OPTOMED AURORA AEYE

USER MANUAL



Optomed Aurora AEYE Camera

User manual of Optomed Aurora AEYE ophthalmic camera

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English 60002791
R 10.0
2026 09 17

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1. Safety

The information in this manual applies to the Optomed Aurora AEYE. 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 module intended to capture images and video of the fundus 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 Portal is a web application which enables registering to the service, administrating background information used to run the service, administrating the Cloud service connecting Optomed Aurora AEYE Camera and the AEYE-DS Service provider, and viewing information such as AI result.

Indications for use

AEYE-DS 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 is indicated for use with the Optomed Aurora camera.

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-mydriatically. 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 with central fixation target 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-DS 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/NCT04612868.*

1.3 Contraindications and limitations

Contraindications for fundus imaging

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

Or alternatively **continuous light**

• 67 min video recording / eye / day for Retinal 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

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.

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.

Contraindications for AEYE-DS

The exclusion criteria for use of AEYE-DS pertain to subjects with the following conditions:

- Uncorrectable vision loss (e.g., with the use of eyeglasses), blurred vision, or floaters.
- Previous diagnoses of macular edema, severe non-proliferative retinopathy, proliferative retinopathy, radiation retinopathy, or retinal vein occlusion.
- History of laser treatment of the retina, injections into one or both eyes, or any history of retinal surgery.
- Contraindicated for fundus imaging:
  - Hypersensitivity to light
  - Recent photodynamic therapy (PDT)
  - Taking medication that causes photosensitivity
  - A history of angle-closure glaucoma or narrow anterior chamber angles (in patients who require dilation)

1.4 Warnings and Precautions

1.4.1. Warnings and Precautions for fundus imaging

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.

1.4.2. Warnings and Precautions for AEYE-DS



WARNING!

To operate AEYE-DS safely and according to the intended purpose, the following prerequisites must be met:

- You should have a general understanding of the use of a personal computer running a standard web browser.
- You should be acquainted with the use of the indicated fundus camera used.
- You must read and understand the Intended Use, Warnings, and Operating Instructions.
- Users must undergo the AEYE-DS device training session provided by Optomed or AEYE Health.



WARNING!

AEYE-DS is only designed to detect more than mild diabetic retinopathy. AEYE-DS is not intended to detect concomitant diseases, ophthalmic diseases, or other systemic diseases. Patients should not rely on AEYE-DS for detection of any other disease.



WARNING!

Patients with an AEYE-DS output indicating more than mild diabetic retinopathy should be immediately referred to an eyecare provider for further assessment and treatment that is consistent with the recommendations of appropriate professional entities. In cases where the AEYE-DS test provides no result, the patient should always be immediately re-tested or referred to an eyecare provider. In cases where the AEYE-DS test does not detect the presence of referable disease, the patient should be strongly encouraged to test again at an appropriate point in the future.



WARNING!

Patients with a known history of diabetic retinopathy should follow up with their eye care provider for monitoring in accordance with recognized patient management recommendations.



WARNING!

Patients who have been previously told by their eyecare provider that they require follow up should be advised to continue to follow up with their eye care provider as per their eye care provider's recommendation.



WARNING!

People with diabetes may be at elevated risk of glaucoma and should be seen by an eyecare provider for glaucoma screening in accordance with recognized patient management recommendations. AEYE-DS does not detect glaucoma.



WARNING!

Patients should be informed that AEYE-DS does not treat retinopathy and that their images are analyzed to determine whether further examination is needed by an eyecare provider. Physicians should review AEYE-DS results and advise patients of recommended referrals to an eyecare provider for evaluation and possible treatment.



WARNING!

If AEYE-DS is not able to generate a diagnostic result on a patient who has been pharmacologically dilated, the patient may have vision threatening diabetic retinopathy or other abnormalities including cataract. Such patients should be promptly seen by an eyecare provider for evaluation.



WARNING!

Patients should be advised to immediately seek an eyecare provider if they experience vision loss, blurred vision, floaters, or any other symptoms, as these symptoms require the immediate attention of an eyecare provider.



WARNING!

Women with diabetes who become pregnant should be examined early and closely in the course of the pregnancy because the disease can progress rapidly, therefore more frequent screenings for diabetic retinopathy should be considered by their healthcare provider.



WARNING!

Do not use AEYE-DS to test for diabetes mellitus. AEYE-DS is only for use in people already diagnosed with diabetes mellitus.

WARNING!

It is important for you, the user, to be aware of the limitations of AEYE-DS. AEYE-DS performs computerized interpretation of retinal images. AEYE-DS may fail to detect diabetic retinopathy when the condition exists (false negative) and erroneously indicate that the condition exists when in reality it does not (false positive).

WARNING!

AEYE-DS is designed to work with good quality, in focus, digital retinal color images of the macula (when using the Optomed Aurora). At minimum a clear macula centered image of both eyes is required in order for the device output to be reliable. Do not submit retinal color images that are of poor quality, retinal color images that were not taken using an indicated digital fundus camera, retinal images that are not in color, images of other tissues or objects other than the retina, or color images that were obtained by scanning images.

WARNING!

AEYE-DS is intended to be used with images acquired with the Optomed Aurora.

WARNING!

Pharmacologic dilation (mydriasis) using a Tropicamide 1.0% solution may be required to capture sufficient quality images in some patients. Refer to the FDA approved label of Tropicamide 1.0% for relevant contraindications, warnings, and precautions.

WARNING!

There may be an increased chance of diabetic patients with mild DR being referred for ophthalmic examination follow-up earlier than required.

WARNING!

The user should attempt to produce a set of sufficient quality images for diagnosis. If an insufficient image quality result is provided by AEYE-DS after the 3rd attempt, then it is recommended to dilate the patient and retake all of the images under dilation. The user should attempt to produce a set of sufficient quality images for diagnosis after dilation has taken effect. If an insufficient image quality result is provided by AEYE-DS after the 3rd attempt after dilation, then it is strongly recommended to refer the patient to an eye specialist.

WARNING!

The user is responsible for ensuring that the corresponding images and filenames for a particular patient are labeled appropriately to avoid mistaken identity with respect to AEYE-DS results.

WARNING!
Users with hand tremors that may interfere with the operation of the fundus camera should not operate the AEYE-DS solution.

WARNING!
Patients who receive a result of “Insufficient Image(s) Quality” after following the full AEYE-DS imaging protocol should be referred to an eyecare professional for evaluation.

WARNING!
Patients who receive an error message after following the AEYE-DS imaging protocol should be referred to an eyecare professional for evaluation.

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 for documentation, screening, and consultation. The camera is used with Retinal Module. The optics module is 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.

