HANDHELD FUNDUS CAMERA

OPTOMED LUMO

User manual

Optomed Lumo®
User manual for the Optomed Lumo Camera and
Optomed Lumo Desktop Base

Contact information:

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The Optomed Lumo Camera is a class IIa CE-marked medical device

CE 0598

The Optomed Lumo Charging Station and Optomed Lumo Desktop Base are class I CE-marked medical device accessories

CE

English 60002650
R10.0 2025 06 17

Contents

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 that could result in patient injury, harm, or death if appropriate safety precautions are not followed.

CAUTION!
Indicates a situation that 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 EU Medical Device Regulation 2017/745 class IIa medical devices and CE marking without notified body identification numbering indicates the conformity of EU Medical Device Regulation 2017/745 class I medical devices.

Medical device
The device is a medical device as defined in EU 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 radio frequency (RF) radiation. Electromagnetic interference from the device is below the 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, chin rest, and head rest, which are in physical contact with the patient, are electrically isolated and protected against electric shock.

Class II power supply

For indoor use only
Power supply designed for indoor use only, according to IEC 60471.

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 that can be recycled.

Manufacturer
The symbol is accompanied by the name and 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 indicate the week (digits 1-2) and year (digits 3-4) of 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

USB-C data port

USB-C power port

To avoid leakage current during imaging, do not touch the USB-C connector of the Desktop Base, the medical PC (IEC 60601-1:2012 or newer approved), or the Charging Station and the patient simultaneously.

Introduction

The Optomed Lumo Camera is intended for non-mydriatic fundus imaging. Mydriasis is not 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. The Optomed Lumo has nine internal fixation targets, which are used to image different areas of an eye fundus. With the Optomed Lumo, data transfer takes place either wirelessly or via USB.

Intended use

The Optomed Lumo® Camera is a medical digital camera intended to be used to capture images of the human fundus for the detection, monitoring, and screening of conditions.

The Optomed Lumo® Desktop Base is an accessory for the Optomed Lumo Camera. The desktop base is used for enabling stationary imaging setup.

Use environment

The Optomed Lumo Camera is suitable for use in a professional healthcare environment.

Intended users

The Optomed Lumo Camera may only be operated by healthcare professionals or people who are familiar with fundus cameras or ophthalmoscopes, or who otherwise have the knowledge to operate the device.

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

Intended patient population

All patients may be imaged with the Optomed Lumo Camera.

Clinical benefits

The images captured with the Optomed Lumo support healthcare professionals in the detection, monitoring, and screening of conditions visible in the human fundus. The applicable specialties include but are not limited to ophthalmology, optometry, diabetology, neurology, pediatry, and primary care.

The Optomed Lumo is a non-mydriatic fundus camera. A 50 degrees x 40 degrees field of view (FOV), together with 9 fixation targets, yields detailed images of different areas of the fundus with high quality for screening. With the Optomed Lumo, digital images can be stored for follow-up or consultation purposes.

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

Contraindications and limitations

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

WARNING!
The Optomed Lumo is classified into 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
6000 still images / eye / day
The Optomed Lumo is classified into Group 1 based on ANSI Z80.36-2021.

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

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. 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!
Persons with aphakia or diseased eyes may be at greater risk of ocular damage, when imaged with the Optomed Lumo Camera.

NOTE!
The following conditions may complicate or prevent imaging: cataract, corneal opacity, nystagmus, strabismus, phoria, and conditions that may cause uncontrolled body movements. People who are not able to cooperate, for example due to unconsciousness or anesthesia, may be difficult to image as they cannot fixate on a target LED.

About safety

The information in this manual applies to the Optomed Lumo Camera and Optomed Lumo Desktop Base. 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 **portal.optomed.com** where you can also find more training 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 Lumo should always be kept accessible to users 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. Read the third-party AI manual carefully before use if AI service is integrated into the Optomed Lumo.

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

Precautions

WARNING!
The Optomed Lumo is not suitable for use in explosion risk areas or in the presence of flammable anesthetics.

WARNING!
Place the PC (not IEC 60601-1 approved) and Optomed Lumo 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, head rest, and chin rest before each use with a new patient.

WARNING!
Do not expose the eye cup, chin rest, or head rest to direct sunlight, as they may heat up and cause burns to the user and/or the patient.

WARNING!
To avoid leakage current during imaging, do not touch the USB-C connector of the Desktop Base, the medical PC (IEC 60601-1:2012 or newer approved), or the Charging Station and the patient simultaneously.

WARNING!
Only use the USB cable and the USB-C medical power supply provided by Optomed Oyj (Plc) with the Optomed Lumo Camera, Charging Station, or Desktop Base.

WARNING!
When operating within the patient environment, the USB cable must be connected only to the medical PC (IEC 60601-1:2012 or newer approved) or operated via a medical isolating transformer (IEC 60601-1:2012 or newer approved). Auxiliary units on the PC (e.g. printer, monitor) must be operated through a medical isolating transformer (IEC 60601-1:2012 or newer approved). Ethernet may only be used through galvanic isolation (IEC 60601-1:2012 or newer approved).

Optomed Oyj (Plc) does not provide either the PC or the isolating transformer. If a medical PC or medical isolating transformer is not available, the only data transfer option is a WLAN connection.

WARNING!
To avoid electric shock, do not plug in the power cord of the USB-C medical power supply if the cord has become frayed, pinched, or exposed. Contact Optomed Customer Service or an Optomed-certified service facility to receive a replacement USB-C medical power supply.

WARNING!
An additional multiple-socket outlet or extension cord is not allowed to be used.

WARNING!
Connect only items that have been specified as part of the medical electrical (ME) system or that have been specified as being compatible with the ME system.

See the chapter Patient environment and medical electrical system for more information.

WARNING!
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.

WARNING!
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.

WARNING!
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 Lumo, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING!
The available scientific evidence does not show that any health problems are associated with using low-power wireless devices. There is no proof, however, that these low-power wireless devices are absolutely safe. Low-power wireless devices emit low levels of radio frequency energy (RF) in the microwave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure to low-level RF that does not produce heating effects causes no known adverse health effects. Many studies of low-level RF exposures have not found any biological effects. Some studies have suggested that some biological effects might occur, but such findings have not been confirmed by additional research. CINDY2MWM1 has been tested and found to comply with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) exposure guidelines.

CAUTION!
The Optomed Lumo is intended for use inside, at 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. Do not expose the battery to direct sunlight for long periods.

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!
The connection between the camera and the PC is USB and/or WLAN. 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 your Optomed representative for repairs and maintenance work on the device.

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
- Acetone (nail polish remover)

CAUTION!
The Optomed Lumo is a precision optics instrument that should be handled with care. Please note the following cleaning instructions:

- Power off the device and remove the battery before cleaning.
- Remove the Charging Station and Desktop Base from the mains before cleaning.
- Remove attached USB cables from the Lumo Camera, Charging Station, and Desktop Base.
- Avoid touching the optics lens in the Lumo Camera unless cleaning it.
- Avoid touching system connectors in the Lumo Camera, Charging Station, and Desktop Base unless cleaning them.
- To ensure no moisture penetrates the system, use a dry or slightly moistened cleaning cloth. Let the device dry properly before use. Keep away from water.

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 using an Optomed-provided medical power supply when it is placed in the charging station, or inside a camera that is placed in a desktop base or with a directly attached power supply, or inside a camera that is placed in the Charging Station. Use of an unrecommended charger may cause battery fluid leakage, overheating of the battery, or an explosion of the battery.

CAUTION!
Use only the USB-C data cable, the batteries, and the USB-C medical power supply provided in the sales package. If you need a replacement for the USB cable, battery, or power source, please contact the manufacturer or your local distributor.

CAUTION!
The USB-C data cable is allowed to be connected only to the USB-A port of a PC that complies with the IEC 62368 (or older IEC 60950) standard.

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.

CAUTION!
If the Optomed Lumo is connected to a third-party AI service, the user must refer to the third-party AI manual to determine whether input images with burned-in data are supported. If burned-in data is not compatible, the user must disable the image markings in the camera settings.

CAUTION!
The user must check that the sent image does NOT have a poor image quality (such as poor contrast or out of focus retina) or artifacts on the lens. Low image quality or the presence of artifacts may compromise the performance of the AI.

CAUTION!
The user must check that the macula and the optics disc are clearly visible in the image when images are sent to a third-party AI service for analysis.

CAUTION!
The user must be aware of the intended use and intended patient population of the AI. Information about the AI service, its intended use and precautions/ contraindications can be found in the third-party AI manual.

CAUTION!
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

CAUTION!
When using an assistive AI algorithm (MDR Class IIa), the healthcare professional should always base their decision on their own interpretation and should not rely solely on the algorithm´s generated result.

CAUTION!
The user must be aware that abnormalities related to a disease or certain patient characteristics (such as retinal scars, birthmarks, etc.) might cause false positive detections.

CAUTION!
If the third-party AI service is unavailable, or if all images are assessed as ungradable, the patient should be referred to a physician for further evaluation.

Controls and connectors

Optomed Lumo camera

No.	Feature	Description
1	Speaker	The speaker gives a sound in the following situations: • The camera is powered on/off • An image is captured • The battery level is low • An USB-C to USB-A cable is connected/disconnected • The camera is placed in or removed from the charging station • The camera gives a notification Adjust or mute the volume in the Quick menu.
2	Power button	Power on the camera by pressing the button for more than 1 second. When the camera is in normal operation: • Go to power save mode with a press of less than 1 second. • Controlled power off with a press of more than 1 second • Forced power off with press of more than 5 seconds When the camera is in power save mode: • Return to normal operation with a press of less than 1 second. • Controlled power off with a press of more than 1 second • Forced power off with a press of more than 5 seconds

3	LCD touchscreen	A user can give input and control the camera by tapping the screen or pinching it to zoom.
4	Quick menu button	The camera Quick menu is opened by pressing the Quick menu button. The Quick menu contains: • Back to home • Log out • Power off • Ability to adjust the screen brightness and volume • Exiting a study
5	Quick menu LED	LED indicator of the Quick menu button: • Charging: White light on. When the battery is full, the light dims. • Power save mode: White light on • Fault state: Light blinks with orange and blue. • Camera out of the charging station: White light on
6	Reusable Eye cup	Helps in aligning the camera to the patient's eyes
7	Power/data port	Power: To charge the battery inside the camera, connect the camera to the mains with the USB-C medical power supply. Data: To transfer images to a medical PC, connect the camera to the medical PC with the USB-C to USB-A cable.
8	Shutter button	Press for image capture
9	Battery cover	Covers the battery compartment
10	Wrist strap bracket	Wrist strap mounting bracket

Screen indicators

Status of connection indicators on screen:

Connection disabled - Icon is not shown

Connection enabled but not connected – Line goes through icon

Connection enabled and connected - Icon is white

Status of battery indicators on screen:

Battery full

Battery low

Charging

Optomed Lumo charging station

No.	Feature	Description
1	System connector	Connects the camera to the charging station
2	Charging indicator LED	LED indicator to show that the spare battery is charging: • Light on: Spare battery charging • Light off: Battery full or no battery inserted • Light blinks: Fault state
3	Spare battery charging	Charge the spare battery by setting the battery connectors to match the charging station.
4	Data port	Port for data transfer via USB cable
5	Power port	To charge the battery, connect the charging station to the mains using the USB-C medical power supply.

First-time set-up

Part list and unpacking

The Optomed Lumo is packaged in a specially designed carry case, which includes the following items.

No.	Item	Description
1	Optomed Lumo Camera	A medical digital camera intended to be used to capture images of the human fundus
2	Optomed Lumo Charging Station	A dual charger used for charging the battery inside the camera and the spare battery
3	Battery (2 pcs)	Li-ion Rechargeable Battery
4	Wrist strap	Can be attached to the camera and put over the wrist to ensure safety if the device is dropped
5	Reusable eye cup (2 pcs) (applied part)	For aligning the camera to the eye (optional use)
6	Lens cover	Can be placed over the front lens to protect the lens from scratches and dirt when device is not in use
7	User Manual	Read the user manual before starting to use the device. Other language versions are available in the Optomed Portal.
8	USB cable	USB-C to USB-A cable to connect the charging station or camera to a medical PC.
9	Power supply	USB-C medical power supply (with 4 plugs) to connect the charging station or the camera to the mains. Use only an Optomed-provided power supply.
10	Cleaning cloth	A cleaning cloth for cleaning the front lens

It is recommended to save the shipping box and packing materials in case you need to store or ship the system.

CAUTION!
Only use the USB cable, battery, and power source provided in the sales package. If you need a replacement for the USB cable, battery, or power source, please contact the manufacturer or your local distributor.

Install wrist strap

Attach the wrist strap to the camera by sliding a part of the webbing through the wrist strap mounting bracket. Create a large opening to loop the rest of the webbing through. Slip the strap over your wrist and tighten the security slide to keep the strap firmly in place.

Battery and charging

Installation of the battery

Ensure that the camera is powered off when replacing the battery. Open the battery cover by sliding the battery cover release knob. The battery slots and arrow guide you to insert the battery in the correct direction. Insert the battery into the camera with the connector head first and press the cover firmly into place. Close the battery cover firmly.

Charging station preparations

1. Place the Optomed Lumo Charging Station on a solid, well-balanced surface next to the PC. The charging station must be outside the patient environment at a distance of at least 1.5 meters from the patient.
2. Attach the correct type of plug to the USB-C medical power supply.
3. Firmly connect the USB-C medical power supply to the power port of the charging station. Connect the USB-C medical power supply to the mains.

Hold the connector when pulling the cable out of the charging station, otherwise it might damage the cable.

WARNING!
Place the PC (not IEC 60601-1 approved) and Optomed Lumo Charging Station outside the patient environment at a distance of at least 1.5 meters from the patient.

Charging the batteries

When charging for the first time, charge the battery full. The light on the Quick menu button is on when the battery is charging. When the battery is full, the LED dims. In daily use, place the camera on the charging station for charging whenever it is not in use.

