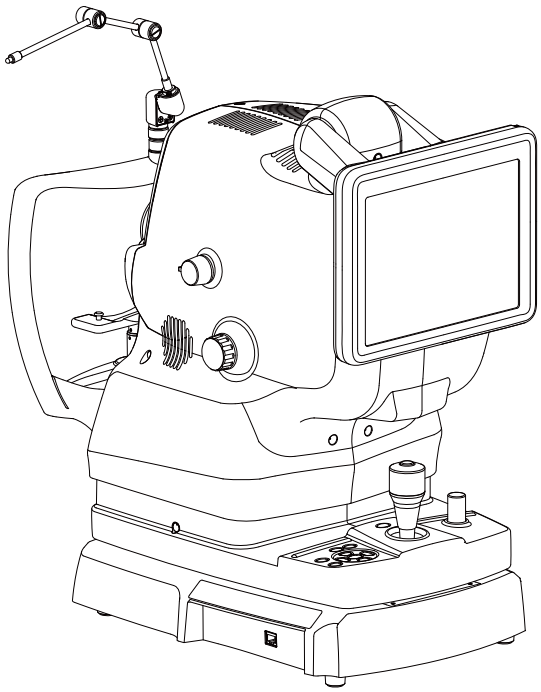
TOPCON



INSTRUCTION MANUAL

3D OPTICAL COHERENCE TOMOGRAPHY

DRI OCT Triton2

[en]	Instruction manuals in official languages of the Member States of the European Union are available on the following website:
[de]	Bedienungsanleitungen in den Amtssprachen der Mitgliedstaaten der Europäischen Union sind auf der folgenden Website verfügbar:
[fr]	Les manuels d'instructions dans les langues officielles des États membres de l'Union européenne sont disponibles sur le site web suivant:
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INTRODUCTION

Thank you for purchasing the 3D Optical Coherence Tomography DRI OCT Triton2.

INTENDED USE

The Topcon 3D Optical Coherence Tomography DRI OCT Triton2 is a non-contact, high-resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing the eye under mydriatic and non-mydriatic conditions.
DRI OCT Triton2 is indicated for use as a diagnostic device to aid in the diagnosis and management of ocular health and diseases.

INDICATIONS FOR USE

1. OCT (Imaging)
DRI OCT Triton2 is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging of posterior ocular structures, including retina, retinal nerve fiber layer, macula, optic disc, vascular structures of the posterior segment of the eye, as well as of anterior ocular structures including cornea, anterior chamber, sclera and iris.

2. OCT (Measurement, Analysis)
DRI OCT Triton2 is also indicated for analysis of posterior ocular structures, including retina, retinal nerve fiber layer, macula and optic disc as well as analysis of anterior structures including segmentation of cornea.

3. Fundus camera (Imaging)
DRI OCT Triton2 is indicated for photographing the data of the retina to be examined under Mydriatic and non-Mydriatic conditions.

4. OCT + Fundus camera (Aid in the diagnosis)
DRI OCT Triton2 in combination with IMAGEnet 7 is indicated for aid in the diagnosis, documentation, and management of ocular health and diseases by displaying images and analysis results on the IMAGEnet7 screen. The images and analysis results include images and analysis results of posterior, anterior OCT, OCT Angiography, fundus images and Reference Database which provide quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects.

CLINICAL BENEFITS

The clinical benefit to patients of DRI OCT Triton2 is the accurate diagnosis and early detection/recognition for a variety of ocular diseases and conditions.

FEATURES

DRI OCT Triton2 is indicated for in vivo capturing device that observes, captures and records fundus, anterior segment and fundus tomographic images to provide them as electronic images for diagnosis.
By using the separately sold attachment kit for anterior segment to the unit, anterior segment tomographic images can be observed, captured and recorded.
By using the separately sold attachment lens for wide field OCT capturing to the unit, the scanning range of fundus images can be expanded.
The captured fundus, fundus tomograms, anterior segment and anterior segment tomographic images can be recorded and saved on a computer with Linkage Software for Triton2 and IMAGEnet 7 installed.

Linkage Software for Triton2 works in conjunction with IMAGEnet 7 to acquire, register and store dedicated images, and to output and acquire supplementary information, and to provide linkage functions with the unit.

PURPOSE OF THIS MANUAL

This manual outlines the 3D Optical Coherence Tomography DRI OCT Triton2, including operating procedures, maintenance.
Before using the instrument, carefully read the "DISPLAYS AND SYMBOLS FOR SAFE USE" and the "GENERAL SAFETY INFORMATION" to familiarize yourself with the features of the TOPCON 3D Optical Coherence Tomography DRI OCT Triton2 and to ensure that you operate it safely.Always keep this manual at hand.

SERIOUS INCIDENT REPORTING

In case any serious incident occurs in relation to the device, please report it to the manufacturer, authorized representative and the competent authority in which the user and/or patient is established.

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- DRI OCT is a trademark of TOPCON CORPORATION.
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2. The contents of this manual are correct to the best of our knowledge. Please inform us of any ambiguous or erroneous descriptions, missing information, etc.
3. This manual is original instructions.

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CONTENTS

DISPLAYS AND SYMBOLS FOR SAFE USE

In order to encourage the safe use of the instrument and to avoid danger to the operator and others as well as damage to properties, warnings are described in the manual and marked on the instrument body.
We suggest you thoroughly understand the meaning of the following displays/icons and Safety Cautions, as well as read the manual, and strictly observe the instructions.

DISPLAY

CONTRAINDICATION	Situations in which the device should not be used because the risk of use clearly outweighs any possible benefit. "Situations" indicate the following conditions of the patient: disease symptoms, primary illness, complication, past medical history, family history, physical constitution, etc.
WARNING	Incorrect handling by ignoring this display may lead to a risk of death or serious injury.
CAUTION	Incorrect handling by ignoring this display may lead to personal injury or physical damage.
NOTE	Useful functions to know. Paying attention to these will prevent the noted problems.

SYMBOL

Symbol	Description
	Alternating Current
	Off (power: disconnection from the mains)
	On (power: connection to the mains)
	Type B applied part
	General warning sign
	Refer to instruction manual/booklet
	Consult instructions for use or consult electronic instructions for use.

Symbol	Description
	Date of manufacture
	Manufacturer
	Authorised Representative in the European Community
	Serial number
	Medical Devices
	Unique Device Identification (UDI)
	Humidity limitation
	Atmospheric pressure limitation
	Temperature limit
	Keep away from sunlight
	Fragile, handle with care
	Keep dry
	This way up
	Maximum number of identical packages which may be stacked on one another.
	General symbol for recovery/recyclable. (for the package)
	Recycling symbol for plastic in the package. Low density polyethylene
	Recycling symbol for plastic in the package. Polypropylene
	Recycling symbol for plastic in the package. Polystyrene
	CE marking Indicates that the product conforms to the requirements of the Medical Device Regulation (EU)2017/745 and of the other applicable Union legislation

Symbol	Description
	WEEE label The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
	Separate collection symbol Batteries must not be disposed of as unsorted general waste but must be treated properly.
	Taiwan Dry Cell Battery Recycling Mark The mark indicates that the product contains dry cell batteries that require recycling.

GENERAL SAFETY INFORMATION

⚠ CONTRAINDICATION

This instrument must not be used for the following patients.

