



Food and Drug Administration  
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July 28, 2016

Topcon Corporation  
% Jonathan Kahan  
Partner  
Hogan Lovells US LLP  
555 Thirteenth Street NW  
Washington, District of Columbia 20004

Re: K161509  
Trade/Device Name: 3D OCT-1 Maestro  
Regulation Number: 21 CFR §886.1570  
Regulation Name: Ophthalmoscope  
Regulatory Class: Class II  
Product Code: OBO, HKI  
Dated: June 1, 2016  
Received: June 1, 2016

Dear Mr. Kahan:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**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)  
K161509

Device Name

3D OCT-1 Maestro

Indications for Use (Describe)

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.

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.

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.

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**510(k) SUMMARY – K161509**

**Topcon Corporation's 3D OCT-1 Maestro**

**Submitter Information:**

Applicant: Topcon Corporation  
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Tokyo, Japan 174-8580

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Date Prepared: July 25, 2016

**Subject Device:**

Device Name: 3D OCT-1 Maestro

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: Optovue's iVue with Normative Database (K121739)

Secondary Predicate: Topcon's TRC-NW300 Non-Mydriatic Retinal Camera (K123460)

## **Indications for Use:**

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.

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.

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.

## **Device Description:**

The Maestro is a non-contact, high-resolution, tomographic and bio-microscopic imaging system that merges OCT and fundus cameras into a single device. The technological characteristics of the OCT employed are similar to those of already 510(k)-cleared OCT products, such as Topcon's 3D OCT-2000 (K092470), in that it employs conventional spectral domain OCT with widely-used 840 nm light source. The technological characteristics of the fundus camera employed are also similar to those of already cleared fundus cameras, such as Topcon's TRC NW300 (K123460), in terms of field of view (FOV) and camera sensor resolution.

The Maestro captures an OCT image and a color fundus image sequentially. It can take anterior OCT images in addition to fundus OCT images. It also includes a reference database for fundus OCT. 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.

Two software programs for installation on an off-the-shelf PC are provided with the device. The first PC software program, called "FastMap", captures the images from the device, analyzes them and enables viewing of the data. The second PC software program, called "OCT Viewer", can only analyze and view the data.

Accessories include the following: power cord; chin-rest paper sheet; monitor cleaner; LAN cable; chin-rest paper pins; external fixation target; dust cover; spare parts case; and stylus pen. An optional Anterior Segment Kit allows the user to activate the anterior segment imaging functionality of the Maestro device.

## **Substantial Equivalence**

The Maestro is substantially equivalent to the primary predicate device Optovue's iVue with Normative Database (iVue) cleared under K121739. The Maestro and the iVue with Normative Database have very similar indication for use statements with respect to the use of the reference database and its ability to provide reference analyses. The Maestro and iVue are both OCT devices and each provide cross-sectional images of the fundus and measurement of posterior ocular structures. Both devices provide analysis functions for both retinal disease and glaucoma. Also, both are intended for use as a diagnostic device to aid in the detection and management of various ocular diseases.

The Maestro and the iVue have similar technological characteristics with respect to the kind of OCT images they capture, the processing methods, and presentation of OCT information. The light source used by both devices is a spectral domain OCT (SD-OCT) using a superluminescent diode (SLD) with a center wavelength of 840 nm. The Maestro has a faster scan speed of 50,000 A-scans per second compared to 26,000 A-scans per second for the iVue. In addition, the Maestro has deeper A-scan depth of 2.6 mm (in tissue) at axial resolution of 6 micron (in tissue) and transverse resolution of 20 micron (in tissue) compared to A-scan depth of 2.0 to 2.3 mm at axial resolution of 5 micron and unspecified transverse resolution for the iVue. Both devices use the 3D Scan pattern and other similar scan patterns for posterior and Radial and Line-like scans for anterior. For the anterior segment feature, the Maestro provides only a visualization function while the iVue also provides automated measurement of central corneal thickness.

In addition to the primary predicate device, Topcon has identified Topcon's TRC-NW300 Non-Mydriatic Retinal Camera (NW300) (K123460) as a secondary predicate device for fundus camera functionality. This secondary predicate device serves as a comparator device to the subject device since the scientific methodology and the device performance for the individual components have already been established. Comparative data between the subject and secondary predicate device will be provided in the device labeling.

Based on the intended use/indications for use and technological characteristics described above, the subject device is substantially equivalent to the primary predicate device.

## **Performance Data**

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

- Axial and Horizontal Resolutions
- Trueness and Precision for Axial and Horizontal Directions
- Testing to Consensus Standards for Ophthalmic Devices
  - ISO 15004-1:2006 Ophthalmic instruments – Fundamental requirements and test methods– Part 1: General requirements applicable to all ophthalmic instruments
  - ISO 10940: 2009 Ophthalmic instruments - Fundus cameras
  - ISO 15004-2:2007 Ophthalmic Instruments – Fundamental requirements and test methods – Part 2: Light hazard protection
- Electrical Safety
  - AAMI ANSI ES 60601-1:2005/A2:2010/(R)2012 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (Third Edition)
- Electromagnetic Compatibility
  - IEC 60601-1-2:2007 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests (Third Edition)

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

## 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 a "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.

## Clinical Data

Topcon conducted clinical studies to determine the comparative agreement, repeatability and reproducibility of the measurement data between the Maestro device and the iVue with normative database. A comparative study between images of the Maestro and the TRC NW300 Non Mydriatic Retinal Camera was also conducted. These studies included data from 25 normal subjects, 26 subjects with retinal disease, and 25 subjects with glaucoma. The studies included five main analyses: 1) a precision analysis, 2) an agreement analysis, 3) a fundus photograph evaluation, 4) an anterior segment image evaluation, and 5) a B scan image quality evaluation.

