July 24, 2019

Canon Inc.
% Ryan Bouchard
VP, Medical Devices
Ora, Inc.
300 Brickstone Square
Andover, MA 01810

Re: K182942
Trade/Device Name: Canon OCT-A1
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, HLI
Dated: June 17, 2019
Received: June 18, 2019

Dear Ryan Bouchard:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Bradley Cunningham
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182942

Device Name
Canon OCT-A1

Indications for Use *(Describe)*
The Canon OCT-A1 is an optical coherence tomography system indicated for the in-vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and an aid in the diagnosis and management of retinal diseases by a clinician.

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

This summary of the 510(k) premarket notification for the Canon OCT-A1 K182942 is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

a. Owner Company name, address

Canon Inc.
9-1, Imaikami-cho
Nakahara-ku, Kawasaki
Kanagawa 211-8501 Japan

Contact person: Tatsuya Yamazaki

b. Contact/Application Correspondent

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c. Date Prepared

July 24, 2019

d. Name of Device

Trade Name:	Canon OCT-A1 *-
Common Names:	Optical Coherence Tomography
Classification Name:	Tomography, optical coherence
Classification Regulation:	21 CFR 886.1570
Product Code:	OBO
510(k) Number:	K182942

e. Predicate Device

Optovue RTVue XR OCT Avanti with Normative Database (K153080)

f. Device Description

The Canon OCT-A1 *- is an Optical Coherence Tomography (OCT) system intended for use as a non-invasive imaging device for viewing and measuring ocular tissue structures with micrometer range resolution. The OCT-A1 is a computer controlled ophthalmic imaging system. The device scans the patient's eye using a low coherence interferometer to measure the reflectivity of retinal tissue. The cross sectional retinal tissue structure is composed of a sequence of A-scans. It has a traditional patient and instrument interface like most ophthalmic devices.

*: “A1” stands for the “Automatic-1” which means the first Canon OCT with the automatic alignment and adjustment feature.

The OCT-A1 uses Fourier Domain OCT, a method that involves spectral analysis of the returned light rather than mechanic moving parts in the depth scan. Fourier Domain OCT allows scan speeds about 65 times faster than the mechanical limited Time Domain scan speeds.

The OCT-A1 quantifies numerous ocular structures. The various retinal layers or structures, which are imaged or measured, include the following:

1) The internal limiting membrane (ILM)
2) The retinal nerve fiber layer (RNFL)
3) The NFL+GCL+IPL thickness
4) The retinal pigment epithelium (RPE)
5) Bruch’s membrane (BM)
6) The full retina thickness

g. Indications for Use

The Canon OCT-A1 is an optical coherence tomography system indicated for the in-vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and an aid in the diagnosis and management of retinal diseases by a clinician.

h. Statement of Substantial Equivalence

Canon, Inc. believes that the Canon OCT-A1 described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed predicate device that is a Class II medical device which is the Optovue RTVue XR OCT cleared in K153080.

Feature	**Canon OCT-A1**	**RTVue XR OCT (K153080)**
Manufacturer	Canon Inc.	Optovue, Inc.
Classification	886.1570	886.1570
Product Code	OBO	HLI, OBO
Indications for use	The Canon OCT-A1 is an optical coherence tomography system indicated for the in-vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and an aid in the diagnosis and management of retinal diseases by a clinician.	The RTVue XR OCT Avanti with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician. The RTVue XR OCT Avanti with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disc measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases. The RTVue XR OCT Avanti with AngioVue™ software is indicated as an aid in the visualization of vascular structures of the retina and choroid.
Technological Characteristics: OCT		
Imaging	Spectral Domain OCT	Spectral Domain OCT
Scan Rate	70,000 A-Scan/s	70,000 A-Scan/s
Light Source		
-Wave Length	860 nm (SLD)	840 nm (SLD)
-Power Output	7.5 mW	Unknown
-Continuous/Pulsed	Pulsed	Unknown
-Pulse Durations	100μs	Unknown
Field of View	Scan width: 3 mm to 10 mm Scan depth: 2 mm	Scan width: 2 mm to 12 mm Scan depth: 2 to 3 mm
Optical Resolution	20μm (in the X and Y directions), 3.4 μm (in the Z direction)	15μm (in the X and Y directions), 5 μm (in the Z direction)
Exposure Power at Pupil	893 μW	≤750 μW

Feature	Canon OCT-A1	RTVue XR OCT (K153080)
Technological Characteristics: SLO		
Imaging	Near IR observation (Confocal laser scanning)	Near IR observation
Light Source		
-Wavelength	780 nm (LD)	735 nm (LED
-Power Output	30mW	Unknown
-Continuous/Pulsed	Pulsed	Unknown
-Pulse Durations	41ns	Unknown
Field of View	45° x 34°	32° x 22°
Optical Resolution	25µm (in the X and Y directions)	25µm (in the X and Y directions)
Technological Characteristics: Light for Anterior Segment Adjustment		
Wavelength	970 nm	Unknown
Power output	5.5mW	Unknown
Continuous/Pulsed	Continuous	Unknown
Pulse Durations	-	Unknown
Technological Characteristics: Internal Fixation Lamp		
Wavelength	590 nm	Unknown
Power output	2.8mW	Unknown
Continuous/Pulsed	Pulsed	Unknown
Pulse Durations	260.ns	Unknown
Technological Characteristics: External Fixation Lamp		
Wavelength	460 nm	Unknown
Power output	2.32 ed	Unknown
Continuous/Pulsed	Continuous	Unknown
Pulse Durations	-	Unknown
Technological Characteristics: Others		
Minimum Pupil Diameter Required	φ 3.0 mm	φ 2.5 mm
Focus Range	- 18 D to +15 D	- 15 D to +12 D

Feature	Canon OCT-A1	RTVue XR OCT (K153080)
Measurement and Analysis		
Imaging of the Fundus	SLO	SLO
Retinal Thickness Measurement		
-Total	ILM to RPE	VRI to RPE
-Inner	No	VRI to IPL
-Outer	No	RPE to IPL
GCC Thickness (NFL+GCL+IPL Thickness)	Yes	Yes
- S - I difference	No	Yes
- Focal loss volume	No	Yes
- Global loss volume	No	Yes
RNFL Thickness Measurement	Along the circumference of a circle of 3.45 mm diameter which is targeted around the ONH	Along the circumference of a circle of 3.45 mm diameter which is targeted around the ONH
Optic Disc Analysis		
-Disc area	Yes	Yes
-Rim area	Yes	Yes
-Cup area	No	Yes
-Cup volume	Yes	Yes
-Rim volume	Yes	Yes
-Nerve head volume	No	Yes
-C/D area	Yes	Yes
-C/D vertical	Yes	Yes
-C/D horizontal	Yes	Yes
-R/D minimum	Yes	No

Both the Canon OCT-A1 and the Optovue XR OCT are OCT devices. The principle of operation is identical in that both devices employ a non-invasive, non-contact low-coherence interferometry technique [specifically, spectral domain optical coherence tomography (SD-OCT)] to generate high-resolution cross-sectional images of internal ocular tissue microstructures by measuring optical reflections from tissue. Both provide cross sectional images of the posterior structures of the eye (i.e., retina, including the ganglion and retinal nerve fiber layers.

There are minor differences in technological characteristics between the Canon OCT-A1 and the predicate device for the OCT including wavelength, size of field of view, optical

resolution, and exposure power at pupil. There are also minor differences in technological characteristics between the Canon OCT-A1 and the predicate device for the SLO including wavelength and field of view. There are also differences related to minimum pupil diameter required for measurement and focus range. Regarding measurement and analysis, the retinal thickness measurement methodology differs between the Canon OCT-A1 and the predicate device. There are also differences in the optic disc analysis.

Performance testing including both bench testing and clinical testing demonstrated substantial equivalence. Therefore, based on the same intended use and similar technological characteristics with substantial equivalence to the predicate device confirmed with performance testing, the Canon OCT-A1 is technologically and functionally equivalent to the predicate device, RTVue XR OCT (K153080). The differences between the proposed device, OCT-A1, and the predicate device are insignificant and do not raise new issues of safety or effectiveness of the device. The Canon OCT-A1 is as safe and effective as its predicate devices, and thus, may be considered substantially equivalent.

i. Performance Testing

Canon, Inc. performed bench tests to ensure safety and effectiveness and to demonstrate substantial equivalence of the OCT-A1 to the predicate device. A list of testing conducted included:

- Scan Speed
- Transverse and Depth Resolution
- Field of View/Angle of View
- Scan Depth
- Testing to the Standards
  Electrical Safety: AAMI/ANSI ES60601-1
  Electromagnetic Compatibility: IEC 60601-1-2
  Safety of Laser Products: IEC 60825-1
  Biocompatibility: ISO 10993-1, ISO 10993-5, ISO 10993-10
  Ophthalmic Instruments: ISO 15004-1, ISO 15004-2
  Optical Radiation Hazard Analysis: ANSI Z80.36-2016.

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-.
The software verification and validation was conducted in two stages, one which included bench testing based on proper recognition of layer and quantitative measurement of thickness or area. The second stage of the software validation was performed by involving human eyes in a clinical evaluation.

Clinical Testing: A clinical study was conducted to demonstrate substantial equivalence of the Canon OCT-A1 (OCT-HS-100) in comparison with Optovue RTVue Avanti. The repeatability and reproducibility were evaluated for the measurements of: Full retinal

thickness; Retinal nerve fiber layer (RNFL) thickness; Ganglion cell complex (GCC) thickness; and Optic nerve head (ONH) The main objective of the clinical study was to assess agreement and precision of the Canon OCT-A1 (OCT-HS-100) in comparison with the Optovue RTVue Avanti. The study was a prospective comparative, randomized, single center study conducted in the US to gather agreement and precision data in at least 99 evaluable eyes, approximately 33 eligible subjects in each of the study subject groups: normal subjects; subjects with glaucoma; and subjects with retinal disease.

The primary inclusion criteria for all groups included: Male or female subjects from 18 years of age or older who have full legal capacity to volunteer on the date the informed consent is signed; Subjects who can follow the instructions by the clinical staff at the clinical site, and can attend examinations on the scheduled examination date; Subjects who agree to participate in the study

In addition each of the groups had inclusion criteria associated with the specific group.

