



January 19, 2018

Topcon Corporation
% Zvi Ladin, Ph.D.
Principal
Boston MedTech Advisors Inc.
990 Washington Street, Suite #204
Dedham, MA 02026

Re: K173119
Trade/Device Name: DRI OCT Triton
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, HKI
Dated: December 18, 2017
Received: December 20, 2017

Dear Zvi Ladin, Ph.D.:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Denise L. Hampton -S

for Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K173119

Device Name
DRI OCT Triton

Indications for Use (Describe)

The Topcon DRI OCT Triton is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions.

The DRI OCT Triton is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula and optic disc as well as imaging of anterior ocular structures.

It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. The DRI OCT Triton is indicated for use as a diagnostic device to aid in the diagnosis, documentation and management of ocular health and diseases in the adult population.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) SUMMARY

Topcon Corporation DRI OCT Triton and Triton (plus)

Submitter Information:

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Date Prepared: January 17, 2018

Subject Device:

Device Name: DRI OCT Triton and Triton (plus)

Common Name: Optical Coherence Tomography

Classification Name: Ophthalmoscope

Regulation: Class II, 21 C.F.R. § 886.1570

Product Code(s): OBO, HKI

Predicate Device(s):

Primary Predicate: Topcon 3D OCT-1 Maestro (#K161509, #K170164)

Secondary Predicate: Topcon TRC-50DX Retinal Camera (#K123101)

Indications for Use:

The Topcon DRI OCT Triton is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions.

The DRI OCT Triton is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula and optic disc as well as imaging of anterior ocular structures.

It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. The DRI OCT Triton is indicated for use as a diagnostic device to aid in the diagnosis, documentation and management of ocular health and diseases in the adult population.

Device Description:

The DRI OCT Triton ("Triton") and the DRI OCT Triton (plus) ("Triton (plus)") are non-contact, high-resolution, tomographic and bio-microscopic imaging systems that merge optical coherence tomography (OCT) and fundus camera into a single device. Triton and Triton (plus) employ the swept source OCT (SS-OCT) technology. Both can take anterior OCT images in addition to fundus OCT images. The fundus camera, in both Triton and Triton (plus), includes color imaging, red-free imaging, and infrared light imaging (hereinafter, IR imaging) capabilities for fundus observation. The Triton (plus) has fluorescein angiography (FA), and fundus autofluorescence angiography (FAF) imaging function in addition to all fundus functions for Triton.

The fundus photographs and OCT images are captured by different system components of this device, which enables Triton to capture an OCT image and a fundus image sequentially. It allows in vivo viewing, axial cross sectional, and three dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula and optic disc as well as imaging of anterior ocular structures. It also has a reference database for posterior ocular measurements of normal subjects, which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head and the macula.

Captured images are transferred from the device to an off-the-shelf personal computer (PC) via LAN cable, where the dedicated software for this device is installed. The transferred data is then automatically processed with analysis functions such as the automatic retinal layers segmentation, the automatic thickness calculation with several grids, the optic disc analysis and comparison with a reference database of eyes free of ocular pathology, and is finally automatically saved to the PC. It allows the user to manually adjust the automated retinal layer segmentation results and optic disc analysis results.

Accessories include the power cord, chin-rest paper sheet, monitor cleaner, LAN cable; chin-rest paper pins, external fixation target, dust cover accessory case, user manual, unpacking and analysis software DVD.

Substantial Equivalence

Triton is substantially equivalent to Topcon's 3D OCT-1 Maestro (#K161509, #K170164, "Maestro") cleared on 7/28/2016 and 3/3/2017 correspondingly. The secondary predicate device is Topcon's TRC-50DX Retinal Camera (#K123101) cleared on 6/5/2013. Triton's indications for use are identical to those of the Maestro device.

Both Triton and Maestro have the same technological characteristics of an optical coherence tomography (OCT) device and a fundus imaging device in a single system. Triton and Maestro are non-contact, high resolution tomographic and biomicroscopic imaging systems that include cameras for both OCT and fundus imaging. These devices can capture fundus OCT and color fundus images sequentially and can capture anterior segment OCT images. Both devices include a reference database tool, used as an aid in the detection and management of the same series of ocular diseases claimed in the indications for use.

Triton incorporates a swept-source (SS) light source to divide wavelengths temporally, while the Maestro incorporates a superluminescent diode (SLD) light source and a splitter to divide wavelengths spatially. Though the methods used to divide wavelengths are different, both are based on optical interference principles, and both spectral domain and swept-source OCT are generally thought to fall under the umbrella classification of Fourier Domain OCT.

Both systems are non-contact, ophthalmic diagnostic devices using infrared to visible light. Triton has a higher scan speed, a higher resolution of 3D scans and additional scan patterns compared to Maestro. There are slight differences in the axial resolutions, center wavelength and bandwidths of the light sources of both devices.

Triton and Maestro have the same technological characteristics regarding the fundus camera function, except for FA/FAF. Both devices employ an Infrared (IR) Light Emitting Diode (LED) for observation light source, a Xenon flash for photographing light source and a complementary metal-oxide semiconductor (CMOS) for camera. Both Triton (plus) and TRC-50DX Retina Camera provide FA/FAF functionality. While Triton (plus) employs an IR LED for observation light source, TRC-50DX employs a Halogen lamp. Both devices employ a Xenon flash for photographing light source. For camera, Triton (plus) employs a CMOS while TRC-50DX employs a charge-coupled device (CCD). The minor differences between the candidate and predicate devices in technological implementation or performance do not raise new or different questions of safety or effectiveness.

Performance Data

Performance bench testing has been conducted on Triton to demonstrate substantial equivalence to the predicate devices. A list of testing conducted is as follows:

- Axial and Transversal Resolutions
- Trueness and Precision for Axial and Transversal Directions

- Testing to Consensus Standards for Ophthalmic Devices
 - ISO 15004-1, Ophthalmic instruments – Fundamental requirements and test methods – Part1: General requirements applicable to all ophthalmic instruments, 2006
 - ISO 10940, Ophthalmic instruments – Fundus cameras, 2009
 - ISO 15004-2, Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection, 2007
- Electrical Safety
 - AAMI/ANSI ES 60601-1, Medical Electrical Equipment – Part1: General requirements for Safety and essential performance, 2005/(R)2012 and A1:2012, C1:2009 /(R) 2012 and A2:2010/(R)2012
- Electromagnetic Compatibility
 - IEC 60601-1-2, Medical electrical equipment – Part1-2: General requirements for Safety and essential performance – Collateral standard : Electromagnetic compatibility – Requirements and tests, 2007
- Software Verification and Validation Testing
 - Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”
 - The software for this device was considered as ‘Moderate Level of Concern’ since a failure or latent flaw in the software could result in an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

Biocompatibility of materials used in the patient contacting components were already evaluated and established in company’s predicate device submissions.

Clinical Data

Topcon conducted two clinical studies to demonstrate substantial equivalence of the investigational Triton device to the predicate devices, 3D OCT-1 Maestro (#K161509, #K170164) and TRC-50DX Retinal Camera (#K123101). An agreement and precision study was conducted at a single clinical site to determine precision (repeatability and reproducibility) and agreement with the predicate Maestro device. A second single-site study was performed to compare the performance of the Triton (plus) and TRC-50DX for FA/FAF imaging. These two studies were performed independently and in parallel. A third multi-center clinical study was performed to collect OCT data in order to establish a reference database for measurement comparisons.

Agreement and Precision Study

Topcon conducted a prospective comparative clinical study, at a U.S. clinical site, to compare the agreement and precision between Triton and Maestro. Participants, with and without eye disease, had OCT images and fundus photographs obtained using both Triton and Maestro devices. The studies included five main analyses: 1) precision analysis, 2) agreement analysis, 3) fundus photograph evaluation, 4) anterior segment image evaluation, and 5) posterior B scan image quality evaluation. The agreement and precision study compared the full retinal thickness, retinal nerve fiber

layer thickness, Ganglion cell layer plus the IPL layer thickness, Ganglion cell complex thickness, and the optic disc measurements. In addition, the study estimated the precision of the small and large super pixel grid and the TSNIT circle profile measurements of the Triton.

Participants were randomized for the selection of study eye, operator order and device order. There were 13 planned scans during a single session, for all subject groups, per subject, per device (3 scans per 3D Wide, 3D Macula and 3D Disc scans; 1 scan per Radial cornea and angle scans; 1 per macula fundus and optic disc fundus photographs). The total number of planned scans for a subject was 78 (39 for each device). While the precision analysis utilized all acceptable scans for all measurement types, all other analysis utilized the first acceptable photograph of each scan type of each device from all study eyes. The image quality of the fundus photographs, and the image quality of anterior and posterior OCT B scans were graded by two masked independent experts on a scale based on the quality and clarity of the images. Quality assurance procedures were instituted to produce a consistent system for assessing, saving and processing study images.

Major eligibility criteria included participants age \geq 18 with: 1) normal eyes (excluding glaucomatous optic nerve damage), 2) Glaucomatous optic nerve damage, based on pattern deviation and Glaucoma hemi-field test or damage based on optic disc or retinal nerve fiber layer structural abnormalities (excluding other ocular pathology), and 3) Retinal pathology diagnosis (excluding glaucoma or any other ocular pathology).

Agreement between Triton and Maestro was evaluated by the 95% LOA, Bland-Altman plots, and the Deming regression for each subject population. The analysis of precision used a two-way random-effect ANOVA model to estimate the repeatability and reproducibility limits, and coefficient of variation of each scan parameter by subject population and study device. Image clarity analysis, for both fundus photographs and anterior and posterior OCT B scans, calculated the percentage of subjects whose Triton grades were equal to or better than their Maestro grades by photograph type and subject population, and the percentage of total inter-grader agreement by photograph type, subject population and study device with exact 95% confidence interval.

The rate of rejected scans for image quality reasons was in the range of 1% – 20%, and was similar for both the Triton and Maestro images. For each of the measurement types, image or scan type and size, and subject eye category, the measurements obtained with the Triton device as compared to the Maestro device were mathematically similar, statistically consistent with, and clinically useful in the assessment of normal and diseased eyes. In sum, the agreement results were expected based on minor differences in axial resolution, validated software and algorithm updates, and a minor difference in the pixel calibration factor between devices. Software and algorithm updates included improved fovea detection, ILM and RPE segmentation, artifact removal and cup map refinement. In addition, the Triton device uses a factory determined pixel calibration factor that is used for thickness calculations. The Maestro device uses a standard, average value for pixel measurements, while each Triton device relies on a device specific pixel size value. These results demonstrate that the Topcon DRI OCT Triton is substantially equivalent to the predicate device Topcon 3D OCT-1 Maestro (#K161509, # K170164).

Table 1: Demographics and Baseline Characteristics

	Normal (N=25)	Retinal (N=26)	Glaucoma (N=25)	Total (N=76)
Age (years)				
n	25	26	25	76
Mean (SD)	42.7 (14.7)	67.2 (11.3)	67.6 (10.4)	59.3 (16.8)
Median	40.0	67.0	68.0	62.0
Age group, n (%)				
<65 years	24 (96)	11 (42)	10 (40)	45 (59)
≥65 years	1 (4)	15 (58)	15 (60)	31 (41)
Gender, n (%)				
Male	14 (56)	9 (35)	12 (48)	35 (46)
Female	11 (44)	17 (65)	13 (52)	41 (54)
Ethnicity, n (%)				
Hispanic or Latino	1 (4)	0 (0)	1 (4)	2 (3)
Not Hispanic and not Latino	24 (96)	26 (100)	24 (96)	74 (97)
Race, n (%)				
American Indian/Alaska Native	0 (0)	0 (0)	0 (0)	0 (0)
Asian	0 (0)	0 (0)	0 (0)	0 (0)
Black/African American	0 (0)	0 (0)	0 (0)	0 (0)
Native Hawaiian/Pacific Islander	0 (0)	0 (0)	0 (0)	0 (0)
White	25 (100)	26 (100)	25 (100)	76 (100)
Other	0 (0)	0 (0)	0 (0)	0 (0)

Agreement Assessment

**Table 2. Limits of Agreement between Triton 7x7 Macula and Maestro 6x6 Macula:
Full Retinal Thickness (mm) Agreement Analysis Population**

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Normal Eyes (N = 25)					
Central Fovea	252.783 (25.344)	252.039 (27.524)	0.744 (6.219)	-1.824, 3.311	-11.695, 13.182
Inner Superior	318.430 (15.531)	321.084 (16.041)	-2.653 (4.541)	-4.527, -0.779	-11.734, 6.428
Inner Nasal	319.948 (16.716)	321.864 (16.700)	-1.916 (4.247)	-3.669, -0.163	-10.410, 6.578
Inner Inferior	313.842 (17.074)	315.470 (17.704)	-1.628 (4.207)	-3.365, 0.108	-10.043, 6.786
Inner Temporal	303.981 (17.133)	305.390 (17.280)	-1.409 (4.432)	-3.238, 0.420	-10.272, 7.454
Outer Superior	273.314 (15.440)	276.887 (16.315)	-3.573 (3.436)	-4.992, -2.155	-10.446, 3.300
Outer Nasal	289.616 (18.592)	291.432 (18.750)	-1.815 (3.269)	-3.165, -0.466	-8.354, 4.723
Outer Inferior	263.023 (17.675)	265.177 (18.321)	-2.154 (3.584)	-3.633, -0.675	-9.322, 5.014
Outer Temporal	257.459 (14.410)	258.748 (15.657)	-1.288 (3.567)	-2.761, 0.184	-8.423, 5.847
Retinal Eyes (N = 26)					
Central Fovea	287.357 (69.085)	289.860 (71.068)	-2.503 (5.865)	-4.872, -0.134	-14.233, 9.227
Inner Superior	319.017 (37.733)	323.572 (40.551)	-4.555 (4.739)	-6.469, -2.640	-14.034, 4.924
Inner Nasal	321.600 (34.510)	325.010 (36.073)	-3.409 (4.412)	-5.191, -1.627	-12.233, 5.414
Inner Inferior	315.722 (36.594)	319.435 (37.898)	-3.712 (5.135)	-5.786, -1.638	-13.982, 6.557
Inner Temporal	310.943 (40.324)	315.846 (43.195)	-4.903 (6.001)	-7.327, -2.479	-16.905, 7.100
Outer Superior	273.324 (25.716)	277.460 (26.634)	-4.136 (3.377)	-5.500, -2.772	-10.890, 2.618
Outer Nasal	285.318 (22.409)	288.067 (22.352)	-2.748 (4.608)	-4.609, -0.887	-11.964, 6.468
Outer Inferior	260.377 (25.022)	265.861 (26.674)	-5.485 (7.538)	-8.529, -2.440	-20.561, 9.592
Outer Temporal	256.704 (25.894)	259.992 (26.967)	-3.287 (4.373)	-5.054, -1.521	-12.033, 5.458
Glaucoma Eyes (N = 25)					
Central Fovea	243.749 (16.276)	245.544 (18.331)	-1.795 (4.937)	-3.833, 0.243	-11.670, 8.079
Inner Superior	286.105 (25.967)	289.968 (28.053)	-3.864 (3.917)	-5.480, -2.247	-11.698, 3.971
Inner Nasal	292.276 (17.609)	296.114 (19.647)	-3.838 (4.251)	-5.592, -2.083	-12.339, 4.664
Inner Inferior	284.798 (19.193)	287.965 (20.269)	-3.167 (3.223)	-4.498, -1.837	-9.613, 3.279
Inner Temporal	278.046 (15.855)	281.840 (17.968)	-3.794 (4.544)	-5.670, -1.919	-12.881, 5.293
Outer Superior	245.268 (17.305)	248.721 (17.825)	-3.453 (3.861)	-5.047, -1.860	-11.174, 4.268
Outer Nasal	259.902 (18.908)	261.922 (19.747)	-2.021 (3.102)	-3.301, -0.740	-8.225, 4.184
Outer Inferior	234.349 (15.412)	237.959 (16.762)	-3.610 (2.900)	-4.807, -2.412	-9.410, 2.191
Outer Temporal	235.496 (13.765)	238.046 (14.187)	-2.550 (2.886)	-3.741, -1.359	-8.323, 3.223

N is the number of eyes with measurements from both devices.

Difference = Triton - Maestro

95% confidence interval (CI) for mean difference is based on t-distribution.

95% limits of agreement (LOA) = mean difference +/- 2 x difference SD

**Table 3. Limits of Agreement between Triton 12x9 Wide and Maestro 12x9 Wide:
Full Retinal Thickness (mm) Agreement Analysis Population**

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Normal Eyes (N = 25)					
Central Fovea	253.285 (25.739)	254.889 (27.233)	-1.604 (5.824)	-4.008, 0.801	-13.253, 10.045
Inner Superior	318.049 (15.025)	319.785 (15.322)	-1.736 (4.501)	-3.594, 0.122	-10.738, 7.266
Inner Nasal	320.078 (15.970)	321.635 (15.551)	-1.557 (4.414)	-3.379, 0.265	-10.385, 7.271
Inner Inferior	313.766 (16.641)	315.520 (16.579)	-1.754 (3.272)	-3.105, -0.403	-8.298, 4.790
Inner Temporal	304.453 (16.725)	306.027 (16.434)	-1.574 (4.205)	-3.310, 0.162	-9.984, 6.837
Outer Superior	273.720 (14.840)	276.277 (16.733)	-2.557 (3.362)	-3.945, -1.169	-9.281, 4.168
Outer Nasal	290.864 (18.051)	292.204 (18.195)	-1.340 (2.915)	-2.544, -0.137	-7.170, 4.489
Outer Inferior	263.360 (17.043)	264.814 (17.018)	-1.453 (2.954)	-2.673, -0.234	-7.361, 4.455
Outer Temporal	259.225 (14.143)	261.355 (14.541)	-2.130 (2.523)	-3.171, -1.088	-7.176, 2.917
Retinal Eyes (N = 26)					
Central Fovea	280.446 (64.997)	284.317 (65.981)	-3.871 (7.183)	-6.904, -0.838	-18.236, 10.494
Inner Superior	318.230 (39.994)	321.523 (39.990)	-3.293 (4.144)	-5.043, -1.543	-11.581, 4.995
Inner Nasal	320.276 (33.435)	323.884 (34.829)	-3.608 (4.875)	-5.666, -1.549	-13.358, 6.142
Inner Inferior	311.013 (35.923)	313.798 (36.435)	-2.786 (8.796)	-6.500, 0.928	-20.378, 14.806
Inner Temporal	304.876 (36.082)	307.938 (34.603)	-3.063 (6.983)	-6.011, -0.114	-17.029, 10.904
Outer Superior	272.455 (24.283)	275.740 (25.617)	-3.285 (3.760)	-4.873, -1.698	-10.806, 4.235
Outer Nasal	287.367 (21.331)	290.301 (23.553)	-2.935 (5.042)	-5.064, -0.806	-13.018, 7.149
Outer Inferior	258.478 (23.809)	261.797 (23.770)	-3.319 (8.331)	-6.836, 0.199	-19.980, 13.343
Outer Temporal	254.986 (25.005)	258.137 (24.698)	-3.151 (4.885)	-5.214, -1.088	-12.922, 6.620
Glaucoma Eyes (N = 25)					
Central Fovea	244.176 (17.544)	246.496 (17.721)	-2.320 (4.084)	-4.045, -0.595	-10.489, 5.849
Inner Superior	289.698 (16.230)	292.570 (16.785)	-2.871 (2.271)	-3.830, -1.912	-7.413, 1.670
Inner Nasal	293.856 (17.489)	296.396 (17.516)	-2.540 (3.067)	-3.835, -1.245	-8.674, 3.594
Inner Inferior	284.328 (19.942)	287.300 (19.458)	-2.972 (2.628)	-4.081, -1.862	-8.228, 2.285
Inner Temporal	279.409 (17.073)	282.387 (17.201)	-2.977 (2.872)	-4.190, -1.765	-8.721, 2.766
Outer Superior	247.638 (14.386)	250.155 (14.277)	-2.517 (2.431)	-3.544, -1.491	-7.379, 2.345
Outer Nasal	261.083 (19.262)	262.721 (19.460)	-1.638 (1.956)	-2.464, -0.812	-5.551, 2.275
Outer Inferior	234.086 (15.662)	236.015 (16.030)	-1.930 (1.765)	-2.675, -1.184	-5.460, 1.600
Outer Temporal	237.022 (14.366)	239.752 (14.588)	-2.730 (2.454)	-3.766, -1.694	-7.638, 2.178

N is the number of eyes with measurements from both devices.