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://auroraaeye.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

Accessories

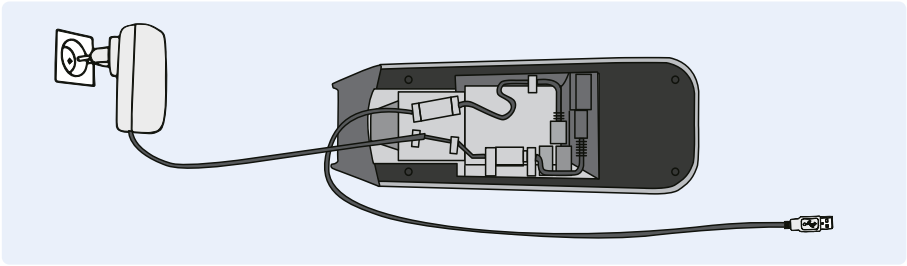
3. Charging Station
4. USB Cable
5. Power Supply
6. Eye Cup (2 pcs)
7. Lens Cover
8. Battery (2 pcs)
9. USB Flash Drive
10. Cleaning Cloth
11. User Manual and other guides

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

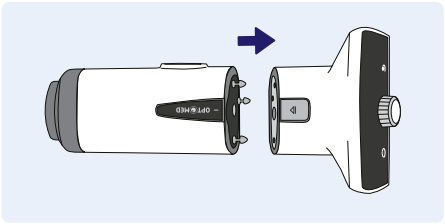
Place **Charging Station (4)** on a table outside the patient environment at a distance of at least 1.5 meters from the patient. Connect the **Power Supply (6)** cable to Charging Station and to the wall outlet. No need to connect USB cable to the PC since AI study uses wireless data transfer.

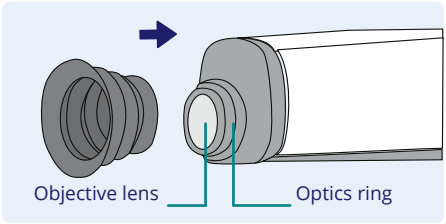


Note!
Position the power supply so that the plug can be easily disconnected.

Retinal Module (2) is 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 with bayonet legs to prevent scratches.

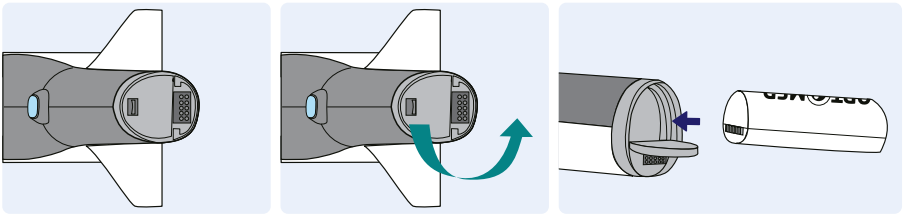
Place the **Eye Cup (7)** on the optics ring of **Retinal Module (2)**. To avoid the risk of contamination, disinfect the Eye Cup before each use with a new patient. If you are using disposable eye cups (E-Safe Disposable eye cups), first place the designated base part to the optics ring and then place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





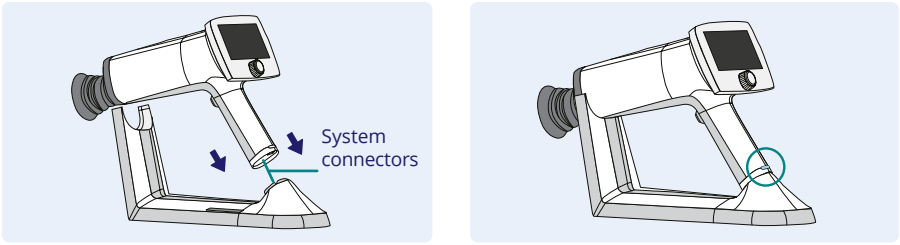
The lens cover can be placed over the front lens to protect the lens from scratches and dirt when device is not used.

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.

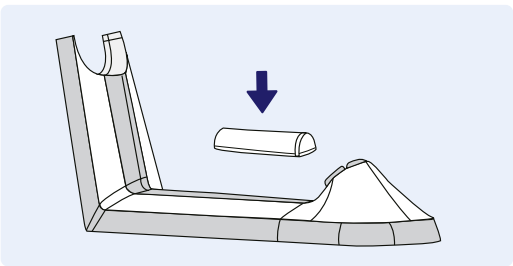


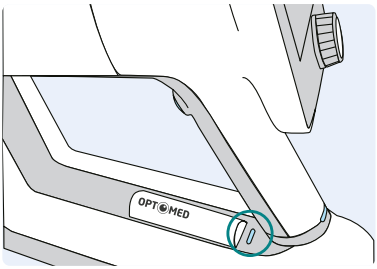
Place the camera on **Charging Station (4)** for charging. The camera will fit on Charging Station when **Retinal Module (2)** is attached. Place the handle of the camera carefully onto the system connector of Charging Station and move the front part of the optics module onto the support. Excessive force 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.

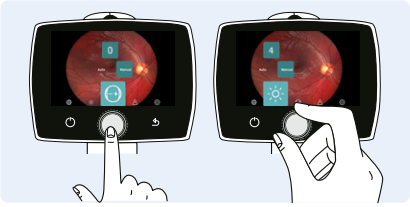
3.3 Controls and display icons



Optomed Aurora AEYE Camera is powered on and off by pressing the power button for few seconds. Opening the Quick menu is done by pressing Optoroller, which is also used for navigating in the menu together with back button.



Power on



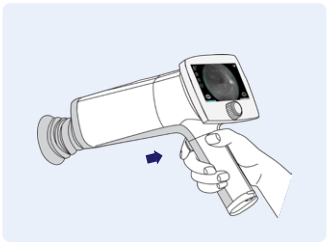
Open Quick menu and navigate

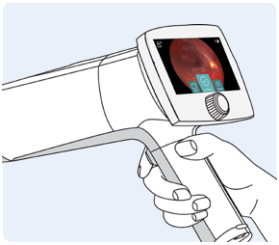


Back button

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 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.





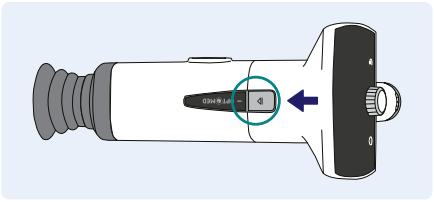
Shutter button for image capture



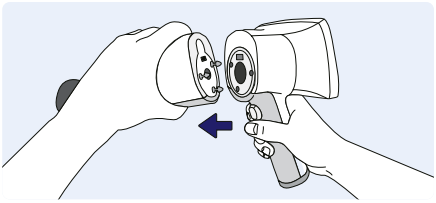
Forced shutdown

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.

Retinal Module is 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

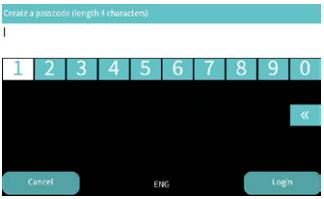
3.4 Start up and camera software set up

Before using the Optomed Aurora AEYE with the AEYE-DS service, you must first register an account on the Optomed Aurora AEYE Portal.

To use the service, the camera must be connected to the cloud via a WLAN network. Follow the steps below to complete the initial setup.

Note!
Additional user accounts can be created later if required.

1. Press *Power* button
2. Create passcode for Admin; choose 4 digits
   - To move between items, rotate Optoroller to the left or right Press Optoroller to select the item. Login by pressing the back button.



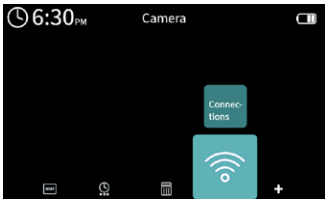
3. Select *No* for Start AI study; *Live view* opens
4. Enter menu by pressing Optoroller * >Settings

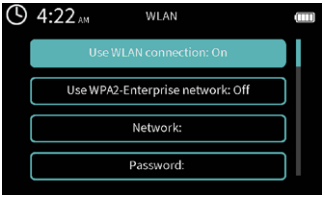


5. > User > Admin > User access
   - Add a user for each cloud account
   - Press Back button to Exit the user settings, until in Settings



6. Set up wireless connection; choose Settings > Camera > Connections > WLAN
   - Use WLAN connection; select On



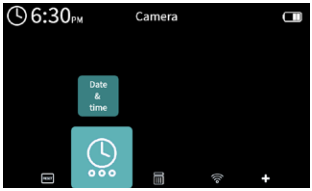


Note!
Optomed Aurora AEYE supports WPA2-PSK and WPA2-Enterprise Network authentication methods. If you are using WPA2-Enterprise Network, see more information from Appendix B. WPA2- Enterprise.

