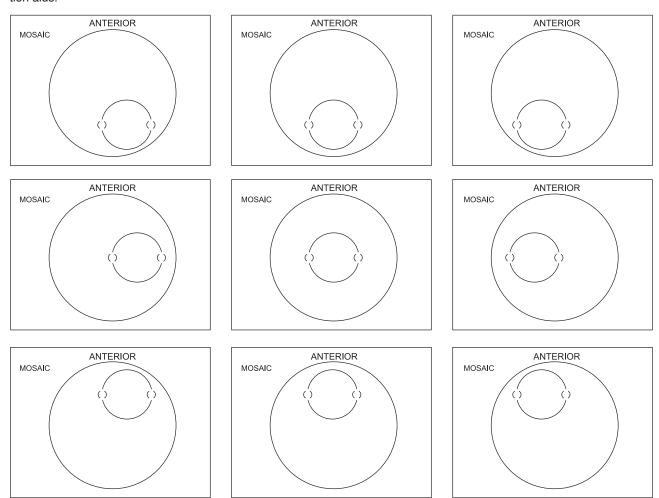
of numerical keypad). When a photograph is taken, the corresponding number becomes highlighted.

7.1.3 Aligning and focusing

In mosaic mode photography, align for anterior segment observation only, switch to retinal observation without changing the position of the instrument, check that the patient eye is correctly fixed, and photograph.

However when you see an excessive flare during retinal observation, position the digital camera appropriately before photographing.

For mosaic mode photography, the alignment position in anterior segment observation appears in different positions as shown in the figures below. Align appropriately so that the working dots fit within the anterior segment working dot position aids.



"FIX TARGET" that indicates the eye fixation direction for you to direct a patient or the position of the internal fixation target visible from a patient appears on the lower right of LCD monitor during retinal observation.

Tell the patient the direction shown on the display and guide the patient's fixation.

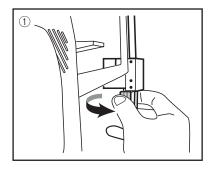
Please note that some photographing parts may not clearly show the focus dots. In such a case, perform focusing using macula and photograph other photographing parts without re-focusing. However you may re-focus when you can see the focus dots clearly.

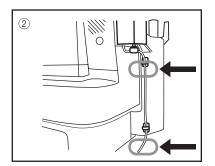
7.2 External fixation target

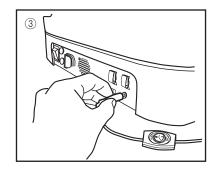
When failed to complete fixation of the patient's eye using the internal fixation target, use the external fixation target (optional accessory: K9L-LE57) to enable the fixation using the other eye.

7.2.1 Installing the external fixation target

- ① Aligning the groove on the external fixation target mount and the chin rest, tighten two mounting screws to lock the lamp.
- (2) Adhere attached cable clamps at two places shown in the figure and fix the cable with the cable clamps.
- 3 Insert the cable into the external fixation target connecting terminal.

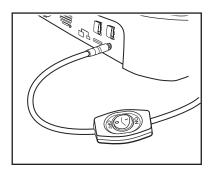






7.2.2 Using the external fixation target

The external fixation target illuminates by turning on the button installed on the cable. (When it is turned ON, the internal fixation target turns OFF.) "EXT" appears on the lower right corner of LCD monitor when the external fixation target is in use.



7.3 Diopter compensation range

When clear focus can not be obtained by focusing, pull out diopter compensation knob.

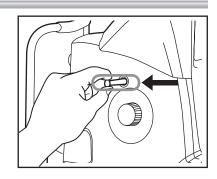
Pulling out diopter compensation knob to the first stop enables the minus diopter compensation (D-) while pulling out to the second stop enables the plus diopter compensation (D+). Slowly pull out the knob until it cricks when it comes into one of the diopter lens insert positions. When you stop pulling the knob before it cricks, you can not obtain a good image.

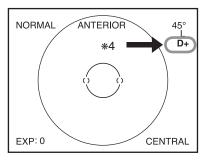
The minus or plus diopter compensation is indicated on the upper right corner of LCD monitor. $^{\!\star 4}$

The focusing range of each compensation position is shown below.



Adjust the focus using the retinal image on the LCD monitor since focus dots do not appear when diopter compensation lens is in use.





Troubleshooting

| Examples of retinal photograph | Possible cause | Remedies |
|---|---|---|
| Dark shadow or bright reflection appears at the top or bottom of the image. | The instrument is positioned too high to the patient's eye. | |
| | The instrument is positioned too low to the patient's eye. | Perform all alignment steps to obtain a clear retinal image with consistent brightness. Depending on the patient's eye fixation condition, you may obtain a good image by locating working dots away from the dot position aid. |
| Dark shadow or bright reflection appears at the left or right of the image. | The instrument is positioned too right or left to the patient's eye. | Perform all alignment steps to obtain a clear retinal image with consistent brightness. Depending on the patient's eye fixation condition, you may obtain a good image by locating working dots away from the dot position aid. |
| | Diopter compensation knob is not in click. | Check that diopter compensation knob is in the correct position by slowly moving the knob to see if it cricks. |
| Peripheral area become whitened. | The instrument is positioned too close to the patient's eye. The instrument is positioned too far from the patient's eye. | Locate the digital camera to the position where working dots become smallest. When flares still persist, pull the digital camera a little or move the optical component to the patient. (Working dots may be fades a little.) |
| The image is too dark. | The pupil diameter is small. | Turn exposure compensation knob to +1 or +2 position. If the patient's pupil diameter equal to or smaller than that shown by the working dots, press SP mode button and photograph in SP mode. |
| The image is out of focus or blurred. | The patient has developed a cataract. | Avoiding the area of white turbidity during alignment may allow you to obtain a good image. |
| | The corneal surface is dry. | Ask the patient to blink before imaging. |
| The image become whitened locally. | | |
| | The objective lens is dirty. | Clean the objective lens. Refer to "10. Maintenance and inspection" for details of the objective lens cleaning. |
| The lower area become whitened. | The eyelid or eyelashes intrude the imaging area. | Ask the patient to open his/her eyes wide so that the eyelid or eyelashes do not intrude the area of the pupil, or you or your assistant help the patient keep the eye wide open. |

| Irregularity | Possible cause | Remedies | |
|--|---|---|--|
| Focus dots do not appear. | A diopter compensation lens is inserted. | Adjust the focus using the retinal image since focus dots do not appear when a diopter compensation lens is in use. | |
| The flash lamp turns on but a black image or partially chipped image is obtained. The shutter speed of digital camera is not set to 1/25 sec. | | Set the shutter speed of digital camera to 1/25 sec. * Refer to "12 Technical information". | |
| The flash lamp does not turn ON | The digital camera is not set to manual mode. | Set the digital camera to manual mode. * Refer to "12 Technical information". | |
| and no image is captured. | Trigger cable is not fully inserted. | Fully insert the trigger cable to the end. | |
| Although image are successfully captured and shown on the LCD monitor of the digital camera, the monitor of the PC presents no image. | The USB cable is not fully inserted. | Fully insert the USB cable to the end. | |
| Images are captured without flash lamp turned on. | The synchronous cable is not fully inserted. | Fully insert the synchronous cable to the end. | |