Difference = Triton - Maestro

95% confidence interval (CI) for mean difference is based on t-distribution.

95% limits of agreement (LOA) = mean difference +/- 2 x difference SD

**Table 4. Limits of Agreement between Triton 7x7 Macula and Maestro 6x6 Macula:
Ganglion Cell + IPL Thickness (mm) Agreement Analysis Population**

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Normal Eyes (N = 25)					
Superior	69.757 (5.703)	72.561 (6.120)	-2.804 (1.492)	-3.419, -2.188	-5.787, 0.179
Superior Nasal	74.469 (6.416)	76.502 (6.824)	-2.032 (1.110)	-2.491, -1.574	-4.252, 0.188
Superior Temporal	71.439 (4.766)	72.628 (5.265)	-1.188 (1.238)	-1.699, -0.677	-3.664, 1.287
Inferior	67.243 (6.226)	69.742 (6.391)	-2.499 (1.242)	-3.011, -1.986	-4.982, -0.016
Inferior Nasal	72.865 (6.786)	74.972 (6.456)	-2.107 (0.833)	-2.451, -1.763	-3.773, -0.441
Inferior Temporal	72.590 (6.395)	73.938 (6.854)	-1.348 (1.238)	-1.859, -0.837	-3.825, 1.129
Average	71.400 (5.756)	73.396 (6.009)	-1.996 (0.782)	-2.319, -1.673	-3.561, -0.431
Retinal Eyes (N = 26)					
Superior	66.450 (6.763)	68.726 (7.568)	-2.276 (1.761)	-2.987, -1.565	-5.797, 1.245
Superior Nasal	69.626 (6.088)	71.558 (6.736)	-1.932 (1.806)	-2.661, -1.202	-5.543, 1.680
Superior Temporal	72.453 (9.902)	72.956 (10.478)	-0.503 (3.274)	-1.826, 0.819	-7.052, 6.046
Inferior	64.326 (8.379)	67.005 (8.407)	-2.680 (2.866)	-3.837, -1.522	-8.411, 3.052
Inferior Nasal	69.661 (7.339)	71.394 (8.164)	-1.733 (2.014)	-2.547, -0.920	-5.762, 2.295
Inferior Temporal	73.395 (12.134)	74.294 (12.198)	-0.899 (2.057)	-1.730, -0.068	-5.014, 3.216
Average	69.331 (7.602)	71.008 (8.053)	-1.677 (1.185)	-2.156, -1.198	-4.047, 0.693
Glaucoma Eyes (N = 25)					
Superior	55.622 (8.631)	56.998 (9.443)	-1.376 (1.457)	-1.978, -0.775	-4.290, 1.538
Superior Nasal	59.672 (9.750)	60.888 (10.400)	-1.216 (1.360)	-1.777, -0.654	-3.935, 1.504
Superior Temporal	61.115 (6.586)	61.802 (7.074)	-0.687 (1.624)	-1.357, -0.016	-3.935, 2.561
Inferior	53.388 (6.721)	55.223 (7.183)	-1.835 (2.017)	-2.668, -1.003	-5.869, 2.198
Inferior Nasal	58.004 (9.676)	59.361 (9.861)	-1.356 (1.564)	-2.002, -0.711	-4.485, 1.772
Inferior Temporal	60.408 (7.330)	60.734 (7.618)	-0.326 (1.820)	-1.077, 0.426	-3.966, 3.314
Average	58.036 (7.172)	59.192 (7.566)	-1.156 (1.045)	-1.587, -0.725	-3.246, 0.934

N is the number of eyes with measurements from both devices.

Difference = Triton - Maestro

95% confidence interval (CI) for mean difference is based on t-distribution.

95% limits of agreement (LOA) = mean difference +/- 2 x difference SD

**Table 5. Limits of Agreement between Triton 12x9 Wide and Maestro 12x9 Wide:
Ganglion Cell + IPL Thickness (mm) Agreement Analysis Population**

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Normal Eyes (N = 25)					
Superior	70.391 (5.561)	72.198 (5.957)	-1.807 (0.985)	-2.214, -1.401	-3.777, 0.162
Superior Nasal	74.646 (6.561)	76.435 (6.870)	-1.789 (0.952)	-2.182, -1.396	-3.692, 0.115
Superior Temporal	70.918 (5.407)	72.358 (5.815)	-1.440 (0.861)	-1.796, -1.084	-3.163, 0.283
Inferior	67.660 (6.299)	69.411 (6.190)	-1.751 (1.165)	-2.232, -1.270	-4.081, 0.580
Inferior Nasal	73.210 (6.506)	75.078 (6.668)	-1.868 (0.954)	-2.262, -1.475	-3.777, 0.040
Inferior Temporal	72.144 (6.457)	74.028 (6.788)	-1.884 (1.004)	-2.298, -1.469	-3.892, 0.125
Average	71.500 (5.857)	73.256 (6.103)	-1.756 (0.593)	-2.001, -1.511	-2.942, -0.570
Retinal Eyes (N = 26)					
Superior	67.840 (6.751)	69.305 (7.067)	-1.466 (2.789)	-2.643, -0.288	-7.043, 4.112
Superior Nasal	72.020 (7.167)	74.356 (9.542)	-2.336 (4.571)	-4.266, -0.406	-11.478, 6.806
Superior Temporal	69.399 (10.325)	70.473 (9.534)	-1.073 (2.257)	-2.026, -0.120	-5.587, 3.440
Inferior	64.227 (8.273)	65.463 (8.917)	-1.235 (4.215)	-3.015, 0.545	-9.666, 7.195
Inferior Nasal	71.283 (7.734)	72.863 (8.840)	-1.580 (2.246)	-2.529, -0.632	-6.072, 2.911
Inferior Temporal	70.758 (10.839)	72.162 (11.077)	-1.404 (3.130)	-2.726, -0.083	-7.664, 4.855
Average	69.254 (7.667)	70.779 (7.956)	-1.525 (0.999)	-1.947, -1.103	-3.523, 0.473
Glaucoma Eyes (N = 25)					
Superior	56.588 (8.355)	57.728 (8.866)	-1.140 (1.125)	-1.615, -0.665	-3.390, 1.110
Superior Nasal	60.501 (9.182)	61.990 (9.248)	-1.488 (0.719)	-1.792, -1.185	-2.926, -0.050
Superior Temporal	58.203 (8.942)	58.782 (9.913)	-0.579 (1.360)	-1.153, -0.005	-3.299, 2.141
Inferior	52.420 (8.545)	53.430 (8.592)	-1.010 (0.815)	-1.355, -0.666	-2.641, 0.620
Inferior Nasal	57.940 (10.485)	59.125 (10.909)	-1.185 (0.881)	-1.557, -0.813	-2.947, 0.577
Inferior Temporal	55.950 (10.765)	56.580 (11.330)	-0.630 (1.422)	-1.231, -0.030	-3.475, 2.214
Average	56.938 (8.605)	57.946 (9.013)	-1.008 (0.752)	-1.326, -0.691	-2.513, 0.496

N is the number of eyes with measurements from both devices.

Difference = Triton - Maestro

95% confidence interval (CI) for mean difference is based on t-distribution.

95% limits of agreement (LOA) = mean difference +/- 2 x difference SD

**Table 6. Limits of Agreement between Triton 7x7 Macula and Maestro 6x6 Macula:
Ganglion Cell Complex Thickness (mm) Agreement Analysis Population**

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Normal Eyes (N = 25)					
Superior	107.598 (7.933)	108.494 (7.993)	-0.896 (1.449)	-1.494, -0.298	-3.793, 2.001
Superior Nasal	118.699 (8.723)	119.427 (9.142)	-0.728 (1.396)	-1.304, -0.152	-3.520, 2.064
Superior Temporal	93.898 (6.339)	94.378 (6.634)	-0.480 (1.420)	-1.066, 0.106	-3.321, 2.361
Inferior	106.720 (9.040)	107.329 (9.340)	-0.609 (1.426)	-1.198, -0.021	-3.461, 2.243
Inferior Nasal	119.495 (10.193)	120.126 (10.434)	-0.631 (1.290)	-1.163, -0.099	-3.210, 1.948
Inferior Temporal	97.209 (7.588)	97.493 (8.034)	-0.284 (1.738)	-1.001, 0.433	-3.760, 3.192
Average	107.268 (7.828)	107.884 (8.129)	-0.616 (1.116)	-1.077, -0.155	-2.847, 1.615
Retinal Eyes (N = 26)					
Superior	113.072 (19.742)	113.830 (20.513)	-0.758 (1.803)	-1.486, -0.030	-4.363, 2.848
Superior Nasal	121.294 (17.619)	121.730 (17.969)	-0.436 (2.076)	-1.275, 0.402	-4.588, 3.715
Superior Temporal	99.000 (15.413)	99.509 (15.809)	-0.509 (1.879)	-1.268, 0.250	-4.268, 3.249
Inferior	108.175 (17.234)	109.512 (18.970)	-1.337 (4.332)	-3.086, 0.413	-10.001, 7.328
Inferior Nasal	122.721 (18.189)	122.751 (20.334)	-0.030 (3.392)	-1.400, 1.340	-6.814, 6.754
Inferior Temporal	99.976 (17.182)	100.722 (17.411)	-0.745 (2.251)	-1.655, 0.164	-5.248, 3.757
Average	110.715 (16.225)	111.373 (17.188)	-0.658 (1.845)	-1.403, 0.087	-4.347, 3.032
Glaucoma Eyes (N = 25)					
Superior	86.832 (15.742)	86.720 (15.991)	0.111 (1.280)	-0.417, 0.640	-2.449, 2.671
Superior Nasal	97.626 (17.241)	97.097 (17.399)	0.529 (2.786)	-0.621, 1.679	-5.043, 6.101
Superior Temporal	78.534 (11.797)	78.363 (12.093)	0.172 (1.240)	-0.340, 0.683	-2.308, 2.651
Inferior	83.838 (14.596)	83.881 (15.292)	-0.044 (1.303)	-0.581, 0.494	-2.649, 2.562
Inferior Nasal	96.685 (18.388)	96.327 (19.027)	0.358 (1.736)	-0.358, 1.074	-3.113, 3.829
Inferior Temporal	77.714 (13.157)	77.519 (13.613)	0.195 (0.920)	-0.185, 0.575	-1.646, 2.036
Average	86.876 (13.385)	86.680 (13.651)	0.196 (1.078)	-0.249, 0.641	-1.959, 2.351

N is the number of eyes with measurements from both devices.

Difference = Triton - Maestro

95% confidence interval (CI) for mean difference is based on t-distribution.

95% limits of agreement (LOA) = mean difference +/- 2 x difference SD

**Table 7. Limits of Agreement between Triton 12x9 Wide and Maestro 12x9 Wide:
Ganglion Cell Complex Thickness (mm) Agreement Analysis Population**

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Normal Eyes (N = 25)					
Superior	107.536 (7.455)	107.604 (8.219)	-0.068 (1.815)	-0.818, 0.681	-3.698, 3.561
Superior Nasal	119.298 (8.820)	119.394 (9.268)	-0.095 (1.486)	-0.709, 0.518	-3.067, 2.876
Superior Temporal	94.647 (6.099)	94.778 (6.761)	-0.132 (1.215)	-0.633, 0.370	-2.562, 2.299
Inferior	106.996 (8.794)	106.672 (8.999)	0.324 (1.295)	-0.211, 0.858	-2.267, 2.915
Inferior Nasal	119.679 (9.927)	119.590 (10.396)	0.089 (1.282)	-0.440, 0.618	-2.474, 2.652
Inferior Temporal	97.922 (7.219)	98.334 (7.825)	-0.412 (1.309)	-0.952, 0.129	-3.030, 2.206
Average	107.688 (7.626)	107.732 (8.138)	-0.044 (1.158)	-0.522, 0.434	-2.361, 2.273
Retinal Eyes (N = 26)					
Superior	112.223 (16.563)	111.426 (17.341)	0.797 (2.185)	-0.126, 1.720	-3.573, 5.167
Superior Nasal	121.542 (16.285)	121.510 (17.564)	0.032 (2.408)	-0.984, 1.049	-4.784, 4.849
Superior Temporal	97.254 (13.954)	96.840 (13.564)	0.415 (2.660)	-0.709, 1.538	-4.905, 5.735
Inferior	108.042 (13.646)	107.501 (15.138)	0.540 (5.328)	-1.710, 2.790	-10.117, 11.197
Inferior Nasal	121.860 (15.448)	121.037 (15.073)	0.824 (2.150)	-0.084, 1.732	-3.476, 5.123
Inferior Temporal	99.482 (14.282)	99.227 (15.210)	0.255 (3.842)	-1.367, 1.877	-7.430, 7.940
Average	110.075 (13.985)	109.600 (14.167)	0.475 (1.732)	-0.256, 1.206	-2.988, 3.938
Glaucoma Eyes (N = 25)					
Superior	88.431 (13.569)	88.082 (13.039)	0.349 (1.287)	-0.195, 0.892	-2.226, 2.923
Superior Nasal	99.618 (15.248)	99.090 (15.198)	0.527 (1.184)	0.028, 1.027	-1.841, 2.896
Superior Temporal	79.828 (11.212)	79.573 (11.597)	0.255 (1.152)	-0.232, 0.741	-2.050, 2.559
Inferior	83.691 (15.095)	82.823 (14.813)	0.868 (1.080)	0.412, 1.324	-1.292, 3.028
Inferior Nasal	96.578 (19.085)	95.675 (18.998)	0.903 (1.141)	0.421, 1.385	-1.380, 3.186
Inferior Temporal	77.887 (13.907)	77.543 (14.068)	0.344 (1.296)	-0.204, 0.891	-2.248, 2.936
Average	87.675 (13.555)	87.138 (13.399)	0.537 (0.791)	0.204, 0.871	-1.044, 2.119

N is the number of eyes with measurements from both devices.

Difference = Triton - Maestro

95% confidence interval (CI) for mean difference is based on t-distribution.

95% limits of agreement (LOA) = mean difference +/- 2 x difference SD

**Table 8. Limits of Agreement between Triton 6x6 Disc and Maestro 6x6 Disc:
Optic Disc Agreement Analysis Population**

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Normal Eyes (N = 25)					
C/D Vertical	0.458 (0.195)	0.454 (0.231)	0.004 (0.110)	-0.041, 0.049	-0.216, 0.224
C/D Area	0.249 (0.156)	0.255 (0.189)	-0.006 (0.118)	-0.055, 0.043	-0.243, 0.231
Disc Area (mm ²)	1.754 (0.407)	2.038 (0.415)	-0.285 (0.145)	-0.345, -0.225	-0.575, 0.006
Cup Area (mm ²)	0.466 (0.341)	0.537 (0.416)	-0.072 (0.211)	-0.159, 0.015	-0.494, 0.350
Rim Area (mm ²)	1.287 (0.302)	1.502 (0.426)	-0.215 (0.277)	-0.329, -0.100	-0.769, 0.340
Cup Volume (mm ³)	0.083 (0.079)	0.089 (0.084)	-0.006 (0.008)	-0.009, -0.003	-0.022, 0.010
Rim Volume (mm ³)	0.235 (0.102)	0.288 (0.145)	-0.053 (0.069)	-0.082, -0.025	-0.191, 0.084
Linear C/D Ratio	0.459 (0.202)	0.453 (0.227)	0.006 (0.090)	-0.031, 0.043	-0.174, 0.186
Retinal Eyes (N = 26)					
C/D Vertical	0.527 (0.230)	0.498 (0.212)	0.029 (0.036)	0.014, 0.044	-0.044, 0.102
C/D Area	0.305 (0.169)	0.280 (0.155)	0.025 (0.024)	0.016, 0.035	-0.023, 0.073
Disc Area (mm ²)	1.763 (0.361)	2.003 (0.434)	-0.240 (0.214)	-0.326, -0.154	-0.668, 0.188
Cup Area (mm ²)	0.549 (0.359)	0.562 (0.365)	-0.013 (0.042)	-0.030, 0.004	-0.097, 0.072
Rim Area (mm ²)	1.214 (0.334)	1.442 (0.434)	-0.228 (0.198)	-0.308, -0.148	-0.625, 0.168
Cup Volume (mm ³)	0.095 (0.084)	0.100 (0.087)	-0.005 (0.008)	-0.008, -0.002	-0.021, 0.011
Rim Volume (mm ³)	0.213 (0.131)	0.258 (0.172)	-0.045 (0.055)	-0.067, -0.023	-0.156, 0.066
Linear C/D Ratio	0.508 (0.219)	0.488 (0.210)	0.021 (0.019)	0.013, 0.029	-0.018, 0.060
Glaucoma Eyes (N = 25)					
C/D Vertical	0.861 (0.097)	0.823 (0.094)	0.038 (0.052)	0.016, 0.060	-0.066, 0.142
C/D Area	0.688 (0.175)	0.623 (0.168)	0.064 (0.055)	0.042, 0.087	-0.046, 0.175
Disc Area (mm ²)	1.796 (0.378)	2.044 (0.473)	-0.247 (0.165)	-0.315, -0.179	-0.576, 0.082
Cup Area (mm ²)	1.247 (0.459)	1.297 (0.524)	-0.050 (0.114)	-0.097, -0.003	-0.277, 0.177
Rim Area (mm ²)	0.549 (0.306)	0.748 (0.332)	-0.198 (0.146)	-0.259, -0.138	-0.491, 0.094
Cup Volume (mm ³)	0.351 (0.212)	0.360 (0.218)	-0.010 (0.057)	-0.033, 0.014	-0.124, 0.104
Rim Volume (mm ³)	0.053 (0.046)	0.071 (0.054)	-0.018 (0.020)	-0.026, -0.010	-0.059, 0.023
Linear C/D Ratio	0.822 (0.116)	0.781 (0.113)	0.041 (0.035)	0.026, 0.055	-0.030, 0.111

N is the number of eyes with measurements from both devices.