Normal Group:

- Subjects with normal eye examinations (without pathology) in one or both eyes on the date of the study visit as observed with a +90 Diopter Fundus Lens;
- Subjects with current best-spectacle-corrected visual acuity (BSCVA) of 20/40 or better in the normal eye(s)

Glaucoma Group:

- Subjects who have been diagnosed with glaucoma in the glaucoma study eye(s)
- with a current BSCVA of 20/40 or better in the glaucoma study eye(s)
- History of visual field defects within the previous two (2) months from the study visit or measured on the day of the study visit that is consistent with glaucomatous optic nerve damage

Retinal Disease Group:

- Subjects with a current BSCVA of 20/400 or better in the retinal disease study eye(s) at the study visit
- Subjects diagnosed with retinal pathology including but not limited to: Non Exudative Macular Degeneration (dry AMD), Diabetic Macular Edema, Macular Hole, Epiretinal Membrane, Cystoid Macular Edema, or other retinal disease in the study eye(s) as confirmed within the past six (6) months, who exhibit structural lesions in the study eye
- Subjects diagnosed with retinal pathology including but not limited to: Neovascular Macular Degeneration (wet AMD), Diabetic Retinopathy, Retinal Artery Occlusion, Retinal Vein Occlusion or other retinal disease in the study eye(s) as confirmed within the past six (6) months, who exhibit vascular and/or ischemic lesions in the study eye.

The exclusion criteria was similar for all groups and included:

- Subjects unable to tolerate ophthalmic imaging;
- Subjects with ocular media not sufficiently clear to obtain acceptable OCT images;
- Subjects with a history of leukemia, dementia or multiple sclerosis.

- Subject has a condition or be in a situation which the investigator feels may put the subject at significant risk, may confound the study results, or may interfere significantly with the subject's participation in the study

Group specific exclusion criteria included:

- Normal Group: Subjects with any current ocular pathology other than cataract in the normal eye(s), as determined by self-report and/or investigator assessment at the study visit;
- Retinal Disease Group: Subjects with glaucoma in the retinal disease study eye(s), as determined by self-report and/or investigator assessment at the study visit

Three Canon OCT-A1 devices and 3 Optovue RTVue Avanti devices were used. Each Canon OCT-A1 device was paired with 1 of the Optovue RTVue Avanti devices. One device operator was assigned to each device pair to create 3 distinct operator/device configurations. Device operators and investigators were masked to the automated results of segmentation.

This study included 125 subjects with 37 in the normal group, 37 in the glaucoma group, and 38 in the retinal disease group. The study included two main analyses: 1) analysis of agreement and 2) analysis of precision.

In the effectiveness population, the mean (SD) age was 39.1 (15.28) years for the normal eye subjects, 71.6 (8.78) years for the glaucoma eye subjects, 62.1 (15.11) years for the retinal disease eye subjects, 53.5 (17.38) years for the FFA normal eye subjects, and 59.3 (14.73) years FFA retinal disease eye subjects. The overall mean age of all subjects was 57.5 (18.67) years. Sixty-one females and 64 males participated (48.8% and 51.2%, respectively), and the majority of subjects were white 92 (73.6%) and not Hispanic or Latino 101 (80.8%).

Analysis of Agreement Summary

Full Retinal Thickness (FRT)

The normal population showed Canon Macula 3D scans tended to have higher FRTs by about 10 to 30 μm depending on the parameter with mean differences ranging from 12.56 to 29.95 μm.

The glaucoma population showed Canon Macula 3D scans tended to have higher FRTs by about 15 to 30 μm depending on the parameter with mean differences ranging from 15.42 to 29.39 μm.

The retinal disease population showed Canon Macula 3D scans tended to have higher FRTs by about 15 to 25 μm depending on the parameter with mean differences ranging from 12.52 to 24.46 μm.

See Table 1 for the mean differences and 95% Limits of Agreement (LOA). Some of the 95% LOAs were fairly wide, as seen in Table 1.

The differences shown between the Canon and the Optovue devices are largely because the two devices use different bands in the RPE as the outer border of the retina. Optovue uses the 2nd hyper reflective band (upper border of RPE) as an outer border of the retina and the Canon uses the 3rd hyper reflective band (lower border of RPE) as an outer border of the retina. In addition, the diameter of the outer section of the grid for the Canon OCT-A1 is 6mm whereas the Optovue uses a 5mm diameter.

FRT is summarized in Table 1.

Table 1 FRT between Macula 3D and Retinal Map (Effectiveness Population)

Subject Population Comparable Parameter	Canon OCT-A1 Mean (SD)	Optovue RTVue Avanti Mean (SD)	Mean Difference (SD)	95% CI for Mean Difference	95% LOA for Differences
All Configurations					
Normal – N	37	37			
Central (µm)	267.20 (19.396)	248.89 (18.222)	18.32 (5.056)	(16.69, 19.95)	(8.20, 28.43)
Para Inferior (µm)	339.95 (15.682)	310.00 (16.159)	29.95 (6.066)	(28.00, 31.91)	(17.82, 42.09)
Para Nasal (µm)	344.05 (17.430)	315.30 (18.034)	28.75 (7.179)	(26.44, 31.06)	(14.39, 43.11)
Para Superior (µm)	343.27 (18.369)	314.62 (18.160)	28.65 (7.468)	(26.25, 31.06)	(13.72, 43.59)
Para Temporal (µm)	329.85 (16.339)	301.92 (16.948)	27.93 (6.769)	(25.75, 30.11)	(14.39, 41.47)
Peri Inferior (µm)	285.94 (13.608)	273.38 (13.303)	12.56 (7.029)	(10.30, 14.83)	(-1.49, 26.62)
Peri Nasal (µm)	314.45 (18.170)	296.76 (16.744)	17.69 (6.606)	(15.56, 19.82)	(4.48, 30.90)
Peri Superior (µm)	300.56 (14.849)	283.70 (14.024)	16.86 (5.773)	(15.00, 18.72)	(5.31, 28.41)
Peri Temporal (µm)	284.87 (12.895)	271.54 (12.747)	13.33 (6.084)	(11.37, 15.29)	(1.16, 25.50)
Glaucoma – N	37	37			
Central (µm)	281.48 (35.758)	261.59 (34.850)	19.90 (24.654)	(11.95, 27.84)	(-29.41, 69.21)
Para Inferior (µm)	325.21 (28.364)	301.11 (28.801)	24.10 (7.184)	(21.78, 26.41)	(9.73, 38.47)
Para Nasal (µm)	336.74 (33.194)	308.35 (26.378)	28.39 (27.059)	(19.67, 37.11)	(-25.73, 82.51)
Para Superior (µm)	327.52 (31.249)	300.97 (25.159)	26.55 (19.224)	(20.35, 32.74)	(-11.90, 64.99)
Para Temporal (µm)	319.34 (39.493)	298.03 (40.564)	21.31 (6.153)	(19.33, 23.29)	(9.00, 33.62)
Peri Inferior (µm)	278.66 (47.999)	262.14 (34.713)	16.53 (21.158)	(9.71, 23.35)	(-25.79, 58.85)
Peri Nasal (µm)	299.82 (40.902)	284.22 (29.109)	15.60 (17.921)	(9.83, 21.37)	(-20.24, 51.44)
Peri Superior (µm)	286.41 (49.447)	268.70 (27.373)	17.71 (34.760)	(6.51, 28.91)	(-51.81, 87.23)
Peri Temporal (µm)	278.93 (38.129)	263.51 (36.210)	15.42 (13.724)	(10.99, 19.84)	(-12.03, 42.86)
Retinal Disease – N	38	38			
Central (µm)	301.31 (76.663)	283.08 (87.687)	18.23 (26.086)	(9.93, 26.52)	(-33.94, 70.40)
Para Inferior (µm)	339.82 (62.561)	318.58 (58.490)	21.24 (26.018)	(12.97, 29.52)	(-30.79, 73.28)
Para Nasal (µm)	341.23 (48.955)	320.34 (56.855)	20.89 (12.453)	(16.93, 24.85)	(-4.02, 45.79)
Para Superior (µm)	340.67 (60.800)	316.21 (60.384)	24.46 (26.722)	(15.97, 32.96)	(-28.98, 77.91)
Para Temporal (µm)	332.88 (73.242)	313.21 (72.336)	19.67 (19.849)	(13.36, 25.98)	(-20.03, 59.37)
Peri Inferior (µm)	292.15 (47.420)	275.61 (40.020)	16.54 (19.180)	(10.44, 22.64)	(-21.82, 54.90)
Peri Nasal	313.46 (35.589)	297.42 (39.443)	16.04 (10.678)	(12.65, 19.44)	(-5.31, 37.40)
Peri Superior (µm)	297.10 (33.689)	284.58 (40.834)	12.52 (14.643)	(7.86, 17.17)	(-16.77, 41.80)
Peri Temporal (µm)	293.17 (65.016)	279.74 (62.990)	13.44 (15.711)	(8.44, 18.43)	(-17.99, 44.86)

Abbreviations: CI = confidence interval; FRT = full retinal thickness; LOA = limit of agreement; N = number of eyes; SD = standard deviation

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. N was the number of eyes with measurements from each device. Difference was calculated as the test device minus the predicate device. The 95% CIs for the mean difference was based on t-distribution. 95% LOA = mean difference +/- 2 x difference SD.

Retinal Nerve Fiber Layer Thickness

Refer to Table 2 for the mean differences and 95% Limits of Agreement (LOA) for measurements of the Retinal Nerve Fiber Layer (RNFL) thickness. Mean differences are

generally less than 10% of the thickness. Some of the RFNL sectors for glaucoma patients and for retinal disease patients show wide limits of agreement. For this population in these sectors subject variability in the scans between the Canon and the Optovue devices resulted in larger mean differences and greater standard deviations (SD) resulting in wide LOA. A review of the patients included in this particular study subgroup shows significant disease and disruption in the layers of the retina. Differences in technology between the test and predicate devices can cause these wider LOAs.

Overall the mean differences were small, ranging from -2.999 to 8.378 µm for all comparable parameters and eye populations. As noted above the LOA for temporal and nasal sectors for the glaucoma population was wide, indicating substantial variation in the measurements between the two devices. (Table 2).