A reference database study of the Maestro was also conducted.

Consistent with the labeling for the test and control devices, the clinical site was permitted to make manual adjustments to automated segmentation based on the clinician's judgment. The study device manual adjustment rates for macula scans ranged from approximately 0-5% for 6x6 macula and 10-15% for 12x9 wide scans. For RNFL thicknesses and optic disc parameters, the overall manual adjustment rates for the Maestro were 11-32% and 20-40% for 6x6 disc and 12x9 wide scans, respectively.

## Precision Assessment:

**Table 1: Full Retinal Thickness - Normal Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device Measurement	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
Central Fovea	25	233.99	2.608	7.302	1.115	3.419	9.573	1.461
Superior Parafoveal	25	309.12	1.647	4.611	0.533	2.435	6.819	0.788
Nasal Parafoveal	25	309.72	1.470	4.116	0.475	2.595	7.266	0.838
Inferior Parafoveal	25	307.29	1.281	3.588	0.417	2.235	6.259	0.727
Temporal Parafoveal	25	296.65	1.417	3.968	0.478	2.294	6.424	0.773
Superior Perifoveal	25	268.84	1.442	4.039	0.536	2.140	5.991	0.796
Nasal Perifoveal	25	286.14	0.818	2.289	0.286	1.681	4.707	0.587
Inferior Perifoveal	25	257.54	1.059	2.965	0.411	1.356	3.796	0.526
Temporal Perifoveal	25	253.97	0.948	2.655	0.373	1.519	4.252	0.598
<b>Maestro 6x6 3D Macula</b>								
Central Fovea	25	231.18	1.581	4.428	0.684	2.370	6.637	1.025
Superior Parafoveal	25	310.61	1.649	4.619	0.531	2.616	7.324	0.842
Nasal Parafoveal	25	309.71	1.328	3.717	0.429	2.468	6.911	0.797
Inferior Parafoveal	25	307.78	1.244	3.484	0.404	2.112	5.913	0.686
Temporal Parafoveal	25	295.58	1.217	3.409	0.412	2.066	5.785	0.699
Superior Perifoveal	25	268.73	1.468	4.111	0.546	2.017	5.648	0.751

			Repeatability			Reproducibility		
Device	N	Mean	SD	Limit	CV%	SD	Limit	CV%
Nasal Perifoveal	25	285.91	0.873	2.445	0.305	1.912	5.354	0.669
Inferior Perifoveal	25	258.27	1.285	3.599	0.498	2.143	6.002	0.830
Temporal Perifoveal	25	251.83	1.088	3.045	0.432	1.963	5.496	0.779

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.

N = Number of subjects

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%

**Table 2: Full Retinal Thickness - Retinal Disease Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
Central Fovea	26	250.15	3.697	10.351	1.478	4.745	13.285	1.897
Superior Parafoveal	26	317.62	1.561	4.371	0.492	2.371	6.639	0.747
Nasal Parafoveal	26	315.72	1.512	4.233	0.479	2.737	7.665	0.867
Inferior Parafoveal	26	313.43	2.060	5.769	0.657	2.983	8.351	0.952
Temporal Parafoveal	26	303.67	2.042	5.718	0.672	3.164	8.860	1.042
Superior Perifoveal	26	276.82	1.356	3.797	0.490	1.758	4.922	0.635
Nasal Perifoveal	26	288.87	1.093	3.059	0.378	1.719	4.812	0.595
Inferior Perifoveal	26	263.37	1.800	5.039	0.683	2.319	6.495	0.881
Temporal Perifoveal	26	261.82	1.950	5.459	0.745	2.279	6.382	0.871
<b>Maestro 6x6 3D Macula</b>								
Central Fovea	26	247.02	2.693	7.541	1.090	3.301	9.242	1.336
Superior Parafoveal	26	317.54	1.754	4.910	0.552	2.714	7.599	0.855
Nasal Parafoveal	26	315.98	1.515	4.241	0.479	2.575	7.210	0.815
Inferior Parafoveal	26	312.70	1.555	4.354	0.497	2.488	6.966	0.796
Temporal Parafoveal	26	301.80	1.484	4.156	0.492	2.704	7.570	0.896
Superior Perifoveal	26	276.60	1.531	4.286	0.553	2.365	6.621	0.855
Nasal Perifoveal	26	288.21	1.083	3.033	0.376	1.902	5.326	0.660
Inferior Perifoveal	26	263.98	1.697	4.751	0.643	2.177	6.095	0.825
Temporal Perifoveal	26	258.61	1.136	3.182	0.439	1.994	5.583	0.771

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.