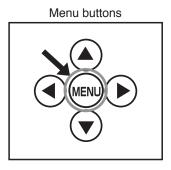
| Irregularity | Possible cause | Remedies |
|---|--|--|
| The error message below is displayed on the LCD monitor. ERROR 1 : HIGHER VOLTAGE POWER OFF AND CALL SER- VICE PERSON | Charged voltage exceeded the limit. There could be a failure of an internal circuit. | Please contact Kowa or your Kowa dealer. |
| The error message below is displayed on the LCD monitor. ERROR 2: LOWER VOLTAGE POWER OFF AND CALL SER- VICE PERSON | Charged voltage does not reach the lower limit. There could be a failure of an internal circuit. | Please contact Kowa or your Kowa dealer. |
| The error message below is displayed on the LCD monitor. NOW COOLING PLEASE WAIT 120 SEC | Cooling has been started since the recharge circuit temperature exceeded the higher limit. | This is not a malfunction. Wait for 120 seconds before you resume photography. |

Menu operation

9.1 Starting menu

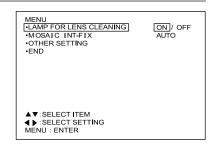
Press down "MENU" button center of menu buttons for approx. 2 seconds to access menu mode.

Use menu buttons " \blacktriangle , \blacktriangledown , \blacktriangleleft , and \blacktriangleright " in menu mode.



9.2 Objective lens cleaning lamp

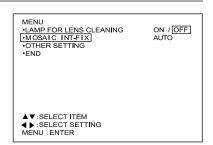
Objective lens cleaning lamp illuminates when you press " ◀ " button to select "ON" while "LAMP FOR LENS CLEANING" is selected. Refer to "10 Maintenance and inspection" for details of the objective lens cleaning.



9.3 Mosaic internal fixation target setting (Switching internal fixation target in mosaic mode photography)

Internal fixation target switching method is defined in this item.

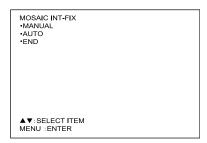
You can select either manual mode that requires a numerical keypad (optional accessory) for operation or "Auto mode" which automatically switches the fixation targets. You also set the illuminating order for auto mode and select the mirror symmetry of illuminating orders for the left and right eyes.



9.3.1 Settings for manual mode

Press menu button while "MOSAIC INT-FIX" is selected to access the display shown in the right figure.

Press menu button while "MANUAL" is highlighted to select "MANUAL" and return to menu item selection.



9.3.2 Settings of auto mode

Press menu button while "AUTO" is highlighted to access "MOSAIC INT-FIX AUTO MODE SETTING". Pressing menu button while "AUTO MODE SETTING" is highlighted makes one of the numbers shown under "PHOTO LOCATION ON THE RIGHT EYE" highlighted and allows you to start setting the photographing order. The current setting appears first when you access "AUTO MODE SETTING".

MOSAIC INT-FIX AUTO MODE SETTING

-AUTO MODE SETTING

PHOTO LOCATION ON THE RIGHT EYE.

923
8114
71615

MIRROR SELECTION YES / NO
-END

AV-SELECT ITEM

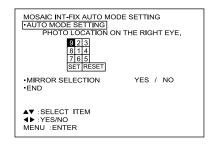
+ YES/NO
MENU : ENTER

Use "▲, ▼, ◄, and ▶" keys to move to the number of your choice. Select and highlight the number corresponding to the photographic state.

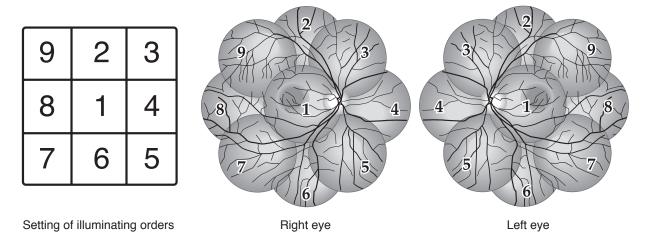
Select and highlight the number corresponding to the photographing part of the eye in the order you want to photograph and press menu button to set the illuminating order.

When you terminate setting, highlight "SET" and press menu button. When you want to restart the setting, highlight "RESET" and press menu button.

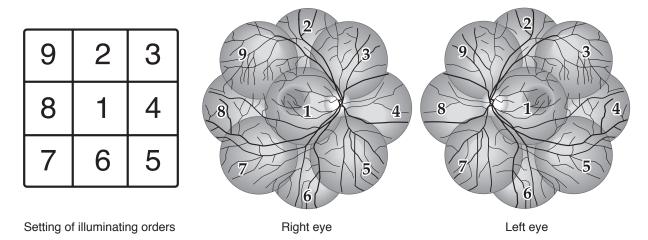
Also you can select the mirror symmetry of illuminating orders for the left and right eyes. When you want to apply the mirror symmetry, highlight "MIRROR SELECTION", select "YES", and press menu button. When you do not apply the mirror symmetry, select "NO" and press menu button.



When you select "YES" for the "MIRROR SELECTION", illuminating orders are as shown below.



When you select "NO" for the "MIRROR SELECTION", illuminating orders are as shown below.

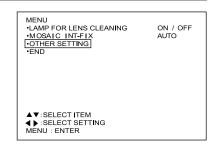


Select "SET" and press menu button in "MOSAIC INT-FIX AUTO MODE SETTING" to save the settings and return to menu item selection.