- Select available wireless network from the list. You may also choose Other in Network list and enter the network manually if it is not shown on the list.
- Enter network password. Press power button to access lowercase and more characters. Select Next with back button.
- Select Connect.

Optomed Aurora AEYE remembers 5 previously used Networks and their passwords and shows them with *.

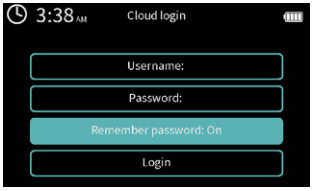
7. Set up Date & Time
   In case the camera does not guide you to Date & time settings, choose Settings, select Camera option followed by Date & time.



   - 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

8. Cloud; for configuration of AEYE-DS Service and Optomed Aurora AEYE Portal. Username and password are the sameas 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

9. Remember password (*on* or *off*).

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

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.



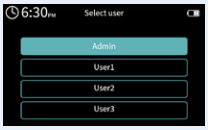
NOTE!

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

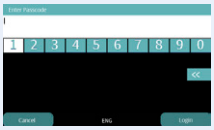
4. Imaging with Optomed Aurora AEYE



Power on

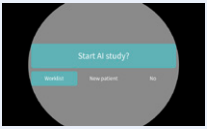


Select user

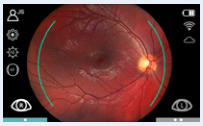


Enter passcode

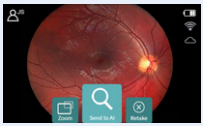
Retake images if insufficient image quality



Start AI study by selecting a patient from the worklist or by creating a new patient



Both eyes are imaged

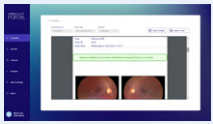


Send to AI/Retake

Retake images if insufficient image quality



AI result in camera display



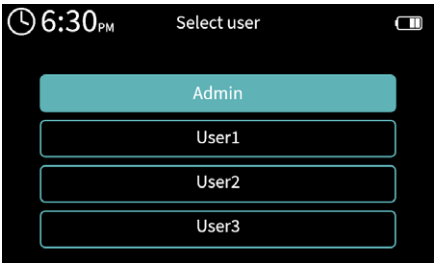
AI result in Optomed Aurora AEYE Portal

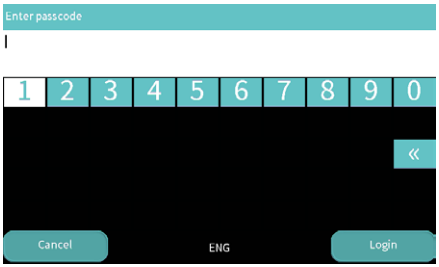


AI result via email

4.1 Overview of AI study

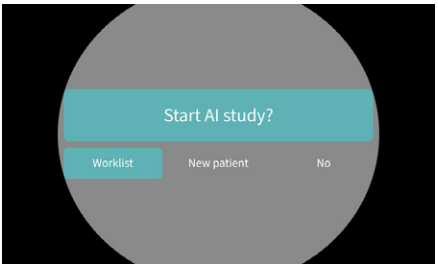
When Optomed Aurora AEYE Camera is powered on, select the user, and enter the passcode followed by a press of back button to log in.

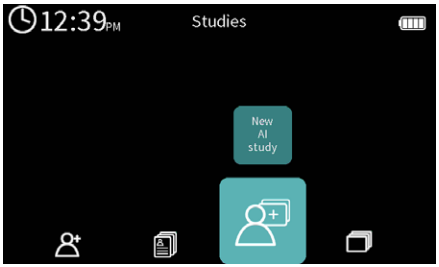




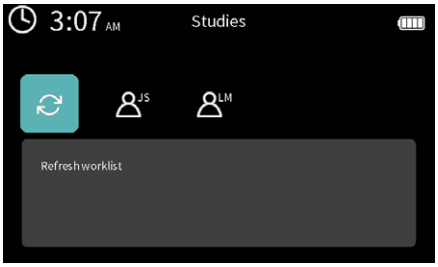
With AI study, the user is guided to take a macula centered image of both eyes and then send images to AEYE-DS analysis.

1. Create a new AI study
   - right after logging in by selecting a. Worklist or b. New patient for "Start AI study?" **or**
   - in the Studies menu by selecting AI study worklist or New AI study item





a. **Worklist** (AI study worklist)

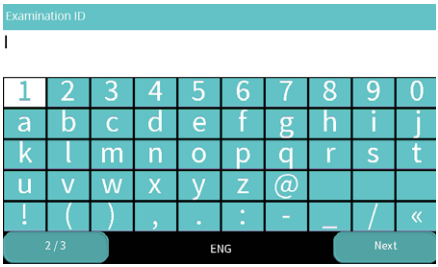


AI study worklists can be created in the Optomed Aurora AEYE Portal by manually entering patient information or by retrieving study lists from electronic health record (EHR) systems through the Portal. A cloud connection is required to use AI study worklists. When an AI study worklist is selected, a list of available studies is displayed. The worklist can be refreshed by selecting the refresh icon. To proceed to imaging, select the desired patient from the worklist.

If the worklist size exceeds the available memory capacity, a notification is displayed. Reduce the number of patients and try again.

b. **New patient** (New AI study)

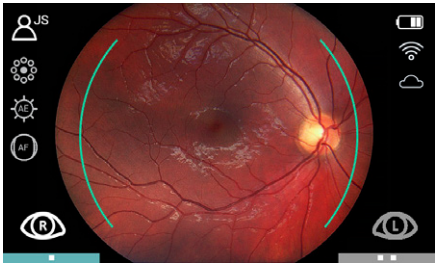
Fill in the Examination ID and Patient name (optional) by rotating and pressing Optoroller. Press back button to select Next.



NOTE!

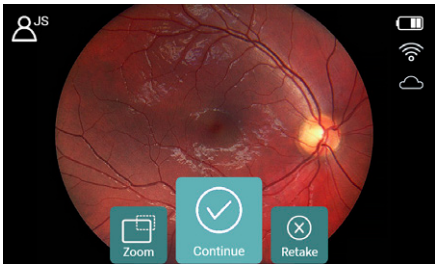
When entering examination information, do not use the same examination identifier for multiple patients. This may result in inaccurate data association. It is not recommended to use a social security number (SSN) as an examination ID.

2. 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

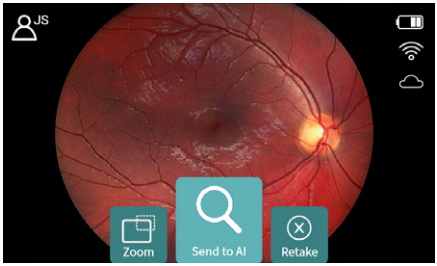


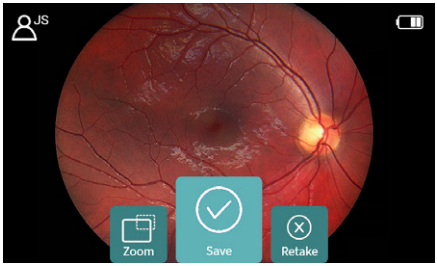
A notification is shown if some imaging settings are automatically changed according to recommendations for AI study. These include capture mode (still), fixation target (macula centered), focus (auto), exposure (auto), IR image (off), additional images (none), and capture settings in image (off).

