



### **Purpose**

This is a quick start reference document that summarizes interaction with and settings of the *MonacoPro* 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 is found at <a href="https://openstage.com/IFU">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 is found at <a href="https://openstage.com/IFU">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 is found at <a href="https://openstage.com/IFU">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 is found at <a href="https://openstage.com/IFU">operating instructions in the IFU (G-108707)</a> prior to operating the device.





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#### Power On

Ensure the Optos image server is powered on before proceeding.

- 1 | If your device is fully powered off:
  - a. Locate the on/off rocker switch on the back of the device and switch to On.
- 2 | If your device is in Standby Mode:
  - a. Touch the blue status indicator on the bottom right front of the device.

### **Creating Device Logins**

Log into the tablet with Administrator privileges to create a new user login.

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

- 1 | Select **To admin**.
- 2 | Select **Users**.
- 3 | Select **New User**.
- 4 | Enter the details for the new login and select privilege:
  - a. **Administrator**: Can create new logins, deactivate existing logins, and operate the device.
  - b. **Operator**: Can log in and operate device.

## Preparing to Image

- 1 | Clean the outside of the device:
  - a. Use a 70% 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 main mirror.
- 2 | Patient demographics from the tablet:
  - a. **Search** for an existing patient using the patient's name and/or patient ID. If the patient is not found, select **New Patient** and enter the details.
  - b. If on **Modality Worklist (MWL)**, search patient orders using patient name, patient ID, or accession number. Additional subsets of search criteria may be available depending on configuration.
- 3 | Patient Communication Messages:
  - a. The device uses flashes of light. Some patients with epilepsy may be sensitive to flashes of light. Caution should be exercised for patients who have a history of reaction to camera flashes or strobe lighting.
  - b. It is non-invasive and painless.





## 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:
  - a. **opto**map: RG and AF imaging.
  - b. **Multi-mode**: Pre-set multi-modality imaging session.
  - c. OCT: OCT scan options.

NOTE: An **opto**map image is captured first regardless of the mode selected.

- 3 | Select **OD** or **OS**.
- 4 | 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.
- 5 | View the live camera view on the tablet and adjust the table height 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.
- 6 | Ask the patient to identify the blue target light and have them turn their head slightly so their nose is outside of the aperture. Ensure the head is vertical and tilting is minimized.
- 7 | Instruct the patient to slowly guide themselves towards the device's forehead rest, keeping the target in their view.
- 8 | Adjust the chin rest to support the patient's position using the hand controller. The chin should not go beyond the edge of the chin rest.
- 9 | The patient is in proper position when:
  - a. They are comfortably resting against the forehead and chin rest.
  - b. Their mouth is closed
  - c. The eye is visible on the tablet.
- 10 | Instruct the patient to remain still as you use the hand controller to adjust alignment.
  - 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.







Too far out



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.

11 | Inform the patient there is a bright green sweep of light as the device captures the image. Ask the patient to open both eyes wide and capture the image using the button on the top of the hand controller.





optomap plus

OD

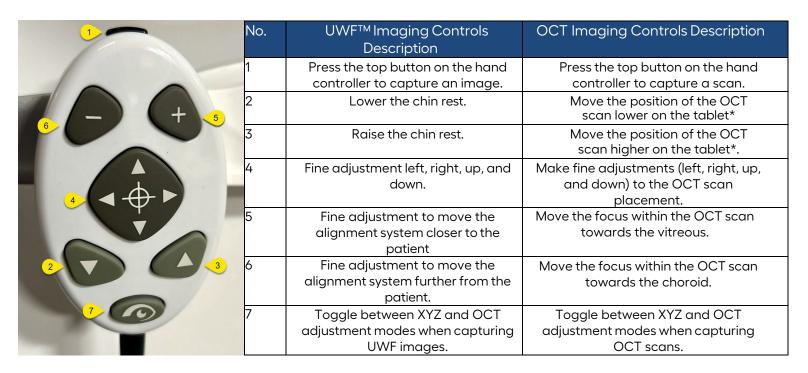
## Monaco PRO Imaging Instructions: Quick Reference Guide



