

OPTOMED AURORA **A**EYE

USER MANUAL



Optomed Aurora AEYE Camera

User manual of Optomed Aurora AEYE ophthalmic camera

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1. Safety

The information in this manual applies to the Optomed Aurora AEYE ophthalmic camera. The specifications in this manual are subject to change without prior notice due to continuing product development. The latest version of this manual can be downloaded at www.optomed.com/us/auroraaeye where you can also find more material.

This user manual explains the safety precautions and introduces the device and its proper operation. The device must be used according to this user manual. The user manual and other documentation enclosed with the Optomed Aurora AEYE should be always kept accessible to users to ensure that the information required for use of the device is readily available.



Read the user manual carefully before commissioning this device. It contains important information regarding user and patient safety.



NOTE!

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

1.1 Symbols

The symbols used in this user manual or on device labels refer to important safety information or manufacturing information. Whenever you see these symbols, read the accompanying information carefully and observe all safety notes and information in this user manual and on device labels.



WARNING!

Indicates a hazardous situation which could result in patient injury, harm, or death if appropriate safety precautions are not followed.



CAUTION!

Indicates a situation which could result in device harm, damage, or malfunction if the appropriate precautions are not followed.



NOTE!

Important information: please read carefully.



Medical device

The device is a medical device as defined in MDR 2017/745.



Read the instructions for use carefully

Failure to follow these instructions could place the patient or operator at risk.



Radio frequency radiation

The device has WLAN functionality. Electromagnetic interference may occur in the vicinity of equipment.



FCC Declaration of conformity

The device emits radiofrequency (RF) radiation. Electromagnetic interference from the device is under limits approved by the Federal Communications Commission.



Prescription device

Symbol for: "Caution: Federal law restricts this device to sale by or on the order of a physician or licensed practitioner."



Type BF applied parts

The eye cup which is in physical contact with patient is electrically isolated and protected against electric shock.



Class II power supply



For indoor use only

Power supply designed primarily for indoor use only according to IEC 60471



Plug socket for power supply (Positive polarity)

Voltage and current



Disposal specification

Disposal in accordance with WEE and/or in accordance with local disposal and recycling laws



Battery disposal specification

Device has rechargeable lithium-ion battery which can be recycled.



Manufacturer

The symbol indicates the name and the address of the manufacturer.



Date of manufacture

The symbol indicates the date that the product was manufactured, expressed as four digits for the year and two digits for the month and where appropriate, two digits for the day.



Serial number

The first four digits of the serial number indicates the week (digits 1-2) and year (digits 3-4) of the manufacture.



Global trade item number



Reference number



GS1 Unique Device Identification



Keep away from water



Fragile

Handle with care.



Do not use hand hooks



Keep out of direct sunlight



Number of units packed



Temperature limitations



Humidity limitations



Atmospheric pressure limitations

1.2 Intended use

Optomed Aurora AEYE Camera is a medical digital camera that is used with dedicated optics modules intended to capture images and video of the fundus of the eye and surface of the eye.

Optomed Aurora AEYE Camera with **Retinal Module** is intended to capture digital images and video of the fundus of the human eye.

Optomed Aurora AEYE Camera with **Anterior Module** is intended to capture digital images and video of the surface of the human eye and surrounding areas.

Optomed Aurora AEYE Portal is a web application which enables registering to the service, administrating background information used to run the service, administrating Cloud service connecting Optomed Aurora AEYE Camera and AEYE-DS Service provider, and viewing information such as AI result.

AEYE-DS Service is intended for use by health-care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. AEYE-DS Service is indicated for use with Retinal Module.

Intended users

Optomed Aurora AEYE Camera may only be operated by persons who have been properly trained, who are familiar with fundus cameras, ophthalmoscopes, etc., or who have the required knowledge to operate the device or a similar device.

The device is intended to be used by health-care professionals of the applicable specialties including but not limiting to ophthalmology, optometry, diabetology, neurology, pediatrics, and primary care.

This device may only be used in accordance with its intended use.

Intended patient population

All patients may be imaged with Optomed Aurora AEYE Camera. AEYE-DS Service is for adults of 22 years old and older.

Clinical benefits

The operation of Optomed Aurora AEYE Camera can be learned quickly, and even an inexperienced camera operator can capture images with sufficient quality for quick screening purposes.

Optomed Aurora AEYE Camera can be operated non-mydratically. 50 degrees x 40 degrees field of view (FOV) together with 9 fixation targets yield detailed images of different areas of fundus. Only one macula centric image of both eyes is needed for AEYE-DS Service to provide analysis. With Optomed Aurora AEYE digital images can be stored for follow-up or consultation purposes.

Optomed Aurora AEYE Camera provides versatility for diagnosing different patient groups that are not able to sit in front of a desktop fundus camera (e.g. supine patients, wheelchair patients). Due to the small size and portability Optomed Aurora AEYE Camera can also be used for homecare visits and remote screening services.

Results of the prospective, multi-center clinical trial intended to assess handheld fundus camera Aurora together with AEYE Health's AI for autonomous detection of more than mild diabetic retinopathy showed that the combined product detected 91.9% (sensitivity), while patients without the eye disease were correctly identified 93.6% of the time (specificity). The observed imageability was over 99%¹.

¹ *ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Feb 29 - . Identifier NCT04612868, Efficacy and Safety of AEYE-DS Software Device for Automated Detection of Diabetic Retinopathy From Digital Fundus Images; 2020 Nov 3 [cited 2022 June 28]; [1 page]. Available from: <https://clinicaltrials.gov/ct2/show/record/NCT04612868>.*

1.3 Contraindications and limitations

The daily usage time and maximum allowed number of pulses presented below is calculated based on optical classification results.



WARNING!

Optomed Aurora AEYE is classified as Group 2 based on standard ISO 15004-2:2007. The light emitted from this instrument is potentially hazardous. The longer the duration of exposure and the greater the number of pulses, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum output will exceed the safety guideline after:

Pulsed light

- 6300 still images / eye / day for Retinal Module
- 250 still images / eye / day for Anterior Module

Or alternatively **continuous light**

- 67 min video recording / eye / day for Retinal Module
- 5 min video recording / eye / day for Anterior Module

Optomed Aurora AEYE is classified as Group 2 based on ANSI Z80.36-2016. Safety guidelines for continuous light:

The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater is the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the recommended maximum exposure (RME) of 2.2 J/cm², after

- 67 min video recording / eye / day for Retinal Module
- 37 min video recording with white light / eye / day for Anterior Module
- 5 min video recording with blue light / eye / day for Anterior Module

Please note that the exposure time in video recording and the number of pulses in still imaging from all light sources are cumulative and additive.

EXAMPLE for Anterior Module:

If patient's right eye is first examined with continuous white light for 14 minutes, this amounts to $(14 \text{ min} / 37 \text{ min}) * 100\% = 37.8\%$ of RME exposure. For subsequent examination of the same eye with blue light, it is not recommended to expose the eye to blue light for more than 3 minutes ($100\% - 37.8\% = 62.2\%$; $5 \text{ min} * (62.2\% / 100\%) = 3.11 \text{ min}$).

Since prolonged intense light exposure can cause ocular damage, the use of the device

for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. Infants and persons with aphakia or diseased eyes will be at greater risk of ocular damage.

The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours.



NOTE!

Exposure to imaging flash, in rare cases, may contribute to migraines or temporary visual disturbances, particularly in patients with a history of light sensitivity or migraines. Multiple flashes per eye in a single exam may increase the likelihood of occurrence.



NOTE!

The following conditions may complicate or prevent imaging: cataract, corneal opacity, nystagmus, and conditions that cause body movement.



NOTE!

Unconscious or anesthetized patients may be difficult to image as the patient cannot fixate on a target led.

1.4 Precautions



WARNING!

Optomed Aurora AEYE is not suitable for use in explosion risk areas or in the presence of flammable anesthetics.



WARNING!

Place the PC and Charging Station outside the patient environment at a distance of at least 1.5 meters from the patient.



WARNING!

To avoid the risk of contamination, disinfect the eye cup before each use with a new patient or use disposable eye cups. See section 6.3 Cleaning.



WARNING!

Do not leave the eye cup in direct sunlight as it may heat up and cause burns.

**WARNING!**

To avoid touch current during imaging, do not touch the system connectors and the patient simultaneously.

**WARNING!**

This product can expose you to chemicals, which is known in the State of California to cause cancer, birth defect or other reproductive harm.

For more information, go to www.P65Warning.ca.gov

**CAUTION!**

Optomed Aurora AEYE is intended for use inside, in normal room temperature and normal humidity. Do not use the device in an environment where there is a possibility of water condensation on or inside the device.

**CAUTION!**

The device may only be used for the specified purpose and according to national regulations, consistent with the applicable industry standards and occupational safety and accident prevention regulations.

**CAUTION!**

Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

**CAUTION!**

No modification of this equipment is allowed.

**CAUTION!**

Only use accessories and battery provided by Optomed Oyj (Plc) with this product.

**CAUTION!**

Only use USB cable and the power supply provided by Optomed Oyj (Plc) with this product. If you need replacement USB cable or power supply, please contact manufacturer. USB cable must be connected only to the USB port of a PC that complies with the IEC 60950 standard. Only connect Charging Station to the walls outlet which corresponds to the specification of the power supply.

**CAUTION!**

The connection between the camera and the PC is USB and/or WLAN. Any authorization procedures should be carried out in the PC. If the PC is connected to a network, make sure the appropriate safety measures are applied, such as Antivirus and Firewall protection.

**CAUTION!**

If there are breaks in device covers or other visual defects, contact Optomed Customer Service or an Optomed-certified service facility.

**CAUTION!**

Repair and maintenance work may only be performed by authorized specialists. Contact Optomed Customer Service or an Optomed-certified service facility for repairs and maintenance work on the device.

2. Device overview



Optomed Aurora AEYE Camera is a modular ophthalmic camera that is designed for use in a medical environment. It is intended to capture digital images and video of the human fundus of the eye and surface of the eye for documentation, screening, and consultation. The camera is used with interchangeable optics modules: Retinal Module and Anterior Module. The optics modules are attached to the camera with bayonet connectors.

Retinal Module is intended for non-mydriatic fundus imaging. In non-mydriatic imaging no mydriasis is needed because infrared light is used for targeting the fundus and white light is flashed when an image is taken. The pupil does not respond to the infrared light, so examination is convenient for the patient. Mydriatic drops are needed when recording a video. Mydriatic drops are also recommended when pupil diameter is small. Retinal Module has nine internal fixation targets for the patient to fixate on during imaging. The middle fixation target provides a macula centered image which is required for AEYE-DS analysis.

Anterior Module is intended for imaging the surface of the eye and the surrounding areas. Anterior Module has two light sources for imaging: white and cobalt blue. Cobalt blue light enables capturing of fluorescent images. There are four focus windows to focus the image.

Optomed Aurora AEYE Camera can be used wirelessly using **WLAN** which enables wireless data transfer to a PC and Cloud. In addition to WLAN, captured images and videos can also be transferred to a PC via USB connection when encryption setting is disabled, and the camera is placed on **Charging Station**. Charging Station is a dual charger used for charging the battery inside the camera and the spare battery.

Optomed Aurora AEYE Portal is a web application which enables registering to the service, administrating background information used to run the service, administrating Cloud service connecting Optomed Aurora AEYE Camera and AEYE-DS Service provider, and viewing information such as AI result. The application is optimized for workstation use. Web browser (Chrome, Edge, Safari, or Mozilla) is used to navigate and launch application log-in screen thus a network connection is required to use the application. Optomed Aurora AEYE Portal login page: <https://auroraeye.optomed.com>.

Optomed Aurora AEYE Camera can be connected to **AEYE-DS Service** for analysis of retinal images for more than mild diabetic retinopathy (mtmDR). The AEYE-DS Service is intended for use by health-care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy.

3. Getting started

3.1 Part list and unpacking

The Optomed Aurora AEYE carrying case contains the following items:

Device

1. Optomed Aurora AEYE Camera
2. Retinal Module
3. Anterior Module

Accessories

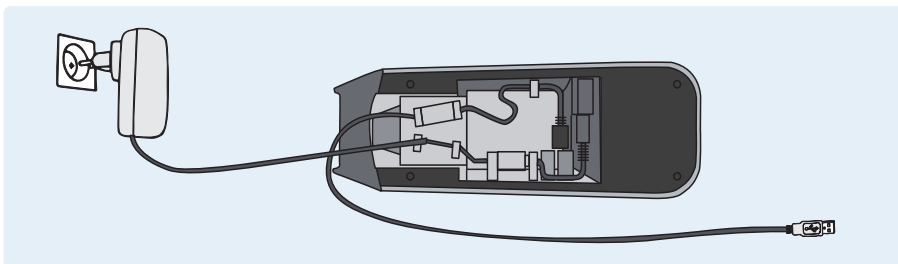
4. Charging Station
5. USB Cable
6. Power Supply
7. Eye Cup (2 pcs)
8. Battery (2 pcs)
9. USB Flash Drive
10. Cleaning Cloth
11. User Manual and other material

Open the sales packaging and the carrying case inside. Remove the Optomed Aurora AEYE Camera and accessories from the carrying case and check that all parts are present and undamaged.