Table 2 RNFL Thickness between Disc 3D and ONH (Effectiveness Population)

Subject Population Comparable Parameter	Canon OCT-A1 Mean (SD)	Optovue RTVue Avanti Mean (SD)	Mean Difference (SD)	95% CI for Mean Difference	95% LOA for Differences
All Configurations					
Normal - N	37	37			
Inferior-4 (µm)	132.792 (17.9680)	124.414 (15.0461)	8.378 (9.3310)	(5.372, 11.385)	(-10.284, 27.040)
Nasal-4 (µm)	85.962 (12.2673)	79.339 (7.2549)	6.623 (9.3357)	(3.615, 9.631)	(-12.048, 25.294)
Superior-4 (µm)	126.668 (14.0183)	124.050 (12.3126)	2.619 (12.3586)	(-1.364, 6.601)	(-22.099, 27.336)
Temporal-4 (µm)	70.409 (14.6871)	73.408 (11.7727)	-2.999 (6.6947)	(-5.156, -0.842)	(-16.389, 10.390)
RNFL TSNIT Average (µm)	103.673 (9.5828)	100.302 (7.9933)	3.371 (4.9991)	(1.760, 4.981)	(-6.628, 13.369)
Glaucoma - N	36	36			
Inferior-4 (µm)	99.744 (25.3340)	92.455 (22.1833)	7.289 (10.3872)	(3.896, 10.683)	(-13.485, 28.064)
Nasal-4 (µm)	70.437 (13.9450)	64.364 (19.0955)	6.073 (17.3258)	(0.413, 11.733)	(-28.579, 40.724)
Superior-4 (µm)	93.855 (19.4669)	92.792 (19.1738)	1.064 (11.2139)	(-2.600, 4.727)	(-21.364, 23.491)
Temporal-4 (µm)	64.696 (23.1708)	62.124 (10.3552)	2.572 (18.0637)	(-3.329, 8.472)	(-33.556, 38.699)
RNFL TSNIT Average (µm)	82.026 (16.5404)	77.934 (15.3871)	4.092 (7.4361)	(1.663, 6.521)	(-10.781, 18.964)
Retinal Disease - N	38	38			
Inferior-4 (µm)	120.532 (19.0732)	116.174 (17.3649)	4.357 (7.5823)	(1.947, 6.768)	(-10.807, 19.522)
Nasal-4 (µm)	79.972 (18.1247)	76.303 (16.4436)	3.669 (11.5128)	(0.008, 7.329)	(-19.357, 26.695)
Superior-4 (µm)	117.430 (22.8718)	113.553 (22.0223)	3.877 (8.7714)	(1.088, 6.665)	(-13.666, 21.419)
Temporal-4 (µm)	73.968 (17.9025)	74.470 (13.7876)	-0.502 (13.8825)	(-4.916, 3.912)	(-28.267, 27.263)
RNFL TSNIT Average (µm)	97.742 (14.7850)	95.124 (13.4346)	2.618 (4.6673)	(1.134, 4.102)	(-6.717, 11.952)

Abbreviations: CI = confidence interval; LOA = limit of agreement; N = number of eyes; RNFL = retinal nerve fiber layer; SD = standard deviation

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. N was the number of eyes with measurements from each device. Difference was calculated as the test device minus the predicate device. The 95% CIs for the mean difference was based on t-distribution. 95% LOA = mean difference +/- 2 x difference SD.

Ganglion Cell Complex Thickness

Refer to Table 3 for a summary of the mean differences and 95% LOAs between the two devices in the measurements of the Ganglion Cell Complex (GCC). Mean differences are generally less than 10% of the GCC thickness. However, some of the GCC sectors for glaucoma patients (e.g., the total and superior sectors) and retinal disease patients (superior sector) have wide LOAs. The

mean difference of -9.689 with a SD of 29.0092 resulted in wide LOA for this parameter. In the glaucoma population of this study, disease severity creates a difference in the devices based on technology.

The thickness measures for GCC were thinner for Canon Glaucoma 3D than Optovue GCC scans with mean differences ranging from -9.689 to -0.334 µm. The LOA for the superior sector for the glaucoma population was wide. Wide LOAs may be attributed to differences in placement of the measurement grid pattern.

Table 3 GCC Thickness between Glaucoma 3D and GCC (Effectiveness Population)

Subject Population Comparable Parameter	Canon OCT-A1 Mean (SD)	Optovue RTVue Avanti Mean (SD)	Mean Difference (SD)	95% CI for Mean Difference	95% LOA for Differences
All Configurations					
Normal – N	37	37			
Inferior (µm)	94.675 (7.5952)	95.009 (7.5194)	-0.334 (3.7451)	(-1.541, 0.872)	(-7.825, 7.156)
Superior (µm)	87.218 (6.9420)	94.097 (6.6213)	-6.880 (3.7008)	(-8.072, -5.687)	(-14.281, 0.522)
Total (µm)	90.934 (6.7238)	94.548 (6.9738)	-3.614 (2.7775)	(-4.509, -2.719)	(-9.169, 1.941)
Glaucoma – N	37	37			
Inferior (µm)	84.135 (14.3771)	85.325 (19.5880)	-1.189 (8.8027)	(-4.026, 1.647)	(-18.795, 16.416)
Superior (µm)	80.215 (14.9530)	89.904 (40.0218)	-9.689 (29.0092)	(-19.037, -0.342)	(-67.708, 48.329)
Total (µm)	82.126 (14.1996)	87.612 (28.7960)	-5.486 (17.0916)	(-10.994, 0.021)	(-39.669, 28.697)
Retinal Disease – N	38	38			
Inferior (µm)	95.534 (14.7452)	98.821 (18.9006)	-3.287 (7.4246)	(-5.648, -0.926)	(-18.136, 11.562)
Superior (µm)	90.975 (18.3027)	99.073 (25.3985)	-8.098 (9.5359)	(-11.130, -5.066)	(-27.170, 10.974)
Total (µm)	93.273 (16.1076)	98.944 (21.5411)	-5.671 (7.5186)	(-8.062, -3.281)	(-20.709, 9.366)

Abbreviations: 3-D = 3-dimensional; CI = confidence interval; GCC= ganglion cell complex; LOA = limit of agreement; N = number of eyes; SD = standard deviation

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. N was the number of eyes with measurements from each device. Difference was calculated as the test device minus the predicate device. The 95% CIs for the mean difference was based on t-distribution. 95% LOA = mean difference +/- 2 x difference SD.

Optic Nerve Head

ONH parameters from Canon Disc 3D scans were converted to millimeters (mm), mm^2 for area and mm^3 for volume comparison. Refer to Table 4 for a summary of the mean differences and 95% LOAs between the two devices in the measurements of the ONH. Overall the mean differences for ONH parameters were close to zero with mean differences ranging from -0.0754 (C/D Horizontal) to 0.2268 (Disc Area).

Table 4 ONH between Disc 3D and ONH (Effectiveness Population)

Subject Population Comparable Parameter	Canon OCT-A1 Mean (SD)	Optovue RTVue Avanti Mean (SD)	Mean Difference (SD)	95% CI for Mean Difference	95% LOA for Differences
All Configurations					
Normal - N	37	37			
ONH Cup Volume (mm^3)	0.1331 (0.13060)	0.1310 (0.12665)	0.0021 (0.04309)	(-0.0124, 0.0166)	(-0.0841, 0.0883)
ONH Disc Area (mm^2)	2.0482 (0.42161)	2.0230 (0.38576)	0.0252 (0.22361)	(-0.0468, 0.0973)	(-0.4220, 0.4725)
ONH C/D Area	0.2483 (0.13460)	0.2926 (0.13372)	-0.0444 (0.03701)	(-0.0568, -0.0319)	(-0.1184, 0.0297)
ONH C/D Horizontal	0.4993 (0.16443)	0.5709 (0.15776)	-0.0716 (0.06384)	(-0.0930, -0.0501)	(-0.1993, 0.0561)
ONH C/D Vertical	0.4750 (0.14179)	0.4944 (0.15118)	-0.0194 (0.05032)	(-0.0364, -0.0025)	(-0.1201, 0.0812)
ONH Rim Area (mm^2)	1.5234 (0.25977)	1.4215 (0.29611)	0.1020 (0.20068)	(0.0345, 0.1694)	(-0.2994, 0.5033)
ONH Rim Volume (mm^3)	0.2864 (0.09048)	0.1686 (0.06336)	0.1177 (0.04805)	(0.1016, 0.1339)	(0.0216, 0.2138)
Glaucoma - N	36	36			
ONH Cup Volume (mm^3)	0.2934 (0.24571)	0.2825 (0.23555)	0.0109 (0.14690)	(-0.0445, 0.0663)	(-0.2829, 0.3047)
ONH Disc Area (mm^2)	2.2282 (0.83476)	2.0014 (0.38825)	0.2268 (0.85919)	(-0.0539, 0.5074)	(-1.4916, 1.9452)
ONH C/D Area	0.5192 (0.19413)	0.5442 (0.16971)	-0.0249 (0.06896)	(-0.0475, -0.0024)	(-0.1629, 0.1130)
ONH C/D Horizontal	0.7111 (0.14728)	0.7794 (0.13771)	-0.0683 (0.07980)	(-0.0944, -0.0422)	(-0.2279, 0.0913)
ONH C/D Vertical	0.7171 (0.16020)	0.7264 (0.15878)	-0.0093 (0.05470)	(-0.0272, 0.0085)	(-0.1187, 0.1001)
ONH Rim Area (mm^2)	1.0198 (0.39995)	0.8894 (0.32102)	0.1304 (0.31822)	(0.0264, 0.2343)	(-0.5061, 0.7668)
ONH Rim Volume (mm^3)	0.1269 (0.08103)	0.0651 (0.05119)	0.0618 (0.03702)	(0.0497, 0.0739)	(-0.0123, 0.1358)
Retinal Disease - N	38	38			
ONH Cup Volume (mm^3)	0.0840 (0.07588)	0.1025 (0.09039)	-0.0185 (0.03338)	(-0.0294, -0.0076)	(-0.0852, 0.0483)
ONH Disc Area (mm^2)	2.0591 (0.43518)	1.9779 (0.37971)	0.0812 (0.24191)	(0.0043, 0.1581)	(-0.4026, 0.5650)
ONH C/D Area	0.2432 (0.14268)	0.3043 (0.12794)	-0.0611 (0.05301)	(-0.0782, -0.0440)	(-0.1671, 0.0449)
ONH C/D Horizontal	0.4895 (0.17092)	0.5649 (0.16441)	-0.0754 (0.08214)	(-0.1018, -0.0489)	(-0.2396, 0.0889)
ONH C/D Vertical	0.4692 (0.18058)	0.5132 (0.17872)	-0.0440 (0.08124)	(-0.0702, -0.0178)	(-0.2065, 0.1185)
ONH Rim Area (mm^2)	1.5533 (0.39718)	1.3627 (0.27079)	0.1906 (0.25459)	(0.1085, 0.2726)	(-0.3186, 0.6998)
ONH Rim Volume (mm^3)	0.2682 (0.10845)	0.1426 (0.06041)	0.1256 (0.05703)	(0.1072, 0.1440)	(0.0115, 0.2397)