3. 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



4. 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)





5. 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.

6. After viewing the result select *Close*
   - Camera prompts a notification *"Study completed. Start new AI study?"*. By choosing *No,* camera enters Live view.
7. Log out when the camera is no longer in use in Settings > User settings > Logout



WARNING!
Patients who receive a result of “Insufficient Image(s) Quality” after following the full AEYE-DS imaging protocol should be referred to an eyecare professional for evaluation.

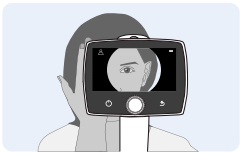
WARNING!
Patients who receive an error message after following the AEYE-DS imaging protocol should be referred to an eyecare professional for evaluation.

4.2 Image capture during AI study with Retinal Module

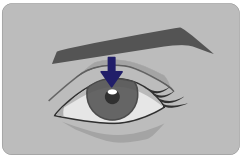
When imaging with Optomed Aurora AEYE, the examination room should be dim. It is recommended that both the patient and the examiner are seated during the examination. It is also possible to perform the examination when the patient is lying down.



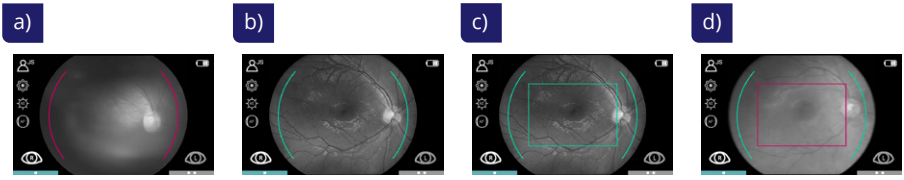
Ask the patient to focus on the red target light (fixation target) and to cover the eye not being imaged but keep both eyes open. Approach the pupil and stabilize the camera by supporting the front part of the camera on your thumb and place your fingers on the patient’s forehead. Press the eye cup firmly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

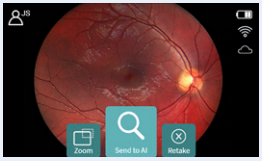
- check the image quality
- *zoom* the image; press Optoroller and rotate it to view different areas. Press Optoroller to Exit.
- *retake* the image; all images are saved to Archive despite of retakes **or**
- *continue* the study to capture the next image of the sequence

User can exit the AI 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.

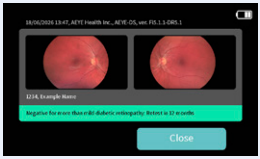
4.2.1. Image analysis

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

SEND TO AI OPTION

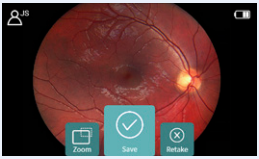


Send study to AI after imaging



View AI result

SAVE OPTION



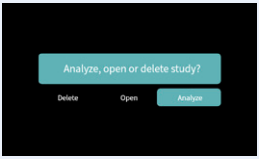
Save



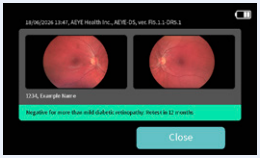
Select Archive



Select study



Select analyze



View AI result

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 eyecare 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 “Unable to do AI analysis". 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 AI study. If Worklist or New patient is selected, new AI study is started. 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 AI 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 or a video is recorded.

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. More information about Optomed Aurora AEYE Client PC software can be found in Appendix C.
- 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 Retinal Optics Module to capture fundus images and video.

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 AI 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 manua 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.

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.



3-5



6-8

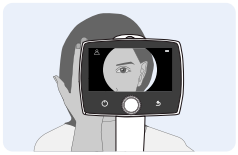
Retinal Module has nine internal **fixation targets** for the patient to focus on during imaging. The middle fixation target is automatically on, and it provides a macula centered image. Change the fixation target from the Quick menu.

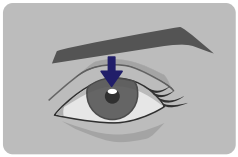
4.3.3. Retinal Module

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.



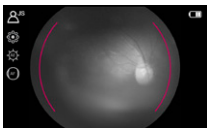
Ask the patient to keep the eye aligned with the target light (fixation target) and to cover the other eye but keep the covered eye open. Approach the pupil and stabilize the camera by supporting the front part of the camera on your thumb and place your fingers on the patient's forehead. Press the eye 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.



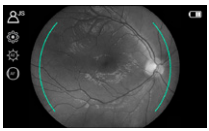


Aim help circle is implemented in the camera to help users approach with the camera and align the camera so that the full view of the retina will be seen on the display and a successful image can be captured. When the retina is not fully in view, the circle is red. Once the aim is good and retina fully 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).

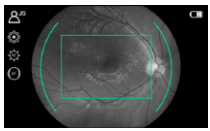
a)



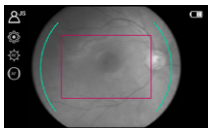
b)



c)



d)



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 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 aiming and then pressing the shutter button all the way down to capture image. An alternative way to capture an autofocused image is to keep the shutter button pressed all the way down, camera will capture image as soon as focus is obtained.
- **Manual focus:** 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. Capture a still image by pressing the shutter button all the way down, or halfway if half press capture is enabled in settings.

Recording videos:

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

4.3.4. After imaging

After capturing a still image, *Instant preview* with image specific options is shown on the camera display. To view the full image without image specific options, press Back button.



To zoom the image on the display, press Optoroller on zoom option. Center of image will be enlarged and displayed. To view the periphery of the image as zoomed, rotate Optoroller 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 Optoroller. This action saves the image to Archive.

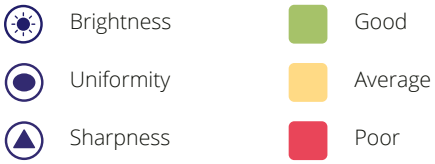
In addition, the captured image can be deleted in *Instant preview*. Note that if the image is deleted, it is not transferred over WLAN or saved to Archive. To exit from Instant preview without selecting the side of the imaged eye, select *Exit preview*. The image is then saved to the Archive and transferred 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 partially block the retinal view and make the imaging more challenging.

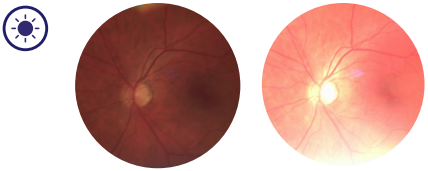
Image Quality Analysis (IQA)

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

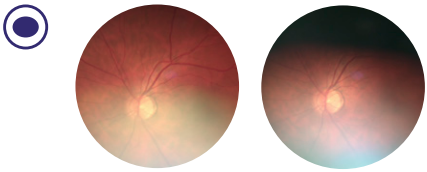
After an image is taken, brightness, uniformity, and sharpness are analyzed to assist the evaluation of the quality of the captured image. The results are shown with the symbols and with three different colors presented below.



Brightness: 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 unstability during image capture, for instance the camera shakes and affects motion blur. User can choose "half press capture" to avoid it.



