

OPTOMED

AURORA®



USER MANUAL

Optomed Aurora

User manual for Optomed Aurora ophthalmic camera

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1. Safety

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

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 should be kept accessible to users at all times to ensure that the information required for use of the device is readily available.



CAUTION!

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.

**European certificate of conformity**

The CE marking with notified body identification numbering indicates the conformity of 93/42/ EEC Medical Device Directive for class IIa devices and CE marking without notified body identification numbering indicates the conformity of 93/42 EEC Medical Device Directive for class I devices.

**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 the 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 60417



Plug socket for power supply (Positive polarity)

Voltage and current



Disposal specification

European directive on waste electrical and electronic equipment (WEEE) 2012/19/EU specifies the disposal.



Battery disposal specification

The device has a rechargeable lithium-ion battery which can be recycled.



Manufacturer

The symbol is accompanied by the date of the manufacture, and the name and the address of the manufacturer.



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

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

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

Intended users

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

Intended patient population

All patients may be imaged with Optomed Aurora.

Clinical benefits

Optomed Aurora can be operated **non-mydratically**. With Optomed Aurora **digital images** can be stored for follow-up or consultation purposes. The **field of view** is 50x40 degrees allowing a detailed diagnosis. The operation of Optomed Aurora can be **learned quickly**, and even an inexperienced camera operator can capture images with sufficient quality for quick screening purposes.

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

1.3 Contraindications and limitations

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



WARNING!

Optomed Aurora 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 Optomed Aurora Retinal Module
- 250 still images / eye / day for Optomed Aurora Anterior Module

Or alternatively **continuous light**

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

Optomed Aurora is classified as Group 2 based on ANSI Z80.36-2016. No limits for pulsed light. 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, unless additional action is taken by the user to minimize exposure, after

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

The risk of retinal injury at an exposure of 2.2 J/cm² is not high, but because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of a significant risk of injury at exposures exceeding 10 J/cm², the user should avoid exposures longer than

- 307 min video recording / eye / day for Optomed Aurora Retinal Module
- 170 min video recording with white light / eye / day for Optomed Aurora Anterior Module
- 22 min video recording with blue light / eye / day for Optomed Aurora Anterior Module

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

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

Since prolonged intense light exposure can cause ocular damage, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. Infants and persons with aphakia or diseased eyes will be at greater risk of ocular damage. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours.



NOTE!

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



NOTE!

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



NOTE!

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

1.4 Precautions



WARNING!

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



WARNING!

Place the PC and Optomed Aurora 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, clean the eye cup before each use with a new patient.



WARNING!

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



WARNING!

In order to avoid touch current during imaging, do not touch the system connector and the patient simultaneously.

**CAUTION!**

Optomed Aurora 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 with this product.

**CAUTION!**

Only use USB cable and the power source provided by Optomed with this product. If you need replacement USB cable or power source, please contact the manufacturer or your local distributor. USB cable must be connected only to the USB port of a PC that complies with the IEC 60950 standard. Only connect Optomed Aurora Charging Station to an electricity supply which corresponds to the supply voltage of the device.

**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 customer 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 your Optomed representative for repairs and maintenance work on the device.

2. Device overview

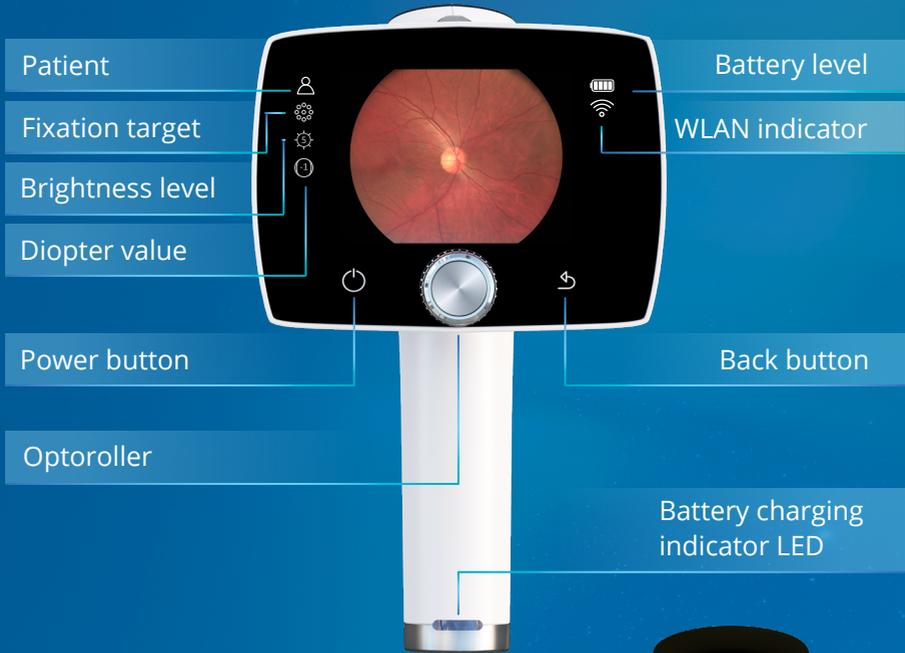


Optomed Aurora is a modular ophthalmic camera that is designed for use in a medical environment. It is intended to capture digital images and video of the fundus of the eye and surface of the eye for documentation, screening and consultation. Optomed Aurora Camera is used with interchangeable optics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

Optomed Aurora 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. With small pupils it is recommended to use mydriatic drops. Optomed Aurora Retinal Module has nine internal fixation targets for the patient to fixate on during imaging. The middle fixation target provides a macula-centred image.

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

Optomed Aurora Camera has a WLAN module which enables wireless data transfer to a PC. In addition to WLAN, captured images and recorded videos can also be transferred to a PC via USB connection when the camera is placed on Optomed Aurora Charging Station. In addition, Optomed Aurora Charging Station is a dual charger used for charging the battery inside the camera and spare battery.