Abbreviations: 3-D = 3-dimensional; CI = confidence interval; LOA = limit of agreement; N = number of eyes; ONH = optic nerve head; SD = standard deviation

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. N was the number of eyes with measurements from each device. Difference was calculated as the test device minus the predicate device. The 95% CIs for the mean difference was based on t-distribution. 95% LOA = mean difference +/- 2 x difference SD. Subjects missing any Disc Area, Rim Area, C/D Vertical, or C/D Horizontal parameters in the Canon Disc 3D or Optovue ONH scans were excluded from all agreement analyses for ONH comparable parameters

Analyses of Precision

Precision analysis results are summarized by measurement in Table 5, Table 6, Table 7 and Table 8.

Both repeatability and reproducibility were calculated for the precision analyses. Repeatability represents the variation among images within a subject within a given configuration of a machine. Reproducibility represents the overall variation among and within the configurations. To assist with the comparison of the Canon OCT-A1 and the Optovue RTVue Avanti, the ratios of the variation components were determined by dividing the component of the Canon OCT-A1 by the corresponding component of the Optovue RTVue Avanti. Ratios less than 1 indicate that OCT-A1 was less variable, while ratios greater than 1 indicate that the Optovue RTVue Avanti was less variable.

Full Retinal Thickness

Repeatability and reproducibility of FRT scans by Canon Macula 3D and Optovue Retinal Map (Effectiveness Population) were compared (Table 5).

For the normal group, central FRT as measured with the Canon OCT-A1 had a repeatability limit of 17.37 as compared with 5.28 for the Optovue RTVue Avanti. The limit ratio was 3.2893 in favor of Optovue RTVue Avanti. Central FRT as measured with the Canon OCT-A1 had a reproducibility limit of 18.10 as compared with 6.20 for the Optovue RTVue Avanti. The limit ratio was 2.9178 in favor of Optovue RTVue Avanti.

For the glaucoma group, central FRT as measured with the Canon OCT-A1 had a repeatability limit of 18.17 as compared with 10.29 for the Optovue RTVue Avanti. The limit ratio was 1.7658 in favor of Optovue RTVue Avanti. Central FRT as measured with the Canon OCT-A1 had a reproducibility limit of 18.24 as compared with 11.31 for the Optovue RTVue Avanti. The limit ratio was 1.6122 in favor of Optovue RTVue Avanti.

For the retinal disease group, central FRT as measured with the Canon OCT-A1 had a repeatability limit of 27.65 as compared with 32.29 for the Optovue RTVue Avanti. The limit ratio was 0.8565 in favor of Canon OCT-A1. Central FRT as measured with the Canon OCT-A1 had a reproducibility limit of 75.42 as compared with 46.36 for the Optovue RTVue Avanti. The limit ratio was 1.6268 in favor of Optovue RTVue Avanti.

Table 5 Repeatability and Reproducibility on FRT between Canon Macula 3D and Optovue Retinal Map (Effectiveness Population)

Device - Scan Type	Overall	Repeatability			Reproducibility		
Comparable Parameter	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Normal - N = 37							
Canon – Macula 3D							
Central (μm)	264.97	6.20	17.37 (3.2893)	2.34%	6.46	18.10 (2.9178)	2.44%
Para Inferior (μm)	338.59	5.70	15.97 (1.8495)	1.68%	5.97	16.71 (1.6483)	1.76%
Para Nasal (μm)	342.85	3.59	10.04 (1.2467)	1.05%	3.92	10.97 (1.1650)	1.14%
Para Superior (μm)	341.83	6.19	17.34 (1.8588)	1.81%	6.56	18.36 (1.8008)	1.92%
Para Temporal (μm)	328.82	5.75	16.10 (1.9315)	1.75%	5.94	16.63 (1.7292)	1.81%
Peri Inferior (μm)	285.18	3.21	8.99 (1.4461)	1.13%	3.44	9.63 (1.3572)	1.21%
Peri Nasal (μm)	313.43	1.28	3.57 (0.5718)	0.41%	1.88	5.28 (0.6739)	0.60%

Device - Scan Type	Overall	Repeatability			Reproducibility		
Comparable Parameter	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Peri Superior (µm)	298.85	4.25	11.90 (1.3352)	1.42%	4.57	12.81 (1.2173)	1.53%
Peri Temporal (µm)	284.37	3.62	10.12 (1.4822)	1.27%	3.90	10.91 (1.4063)	1.37%
Optovue – Retinal Map							
Central (µm)	246.73	1.89	5.28	0.76%	2.22	6.20	0.90%
Para Inferior (µm)	309.29	3.08	8.63	1.00%	3.62	10.14	1.17%
Para Nasal (µm)	313.95	2.88	8.06	0.92%	3.36	9.42	1.07%
Para Superior (µm)	313.00	3.33	9.33	1.06%	3.64	10.19	1.16%
Para Temporal (µm)	300.88	2.98	8.33	0.99%	3.43	9.62	1.14%
Peri Inferior (µm)	272.23	2.22	6.22	0.82%	2.53	7.10	0.93%
Peri Nasal (µm)	295.48	2.23	6.25	0.76%	2.80	7.83	0.95%
Peri Superior (µm)	282.58	3.18	8.91	1.13%	3.76	10.52	1.33%
Peri Temporal (µm)	270.74	2.44	6.83	0.90%	2.77	7.76	1.02%
Glaucoma - N = 37							
Canon – Macula 3D							
Central (µm)	282.98	6.49	18.17 (1.7658)	2.29%	6.51	18.24 (1.6122)	2.30%
Para Inferior (µm)	324.54	4.43	12.39 (1.3017)	1.36%	4.89	13.69 (1.2105)	1.51%
Para Nasal (µm)	337.21	3.53	9.89 (0.3651)	1.05%	4.03	11.28 (0.4154)	1.20%
Para Superior (µm)	326.69	6.75	18.89 (2.0787)	2.07%	7.11	19.90 (1.9196)	2.18%
Para Temporal (µm)	317.03	5.61	15.72 (1.6606)	1.77%	5.68	15.89 (1.5209)	1.79%
Peri Inferior (µm)	277.99	7.00	19.60 (1.3309)	2.52%	8.28	23.17 (1.5649)	2.98%
Peri Nasal (µm)	299.83	7.14	19.99 (2.6399)	2.38%	7.31	20.47 (2.4075)	2.44%
Peri Superior (µm)	286.37	7.87	22.03 (1.7060)	2.75%	8.10	22.69 (1.7533)	2.83%
Peri Temporal (µm)	278.06	4.49	12.59 (1.2493)	1.62%	4.57	12.80 (1.1665)	1.64%
Optovue – Retinal Map							
Central (µm)	260.13	3.67	10.29	1.41%	4.04	11.31	1.55%
Para Inferior (µm)	299.90	3.40	9.52	1.13%	4.04	11.31	1.35%
Para Nasal (µm)	309.49	9.68	27.09	3.13%	9.70	27.16	3.13%
Para Superior (µm)	301.63	3.25	9.09	1.08%	3.70	10.37	1.23%
Para Temporal (µm)	295.08	3.38	9.47	1.15%	3.73	10.45	1.26%
Peri Inferior (µm)	261.54	5.26	14.73	2.01%	5.29	14.81	2.02%
Peri Nasal (µm)	284.96	2.70	7.57	0.95%	3.04	8.50	1.07%
Peri Superior (µm)	269.86	4.61	12.91	1.71%	4.62	12.94	1.71%
Peri Temporal (µm)	263.70	3.60	10.07	1.36%	3.92	10.98	1.49%
Retinal Disease - N = 38							
Canon – Macula 3D							
Central (µm)	299.21	9.88	27.65 (0.8565)	3.30%	26.94	75.42 (1.6268)	9.00%
Para Inferior (µm)	340.54	10.22	28.60 (1.7561)	3.00%	13.08	36.61 (1.5940)	3.84%
Para Nasal (µm)	339.14	11.53	32.28 (1.3368)	3.40%	19.06	53.36 (0.5247)	5.62%
Para Superior (µm)	333.01	15.89	44.49 (1.4614)	4.77%	25.64	71.78 (0.7910)	7.70%
Para Temporal (µm)	327.97	8.63	24.17 (1.2939)	2.63%	18.58	52.02 (2.5658)	5.67%
Peri Inferior (µm)	292.90	8.62	24.14 (1.5210)	2.94%	12.52	35.05 (1.9836)	4.27%
Peri Nasal (µm)	312.57	7.77	21.75 (1.0839)	2.48%	15.79	44.20 (0.3722)	5.05%
Peri Superior (µm)	296.44	6.56	18.36 (0.4615)	2.21%	23.17	64.88 (0.8008)	7.82%
Peri Temporal (µm)	287.19	8.30	23.23 (1.2057)	2.89%	10.11	28.30 (1.2377)	3.52%
Optovue – Retinal Map							
Central (µm)	277.60	11.53	32.29	4.15%	16.56	46.36	5.96%
Para Inferior (µm)	315.70	5.82	16.29	1.84%	8.20	22.97	2.60%
Para Nasal (µm)	321.55	8.62	24.15	2.68%	36.33	101.71	11.30%
Para Superior (µm)	314.62	10.87	30.44	3.46%	32.41	90.75	10.30%
Para Temporal (µm)	306.08	6.67	18.68	2.18%	7.24	20.28	2.37%
Peri Inferior (µm)	275.51	5.67	15.87	2.06%	6.31	17.67	2.29%
Peri Nasal (µm)	300.76	7.17	20.06	2.38%	42.41	118.76	14.10%
Peri Superior (µm)	284.87	14.20	39.77	4.99%	28.93	81.02	10.16%
Peri Temporal (µm)	274.07	6.88	19.27	2.51%	8.17	22.87	2.98%

Abbreviations: 3-D = 3-dimensional; CV% = coefficient of variance; FRT = full retinal thickness; N = number of eyes; SD = standard deviation

Limit (Ratio) is defined as the ratio between the repeatability limit for the Canon device and the predicate device and calculated by dividing the Canon device limit by the predicate device limit (C/P).

