December 13, 2024

Heidelberg Engineering GmbH
℅ Lena Sattler
Consultant
Orasi Consulting, LLC.
226 1st Street
Bonita Springs, Florida 34134

Re: K240924
Trade/Device Name: Anterion
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: April 4, 2024
Received: November 5, 2024

Dear Lena Sattler:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Alexander Beylin -S 2024.12.13 12:23:06 -05'00'

for Elvin Ng
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240924

Device Name

ANTERION

Indications for Use *(Describe)*

The ANTERION is a non-contact ophthalmic imaging and analysis device for the eye. It is intended for visualization and measurement of the anterior segment and measurement of the axial length.

The analysis covers:
- Cornea Thickness
- Anterior Segment
  - o Anterior chamber width, depth, volume and angle parameters
  - o Lens Thickness
- Axial Length

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

Date Prepared December 10, 2024

SPONSOR/510(K) OWNER/ MANUFACTURER

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PROPRIETARY OR TRADE NAMES

ANTERION

CLASSIFICATION INFORMATION

Regulation Number:	21 CFR 886.1570
Classification name:	Ophthalmoscope, Tomography, Optical Coherence
Medical Specialty	Ophthalmic
Device Class:	II
Classification Panel:	Ophthalmic Device Panel
Product Code:	OBO

PREDICATE DEVICE

ANTERION (K230897), Heidelberg Engineering GmbH

REFERENCE DEVICE

CIRRUS HD-OCT 5000 (K181534), Carl Zeiss Meditec Inc.

INDICATIONS FOR USE

The ANTERION is a non-contact ophthalmic imaging and analysis device for the eye. It is intended for visualization and measurement of the anterior segment and the measurement of the axial length.

The analysis covers:

- Cornea Thickness
- Anterior Segment
  - Anterior chamber width, depth, volume and angle parameters
  - Lens Thickness
- Axial Length

GENERAL DEVICE DESCRIPTION

The ANTERION is a diagnostic imaging device for the eye. The technology is based on swept-source optical coherence tomography (SS-OCT) technology. The device itself has two basic component groups:

- ANTERION Hardware (Imager/Base) with integrated forehead/ chin rest: The hardware includes imaging hardware (e.g., laser, LEDs, optics, detectors, hardware for spatial encoding) as well as a touch screen.

- ANTERION Software (V.1.5) (PC): The ANTERION Software includes the main user interface. The software allows for device control, such as selection of examination(s) and imaging parameter(s). The ANTERION software provides an interface for a Medical Image Management and Processing System.

The ANTERION hardware is separated in three parts: the Base (bottom part), the Imager (top part), and the Head Rest (forehead/chin rest).

For examinations, the patient places his/her head in the forehead/chin rest. The Head Rest is mechanically and electronically connected to the Base and controlled via a joystick. Within its stand, a stepper motor with additional mechanic parts and a controller board are placed, allowing the operator to move the motorized chin rest up or down for optimally positioning the patients' eye. An external fixation light is mounted at the forehead rest.

The Base mainly contains the power supply and PC connection of the device. In the Imager, the components for scanning, signal generation, and signal processing are contained.

The operator directly accesses two software modules, which are named AQM (acquisition module) and VWM (viewing module). The AQM allows selecting between examinations. The VWM shows acquired images, parameters, and reports.

The ANTERION device contains two imaging modalities, a scanning optical coherence tomography (OCT) modality and an infrared (IR) camera. The OCT modality allows for cross-sectional imaging and biometry, while the IR camera allows

for en-face imaging of a patient's eye.