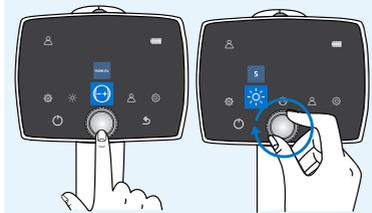
2.1 Controls and display icons

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

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



Power on

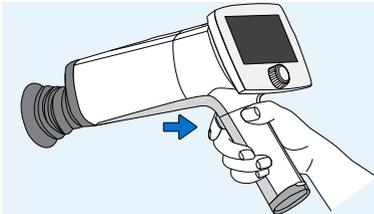


Open camera menu and navigate

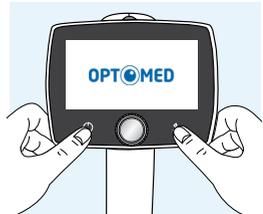
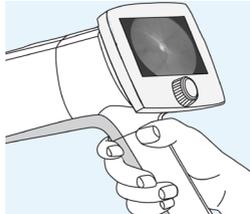


Back button

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



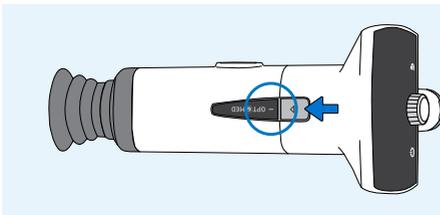
Shutter button for image capture



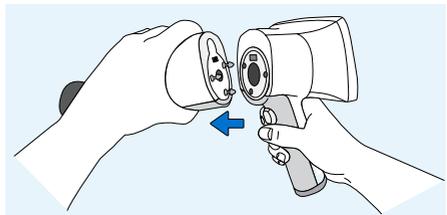
Forced shutdown

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

Optics modules are detached by pressing the eject button on the top of the camera.



Press eject button



Detach the module

3. Getting started

3.1 Part list and unpacking

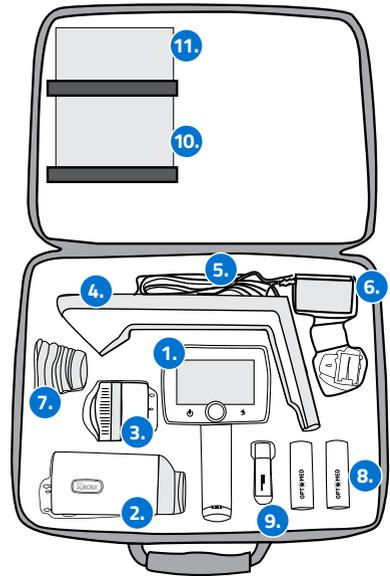
The Optomed Aurora sales package contains the following items:

DEVICES

- 1. Camera
- 2. Retinal Module
- 3. Anterior Module

ACCESSORIES

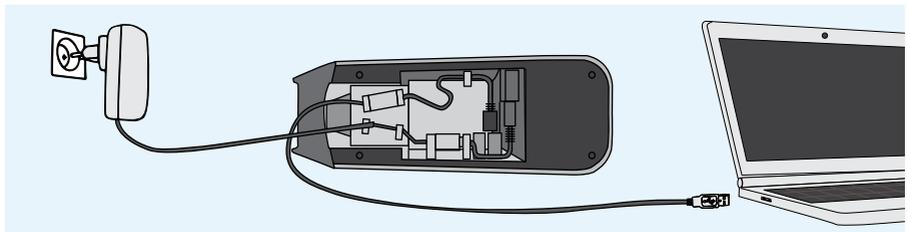
- 4. Charging Station
- 5. USB Cable
- 6. Power Supply
- 7. Eye Cup (2 pcs)
- 8. Battery (2 pcs)
- 9. USB Flash Drive
- 10. Cleaning Cloth
- 11. User Manual and other material



Open the sales packaging. Remove Optomed Aurora and accessories from the sales package and check that all parts are present and undamaged. Packaging materials should be retained for future relocation or repair.

3.2 Preparations

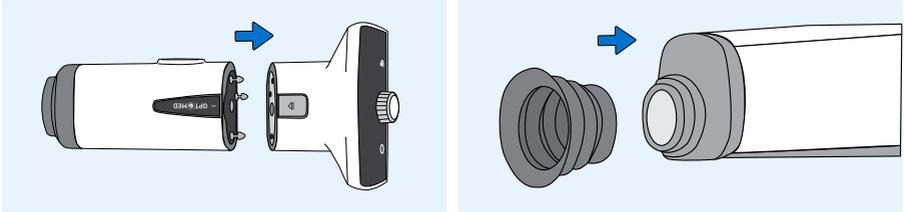
Place **Charging Station (4)** next to the PC. Charging Station must be outside the patient environment at a distance of least 1.5 meters from the patient. Connect the **USB cable (5)** and the **power supply cable (6)** to Charging Station and to the PC and to the mains.



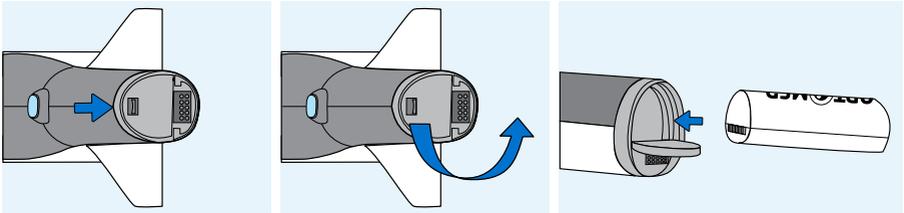
NOTE!

Position the power supply so that the mains plug is easily disconnected.

Both **Retinal Module (2)** and **Anterior Module (3)** are attached to **Optomed Aurora Camera (1)** by connecting firmly the bayonet legs of the optics module to the bayonet holes of the camera. Avoid touching the camera lens with bayonet legs in order to prevent scratches. To detach the optics module, press the eject button on the top of the camera and take the camera and optics module apart. Place the **eye cup (7)** on the optics ring of **Optomed Aurora Retinal Module (2)**.

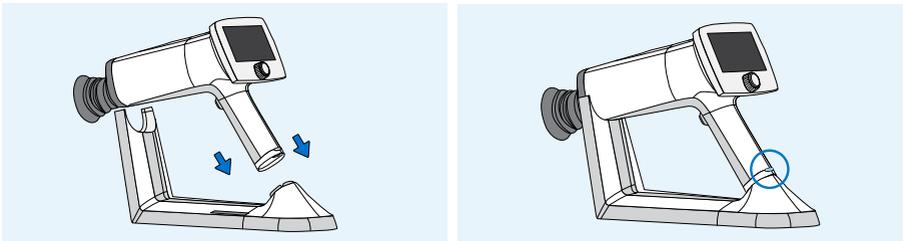


Install the **battery (8)** in **Optomed Aurora Camera (1)**. Ensure that the camera is powered off when placing the battery. Open the battery cover by sliding the battery cover release knob. Insert the battery and press the cover firmly into place.