- Patients with a history of photosensitivity
- Patients who recently underwent photodynamic therapy (PDT) (refer to the package insert of the photosensitizing agent administered for the PDT prohibited period.)
- Patients taking medication that may cause photosensitivity as a side effect

⚠ WARNING

Ensuring the Safety of Patients and Operators

- The following patients should be carefully applied:
  The patient with a history of epilepsy and the patient who is suspected of epilepsy.
  If a symptom of photosensitive epilepsy appears in a patient during capture, please stop capture and measurement immediately.
- Be careful not to hit the patient's eyes or nose with the instrument during use.The patient may be injured.
- Modification of this instrument is not permitted.
  Modifying the instrument may cause people to be injured, make the burden on the human body, lower the reliability of the measurement results or cause the devices to malfunction.

⚠ WARNING

Preventing Fire and Electric Shock

- To avoid fire in the event of an instrument malfunction, immediately turn OFF the POWER SWITCH and unplug the cable if you see smoke coming from the instrument or if you detect other problems. Don't install the instrument where it is difficult to unplug the cable from the instrument body. Ask your dealer for repairs.
- Connect only items that have been specified as part of the ME system or that have been specified as being compatible with the ME system.
- To avoid electric shock and fire, do not disassemble, modify or repair the equipment. Ask your dealer for repairs.

⚠ CAUTION

Important caution

- Use this instrument carefully on the following patients.
  - Patients who have epidemic kerato conjunctivitis or any other infectious disease

⚠ CAUTION

Ensuring the Safety of Patients and Operators

- To avoid injury, be careful not to pinch the patient's hand when operating the CHINREST UP/DOWN SWITCH.
- To avoid injury, be careful not to pinch your fingers in the outer cover when operating the control lever.
- To avoid injury, be careful not to let the main unit or external fixation target come into contact with the patient's eyes or nose when operating the instrument.

⚠ CAUTION

Ensuring the Safety of Patients and Operators

- To avoid injury, be careful not to let the external fixation target come into contact with the patient's eyes or nose when operating the external fixation target.
- To prevent the instrument from falling and to avoid injury during carrying, be sure to secure the instrument with the base clamping knob at the bottom.
- To avoid injury or damage, two people should be employed for supporting the instrument from the underside. Carrying by one person may result in personal injury and/or damage to the instrument should the person slip or fall. If you support any other part except the underside, you may be pinched by the instrument or injured by falling. Use caution as the underside of the instrument has a convex surface that may cause injury.
- To prevent injury, be careful not to pinch your fingers between the instrument and the automatic instrument table when placing the instrument on the table.
- To avoid falling and injury while moving the table with the instrument on top of it, be sure to use an approved automatic instrument table.
- To prevent the instrument from falling and to avoid injury, install the instrument on a level surface.
- Do not place any objects on the vent. If the vent is covered, the temperature of the power supply unit may rise abnormally to cause a malfunction. To prevent the instrument from malfunction, do not drop any liquid into the vent.
- Do not use power cords other than those supplied with the instrument.
- Do not use LAN cables other than those supplied with the instrument.
- Do not brighten the photography light more than necessary.It may cause discomfort to the patient, and may damage the eye.
- Mount the ANTERIOR ATTACHMENT on the forehead rest securely. Otherwise, the attachment may come off during capture and the patient may be injured.
- To avoid injury of the patient, be careful not to bump the patient's eye or nose with the anterior segment lens unit when operating the instrument.
- To avoid injury of the patient, be careful not to bump the wide field OCT attachment lens and the patient's eye or nose when operating the instrument.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser exposure.
- Do not remove the enclosures. Laser high-power is radiated.
- Do not use in environments where device that generates strong magnetic fields, such as MRI device is installed.
- The external device connected to the analog and digital interfaces must comply with the respective IEC or ISO standards (e.g. IEC 62368-1 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems.

⚠ CAUTION

Preventing Electric Shock

- Do not remove the outer cover. There is a risk of injury from electric shock.
- To avoid fire and electric shock, install the instrument in a place free of water and other liquids, and do not put cups or vessels containing liquids near the instrument.
- To avoid electric shock, do not insert metal objects into any vents and/or slots.
- To avoid fire and electric shock in case of leakage, be sure to use a power supply equipped with a 3-pin plug AC receptacle for proper grounding.
- To avoid electric shock, do not plug or unplug the power cord with wet hands.

⚠ CAUTION

Preventing Electric Shock

- To avoid electric shock, do not touch the external connection terminal, the cable terminal from the external device and the patient at the same time.
- Do not connect an additional power strip or an extension cord to the system.
- In the patient's environment, use devices conforming to IEC 60601-1. If you are compelled to use any device not conforming to IEC 60601-1, use an insulation transformer.
- The total 1kVA is the maximum allowable load of the auxiliary power supply socket for the insulation transformer, which is provided for the system. Do not connect the device exceeding this capacity.
- Use the auxiliary power supply socket of the insulation transformer to power only a device that will be a component of the system.
- It is dangerous to connect any device which is not used as a component of the system, to the insulation transformer.
- When the insulation transformer is not used, the personal computer and the monitor for the personal computer must be installed out of the patient's environment.

⚠ CAUTION

Ensuring Security

- When connecting this instrument to an external device through LAN, apply the security update to the external device, make use of anti-virus software and take other countermeasures against computer virus properly.
- Do not connect any USB storage device that is not checked with the anti-virus software to the USB port of this instrument.
- When connecting this instrument to an external device through LAN, set the ID and password of the user to the external device.
- When connected with an IT network, ensure the appropriate and sufficient security to prevent the infection with malware and a computer virus, the leak of information, etc. There is a risk of data leakage.
- To avoid leakage of personal information, erase the data before discarding the storage device.
- If you need information about SBOM, ask your dealer. Information can be provided in xlsx and SPDX-Lite formats.
- Vulnerability and software update information is available at the following link. https://topconhealthcare.com/product-updates/
- The manufacturer or your dealer will provide you with information about the end of security support for the device.
- Software updates include security updates such as SOUPs, etc. The user shall apply the latest software.
- If there is a possibility that some security incident has occurred, disconnect the device from the hospital network and take initial action according to hospital policy, such as running anti-virus software and checking access logs, if necessary.

⚠ CAUTION

Misdiagnosis

- Users should not rely solely on images made using this instrument in making decisions re-garding diagnosis or other therapeutic procedures, but should rely on their own expertise and judgment. The pertaining doctors should take the responsibility for diagnoses. There is a risk of misdiagnosis.

⚠ CAUTION

Electromagnetic Compatibility (EMC)

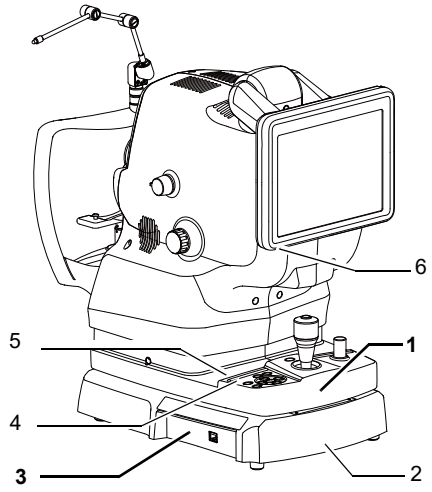
- This instrument has been tested (with 100V/120V/230V/240V) and found to comply with IEC60601-1-2:2014 +AMD1: 2020 (Ed.4.1). This instrument radiates radio frequency energy within standard and may affect other devices in the vicinity. If you have discovered that turning on/off the instrument affects other devices, we recommend you change its position, keep a proper distance from other devices, or plug it into a different outlet. Please consult the dealer from whom you purchased the instrument if you have any additional questions.
- The external devices to be connected must comply with the corresponding EMC standards(e.g. CISPR 32/ CISPR 35).
  - The patient may be injured.
  - It may affect other devices in the vicinity.