3.2 Preparations

Place **Charging Station (4)** on a table outside the patient environment at a distance of at least 1.5 meters from the patient. Connect the **Power Supply (6)** cable to Charging Station and to the wall outlet. No need to connect USB cable to the PC since Aurora AEYE study uses wireless data transfer.

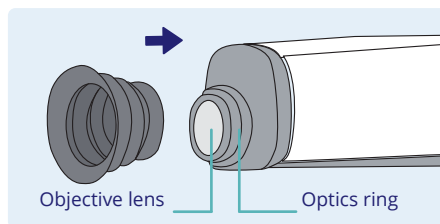
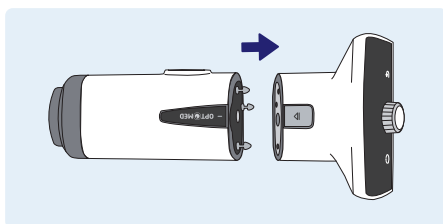


Note!

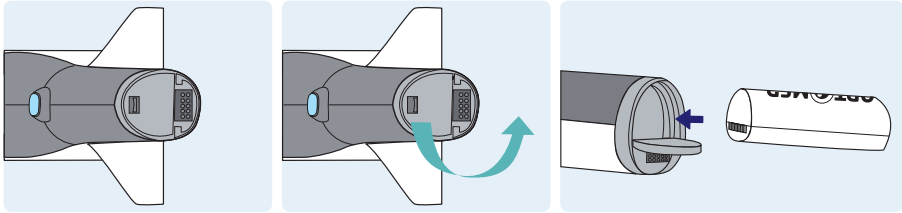
Position the power supply so that the mains plug can be easily disconnected.

Both **Retinal Module (2)** and **Anterior Module (3)** (option for Other study only) are attached to **Camera (1)** by connecting the bayonet legs of the optics module firmly to the bayonet holes of the camera. Avoid touching the camera window with bayonet legs to prevent scratches.

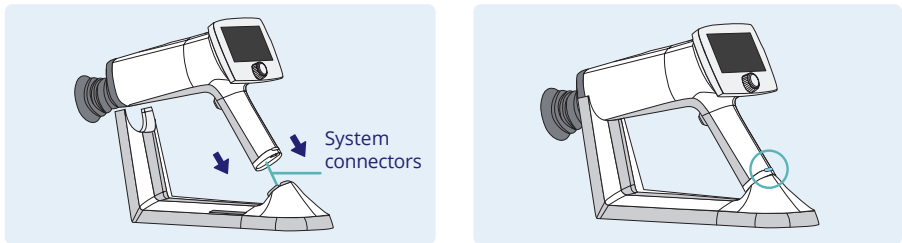
Place the **Eye Cup (7)** on the optics ring of **Retinal Module (2)**. To avoid the risk of contamination, disinfect the Eye Cup before each use with a new patient. If you are using disposable eye cups (E-Safe Disposable eye cups), first place the designated base part to the optics ring and then place the disposable eye cup on top of it. E-Safe Disposable eye cups can be bought separately. Detailed instructions are in the package.



Install the **Battery (8)** in **Camera (1)**. Ensure that the camera is powered off when replacing the battery. Open the battery cover by depressing the door latch and opening battery door. Insert the battery and press the cover firmly into place.

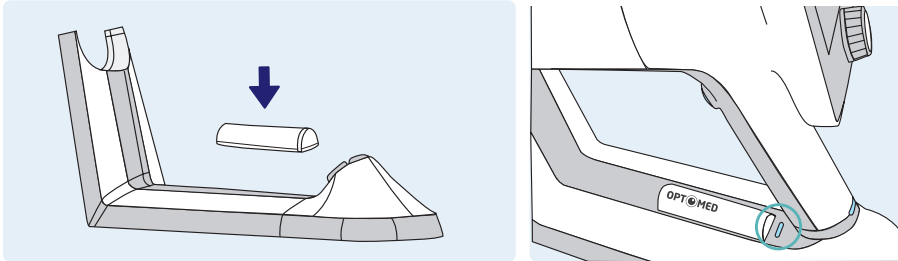


Place the camera on **Charging Station (4)** for charging. The camera will fit on Charging Station when **Retinal Module (2)** is attached. Place the handle of the camera carefully onto the system connector of Charging Station and move the front part of the optics module onto the support. Excessive force should be avoided to prevent the camera and Charging Station connectors from breaking. The camera enters power save mode while placed on Charging Station and it wakes up when lifted from Charging Station.



The battery charging indicator LEDs on the handle of the camera blink when battery is being charged. When the battery is fully charged, all indicator LEDs are lit. When charging for the first time, charge the battery until full (at least 4 hours). In daily use, place the camera to Charging Station for charging whenever it is not used.

Charging Station can be used as external charger for the spare battery. Set the **spare battery (8)** connectors to match with the **Charging Station (4)** connectors and put the spare battery in place. The spare battery charging indicator LED on Charging Station blinks when the battery is being charged and is lit when the spare battery is fully charged.

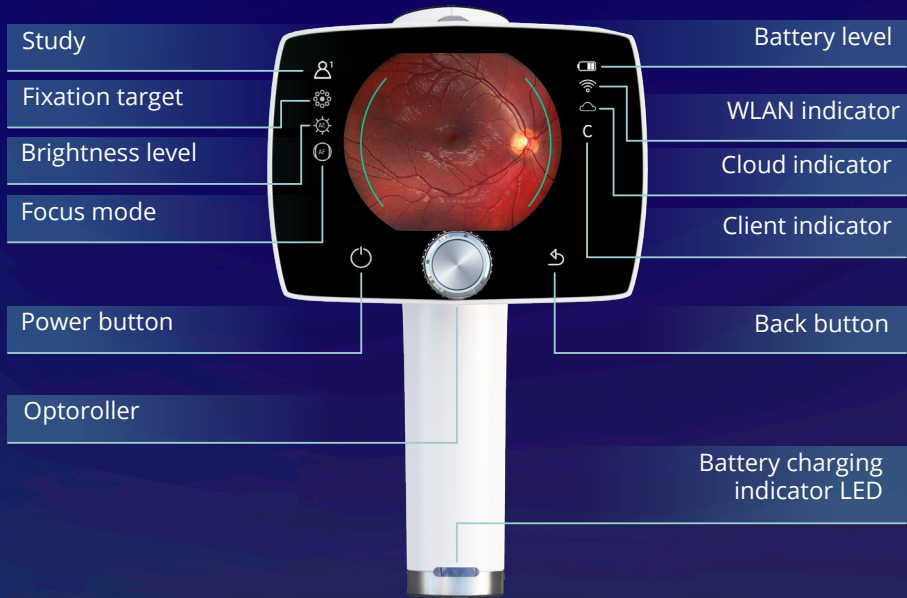


Remove Optomed Aurora AEYE Camera from Charging Station by first lifting the optics module from the support and then carefully lifting the handle of the camera from the Charging Station connectors.

If Optomed Aurora AEYE Camera is not used for more than two minutes, the device enters power save mode. It wakes up from power save mode by using any control button. The camera will power off if not used in 10 minutes. Power off does not occur if the camera is in Charging Station.

Optomed Aurora AEYE Camera can be used wirelessly using WLAN which enables wireless data transfer to a PC and Cloud. The separate Optomed Aurora AEYE Client PC software needs to be installed on the PC to allow wireless data transfer to it for non AEYE-DS studies. Instructions on the operation of wireless settings and PC software are guided in Appendix A.

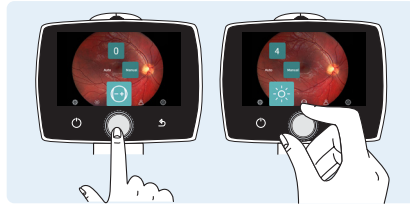
3.3 Controls and display icons



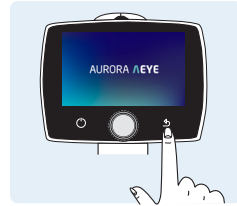
Optomed Aurora AEYE Camera is powered on and off by pressing the power button for few seconds. Powering on switches the lights on and turning off in turn opens a notification about powering off. Opening the Quick menu is done by pressing Optoroller, which is also used for navigating in the menu together with back button.



Power on



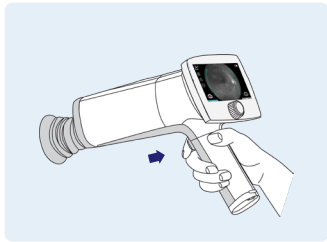
Open Quick menu and navigate



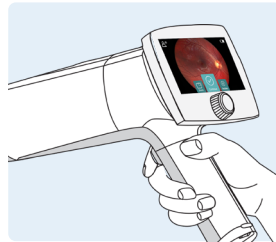
Back button

Battery level, WLAN, Client, Cloud, study folder number or patient initials, fixation target, brightness level, and diopter value indicators are shown on the camera display.

Images are captured by pressing the dual action shutter button. If Optomed Aurora AEYE Camera is unresponsive, it can be forced to shut down by pressing the power and back buttons simultaneously for seven seconds or longer.



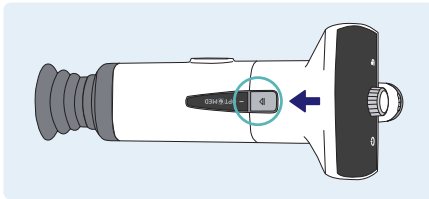
Shutter button for image capture



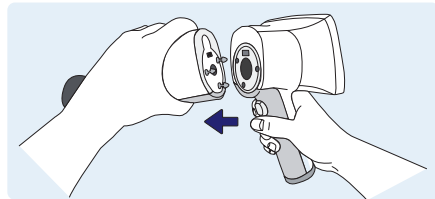
Forced shutdown

The battery charging indicator LED is on when the camera is placed on Charging Station for charging. There is also an LED indicator in Charging Station for indicating spare battery charging.

Both Retinal Module and Anterior Module are attached to Optomed Aurora AEYE Camera by connecting firmly the bayonet legs of the optics module to the bayonet holes of the camera. Optics modules are detached by pressing the eject button on the top of the camera.



Press eject button




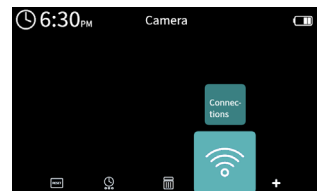
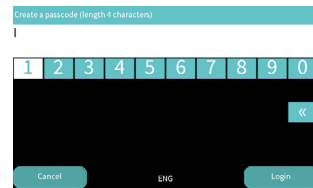
Detach the module

3.4 Start up and camera software set up

On first time use, Admin passcode is created, and basic configuration of the camera is set. It is possible to create other users at a later stage.

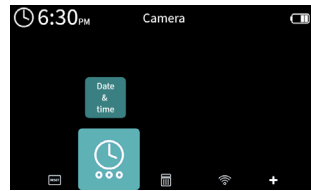
First time use:

1. Press *Power* button
2. Create passcode for Admin; choose 4 digits
 - To move between items, rotate Oporoller to the left or right Press Oporoller to select the item. Login by pressing the back button.
3. Select *No* for Start Aurora AEYE study; *Live view* opens
4. Set up wireless connection; choose Settings ()
 - > Camera > Connections > WLAN
 - Use WLAN connection; select *On*
 - Network; select *available wireless network* from the list by rotating and pressing Oporoller
 - Enter *network password*; rotate and press Oporoller, press power button to access lowercase and more characters. Select *Next* with back button.
 - Select *Connect* by pressing Oporoller



5. Set up Date & Time

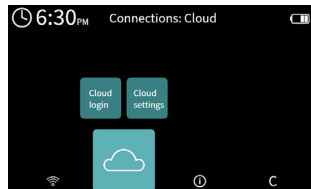
In case the camera does not guide you to Date & time settings, choose Settings, select Camera option followed by Date & time.



- Daylight saving time; *On* or *Off*. Press Optoroller to choose if applicable.
- Time zone; choose AST, EST, CST, MST, PST, AKST, HST, SST, or CHST by rotating and pressing Optoroller
- Automatic time sync; *On* or *Off*. Automatic synchronization is recommended. Press Optoroller to choose desired option.
- Sync On; Press *Sync now*
- Sync Off; Select *Set time manually*. Select month, day, year, hour, minutes, and AM or PM by rotating and pressing Optoroller

6. Cloud; for configuration of AEYE-DS Service and Optomed Aurora AEYE Portal. Username and password are the same as for Optomed Aurora AEYE Portal.