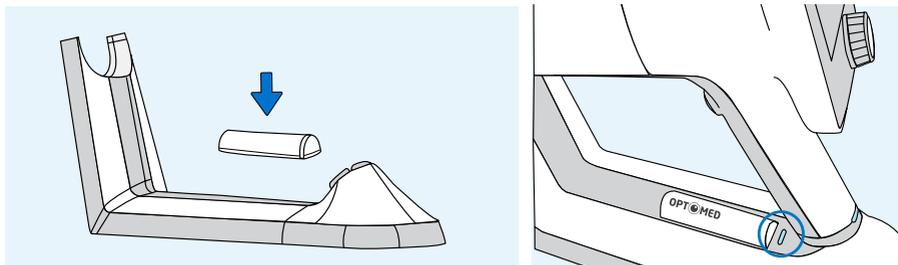


Place the camera on **Charging Station (4)** for charging. The camera will fit on Charging Station when **Retinal Module (2)** is attached. Place the handle of the camera carefully onto the connector of Charging Station and move the front part of the optics module onto the support. Excessive force should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

The battery charging indicator LEDs on the handle of the camera blink when the battery is being charged. When the battery is fully charged, all indicator LEDs are lit. When charging for the first time, charge the battery fully. In daily use, charge the battery when the battery level is low. Charging the battery at any level is not harmful for the battery.

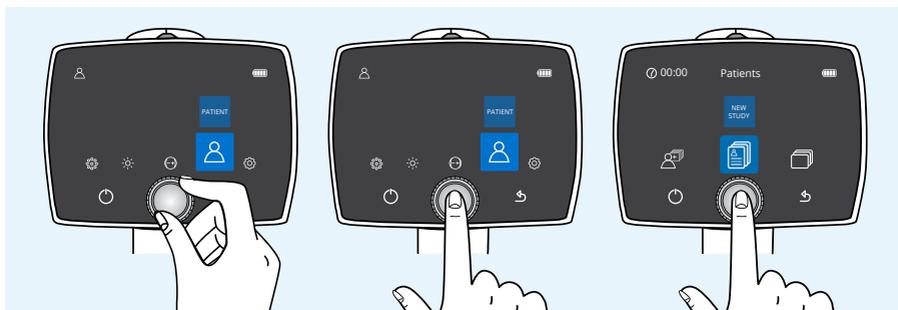


Optomed Aurora Charging Station can be used as an external charger for the spare battery. Set the **spare battery (8)** connectors to the **Charging Station (4)** connectors and put the spare battery in place. The spare battery charging indicator LED on Charging Station blinks when the battery is being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



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

It is recommended to create a new study for each patient. A new study is created in the *Patient menu* by selecting the 'New study' item. It is also recommended that image data storage is always erased between patients after the images have been transferred to the PC.



NOTE!

When manually entering patient information, do not use the same patient identifier for multiple patients. This may result in inaccurate data association.



NOTE!

Results deleted on the device cannot be recovered.

If Optomed Aurora Camera is not used for more than two minutes, the device will go into power save mode. It is powered on from power save mode by using any control button. Optomed Aurora Camera will power off if not used for 10 minutes.

Optomed Aurora Camera has a WLAN module which enables wireless data transfer to the PC. The separate PC software needs to be installed on the PC to allow wireless data transfer. Instructions on the operation of wireless settings and PC software are in Appendix A.

4. Features

When Optomed Aurora Camera is powered on, enter the menu by either pressing or rotating Oporoller.

To move between menu items, turn Oporoller to the left or right. Press Oporoller to select the item. Exit the menu level by pressing the back button.



4.1 Quick menu



FOCUS

Change focus mode by selecting the focus item by pressing Oporoller and choose either manual or autofocus. When focus mode is set to *manual*, a diopter scale is shown on the screen and focus can be adjusted from -20 to +20 diopters. Accept the selection by pressing Oporoller. In *autofocus* mode, the camera finds correct focus automatically. The autofocus range is from -15 to +10 diopters.



BRIGHTNESS

Imaging light brightness (exposure) for *Optomed Aurora Retinal Module* 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, if needed. In auto exposure mode Optomed Aurora calculates the optimal brightness value. To adjust brightness, select the brightness item, choose either manual or auto exposure mode and a suitable value by turning Oporoller and press Oporoller to confirm the settings.

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



PATIENT

In the *Patient menu* it is possible to create a new study for images, to browse captured images or select four image sequence (only when Optomed Aurora Retinal Module is used).

A new study is recommended for each patient. Select the *New study* item by pressing Optoroller. Either *New anonymous study*, *New patient study* or *a patient from the list* can be selected. An anonymous study creates a folder without patient name and creates an ID for the patient. In New patient study the patient name and ID can be entered to provide better identification. Write the patient name and patient ID by turning Optoroller left or right and pressing it to select characters. To erase a character press '<<' with Optoroller. Press the power button to change between the tabs for more character options. Press 'next' with back button to add Patient ID. After the patient ID is written, press 'add' to add the patient to the patient list. The newly added patient study is active. The keyboard language can be changed by pressing the power button for several seconds and then turning Optoroller left or right. Confirm the language by pressing Optoroller.

A *patient list* or a worklist can be uploaded to Optomed Aurora via Optomed Cloud, Sync software, Orbit image viewer or as a text document patlist.txt. *Update worklist* icon is shown in Patient menu when Cloud service with worklist download is enabled. To browse the imported worklist, choose *New study*. Select the patient from the worklist by using Optoroller. A patient can also be deleted from the worklist. For more information about each service, please contact Optomed customer service, your local distributor or refer to appropriate user manual.

Select the *Image browser* item by pressing Optoroller to browse patient folders and captured images. Patient folder shows Patient name, Date of the image capture, ID, and folder name. Select the patient whose images you wish to preview by pressing Optoroller. The select the desired image from the selected study. When the image is shown the image can be zoomed by pressing Optoroller. It is also possible to delete complete patient folders or single images.

When imaging with Optomed Aurora Retinal Module, there is a possibility to select the *Four image sequence* item by pressing Optoroller. By selecting four image sequence, you can choose a patient from the patient list, a new patient study or an anonymous study. After the study is created the camera will guide to take both macula and optic disc centred images from patient's right and left eyes. After each capture, the image can be zoomed, retaken or you can choose to continue to the next sequence.



TARGET LEDS FOR OPTOMED AURORA RETINAL MODULE

Optomed Aurora Retinal Module has nine internal fixation targets for the patient to fixate on during imaging. The middle fixation target is on by

default and it provides a macula centred image. To change the fixation target, select the target LEDs item, then turn Optoroller left or right to choose the 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)



FOCUS WINDOWS FOR OPTOMED AURORA ANTERIOR MODULE

Optomed Aurora Anterior Module has four focus windows for the user to focus the image on different areas during autofocus imaging. The right focus window is selected by default and the image is focused to the right side. To change the focus window, select the focus window item, then turn Optoroller left or right to choose a suitable area and press Optoroller to set the focus window area.