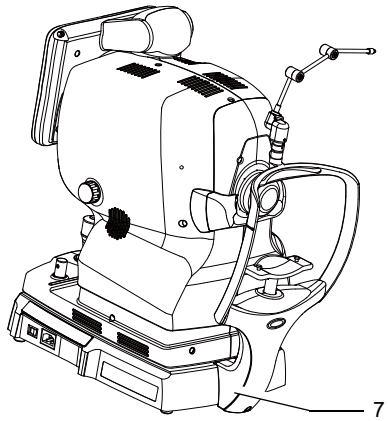
DISCLAIMERS

- TOPCON shall not take any responsibility for damage due to fire, natural catastrophes, actions by outsiders, or other accidents, or for damage due to negligence and misuse by the user, or from abnormal conditions.
- TOPCON shall not take any responsibility for damage derived from inability to properly use this instrument, such as loss of business profit and suspension of business.
- TOPCON shall not take any responsibility for damage caused from using this instrument in a manner other than that described in this manual.
- Diagnoses made shall be the responsibility of pertaining doctors and TOPCON shall not take any responsibility for the results of such diagnoses.
- The customer shall take the responsibility to save data and perform backup in case data should be lost. When the customer has obtained data through this software and has saved or backed up the data in a server or personal computer, TOPCON shall not take any responsibility for the loss of the data, loss of profit or other damages on the customer.
- TOPCON is not responsible for any damage caused by unauthorized access from outside, malware or viruses.

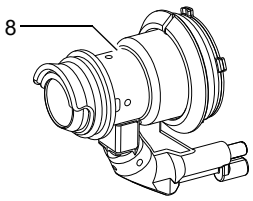
POSITIONS OF WARNING AND CAUTION INDICATIONS

To ensure safety, this machine provides warning displays. Use the instrument correctly by observing the display instructions. If any of the following display labels are missing, contact your TOPCON dealer at the address listed on the back cover.

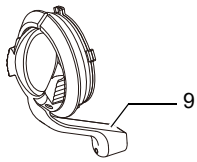




Optional accessory:
Attachment kit for Anterior segment
(Anterior segment lens unit)



Wide field OCT attachment lens

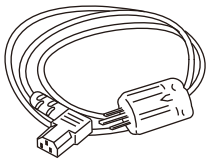


No.	Label	Meaning
1		**WARNING** Be careful not to hit the patient's eyes or nose with the instrument during use.The patient may be injured.
2		**CAUTION** Do not remove the outer cover. There is a risk of injury from electric shock.
3		**WARNING** To avoid electric shock, do not connect any devices other than those specified to the external input/output terminals.
4		**CAUTION** To avoid injury, be careful not to pinch the patient's hand when operating the CHINREST UP/DOWN SWITCH.
5		**CAUTION** To avoid injury, be careful not to pinch your fingers in the outer cover when operating the control lever.
6		**CAUTION** To avoid injury, be careful not to let the main unit or external fixation target come into contact with the patient's eyes or nose when operating the instrument.
7		Degree of protection against electric shock : TYPE B APPLIED PART
8		**CAUTION** To avoid injury of the patient, be careful not to bump the patient's eye or nose with the anterior segment lens unit when operating the instrument.
9		**CAUTION** To avoid injury of the patient, be careful not to bump the wide field OCT attachment lens and the patient's eye or nose when operating the instrument.

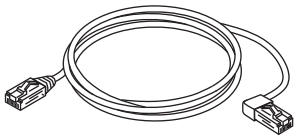
STANDARD ACCESSORIES

Figures in ( ) are the quantities.

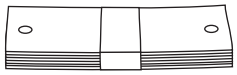
Power cord (1)



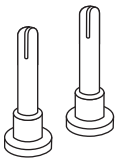
LAN cable (1)



Chinrest tissue (1)



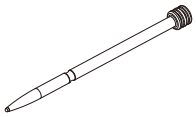
Chinrest tissue pins (2)



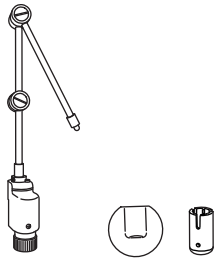
Dust cover (1)

Monitor cleaner (1)

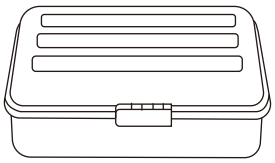
Stylus pen (1)



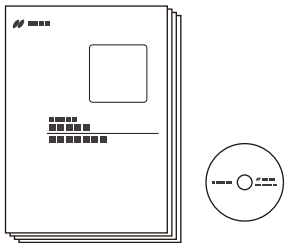
External fixation target (1)



Accessory case (1)



User manual (2)
Instruction manual (2)
“ Linkage Software for Triton2 ” Software (1)



MAINTENANCE

DAILY CHECKUPS

Manufacturer maintenance items

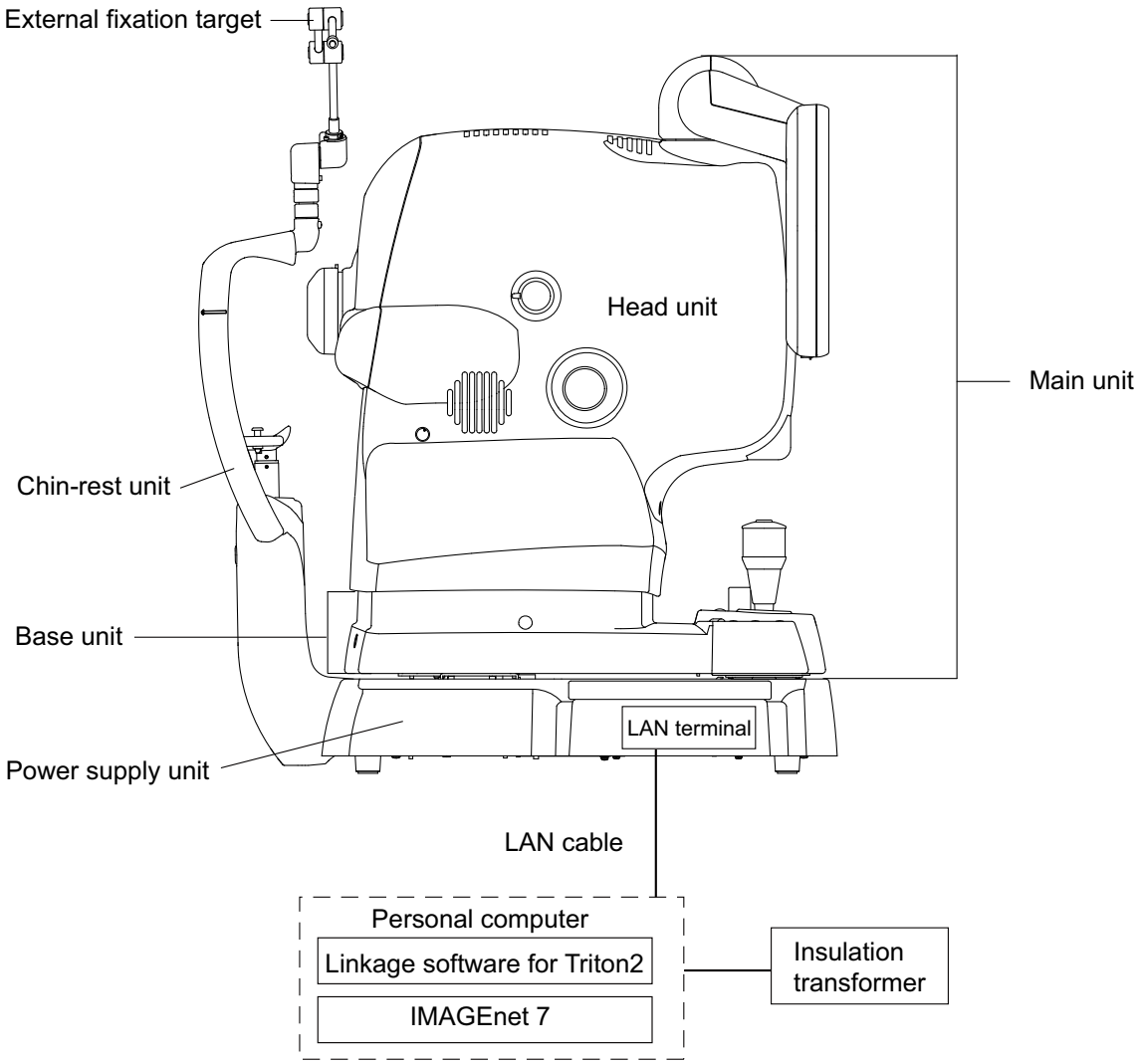
Item	Inspection interval	Details
Cleaning each unit	Within 12 months from the last maintenance	Cleaning the external section Cleaning the optical system Cleaning the base unit
Checking the operation	Within 12 months from the last maintenance	Anterior segment observation function Internal fixation target Display on the screen Adjusting the observation illumination Fundus observation Fundus tomography
Checking the light intensity	Within 12 months from the last maintenance	Checking each light source