4.3.5. Image saving and transfer

For the data transfer of Other Study and Client connection, 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 C.

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

either one is displayed at a time

Active study folder number or patient initials *(if available)*

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 (seen highlighted in above figure)

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.

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 *AI study worklist or new AI 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.

AI study

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

To create AI study, select a patient from the AI study worklist or create a new AI study by entering examination ID and patient name (optional).

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 AI study.

After selecting a patient from the AI study worklist or entering patient information, 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 AI study.



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, patient name, study type (AI 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 AI 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.

AI 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
- Logout timeout;
  5, 10, 15, or 30 minutes
- Encryption On/Off

User settings for basic user

- User list
- Logout
- Change passcode



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** 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. Optics settings for Retinal Module



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 AI study.

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



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 shutter button is changed to:

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

Manual focus: image is captured when the 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 Optoroller. 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.*



5.3.2.1. Advanced Optics settings

To see more optics specific settings, press Optoroller. 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 Optoroller 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)

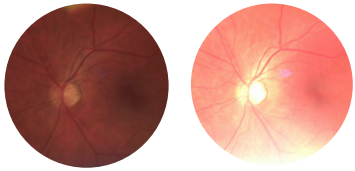
Occasionally artifacts may occur in images. The Image Quality Analysis (IQA) assists to evaluate the image quality of the captured image. The analysis level can be set to be *Basic, Strict, or Very strict* by using Optoroller. Images with lesser quality are accepted more easily as good with the basic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

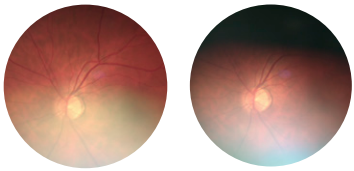
Brightness
Uniformity
Sharpness

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 unstability 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. Camera settings



RESET

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



DATE & TIME

To change the date and time settings, press Optoroller. 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 Optoroller 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. 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 Optoroller. 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.

5.3.3.1. 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 Optoroller.



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 Optoroller.

Enable the WLAN connection to use wireless network. To use WPA2 Enterprise network, refer Appendix B. The network mode is the only option to connect the camera to AEYE-DS Service in AI study.

Wireless data transfer after Other study can be done either with network mode or access point. More information about transfering data to Optomed Aurora AEYE Client can be found in Appendix C.



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.



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.

5.3.3.2. Advanced camera settings

To see more camera specific settings, press Optoroller. 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; AI 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. AI 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://auroraaeye.optomed.com
  - Camera not active: Cloud service is not purchased, or starting date is not chosen
  - Login failed: either username or password was incorrect
  - Unable to perform AI analysis: Check the network connection and log in to the cloud again

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. Two types of batteries are allowed to use:

Type 1.

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

Manufacturer of the battery:
Celltech (Zhongshan) Ltd
4th Floor, Building 3, No 6 Jiusha Road, Torch Development District, Zhongshan, China
www.celltechchina.com
info@celltech.fi

Place of manufacture: Zhongshan, China
Weight of battery: approx. 55g
Hazardous substances present in the battery: No
Usable extinguishing agent: Dry chemical, alcohol-resistant foam, powder, atomized water, carbon dioxide and dry sand are effective.

Critical raw materials present in the battery in a concentration of more than 0,1 % weight by weight:

Chemical composition	Chemical formula	CAS No.	Weight (%)
Lithium nickel oxide	Li2NiO2	12325-84-7	10-20
Carbon	Carbon activated	7440-44-0	
Iron	Fe	7439-89-6	
Copper	Cu	7440-50-8	5-15
Lithium nickel dioxide	Lithium nickelate	12031-65-1	1-10
Aluminum	Al	7429-90-5	
Cobalt lithium dioxide	Lithium cobaltite	12190-79-3	
Dimethyl carbonate	Carbonic acid dimethyl ester	616-38-6	
Lithium manganese oxide	LiMn2O4	12057-17-9	
Polyethylene	Ethene, homopolymer	9002-88-4	
Ethylene carbonate	1,3-Dioxolan-2-one	96-49-1	1-3
Lithium hexafluorophosphate	Lithium hexafluorophosphate	21324-40-3	
Graphite	Grafito	7782-42-5	
Ethyl methyl carbonate	EMC	623-53-0	

Nickel	Ni	7440-02-0	<1
1,4-Benzenedicarboxylic acid, 1,4-dimethyl ester, polymer with 1,4- cyclohexanedimethanol and 1,2-ethanediol	1,2 ethanediol	25640-14-6	
1-Propene, homopolymer	Polypropylene	9003-07-0	
Nickel sulphide	Nickel monosulfide	16812-54-7	
Poly[N,N'-(1,4-phenylene)- 3,3',4,4'-benzophenonetetracarboxy lic imide/amic acid	Imide resin	26023-21-2	
Silicon	Ferro silicon	7440-21-3	
Lithium carbonate	Carbonic acid, dilithium salt	554-13-2	
Carbon black	Carbon	1333-86-4	
1,3 Butadiene/styrene copolymers	Styrene, butadiene copolymer	9003-55-8	
Acetic acid ethenyl ester, polymer with carbon monoxide and ethene	--	26337-35-9	
Carboxymethyl cellulose sodium salt	Cellulose, carboxymethyl ether, sodium salt	9004-32-4	
Succinonitrile	Butanedinitrile	110-61-2	
Aluminum lithium oxide	AlLiO2	11089-89-7	

Type 2.

Battery label:
Li-ion Rechargeable Battery 3.6V / 3450mAh / 12.42Wh
50002426, 1INR19/66, INR-18650-M35A
Assembled by Shenzhen Hypercell Co., Ltd
MFD: yy/mm/dd

Manufacturer of battery:
Shenzhen Hypercell Co., Ltd
Building 1001, Aohua Industrial Park, Huarong Road, Dalang Community, Longhua District, Shenzhen, Guangdong, 518109 China
www.hypercellbattery.com
info@hypercellbattery.com

Place of manufacture: Dongguan, China
Weight of battery: approx. 56g
Hazardous substances present in the battery: No
Usable extinguishing agent: Cold water and dry powder in large amounts are applicable. Use metal fire extinction powder or dry sand if only a few cells are involved.

Critical raw materials present in the battery in a concentration of more than 0,1 % weight by weight:

Chemical composition	Chemical formula	CAS No.	Weight (%)
Lithium Cobalt Oxide	LiCoO2	12190-79-3	20-50
Manganese	Mn	7439-96-5	
Nickel	Ni	7440-02-0	
Aluminium	Al	7429-90-5	
Graphite	C24X12	7782-42-5	13-18
Carbon Black	C	1333-86-4	
Lithium Hexafluorophosphate	LiPF6	21324-40-3	1-5
Ethylene Carbonate	C3H4O3	96-49-1	5-20
Propylene Carbonate	C4H6O3	108-32-7	
Diethyl Carbonate (DEC)	C5H10O3	105-58-8	
Dimethyl Carbonate	C3H6O3	616-38-6	
Ethyl Methyl Carbonate	C4H8O3	623-53-0	
Polyvinylidene Fluoride (PVDF)	(CH2-CF2)n	24937-79-9	<1
Copper	Cu	7440-50-8	9-18
Aluminium	Al	7429-90-5	17-27
Contains Electrolyte salt and solvents	--	--	5-20

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

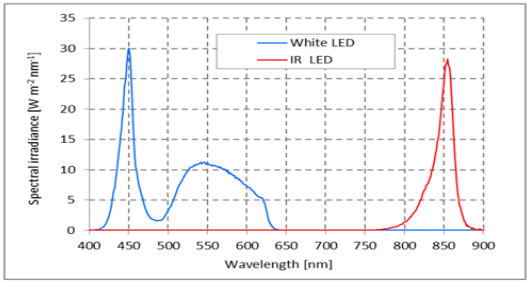
CAUTION!
Only use the USB cable, battery and power supply provided in the sales package. If you need replacement to the USB cable, battery, or power supply, please contact Optomed Customer Service.