SETTINGS

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

4.2 User settings



USER LIST

User list shows all the users that have been added by admin user. The maximum number of users is 20. 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

The 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 and lifting the camera from the charging station (USB write protection must be set off). Admin can reset user passcode by selecting *User access*, *Edit user* and *Reset passcode*. Admin can also enable/disable passcode and login and set the time 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 list by pressing back button for 10 seconds when in user list.

4.3 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 and worklists, users, and Date & Time settings remain in camera memory. To delete worklist and reset users, please refer to chapter 4.2 User settings and Admin.



LANGUAGE

There are ten language options in Optomed Aurora: *English (default), Finnish, German, French, Italian, Portuguese, Spanish, Russian, Japanese and Chinese*. To change language, press Optoroller, then turn 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.



ERASE IMAGE MEMORY

To erase images and videos from the camera's memory card, press Oporoller. Ensure that you have transferred images and videos to a safe location before erasing the image memory.



WIRELESS

Optomed Aurora has a WLAN module that enables wireless connection to a PC. To change wireless settings, press Oporoller. Appendix A provides instructions for wireless settings.



ADVANCED CAMERA SETTINGS

To see more camera-specific settings, press Oporoller. The advanced camera settings include Date & Time, USB write protection, Camera information, Start query options, and Cloud service which are described below.



DATE & TIME

To change the date and time settings, press Oporoller. Select *daylight saving time* if applicable and *Time zone* in Coordinated Universal Time (UTC). Press *Set time manually* to set the day, month, year, hours and minutes by turning Oporoller left or right and press Oporoller to select the next field. The date format is exceptionally MM DD YYYY for Japanese and Chinese. Time is shown in the 24-hour format.

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



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 is prevented. Copying files from the memory card to PC is possible.



CAMERA INFORMATION

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



START QUERY

Choose the start query from erasing image memory, creating a new study, starting four image sequence or no query at all. 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 should be created. If *Four image sequence* is selected, the camera will guide to take both macula and optic disc centered images from patient's right and left eyes. If *No query* is selected, the camera will go directly to live view after powering on or when removed from Optomed Aurora Charging Station.



CLOUD SERVICE

Cloud service can be enabled or disabled. The choice affects the contents of Patient and Wireless menus. When Cloud service is enabled, Optomed Aurora can be connected to Optomed Cloud that provides AI-based screening for various eye diseases, patient list upload and download, and image storage services. Cloud services need wireless connection to work. More information about Cloud connection can be found in Appendix X.

Accessing to Cloud is only available in certain market areas. Send an inquiry to your local distributor or Optomed customer service for more information.

4.4 Optics settings for Optomed Aurora Retinal Module



QUICK IMAGING

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 choices is shown after imaging. In instant preview, it is possible to zoom, mark the imaged eye (right/left) and delete the image. Quick imaging is off by default.



HALF-PRESS CAPTURE

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

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



CAPTURE MODE

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



ADDITIONAL IMAGE

In addition to color image, there are two alternative imaging modes in Optomed Aurora: Red-free and Low-red. When either one is selected, the camera saves an additional image (Red-free or Low-red) together with the original image. To save only the original image, choose 'None'. In the *Red-free* setting, the camera uses only the green channel to save the image, and in the *Low-red* setting the camera saves a red reduced image in addition to the original image. Low-red may be unavailable in some devices due to changes in optics.



ADVANCED OPTICS SETTINGS

To see more optics-specific settings, press Optoroller. The advanced optics settings include Capture settings in image, automatic 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 in the lower right-hand corner of the image. The writing capture settings in image is off by default.



AUTOMATIC IR CONTRAST STRETCHING

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



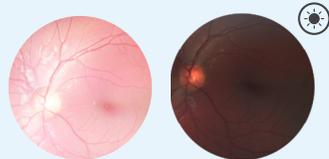
IMAGE QUALITY ANALYSIS

Occasionally artifacts may occur in images. The image quality analysis 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. The image quality analysis is off by default.

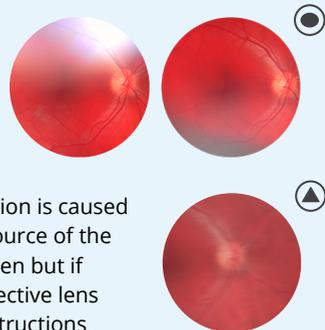
After an image is taken, brightness, reflection and shadowing, and sharpness are analyzed to assist the evaluation of the quality of the captured image. The results are shown with the symbols and with three different colors presented below.

 Brightness	 No reductions in image
 Reflection and shadowing	 Some reductions in image
 Sharpness	 Much reductions in image

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.



Reflections and shadowing: If there is *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. 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.



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 turning Optoroller.

4.5 Optics settings for Optomed Aurora Anterior Module



QUICK IMAGING

Quick imaging can be enabled or disabled. When quick imaging is on, the camera returns to live view right after image capturing and when it is off, instant preview with different choices is shown after imaging. In instant preview, it is possible to zoom, mark the imaged eye (left/right), and delete the image. Quick imaging is off by default.



HALF-PRESS CAPTURE

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

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



CAPTURE MODE

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

5. Imaging with Optomed Aurora

Optomed Aurora Camera is used with interchangeable optics modules Optomed Aurora Retinal Module and Optomed Aurora Anterior Module. Use Optomed Aurora Retinal Module to capture fundus images and Optomed Aurora Anterior Module to capture images of the surface of the eye and surrounding areas.

Optomed Aurora has two **capture modes: still imaging** and **video recording**. When recording video with Optomed Aurora Retinal Module, the patient's eyes need to be dilated. Capture mode is selected from the optics- specific settings in the menu.

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

- For *Optomed Aurora Retinal Module*, it is recommended to use manual focus. Manual focus is adjusted according to the patient's refractive error. When the patient has hyperopia, set the focus to be positive by turning Optoroller to right, and when the patient has myopia, set the focus to be negative by turning Optoroller left.
- For *Optomed Aurora Anterior Module*, it is recommended to use autofocus.

Select **imaging light brightness** to manual or auto exposure mode from quick menu. Imaging light brightness can be adjusted in manual mode from 0 to 10. In auto exposure mode Optomed Aurora calculates the optimal brightness value.

- When imaging with *Optomed Aurora 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 3 to 5 and for patients with brown eyes 6 to 8. If images are too bright, it is possible to reduce brightness below 3. Respectively, brightness can be increased up to 10, if images are too dark.



- When imaging with *Optomed Aurora Anterior Module*, first select the imaging light to be white or blue and then set the brightness. The default value is 5, which is suitable for most imaging situations.