SPECIFICATIONS AND PERFORMANCE

SYSTEM DIAGRAM

This instrument is composed of the following units.

- Instrument body (main unit (head unit, base unit), chin-rest unit and power supply unit)
- External fixation target
- Power cord
- LAN cable
- Stylus pen
- Personal computer (including the personal computer main unit, monitor, mouse and keyboard)
- Insulation transformer
- Linkage Software for Triton2 and IMAGEnet 7



SPECIFICATIONS

Observation and Photography of Fundus Image	
Photography type	Color Infrared light (IR)
Angular Field of View	50°±5%
Operating distance	35.5mm±0.1mm
Photographable diameter of pupil	ϕ2.0mm or more
Fundus image resolution (on fundus) [Optical resolution]	Color Center: 60 lines/mm or more Middle (r/2): 40 lines/mm or more Periphery (r): 25 lines/mm or more Infrared light (IR) Center: 5 lines/mm or more * * Infrared (IR) photography is for adjusting the position of the area to be photographed, not for generating a fundus image. The resolution required for adjusting the position of the area to be photographed has been set as our own in-house standard.
Measurable range of dioptric power	-33D to +40D Without the diopter compensation lens : -13D to +12D When the concave compensation lens is used *1: -33D to -12D When the convex compensation lens is used *1: +11D to +40D
Observation and Capture of Fundus Tomographic Image	
Scan range (on fundus)	Horizontal: 3 to 12mm ±5% Vertical: 3 to 12mm ±5%
Scan pattern	3D scan
	Linear scan (Line-scan/Cross-scan/Radial-scan)
Scan speed	100,000±5,000 A-Scans per second
Lateral resolution	20μm
In-depth resolution	Optical function: 8μm Digital: 2.6μm ±3%
Photographable diameter of pupil	ϕ2.5mm or more
Observation and Photography of Fundus Image / Observation and Capture of Fundus Tomographic Image	
Fixation target	Internal fixation target : Dot matrix type organic ELD display The display position can be changed and adjusted. The displaying method can be changed. Peripheral fixation target : This is displayed according to the internal fixation target displayed position. External fixation target
Measurable range of dioptric power for the patient's eye *2	Without the diopter compensation lens : -13D to +12D When the concave compensation lens is used *1: -33D to -12D When the convex compensation lens is used *1: +11D to +40D
Observation and Photography of Anterior Segment Image *3	
Photography type	Infrared light (IR)
Operating distance	17 ±0.3mm

Observation and Capture of Anterior Segment Tomographic Image [*3]	
Operating distance	17 ±0.3mm
Scan range (on cornea)	Horizontal: 3 to 16mm ±5% Vertical: 3 to 16mm ±5%
Scan pattern	3D scan
	Linear scan (Line-scan/Radial-scan)
Scan speed	100,000±5,000 A-Scans per second
Fixation target	External fixation target
Observation and Capture of Wide field Fundus Tomographic Image [*4]	
Scan range (on fundus)	Horizontal: 21mm ±10% (63.4°±8%) Vertical: 21mm ±10% (63.4°±8%)
Scan pattern	3D scan
	Linear scan (Line-scan/Cross-scan/Radial-scan)
Scan speed	100,000±5,000 A-Scans per second
Lateral resolution	30μm
In-depth resolution	8μm
Observation of Wide field Fundus Image / Observation and Capture of Wide field Fundus Tomographic Image[*4]	
Measurable range of dioptric power for the patient's eye	Without the diopter compensation lens : -7D to +40D When the concave compensation lens is used [*1]: -33D to -5D When the convex compensation lens is used [*1]: -

*1 Split autofocus and manual focus with split lines cannot be used when using concave compensation lens or convex compensation lens.

*2 Fundus tomography observation and capturing only

*3 Observation and Photography of Anterior segment image and tomogram are available only when using ANTERIOR SEGMENT ATTACHMENT KIT AA-1.

*4 Observation and Photography of Wide field fundus tomogram are available only when using Wide field OCT attachment lens WA-1.

NOTE	• The instrument conforms to the retinal camera standard JIS T 7320: 2015 (ISO 10940: 2009). * Excluding wide field fundus capturing. • The instrument uses a 12MP digital camera, and the pixel distance on the fundus in an emmetropic eye (focal length 17mm) is 5.6μm.

OTHER SPECIFICATIONS

Laser product (for fundus tomography)	
Class for laser product	Class 1
Laser aperture	Objective lens
Output on cornea	Pulse average light intensity: 1050μW or less
Laser product (for fundus observation)	
Class for laser product	Class 1
Laser aperture	Objective lens
Output on cornea	Pulse average light intensity: 530μW or less
Laser light source (for fundus tomography)	
Type	Tunable wavelength laser
Laser class	Class 3B
Wavelength	1050nm
Laser light source (for fundus observation)	
Type	VCSEL
Laser class	Class 3B
Wavelength	850nm
Base movement	
Coarse movement	Back-and-forth 59mm, Right-and-left 100mm
Fine movement	16mm in each of back-and-forth & right-and-left directions
Base up-and-down movement	
	30mm
Chinrest movement	
	67mm

SPECIFICATIONS OF THE PERSONAL COMPUTER (COMMERCIAL PRODUCT) TO BE CONNECTED

Please refer to the user manual of Linkage Software for Triton2 and IMAGEnet 7.

GENERAL INFORMATION ON USAGE AND MAINTENANCE

INTENDED PATIENT POPULATION

The intended patient population is patients who meet the following patient selection criteria.
Patients of any age, weight, or health status who are able to perform the following actions during the examination time:

- Hold the face to the chin rest and forehead pad
- Keep eyelids open
- Understand and follow instructions during the examination

However, patients who are able to perform the above actions but have any of the product's contraindications are excluded

INTENDED USER PROFILE

Healthcare professionals (Ophthalmologists/ Ophthalmic Photographers/ Optometrists/ Opticians/ General practitioners/ Nurses) who are legally authorized to operate an Optical Coherence Tomography and Fundus Camera for ophthalmic examination in their country.