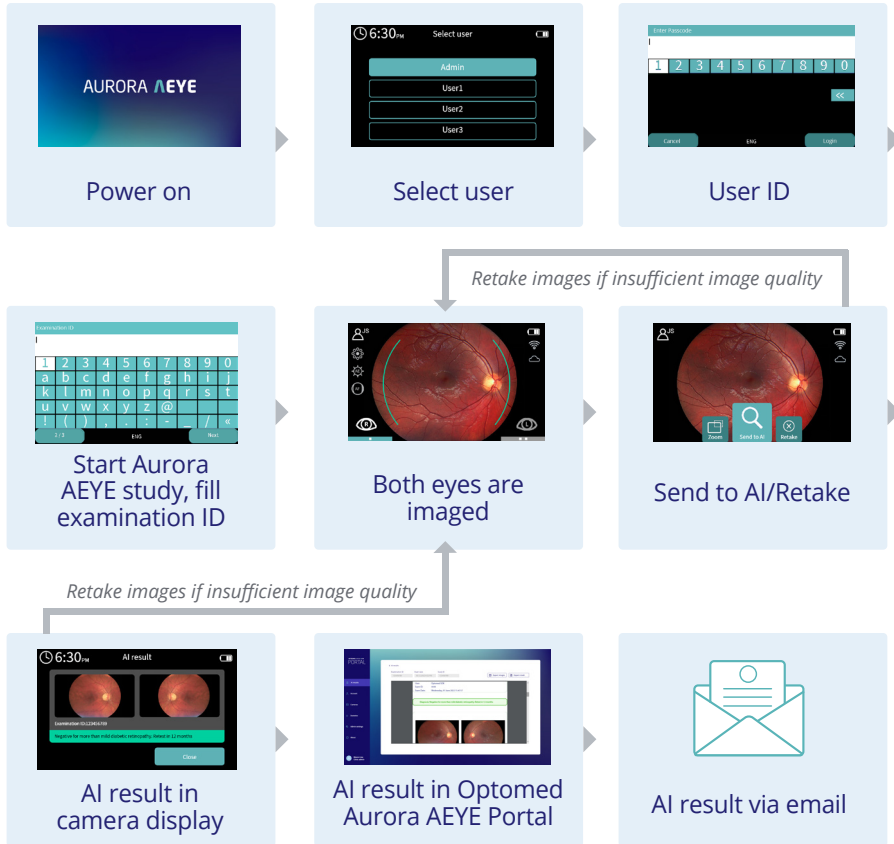
In case the camera does not guide you to Cloud menu, choose Settings > Camera > Connections > Cloud.



- Enter *Cloud username*; fill in your email address by rotating and pressing Optoroller, press power button to access lowercase and more characters press back button for *Next*
- Enter *Cloud password*; fill in your password, press back button for *Next*
- Press Optoroller to Login

7. Press back button to *Exit* the settings, until in *Live view*

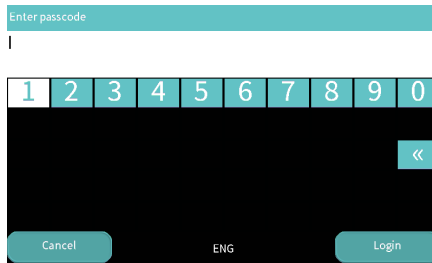
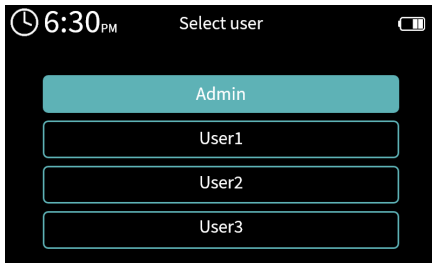
4. Imaging with Optomed Aurora AEYE



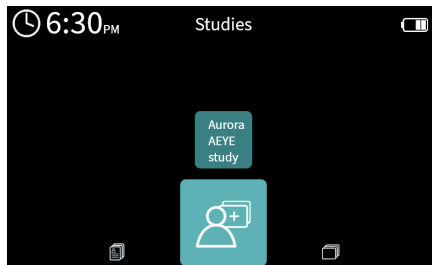
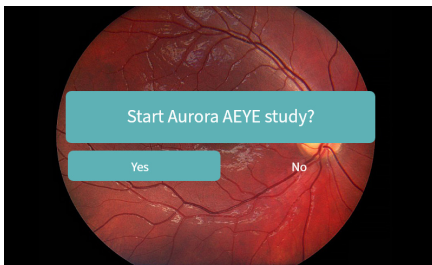
4.1 Overview of Aurora AEYE study

When Optomed Aurora AEYE Camera is powered on, select the user, and enter the passcode followed by a press of back button to log in.

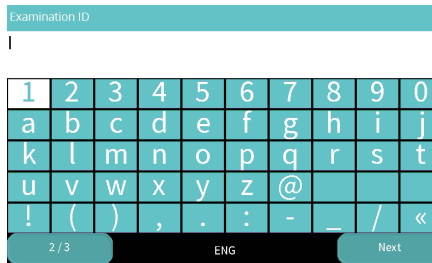
With Aurora AEYE study, the user is guided to take a macula centered image of both eyes and then send images to AEYE-DS analysis.



1. Create a new Aurora AEYE study
 - right after logging in by selecting Yes for "Start Aurora AEYE study?" **or**
 - in the *Studies* menu by selecting the *Aurora AEYE study* item



2. Fill in the Examination ID by rotating and pressing Optoroller, press back button to select *Next*



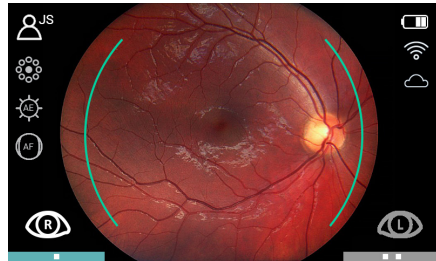
NOTE!

When entering examination information, do not use the same examination identifier for multiple patients. This may result in inaccurate data association. It is not recommended to use a social security number (SSN) as an examination ID.

A notification is shown if some imaging settings are automatically changed according to recommendations for Aurora AEYE study. These include a capture mode (still), a fixation target (macula centered), a focus (auto), an exposure (auto), an IR image (off), additional images (none), and capture settings in image (off).

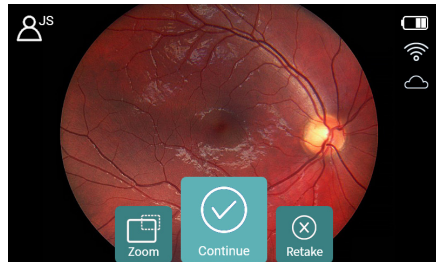
3. The camera goes to *Live view* for image capture with two-image sequence, see the next chapter for detailed information of image capture

- Brightness and/or focus can be changed to manual mode while in *Live view* by rotating or pressing Optoroller and choosing values in their respective settings menu



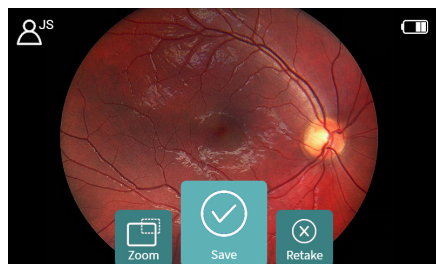
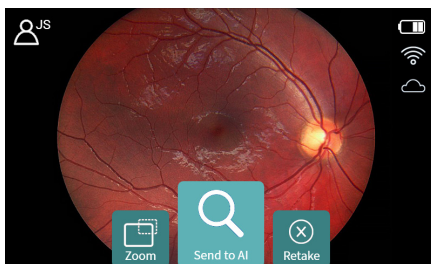
4. Image is captured first from the right eye. After each image, user can

- *zoom* for better investigation of the image
- *continue* the study to take an image from the left eye, **or**
- *retake* the image in case image quality is insufficient



5. When images of both eyes are taken, study can be sent to AEYE-DS analysis by selecting *Send to AI*

- Images are saved automatically to Archive menu in camera
- If Cloud connection is not available and the images cannot be sent to AEYE-DS Service, they can be analyzed later from Archive (*Save* option on image preview screen)



6. Camera shows the AI analysis result which is also sent to Optomed Aurora AEYE Portal
 - It is possible to get the result in addition by email by enabling the option in Optomed Aurora AEYE Portal



Negative for more than mild diabetic retinopathy: retest in 12 months

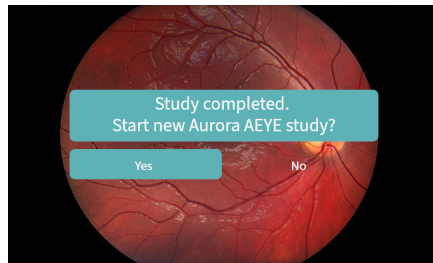


More than mild diabetic retinopathy is detected: refer to an eyecare professional



Failed analysis with a red frame drawn around the poor quality image(s). Retake(s) needed.

7. After viewing the result select *Close*
 - Camera prompts a notification “Study completed. Start new Aurora AEYE study?” By choosing *Yes*, camera opens Examination ID view. By choosing *No*, camera enters Live view.
8. Log out when the camera is no longer in use in *Settings > User settings > Logout*



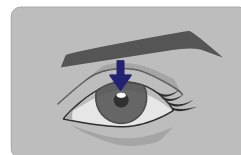
4.2 Image capture during Aurora AEYE study with Retinal Module

When imaging with Optomed Aurora AEYE, the examination room should be dim. It is recommended that both the patient and the examiner are seated during the examination. It is also possible to perform the examination when the patient is lying down.

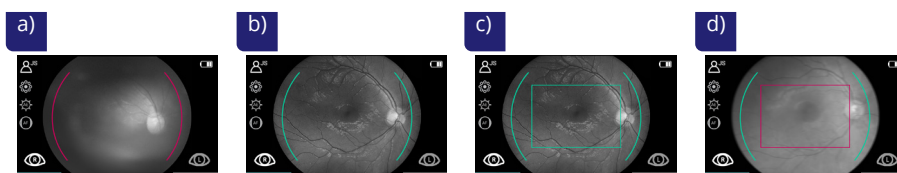
Ask the patient to focus on the red target light (fixation target) and to cover the eye not being imaged but keep both eyes open. Approach the pupil and stabilize the camera by supporting the front part of the camera on your thumb and place your fingers on the patient's forehead. Press the eye cup firmly around the



examined eye. Aim at the grey, oval shaped reflection on top of the pupil. Make micro adjustments with your front supporting hand to fine tune the aiming. The pupil is approached and kept centered until the grey reflection of fundus fills the screen. The right imaging distance is about 2 cm (0.8 inch) from the objective lens to the surface of the eye.



Aim help circle is implemented in the camera to help users approach and align the camera so that the full view of the retina will be seen on the display and a successful image can be captured. When the retina is not fully in view, the circle is red. Once the aim is good and retina fully appears on screen, the circle turns green, and camera is ready for focusing. Focusing is ready when a green rectangle appears on screen. If the rectangle is red the focusing failed and the camera starts focusing again. See more information about the right distance from section 4.3.4 After imaging and Image Quality Analysis (IQA).



a) Aim help is red, retina is not fully in view. b) Aim help circle turns green when retina is in full view and focusing starts. c) Green rectangle indicates that focusing is ready, thus shutter button can be pressed. d) Red rectangle indicates that focusing has failed. Focusing starts again.