Difference = Triton - Maestro

95% confidence interval (CI) for mean difference is based on t-distribution.

95% limits of agreement (LOA) = mean difference +/- 2 x difference SD

**Table 9. Limits of Agreement between Triton 12x9 Wide and Maestro 12x9 Wide:
Optic Disc Agreement Analysis Population**

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Normal Eyes (N = 25)					
C/D Vertical	0.476 (0.208)	0.453 (0.199)	0.023 (0.047)	0.003, 0.042	-0.072, 0.118
C/D Area	0.254 (0.166)	0.232 (0.160)	0.022 (0.020)	0.014, 0.030	-0.017, 0.061
Disc Area (mm ²)	1.923 (0.411)	2.232 (0.370)	-0.308 (0.168)	-0.378, -0.239	-0.644, 0.027
Cup Area (mm ²)	0.518 (0.393)	0.540 (0.410)	-0.022 (0.047)	-0.042, -0.003	-0.116, 0.071
Rim Area (mm ²)	1.406 (0.327)	1.693 (0.375)	-0.287 (0.175)	-0.360, -0.215	-0.638, 0.063
Cup Volume (mm ³)	0.086 (0.086)	0.092 (0.091)	-0.006 (0.013)	-0.012, -0.001	-0.032, 0.019
Rim Volume (mm ³)	0.261 (0.123)	0.324 (0.157)	-0.063 (0.058)	-0.087, -0.039	-0.178, 0.053
Linear C/D Ratio	0.463 (0.205)	0.440 (0.205)	0.024 (0.022)	0.014, 0.033	-0.021, 0.068
Retinal Eyes (N = 26)					
C/D Vertical	0.525 (0.232)	0.510 (0.205)	0.015 (0.058)	-0.008, 0.039	-0.101, 0.131
C/D Area	0.294 (0.169)	0.272 (0.153)	0.022 (0.027)	0.011, 0.033	-0.032, 0.077
Disc Area (mm ²)	1.923 (0.376)	2.222 (0.442)	-0.298 (0.148)	-0.358, -0.239	-0.595, -0.002
Cup Area (mm ²)	0.577 (0.382)	0.612 (0.395)	-0.035 (0.040)	-0.051, -0.019	-0.115, 0.045
Rim Area (mm ²)	1.347 (0.371)	1.609 (0.438)	-0.262 (0.154)	-0.325, -0.200	-0.570, 0.046
Cup Volume (mm ³)	0.094 (0.088)	0.103 (0.094)	-0.010 (0.012)	-0.015, -0.005	-0.034, 0.015
Rim Volume (mm ³)	0.242 (0.149)	0.290 (0.181)	-0.048 (0.044)	-0.066, -0.031	-0.137, 0.040
Linear C/D Ratio	0.498 (0.219)	0.485 (0.193)	0.013 (0.047)	-0.006, 0.032	-0.080, 0.106
Glaucoma Eyes (N = 25)					
C/D Vertical	0.855 (0.119)	0.816 (0.105)	0.038 (0.057)	0.015, 0.062	-0.075, 0.152
C/D Area	0.679 (0.191)	0.624 (0.184)	0.056 (0.052)	0.034, 0.077	-0.049, 0.160
Disc Area (mm ²)	1.958 (0.384)	2.225 (0.562)	-0.267 (0.247)	-0.369, -0.165	-0.760, 0.226
Cup Area (mm ²)	1.338 (0.498)	1.390 (0.541)	-0.051 (0.086)	-0.087, -0.016	-0.223, 0.121
Rim Area (mm ²)	0.620 (0.382)	0.836 (0.444)	-0.216 (0.212)	-0.303, -0.128	-0.640, 0.209
Cup Volume (mm ³)	0.359 (0.223)	0.375 (0.236)	-0.016 (0.025)	-0.026, -0.005	-0.065, 0.034
Rim Volume (mm ³)	0.063 (0.061)	0.087 (0.078)	-0.024 (0.035)	-0.038, -0.010	-0.094, 0.046
Linear C/D Ratio	0.814 (0.132)	0.780 (0.126)	0.034 (0.034)	0.020, 0.048	-0.034, 0.102

N is the number of eyes with measurements from both devices.

Difference = Triton - Maestro

95% confidence interval (CI) for mean difference is based on t-distribution.

95% limits of agreement (LOA) = mean difference +/- 2 x difference SD

**Table 10. Limits of Agreement between Triton 6x6 Disc and Maestro 6x6 Disc:
Retinal Nerve Fiber Layer Thickness (mm) Agreement Analysis Population**

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Normal Eyes (N = 25)					
Average	105.171 (10.641)	105.988 (11.016)	-0.817 (1.341)	-1.370, -0.263	-3.499, 1.865
Superior Quadrant	128.772 (16.413)	130.712 (17.175)	-1.940 (3.498)	-3.384, -0.496	-8.936, 5.056
Nasal Quadrant	86.666 (15.590)	84.632 (15.599)	2.034 (3.442)	0.613, 3.455	-4.851, 8.918
Inferior Quadrant	137.382 (18.034)	140.049 (18.778)	-2.667 (3.141)	-3.963, -1.370	-8.949, 3.615
Temporal Quadrant	67.763 (11.057)	68.887 (12.430)	-1.124 (3.112)	-2.409, 0.160	-7.348, 5.099
12-Sector - T	56.555 (9.167)	57.592 (10.271)	-1.037 (2.600)	-2.110, 0.036	-6.236, 4.163
12-Sector - TS	80.670 (13.210)	82.116 (14.824)	-1.446 (3.994)	-3.094, 0.203	-9.433, 6.542
12-Sector - ST	135.753 (23.322)	137.138 (22.846)	-1.385 (5.559)	-3.680, 0.909	-12.503, 9.733
12-Sector - S	130.320 (29.968)	133.122 (31.334)	-2.802 (6.408)	-5.447, -0.157	-15.617, 10.014
12-Sector - SN	120.430 (24.561)	121.726 (24.006)	-1.295 (6.023)	-3.781, 1.191	-13.341, 10.750
12-Sector - NS	106.190 (21.212)	104.049 (21.605)	2.142 (6.032)	-0.348, 4.631	-9.922, 14.206
12-Sector - N	68.901 (13.540)	66.560 (12.047)	2.341 (3.369)	0.950, 3.731	-4.396, 9.078
12-Sector - NI	84.982 (16.951)	83.355 (17.139)	1.627 (4.641)	-0.288, 3.543	-7.655, 10.909
12-Sector - IN	123.131 (28.022)	125.184 (27.116)	-2.054 (5.219)	-4.208, 0.101	-12.491, 8.384
12-Sector - I	151.904 (24.673)	155.778 (25.809)	-3.874 (5.944)	-6.327, -1.421	-15.761, 8.013
12-Sector - IT	137.190 (25.698)	139.116 (26.460)	-1.926 (6.892)	-4.771, 0.918	-15.710, 11.857
12-Sector - TI	66.050 (14.161)	66.879 (15.433)	-0.829 (3.908)	-2.442, 0.784	-8.644, 6.986
Retinal Eyes (N = 26)					
Average	100.435 (17.661)	100.430 (15.504)	0.005 (4.542)	-1.829, 1.840	-9.079, 9.089
Superior Quadrant	115.893 (26.424)	117.700 (22.481)	-1.807 (12.122)	-6.703, 3.089	-26.050, 22.437
Nasal Quadrant	79.862 (18.809)	77.393 (16.593)	2.469 (3.966)	0.867, 4.071	-5.464, 10.402
Inferior Quadrant	126.865 (27.458)	128.233 (23.241)	-1.368 (8.174)	-4.670, 1.933	-17.716, 14.979
Temporal Quadrant	79.017 (13.687)	78.399 (14.980)	0.618 (5.460)	-1.587, 2.824	-10.302, 11.539
12-Sector - T	68.023 (13.965)	66.158 (14.830)	1.865 (7.680)	-1.237, 4.967	-13.494, 17.224
12-Sector - TS	96.645 (19.772)	96.904 (20.124)	-0.260 (4.793)	-2.196, 1.676	-9.846, 9.326
12-Sector - ST	130.406 (24.977)	133.053 (23.804)	-2.648 (8.696)	-6.160, 0.865	-20.040, 14.744
12-Sector - S	110.586 (39.114)	112.312 (33.024)	-1.726 (17.118)	-8.640, 5.189	-35.963, 32.511
12-Sector - SN	106.680 (27.637)	107.807 (22.876)	-1.128 (14.292)	-6.900, 4.645	-29.711, 27.456
12-Sector - NS	96.660 (22.892)	93.253 (20.543)	3.407 (5.571)	1.156, 5.657	-7.735, 14.548
12-Sector - N	67.715 (16.876)	65.670 (16.091)	2.044 (2.831)	0.901, 3.188	-3.617, 7.705
12-Sector - NI	75.138 (20.824)	73.229 (17.150)	1.908 (8.323)	-1.453, 5.270	-14.738, 18.555
12-Sector - IN	103.739 (30.167)	102.947 (23.195)	0.792 (13.453)	-4.641, 6.226	-26.114, 27.698
12-Sector - I	138.697 (36.060)	140.203 (33.132)	-1.507 (9.879)	-5.497, 2.483	-21.264, 18.251
12-Sector - IT	138.181 (28.232)	141.444 (25.715)	-3.263 (8.790)	-6.813, 0.287	-20.842, 14.316
12-Sector - TI	72.435 (11.994)	72.117 (14.157)	0.318 (7.489)	-2.707, 3.343	-14.660, 15.296
Glaucoma Eyes (N = 25)					

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Average	75.239 (16.078)	73.710 (16.200)	1.528 (2.546)	0.477, 2.579	-3.564, 6.621
Superior Quadrant	88.304 (20.229)	86.330 (20.180)	1.975 (5.862)	-0.445, 4.394	-9.748, 13.698
Nasal Quadrant	61.433 (13.876)	59.520 (12.802)	1.913 (3.943)	0.285, 3.541	-5.974, 9.800
Inferior Quadrant	92.212 (27.030)	91.191 (27.473)	1.021 (3.818)	-0.555, 2.597	-6.616, 8.658
Temporal Quadrant	59.038 (16.687)	57.782 (17.115)	1.256 (1.328)	0.708, 1.804	-1.399, 3.911
12-Sector - T	51.982 (12.679)	50.962 (13.564)	1.020 (1.978)	0.204, 1.837	-2.936, 4.977
12-Sector - TS	67.155 (22.260)	65.123 (21.840)	2.032 (2.820)	0.868, 3.196	-3.608, 7.672
12-Sector - ST	95.830 (30.338)	94.912 (28.697)	0.918 (6.753)	-1.869, 3.706	-12.588, 14.425
12-Sector - S	89.571 (26.762)	88.121 (28.353)	1.450 (10.658)	-2.949, 5.849	-19.866, 22.766
12-Sector - SN	79.480 (20.953)	75.993 (21.640)	3.488 (10.123)	-0.691, 7.666	-16.759, 23.734
12-Sector - NS	70.668 (16.907)	67.967 (16.928)	2.700 (5.434)	0.457, 4.944	-8.168, 13.569
12-Sector - N	53.123 (12.757)	51.976 (11.143)	1.147 (6.414)	-1.500, 3.795	-11.681, 13.975
12-Sector - NI	60.577 (16.930)	58.564 (15.905)	2.013 (3.398)	0.610, 3.415	-4.783, 8.809
12-Sector - IN	76.783 (25.112)	76.852 (26.862)	-0.070 (4.936)	-2.107, 1.968	-9.941, 9.802
12-Sector - I	102.504 (34.978)	101.589 (33.331)	0.915 (7.116)	-2.022, 3.852	-13.317, 15.146
12-Sector - IT	97.296 (35.771)	95.094 (40.387)	2.202 (7.800)	-1.017, 5.422	-13.397, 17.802
12-Sector - TI	58.015 (18.706)	57.283 (20.613)	0.732 (3.828)	-0.848, 2.312	-6.923, 8.387

T=Temporal; S=Superior; N=Nasal; I=Inferior

N is the number of eyes with measurements from both devices.

Difference = Triton - Maestro

95% confidence interval (CI) for mean difference is based on t-distribution.

95% limits of agreement (LOA) = mean difference +/- 2 x difference SD

**Table 11. Limits of Agreement between Triton 12x9 Wide and Maestro 12x9 Wide:
Retinal Nerve Fiber Layer Thickness (mm) Agreement Analysis Population**

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Normal Eyes (N = 25)					
Average	107.354 (11.015)	108.169 (11.566)	-0.814 (1.908)	-1.602, -0.027	-4.630, 3.001
Superior Quadrant	130.096 (17.098)	131.482 (20.499)	-1.386 (7.274)	-4.389, 1.616	-15.935, 13.162
Nasal Quadrant	88.743 (15.978)	88.482 (15.462)	0.261 (3.208)	-1.063, 1.585	-6.154, 6.676
Inferior Quadrant	139.378 (17.855)	140.770 (17.669)	-1.392 (3.707)	-2.923, 0.138	-8.807, 6.022
Temporal Quadrant	71.185 (11.286)	71.876 (12.218)	-0.691 (2.626)	-1.775, 0.393	-5.942, 4.560
12-Sector - T	60.930 (9.436)	60.679 (9.919)	0.252 (2.984)	-0.980, 1.483	-5.716, 6.219
12-Sector - TS	83.732 (13.893)	85.200 (15.400)	-1.468 (3.863)	-3.063, 0.126	-9.194, 6.257
12-Sector - ST	135.459 (21.305)	135.347 (20.653)	0.112 (4.739)	-1.844, 2.069	-9.366, 9.590
12-Sector - S	131.586 (31.448)	132.920 (33.696)	-1.334 (8.921)	-5.017, 2.348	-19.177, 16.508
12-Sector - SN	123.160 (25.442)	126.225 (29.338)	-3.064 (13.800)	-8.761, 2.632	-30.665, 24.536
12-Sector - NS	107.792 (22.235)	108.904 (21.782)	-1.112 (5.186)	-3.253, 1.028	-11.484, 9.259
12-Sector - N	71.100 (13.089)	70.450 (13.262)	0.650 (2.948)	-0.567, 1.867	-5.247, 6.547
12-Sector - NI	87.380 (17.264)	86.082 (16.425)	1.298 (5.874)	-1.126, 3.723	-10.451, 13.047
12-Sector - IN	126.187 (29.784)	127.289 (26.679)	-1.102 (7.030)	-4.004, 1.800	-15.163, 12.958
12-Sector - I	153.376 (23.110)	155.705 (24.597)	-2.329 (5.984)	-4.799, 0.141	-14.297, 9.639
12-Sector - IT	138.362 (24.574)	139.548 (25.863)	-1.185 (6.934)	-4.047, 1.677	-15.052, 12.682
12-Sector - TI	68.938 (13.733)	69.716 (15.192)	-0.779 (3.352)	-2.163, 0.605	-7.484, 5.926
Retinal Eyes (N = 26)					
Average	101.483 (18.437)	100.567 (17.514)	0.916 (3.584)	-0.531, 2.364	-6.251, 8.083
Superior Quadrant	117.027 (23.434)	116.987 (21.533)	0.040 (10.090)	-4.036, 4.115	-20.139, 20.219
Nasal Quadrant	81.328 (19.988)	78.570 (18.803)	2.758 (4.512)	0.936, 4.581	-6.266, 11.782
Inferior Quadrant	126.324 (29.867)	126.047 (31.537)	0.277 (6.126)	-2.198, 2.751	-11.975, 12.528
Temporal Quadrant	81.147 (13.619)	80.771 (13.617)	0.376 (3.045)	-0.854, 1.605	-5.713, 6.465
12-Sector - T	70.817 (11.701)	69.671 (12.591)	1.146 (3.818)	-0.396, 2.688	-6.489, 8.781
12-Sector - TS	98.327 (18.655)	98.862 (18.728)	-0.535 (4.284)	-2.265, 1.196	-9.102, 8.033
12-Sector - ST	131.285 (22.930)	132.223 (22.664)	-0.938 (11.287)	-5.497, 3.620	-23.512, 21.635
12-Sector - S	111.873 (33.165)	112.355 (31.226)	-0.482 (15.060)	-6.565, 5.601	-30.602, 29.638
12-Sector - SN	108.051 (25.327)	106.500 (23.645)	1.551 (10.750)	-2.791, 5.893	-19.950, 23.051
12-Sector - NS	96.147 (26.152)	93.692 (23.966)	2.455 (9.044)	-1.198, 6.108	-15.634, 20.543
12-Sector - N	71.181 (16.450)	68.018 (16.055)	3.163 (3.780)	1.636, 4.689	-4.396, 10.722
12-Sector - NI	76.690 (20.512)	74.092 (19.829)	2.598 (5.243)	0.480, 4.715	-7.889, 13.084
12-Sector - IN	105.134 (29.867)	101.650 (30.308)	3.483 (8.076)	0.221, 6.745	-12.669, 19.636
12-Sector - I	138.033 (37.295)	138.178 (38.677)	-0.145 (9.222)	-3.870, 3.580	-18.590, 18.300
12-Sector - IT	135.828 (32.544)	138.310 (34.948)	-2.482 (9.851)	-6.461, 1.497	-22.184, 17.219
12-Sector - TI	74.327 (15.359)	73.764 (16.108)	0.562 (5.924)	-1.831, 2.955	-11.286, 12.411
Glaucoma Eyes (N = 25)					

Eye Population Measurement	Triton Mean (SD)	Maestro Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
Average	75.922 (16.232)	74.327 (16.764)	1.594 (2.491)	0.566, 2.622	-3.387, 6.575
Superior Quadrant	87.176 (21.723)	85.305 (22.301)	1.871 (4.917)	-0.159, 3.901	-7.964, 11.706
Nasal Quadrant	63.545 (12.881)	60.888 (14.002)	2.657 (5.273)	0.480, 4.834	-7.890, 13.204
Inferior Quadrant	91.852 (27.651)	90.576 (26.655)	1.275 (5.822)	-1.128, 3.679	-10.369, 12.920
Temporal Quadrant	61.036 (16.731)	60.584 (17.475)	0.452 (2.725)	-0.673, 1.577	-4.998, 5.902
12-Sector - T	55.343 (13.456)	53.978 (13.430)	1.365 (2.598)	0.292, 2.437	-3.832, 6.562
12-Sector - TS	68.714 (21.816)	67.882 (23.312)	0.832 (4.834)	-1.163, 2.827	-8.836, 10.500
12-Sector - ST	95.236 (29.815)	95.524 (29.402)	-0.288 (7.453)	-3.365, 2.789	-15.194, 14.618
12-Sector - S	87.299 (27.281)	85.454 (29.440)	1.845 (7.227)	-1.138, 4.828	-12.608, 16.298
12-Sector - SN	79.082 (23.146)	74.832 (24.032)	4.250 (7.595)	1.115, 7.385	-10.941, 19.441
12-Sector - NS	71.338 (15.840)	67.757 (20.494)	3.581 (10.783)	-0.870, 8.032	-17.986, 25.148
12-Sector - N	55.734 (10.833)	53.993 (10.984)	1.740 (3.783)	0.179, 3.302	-5.826, 9.307
12-Sector - NI	63.469 (16.602)	61.000 (15.838)	2.469 (5.866)	0.048, 4.890	-9.262, 14.200
12-Sector - IN	78.248 (26.112)	77.536 (26.737)	0.713 (7.721)	-2.474, 3.900	-14.730, 16.156
12-Sector - I	102.256 (34.631)	99.734 (34.025)	2.522 (9.935)	-1.579, 6.623	-17.347, 22.391
12-Sector - IT	95.183 (35.802)	94.271 (36.536)	0.912 (7.374)	-2.132, 3.956	-13.836, 15.660
12-Sector - TI	59.019 (18.529)	59.911 (20.885)	-0.892 (4.240)	-2.642, 0.858	-9.371, 7.587

T=Temporal; S=Superior; N=Nasal; I=Inferior

N is the number of eyes with measurements from both devices.