When the power supply is turned OFF before pressing "SET", the settings you have made will not be saved.

9.4 Other setting menu

Press menu button while "OTHER SETTING" is highlighted to access the sub menu screen for other settings of this instrument.



9.4.1 POWER ON MODE 1

This item allows you to select the photography mode when the instrument is turned ON.

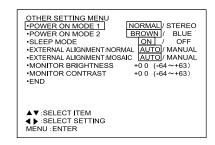
Setting

NORMAL: Normal mode (Factory setting)

STEREO: Stereo mode

How to set

Press " ◀ " or " ▶ " button to switch the setting while "POWER ON MODE 1" is selected. Press menu button while the setting of your choice is highlighted to select the setting and return to menu item selection.



9.4.2 POWER ON MODE 2

This item allows you to select the state of Blue/Brown selection switch when turning the instrument is turned ON.

Setting

BROWN : Brown eye (Factory setting)

BLUE : Blue eye

How to set

Press " ◀ " or " ▶ " button to switch the setting while "POWER ON MODE 2" is selected. Select "END" and press menu button while the setting of your choice is highlighted to confirm the setting and return to menu item selection.

9.4.3 SLEEP MODE

You can select "SLEEP MODE" (power saving mode) as the initial power mode when the instrument is turned ON. When this instrument is not operated for a certain period of time (approximately 10 minutes) it goes into "SLEEP MODE". In "SLEEP MODE, the LCD" monitor and all lamps of observation illumination lamps except the chin rest raising and lowering button indicator lamp (the indicator lamp flashes during "SLEEP MODE") turn OFF. When you activate any part of the instrument, it recovers from "SLEEP MODE".

Setting

ON : SLEEP MODE (Factory setting)

OFF : Normal mode

How to set

Press " ◀ " or " ▶ " of menu buttons to switch the setting while "SLEEP MODE" is selected.

9.4.4 EXTERNAL ALIGNMENT: NORMAL

In normal mode, you can set whether or not the display automatically switches back to anterior segment observation after photography.

Setting

AUTO : The display automatically switches back to anterior

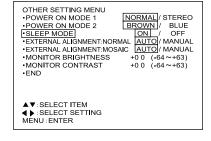
seament.

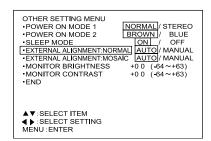
MANUAL: The display does not automatically switch back to anterior

segment.

How to set

Press " ◀ " or " ▶ " button to switch the setting while "EXTERNAL ALIGNMENT: NORMAL" is selected. Select "END" and press menu button while the setting of your choice is highlighted to select the setting and return to menu item selection.





9.4.5 EXTERNAL ALIGNMENT: MOSAIC

In mosaic mode photography, you can set whether or not the display automatically switches back to anterior segment observation after photography.

Setting

AUTO : The display automatically switches back to anterior

segment.

MANUAL: The display does not automatically switch back to anterior

segment.

How to set

Press " ◀ " or " ▶ " button to switch the setting while "EXTERNAL ALIGNMENT: MOSAIC" is selected. Select "END" and press menu button while the setting of your choice is highlighted to select the setting and return to menu item selection.

9.4.6 MONITOR BRIGHTNESS / CONTRAST

Press menu button while "MONITOR BRIGHTNESS" or "MONITOR CONTRAST" is selected to display an observation image. Use the image to set the LCD monitor screen brightness or contrast.

Press "▲" or "▼" key to increase or decrease the brightness or contrast. While looking at the observation image on the LCD monitor, select an appropriate brightness or contrast and press menu button.

OTHER SETTING MENU
-POWER ON MODE 1
-POWER ON MODE 2
-SLEEP MODE
-SLEEP MODE
-SXTERNAL ALIGNMENT-NORMAL
-EXTERNAL ALIGNMENT-MOSAIC
-MONITOR BRIGHTNESS
-MONITOR CONTRAST
-END

A▼: SELECT ITEM
-SELECT ITEM
MENU: ENTER

▲▼:SELECT ITEM ◀▶:SELECT SETTING MENU:ENTER

9.4.7 Exiting a menu

To exit menu mode, select "END" in any of the menu screen.

OTHER SETTING MENU
POWER ON MODE 1 NORMAL / STEREO
POWER ON MODE 2 BROWN / BLUE
SLEEP MODE ON / OFF
EXTERNAL ALIGNMENT:NORMAL AUTO / MANUAL
EXTERNAL ALIGNMENT:MOSAIC AUTO / MANUAL
MONITOR BRIGHTNESS +0 0 (-64~+63)
MONITOR CONTRAST +0 0 (-64~+63)

▲▼:SELECT ITEM ◀▶:SELECT SETTING MENU:ENTER

MENU
-LAMP FOR LENS CLEANING
-MOSAIC INT-FIX
-OTHER SETTING
-END

AUTO

ON / OFF

▲▼:SELECT ITEM ◀ ▶:SELECT SETTING MENU:ENTER

Maintenance and inspection

This instrument is a precision instrument and daily maintenance and inspection would affect the imaging results. Please read the following information carefully in order to use this product correctly and safely.

10.1 Daily maintenance

- 1. What to do after use:
 - Turn the power switch OFF
 - Place the lens cap on the objective lens
 - Place the dust cover over the instrument
- 2. Check that no dust, debris, finger print, or body fluid is found on the objective lens.
- Determine that the objective lens is clean before you start using the instrument the first time each day.
 Dirty objective lens is readily identified under the objective lens cleaning lamp (see "9.2 objective lens cleaning lamp").
 - When the objective lens is dirty, follow the steps described in "10.4 Cleaning the objective lens" to clean it.
- 4. Condensation may occur on the objective lens when the instrument is moved into an environment where there is temperature difference. When condensation occurs, wait until it disappears before use.
- When condensation occurs repeatedly, lenses may get moldy.
 When such a case has occurred to you, contact Kowa or your Kowa dealer.
- 6. Disconnect the power supply cable when the instrument is not used for an extended period of time.

10.2 Daily inspection (by users)

Inspect this instrument in accordance with "KOWA nonmyd WX daily inspection table".

When an anomaly found during the inspection may not be solved using any of the maintenance methods described in this instruction manual, contact Kowa or your Kowa dealer.