N = Number of subjects

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%

**Table 3: Full Retinal Thickness - Glaucoma Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
Central Fovea	25	243.09	2.914	8.159	1.199	3.985	11.158	1.639
Superior Parafoveal	25	304.59	1.921	5.380	0.631	2.727	7.635	0.895
Nasal Parafoveal	25	307.97	1.520	4.255	0.493	2.676	7.492	0.869
Inferior Parafoveal	25	299.65	2.012	5.633	0.671	2.723	7.624	0.909
Temporal Parafoveal	25	293.57	1.587	4.444	0.541	2.687	7.524	0.915
Superior Perifoveal	25	261.20	1.731	4.846	0.663	2.308	6.463	0.884
Nasal Perifoveal	25	276.95	1.393	3.901	0.503	1.831	5.127	0.661
Inferior Perifoveal	25	246.04	1.726	4.832	0.701	2.225	6.230	0.904
Temporal Perifoveal	25	247.98	1.685	4.718	0.679	2.229	6.241	0.899
<b>Maestro 6x6 3D Macula</b>								
Central Fovea	25	241.05	1.677	4.695	0.696	2.986	8.361	1.239
Superior Parafoveal	25	305.20	1.462	4.095	0.479	2.555	7.154	0.837
Nasal Parafoveal	25	307.46	1.245	3.487	0.405	2.791	7.815	0.908
Inferior Parafoveal	25	299.20	1.270	3.556	0.424	2.644	7.404	0.884
Temporal Parafoveal	25	292.57	1.222	3.421	0.418	2.636	7.380	0.901
Superior Perifoveal	25	261.20	1.379	3.860	0.528	2.142	5.998	0.820
Nasal Perifoveal	25	276.37	0.919	2.573	0.332	1.987	5.563	0.719
Inferior Perifoveal	25	246.18	1.492	4.177	0.606	2.298	6.433	0.933
Temporal Perifoveal	25	245.71	1.030	2.884	0.419	2.366	6.624	0.963
<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>N = Number of subjects</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</p> <p>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>								

**Table 4: Ganglion Cell + IPL - Normal Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device Measurement	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
Superior	25	70.37	0.641	1.795	0.911	0.715	2.001	1.015
Superior Nasal	25	74.66	0.671	1.878	0.898	0.707	1.980	0.947
Superior Temporal	25	71.46	0.590	1.651	0.825	0.831	2.326	1.162
Inferior	25	68.11	0.634	1.776	0.931	0.663	1.856	0.973
Inferior Nasal	25	73.59	0.699	1.957	0.950	0.768	2.150	1.043
Inferior Temporal	25	73.12	0.553	1.550	0.757	0.708	1.983	0.968
Average	25	71.89	0.291	0.814	0.404	0.365	1.023	0.508
<b>Maestro 6x6 3D Macula</b>								
Superior	25	70.48	0.736	2.060	1.044	0.809	2.266	1.148
Superior Nasal	25	74.62	0.394	1.102	0.528	0.548	1.535	0.735
Superior Temporal	25	71.93	0.611	1.712	0.850	0.712	1.993	0.989
Inferior	25	68.33	0.453	1.268	0.663	0.657	1.841	0.962
Inferior Nasal	25	73.58	0.436	1.220	0.592	0.595	1.667	0.809
Inferior Temporal	25	73.46	0.562	1.573	0.765	0.611	1.712	0.832
Average	25	72.08	0.263	0.735	0.364	0.401	1.124	0.557
<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>N = Number of subjects</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</p> <p>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>								

**Table 5: Ganglion Cell + IPL - Retinal Disease Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device Measurement	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
Superior	26	69.57	1.234	3.456	1.774	1.779	4.982	2.558
Superior Nasal	26	73.78	0.768	2.150	1.041	0.812	2.274	1.101
Superior Temporal	26	70.05	0.963	2.696	1.375	1.734	4.854	2.475
Inferior	26	65.84	1.760	4.928	2.673	1.826	5.113	2.774
Inferior Nasal	26	70.86	1.834	5.136	2.589	1.844	5.164	2.603
Inferior Temporal	26	70.39	1.427	3.995	2.027	2.537	7.103	3.604
Average	26	70.08	0.762	2.134	1.088	0.819	2.294	1.169
<b>Maestro 6x6 3D Macula</b>								
Superior	26	68.87	0.687	1.923	0.997	0.695	1.945	1.008
Superior Nasal	26	74.04	0.841	2.355	1.136	0.926	2.593	1.251
Superior Temporal	26	70.49	1.023	2.866	1.452	1.286	3.601	1.824
Inferior	26	66.77	0.810	2.268	1.213	0.940	2.633	1.408
Inferior Nasal	26	71.07	0.491	1.374	0.690	0.699	1.958	0.984
Inferior Temporal	26	71.37	0.993	2.782	1.392	1.078	3.017	1.510
Average	26	70.45	0.375	1.049	0.532	0.465	1.302	0.660
<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%</p>								