Difference = Triton - Maestro

95% confidence interval (CI) for mean difference is based on t-distribution.

95% limits of agreement (LOA) = mean difference +/- 2 x difference SD

Fundus Photograph Evaluation

An agreement analysis of fundus photograph image quality between the Triton and Maestro was performed for normal, retinal, and glaucoma eyes. Fundus photographs were graded on a 5-point scale, where a "1" indicated that the photograph was insufficient for any interpretation, "2" indicated that the photograph was insufficient for full interpretation, "3" represented an adequate photograph, "4" characterized a good photograph and "5" represented an excellent photograph. Grades of 1-2 represented images that provided no or little information to aid clinical decision making, whereas grades 3-5 indicated images which provided sufficient information for clinical judgment with various degrees of artifacts. Thus, images scoring 3 or above can be considered clinically useful.

Majority of the photographs were graded as good or excellent by both graders. The response rates (*i.e.*, percentage of subjects whose Triton grades were equal to or better than their Maestro grades) ranged between 65.4% and 96%. Furthermore, the total agreement between graders for the Triton and Maestro fundus photograph grades ranged between 28% and 68% among the Triton photographs, and between 28% and 64% among Maestro photographs.

There were a total of 304 color fundus images evaluated by both graders in this study. Two-hundred and eighty nine (289) (95.1%) and 303 (99.7%) images received grade 3 or higher by graders 1 and 2, respectively. Importantly, over 95% of the photographs were considered clinically useful by both experts. Since this type of evaluation is subjective, the company performed a further analysis on image quality grades that differed by 1 point, as this difference is not considered significantly different when both graders' scores are 3 or above or 2 or below.

The images were categorized into two groups based on the grade differences where group 1 included images where the grades were off by at most one point between the graders and group 2 consisted of images that had a grade difference larger than 1 point between graders. Notably, the majority of images were in group 1 (n=291 (95.7%); 146 Triton and 145 Maestro).

Among all images (*i.e.*, across groups 1 and 2), 14 images were considered clinically useful by one grader (grade 3 or above) and partial/not useful by the other grader (grade 2 or below). This was only a small fraction (4.6%) of all of the fundus photographs evaluated. Therefore, it is reasonable to conclude that the two graders generally agreed on the clinical utility of majority of the images.

Agreement Analysis of Anterior B Scan Image Quality

An agreement analysis of image quality of anterior corneal and anterior angle scans was performed for normal, retinal, and glaucoma eyes, respectively. B scans were graded on a 4-point scale, where "0" indicated a failure, "1" represented a poor image, "2" characterized a fair image and "3" represented a good image. Nearly all of the images (all Triton and 74 out of 76 Maestro images) were graded as fair or good by both graders. Notably, the response rates (*i.e.*, percentage of subjects whose Triton grades were equal to or better than their Maestro grades) ranged between 92% and 100%.

Furthermore, the total agreement between graders was generally higher for Triton images (72% - 100%) compared to Maestro images (48% - 80%).

Agreement Analysis of Posterior B Scan Image Quality

An agreement analysis of posterior B scan quality was also performed for normal, retinal, and glaucoma eyes, respectively. The posterior B scan images were graded using the same 4-point scale as the anterior B scan images. Similar to the previous sections, all of the grades were good or fair by both graders. Notably, the response rates (*i.e.*, percentage of subjects whose Triton grades were equal to or better than their Maestro grades) ranged between 84.6% and 100%.

Agreement between graders was similar between the Triton and Maestro images, ranging between 64% and 96% among the Triton scans, and between 68% and 96% among Maestro scans. 34% of the images differed by one grade. These images all received grades of 2 or higher by both graders and can therefore be considered clinically useful.

Precision Assessment

Table 12: Full Retinal Thickness – Normal Eyes Repeatability and Reproducibility

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
Central Fovea	252.59	1.324	3.708 (0.378)	0.524	1.678	4.699 (0.420)	0.664
Inner Superior	317.88	0.882	2.470 (0.486)	0.278	1.621	4.539 (0.648)	0.510
Inner Nasal	319.99	0.658	1.844 (0.367)	0.206	1.501	4.202 (0.582)	0.469
Inner Inferior	313.56	0.708	1.982 (0.297)	0.226	1.474	4.126 (0.480)	0.470
Inner Temporal	304.26	0.669	1.873 (0.371)	0.220	1.447	4.051 (0.556)	0.475
Outer Superior	273.69	1.065	2.982 (0.729)	0.389	1.579	4.420 (0.802)	0.577
Outer Nasal	290.85	0.687	1.923 (0.646)	0.236	1.462	4.094 (0.869)	0.503
Outer Inferior	263.16	0.816	2.285 (0.655)	0.310	1.422	3.982 (0.810)	0.540
Outer Temporal	259.08	0.713	1.995 (0.690)	0.275	1.379	3.861 (0.918)	0.532
Triton 7x7 3D Macula							
Central Fovea	252.63	1.003	2.809 (0.486)	0.397	1.535	4.298 (0.587)	0.608
Inner Superior	318.34	0.833	2.334 (0.480)	0.262	1.457	4.080 (0.629)	0.458
Inner Nasal	319.64	0.996	2.788 (0.646)	0.311	1.835	5.137 (0.830)	0.574
Inner Inferior	313.69	0.970	2.717 (0.573)	0.309	1.762	4.934 (0.750)	0.562
Inner Temporal	303.77	0.992	2.776 (0.620)	0.326	1.877	5.254 (0.932)	0.618
Outer Superior	273.55	0.971	2.718 (0.614)	0.355	1.545	4.325 (0.660)	0.565
Outer Nasal	289.79	0.609	1.706 (0.576)	0.210	1.395	3.905 (0.845)	0.481
Outer Inferior	262.96	0.984	2.755 (0.889)	0.374	1.702	4.765 (0.971)	0.647
Outer Temporal	257.36	0.994	2.784 (0.827)	0.386	1.653	4.629 (0.902)	0.642
Maestro 12x9 3D Wide							
Central Fovea	253.28	3.508	9.822	1.385	3.999	11.198	1.579
Inner Superior	319.05	1.814	5.080	0.569	2.501	7.002	0.784
Inner Nasal	320.63	1.793	5.019	0.559	2.579	7.222	0.804
Inner Inferior	314.57	2.387	6.684	0.759	3.071	8.598	0.976
Inner Temporal	304.92	1.801	5.042	0.591	2.603	7.289	0.854
Outer Superior	275.89	1.461	4.091	0.530	1.970	5.515	0.714
Outer Nasal	291.56	1.063	2.978	0.365	1.683	4.713	0.577
Outer Inferior	264.28	1.247	3.491	0.472	1.756	4.916	0.664
Outer Temporal	260.87	1.033	2.892	0.396	1.501	4.204	0.576
Maestro 6x6 3D Macula							
Central Fovea	251.10	2.063	5.777	0.822	2.615	7.321	1.041
Inner Superior	320.29	1.736	4.862	0.542	2.316	6.484	0.723

		N=25					
		Repeatability			Reproducibility		
Device	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Measurement							
Inner Nasal	321.16	1.540	4.313	0.480	2.212	6.192	0.689
Inner Inferior	314.86	1.694	4.742	0.538	2.349	6.576	0.746
Inner Temporal	304.67	1.598	4.475	0.525	2.012	5.635	0.661
Outer Superior	275.81	1.580	4.423	0.573	2.341	6.555	0.849
Outer Nasal	290.89	1.058	2.962	0.364	1.649	4.618	0.567
Outer Inferior	264.49	1.107	3.098	0.418	1.753	4.909	0.663
Outer Temporal	258.04	1.203	3.369	0.466	1.832	5.130	0.710

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Mean = Intercept of the ANOVA model
Repeatability SD = Square root of the residual variance
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD Repeatability CV% = (Repeatability SD)/Intercept x 100%
Reproducibility CV% = (Reproducibility SD)/Intercept x 100%
Ratio is relative to Maestro

Table 13: Full Retinal Thickness - Retinal Disease Eyes Repeatability and Reproducibility

		N=26					
		Repeatability			Reproducibility		
Device	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Measurement							
Triton 12x9 3D Wide							
Central Fovea	280.33	1.744	4.883 (0.383)	0.622	3.278	9.179 (0.638)	1.169
Inner Superior	317.80	1.730	4.844 (0.848)	0.544	2.241	6.275 (0.920)	0.705
Inner Nasal	320.34	1.091	3.055 (0.492)	0.341	2.548	7.134 (0.874)	0.795
Inner Inferior	311.02	2.080	5.825 (0.499)	0.669	2.966	8.304 (0.635)	0.954
Inner Temporal	304.94	1.111	3.110 (0.285)	0.364	1.989	5.568 (0.423)	0.652
Outer Superior	271.85	1.351	3.782 (0.698)	0.497	2.347	6.571 (0.816)	0.863
Outer Nasal	287.08	0.850	2.379 (0.263)	0.296	1.671	4.678 (0.508)	0.582
Outer Inferior	258.50	1.584	4.434 (0.516)	0.613	2.420	6.777 (0.617)	0.936
Outer Temporal	254.49	0.958	2.681 (0.346)	0.376	1.822	5.102 (0.585)	0.716
Triton 7x7 3D Macula							
Central Fovea	287.46	2.306	6.457 (0.579)	0.802	2.513	7.037 (0.573)	0.874
Inner Superior	319.75	1.223	3.425 (0.692)	0.383	2.691	7.536 (1.063)	0.842

		N=26					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Inner Nasal	321.74	1.503	4.208 (0.871)	0.467	2.356	6.596 (0.846)	0.732
Inner Inferior	314.69	2.706	7.577 (0.755)	0.860	2.948	8.255 (0.651)	0.937
Inner Temporal	310.48	1.427	3.995 (0.701)	0.460	2.338	6.548 (0.721)	0.753
Outer Superior	273.46	1.414	3.960 (0.767)	0.517	2.057	5.760 (0.804)	0.752
Outer Nasal	285.76	1.581	4.426 (0.801)	0.553	2.046	5.728 (0.785)	0.716
Outer Inferior	260.01	1.580	4.425 (0.582)	0.608	1.982	5.549 (0.499)	0.762
Outer Temporal	256.36	1.827	5.115 (0.795)	0.713	2.134	5.976 (0.816)	0.832
Maestro 12x9 3D Wide							
Central Fovea	283.84	4.551	12.744	1.603	5.136	14.381	1.810
Inner Superior	321.04	2.039	5.710	0.635	2.436	6.821	0.759
Inner Nasal	322.71	2.220	6.215	0.688	2.917	8.167	0.904
Inner Inferior	313.47	4.172	11.682	1.331	4.670	13.075	1.490
Inner Temporal	308.35	3.900	10.919	1.265	4.704	13.170	1.525
Outer Superior	275.47	1.936	5.420	0.703	2.876	8.054	1.044
Outer Nasal	289.01	3.226	9.033	1.116	3.290	9.211	1.138
Outer Inferior	261.73	3.069	8.593	1.173	3.925	10.990	1.500
Outer Temporal	258.43	2.768	7.749	1.071	3.115	8.722	1.205
Maestro 6x6 3D Macula							
Central Fovea	289.94	3.981	11.147	1.373	4.389	12.289	1.514
Inner Superior	323.40	1.767	4.947	0.546	2.532	7.091	0.783
Inner Nasal	324.67	1.725	4.829	0.531	2.784	7.796	0.858
Inner Inferior	318.98	3.583	10.031	1.123	4.529	12.681	1.420
Inner Temporal	315.77	2.035	5.697	0.644	3.244	9.083	1.027
Outer Superior	276.69	1.843	5.162	0.666	2.560	7.168	0.925
Outer Nasal	287.87	1.974	5.528	0.686	2.605	7.295	0.905
Outer Inferior	265.57	2.716	7.606	1.023	3.968	11.110	1.494
Outer Temporal	259.89	2.298	6.434	0.884	2.617	7.327	1.007
<p>All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.</p> <p>Mean = Intercept of the ANOVA model</p> <p>Repeatability SD = Square root of the residual variance</p> <p>Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance</p> <p>Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD Repeatability CV% = (Repeatability SD)/Intercept x 100%</p> <p>Reproducibility CV% = (Reproducibility SD)/Intercept x 100%</p> <p>Ratio is relative to Maestro</p>							

Table 14: Full Retinal Thickness - Glaucoma Eyes Repeatability and Reproducibility

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
Central Fovea	243.46	1.336	3.740 (0.547)	0.549	1.723	4.825 (0.595)	0.708
Inner Superior	289.35	0.639	1.790 (0.532)	0.221	1.261	3.531 (0.695)	0.436
Inner Nasal	293.46	0.517	1.447 (0.377)	0.176	1.330	3.725 (0.734)	0.453
Inner Inferior	284.12	0.682	1.909 (0.425)	0.240	1.196	3.348 (0.578)	0.421
Inner Temporal	279.25	0.651	1.822 (0.484)	0.233	1.414	3.960 (0.817)	0.507
Outer Superior	247.48	0.781	2.187 (0.593)	0.316	1.164	3.260 (0.648)	0.470
Outer Nasal	260.96	0.628	1.759 (0.786)	0.241	1.240	3.471 (1.055)	0.475
Outer Inferior	234.09	0.709	1.986 (0.769)	0.303	1.164	3.259 (0.932)	0.497
Outer Temporal	236.77	0.627	1.755 (0.646)	0.265	1.225	3.430 (0.874)	0.517
Triton 7x7 3D Macula							
Central Fovea	242.89	1.168	3.270 (0.964)	0.481	1.837	5.145 (0.837)	0.757
Inner Superior	285.91	0.741	2.075 (0.689)	0.259	1.394	3.902 (0.738)	0.487
Inner Nasal	291.98	1.093	3.059 (1.193)	0.374	1.701	4.763 (0.915)	0.583
Inner Inferior	284.67	0.787	2.204 (0.750)	0.277	1.448	4.054 (0.750)	0.509
Inner Temporal	278.01	0.939	2.630 (0.888)	0.338	1.670	4.677 (0.933)	0.601
Outer Superior	245.09	1.723	4.825 (1.647)	0.703	1.870	5.235 (1.171)	0.763
Outer Nasal	259.83	0.620	1.735 (0.707)	0.238	1.249	3.496 (0.852)	0.481
Outer Inferior	234.38	0.953	2.667 (0.886)	0.406	1.479	4.141 (0.947)	0.631
Outer Temporal	235.39	0.734	2.054 (0.950)	0.312	1.307	3.658 (0.954)	0.555
Maestro 12x9 3D Wide							
Central Fovea	245.56	2.443	6.840	0.995	2.895	8.106	1.179
Inner Superior	292.28	1.201	3.362	0.411	1.814	5.080	0.621
Inner Nasal	295.99	1.371	3.838	0.463	1.813	5.075	0.612
Inner Inferior	286.72	1.605	4.493	0.560	2.068	5.791	0.721
Inner Temporal	282.13	1.345	3.765	0.477	1.732	4.849	0.614
Outer Superior	250.04	1.317	3.687	0.527	1.796	5.028	0.718
Outer Nasal	262.55	0.799	2.238	0.304	1.175	3.291	0.448
Outer Inferior	235.74	0.922	2.583	0.391	1.249	3.496	0.530
Outer Temporal	239.35	0.971	2.718	0.406	1.402	3.925	0.586
Maestro 6x6 3D Macula							
Central Fovea	245.22	1.212	3.393	0.494	2.196	6.150	0.896
Inner Superior	289.35	1.075	3.010	0.372	1.889	5.289	0.653
Inner Nasal	295.42	0.916	2.565	0.310	1.858	5.203	0.629
Inner Inferior	287.51	1.050	2.939	0.365	1.931	5.407	0.672

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Inner Temporal	281.56	1.058	2.963	0.376	1.791	5.015	0.636
Outer Superior	248.27	1.046	2.929	0.421	1.597	4.470	0.643
Outer Nasal	261.64	0.876	2.453	0.335	1.465	4.102	0.560
Outer Inferior	237.05	1.075	3.011	0.454	1.562	4.374	0.659
Outer Temporal	237.44	0.772	2.163	0.325	1.370	3.835	0.577

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Mean = Intercept of the ANOVA model
Repeatability SD = Square root of the residual variance
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 x Repeatability SD
Reproducibility limit = 2.8 x Reproducibility SD
Repeatability CV% = (Repeatability SD)/Intercept x 100%
Reproducibility CV% = (Reproducibility SD)/Intercept x 100%
Ratio is relative to Maestro