KOWA nonmyd WX daily inspection table

| Inspection | Procedure | Acceptability criteria |
|-------------------------------|---|---|
| Power cable | Visually verify that the cable has no flaw or damage. | No flaw or damage should be found. |
| Objective lens | See "10.4 Cleaning the objective lens". | No dust, debris, fingerprint, teardrop must be found. |
| Exterior | Visually verify that the exterior has no flaw, crack, deformation or rust. | Exterior components must have no flaw, crack, deformation or rust. |
| Plates and labels | Visually verify that the ID plate and labels is readily readable and not contaminated. | Rating plates and labels must be readable. |
| Shutter button and flash lamp | Make the instrument ready for photography. Hold your hand in front of the objective lens. Push the shutter button and visually verify that the flash light emitted through the objective lens illuminates the hand (do not look into the objective lens). | Pressing the shutter button must activate the flash lamp to emit the light. |

10.3 Regular inspection (by manufacturer)

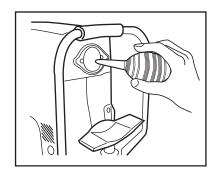
In order to use this instrument safely over its useful life, we recommend you to have it inspected annually. Contact Kowa or your Kowa dealer for details and cost of inspections.

- 1. External components and their installation
- 2. Optical components
- 3. Operations and functions of components
- 4. Photograph quality inspection using standard model eye (0D)
- 5. Photography light intensity

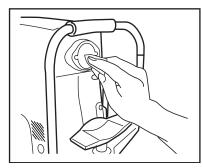
10.4 Cleaning the objective lens

You can not obtain a good image if the objective lens is contaminated with fingerprints, etc. Clean the lens as described below:

- 1 Turn ON power switch.
- ② In order to identify soils on the objective lens clearly, reduce room's luminance, and turn ON the objective lens cleaning lamp.
 - (Refer to "9.2 Objective lens cleaning lamp" for details of how to turn ON the objective lens cleaning lamp.)
- ③ Using high-pressure air, blow off debris or dust.



When the air does not clean the objective lens, moisten soft cloth or cleaning paper with cleaning solution made from ethyl alcohol and ether (1:1) and clean the lens starting from its center in a circular motion.



🏅 Key 🕳

- Tips for lens cleaning
 - Do not reuse soft cloth or cleaning paper but use new soft cloth or cleaning paper moistened with cleaning solution to obtain the best results.
- * Cleaning the lens without removing soils or applying a strong force when wiping may scratch the lens surface.
- * Do not use chamois leather, silicon cloth, or eyeglass cleaner paper, etc.
- * Carefully store and handle the flammable and combustible cleaning solution.
- ⑤ If any soil is left out after cleaning with the cleaning solution, gently wipe off the soiled area with a cotton swab soaked with a little amount of water. After this cleaning step, wipe the lens using the cleaning solution described above. Should you have stubborn soil that cannot be removed by the steps above, contact Kowa or your Kowa dealer.
- (6) Turn OFF the objective lens cleaning lamp after the lens cleaning is completed.

10.5 Disinfection

Wipe the forehead rest with rubbing alcohol as soon as a patient completes the examination. Also wipe the chin rest with rubbing alcohol when no chin rest paper is used.

10.6 Outer cleaning



Caution



Do not wipe the outer surface of the instrument with solvents such as benzene, alcohol, thinner, ether. Such substances may cause the surface to be discolored or deteriorated.



Key

- Wipe the outer surface with soft cloth, from which water (used to moisten the cloth) was firmly squeezed off.
- Lightly wipe the LCD monitor screen cover with soft cloth such as gauze because it is easily damaged. Wipe off the obstinate dirt with soft cloth, from which water or lukewarm water used to dilute a small amount of neutral detergent was squeezed off.

10.7 Replacing flash lamp



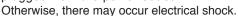
Warning





Warning High-Voltage

When replacing the flash lamp, make sure the instrument is turned OFF and unplugged from the power outlet.





Warning





This instrument is equipped with a storage capacitor for photography light. Replacing the flash lamp while this capacitor is still not yet fully discharged causes a danger of an electric shock. Check that the discharge indicator LED is turned OFF before replacing the flash lamp.



Caution





Do not replace the flash lamp immediately after turning the instrument OFF. You could be burned by a lamp heated to a high temperature. Allow 10 minutes to cool it down before replacing.



Caution

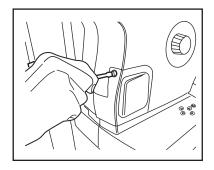


Do not touch the flash lamp bulb with your bare hands. Otherwise, the lamp may reduce the light intensity and longevity.

10 Maintenance and inspection

- (1) Rotate control lever to move optical head to the uppermost location.
- ② Turn OFF the power switch and unplugged from the power outlet.
- 3 Loosen lamp cover screws with a coin or a screwdriver and then remove lamp cover.

Make sure that the flash lamp has been cooled down before proceeding to the next step.

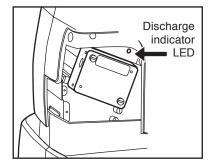


4 Check that the discharge indicator LED shown in the figure is completely turned OFF.

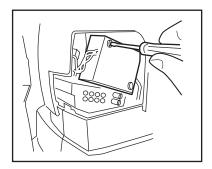
It normally turns OFF completely within three minutes after the instrument is turned OFF. If it does not turn OFF even after above period of time, contact Kowa or your Kowa dealer as it may carry a risk of failure.

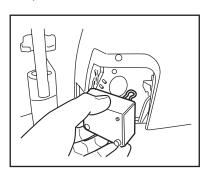
In such a case, never touch the instrument.

* Discharge indicator LED illuminates only when it discharges after the instrument is turned OFF.

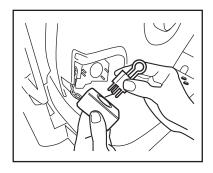


(5) After the discharge indicator LED is turned OFF and the flash lamp is fully cooled down (about 10 minutes after the power is turned OFF), unscrew two screws by a screwdriver and remove the flash lamp socket.





- 6 Hold the lamp and its socket in your hand, remove the flash lamp, and install a new lamp in the socket.
 - * When replacing the flash lamp, pull straight out and push straight in the bulb towards the direction of electrode pin. Do not twist the flash lamp when fitting or removing it.
 - * Fully insert the flash lamp to the end of the socket.
 - * Do not touch the flash lamp bulb.