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. CV% was calculated as the repeatability or reproducibility SD/overall mean.

Average TSNIT Retinal Nerve Fiber Layer Thickness

Repeatability and reproducibility of RNFL thickness scans by Canon Disc 3D and Optovue ONH were compared (Table 6).

For the normal gA1roup, the RNFL TSNIT average across all areas had a repeatability limit of 3.638 for Canon OCT-A1 and 5.631 for Optovue ONH. The limit ratio was 0.6460, in favor of Canon OCT-A1. The RNFL TSNIT average across all areas had a reproducibility limit of 4.540 for Canon OCT-A1 and 5.804 for Optovue ONH. The limit ratio was 0.7823, in favor of Canon Disc 3D.

For the glaucoma group, the RNFL TSNIT average across all areas had a repeatability limit of 5.129 for Canon OCT-A1and 4.197 for Optovue ONH. The limit ratio was 1.2223, in favor of Optovue ONH. The RNFL TSNIT average across all areas had a reproducibility limit of 5.430 for Canon OCT-A1and 5.623 for Optovue ONH. The limit ratio was 0.9656, in favor of Canon OCT-A1.

For the retinal disease group, the RNFL TSNIT average across all areas had a repeatability limit of 5.932 for Canon OCT-A1and 6.398 for Optovue ONH. The limit ratio was 0.9272, in favor of Canon OCT-A1. The RNFL TSNIT average across all areas had a reproducibility limit of 7.244 for Canon OCT-A1 and 12.402 for Optovue ONH. The limit ratio was 0.5841, in favor of Canon OCT-A1.

Table 6 Repeatability and Reproducibility on RNFL Thickness between Canon Disc 3D and Optovue ONH (Effectiveness Population)

Device - Scan Type	Overall	Repeatability			Reproducibility		
Comparable Parameter	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Normal - N = 37							
Canon – Disc 3D							
Inferior-4 (μm)	134.198	2.857	8.000 (0.7439)	2.129%	3.144	8.804 (0.7979)	2.343%
Nasal-4 (μm)	87.810	2.438	6.827 (0.9373)	2.777%	2.736	7.662 (1.0503)	3.116%
Superior-4 (μm)	126.694	3.308	9.263 (0.6268)	2.611%	3.845	10.766 (0.7230)	3.035%
Temporal-4 (μm)	69.131	2.803	7.847 (0.8852)	4.054%	2.805	7.854 (0.8716)	4.057%
RNFL TSNIT Average (μm)	104.171	1.299	3.638 (0.6460)	1.247%	1.622	4.540 (0.7823)	1.557%
Optovue - ONH with 3D Disc							
Inferior-4 (μm)	124.523	3.841	10.754	3.084%	3.941	11.034	3.165%
Nasal-4 (μm)	79.729	2.601	7.283	3.263%	2.605	7.295	3.268%
Superior-4 (μm)	124.560	5.278	14.779	4.237%	5.318	14.890	4.269%
Temporal-4 (μm)	73.102	3.166	8.865	4.331%	3.218	9.011	4.402%
RNFL TSNIT Average (μm)	100.478	2.011	5.631	2.001%	2.073	5.804	2.063%
Glaucoma - N = 37							
Canon – Disc 3D							
Inferior-4 (μm)	97.605	3.955	11.075 (1.1489)	4.052%	4.011	11.230 (1.1026)	4.109%
Nasal-4 (μm)	68.881	3.941	11.036 (1.2720)	5.722%	4.141	11.594 (0.8202)	6.012%
Superior-4 (μm)	94.472	4.309	12.067 (1.3962)	4.562%	4.475	12.529 (1.3303)	4.737%

Device - Scan Type Comparable Parameter	Overall Mean	Repeatability SD	Repeatability Limit (Ratio)	Repeatability CV%	Reproducibility SD	Reproducibility Limit (Ratio)	Reproducibility CV%
Temporal-4 (µm)	61.692	2.891	8.095 (0.9397)	4.686%	2.909	8.145 (0.8950)	4.716%
RNFL TSNIT Average (µm)	80.512	1.832	5.129 (1.2223)	2.275%	1.939	5.430 (0.9656)	2.409%
Optovue - ONH with 3D Disc							
Inferior-4 (µm)	92.026	3.443	9.639	3.741%	3.637	10.185	3.953%
Nasal-4 (µm)	61.658	3.099	8.676	5.025%	5.048	14.135	8.188%
Superior-4 (µm)	90.725	3.086	8.642	3.402%	3.364	9.418	3.708%
Temporal-4 (µm)	60.443	3.077	8.614	5.090%	3.250	9.101	5.378%
RNFL TSNIT Average (µm)	76.213	1.499	4.197	1.967%	2.008	5.623	2.635%
Retinal Disease - N = 38							
Canon – Disc 3D							
Inferior-4 (µm)	120.867	4.319	12.094 (1.1550)	3.573%	4.508	12.622 (1.1977)	3.730%
Nasal-4 (µm)	80.339	4.219	11.813 (0.9203)	5.251%	4.647	13.011 (1.0137)	5.784%
Superior-4 (µm)	119.823	5.573	15.604 (1.3015)	4.651%	5.689	15.928 (1.0044)	4.747%
Temporal-4 (µm)	75.233	2.070	5.795 (0.5239)	2.751%	7.276	20.374 (0.6229)	9.672%
RNFL TSNIT Average (µm)	98.778	2.119	5.932 (0.9272)	2.145%	2.587	7.244 (0.5841)	2.619%
Optovue - ONH with 3D Disc							
Inferior-4 (µm)	115.347	3.739	10.470	3.242%	3.764	10.539	3.263%
Nasal-4 (µm)	74.826	4.584	12.836	6.126%	4.584	12.836	6.126%
Superior-4 (µm)	114.919	4.282	11.989	3.726%	5.664	15.858	4.928%
Temporal-4 (µm)	76.014	3.950	11.060	5.197%	11.682	32.710	15.368%
RNFL TSNIT Average (µm)	95.276	2.285	6.398	2.398%	4.429	12.402	4.649%

Abbreviations: 3-D = 3-dimensional; CV% = coefficient of variance; N = number of eyes; ONH = optic nerve head; RNFL = retinal nerve fiber layer; SD = standard deviation

Limit (Ratio) is defined as the ratio between the repeatability limit for the Canon device and the predicate device and calculated by dividing the Canon device limit by the predicate device limit (C/P).

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. CV% was calculated as the repeatability or reproducibility SD/overall mean.

Ganglion Cell Complex Thickness

Repeatability and reproducibility of GCC thickness scans by Canon Glaucoma 3D and Optovue GCC were compared. Total GCC thickness values are summarized below, with superior and inferior values individually listed in Table 7.

For the normal group, total GCC thickness had a repeatability limit of 1.740 for Canon OCT-A1 and 2.773 for Optovue GCC. The limit ratio was 0.6275, in favor of Canon OCT-A1. Total GCC thickness had a reproducibility limit of 2.405 for Canon OCT-A1 and 2.786 for Optovue GCC. The limit ratio was 0.8633, in favor of Canon OCT-A1.

For the glaucoma group, total GCC thickness had a repeatability limit of 6.901 for Canon OCT-A13D and 18.896 for Optovue GCC. The limit ratio was 0.3652, in favor of Canon OCT-A1. Total GCC thickness had a repeatability limit of 7.002 for Canon OCT-A1 and 18.896 for Optovue GCC. The limit ratio was 0.3705, in favor of Canon OCT-A1.

For the retinal disease group, total GCC thickness had a repeatability limit of 4.917 for Canon OCT-A1 and 8.220 for Optovue GCC. The limit ratio was 0.5982, in favor of Canon OCT-A1.

Total GCC thickness had a reproducibility limit of 10.006 for Canon OCT-A1 and 11.035 for Optovue GCC. The limit ratio was 0.9067, in favor of Canon OCT-A1.

Table 7 Repeatability and Reproducibility on GCC Thickness between Canon Glaucoma 3D and Optovue GCC (Effectiveness Population)

Device - Scan Type		Repeatability			Reproducibility		
Comparable Parameter	Overall Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Normal - N = 37							
Canon – Glaucoma 3D							
Inferior (μm)	94.329	1.931	5.407 (1.7919)	2.047%	2.163	6.058 (1.9943)	2.294%
Superior (μm)	87.004	1.125	3.150 (1.1102)	1.293%	1.312	3.673 (1.2229)	1.508%
Total (μm)	90.650	0.621	1.740 (0.6275)	0.686%	0.859	2.405 (0.8633)	0.948%
Optovue – GCC							
Inferior (μm)	94.628	1.078	3.017	1.139%	1.085	3.037	1.146%
Superior (μm)	93.721	1.013	2.838	1.081%	1.073	3.004	1.145%
Total (μm)	94.169	0.990	2.773	1.052%	0.995	2.786	1.057%
Glaucoma - N = 37							
Canon – Glaucoma 3D							
Inferior (μm)	83.941	2.886	8.080 (0.5765)	3.438%	3.189	8.93 (0.5948)	3.799%
Superior (μm)	80.348	2.221	6.218 (0.2053)	2.764%	2.263	6.336 (0.2092)	2.816%
Total (μm)	82.138	2.465	6.901 (0.3652)	3.001%	2.501	7.002 (0.3705)	3.044%
Optovue – GCC							
Inferior (μm)	84.553	5.005	14.014	5.920%	5.361	15.012	6.341%
Superior (μm)	86.284	10.817	30.287	12.536%	10.817	30.287	12.536%
Total (μm)	85.419	6.749	18.896	7.901%	6.749	18.896	7.901%
Retinal Disease - N = 38							
Canon – Glaucoma 3D							
Inferior (μm)	95.728	3.540	9.911 (0.9337)	3.698%	4.023	11.266 (0.7006)	4.203%
Superior (μm)	90.160	1.555	4.354 (0.5650)	1.725%	4.975	13.931 (1.6795)	5.518%
Total (μm)	92.972	1.756	4.917 (0.5982)	1.889%	3.574	10.006 (0.9067)	3.844%
Optovue – GCC							
Inferior (μm)	98.768	3.791	10.615	3.838%	5.743	16.080	5.815%
Superior (μm)	97.256	2.752	7.705	2.829%	2.962	8.295	3.046%
Total (μm)	98.009	2.936	8.220	2.995%	3.941	11.035	4.021%

Abbreviations: 3-D = 3-dimensional; CV% = coefficient of variance; GCC = ganglion cell complex; N = number of eyes; SD = standard deviation

Limit (Ratio) is defined as the ratio between the repeatability limit for the Canon device and the predicate device and calculated by dividing the Canon device limit by the predicate device limit (C/P).