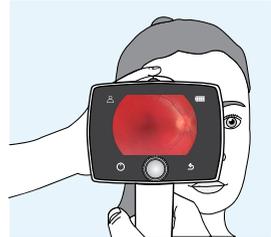
Optomed Aurora Retinal Module has nine internal **fixation targets** for the patient to fixate on during imaging. The middle fixation target is automatically on and it provides a macula center image. Change the fixation target from the quick menu. There are four focus windows in *Optomed Aurora Anterior Module* to focus the image on different areas during autofocus imaging. The

right focus window is selected by default. Change the focus window from the quick menu.

Create a **new study** for each patient from the *Patient menu*.

5.1 Retinal Module

When imaging with Optomed Aurora Retinal Module, the examination room should be as dim as possible. 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 and to cover the other eye but to keep the covered eye open. Approach the pupil and stabilize the camera by supporting the optics module on your thumb and place your fingers on the patient's forehead. Press the eye cup firmly around the examined eye. Make micro adjustments with your supporting hand to fine tune the focusing. The pupil is approached until the reflection from the eye fundus can be seen. The right imaging distance is about 2 cm (0.8 inch).

The aim help circle on the display guides when to capture an image. When the retina is not fully in view, the circle is red. Once the aim is good and the retina fully appears on the screen, the circle turns green.

CAPTURING STILL IMAGES:

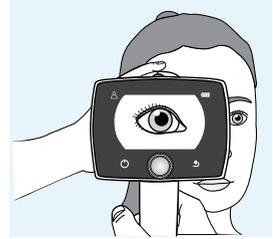
- **Manual focus:** Capture a still image by pressing the dual action shutter all the way down.
- **Autofocus:** Automatic focusing begins when the dual action shutter is pressed half way down. After successful focusing, an image is captured when the dual action shutter is pressed all the way down. An alternative way to capture an autofocused image is to keep the dual action shutter pressed all the way down when the camera first focuses and then captures an image.

RECORDING VIDEOS:

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

5.2 Anterior Module

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



CAPTURING STILL IMAGES:

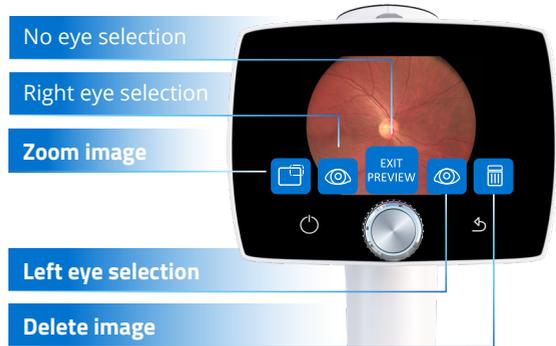
- **Manual focus:** Capture a still image by pressing the dual action shutter all the way down.
- **Autofocus:** Automatic focusing begins when the dual action shutter is pressed half way down. After successful focusing, an image is captured when the dual action shutter is pressed all the way down. An alternative way to capture an autofocused image is to keep the dual action shutter pressed all the way down when the camera first focuses and then captures an image.

RECORDING VIDEOS:

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

5.3 After imaging

After capturing a still image, the image preview is shown on camera display with Optomed logo in the top-right corner as a directional mark. The image specific query is shown after pressing or rotating Optoroller. In preview query there is the possibility to zoom the captured image, select a side of imaged eye and delete the captured image. The image is shown slightly zoomed in the preview. To view the full image without query icons, press back button.



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

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

If the *image quality analysis* is enabled, the results are shown in the top right corner of the image. Occasionally artifacts may occur in images. If the imaging distance is not optimal, the light may reflect either from the cornea or the ocular lens and cause unwanted reflection in the image. Failed focusing may result in blurry images. Stains and dust on the objective lens may also cause artifacts. In addition, eyelids, eyelashes and iris may partly block the retinal view and make the imaging more challenging. More detailed information about artifacts and image quality analysis can be found in Chapter 4.4 Optics settings for Optomed Aurora Retinal Module and Image Quality Analysis.

Captured images and recorded videos are saved to the memory card. When WLAN and Optomed Client PC software are used, Optomed Aurora Camera transfers captured images and recorded videos to the PC automatically immediately after imaging. Please note that wireless transfer is paused if the camera is placed on Optomed Aurora Charging Station during wireless transfer. The camera will continue wireless transfer when removed from Optomed Aurora Charging Station. More information about Optomed Client PC software in Appendix A.

Images and videos can also be transferred to PC from the memory card when the camera is placed on Optomed Aurora Charging Station. Optomed Aurora Camera will display a

'Connected' message when the device is connected to a PC via USB. The image data transfer method to PC is similar as with any other USB mass storage device. The device does not need any drivers to be installed on the PC. Writing to the memory card from PC is disabled by default.

When the Optomed Aurora Camera is not used, it may be stored on Optomed Aurora Charging Station. Storing the device on Charging Station is not harmful for the battery.

When the memory card or image counter is full, Optomed Aurora Camera will display a message with request to erase the image memory. First copy the images to a safe location and then select '*Erase image memory*' from the device menu to erase images and videos from the camera memory card. The image counter will also be reset.



NOTE!

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

6. Important information

6.1 Environmental conditions

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

	USE	STORAGE	TRANSPORTATION
Temperature	-10 °C to +35 °C	-20 °C to +35 °C	-20 °C to +50 °C
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!

THIS INSTRUMENT DOES NOT MEET THE REQUIREMENTS OF ISO 15004-1 FOR STORAGE. DO NOT STORE THIS INSTRUMENT IN CONDITIONS WHERE THE TEMPERATURE MAY RISE ABOVE +35 °C OR FALL BELOW -20 °C.

Please also note that electromagnetic compatibility information and recommended separation distances between portable and mobile RF communications equipment and Optomed Aurora 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 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 and restart the camera. Error code # identifies the error and it may be needed by customer service.

Light source temperature too high	This indicates that the light source temperature exceeds the safety 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 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 and restart the camera.
Patient list upload failure	This indicates that there is a problem with patient list uploading. Please retry. If the problem persists, please contact customer service.
Unable to create new study	The patient already has five studies and it is not possible to create a new study. Copy images to a safe location and select ' <i>Erase image memory</i> ' from Camera settings.
Charging failure	This indicates that Optomed Aurora 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 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 customer service.
System memory not available	This indicates that there is a problem with the system memory. Please restart the camera.
Image counter full	Optomed Aurora Camera can store 9,999 images. Once the image counter is full, copy the images to a safe location and select ' <i>Erase image memory</i> ' from Camera settings.
WLAN malfunction. Code:	Error code changes depending on the error at hand. The code will help customer service to solve the problem.
System file recovery failed	Contact customer service

Image is too bright for auto exposure. Try manual brightness #

Image is too bright, and camera suggests to take a new image with recommended manual brightness value.