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-PSK, WPA2 Enterprise 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:	Compatible with Microsoft operating systems that are within the manufacturers' official support lifecycle. No driver installation needed.
Dimensions:	122 (w) x 202 (h) x 97 (d) mm
Weight:	473 g
Battery: Type 1: Type 2:	 50001559, 3.65 V / 2750 mAh Rechargeable Li-ion battery Li-ion cell with integrated safety circuit 50002426, 3.6V / 3450mAh Rechargeable Li-ion battery Li-ion cell with integrated safety circuit
Usage time:	Up to 7 hours/ approx. 3.5 hours per battery (in typical use: Image capture of 4 patients per hour, 4 images per patient, camera in standby mode between patients)
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
Illumination:	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.
Maximum luminance:	3.0 cd/cm2
Field of view:	50º (total FOV 50ºx40º)
Diopter compensation:	from -20 D to +20 D manual focus from -15 D to +10 D autofocus
Image resolution:	2368 x 1776 pix (total 4.2 Mpix, effective area 3.38 Mpix)
Pixel pitch on fundus:	6.9 µm (for emmetropic eye with 17 mm focal length)
Spectral output at working distance:	 White and Infrared LED when operated in continuous mode

CHARGING STATION

Model:	Charging Station
Dimensions:	107 (w) x 147 (h) x 300 (d) mm
Weight:	683 g
Switching power supply: Type 1: Type2:	 CINCON TRG10R090 Input: 100-240 V, ~0.4 A, 47-63 Hz Output: 9 V, 1.1 A, 10 W 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: Disposable part:	 Liquid silicone rubber Reusable, free from latex, PVC, and DEHP Thermoplastic polyurethane (TPU) Disposable, 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

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.

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz & 6 Vrms ISM frequency	3 Vrms 150 kHz to 80 MHz & 6 Vrms ISM frequency	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. Recommended separation distance d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveyA, should be less than the compliance level in each frequency range B. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz AM Modulation & 9–28 V/m 385 MHz to 6.0 GHz Pulse Modulation	3 V/m 80 MHz to 2.7 GHz AM Modulation & 9–28 V/m 385 MHz to 6.0 GHz Pulse Modulation	

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 √P	from 80 MHz to 800 MHz d = 1.2 √P	from 800 MHz to 2.7 GHz d = 2.3 √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.

Proximity fields from RF wireless communications equipment		IEC 61000-4-3: 2006 +A1: 2007 +A2: 2010	
Frequency Range and Level: RF wireless communication EQUIPMENT			
Test Frequency (MHz)	Modulation	Minimum IMMUNITY Level (V/m)	IMMUNITY Level Applied (V/m)
385	Pulse Modulation: 18 Hz	27	27
450	Pulse Modulation: 18 Hz	28	28
710 745 780	Pulse Modulation: 217 Hz	9	9
810 870 930	Pulse Modulation: 18 Hz	28	28
1720 1845 1970	Pulse Modulation: 217 Hz	28	28
2450	Pulse Modulation: 217 Hz	28	28
5240 5500 5785	Pulse Modulation: 217 Hz	9	9

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**	**Charging station**
FDA 21 CFR 886.1120	Class 2		
ISO 10940:2009	-	Complies	-
ISO 15004-1:2006	-	Complies	-
ISO 15004-2:2007	-	Group 2	-
IEC 62471:2006	-	Exempt Group	-
ANSI Z80.36-2016	-	Group 2	-

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

6.10 Cyber security

6.10.1. Cyber security of Optomed Aurora AEYE

Cybersecurity in Optomed Aurora AEYE camera is managed in multiple ways, including the use of HTTPS on WPA2-protected networks, USB write protection and data encryption.

WPA2 (Wi-Fi Protected Access 2) is a security protocol used to protect wireless networks. It encrypts data using AES (Advanced Encryption Standard) and ensures secure communication between devices and Wi-Fi routers. WPA2 uses a 128-bit AES key for encryption.

HTTPS (HyperText Transfer Protocol Secure) is used as a communication protocol between the camera and the portal. HTTPS improves cybersecurity by encrypting data, ensuring integrity, and verifying the authenticity of the portal. It protects against MITM (Man-in-the-Middle) attacks, prevents data leaks, and enhances user trust.

- **Encryption:** HTTPS uses **TLS 1.2** to encrypt the data. This prevents eavesdroppers from seeing or stealing information while it's in transit.
- **Authentication:** TLS relies on digital certificates (often referred to as SSL/TLS certificates) to confirm the portal's identity, so the camera knows it's sending data to the correct destination.
- **Data Integrity:** By employing cryptographic checks, HTTPS ensures that any alteration to the data during transmission can be detected immediately.

6.10.2. Cyber security of Optomed Aurora AEYE Portal

For cyber security of Optomed Aurora AEYE Portal refer Optomed Aurora AEYE Portal user manual.

6.10.3. Cyber security of AEYE-DS

AEYE-DS is comprised of the AEYE-DS Service, an application backend service ("Backend") hosted on Amazon Web Services and operated by AEYE Health, and a means to interface the service. AEYE-DS provides a SDK or API to enable third party applications to send patient exams programmatically. The backend exposes an API accessible only to authorized requests sent over a secure HTTPS communication channel.

AEYE Health operates the application backend and assumes full responsibility for maintaining its security, including patching and securing the infrastructure and application code. Backend services running on AWS are managed by AEYE Health, including any and all security events/incidents.

Backup and Restore Features

On the server, de-identified data is stored on an encrypted server database and images are stored on an encrypted cloud storage. As part of its commitment to manage the AEYE-DS service, AEYE Health performs periodic backups of the service database and other storage repositories to ensure data availability in case of a disaster.

Cybersecurity Event Notification

If the user becomes aware of a cybersecurity event, then the user should contact AEYE Health immediately using the contact information provided in this User Manual.

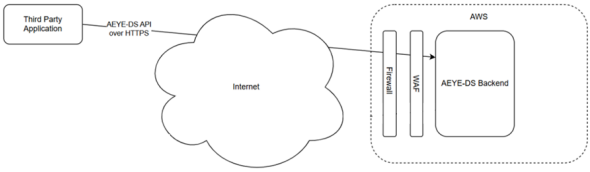
Cybersecurity Event Logging

AEYE-DS is a managed solution administered by AEYE Health. All cybersecurity events related to the service are reported to and handled by AEYE Health.

Cybersecurity/Software Bill of Materials (CBOM/SBOM)

The cybersecurity/software bill of materials (CBOM/SBOM) is available upon request. Please contact AEYE Health's technical support to get a copy.

The product label is available upon request. Please contact AEYE Health's technical support to get a copy.



Protected Health Information (PHI)

AEYE-DS requires two images and an exam identifier to perform its analysis and return a result. AEYE Health discourages the use of PHI in the exam ID field to avoid the need to process PHI with all its related safeguards.