**Table 6: Ganglion Cell + IPL - Glaucoma Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device Measurement	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
Superior	25	63.55	0.884	2.476	1.392	1.011	2.832	1.591
Superior Nasal	25	68.77	0.996	2.790	1.449	1.169	3.274	1.700
Superior Temporal	25	63.93	0.883	2.472	1.381	0.908	2.542	1.420
Inferior	25	59.61	0.932	2.608	1.563	1.063	2.977	1.784
Inferior Nasal	25	66.07	0.868	2.432	1.315	0.980	2.743	1.483
Inferior Temporal	25	63.34	0.902	2.526	1.424	0.935	2.618	1.476
Average	25	64.22	0.403	1.129	0.628	0.460	1.288	0.716
<b>Maestro 6x6 3D Macula</b>								
Superior	25	64.27	0.592	1.658	0.921	0.708	1.983	1.102
Superior Nasal	25	69.54	0.480	1.345	0.691	0.559	1.566	0.804
Superior Temporal	25	66.21	0.766	2.145	1.157	0.924	2.586	1.395
Inferior	25	60.86	0.784	2.194	1.288	0.883	2.472	1.451
Inferior Nasal	25	66.11	0.503	1.407	0.760	0.689	1.928	1.042
Inferior Temporal	25	66.00	0.765	2.142	1.159	0.891	2.494	1.350
Average	25	65.53	0.388	1.087	0.593	0.483	1.351	0.736
<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>N = Number of subjects</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</p> <p>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>								

**Table 7: Ganglion Cell Complex Thickness - Normal Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device Measurement	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
Superior	25	106.36	0.731	2.046	0.687	0.872	2.441	0.819
Superior Nasal	25	118.01	0.969	2.713	0.821	1.070	2.995	0.906
Superior Temporal	25	94.11	0.595	1.665	0.632	0.755	2.115	0.803
Inferior	25	106.27	0.746	2.087	0.702	1.007	2.820	0.948
Inferior Nasal	25	120.43	0.887	2.483	0.736	1.272	3.562	1.056
Inferior Temporal	25	97.48	0.640	1.791	0.656	0.821	2.299	0.842
Average	25	107.11	0.504	1.411	0.470	0.691	1.936	0.645
Superior Average	25	106.16	0.608	1.702	0.573	0.729	2.042	0.687
Inferior Average	25	108.06	0.579	1.621	0.536	0.845	2.367	0.782
<b>Maestro 6x6 3D Macula</b>								
Superior	25	106.95	1.497	4.192	1.400	1.719	4.813	1.607
Superior Nasal	25	118.02	0.634	1.776	0.537	0.942	2.637	0.798
Superior Temporal	25	93.78	0.711	1.992	0.759	0.924	2.587	0.985
Inferior	25	107.29	0.681	1.908	0.635	1.137	3.184	1.060
Inferior Nasal	25	121.27	0.687	1.925	0.567	0.901	2.522	0.743
Inferior Temporal	25	97.09	0.682	1.909	0.702	0.979	2.741	1.008
Average	25	107.43	0.535	1.497	0.498	0.783	2.193	0.729
Superior Average	25	106.25	0.707	1.981	0.666	0.895	2.507	0.843
Inferior Average	25	108.55	0.541	1.515	0.498	0.845	2.365	0.778

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.

N = Number of subjects

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%

**Table 8: Ganglion Cell Complex Thickness - Retinal Disease Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device Measurement	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
Superior	26	108.98	1.462	4.095	1.342	2.295	6.425	2.106
Superior Nasal	26	120.00	0.926	2.593	0.772	0.985	2.758	0.821
Superior Temporal	26	94.96	1.024	2.867	1.078	1.262	3.534	1.329
Inferior	26	105.20	2.236	6.259	2.125	2.236	6.259	2.125
Inferior Nasal	26	116.09	3.729	10.442	3.213	3.752	10.506	3.232
Inferior Temporal	26	97.86	2.231	6.248	2.280	2.420	6.775	2.473
Average	26	107.20	1.192	3.337	1.112	1.192	3.337	1.112
Superior Average	26	107.98	0.756	2.118	0.700	1.157	3.240	1.072
Inferior Average	26	106.39	2.280	6.383	2.143	2.288	6.407	2.151
<b>Maestro 6x6 3D Macula</b>								
Superior	26	107.96	0.899	2.518	0.833	1.081	3.027	1.001
Superior Nasal	26	120.10	0.793	2.221	0.660	0.952	2.665	0.792
Superior Temporal	26	93.87	0.741	2.076	0.790	0.972	2.721	1.035
Inferior	26	106.13	1.160	3.248	1.093	1.160	3.248	1.093
Inferior Nasal	26	117.24	0.721	2.019	0.615	0.862	2.414	0.736
Inferior Temporal	26	95.85	0.780	2.184	0.814	0.901	2.524	0.940
Average	26	106.88	0.518	1.452	0.485	0.643	1.799	0.601
Superior Average	26	107.31	0.599	1.677	0.558	0.802	2.246	0.747
Inferior Average	26	106.41	0.612	1.712	0.575	0.686	1.920	0.644

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.