The ANTERION device provides four separate software functionalities (Apps) to acquire various imaging and measurements of the anterior segment of the eye: (1) the Imaging App, (2) the Cornea App, (3) the Cataract App and (4) the Metrics App. The Cornea App provides tomographic data and measurements for the patient´s individual corneal geometry and corneal characteristics. The Cornea App provides tomographic data and parameters, such as corneal curvature and thickness. The Cataract App provides key measurements for cataract surgery planning, such as corneal thickness, anterior chamber depth and axial length. The Metrics App generates OCT images and scan parameters for the anterior chamber such as anterior chamber angle and volume. The four ANTERION Apps are locked/unlocked independently by a license mechanism for each App. The software implementation of these Apps is realized within the AQM and VWM.

The following modification has been applied to the device, subject of this 510(k):

- Addition of the Epithelial Thickness Module (separate License in the Cornea App) with maps and parameters of the corneal epithelial and stromal thickness.

To function as intended, the ANTERION must be connected to a Medical Image Management and Processing system (MIMPS) with compatible interface. To date, HEYEX 2 / HEYEX PACS is the only available MIMPS with compatible interface.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS BETWEEN THE SUBJECT AND THE PREDICATE DEVICE

The predicate ANTERION (K230897) and the subject ANTERION do not share identical technological characteristics. However, the differences in design are marginal and do not raise different questions of safety and effectiveness. The software of both devices, the predicate ANTERION (K230897) and the subject ANTERION, includes all available imaging functions (Imaging App, Cornea App, Cataract App, Metrics App) which are locked/ unlocked independently by a license mechanism for each App. The main difference between both devices is a software modification which provides measurements of the epithelial and stromal thickness in the Cornea App for the subject device. This change, i.e. the addition of the Epithelial Thickness Module, doesn´t change the data acquisition process, the intended use/ indications for use or the used imaging technologies (OCT, IR camera) of ANTERION. Regarding the hardware, only maintenance changes regarding assembling processes were implemented for the subject device which have no impact on the technology and performance of the ANTERION.

	SUBJECT DEVICE ANTERION	PREDICATE DEVICE ANTERION(K230897)	Same, similar or different
Intended use/ Indications for use	The ANTERION is a non-contact ophthalmic imaging and analysis device for the eye. It is intended for visualization and measurement of the anterior segment and the measurement of the axial length. The analysis covers: • Cornea thickness • Anterior segment ○ Anterior chamber width, depth, volume, and angle parameters ○ Lens thickness • Axial Length	The ANTERION is a non-contact ophthalmic imaging and analysis device for the eye. It is intended for visualization and measurement of the anterior segment and the measurement of the axial length. The analysis covers: • Cornea thickness • Anterior segment ○ Anterior chamber width, depth, volume, and angle parameters ○ Lens thickness • Axial Length	Same
Main Technology	Swept Source OCT Technology	Swept Source OCT Technology	Same
Supporting Technologies	Infrared Camera	Infrared Camera	Same
OCT center wave length	1310 nm	1310 nm	Same
OCT axial resolution	<10 µm (tissue)	<10 µm (tissue)	Same
OCT lateral resolution	30 µm, 45 µm	30 µm, 45 µm	Same
Scan length	5 – 16.5 mm	5 – 16.5 mm	Same
Number of A-Scans per B-Scan	256; 512; 768; 1024	256; 512; 768; 1024	Same
A-scan rate	50,000 Hz	50,000 Hz	Same
Number of B- Scans	1-65	1-65	Same
Scan Pattern	Line, Volume, Arc, Radial	Line, Volume, Arc, Radial	Same
Scan Center	Adjustable	Adjustable	Same
Tracking	Available	Available	Same
Number of averaged Scans	1; 2; 4; 8	1; 2; 4; 8	Same
IR camera image size (px)	768 x 576	768 x 576	Same
Software Functions	• Imaging App • Cornea App • Cataract App • Metrics App	• Imaging App • Cornea App • Cataract App • Metrics App	Same
Main Parameters of Cornea App	Cornea App: • Cornea Curvature • Cornea Thickness - Epithelial Thickness - Stromal Thickness	Cornea App: • Cornea Curvature • Cornea Thickness	Similar, additional measurements in the Cornea App
Scan types for corneal thickness parameters	65 B-Scans (Cornea App)	65 B-Scans (Cornea App)	Same
Dilation of pupil required?	No	No	Same
Eye contact required?	No	No	Same
Fixation light	Internal, external	Internal, external	Same
Working position	Upright sitting position of the patient, using chin rest	Upright sitting position of the patient, using chin rest	Same
User Interface	Joystick for user to move and align device, device has GUI (Graphical user interface) for display and analysis of data	Joystick for user to move and align device, device has GUI (Graphical user interface) for display and analysis of data	Same