## **Imaging Tips**

- 1 | If you did not choose the correct laterality prior to capture, the laterality confirmation will appear after image capture. Select the correct eye in the bright orange boxes at the bottom right of the screen.
- 2 | If the image quality is not acceptable, delete the image by selecting the discard icon.
- 3 | Some patients may require assistance holding lids open when taking an image.
- 4 | Ask patients to blink and open both eyes wide just before capturing all **opto**map images.
- 5 | Some dry eye patients may benefit from the use of artificial tears prior to imaging OCT.
- 6 | Instruct patients to relax and blink normally between image and OCT scans.





<sup>\*</sup> If OCT scan is inverted. use the arrow buttons to change the OCT position.





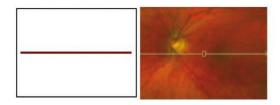


## Types of OCT Scans Widefield Line Scan

12mm line

Average of 25 B-scans

Adjustment of the line scan within the widefield box is required prior to auto-routines



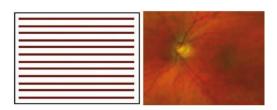
#### Widefield Raster Scan

12mm x 9mm volume scan

65 B-scans

Captures the macula and the optic nerve head within a single volume scan.

Adjustment of the volume box within the widefield area is required prior to auto-routines.



### Retinal Topography Scan

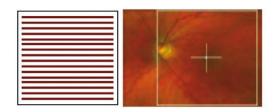
8.8mm x 8.8 mm volume scan

97 B-scans

Adjustment of the crosshair to the center of the macula is required prior to auto-routines.

Segmentation reports:

Total Retinal Thickness (TRT), Ganglion Cell Complex (GCC).



#### ONH (Optic Nerve Head) Topography Scan

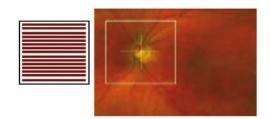
5.28mm x 5.28mm volume scan

97 B-scans

Adjustment of the crosshair to the center of the optic nerve head is required prior to auto-routines.

Segmentation reports:

ONH Analysis (ONH), Retinal Nerve Fiber Layer (RNFL).



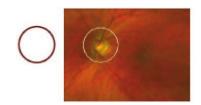
#### Retinal Nerve Fiber Layer (RNFL) Circle Scan

3.4 diameter circular ring scan

Average of 4 B-scans

Adjustment of the RNFL circle centered around the optic nerve head is required prior to auto-routines.

NOTE: RNFL is auto extracted from the ONH Topography Scan for Segmentation reporting. As such, the capture of RNFL Circle Scan is not required.



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### **Screen Definitions**

**UWF Imaging Screen: Navigating to OCT** 



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

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## Capturing OCT Images

- 1 | Select **OCT** mode from the **opto**map button on the tablet. NOTE: **opto**map images are required before all OCT scans.
- 2 | Align the patient per the instructions outlined in the <u>Positioning and Capturing optomap</u> <u>Images</u> section of this document and capture the **opto**map image. The **opto**map image will display on the tablet background.
- 3 | Select the **OCT** scan type and adjust the placement by dragging the scan on the tablet to the desired location.
- 4 | Ensure the target is green and press the Capture button on the top of the hand controller to begin automatic auto-routine.
  - a. Instruct the patient to blink normally during the 5-stage auto-routine process.
  - b. Instruct the patient to maintain their focus on a corner of the "x" target while ignoring the red lines or circles.
  - c. When auto-routines complete, the OCT B-scan, scan-placement view, and SNR display
- 5 | Ensure the scan placement is on the required area of the retina. Make any necessary fine adjustments to the scan placement using the middle directional controls on the hand controller.
  - a. For example, the optic nerve head scan placement crosshair is in the center of the scan placement view.
- 6 | Adjust the OCT scan position on the tablet to the upper half of the window using the up/down arrows on the hand controller.
- 7 | If the SNR value is lower than a 6, instruct the patient to blink. NOTE: A high SNR will display a full and dense scan while a low SNR will display a pixelated and faint scan.
- 8 | To reset the OCT scan due to quality issues:
  - a. Select **Redo OCT Setup**.
  - b. Select to either reoptimize auto-location, auto-focus, auto-depth, or all.
- 9 | To capture the scan, advise patient to blink, fixate, and ignore the red lines. Instruct the patient to hold blinks and gaze just prior to capture. Press the Capture button on the hand controller.
- 10 | Review the OCT scan:
  - a. Review of volume scans Raster, Retinal Topography, and ONH Topography can be checked by selecting the arrow in the scan placement view to replay the scan.