If the device behaves abnormally, Optomed Aurora 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 will provide software updates as needed throughout the lifecycle of Optomed Aurora to continue to guarantee its safety and effectiveness.



NOTE!

If a malfunction cannot be rectified, please contact your local distributor or Optomed customer service.

6.3 Cleaning

Optomed Aurora has been tested to verify that it is compatible with the approved disinfectant agents. Do not use unapproved disinfection agents. Use of these agents may cause damage to components. Clean and disinfect on a routine basis according to your facility's protocols and standards or local regulations.



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.

Optomed Aurora 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 and system connectors in Optomed Aurora Camera and Optomed Aurora Charging Station.

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 and system connectors in the camera and the 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

- 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.

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

If a replacement eye cup is needed, please contact customer service or your local distributor. The eye cup should be replaced when:

- Discolored
- Deteriorated
- hattered, cracked or disintegrated



NOTE!

Optomed Aurora is not intended to be sterilized.



NOTE!

Ensure that no moisture penetrates the system during cleaning and disinfection.

Optomed Aurora has been tested to verify these instructions as being capable of preparing Optomed Aurora 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 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 other servicing and repairs 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 warranty, extended warranty or non-warranty repair service, contact Optomed Customer Service (service@optomed.com) or your local distributor. Estimates for non-warranty repairs are provided at the currently valid charge; however the device must be sent to Optomed for an estimate. When you contact customer service, the representative will record all necessary information and will provide a Return Authorization Number. Prior to returning any product for repair, a Return Authorization Number must be obtained.

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 Aurora 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 Camera has a rechargeable Li-ion battery that is charged when the camera is placed on Optomed Aurora Charging Station, which is connected to the mains. Optomed Aurora 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 or your local distributor provide suitable battery packs. The label on the battery includes one of the following information:

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

Li-ion Rechargeable Battery 3.65 V / 2750 mAh / 10.038 Wh
50001508, 11NR19/65, 11NR18650-29E, WWYY
Assembled by Celltech (Zhongshan) Ltd.)

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

Prepare the device for reuse or separate collection as specified by Directive 2012/19/EU of the European Parliament and Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply.

In accordance with applicable EU guidelines and national regulations at the time at which the product was brought onto the market, the product specified on the consignment note is not to be disposed of via the domestic waste disposal system or communal waste disposal facilities. 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 should 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 source provided in the sales package. If you need replacement USB cable, battery or power source, please contact the manufacturer or your local distributor.



CAUTION!

The development, production and maintenance of this device, together with associated

risks, are based on an expected device life time 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.

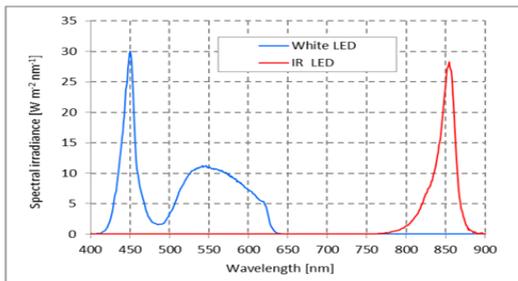
CAMERA

Model:	Optomed Aurora Camera
Image sensor:	CMOS, 5.0 Megapixels
Magnification:	0.317X
Image memory type:	Internal 8 GB memory
Display:	4", TFT-LCD, 800x480 pixels, 16.7 M colors
Image format:	JPEG (file extension: .jpg)
Video format:	MPEG-4 (640 x 480)
USB Connectivity:	USB 1.1, compatible with USB 2.0 and 3.0
WLAN Connectivity:	802.11 bgn, wpa2 Operating frequency range: 2412 – 2472MHz (Ch 1-13) Modulation: OFDM (802.11 a/g/n), DSSS/CCK (802.11b) Maximum output power: 17.25 dBm Maximum antenna gain: 1.9 dBi
Operating systems:	Microsoft Windows 8.1®, Windows 10® macOS (three latest versions) No driver installation needed
Dimensions:	122 (w) x 202 (h) x 97 (d) mm
Weight:	473 g
Battery:	
Type 1.	50000655, 3.63V, 2600 mAh Rechargeable Li-Ion battery Li-Ion cell with integrated safety circuit
Type 2.	50001508, 3.65V, 2750 mAh Rechargeable Li-Ion battery Li-Ion cell with integrated safety circuit
Usage time:	Approximately 2 h
Device life time:	Approximately five years

OPTICS FOR RETINAL IMAGING

Model:	Optomed Aurora 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, 10 illumination brightness levels. 9 red LEDs for internal fixation targeting
Maximum luminance:	3.0 cd/cm ²
Field of view:	50 x 40°
Diopter compensation:	from -20 D to +20 D in manual focus from -15 D to +10 D in 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:

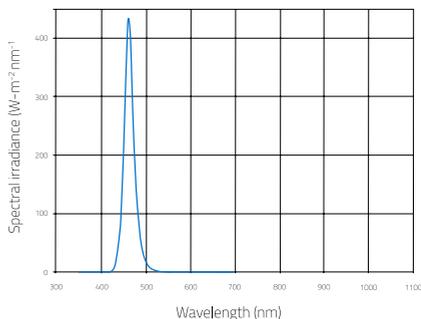
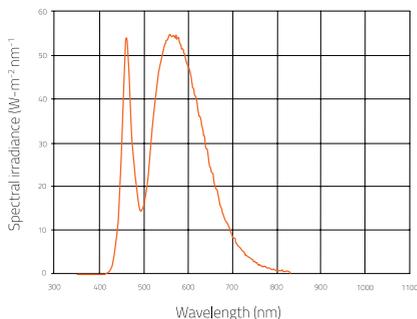


White and Infrared LED when operated in continuous mode

OPTICS FOR ANTERIOR IMAGING

Model:	Optomed Aurora Anterior Module
Dimensions:	71 (w) x 80 (h) x 78 (d) mm
Weight:	105 g
Illumination:	Visible white and cobalt blue LED for imaging, 10 illumination brightness levels
Maximum luminance output level towards eye:	192 cd/cm ²
Image resolution:	2560 x 1920 pix

Spectral output at working distance:



White LED when operated in continuous mode

Blue LED when operated in continuous mode

CHARGING STATION

Model: Optomed Aurora Charging Station

Dimensions: 107 (w) x 147 (h) x 300 (d) mm

Weight: 683 g

Switching power supply

Type 1:

CINCON TRG10R090

Input: 100 – 240 V, ~0.4 A, 47 – 63 Hz

Output: 9 V, 1.1 A, 10 W

Type 2:

XP Power ACM12US09

Input: 100-240 V, 0.5 A, 50-60 Hz

Output: 9 V, 1.33 A, 12 W

USB cable:

Type: A to mini B

Length: 1.5 m

MEMORY STICK

Memory stick including Optomed Client PC Software, Sync software and Instructions for use.