NON-CLINICAL PERFORMANCE TESTING

Software documentation was provided, and software verification and validation was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Documentation regarding cybersecurity was submitted as recommended by FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" and an overall risk assessment regarding security and safety of the device was conducted due to ISO 14971:2019.

Bench verification testing was conducted to demonstrate OCT spatial performance, device sensitivity, depth attenuation and performance of auxiliary functions. The device met all pre-determined acceptance criteria.

Tests for electrical safety (IEC 60601-1:2020) and electromagnetic compatibility (IEC 60601-1- 2:2020 and IEC TR 60601-4-2: 2016) were performed with ANTERION and passed the relevant requirements of the applied standards.

Laser safety testing for the light sources used in ANTERION was submitted in the previous ANTERION 510(k) K230897 and showed that the requirements according to FDA recognized standards IEC-60825- 1:2007 and ANSI Z80.36:2016 were fulfilled. The test results are still valid for the subject ANTERION.

Biocompatibility of the device was previously demonstrated by cytotoxicity testing, skin sensitization testing and chemical analysis according to ISO 10993-5:2009, ISO 10993-10:2021 and ISO 10993-18:2005, respectively, and supported by biocompatibility assessment according to 10993-1:2018. The test results remain valid for the subject ANTERION.

CLINICAL PERFORMANCE TESTING

B-2020-1 was a prospective, randomized precision and agreement clinical study conducted at one diverse clinical site, located in the United States. In the study, the investigational ANTERION device (Cornea App with Epithelial Thickness Module) was compared with Cirrus HD-OCT 5000 with Anterior Segment Premier Module (K181534). For Protocol B-2020-1, eligible participants age 22 or older were assigned to one of two groups: eyes with normal cornea (Group A), eyes with abnormal cornea (Group B). Participants in the eyes with abnormal cornea population had at least one eye with at least one of the following: keratoconus, contact lens wearer, status post-keratorefractive surgery and/or dry eye disease. One eye of each study subject was enrolled. Eyes enrolled in the study that met all inclusion criteria and did not meet any exclusion criteria were assigned to the corresponding subject population and subgroup. Any enrolled subject that did not meet inclusion/exclusion criteria was screen failed. A baseline eye examination that

included manifest refraction, slit-lamp biomicroscopy, assessment of best-corrected visual acuity (BCVA), OSDI score, Keratograph, tonometry was performed to verify eligibility. One eye per participant was randomly selected as the study eye. Three ANTERION and three CIRRUS 5000 HD-OCT devices were used. These six instruments were paired with three operators to form three device-operator configurations. All participants were imaged repeatedly on all three configurations. Three replicates per acquisition type, per configuration were obtained from each participant. The order of imaging by configuration and device order within configuration were randomized. Image quality was assessed by the operator after each acquisition. Image quality assessment of CIRRUS images were performed consistent with the CIRRUS instructions for use. Repeatability and reproducibility of measurements were estimated using a two-way, random-effects analysis of variance (ANOVA) model. Agreement was characterized using Bland-Altman and Deming regression analyses.