No.	Action	Description
1	Charging on the charging station	Connect the charging station to the mains using the USB-C medical power supply. The battery inside the camera and the spare battery start charging once the camera and the spare battery are placed on the charging station.
2	Spare battery charging	Set the spare battery connectors to match the charging station connectors and slide the spare battery in. The spare battery charging indicator LED on the charging station is on when the battery is being charged and is off when the spare battery is fully charged.
3	Direct charging	Connect the camera directly to the mains using the USB-C medical power supply. Once plugged in, the battery inside the camera starts charging. Direct charging does not prevent imaging while charging.

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

NOTE!
Check the connection of the cable in the charging station if the camera is not charging.

Power save mode

The Optomed Lumo Camera enters power save mode when placed on the charging station, after 2 minutes of no user action or by short pressing the power button. The camera then shows an info screen for 5 seconds, with date and time information and battery state.

The camera wakes up from power save mode when lifted from the charging station, or when the Power button, Shutter button, Quick Menu button, or touchscreen is activated. Without a power connection via a power cable or charging station, the camera will power off if not used within 30 minutes.

Placing the camera on the charging station

Place the camera on the charging station by first placing the front part of the camera on the supporting pins so that the pins sink into the slots in the camera. Then place the handle of the camera carefully onto the charging station.

Remove the camera from the charging station by lifting the front part of the camera module from the supporting pins. Excessive force should be avoided to prevent the camera and the charging station connectors from breaking.

User hierarchy

The camera's user hierarchy has two levels: Admin and User. The first Admin is created during the camera's first-time use sequence. Compared to an Admin, a User's rights are limited.

In addition to User rights, an Admin is able to:

- create and delete Admins and Users
- set a PIN code on/off (a PIN code is mandatory for an Admin)
- reset PIN codes for all users
- send logs and export audit logs
- back up and restore system data
- restore factory settings
- receive notifications of a new software version and update the software
- view and clear data for all users
- configure the DICOM connection for the camera
- change region settings

First-time use sequence

When starting the camera for the first time, the user is guided through the first-time use sequence to create an Admin and define the basic settings for the camera.

1. Select language

The user interface language is user-specific.

Supported languages are: English (default), Finnish, French, German, Italian, Norwegian, Portuguese, and Spanish.

The keyboard language can be changed by clicking when the keyboard view is open.

2. Register in the Optomed Portal

It is highly recommended to register the camera in the Optomed Portal. To register your camera, go to **portal.optomed.com**. See the chapter *Optomed Portal*.

3. Select region

Alternative regions are: Australia, Bahrain, Brazil, Canada, China, European Union, India, Indonesia, Israel, Japan, New Zealand, Russia, Singapore, South Africa, South Korea, Taiwan, Turkey, United Kingdom, United States, Vietnam, and Rest of the world.

The region can only be changed by an admin.

4. Create Admin and Users

The number of admins and users is not limited. Define the admin and add more admins and users by defining a user type and PIN code for each new user. See more information in the chapters *User hierarchy and PIN code and Two-factor authentication*.

5. Define integrations

See the chapter *Data transfer options*.

Note! If you want to transfer images to a PC or mobile device, install Optomed Client (see the chapter *Data transfer SW*)

6. Set date and time

Use the network-provided time and date for automatic time and date setting if an internet connection is available. Turn this off to set the time manually. (Network-provided time selection is recommended.)

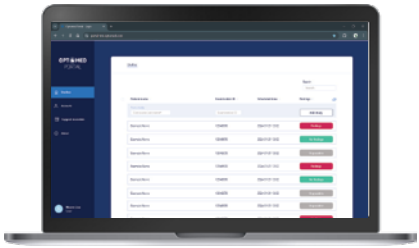
More information about the selections can be viewed by pressing the (?)-sign on the camera screen.

When the first-time use sequence is completed successfully and preparations for the Charging Station and USB-C medical power supply are done, the camera is ready to start a study.

Find the quick guide to imaging on the back cover of the user manual.

Optomed Portal

The Optomed Portal is a web application that enables



- access to features such as a worklist function, two-factor authentication, password reset, log file download, and software update
- downloading the Optomed Client
- viewing and downloading user guides
- administrating Cloud service
- connecting the Optomed Lumo Camera and a third-party AI service provider. Accessing AI service via the cloud is only available in certain market areas. Third-party AI services deployed in Europe are CE certified.

NOTE!
The portal is not intended for storing patient information. Export the reports and images to a safe location.

A network connection is required to use the application.

It is highly recommended to register the camera in the Optomed Portal. To register your camera, go to **portal.optomed.com**

PIN code and two-factor authentication

The user can protect the device and its data by setting a PIN code and requiring an additional authentication (two-factor authentication) every time a user logs in. Protecting the data with a PIN code is highly recommended.

PIN code

A PIN code is mandatory for Admins and optional for Users. The user must enter a four-digit code to log in when PIN code is enabled. The user is automatically logged out if they are inactive for 30 minutes.

An Admin enables and sets a PIN code when adding new users. It is recommended for the user to change it after their first login. In the case of a forgotten PIN code, an Admin may reset the PIN code to enable a new login by selecting the user from the user list and choosing Reset PIN code.

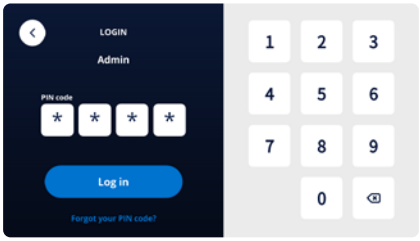
NOTE!
A PIN code is highly recommended due to the higher level of data security.

Two-factor authentication

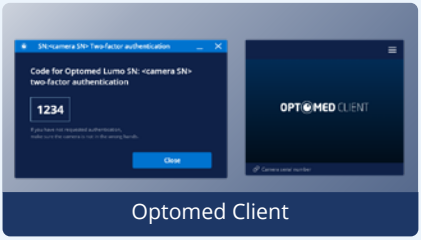
Secure the device and patient data by requiring an additional authentication method every time user logs in. Authentication is done via the Optomed Portal or data transfer SW

Two-factor authentication process:
The user is guided to verify login via either the Optomed Portal or the Optomed Client, depending on which connection is created and available. Enable two-factor authentication in the system of your choice. If the WLAN connection is not in use, create a USB connection to the Optomed Client by placing the camera on the charging station.

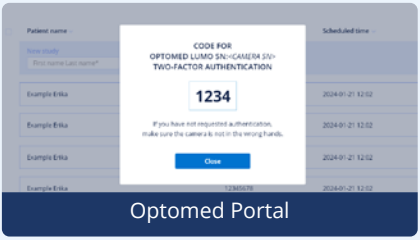
1. Log in to the Optomed Portal or open the Optomed Client.
2. Power on the camera, select a user, and when the login screen opens, enter your PIN code.



3. Select Send verification link. The verification query is screened at the Optomed Portal or Optomed Client, depending on which connection is created.

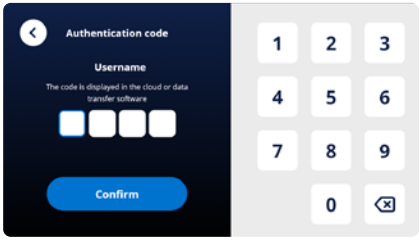


Optomed Client



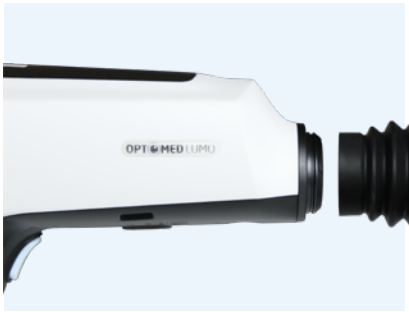
Optomed Portal

4. Enter the verification code from the Optomed Portal or Optomed Client on the camera. When the code is successfully entered, the home view opens.



Eye cup

It is recommended to use the eye cup with the Optomed Lumo Camera to help align the camera to the patient´s eye. Place the reusable eye cup by firmly pressing the eye cup to the optics ring of the camera.



To avoid the risk of contamination, clean the eye cup before each use. For more information about cleaning, see the chapter *Maintenance - Cleaning.*

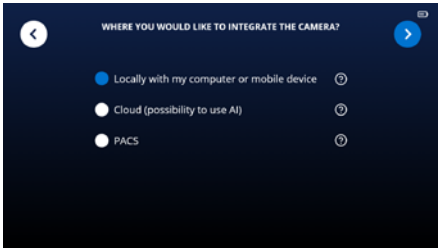
If a replacement for the eye cup or additional disposable eye cups (E-safe Disposable Eye Cups) are needed, contact Optomed Customer Service or your local distributor.

The reusable eye cup should be replaced when:

- Discolored
- Deteriorated
- Shattered, cracked, or disintegrated
- Hardened

Data transfer options

The user is guided through the first-time use sequence to define the data transfer method and integration with other systems. The settings may be changed later in the Connections menu.



Data transfer options

Integration method	Connection type	Description
Locally with my computer or mobile device	WLAN/AP*/USB	By connecting the camera to a computer or mobile device, the studies are sent to the selected device via data transfer SW such as Optomed Client. The connection enables a worklist function, two-factor authentication, password reset, log file download, and software update from the computer/mobile device to which the update package was downloaded from the Optomed Portal. To connect locally, install the data transfer SW.
Cloud	WLAN	By connecting the camera to the cloud, studies can be sent to third-party artificial intelligence for analysis. The connection enables a worklist function, two-factor authentication, password reset, log file download, and software update through the Optomed Portal.
DICOM	WLAN	By selecting DICOM, the camera can receive worklists and send studies to the PACS system in DICOM format. The DICOM interface requires a WLAN connection. Enable two-factor authentication, password reset, and log file download by establishing a local connection to your computer or mobile device by installing data transfer SW such as Optomed Client.

*AP = access point

Some connection settings are camera-specific, and some are user-specific. The WLAN connection settings are saved for all camera users, but cloud settings are user-specific, for example. The camera and user-specific connection settings are presented in the table below.

Data transfer settings

Integration method	User-specific settings	Camera-specific settings
Locally with my computer or mobile device	Optomed Client login details and settings	USB WLAN AP
Cloud	Optomed Portal login details and settings	WLAN
DICOM	-	WLAN DICOM*

*Can only be configured by an Admin

Connections

A data transfer method shall be defined to integrate with other systems (cloud, data transfer SW, or DICOM). Connection options for data transfer are WLAN, access point, and USB. Integration-specific connection options are presented in the chapter *Data Transfer Options.*

WLAN and access point connections are defined in the camera´s Connection menu. A USB connection does not require any settings to be defined in the camera.

After connection configuration is done and the connection is successful, it is possible to enable and disable the connection by clicking the switch.

The status of the defined connection is shown in the upper right corner of the screen and in the Connection view.

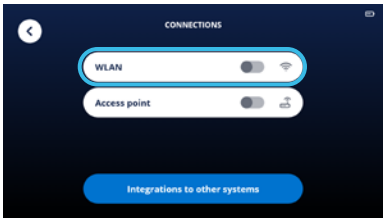
Status of connection icons:

- Connection disabled - Icon is gray
- Connection enabled but not connected - Line goes through icon
- Connection enabled and connected - Icon is green

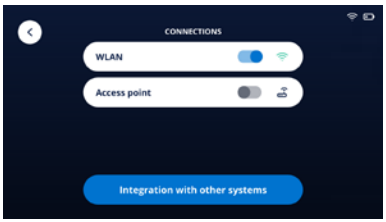
WLAN

Create a WLAN connection for transfer data wirelessly to the cloud via the Optomed Portal, to the PC via the Optomed Client, or to DICOM services such as remote storage and worklist.

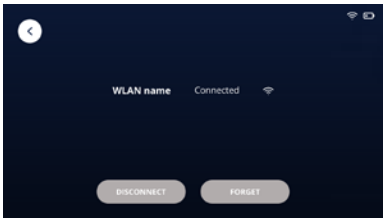
1. Select *WLAN* from the Connection menu. The system starts searching for available networks. When the search is finished, the Select WLAN view opens with a list of available network options.
2. Select the desired network from the list of available networks or select a hidden network by selecting Other. (If Other is selected, the user manually enters the network SSID and password.)
3. Fill in the network password (if required)
4. Select *Connect*
5. When a WLAN connection is created successfully, a pop-up message with "Connected to WLAN NAME" shows in the top right corner of the screen.



If connection settings are set earlier, the connection can be enabled by clicking the switch in the Connections menu or by opening the Select WLAN view and clicking *Use WLAN.*



Disable the connection from the Select WLAN view by selecting *Disconnect*. If you select *Forget*, the network password is erased from the device´s memory.



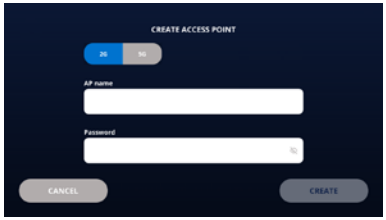
NOTE!
It is recommended to use a password-protected WLAN network.

NOTE!
The selected region can affect the available WLAN channels.

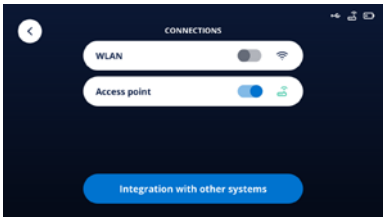
Access point

Create an access point to transfer data to a PC without an available WLAN network or USB connection. WLAN and access point cannot be enabled at the same time.

1. Select *Access point* from the Connection menu. The access point view opens.
2. Select between *2G* or *5G*
3. Enter a freely chosen name and an eight-character password.
4. Select *Create*
5. When an access point connection is created successfully, a pop-up message with “Access point created“ shows in the top right corner of the screen.
6. Connect the computer to the network created by the camera.



If connection settings are set earlier, the connection can be enabled by clicking the switch in the Connections menu or by opening the access point view and clicking *Create*. The connection can be disabled from the access point view.



