

Topcon Maestro Retinal Imaging Protocol for AI/ML Dataset Creation

SpectOcular, LLC | Draft SOP / Protocol Insert

Prepared for standardized retinal image acquisition, quality control, metadata capture, and downstream AI/ML analysis.

Protocol Element	Standard
Device	Topcon Maestro2, Maestro3, or substantially equivalent Topcon Maestro platform
Dilation	All imaging should be performed after standard-of-care dilation unless contraindicated, declined, or otherwise not clinically appropriate
Minimum image set per eye	Macula-centered fundus photo; disc-centered fundus photo; macular OCT cube; optic nerve/RNFL OCT cube
Preferred expanded image set	3D Wide 12 x 9 mm OCT and macula OCT-A if available; disc OCT-A optional
Data preservation	Native device format and/or DICOM preferred; high-resolution image files retained; PDF reports secondary only
Quality control	Image quality grading, repeat imaging rules, and retention of poor/gradable/ungradable scans with labels
AI/ML handling	Patient-level dataset splitting, standardized metadata, de-identification/coding, and secure storage

Purpose

The purpose of this imaging protocol is to obtain standardized, high-quality, multimodal retinal images suitable for downstream artificial intelligence and machine learning analysis. The protocol is designed to maximize image gradability, reproducibility, and consistency across subjects, imaging sessions, technicians, and clinical sites.

Retinal imaging data will be used for research and AI/ML model development, including potential analysis of ocular disease, retinal structure, retinal vascular features, and systemic disease risk. The imaging protocol is intended to support creation of an AI-ready dataset by standardizing image acquisition, documenting image quality, and preserving device-generated imaging metadata.

Large ophthalmic AI datasets require consistent image acquisition, quality control, and separation of training, validation, and testing datasets. Technical reviews of deep learning in ophthalmology emphasize the importance of preprocessing, gradability assessment, standardized datasets, and independent testing to ensure model generalizability. The AI-READI manual similarly describes a multimodal retinal imaging protocol designed to generate an AI-ready dataset and includes OCT, OCT-A, fundus photography, standardized retinal imaging checklists, and secure data transfer workflows.

Required Device

Primary imaging platform: Topcon Maestro2 or Topcon Maestro3 OCT system, or substantially equivalent Topcon Maestro platform capable of color fundus photography, spectral-domain OCT, and OCT angiography if available.

All imaging should be performed using the same device model and software version whenever possible. If multiple devices or software versions are used, the device model, serial number, software version, scan protocol, operator, site, and date/time of acquisition must be recorded as metadata.

Required Dilation Standard

All imaging should be performed after standard-of-care pupillary dilation unless dilation is medically contraindicated or declined by the patient.

Dilation should be performed according to the site's routine clinical standard of care. Imaging should begin only after adequate dilation is achieved. For SpectOcular, the preferred standard is bilateral dilation before Topcon Maestro imaging.

Minimum target pupil size: ≥ 4.0 mm if achievable, with documentation if smaller. If dilation is inadequate, the technician should wait additional time, recheck fixation and alignment, and repeat acquisition when feasible.

Acceptable reasons for nondilated or partially dilated imaging should be documented, including narrow angle concern, allergy, patient refusal, physician decision, or other clinical contraindication.

Imaging Sequence

Images should be acquired in a consistent order for each subject to reduce protocol variability. Before acquisition, confirm the patient or coded study ID, laterality, date/time of imaging, technician/operator ID, device model, device serial number, software version, dilation status, approximate pupil size, lens status if known, presence of major media opacity if known, and whether artificial tears were used before imaging.

The participant should be positioned comfortably with forehead and chin stabilized. The patient should be instructed to blink before each scan and then keep the eye open during acquisition.

Minimum Required Image Set Per Eye

At a minimum, the following should be obtained for both eyes **after standard-of-care dilation**.

Color Fundus Photography

- Acquire high-quality color fundus photographs for each eye.
- Required views per eye: macula-centered color fundus photo and optic disc-centered color fundus photo.
- Preferred field: use the Maestro's standard color fundus field, typically posterior pole coverage. If a single fundus photo captures both disc and macula clearly, it may be retained, but separate macula- and disc-centered images are preferred for AI/ML analysis.
- Quality requirements: sharp focus on retinal vessels; adequate illumination without significant underexposure or overexposure; macula visible and centered for macula image; optic nerve visible and centered for disc image; minimal eyelid/lash artifact; no major blink artifact; no severe motion artifact; no major defocus or haze obscuring vascular arcades.