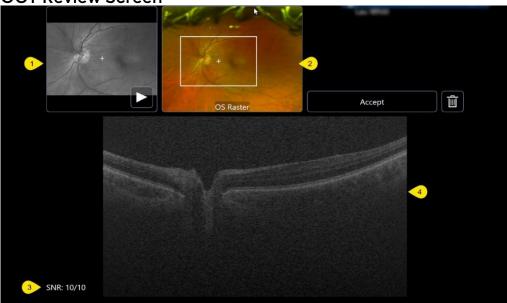


- b. Identify if there are any blinks, missing areas of information, or quality issues.
- 11 | After reviewing, select **Accept**. If needed, you can recapture the same scan or discard.









No.	Description
1	Scan placement view and replay of volume scans
2	SLO reference image
3	SNR (Signal to Noise Ratio) of current scan
4	OCT B-scan

### **OCT Messages**

#### **SNR**

For optimal scans, it is suggested that SNR be no lower than 6/10. You should ensure the quality of the scan is acceptable with the SNR obtained, otherwise recapture the scan.

#### **Averages**

Where image averaging is used (Line Scan and RNFL Scan), the scan result shows the number of scans included. For example, 20/25 indicates 20 scans were included from 25 captured.

#### Movement

Movement detection indicates the extent of the eye movement during capture. 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**

A reminder to confirm the ONH scan is centered on the optic nerve head in the scan placement view.

#### **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.

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## **Optimizing OCT Scan Quality**

- Instruct the patient when to blink during the process. Use of artificial tears is helpful.
  - o A few seconds after and during the auto-routines
  - o Before capturing the scan
  - o After capturing the scan
- Ensure the live OCT feed is in the top half 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 a 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 they are centered and fixating on a corner of the "x" of the alignment target. Select **Cancel** and repeat the alignment process.
- If the SNR is below 6/10, you can select the "+" or "-" on the hand controller to change focus
- Myopic eyes may slant the OCT scan. To flatten the OCT scan:
- 4
- Prior to capture, in the live OCT screen, press the eye button on the hand controller to change to XYZ mode.
- Move the device left or right to flatten, which causes the beam to move to the optical center of the eye.
- o Press the eye button to return to OCT controls.



#### Capturing Multi-mode

Multi-mode allows the operator to perform a defined sequence of **opto**map and OCT images. To customize multi-mode on the tablet: Select **To admin**, then **Multi-mode**. Multi-mode allows three defined sequences with up to 5 image modalities. Create your custom multi-mode(s) and tap **Save**. These display on the tablet from the **opto**map button in the bottom right.

- 1 | Select the desired multi-mode and the laterality.
- 2 | Align the patient per the instructions outlined in the <u>Positioning and Capturing optomap</u> <u>Images</u> section of this document and capture the images and OCT scan per the instructions outlined in the <u>Capturing OCT Images</u> section of this document.
- 3 | The device will automatically select the next step in the multi-mode workflow. If you need to re-capture a sequence, select the image type from the multi-mode sequence menu displayed on the tablet.

#### **Power Off**

- 1 | Select the power button on the tablet to put the device in Standby mode.
- 2 | When the status indicator on the bottom right of the device is blue, locate the on/off rocker switch on the back of device and switch to OFF.



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