- **Autofocus:** Automatic focusing begins when the camera detects retina in full view and the aim help circle turns green on the camera screen. After successful focusing, green rectangle appears in middle of display. Image is captured when the dual action shutter button is pressed all the way down, or halfway if half press capture is enabled in settings. User can also force the autofocus by pressing the shutter button halfway down during the aiming and then pressing the shutter button all the way down to capture the image. An alternative way to capture an autofocused image is to keep the dual action shutter button pressed all the way down when the camera first focuses and then captures an image.
- **Manual focus:** Focus can be changed to manual mode while in *Live view* by rotating or pressing Optoroller. Select the focus item from the Quick menu and choose manual focus. A diopter scale is shown on the screen and focus can be adjusted between -20 and $+20$ diopters. Accept the selection by pressing Optoroller. Capture a still image by pressing the dual action shutter button all the way down, or halfway if half press capture is enabled in settings.
- **Brightness** can be changed to manual mode while in *Live view* by rotating or pressing Optoroller and choosing proper value for it in case image quality is not sufficient. If image is underexposed and dark, increase brightness level. If overexposed and washed out, reduce

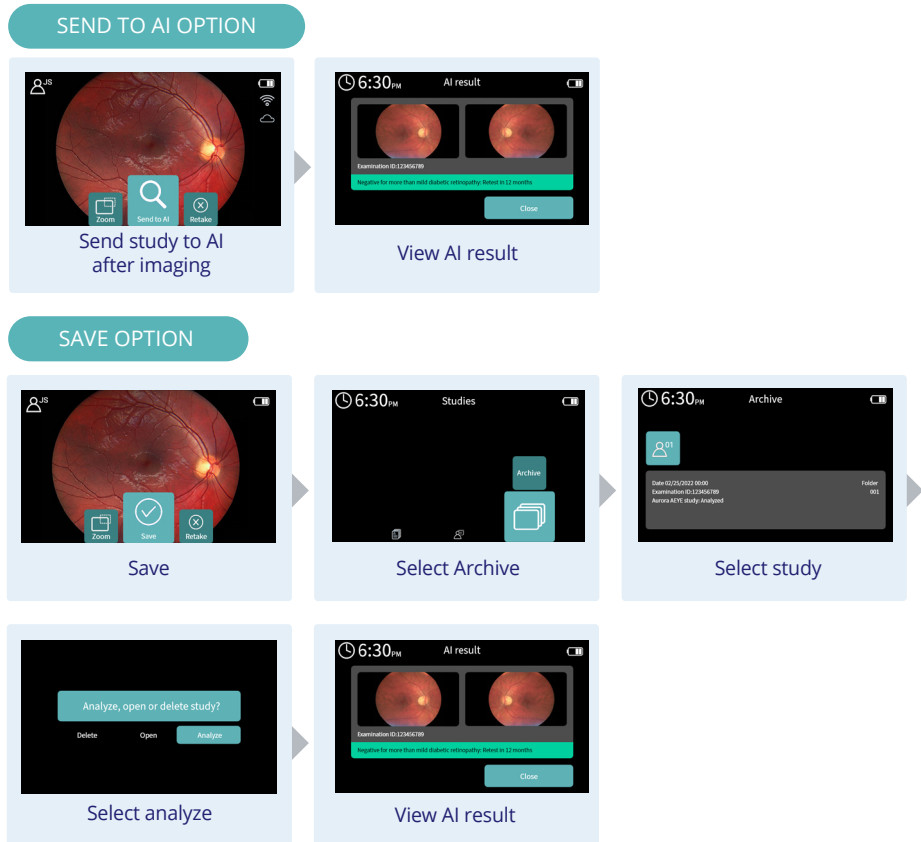
brightness level. See section 4.3.1 for more information on brightness setting.
After each image capture, *Instant review* opens. You may

- check the image quality
- *zoom* the image; press Optoroller and rotate it to view different areas. Press Optoroller to Exit.
- *retake* the image; all images are saved to Archive despite of retakes **or**
- *continue* the study to capture the next image of the sequence

User can exit the Aurora AEYE study by pressing back button for few seconds and selecting *Leave*. All images captured in the study will be saved to Archive. Later user may use AEYE-DS analysis service from Archive if a good quality image of both eyes is available for the AEYE-DS.

4.2.1. Image analysis

User can send images for AEYE-DS analysis either right after completing the Aurora AEYE study in *Instant review* (*Send to AI* option) or later from *Archive* (if no current cloud connection) after the study (*Save* option).



After the analysis of the study, the camera display shows the result for more than mild diabetic retinopathy.



Result in green indicates negative for more than mild diabetic retinopathy: retest in 12 months



Result in red indicates that more than mild diabetic retinopathy is detected: refer to an eye care professional



If study cannot be analyzed for some reason the result is grey. If analysis failed due to insufficient image quality, the red frame is drawn around the poor image(s). Possible reasons for poor image quality include image artifacts such as reflections, blurriness, inappropriate brightness, or eyelids and eyelashes blocking the view.

Retake option allows user to capture the failed image again. Image quality analysis helps to evaluate the quality of the image in case it is enabled. See more information from section 4.3.4 After imaging and Image Quality Analysis (IQA). Insufficient quality image cannot be used for screening purposes and comes back as ungradable, or it may result in false positive or false negative result in very rare cases.

If error occurs during AI analysis process, user will get a notification "AI analysis failed. Images are then saved in Archive. You can try sending the images again from Archive for AI analysis." If the study is closed before finishing the two-image sequence, the image(s) are saved to Archive but they cannot be sent to AI analysis. The study must be repeated for the patient.

When study is ready and user selects *Close* by pressing Optoroller, user is asked if they want to start new Aurora AEYE study. If *Yes*, new Aurora AEYE study is created for a new patient; if *No*, camera goes back to *Live view* and creates an anonymous study. Images captured in Live view are saved to the active anonymous study.

User can view all AI results from Optomed Aurora AEYE Portal and Archive after AI analysis has been done.

4.2.2. Image saving and transfer

Captured images are saved to the memory card. When WLAN is enabled and Cloud login performed, Optomed Aurora AEYE Camera transfers captured images to AEYE-DS Service (*Send to AI*), and from there the AI result with images are sent to Optomed Aurora AEYE Portal. Images can be downloaded to PC from Optomed Aurora AEYE Portal.

Data transfer via USB is not used when Aurora AEYE study is chosen.

It is recommended that image data storage in camera is erased daily after the images have been transferred.

When the memory card or image counter is almost full, Optomed Aurora AEYE Camera will display a message with request to erase the study memory. First copy the images to a safe location and then select *Erase study memory* from the *Camera settings* to erase images and videos taken by all users from the camera memory card.



NOTE!

Deleted studies on the device cannot be recovered.

4.3 Other study

Other study is chosen when AEYE-DS Service is not used. For instance, if imaging other than two-image sequence is needed, a video is recorded, or an image of the surface of the eye is captured.

Some settings need to be changed for Other study before starting:

- Software installation
 - install Optomed Aurora AEYE Client software to PC from USB Flash Drive
- Connections settings within camera:
 - Client connection: turn on (Cloud turns off automatically)

- Settings for data transfer:
 - via wireless: turn WLAN on and connect to network or create Access Point **or**
 - via USB: turn Encryption off (**Note! this deletes all studies including images and videos from the camera**) and connect the USB cable from Charging Station to the PC

Optomed Aurora AEYE Camera is used with interchangeable optics modules

- Retinal Module; to capture fundus images and video
- Anterior Module; to capture images and video of the surface of the eye and surrounding areas

Optomed Aurora AEYE Camera has two capture modes in optics-specific settings menu, Settings > Optics > Capture Mode

- Still imaging
- Video recording
 - when recording video with Retinal Module, the patient's pupils need to be dilated

4.3.1. Other study menu

Patient management and creation can be performed from the Other study menu. Other Study allows the user to take images not following the two image sequence as used in Aurora AEYE study.

Select the *Other study* item by rotating and pressing Optoroller. Either *New anonymous study* or *New patient study* (with Examination ID) can be selected.

An *anonymous study* creates a folder with an automatic ID for the study. The folder nor the images contain any information about the patient.

In *New patient study* the examination ID and name (optional) can be entered to provide better identification. Write the examination ID and name (optional) by rotating Optoroller left or right and pressing it to select characters. To erase a character, select <<. Press power button to access more characters. Select *Next* with back button to confirm the entries.

A study can also be deleted from Other study menu.



After choosing the patient type, the camera goes directly to *Live view* for image capture/video recording. Imaging settings can be changed at this point if default settings are not suitable for a patient.

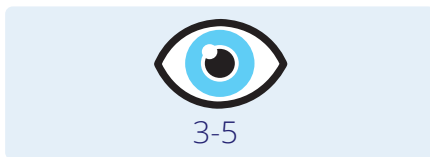
4.3.2. Imaging settings for Other study

Change **focus mode** to autofocus or manual focus from the Quick menu. In autofocus mode, the camera finds correct focus automatically. When focus mode is set to manual, a diopter scale is shown on the screen and focus can be adjusted to the nearest whole number.

- For *Retinal Module*, automatic focus mode is recommended. Manual focus is adjusted according to the patient's refractive error. When the patient has hyperopia, set focus to be positive by rotating Optoroller to right, and when the patient has myopia, set focus to be negative by rotating Optoroller to left.
- For *Anterior Module*, automatic focus mode is recommended..

Imaging **brightness** can be selected from the Quick menu. In auto exposure mode the camera calculates the optimal brightness value. Imaging brightness can be adjusted in manual mode from 0 to 10.

- When imaging with *Retinal Module*, the suitable brightness setting depends on the pigmentation of the patient's eye and age of the patient. For adult patients with blue or green eyes, the right setting is approximately from 3 to 5 and for patients with brown eyes from 6 to 8. If images are too bright, it is possible to reduce brightness below 3. Respectively, brightness can be increased up to 10 if images are too dark.
- When imaging with *Anterior Module*, first select the imaging light to be white or blue and then set the brightness. The default value is 5, which is suitable for most imaging situations.



Retinal Module has nine internal **fixation targets** for the patient to focus on during imaging. The middle fixation target is automatically on, and it provides a macula centered image. Change the fixation target from the Quick menu.

Anterior module has **four focus windows** for user to guide camera on which area of subject to

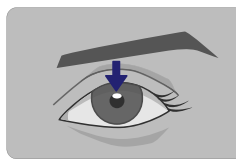
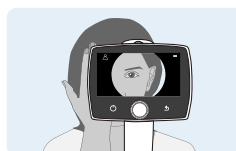
focus on during autofocusing. The right focus window is selected by default. To change the focus window, select the focus window item, then rotate Optoroller left or right to choose a suitable area and press Optoroller to set the focus window area.

4.3.3. Retinal Module

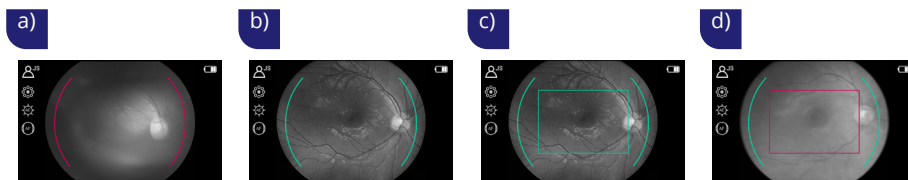
When imaging with Retinal Module, the examination room should be dim. It is recommended that both the patient and the examiner are seated during the examination. It is also possible to perform the examination when the patient is lying down.



Ask the patient to keep the eye aligned with the target light (fixation target) and to cover the other eye but keep the covered eye open. Approach the pupil and stabilize the camera by supporting the front part of the camera on your thumb and place your fingers on the patient's forehead. Press the eye cup firmly around the examined eye. Aim at the grey, oval shaped reflection on top of the pupil. Make micro adjustments with your supporting hand to fine tune the aiming. The pupil is approached until the grey reflection of fundus fills the screen. The right imaging distance is about 2 cm (0.8 inch) from the objective lens to the surface of the eye.



Aim help circle is implemented in the camera to help users approach with the camera and align the camera so that the full view of the retina will be seen on the display and a successful image can be captured. When the retina is not fully in view, the circle is red. Once the aim is good and retina fully appears on screen, the circle turns green, and camera is ready for focusing. Focusing is ready when a green rectangular appears on screen. If the rectangular is red the focusing failed and the camera starts focusing again. See more information about the right distance from section 4.3.4 After imaging and Image Quality Analysis (IQA).



a) Aim help is red, retina is not fully in view. b) Aim help circle turns green when retina is in full view and focusing starts. c) Green rectangle indicates that focusing is ready thus shutter button can be pressed. d) Red rectangle indicates that focusing has failed. Focusing starts again.

Capturing still images:

- **Autofocus:** Automatic focusing begins when the camera detects retina in full view and the aim help circle turns green on the camera screen. After successful focusing, a green rectangle appears in the display. Image is captured when the dual action shutter button is pressed all the way down, or halfway if half press capture is enabled in settings. User can also force the autofocus by pressing the shutter button halfway down during the aiming and then pressing the shutter button all the way down to capture the image. An alternative way to capture an autofocused image is to keep the dual action shutter button pressed all the way down when the camera first focuses and then captures an image.
- **Manual focus:** Change focus mode by selecting the focus item by pressing Oporoller and choose manual focus. A diopter scale is shown on the screen and focus can be adjusted between -20 and +20 diopters. Accept the selection by pressing Oporoller. Capture a still image by pressing the dual action shutter button all the way down, or halfway if half press capture is enabled in settings.

Recording videos:

- **Autofocus:** Automatic focusing starts when the dual action shutter button is pressed halfway down. After successful focusing, a video is recorded when the dual action shutter button is pressed all the way down. When the dual action shutter button is released, the recording ends. An alternative way to record an autofocused video is to keep the dual action shutter button pressed all the way down when the camera first focuses and then begins a video recording. When the dual action shutter button is released, the recording ends.
- **Manual focus:** To record a video keep the dual action shutter button pressed all the way down. When the dual action shutter button is released, the recording ends.

4.3.4. Anterior Module

It is recommended that both the patient and the examiner are seated during imaging with Anterior Module. Place the eye cup of Anterior Module around the patient's eye. Stabilize the camera by supporting the optics module on your thumb and place your fingers on the patient's forehead. Aim the image so that reflection of imaging light on eye is outside of the focus window shown on the display. Ask patient to look in different directions so that different areas can be imaged.

Capturing still images:

- **Autofocus:** Automatic focusing begins when the dual action shutter button is pressed halfway down. After successful focusing, an image is captured when the dual action shutter

button is pressed all the way down. Alternative way to capture an autofocused image is to keep the dual action shutter button pressed all the way down when the camera first focuses and then captures an image.