Macular OCT Cube

- Acquire a macular OCT volume scan for each eye.

- Recommended Maestro scan: 3D Macula 6 x 6 mm OCT cube using the highest practical scan density available within routine workflow; prefer a protocol equivalent to 512 x 128 or comparable high-density cube when available.
- Required quality elements: fovea centered; full retinal thickness visible; no major motion artifact; no scan truncation; signal strength/quality score documented; segmentation lines retained for review but raw B-scan data preserved; repeat scan if the fovea is decentered, signal is poor, or motion artifact prevents layer analysis.
- Macular OCT is critical because retinal layer thickness and OCT-derived structural features have been linked to ocular and systemic health in large cohort analyses.

Optic Nerve / RNFL OCT

- Acquire optic nerve head and retinal nerve fiber layer imaging for each eye.
- Recommended Maestro scan: 3D Disc / optic nerve cube, including peripapillary RNFL analysis if available, with the optic nerve centered.
- Required quality elements: optic disc centered; circumpapillary scan not truncated; RNFL segmentation present and reviewable; signal strength documented; no major motion artifact; repeat if segmentation failure or decentration is present.
- This imaging is important for glaucoma-related model development and for systemic biomarker analysis involving inner retinal layers, RNFL, ganglion cell complex, and neurodegenerative risk features.

OCT Angiography, If Available

- If the Topcon Maestro unit has OCT-A capability, acquire OCT-A for each eye.
- Recommended minimum OCT-A scans: macula OCT-A 6 x 6 mm; optional but preferred optic nerve/disc OCT-A 4.5 x 4.5 mm or 6 x 6 mm, if available.
- Quality requirements: minimal motion artifact; acceptable signal strength; no major segmentation failure; superficial and deep capillary plexus outputs preserved if available; vessel density maps and en face images exported when available; raw volume data retained when possible.

Preferred Expanded Image Set Per Eye

For a stronger AI/ML dataset, the preferred SpectOcular standard should include the following:

Modality	Required?	Scan/View
Color fundus	Yes	Macula-centered
Color fundus	Yes	Disc-centered
OCT	Yes	3D Macula 6 x 6 mm
OCT	Yes	3D Disc / RNFL cube
OCT	Preferred	3D Wide 12 x 9 mm posterior pole
OCT-A	Preferred if available	Macula 6 x 6 mm
OCT-A	Optional	Disc OCT-A
Repeat scans	Preferred	Repeat one high-quality macula OCT and OCT-A when feasible for test-retest/reproducibility

The 3D Wide 12 x 9 mm scan is particularly attractive for AI/ML because it captures broad posterior pole anatomy in a single standardized volume, which may help future models evaluate macula, nerve, posterior pole contour, staphyloma/myopia features, vascular shadows, and structural disease patterns.

Repeat Imaging Rules

Repeat imaging should be performed during the same visit when feasible if any of the following are present:

- Poor signal strength
- Fovea or optic nerve decentered
- Motion artifact affecting central macula or disc
- Blink artifact
- Eyelid or lash obstruction
- Segmentation failure
- Image truncation
- Poor focus
- Media haze severe enough to obscure vascular or retinal layer detail
- OCT-A projection/motion artifact limiting vessel analysis

For each eye and modality, the best-quality image should be designated as the primary research image, but repeat images should also be retained because they may be useful for AI robustness, quality modeling, and reproducibility analysis.

Image Quality Grading

Each image or scan should receive a quality designation. For AI/ML purposes, poor or ungradable images should not be automatically deleted. Instead, they should be retained with quality labels because they may support gradability and image-quality model development.