USB

USB enables direct data transfer to a PC via the Optomed Client. Using the USB connection to transfer data does not require any selection in the camera.

a

b

1. Connect the camera
   a. directly to a medical PC using the USB-C to USB-A cable (see the chapter Patient environment and medical electrical system)
   b. to a PC via the charging station using the USB-C to USB-A cable
2. When the USB connection is successfully established, the USB icon appears in the upper right corner of the screen.

Disable the connection by disconnecting the USB cable.

WARNING!
When operating within the patient environment, the USB cable must be connected only to the medical PC (IEC 60601-1:2012 or newer approved) or must operate via a medical isolating transformer (IEC 60601-1:2012 or newer approved). Auxiliary units on the PC (e.g., printer, monitor) must be operated through a medical isolating transformer (IEC 60601-1:2012 or newer approved). Ethernet may only be used through galvanic isolation (IEC 60601-1:2012 or newer approved). Optomed Oyj (Plc) does not provide either the PC or the isolating transformer. If a medical PC or a medical isolating transformer are not available, the only data transfer option is a WLAN connection.

NOTE!
If a medical PC is not available, one option is to use wireless data transfer or to operate via a medically approved isolating transformer.

NOTE!
Data transfer to a PC via USB requires Optomed Client installation.

NOTE!
Check the connection of the cable in the charging station if the USB connection is not working.

NOTE!
Excessive force should be avoided to prevent the USB-C cable connectors from breaking.

Integration with other systems

Integrations with other systems define where studies are sent. The Optomed Lumo can be integrated either into the cloud (Optomed Portal), data transfer SW (Optomed Client), or DICOM. Integration-specific connection options are presented in the table Data Transfer Options.

The status of the defined integration is shown in the upper right corner of the screen and in view of integration with other systems.

Status of integrations icons:

- Connection disabled - Icon is gray
- Connection enabled but not connected – Line goes through icon
- Connection enabled and connected - Icon is green

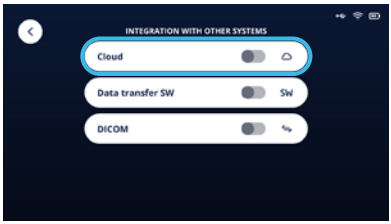
Other connections, apart from data transfer SW and DICOM, cannot be enabled at the same time. If these two options are enabled at the same time, DICOM is used for the worklist function and study transfer, and data transfer SW is used for two-factor authentication, password reset, software update, and log file download.

After integration configuration is done and a connection has been created successfully, it is possible to enable and disable the connection by clicking the switch. A new integration can be configured or a predefined integration enabled by disabling the existing one by clicking the switch.

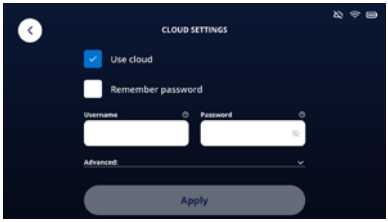
Cloud

A WLAN connection is required for using Cloud (Optomed Portal). By connecting the camera to the cloud, studies can be sent to third-party artificial intelligence for analysis. The connection also enables a worklist function, two-factor authentication, password reset, log file download, and software update through the Optomed Portal. Cloud connection is user-specific.

1. Register for the Optomed Portal (see the chapter *Optomed Portal*)
2. Select *Cloud* in the Connection menu/ Integration with other systems
3. If not done during first-time use
   a. Create/enable a WLAN connection (see the chapter *Connections*)
   b. Check that the time and date settings are correct in the camera



4. Fill in a Cloud username and password
    - Enter the Optomed Portal username and password as Username and password
5. Fill in advanced information: server address and port
    - Find the server address and port from the Optomed Portal About page



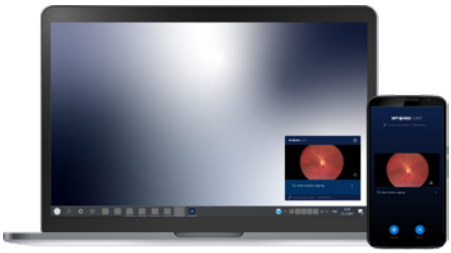
6. Press the Apply button. The button turns green when the connection is established. If the button turns red, check the connection settings.

NOTE!
Connecting the camera to a third-party AI service via the cloud service requires establishing the connection by Optomed. The camera is not directly connected to the AI service. Accessing third-party AI services via the cloud is only available in certain market areas and is purchased separately. Send an inquiry to Optomed Customer Service or your local distributor for more information.

Data transfer SW

Optomed Client

Studies can be sent to a computer or mobile device using data transfer SW (Optomed Client).



In addition to image transfer to a computer or mobile device, Optomed Client enables access to features such as a worklist function, two-factor authentication, password reset, and log file download and software update from the computer or mobile device to which the software update package was previously downloaded from the Optomed portal.

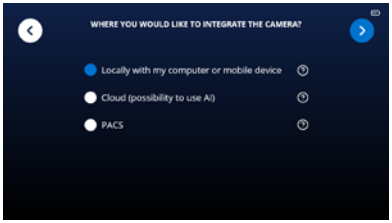
Use a WLAN, USB or access point connection method to create a connection between the camera and the data transfer SW. Installation of the Optomed Client software is, in this case, mandatory. Install Optomed Client from the Optomed Portal or from a mobile device-specific store.

Optomed Client preconditions

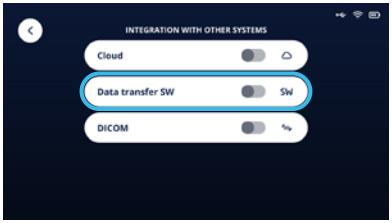
1. Install the Optomed Client software on a PC, tablet, or mobile phone. Refer to the Optomed Client User Manual for more instructions.
2. Open Optomed Client and configure the initial settings in the first-time use sequence or in Settings.
   - Create a username and password for the Optomed Lumo connection and select *Apply*
   - Select *Start pairing*

Pair Optomed Lumo and Optomed Client

3. Define the integration method
   a. Select *Locally with my computer or mobile device* in the camera's first-time use sequence. Follow the first-time use sequence to configure the connection and date and time settings.



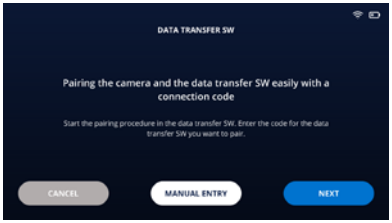
   b. Select Data transfer SW in the Connection menu/Integration with other systems. The following must be done before creating the connection to the data transfer SW:
      - Create/enable a WLAN, access point or USB connection for the camera (see the chapter *Connections*)
      - Check that the time and date settings are correct in the camera



4. Pair the camera and Optomed Client by following the pairing with a connection code procedure. Select *Next*.

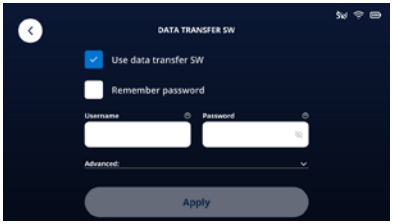
   Note! The workstation IP address can also be entered manually by selecting *Manual entry*.

   Note! Optomed Client must be in Pairing mode in both cases.



5. Enter the Optomed Client username and password created in Optomed Client.
6. Use the default Port value.

   Note! If the value is changed, it must also be changed in Optomed Client.
7. Press the Apply button. The button turns green when the connection is established.

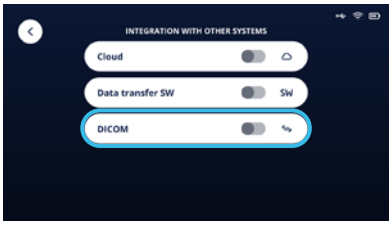


DICOM

Connect the Optomed Lumo to DICOM services such as remote storage and worklist via WLAN. By connecting the camera to the DICOM services, the camera can receive worklists and send studies in DICOM format to the PACS system. When the DICOM connection is configured, studies will be automatically sent to PACS.

Only an Admin is allowed to edit and view DICOM settings. If DICOM integration is established by the first Admin, the rest of the users cannot select any other integration option. Other options are disabled. The user can set DICOM on/off, choose a worklist date range, and test the DICOM connection using the Apply button.

1. Select *DICOM* in the Connection menu/ Integration with other systems
   - Camera AE title (automatically filled, can be changed according to customer needs)



2. If not done during first-time use
   a. Create/enable a WLAN connection (see the chapter *Connections)*

3. Select *Remote storage* and fill in the information about the remote storage
   - Remote AE title for storage
   - Remote IP address for storage
   - Port for storage
   - Modality (automatically filled, can be changed according to customer needs)

4. Press the Apply button. The button turns green when the connection is established.
5. Go back with the back button and select *Worklist*. Fill in connectivity information
   - Remote AE title for worklist
   - Remote IP address for worklist
   - Scheduled station AE title
   - Modality (automatically filled, can be changed according to customer needs)
   - Port for worklist

6. Press the Apply button. The button turns green when the connection is established.

NOTE!
Enable two-factor authentication, password reset, log file download, and software update by establishing a local connection to your computer or mobile device by installing data transfer SW such as Optomed Client.

Install the Optomed Client software on your computer or mobile device. See the Optomed Client User Manual and the chapter *Data Transfer SW* for more instructions.

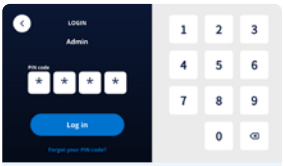
Using the Optomed Lumo

Camera startup and log in

** When a user logs in for the first time, the PIN code is recommended to be changed.*

Press the power button for more than 1 second to power on the camera.

Select a username.



Enter the personal PIN code (optional).*

NOTE!
Do not hold down the shutter button while the camera is powering on.

Home view

The home view is shown after the startup procedure.

Home view functions

No.	Function	Note
1	Start new study	Start a new patient study by defining the patient information, or select a study from an imported worklist
2	Open Archive	The archive contains all the studies done by the logged-in user. A list of studies is shown with date, name, and status information. notifies that there are unsent files in the archive
3	Open Connections	View and change connection settings such as WLAN, AP, Cloud, Data transfer SW, and DICOM (see the chapter *Data Transfer Options* for more information)
4	Open Settings	View and change camera settings such as general and user settings, clear data, update software, and restore factory settings (see the chapter *Camera settings*). indicates that there is a software update available

The Quick menu is opened by pressing the Quick menu button.

The Quick menu includes some of the following, depending on the camera status:

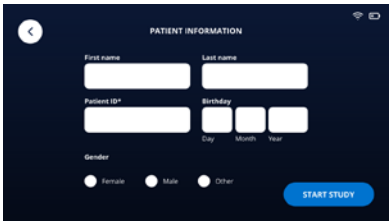
- Back to home
- Log out
- Power off
- Ability to adjust the screen brightness and volume

Start new study

It is necessary to create a new study for each patient. A new study is created by selecting *Start new study* in the Home view. This can be a new patient study or a study from an imported worklist.

New patient

Fill in the patient information. The only mandatory information is the patient ID. The camera opens the Live view for imaging by selecting *Start study*.

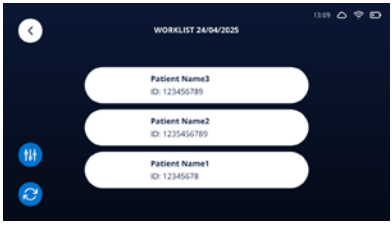


NOTE!
Do not use the same patient identifier for multiple patients when manually entering patient information. This may result in inaccurate data association. A social security number is not recommended to be used as a patient ID.

NOTE!
Take caution when manually inputting the patient ID to prevent data inconsistencies or misidentification.

Worklist

A study can also be started using a worklist that is downloaded to the camera through either a DICOM, Optomed Client or Optomed Portal connection. The worklist is common for all users, so it is visible for all user levels.

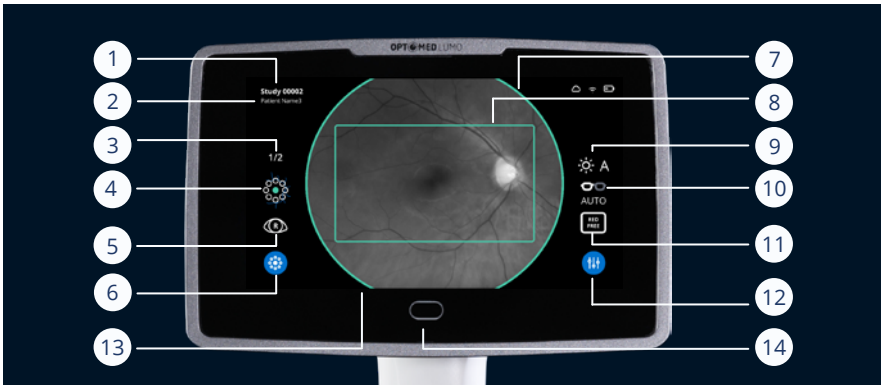


1. Search for a patient from the list for the current date, or modify the date range by clicking the icon and then unselecting “Search list for current date”.
2. Select the patient from the worklist. The camera goes automatically to Live view after selecting a patient.
3. The study will be removed from the list when it is completed.

The existing list is replaced with a new imported worklist when the user clicks the Refresh button. The existing list is erased only when a new list is successfully received or if the worklist is deleted in clear data selection.

See the Optomed Client or Optomed Portal User Manuals for more information on how to use worklist functions using these products.

