





Purpose

This is a quick start reference document that summarizes interaction with, and settings of, the *Monaco* device.

NOTE: Full operating instructions and device warning and cautionary messaging are provided in the Instructions for Use (IFU). Please review the IFU (G-108707) prior to operating the device. The IFU can be found at optos.com/IFU. Scan the QR Code below for direct access:



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Setup

Always begin by ensuring that the image server is switched on prior to imaging.

Server Login: Username:	optosadmin
Monaco Logir Username:	n:
Optos <i>Advand</i> Username:	<i>e™</i> Login:

Note: You are responsible for the security of user accounts and password maintenance.

Creating New Users

After logging into the tablet, follow the steps below to create a new user.

- 1 | Select To admin.
- 2 | Select Users.
- 3 | Select New user.
- 4 | Enter the details for the new user and select if they will be an Administrator or Operator.

Preparing to Image

- Use an alcohol wipe to clean the chin rest, forehead rest, and face pad. Let the alcohol air dry. Do not use lint cloths, tissues, or other materials, as it may create dust on the camera mirror.
- It is preferable that imaging is performed in a dimly lit room; however, images can be captured in any illumination.
- Search to see if the patient has been imaged previously using a variation of the patient name and/or patient ID. If the patient is not found, select New patient and enter the name, date of birth, and patient ID.
- If on Modality Worklist, search the patient name, patient ID, or accession number.
- If the patient needs reassurance prior to imaging, some key points to communicate include:
 - o It is non-invasive and painless.
 - o **opto**map UWF imaging is world-leading digital technology.
 - o UWF and OCT imaging use eye-safe scanning light.



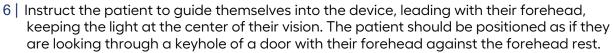




Positioning and Capturing optomap Images

- 1 | Select the To Capture icon in the top right of the tablet to proceed to image capture.
- 2 | Select the desired imaging mode: optomap, Multi-mode, or *OCT*.

 Note: An optomap image will be taken first regardless of the mode selected.
- 3 | Instruct the patient to sit straight up, directly in front of the device, and look straight ahead with their feet flat on the floor and hands in their lap.
- 4 | View the live camera view on the tablet to position the horizontal line across the bridge of their nose. You may also use the canthus markers on the device as an additional guide.
- 5 | Ask the patient if they can see the blue light and have them turn their head slightly so that their nose is outside of the aperture. Ensure the head is vertical and tilting is minimized.



- 7 | Adjust the chin rest up/down to support the patient's chin. The chin should not go beyond the edge of the chin rest.
 - The patient should be comfortably resting their head against the forehead rest and their chin atop the chin rest.
- 8 | Instruct patient to remain in position as you use the hand controller to adjust the X, Y, and Z alignment (see <u>List of Hand Control Buttons for Monaco</u>).
 - a. Use the "+" and "-" buttons on the hand controller to bring the device closer or further away from the eye. The alignment target should be green when correctly positioned.







Blue Too far out



Green Properly Aligned



Red Too close

- b. Use the fine adjustment alignment on the hand controller to finish aligning the crosshair to the center of the patient's pupil.
- 9 Inform the patient that there will be a bright green sweep of light as the device captures the image. Ask the patient to keep their mouth closed to reduce movement, blink, and then open both eyes wide and capture the image using the button on the top of the hand controller.









10 | Ask the patient to remain in position to capture all required scans.

11 | Review the image:

- a. If you did not choose the correct laterality prior to capture, the laterality confirmation will appear after image capture. You will be given the opportunity to select the correct eye in the bright orange boxes at the bottom right of the screen.
- b. If the image quality is not acceptable, you can delete the image by selecting the delete icon.



Imaging Tips

- Some patients may require assistance holding lids open when taking an image.
- Ask patient to blink and open both eyes wide just before capturing the image.
- Tell the patient to relax and blink normally between scans.
- Slow gentle movements are key.