Grade	Designation	Definition
1	Excellent	Clear, centered, high signal, no meaningful artifact
2	Good	Minor artifact but fully interpretable and suitable for AI/ML
3	Adequate	Usable but with mild/moderate limitations
4	Poor	Limited interpretability; may be usable only for some analyses
5	Ungradable	Not suitable for disease model training or clinical feature labeling, but retain for image-quality/gradability modeling

Minimum Metadata to Capture

For each imaging session, capture the following metadata:

- Study participant ID / coded ID
- Eye: OD or OS
- Date and time of imaging
- Imaging site
- Device model
- Device serial number
- Software version

- Scan protocol name
- Scan dimensions and resolution
- Operator/technician ID
- Dilation status
- Approximate pupil size if available
- Signal strength / image quality score
- Laterality confirmation
- Lens status if known
- Media opacity if present
- Artificial tears used: yes/no
- Repeat scan performed: yes/no
- Reason for repeat or failed image
- Whether image is primary or repeat
- Any protocol deviation

This metadata should be exported with the image files whenever possible.

File Export and Data Preservation

For AI/ML analysis, retain the most complete native data possible.

Preferred export hierarchy

1. Native Topcon raw/proprietary imaging files, if accessible
2. DICOM files, preferred for interoperability and metadata preservation
3. High-resolution PNG or TIFF for fundus images if DICOM is not available
4. JPEG only as secondary copy, not as the sole research file when avoidable
5. PDF reports may be stored for clinical review but should not be the primary AI training format

For OCT and OCT-A, retain

- Raw B-scan volume data
- En face images
- Thickness maps
- Segmentation outputs
- OCT-A vessel maps if available
- Device-generated reports as secondary documentation

De-identification and Naming Convention

All exported files should be named using a coded study identifier and should not include patient name, date of birth, medical record number, or other direct identifiers in the file name.

Recommended naming convention: STUDYID_VISIT_EYE_MODALITY_SCAN_DATE_VERSION

Example: SPT000123_V1_OD_OCT_MAC6x6_2026-04-26_PRIMARY

A separate linkage file connecting the coded study ID to patient identity should be stored securely, access-restricted, and maintained separately from the AI/ML image dataset.

AI/ML Dataset Handling

Images should be categorized by participant ID, eye, visit, modality, scan protocol, quality grade, disease labels if available, clinical diagnosis labels, systemic disease labels, available laboratory/vital sign metadata, and longitudinal outcome availability.

For supervised model development, dataset splitting should occur at the patient level, not image level, so that images from the same patient do not appear in both training and testing sets.

Suggested Protocol Language for IRB Submission

Retinal imaging will be performed using a Topcon Maestro OCT platform or substantially equivalent FDA-cleared retinal imaging device as part of routine clinical care. To optimize image quality and standardization for downstream AI/ML analysis, all imaging should be performed after standard-of-care pupillary dilation unless dilation is medically contraindicated, declined by the patient, or otherwise not clinically appropriate. Imaging will include, at a minimum, bilateral color fundus photography, macular OCT, and optic nerve/RNFL OCT, with OCT angiography obtained when available. Images will be acquired using standardized scan protocols and saved with associated metadata, including laterality, scan type, device model, software version, date/time of acquisition, operator, dilation status, and image quality metrics.

Images will be reviewed for technical quality, including focus, illumination, centration, signal strength, motion artifact, blink artifact, media opacity, and segmentation accuracy when applicable. Repeat imaging may be performed during the same routine clinical encounter when image quality is insufficient and repeat acquisition is clinically feasible. Poor-quality and ungradable images may be retained with appropriate quality labels for research purposes, including development of image gradability and quality-control algorithms.

Image files will be exported in the most complete format available, preferably native device format and/or DICOM, with high-resolution image files retained when applicable. PDF reports may be stored as secondary documentation but will not serve as the primary format for AI/ML model development when raw or DICOM imaging data are available. All research datasets will be coded or de-identified to the extent practicable and stored on secure, access-controlled systems.

Practical SpectOcular Minimum Standard

6. Dilated imaging of both eyes
7. Macula-centered fundus photo
8. Disc-centered fundus photo
9. Macula OCT cube
10. Optic nerve/RNFL OCT cube
11. Macula OCT-A if available
12. Repeat any scan below quality threshold
13. Export DICOM/native files whenever possible
14. Capture full metadata and image-quality grade
15. Split future AI datasets by patient, not by image

References

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Drafting note: This document is intended as a clinical research SOP/protocol insert and should be reviewed by the study PI, imaging lead, IRB/regulatory advisor, and legal counsel before final submission or operational deployment.