- **Manual focus:** Capture a still image by pressing the dual action shutter button all the way down.

Recording videos:

- **Autofocus:** Automatic focusing starts when the dual action shutter button is pressed halfway down. After successful focusing, a video is recorded when the dual action shutter button is pressed all the way down. When the dual action shutter button is released, the recording ends. An alternative way to record an autofocused video is to keep the dual action shutter button pressed all the way down when camera first focuses and then begins a video recording. When the dual action shutter button is released, the recording ends.
- **Manual focus:** To record a video, keep the dual action shutter button pressed all the way down. When the dual action shutter button is released, the recording ends.

4.3.5. After imaging

After capturing a still image, *Instant preview* with image specific options is shown on the camera display. It is possible to zoom the captured image, select a side of imaged eye (saves the image), and delete the captured image. The image is shown slightly zoomed in the preview. To view the full image without image specific options, press Back button.



When the image is zoomed by pressing Oporoller, first the center of image is displayed as zoomed. To view the periphery of the image as zoomed, rotate Oporoller left or right. Note that the zoomed areas overlap.

It is possible to select the side of the imaged eye in *Instant preview* by choosing either *Right (OD)* or *Left (OS)* by using Oporoller. This action saves the image to Archive. In addition, the captured image can be deleted in *Instant preview*. Note that if the image is deleted, it is not transferred over WLAN or saved to Archive. To exit from *Instant preview* without selecting the side of the imaged eye, select *Exit preview*. The image is then saved to the Archive and transferred over WLAN.

If the *image quality analysis* is enabled, the results are shown in the top right corner of the image. Occasionally artifacts may occur in images. If the imaging distance is not optimal the light may

reflect either from the cornea or the ocular lens and cause unwanted reflection in the image. Failed focusing may result in blurry images. Stains and dust on the objective lens may also cause artifacts. In addition, eyelids, eyelashes, and iris may partly block the retinal view and make the imaging more challenging.

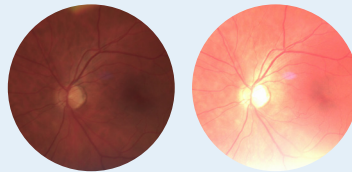
Image Quality Analysis (IQA)

The image quality analysis assists to evaluate the image quality of the captured image. The image quality analysis is off by default.

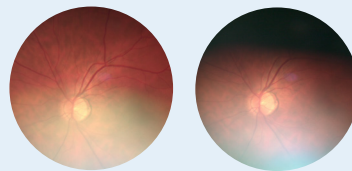
After an image is taken, brightness, uniformity, and sharpness are analyzed to assist the evaluation of the quality of the captured image. The results are shown with the symbols and with three different colors presented below.

 Brightness	 Good
 Uniformity	 Average
 Sharpness	 Poor

Brightness: If the image appears too bright or too dark the brightness level must be adjusted. Adjust the brightness level to brighten or darken the image.



Uniformity: If there is a reflection in the upper part of the image, the imaging distance is too short, and if the reflection is in the lower part of the image, the imaging distance is too long. Occasionally the lower reflection appears even though the aim help and the rectangular are green, in which case you need to move closer. Poor or average uniformity can be caused also by shadowing due to non-optimal aiming. Central reflection is caused by internal reflection of the light source of the objective lens. Normally it is not seen but if there are stains or dust on the objective lens the reflection may be stronger.



Instructions for cleaning can be found in chapter 6.3.

Sharpness: If the image is out of focus, check the patient's refractive error and adjust the manual focus accordingly or use autofocus. Sharpness issue can also be caused by instability during image capture, for instance the camera shakes and affects motion blur. User can choose "half press capture" to avoid it.



4.3.6. Image saving and transfer

For the data transfer Cloud connection needs to be turned off and Client connection on for Other study:

- via wireless: turn WLAN on
- via USB: turn Encryption off (**Note! this deletes all studies including images and videos from the camera**) and connect the USB cable from Charging Station to the PC

Wireless transfer

Captured images and recorded videos are saved to the memory card. When WLAN and Optomed Aurora AEYE Client PC software are used, Optomed Aurora AEYE Camera transfers captured images and recorded videos to the PC automatically after imaging. Please note that wireless transfer is changed to USB transfer if the camera is placed on Charging Station during wireless transfer and encryption is off, otherwise it continues the wireless transfer. More information about Optomed Aurora AEYE Client PC software can be found in Appendix A.



NOTE!

If images are corrupted or not transferred to the PC, the original images are saved in the memory card. Please try again to transfer images to the PC via USB.

USB data transfer


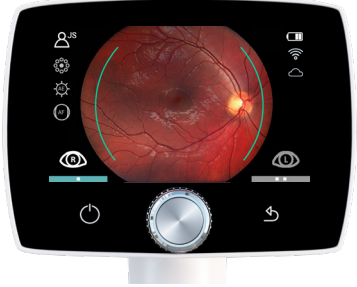









When using USB data transfer data encryption must be turned off before image capture since it deletes all studies including images and videos from the camera. Optomed Aurora AEYE Client PC software needs to be installed on the PC. Images and videos can be transferred to PC from the memory card when the camera is placed on Charging Station, and the USB cable is connected from Charging Station to PC. Optomed Aurora AEYE Camera displays a *Connected* message when device is connected to a PC via USB. Writing to the memory card from PC is disabled by default.

When the memory card or image counter is full, Optomed Aurora AEYE Camera will display a message with request to erase the study memory. First copy the images to a safe location and then select *Erase study memory* from the *Camera settings* to erase images and videos taken by all users from the camera memory card.

5. Features

5.1 Live view

When the camera is on *Live view*, it is ready to take images to the active study folder or settings can be changed. The display has the following icons:

	Battery state	
	Wireless connection	
	Cloud for AEYE-DS/ Portal connection	
	Client connection	
	Active study folder number (<i>in Aurora AEYE study or anonymous Other study</i>) or patient initials (<i>in Other study</i>)	
	Fixation target; filled dot indicates the fixation target for current imaging	
	Brightness; AE for automatic exposure or a number of manually chosen value	
	Focus; AF for automatic focusing or a chosen diopter value for the imaging eye	
	Image of right eye to be captured, active in the picture	
	Image of left eye to be captured	

5.2 Quick menu

Quick menu appears when Optoroller is rotated or pressed while in *Live view*. To move between menu items, rotate Optoroller to the left or right. Press Optoroller to select the item. Exit the menu level by pressing the back button. *Fixation target*, *Brightness*, *Focus*, *Studies*, and *Settings* are found in Quick menu.



FIXATION TARGET

Retinal Module has nine internal fixation targets for the patient to fixate during imaging. The middle fixation target is on by default, and it provides a macula centered image. To change the fixation target, select the target LEDs item, then rotate Optoroller left or right to choose suitable LED and press Optoroller to set the fixation target.



Optic disc centric image (right eye)



Macula centric image (both eyes)



Optic disc centric image (left eye)



BRIGHTNESS

In auto exposure mode, Optomed Aurora AEYE Camera calculates the optimal image brightness (exposure) value automatically for imaging. Automatic brightness is on by default. The brightness can be adjusted in manual mode from 0 to 10, and the default value is 5. It is also possible to reduce the brightness setting below 1, to 0.8, 0.6, 0.4 and 0.2, or set brightness to zero, which results to disabling the white LED illumination for image capture. To adjust brightness, select brightness item, choose manual mode and suitable value by rotating Optoroller and press Optoroller to confirm the settings.

For Anterior Module, it is possible to change the imaging LED between white and blue. When the desired LED is selected, the imaging brightness can be adjusted manually from 0 to 10 in similarly as described above.



FOCUS

In autofocus mode, the camera finds correct focus automatically. Autofocus range is from -15 to +10 diopters. Automatic focus is on by default. Change focus mode by selecting the focus item by pressing Optoroller and choose manual focus. A diopter scale is shown on the screen and focus can be adjusted between -20 and +20 diopters. Accept the selection by pressing Optoroller.



STUDIES

In Studies menu it is possible to create a new study for images (*Other study*), select *Aurora AEYE study* for two-image sequence, or browse studies from *Archive*.

Other study

A new patient study is recommended for each patient. Select the *Other study* item by pressing Optoroller. Either *New anonymous study* or *New patient study* can be selected.

An anonymous study creates a new folder with a sequential number. The folder will have images inside which receive the generated ID number without the patient's name.

In *New patient study* the examination ID and name (optional) are entered to provide better identification.

Write the examination ID and name (optional) by rotating Optoroller left or right and pressing it to select characters. To erase a character press << with Optoroller. Press the power button to access a keyboard with lowercase and more characters. The keyboard language (English or Spanish) can be changed by pressing the power button for several seconds and then rotating Optoroller left or right.

Confirm the language by pressing Optoroller. Press Next with Back button after filling the information. The study is added to the list. The newly added study is active, and images are captured for it.

Aurora AEYE study

New Aurora AEYE study can be started either from Startup query or from Studies menu. With Aurora AEYE study, the user is guided to take one macula centered image of both eyes and then sent images to AEYE-DS analysis.

To create Aurora AEYE study, an examination ID is entered.



NOTE!

When manually entering patient or study information, do not use the same examination identifier for multiple patients. This may result in inaccurate data association. Social security number (SSN) is not recommended to be used as an examination ID.

A notification is shown if some imaging settings, such as capture mode, fixation target, focus, exposure, IR image, additional images, and capture settings in image, are automatically changed as recommended for Aurora AEYE study.

After entering the examination ID, the camera goes to *Live view*. Brightness and focus can be changed while in *Live view* by rotating or pressing Optoroller.

Image is first taken from the right eye. After each image, user can zoom the image, continue the study, or retake the image. If image quality is insufficient, it is recommended to retake the image. When image from right eye is taken, user is guided to take an image from the left eye. When both images are taken, study can be sent to AEYE-DS analysis by selecting *Send to AI*. When AI analysis is ready, user can view result in camera display and in Optomed Aurora AEYE Portal. Result can be received in addition by email if enabling it in Portal.

When study is ready and user selects *Close* by pressing Optoroller, user is asked if they want to start new Aurora AEYE study. If *Yes*, Aurora AEYE study starts from beginning with new patient, if *No*, camera goes back to *Live view*.



ARCHIVE

Select the *Archive* item by pressing Optoroller to browse studies and captured images. Study folder shows date of the image capture (mm/dd/yyyy), examination ID, study type (Aurora AEYE study or Other study) with

analysis information (analyzed/not analyzed), and folder name. Select the study whose images you wish to preview by pressing Optoroller. Choose whether you like to delete the study, open/select it, view AI results, or analyze it (only Aurora AEYE study) if not already done. Then select the desired image from the selected study by rotating and pressing the Optoroller. When the image is shown, the image can be zoomed by pressing Optoroller. Choose different zoomed areas by rotating the Optoroller. Zoom out by pressing the Optoroller. It is also possible to delete studies or single image(s) of a study when opening the study and the image respectively. It is not possible to delete single images of AEYE study even if it is not yet analyzed.

Aurora AEYE study can be sent to AEYE-DS analysis by selecting *Send to AI*. When AI analysis is ready, user can view result in camera display and in Optomed Aurora AEYE Portal. If error occurs in AI analysis process, user gets notification "AI analysis failed. Try AI analysis again after few minutes."



SETTINGS

To change user, optics, or camera specific settings, select the Settings item by pressing Optoroller. User, optics, and camera specific settings are described in the following chapters.

5.3 Settings

5.3.1. User settings

User settings for admin user

- User list
- Logout
- Change passcode
- Admin
 - User access: Add user and Edit user
 - Passcode On/Off
 - Login On/Off
 - Logout timeout;
5, 10, 15, or 30 minutes
 - Encryption On/Off

User settings for basic user

- User list
- Logout
- Change passcode

5.3.2. Optics settings for Retinal Module



USER LIST

User list shows all the users that have been added by admin user. The maximum number of users is 20. User can login by selecting him/herself from the user list. If passcode is enabled, a passcode is created when first time selecting the user. The passcode requires 4 digits. Device will lock the user for 5 minutes if the passcode is entered wrong 5 times in a row. Device will lock the user permanently if wrong passcode is entered 15 times in a row. Admin user may reset the passcode to enable new login.



LOGOUT

User can log out from the camera by selecting *Logout* with Optoroller.



CHANGE PASSCODE

User can change their personal camera passcode by selecting *Change passcode* with Optoroller and entering the old passcode and new passcode. Camera then shows a notification informing that the passcode has been changed. The passcode requires 4 digits.