A. Appendix – Clinical Study Results with Optomed Aurora

The AEYE-DS device performance for automated detection of more than mild Diabetic Retinopathy (mtmDR) from digital funduscopic images was demonstrated in several clinical studies. Both studies were prospective, multi-center, single-arm, blinded studies. The studies were conducted at study sites in the United States. The study populations represented the target population for the use of this device and consisted of stable, visually asymptomatic subjects who were previously diagnosed with diabetes and had no prior diagnosis of DR. Subjects participated in a routine retinal screening test for diabetic retinopathy (DR) in hospitals, primary care clinics or medical research centers. Patients of both genders, all ethnicities and ≥22 years of age were recruited to the study. General patient demographics, medical history, concomitant medications, fundoscopy system used, OCT system used, etc., were obtained for each study subject.

Novice operators, who had not previously performed ocular imaging, obtained fundoscopy images from each eye of the patient, using the Optomed Aurora funduscopic camera. Upon submission of the fundoscopy images to the AEYE-DS client software, a diagnostic result (and PDF diagnostics report) of more than mild DR (mtmDR) detected or more than mild DR not detected was produced. A result of 'insufficient quality' was determined if the novice operator reached a maximum of 6 image submission attempts and one or more of the images was still of insufficient image quality. After the novice operator generated an AEYE-DS diagnostic output, each participant underwent additional retinal imaging captured by a professional ophthalmic photographer, to obtain dilated four widefield color fundus images, lens photography for media opacity assessment and macular optical coherence tomography (OCT) imaging. The professional images were sent to an independent reading center where the severity of retinopathy and clinically significant diabetic macular edema (DME) were determined according to the Early Treatment for Diabetic Retinopathy Study severity (ETDRS) scale. The Reading Center diagnostic results formed the reference standard (ground truth) for the study. As part of the final clinical assessment, each participant was categorized as mtmDR+ or mtmDR-, based on the worst of two eyes. The final clinical assessment based on the worst of two eyes was compared with the AEYE- DS output, at the participant level.

In Study 1 a total of 317 subjects were enrolled in the study. The baseline demographic data and characteristics analysis showed that the mean age was 55 years, 51% were male and 49% were female, 26% were African-American, 47% White and 22% Hispanic or Latino, the remainder were of other racial/ethnic origins. Approximately 94% of the subjects in the study were diagnosed with type 2 diabetes while approximately 6% percent were diagnosed with type 1 diabetes. Average duration of diabetes since was 10 years (SD=8). Mean HbA1c level was 8.2% (SD=2.1).

The results of sensitivity and specificity in Study 1 based on images obtained from the handheld Optomed Aurora camera were 92% [CI:79%; 97%] and 94% [CI: 90%; 96%] (fundus and multi-modality based), respectively. The AEYE-DS device successfully identified all participants with ETDRS level 43 or higher. Positive Predictive Value (PPV) was 68.00% [CI: 54.19%; 79.24%] and the Negative

Predictive Value (NPV) was 98.73% [CI: 96.33%; 99.57%]. Further sub-analyses showed that there were no significant effects of age, sex, race/ethnicity, HbA1c, diabetic duration since diagnosis, lens status, positive ETDRS levels, or pharmacological dilation on sensitivity and specificity. 89% of the subjects did not require pharmacologic dilation. In Study 2 a total of 362 subjects were enrolled in the study. The baseline demographic data and characteristics analysis showed that the mean age was 58 years, 45% were male and 55% were female, 19% were African-American, 46% White and 30% Hispanic or Latino, the remainder were of other racial/ethnic origins. Approximately 97% of the subjects in the study were diagnosed with type 2 diabetes while approximately 3% percent were diagnosed with type 1 diabetes. Average duration of diabetes since was 10 years (SD=8). Mean HbA1c level was 8.3% (SD=2.2).

The results in Study 2 based on images obtained from the handheld Optomed Aurora camera were 93% [CI:80%; 97%] (fundus based) and 90% (CI:77%; 96%) (multi-modality based) for sensitivity and 89% [CI: 85%; 92%] (fundus based) and 89% [CI: 84%; 92%] (multi-modality based) for specificity. The AEYE-DS device successfully identified all participants with ETDRS level 43 or higher. Positive Predictive Value (PPV) was 53% [CI: 41%; 64%] (for both modalities) and the Negative Predictive Value (NPV) was 99% [CI: 97%; 100%] (fundus based) and 98% [CI: 96%; 99%] (multi-modality based). Further sub-analyses showed that there were no significant effects of sex, race/ethnicity, HbA1c, diabetic duration since diagnosis, lens status, positive ETDRS levels, or pharmacological dilation on sensitivity and specificity. The only sub-analyses which showed a significant effect was age, with the lower age group (<55 years) showing better results than the higher age group. 75% of the subjects received an AEYE-DS diagnostic output result on the first submission attempt. 90% of subjects did not require pharmacologic dilation.

PPV in both studies was influenced by the actual prevalence of mtmDR+ patients in the studies diabetic population (i.e., 12%), as these were not enriched studies. Furthermore, the PPV and NPV results obtained in both studies were similar, demonstrating the robustness of the studies.

Key results from the clinical studies are summarized in the table below.

	AEYE-DS Device Fundus-based Analysis		AEYE-DS Device Multi-modality-based Analysis	
	AEYE-DS Study 1	AEYE-DS Study 2	AEYE-DS Study 1	AEYE-DS Study 2
Sensitivity	92% [79%; 97%]	93% [80%; 97%]	92% [79%; 97%]	90% [77%; 96%]
Specificity	94% [90%; 96%]	89% [85%; 92%]	94% [90%; 96%]	89% [84%; 92%]
Imageability	99% [98%; 100%]	99% [97%; 100%]	99% [98%; 100%]	99% [97%; 100%]
PPV	68% [54%; 79%]	53% [41%; 64%]	68% [54%; 79%]	53% [41%; 64%]
NPV	99% [96%; 100%]	99% [97%; 100%]	99% [96%; 100%]	98% [96%; 99%]

The imageability results from both Study 1 and Study 2, reflecting data on the usability in the hands of the study novice operators, reported 99% imageability for the AEYE-DS device using the Optomed Aurora fundoscopy camera.

Usability of the AEYE-DS device with the Optomed Aurora camera was also assessed in a human factors validation study with the Optomed Aurora handheld camera, including User Manual comprehension and usability of the device in the hands of potential users. Once the users underwent initial, one-time training and practice, all users stated that the device was easy and straightforward, and all were successful in submitting images for diagnosis and obtaining a diagnosis output result and PDF report. All users stated that the user manual was clear and easy to use.

A separate precision (repeatability and reproducibility) study was conducted on 21 participants. All 21 participants completed the entire AEYE-DS device imaging protocol and diagnostic output twelve consecutive times, imaged by three different novice operators, using two different Optomed Aurora fundoscopy devices, except for one subject who withdrew consent after 10 image sets (operator #3 did not use camera #2) for a total of 250 image sets/diagnoses in total. Per protocol, operators allowed subjects at least 8 minutes between successive imaging. The results are presented in the following tables.