List of Hand Control Buttons for *Monaco*



No.	UWF Imaging Controls Description	OCT Imaging Controls Description
1	Press the top button on the hand controller to capture an image	Press the top button on the hand controller to capture a scan
2	Lower the chin rest	Move the position of the <i>OCT</i> scan lower on the tablet*
3	Raise the chin rest	Move the position of the <i>OCT</i> scan higher on the tablet*
4	Fine adjustment left, right, up, and down	Make fine adjustments (left, right, up, and down) to the <i>OCT</i> scan placement
5	Fine adjustment to move the alignment system closer to the patient	<i>Ts</i> can to improve the signal to noise ratio (SNR)
6	Fine adjustment to move the alignment system further from the patient	Move the focus within the <i>OCT</i> scan to improve the SNR
7	Toggle between XYZ and <i>OCT</i> adjustment modes when capturing	Toggle between XYZ and <i>OCT</i> adjustment modes when capturing

 $^{^{\}star}$ If $\textit{OCT}\xspace$ scan is inverted, lower the $\textit{OCT}\xspace$ position by clicking the down arrow.



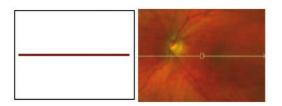




Types of *OCT*Scans

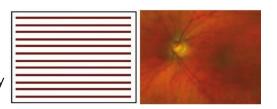
Widefield Line Scan

Allows you to capture cross sectional B-scan of a selected location on the retina that is 12mm in length (an average of 25 B-scans). The line scan can be moved by sliding the horizontal line up and down on the screen. Movement is limited to the widefield box.



Widefield Raster Scan

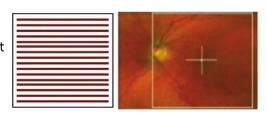
Covers a 12mm x 9mm central field of view. It is comprised of 65 horizontal scans. It captures the macula and the optic nerve head within a single *OCT* volume scan. Adjustment of the crosshair and widefield box can be moved to various locations by moving the box around the macula.



Once captured, you can review the scan by tapping on the infrared image and see if blinks or movement affected the overall *OCT*. If blinks and/or movement occurred in the desired location, delete and recapture.

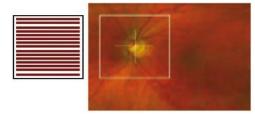
Retinal Topography Scan

Covers an 8.8mm x 8.8mm field of view and is centered around the macula. It is comprised of 97 horizontal line scans. Adjustment of the crosshair and widefield box can be moved to various locations by moving the box around the macula. Required for Segmentation reporting.



ONH (Optic Nerve Head) Topography Scan

Covers a 5.28mm x 5.28mm field of view centered around the optic nerve head. It is comprised of 97 horizontal line scans. Adjustment of the box is required prior to optimization and must be centered around the optic nerve. Required for Segmentation reporting.



RNFL Circle Scan

Captures a 3.4 diameter ring scan (an average of 4 B-Scans) centered around the optic nerve head. Adjustment of the RNFL circle is required prior to optimization.



NOTE: RNFL will be auto extracted from ONH Topography Scan for Segmentation reporting. As such, the physical RNFL Circle Scan will not be required.







Capturing OCT Images

- 1 | Select *OCT* mode or Multi-mode from the optomap button displayed at the bottom of the screen. See section titled: <u>Capturing Multi-mode</u>

 Note: optomap images will be captured first unless already captured.
- 2 | Align the patient as per the instructions outlined in Positioning and Capturing optomap Images above.
- 3 | Ensure that the target is still green and then click the Capture button on the top of the hand controller to begin automatic optimization.
 - a. The patient can blink normally during the 5-stage optimization process.
 - b. Patient should maintain their focus on a corner of the green "x" target while ignoring the red lines or circles.
 - c. When optimization is complete, the *OCT* scan, scan-placement, and SNR should be displayed.
- 4 | Make any necessary fine adjustments to the scan placement using the middle directional controls on the hand controller.
- 5 | Adjust the *OCT* scan position on the tablet using the up/down arrows on the hand controller.
- 6 | If the SNR value is lower than a 6, use the "+" or "-" for SNR improvement. Note: SNR is related to the quality of the *OCT* scan. A high SNR will display a full and dense scan while a low SNR will display a pixelated and faint scan.