- Tighten two screws of the flash lamp socket with a driver. Pay attention not to pinch the cables around the instrument when installing the flash lamp socket.
- (8) Place lamp cover and tighten lamp cover screws with a coin or a driver.
 - * When installing the lamp cover, make sure that the cable of the illumination lamp socket is snugly housed within the external sheath.
- Onnect the power supply cable plug to the power outlet and turn ON the power switch.
- 10 Turn ON the instrument and perform test photography.

10.8 Fuse replacement



Warning



Warning High-Voltage

When replacing the fuse, make sure the instrument is turned OFF and unplugged from the power outlet.

If the fuse holder cover is removed with the instrument unplugged, there may occur electrical shock.

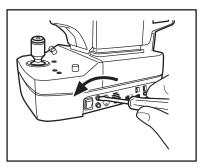


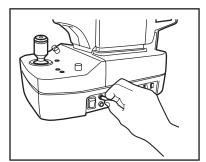


Use a designated fuse only.

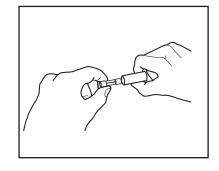
Otherwise, the instrument may malfunction or a fire may break out.

- 1) Turn OFF the power switch and pull the plug from the power outlet.
- (2) Make sure that the instrument is turned OFF and wait for discharge at least 5 minutes for safety.
- ③ Press down the fuse holder with a screwdriver and turn the fuse holder to the direction of the arrow (counterclockwise) for removal.





- ④ Pull the old fuse and replace it with a new one. Make sure that the fuse type and rating are correct.
- ⑤ Press down the fuse holder with a screwdriver and turn the fuse holder to the opposite direction of the arrow (clockwise) and install it in place.
- 6 Connect the power cable plug to an power outlet.



10.9 Refilling and replacing consumables

Order spare parts by purchase order numbers listed below to Kowa or your Kowa dealer.

| Part name | Purchase order number | |
|-------------------------------|--------------------------|--|
| Flash lamp | K9L39FU | |
| Fuses | 21802.5M (T2.5AL250V) | |
| Chin rest paper | K9L-TB45#102 | |
| Chin rest paper retaining pin | K9L-TB45#101 | |
| Dust cover | AFT2#179 | |



Specifications

| Shooting mode | Normal / SP / Stereo (electrically switched) | |
|--|--|--|
| Stereoscopic photography method | Simultaneous stereo photography | |
| Stereo photography parallax | 7.4° (at the 0 diopter eye) | |
| Field angle | Normal mode : 45° SP mode : 45° Stereo mode : 34° (20° horizontal and 27° vertical directions) * Some eyes may cause a flare around their circumference. | |
| Tolerance of pixel pitch on fundus (ISO 10940) | Normal image : S*(9 \(\mu \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \text{m} \t | |
| (100 10040) | Stereo image : $S*(5.5 \mu m \pm 7 \%)$ $L*(2.7 \mu m \pm 7 \%)$ | |
| Working distance | 30 mm | |
| Minimum pupil size | Normal mode : ϕ 4.0 mm SP mode : ϕ 3.5 mm Stereo mode : ϕ 4.0 mm | |
| Compensation range of examined eye | Without compensation $: -12 \text{ m}^{-1}(D) \text{ to } +13 \text{ m}^{-1}(D)$ Compensation + $: +10 \text{ m}^{-1}(D) \text{ to } +35 \text{ m}^{-1}(D)$ Compensation - $: -32 \text{ m}^{-1}(D) \text{ to } -10 \text{ m}^{-1}(D)$ | |
| Focusing | Split luminous bars coincidence | |
| Working distance adjustment | 2 luminous dots indication type | |
| Camera | Specific Nikon digital SLR camera | |
| Monitor | 5.7-inch LCD monitor | |
| Light source | Observation : Near-infrared LED Photography : Xenon flash lamp | |
| Internal fixation target | Central, Disc, Macula, mosaic 8 positions | |
| Optical head base adjustment range | Movable 40mm forward/backward Movable 98mm leftward/rightward Movable 27mm vertically (electric) | |
| Chin rest adjustment range | Movable 55mm (electric) | |
| Interfaces | Image output : USB (B type) Imaging conditions output : USB (mini-B type) Numerical keypad input : USB (A type) | |
| Power supplies | Input : AC100-240V, 50/60Hz Power consumption : 150VA | |
| Dimensions | 310(W)x504(D)x548(H)mm | |
| Weight | 21kg / 46lbs (excluding the attached digital SLR camera) | |

^{*}S/L: Image size set on the digital camera

Compliance standard

- EN 60601-1:1990+A1:1993+A2:1995
- EN 60601-1-2:2001+A1:2006

Classification of equipment based on EN 60601-1

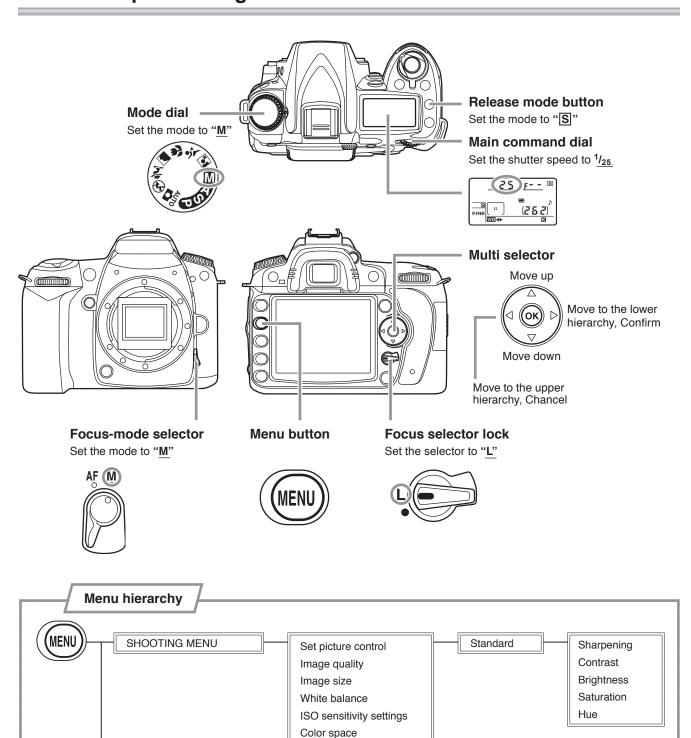
- According to the type of protection against electric shock (Class I device)
- According to the degree of protection against electric shock (Type B applied part)
- According to the type of protection against ingress of water as detailed in the current edition of IEC60529.
 (IPX0)
- According to the degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
 - (Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide)
- According to the mode of operation.
 (continuous operation)