N = Number of subjects

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%

**Table 9: Ganglion Cell Complex Thickness - Glaucoma Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device Measurement	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
Superior	25	95.85	1.053	2.947	1.098	1.188	3.327	1.240
Superior Nasal	25	108.78	0.850	2.379	0.781	0.897	2.513	0.825
Superior Temporal	25	85.28	1.014	2.840	1.189	1.033	2.893	1.211
Inferior	25	91.59	1.037	2.903	1.132	1.071	2.998	1.169
Inferior Nasal	25	105.43	0.777	2.175	0.737	0.974	2.728	0.924
Inferior Temporal	25	85.08	0.756	2.116	0.888	0.818	2.289	0.961
Average	25	95.34	0.608	1.703	0.638	0.655	1.833	0.687
Superior Average	25	96.64	0.805	2.255	0.833	0.857	2.400	0.887
Inferior Average	25	94.03	0.651	1.823	0.692	0.724	2.028	0.770
<b>Maestro 6x6 3D Macula</b>								
Superior	25	96.85	0.700	1.960	0.723	0.908	2.542	0.937
Superior Nasal	25	108.81	0.691	1.935	0.635	0.892	2.498	0.820
Superior Temporal	25	84.93	0.597	1.671	0.703	0.809	2.264	0.952
Inferior	25	92.15	1.042	2.917	1.131	1.166	3.264	1.265
Inferior Nasal	25	105.99	0.706	1.977	0.666	0.914	2.558	0.862
Inferior Temporal	25	84.51	0.742	2.079	0.878	0.939	2.629	1.111
Average	25	95.59	0.486	1.360	0.508	0.648	1.814	0.678
Superior Average	25	96.86	0.509	1.425	0.526	0.676	1.893	0.698
Inferior Average	25	94.22	0.642	1.798	0.682	0.782	2.189	0.830

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.

N = Number of subjects

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%

**Table 10: Retinal Nerve Fiber Layer - Normal Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device								
Measurement	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
Average	25	105.30	1.388	3.887	1.318	1.598	4.474	1.517
Superior	25	127.89	3.754	10.512	2.936	3.893	10.901	3.044
Nasal	25	79.37	2.765	7.743	3.484	3.044	8.522	3.835
Inferior	25	135.23	3.375	9.449	2.495	4.094	11.464	3.028
Temporal	25	78.68	1.356	3.796	1.723	2.087	5.843	2.652
12-hour - T	25	65.26	1.606	4.496	2.461	1.984	5.554	3.040
12-hour - TS	25	93.36	2.636	7.381	2.824	3.024	8.467	3.239
12-hour - ST	25	138.21	4.533	12.691	3.280	4.933	13.812	3.569
12-hour - S	25	125.15	5.968	16.711	4.769	6.355	17.795	5.078
12-hour - SN	25	120.31	5.282	14.789	4.390	5.534	15.496	4.600
12-hour - NS	25	98.29	5.169	14.474	5.259	5.483	15.353	5.579
12-hour - N	25	62.75	2.490	6.972	3.968	3.514	9.840	5.600
12-hour - NI	25	77.11	4.042	11.318	5.242	4.072	11.402	5.281
12-hour - IN	25	113.67	5.013	14.035	4.410	5.880	16.463	5.173
12-hour - I	25	145.75	5.964	16.700	4.092	6.621	18.538	4.543
12-hour - IT	25	146.36	4.057	11.359	2.772	4.904	13.732	3.351
12-hour - TI	25	77.41	2.295	6.426	2.965	3.490	9.771	4.508
<b>Maestro 6x6 3D Disc</b>								
Average	25	104.32	0.973	2.724	0.933	1.147	3.211	1.099
Superior	25	128.41	2.627	7.356	2.046	2.917	8.167	2.272
Nasal	25	78.14	2.007	5.619	2.569	2.302	6.445	2.946
Inferior	25	135.51	2.003	5.610	1.478	2.503	7.008	1.847
Temporal	25	75.22	1.335	3.738	1.775	1.859	5.206	2.471
12-hour - T	25	61.65	1.396	3.908	2.264	1.816	5.086	2.946
12-hour - TS	25	90.01	2.161	6.050	2.401	2.792	7.817	3.101
12-hour - ST	25	139.48	3.271	9.157	2.345	4.344	12.163	3.114
12-hour - S	25	125.52	4.964	13.898	3.954	5.145	14.407	4.099
12-hour - SN	25	120.20	4.160	11.647	3.461	4.294	12.024	3.573
12-hour - NS	25	97.39	3.622	10.143	3.720	4.295	12.025	4.410
12-hour - N	25	61.11	1.526	4.273	2.497	1.759	4.926	2.879
12-hour - NI	25	75.87	2.995	8.385	3.947	3.423	9.585	4.511
12-hour - IN	25	113.57	3.298	9.234	2.904	3.590	10.052	3.161
12-hour - I	25	147.83	3.633	10.172	2.457	4.388	12.287	2.968
12-hour - IT	25	145.02	3.980	11.144	2.745	4.366	12.224	3.010
12-hour - TI	25	73.98	2.212	6.194	2.990	3.259	9.125	4.405

			Repeatability			Reproducibility		
Device	N	Mean	SD	Limit	CV%	SD	Limit	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.  
 N = Number of subjects  
 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%