ADMIN

Icon is shown for admin users only. Admin user can add users to and delete users from the user list by selecting **User access** and either *Add user* or *Edit user*. Users can be added manually or by loading a user list from PC via USB connection by copying a userlist.txt file to camera (Aurora AEYE drive) and lifting the camera from Charging Station (USB write protection must be set off). Admin user can reset user passcode by selecting *User access*, *Edit user*, and *Reset passcode*. A user can be deleted from *Edit user* menu. Admin can also enable/disable **passcode**, **login**, and **encryption**, as well as set the timer in which the user is automatically **logged out** from the camera if the camera is not being used. Admin user is also able to reset the user settings by pressing back button for 10 seconds when in user list.

5.3.2.1. Advanced Optics settings



QUICK IMAGE

Quick imaging can be enabled or disabled. When quick imaging is on, the camera returns to *Live view* immediately after image capturing, and when it is off, *Instant preview* with different image specific options is shown after imaging. In *Instant preview*, it is possible to zoom, mark the imaged eye side (left/right), and save/delete the image. Quick imaging is off by default. Quick imaging can be used with Other study, not with Aurora AEYE study.



HALF-PRESS CAPTURE

Half-press capture can be enabled or disabled. Half-press capture is off by default. When half-press capture is on, the functionality of dual action shutter button is changed to:

Autofocus: image is captured after focusing when the dual action shutter button is kept pressed halfway down

Manual focus: image is captured when the dual action shutter button is pressed halfway down



CAPTURE MODE

There are two capture modes in Optomed Aurora AEYE: still imaging and video recording. To choose capture mode, press Oporoller. Still imaging is on by default.



ADDITIONAL IMAGE

In addition to default imaging mode, there is an alternative additional imaging mode in Optomed Aurora AEYE: *Red free*. In *Red free* setting the camera saves a red reduced image in addition to the original image. To save only the original image, choose *None*.



To see more optics specific settings, press Oporoller. The advanced optics settings include Capture settings in image, IR contrast stretching, IR image, Image Quality Analysis, and Centering options.



CAPTURE SETTINGS IN IMAGE

Writing capture settings to the image can be enabled or disabled. If it is on, the brightness level and diopter value are written to the bottom right corner of the image. The writing capture settings in image is off by default.



IR CONTRAST STRETCHING

IR contrast stretching can be enabled or disabled. If IR contrast stretching is on, the infrared live view brightness and contrast is adjusted automatically according to the image content. IR contrast stretching is off by default.



IR IMAGE

In addition to color image, there is also the possibility to capture an IR image. Use Oporoller to choose whether to aim and to capture the image with IR light. Only image captured with IR light will be saved.



IMAGE QUALITY ANALYSIS (IQA)

Occasionally artifacts may occur in images. The Image Quality Analysis (IQA) assists to evaluate the image quality of the captured image. The analysis level can be set to be *Basic*, *Strict*, or *Very strict* by using Oporoller. Images with lesser quality are accepted more easily as good with the basic level than with strict or with very strict levels. The Image Quality Analysis is off by default.

After an image is taken, brightness, uniformity, and sharpness are analyzed to assist the evaluation of the quality of the captured image. The results are shown with the symbols and with three different colors presented below.



Brightness



Uniformity



Sharpness



Good

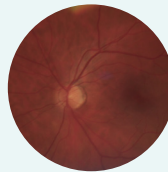


Average

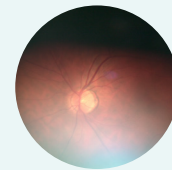
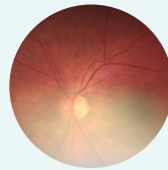


Poor

Brightness: If the image appears too bright or too dark the brightness level must be adjusted. Adjust the brightness level to brighten or darken the image.



Uniformity: If there is a reflection in the upper part of the image, the imaging distance is too short, and if the reflection is in the lower part of the image, the imaging distance is too long.



Occasionally the lower reflection appears even though the aim help and the rectangular are green, in which case you need to move closer. Poor or average uniformity can be caused also by shadowing due to non-optimal aiming. Central reflection is caused by internal reflection of the light source of the objective lens. Normally it is not seen but if there are stains or dust on the objective lens the reflection may be stronger. Instructions for cleaning can be found in chapter 6.3.

Sharpness: If the image is out of focus, check the patient's refractive error and adjust the manual focus accordingly or use autofocus. Sharpness issue can also be caused by instability during image capture, for instance the camera shakes and affects motion blur. User can choose "half press capture" to avoid it.



CENTERING

Centering allows adjustment of the imaging area to correspond with the view area. First select vertical or horizontal adjusting by using Optoroller. Move the image to the middle of the screen by rotating Optoroller.



NOTE!

There is no need to change the centering in normal use.

5.3.3. Optics settings for Anterior Module



QUICK IMAGING

Quick imaging can be enabled or disabled. When quick imaging is on, the camera returns to *Live view* right after image capturing and when it is off, *Instant preview* with different image specific options is shown after imaging. In *Instant preview*, it is possible to zoom, mark the imaged eye side (left/right), and save/delete the image. Quick imaging is off by default. Quick imaging is only for Other study.



HALF-PRESS CAPTURE

Half-press capture can be enabled or disabled. Half-press capture is off by default. When half-press capture is on, the functionality of the dual action shutter button is changed to:

Manual focus: image is captured when the dual action shutter button is pressed halfway down

Autofocus: image is captured after focusing when the dual action shutter button is kept pressed halfway down



CAPTURE MODE

There are two capture modes in Optomed Aurora AEYE: still imaging and video recording. To choose capture mode, use Oporoller.

5.3.4. Camera settings



RESET

To restore settings to factory defaults, choose the reset item by pressing Oporoller. The camera prompts a question "*Restore default settings?*" for confirmation. The camera is restarted to reset. Patient studies, users, and Date & Time settings remain in camera memory. To reset users, please refer to chapter 5.3.1 User settings and Admin.



DATE & TIME

To change the date and time settings, press Oporoller. Select *Daylight saving time*, if applicable, and *Time zone*. Optomed Aurora AEYE uses nine time zones: Atlantic Standard Time (AST), Eastern Standard Time (EST), Central Standard Time (CST), Mountain Standard Time (MST), Pacific Standard Time (PST), Alaskan Standard Time (AKST), Hawaii-Aleutian Standard Time (HST), Samoa standard time (SST), and Chamorro Standard Time (CHST). Press Set time manually to set the month, day, year, hours, minutes, and AM/PM by rotating Oporoller left or right and press it to select the next field. Time is shown in 12-hour format.

An accurate time can also be received from the Internet with *Automatic time sync*. First connect the device to network in WLAN menu (more information in Appendix A). When the connection is achieved, go to Date & Time settings, and set *Daylight saving time* on (if applicable), and the *Time zone*. Then set *Automatic time sync* on and select *Sync now*. If Automatic time sync is on, the device will synchronize the time every time the device is connected to a network.



ERASE STUDY MEMORY

To erase images and videos from the camera's memory card, press Oporoller. All patient studies, both with ID and anonymous studies by all users, will be deleted. Ensure that you have transferred images and videos to a safe location before erasing the study memory.



5.3.4.1. Connections

Optomed Aurora AEYE Camera can be used wirelessly using WLAN which enables wireless data transfer to a PC and Cloud. To change wireless settings press Oporoller. Appendix A provides additional instructions for wireless settings; WLAN, Cloud, Client.



WLAN

Optomed Aurora AEYE Camera can be used wirelessly using WLAN which enables wireless data transfer to a PC and Cloud. In order to change wireless settings, open the Connections menu from camera settings by using Oporoller.

First set WLAN connection on to enable wireless connection. When wireless

connection is on, either network mode or Access Point mode can be used, but not at the same time. The network mode is the only option to connect the camera to AEYE-DS Service in Aurora AEYE study. Wireless data transfer after Other study can be done either with network mode or access point. More information about WLAN can be found in Appendix A.



CLOUD MODE

Optomed Aurora AEYE Camera can be connected to Cloud that provides AEYE-DS-based screening (Cloud login) using certain server address (Cloud settings). Cloud service needs wireless connection to work. More information about Cloud connection can be found in Appendix A.



NETWORK INFORMATION

Network name, IP Address, and MAC Address are shown in Network information menu.



CLIENT

Optomed Aurora AEYE Client PC software enables WLAN connectivity from PC or another client device to Optomed Aurora AEYE Camera. With Client software you can wirelessly connect PC or other device to Camera and define the image destination folder into which images will be transferred. Enable Client mode and choose either network mode or Access Point mode for wireless connection. Use Client mode for Other study only.



ACCESS POINT

Access Point mode is used when there is no wireless network available. In Access Point mode Optomed Aurora AEYE Camera sets up a camera specific access point to which PC can connect. Access Point mode menu item is only visible and usable in Client mode.



5.3.4.2. Advanced camera settings

To see more camera specific settings, press Oporoller. The advanced camera settings include Language, USB write protection, Camera information, and Start query options, which are described below.



SELECT LANGUAGE

There are two language options in Optomed Aurora AEYE: *English* (default) and *Spanish*. To change language, press Optoroller, then rotate left or right to choose the desired language and set the language by pressing Optoroller. The camera needs to be restarted to activate the new language.

The keyboard language is the selected language by default. This can be changed by pressing the power button for several seconds and then rotating Optoroller left or right when the keyboard item is active. Confirm the change by pressing Optoroller.



USB WRITE PROTECTION

USB write protection can be enabled or disabled, by default USB write protection is on. When USB write protection is on, modifying the memory card content by user from attached PC is prevented. Copying files from the memory card to PC is possible. Capturing images and videos is possible even though USB write protection is on.



CAMERA INFORMATION

Check camera information by pressing Optoroller. To browse software version, software build, WLAN software version, HW version, and camera serial number (Device ID), press Optoroller.



START QUERY

Choose the start query; *Aurora AEYE study*, *Study (Other study)*, *None*, or *Erase* (Erase study memory). The camera prompts the start query after powering on the device. When the *Erase* query is chosen, the camera will ask whether all images and videos should be deleted. When the *Study* query is chosen, the camera will ask if a new study from Other study should be created. If *Create AEYE study* is selected, the camera will guide to take macula centered image from patient's right and left eyes. If *None* is selected, the camera will go directly to *Live* view after powering on or when removed from Charging Station. Aurora AEYE study start query is on by default.

6. Other information

6.1 Environmental conditions

The device is intended for indoor use. Do not store or use the device in ambient conditions other than those prescribed.

	USE	STORAGE	TRANSPORTATION
Temperature	+10 °C to +35 °C +50 °F to +95 °F	-20 °C to +35 °C -4 °F to +95 °F	-20 °C to +50 °C -4 °F to +122 °F
Relative humidity	10% to 80%	10% to 85%	10% to 85%
Atmospheric pressure	800 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa



NOTE!

Do not store this instrument in conditions where the temperature may rise above +35 °C (+95 °F) or fall below -20 °C (-4 °F).

Please note that electromagnetic compatibility information and recommended separation distances between portable and mobile RF communications equipment and Optomed Aurora AEYE are given in Chapter 6.8.

Protection against harmful ingress of water or particulate matter is defined as IPX0 (Equipment not protected against the ingress of water).



NOTE!

Avoid using the device in a dusty environment.



NOTE!

Avoid subjecting the device to vibration or shock.

6.2 Error messages

Optomed Aurora AEYE will display error messages to indicate error situations. An error message is always displayed with an explanatory message providing information about possible actions.

ERROR MESSAGE	POSSIBLE ACTION
Optics failure #	Please detach the optics module, place it back, and restart the camera. Error code # identifies the error and it may be needed by Optomed Customer Service.
Light source temperature too high	This indicates that the light source temperature exceeds the safe limits. Please wait until the camera cools down. This may take several minutes.
Image storage not found	This indicates that there is a problem with the memory card. Please contact Optomed Customer Service for more information.
Battery failure	The battery is either not properly in place or has been damaged. Please try reinstalling or replacing the battery and restart.
Optics type not detected	The camera is not able to detect the optics module. Please detach the optics module, place it back, and restart the camera.
Unable to create new study	The patient has already five studies and it is not possible to create a new study. Copy images to a safe location and select Erase study memory from camera settings.
Charging failure	This indicates that Optomed Aurora AEYE Camera is not properly connected to Charging Station. Please reconnect the camera to Charging Station.
Optics communication failure	This indicates that there is a problem with the optics module. Please reattach the optics module.
Autofocus calibration needed	Optomed Aurora AEYE Camera needs to be calibrated. Please hold the camera horizontally and press Optoroller to calibrate.
Memory erasing failed	This indicates that there is a problem with memory erasing. Please retry. If the problem persists, please contact Optomed Customer Service.

System memory not available	This indicates that there is a problem with system memory. Please restart camera.
Image counter full	Optomed Aurora AEYE Camera can store 9,999 images. Once the image counter is full, copy images to safe a location and select Erase study memory from camera settings.
WLAN malfunction. Code:	Error code changes depending on the error at hand. The code will help Optomed Customer Service to solve the problem.
System file recovery failed	Contact Optomed Customer Service
Image is too bright for auto exposure. Try manual brightness #	Image is too bright, and camera suggests taking a new image with recommended manual brightness value.