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. CV% was calculated as the repeatability or reproducibility SD/overall mean.

Optic Nerve Head

Repeatability and reproducibility of ONH scans by Canon Disc 3D and Optovue ONH were compared. ONH disc area measurements are summarized below with cup volume, C/D area, C/D horizontal, C/D vertical, rim area, and rim volume detailed in Table 8.

For the normal group, ONH disc area (mm^2) had a repeatability limit of 0.1998 for Canon OCT-A1 and 0.2942 for Optovue ONH. The limit ratio was 0.6792, in favor of Canon OCT-A1. Total GCC thickness had a reproducibility limit of 0.1998 for Canon OCT-A1 and 0.3348 for Optovue GCC. The limit ratio was 0.5968, in favor of Canon OCT-A1.

For the glaucoma group, ONH disc area (mm^2) had a repeatability limit of 0.9532 for Canon OCT-A1 and 0.4238 for Optovue ONH. The limit ratio was 2.2489, in favor of Optovue ONH. Total GCC thickness had a reproducibility limit of 1.0000 for Canon OCT-A1 and 0.4288 for Optovue GCC. The limit ratio was 2.3321, in favor of Optovue ONH.

For the retinal disease group, ONH disc area (mm^2) had a repeatability limit of 0.2139 for Canon OCT-A1 and 0.4350 for Optovue ONH. The limit ratio was 0.4917, in favor of Canon OCT-A1. ONH disc area (mm^2) had a reproducibility limit of 0.2776 for Canon OCT-A1 and 0.4628 for Optovue ONH. The limit ratio was 0.5999, in favor of Canon OCT-A1.

Table 8 Repeatability and Reproducibility on ONH between Canon Disc 3D and Optovue ONH (Effectiveness Population)

Device - Scan Type	Overall	Repeatability			Reproducibility		
Comparable Parameter	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Normal N= 37							
Canon – Disc 3D							
ONH Cup Volume (mm^3)	0.1221	0.0069	0.0193 (0.2955)	5.6514%	0.0069	0.0193 (0.2583)	5.6514%
ONH Disc Area (mm^2)	2.0505	0.0714	0.1998 (0.6792)	3.4800%	0.0714	0.1998 (0.5968)	3.4800%
ONH C/D Area	0.2488	0.0106	0.0296 (0.5278)	4.2453%	0.0107	0.0299 (0.4860)	4.2919%
ONH C/D Horizontal	0.4993	0.0166	0.0466 (0.5042)	3.3297%	0.0166	0.0466 (0.4693)	3.3297%
ONH C/D Vertical	0.4786	0.0268	0.0752 (0.5813)	5.6085%	0.0297	0.0831 (0.6023)	6.2053%
ONH Rim Area (mm^2)	1.5427	0.0629	0.1761 (0.6689)	4.0760%	0.0629	0.1761 (0.6185)	4.0760%
ONH Rim Volume (mm^3)	0.2892	0.0147	0.0411 (1.0155)	5.0756%	0.0147	0.0412 (0.9004)	5.0839%
Optovue – ONH with 3D Disc							
ONH Cup Volume (mm^3)	0.1244	0.0233	0.0654	18.7617%	0.0267	0.0748	21.4684%
ONH Disc Area (mm^2)	2.0036	0.1051	0.2942	5.2436%	0.1196	0.3348	5.9674%
ONH C/D Area	0.2928	0.0200	0.0560	6.8342%	0.0220	0.0615	7.5027%
ONH C/D Horizontal	0.5597	0.0330	0.0923	5.8911%	0.0354	0.0992	6.3297%
ONH C/D Vertical	0.4983	0.0462	0.1293	9.2662%	0.0493	0.1381	9.8947%
ONH Rim Area (mm^2)	1.4122	0.0940	0.2632	6.6569%	0.1017	0.2847	7.1992%
ONH Rim Volume (mm^3)	0.1696	0.0145	0.0405	8.5205%	0.0163	0.0457	9.6253%
Glaucoma N= 37							
Canon – Disc 3D							
ONH Cup Volume (mm^3)	0.2019	0.0070	0.0197 (0.1629)	3.4915%	0.0070	0.0197 (0.1483)	3.4915%
ONH Disc Area (mm^2)	2.1704	0.3404	0.9532 (2.2489)	15.6849%	0.3571	1.0000 (2.3321)	16.4553%
ONH C/D Area	0.5206	0.0253	0.0709 (0.8589)	4.8637%	0.0262	0.0735 (0.7757)	5.0424%
ONH C/D Horizontal	0.7129	0.0262	0.0735 (0.9153)	3.6805%	0.0270	0.0757 (0.8176)	3.7915%
ONH C/D Vertical	0.7209	0.0378	0.1058 (0.9385)	5.2398%	0.0399	0.1119 (0.8971)	5.5412%
ONH Rim Area (mm^2)	1.0091	0.1553	0.4348 (1.4948)	15.3868%	0.1553	0.4348 (1.3831)	15.3868%
ONH Rim Volume (mm^3)	0.1260	0.0159	0.0445 (1.5257)	12.6084%	0.0162	0.0453 (1.3531)	12.8380%
Optovue – ONH with 3D Disc							
ONH Cup Volume (mm^3)	0.2074	0.0433	0.1212	20.8668%	0.0475	0.1330	22.9132%
ONH Disc Area (mm^2)	2.0282	0.1514	0.4238	7.4635%	0.1531	0.4288	7.5508%
ONH C/D Area	0.5477	0.0295	0.0825	5.3824%	0.0338	0.0947	6.1789%
ONH C/D Horizontal	0.7786	0.0287	0.0803	3.6819%	0.0331	0.0926	4.2462%
ONH C/D Vertical	0.7321	0.0403	0.1127	5.4981%	0.0445	0.1247	6.0823%
ONH Rim Area (mm^2)	0.8927	0.1039	0.2908	11.6352%	0.1123	0.3143	12.5749%
ONH Rim Volume (mm^3)	0.0646	0.0104	0.0292	16.1236%	0.0120	0.0335	18.5109%
Retinal Diseases N = 38							
Canon – Disc 3D							
ONH Cup Volume (mm^3)	0.0763	0.0048	0.0135 (0.2076)	6.3388%	0.0063	0.0176 (0.2284)	8.2219%
ONH Disc Area (mm^2)	2.0727	0.0764	0.2139 (0.4917)	3.6856%	0.0992	0.2776 (0.5999)	4.7840%
ONH C/D Area	0.2576	0.0130	0.0365 (0.4240)	5.0606%	0.0200	0.0561 (0.6521)	7.7835%
ONH C/D Horizontal	0.5080	0.0213	0.0596 (0.6609)	4.1888%	0.0280	0.0783 (0.8414)	5.5056%

Device - Scan Type	Overall	Repeatability			Reproducibility		
Comparable Parameter	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
ONH C/D Vertical	0.4997	0.0241	0.0674 (0.4202)	4.8203%	0.0277	0.0776 (0.4753)	5.5478%
ONH Rim Area (mm^2)	1.5431	0.0621	0.1738 (0.4367)	4.0225%	0.0808	0.2263 (0.5625)	5.2371%
ONH Rim Volume (mm^3)	0.2602	0.0119	0.0334 (0.6895)	4.5789%	0.0161	0.0451 (0.8410)	6.1856%
Optovue – ONH with 3D Disc							
ONH Cup Volume (mm^3)	0.0906	0.0233	0.0652	25.7085%	0.0275	0.0769	30.3072%
ONH Disc Area (mm^2)	1.9706	0.1554	0.4350	7.8835%	0.1653	0.4628	8.3875%
ONH C/D Area	0.3198	0.0307	0.0861	9.6141%	0.0307	0.0861	9.6141%
ONH C/D Horizontal	0.5908	0.0322	0.0902	5.4509%	0.0332	0.0931	5.6270%
ONH C/D Vertical	0.5372	0.0573	0.1605	10.6702%	0.0583	0.1633	10.8569%
ONH Rim Area (mm^2)	1.3448	0.1421	0.3980	10.5695%	0.1437	0.4023	10.6843%
ONH Rim Volume (mm^3)	0.1388	0.0173	0.0484	12.4494%	0.0191	0.0536	13.7880%

Abbreviations: 3-D = 3-dimensional; CV% = coefficient of variance; N = number of eyes; ONH = optic nerve head; SD = standard deviation

Limit (Ratio) is defined as the ratio between the repeatability limit for the Canon device and the predicate device and calculated by dividing the Canon device limit by the predicate device limit (C/P).

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. CV% was calculated as the repeatability or reproducibility SD/overall mean. Ratios, noted with C/D, are unitless.

Analyses of Other Measurements

Repeatability and Reproducibility for Canon-only Parameters

Repeatability and reproducibility analysis was performed for parameters measured by the Canon OCT-A1 for which there was no comparator in the Optovue device. These included:

- Canon Macula 3D
- Canon Disc 3D
- Canon Glaucoma 3D

Macula 3D

For the normal group, Macula 3D had an average (µm) repeatability limit of 7.95 and a reproducibility limit of 8.87. For the glaucoma group, Macula 3D had an average (µm) repeatability limit of 11.43 and a reproducibility limit of 11.88. For the retinal disease group, Macula 3D had an average (µm) repeatability limit of 15.18 and a reproducibility limit of 27.74.