Live view



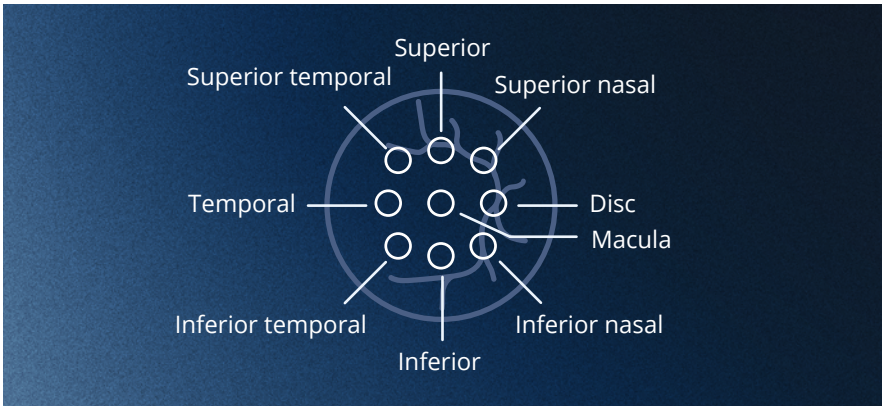
No.	Function
1	Study number
2	Patient name
3	Image number of the sequence
4	Fixation target
5	Eye side
6	Imaging sequence - press to redefine
7	Aim help
8	Focus window
9	Exposure type and possible value (AUTO=automatic, value=manual)

10	Focusing mode and possible value (AUTO=automatic, value/value=diopter values for manual focusing)
11	Red free image copy (if enabled)
12	Imaging settings - press to redefine
13	The view through the optics
14	Exit Live view

Imaging sequence

The Optomed Lumo Camera has nine internal fixation targets for the patient to fixate during imaging.

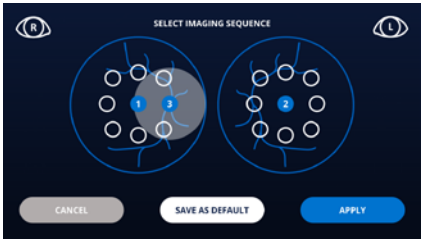
The user can define their own imaging sequence by selecting the fixation target(s) per eye(s). The camera will guide the user to take images based on the defined sequence. Macula-centered images of both eyes are selected as the default sequence.



Setting an imaging sequence

Select the desired fixation targets for both eyes to create an imaging sequence.

- A blue dot with a number indicates the selected fixation target and its position in the imaging sequence.
- Blood vessels in the icon and the indicators in the top corners indicate the side of the imaged eye.
- The middle fixation target provides a macula-centered image.



The user can select and deselect each area and change the order and number of images by clicking on the location of each target. At least one target needs to be chosen. When a certain area is chosen, an approximation of the imaged area is shown in gray for a couple of seconds.

Apply Confirms the changed settings for the current study.

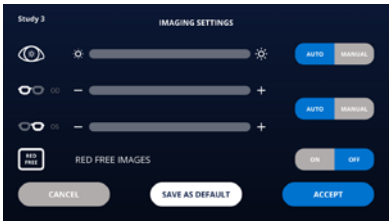
Save as default Saves the changed settings as the default for all studies onwards for the logged-in user.

Cancel Cancels the action and no changes are saved.

Pressing Cancel, Save as default, or Apply returns to Live view, which allows the image capture.

Imaging settings

The menu is for selecting imaging settings.



Brightness

Imaging brightness (exposure) can be adjusted automatically or manually. In auto exposure mode, the Optomed Lumo Camera adjusts the image brightness automatically. Auto exposure is set as a default.

To adjust the brightness manually, choose manual mode for the brightness. In manual mode, the scale is from –10 to +10. The default value is 0.

- For adult patients with blue or green eyes, the right setting is approximately from -2 to 0.
- For adult patients with brown eyes, the right setting is approximately from 1 to 3.

Select a suitable value with the slider and press *Accept* to confirm the setting.
If images are too bright, it is possible to reduce the brightness below 0. Conversely, the brightness can be increased up to 10 if images are too dark.

Focus

Focusing can be done automatically or manually. In autofocus mode, the camera finds the correct focus automatically on a scale of -15 to +10 diopters. As a default, focusing is set to Auto, which is recommended.

To adjust the focus, choose manual mode for focusing. Manual focus is adjusted according to the patient's refractive error, between –20 and +20 diopters.

- When the patient has hyperopia, set the focus to be positive by sliding the scale to the right.
- When the patient has myopia, set the focus to be negative by sliding left towards the minus values.

Red free image

A red free (grayscale) copy of the color image can be saved in addition to the color image. Only the green color channel information for the image is used when red free image is enabled. To save only the original image, select *OFF*, which is also the default setting. If red free image copy is enabled, a red free icon will appear below the Spectacles icon in the Live view.

After configuring the imaging settings, select the desired option:

Accept Confirms the changed settings for the current study.

Save as default Saves the changed settings as the default for all studies onwards for the logged-in user.

Cancel Cancels the action and no changes are saved.

Pressing Cancel, Save as default, or Apply returns to the Live view, which allows the image capture

Image capture

Preparations

Dim the lights in the examination room for imaging.

Clean the eye cup before each patient or use disposable eye cups.

Imaging position

It is recommended that both the patient and the examiner are seated during the examination. The patient, camera, and examiner should be aligned in a straight line. It is also possible to perform the examination when both the examiner and patient are standing, or the patient is lying down while the examiner stands.

To achieve the most stable imaging position, get close enough to the patient and avoid unnecessary reaching. Take a firm grip on the camera handle with one hand, so that you can press the shutter with your index or middle finger. Stabilize the camera with the other hand by supporting the front part of the camera on your thumb, and place your fingers on the patient's forehead.

To avoid unnecessary muscle strain, keep your back straight and your shoulders down. You may also brace your arms against your body to help keep the imaging position steady. When imaging for long periods of time, take breaks as needed. The image above shows an ergonomic imaging position when both the patient and the examiner are seated.

Instructions for patients

- Ask the patient to remove their glasses. Contacts can remain in place.
- Ask the patient to cover the other eye but keep both eyes wide open.
- Ask the patient to keep their eye aligned to the fixation target and hold their head still.

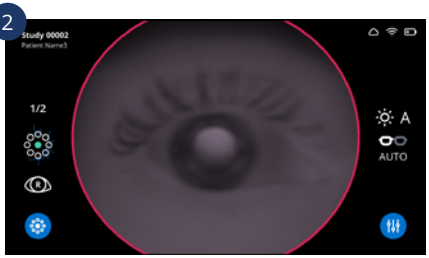
Positioning the camera

1

Approach and center the pupil from 5-10 cm distance and press the eye cup firmly around the eye.

Stabilize the camera by supporting the front part of the camera on your thumb, and place your fingers on the patient's forehead.

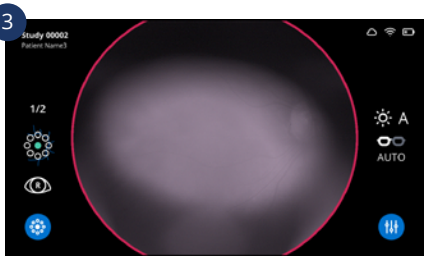
2



Approach the gray oval reflection at the top of the pupil until the retina appears fully on the screen.

The right imaging distance is about 2 cm (0.8 inch) from the surface of the eye to the lens of the camera.

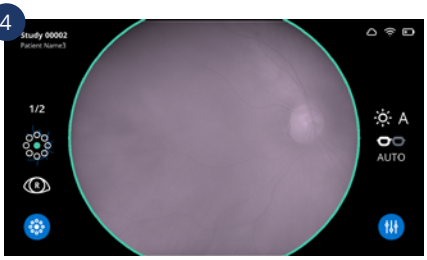
3



When the aim help is red, the retina is not yet in full view. Make micro adjustments with your front hand to fine-tune the aim.

The aim help guides the user to approach the retina and align the camera so that the full view of the retina is shown on the screen and a successful image can be captured.

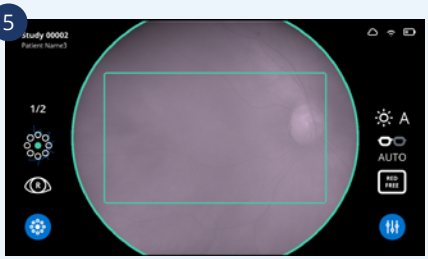
4



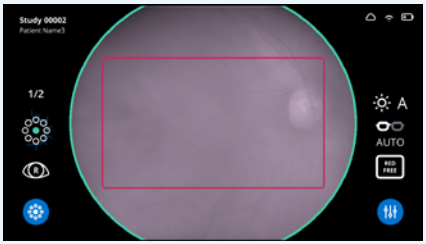
The aim help turns from red to green when aiming alignment is good and when the camera detects the retina in full view.

Image capture/autofocus

5



Autofocusing starts when the aim is successful (the aim help circle is green). Successful autofocus is indicated to the user by showing a green rectangle on the screen.



Unsuccessful autofocus is indicated to the user by showing a red rectangle on the screen. Autofocusing starts automatically again when the aim is successful.

6

When autofocus is successful, press the shutter button to capture an image.

If the shutter button was pressed before autofocusing was completed, an image is captured after autofocusing is finished, regardless of whether it was successful or not.

Image capture/manual focus

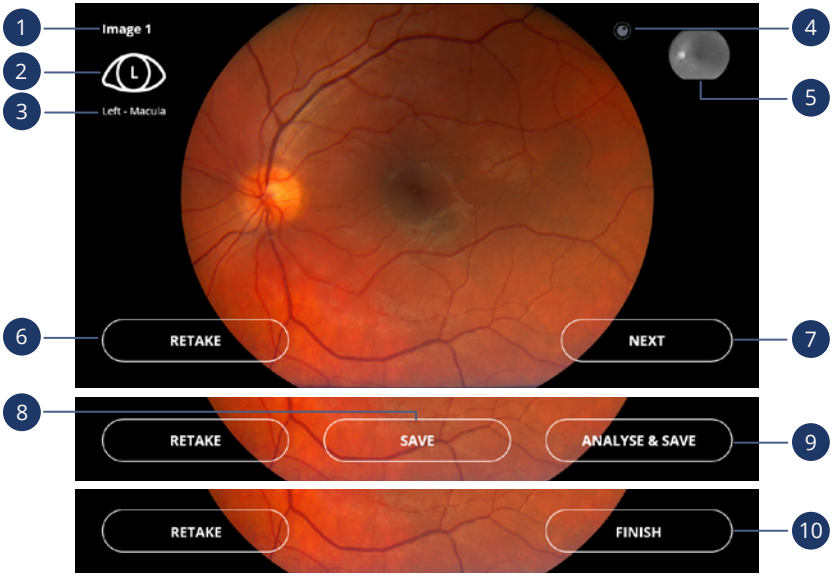
5

Press the shutter button to capture an image when the aim help circle is green.

Instant preview

After capturing an image, the instant preview is shown on the camera display. The image is zoomed in by pinching out and zoomed out by pinching in. The user can move around the viewing area using finger movements on the screen and can return to the instant preview by pinching in.

Previous images of the sequence are viewed by swiping the screen (when not zoomed).



No.	Function	Note
1	Image counter	Individual ID of an image file (sequence number of the image)
2	Eye side	R for right eye, L for left eye
3	Left – Macula	Information of the eye side and fixation target. Options: • Right/Left • Macula/Superior/Superior nasal/Disc/Inferior nasal/ Inferior/Inferior temporal/Temporal/Superior temporal
4	Optomed logo	A directional watermark in the picture
5	Red free image	A thumbnail of the red free image if available. Tap to open.

Options for available buttons in the instant preview window depend on the order number of the captured image and whether a cloud connection (AI) has been enabled:

No.	Function	Note
6	Retake	Capture the same image in the sequence again. The current image can be saved as a backup if desired (a notification is given to the user). Live view opens.
7	Next	Accepts the image taken. Continue to capture the next image in the imaging sequence. Live view opens.
8	Save	After the last image in the sequence is taken, select *Save* to save captured images in the study to Archive. The home view opens.
9	Analyze	When a cloud connection (AI) has been enabled and the last image in the sequence is taken, select A*nalyze* to send accepted images to AI for analysis. If there are several versions of the same image, the user is guided to select one for AI analysis. After the data analysis, the AI result pops up on the camera screen. All captured images from the study and the AI result are saved to Archive. Press *Close* to return to the home view.
10	Finish	After the last image in the sequence is taken, select *Finish* to accept the last image in the sequence and save all captured images in the study to Archive. The home view opens.

By pressing the Shutter button, the image is accepted, and the camera continues to capture the next image in the imaging sequence. Live view opens.

Saving and image transfer

All captured images in the study are saved to Archive. Images are also sent to a predefined location if the connection is available:

- Images are sent automatically to Optomed Client if a WLAN connection is available and Optomed Client configuration is done. Images can also be transferred to Optomed Client via USB when the camera is placed on a charging station or desktop base, or when the camera is connected to a medical PC via a USB-C to USB-A cable.
- Images are sent automatically to AI if WLAN and cloud connections are available and Optomed Portal configuration is done. If a WLAN connection is not available during imaging, images can be sent to artificial intelligence later from the archive. In this case, the number of images must be sufficient for the artificial intelligence used.
- Images are sent automatically to PACS if a WLAN connection is available and PACS configuration is done.

See the chapter *Data transfer options* for more information.

NOTE!
The camera is not intended for storing patient information. Export studies to a safe location.

NOTE!
If image transfer fails or transferred images are corrupted, they can be found in Archive. Please try again to send images to the PC via USB.

Archive

The completed studies, as well as related images and AI results, can be viewed in Archive. Images can also be sent to AI from Archive, if the AI connection is configured. Archive is entered from the home view.

The archive contains all the studies done by the logged-in user. A list of studies is shown with date, name, and status information.

Indicator	Note
	The study has been sent to remote storage
	The study has not been sent to remote storage
AI	Study has been analyzed by AI

Studies can be opened by clicking the corresponding study row. Study information and a thumbnail list of images are shown.

No.	Function	Note
1	Open image	View an image by clicking on the thumbnail. A red free copy (if available) can be viewed by opening a color image and clicking the thumbnail image of the red free copy.
2	Trash can icon	Deletes the whole study when study information is open. It is also possible to delete an individual image using the trash can button when its thumbnail image is opened.
3	Resend	Send images to remote storage

The image can be opened for viewing by clicking on the thumbnail. The list of other available images is shown in the right side (eye icons with either R for right or L for left eye). Switch between preview images by swiping (up/down) or clicking the eye icons.

