



USER'S MANUAL

Optomed Smartscope PRO & Smartscope FA

Optomed SMARTSCOPE PRO & SMARTSCOPE FA are manufactured by Optomed Plc

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This manual describes guidelines for the following modules:

Model:	Description:	Accessories
Smartscope M5	medical digital camera	
Smartscope EY4	module for retinal imaging	eye cup quick user guide
Smartscope FA	module for fundus fluorescein angiography imaging	eye cup quick user guide
Smartscope ES2	module for anterior ophthalmic imaging	
Smartscope Cradle V1	for data transmission and battery charging	USB cord Power unit

If not all optics modules were purchased then the sales case does not include them or the accessories related to that optics module.

In addition, the sales case includes:

- Batteries (2 pcs)
- Cleaning cloth
- User manual
- USB memory stick (Includes training material, Optomed Orbit software and user manual, and Optomed Client PC software in case device has WLAN functionality).

The following accessories can be purchased separately:

- **Optomed Slit Lamp Adapter** that enables the camera to be used as stationary imaging tool.

Quick start guide

WHAT TO DO BEFORE THE FIRST USE:

1. Remove Optomed Smartscope M5 from the sales package and check that all parts are undamaged.
2. Install Battery as instructed in the **Appendix B**.
3. Place Cradle on a desk next to the PC (Personal Computer).
4. Connect the USB cable to the PC.
5. Connect power unit to the wall plug (mains)
6. Place Optomed Smartscope M5 to the cradle.



Battery starts to charge. Charge battery for 4 hours before the first use. When device is not used, it may be stored in the Cradle.

7. Camera will not automatically power up in the cradle without the charger. User needs to press the power button.



Guideline for placing the camera to the cradle:

Camera will fit to the cradle when it's held straight while placing it. Excessive force shall be avoided in order to prevent the camera and cradle connectors from breaking.



Guideline for battery and device storage:

If battery is stored out of the camera for longer period of time, ensure that battery is fully charged before storage. During storage battery shall be re-charged occasionally (e.g. every 3-9 months).

If battery is stored in the camera, camera shall be placed in the cradle with cradle power cable connected.

Device is not allowed to be used when battery cover is open.

Normal battery lifetime is expected to be 1-2 years.

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1. Indications for use

Smartscope M5 is a medical digital camera that is used with dedicated optics modules intended to take images of the eye fundus and surface of the eye.

Supported optics modules and their intended uses are:

Model:	Description:
Smartscope EY4	Optomed Smartscope M5 digital camera with EY4 optics module is intended to capture digital images and video of the fundus of the human eye.
Smartscope FA	Optomed Smartscope M5 digital camera with FA optics module is intended to capture fluorescein angiograms of the human eye.
Smartscope ES2	Optomed Smartscope M5 digital camera with ES2 optics module is intended to capture images and video of the surface of the human eye and surrounding areas.

Smartscope M5 with optics modules is a prescription device: Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

2. Contraindications for use of the optics modules EY4, FA and ES2

Because prolonged intense light exposure can damage the retina, 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.

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants and persons with aphakia or diseased eyes will be at greater risk. 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. This will apply particularly if the eye has been exposed to retinal photography.

Smartscope EY4, FA and ES2 are classified as Group 2 based on standard ISO 15004-2:2007. Smartscope FA module has also been classified as Group 1 based on ANSI Z80.36-2016. The daily usage time and maximum allowed number of pulses is calculated based on optical classification results according to standard ISO 15004-2:2007 and ANSI Z80.36-2016.



WARNING:

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:

Maximum number of pulses (still images) allowed daily:

- EY4: 6300 pulses (still images) / eye
- FA: 3000 pulses (still images) / eye
- ES2: 250 pulses (still images) / eye

Or alternatively

Total daily usage time for continuous light (= video usage time + aiming light duration) shall be limited to:

- EY4: 1 h 30 min video usage / eye
- ES2: 8 min video usage / eye

3. Warnings and cautions



Place PC and cradle outside the patient environment (at least 1.5 meters distance from the patient).



Use only accessories and battery provided by Optomed with this product.



Connection between camera and workstation is USB and/or WLAN. Any authorization procedures should be carried out in workstation.



Images and videos can be copied from camera to workstation via USB and/or WLAN and then viewed in workstation.



USB write protection is on by default. When protection is on this feature will prevent writing to camera memory card from PC when connected to the cradle. In case device has WLAN functionality, USB write protection must be turned off.




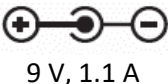







USB connection works without power cable. There is no USB charging in M5

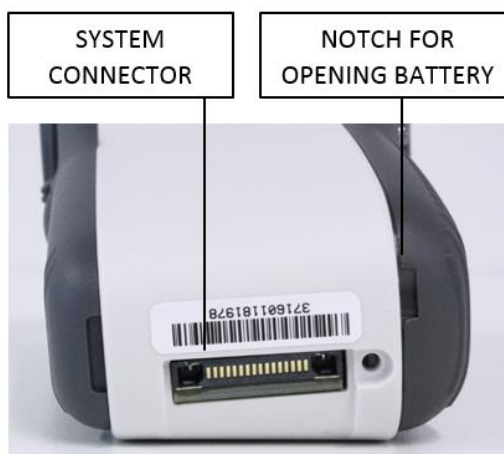


No modification of this equipment is allowed.

4. Important symbols

Symbol	Description
	<p>European certificate of conformity</p> <p>CE marking with notified body identification numbering indicates the conformity of 93/42/EEC Medical Device Directive for class IIa devices and CE marking without notified body identification numbering indicates the conformity of 93/42/EEC Medical Device Directive for class I devices.</p>
	<p>Read accompanying user documentation indicates that important operating instructions are included in this User's and Maintenance Manual. Failure to follow these instructions could place the patient or operator at risk.</p>
	<p>Type BF applied parts.</p> <p>Applied part is a part of Smartscope that in normal use necessarily comes into physical contact with the patient.</p>
	<p>Charger polarity symbol, voltage and power</p>
	<p>Interference may occur in the vicinity of equipment (in case device has WLAN functionality).</p>
	<p>Prescription device</p> <p>Symbol for: "Caution: Federal law restricts this device to sale by or on the order of a physician or licensed practitioner."</p>
	<p>Prepare the device for reuse or separate collection as specified by Directive 2002/96/EC 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.</p>
 	<p>WARNING</p> <p>Indicates a hazardous situation which could result in patient injury, harm or death if the appropriate safety precautions are not followed.</p> <p>CAUTION</p> <p>Indicates a situation which could result in device harm, damage or mal-function if the appropriate cautions / precautions are not followed.</p>

5. Parts of the device







Cradle:





Soft key indicators:

Position	Indicator	Purpose
Left soft key		To power on the device To power off the device, with long press
Right soft key		Open menu with long press

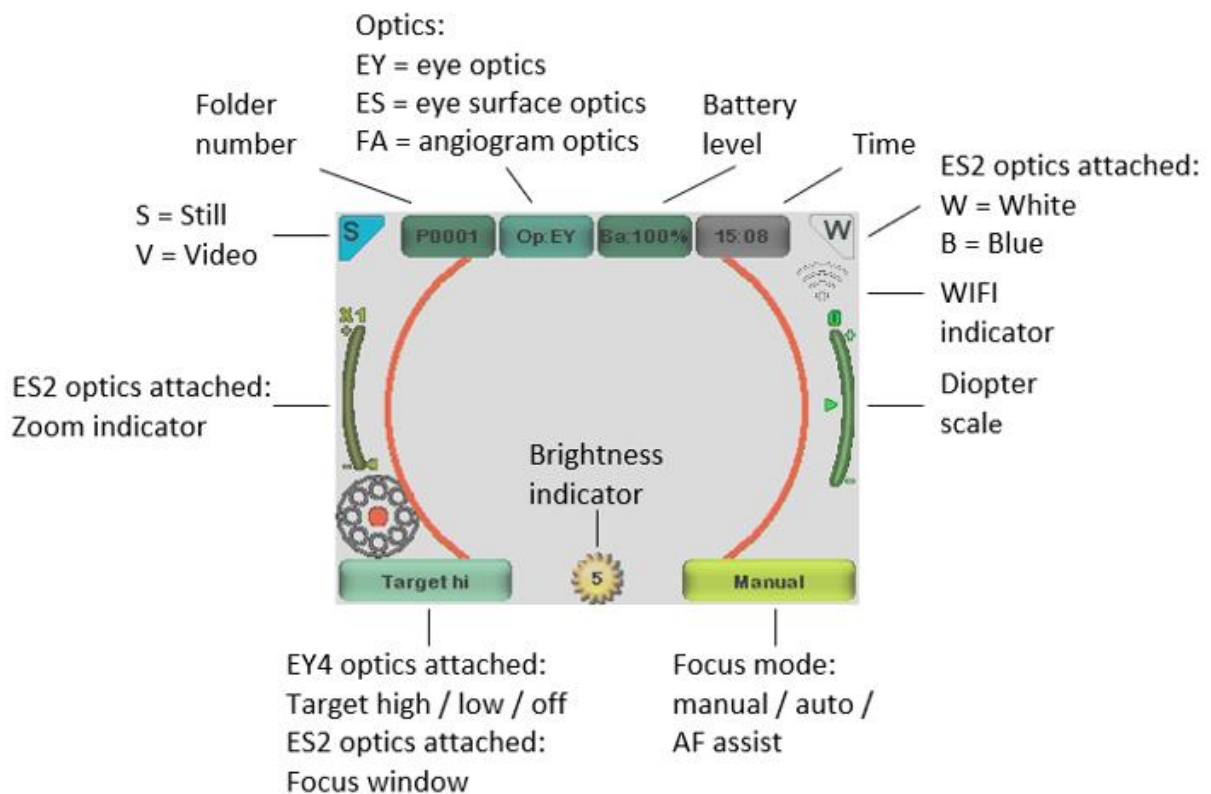
LED indicators:

The recharging and connection to PC is indicated with green (charging) and blue (connection) LED-lights:

Position	Indicator	Purpose
Left LED-indicator Green		Active when device is powered on, blinking when charging in cradle.
Right LED-indicator Blue		Active when devices is placed to the cradle and connected to a PC.

Graphical indicators:

These indicators are displayed on the top row of the display during imaging:



6. Usage environment requirements



WARNING

Smartscope is not suitable for use in the presence of flammable anesthetics.