The analysis population of this study included 115 subjects: thirty-two (32) in the Normal Cornea population and eighty-two (82) in the Abnormal Cornea population which include; twenty-five (25) in the Keratoconus subgroup, twenty (20) in the Contact Lens Wearer subgroup, eighteen (18) in the Status Post-Keratorefractive Surgery subgroup, and nineteen (19) in the Dry Eye Disease subgroup. One eye was not allocated to a group before screen failure. Data from 32 Group A participants and 81 Group B participants were included in the precision analyses, respectively. Data from 32 Group A and 80 Group B participants were included in the agreement analyses, respectively. The mean age in the safety population was 46.3 ± 15.7 years overall (mean 41.6±15.4 years in Group A, 48.2±15.5 years in Group B). 63.2% (72/114) were women (62.5% [20/32] Group A, 63.4% [52/82] Group B). 91.2% (104/114) were Caucasian (93.8% [30/32] in Group A, 90.2% [74/82] in Group B), 6.1% (7/114) were Black/African American (6.3% [2/32] Group A, 6.1% [5/82] Group B), 4.4% (5/114) were Asian (9.4% [3/32] Group A, 2.4% [2/82] Group B). 11.4% (13/114) were Hispanic/Latino (12.5% [4/32] Group A, 11.0% [9/82] Group B). Demographics are similar for the Precision Analysis Population and the Agreement Analysis Population. There were no adverse events related to this study.

The following quantitative parameters were evaluated:

- Corneal Epithelial Thickness 0-2mm ring
- Average Thickness
- Corneal Epithelial Thickness 2-5mm ring
  - Average Thickness
  - Average Thickness Nasal Sector
  - Average Thickness Superior Sector
  - Average Thickness SuperiorNasal Sector
  - Average Thickness SuperiorTemporal Sector
  - Average Thickness Temporal Sector
  - Average Thickness InferiorTemporal Sector
  - Average Thickness Inferior Sector
  - Average Thickness InferiorNasal Sector
- Corneal Epithelial Thickness 5-7mm ring
  - Average Thickness
  - Average Thickness Nasal Sector
  - Average Thickness Superior Sector
  - Average Thickness SuperiorNasal Sector
  - Average Thickness SuperiorTemporal Sector
  - Average Thickness Temporal Sector
  - Average Thickness InferiorTemporal Sector
  - Average Thickness InferiorSector
  - Average Thickness InferiorNasal Sector
- Minimum Thickness from 7mm zone [µm]
- Maximum Thickness from 7mm zone [µm]
- Corneal Epithelial Average Thickness 2-4mm ring
- Corneal Epithelial Average Thickness 4-6mm ring
- Corneal Epithelial Average Thickness 6-7mm ring
- Corneal Epithelial Mean Average Thickness from 7mm zone [µm]
- Corneal Epithelial Superior Thickness 2-7 mm
- Corneal Epithelial Inferior Thickness 2-7 mm

Rates of acquisition acceptability, as determined by the investigator/operator, were higher for ANTERION Cornea App acquisitions (83.0%) than Cirrus Pachymetry Scans (66.3%) for all eyes. These acceptance rates were similar between the Normal Cornea Eyes and Abnormal Cornea Eyes populations, for both devices.

ANTERION precision results are presented in the tables below:

Table 1 below provides the results of the repeatability and reproducibility analyses for the ANTERION for corneal epithelial thickness measurements for the Normal Cornea Eyes Population.

Table 1 Repeatability and Reproducibility of ANTERION Precision Analysis Population of Normal Cornea Eyes