Other possible events:

- Cloud access for AEYE-DS Service and Optomed Aurora AEYE Portal not available: please check WLAN connection and cloud login information.
- Camera does not connect to USB: please check that the data encryption setting is off.
- Cloud login errors
 - Camera not assigned to user: Admin can create new users
 - Camera not registered: register the camera at <https://auroraeye.optomed.com>
 - Camera not active: Cloud service is not purchased, or starting date is not chosen
 - Login failed: either username or password was incorrect

If the device behaves abnormally, Optomed Aurora AEYE Camera can be forced to shut down by pressing the power and back buttons simultaneously for seven seconds or longer.

The manufacturer of Optomed Aurora AEYE will provide software updates as needed throughout the lifecycle of Optomed Aurora AEYE to continue to guarantee its safety and effectiveness.



NOTE!

If a malfunction cannot be rectified, please contact Optomed Customer Service.

6.3 Cleaning

Optomed Aurora AEYE has been tested to verify that it is compatible with the approved disinfectant agents. Clean and disinfect device parts on a routine basis according to your facility's protocols and standards or local regulations. Optomed Aurora AEYE is a precision optics instrument that should be handled with care. Please note the following cleaning instructions:

- Shut down the device and remove battery before cleaning
- Remove Charging Station from mains before cleaning
- Avoid touching lenses, windows, and system connectors in Optomed Aurora AEYE Camera and Charging Station unless cleaning them

Clean the device parts from visible dirt before disinfection to maximize its effectiveness.

Device parts

- To clean the device parts, use a pre-moistened wipe or soft cloth slightly moistened with a cleaner
- Disinfect with soft cloth moistened with alcohol (60-80% ethanol or isopropyl alcohol) or hydrogen peroxide solution (e.g. 1-3%)
- Avoid touching lenses, windows, and system connectors in the camera and Charging Station

Screen

- Clean the screen using a soft, clean cloth moistened with neutral cleaning agents
- Disinfect the screen with a soft cloth moistened with alcohol (60-80% ethanol or isopropyl alcohol) or hydrogen peroxide solution (e.g. 1-3%)
- Do not use any chemical solvents, acids, or alkaline solutions

Lenses and windows

- First remove loose particles by gently blowing visible particles off with air blower or compressed air or wiping with soft brush
- Clean the lenses with a cleaning cloth. Grease on lens may be removed with a soft cloth moistened with alcohol (60-80% ethanol or isopropyl alcohol) or lens cleaning solution. Possible residue from moist cleaning tissues may be removed with a dry microfiber cloth.

System connectors

- Clean the system connectors with compressed air or with a lint-free cotton swap moistened with 99% isopropyl alcohol. Ensure that the alcohol has completely evaporated before putting the battery back in, connecting the cables, and using the camera and Charging Station.

Eye cup

- Clean and disinfect the eye cup before each use on a new patient
- Use a pre-moistened wipe or soft cloth slightly moistened with a cleaner to gently clean the eye cup. The eye cup may also be cleaned with liquid soap following a thorough rinsing.
- Disinfect the eye cup with a soft cloth moistened with alcohol (60-80% ethanol or isopropyl alcohol) or hydrogen peroxide solution (e.g. 1-3%)
- Rinse the eye cup under running water
- Dry the eye cup (e.g. with clean paper towel) before subsequent use

Do not use unapproved disinfection agents. Use of these agents may cause damage to components.



CAUTION!

Do NOT use aggressive or abrasive cleaning agents or the following chemicals for cleaning:

- Mineral spirits, paint thinner, benzene, gasoline, lamp oil
- Strong / corrosive acids (such as sulphuric acid)
- Strong / corrosive bases (such as sodium hydroxide)
- Bleaching agents
- Nail polish remover

Use of ammonia-based cleaners on the liquid crystal display (LCD) may cause damage to the display.

If a replacement for eye cup or additional disposable eye cups (E-safe Disposable Eye Cups) are needed, please contact Optomed Customer Service. The eye cup should be replaced when:

- Discolored
- Deteriorated
- Shattered, cracked, or disintegrated



NOTE!

If disposable eye cups are in use, they should be discarded after each patient.



NOTE!

Optomed Aurora AEYE is not intended to be sterilized.

**NOTE!**

Ensure that no moisture penetrates the device covers and does not end up in the internal parts during cleaning and disinfection. Use only lightly moistened cleaning cloth.

Optomed Aurora AEYE has been tested to verify these instructions as being capable of preparing Optomed Aurora AEYE for re-use. You must ensure that cleaning and disinfection as actually performed by your personnel, with your equipment and materials, achieves the desired results.

The national disinfecting regulations must be observed in the choice of disinfectants and disinfection procedures. Please note that some cleaning agents and disinfectants may have an adverse effect on plastic and rubber components. Damage caused by such disinfectants is not covered by our warranty. The surfaces of the device have been tested and are guaranteed to resist frequent treatment with alcoholic and hydrogen peroxide disinfectants in the long term.

6.4 Service and repair

The user of the device is allowed to replace the battery and to clean the device, which are instructed in this user manual. There are no other maintenance procedures that can be carried out by the user. All servicing and repairs other than replacing the battery and cleaning the device must be carried out by Optomed or Optomed-authorized service facilities and service personnel. Optomed will make available work instructions to repair those parts of medical electrical equipment that Optomed has designated as repairable by service personnel.

If your device requires a repair service, contact Optomed Customer Service (support.us@optomed.com). All maintenance, service, warranty conditions are described in the leasing agreement.

6.5 Battery

**CAUTION!**

Only use the battery provided by Optomed with this product. Do not use a damaged or leaking battery. Do not disassemble, modify, crush, or destroy the battery pack. Doing so can cause battery fluid leakage, heat generation, burns, fire, and/or explosion.

**CAUTION!**

Charge the battery with Charging Station only. Use of an unrecommended charger may cause battery fluid leakage, overheating of the battery, or may cause the battery to explode.

Optomed Aurora AEYE Camera has a rechargeable Li-ion battery that is charged when the camera is placed on Charging Station, which is connected to the mains. Charging Station can also be used as an external battery charger for the spare battery included in sales case. The battery pack is specially designed and manufactured for this device. Optomed Customer Service provides suitable battery packs. The label on the battery includes one of the following information:

Li-ion Rechargeable Battery 3.63 V / 2600 mAh / 9.438 Wh
50000655, 1ICR19/65, ICR18650-26J, WWYY (WW is week and YY is year of manufacture)
Provided for Optomed Oy by Celltech Oy, Finland

Li-ion Rechargeable Battery 3.65 V / 2750 mAh / 10.038 Wh
50001559, 1INR19/65, 1INR18650-29E
Provided for Optomed Oy by Celltech (Zhongshan) Ltd.

Normal battery service life is expected to be 1–2 years. When the battery is at the end of its service life, the usage time of the device is reduced. It is recommended to remove the battery if device is stored for more than 2 months.

6.6 Disposal



NOTE!

Electrical and electronic devices must be disposed of separately from household waste.

The device contains electronic components. At the end of its lifetime, the device and its integrated batteries should be disposed of in accordance with relevant national regulations.



DISPOSAL OF THE PRODUCT WITHIN THE US

Prepare the device for reuse or separate collection as specified by WEEE and/or according to all federal, state, regional, and/or local laws and regulations for the safe disposal of medical devices and accessories.

For further information on disposal of this product, please contact your Optomed representative. This will guarantee that no hazardous substances enter the environment and that valuable raw materials are recycled.

Where the product or its components are resold, the seller must inform the buyer that the product is to be disposed of in accordance with the currently applicable national regulations.

**NOTE!**

Packaging materials is recommended to be retained for future relocation or repair. If you decide to dispose of the packaging material, submit it to a recognized collection system for recycling.

6.7 Technical description

**CAUTION!**

Only use the USB cable, battery and power supply provided in the sales package. If you need replacement to the USB cable, battery, or power supply, please contact Optomed Customer Service.

**CAUTION!**

The development, production, and maintenance of this device, together with associated risks, are based on an expected device lifetime of five years. Modifications to the product or failure to follow the manufacturer's instructions may substantially reduce the expected service life and significantly increase the risks associated with the use of this device.

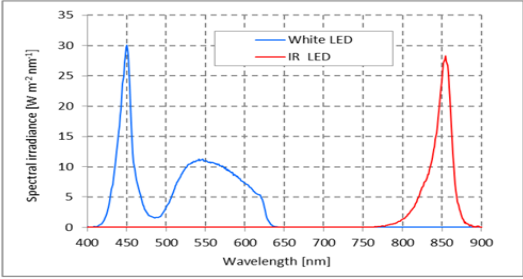
CAMERA

Model:	Optomed Aurora AEYE Camera
Image sensor:	CMOS, 5.0 Megapixels
Magnification:	0.317X
Image memory type:	Internal 16 GB memory
Display:	4", TFT-LCD, 800x480 pixels, 16.7 M colors
Image format:	JPEG (file extension: .jpg)
USB Connectivity:	USB 1.1, compatible with USB 2.0 and USB 3.0

WLAN Connectivity:	802.11 bgn, wpa2 Operating frequency range: 2412 – 2472MHz (Channels 1-13) Modulation: OFDM (802.11 a/g/n), DSSS/CCK (802.11b) Maximum output power: 17.25 dBm Maximum antenna gain: 1.9 dBi
Operating systems:	Microsoft Windows 8.1®, Windows 10®, Windows 11® No driver installation needed.
Dimensions:	122 (w) x 202 (h) x 97 (d) mm
Weight:	473 g
Battery:	
Type 1:	50000655, 3.63V, 2600 mAh Rechargeable Li-ion battery Li-ion cell with integrated safety circuit
Type 2:	50001559, 3.65V, 2750 mAh Rechargeable Li-ion battery Li-ion cell with integrated safety circuit
Usage time:	Approximately 2 h
Device lifetime:	Approximately five years

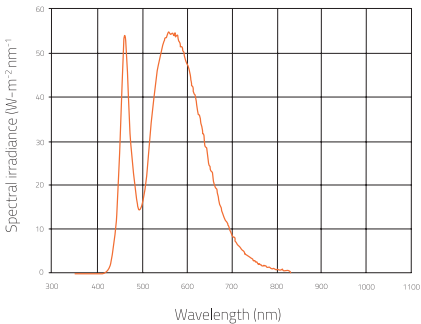
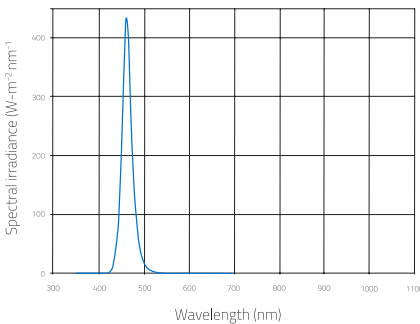
OPTICS FOR RETINAL IMAGING

Model:	Retinal Module
Dimensions:	69 (w) x 74 (h) x 160 (d) mm
Weight:	324 g

<p>Illumination:</p>	<p>Infrared LED for aiming. Visible white LED for imaging. 15 illumination brightness levels: 0, 0.2, 0.4, 0.6, 0.8, 1, 2, 3, 4, 5 (default), 6, 7, 8, 9 and 10. 9 red LEDs for internal fixation targeting.</p>
<p>Maximum luminance:</p>	<p>3.0 cd/cm²</p>
<p>Field of view:</p>	<p>50° (total FOV 50°x40°)</p>
<p>Diopter compensation:</p>	<p>from -20 D to +20 D manual focus from -15 D to +10 D autofocus</p>
<p>Image resolution:</p>	<p>2368 x 1776 pix (total 4.2 Mpix, effective area 3.38 Mpix)</p>
<p>Pixel pitch on fundus:</p>	<p>6.9 μm (for emmetropic eye with 17 mm focal length)</p>
<p>Spectral output at working distance:</p>	<div style="text-align: center;">  <p>The graph plots Spectral Irradiance [W m⁻² nm⁻¹] on the y-axis (0 to 35) against Wavelength [nm] on the x-axis (400 to 900). The White LED curve (blue) shows a primary peak of approximately 30 W m⁻² nm⁻¹ at 450 nm and a secondary peak of approximately 11 W m⁻² nm⁻¹ at 550 nm. The IR LED curve (red) shows a sharp peak of approximately 28 W m⁻² nm⁻¹ at 850 nm.</p> </div> <p>White and Infrared LED when operated in continuous mode</p>

OPTICS FOR ANTERIOR IMAGING

<p>Model:</p>	<p>Anterior Module</p>
<p>Dimensions:</p>	<p>71 (w) x 80 (h) x 78 (d) mm</p>
<p>Weight:</p>	<p>105 g</p>

Illumination: Maximum luminance output level towards eye: Image resolution:	Visible white and cobalt blue LED for imaging, 10 illumination brightness levels 192 cd/cm ² 2560 x 1920 pix
Spectral output at working distance:	
 <p>White LED when operated in continuous mode</p>	 <p>Blue LED when operated in continuous mode</p>

CHARGING STATION

Model:	Charging Station
Dimensions:	107 (w) x 147 (h) x 300 (d) mm
Weight:	683 g
Switching power supply:	
Type 1:	CINCON TRG10R090 Input: 100-240 V, ~0.4 A, 47-63 Hz Output: 9 V, 1.1 A, 10 W
Type2:	XP Power ACM12US09 Input: 100-240 V, 0.5 A, 50-60 Hz Output: 9 V, 1.33 A, 12 W

USB cable	Type: USB-A to USB mini-B Length: 1.8 m
-----------	--

EYE CUPS

Material:	
Eye cup for Retinal Module:	Liquid silicone rubber Reusable, free from latex, PVC, and DEHP
E-Safe Disposable eye cups:	
Base part:	Liquid silicone rubber Reusable, free from latex, PVC, and DEHP
Disposable part:	Thermoplastic polyurethane (TPU) Disposable, free from latex, PVC, and DEHP
Eye cup for Anterior Module:	Liquid silicone rubber Reusable, free from latex, PVC, and DEHP

MEMORY STICK

Memory stick including Optomed Aurora AEYE Client PC Software, and Instructions for use.