WARNING

Place PC and cradle outside the patient environment (at least 1.5 meters distance from the patient).



CAUTION

Smartscope is intended to be used inside in a normal room temperature and normal humidity. Do not use Smartscope in an environment where there is possibility that water condenses to or inside the Smartscope.



CAUTION

If the PC is connected to a customer network make sure to apply appropriate safety measures, such as Antivirus and Firewall protection.



CAUTION

It is only allowed to attach USB cable and Power source provided in the sales package into the cradle. If you need replacement to the USB cable or Power source, please contact Manufacturer or your own Retailer.

USB Cable must be connected only to the USB port of a PC computer that complies with the IEC 60950 standard. Avoid using excessive power or twisting the connector when connecting the USB cord to a PC.

To transfer patient image data the device must be used together with a PC (Personal Computer) running either Microsoft Windows 8.1® or Windows 10®. The device does not need any drivers to be installed on a PC.

Writing to the memory card from PC is disabled by default.

Device shall be used according to this manual, quick reference guide and/or information found on Optomed website www.optomed.com.

Electromagnetic compatibility information and recommended separation distances between portable and mobile RF communications equipment and the Optomed Smartscope are given in the Appendix A.

7. Operating instructions

This chapter gives instructions for using the device. More specific instructions for using optics modules are given in the optics modules specific chapters.

7.1. Preparations

Smartscope is both charged and connected to PC (Personal Computer) using the provided cradle. When Smartscope is not used, it may be stored in the cradle. Storing device in the cradle is not harmful for the battery.

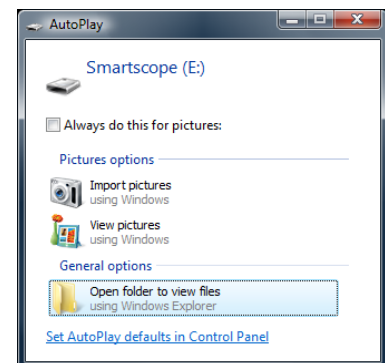
Device can be connected to the cradle with optics attached.

7.2. Connection to a PC

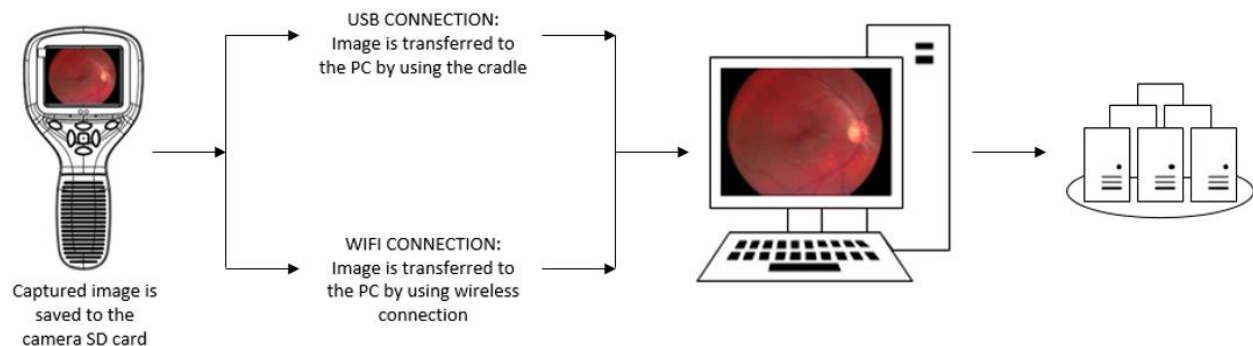
Image data transfer method to PC is similar as with a digital camera.

When connected to a PC running Microsoft Windows 8.1® or Windows 10®, operating system displays query for AutoPlay. It is possible to select appropriate image viewing program or simply open the folder to view and then store files to the hard disk of the PC.

Writing to the memory card from PC is disabled by default.



In case device has WLAN functionality, USB write protection must be turned off. WLAN enables wireless image transfer from camera to PC. Image transmission system is shown below:



Instructions how to establish WLAN connection with Optomed Client refer to Appendix C.

7.2.1. Pay-per-study

In case camera is in pay-per-study mode, images can be viewed only with Optomed Workstation Software. There are no other changes in camera functionality.

7.3. Basic use – starting up, shutting down and taking an image

Device is powered on by pressing left soft key.

It is possible to capture both images and video. Image capture mode is changed from camera menu (optics specific tab) that opens by pressing right soft key for 1s.

Still image is captured by using the dual action shutter to the second position. Video is captured by keeping the dual action shutter pressed down in the second position.

Taken image will stay on display until it is cleared by pressing right or left soft key. Image can be zoomed in instant preview by pressing middle key. There are four zoom levels. Pressing middle key activates the next level. Move around the image by using arrow keys.

To transfer images to a PC via USB connection, place device to the cradle. The image transfer and charging is indicated with green and blue LED-lights and text on LCD-screen. In case the WLAN connection is active images are transferred to the PC automatically.

NOTE:

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

Smartscope verifies if image data is erased either when device is powered on from power off mode or power save mode or when device is removed from the cradle. It is recommended that image data storage is always erased with a new patient.

Device is powered off by keeping left soft key pressed down over 1 second.

NOTE:

When device is powered on, powered off or goes to standby mode the camera focus motor may make a sound. This sound is normal and is not a sign of any damage or problem.

7.3.1. Image quality analysis

After capturing an image, the image quality analysis is performed if image quality analysis is enabled from optics menu. The results of image quality analysis are shown in instant review with the image.

Letter **B** represents the *brightness* of the image. If the brightness of the image is good, the indicator is shown as green. The indicator is shown as yellow if the image is little bit over or under exposed. If the image is severely over or under exposed the indicator is shown as red.

Letter **R** represents *reflections and shadowing*. If the image has no reflections or shadowing, the indicator is shown as green. The indicator is shown as yellow if the image has small reflections or shadows. If the image has large reflections or shadows, the light is red.

Letter **S** represents *sharpness*. If the image is sharp, the sharpness value is green. The indicator is yellow if the image is not sharp enough. For un-sharp image, the indicator light is shown as red.



7.4. Attaching and detaching optics module

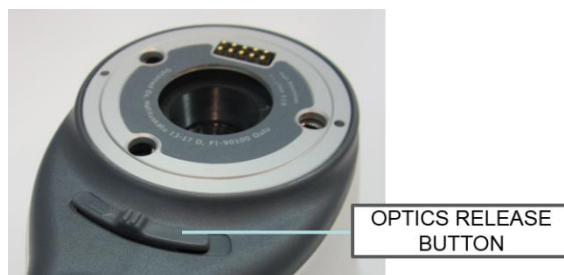
NOTE:

Optic modules used with Optomed Smartscope M5 must include text “SMARTSCOPE”. It is not allowed to attach other objects to the bayonet connector.

Optics is attached by placing it in front of the bayonet area of the device. Three bayonet legs are placed on the holes and optics is pressed firmly to the device:



Optics is released by sliding release button that is located in front of the device above the dual action shutter:

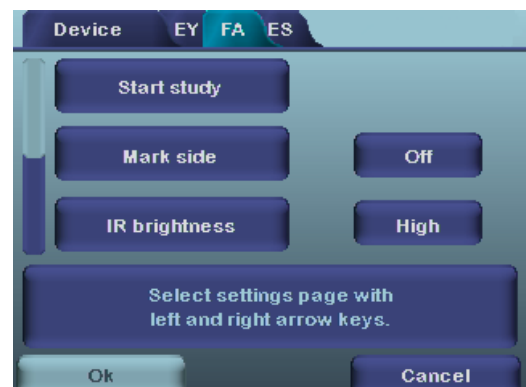


7.5. Device Menu

Menu is opened by pressing right soft key  for 1s.

Menu has different tabs. One is for device settings such as language selection. There is one tab for retinal imaging (EY), fundus angiogram imaging (FA) and anterior eye imaging (ES).

Arrow keys are used to move between tabs: use arrow key up until tab is active and use left and right arrow keys to change active tab. Light blue color indicates active tab.



Arrow keys change values in the menu. Active value is indicated with light blue color. Changed values are saved by using left soft key (“Ok”) and cancelled by pressing right soft key (“Cancel”). Some values are confirmed by pressing the Middle key.

Table below includes explanations of the Device settings tab:

Setting	Values (default bolded)	Purpose
Preview images	Ok	To preview the images on camera, press middle button.
New patient folder	Ok	To create a new patient folder, press middle button. New patient folder can also be created in live view by long pressing the middle key.
Erase image memory	Ok	Select middle button to erase images and videos from camera SD card.
Edit patient list	Ok	Press middle key to edit patient list
Patient information	On/Off	Enable or disable patient information linking
Display brightness	Low-Med-High	Use left and right arrow keys to adjust display brightness
Icons	On/Off	Show graphical icons when imaging
Sounds	On/Off	When enabled, sound is played during image capture
Keyboard backlight	On/Off	When enabled, keyboard illumination is on
Select language	ENG-FIN-FRA-GER-ITA-JPN-POR-SPA-ZHO	Use left and right arrow keys to select camera language
USB write protection	On/Off	When enabled, writing to SD card is not allowed when device is in cradle. This feature helps prevent any viruses getting from PC to the camera. Note that if device contains WLAN card, during its setup or updating of its firmware, USB write protection need to be temporarily set off.
Video file format	MPEG4/MPEG1	Use left and right arrow keys to select video file format
Image transfer method	UMS/WIA	Use WIA for automatic and UMS for end-user activated image transfer. UMS can be used in most cases.
Restore factory Setting	Ok	To restore all settings menus to factory defaults. Activate using the middle key. Note that also Wireless password is restored to default.
SD card firmware update mode	Ok	To start SD card firmware update mode, press middle button.
Date	DD-MM-YYYY	Use up and down arrow keys to set date.
Time	HH:MM	Use up and down arrow keys to set time.
Camera SW version	Show camera SW version	Browse version information with left and right arrow key
Start query	Era./Fol./None	Choose the startup query between memory erase, new patient folder or no query at all.
Wireless	On/Off	Enable or disable wireless connection
Wireless info	Ok	To view 'WLAN SSID' and 'WLAN Password', press middle button.

Preview images

Image preview is opened by selecting "Preview files" with a middle key. Images are browsed by using arrow keys. Display gives information about usage of the image preview.