Complied EC Directive

Medical Device Detective 93/42/EEC : **C€** WEEE Directive 2002/96/EC

Technical information

12.1 Description of digital camera



Long exp. NR High ISO NR

CUSTOM SETTING MENU

SETUP MENU

12.2 digital camera setting

Ensure that the digital camera settings are correctly configured.

| Dial setting | | |
|---------------------|------------------------------|--|
| Menu items | Setting | |
| Mode dial | М | |
| Focus-mode selector | М | |
| Focus selector lock | L | |
| Shutter speed *5 | ¹ / ₂₅ | |

^{*5} Use Main command dial to set the shutter speed.

| Custom menu | | |
|--------------------|------|--|
| Menu items Setting | | |
| No memory card? | LOCK | |

| Set-up menu | | |
|--------------------|---------|--|
| Menu items Setting | | |
| Language | English | |

| Photography menu | | | |
|--------------------------|---------------------|--|--|
| Menu items | | Setting | |
| 5 | Set picture control | Standard | |
| | Sharpening | +4 | |
| | Contrast | 0 | |
| | Brightness | 0 | |
| | Saturation | –1 | |
| | Hue | +2 | |
| Image quality*6 | | FINE | |
| Image size*6 | | S (2144×1424) | |
| White balance | | color temperature setting 5560(A4,M1) | |
| ISO sensitivity settings | | 400 | |
| Color space | | sRGB | |
| Long exp. NR | | OFF | |
| High ISO NR | | OFF | |

| Release mode | | | |
|--------------------|--------------|--|--|
| Menu items Setting | | | |
| Release mode | Single frame | | |

*6 You may change photo quality mode and Image size at your discretion.

Image quality : FINE, NORMAL, BASIC

Image size : L, M, S

å Key

- \diamondsuit Do not turn OFF the digital camera when communication is ongoing between the digital camera and the PC.
- \diamondsuit The items not shown above may use their default settings.

12.3 Imaging conditions output

This instrument outputs the imaging conditions from Imaging condition output terminal. If you want to read the imaging conditions using application software other than that provided with the instrument, refer to the specifications below: For this purpose, you need to install FTDI "Direct (D2XX) driver Ver 2.04.06 or later" into your PC to which this instrument is connected.

Communication related specifications

Baud rate : 38400
Data length : 8 bit
Parity : even
Stop bit : 1 bit
Flow control : none

Output data

| Output item | Description | Example |
|--|---|-----------|
| Model name | Fixed value | K9L57 |
| Instrument number | 10-digit number | 16174**** |
| Photography mode | NORMAL/SP/STEREO | STEREO |
| Light intensity selector knob position | -2/-1/0/+1/+2 | 0 |
| Blue or brown eye | BLUE/BROWN | BLUE |
| Diopter compensation | 0/D+/D- | 0 |
| Left or right eye | L/R | R |
| Fixation target | 1 to 7/EXT | 1 to 7 |
| Internal fixation target illuminating position | C (Posterior), N (optic disc), M (Macula), U (Up) UR (Upper right), UL (Upper left), R (Right), L (Left), D (Down), LR (Lower right), LL (Lower left) | С |
| Observation screen | ANTE/FUNDS | FUNDS |

 $^{\ *\} A$ linefeed code is inserted every output of an item.



Electromagnetic compatibility (IEC60601-1-2)

This instrument is a medical electrical instrument. Medical electrical instruments are required special attention to the electromagnetic compatibility (EMC). The following section describes the EMC and precautions regarding this instrument. When installing or using this instrument, read the description carefully and follow the directions described. (The EMC of this instrument was tested based on IEC60601-1-2.)

1. Please note that portable- or mobile-type radio frequency communication devices (RF communications instrument) may adversely affect this instrument resulting in malfunctioning.

 The electromagnetic compatibility (EMC) of this instrument was tested with the options and accessories shown below. Since using an option or accessory other than those specified may cause malfunctioning of this instrument due to interferences of other device or cause malfunctioning of other device, use only the options or accessories specified for this instrument.

100V power supply cable
 120V power supply cable
 KP300VCTF3X1.25SQKS16A, 2.5 m
 KP320SJT18X3KS31, 2.5 m

120V power supply cable : KP320SJ118X3KS31, 2.5
 230V power supply cable : KP-4819Y KS-31A, 2.5 m

PC : CE Marking, VCCI, and FCC approved PC

USB cable (Type A-B) : 3 mUSB cable (Type A-Mini- B) : 3 m

Numerical keypad

External fixation target (K9L-LE57)

- 3. This instrument is not designed such that it can be used adjacent to other instrument or placing one on top of another. Therefore, do not apply such use. Nevertheless, if such use is inevitable, it is necessary to monitor constantly if the instrument is functioning normally after such use has been adopted.
- 4. Accessories and options used with this instrument are tested for EMC when combined with instrument below. Since using with an instrument other than that specified may cause malfunctioning of this instrument due to interferences of other devices or cause malfunctioning of other devices, do not use any instrument other than specified below. Option 1: CE Marking, VCCI, and FCC approved PC
- 5. We specified the functions listed in the table blow as the basic performance of this instrument to determine EMC of this instrument.

| Functions | Essential performance | |
|--------------------------------|--|--|
| | Light-emitting function | |
| | Illumination light intensity setting and switching | |
| Light-emitting functions | Illumination light intensity settings | |
| | Charge function | |
| | Optical head vertical movement | |
| | Chin rest vertical movement | |
| | Anterior segment/retinal switching | |
| | Normal mode switching | |
| Instrument operation functions | SP mode switching | |
| instrument operation functions | Stereo mode switching | |
| | Anterior segment illumination | |
| | Retinal observation light intensity adjustment | |
| | W.D. ON/OFF | |
| | F.D. ON/OFF | |
| Photography functions | Image signal output | |
| LCD monitor display functions | LCD monitor screen display (OSD) | |
| LOD Monitor display functions | LCD monitor screen display (through image) | |