Table 15: Ganglion Cell + IPL - Normal Eyes Repeatability and Reproducibility

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
Superior	70.43	0.533	1.491 (0.835)	0.756	0.670	1.875 (0.961)	0.951
Superior Nasal	74.84	0.402	1.125 (0.787)	0.537	0.488	1.365 (0.798)	0.651
Superior Temporal	70.78	0.492	1.378 (0.954)	0.695	0.593	1.659 (0.988)	0.837
Inferior	67.82	0.406	1.135 (0.709)	0.598	0.466	1.304 (0.609)	0.687
Inferior Nasal	73.32	0.361	1.010 (0.632)	0.492	0.442	1.239 (0.650)	0.603
Inferior Temporal	72.25	0.495	1.386 (0.910)	0.685	0.575	1.610 (0.933)	0.796
Average	71.58	0.268	0.749 (1.235)	0.374	0.339	0.950 (1.019)	0.474
Triton 7x7 3D Macula							
Superior	69.96	0.430	1.204 (0.824)	0.615	0.600	1.681 (0.991)	0.858
Superior Nasal	74.62	0.375	1.051 (0.794)	0.503	0.485	1.358 (0.926)	0.650
Superior Temporal	71.62	0.589	1.650 (1.029)	0.823	0.700	1.961 (1.123)	0.978
Inferior	67.36	0.452	1.266 (0.926)	0.671	0.621	1.739 (0.879)	0.922
Inferior Nasal	73.02	0.467	1.308 (1.103)	0.640	0.591	1.656 (1.005)	0.810

Inferior Temporal	72.86	0.657	1.839 (1.353)	0.902	0.761	2.131 (1.217)	1.045
Average	71.58	0.227	0.635 (0.907)	0.317	0.388	1.087 (1.015)	0.543
Maestro 12x9 3D Wide							
Superior	72.13	0.638	1.787	0.885	0.697	1.952	0.966
Superior Nasal	76.50	0.511	1.430	0.667	0.611	1.711	0.799
Superior Temporal	72.44	0.516	1.445	0.712	0.600	1.679	0.828
Inferior	69.15	0.572	1.601	0.827	0.765	2.142	1.106
Inferior Nasal	74.89	0.571	1.599	0.763	0.680	1.905	0.908
Inferior Temporal	73.92	0.544	1.522	0.736	0.616	1.725	0.833
Average	73.17	0.217	0.607	0.296	0.333	0.932	0.455
Maestro 6x6 3D Macula							
Superior	72.21	0.522	1.461	0.723	0.606	1.697	0.839
Superior Nasal	76.41	0.473	1.324	0.619	0.524	1.467	0.686
Superior Temporal	72.53	0.573	1.604	0.790	0.623	1.745	0.859
Inferior	69.60	0.488	1.367	0.701	0.707	1.980	1.016
Inferior Nasal	74.89	0.424	1.186	0.566	0.588	1.648	0.786
Inferior Temporal	74.05	0.485	1.359	0.655	0.625	1.751	0.845
Average	73.30	0.250	0.700	0.341	0.383	1.071	0.522
<p>All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Mean = Intercept of the ANOVA model Repeatability SD = Square root of the residual variance Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD Repeatability CV% = (Repeatability SD)/Intercept x 100% Reproducibility CV% = (Reproducibility SD)/Intercept x 100% Ratio is relative to Maestro</p>							

Table 16: Ganglion Cell + IPL - Retinal Disease Eyes Repeatability and Reproducibility

		N=26					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
Superior	67.77	1.374	3.846 (0.799)	2.027	1.624	4.548 (0.798)	2.397
Superior Nasal	72.16	1.088	3.046 (0.442)	1.508	1.108	3.103 (0.432)	1.536
Superior Temporal	68.94	1.817	5.089 (0.765)	2.636	2.243	6.281 (0.944)	3.254
Inferior	64.28	1.074	3.007 (0.575)	1.671	1.324	3.706 (0.625)	2.059
Inferior Nasal	71.26	1.019	2.854 (0.710)	1.430	1.244	3.483 (0.803)	1.746
Inferior Temporal	70.87	1.301	3.644 (0.795)	1.836	1.361	3.810 (0.630)	1.920

		N=26					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Average	69.21	0.547	1.532 (0.698)	0.790	0.732	2.049 (0.872)	1.057
Triton 7x7 3D Macula							
Superior	66.83	0.996	2.789 (0.994)	1.490	1.251	3.503 (0.889)	1.872
Superior Nasal	70.15	1.036	2.901 (0.860)	1.477	1.207	3.379 (0.768)	1.720
Superior Temporal	72.16	1.370	3.836 (1.025)	1.899	1.660	4.648 (0.967)	2.300
Inferior	64.20	0.965	2.703 (0.742)	1.504	1.065	2.982 (0.553)	1.659
Inferior Nasal	69.54	1.063	2.976 (0.905)	1.528	1.096	3.068 (0.758)	1.575
Inferior Temporal	73.32	0.835	2.338 (0.694)	1.139	1.069	2.994 (0.719)	1.459
Average	69.38	0.499	1.397 (0.942)	0.719	0.578	1.619 (0.920)	0.833
Maestro 12x9 3D Wide							
Superior	69.55	1.719	4.813	2.471	2.037	5.702	2.928
Superior Nasal	73.91	2.461	6.890	3.329	2.564	7.180	3.469
Superior Temporal	70.61	2.375	6.651	3.364	2.375	6.651	3.364
Inferior	65.72	1.868	5.229	2.842	2.118	5.930	3.223
Inferior Nasal	72.78	1.436	4.021	1.973	1.550	4.340	2.130
Inferior Temporal	72.59	1.637	4.584	2.255	2.159	6.045	2.974
Average	70.84	0.784	2.195	1.106	0.839	2.349	1.184
Maestro 6x6 3D Macula							
Superior	68.47	1.002	2.805	1.463	1.407	3.940	2.055
Superior Nasal	71.44	1.205	3.375	1.687	1.570	4.397	2.198
Superior Temporal	72.98	1.336	3.741	1.831	1.717	4.808	2.353
Inferior	66.85	1.300	3.640	1.945	1.927	5.397	2.883
Inferior Nasal	71.33	1.174	3.289	1.646	1.446	4.048	2.027
Inferior Temporal	74.89	1.203	3.368	1.606	1.488	4.166	1.987
Average	70.99	0.530	1.483	0.746	0.629	1.760	0.886
<p>All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.</p> <p>Mean = Intercept of the ANOVA model</p> <p>Repeatability SD = Square root of the residual variance</p> <p>Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance</p> <p>Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD Repeatability CV% = (Repeatability SD)/Intercept x 100%</p> <p>Reproducibility CV% = (Reproducibility SD)/Intercept x 100%</p> <p>Ratio is relative to Maestro</p>							

Table 17: Ganglion Cell + IPL - Glaucoma Eyes Repeatability and Reproducibility

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
Superior	56.47	0.892	2.496 (0.779)	1.579	1.002	2.806 (0.757)	1.774
Superior Nasal	60.62	0.454	1.272 (0.656)	0.749	0.531	1.487 (0.730)	0.876
Superior Temporal	58.02	0.754	2.112 (0.567)	1.300	0.860	2.408 (0.591)	1.482
Inferior	52.63	0.597	1.671 (0.620)	1.134	0.656	1.837 (0.602)	1.246
Inferior Nasal	57.96	0.572	1.601 (0.619)	0.986	0.628	1.758 (0.665)	1.083
Inferior Temporal	55.91	0.936	2.621 (0.438)	1.674	1.109	3.106 (0.459)	1.984
Average	56.94	0.354	0.990 (0.459)	0.621	0.460	1.288 (0.522)	0.808
Triton 7x7 3D Macula							
Superior	55.58	0.514	1.439 (0.847)	0.925	0.652	1.826 (0.993)	1.173
Superior Nasal	59.67	0.419	1.172 (0.991)	0.702	0.495	1.386 (0.939)	0.830
Superior Temporal	61.24	0.829	2.320 (1.117)	1.353	0.868	2.429 (1.091)	1.417
Inferior	53.45	0.544	1.522 (0.650)	1.017	0.717	2.008 (0.816)	1.342
Inferior Nasal	58.12	0.641	1.794 (0.902)	1.102	0.756	2.116 (0.955)	1.300
Inferior Temporal	60.85	0.825	2.309 (1.135)	1.355	1.013	2.836 (1.138)	1.664
Average	58.16	0.300	0.840 (0.848)	0.516	0.419	1.173 (0.947)	0.720
Maestro 12x9 3D Wide							
Superior	57.55	1.145	3.205	1.989	1.323	3.704	2.299
Superior Nasal	62.01	0.693	1.939	1.117	0.727	2.036	1.173
Superior Temporal	58.60	1.331	3.727	2.271	1.456	4.076	2.484
Inferior	53.37	0.963	2.696	1.804	1.090	3.052	2.043
Inferior Nasal	59.08	0.923	2.584	1.562	0.944	2.644	1.598
Inferior Temporal	56.34	2.136	5.981	3.791	2.418	6.771	4.292
Average	57.83	0.771	2.158	1.333	0.881	2.468	1.524
Maestro 6x6 3D Macula							
Superior	57.21	0.607	1.699	1.061	0.657	1.839	1.148
Superior Nasal	61.02	0.423	1.183	0.692	0.528	1.477	0.864
Superior Temporal	61.74	0.742	2.078	1.202	0.795	2.226	1.288
Inferior	54.91	0.836	2.342	1.523	0.879	2.462	1.601
Inferior Nasal	59.39	0.710	1.989	1.196	0.792	2.216	1.333
Inferior Temporal	60.86	0.727	2.035	1.194	0.890	2.492	1.463
Average	59.21	0.353	0.990	0.597	0.443	1.239	0.747
All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Mean = Intercept of the ANOVA model							

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Repeatability SD = Square root of the residual variance Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD Repeatability CV% = (Repeatability SD)/Intercept x 100% Reproducibility CV% = (Reproducibility SD)/Intercept x 100% Ratio is relative to Maestro							

Table 18: Ganglion Cell Complex Thickness - Normal Eyes Repeatability and Reproducibility

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
Superior	107.53	0.733	2.053 (0.976)	0.682	0.850	2.381 (0.819)	0.791
Superior Nasal	119.49	0.611	1.711 (0.904)	0.511	0.805	2.253 (0.776)	0.673
Superior Temporal	94.52	0.565	1.583 (1.090)	0.598	0.771	2.159 (1.132)	0.816
Inferior	106.94	0.598	1.673 (0.875)	0.559	0.785	2.198 (0.938)	0.734
Inferior Nasal	119.67	0.548	1.534 (0.820)	0.458	0.787	2.205 (0.929)	0.658
Inferior Temporal	97.88	0.542	1.518 (0.885)	0.554	0.818	2.290 (1.129)	0.836
Average	107.68	0.445	1.247 (0.988)	0.413	0.640	1.792 (1.060)	0.594
Triton 7x7 3D Macula							
Superior	107.79	0.683	1.913 (1.069)	0.634	0.875	2.449 (1.048)	0.811
Superior Nasal	118.85	0.498	1.395 (0.839)	0.419	0.674	1.887 (0.857)	0.567
Superior Temporal	93.99	0.723	2.024 (1.129)	0.769	0.933	2.612 (1.121)	0.993
Inferior	106.91	0.677	1.894 (1.023)	0.633	0.918	2.570 (1.112)	0.859
Inferior Nasal	119.68	0.660	1.849 (1.068)	0.552	0.803	2.249 (0.997)	0.671
Inferior Temporal	97.37	0.733	2.051 (1.095)	0.752	1.014	2.840 (1.083)	1.042
Average	107.43	0.461	1.292 (1.050)	0.430	0.654	1.830 (1.164)	0.608
Maestro 12x9 3D Wide							
Superior	107.56	0.751	2.104	0.699	1.038	2.905	0.965
Superior Nasal	119.41	0.676	1.893	0.566	1.037	2.905	0.869
Superior Temporal	94.90	0.519	1.453	0.547	0.681	1.908	0.718
Inferior	106.60	0.683	1.912	0.641	0.837	2.343	0.785
Inferior Nasal	119.63	0.668	1.871	0.558	0.847	2.372	0.708
Inferior Temporal	98.30	0.612	1.714	0.623	0.724	2.028	0.737

Average	107.74	0.451	1.262	0.418	0.604	1.692	0.561
Maestro 6x6 3D Macula							
Superior	108.45	0.639	1.790	0.589	0.834	2.336	0.769
Superior Nasal	119.43	0.594	1.662	0.497	0.786	2.201	0.658
Superior Temporal	94.34	0.640	1.792	0.679	0.832	2.330	0.882
Inferior	107.32	0.662	1.853	0.616	0.826	2.312	0.769
Inferior Nasal	120.13	0.618	1.731	0.515	0.806	2.257	0.671
Inferior Temporal	97.66	0.669	1.874	0.685	0.937	2.623	0.959
Average	107.91	0.439	1.230	0.407	0.562	1.572	0.520
<p>All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Mean = Intercept of the ANOVA model Repeatability SD = Square root of the residual variance Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD Repeatability CV% = (Repeatability SD)/Intercept x 100% Reproducibility CV% = (Reproducibility SD)/Intercept x 100% Ratio is relative to Maestro</p>							

Table 19: Ganglion Cell Complex Thickness - Retinal Disease Eyes Repeatability and Reproducibility

		N=26					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
Superior	111.84	1.191	3.334 (0.358)	1.065	1.623	4.546 (0.486)	1.452
Superior Nasal	121.50	0.972	2.722 (0.588)	0.800	1.281	3.588 (0.763)	1.055
Superior Temporal	97.08	0.783	2.192 (0.494)	0.806	1.121	3.138 (0.678)	1.155
Inferior	108.10	0.988	2.767 (0.417)	0.914	1.308	3.662 (0.539)	1.210
Inferior Nasal	121.86	0.863	2.417 (0.635)	0.708	1.144	3.203 (0.752)	0.939
Inferior Temporal	99.58	0.793	2.222 (0.467)	0.797	1.179	3.301 (0.606)	1.184
Average	110.00	0.558	1.562 (0.503)	0.507	0.949	2.658 (0.837)	0.863
Triton 7x7 3D Macula							
Superior	113.26	1.257	3.519 (1.071)	1.110	1.433	4.014 (1.150)	1.266
Superior Nasal	121.49	1.051	2.943 (1.110)	0.865	1.207	3.381 (1.044)	0.994
Superior Temporal	98.87	1.049	2.938 (1.027)	1.061	1.231	3.448 (0.968)	1.245
Inferior	107.98	1.099	3.078 (0.570)	1.018	1.264	3.539 (0.560)	1.170

		N=26					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Inferior Nasal	122.86	1.402	3.925 (1.107)	1.141	1.465	4.103 (1.079)	1.193
Inferior Temporal	99.92	0.990	2.772 (1.040)	0.991	1.125	3.151 (0.773)	1.126
Average	110.74	0.895	2.506 (1.221)	0.808	0.985	2.759 (1.130)	0.890
Maestro 12x9 3D Wide							
Superior	111.53	3.321	9.300	2.978	3.339	9.350	2.994
Superior Nasal	121.29	1.652	4.626	1.362	1.680	4.705	1.385
Superior Temporal	97.38	1.584	4.435	1.626	1.654	4.631	1.698
Inferior	107.44	2.371	6.638	2.207	2.426	6.794	2.258
Inferior Nasal	121.19	1.359	3.806	1.122	1.521	4.258	1.255
Inferior Temporal	99.42	1.698	4.753	1.707	1.947	5.452	1.958
Average	109.71	1.109	3.104	1.010	1.134	3.175	1.034
Maestro 6x6 3D Macula							
Superior	113.61	1.173	3.285	1.033	1.247	3.490	1.097
Superior Nasal	121.98	0.947	2.651	0.776	1.157	3.239	0.948
Superior Temporal	99.53	1.022	2.860	1.026	1.272	3.563	1.278
Inferior	109.50	1.929	5.400	1.761	2.256	6.318	2.061
Inferior Nasal	122.82	1.266	3.545	1.031	1.357	3.801	1.105
Inferior Temporal	100.82	0.952	2.665	0.944	1.455	4.075	1.444
Average	111.40	0.733	2.053	0.658	0.872	2.443	0.783
<p>All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Mean = Intercept of the ANOVA model Repeatability SD = Square root of the residual variance Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD Repeatability CV% = (Repeatability SD)/Intercept x 100% Reproducibility CV% = (Reproducibility SD)/Intercept x 100% Ratio is relative to Maestro</p>							

Table 20: Ganglion Cell Complex Thickness - Glaucoma Eyes Repeatability and Reproducibility

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
Superior	88.57	0.562	1.574 (0.758)	0.635	0.669	1.873 (0.764)	0.755
Superior Nasal	99.75	0.575	1.609 (0.942)	0.576	0.716	2.006 (0.894)	0.718
Superior Temporal	79.84	0.516	1.444 (0.784)	0.646	0.728	2.037 (1.069)	0.911
Inferior	83.89	0.543	1.521 (0.752)	0.647	0.687	1.922 (0.849)	0.818
Inferior Nasal	96.57	0.563	1.578 (0.867)	0.583	0.723	2.026 (0.847)	0.749
Inferior Temporal	78.07	0.526	1.472 (0.785)	0.673	0.783	2.191 (1.029)	1.002
Average	87.79	0.380	1.065 (0.917)	0.433	0.568	1.590 (1.138)	0.647
Triton 7x7 3D Macula							
Superior	86.95	0.568	1.591 (0.845)	0.653	0.659	1.844 (0.785)	0.757
Superior Nasal	97.69	0.641	1.795 (0.768)	0.656	0.827	2.314 (0.763)	0.846
Superior Temporal	78.60	0.555	1.555 (0.980)	0.707	0.699	1.958 (1.097)	0.890
Inferior	84.05	0.560	1.569 (0.788)	0.667	0.785	2.197 (0.953)	0.934
Inferior Nasal	96.81	0.551	1.541 (0.718)	0.569	0.822	2.301 (0.896)	0.849
Inferior Temporal	77.95	0.526	1.472 (1.039)	0.674	0.743	2.081 (1.127)	0.953
Average	87.01	0.356	0.998 (0.869)	0.410	0.571	1.599 (1.061)	0.656
Maestro 12x9 3D Wide							
Superior	88.16	0.742	2.077	0.841	0.876	2.453	0.993
Superior Nasal	99.17	0.610	1.707	0.615	0.801	2.243	0.808
Superior Temporal	79.70	0.658	1.842	0.825	0.681	1.906	0.854
Inferior	83.04	0.722	2.023	0.870	0.809	2.265	0.974
Inferior Nasal	95.79	0.650	1.820	0.679	0.854	2.392	0.892
Inferior Temporal	77.64	0.669	1.874	0.862	0.761	2.130	0.980
Average	87.26	0.415	1.162	0.475	0.499	1.397	0.572
Maestro 6x6 3D Macula							
Superior	86.72	0.672	1.882	0.775	0.839	2.349	0.968
Superior Nasal	97.45	0.835	2.338	0.857	1.084	3.035	1.112
Superior Temporal	78.45	0.567	1.588	0.723	0.637	1.784	0.812
Inferior	83.75	0.711	1.992	0.849	0.823	2.305	0.983
Inferior Nasal	96.34	0.766	2.146	0.796	0.918	2.570	0.953
Inferior Temporal	77.53	0.506	1.416	0.653	0.659	1.846	0.850
Average	86.73	0.410	1.149	0.473	0.538	1.508	0.621
All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Mean = Intercept of the ANOVA model							