Image can be zoomed while previewing by pressing middle key. Move around the image by pressing arrow keys. Change between the four zoom levels by pressing middle key. Patient ID information can be edited in image browser.

New Patient Folder

A new patient folder is created by pressing middle key when the new patient folder selection is active in Device menu. A new patient folder can also be created by pressing Middle key for 3 seconds when in live view. If the current patient folder is empty a new folder cannot be created.

Erase Image Memory

Image memory can be erased by selecting “Erase Image Memory” in Device menu. This selection is activated by pressing middle key. The camera also prompts the question “Erase image memory?” when camera is powered on or removed from cradle.

Edit patient list

User can add or remove patients from patient list.

Patient information

Enable or disable patient information linking.

Display brightness

The Display brightness selection has three options: low, medium, and high. Choose the suitable level of display brightness according to for example how the examination room is lit up.

Icons

The icons shown on camera screen can be enabled or disabled to the user’s liking. The most essential icons such as Menu icon are always visible.

Sounds

By default, the camera makes a sound during image capture. This sound can be turned off from Device menu.

Keyboard backlight

By default, the camera keys have a backlight lit up when the camera is turned on. This light can be turned off from Device menu if it disturbs the user while taking images.

Language

Camera has nine (9) different languages the user can choose from: *English (default), Finnish, German, French, Italian, Spanish, Portuguese, Japanese and Chinese*. The language selection is always shown in English in menu. If language is changed camera must be re-started.

USB write protection

USB write protection is on by default. When protection is on this feature will prevent any virus from entering the camera from a PC when connected to the cradle. In case device has WLAN functionality, USB write protection must be turned off.

Video file format

Camera has two file formats that user can choose for videos: MPEG4 and MPEG1. MPEG4 is a higher quality file format but may not be viewed with all video players. MPEG1 format is more widely supported by different SW applications.

Image transfer method

There are three options for the image transfer method: UMS (USB Mass Storage), WIA (Windows Image Acquisition) and WLAN. NOTE: WLAN supported only if device has WLAN functionality.

Restore factory settings

Press middle key to restore factory defaults selection. Note that also Wireless password is restored to default.

SD card firmware update mode

In case the device has WLAN functionality, SD card firmware can be updated by pressing middle button. The device must be placed on cradle for SD card firmware update. If PC prompts a message to insert the SD card, press any camera key to continue update. For more specific instructions, see Appendix C.

Date

Press middle key to change date settings. Date can be set using the up and down arrow keys. Move between day, month, and year by pressing the left and right keys. Date format is DD MM YYYY for Finnish, German, French, Italian, Spanish and Portuguese. Date format is MM DD YYYY for Japanese and Chinese.

Time

Press middle key to change time settings. Time can be set using the up and down arrow keys. Move between hours and minutes by pressing the left and right arrow keys.

Camera SW version

This item in Device menu tells the camera SW version.

Start query

User can choose start-up query between erasing images, creating new patient folder or no query at all. When erasing images is chosen as the query the camera will prompt user on start-up whether all images and videos shall be deleted. When new patient folder query is chosen the camera will ask if a new patient folder shall be created upon start-up to prevent from mixing images with previous patient. If no query is selected, the camera will go directly to live view upon start-up.

Wireless

By default, wireless connection is on. User can enable or disable wireless connection. When wireless connection is enabled, the wireless symbol is shown on display next to the battery level indicator.

Wireless info

Press middle key to view wireless connection information. 'WLAN SSID' and 'WLAN Password' are shown.

7.6. Patient editor

Patient information usage can be enabled / disabled. There can be maximum of 500 patients on the list. Name of the patient is shown in low right-hand side above right soft key, if current folder is linked to a patient.

7.6.1. Adding new patient

User can add new patient from Device menu by selecting Edit Patient list. User can add Patient ID and Patient name after choosing New patient. New patient can be added also after creating new folder.

7.6.2. Patient folder linking

User can link or unlink patient to/from current folder (not earlier ones). It is possible to link 5 folders to each patient.

Linking can be done:

1. After erasing image memory, choose 'yes' when camera asks to 'choose patient for the folder'.
2. Choosing Link in image browser when folders and files are visible. Link key is grey and unresponsive if current folder is not chosen. After folder is linked to a patient, folder is named by the patient.
3. After creating new folder by long pressing middle key or from menu, choose 'yes' when camera asks to 'choose patient for the folder'.

NOTE: Exiting from image browser is done by pressing left key.

7.6.3. Patient list exporting

User can export patient list via WLAN. New file is created containing patient list with 16 KBytes of padding bytes added to the end of file. File is named pehhmmss.jpg (hh is current hours, mm minutes and ss seconds). File is written under DCIM folder in SD card. File is exported over WLAN.


Patient list can be exported also via USB. Patient list is written as text file (patexp.txt) to SD card root. If patient list is modified in camera (new patient created) or SD card is erased, patient list is updated.

7.7. Adjusting focus and automatic focus

Camera has an autofocus function where camera finds correct focus place automatically. For EY4 and FA square indicator appears when focusing is finished. For ES2 focus window turns green when focusing is finished. Automatic focusing starts when shutter button is pressed halfway down. Focus mode can be changed by pressing right soft key.

Image focus can be adjusted manually by pressing arrow keys up and down. When focus mode is set to manual a diopter scale is visible on the screen.

7.8. Reset button

Reset button can be used if device behavior is abnormal. Reset button is located in a small opening under display. Button is marked with circle. 

Reset button can be pressed with a thin object such as a paper clip. Button needs to be pressed for over 7 seconds.



8. Retinal imaging using optics module Smartscope EY4

Optomed Smartscope EY4 digital ophthalmic camera is intended to capture digital images and video of the fundus of the human eye. The device set for retinal imaging consists of:

- Camera handset M5
- Attachable ophthalmic lens EY4
- Eye cup for EY4
- Cradle for charging and image transfer

Smartscope EY4 is intended for non-mydriatic imaging. This means that infrared is used for targeting image to the eye fundus and visible light is flashed when image is taken. Pupil does not respond to the infrared light, so examination is convenient for the patient. Constant illumination can be selected from device menu if mydriatic drops are used. Pictures can also be taken using infrared light for both aiming and capturing.

Smartscope EY4 has 9 internal fixation targets for the patient to fixate at while imaging. Below section will guide how to control the fixation lights.

STEPS FOR RETINAL IMAGING:

1. The examination room should be as dark as possible.
2. Both the patient and the examiner shall be seated while taking the images.
3. Either autofocus or manual focus can be used. Autofocus range is -15 to +10 diopters.

If patient has a refractive error and **autofocus is off**, focus needs to be adjusted:

- Hyperopia: camera is focused to distance by pressing arrow key up. One click of the key is approximately 1 Diopter.
- Myopia: camera is focused closer by pressing arrow key down. One click of the key is approximately 1 Diopter.

4. Aiming light is automatically turned on when camera enters live view.
5. Middle fixation target is lit when pressing left soft key and it provides a macula centered image. To change the fixation target press Left Soft Key and use arrow keys to navigate between the 9 targets as shown in the graphics in lower left corner of the display. If fixation target is turned off, ask patient to look at a target in a wall 2-3 meters behind the operator.
6. Capturing light is adjusted using left and right arrow key. There are brightness levels from 0 to 10, default value is 5, and typical levels are from 2 to 8. There are also low brightness levels 0.2, 0.4, 0.6 and 0.8 if brightness level 1 is too bright.

When using IR/White capture mode changing illumination brightness affects only the white capturing flash. If using IR/IR or White/White both aiming and capturing light are changed.

7. Aim help circle on the screen guides user when to take image. When retina is not fully in view the circle is red. Once the aim is good and retina fully appears on screen the circle turns green indicating a good moment for capturing the image.
8. Approaching the eye is started from 10 centimeters (4 inch) distance. If internal fixation target is not used patient is asked to look at a target in a wall 2-3 meters behind the operator (patient's eye targets to infinity and stays still). Pupil is approached until the reflection from the eye fundus can be seen.

The right imaging distance is about 2 cm (0.8 inch). Eye cup must be compressed approximately halfway down. Aim help circle on the display guides to take image once it turns from red to green.

Camera is stabilized by keeping the outer side of the hand against the patient's forehead. Example of the correct usage position is shown below:



9. Still image is captured by pressing the shutter button all the way down. If half-press capture is enabled, still image can be captured by pressing shutter button halfway down. Taken image is displayed on screen until user clears the image by pressing shutter button, left or right soft key.

Instant review can be enabled/ disabled in the Smartscope EY4 optics menu.

10. Image can be zoomed in instant preview by pressing middle key. There are four zoom levels (1, 2, 4, 8). Pressing middle key activates the next level. Move around the image by using arrow keys. Scroll between images by using left and right arrow keys.
11. Video is captured by keeping shutter button down. If half-press capture is enabled, video image can be captured by pressing shutter button halfway down. Video capturing is finished by pressing shutter button all the way down.
12. If multiple patients are examined during one session, new file folder is created for each patient by pressing middle key for over 3 seconds.
13. Transfer images to a PC after capturing images. Images are transferred via USB connection to the PC when camera is placed to the cradle or images are automatically transferred wirelessly to the PC if WLAN connection is active. Smartscope works as any other digital camera.
14. To erase the image/video manually, choose Menu, then Preview Images. There will be an option to erase a specific image or a specific folder.
15. When camera is removed from the cradle it verifies image data storage erase. It is recommended that image data storage is always erased before images are captured of a new patient.