CLEANING CLOTH

Cleaning cloth for cleaning lens and display.

INTELLECTUAL PROPERTY RIGHT INFORMATION

Windows 8.1 and Windows 10 are trademarks of Microsoft Corporation. macOS is a trademark of Apple Inc. 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 with regard to 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 is lost or degraded due to electromagnetic disturbances, it may cause unexpected or adverse operation of this device. If a malfunction cannot be rectified, please contact your local distributor or 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 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 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% U_T for 0.5 at 8 ϕ angles; 0% 1 cycle; 70% U_T for 25 cycles; 0% for 5 sec	0 % U_T for 0.5 at 8 ϕ angles; 0% 1 cycle; 70% U_T 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 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, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
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	

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey⁴, should be less than the compliance level in each frequency range⁵.

Interference may occur in the vicinity of equipment marked with the following symbol:



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 is used exceeds the applicable RF compliance level above, Optomed Aurora 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.

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 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.

Emission test	Compliance level	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	Optomed Aurora 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
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Optomed Aurora 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.

SEPARATION DISTANCES

Optomed Aurora 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 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Optomed Aurora as recommended below, according to the maximum output power of the communications equipment.

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

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

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

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

6.9 Compliance

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

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

Optomed Aurora complies with EU Medical Device Directive 93/42/EEC and its national implementation in the form of the Finnish Medical Devices Act (629/2010). The valid Declaration of Conformity is available upon request.

	Optomed Aurora Camera	Optomed Aurora Retinal Module	Optomed Aurora Anterior Module	Optomed Aurora Charging Station
EU Directive 93/42/EEC	Class I	Class IIa	Class 1	Accessory
FDA 21 CFR 886.1120	Class 1	Class 2	Class 1	Accessory
ISO 10940:2009	-	Complies	-	-
ISO 15004-1:2006	-	Complies	Complies	-
ISO 15004-2:2007	-	Group 2	Group 2	-
IEC 62471:2006	-	Exempt Group	Exempt Group	-
ANSI Z80.36-2016	-	Group 2	Group 2	-

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

6.10 Warranty

Optomed Aurora is covered by a limited warranty granted by Optomed Oyj (Plc).

SUBMITTING A CLAIM

Any claim under this warranty must be submitted in writing before the end of warranty period to Optomed Oyj (Plc). The claim must include a written description of the failure to the device.

WARRANTY DOES NOT COVER

Products that have been subjected to abuse, accident, alternation, modification, tampering, misuse, faulty installation, lack of reasonable care, repair or service in any way that is not contemplated in the documentation of the product, or if the model or serial number has been altered, tampered with, defaced or removed. The warranty does not cover damage caused by dropping the device or damage caused by normal wear. Repair or service done by a non-Optomed-authorized service facility is not covered by the warranty.

A. Appendix - WLAN

A.1 Wireless settings

Optomed Aurora Camera has a WLAN module that enables wireless connection to a PC or other client device. In order to change wireless settings, open the wireless menu from Camera settings by using Optoroller.



WIRELESS

In wireless menu, there are four options: Wireless, Access point mode, Network mode and Connection details.

Wireless

First you need to set *wireless connection on* to enable WLAN. When wireless connection is on, either access point mode or network mode can be used, but not at the same time.

Access point mode

Access point mode is used when there is no wireless network available. In access point mode Optomed Aurora Camera sets up a camera-specific access point to which the 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 Client on PC. The camera is shown on Optomed Client device list (you can check the IP address from camera's connection details).



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 and PC is still achieved.

Network mode

In network mode Optomed Aurora Camera can connect to available networks. Select Network mode in Wireless 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 to the camera (Optomed Aurora remembers 5 previously used Networks and their passwords and shows them with *). After the connection is achieved, open Optomed Client on PC. The camera is shown on the Optomed Client device list (you can check the IP address from camera's connection details).

**NOTE!**

Camera IP address may change if both Network and Access point mode are used in turns.



When the connection to 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 and the PC are connected to the same network (Network mode) or the PC is connected to Optomed Aurora's access point (access point mode). You may also try to disconnect and reconnect both Optomed Aurora and Client PC software. Three dots under the Client icon indicate active image transfer from Optomed Aurora to PC.

CONNECTION DETAILS

Connection details menu shows the information of the established connection. The information consists of network name and camera IP and MAC addresses.

WIRELESS COMMUNICATION ISSUES

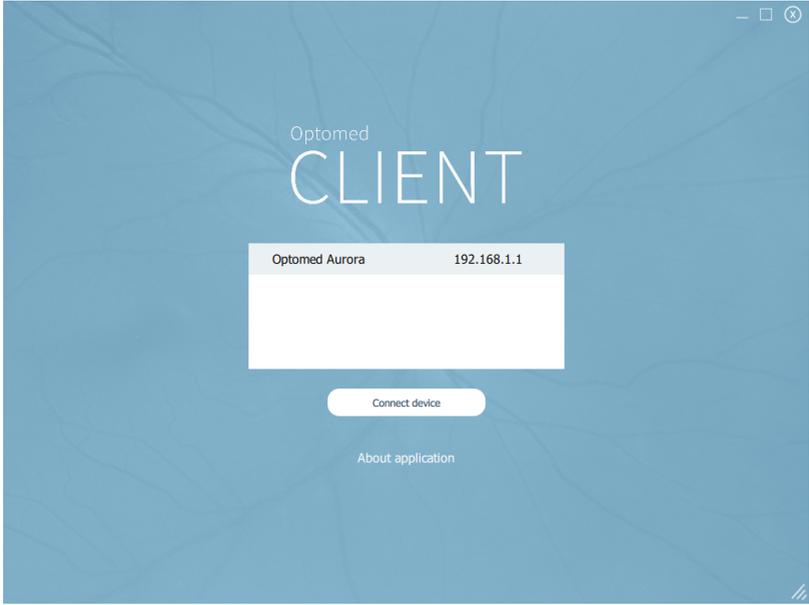
In case the wireless communication between the camera and the PC delays, the images will transfer slowly. You can follow the progress of the transfer from Optomed Client PC software. Optomed Client PC software will inform, if the wireless communication between the camera and the PC fails and images cannot be transferred. In case the wireless transfer will not be completed, images can be transferred via USB connection.