ENVIRONMENTAL CONDITIONS FOR USE

Temperature	10°C to 35°C
Humidity	30% to 90% (non-condensing)
Pressure	800hPa to 1060hPa

STORAGE, USAGE PERIOD

1. Environmental conditions in storage

Temperature	-10°C to 55°C
Humidity	10% to 95% (non-condensing)
Pressure	700hPa to 1060hPa

2. Environmental conditions on transportation

Temperature	-40°C to 70°C
Humidity	10% to 95%
Pressure	700hPa to 1060hPa

3. When storing the instrument, ensure that the following conditions are met:
   (1) The instrument must not be splashed with water.
   (2) Store the instrument away from environments where air pressure, temperature, humidity, ventilation, sun-light, dust, salty/sulfurous air, etc. could cause damage.
   (3) Do not store or transport the instrument on a slanted or uneven surface or in an area where it is subject to vibrations or instability.
   (4) Do not store the instrument where chemicals are stored or gas is generated.
4. Normal life span of the instrument:
   8 years from delivery providing regular maintenance is performed [TOPCON data]

Follow the respective handling methods for the transportation and storage conditions of external I / O devices.

ELECTRIC RATING

Source voltage	100-240V AC
Frequency	50-60Hz
Power input	130VA

DIMENSIONS AND WEIGHT

Dimensions	321~454mm (W) × 523~664mm (D) × 573~657mm (H)
Weight	24.3kg±10%

SYSTEM CLASSIFICATION

- Types of protection against electric shocks:
  This instrument is classified as Class I equipment.
  Class I equipment does not depend only on basic insulation for protection against electric shocks, but also provides a means of connection to a protective earth system of facilities so that metal parts that come into contact do not become conductive while the basic insulation is in failure.
- Grade of protection against electric shocks:
  This instrument is classified as Type B applied part.
  Type B applied part provides a specified grade of protection to prevent electric shocks, particularly for reliability against current leaks, measuring current and protective earth current (in case of Class I equipment).
- Degree of protection against harmful ingress of water: IPX0
  The DRI OCT Triton2 has no protection against ingress of water. (The degree of protection against harmful ingress of water defined in IEC 60529 is IPX0.)
- Classification according to the method(s) of sterilization or disinfection recommended by the manufacturer: not applicable.
  The DRI OCT Triton2 has no part to be sterilized or disinfected.
- Classification according to the degree of safety of application in the presence of a flammable anesthetic 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.
  - The DRI OCT Triton2 should be used in environments where no flammable anesthetics and/or flammable gases are present.
- Classification according to the mode of operation: Continuous operation.
  Continuous operation is the operation under normal load for an unlimited period, without the specified limits of temperature being exceeded.
- Class of laser product: Class 1 laser product according to IEC 60825-1:2014
  Class 1 equipment is a laser product which is safe under the rationally predictable operation conditions, and keeps safety for human eyes even if any optical system (lens or telescope) is used as a condensing unit.

OPERATION PRINCIPLE

Observation

The infrared light, which emitted from the infrared light source (laser) of the illumination optical system, illuminates the fundus linearly. The illuminated position on the fundus is controlled by the scanner of the illumination optical system and the fundus is repeatedly scanned. The light reflected by the fundus is received by the fundus observation/photography camera of the observation/photography optical system. Then, the observation image is generated.

Photography (fundus image)

Visible light is emitted from the visible light source (LED and LD excitation fluorescent light source) of the illumination optical system. This visible light illuminates the fundus linearly. The illuminated position is controlled by the scanner of the illumination optical system and the fundus is scanned. The light reflected by the fundus is received by the fundus observation/photography camera of the observation/photography optical system. Then, the photography image is generated.

Photography (tomogram)

The light, which is emitted from the light source (wavelength sweep laser), is divided into two types of light by No. 1 fiber coupler. One is the reference light and the other is the signal light. The signal light is led to the patient's eye through the lens optical system, is reflected by the fundus tissues or cornea tissues and is returned to No. 1 fiber coupler. The transmitted light is led to No. 2 fiber coupler. The reference light is attenuated by the attenuator, is led to No. 2 fiber coupler and is synthesized with the signal light. The two kinds of light are overlapped to generate interference wave. The photodetector receives this light and converts this energy to electric signal. Mathematical processing is executed for the electric signal to generate the fundus and anterior segment tomograms.

Recording

The photographed image is output as the electronic data to an external device (personal computer, server (DICOM server, etc.)) (commercially available item) and is saved.

Alignment function

The alignment mechanism works as follows: the sensor, which is built in the anterior segment observation stereo camera, detects the pupil and instrument positions, and displays the detected position as the alignment bright spot on the fundus observation image.

Auto focus function

There are two types of auto focus mechanism. One is "fundus auto focus" and the other is "OCT auto focus". The fundus auto focus works as follows: the infrared light (for focus target), which is emitted from the infrared light source (LED) of the illumination optical system, is projected on the fundus. The focus target is displayed on the observation image. Arithmetic processing is performed for the displayed target and the drive amount of the focusing lens is calculated. According to the calculated drive amount, the focusing lens drive mechanism, which is built in the instrument, places the focusing lens in a proper position to perform focusing automatically. In the case of the OCT auto focus, in order to obtain the optimum image quality level (the coefficient calculated by SN ratio) of the observation image of the fundus tomogram, the auto focus mechanism moves the lens, which is in the observation/photography optical system, to a proper position and performs focusing.

Auto shoot

The auto shoot mechanism works as follows: when the alignment bright spot is aligned and the focus and photographed position are properly adjusted for shooting by the auto focus and alignment mechanisms, photographing starts automatically without pressing the photography button.

Auto Z function"

The auto Z mechanism works as follows: according to the signal level received by the photodetector, the position of the tomography optical system is automatically adjusted so that the photographed positions of the fundus and anterior segment tomograms may be proper.

Auto polarization function

The auto polarization mechanism works as follows: according to the signal level received by the photodetector, adjustment is automatically performed so that the signal strength of the fundus and anterior segment tomograms may be proper.

Auto tracking function

The auto tracking function works as follows: by using Phase Only Correlation (POC), the amount of deviation of the fundus image (the amount of eye movement) since the OCT scan start time is detected. According to the amount of deviation, the scan position is corrected. When the amount of deviation is beyond the threshold, scanning is performed again.

DISPOSAL

1. Please follow your national or regional law for environmentally safe disposal of electrical and electronic equipment.
2. For customers:
   - Do not dispose this device or any part of it as unsorted municipal waste;
   - Dispose the device at the municipal collection centers or using the available alternative collection schemes and keep a proof of evidence of the disposal; or
   - Contact your dealer.

NOTE

WEEE Information

This symbol is applicable in EU member states and the UK.

This product should not be disposed of as unsorted household waste. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.
For more detailed information about the take-back and recycling of this product, please contact your supplier where you purchased the product or consult.

This Product Contains a coin cell.
You cannot replace batteries by yourself. When you need to replace and/or dispose batteries, contact your dealer or TOPCON listed on the back cover.

Battery Information

This symbol is applicable in EU member states and the UK.

Battery users must not dispose of batteries as unsorted general waste, but treat properly.
If a chemical symbol is printed beneath the symbol shown above, this chemical symbol means that the battery or accumulator contains a heavy metal at a certain concentration.
This will be indicated as follows:
Hg: mercury (0.0005%), Cd: cadmium (0.002%), Pb: lead (0.004%)
These ingredients may be seriously hazardous to human and the global environment.