Camera keys function as shown in image below when Smartscope EY4 optics module is attached:

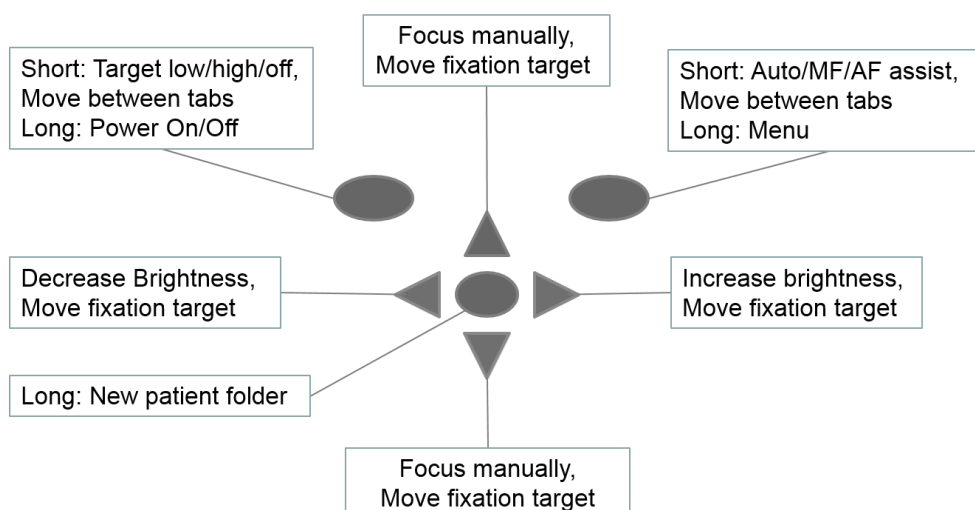


Table below provides explanations for the key functions:

Key	Press	Function	Explanation
Left soft key	Short	Control Fixation target level and selection	Fixation target is off by default and can be turned on by pressing left soft key. Fixation target light has two levels: Low and High. If the patient cannot see the light on low level turn it up to high.
	Long	Power On / Off	Camera is powered on and off by pressing the Left soft key for longer than 2s.
Right soft key	Short	Manual / Auto / AF assist	Switch between focus modes by pressing Right soft key. Manual focus is on by default. Autofocus range is -15 to +10 diopters.
	Long	Open Menu	Enter camera menu by pressing Right soft key for longer than 1s.
Middle key	Long	New patient folder	If multiple patients are examined during a same session, it is recommended to create a new file folder for each patient's images. New folder is created by pressing middle key for 3 seconds. Icon P at the top of the screen indicates number of the current patient folder. If the current folder does not have any images in it, a new folder cannot be created.
Left/Right arrow	-	Change brightness	Use left and right arrow keys to adjust capture light brightness. Icon above right soft key must be selected to change brightness.
		Move fixation target	Move between 9 internal fixation targets. Icon above left soft key turns to lighter color when fixation target selection mode is active.
Up/Down arrow	-	Focus manually	When manual focus is active use up and down arrow keys to focus. Press arrow key up when patient has hyperopia. Press arrow key down when patient has myopia.
		Move fixation target	Move between 9 internal fixation targets. Icon above left soft key turns to lighter color when fixation target selection mode is active.

Table below includes explanations of the EY settings tab for retinal imaging:

Setting	Values (default bolded)	Purpose
Capture mode	Still / Video	Use left and right arrow keys to move between still capture and video capture.
Half press capture	On/ Off	Enable capture by pressing shutter button halfway down.
Mark side	On/ Off	Mark side of the eye to the image data.
Red-free	On /Off	Saves a copy of an eye image using green color channel only.
Save IR image	On/ Off	Saves an image taken with IR light in addition to white light image when turned on.
Low red	On/ Off	Capture red reduced copy in addition to normal fundus image.
Illumination mode	IR/Wh , IR/IR, Wh/Wh	Use left and right arrow keys to select aiming and capture light source.
Automatic IR contrast	On /Off	Enable automatic IR contrast
Target blinking	On / Off	Fixation target light can be set to constant if needed.
Capture setting in image	On/ Off	Enable or disable writing of capture settings to image.
Instant Review	On /Off	Instant review can be ON/OFF according to user need, as available in EY Optics menu. Instant review image can be changed from left and right arrow keys.
Image quality analysis	On /Off	Enable or disable the image quality analysis after image capture.

Capture mode

Both still images and video can be taken with the Smartscope M5 camera. When taking video, the shutter button must be held down while taking the video. The video recording will stop once the shutter button is released.

Half-press capture

It is possible to take images and video by pressing shutter button halfway down.

Marking side

It is possible to mark which eye was imaged. Marking side is enabled from the menu. When On side is marked to the file name and to the image. For video files, side is always marked only to the file name. When marking side is enabled, camera verifies side after each captured image. Identifiers used for eye images are OS for left and OD for right.

Save Red-free

If red-free image is enabled from menu, then camera will save a picture using only green channel at the same time when saving original picture.

Save IR image

If Save IR image is enabled from menu the camera will save an image taken with IR image in addition to saving a color image taken with white light.

Low red

It is possible to capture red reduced image.

Illumination mode

Illumination mode can be set to IR/White, IR/IR or White/White. In IR/White mode aiming is done using infrared light and image is captured using white light. The pupil does not react to infrared light and thus it is recommended to use IR/White mode whenever possible. In IR/IR mode both aiming and image capture are done with infrared light. In White/White mode aiming and image capture are done with white light.

Automatic IR contrast

Automatically adjust infrared live view brightness and contrast according to image content. Improves visibility of fundus features during aiming. Same contrast and brightness settings are applied to IR still captures.

NOTE: In IR/IR mode, IR brightness adjustment does not always directly affect brightness on screen when automatic contrast is enabled. This happens because automatic contrast feature always tries to adjust screen brightness to same level. IR brightness setting still works, but the effect is only visible when adjustment range of automatic contrast adjustment runs out. It is advisable to use highest brightness that does not cause image saturation (pink or white “washed out” effect)."

Target blinking

By default, the fixation target light is on with blinking illumination. If patient cannot keep their eye targeted well the light can be changed to constant to help focus on the target light.

Capture setting in image

It is possible to write brightness and diopter settings to image.

Instant review

Instant review can be ON/OFF according to user need, as available in EY Optics menu. When the reviewing zoom level is 1x, user can change the image to be reviewed with left and right arrow keys. Images are in showing order Normal, Low-red, Red-free, IR.

NOTE: Camera stores selected menu settings when it is powered off.

Image quality analysis

When image quality analysis is turned on, the camera analyses the taken image and shows the results related to brightness, reflection and shadowing, and image sharpness.

9. Eye imaging using anterior ophthalmic module Smartscope ES2

Optomed Smartscope ES2 is intended to capture images and video of the surface of the human eye and surrounding areas. The device set for anterior ophthalmic imaging consists of:

- Camera handset M5
- Attachable anterior ophthalmic lens ES2
- Cradle for charging and image transfer

Smartscope ES2 optics module has two light sources, white and cobalt blue light. User can choose between the light sources by pressing middle key when ES2 module is attached. Cobalt blue light enables taking fluorescent pictures of the surface of the eye to reveal any cuts or defects.

STEPS FOR EYE SURFACE IMAGING:

1. After ES2 optics module is attached the light source is chosen by pressing middle key.
2. Still or video image is selected. Selection is made in ES menu.
3. It is recommended to use autofocus.
4. Aiming light is turned on by pressing the shutter key (in front of the device) halfway down.
5. Light is adjusted using left and right arrow key. There are altogether 10 brightness levels. Default value is 5. Suitable illumination is typically 2 to 8.
6. Place the optics module cup on patient's eye. Patient can be asked to look at different directions depending on what area of the eye needs to be captured.

Camera is stabilized by keeping the outer side of the hand against the patient's forehead. Example of the correct usage position is shown below:



7. Still image is captured by pressing the shutter key all the way down. If half-press capture is enabled, still image can be captured by pressing shutter button halfway down. Taken image is displayed on screen until user clears the image by pressing shutter button, left or right soft key.

Instant review can be enabled/ disabled in the Smartscope ES2 optics menu.

8. Image can be zoomed in instant preview by pressing middle key. There are four zoom levels (1, 2, 4, 8). Pressing middle key activates the next level. Move around the image by using arrow keys. Scroll between images by using left and right arrow keys.
9. Video is captured by keeping shutter button down. If half press-capture is enabled, video image can be captured by pressing shutter button halfway down. Video capturing is finished by pressing shutter button all the way down.

10. If multiple patients are examined during one session, new file folder is created for each patient by pressing middle key for over 3 seconds.
16. Transfer images to a PC after capturing images. Images are transferred via USB connection to the PC when camera is placed to the cradle or images are automatically transferred wirelessly to the PC if WLAN connection is active. Smartscope works as any other digital camera.
11. Erase manually image / video by choosing Menu – Preview images. There can be chosen either the specific image or the specific folder to be erased.
12. When camera is removed from the cradle it verifies image data storage erase. It is recommended that image data storage is always erased before images are captured of a new patient.

Camera keys function as shown in image below when ES2 optics module is attached:

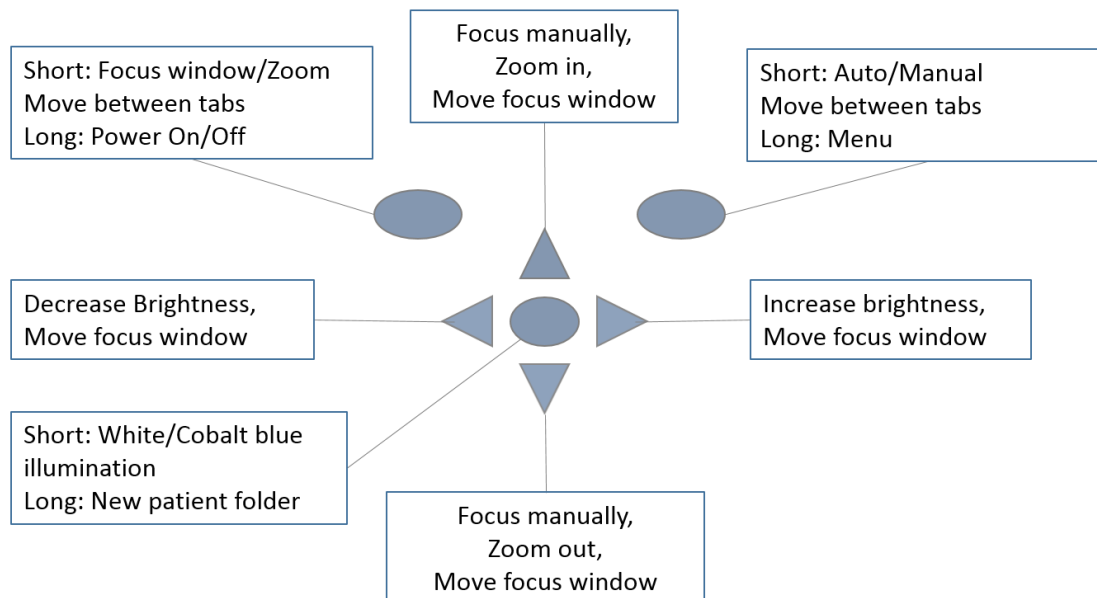


Table below provides explanations for the key functions:

Key	Press	Function	Explanation
Left soft key	Short	Edit focus window/ Activate Zoom	When focus window is visible it is possible to move it using arrow keys to better capture the wanted area. Digital zoom can be used for close up of features and image focus. Zoom value is saved to camera memory.
	Long	Power On / Off	Camera is powered on and off by pressing the Left soft key for longer than 2s.
Right soft key	Short	Auto / Manual focus / Activate Zoom	Switch between Auto and Manual focus by pressing Right soft key. Press Right soft key to activate zoom function. Digital zoom can be used for close up of features and image focus. Zoom value is saved to camera memory.
	Long	Open Menu	Enter camera menu by pressing Right soft key for longer than 1s.
Middle key	Short	White / Blue	Choose between white and blue illumination by pressing left soft key. Blue light can be used with fluorescent applied on the eye to reveal any cuts or defects.
	Long	New patient folder	If multiple patients are examined during a same session, it is recommended to create a new file folder for each patient's images. New folder is created by pressing middle key for 3 seconds. Icon P at the top of the screen indicates number of the current patient folder. If the current folder does not have any images in it, a new folder cannot be created.
Left/Right arrow	-	Change brightness	Use left and right arrow keys to adjust capture light brightness.
	-	Move AF window	Move focus window left and right after pressing Middle key to activate. Window returns to original position when camera is put to cradle, turned off or optics module detached.
Up/Down arrow	-	Focus manually	Use up and down arrows to focus manually.
		Zoom In / Out	Zoom in using arrow key up. Zoom out using arrow key down. There are four zoom levels: 1, 2, 4 and 6. Zoom value is saved to camera memory.
	-	Move AF window	Move focus window left and right after pressing Middle key to activate.

Table below includes explanations of the ES settings tab for anterior eye imaging:

Setting	Values (default bolded)	Purpose
Capture mode	Still / Video	Use left and right arrow keys to choose between still capture and video capture.
Half-press capture	On/ Off	Enable capture by pressing shutter button halfway down.
Focus windows	Visible /Hidden	Use left and right arrow keys to choose between having focus window visible or hidden.
Mark side	On/ Off	Mark side of the eye to the image data.
Zoom cropping	On /Off	When turned on camera will save the zoomed area only. When turned off camera will save the whole image area even when zoom is used.
Instant Review	On /Off	Instant review can be ON/OFF according to user need, as available in ES Optics menu. Instant review image can be changed from left and right arrow keys.

Capture mode

Both still images and video can be taken with the Smartscope M5 camera. When taking video, the shutter button must be held down while taking the video. The video recording will stop once the shutter button is released.

Half-press capture

It is possible to take images and video by pressing shutter button halfway down.

Focus Window

Focus Window helps user position the image. Focus Window can be moved on the screen by using Left soft key and then using the arrow keys when aiming.

Marking side

It is possible to mark which eye was imaged. Marking side is enabled from the menu. When On side is marked to the file name and to the image. For video files, side is always marked only to the file name.

When marking side is enabled, camera verifies side after each captured image.

- Identifiers used for normal eye images are OS for left and OD for right.
- Identifiers used for red-free images are SG for left and DG for right.
- Identifiers used for saving IR images are SI for left and DI for right.
- Identifiers used for low-red images are SC for left and DC for right.

Zoom cropping

With zoom cropping on the camera will save the zoomed area instead of the whole image area. By default, zoom cropping is turned off and camera will save the whole image area instead of the area that is visible on the camera screen when user has zoomed in.

Instant review

Instant review can be ON/OFF according to user need, as available in ES Optics menu. When the reviewing zoom level is 1x, user can change the image to be reviewed with left and right arrow keys. Images are in showing order Normal, Low-red, Red-free, IR.

NOTE: Camera stores selected menu settings when it is powered off.

10. Fluorescein Angiography imaging using optics module Smartscope FA

Optomed Smartscope FA digital ophthalmic camera is intended to capture digital images of the fundus angiography of the human eye. The device set for fundus angiography imaging consists of:

- Camera handset M5
- Attachable Smartscope FA
- Eye cup for FA
- Cradle for charging and image transfer

Infrared is used for targeting image to the eye fundus and blue light is flashed when image is taken. Pupil does not respond to the infrared light, so examination is convenient for the patient.

Smartscope FA has 9 internal fixation targets for the patient to fixate at while imaging. Below section will guide how to control the fixation lights.

STEPS FOR RETINAL IMAGING:

1. The examination room should be as dark as possible.
2. Both the patient and the examiner shall be seated while taking the images.
3. When using Smartscope FA optics it is recommended to mount the device on a slit lamp base using Slit lamp Adapter to achieve good images.
4. Either autofocus or manual focus can be used. Autofocus range is -11 to +3 diopters.

If patient has a refractive error and autofocus is off, focus need to be adjusted:

- Hyperopia: camera is focused to distance by pressing arrow key up. One click of the key is approximately 2 Diopters.
 - Myopia: camera is focused closer by pressing arrow key down. One click of the key is approximately 2 Diopters.
5. Aiming light is automatically turned on when camera enters live view.
 6. The middle fixation target is lit when pressing left soft key and it provides a macula centered image. To change the fixation target press Left Soft Key and use arrow keys to navigate between the 9 targets as shown in the graphics in lower left corner of the display. If fixation target is turned off, ask patient to look at a target in a wall 2-3 meters behind the operator.
 7. Light is adjusted using left and right arrow key. There are altogether 10 brightness levels. Default value is 5. Suitable illumination is typically 2 to 8. Changing illumination brightness affects only the blue capturing flash.
 8. Aim help square on the screen guides user when to take image. When retina is not fully in view the square is red. Once the aim is good and retina fully appears on screen the Square turn's green indicating a good moment for capturing the image.
 9. Approaching the eye is started from 10 centimeters (4 inch) distance. Pupil is approached until the reflection from the eye fundus can be seen. The right imaging distance is about 2 cm (0.8 inch). Eye cup must be compressed approximately halfway down. Aim help square on the display guides to take image once it turns from red to green.

Camera is stabilized by keeping the outer side of the hand against the patient's forehead. Example of the correct usage position is shown below:



10. Still image is captured by pressing the shutter button halfway down. If half-press capture is enabled, still image can be captured by pressing shutter button halfway down. Taken image is displayed on screen until user clears the image by pressing shutter button, left or right soft key.

Instant review can be enabled/ disabled in the Smartscope FA optics menu.

11. Image can be zoomed in instant preview by pressing middle key. There are four zoom levels (1, 2, 4, 8). Pressing middle key activates next level. Move around the image by using arrow keys. Scroll between images by using left and right arrow keys.
12. Starting and ending the burst capturing: In order to start the burst capturing, keep the shutter button pressed halfway or all the way down during image capturing. Burst mode is enabled until user releases shutter button.
13. If multiple patients are examined during one session, new file folder is created for each patient by pressing middle key for over 3 seconds.
14. Transfer images to a PC after capturing images. Images are transferred via USB connection to the PC when camera is placed to the cradle or images are automatically transferred wirelessly to the PC if WLAN connection is active. Smartscope works as any other digital camera.
15. When camera is removed from cradle it verifies image data storage erase. It is recommended that image data storage is always erased before images are captured of a new patient.

Camera keys function as shown in image below when Smartscope FA optics module is attached:

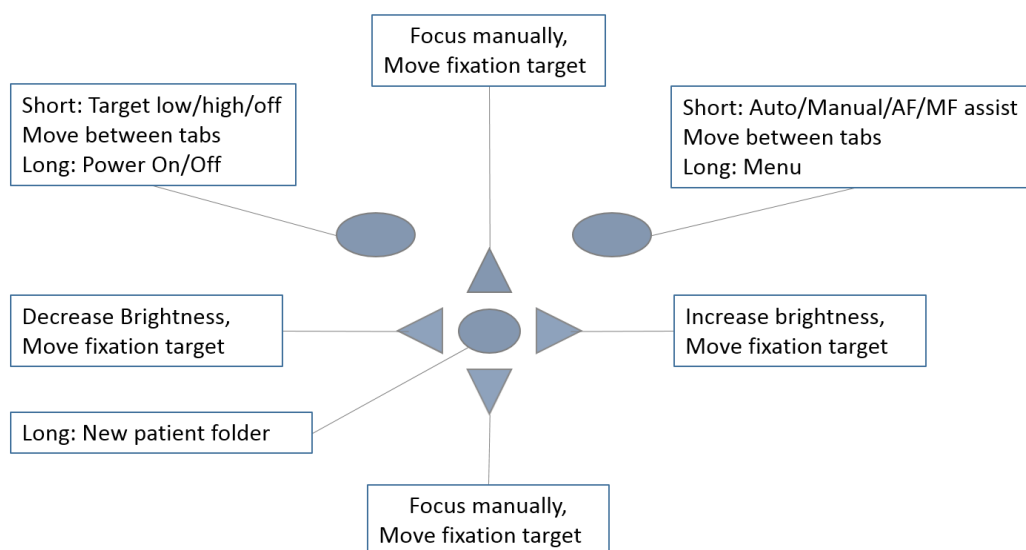


Table below provides explanations for the key functions:

Key	Press	Function	Explanation
Left soft key	Short	Control Fixation target level and selection	Fixation target is off by default and can be turned on by pressing left soft key. Fixation target light has two levels: Low and High. If the patient cannot see the light on low level turn it up to high.
	Long	Power On / Off	Camera is powered on and off by pressing the Left soft key for longer than 2s.
Right soft key	Short	Auto / Manual / AF / MF assist	Switch between focus modes by pressing Right soft key. Manual focus is on by default. Autofocus range is -11 to +3 diopters.
	Long	Open Menu	Enter camera menu by pressing Right soft key for longer than 1s.
Middle key	Long	New patient folder	If multiple patients are examined during a same session, it is recommended to create a new file folder for each patient's images. New folder is created by pressing middle key for 3 seconds. Icon P at the top of the screen indicates number of the current patient folder. If the current folder does not have any images in it, a new folder cannot be created.
Left/Right arrow	-	Change brightness	Use left and right arrow keys to adjust capture light brightness. Icon above right soft key must be selected (lighter color) to change brightness.
		Select fixation target	Move between 9 internal fixation targets. Icon above left soft key turns to lighter color when fixation target selection mode is active.
Up/Down arrow	-	Focus manually	When manual focus is active use up and down arrow keys to focus. Press arrow key up when patient has hyperopia. Press arrow key down when patient has myopia.
		Select fixation target	Move between 9 internal fixation targets. Icon above left soft key turns to lighter color when fixation target selection mode is active.