[Compliance verification and guidance]

| Guidance and manufacturer's declaration - electromagnetic emissions | | | | | |
|--|----------|--|--|--|--|
| KOWA nonmyd WX is intended for use in the electromagnetic environment specified below. The customer or the user of KOWA nonmyd WX should assure that it is used in such an environment. | | | | | |
| Emissions test Compliance Electromagnetic environment - guidance | | | | | |
| RF emissions CISPR 11 | Group 1 | KOWA nonmyd WX uses RF energy only for its internal function. There fore, its RF emissions are very low and are not likely to cause any interfer ence in nearby electronic instrument. | | | |
| RF emissions CISPR 11 | Class B | | | | |
| Harmonic emissions IEC 61000-3-2 | Class B | KOWA nonmyd WX is acceptable in all types of facilities without any limitation to the electrical supply network connected to KOWA nonmyd WX. | | | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | — tion to the electrical supply network connected to KOWA nonlinyd WA. | | | |

| | Guidance and manu | facturer's declaration - | electromagnetic immunity |
|---|---|---|---|
| • | (is intended for use in the user of tKOWA nonmyd | • | onment specified below. It it is used in such an environment. |
| Immunity test | IEC60601 test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge(ESD) IEC61000-4-2 | ±6kV contact ±8kV air | ±6kV contact ±8kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC61000-4-4 | ±2kV for power supply lines ±1kV for input/output lines | ±2kV for power supply lines ±1kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC61000-4-5 | ±1kV differential mode ±2kV common mode | ±1kV differential mode ±2kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11 | <5% U ^T (>95% dip in U ^T) for 0.5 cycle 40% U ^T (60% dip in U ^T) for 5 cycles 70% U ^T (30% dip in U ^T) for 25 cycles <5% U ^T (>95% dip in U ^T) for 5 sec | <5% U ^T (>95% dip in U ^T) for 0.5 cycle 40% U ^T (60% dip in U ^T) for 5 cycle 70% U ^T (30% dip in U ^T) for 25 cycle <5% U ^T (>95% dip in U ^T) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of KOWA nonmyd WX requires continued operation during power mains interruptions, it is recommended that KOWA nonmyd WX be powered from an uninterruptible power supply. |
| Power frequency (50/60Hz) magnetic field IEC61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE U [⊤] is the a.c. | mains voltage prior to ap | plication of the test leve | el. |

Guidance and manufacturer's declaration - electromagnetic immunity

KOWA nonmyd WX is intended for use in the electromagnetic environment specified below. The customer or the user of KOWA nonmyd WX should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment– guidance |
|-------------------------------|-----------------------------|------------------|--|
| | | | Portable and mobile RF communications instrument should be used no closer to any part of KOWA nonmyd WX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | Recommended separation distance |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 V | d=1.2 √ P |
| 120 01000 1 0 | 100 101 12 10 00 1011 12 | | d=1.2 \sqrt{P} 80 MHz to 800 MHz d=2.3 \sqrt{P} 800 MHz to 2.5 GHz |
| Radiated RF | 3 V/m | 3 V/m | |
| IEC 61000-4-3 | 80 MHz to 2.5 GHz | | where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). |
| | | | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency rangeb. |
| | | | Interference may occur in the vicinity of instrument marked with the following symbol: |

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the KOWA nonmyd WX is used exceeds the applicable RF compliance level above, the KOWA nonmyd WX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reconfiguring or relocating the KOWA nonmyd WX
- b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications instrument and KOWA nonmyd WX

KOWA nonmyd WX is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of KOWA nonmyd WX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications instrument (transmitters) and KOWA nonmyd WX as recommended below, according to the maximum output power of the communications instrument.

| Rated maximum output power of transmitter | Separation distance according to frequency of transmitter m | | | |
|---|---|--------------------------------|---------------------------------|--|
| W W | 150 kHz to 80 MHz d=1.2 √P | 80 MHz to 800 MHz d=1.2 √ P | 800 MHz to 2.5 GHz d=2.3 √ P | |
| 0.01 | 0.12 | 0.12 | 0.23 | |
| 0.1 | 0.37 | 0.37 | 0.74 | |
| 1 | 1.2 | 1.2 | 2.3 | |
| 10 | 3.7 | 3.7 | 7.4 | |
| 100 | 12 | 12 | 23 | |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

For EU market.



Likvidace tohoto výrobku

Likvidace tohoto výrobku musí být podle zákona provedena ekologicky a výrobek je třeba individuálně soustřeďovat na sběrných místech. Při likvidaci tohoto výrobku postupujte podle pokynů na následující webové stránce. Nemůžete-li tuto webovou stránku použít, obratte se na prodejce.

URL: http://www.kowa-europe.com/

Bortskaffelse af dette produkt

Miljørigtig bortskaffelse er angivet ved lov for dette produkt, og det skal bortskaffelse særskilt. Bortskaffelse af dette produkt skal foregå i overensstemmelse med proceduren på følgende webside.

Hvis du ikke kan finde det på websiden, skal du kontakte din forhandler.

URL: http://www.kowa-europe.com/

Procedure voor opruimen van dit product

Dit product dient volgens een wettelijke bepaling op een milieuvriendelijke manier te worden opgeruimd en dient afzonderlijk voor opruimen opgehaald te worden. Ruim dit product op overeenkomstig de procedure door de volgende website te raadplegen.

Als u de website niet kunt raadplegen, contact opnemen met uw dealer.

URL: http://www.kowa-europe.com/

Disposal procedure for this product

An environmentally-friendly disposal method is specified by law for this product and it must be collected individually for disposal. Please discard this product in accordance with the procedure referred to in the following website.

If you cannot access the website, please contact your dealer.

URL: http://www.kowa-europe.com/

Toote äraviskamise eeskirjad

Seadusega on ette nähtud keskkonna sõbralik meetod selle toote jaoks ja seda peab väljaviskamise jaoks eraldi korjama. Palun visake see toode ära vastavalt protseduurile mis on kirjeldatud alljärgnevas veebsaidis. Kui Te ei saa kätte veebsaiti, palun võtke ühendust oma diileriga.

URL: http://www.kowa-europe.com/

Tuotteen hävittämistapa

Laki määrittelee, että tämä tuote on hävitettävä ympäristöystävällisellä tavalla ja että se on toimitettava erikseen hävitettäväksi. Hävittäkää tämä tuote seuraavassa sivustossa kuvatulla tavalla. Jos ette voi käyttää sivustoa, ottakaa yhteys jälleenmyyjään.