Taiwan Battery Information

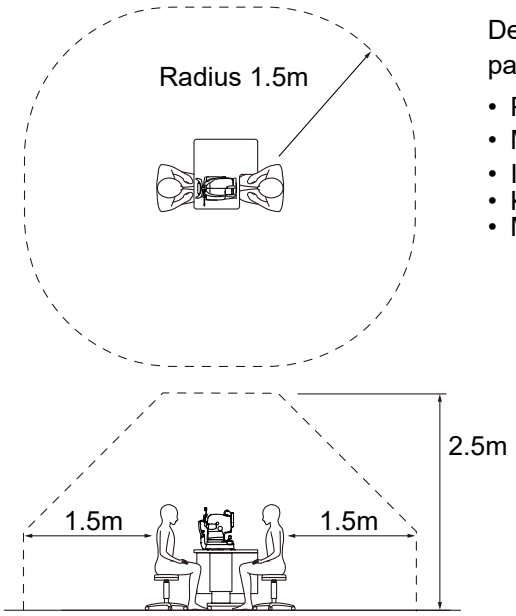
This symbol is applicable in Taiwan.

This product contains dry cell batteries that should be recycled. When you need to replace and/or dispose dry cell batteries, contact your dealer.

PATIENT'S ENVIRONMENT

When the patient or inspector may touch the devices (including the connecting devices) or when the patient or inspector may touch the person that comes into contact with the devices (including the connecting devices), the patient's environment is shown below.
In the patient's environment, use the device conforming to IEC60601-1. If you are compelled to use any device not conforming to IEC60601-1, use an insulation transformer.

Do not use the power strip in the patient's environment. Connect the power supply of the device to the commercial power supply.



Devices applicable to the use in patient's environment

- Personal computer *1 *2
- Monitor for personal computer *1
- Insulation transformer *3
- Keyboard
- Mouse

*1 Use the device conforming to IEC62368-1.
*2 Don't remove the cover from the personal computer.
*3 Use the insulation transformer conforming to IEC 60601-1.

WARNING	Connect only items that have been specified as part of the ME system or that have been specified as being compatible with the ME system.

CAUTION	• Do not connect an additional power strip or an extension cord to the system. • In the patient's environment, use devices conforming to IEC 60601-1. If you are compelled to use any device not conforming to IEC 60601-1, use an insulation transformer. • The total 1kVA is the maximum allowable load of the auxiliary power supply socket for the insulation transformer, which is provided for the system. Do not connect the device exceeding this capacity. • Use the auxiliary power supply socket of the insulation transformer to power only a device that will be a component of the system. • It is dangerous to connect any device which is not used as a component of the system, to the insulation transformer. • When the insulation transformer is not used, the personal computer and the monitor for the personal computer must be installed out of the patient's environment.

REQUIREMENTS FOR THE EXTERNAL DEVICE

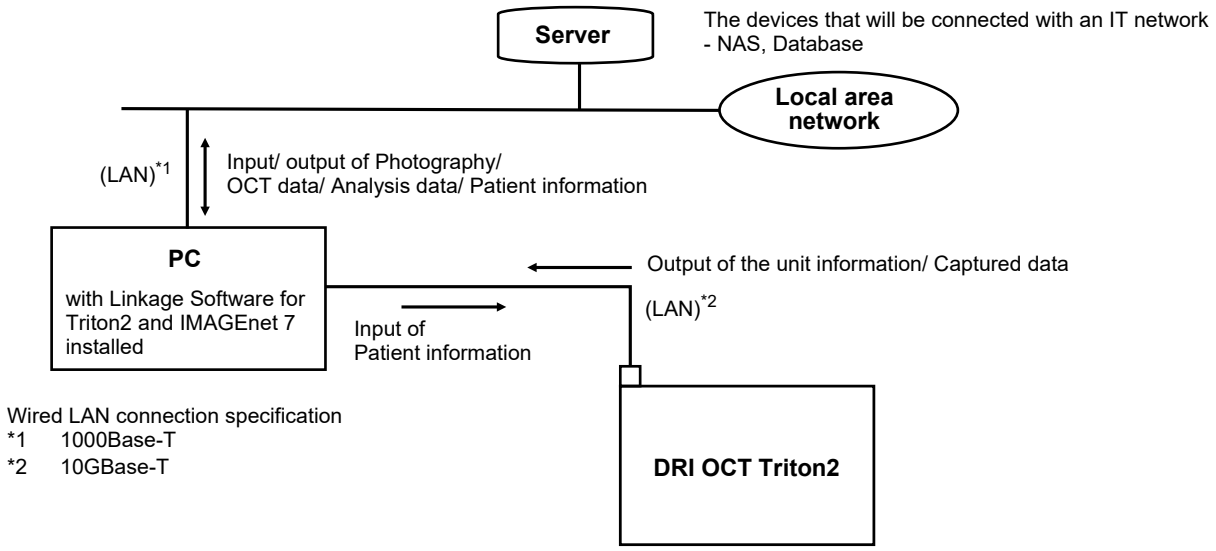
CAUTION	The external device connected to the analog and digital interfaces must comply with the respective IEC or ISO standards (e.g. IEC 62368-1 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. In addition, the external devices to be connected must comply with the corresponding EMC standards (e.g. CISPR 32/CISPR 35). Attention is drawn to the fact that local laws take priority over the above mentioned requirements.

If in doubt, contact your dealer or TOPCON (see the back cover).

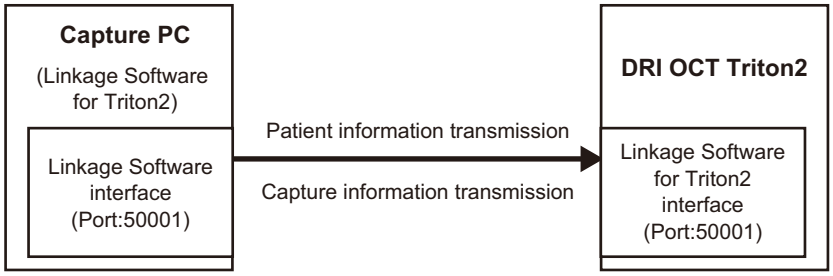
IT NETWORK ENVIRONMENT

CAUTION	When connected with an IT network, ensure the appropriate and sufficient security to prevent the infection with malware and a computer virus, the leak of information, etc. There is a risk of data leakage.

- DRI OCT Triton2 is connected with an external personal computer (PC). PC can be connected with Database and NAS in order to input/ output photography, OCT data, Analysis data and other data.
- Refer to the figure below for the characteristics, configuration, technical specification, intended information flow and route when connected with an IT network.
- When connected with an IT network, ensure the appropriate and sufficient security to prevent the infection with a computer virus, the leak of information, etc.
- When any failure occurs in IT systems, some troubles may be caused by it. For example, the input data/output data cannot be sent/received to/from the devices connected with network.
- When connected with an IT network with which a device other than DRI OCT Triton2 is connected, the patient, the operator or the third party may suffer unexpected and unacceptable risks. Before using DRI OCT Triton2, it is recommended to identify, analyze, evaluate and manage these risks.
- When the IT network has been changed after the connection, a new risk may occur. So an additional analysis is necessary.
- The change of IT network includes the following items:
  - Change in the IT network configuration;
  - Connection of additional items to IT network;
  - Removal of items from IT network;
  - Update of the device connected with IT network;
  - Upgrade of the device connected with IT network.