**Table 11: Retinal Nerve Fiber Layer - Retinal Disease Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
Average	26	101.46	1.618	4.529	1.594	1.916	5.364	1.888
Superior	26	123.56	4.099	11.476	3.317	4.517	12.648	3.656
Nasal	26	76.76	3.346	9.370	4.359	3.948	11.055	5.143
Inferior	26	128.81	3.343	9.360	2.595	5.427	15.194	4.213
Temporal	26	76.73	1.708	4.783	2.226	2.166	6.064	2.823
12-hour - T	26	67.02	1.942	5.438	2.898	2.510	7.028	3.745
12-hour - TS	26	91.79	2.691	7.535	2.932	3.143	8.799	3.424
12-hour - ST	26	133.09	4.608	12.901	3.462	5.515	15.443	4.144
12-hour - S	26	122.77	6.633	18.572	5.403	7.191	20.135	5.857
12-hour - SN	26	114.84	6.720	18.816	5.852	6.720	18.816	5.852
12-hour - NS	26	91.74	6.559	18.365	7.150	6.839	19.149	7.455
12-hour - N	26	64.72	3.133	8.772	4.840	3.512	9.833	5.426
12-hour - NI	26	73.86	6.014	16.839	8.143	6.407	17.939	8.675
12-hour - IN	26	111.63	5.625	15.749	5.039	9.004	25.210	8.066
12-hour - I	26	146.30	5.483	15.353	3.748	6.994	19.583	4.781
12-hour - IT	26	128.52	5.212	14.593	4.055	5.932	16.610	4.616
12-hour - TI	26	71.39	2.549	7.136	3.570	2.791	7.815	3.910
<b>Maestro 6x6 3D Disc</b>								
Average	26	101.72	1.102	3.086	1.084	1.505	4.214	1.480
Superior	26	125.25	2.512	7.034	2.006	2.609	7.305	2.083
Nasal	26	76.24	2.175	6.090	2.853	3.523	9.863	4.620
Inferior	26	131.15	2.293	6.419	1.748	2.830	7.924	2.158
Temporal	26	74.25	1.287	3.603	1.733	1.446	4.048	1.947
12-hour - T	26	64.47	1.600	4.480	2.482	1.916	5.365	2.972
12-hour - TS	26	89.31	2.218	6.210	2.483	2.644	7.404	2.961
12-hour - ST	26	134.93	4.220	11.815	3.127	5.015	14.042	3.717
12-hour - S	26	123.86	5.350	14.980	4.320	5.865	16.423	4.736
12-hour - SN	26	116.90	3.694	10.343	3.160	4.234	11.854	3.622
12-hour - NS	26	91.83	4.177	11.694	4.548	6.026	16.873	6.562
12-hour - N	26	63.16	3.237	9.065	5.125	3.583	10.031	5.672
12-hour - NI	26	73.70	4.219	11.814	5.725	5.444	15.242	7.387
12-hour - IN	26	114.30	4.239	11.869	3.709	5.469	15.314	4.785
12-hour - I	26	150.51	4.359	12.206	2.896	4.874	13.648	3.239
12-hour - IT	26	128.61	3.770	10.556	2.932	4.834	13.535	3.759
12-hour - TI	26	68.95	2.020	5.656	2.930	2.473	6.925	3.587

			Repeatability			Reproducibility		
Device	N	Mean	SD	Limit	CV%	SD	Limit	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.  
 N = Number of subjects  
 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%

**Table 12: Retinal Nerve Fiber Layer - Glaucoma Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device								
Measurement	N	Mean	SD	Limit	CV%	SD	Limit (Ratio)	CV%
<b>Maestro 12x9 3D Wide</b>								
Average	25	83.55	1.646	4.609	1.970	1.752	4.906	2.097
Superior	25	97.32	3.814	10.679	3.919	3.948	11.055	4.057
Nasal	25	70.63	3.805	10.653	5.387	4.036	11.301	5.715
Inferior	25	102.90	3.271	9.160	3.179	3.402	9.526	3.306
Temporal	25	63.29	1.370	3.837	2.165	1.941	5.434	3.066
12-hour - T	25	55.91	1.779	4.980	3.181	2.534	7.094	4.532
12-hour - TS	25	73.53	2.471	6.918	3.360	2.882	8.071	3.920
12-hour - ST	25	101.84	4.691	13.134	4.606	4.731	13.246	4.645
12-hour - S	25	99.85	6.176	17.294	6.185	7.648	21.415	7.659
12-hour - SN	25	90.18	5.725	16.031	6.349	5.828	16.318	6.463
12-hour - NS	25	80.96	6.688	18.727	8.261	6.719	18.813	8.299
12-hour - N	25	58.29	4.138	11.586	7.099	4.436	12.422	7.611
12-hour - NI	25	72.63	4.578	12.819	6.304	4.903	13.727	6.750
12-hour - IN	25	94.44	4.453	12.468	4.715	5.457	15.280	5.778
12-hour - I	25	117.00	6.214	17.400	5.311	6.214	17.400	5.311
12-hour - IT	25	97.27	4.222	11.822	4.341	4.684	13.114	4.815
12-hour - TI	25	60.46	2.243	6.280	3.709	2.530	7.083	4.184
<b>Maestro 6x6 3D Disc</b>								
Average	25	83.70	1.615	4.521	1.929	1.618	4.530	1.933
Superior	25	100.60	3.584	10.035	3.563	3.732	10.450	3.710
Nasal	25	70.12	2.264	6.338	3.228	2.364	6.619	3.371
Inferior	25	103.11	3.435	9.617	3.331	3.619	10.132	3.510
Temporal	25	61.03	2.104	5.892	3.448	2.126	5.954	3.484
12-hour - T	25	53.80	2.642	7.397	4.911	2.740	7.671	5.092
12-hour - TS	25	72.04	3.961	11.090	5.498	3.961	11.090	5.498
12-hour - ST	25	103.27	4.067	11.386	3.938	5.553	15.548	5.377
12-hour - S	25	103.83	6.085	17.039	5.861	7.046	19.730	6.786
12-hour - SN	25	94.79	5.678	15.898	5.990	5.727	16.036	6.042
12-hour - NS	25	82.98	4.307	12.061	5.191	4.469	12.512	5.386
12-hour - N	25	55.65	2.670	7.477	4.798	2.734	7.656	4.913
12-hour - NI	25	71.73	3.964	11.099	5.527	4.035	11.297	5.625
12-hour - IN	25	94.94	6.152	17.226	6.480	6.716	18.805	7.074
12-hour - I	25	119.03	5.620	15.735	4.721	5.740	16.072	4.822
12-hour - IT	25	95.37	4.607	12.899	4.831	4.691	13.135	4.919
12-hour - TI	25	57.26	2.278	6.379	3.978	2.572	7.200	4.491