Table below includes explanations of the FA settings tab for fundus Angiography imaging:

Setting	Values (default bolded)	Purpose
Start Study /Stop Study		Start study enables study to start. For every new study, user needs to go into the menu and start study to enable the study or Time counter. Stop study will finish study session.
Half press capture	On/Off	Enable capture by pressing shutter button halfway down.
Mark side	On/Off	Mark side of the eye to the image data.
Automatic IR contrast	On/Off	Enable automatic IR contrast
Target Blinking	On/Off	By default, the fixation target light is on with constant illumination. If patient cannot keep their eye targeted well the light can be changed to blink to help the patient to focus on the target light.
Automatic exposure	On/Off	Turn automatic exposure on or off for captured images.
Capture setting in image	On/Off	Enable or disable writing of capture settings to image.
Instant Review	On/Off	Instant review can be ON/OFF according to user need, as available in FA Optics menu.

Start Study/Stop Study

Start study enables fluorescein angiography study to start. For every new study, user needs to go into the menu and select start to enable the study or Time counter. Stop study finishes fluorescein angiography study session.

Half-press capture

It is possible to take images by pressing shutter button halfway down.

Marking side

It is possible to mark which eye was imaged. Marking side is enabled from the menu. When On, side is marked to the file name and to the image. When marking side is enabled, camera verifies side after each captured image. Identifiers used for eye images are OS for left and OD for right.

Automatic IR contrast

Automatically adjust infrared live view brightness and contrast according to image content. Improves visibility of fundus features during aiming. Same contrast and brightness settings are applied to IR still captures.

NOTE: In IR/IR mode, IR brightness adjustment does not always directly affect brightness on screen when automatic contrast is enabled. This happens because automatic contrast feature always tries to adjust screen brightness to same level. IR brightness setting still works, but the effect is only visible when adjustment range of automatic contrast adjustment runs out. It is advisable to use highest brightness that does not cause image saturation (pink or white “washed out” effect).

Target blinking

By default, fixation target light is on with constant illumination. If patient cannot keep their eye targeted well light can change to blink to help focus on the target light.

Automatic exposure

Brightness of captured still image is optimized to be as bright as possible i.e. having maximum brightness. By default, brightness optimization is on.

Capture setting in image

It is possible to write brightness and diopter settings to image.

Instant review

Instant review can be ON/OFF according to user need, as available in FA Optics menu. When the reviewing zoom level is 1x, user can change the image to be reviewed with left and right arrow keys. Images are in showing order Normal, Low-red, Red-free, IR.

NOTE: Camera stores selected menu settings when it is powered off.

Menu:

1. Default Display window when FA optics is attached using Manual Mode. You can adjust the diopter scale according to patient diopter manually. Image can be taken when shutter button is pressed all the way down.
2. op:FA → Optics recognized as FA for fundus angiography imaging.
3. Default Display window when FA optics is attached using AF Assist mode. Diopter scale is automatically adjusted, Image can be captured when shutter button is pressed half a way.
4. Default Display window when FA optics is attached using MF Assist mode. Diopter scale is manually adjusted, Image can be captured when shutter button is pressed half a way.
5. When Right Soft key is long pressed, Menu table appears on display.
Default Device tab will be ON. By using left and right arrow keys you slide to the next tab.

Time Counter:

Start study can be selected from the FA optics menu or by pressing shutter button halfway (half-press is enabled) or by pressing shutter button all the way down. Time counter will appear on the upper right on the screen.

Time counter will be printed on the final images. Time counter will guide you through all the phases of Angiography.

To stop the time counter after finishing the study, user need to go to FA optics menu and press the STOP STUDY button.

11. Error messages

Optomed Smartscope M5 will display error messages for the limitations of the usage. Error message is always displayed with explanatory message providing information about possible actions.

List of error messages:

Error message:	What to do:
Autofocus calibration needed	Please hold camera horizontal and press OK to calibrate.
Battery failure	Remove battery completely from camera. Re-install or replace.
Charging failure	Please remove and reconnect device to cradle.
Image counter full	Copy images to safe location and then choose Erase image memory from device menu.
Image storage not found	Please contact service for more information.
Light source temperature too high	Restart camera.
Memory erasing failed	Please contact service for more information.
Memory full	Memory is full, store images and erase memory card.
Optic type not detected	Please re-attach optics.
Optic communication failed	Please re-attach optics.
Optic control failed	Please detach optics and restart camera.
Patient list upload failed	Please verify list against instructions.
System flash memory not available	Please contact service for more information.
Low battery. Please Charge. Powering down.	Charge battery or change it to a new one.
Failed to access image memory	Erasing image memory might help
Previous startup did not finish successfully	Erasing image memory might help.
Failed to change wireless password #	New password is invalid, or the change otherwise failed. Retry to change the password. Contact maintenance if same error happens again. The number after the text is an error code that can be needed by customer service.

12. Cleaning instructions

Optomed Smartscope M5 is a precision optics instrument that should be handled with care. Please note following cleaning instructions for camera and optics modules:

- Shut down device before cleaning it
- Remove cradle from mains before cleaning it
- Disinfect housing with soft cloth moistened with alcohol (e.g. 70% ethanol). Avoid touching System connectors in the handset and cradle.
- Lenses may be cleaned with cleaning cloth. Also, moist-cleaning tissue such as Hama Pro-Optic® cleaning tissue can be used.

Optomed Smartscope is not intended to be sterilized.

Clean Eye optics (EY4, FA) and Eye surface optics (ES2) eye cup before each use on a new patient:

- disinfect eye cup with soft cloth moistened with alcohol (e.g. 70% ethanol), or
- soak eye cup in glutaraldehyde based solution, or hydrogen peroxide and peracetic acid solution such as Erisan OXY+
- rinse the eye cup under running water
- dry the eye cup (e.g. with clean paper towel) before subsequent use

If replacement for eye cup (EY4, FA) is needed, please contact Optomed or your own retailer.

Eye cup should be replaced if/when:

- eye cup is discolored
- eye cup form is deteriorated
- eye cup is shattered, cracked or disintegrated



WARNING

Clean eye cup before each use on a new patient to avoid contamination.

13. Device maintenance

Optomed Smartscope contains rechargeable Ni-MH battery pack. Service life of the battery is approximately 1-2 years. Battery needs to be replaced on planned intervals. When battery is at end of its service life, usage time of the device goes down.

Appendix B gives instructions for battery replacement.

There are no other maintenance procedures that can be carried out by the user. All servicing and repairs other than replacing the battery must be carried out by Optomed or Optomed certified service facilities and service personnel. Optomed Plc will make available work instructions to repair those parts of medical electrical equipment that Optomed Plc has designated as repairable by service personnel.



CAUTION

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

14. Technical description

CAMERA:

Type:	OPTOMED SMARTSCOPE M5
Image sensor:	CMOS, 5.0 Megapixels
Image memory type:	Micro SDHC card or WLAN SDHC card
Display:	2.4", TFT-LCD, 262 000 colors, antireflective coating
Image format:	JPEG (file extension: jpg)
Video format:	MPEG-4 and MPEG-1
USB Connectivity:	PC with USB or WLAN (WPA2)
WLAN Connectivity:	802.11gn, WPA2 Frequency range: 2412 – 2462 MHz Max radiated power: 17 dBm
Operating systems:	Microsoft Windows 8.1®, Windows 10® No driver installation needed.
Dimensions:	82,30(w) x166,50(h) x 66,50(d) mm
Weight:	400 g
Battery:	Rechargeable Ni-MH Cylinder cell, 4xAAA, 4.8 V, 1000 mAh User can change battery. Batteries provided by Optomed.
Usage time:	1h 30min with full battery



CHARGING CRADLE:

Type:	OPTOMED SMARTSCOPE CRADLE V1
Dimensions:	170(w) x 35(h) x 150(d) mm
Weight:	380 g
Switching power supply connected to cradle:	CINCON TRG10R090 Input: 100-240 V ~0.4A 47-63 Hz Output: 9V, 1.1A, 10 W
USB cable:	Type A to mini B, high-speed, unshielded, length 1.8 m



CAUTION

It is only allowed to attach Battery and Power source provided in the sales package into the Cradle. If you need replacement to the Battery or Power source, please contact Optomed Customer Service or your local Retailer.

NON-MYDRIATIC OPHTHALMIC MODULE CONNECTED TO SMARTSCOPE M5 CAMERA

Type:	Smartscope EY4
Intended use:	Intended to capture digital images and video of the fundus of the human eye.
Illumination:	Infrared LED for targeting Visible white LED for photographing, 10 illumination brightness levels 9 red Internal fixation target LEDs
Maximum Luminance output level towards eye:	95,8 cd/cm ²
Field of view:	40°
Dioptric compensation:	- 20 D to + 20 D manual focus - 15 D to +10 D autofocus
Image resolution:	1536x1152 px (total 1,8 Mpix, informational area 1,41 Mpix)
Dimensions:	160x73mm
Weight:	310 g



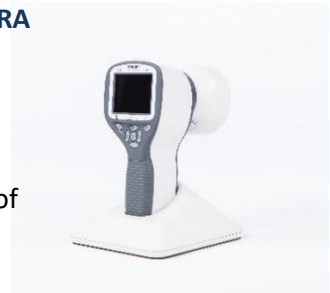
FUNDUS ANGIOGRAPHY MODULE CONNECTED TO SMARTSCOPE M5 CAMERA

Type:	Smartscope FA
Intended use:	Intended to capture digital images of the fundus angiograms of the human eye.
Illumination:	Infrared LED for targeting Blue LED for photographing, 10 illumination brightness levels 9 red internal fixation target LEDs
Maximum Luminance output level towards eye:	8,07 cd/cm ²
Field of view:	40°
Dioptric compensation:	- 20 D to + 20 D manual focus - 11 D to +3 D autofocus
Image resolution:	1536x1152 px (total 1,8 Mpix, informational area 1,41 Mpix)
Dimensions:	160x73 mm
Weight:	310 g



EXTERNAL OPHTHALMIC MODULE CONNECTED TO SMARTSCOPE M5 CAMERA

Type:	Smartscope ES2
Intended use:	Digital eye anterior optics module. Intended to capture digital images and video of the surface of the human eye and surrounding areas.
Illumination:	Visible white and cobalt blue LED for photographing, 10 illumination brightness levels
Maximum Luminance output level towards eye:	192 cd/cm ²
Image resolution:	2560x1920 px
Dimensions:	79x70 mm
Weight:	90 g



ENVIRONMENTAL CONDITIONS FOR USE, STORAGE AND TRANSPORTATION

IP Code: IPX0 (Equipment not protected against the ingress of water)

Intended to be use indoors:

Temperature, use: + 10 °C to 35 °C
Relative humidity, use: 10 % to 80 %
Atmospheric pressure: 800 hPa to 1060 hPa

Please note also EMC information given in Annex A.