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Repeatability SD = Square root of the residual variance Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD Repeatability CV% = (Repeatability SD)/Intercept x 100% Reproducibility CV% = (Reproducibility SD)/Intercept x 100% Ratio is relative to Maestro							

Table 21: Retinal Nerve Fiber Layer - Normal Eyes Repeatability and Reproducibility

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
Average	107.44	0.938	2.626 (0.718)	0.873	1.123	3.146 (0.815)	1.046
Superior Quadrant	130.51	2.945	8.246 (0.751)	2.257	3.123	8.744 (0.739)	2.393
Nasal Quadrant	89.22	1.730	4.845 (0.845)	1.940	2.128	5.960 (0.930)	2.386
Inferior Quadrant	138.76	2.238	6.265 (0.825)	1.613	2.313	6.476 (0.757)	1.667
Temporal Quadrant	71.27	1.026	2.872 (0.860)	1.439	1.392	3.897 (1.066)	1.953
12-Sector - T	60.67	1.087	3.043 (0.757)	1.791	1.402	3.926 (0.854)	2.311
12-Sector - TS	84.33	1.808	5.061 (0.933)	2.143	2.068	5.790 (0.950)	2.452
12-Sector - ST	136.50	3.515	9.842 (0.914)	2.575	3.976	11.132 (0.925)	2.913
12-Sector - S	131.83	4.887	13.684 (0.775)	3.707	5.123	14.343 (0.767)	3.886
12-Sector - SN	123.16	4.486	12.561 (0.671)	3.642	4.661	13.051 (0.648)	3.785
12-Sector - NS	107.10	3.628	10.160 (0.894)	3.388	4.080	11.423 (0.854)	3.809
12-Sector - N	71.92	1.417	3.967 (0.619)	1.970	1.873	5.244 (0.783)	2.604
12-Sector - NI	88.58	2.843	7.961 (0.913)	3.210	3.522	9.862 (1.011)	3.976
12-Sector - IN	126.13	4.001	11.204 (0.860)	3.172	4.179	11.701 (0.856)	3.313
12-Sector - I	153.34	3.467	9.708 (0.776)	2.261	3.943	11.040 (0.740)	2.571
12-Sector - IT	136.73	3.984	11.154 (0.922)	2.913	4.711	13.189 (1.077)	3.445
12-Sector - TI	68.82	1.603	4.489 (0.839)	2.330	2.232	6.249 (1.009)	3.243
Triton 6x6 3D Disc							
Average	105.82	0.759	2.125 (0.951)	0.717	1.025	2.871 (0.991)	0.969
Superior Quadrant	129.81	2.136	5.980 (0.843)	1.645	2.369	6.634 (0.921)	1.825
Nasal Quadrant	87.61	1.397	3.913 (0.951)	1.595	1.726	4.833 (0.966)	1.970
Inferior Quadrant	137.96	1.440	4.033 (0.701)	1.044	1.793	5.022 (0.757)	1.300

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Temporal Quadrant	67.87	0.776	2.174 (0.736)	1.144	1.079	3.020 (0.818)	1.589
12-Sector - T	56.90	0.889	2.490 (0.817)	1.563	1.232	3.451 (0.934)	2.166
12-Sector - TS	80.92	1.443	4.040 (0.768)	1.783	1.948	5.455 (0.889)	2.407
12-Sector - ST	136.02	3.001	8.402 (0.910)	2.206	3.779	10.581 (1.029)	2.778
12-Sector - S	132.54	4.288	12.007 (0.923)	3.236	4.390	12.292 (0.918)	3.312
12-Sector - SN	120.97	3.326	9.314 (0.885)	2.750	3.705	10.374 (0.917)	3.063
12-Sector - NS	107.39	3.027	8.476 (0.950)	2.819	3.535	9.898 (0.990)	3.292
12-Sector - N	69.36	1.187	3.323 (0.798)	1.711	1.541	4.314 (0.919)	2.221
12-Sector - NI	86.06	2.174	6.089 (0.927)	2.527	2.825	7.911 (1.057)	3.283
12-Sector - IN	123.84	2.726	7.633 (0.705)	2.201	3.087	8.644 (0.747)	2.493
12-Sector - I	152.70	2.897	8.112 (0.784)	1.897	3.321	9.300 (0.772)	2.175
12-Sector - IT	137.33	2.859	8.006 (0.715)	2.082	3.685	10.318 (0.834)	2.683
12-Sector - TI	65.80	1.531	4.287 (0.871)	2.327	1.858	5.201 (0.768)	2.823
Maestro 12x9 3D Wide							
Average	107.58	1.307	3.659	1.215	1.379	3.860	1.282
Superior Quadrant	131.04	3.921	10.978	2.992	4.225	11.829	3.224
Nasal Quadrant	87.61	2.047	5.733	2.337	2.290	6.411	2.613
Inferior Quadrant	139.40	2.713	7.597	1.946	3.056	8.557	2.192
Temporal Quadrant	72.27	1.193	3.340	1.651	1.305	3.654	1.806
12-Sector - T	60.86	1.436	4.022	2.360	1.642	4.597	2.698
12-Sector - TS	85.98	1.937	5.423	2.253	2.178	6.097	2.533
12-Sector - ST	137.50	3.847	10.772	2.798	4.298	12.034	3.126
12-Sector - S	131.95	6.302	17.647	4.776	6.679	18.702	5.062
12-Sector - SN	123.73	6.687	18.724	5.405	7.188	20.127	5.810
12-Sector - NS	106.26	4.060	11.367	3.821	4.778	13.378	4.496
12-Sector - N	70.34	2.290	6.413	3.256	2.392	6.696	3.400
12-Sector - NI	86.22	3.113	8.715	3.610	3.482	9.751	4.039
12-Sector - IN	124.95	4.654	13.032	3.725	4.882	13.671	3.908
12-Sector - I	154.05	4.465	12.503	2.899	5.329	14.920	3.459
12-Sector - IT	139.26	4.319	12.093	3.101	4.372	12.241	3.139
12-Sector - TI	69.99	1.911	5.351	2.731	2.211	6.191	3.159
Maestro 6x6 3D Disc							
Average	106.01	0.798	2.235	0.753	1.035	2.898	0.976
Superior Quadrant	130.21	2.535	7.098	1.947	2.572	7.202	1.975
Nasal Quadrant	85.06	1.470	4.115	1.728	1.787	5.003	2.101
Inferior Quadrant	139.89	2.054	5.750	1.468	2.368	6.630	1.693

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Temporal Quadrant	68.86	1.055	2.954	1.532	1.319	3.693	1.916
12-Sector - T	57.63	1.088	3.046	1.888	1.319	3.693	2.289
12-Sector - TS	82.12	1.878	5.257	2.286	2.190	6.133	2.667
12-Sector - ST	136.56	3.298	9.233	2.415	3.673	10.286	2.690
12-Sector - S	132.41	4.646	13.008	3.509	4.785	13.397	3.614
12-Sector - SN	121.51	3.757	10.520	3.092	4.041	11.315	3.326
12-Sector - NS	104.42	3.187	8.924	3.052	3.572	10.001	3.421
12-Sector - N	67.30	1.487	4.164	2.210	1.676	4.694	2.491
12-Sector - NI	83.41	2.346	6.569	2.813	2.673	7.484	3.205
12-Sector - IN	124.83	3.864	10.820	3.095	4.133	11.573	3.311
12-Sector - I	155.70	3.695	10.345	2.373	4.302	12.045	2.763
12-Sector - IT	139.12	3.999	11.198	2.875	4.417	12.369	3.175
12-Sector - TI	66.79	1.759	4.924	2.633	2.419	6.774	3.622

T=Temporal; S=Superior; N=Nasal; I=Inferior
All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Mean = Intercept of the ANOVA model
Repeatability SD = Square root of the residual variance
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 x Repeatability SD
Reproducibility limit = 2.8 x Reproducibility SD
Repeatability CV% = (Repeatability SD)/Intercept x 100%
Reproducibility CV% = (Reproducibility SD)/Intercept x 100%
Ratio is relative to Maestro

Table 22: Retinal Nerve Fiber Layer - Retinal Disease Eyes Repeatability and Reproducibility

		N=26					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
Average	101.41	1.100	3.079 (0.420)	1.084	1.439	4.028 (0.545)	1.419
Superior Quadrant	116.77	3.005	8.415 (0.616)	2.574	3.176	8.893 (0.649)	2.720
Nasal Quadrant	81.02	1.917	5.368 (0.717)	2.366	2.653	7.428 (0.968)	3.274
Inferior Quadrant	126.43	2.485	6.957 (0.487)	1.965	2.752	7.705 (0.537)	2.177
Temporal Quadrant	81.36	1.809	5.066 (0.537)	2.224	1.958	5.482 (0.581)	2.406

		N=26					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
12-Sector - T	71.03	1.890	5.292 (0.494)	2.661	2.514	7.039 (0.658)	3.539
12-Sector - TS	98.53	2.308	6.462 (0.717)	2.342	2.439	6.828 (0.734)	2.475
12-Sector - ST	131.12	4.239	11.868 (0.740)	3.233	4.427	12.396 (0.770)	3.376
12-Sector - S	111.69	5.450	15.260 (0.803)	4.880	5.450	15.260 (0.743)	4.880
12-Sector - SN	107.53	3.987	11.163 (0.622)	3.707	5.351	14.983 (0.835)	4.976
12-Sector - NS	95.74	4.631	12.966 (0.890)	4.837	5.455	15.274 (0.952)	5.698
12-Sector - N	70.82	1.599	4.477 (0.536)	2.258	2.350	6.579 (0.787)	3.318
12-Sector - NI	76.50	2.216	6.206 (0.699)	2.897	2.948	8.255 (0.856)	3.854
12-Sector - IN	104.52	3.140	8.791 (0.530)	3.004	3.552	9.946 (0.597)	3.398
12-Sector - I	137.61	4.522	12.662 (0.589)	3.286	4.779	13.382 (0.622)	3.473
12-Sector - IT	137.25	4.501	12.603 (0.620)	3.280	5.313	14.876 (0.732)	3.871
12-Sector - TI	74.52	2.743	7.679 (0.524)	3.680	3.661	10.252 (0.699)	4.913
Triton 6x6 3D Disc							
Average	100.73	1.579	4.420 (0.895)	1.567	1.866	5.224 (1.028)	1.852
Superior Quadrant	116.44	3.425	9.589 (0.678)	2.941	3.599	10.076 (0.698)	3.090
Nasal Quadrant	79.96	1.817	5.088 (0.749)	2.272	2.450	6.859 (0.974)	3.064
Inferior Quadrant	127.22	4.049	11.337 (0.941)	3.182	4.161	11.650 (0.945)	3.270
Temporal Quadrant	79.27	1.347	3.772 (0.551)	1.700	1.735	4.858 (0.647)	2.189
12-Sector - T	68.15	1.904	5.330 (0.526)	2.793	2.497	6.991 (0.583)	3.663
12-Sector - TS	96.81	1.954	5.470 (0.815)	2.018	2.398	6.714 (0.882)	2.477
12-Sector - ST	131.38	3.851	10.782 (0.852)	2.931	4.251	11.903 (0.810)	3.236
12-Sector - S	110.70	7.410	20.749 (0.873)	6.694	7.689	21.530 (0.906)	6.946
12-Sector - SN	107.27	4.304	12.051 (0.771)	4.012	4.713	13.197 (0.823)	4.394
12-Sector - NS	96.61	3.411	9.551 (0.919)	3.531	3.819	10.693 (0.809)	3.953
12-Sector - N	67.88	1.845	5.167 (1.022)	2.719	2.095	5.866 (1.098)	3.087
12-Sector - NI	75.41	3.099	8.678 (0.842)	4.110	4.060	11.368 (1.093)	5.384
12-Sector - IN	103.82	3.886	10.881 (0.824)	3.743	4.651	13.022 (0.771)	4.480
12-Sector - I	138.72	6.677	18.696 (0.849)	4.813	6.687	18.725 (0.849)	4.821
12-Sector - IT	139.14	5.606	15.696 (1.072)	4.029	5.799	16.236 (1.109)	4.167
12-Sector - TI	72.83	2.793	7.820 (0.701)	3.834	3.377	9.455 (0.845)	4.636
Maestro 12x9 3D Wide							
Average	101.02	2.618	7.329	2.591	2.637	7.384	2.611
Superior Quadrant	117.10	4.876	13.653	4.164	4.894	13.704	4.180
Nasal Quadrant	78.46	2.675	7.490	3.409	2.741	7.676	3.494
Inferior Quadrant	127.34	5.106	14.296	4.010	5.123	14.343	4.023
Temporal Quadrant	81.15	3.370	9.436	4.153	3.370	9.436	4.153

		N=26					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
12-Sector - T	69.97	3.823	10.705	5.464	3.823	10.705	5.464
12-Sector - TS	98.99	3.220	9.017	3.253	3.321	9.300	3.355
12-Sector - ST	131.92	5.724	16.029	4.339	5.748	16.095	4.358
12-Sector - S	112.37	6.785	18.998	6.038	7.336	20.541	6.529
12-Sector - SN	107.06	6.411	17.950	5.988	6.411	17.950	5.988
12-Sector - NS	93.05	5.200	14.560	5.589	5.727	16.037	6.155
12-Sector - N	68.28	2.985	8.358	4.372	2.985	8.358	4.372
12-Sector - NI	74.12	3.169	8.873	4.275	3.446	9.649	4.649
12-Sector - IN	103.50	5.921	16.579	5.721	5.948	16.654	5.747
12-Sector - I	139.76	7.683	21.513	5.497	7.683	21.513	5.497
12-Sector - IT	138.73	7.262	20.333	5.235	7.262	20.333	5.235
12-Sector - TI	74.51	5.236	14.660	7.027	5.236	14.660	7.027
Maestro 6x6 3D Disc							
Average	100.68	1.764	4.939	1.752	1.816	5.084	1.804
Superior Quadrant	117.19	5.052	14.147	4.311	5.157	14.440	4.400
Nasal Quadrant	77.59	2.425	6.789	3.125	2.516	7.044	3.242
Inferior Quadrant	128.78	4.304	12.051	3.342	4.401	12.322	3.417
Temporal Quadrant	79.12	2.444	6.842	3.088	2.682	7.510	3.390
12-Sector - T	67.83	3.619	10.134	5.336	4.282	11.988	6.313
12-Sector - TS	97.26	2.396	6.710	2.464	2.718	7.612	2.795
12-Sector - ST	132.79	4.517	12.647	3.402	5.250	14.699	3.953
12-Sector - S	111.97	8.483	23.754	7.577	8.483	23.754	7.577
12-Sector - SN	106.86	5.579	15.622	5.221	5.728	16.037	5.360
12-Sector - NS	93.08	3.712	10.393	3.988	4.722	13.222	5.073
12-Sector - N	66.07	1.806	5.056	2.733	1.908	5.341	2.887
12-Sector - NI	73.64	3.680	10.305	4.998	3.713	10.397	5.042
12-Sector - IN	104.21	4.718	13.209	4.527	6.030	16.883	5.786
12-Sector - I	141.54	7.867	22.027	5.558	7.877	22.056	5.565
12-Sector - IT	140.45	5.228	14.637	3.722	5.228	14.637	3.722
12-Sector - TI	72.29	3.986	11.160	5.514	3.995	11.185	5.526

		N=26					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
T=Temporal; S=Superior; N=Nasal; I=Inferior All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Mean = Intercept of the ANOVA model Repeatability SD = Square root of the residual variance Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD Repeatability CV% = (Repeatability SD)/Intercept x 100% Reproducibility CV% = (Reproducibility SD)/Intercept x 100% Ratio is relative to Maestro							

Table 23: Retinal Nerve Fiber Layer - Glaucoma Eyes Repeatability and Reproducibility

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
Average	76.10	1.058	2.962 (0.730)	1.390	1.217	3.408 (0.711)	1.599
Superior Quadrant	87.49	2.281	6.387 (0.668)	2.607	2.571	7.199 (0.714)	2.939
Nasal Quadrant	63.67	1.825	5.109 (0.587)	2.866	2.196	6.148 (0.601)	3.449
Inferior Quadrant	91.99	2.318	6.490 (0.782)	2.520	2.512	7.032 (0.773)	2.730
Temporal Quadrant	61.22	1.065	2.983 (0.879)	1.740	1.295	3.626 (0.983)	2.115
12-Sector - T	55.37	1.177	3.296 (0.773)	2.126	1.303	3.649 (0.792)	2.353
12-Sector - TS	68.95	1.610	4.507 (0.803)	2.335	1.828	5.119 (0.886)	2.652
12-Sector - ST	96.33	3.315	9.282 (0.755)	3.441	3.818	10.689 (0.869)	3.963
12-Sector - S	87.49	3.846	10.768 (0.674)	4.395	4.058	11.361 (0.678)	4.638
12-Sector - SN	78.68	3.792	10.616 (0.739)	4.819	4.619	12.933 (0.783)	5.871
12-Sector - NS	71.04	3.610	10.109 (0.601)	5.083	4.007	11.218 (0.540)	5.640
12-Sector - N	56.46	1.999	5.598 (0.693)	3.541	2.503	7.009 (0.868)	4.434
12-Sector - NI	63.52	2.299	6.436 (0.636)	3.619	2.505	7.014 (0.541)	3.943
12-Sector - IN	78.62	2.765	7.741 (0.580)	3.517	3.148	8.814 (0.653)	4.004
12-Sector - I	101.72	4.394	12.302 (1.010)	4.319	4.603	12.889 (0.837)	4.525
12-Sector - IT	95.66	3.763	10.536 (0.939)	3.933	3.764	10.540 (0.843)	3.935
12-Sector - TI	59.34	1.786	5.000 (0.932)	3.009	2.137	5.983 (0.940)	3.601