			Repeatability			Reproducibility		
Device	N	Mean	SD	Limit	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.  
 N = Number of subjects  
 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%

**Table 13: Optic Disc - Normal Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device Measurement	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
C/D Vertical	25	0.46	0.030	0.085	6.600	0.031	0.088	6.863
C/D Area	25	0.25	0.013	0.037	5.172	0.015	0.043	6.023
Disc Area	25	2.10	0.074	0.207	3.520	0.089	0.249	4.233
Cup Area	25	0.57	0.022	0.062	3.890	0.025	0.071	4.474
Rim Area	25	1.54	0.072	0.203	4.711	0.087	0.243	5.640
Cup Volume	25	0.10	0.006	0.016	5.322	0.007	0.020	7.014
Rim Volume	25	0.28	0.018	0.051	6.571	0.022	0.062	7.967
<b>Maestro 6x6 3D Disc</b>								
C/D Vertical	25	0.46	0.021	0.059	4.549	0.023	0.066	5.089
C/D Area	25	0.26	0.013	0.036	4.937	0.014	0.040	5.406
Disc Area	25	1.92	0.064	0.178	3.313	0.078	0.219	4.074
Cup Area	25	0.54	0.020	0.055	3.666	0.025	0.071	4.730
Rim Area	25	1.39	0.065	0.183	4.708	0.075	0.211	5.443
Cup Volume	25	0.10	0.005	0.014	4.747	0.007	0.020	6.759
Rim Volume	25	0.24	0.015	0.043	6.359	0.020	0.055	8.139
<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>N = Number of subjects</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</p> <p>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>								

**Table 14: Optic Disc - Retinal Disease Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
C/D Vertical	26	0.47	0.025	0.071	5.377	0.030	0.085	6.430
C/D Area	26	0.26	0.019	0.054	7.387	0.020	0.057	7.789
Disc Area	26	2.25	0.087	0.243	3.858	0.112	0.314	4.981
Cup Area	26	0.61	0.041	0.115	6.728	0.043	0.121	7.080
Rim Area	26	1.64	0.095	0.265	5.762	0.116	0.326	7.088
Cup Volume	26	0.11	0.009	0.025	8.404	0.022	0.061	20.586
Rim Volume	26	0.28	0.020	0.056	7.186	0.027	0.076	9.775
<b>Maestro 6x6 3D Disc</b>								
C/D Vertical	26	0.46	0.019	0.053 (0.439)	4.117	0.021	0.058 (0.472)	4.519
C/D Area	26	0.25	0.009	0.024 (0.469)	3.400	0.010	0.029 (0.533)	4.079
Disc Area	26	2.07	0.065	0.183 (0.853)	3.163	0.079	0.220 (0.754)	3.803
Cup Area	26	0.55	0.016	0.044 (0.441)	2.855	0.019	0.053 (0.513)	3.438
Rim Area	26	1.52	0.062	0.172 (0.818)	4.057	0.073	0.205 (0.732)	4.817
Cup Volume	26	0.10	0.005	0.014 (0.192)	4.827	0.012	0.032 (0.420)	11.024
Rim Volume	26	0.26	0.015	0.041 (0.926)	5.627	0.017	0.046 (0.949)	6.419
<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>N = Number of subjects</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</p> <p>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>								