No.	Function	Note
1	Red free image	Open a red free image from the thumbnail in the upper right corner (if available)
2	Zoom	Zoom in by pinching out, zoom out by pinching in. Move around the viewing area by moving two fingers on the screen.
3	Trash can icon	Delete an image using the trash can button. **Note!** If the image is part of an analyzed study, the whole study needs to be deleted instead of a single image.

AI analysis (optional)

The Optomed Lumo Camera can be connected to the Optomed-provided Cloud, which provides access to third-party screening services using artificial intelligence (AI). Accessing AI service via the cloud is only available in certain market areas. Third-party AI services deployed in Europe are CE certified.

AI services are additional features that are available separately. After purchasing the service, Optomed connects the camera to the selected AI service. Send an inquiry to Optomed Customer Service or your local distributor to purchase the service.

CAUTION!
The user must be aware of the intended use and intended patient population of the AI. Information about the AI service, its intended use, and precautions/ contraindications can be found in the third-party AI manual.

NOTE!
The camera sends the original color images to the AI service. The user cannot edit the images before sending.

AI analysis right after imaging

- Send images to the AI service after the image sequence is completed in instant preview by selecting *Analyze*.
- If there are multiple images for the same fixation position(s), select which images are sent to AI.
- The AI result appears on the camera screen after the analysis result is available and is found later from the archive by selecting *Analysis Result*.

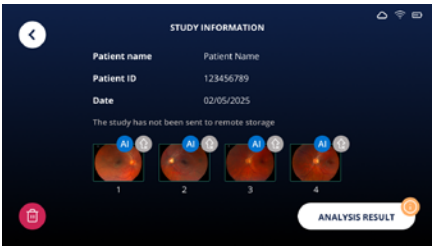
AI analysis from the archive

- Send images to the AI service later, from the archive, by opening the desired study in the study list.
- Select *Analyze*.
- If there are multiple images for the same fixation position(s), select which images are sent to AI.
- The AI result appears on the camera screen after the analysis result is available and is found later from the archive by selecting *Analysis Result*.

CAUTION!
The user must check that the sent image does NOT have a poor image quality (such as poor contrast or out of focus retina) or artifacts on the lens. Low image quality or the presence of artifacts may compromise the performance of the AI.

CAUTION!
The user must check that the macula and the optic disc are clearly visible in the images when images are sent to a third-party AI service for analysis.

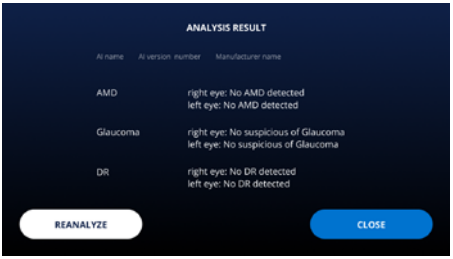
CAUTION!
If the Optomed Lumo is connected to a third-party AI service, the user must refer to the third-party AI manual to determine whether input images with burned-in data are supported. If burned-in data is not compatible, the user must disable the image markings in the camera settings.



Icon	Description
AI	Indicates that the study has been analyzed by AI
ANALYSIS RESULT	Indicates that there is something to view: • There are findings by AI or • The study was ungradable by AI
ANALYSIS RESULT	Indicates that there are no findings by AI

AI result

The complete third-party AI result report can be viewed in the Optomed Portal and a summary of the report on the camera. The third-party result is presented on the screen as it comes from the service provider and is not modified by the camera or the cloud service. AI results are reported for both eyes separately for each available indication.



More information about the AI result and its meaning can be received from the third-party AI service provider and the AI user manual. If the result is not received or the camera gives an error message, the connection or the third-party AI service is not available. In such a case, the data is not lost, and the images can be sent to the AI service later from the archive. Check the connection settings and if the problem persists, contact Optomed Customer Service.

CAUTION!
The user must be aware that abnormalities related to a disease or certain patient characteristics (such as retinal scars, birthmarks, etc.) might cause false positive detections.

CAUTION!
When using an assistive AI algorithm (MDR Class IIa), the healthcare professional should always base their decision on their own interpretation and should not rely solely on the algorithm´s generated result.

CAUTION!
If the third-party AI service is unavailable, or if all images are assessed as ungradable, the patient should be referred to a physician for further evaluation.

Reanalyze

- It is possible to run the analysis again by selecting *Reanalyse* in the Analysis result view, if some images did not yield a result.
- The user can then choose another image of the same fixation target for analysis by selecting the image from the thumbnail list of images and selecting *Send*. The analysis result view opens with a new report.

Camera settings

The camera settings can be viewed and changed in Settings. Settings can be accessed from the home view. The settings views for an Admin and User differ from each other.

User

Admin

General settings	
Language	Select the language of the user interface. Options: English (default), Finnish, French, German, Italian, Norwegian, Portuguese and Spanish . Language settings are user specific.
Region (only for Admin)	Select a region from the list. The selected region affects the availability of usable WLAN channels and can only be changed by an admin. Options: Australia, Bahrain, Brazil, Canada, China, European Union, India, Indonesia, Israel, Japan, New Zealand, Russia, Singapore, South Africa, South Korea, Taiwan, Turkey, United Kingdom, United States, Vietnam, and Rest of the world.
Time and date	Change the time and date. Use network-provided time and date for automatic time and date setting if a WLAN connection is available. Turn network-provided time and date off to set time manually; choose 12- or 24-hour format and set the date and time. Network-provided time selection is recommended.
Image markings	Enable the patient ID and/or side mark of the imaged eye to be burned to exported images. Both settings are set off by default. Image markings settings are user specific.

Admin settings

Admin settings (available only for Admin)

Users	Manage existing users and view user information by selecting a username from the list. It is mandatory to have at least one Admin-level user.
Logs	Send system logs to Optomed (for example, in a case of malfunction) or export audit logs to enable monitoring and tracking access to protected health information.
Add new user	Add a new Admin or User by filling in their user information.

System (available only for Admin)

About device	General information about the device (product model, SW version date, optics FW version, AF FW version, MAC address, IP address, licenses, and amount of free space in Archive (%)).
Software update	Update the software version or return to the previous software version installed in the camera.
Save system settings	It is possible to back up the current system settings data (excluding studies) to the camera. This can be done manually (Manual save) or scheduled to be daily/weekly/monthly/never (Schedule saving). It is also possible to restore the previous system data from a created backup by selecting the desired version and selecting *Restore*. The user can roll back only to saved system settings that are compatible with the current software version.
Restore factory settings	It is possible to return the camera to the state in which it is delivered from the factory, meaning that everything is wiped from the camera. The software version remains unchanged. After selecting and confirming *Restore factory settings*, the camera will shut down. When turning on the camera again, the first-time use sequence is started.

CLEAR DATA (available only for Admin)

Clearing data will remove all admin/user configured data and settings from the corresponding fields:

- My studies
- All studies
- General settings
- All users and PIN codes
- My settings
- WLAN settings
- Worklist. *Note! The worklist on the camera is common to all users, so each user can clear the worklist from the camera.*

User settings

USER SETTINGS

View your own user information or change your personal PIN code by selecting *Change PIN code*.

ABOUT DEVICE

General information about the device: product model, SW version date, optics FW version, AF FW version, MAC address, IP address, licenses and amount of free space in Archive (%).

CLEAR DATA

Clearing data will remove all user configured data and settings from the corresponding fields:

- My studies
- My settings
- Worklist from all users. *Note! The worklist on the camera is common to all users, so each user can clear the worklist from the camera.*

Software update

The camera can be updated remotely via the Optomed Portal or Optomed Client. An admin is notified of an available update on the camera screen with a pop-up message and with the screen icon:

 SW update available

The admin can update the latest released software version via the Optomed Portal or Optomed Client. It is also possible to return to the previous software version installed on the camera.

A user cannot update the camera but is notified of the available software updates. It is highly recommended to keep the camera up to date, so the admin shall be notified about available important update.

NOTE!
Make sure that there is at least 50% battery left in the camera before starting the update process, or place the camera on the charging station.

NOTE!
The update process typically takes several minutes. Interrupting the update procedure by, for example, removing the battery during the update, may lead to device malfunction.

NOTE!
No patient or user data will be lost during a software update.

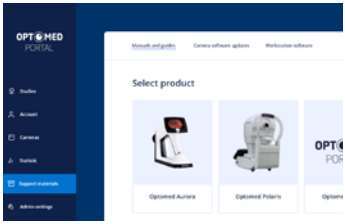
Software update via Optomed Portal

To update the camera via the Optomed Portal, the camera should be connected to the cloud.

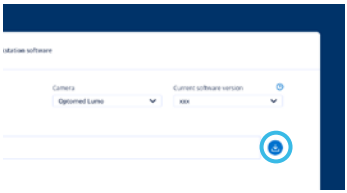
1. Power on the camera. Go to System Settings > *Software update.*
2. Select *Update to latest*.
3. View the content of the software update on the camera screen and select *Update.*
4. If the camera does not restart automatically after a successful update, restart the camera.
5. Log in to the Optomed Portal and download an updated user manual from Support materials to your PC or mobile device.
6. If Optomed Client is used and a new version is available, download the Optomed Client software installation package from Support materials and install an updated version to your PC or mobile device.

Software update via Optomed Client

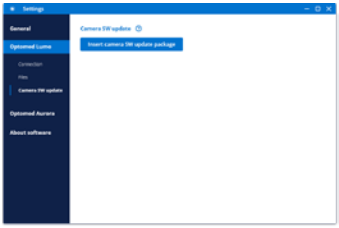
If a cloud connection is not available, an admin can update the camera via Optomed Client.



1. Log in to the Optomed Portal (see the chapter *Optomed Portal*).
2. Go to Support Materials and select *Camera software update*.
3. Select the right camera and current camera software version from the dropdown menu (the software version is found from Settings; About Device). After selecting these, the portal shows the available software update package.



4. Download the software update package. Do not unzip the file. The file contains
   a. camera software update files
   b. an updated Optomed Lumo user manual
   c. software release notes
   d. instructions for Optomed Lumo software update
5. Connect the camera to the Optomed Client either via WLAN or USB.
6. Open Optomed Client. Go to Optomed Lumo settings > Camera SW update.



7. Insert the camera software update package.
8. Power on the camera. Go to System Settings > *Software update.*
9. Select *Update to latest.*
10. View the content of the software update on the camera screen and select *Update*.
11. If the camera does not restart automatically after a successful update, restart the camera.
12. Update the Optomed Client software, too, if a new version is available. Download the Optomed Client software installation package from Support materials, and install the updated version on your PC or mobile device.

Logs

An admin can send system and audit logs from Admin Settings.

System logs

The camera logs all user actions and generates a log file with information about usage patterns, activities, and operations within the system. The system logs contain only anonymous information.

Select *Send system logs* from Admin Settings either to send the data to the Optomed Portal or to export it to a PC or mobile device via Optomed Client, depending on the selected data transfer method. In the Optomed Portal, system logs can be found on the Cameras page. For example, in the case of a malfunction, an admin can send the system logs to Optomed Customer Service by email.

Audit logs

An audit log is created to enable monitoring and tracking access to protected health information. It contains log data of camera usage to which organization IT administration or the authorities might require access. This data includes personal data.

Select *Send audit logs* from Admin settings to export the audit log to a PC or mobile device via Optomed Client, if the connection is established. Upon successful export, the audit log data is erased from the camera and a new log is started. The camera shows a periodical warning message when 90% or more of the audit log storage capacity is used. The oldest audit log data will be deleted automatically when 100% of storage capacity is used. A technical description of audit log functionality and content is available upon request.

Optomed Lumo Desktop Base

The Optomed Lumo Desktop Base is a medical device accessory for the Optomed Lumo Camera. The desktop base is used for enabling stationary imaging setup. The camera is placed on the desktop base, and the right imaging position is adjusted manually. Patients rest their chin and forehead on a head rest in a position that stabilizes the head during examination. The desktop base can also be used for battery charging and image transfer.

Part list and unpacking

The Optomed Lumo Desktop Base is packaged with the following items. Confirm that all items are included and undamaged.

No.	Item	Description
1	Optomed Lumo Desktop Base	The Optomed Lumo Desktop Base is an accessory for the Optomed Lumo Camera. The desktop base is used for enabling stationary imaging setup.

2	Power supply	USB-C medical power supply (with 4 plugs) to connect the desktop base, charging station, or camera to the mains. Use only an Optomed-provided power supply.
3	USB cable	USB-C to USB-A cable to connect the desktop base, charging station, or camera to a medical PC.
4	User Manual	Read the user manual before starting to use the device. Other language versions are available in the Optomed Portal.

Controls and connectors

No.	Item	Description
1	System Connector	Connects the camera to the desktop base
2	Shutter button	Press for image capture
3	Joystick	Use the joystick to manually position the camera (horizontal movement) when approaching the eye

4	Eye-level indicator	Adjust the chin rest to a position where the patient's eyes are on the eye-level mark
5	Head rest (applied part)	The patient rests their chin and forehead on the head rest in a position that stabilizes the head during examination
6	Head rest height adjustment knob	Use the knob to manually adjust the height of the chin rest
7	Camera height adjustment knob	Use the knob to manually position the camera height when approaching the eye

NOTE!
The Optomed Lumo Desktop Base is intended for use only with the Optomed Lumo Camera.

No.	Item	Description
8	Cable holders	Hooks to hold cables in place
9	USB port	Port for data transfer via USB-C to USB-A cable
10	Power port	To charge the battery inside the camera, connect the desktop base to the mains using the USB-C medical power supply

Preparations

NOTE!
Handle the desktop base without the camera during preparations.