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 6x6 3D Disc							
Average	75.34	1.001	2.802 (0.822)	1.328	1.262	3.535 (0.945)	1.676
Superior Quadrant	88.72	2.556	7.157 (1.053)	2.881	2.825	7.911 (1.096)	3.184
Nasal Quadrant	61.27	1.668	4.670 (0.680)	2.722	1.932	5.410 (0.661)	3.154
Inferior Quadrant	92.36	1.857	5.199 (0.687)	2.010	2.106	5.896 (0.774)	2.280
Temporal Quadrant	59.03	0.901	2.524 (0.650)	1.527	1.076	3.013 (0.720)	1.823
12-Sector - T	52.00	1.136	3.182 (0.806)	2.185	1.311	3.670 (0.810)	2.521
12-Sector - TS	66.89	1.421	3.980 (0.760)	2.125	1.747	4.891 (0.886)	2.612
12-Sector - ST	96.98	3.473	9.724 (1.077)	3.581	3.976	11.132 (1.017)	4.100
12-Sector - S	89.31	5.133	14.374 (1.191)	5.748	5.169	14.474 (1.199)	5.788
12-Sector - SN	79.89	3.933	11.013 (0.949)	4.923	4.317	12.088 (0.961)	5.404
12-Sector - NS	70.52	3.238	9.068 (0.769)	4.592	4.457	12.479 (0.886)	6.321
12-Sector - N	52.54	1.749	4.896 (0.479)	3.328	1.780	4.985 (0.473)	3.388
12-Sector - NI	60.73	1.912	5.353 (0.834)	3.148	2.130	5.965 (0.719)	3.507
12-Sector - IN	77.13	2.751	7.702 (0.957)	3.566	3.023	8.465 (0.940)	3.919
12-Sector - I	102.34	3.593	10.062 (0.791)	3.511	3.940	11.031 (0.789)	3.849
12-Sector - IT	97.58	2.671	7.479 (0.619)	2.737	3.027	8.477 (0.697)	3.102
12-Sector - TI	58.20	1.623	4.543 (0.641)	2.788	1.860	5.208 (0.630)	3.196
Maestro 12x9 3D Wide							
Average	74.59	1.450	4.060	1.944	1.712	4.795	2.296
Superior Quadrant	85.81	3.413	9.557	3.978	3.599	10.078	4.195
Nasal Quadrant	60.82	3.107	8.700	5.108	3.653	10.229	6.006
Inferior Quadrant	90.95	2.966	8.304	3.261	3.251	9.103	3.574
Temporal Quadrant	60.80	1.212	3.395	1.994	1.317	3.687	2.166
12-Sector - T	54.44	1.523	4.263	2.797	1.646	4.609	3.024
12-Sector - TS	68.62	2.004	5.613	2.921	2.064	5.778	3.007
12-Sector - ST	96.98	4.391	12.294	4.527	4.391	12.294	4.527
12-Sector - S	85.28	5.703	15.968	6.688	5.984	16.756	7.018
12-Sector - SN	75.16	5.134	14.374	6.830	5.897	16.512	7.846
12-Sector - NS	67.20	6.009	16.826	8.942	7.414	20.760	11.033
12-Sector - N	53.93	2.884	8.076	5.348	2.884	8.076	5.348
12-Sector - NI	61.39	3.616	10.126	5.891	4.630	12.963	7.541
12-Sector - IN	77.63	4.768	13.351	6.142	4.818	13.490	6.206
12-Sector - I	100.02	4.349	12.177	4.348	5.501	15.403	5.500
12-Sector - IT	95.12	4.005	11.215	4.211	4.464	12.498	4.693
12-Sector - TI	59.35	1.916	5.365	3.228	2.272	6.361	3.828

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%

Maestro 6x6 3D Disc							
Average	73.96	1.217	3.407	1.645	1.336	3.740	1.806
Superior Quadrant	86.75	2.427	6.797	2.798	2.578	7.218	2.972
Nasal Quadrant	59.53	2.454	6.872	4.123	2.924	8.187	4.912
Inferior Quadrant	91.40	2.701	7.563	2.955	2.721	7.619	2.977
Temporal Quadrant	58.14	1.386	3.880	2.383	1.494	4.183	2.570
12-Sector - T	51.37	1.410	3.949	2.746	1.619	4.533	3.152
12-Sector - TS	66.02	1.870	5.235	2.832	1.972	5.522	2.987
12-Sector - ST	96.07	3.225	9.031	3.358	3.911	10.951	4.071
12-Sector - S	86.73	4.312	12.073	4.971	4.312	12.073	4.971
12-Sector - SN	77.43	4.146	11.607	5.354	4.493	12.581	5.803
12-Sector - NS	68.19	4.214	11.798	6.179	5.033	14.092	7.381
12-Sector - N	51.18	3.651	10.223	7.133	3.760	10.528	7.346
12-Sector - NI	59.15	2.293	6.420	3.876	2.962	8.293	5.007
12-Sector - IN	77.06	2.874	8.047	3.729	3.215	9.002	4.172
12-Sector - I	101.85	4.542	12.717	4.460	4.993	13.981	4.903
12-Sector - IT	95.32	4.317	12.088	4.529	4.341	12.154	4.554
12-Sector - TI	57.06	2.532	7.089	4.437	2.955	8.273	5.178

T=Temporal; S=Superior; N=Nasal; I=Inferior
All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Mean = Intercept of the ANOVA model
Repeatability SD = Square root of the residual variance
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 x Repeatability SD
Reproducibility limit = 2.8 x Reproducibility SD
Repeatability CV% = (Repeatability SD)/Intercept x 100%
Reproducibility CV% = (Reproducibility SD)/Intercept x 100%
Ratio is relative to Maestro

Table 24: Optic Disc - Normal Eyes Repeatability and Reproducibility

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
C/D Vertical	0.47	0.022	0.063 (0.600)	4.787	0.027	0.075 (0.716)	5.714
C/D Area	0.25	0.009	0.026 (0.786)	3.723	0.012	0.033 (0.906)	4.666
Disc Area	1.91	0.059	0.166 (0.938)	3.105	0.062	0.173 (0.727)	3.236
Cup Area	0.51	0.020	0.057 (0.849)	4.001	0.025	0.069 (1.006)	4.851
Rim Area	1.40	0.056	0.157 (0.907)	3.998	0.059	0.166 (0.734)	4.228
Cup Volume	0.09	0.005	0.015 (1.120)	6.183	0.006	0.016 (0.986)	6.845
Rim Volume	0.26	0.013	0.037 (0.809)	5.107	0.015	0.042 (0.721)	5.765
Linear C/D Ratio	0.46	0.011	0.030 (0.638)	2.301	0.014	0.038 (0.817)	2.948
Triton 6x6 3D Disc							
C/D Vertical	0.46	0.019	0.054 (0.415)	4.174	0.026	0.074 (0.570)	5.757
C/D Area	0.25	0.007	0.021 (0.180)	2.958	0.010	0.028 (0.241)	4.014
Disc Area	1.75	0.034	0.094 (0.546)	1.919	0.049	0.137 (0.687)	2.803
Cup Area	0.47	0.011	0.030 (0.142)	2.306	0.013	0.036 (0.171)	2.768
Rim Area	1.28	0.031	0.088 (0.336)	2.438	0.045	0.125 (0.445)	3.490
Cup Volume	0.08	0.004	0.010 (0.891)	4.259	0.004	0.012 (1.028)	5.332
Rim Volume	0.23	0.008	0.022 (0.401)	3.370	0.010	0.029 (0.498)	4.410
Linear C/D Ratio	0.46	0.011	0.030 (0.308)	2.358	0.017	0.047 (0.477)	3.665
Maestro 12x9 3D Wide							
C/D Vertical	0.45	0.037	0.104	8.217	0.037	0.104	8.217
C/D Area	0.23	0.012	0.033	5.067	0.013	0.036	5.507
Disc Area	2.20	0.063	0.177	2.873	0.085	0.238	3.868
Cup Area	0.54	0.024	0.067	4.493	0.025	0.069	4.594
Rim Area	1.66	0.062	0.173	3.707	0.081	0.226	4.841
Cup Volume	0.09	0.005	0.013	5.191	0.006	0.017	6.523
Rim Volume	0.32	0.016	0.046	5.169	0.021	0.058	6.546
Linear C/D Ratio	0.44	0.017	0.046	3.739	0.017	0.046	3.740
Maestro 6x6 3D Disc							
C/D Vertical	0.44	0.046	0.129	10.576	0.046	0.130	10.619
C/D Area	0.23	0.041	0.115	17.581	0.041	0.116	17.810
Disc Area	2.03	0.061	0.172	3.026	0.071	0.200	3.515
Cup Area	0.49	0.075	0.211	15.290	0.076	0.212	15.307
Rim Area	1.54	0.093	0.261	6.053	0.101	0.282	6.548
Cup Volume	0.09	0.004	0.011	4.507	0.004	0.012	4.889
Rim Volume	0.29	0.020	0.055	6.660	0.021	0.058	7.025

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Linear C/D Ratio	0.44	0.035	0.098	7.961	0.035	0.098	8.000
<p>All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.</p> <p>Mean = Intercept of the ANOVA model</p> <p>Repeatability SD = Square root of the residual variance</p> <p>Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance</p> <p>Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD</p> <p>Repeatability CV% = (Repeatability SD)/Intercept x 100%</p> <p>Reproducibility CV% = (Reproducibility SD)/Intercept x 100%</p> <p>Ratio is relative to Maestro</p>							

Table 25: Optic Disc - Retinal Disease Eyes Repeatability and Reproducibility

		N=26					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
C/D Vertical	0.53	0.019	0.054 (0.421)	3.679	0.020	0.057 (0.439)	3.862
C/D Area	0.30	0.011	0.030 (0.518)	3.604	0.012	0.032 (0.558)	3.909
Disc Area	1.90	0.059	0.165 (0.748)	3.106	0.068	0.192 (0.709)	3.606
Cup Area	0.57	0.023	0.064 (0.502)	3.968	0.024	0.067 (0.513)	4.182
Rim Area	1.32	0.052	0.145 (0.638)	3.900	0.060	0.168 (0.704)	4.546
Cup Volume	0.09	0.004	0.012 (0.699)	4.438	0.005	0.013 (0.756)	5.052
Rim Volume	0.24	0.010	0.027 (0.586)	4.106	0.012	0.034 (0.678)	5.082
Linear C/D Ratio	0.50	0.009	0.025 (0.281)	1.755	0.010	0.028 (0.291)	1.964
Triton 6x6 3D Disc							
C/D Vertical	0.52	0.017	0.048 (0.912)	3.287	0.018	0.049 (0.870)	3.362
C/D Area	0.30	0.010	0.027 (1.016)	3.195	0.010	0.029 (0.927)	3.411
Disc Area	1.76	0.041	0.114 (0.617)	2.306	0.047	0.131 (0.667)	2.665
Cup Area	0.54	0.019	0.053 (0.914)	3.508	0.020	0.055 (0.792)	3.650
Rim Area	1.22	0.038	0.107 (0.629)	3.120	0.042	0.118 (0.667)	3.452
Cup Volume	0.09	0.004	0.012 (0.802)	4.626	0.005	0.013 (0.794)	4.836
Rim Volume	0.21	0.008	0.022 (0.616)	3.743	0.010	0.028 (0.701)	4.599
Linear C/D Ratio	0.51	0.008	0.023 (0.934)	1.651	0.009	0.024 (0.845)	1.708

Maestro 12x9 3D Wide							
C/D Vertical	0.51	0.046	0.129	9.006	0.046	0.130	9.071
C/D Area	0.27	0.021	0.058	7.673	0.021	0.058	7.728
Disc Area	2.22	0.079	0.221	3.546	0.096	0.270	4.341
Cup Area	0.60	0.045	0.127	7.504	0.047	0.131	7.733
Rim Area	1.62	0.081	0.227	5.006	0.085	0.239	5.285
Cup Volume	0.10	0.006	0.017	5.873	0.006	0.018	6.183
Rim Volume	0.29	0.017	0.047	5.741	0.018	0.050	6.146
Linear C/D Ratio	0.48	0.031	0.088	6.484	0.034	0.095	7.014
Maestro 6x6 3D Disc							
C/D Vertical	0.50	0.019	0.053	3.772	0.020	0.057	4.048
C/D Area	0.28	0.009	0.026	3.410	0.011	0.031	3.992
Disc Area	2.00	0.066	0.184	3.293	0.070	0.197	3.515
Cup Area	0.56	0.021	0.058	3.710	0.025	0.070	4.453
Rim Area	1.44	0.060	0.169	4.200	0.063	0.177	4.384
Cup Volume	0.10	0.005	0.015	5.438	0.006	0.016	5.748
Rim Volume	0.26	0.013	0.036	5.042	0.014	0.039	5.448
Linear C/D Ratio	0.48	0.009	0.025	1.842	0.010	0.029	2.104
<p>All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Mean = Intercept of the ANOVA model Repeatability SD = Square root of the residual variance Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD Repeatability CV% = (Repeatability SD)/Intercept x 100% Reproducibility CV% = (Reproducibility SD)/Intercept x 100% Ratio is relative to Maestro</p>							

Table 26: Optic Disc - Glaucoma Eyes Repeatability and Reproducibility

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Triton 12x9 3D Wide							
C/D Vertical	0.86	0.023	0.063 (0.688)	2.626	0.028	0.079 (0.857)	3.273
C/D Area	0.68	0.013	0.038 (0.631)	1.980	0.024	0.067 (0.881)	3.508
Disc Area	1.94	0.052	0.145 (0.608)	2.662	0.067	0.189 (0.711)	3.474
Cup Area	1.33	0.034	0.094 (0.611)	2.531	0.041	0.114 (0.621)	3.045

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Rim Area	0.61	0.038	0.107 (0.587)	6.260	0.057	0.159 (0.766)	9.355
Cup Volume	0.36	0.009	0.025 (0.484)	2.493	0.010	0.028 (0.544)	2.813
Rim Volume	0.06	0.006	0.016 (0.582)	8.936	0.008	0.021 (0.759)	12.188
Linear C/D Ratio	0.82	0.008	0.024 (0.593)	1.035	0.015	0.043 (0.891)	1.882
Triton 6x6 3D Disc							
C/D Vertical	0.86	0.023	0.063 (0.817)	2.626	0.023	0.063 (0.751)	2.626
C/D Area	0.68	0.018	0.051 (0.820)	2.679	0.018	0.052 (0.768)	2.721
Disc Area	1.80	0.048	0.135 (0.677)	2.667	0.054	0.152 (0.710)	3.005
Cup Area	1.24	0.036	0.102 (0.730)	2.927	0.037	0.103 (0.668)	2.961
Rim Area	0.56	0.034	0.096 (0.580)	6.101	0.039	0.109 (0.628)	6.936
Cup Volume	0.35	0.012	0.033 (0.567)	3.333	0.012	0.033 (0.485)	3.366
Rim Volume	0.05	0.005	0.014 (0.746)	9.661	0.006	0.016 (0.739)	10.513
Linear C/D Ratio	0.82	0.013	0.036 (0.831)	1.574	0.013	0.036 (0.755)	1.574
Maestro 12x9 3D Wide							
C/D Vertical	0.82	0.033	0.092	3.980	0.033	0.092	3.984
C/D Area	0.63	0.021	0.060	3.378	0.027	0.076	4.283
Disc Area	2.19	0.085	0.238	3.880	0.095	0.265	4.328
Cup Area	1.39	0.055	0.154	3.981	0.065	0.183	4.711
Rim Area	0.80	0.065	0.182	8.074	0.074	0.208	9.251
Cup Volume	0.38	0.019	0.052	4.940	0.019	0.052	4.953
Rim Volume	0.08	0.010	0.027	11.557	0.010	0.028	12.077
Linear C/D Ratio	0.79	0.014	0.040	1.811	0.017	0.048	2.190
Maestro 6x6 3D Disc							
C/D Vertical	0.82	0.028	0.077	3.344	0.030	0.084	3.639
C/D Area	0.63	0.022	0.062	3.539	0.024	0.067	3.838
Disc Area	2.03	0.071	0.199	3.508	0.076	0.214	3.764
Cup Area	1.29	0.050	0.139	3.852	0.055	0.154	4.261
Rim Area	0.74	0.059	0.166	8.040	0.062	0.174	8.429
Cup Volume	0.37	0.021	0.058	5.630	0.024	0.068	6.646
Rim Volume	0.07	0.007	0.019	9.784	0.008	0.021	10.740
Linear C/D Ratio	0.78	0.015	0.043	1.975	0.017	0.048	2.173

		N=25					
		Repeatability			Reproducibility		
Device Measurement	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
<p>All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Mean = Intercept of the ANOVA model Repeatability SD = Square root of the residual variance Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance Repeatability limit = 2.8 x Repeatability SD Reproducibility limit = 2.8 x Reproducibility SD Repeatability CV% = (Repeatability SD)/Intercept x 100% Reproducibility CV% = (Reproducibility SD)/Intercept x 100% Ratio is relative to Maestro</p>							

Reference Database

Topcon conducted a prospective, multicenter study at six U.S. clinical sites, in which subjects without eye disease had OCT images obtained with the Triton device. The study collected measurements of normal eyes for full retinal thickness, retinal nerve fiber layer thickness, ganglion cell layer plus the IPL layer thickness, ganglion cell complex and the optic disc in addition to TSNIT circle profile measurements. The reference limits at the 1st, 5th, 95th and 99th percentile points established thresholds to provide for the quantitative comparison of the retinal nerve fiber layer, optic nerve head and the macula in the human retina to a database of known normal subjects.

Major eligibility criteria included participants age ≥ 18 presenting at the site with normal eyes bilaterally (excluding glaucomatous optic nerve damage, based on pattern deviation or Glaucoma hemi-field test).

One eye of each subject was randomly selected and measured with the study device. Subjects were enrolled with a wide range of ethnicities including Asian, Caucasian, Hispanic/Latino, African-American, and others. The number of subjects within each age group (18-30, 31-40, 41-50, 51-60, 61-70 and 70+ years) was evenly distributed. The total number of evaluable eyes was 410.

There were nine scans taken during a single session, for each subject (3 scans per 3D Wide 12x9, 3D Macula 7x7, and 3D Disc 6x6 scans). The first accepted scan of each scan parameter from each eligible subject was included in the analysis. The 1st, 5th, 95th and 99th percentile were estimated by quantile regression. Age and/or disc area were used as the regression covariates for the scan parameters.