Temperature, storage: - 10 °C to 40 °C
Relative humidity, storage: 10 % to 95 %
Atmospheric pressure: 500 hPa to 1060 hPa

NOTE

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

NOTE

If stored over 1 month, it is recommended to remove battery. Appendix B gives instructions for removing the battery.

Transported in protective aluminum carrying case:

Temperature: - 40 °C to + 70 °C
Relative humidity: 10 % to 95 %
Atmospheric pressure: 500 hPa to 1060 hPa
Sinusoidal vibration: 10 Hz to 500 Hz: 0,5 g
Shock: 30 g, duration 6 ms
Bump: 10 g, duration 6 ms



WARNING

Do not leave the eye cup in direct sunlight as it may warm up and burn patient's face when taking image.

SERIAL NUMBERING

Year of manufacture can be found from the serial number (digits 3 to 4).

Serial number of the cradle is in a sticker attached to the underside of the cradle.

Serial numbers of the attachable optics modules are attached to the modules.

SW version is displayed in the device menu.

EXPECTED USAGE LIFE OF THE SMARTSCOPE

There are no strict limitations on expected usage life of the Smartscope. Usage life is approximately five years.

INTELLECTUAL PROPERTY RIGHT INFORMATION

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

TRADEMARK

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DISPOSING OPTOMED SMARTSCOPE PRODUCTS

Do not dispose Optomed Smartscope products as unsorted municipal waste. Prepare Optomed Smartscope products for reuse or separate collection as specified by Directive 2002/96/EC 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.

Packaging materials: Sales case and transportation cardboard packaging should be retained for future relocation or repair. If you decide to dispose of the packaging material, submit it to a recognized collection system of recycling (Sales case consists of aluminum, plastic, foam, and fabric).

For more specific information, please contact Optomed Plc or your local retailer.

CONTACT

For after sales services please contact your local distributor.

If you need to contact Optomed Plc additional information can be obtained:

Optomed Plc Customer Service number: +358 20 741 3380

Optomed Plc Customer Service email: service@optomed.com

Latest version of User Manual can be found: www.optomed.com

15. Warranty

Optomed Plc gives device a 1 year warranty for the parts and labor. Warranty for battery is 6 months.

Submitting claim:

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

Warranty does not cover:

Products that have been subjected to abuse, accident, alternation, modification, tampering, misuse, faulty installation, lack of reasonable care, repair or service in any way that is not contemplated in the documentation of the product, or if the model or serial number has been altered, tampered with, defaced or removed. Warranty does not cover damage caused by dropping the device or damage caused by normal wearing. Any issue related to the stickers attached to the device coming off are not covered by warranty. Repair or service done by non Optomed certified service facility is not covered by warranty.

Appendix A - Electromagnetic compatibility information

Special precautionary measures apply to this device with regard to electromagnetic compatibility (EMC). If the performance of Optomed Smartscope M5 is lost or degraded due to electromagnetic disturbances, it may cause unexpected or adverse operation of this device. If a malfunction cannot be rectified, please contact your local distributor or Optomed customer service.




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.

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.

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 Smartscope M5, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Manufacturer's declaration – electromagnetic immunity:

Smartscope M5 maintains basic safety and performance when used in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV indirect contact ±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for AC power supply	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0,5 at 8 ϕ angles; 0 % 1 cycle; 70 % U_T for 25 cycles; 0 % for 5 sec	0 % U_T for 0,5 at 8 ϕ angles; 0 % 1 cycle; 70 % U_T for 25 cycles; 0 % for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Smartscope M5 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 Smartscope M5, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz AM Modulation & 9–28 V/m 385 MHz to 6.0 GHz Pulse Modulation	3 V/m 80 MHz to 2.7 GHz AM Modulation & 9–28 V/m 385 MHz to 6.0 GHz Pulse Modulation	<p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2.7 GHz,}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^A, should be less than the compliance level in each frequency range^B.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1: U_T is the AC mains voltage prior to application of the test level</p> <p>NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>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.</p> <p>NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>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 Smartscope M5 is used exceeds the applicable RF compliance level above, Smartscope M5 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Smartscope M5.</p> <p>B) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Manufacturer's declaration – electromagnetic emissions:

Smartscope M5 maintains basic safety and performance when used in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	Compliance level	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	Smartscope M5 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	Smartscope M5 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Separation distances:

Smartscope M5 maintains basic safety and performance when used in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Smartscope M5 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Smartscope M5 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	from 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	from 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	from 800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix B - Replacing the battery

Battery pack is specially designed and manufactured for this device. Optomed and Optomed retailers provide suitable battery packs. Labels in the battery display following information:

Optomed
50600001 4xAAA
4.8V/1000 mAh
Rechargeable Ni-MH battery

Procedure for replacing the battery:



1. Ensure that camera is powered off.
2. Open the battery compartment cover by lifting from the notch in the bottom of the device with your finger. If the cover is tight, you may use a small tool like pen to assist in opening.



3. Remove the battery compartment cover by lifting it up.



4. Remove the old battery by placing your fingernail underneath the connector's edge and lifting the connector and the battery out of their sockets to disconnect the battery.

Note! Do not lift the connector by the cables as they may be damaged.

Note! Avoid any unnecessary horizontal or wiggling movement when disconnecting the battery.



5. Put the new battery in the same position and attach the connector to its socket.



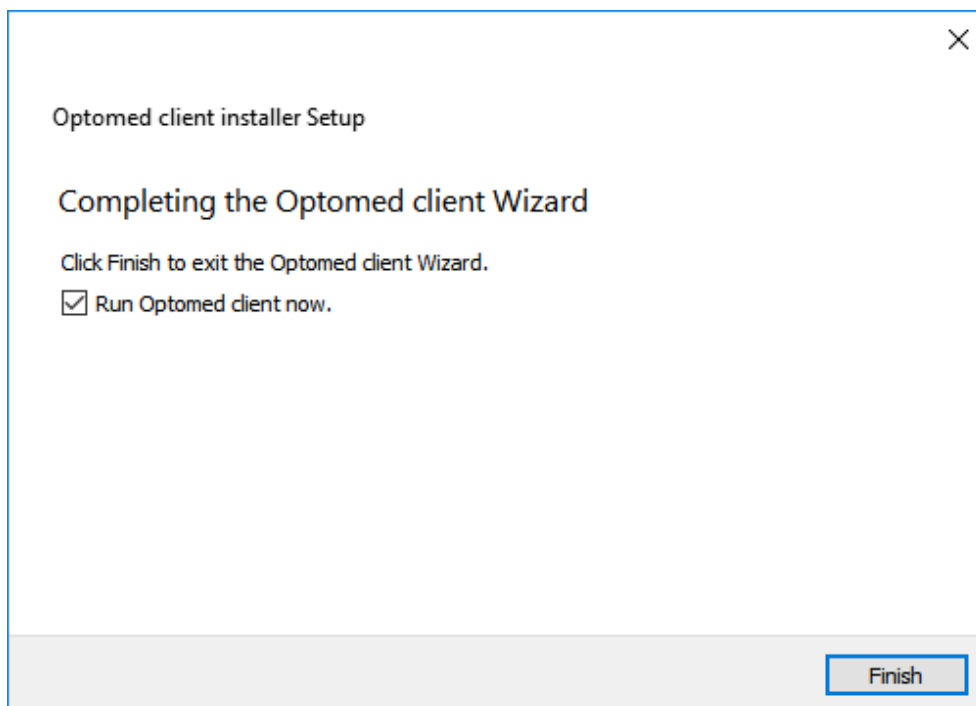
6. Replace the battery compartment cover by snapping it firmly to place.

Appendix C - WLAN functionality

Optomed Client is a PC software which enables the wireless connection between the camera and the PC.

Installing / Uninstalling

Optomed Client software is installed by executing *Optomed Client Smartscope install.exe*. Please, follow the installer instructions to complete installation. First select where the application will be installed and then select the components you want to install. Before installation, you need to accept the license. You can also select the start menu in which you would like to create the shortcut, or you can enter a name to create a new directory.



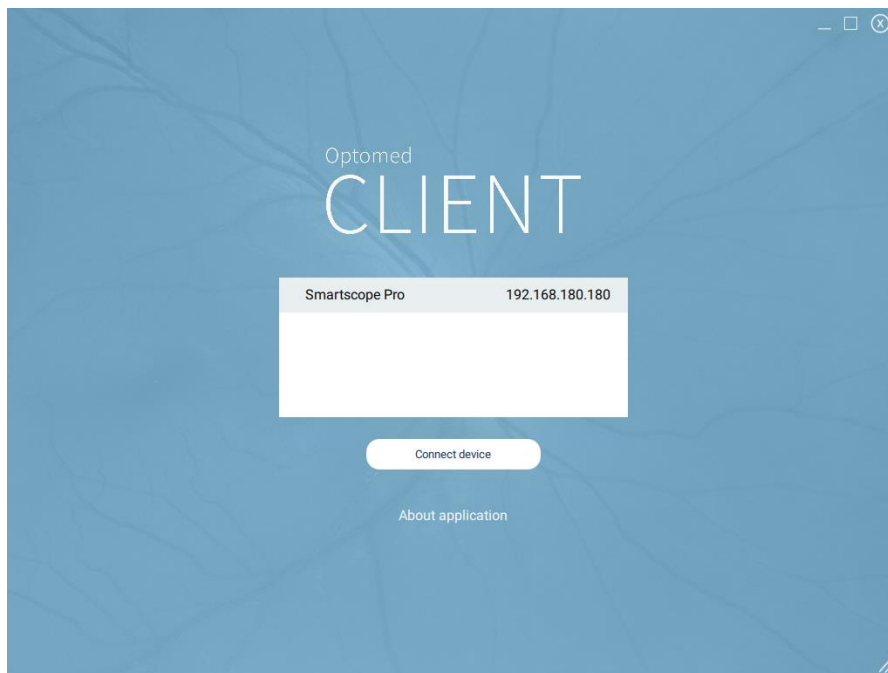
In case you need to uninstall Optomed Client software, it can be uninstalled from Windows Control Panel by opening Programs and Features, selecting Uninstall for the application and following the uninstaller instructions.