Power supply

Connecting the desktop base to the mains with the power supply is optional. The base acts only as a stationary support for imaging and does not require an external power source for its functions. Connect the base to the mains if you want to charge the battery of the camera when the camera is placed on the desktop base. In other cases, charge the battery in the charging station or directly by connecting the camera to a USB-C medical power supply.

Data transfer

There are three options for setting up the camera for data transfer while on the desktop base.

a. Data transfer via USB cable: Connect the desktop base to a medical PC using the USB-C to USB-A cable (see the chapter *Patient environment and medical electrical system*)

b. Wireless data transfer via network: connect the camera to any wireless network.

c. Wireless data transfer via access point

See more information about data transfer options in the chapter *Data Transfer Options*.

NOTE!
If a medical PC is not available, one option is to use wireless data transfer or to operate via a medically approved isolating transformer.

NOTE!
Position the USB-C medical power supply so that the mains plug can be easily disconnected.

NOTE!
Excessive force should be avoided to prevent the USB-C cable connectors from breaking.

NOTE!
Check the connections of the cables in the base if the camera is not charging or if the USB connection is not working.

Placing the desktop base on a table

Place the desktop base on a table so that the head rest of the base is in line with the edge of the table. It is recommended to use a height-adjustable table.

Placing the camera on the desktop base

Place the camera with a battery in the desktop base by first placing the front part of the camera on the supporting pins so that the pins sink into the slots in the camera.

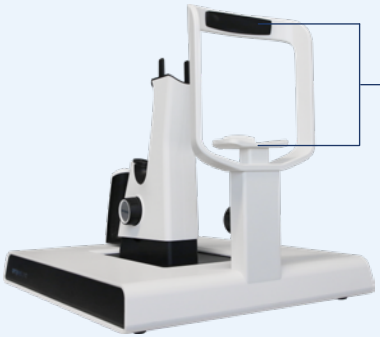
Remove the camera from the desktop base by lifting the front part of the camera from the supporting pins. Excessive force should be avoided to prevent the camera and the desktop base connectors from breaking.

Imaging with the Optomed Lumo Desktop Base

Preparations

Dim the lights in the examination room for imaging.

The use of an eye cup with the desktop base is optional. Clean the eye cup before each patient or use disposable eye cups.



Clean the head rest and chin rest before each patient.

Positioning the patient

- Ask the patient to rest their chin and forehead on the head rest.
- Adjust the height of the headrest using the adjustment knob so that the patient's eyes are at the same level as the eye height mark.
- If there is not enough lateral movement of the camera, move the patient's head laterally.

Camera startup and imaging settings

Image capture begins by starting a new study by either creating a new patient or selecting a patient from a worklist. Imaging settings are chosen from the Live view: imaging sequence, brightness, focus, and red free image (optional).

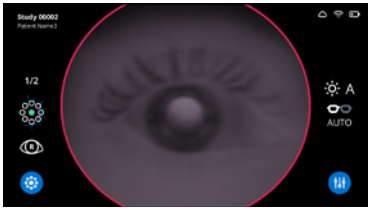
See the chapter Using the Optomed Lumo for more information about the usage of the camera.

Positioning the camera

- Move the camera into imaging position by pushing the joystick forward and turning it horizontally.
- Adjust the height of the camera with the camera height adjustment knob.
- Ask the patient to keep their eye aligned with the fixation target. Make micro adjustments with the joystick, and adjust the height with the height adjustment knob to fine tune the aim.

Image capture

- Approach the gray oval reflection at the top of the pupil until the retina fully appears on the screen.
- The right imaging distance is about 2 cm (0.8 inch) from the surface of the eye to the lens of the camera.



- Press the shutter button in the joystick or in the camera for image capture.

See the chapter Using the Optomed Lumo for more information about aim help, imaging with autofocus/manual focus, and image transfer.

Troubleshooting

Forgotten PIN code

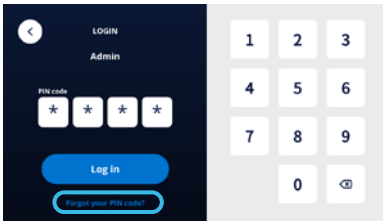
There are three ways to solve a situation in which the user has forgotten their PIN code.

- The user can verify their login via the Optomed Portal or Optomed Client and change their password.
- An admin can change the password for the user in Admin settings.
- The user can restore factory settings.

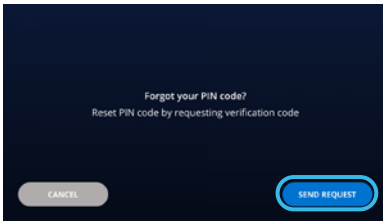
Forgot your PIN code process via the Optomed Portal or Optomed Client

The user is guided to verify their login via either the Optomed Portal or Optomed Client, depending on which connection is created and available when following the forgot your PIN code process. After successful verification, the user is asked to create a new PIN code. This action requires that camera is connected to either the Optomed Portal or Optomed Client. If a WLAN connection is not in use, create a USB connection to Optomed Client by placing the camera on the charging station.

1. Log in to the Optomed Portal or open Optomed Client
2. Power on the camera, select a user, and when the login screen opens, select *Forgot your PIN code*

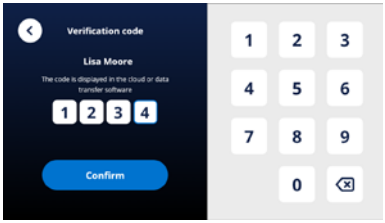


3. Select *Send verification request*. A verification query popup appears in the Optomed Portal or Optomed Client, depending on which connection is created.

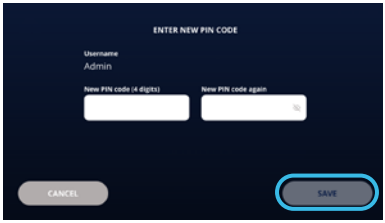


Optomed Client | Optomed Portal

4. Enter the verification code from the Optomed Portal or Optomed Client on the camera.



5. When the code is successfully entered, the camera prompts the user to create a new PIN code.
6. Create a new PIN and select Save.



Restore factory settings in the case of a forgotten PIN code

Restoring the camera to factory settings can be done even if no user is logged in. This should be done only in situations when the admin has forgotten their PIN code and there is no possibility to return a PIN code via the Optomed Portal or Optomed Client.

NOTE!
All patient and user data will be lost when restoring factory settings.

1. Restore factory settings by clicking the circled area five times.
2. Confirm that you really want to restore factory settings by selecting *Restore*.
3. After successfully restoring factory settings, the camera will automatically shut down.
4. When turning the camera ON again, the camera has returned to the state in which it was delivered from the factory, and the first-time use sequence is started.

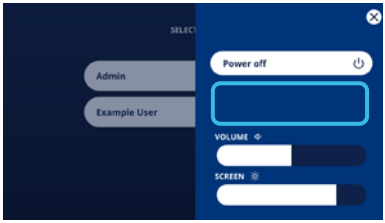
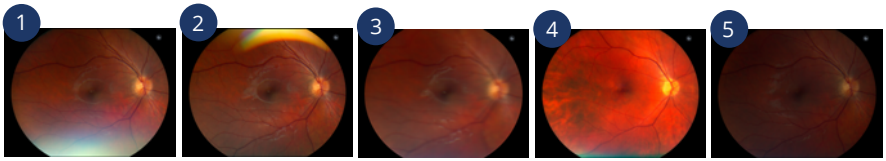


Image quality issues

The following show image artifacts and ways to correct them.



No.	Area	Quality issue	Description
1	Uniformity	Reflection in the lower part of the image	Imaging distance is too long. Get closer to the fundus and take a new image.
2	Uniformity	Reflection in the upper part of the image	Imaging distance is too short. Pull back a bit and take a new image.
3	Sharpness	Image out of focus	If the image is captured with autofocus and it is out of focus, ask the patient to fixate on the fixation target and take a new image. If the image is still out of focus, check the patient's refractive error and adjust the focus manually accordingly.
4 & 5	Brightness	Image too bright or too dark	If the image with autoexposure appears too bright or too dark, the brightness level must be adjusted manually. Adjust the brightness level to brighten (increase the value) or darken (decrease the value) the image.

Forced shut down

If the camera is unresponsive to touch-screen controls or button presses, it can be forced to shut down by pressing the Power button for 10 seconds or longer.

Error messages

The Optomed Lumo Camera displays error messages to indicate error situations. An error message is always displayed with an explanatory message providing information about possible actions.

Error Code	Instructions
0x0000 - 0x0002	Try performing the operation again. If the issue persists, restart the camera.
0x0100 - 0x0104 0x0107 - 0x0109 0x010B, 0x010C	Restart the camera when this error occurs.
0x010F	Wait for at least 3 minutes for the camera to cool down. The notification should disappear automatically when the camera is ready for use
0x0201 0x0202 0x0203	Restart the camera when this error occurs.
0x0300	Restart the camera when this error occurs.
0x0301 0x0302	Perform the same operation again. If the error persists, restart the camera and send the request again.
0x0303	Ensure you have an active client or cloud account and you are able to log in to your account with your credentials. Make sure the correct credentials have been configured in the systems integrations page.
0x0304 0x0305	Ensure you are able to log in to the Optomed cloud or, if you are using the Optomed Client application, ensure that the workstation running the application is powered on. If the cloud or client is up and running and you are able to log in, then talk to your network administrator and ensure your local network is able to access external networks. This could be caused by a firewall or any restrictions set on your local network by your administrator.
0x030B	Talk to your network administrator and ensure your local network is able to access external networks. This could be caused by a firewall or any restrictions set on your local network by your administrator.
0x0306 - 0x0309 0x030A - 0x030E	Perform the same operation again. If the error persists, restart the camera and send the request again.
0x0400 - 0x0406	Refer to the 0x05XX error code.
0x0500 0x0501	Turn off WLAN in the connections menu and wait for a minute before turning WLAN back on. If the same issue persists, restart the camera and turn on WLAN.
0x0502 0x0504	Try turning off WLAN again. If the error persists, restart the camera and turn off WLAN if it is still active.

0x0506	Turn the WLAN setting off and on and retry connecting to your network.
0x0507	The password or configuration of the network you are trying to connect to has probably changed. Check if the password that is being used is the correct one. Talk to your network administrator if this issue persists.
0x0509	Try turning off the access point setting again. If the issue persists, restart the camera and turn off the access point setting if it is still active.
0x050A	Try turning on the access point setting again. If the issue persists, restart the camera and turn on the access point setting. Ensure the access point name and password have been filled in before turning on.
0x0508	Ensure the access point name and password have been filled in before activating.
0x050B	Restart the camera, configure the access point settings (i.e., AP name and password), then activate the access point.
0x050C - 0x050E	Try performing the operation again. If the issue persists, restart the camera.
0x0505	Try performing the operation again. If the issue persists, restart the camera.
0x0600	Retry the operation multiple times or try to delete one category at a time.
0x0601, 0x0602	Retry the operation multiple times. If the issue persists, restart the camera and try again.

NOTE!
If a malfunction cannot be rectified, please contact your local distributor or Optomed Customer Service.

Optomed, as the manufacturer of the Optomed Lumo Camera, provides software updates as needed throughout the life cycle of the camera to continue to guarantee its safety and effectiveness. See the chapter Software update for more information.

Maintenance

Cleaning and disinfection

See the following Optomed Lumo Cleaning and Disinfecting Guidelines to minimize the spread of infectious diseases for your patients and clinical staff. Note that cleaning and disinfection procedures are done for different purposes. Cleaning is the physical removal of visible and invisible dirt and contaminants. Disinfection is intended to kill microorganisms.

The following instructions have been verified to be capable of preparing the Optomed Lumo for reuse. Clean and disinfect on a routine basis according to your facility's protocols and standards or local regulations by using approved cleaning and disinfectant agents. The use of unapproved cleaning agents and disinfectants may have an adverse effect on plastic and rubber components. Damage caused by such disinfectants is not covered by the warranty. The surfaces of the device have been tested and are guaranteed to resist frequent treatment with alcoholic disinfectants in the long term.

APPROVED CLEANERS AND DISINFECTANTS

Cleaner/ Disinfectant	Recommended for Basic Cleaning/ Disinfecting	Maintain Wetness (Disinfection Contact Time)	Contact information
Oxivir Tb Wipes	Disinfecting	1 minute	www.diversey.com
Clorox Hydrogen Peroxide Cleaner Disinfectant Wipes	Disinfecting	4 minutes	www.cloroxpro.com
CaviWipes1 - Metrex	Cleaning/ Disinfecting	1 minute	www.metrex.com
Sani-Cloth® AF3 Germicidal Disposable Wipe	Disinfecting	3 minutes	www.pdihc.com
Super Sani-Cloth® Germicidal Disposable Wipe	Disinfecting	2 minutes	www.pdihc.com
Sani-Cloth® Plus Germicidal Disposable Cloth	Disinfecting	2 minutes	www.pdihc.com

60-80% ethanol or isopropyl alcohol	Cleaning (front lens)	-
Lens cleaning solution*	Cleaning (front lens)	-

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

To avoid personal injury and/or equipment damage, follow these precautions:

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 sulfuric acid)
- Strong/corrosive bases (such as sodium hydroxide)
- Bleaching agents
- Acetone (nail polish remover)

CAUTION!
The Optomed Lumo is a precision optics instrument that should be handled with care. Please note the following cleaning instructions:

- Power off the device and remove the battery before cleaning
- Remove the charging station and desktop base from the mains before cleaning
- Remove attached USB cables from the Lumo camera, charging station, and desktop base
- Avoid touching the optics lens in the Lumo camera unless cleaning it
- Avoid touching system connectors in the Lumo camera, charging station, and desktop base unless cleaning them

Make sure no moisture penetrates the system, and let the device dry properly before use. Keep it away from water.