Table 27: Triton Reference Database Demographic Data

	Total (N=410)
Age (years)	
Mean (SD)	48.6 (16.7)
95% CI	46.9, 50.2
Median	49.0
Min, Max	18, 90
Age group, n (%)	
18-30 years	76 (19)
31-40 years	73 (18)
41-50 years	73 (18)
51-60 years	69 (17)
61-70 years	69 (17)
70+ years	50 (12)
Gender, n (%)	
Male	194 (47)
Female	216 (53)
Ethnicity, n (%)	
Hispanic or Latino	73 (18)
Not Hispanic and not Latino	337 (82)
Race, n (%)	
American Indian/Alaska Native	5 (1)
Asian	32 (8)
Black/African American	92 (22)
Native Hawaiian/Pacific Islander	12 (3)
White	236 (58)
Other	48 (12)
Disc Area of 12x9 Wide (mm ²)	
n	409
Mean (SD)	1.940 (0.365)
95% CI	1.904, 1.975
Median	1.920
Min, Max	1.11, 3.30

Disc Area of 6x6 Disc (mm ²)	
n	409
Mean (SD)	1.810 (0.365)
95% CI	1.775, 1.846
Median	1.780
Min, Max	1.03, 3.29

Table 28: Full Retinal Thickness (µm) – Summary

Measurement	Triton 12x9 3D Wide (N=410)	Triton 7x7 3D Macula (N=410)
Central Fovea		
n	409	404
Mean (SD)	239.861 (20.973)	239.619 (21.156)
95% CI	237.822, 241.899	237.550, 241.688
Median	240.990	240.530
Inner Superior		
n	409	404
Mean (SD)	310.489 (16.778)	310.623 (16.869)
95% CI	308.858, 312.119	308.973, 312.273
Median	310.840	310.735
Inner Nasal		
n	409	404
Mean (SD)	311.643 (16.657)	311.166 (16.863)
95% CI	310.024, 313.262	309.516, 312.815
Median	312.650	311.750
Inner Inferior		
n	409	404
Mean (SD)	307.438 (16.220)	307.577 (16.342)
95% CI	305.862, 309.015	305.979, 309.176
Median	308.450	308.045
Inner Temporal		
n	409	404
Mean (SD)	299.177 (15.373)	298.357 (15.624)
95% CI	297.682, 300.671	296.829, 299.885
Median	299.580	298.325
Outer Superior		
n	409	404
Mean (SD)	270.110 (14.968)	269.368 (14.701)
95% CI	268.655, 271.565	267.930, 270.806
Median	270.440	269.445
Outer Nasal		
n	409	404
Mean (SD)	285.007 (17.111)	284.056 (16.950)
95% CI	283.344, 286.670	282.398, 285.713
Median	286.730	285.210
Outer Inferior		
n	409	404
Mean (SD)	258.388 (14.515)	257.808 (14.539)
95% CI	256.977, 259.798	256.386, 259.230

Measurement	Triton 12x9 3D Wide (N=410)	Triton 7x7 3D Macula (N=410)
Median	259.490	258.135
Outer Temporal		
n	409	404
Mean (SD)	254.954 (14.098)	253.040 (14.019)
95% CI	253.583, 256.324	251.669, 254.411
Median	254.800	253.260

Table 29: Ganglion Cell + IPL Thickness (μm) – Summary

Measurement	Triton 12x9 3D Wide (N=410)	Triton 7x7 3D Macula (N=410)
Superior		
n	405	405
Mean (SD)	69.999 (5.880)	69.376 (5.883)
95% CI	69.424, 70.573	68.801, 69.950
Median	70.340	69.410
Superior Nasal		
n	405	405
Mean (SD)	73.710 (6.554)	73.450 (6.527)
95% CI	73.070, 74.350	72.812, 74.087
Median	74.290	73.830
Superior Temporal		
n	405	405
Mean (SD)	70.733 (5.880)	71.758 (5.591)
95% CI	70.158, 71.307	71.212, 72.305
Median	70.750	71.840
Inferior		
n	405	405
Mean (SD)	66.977 (5.744)	66.362 (5.717)
95% CI	66.416, 67.538	65.803, 66.920
Median	66.970	66.350
Inferior Nasal		
n	405	405
Mean (SD)	72.128 (6.542)	71.944 (6.655)
95% CI	71.489, 72.767	71.294, 72.594
Median	72.610	72.450
Inferior Temporal		
n	405	405

Measurement	Triton 12x9 3D Wide (N=410)	Triton 7x7 3D Macula (N=410)
Mean (SD)	71.830 (5.878)	72.422 (5.739)
95% CI	71.256, 72.405	71.862, 72.983
Median	71.500	72.440
Average		
n	405	405
Mean (SD)	70.899 (5.757)	70.888 (5.676)
95% CI	70.336, 71.461	70.334, 71.443
Median	71.000	71.100

Table 30: Ganglion Cell Complex Thickness (μm) – Summary

Measurement	Triton 12x9 3D Wide (N=410)	Triton 7x7 3D Macula (N=410)
Superior		
n	409	405
Mean (SD)	107.927 (8.769)	107.835 (8.751)
95% CI	107.075, 108.780	106.981, 108.690
Median	108.490	108.370
Superior Nasal		
n	409	405
Mean (SD)	118.673 (9.691)	118.020 (9.572)
95% CI	117.731, 119.615	117.085, 118.955
Median	119.180	118.830
Superior Temporal		
n	409	405
Mean (SD)	94.841 (6.880)	94.053 (6.879)
95% CI	94.172, 95.509	93.381, 94.725
Median	94.820	94.100
Inferior		
n	409	405
Mean (SD)	105.945 (8.230)	106.024 (8.412)
95% CI	105.145, 106.745	105.202, 106.845
Median	106.010	106.160
Inferior Nasal		
n	409	405
Mean (SD)	118.695 (10.398)	118.652 (10.373)
95% CI	117.684, 119.705	117.638, 119.665
Median	119.200	119.050

Measurement	Triton 12x9 3D Wide (N=410)	Triton 7x7 3D Macula (N=410)
Inferior Temporal		
n	409	405
Mean (SD)	97.502 (6.865)	96.949 (6.941)
95% CI	96.834, 98.169	96.271, 97.627
Median	97.590	96.930
Average		
n	409	405
Mean (SD)	107.267 (7.943)	106.927 (7.949)
95% CI	106.495, 108.040	106.151, 107.704
Median	108.000	107.500

Table 31: Retinal Nerve Fiber Layer Thickness (μm) – Summary

Measurement	Triton 12x9 3D Wide (N=410)	Triton 6x6 3D Disc (N=410)
Average		
n	409	409
Mean (SD)	106.350 (10.537)	105.090 (10.355)
95% CI	105.326, 107.374	104.083, 106.096
Median	106.930	105.760
Superior Quadrant		
n	409	409
Mean (SD)	129.044 (17.862)	128.791 (17.250)
95% CI	127.307, 130.780	127.115, 130.468
Median	129.700	129.980
Nasal Quadrant		
n	409	409
Mean (SD)	81.275 (14.747)	80.765 (15.603)
95% CI	79.841, 82.708	79.249, 82.282
Median	81.370	80.910
Inferior Quadrant		
n	409	409
Mean (SD)	138.281 (16.785)	136.952 (16.692)
95% CI	136.650, 139.913	135.330, 138.575
Median	137.570	136.650
Temporal Quadrant		
n	409	409
Mean (SD)	76.778 (11.877)	73.838 (11.875)

Measurement	Triton 12x9 3D Wide (N=410)	Triton 6x6 3D Disc (N=410)
95% CI	75.624, 77.933	72.683, 74.992
Median	75.790	72.900
12-Sector - T		
n	409	409
Mean (SD)	65.195 (9.237)	61.842 (9.494)
95% CI	64.297, 66.093	60.919, 62.764
Median	65.080	61.090
12-Sector - TS		
n	409	409
Mean (SD)	91.576 (16.825)	88.503 (16.547)
95% CI	89.941, 93.212	86.895, 90.112
Median	90.570	86.800
12-Sector - ST		
n	409	409
Mean (SD)	138.155 (23.883)	137.967 (24.893)
95% CI	135.834, 140.477	135.547, 140.386
Median	137.430	138.580
12-Sector - S		
n	409	409
Mean (SD)	128.377 (27.937)	128.435 (28.389)
95% CI	125.662, 131.093	125.676, 131.195
Median	126.500	127.980
12-Sector - SN		
n	409	409
Mean (SD)	120.613 (23.571)	119.982 (23.321)
95% CI	118.322, 122.904	117.715, 122.248
Median	119.940	118.690
12-Sector - NS		
n	409	409
Mean (SD)	97.187 (20.967)	98.756 (22.579)
95% CI	95.149, 99.225	96.562, 100.951
Median	97.210	99.510
12-Sector - N		
n	409	409
Mean (SD)	68.029 (13.016)	65.882 (13.710)
95% CI	66.764, 69.294	64.549, 67.214
Median	66.520	64.060
12-Sector - NI		
n	409	409

Measurement	Triton 12x9 3D Wide (N=410)	Triton 6x6 3D Disc (N=410)
Mean (SD)	78.595 (16.965)	77.690 (17.639)
95% CI	76.946, 80.244	75.976, 79.405
Median	78.430	76.930
12-Sector - IN		
n	409	409
Mean (SD)	119.511 (25.625)	117.930 (26.191)
95% CI	117.020, 122.002	115.384, 120.476
Median	117.350	114.990
12-Sector - I		
n	409	409
Mean (SD)	154.790 (26.388)	152.367 (26.543)
95% CI	152.225, 157.355	149.787, 154.947
Median	154.290	152.870
12-Sector - IT		
n	409	409
Mean (SD)	140.556 (25.934)	140.585 (27.175)
95% CI	138.035, 143.077	137.944, 143.227
Median	140.350	142.530
12-Sector - TI		
n	409	409
Mean (SD)	73.560 (13.949)	71.178 (14.284)
95% CI	72.204, 74.916	69.790, 72.566
Median	72.240	70.080
T=Temporal; S=Superior; N=Nasal; I=Inferior		

Table 32: Optic Disc – Summary

Measurement	Triton 12x9 3D Wide (N=410)	Triton 6x6 3D Disc (N=410)
C/D Vertical		
n	409	409
Mean (SD)	0.506 (0.210)	0.501 (0.198)
95% CI	0.486, 0.527	0.482, 0.520
Median	0.560	0.550
C/D Area		
n	409	409
Mean (SD)	0.306 (0.183)	0.305 (0.174)
95% CI	0.288, 0.323	0.288, 0.322

Measurement	Triton 12x9 3D Wide (N=410)	Triton 6x6 3D Disc (N=410)
Median	0.310	0.310
Disc Area (mm ²)		
n	409	409
Mean (SD)	1.940 (0.365)	1.810 (0.365)
95% CI	1.904, 1.975	1.775, 1.846
Median	1.920	1.780
Cup Area (mm ²)		
n	409	409
Mean (SD)	0.620 (0.433)	0.580 (0.396)
95% CI	0.578, 0.662	0.542, 0.619
Median	0.600	0.550
Rim Area (mm ²)		
n	409	409
Mean (SD)	1.319 (0.346)	1.230 (0.301)
95% CI	1.286, 1.353	1.201, 1.259
Median	1.290	1.200
Cup Volume (mm ³)		
n	409	409
Mean (SD)	0.117 (0.122)	0.115 (0.116)
95% CI	0.106, 0.129	0.104, 0.126
Median	0.080	0.080
Rim Volume (mm ³)		
n	409	409
Mean (SD)	0.237 (0.126)	0.214 (0.104)
95% CI	0.224, 0.249	0.204, 0.224
Median	0.210	0.190
Linear C/D Ratio		
n	409	409
Mean (SD)	0.510 (0.212)	0.513 (0.204)
95% CI	0.490, 0.531	0.494, 0.533
Median	0.560	0.560

Fundus Autofluorescence and Fluorescein Angiography Image Quality Evaluation Study

A prospective clinical study was conducted at one clinical site, located in the United States, The predicate device used in the study was the TRC-50DX, cleared for fundus autofluorescence (FAF) and fluorescein angiography (FA) uses (K123101). The objectives of this study were to compare the

image quality of the fundus autofluorescence (FAF) and the fluorescein angiography (FA) photographs between DRI OCT Triton (plus) and TRC-50DX retinal camera.

Major inclusion criteria included age (≥ 18 years) and medical need to undergo dye injection for FA imaging. Major exclusion criteria included ocular motility dysfunction. Subjects were randomized for device order. FA images were captured in two time intervals after the intravenous fluorescein dye injection. The FAF and FA images that met the image acceptance criteria were graded by two masked independent graders in a blinded and randomized fashion. The agreement analysis of FA and FAF photograph image quality for eyes with retinal pathologies was based on a 5-point scale, where a "1" indicated that the photograph was insufficient for any interpretation, and "5" represented an excellent photograph.

Majority of the FAF and FA images were graded as good or excellent by both graders. The response rates (i.e., percentage of subjects whose Triton grades were equal to or better than the corresponding TRC-50DX grades) favorably ranged between 85.2% – 94.9%, confirming that the subject Triton device performed at least as well as the predicate TRC-50DX device. Notably, the Triton device had higher rates of agreement across FAF and FA images (68.3% - 73.2%) as compared to the TRC-50DX (56% - 61.7%).

There were no adverse events in any of the clinical studies.

Conclusion

Based on the intended use/indications for use, the technological characteristics described above, and the safety and effectiveness demonstrated in the clinical trials, the subject device is substantially equivalent to the predicate devices.

Substantial Equivalence Comparison Table

Applicant	TOPCON	TOPCON
Device Name	DRI OCT Triton DRI OCT Triton (plus)	3D OCT-1 Maestro
510k Number	K173119	K161509 K170164
Product Code	OBO, HKI	OBO, HKI
Regulation number	21CFR§886.1570	21CFR§886.1570
Indications for Use	<p>The Topcon DRI OCT Triton is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions.</p> <p>The DRI OCT Triton is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula and optic disc as well as imaging of anterior ocular structures.</p> <p>It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. The DRI OCT Triton is indicated for use as a diagnostic device to aid in the diagnosis, documentation and management of ocular health and diseases in the adult population.</p>	<p>The Topcon 3D OCT-1 Maestro is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions.</p> <p>The 3D OCT-1 Maestro is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula and optic disc as well as imaging of anterior ocular structures.</p> <p>It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. The 3D OCT-1 Maestro is indicated for use as a diagnostic device to aid in the diagnosis, documentation and management of ocular health and diseases in the adult population.</p>

Applicant	TOPCON	TOPCON
Device Name	DRI OCT Triton DRI OCT Triton (plus)	3D OCT-1 Maestro
510k Number	K173119	K161509 K170164
Technological Characteristics	<p>OCT: Optical coherence tomography is employed to obtain cross-sectional images of the fundus and the anterior segment of the eye.</p> <p>Fundus Camera (Triton): A Xenon flash and a CMOS camera are employed to obtain fundus/anterior Color/digital red-free images.</p> <p>Fundus Camera (Triton (plus)): A Xenon flash and a CMOS camera are employed to obtain fundus/anterior Color/digital red-free/FA/FAF images.</p>	<p>OCT: Optical coherence tomography is employed to obtain cross-sectional images of the fundus and the anterior segment of the eye.</p> <p>Fundus Camera: A Xenon flash and a CMOS camera are employed to obtain fundus/anterior Color/digital red-free images.</p>
OCT		
Light Source	Swept source OCT (SS-OCT) using a wavelength swept laser with a center wavelength 1050 nm.	Spectral domain OCT (SD-OCT) using a superluminescent diode (SLD) with a center wavelength 840 nm.
Measurement scan	3D 12x9 mm (Wide) 3D 7x7 mm (Macula) 3D 6x6 mm (Disc)	3D 12x9 mm (Wide) 3D 6x6 mm (Macula) 3D 6x6 mm (Disc)

Analysis	<u>For posterior:</u> <ul style="list-style-type: none"> - Full retinal thickness - Ganglion cell plus Inner plexiform layer (GCL+) thickness - Ganglion cell complex (GCL++) thickness - Retinal nerve fiber layer (RNFL) thickness <ul style="list-style-type: none"> - Optic disc analysis <ol style="list-style-type: none"> 1. DA (Disc area) 2. RA (Rim area) 3. CV (Cup volume) 4. LCDR (Linear Cup Disc ratio) 5. VCDR (Vertical Cup Disc ratio) 6. CA (Cup area) 7. RV (Rim volume) 8. CDR (Cup Disc ratio) 9. Optic disc diameter (vertical direction) 10. Optic disc diameter (horizontal direction) <p>Software and algorithm updates included improved fovea detection, ILM and RPE segmentation, artifact removal and cup map refinement.</p>	<u>For posterior:</u> <ul style="list-style-type: none"> - Full retinal thickness - Ganglion cell plus Inner plexiform layer (GCL+) thickness - Ganglion cell complex (GCL++) thickness - Retinal nerve fiber layer (RNFL) thickness <ul style="list-style-type: none"> - Optic disc analysis <ol style="list-style-type: none"> 1. DA (Disc area) 2. RA (Rim area) 3. CV (Cup volume) 4. LCDR (Linear Cup Disc ratio) 5. VCDR (Vertical Cup Disc ratio) 6. CA (Cup area) 7. RV (Rim volume) 8. CDR (Cup Disc ratio) 9. Optic disc diameter (vertical direction) 10. Optic disc diameter (horizontal direction)
	<u>For anterior:</u> NA	<u>For anterior:</u> NA

Fundus Camera		
Observation	Light source	Light source

Applicant	TOPCON	TOPCON
Device Name	DRI OCT Triton DRI OCT Triton (plus)	3D OCT-1 Maestro
510k Number	K173119	K161509 K170164
	- IR LED Camera - CMOS camera (0.3M pixels)	- IR LED Camera - CMOS camera (0.3M pixels)

Applicant	TOPCON	TOPCON
Device Name	DRI OCT Triton (plus)	TRC-50DX
510k Number	K173119	K123101
Product Code	OBO, HKI	HKI
Regulation number	21CFR§886.1570	21CFR§886.1120
Indications for Use	<p>The Topcon DRI OCT Triton is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions.</p> <p>The DRI OCT Triton is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula and optic disc as well as imaging of anterior ocular structures.</p> <p>It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. The DRI OCT Triton is indicated for use as a diagnostic device to aid in the diagnosis, documentation and management of ocular health and diseases in the adult population.</p>	<p>The TRC-50DX Retinal Camera is intended for use in capturing images of the retina and anterior segment of the eye and presenting the data to the eye care professional, with the use of a mydriatic.</p>

Applicant	TOPCON	TOPCON
Device Name	DRI OCT Triton (plus)	TRC-50DX
510k Number	K173119	K123101
Technological Characteristics	<p><u>OCT:</u> Optical coherence tomography is employed to obtain cross-sectional images of the fundus and the anterior segment of the eye.</p> <p><u>Fundus Camera:</u> A Xenon flash and a CMOS camera are employed to obtain fundus/anterior Color/digital red-free/FA/FAF images.</p>	<p><u>OCT:</u> NA</p> <p><u>Fundus Camera:</u> A Xenon flash and a CCD camera are employed to obtain fundus/anterior Color/red-free/FA/FAF/ICG images.</p>
Fundus Camera		
Observation	<p>Light source</p> <ul style="list-style-type: none"> - IR LED <p>Camera</p> <ul style="list-style-type: none"> - CMOS camera (0.3M pixels) 	<p>Light source</p> <ul style="list-style-type: none"> - Halogen lamp <p>Camera (Color/red-free/FA/FAF)</p> <ul style="list-style-type: none"> - NA (optical finder) <p>Camera (ICG)</p> <ul style="list-style-type: none"> - CCD camera (0.4M pixels)