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 in order to try to improve the wireless communication.

A.2 Optomed Client PC software

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

The memory stick provided with the device includes Optomed Client software and Optomed Client Quick Guide. The Quick Guide instructs more specifically how to use Optomed Client and how to install/uninstall Optomed Client software. Optomed Client has a support for Windows 8.1® and Windows 10® in addition to iPad with iOS 11.0 or newer and Android 7.1 Tablet or newer.



A.3 Optomed Cloud service

Optomed Cloud service provides wireless connection between Optomed Aurora and remote server, 3rd party retinal disease screening services and an integration to Picture Archiving and Communication System (PACS) to enable fast and reliable screening by AI-algorithm and image archiving. The AI-algorithm grades the fundus images within minutes and the results are then sent back to Optomed Aurora. In addition, Optomed Cloud can be used to upload and download worklists, and fundus images and screening results can be stored to Optomed Cloud for further use. Optomed Aurora supports diabetic retinopathy (DR), age-related macular degeneration (AMD) and glaucoma screening results. However, the 3rd party screening services may vary between market areas and may not give results of all the above-mentioned eye diseases.



NOTE

Optomed Cloud is a screening tool for DR. System does not give diagnosis.



NOTE!

Accessing to Cloud service is available in certain market areas only. Send an inquiry to your local distributor or Optomed customer service for information.

When you purchase Cloud services, you will be registered to Optomed Cloud. Optomed Cloud service can then be enabled from Advanced Camera settings. When Cloud is enabled for the first time, you need to set Site ID, Server address, Server port and Application Entity

title to be able to link Optomed Aurora to Cloud and the remote server. These parameters and Cloud login information can be acquired from *orders@optomed.com*. Note that Optomed Aurora needs to be connected to network before connecting to Cloud.

Cloud services may affect the contents of Patient and Wireless menus.



When Cloud service is enabled a worklist can be downloaded to Optomed Aurora from a remote server and Update worklist item is shown in the Patient menu. To browse the worklist, go to New study.



WIRELESS

Wireless settings can be changed in Wireless menu found in Camera settings. Wireless menu includes four options: Wireless On/Off, Client menu, Cloud menu and Connection details.

Wireless

Set wireless on to enable wireless connection.

Client menu

Client menu contains the same features as described in Appendix A.1.



Cloud menu

To connect Optomed Aurora to Optomed Cloud and screening services, select Cloud menu and Network selection. In Network mode Optomed Aurora can connect to available networks. Select 'Network' to scan available networks (Optomed Aurora remembers previously used Network and its password and shows them with *). After the scan, a network list is shown on camera display. Select a network, enter the network password, and select connect. You may also choose 'other' in Network list and enter the network manually if it is not shown on the list. After the connection is achieved go to Cloud login in Cloud menu, fill Cloud username and password, and log in.



When the connection to Cloud has been successful, Cloud icon is shown 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 under the Cloud icon



indicate active image transfer from Optomed Aurora to Cloud and remote server.



If Optomed Aurora has been connected to Cloud and the network disconnects the images go to upload-queue and wait for the reconnection to network.

In Cloud settings you can set Site ID, Server address, Server port and Application Entity title.

**NOTE!**

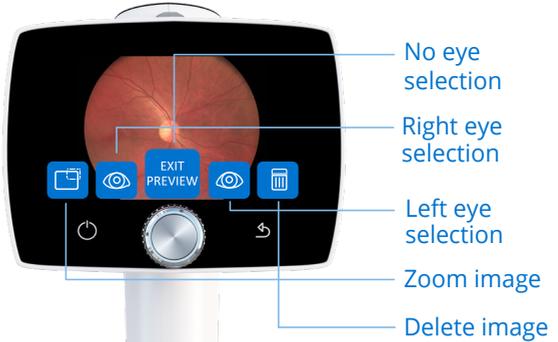
Optomed Aurora's Date & Time must be set correctly in order to connect to Optomed Cloud. Date & Time settings are found in Advanced Camera settings.

Connection details

Connection details menu shows the information of established network connection. The information consists of network name, and camera IP and MAC addresses.

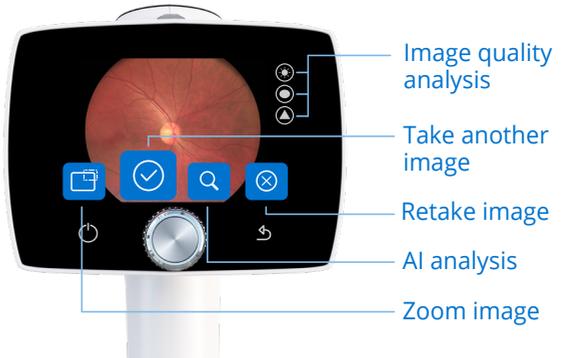
AFTER IMAGING

When Cloud service is enabled, fundus images can be sent to Optomed Cloud for screening. After the fundus image has been taken and the display is in the image preview, select the side of the imaged eye (Right or Left), and camera shows new options: Zoom the taken image, send the image for AI Analysis, Continue and take more images before sending the images and retake the image.

**NOTE!**

Images cannot be sent to analysis without selecting eye side nor if you exit image preview.

Image quality analysis helps to evaluate the quality of the image. Poor quality image cannot be used for screening purposes and comes back as ungradable or it may result in false positive or false negative results.



Single images can be sent for AI screening by selecting Analyse. When imaging both eyes or taking several images of the same eye, take the first image, select the side of the eye, and select Continue to take another image. You may take and send up to four images at a time for analysis. When all images have been taken, select Analyse. Multiple images give more accurate results. In Four image sequence the AI analysis is available after taking the final image. Images are stored to Cloud during the analysis.

After the analysis from screening, the display shows the results of diabetic retinopathy, age-related macular degeneration, and/or glaucoma. More specific results can be read by selecting 'More information'.



NOTE!

The 3rd party screening services may vary between market areas and hence may not give results to all the above-mentioned eye diseases.



Color	Result	Description
	No apparent findings	No apparent findings by the algorithm. Patient can be rescreened at normal time interval.
	Refer to ophthalmologist	The algorithm found alterations. Patient should be referred to ophthalmologist for further examination and diagnosis.
	Ungradable	Image quality is too low for analysis. Possible reasons include image artifacts such as reflections, blurriness, inappropriate brightness, or eyelids and eyelashes blocking the view. Take another image and try again. If pupil diameter is too small, dilation may be needed.

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