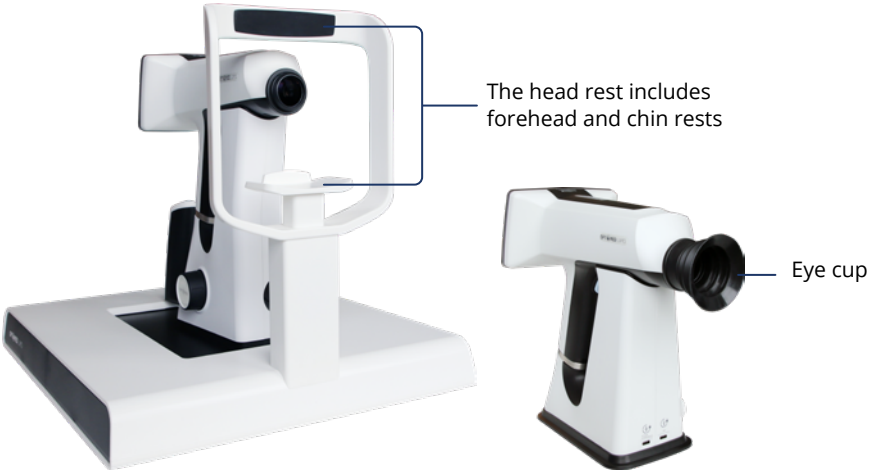
NOTE!
Clean the device of visible dirt before disinfection to maximize its effectiveness.

NOTE!
The Optomed Lumo is not intended to be sterilized.

Cleaning parts that touch the patient

Clean parts that touch patient prior to each use on a new patient. Use an approved cleaning agent (see the table *Approved cleaners and disinfectants)*.

1. Remove visible dirt from the eye cup and the headrest using approved cleaning wipes.
2. Use as many wipes as needed to remove the dirt. Always replace a wipe when it is visibly soiled or contaminated.
3. Wipe the part with a cleaning wipe for the time specified for the cleaner. Use firm pressure.
   - The eye cup may be turned inside out when wiping, to ensure thorough wiping of all folds.
4. Disinfect the parts after cleaning. Let them air-dry before disinfection.



Cleaning the front lens

Clean the front lens when there is visible dirt on the lens or there is a visible central reflection or artifacts in the images taken.

1. Remove loose particles by gently blowing visible particles off with an air blower or compressed air or wiping with a soft brush.
2. Clean the lens with a cleaning cloth using a circling motion from the center of the lens to the border.

- Grease may be removed with a soft cloth moistened with alcohol (60-80% ethanol or isopropyl alcohol) or lens cleaning solution (see the Caution: Do NOT use aggressive or abrasive cleaning agents or the following chemicals for cleaning).

3. Possible residue from moist cleaning tissues may be removed with a dry cleaning cloth (included in the sales package).
   - If a replacement for a cleaning cloth is needed, contact Optomed Customer Service or your local distributor. The cleaning cloth should be replaced when the cloth has visible dirt or if it has disintegrated.

Cleaning other parts

Clean the camera screen and external surfaces regularly and at least when there is visible dirt or the part is contaminated. Use an approved cleaning agent (see the table *Approved cleaners and disinfectants*).

Prepare the Optomed Lumo for cleaning and disinfection by following the steps below.

1. Remove the camera from the charging station or desktop place if it is placed on one of these devices.
2. Power off the camera and remove the battery.
3. Unplug the charging station and the desktop base from the mains.
4. Detach the USB cables from the camera, charging station and desktop base.

Clean the other parts by following the steps below.

1. Remove visible dirt by using approved cleaning wipes.
2. Use as many wipes as needed to remove the dirt. Always replace the wipe when it is visibly soiled or contaminated.
3. Wipe the part with a cleaning wipe for the time specified for the cleaner. Use firm pressure.
   - Note! Do not apply force when wiping the camera screen as this may cause damage.
4. Disinfect the parts after cleaning. Let them air-dry before disinfection.

Disinfection

1. Use approved disinfectant wipes to gently wipe all exterior surfaces of the Optomed Lumo.
   - Note! Do not disinfect the lens if there is no known contamination.
2. Make sure the surfaces remain wet with the disinfectant for the specified contact time. Repeat wiping with a new wiping cloth if necessary.
3. Allow all disinfected surfaces sufficient time to dry.

Service and repair

There are no maintenance procedures that can be carried out by the user other than replacing the battery, updating the software, and cleaning the device. See the applicable chapters in this user manual for more information on performing these actions.

NOTE!
Only use the battery provided by Optomed with this product.

All other servicing actions and repairs must be carried out by Optomed or Optomed-authorized service facilities and service personnel. Work instructions to repair those parts of medical electrical equipment that Optomed has designated as repairable by service personnel will be provided by Optomed.

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 to get an exact cost of repair. When you contact Optomed 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.

Disposal

The device and its accessories, including packing material, shall be disposed of following federal, state, regional, and/or local laws and regulations. The device contains plastic and metallic parts, electronic components, and batteries. There are also optic parts containing glass and other material.

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

NOTE!
It is recommended to save the shipping box and packing materials in case you need to store or ship the system. If you decide to dispose of the packaging materials, submit them to a recognized collection system for recycling.

Information on packaging materials

Optomed Lumo Camera

Item	Type	Mass (g)
Shipping box	Cardboard	650
Plastic bags	Low density polyethylene (LDPE)	40

Optomed Lumo Desktop Base

Item	Type	Mass (g)
Shipping box	Cardboard	1900
Plastic bags	Low density polyethylene (LDPE)	40
Foam	Plastics, expanded polyethylene (EPE)	1400

Specification

Environmental conditions

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

	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	700 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa

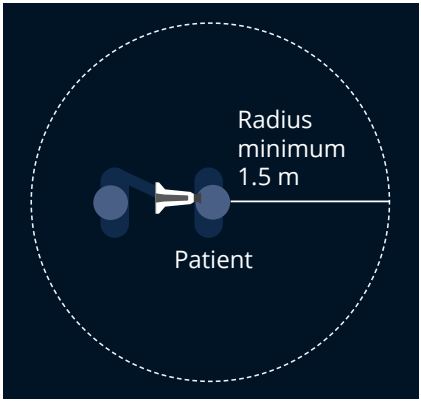
NOTE!
Do not store this instrument in conditions where the temperature may rise above +35°C or fall below -20°C. This instrument is not conditioned as per ISTA2A to cover the Australian climate zone (extreme temperature -29°C - +50°C) for packaging validation.

Please also note that electromagnetic compatibility information and recommended separation distances between portable and mobile RF communications equipment and the Optomed Lumo Camera are given in the chapter Electromagnetic compatibility.

NOTE!
Avoid using the device in a dusty environment.

NOTE!
Avoid subjecting the device to vibration or shock.

Patient environment and medical electrical system



The patient environment is defined as an area within a medically used room around a patient. It is any area where intentional or unintentional contact can occur either between a patient and parts of a medical device or system, or between a patient and some other person who is touching parts of the medical device or system. The minimum distance around the patient is 1.5 m (59”).

There are several options for setting up the medical electrical system considering the patient environment standard. The chosen data transfer method to a PC and the battery charging method determine if additional medically approved equipment (IEC 60601-1:2012 or newer approved) is needed within the patient environment. This includes a medical PC with medical power supply and a medical isolating transformer for a standard PC and for auxiliary units such as a printer or a monitor.

Devices applicable to the patient environment

- Optomed Lumo Camera with a battery
- Optomed Lumo Desktop Base
- Eye cup
- USB-C Medical Power Supply
- Personal computer
  - The medical PC (IEC 60601-1:2012 or newer approved) or operation via a medical isolating transformer (IEC 60601-1:2012 or newer approved)
- Monitor for personal computer, printer
  - Operation through a medical isolating transformer (IEC 60601-1:2012 or newer approved)
- Medical isolating transformer
  - IEC 60601-1:2012 or newer approved
- Medical Ethernet isolation (galvanic isolation)
  - IEC 60601-1:2012 or newer approved
- Mouse

WARNING!
When operating within the patient environment, the USB cable must be connected only to the medical PC (IEC 60601-1:2012 or newer approved) or operated via a medical isolating transformer (IEC 60601-1:2012 or newer approved). Auxiliary units on the PC (e.g. printer, monitor) must be operated through a medical isolating transformer (IEC 60601-1:2012 or newer approved). Ethernet may only be used through galvanic isolation (IEC 60601-1:2012 or newer approved).
Optomed Oyj (Plc) does not provide either the PC or the isolating transformer.
If a medical PC or medical isolating transformer is not available, the only data transfer option is a WLAN connection.

WARNING!
An additional multiple-socket outlet or extension cord is not allowed to be used.

WARNING!
Connect only items that have been specified as part of the medical electrical (ME) system or that have been specified as being compatible with the ME system.

WARNING!
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.

Connectivity requirements

Required configuration of the IT network:

- WLAN: The IT network must provide WPA2-PSK support (WPA2-Enterprise is not supported)
- DICOM: the DICOM server is reachable by the camera

Intended information flow between the software, the IT network, and other devices on the IT network, and the intended routing through the IT network are shown below.

The camera uses either Standard DICOM on TCP/IP or partly Custom DICOMWeb on HTTPS for communication. The requirement is to support TCP/IP and HTTPS. In addition, DICOM services must support Standard DICOM and any third-party services partly Custom DICOMWeb for the Optomed Lumo Camera.

The camera can connect to the cloud (external, hybrid, or internal), which requires allowing the IT network to connect to it if needed. For the cloud, a URI (uniform resource identifier) is used, so there are no specific requirements except for the URI to be reachable by the camera and for the camera to have enough privileges.

See the Optomed Client User Manual for other system requirements.

NOTE!
Connection to IT networks including other equipment could result in previously unidentified risks to patients, operators, or third parties. The responsible end user organization identifies, analyzes, evaluates, and controls these risks. Changes to the IT network could introduce new risks that require additional analysis. Changes to the IT network include changes in network configuration, connection of additional items, disconnection of items, update of equipment, and upgrade of equipment.

Technical description

CAUTION!
Only use the USB cable, battery, and power source provided in the sales package. If you need a replacement for the USB cable, battery, or power source, please contact the manufacturer or your local distributor.

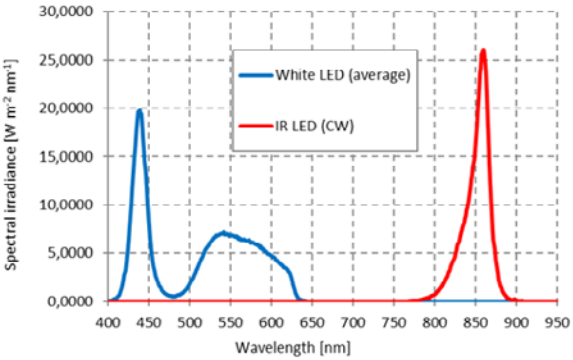
CAUTION!
The development, production, and maintenance of this device, together with associated risks, are based on an expected device lifetime of five years. Modifications to the product or failure to follow the manufacturer's instructions may substantially reduce the expected service life and significantly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

NOTE!
To isolate medical electrical (ME) equipment from the supply mains, unplug the USB-C medical power supply.

Camera	
Model	Optomed Lumo Camera
Image sensor	1/2.3” 12.3 Megapixels
Image memory type	Internal 16 GB memory
Display	5”, TFT-LCD, 1280x720 pixels, 16.7 M colors
Image format	8 bit JPEG (file extension: jpg) (consisting of 3 color channels in the RGB format). Typical color image size is 2-3 MB
Data transfer	DICOM (UTF-8), DICOMweb
USB connectivity	USB-C, USB 2.0 High Speed Device
WLAN connectivity	IEEE 802.11a/b/g/n/ac, WPA2 Operating frequency range: 2412 – 2472 MHz (Channels 1-13), 5180-5825 MHz (Channels 36-165). Note! Available frequency ranges and channels vary depending on the region. Modulation: OFDM (802.11 a/g/n/ac), DSSS/CCK (802.11b) Maximum output power: 19.5 dBm Maximum antenna gain: +0.1 dBi
Operating systems	Supports Windows, macOS, Android, iOS and iPadOS operating systems through Optomed Client. See the Optomed Client User Guide for more information.
Dimensions	141 (w) x 200 (h) x 240 (d) mm
Weight	930 g

Battery	50002243, 7.2 V / 3450 mAh / 24.84 Wh Rechargeable Li-ion battery Li-ion cell with integrated safety circuit 1-2 years of lifetime
Usage time	6 hours (in typical use: image capture of 4 patients per hour, 4 images per patient, camera in standby mode between patients)
Spare battery charging time	2 hours
Device lifetime	5 years
Illumination	Infrared LED for aiming. Visible white LED for imaging, 21 illumination brightness levels. 9 red LEDs for internal fixation targeting.
Field of view	50°, total field of view 50° x 40°
Minimum pupil size	3 mm
Diopter compensation	from -20 D to +20 D manual focus from -15 D to +10 D autofocus
Image resolution	3392 x 2544 pix (total 8.6 Mpix, effective area 6.4 Mpix)
Pixel pitch on fundus	4.8 µm (for emmetropic eye with 17 mm focal length)

Spectral output at working distance: White and infrared LED spectral irradiance



Charging station	
Model	Optomed Lumo Charging Station
Dimensions	102 (w) x 211 (h) x 209 (d) mm
Weight	680 g
Power supply	Type XP power, ACM18US053-3A, USB-C medical power supply Input 100-240 V, ~0.5 A, 50/60 Hz Output 5.3 V, 3 A, 15.9 W
USB cable	Type USB-A to USB-C Length 1.8 m

Desktop base	
Model	Optomed Lumo Desktop Base

Dimensions	409 (w) x 403 (h) x 460 (d) mm
Weight	5.05 kg
Power supply	Type XP power, ACM18US053-3A, USB-C medical power supply Input 100-240 V, ~0.5 A, 50/60 Hz Output 5.3 V, 3 A, 15.9 W
USB cable	Type USB-A to USB-C Length 1.8 m

Eye cups	
Reusable eye cup	Material: Liquid silicone rubber Reusable, free from latex, PVC, and DEHP BASIC UDI-DI: 643004626REUSEYECUPU2 UDI-DI: 6430046261181 REF: 30500005
E-Safe disposable eye cups Base part	Material: Liquid silicone rubber Reusable, free from latex, PVC, and DEHP
E-Safe disposable eye cups Disposable part	Material: Thermoplastic polyurethane (TPU) Disposable, free from latex, PVC, and DEHP May be used multiple times on a single patient

Intellectual property rights information

Windows 10® and Windows 11® are trademarks of Microsoft Corporation.