Software configuration and connectivity support

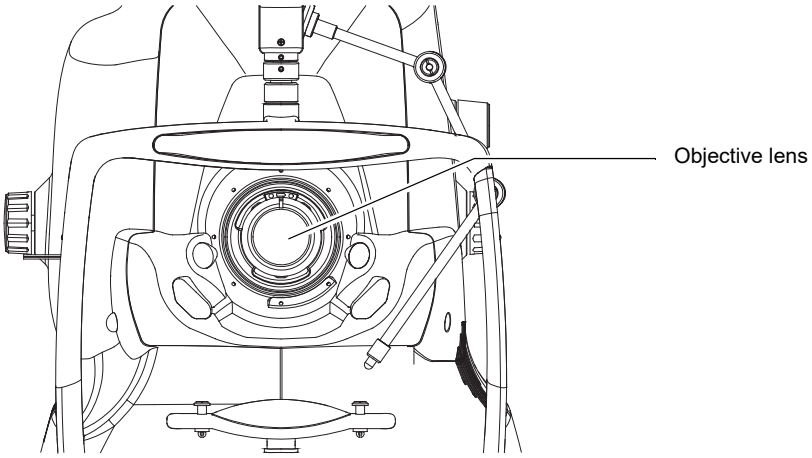


SAFETY OF LASER PRODUCT

CAUTION	• Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser exposure. • Do not remove the enclosures. Light high-power is radiated.

Class of LASER product	CLASS1	
LASER PRODUCT	Tunable wavelength laser (for tomography)	
	Aperture of laser	Objective lens*
	Output of cornea	1050μW
	Wavelength	1050nm
	Half width	100nm
	Beam divergence	13mrad
	Pulse width	6μs
	VCSEL (for fundus observation)	
	Aperture of laser	Objective lens*
	Output of cornea	530μW
	Wavelength	850nm
	Half width	1nm
	Beam divergence	H:21.5mrad / V:2.8mrad
	Pulse width	47ms
LASER light source	Tunable wavelength laser (for tomography)	
	Output	24.5mW
	Class of laser	Class 3B
	Wavelength	1050nm
	Half width	100nm
	Beam divergence	0.56rad
	Pulse width	6μs
	VCSEL (for fundus observation)	
	Output	4.82mW
	Class of laser	Class 3B
	Wavelength	850nm
	Half width	1nm
	Beam divergence	H:1.82rad / V:1.47rad
	Pulse width	47ms

* The laser light is emitted from the objective lens and converges at a point 37mm away from the objective lens. The light area and optical power are measured at this position.



ELECTROMAGNETIC COMPATIBILITY

This product conforms to the EMC standard (IEC60601-1-2:2014+AMD1:2020 (Ed.4.1)).
The expected electromagnetic environment for the whole life cycle is home medical treatment environment.

1. MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.
2. Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
3. The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or SYSTEM as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or SYSTEM.
4. The EQUIPMENT or SYSTEM should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the EQUIPMENT or SYSTEM should be observed to verify normal operation in the configuration in which it will be used.
5. The use of the ACCESSORY, transducer or cable with EQUIPMENT and SYSTEMS other than those specified may result in increased EMISSION or decreased IMMUNITY of the EQUIPMENT or SYSTEM.
6. Do not use the devices generating electromagnetic waves within 30cm from all the parts of the instrument and system. Those devices may have influence on this instrument.

Item	Length (m)	Shield	Ferrite core
AC power cord (AC100/120V)	1.5	No	No
AC power cord (AC230/240V)	3.0	No	No
LAN cable	3.0	Yes	No
AC power cord (for PC)	2.0	No	No
DPcable	1.7	Yes	Yes
AC power cord (for Display)	1.7	No	No
Keyboard cable	1.8	Yes	No
Mouse cable	1.8	Yes	No
AC power cord (for ME ISOLATION TRANSFORMER)	1.5	No	No
FG cable	2.0	No	No
External fixation target	-	-	-
Personal computer	-	-	-
Display	-	-	-
Keyboard	-	-	-
Mouse	-	-	-
ME ISOLATION TRANSFORMER	-	-	-

Guidance and manufacturer's declaration - electromagnetic emissions		
The DRI OCT Triton2 is intended for use in the electromagnetic environment specified below. The customer or the user of the DRI OCT Triton2 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The DRI OCT Triton2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The DRI OCT Triton2 is suitable for use in all establishments including domestic and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The DRI OCT Triton2 is intended for use in the electromagnetic environment specified below. The customer or the user of the DRI OCT Triton2 should assure that it is used in such an environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV 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 IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines Repetition frequency 100kHz	± 2 kV for power supply lines ± 1 kV for input/output lines Repetition frequency 100kHz	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and Voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle (with phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T for 1 cycle 0° 70% U_T for 25/30 cycles 0° 0% U_T for 250/300 cycles	0% U_T for 0.5 cycle (with phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T for 1 cycle 0° 70% U_T for 25/30 cycles 0° 0% U_T for 250/300 cycles	Main power quality should be that of a typical commercial or hospital environment. If the user of the DRI OCT Triton2 requires continued operation during main power interruptions, it is recommended that the DRI OCT Triton2 be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. main voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The DRI OCT Triton2 is intended for use in the electromagnetic environment specified below. The customer or the user of the DRI OCT Triton2 should assure that it is used in such an environment.

Immunity test	Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 6Vrms Within ISM band and amateur radio band of 150kHz to 80MHz 10V/m 80MHz to 2.7GHz Proximity electromagnetic field from radio communication equipment*	3Vrms 150kHz to 80MHz 6Vrms Within ISM band and amateur radio band of 150kHz to 80MHz 10V/m 80MHz to 2.7GHz Proximity electromagnetic field from radio communication equipment*	Portable and mobile RF communications equipment should be used no closer to any part of the DRI OCT Triton2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the radiation electromagnetic field level in volt/meter (V/m).
Proximity magnetic fields IEC 61000-4-39	30kHz CW 8A/m 134.2kHz PM2.1kHz 50% 65A/m 13.56MHz PM50kHz 50% 7.5A/m	30kHz CW 8A/m 134.2kHz PM2.1kHz 50% 65A/m 13.56MHz PM50kHz 50% 7.5A/m	The exterior surface of the DRI OCT Triton2 should be kept at least 0.15m from RF emitters such as RFID readers.

NOTE 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

* The table below shows the proximity electromagnetic field from radio communication equipment.

Test frequency [MHz]	Band [MHz]	Equipment	Modulation	Maximum output (W)	Distance (m)	Immunity test value [V/m]
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ±5kHz 1kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900 TETRA 800 iDEN820 CDMA850 LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800 CDMA1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band7	Pulse modulation 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9

RELATION BETWEEN THE SETTING OF THE ILLUMINATION/ FLASH LEVEL AND MAXIMUM RADIANCE

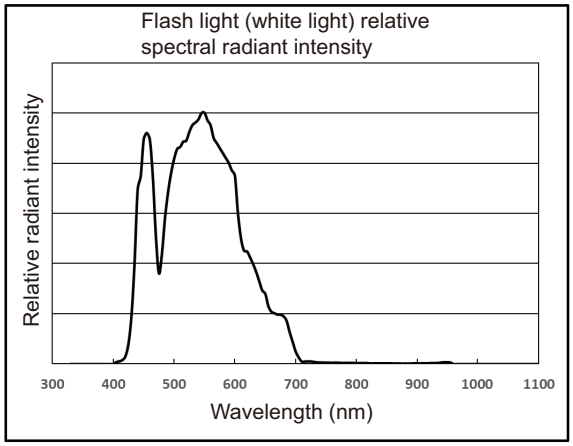
When the maximum radiance is "1", the ratio of radiance is shown below in the setting of the illumination/flash level.