Operation

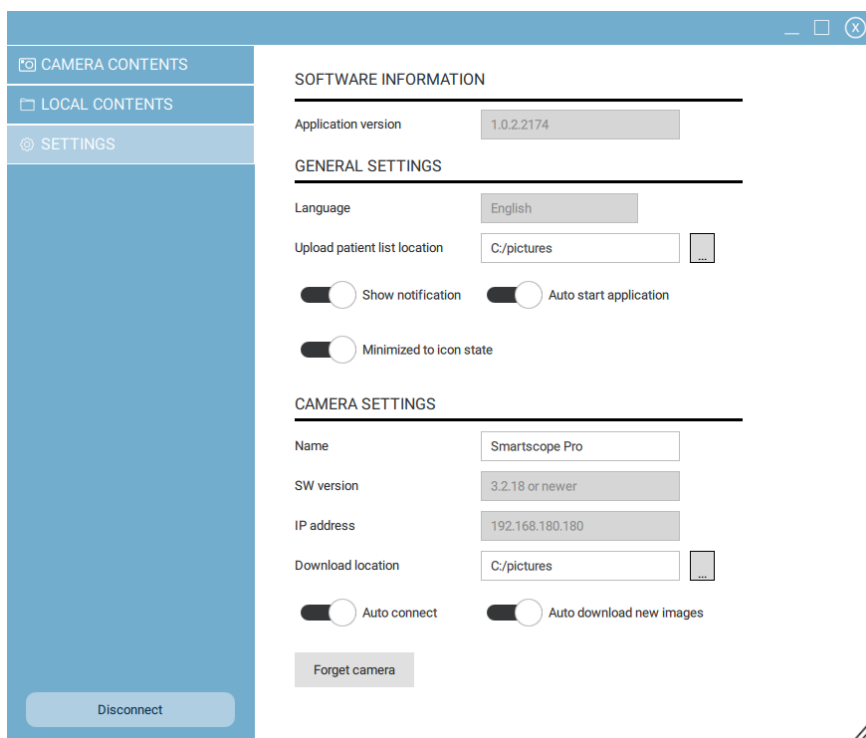
First you need to set wireless connection to on from device menu to enable WLAN. When wireless connection is enabled, the wireless symbol is shown on display next to the battery level indicator. To view 'WLAN SSID' and 'WLAN Password', select wireless info from device menu.

When WLAN is enabled, the camera-specific access point is set up. Connect PC to the created access point, that can be found from Windows Network & Internet settings.

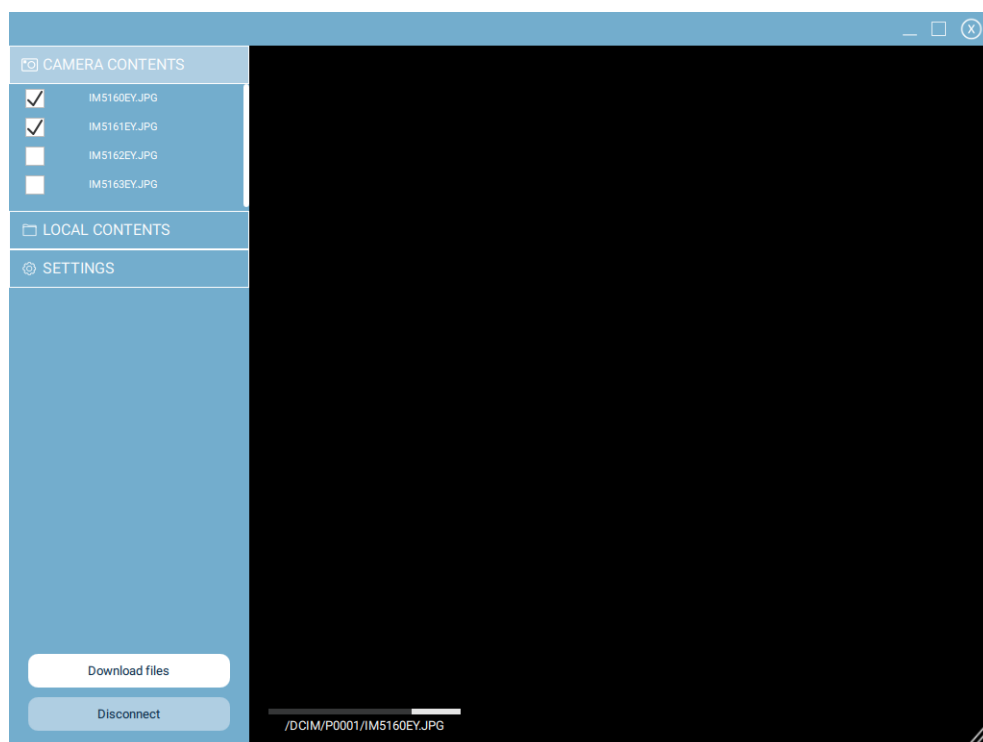
Then open Optomed Client. The camera in the network is shown on the list. Select the camera that you want to connect and press 'Connect device' (figure below).



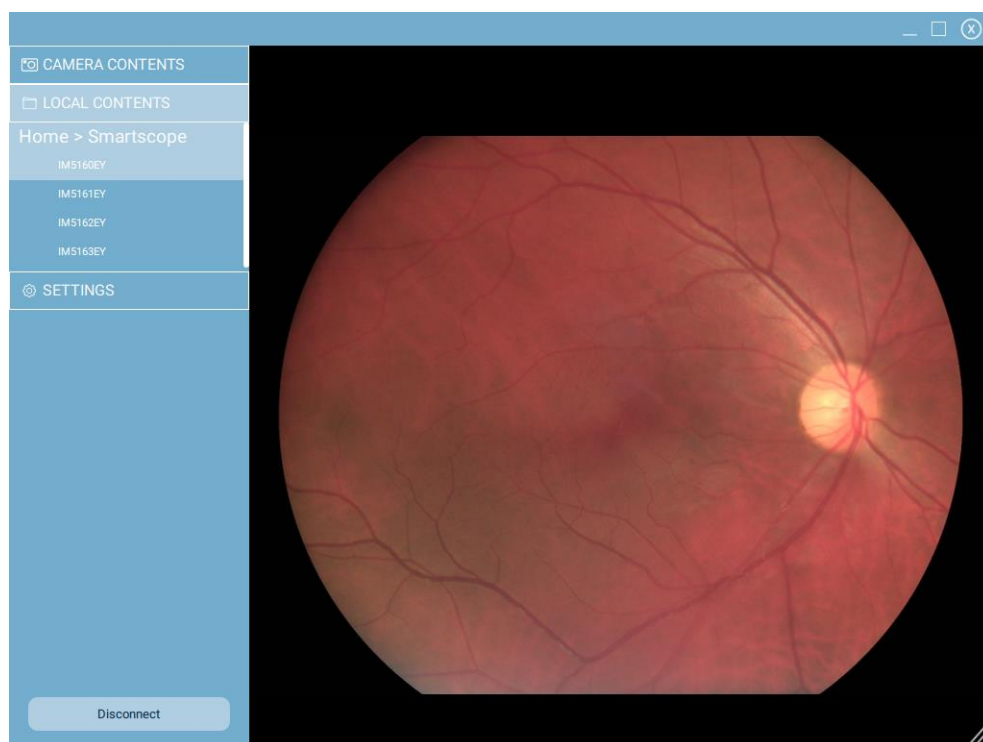
For the first time you connect the camera, you are directed to view and change general and camera specific settings (figure below). Here you can specify the location where the images from the selected camera will be downloaded and the location where the patient list will be uploaded to the selected camera. For the next time, the camera connects automatically to the PC and captured images will be automatically downloaded unless you change these settings.



To download images manually from the selected camera, go to Camera contents (figure below). Select images which you want to download from the list on left and press 'Download files'.



To preview images that you have downloaded, go to Local contents (figure below). Select an image for preview from the list on the left.



To disconnect the selected camera from Optomed Client, press 'Disconnect'

WLAN SD card firmware update

The WLAN SD card has its own firmware, that can be updated if needed. Follow instructions below to update the firmware.

Preparations:

1. Download latest FlashAirFWUpdateTool from Toshiba FlashAir support pages.
2. Install FlashAirFWUpdateTool to Windows. After install, UpdateTool is found from Windows start menu under TOSHIBA.

Update process:

1. Set USB write protection 'Off' from Device menu.
2. Select 'SD card firmware update mode' from Device menu.
3. Place the camera onto the cradle. The camera displays 'SD card firmware update mode' message.
4. Wait for the camera USB drive to get connected to the PC.
5. Start FlashAirFWUpdateTool in PC.
6. Select the camera USB drive as update target and press 'Update'.
7. Wait for UpdateTool progress bar to complete.
8. When UpdateTool asks to remove the card, use Windows 'Safely Remove Hardware' function from task tray to disconnect the camera USB drive.
9. When UpdateTool asks to insert the card, press any key from the camera to reset the SD card.
10. Do not yet press 'OK' button from UpdateTool. Wait approximately 1 minute while the camera displays 'Programming SD card' message.
11. When the camera shows 'SD card firmware update mode' message again, camera USB drive should get reconnected.
12. If the camera USB drive is not properly mounted (may take several seconds), repeat from step 9.
13. When the camera USB drive is reconnected to PC, answer OK to UpdateTool query about inserting the card.
14. Repeat from step 6. (normally will repeat 3 times)
15. When UpdateTool reports 'Updated Successfully', remove Camera from cradle and it will power off automatically.
16. Update completed.