Intra-Operator Repeatability	Repeat 2 - mtmDR		
Repeat 1 - mtmDR	mtmDR +	mtmDR -	Insufficient quality
mtmDR +	58	0	0
mtmDR -	1	66	0
Insufficient quality	0	0	0
OA	99% (124/125) [96%; 100%]		
APA	99% [95%; 100%]		
ANA	99% [96%; 100%]		
AUA	Not presented as all cases were of sufficient quality		

Between – Operator Reproducibility	Operator 3		
Operator 1	mtmDR + Operator 2	mtmDR - Operator 2	Insufficient quality Operator 2

	mtmDR +	mtmDR -	IQ	mtmDR +	mtmDR -	IQ	mtmDR +	mtmDR -	IQ
mtmDR +	18	2	0	0	0	0	0	0	0
mtmDR -	0	0	0	0	21	0	0	0	0
Insufficient quality	0	0	0	0	0	0	0	0	0
OA	95% (39/41) [84%; 99%]								
APA	97% [88%; 99%]								
ANA	97% [90%; 99%]								
AUA	Not presented as all cases were of sufficient quality								

Between-Device Reproducibility	Device 2 mtmDR		
Device 1 - mtmDR	mtmDR +	mtmDR -	Insufficient quality
mtmDR +	28	1	0
mtmDR -	1	32	0
Insufficient quality	0	0	0
OA	97% (60/62) [89%; 99%]		
APA	97% [88%; 99%]		
ANA	97% [90%; 99%]		
AUA	Not presented as all cases were of sufficient quality		

In summary, the AEYE-DS device using 1 image per eye acquired from the Optomed Aurora fundoscopy camera demonstrates successful performance, in terms of sensitivity, specificity, PPV and NPV, as well as imageability and usability.

B. Appendix - WPA2-Enterprise

Optomed Aurora AEYE camera supports WPA2-Personal and WPA2-Enterprise network authentication methods. WPA2-Enterprise authentication can be configured using either **credential-based** or **certificate-based** authentication.

B.1 Authentication methods

Credential-based authentication

- Authentication method: EAP-PEAP (Extensible Authentication Protocol – Protected EAP)
- The following file is required to establish a secure connection:

Certificate name	Purpose	File name
Root CA Certificate	to verify the RADIUS server	ca.der

Certificate-based authentication

- Authentication Method: EAP-TLS (Extensible Authentication Protocol-Transport Layer Security).
- The following files are required to establish a secure connection:

Certificate name	Purpose	File name
Root CA Certificate	to verify the RADIUS server	ca.der
Client Certificate	the device's identity credential	client.der
Client Private Key	the private key pair corresponding to the client cert	private.der

B.2 Connecting to WPA2-Enterprise network

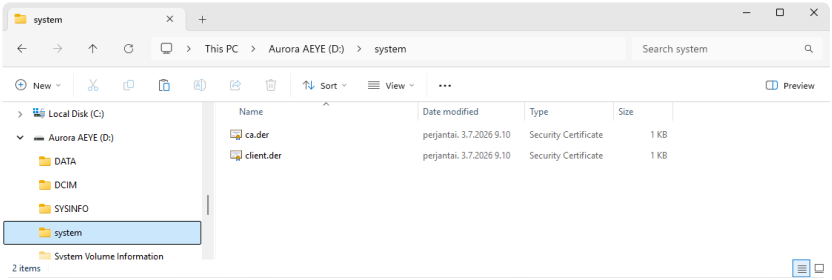
Step 1: Upload certificates required by selected authentication method to the camera

1. Create needed certificate files in certificate authority and export them.
2. Power on camera and navigate to Admin Settings (Settings > User > Admin) and turn Encryption off. Encryption can only be disabled by a user with Admin privileges.

NOTE!
Disabling encryption deletes all studies, including images and videos, from the camera.

3. Connect the camera to the PC by connecting the USB cable from the charging station to the PC and placing the camera in the charging station.
4. Create a folder named System in the root directory of the camera memory. Ensure that the folder is created directly in the root directory and not inside another folder.

5. Copy the required certificate files to the System folder. Ensure that each file has the correct filename and file format for its intended purpose.

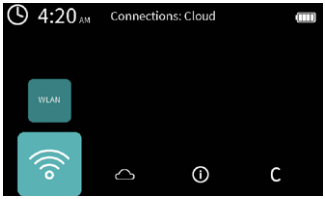


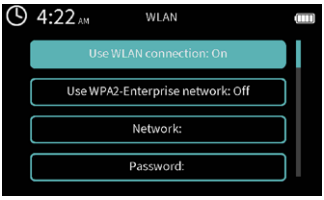
NOTE!
Certificates are camera-specific, not user-specific.

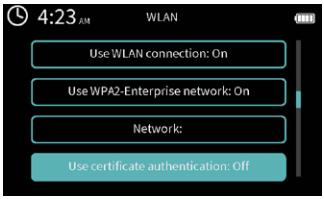
6. Remove the camera from the charging station. The certificates are automatically imported into the camera.
7. Navigate back to Admin Settings and turn Encryption on.

Step 2: Set camera connection settings

8. Navigate to WLAN Settings (Settings > Camera > Connections > WLAN).
9. Set Use WLAN Connection to On.







10. Set Use WPA2-Enterprise Network to On.
11. Select the wireless network from the list of available networks. If the network is not listed, select Other and enter the network details manually.
12. Configure the authentication method:
    - Credential-based authentication:
      - Set Use Certificate Authentication to Off.
      - Enter the Identity, Password, and optionally the Anonymous Identity.
    - Certificate-based authentication:
      - Set Use Certificate Authentication to On.
      - Enter the Identity, and Password if needed
13. Select Connect.

B.3 Update or delete certificates when needed

Update Certificates

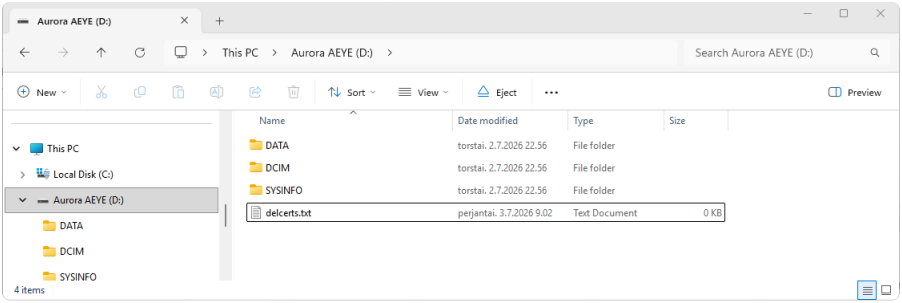
To update a certificate, follow the instructions in Upload Certificates to the Camera. The new certificate automatically replaces the existing certificate if it has the same filename.

Delete Certificates

To delete all installed certificates, copy a file named delcerts.txt to the root directory of the camera memory.

Before copying the file:

- Turn Encryption off.
- Place the camera in the charging station.



When the camera is removed from the charging station, all installed certificates are deleted.

NOTE!
Restoring the camera to factory settings does not remove installed certificates or user specific WPA2-Enterprise settings.

C. Optomed Aurora AEYE Client (Other study)

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.

For the data transfer of Other Study and Client connection, 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

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.

a. Network mode

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 *. 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!
Optomed Aurora AEYE supports WPA2-PSK and WPA2-Etnerprise Network authentication methods. If you are using WPA2 Enterprise Network, see more information from Appendix B. WPA2- Enterprise.

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

b. Access Point mode

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.

NOTE!

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

USB Connection

In addition to wireless connection, 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. Note! When turning encrypting off, all studies including images and videos are deleted from the camera. After the wireless or USB 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).

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



Camera is connected to a network



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

If slow network connection 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.

Notes

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https://www.optomed.com/us