- 7 If the OCT scan and/or SNR need to be reset:
 - a. Select Redo OCT Setup
 - b. Select to either reoptimize auto-location, auto-focus, auto-depth, or all
- 8 | When it is time to capture the scan, advise patient to blink, then fixate, and ignore the red lines. Advise, "don't blink, don't move" just prior to capture. Press the Capture button on the hand controller.
- 9 | Review the OCT scan:
 - a. Quality of Raster, Retinal Topography, and ONH Topography can be checked by selecting the arrow to replay the scan.



- b. Identify if there are any blinks, missing areas of information, or quality issues.
- 10 | After reviewing, save and complete the current scan. If needed, you can recapture the same scan or delete.
- 11 | Check to ensure the proper images and scans were captured by selecting the stacked images icon.
- 12 | Select the arrow at the top right of the screen and then Finished Patient to senimages to the image review software.









Optimizing OCT Scan Quality

- Ensure the live OCT feed is in the top third of the screen. Use the up and down arrow buttons on the hand controller for proper positioning.
 OCT scans are strongest when positioned at the highest area of the screen without cutting off any visible area of the retina.
- The live *OCT* feed should fill the width of the window. If there is signal loss on the edges, the patient's pupil may no longer be aligned. Ensure the patient's forehead is still in contact with the forehead rest and that they are centered and fixating on a corner of the "x" of the alignment target.
 - Select Cancel and repeat the alignment process, if necessary.
- If the SNR is below 6/10, you can select the "+" or "-" on the hand controller to improve focus. You may also have the patient blink or use an artificial tear.

 Ensure that the patient blinks before capturing the image so that the cornea is lubricated.
- Myopic eyes may slant the OCT scan. If this is the case you may flatten the OCT scan:
 - o Prior to capture, in the live *OCT* screen, click on the eye button on the hand controller to change to XYZ mode.
 - o Move the scan head left or right to flatten, which causes the beam to move to the optical center of the eye.
 - o Click the eye button to return to OCT controls.

OCTMessages

Averages

Where image averaging is applied (Line Scan and RNFL Scan), the scan result shows the number of scans included.

Movement

Movement detection indicates the extent of the eye movement during capture. You should replay the frames and assess if movement is significant.

Blink

Blink detection indicates the number of frames where the tracking system could not detect retinal content. Replay the frames and assess if this is significant.

Check ONH Center

The ONH scan should be centered in the capture window.

Scan Position Error

Indicates that the scan position cross-referenced to the **opto**map image could not be established. You should attempt to recapture the scan.







Low SNR

For optimal scans, it is suggested that SNR be no lower than 6/10. If a scan is acquired that does not meet this threshold, you will see a message above the Accept button, highlighted in orange, that indicates "Minimum SNR < 6". You should ensure quality of the scan is acceptable with the SNR obtained, otherwise recapture the scan.

Screen Definitions

UWF Imaging Screen: Navigating to OCT



No.	Description		
1	1 Live external view		
2	Primary scan type selector		
3	OCT scan type options		
4	Image Browser displays all the captured images and scans		











No.	Description
1	Replay OCT scan
2	Review scan placement
3	SNR (Signal to Noise Ratio) of current scan
4	Still frame of current scan, will animate if Replay OCT (1) is selected

Capturing Multi-mode

Multi-mode allows the operator to perform a defined sequence of optomap and *OCT* captures.

To customize Multi-mode, go to To admin, tap Multi-mode, and then create your custom Multi-mode and tap Save. These will now be available in the image capture screen.

- 1 | Select the desired Multi-mode and the laterality.
- 2 | Position the patient.
- 3 | Image the patient by pressing the Capture button on the hand controller. This will automatically move you through the programmed imaging modalities.
- 4 | Select Accept to save the scan or click the Capture button to accept and step forward.
- 5 | Select the arrow at the top right of the screen and then Finished Patient from the summary screen.



Optos UK/Europe +44 (0)1383 843350 ics@optos.com Optos North America 800 854 3039 usinfo@optos.com Optos DACH
DE: 0800 72 36 805
AT: 0800 24 48 86
CH: 0800 55 87 39
ics@optos.com

Optos Australia +61 8 8444 6500 auinfo@optos.com