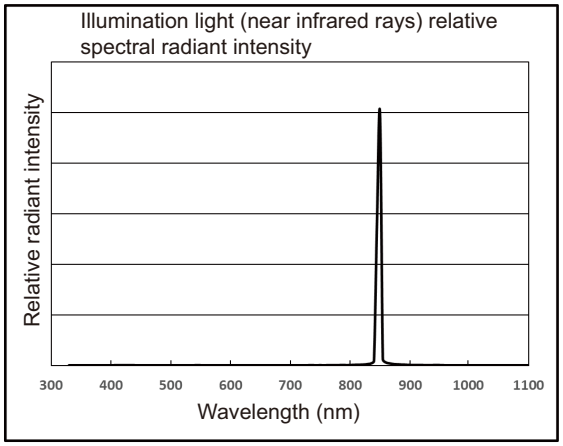
Illumination level

Display level	Ratio of radiance
1	0.417
2	0.500
3	0.646
4	0.875
5	1.000

Flash level (in OCT+Color photography and Color photography)

Display level	Ratio of radiance	Ratio of camera gain [dB]	Ratio of brightness
	1.000	+18.0	7.94
	1.000	+16.5	6.68
	1.000	+15.0	5.62
	1.000	+13.5	4.73
	1.000	+12.0	3.98
	1.000	+10.5	3.35
	1.000	+9.0	2.82
	1.000	+7.5	2.37
+4	1.000	+6.0	2.00
+3	1.000	+4.5	1.68
+2	1.000	+3.0	1.41
+1	1.000	+1.5	1.19
0	1.000	0	1.00
-1	0.843	0	0.84
-2	0.709	0	0.71
-3	0.598	0	0.60
-4	0.504	0	0.50





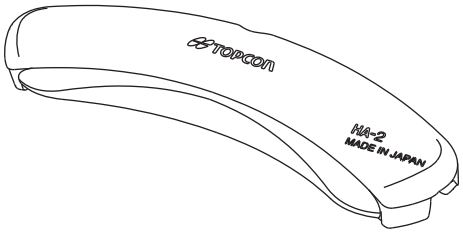
OPTIONAL ACCESSORIES

ANTERIOR SEGMENT ATTACHMENT KIT AA-1

This is used to observe, photograph and record the images and tomograms of anterior segment.

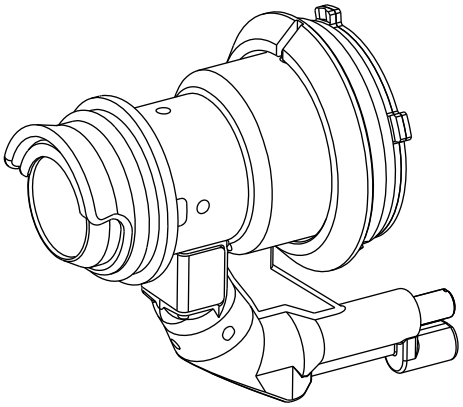
●ANTERIOR ATTACHMENT HA-2

Specifications	
Dimensions	180mm (Width) × 35mm (Height) × 61mm (Depth)
Weight	125g
Material	Silicone rubber



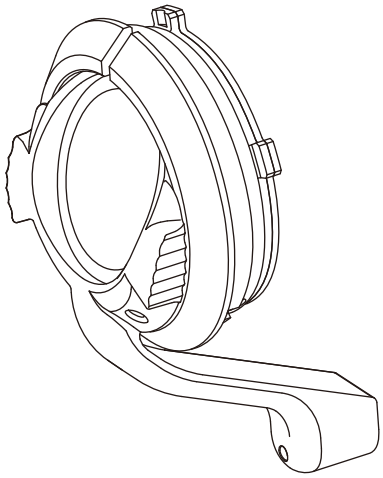
●Anterior segment lens unit

Specifications	
Dimensions	46mm (Width) × 83mm (Height) × 71mm (Depth)
Weight	123g
Material	Aluminum alloy



WIDE FIELD OCT ATTACHMENT LENS WA-1

Specifications	
Dimensions	46.0mm (Width) × 71.2mm (Height) × 40.9mm (Depth)
Weight	76g
Material	Aluminum alloy



REFERENCE MATERIAL

ABOUT THE BARCODE AND THE QR CODE OF THE BACK COVER

The barcode and the QR code of the back cover indicates the parts management code of the manual.

OPERATING AND USAGE METHOD

USAGE METHOD

1. Connect the computer to the isolation transformer.
2. Connect the instrument and the PC with a LAN cable.
3. Connect the instrument and the isolation transformer to a commercial power source.
4. Turn on the power switch of the transformer.
5. Turn on the power switch of the personal computer.
6. Turn on the power switch of the instrument.
7. Start IMAGEnet 7 on the PC.
8. Log in to IMAGEnet 7.
9. Enter the patient's information from IMAGEnet 7.
10. Click on the DRI OCT Triton2 icon in the IMAGEnet 7 list of imaging devices.
11. Tap the icon on the control panel or PC[*1] of the instrument and select the imaging settings.[*2] [*3] (You can also use PC, the control panel, and the switch panel to set detailed imaging conditions such as imaging items, scan patterns, and areas to be scanned.)
12. Fix the patient's face to the chin rest and forehead pad. Adjust the chin rest with the chin rest up/down button on the switch panel so that the height of the patient's eye is aligned with the height mark on the chin rest support.
13. Guide the patient's eye to the area to be photographed using the internal fixation target, peripheral fixation target[*4] or external fixation target.
14. Operate the control lever while watching the control panel or PC[*1] display to adjust the imaging position.
15. When the main unit is in the appropriate position for shooting, various automatic functions activate to set focus. Confirm that the camera is in focus on the control panel display and start shooting. (Focusing can also be done manually through settings.)[*5]
16. Check the display on the control panel or PC[*1] to see if the intended image was taken.
17. Repeat operations 9 to 15 as necessary to take pictures.
18. When the imaging is finished, turn off the power switch of the instrument. [*6] [*7]
19. Exit IMAGEnet 7.
20. Turn off the power switch of the computer.
21. Turn off the power switch of the isolation transformer.
22. Disconnect the instrument and isolation transformer from the commercial power supply.

*1 PC mode only.
*2 Attach the anterior segment attachment kit AA-1 when performing anterior segment observation/photography and anterior segment tomographic observation/photography.
*3 When performing wide field fundus tomography, attach wide field OCT attachment lens WA-1.
*4 For fundus imaging and tomography only.
*5 Auto fundus imaging can be performed by setting.
*6 Remove AA-1 when observation/photography of the anterior segment of the eye and observation/photography of anterior segment tomograms are completed.
*7 Remove WA-1 when wide-angle fundus tomogram observation/photography is completed.

Please refer to the User Manual.

Please provide the following information when contacting us regarding questions about this instrument:

- Model name: DRI OCT Triton2
- Serial No.: This is printed on the rating nameplate on the right side of the power supply unit.
- Period of use: Please inform us of the date of purchase.
- Defective condition: Please provide us with as much detail as possible on the problem.

3D OPTICAL COHERENCE TOMOGRAPHY
DRI OCT Triton2

INSTRUCTION MANUAL

Revision.2.00
Date of issue 2025-9-8

Published by TOPCON CORPORATION

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3D OPTICAL COHERENCE TOMOGRAPHY

DRI OCT Triton2

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Parts management code
1074881-01-B
Printed in Japan 2509