CLEANING CLOTH

Cleaning cloth for cleaning lens, windows, and display.

INTELLECTUAL PROPERTY RIGHT INFORMATION

Windows 8.1, Windows 10, and Windows 11 are trademarks of Microsoft Corporation.

Camera software: This software is based in part on the work of the Independent JPEG Group.

This product is protected by patents that are listed at www.optomed.com/IPR. Additional patent applications are pending.

6.8 Electromagnetic compatibility

This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2014. Special precautionary measures apply to this device regarding electromagnetic compatibility (EMC). To avoid electromagnetic disturbances, the device may only be operated and serviced in accordance with the user manual and using the components supplied by Optomed.

If the performance of Optomed Aurora AEYE is lost or degraded due to electromagnetic disturbances, it may cause unexpected or adverse operation of the device. If a malfunction cannot be rectified, please contact Optomed Customer Service.



CAUTION!

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The device should not be operated in the vicinity of high-frequency surgical equipment.



CAUTION!

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



CAUTION!


Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Optomed Aurora AEYE, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Replacement cables may only be purchased at Optomed. The use of accessories, any converters or cables which are not specified in this user manual or have not been purchased as spare parts from Optomed can result in increased emissions or reduced immunity of the device.

MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Optomed Aurora AEYE maintains basic safety and performance when used in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV indirect contact ±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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	±2 kV for AC power supply	Mains 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 differential mode ±2 kV 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 IEC 61000-4-11	0% UT for 0,5 at 8 φ angles; 0% 1 cycle; 70% UT for 25 cycles; 0% for 5 sec	0% UT for 0,5 at 8 φ angles; 0% 1 cycle; 70% UT for 25 cycles; 0% for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Optomed Aurora AEYE requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a 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.

<p>Conducted RF IEC 61000-4-6</p>	<p>3 Vrms 150 kHz to 80 MHz & 6 Vrms ISM frequency</p>	<p>3 Vrms 150 kHz to 80 MHz & 6 Vrms ISM frequency</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of Optomed Aurora AEYE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 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 meters (m).</p>
<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz to 2.7 GHz AM Modulation & 9–28 V/m 385 MHz to 6.0 GHz Pulse Modulation</p>	<p>3 V/m 80 MHz to 2.7 GHz AM Modulation & 9–28 V/m 385 MHz to 6.0 GHz Pulse Modulation</p>	<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^A, should be less than the compliance level in each frequency range B.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 U_T is the AC mains voltage prior to application of the test level
NOTE 2 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 3 The ISM (industrial, scientific, and medical) bands between 0.15 MHz and 80 MHz are 6.765–6.795 MHz; 13.553–13.567 MHz; 26.957–27.283 MHz and 40.66–40.70 MHz.
NOTE 4 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 Optomed Aurora AEYE is used exceeds the applicable RF compliance level above, Optomed Aurora AEYE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Optomed Aurora AEYE.

B) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

Optomed Aurora AEYE maintains basic safety and performance when used in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

EMISSION TEST	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	Optomed Aurora AEYE 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 Complies	Optomed Aurora AEYE is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

SEPARATION DISTANCES

Optomed Aurora AEYE maintains basic safety and performance when used in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Optomed Aurora AEYE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Optomed Aurora AEYE as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	from 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	from 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	from 800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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: At 80 MHz and 800 MHz, 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.

6.9 Compliance

The classification of Optomed Aurora AEYE according to the standard IEC 60601-1:2005+A1:2012

- Optomed Aurora AEYE is internally powered ME equipment
- Optomed Aurora AEYE has type BF applied parts
- Protection against harmful ingress of water or particulate matter is classified as IPX0
- Optomed Aurora AEYE is not intended to be sterilized
- Optomed Aurora AEYE is not intended for use in an oxygen rich environment
- Optomed Aurora AEYE is classified for continuous operation

Optomed Aurora AEYE complies with FDA 21 CFR 886.1120 and ISO 13485:2016 standard. Declaration of Conformity is available upon request. The product is also in conformity with EU/2015/863 (ROHS3) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

	Optomed Aurora AEYE CAMERA	RETINAL MODULE	ANTERIOR MODULE	CHARGING STATION
FDA 21 CFR 886.1120	Class 2			
ISO 10940:2009	-	Complies	-	-
ISO 15004- 1:2006	-	Complies	Complies	-
ISO 15004- 2:2007	-	Group 2	Group 2	-
IEC 62471:2006	-	Exempt Group	Exempt Group	-
ANSI Z80.36- 2016	-	Group 2	Group 2	-

This declaration shall be rendered invalid if changes are made to the product without the manufacturer's authorization.

A. Appendix - Wireless Local Area Network (WLAN), Client, and Cloud

	Aurora AEYE study	Other study	Other study	Other study
	<i>Wireless data transfer</i>	<i>Wireless data transfer; Network mode</i>	<i>Wireless data transfer; Access Point mode</i>	<i>USB data transfer</i>
1.	Cloud On (as default)	Client enabled	Client enabled	Encryption off (User settings > Admin)
2.	Network connected	Network connected	Access Point On	Client enabled
3.	Date & Time set	Date & Time set	Date & Time set	Date & Time set
4.	Cloud Login	-	Connection to Access Point in PC	USB cable connected from Charging Station to PC
5.	Image capture and AI analysis	Image capture	Image capture	Image capture
6.	Images from Optomed Aurora AEYE Portal to PC	Images to PC via wireless network	Images to PC via wireless Access Point	Images to PC via USB when Camera on Charging Station

A.1 Connecting to Cloud

1. Set up wireless connection; choose Settings > Camera > Connections > WLAN
 - Use WLAN connection; select *On*
 - Network; select *available wireless network* from the list
 - Enter *network password*
 - Select *Connect*
2. Set up Date & Time
3. Set up Cloud connection; username and password are the same as for Optomed Aurora AEYE Portal
 - Enter *Cloud username*; fill in your email address
 - Enter *Cloud password*; fill in your password
 - Select *Login*

A.2 Wireless connections settings

Optomed Aurora AEYE Camera can be used wirelessly using WLAN which enables wireless data transfer to a PC and Cloud. In order to change wireless connections, open the *Connections* menu from camera settings by using Optoroller.

Wireless

First set *wireless connection* on to enable WLAN. When wireless connection is on, either network mode (a) or Access Point mode (b) can be used, but not at the same time. The network mode is the only option to connect the camera to AEYE-DS Service in Aurora AEYE study. Wireless data transfer after Other study can be done either with network mode or Access Point.

a) Network mode (for Aurora AEYE study and Other study)

In network mode Optomed Aurora AEYE Camera is connected to available networks. Select *WLAN* in Connections menu, browse available networks by selecting Network and select the desired network by using Optoroller. You may also choose *Other* in Network list and enter the network manually if it is not shown on the list. Enter the network password and press *Connect*. Optomed Aurora AEYE remembers 5 previously used Networks and their passwords and shows them with *.

For Other study: After the connection is achieved, open Optomed Aurora AEYE Client on PC. The camera is shown on the Client device list (you can check the IP address from camera's Network information).



NOTE!

Camera IP address may change if both Network and Access Point modes are used in turns.

b) Access Point mode (only for transferring images to PC)

Access Point mode is used when there is no wireless network available. In Access Point mode Optomed Aurora AEYE Camera sets up a camera specific access point to which PC can connect. First set Access Point on in camera menu. Then connect PC to the created Access Point by selecting it from PC's Network list. Enter the security key found in Access Point mode menu. After connection is achieved, open Optomed Aurora AEYE Client on PC. The camera is shown on the Client device list (you can check the IP address from camera's Network information).



NOTE!

When Access Point mode has been created successfully and PC is connected to the Access Point, PC's Network list may show text 'No Internet, secured'. The connection between Optomed Aurora AEYE and PC is still achieved.

Optomed Aurora AEYE Client connection (only for transferring images to PC)

When the connection to Optomed Aurora AEYE Client has been successfully achieved, Client icon is shown *white* in camera *Live view*. The icon is *grey* if there is no connection and *red* if there is a communication error. If a communication error occurs, check that both Optomed Aurora AEYE and the PC are connected to the same network (Network mode), or the PC is connected to Optomed Aurora AEYE's Access Point (Access Point mode). You may also try to disconnect and reconnect both Optomed Aurora AEYE and Client PC software. *Three dots* under the Client icon indicate active image transfer from Optomed Aurora AEYE to PC.



Wireless communication issues (only for transferring images to PC)



Camera is connected to a network

WLAN is enabled in camera settings but not connected to a network

In case there are slowness or other issues with wireless communication between the camera and the PC, the images will transfer slowly. You can follow the progress of the transfer from Optomed Aurora AEYE Client PC software. Client PC software will inform, if the wireless communication between the camera and the PC fails and images cannot be transferred. In case the wireless transfer will not be completed, images can be transferred via USB connection. Some settings need to be changed to use USB data transfer:

- Connections settings:
 - Client connection; turn on (Cloud turns off automatically)
- Settings for data transfer:
 - via USB: turn Encryption off (**Note! this deletes all studies including images and videos from the camera**)
- Other preparation:
 - Connect the USB cable from Charging Station to the PC

To improve wireless communication between the camera and the PC, you can move the camera closer to the PC and ensure that there are no large obstacles between the camera and the PC. Check that there are no other RF sources near the camera or the PC. You can also change the network to try to improve the wireless communication.

A.3 AEYE-DS Service via Cloud

Cloud service provides wireless connection between Optomed Aurora AEYE Camera and AEYE-DS for diabetic retinopathy screening services to enable fast and reliable screening by AI-algorithm. The AI-algorithm grades the fundus images within minutes and the results are then sent back to Optomed Aurora AEYE Camera and to Optomed Aurora AEYE Portal as well as by email if chosen in Portal. AEYE-DS supports only diabetic retinopathy (DR) screening results.

When you purchase Cloud services, you will be registered to Optomed Aurora AEYE Portal (Cloud). Cloud service can then be enabled from Connections menu under Camera settings. When Cloud is enabled, you need to fill in username (email address) and password for Cloud login. Note that Optomed Aurora AEYE needs to be connected to network before connecting to Cloud.

When the connection to Cloud has been successful, Cloud icon is shown in *white* in camera *Live view*. If the connection has not been achieved, the icon is *grey*, and *red* if there is a communication error. If a communication error occurs, logout from Cloud, disconnect from network and try connecting again. *Three dots* inside the Cloud icon indicate active image transfer from Optomed Aurora AEYE to Cloud and remote server. If Optomed Aurora AEYE has been connected to Cloud and the network disconnects the images go to upload-queue and wait for the reconnection to network.



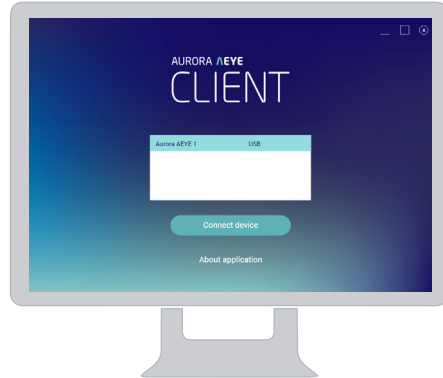
NOTE!

Date & Time must be set correctly to connect to Cloud. Date & Time settings are found in Camera settings.

A.4 Optomed Aurora AEYE Client PC software (only for transferring images to PC)

Optomed Aurora AEYE Client PC software enables WLAN connectivity from PC or another client device to Optomed Aurora AEYE Camera. With Client software you can wirelessly connect PC or other device to Camera and define the image destination folder into which images will be transferred.

The memory stick provided with the device includes Optomed Aurora AEYE Client software and Optomed Aurora AEYE Client Quick Guide. The Quick Guide instructs more specifically how to use Client and how to install/uninstall Client software. Client has a support for Windows 8.1®, Windows 10®, and Windows 11®.



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