**Table 15: Optic Disc - Glaucoma Eyes Repeatability and Reproducibility**

			Repeatability			Reproducibility		
Device								
Measurement	N	Mean	SD	Limit	CV%	SD	Limit	CV%
<b>Maestro 12x9 3D Wide</b>								
C/D Vertical	25	0.77	0.031	0.086	4.030	0.032	0.090	4.185
C/D Area	25	0.59	0.020	0.057	3.469	0.024	0.068	4.130
Disc Area	25	2.35	0.075	0.209	3.179	0.089	0.251	3.811
Cup Area	25	1.40	0.048	0.134	3.430	0.056	0.157	4.017
Rim Area	25	0.95	0.064	0.179	6.722	0.080	0.225	8.449
Cup Volume	25	0.41	0.058	0.164	14.274	0.070	0.196	17.103
Rim Volume	25	0.12	0.011	0.030	8.953	0.014	0.038	11.152
<b>Maestro 6x6 3D Disc</b>								
C/D Vertical	25	0.76	0.020	0.055	2.575	0.021	0.058	2.743
C/D Area	25	0.59	0.011	0.031	1.852	0.012	0.032	1.959
Disc Area	25	2.15	0.065	0.182	3.013	0.071	0.198	3.285
Cup Area	25	1.28	0.045	0.125	3.485	0.048	0.134	3.755
Rim Area	25	0.87	0.038	0.107	4.379	0.041	0.115	4.701
Cup Volume	25	0.41	0.024	0.067	5.813	0.024	0.068	5.859
Rim Volume	25	0.11	0.007	0.020	6.682	0.008	0.022	7.201
<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>N = Number of subjects</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</p> <p>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>								

## Reference Database:

The reference database study included the assessment of 399 subject eyes from normal study subjects across a predefined range of ages and ethnicities. 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 small and large super pixel grid and TSNIT circle profile measurements. The reference limits at the 1<sup>st</sup>, 5<sup>th</sup>, 95<sup>th</sup> and 99<sup>th</sup> percentile points were determined. The database age range is 18 – 88 years.

**Table 16: Reference Database Demographic Data**

	Total (N=399)
Age (years)	
n	399
Mean (SD)	46.3 (16.3)
Median	47.0
Min, Max	18, 88
Age group, n (%)	
18-30 years	89 (22)
31-40 years	76 (19)
41-50 years	66 (17)
51-60 years	78 (20)
61-70 years	55 (14)
70+ years	35 (9)
Gender, n (%)	
Male	173 (43)
Female	226 (57)
Ethnicity, n (%)	
Hispanic or Latino	71 (18)
Not Hispanic and not Latino	328 (82)
Race, n (%)	
White	234 (59)
Black/African American	81 (20)
American Indian/Alaskan Native	4 (1)
Asian	51 (13)
Native American/Pacific Islander	7 (2)
Other	22 (6)

**Substantial Equivalence Comparison Table**

	<b>Subject Device: Topcon 3D OCT-1 Maestro</b>	<b>Primary Predicate: Optovue iVue (K121739)</b>	<b>Secondary Predicate Device: Topcon TRC-NW300 (K123460)</b>
<b>Indications for Use</b>	<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>	<p>The iVue with Normative Database is an optical coherence tomography system intended for in vivo imaging, axial cross-sectional, three-dimensional imaging and measurement of anterior and posterior ocular structures. The iVue is a non-contact, high resolution tomographic imaging device. It is intended for in vivo imaging, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including retina, retinal nerve fiber layer, ganglion cell complex (GCC), optic disc, cornea, and anterior chamber of the eye. The iVue with Normative Database is a quantitative tool for the comparison of retina, retinal nerve fiber layer, ganglion cell complex, and optic disc measurements to a database of known normal subjects. The iVue with Normative Database is indicated for use as a device to aid in the diagnosis, documentation, and management of ocular health and diseases in the adult population.</p>	<p>The TRC-NW300 intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, without the use of a mydriatic.</p>
<b>Product Code</b>	OBO, HKI	HKI	HKI
<b>Technological Characteristics</b>	<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 images.</p>	<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 CCD camera are employed to obtain fundus/anterior Color images.</p>
<b>OCT</b>			
<b>Light Source</b>	Spectral domain OCT (SD-OCT) using a superluminescent diode (SLD) with center wavelength 840 nm.	Spectral domain OCT (SD-OCT) using a superluminescent diode (SLD) with center wavelength 840 nm.	N/A

	<b>Subject Device: Topcon 3D OCT-1 Maestro</b>	<b>Primary Predicate: Optovue iVue (K121739)</b>	<b>Secondary Predicate Device: Topcon TRC-NW300 (K123460)</b>
<b>Analysis</b>	<u>For posterior:</u> - Retinal layer segmentation - Thickness calculation - Optic disc analysis  <u>For anterior:</u> NA	<u>For posterior:</u> - Retinal layer segmentation - Thickness calculation - Optic disc analysis  <u>For anterior:</u> - Pachymetry measurement - Pachymetry map - Angle measurement	N/A
<b>Fundus Camera</b>			
<b>Observation</b>	Light source - IR LED Camera - CMOS camera	N/A	Light source - Halogen lamp Camera - CCD camera

## Conclusion

As described in this 510(k) Summary, the performance testing deemed necessary was conducted and the resultant data support the substantial equivalence of the 3D OCT-1 Maestro to the primary predicate device Optovue's iVue with Normative Database (iVue) (K121739).