Table 13.9 Canon Repeatability and Reproducibility on Macula 3D (Effectiveness Population)

Device - Scan Type	Overall	Repeatability			Reproducibility		
Comparable Parameter	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Normal N= 37							
Canon – Macula 3D							
Average (µm)	304.09	2.84	7.95 (N/A)	0.93%	3.17	8.87 (N/A)	1.04%
Minimum (µm)	216.14	10.26	28.73 (N/A)	4.75%	10.49	29.38 (N/A)	4.86%
Volume (µm))	8.59	0.16	0.45 (N/A)	1.87%	0.17	0.47 (N/A)	1.95%
Glaucoma N= 37							
Canon – Macula 3D							
Average (µm)	294.57	4.08	11.43 (N/A)	1.39%	4.24	11.88 (N/A)	1.44%
Minimum (µm)	224.22	18.62	52.13 (N/A)	8.30%	18.76	52.53 (N/A)	8.37%
Volume (µm))	8.33	0.13	0.36 (N/A)	1.52%	0.13	0.37 (N/A)	1.57%
Retinal Diseases N = 38							
Canon – Macula 3D							
Average (µm)	305.73	5.42	15.18 (N/A)	1.77%	9.91	27.74 (N/A)	3.24%
Minimum (µm)	239.29	28.71	80.38 (N/A)	12.00%	40.44	113.24 (N/A)	16.90%
Volume (µm))	8.64	0.18	0.50 (N/A)	2.05%	0.29	0.82 (N/A)	3.41%

Abbreviations: 3-D = 3-dimensional; CV% = coefficient of variability percentage; N = number of eyes; ONH = optic nerve head; SD = standard deviation; N/A = Not Applicable

Limit (Ratio) is defined as the ratio between the repeatability limit for the Canon device and the predicate device and calculated by dividing the Canon device limit by the predicate device limit (C/P).

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. CV% was calculated as the repeatability or reproducibility SD/overall mean. Ratios, noted with C/D, are unitless.

Disc 3D

For the normal group, Disc 3D had an RNFL TSNIT SD (µm) overall mean of 38.166, a repeatability limit of 3.624 and a reproducibility limit of 4.094. For the glaucoma group, Disc 3D had an RNFL TSNIT SD (µm) overall mean of 27.654, a repeatability limit of 5.900 and a reproducibility limit of 5.900. For the retinal disease group, Disc 3D had an RNFL TSNIT SD (µm) overall mean of 34.132, a repeatability limit of 7.086 and a reproducibility limit of 7.304.

Table 13.10 Canon Repeatability and Reproducibility on Disc 3D (Effectiveness Population)

Device - Scan Type Comparable Parameter	Overall Mean	Repeatability SD	Repeatability Limit (Ratio)	Repeatability CV%	Reproducibility SD	Reproducibility Limit (Ratio)	Reproducibility CV%
Normal N= 37							
Canon – Disc 3D							
Inferior-12 (µm)	139.003	5.129	14.362 (N/A)	3.690%	5.541	15.516 (N/A)	3.987%
Inferior-Inf-Nasal (µm)	110.670	5.606	15.696 (N/A)	5.065%	5.921	16.580 (N/A)	5.350%
Inferior-Inf-Temporal (µm)	149.577	5.963	16.697 (N/A)	3.987%	6.132	17.169 (N/A)	4.099%
Nasal-12 (µm)	73.383	2.929	8.200 (N/A)	3.991%	3.188	8.926 (N/A)	4.344%
Nasal-Inf-Nasal (µm)	74.305	3.486	9.762 (N/A)	4.692%	3.792	10.617 (N/A)	5.103%
Nasal-Sup-Nasal (µm)	113.552	5.222	14.621 (N/A)	4.599%	5.980	16.745 (N/A)	5.267%
Superior-12 (µm)	139.540	6.283	17.591 (N/A)	4.502%	6.965	19.501 (N/A)	4.991%
Superior-Sup-Nasal (µm)	121.330	4.832	13.529 (N/A)	3.982%	5.051	14.144 (N/A)	4.163%
Superior-Sup-Temporal (µm)	118.369	4.849	13.577 (N/A)	4.096%	5.275	14.769 (N/A)	4.456%
Temporal-12 (µm)	53.673	3.880	10.865 (N/A)	7.230%	3.885	10.879 (N/A)	7.239%
Temporal-Inf-Temporal (µm)	79.230	4.964	13.900 (N/A)	6.266%	5.063	14.176 (N/A)	6.390%
Temporal-Sup-Temporal (µm)	72.832	2.561	7.170 (N/A)	3.516%	2.731	7.646 (N/A)	3.750%
RNFL TSNIT SD (µm)	38.166	1.294	3.624 (N/A)	3.391%	1.462	4.094 (N/A)	3.831%
Glaucoma N= 37							
Canon – Disc 3D							
Inferior-12 (µm)	106.298	7.187	20.123 (N/A)	6.761%	7.313	20.477 (N/A)	6.880%
Inferior-Inf-Nasal (µm)	89.843	6.491	18.174 (N/A)	7.225%	6.491	18.174 (N/A)	7.225%
Inferior-Inf-Temporal (µm)	103.312	6.205	17.373 (N/A)	6.006%	6.402	17.924 (N/A)	6.196%
Nasal-12 (µm)	61.748	4.795	13.426 (N/A)	7.765%	5.144	14.403 (N/A)	8.331%
Nasal-Inf-Nasal (µm)	64.706	5.404	15.132 (N/A)	8.352%	5.649	15.817 (N/A)	8.730%
Nasal-Sup-Nasal (µm)	83.759	8.531	23.887 (N/A)	10.185%	8.531	23.887 (N/A)	10.185%
Superior-12 (µm)	105.426	8.967	25.108 (N/A)	8.506%	9.052	25.345 (N/A)	8.586%
Superior-Sup-Nasal (µm)	93.052	6.991	19.574 (N/A)	7.513%	7.441	20.834 (N/A)	7.996%
Superior-Sup-Temporal (µm)	87.523	4.960	13.888 (N/A)	5.667%	5.182	14.508 (N/A)	5.920%
Temporal-12 (µm)	55.136	5.743	16.081 (N/A)	10.416%	5.902	16.526 (N/A)	10.705%
Temporal-Inf-Temporal (µm)	69.688	6.568	18.389 (N/A)	9.424%	7.030	19.685 (N/A)	10.088%
Temporal-Sup-Temporal (µm)	68.302	7.648	21.415 (N/A)	11.197%	7.648	21.415 (N/A)	11.197%
RNFL TSNIT SD (µm)	27.654	2.107	5.900 (N/A)	7.620%	2.107	5.900 (N/A)	7.620%
Retinal Diseases N = 38							
Canon – Disc 3D							
Inferior-12 (µm)	123.174	6.614	18.519 (N/A)	5.369%	6.669	18.673 (N/A)	5.414%
Inferior-Inf-Nasal (µm)	100.675	6.019	16.852 (N/A)	5.978%	6.552	18.345 (N/A)	6.508%
Inferior-Inf-Temporal (µm)	135.859	5.649	15.816 (N/A)	4.158%	5.765	16.143 (N/A)	4.244%
Nasal-12 (µm)	68.882	7.639	21.390 (N/A)	11.090%	8.022	22.463 (N/A)	11.647%
Nasal-Inf-Nasal (µm)	69.318	3.834	10.735 (N/A)	5.531%	4.175	11.689 (N/A)	6.023%
Nasal-Sup-Nasal (µm)	100.821	7.410	20.747 (N/A)	7.349%	7.504	21.012 (N/A)	7.443%
Superior-12 (µm)	127.399	11.726	32.832 (N/A)	9.204%	11.902	33.325 (N/A)	9.342%
Superior-Sup-Nasal (µm)	113.969	7.019	19.654 (N/A)	6.159%	7.089	19.848 (N/A)	6.220%
Superior-Sup-Temporal (µm)	116.116	6.068	16.992 (N/A)	5.226%	6.145	17.206 (N/A)	5.292%
Temporal-12 (µm)	60.615	2.205	6.174 (N/A)	3.637%	8.143	22.801 (N/A)	13.434%
Temporal-Inf-Temporal (µm)	83.244	4.114	11.518 (N/A)	4.942%	11.377	31.857 (N/A)	13.667%
Temporal-Sup-Temporal (µm)	80.498	4.814	13.480 (N/A)	5.981%	5.091	14.254 (N/A)	6.324%
RNFL TSNIT SD (µm)	34.132	2.531	7.086 (N/A)	7.414%	2.609	7.304 (N/A)	7.643%

Abbreviations: 3-D = 3-dimensional; CV% = coefficient of variability percentage; N = number of eyes; ONH = optic nerve head; SD = standard deviation; N/A = Not Applicable

Limit (Ratio) is defined as the ratio between the repeatability limit for the Canon device and the predicate device and calculated by dividing the Canon device limit by the predicate device limit (C/P).

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. CV% was calculated as the repeatability or reproducibility SD/overall mean. Ratios, noted with C/D, are unitless.

Glaucoma 3D

For the normal group, Glaucoma 3D had a Para (μm) repeatability limit (inferior nasal/ temporal, superior nasal/ temporal) that ranged from 2.570 (Para Temporal) to 9.073 (Para Superior) with a reproducibility limit that ranged from 3.463 (Para Temporal) to 9.293 (Para Superior).

For the normal group, Glaucoma 3D had a Peri (μm) repeatability limit (inferior nasal/ temporal, superior nasal/ temporal) that ranged from 2.983 (Peri Temporal) to 13.279 (Peri Inferior) with a reproducibility limit that ranged from 3.432 (Peri Temporal) to 16.624 (Peri Inferior).

For the glaucoma group, Glaucoma 3D had a Para (μm) repeatability limit (inferior nasal/ temporal, superior nasal/ temporal) that ranged from 5.153 (Para Nasal) to 10.017 (Para Inferior) with a reproducibility limit that ranged from 5.566 (Para Nasal) to 14.220 (Para Inferior).

For the glaucoma group, Glaucoma 3D had a Peri (μm) repeatability limit (inferior nasal/ temporal, superior nasal/ temporal) that ranged from 6.442 (Peri Temporal) to 16.392 (Peri Superior) with a reproducibility limit that ranged from 6.483 (Peri Temporal) to 16.451 (Peri Superior).