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

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

Li-ion 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 an Optomed-provided medical power supply when it is placed in the charging station, or inside the camera when it is placed in the desktop base or has a power supply attached directly to it. Use of an unrecommended charger may cause battery fluid leakage or overheating of the battery, or may cause the battery to explode.

The Optomed Lumo Camera has a rechargeable portable Li-ion battery. For more information about the charging options, see the chapters:

- First-time use - Battery and charging - Charging of batteries
- Optomed Lumo Desktop Base - Preparations - Power supply

The battery pack is specially designed and manufactured for this device. Contact Optomed Customer Service or your local distributor for a replacement battery.

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
Weight of battery: 0.12 kg
Hazardous substances present in the battery: No
Usable extinguishing agent: H_2O, CO_2

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	$LiCoO_2$	12190-79-3	20-50
Manganese	Mn	7439-96-5	
Nickel	Ni	7440-02-0	
Aluminum	Al	7429-90-5	

Polyvinylidene Fluoride (PVDF)	$C_2H_2F_2$	24937-79-9	<1
Graphite	$C_{24}X_{12}$	7782-42-5	13-18
Carbon Black	C	1333-86-4	
Lithium Hexafluorophosphate	$LiPF_6$	21324-40-3	1-5
Ethylene Carbonate	$C_3H_4O_3$	96-49-1	5-20
Propylene Carbonate	$C_4H_6O_3$	108-32-7	
Diethyl Carbonate (DEC)	$C_5H_{10}O_3$	105-58-8	
Dimethyl Carbonate	$C_3H_6O_3$	616-38-6	
Ethyl Methyl Carbonate	$C_4H_8O_3$	623-53-0	
Copper (Cu)	Cu	7440-50-8	9-18
Aluminum (Al)	Al	7429-90-5	17-27
Electrolyte	--	--	5-20

Importer of battery:
Optomed Oyj (Plc)
Yrttipellontie 1
FI-90230 Oulu, Finland
info@optomed.com
www.optomed.com

The label on the battery includes the following information:
Li-ion Rechargeable Battery 7.2 V / 3450 mAh / 24.84 Wh
50002243, 2INR19/66, INR-18650-M35A, MFD: YY/MM/DD (where YY is a year, MM is a month, and DD is a day of manufacture)
CAUTION
Do not disassemble or modify
Do not short-circuit
Do not dispose in fire
Do not expose to high temperature
Assembled by Shenzhen Hypercell Co., 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 from the device if the device is stored for more than 2 months.

Electromagnetic compatibility

This device has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:2020 ed4.1. 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 components supplied by Optomed.

If the performance of the Optomed Lumo 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 your local distributor or Optomed Customer Service.

WARNING!
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.

WARNING!
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.

WARNING!
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 Lumo, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Contact Optomed Customer Service or your local distributor for replacement cables. The use of accessories, converters, or cables that are not specified in this user manual or that have not been purchased as spare parts from Optomed can result in increased emissions or reduced immunity of the device.

SAR exposure

System	$SAR_{1\,g}$ (head/body) (W/kg)	$SAR_{10\,g}$ (limb) (W/kg)
WLAN 2.4 GHz	0.46	0.22
WLAN 5 GHz	0.31	0.10

Manufacturer's declaration – electromagnetic immunity

The Optomed Lumo 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 power supply lines	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)	±1 kV differential 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 Lumo 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 the Optomed Lumo, 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey A, should be less than the compliance level in each frequency range B. 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	3 V/m 80 MHz to 2.7 GHz AM	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	385 MHz PM 27 V/m 450 MHz PM 28 V/m 710-780 MHz PM 9 V/m 810-930 MHz PM 28 V/m 1720-1970 MHz PM 28 V/m 2450 MHz PM 28 V/m 5240-5785 MHz PM 9 V/m	385 MHz PM 27 V/m 450 MHz PM 28 V/m 710-780 MHz PM 9 V/m 810-930 MHz PM 28 V/m 1720-1970 MHz PM 28 V/m 2450 MHz PM 28 V/m 5240-5785 MHz PM 9 V/m	
Proximity magnetic fields IEC 61000-4-39	134.2 kHz PM 65 A/m 13.56 MHz PM 7.5 A/m	134.2 kHz PM 65 A/m 13.56 MHz PM 7.5 A/m	The Optomed Lumo, including cables, should not be used in close proximity to strong magnetic field sources, such as induction cooking appliances, RFID readers, wireless power transfer charging systems, or anything similar.

NOTE 1 UT 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 Lumo is used exceeds the applicable RF compliance level above, the Optomed Lumo 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 Lumo.

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

Manufacturer's declaration – electromagnetic emissions

The Optomed Lumo 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	The Optomed Lumo uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Optomed Lumo 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Separation distances

The Optomed Lumo maintains basic safety and performance when used in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Optomed Lumo can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Optomed Lumo 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	from 80 MHz to 800 MHz	from 800 MHz to 2.7 GHz
	d = 1.2 √P	d = 1.2 √P	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.

Cybersecurity

In today's connected world, cybersecurity is more important than ever. That's why we have built robust security measures into your Optomed Lumo device to protect your data and ensure safe operation. Cybersecurity has been considered throughout the development process, from the very beginning. Special attention has been given to these aspects:

Encrypted eMMC Storage: The Optomed Lumo stores all your data using strong encryption. This means that only authorized users can access the information, keeping it confidential and intact.

Minimal Attack Surface: Only essential services and components are enabled. This reduces potential vulnerabilities that could be exploited by attackers.

Secure Communication: When the device communicates over a network, it uses secure connections (HTTPS with TLS 1.2 or higher) to protect your data from eavesdropping and man-in-the-middle attacks.

Only Trusted Software Updates: The Optomed Lumo only accepts software updates that are digitally signed by Optomed. This ensures that updates are secure and prevents unauthorized or malicious changes to the device.

These cybersecurity features help ensure your Optomed Lumo device operates securely and reliably, protecting your data while maintaining peak performance.

WLAN module information

The Optomed Lumo Camera contains a WLAN module for wireless connectivity. It operates on the 2.4 GHz and 5 GHz bands. The following information is applicable to certain market areas.

Regional information (US)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

NOTE!
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules (47 CFR 15.105). These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

NOTE!
“Harmful interference” is defined in 47 CFR §2.1 by the FCC as follows: Interference that endangers the functioning of a radionavigation service or of other safety services, or that seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the International Telecommunication Union (ITU) Radio Regulations.

Compliance with FCC requirement 15.407(c):
Data transmission is always initiated by software, and is then passed down through the MAC, through the digital and analog baseband, and finally to the RF chip. Several special packets are initiated by the MAC. These are the only ways the digital baseband portion will turn on the RF transmitter, which it then turns off at the end of the packet. Therefore, the transmitter will be on only while one of the aforementioned packets is being transmitted.

In other words, this device automatically discontinues transmission in the case of either absence of information to transmit or operational failure. Frequency tolerance: ±20 ppm. This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

WARNING!
The available scientific evidence does not show that any health problems are associated with using low-power wireless devices. There is no proof, however, that these low-power wireless devices are absolutely safe. Low-power wireless devices emit low levels of radio frequency energy (RF) in the microwave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure to low-level RF that does not produce heating effects causes no known adverse health effects. Many studies of low-level RF exposure have not found any biological effects. Some studies have suggested that some biological effects might occur, but such findings have not been confirmed by additional research. Regional information (Canada): CINDY2MWM1 has been tested and found to comply with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines.

CAUTION!
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Regional information (Canada)

Data transmission is always initiated by software, and is passed down through the MAC, through the digital and analog baseband, and finally to the RF chip. Several special packets are initiated by the MAC. These are the only ways the digital baseband portion will turn on the RF transmitter, which then turns off at the end of the packet. Therefore, the transmitter will be on only while one of the aforementioned packets is being transmitted. In other words, this device automatically discontinues transmission in the case of either absence of information to transmit or operational failure.

La transmission des données est toujours initiée par le logiciel, puis les données sont transmises par l'intermédiaire du MAC, par la bande de base numérique et analogique et, enfin, à la puce RF. Plusieurs paquets spéciaux sont initiés par le MAC. Ce sont les seuls moyens pour qu'une partie de la bande de base numérique active l'émetteur RF, puis désactive celui-ci à la fin du paquet. En conséquence, l'émetteur reste uniquement activé lors de la transmission d'un des paquets susmentionnés. En d'autres termes, ce dispositif interrompt automatiquement toute transmission en cas d'absence d'information à transmettre ou de défaillance.

Regional information (Canada, EU)

For indoor use only (5150-5250MHz band and channel 52, 54, 58).
A utiliser en intérieur uniquement (bande 5150-5250Mhz et canal 52, 54, 58).

Compliance

The classification of the Optomed Lumo according to the standard IEC 60601-1:2005+A1:2012+A2:2020

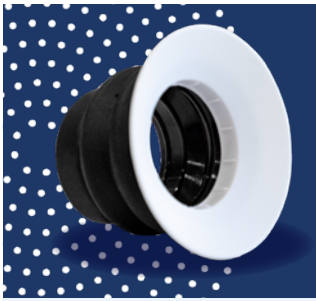
- The Optomed Lumo Camera is internally powered medical electrical (ME) equipment when not connected to a supply mains, and it complies with the requirements for Class II medical electrical equipment when so connected.
- The Optomed Lumo Charging Station is Class II medical electrical equipment.
- The Optomed Lumo Desktop Base is Class II medical electrical equipment when connected to a supply mains.
- The Optomed Lumo Camera and Optomed Lumo Desktop Base have type body floating (BF) applied parts (eye cup, head rest, chin rest).
- Protection against harmful ingress of water or particulate matter is classified as IPX0.
- The Optomed Lumo is not intended to be sterilized.
- The Optomed Lumo is not intended for use in an oxygen-rich environment.
- The Optomed Lumo is classified for continuous operation.

The Optomed Lumo complies with the EU Medical Device Regulation 2017/745 and the national implementation in the form of the Finnish Medical Device Act 719/2021 as illustrated in the table below. The Declaration of Conformity is available upon request.

	Optomed Lumo Camera	**Optomed Lumo Charging Station**	**Optomed Lumo Desktop Base**
EU Medical Device Regulation 2017/745	Class IIa	Medical device accessory (class I)	Medical device accessory (class I)
ISO 10940:2009	Complies	–	–
ISO 15004-1:2020	Complies		
ISO 15004-2:2007	Group 2	–	–
IEC 62471:2006	Exempt Group	–	–
ANSI Z80.36-2021	Group 1	–	–

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

Optomed Lumo accessories



OPTOMED E-SAFE

Disposable eye cups for hygienic retinal imaging

Optomed E-Safe disposable eye cups are intended for hygienic retinal imaging.

One eye cup is used for one patient and discarded after use.

Base part

Disposable part

OPTOMED TRAVEL PACK

The Optomed Travel Pack enables maximum portability for your handheld fundus camera and is designed to fit the essential parts for retinal imaging on the go.

Warranty

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

Submitting claim

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

Warranty does not cover
Products that have been subjected to abuse, accident, alteration, 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. The warranty does not cover batteries.

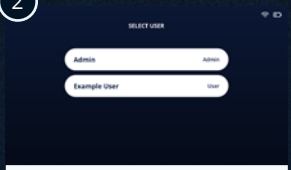
The term of the warranty is stated in the purchase agreement.
In the case of discrepancies between the warranty of the purchase agreement and the warranty information above, the purchase agreement shall prevail.

Imaging quick guide

1

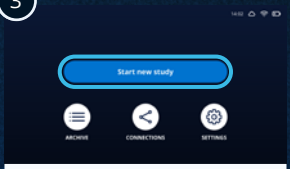
Power on

2



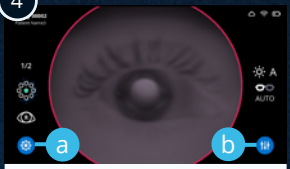
Select the user, enter the PIN code, and log in

3



Start a new study (new patient/worklist)

4

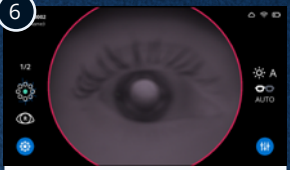


Use the default settings or define an imaging sequence (a) and imaging settings (b)

5

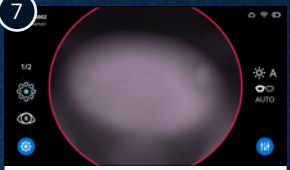
Approach and center the pupil from 5-10 cm distance by supporting the device with both hands (stabilize from the forehead)

6



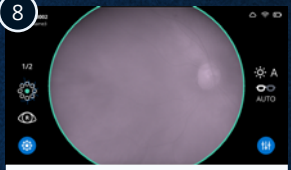
Approach the GRAY oval reflection at the top of the pupil until the retina appears fully on the screen

7



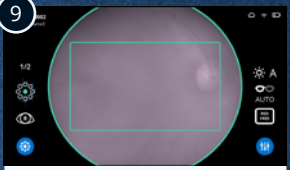
Red aim help; retina not yet in full view. Fine-tune with the front hand.

8



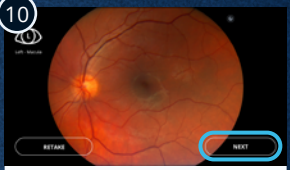
Green aim help; focusing has started. Hold still.

9



Green rectangle on screen; focusing ready. Press the shutter.

10



Select Next until the imaging sequence is complete

11

Select Save or send the images to AI to be analyzed