URL: http://www.kowa-europe.com/

Procédures d'élimination de cet appareil

La loi prescrit comment vous débarasser de cet appareil dans le respect de l'environnement en recourant à la collecte sélective individuelle. Veuillez vous débarasser de cet appareil en procédant de la façon indiquée sur le site Web.

Si vous ne pouvez pas consulter le site Web, adressez-vous à votre revendeur.

URL: http://www.kowa-europe.com/

Entsorgung des Produkts

Das Gesetz schreibt die umweltverträgliche Entsorgung dieses Produkts vor. Es darf nicht in den normalen Haushaltsmüll gegeben werden. Bitte entsorgen Sie das Produkt entsprechend den Hinweisen auf dieser Website. Falls Sie diese Website nicht besuchen können, wenden Sie sich bitte an Ihren zuständigen Fachhändler.

URL: http://www.kowa-europe.com/

Διαδικασία απόρριψης του παρόντος προϊόντος

Η φιλική προς το περιβάλλον μέθοδος απόρριψης καθορίζεται από το νόμο για το παρόν προϊόν το οποίο πρέπει να συλλέγεται μεμονωμένα για την απόρριψη. Απορρίψτε το παρόν προϊόν σύμφωνα με τη διαδικασία που αναφέρεται στον παρακάτω ισοτοχώρο.

Εάν δεν μπορείτε να κάνετε αναφορά τον ιστοχώρο, επικοινωνήστε νε τον αντιπρόσωπο.

URL: http://www.kowa-europe.com/

Termék-elhelyezési munkafolyamat

Egy – a törvény által előírt - környezetbarát lerakási módszer létezik erre a termékre, melyet egyesével kell összegyűjteni. Kérjük az ezen a honlapon található folyamat alapján selejtezze ki ezt a terméket. Ha nem tudja elérni a honlapot, kérjük keresse fel a termékforgalmazót.

URL: http://www.kowa-europe.com/

Per lo smaltimento di questo prodotto

Un metodo di smaltimento corretto per la salvaguardia dell'ambiente è specificato per legge e il prodotto deve essere raccolto in modo differenziato. A fine uso, disfarsi del prodotto seguendo la procedura indicata nel sito web seguente. Senza accesso al sito web, rivolgersi al proprio rivenditore di fiducia.

URL: http://www.kowa-europe.com/

Šim izstrādājumam paredzētā iznīcināšanas procedūra

Videi draudzīgo šī produkta iznīcināšanas procedūru nosaka likumdošana, un tam nepieciešama atsevišķa, iznīcināšanai paredzēta, savākšana. Lūdzu, izmetiet šo produktu atbilstoši šajā interneta lapā norādītajai procedūrai. Ja Jūs nevarat piekļūt šai interneta lapai, lūdzu, sazinieties ar savu dīleri.

URL: http://www.kowa-europe.com/

Šio gaminio išmetimo procedūra

Nežalingą aplinkai šio gaminio išmetimo būdą apibrėžia įstatymas ir išmetimui jį reikia išvežti atskirai. Šį gaminį išmeskite pagal šioje svetainėje nurodytą procedūrą.

Jeigu negalite pasinaudoti šia svetaine, prašome susisiekti su savo prekybos agentu.

URL: http://www.kowa-europe.com/

Procedura ta' rimi ghal dan il-prodott

Metodu ta' rimi li ma jaghmilx hsara lill-ambjent huwa speċifikat bil-liģi ghal dan il-prodott u dan ghandu jinġabar individwalment biex jintrema'. Armi dan il-prodott skond il-proċedura riferita fil-websajt li ģejja. Jekk ma tistax tfittex fil-websajt, jekk joghġbok ikkuntattja lin-negozjant li minn ghandu xtrajtu.

URL: http://www.kowa-europe.com/

Procedura utylizacji produktu

Odpowiednią, przyjazną dla środowiska metodę utylizacji tego produktu określają przepisy prawne.

Produkt należy utylizować zgodnie z procedurą podaną w poniższym serwisie WWW.

Jeżeli skorzystanie z podanego serwisu WWW nie jest możliwe, prosimy o kontakt z lokalnym przedstawicielem.

URL: http://www.kowa-europe.com/

Procedimento de eliminação para este produto

O método de eliminação sem prejudicar o meio ambiente é especificado pela lei aplicável a este produto e este deve ser eliminado individualmente. Elimine este produto de acordo com o procedimento referido no seguinte website. Caso não consulte o website, contacte o seu vendedor.

URL: http://www.kowa-europe.com/

Postup odstránenia tohto výrobku do odpadu

Zákonom je pre tento výrobok stanovený spôsob odstránenia do odpadu tak, aby nedošlo k poškodeniu životného prostredia a preto sa musí individuálne zbierať do odpadu. Odstráňte prosím tento výrobok do odpadu podľa postupu, ktorý je uvedený na nasledovnej webovej stránke.

Ak nemáte prístup k tejto webovej stránke, skontaktujte sa prosím s predajcom.

URL: http://www.kowa-europe.com/

Postopek odstranitve za ta izdelek

Okolju prijazen postopek odstranjevanja je določen z zakonom za ta izdelek in mora biti zbran individualno za odstranitev. Prosimo, odvrzite ta izdelek ustrezno s postopkom, ki je opisan na sledeči spletni strani.

V kolikor nimate dostopa do spletne strani, prosimo, da se obrnete na vašega trgovca.

URL: http://www.kowa-europe.com/

Procedimiento para desechar este producto

La ley prevé un método ecológico específico para desechar este producto, el cual debe recogerse en forma individual para su descarte. Respete este procedimiento, de acuerdo con el siguiente sitio Web. Si no puede consultar el sitio Web, contacte con el distribuidor.

URL: http://www.kowa-europe.com/

Procedur för att kasta bort denna produkt

Miljövänliga källsorteringsmetoder ska enligt lag användas för denna produkt och delarna måste sorteras individuellt innan de kastas bort. Vänligen gör dig av med denna produkt i enlighet med proceduren som beskrivs på följande webbplats. Om du inte kan nå webbplatsen, ska du kontakta din återförsäljare.

URL: http://www.kowa-europe.com/





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