For the retinal disease group, Glaucoma 3D had a Para (μm) repeatability limit (inferior nasal/ temporal, superior nasal/ temporal) that ranged from 6.306 (Para Inferior) to 13.572 (Para Nasal) with a reproducibility limit that ranged from 10.908 (Para Temporal) to 54.284 (Para Superior).

For the retinal disease group, Glaucoma 3D had a Peri (μm) repeatability limit (inferior nasal/ temporal, superior nasal/ temporal) that ranged from 4.617 (Peri Temporal) to 13.366 (Peri Nasal) with a reproducibility limit that ranged from 5.088 (Peri Temporal) to 18.035 (Peri Superior).

Table 13.11 Canon Repeatability and Reproducibility on Glaucoma 3D (Effectiveness Population)

Device - Scan Type	Overall	Repeatability			Reproducibility		
Comparable Parameter	Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Normal N= 37							
Canon – Glaucoma 3D							
Para Inferior (µm)	112.358	1.497	4.191 (N/A)	1.332%	1.836	5.140 (N/A)	1.634%
Para Nasal (µm)	100.794	1.070	2.996 (N/A)	1.062%	1.387	3.883 (N/A)	1.376%
Para Superior (µm)	112.070	3.240	9.073 (N/A)	2.891%	3.319	9.293 (N/A)	2.961%
Para Temporal (µm)	95.860	0.918	2.570 (N/A)	0.958%	1.237	3.463 (N/A)	1.290%
Peri Inferior (µm)	114.769	4.743	13.279 (N/A)	4.132%	5.937	16.624 (N/A)	5.173%
Peri Nasal (µm)	76.667	1.943	5.441 (N/A)	2.534%	2.242	6.279 (N/A)	2.925%
Peri Superior (µm)	102.714	2.561	7.171 (N/A)	2.493%	2.939	8.230 (N/A)	2.861%
Peri Temporal (µm)	68.860	1.066	2.983 (N/A)	1.547%	1.226	3.432 (N/A)	1.780%
Glaucoma N= 37							
Canon – Glaucoma 3D							
Para Inferior (µm)	102.437	3.578	10.017 (N/A)	3.493%	5.078	14.220 (N/A)	4.958%
Para Nasal (µm)	90.533	1.841	5.153 (N/A)	2.033%	1.988	5.566 (N/A)	2.196%
Para Superior (µm)	102.851	2.672	7.480 (N/A)	2.598%	2.742	7.679 (N/A)	2.666%
Para Temporal (µm)	87.778	2.082	5.829 (N/A)	2.371%	2.331	6.526 (N/A)	2.655%
Peri Inferior (µm)	93.487	3.350	9.379 (N/A)	3.583%	4.046	11.330 (N/A)	4.328%
Peri Nasal (µm)	71.259	2.941	8.235 (N/A)	4.127%	2.949	8.256 (N/A)	4.138%
Peri Superior (µm)	88.205	5.854	16.392 (N/A)	6.637%	5.875	16.451 (N/A)	6.661%
Peri Temporal (µm)	67.250	2.301	6.442 (N/A)	3.421%	2.315	6.483 (N/A)	3.443%
Retinal Diseases N = 38							
Canon – Glaucoma 3D							
Para Inferior (µm)	114.880	2.252	6.306 (N/A)	1.961%	7.208	20.184 (N/A)	6.275%
Para Nasal (µm)	102.530	4.847	13.572 (N/A)	4.728%	5.430	15.203 (N/A)	5.296%
Para Superior (µm)	116.272	3.031	8.486 (N/A)	2.606%	19.387	54.284 (N/A)	16.674%
Para Temporal (µm)	97.288	3.018	8.449 (N/A)	3.102%	3.896	10.908 (N/A)	4.004%
Peri Inferior (µm)	111.539	3.141	8.796 (N/A)	2.816%	3.522	9.863 (N/A)	3.158%
Peri Nasal (µm)	79.734	4.774	13.366 (N/A)	5.987%	4.904	13.732 (N/A)	6.151%
Peri Superior (µm)	103.720	3.030	8.485 (N/A)	2.922%	6.441	18.035 (N/A)	6.210%
Peri Temporal (µm)	73.115	1.649	4.617 (N/A)	2.255%	1.817	5.088 (N/A)	2.485%

Abbreviations: 3-D = 3-dimensional; CV% = coefficient of variability percentage; N = number of eyes; ONH = optic nerve head; SD = standard deviation; N/A = Not Applicable

Limit (Ratio) is defined as the ratio between the repeatability limit for the Canon device and the predicate device and calculated by dividing the Canon device limit by the predicate device limit (C/P).

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. CV% was calculated as the repeatability or reproducibility SD/overall mean. Ratios, noted with C/D, are unitless.

Disc 3D - ONH

For the normal group, Disc 3D-ONH had an ONH C/D Minimum repeatability limit of 0.0294 and a reproducibility limit of 0.0294. Disc 3D-ONH had an ONH DDLS repeatability limit of 0.8491 and a reproducibility limit of 0.9171. For the glaucoma group, Disc 3D-ONH had an ONH C/D Minimum repeatability limit of 0.0392 and a reproducibility limit of 0.0393. Disc 3D-ONH had an ONH DDLS repeatability limit of 1.4086 and a reproducibility limit of 1.4537. For the retinal disease group, Disc 3D-ONH had an ONH C/D Minimum repeatability limit of 0.0548 and a reproducibility limit of 0.0638. Disc 3D-ONH had an ONH DDLS repeatability limit of 1.0373 and a reproducibility limit of 1.

Table 13.12 Canon Repeatability and Reproducibility on Disc 3D ONH (Effectiveness Population)

Device - Scan Type Comparable Parameter	Overall Mean	Repeatability SD	 Limit (Ratio)	 CV%	Reproducibility SD	 Limit (Ratio)	 CV%
Normal N= 37 Canon – Disc 3D							
ONH C/D Minimum	0.1399	0.0105	0.0294 (N/A)	7.5100%	0.0105	0.0294 (N/A)	7.5100%
ONH DDLS	4.2414	0.3032	0.8491 (N/A)	7.1495%	0.3275	0.9171 (N/A)	7.7224%
Glaucoma N= 37 Canon – Disc 3D							
ONH C/D Minimum	0.0502	0.0140	0.0392 (N/A)	27.8771%	0.0140	0.0392 (N/A)	27.8854%
ONH DDLS	5.2901	0.5031	1.4086 (N/A)	9.5097%	0.5192	1.4537 (N/A)	9.8141%
Retinal Diseases N = 38 Canon – Disc 3D							
ONH C/D Minimum	0.1282	0.0196	0.0548 (N/A)	15.2739%	0.0228	0.0638 (N/A)	17.7852%
ONH DDLS	4.4379	0.3705	1.0373 (N/A)	8.3481%	0.4265	1.1942 (N/A)	9.6108%

Abbreviations: 3-D = 3-dimensional; CV% = coefficient of variability percentage; N = number of eyes; ONH = optic nerve head; SD = standard deviation; N/A = Not Applicable

Limit (Ratio) is defined as the ratio between the repeatability limit for the Canon device and the predicate device and calculated by dividing the Canon device limit by the predicate device limit (C/P).

Note: The effectiveness population was defined as any subject with at least 1 acceptable scan on each device from any 1 configuration, excluding any subjects with major protocol deviations. CV% was calculated as the repeatability or reproducibility SD/overall mean. Ratios, noted with C/D, are unitless.

Discussion and Overall Conclusions

This study evaluated the agreement and precision of the Canon OCT-A1 ultra-high resolution ophthalmic imaging system for fundus imaging and axial, cross-sectional, and 3-dimensional (3D) imaging of retinal structures with Optovue RTVue Avanti XR OCT as the predicate device. Optovue RTVue Avanti XR OCT is an FDA-cleared and commercially available device that is similar in characteristics and features to the Canon device. It also has similar technologies and intended uses as the Canon OCT-A1.

However, the measurement methodologies for the full retinal thickness and the area measurement specifications are slightly different between the Canon OCT-A1 and the Optovue RTVue Avanti XR OCT resulting in a constant thickness difference between them and a different behavior of measurement at the central area. These differences result in a difference of thickness parameters as seen in the study results. The difference in methodology is that each OCT instrument produced by each manufacturer uses a different hyper reflective band as an outer border of the retina. The Optovue (RTVue) uses the 2nd hyper reflective band (upper border of RPE) as an outer border of the retina whereas the Canon OCT-A1 uses the 3rd hyper reflective band (lower border of RPE) as the outer border of the retina. Therefore, about 25 um difference is observed in the FRT measurement between Canon and Optovue. This difference is just equal to the thickness of RPE. Canon includes RPE in the FRT measurement while the Optovue does not include the RPE. Overall, agreement of the measurements with the Canon OCT-A1 and the Optovue RTVue Avanti was found to be acceptable. Measurements from both cameras were compared across three groups: normal eye, glaucoma eye, and retinal disease eye populations. Measurements of full retinal thickness, retinal nerve fiber layer thickness, ganglion cell complex thickness, and the optic nerve head were all assessed.

Agreement between Canon OCT-A1 and Optovue RTVue Avanti was determined by comparing the mean differences in measurements. Mean differences, LOAs, and LOAs that included 0 are reviewed for the agreement analyses.

Both repeatability and reproducibility were calculated for the precision analyses. Repeatability represents the variation among images within a subject within a given configuration of a machine. The ratios of the variation components were determined by dividing the component of the Canon OCT-A1 by the corresponding component of the Optovue RTVue Avanti. Ratios less than 1 indicate that OCT-A1 was less variable, while ratios greater than 1 indicate that the Optovue RTVue Avanti XR was less variable. For FRT central, Optovue RTVue Avanti generally had less variable values than Canon OCT-A1 due to the difference in measurement methodology. For FRT para and peri parameters and for RNFL, the two cameras had similar precision values, respectively. GCC and ONH parameters had mixed results, with the Canon OCT-A1 camera having better precision in 2 out of the 3 eye populations for each parameter.

In summary, based upon the overall assessment of non-clinical and clinical performance testing, a determination of substantial equivalence was made.