Eye Population Parameter (µm)	# of Eyes	# of Scans	Intercept	Repeatability			Reproducibility		
				SD	Limit	CV%	SD	Limit	CV%
Normal Cornea Eyes									
0-2 mm Ring Average	32	285	50.79	0.72	2.02	1.42	0.99	2.77	1.94
2-5 mm Ring Average	32	285	50.00	0.59	1.66	1.18	0.86	2.42	1.73
2-5 mm Ring Nasal	32	285	50.52	0.96	2.68	1.89	1.09	3.07	2.17
2-5 mm Ring Superior Nasal	32	285	50.00	0.80	2.23	1.59	1.03	2.88	2.06
2-5 mm Ring Superior	32	285	48.90	0.81	2.26	1.65	0.97	2.71	1.98
2-5 mm Ring Superior Temporal	32	285	48.58	0.79	2.22	1.63	0.97	2.72	2.00
2-5 mm Ring Temporal	32	285	48.93	0.75	2.10	1.53	0.97	2.73	1.99
2-5 mm Ring Inferior Temporal	32	285	50.45	0.88	2.48	1.75	1.25	3.51	2.48
2-5 mm Ring Inferior	32	285	51.42	0.76	2.13	1.48	1.06	2.96	2.05
2-5 mm Ring Inferior Nasal	32	285	51.14	0.88	2.48	1.73	1.09	3.05	2.13
5-7 mm Ring Average	32	285	49.95	0.60	1.68	1.20	0.80	2.25	1.61
5-7 mm Ring Nasal	32	285	50.81	0.88	2.47	1.74	1.03	2.90	2.04
5-7 mm Ring Superior Nasal	32	285	50.45	0.89	2.49	1.76	1.13	3.16	2.23
5-7 mm Ring Superior	32	285	48.01	0.98	2.73	2.03	1.11	3.10	2.31
5-7 mm Ring Superior Temporal	32	285	48.17	0.95	2.66	1.98	1.17	3.27	2.42
5-7 mm Ring Temporal	32	285	48.91	0.95	2.67	1.95	1.10	3.08	2.25
5-7 mm Ring Inferior Temporal	32	285	50.84	1.09	3.05	2.14	1.38	3.87	2.72
5-7 mm Ring Inferior	32	285	51.25	0.95	2.66	1.85	1.18	3.31	2.31
5-7 mm Ring Inferior Nasal	32	285	50.79	1.02	2.87	2.02	1.20	3.37	2.37
7 mm Zone Minimum	32	285	42.24	1.73	4.84	4.09	1.78	4.98	4.21
7 mm Zone Maximum	32	285	57.74	1.73	4.84	2.99	1.78	4.97	3.08
2-4 mm Ring Average	32	285	49.96	0.63	1.77	1.27	0.86	2.42	1.73
4-6 mm Ring Average	32	285	50.01	0.60	1.67	1.19	0.85	2.39	1.70
6-7 mm Ring Average	32	283	49.87	0.67	1.88	1.34	0.87	2.43	1.74
7 mm Zone Average	32	285	50.00	0.58	1.63	1.16	0.84	2.34	1.67
2-7 mm Ring Superior	32	285	49.19	0.62	1.75	1.27	0.86	2.42	1.76
2-7 mm Ring Inferior	32	285	50.72	0.66	1.85	1.31	0.90	2.53	1.78

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Per study protocol, each operator had a maximum number of 9 attempts to acquire 3 acceptable scans (i.e., theoretically, 3 repeated scans from each of the 3 operator/device pairs for a total of 9 scans for each study eye). In the study, 31 Normal Cornea population study eyes had 3 acceptable scans from each of the 3 operator/device pairs, and one study eye had 6 acceptable scans (one operator/device pair did not have any acceptable scans). Therefore, a total of $9 \times 31 + 6 \times 1 = 285$ scans were included in the analysis for all parameters, except for 6-7 mm Ring Average which had missing values for two acceptable scans (i.e., $285 - 2 = 283$).
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.

Table 2 below provides the results of the repeatability and reproducibility analyses for the ANTERION for corneal epithelial thickness measurements for the Abnormal Cornea Eyes Population.

Table 2 Repeatability and Reproducibility of ANTERION Precision Analysis Population of Abnormal Cornea Eyes

Eye Population Parameter (µm)	# of Eyes	# of Scans	Intercept	Repeatability			Reproducibility		
				SD	Limit	CV%	SD	Limit	CV%
Abnormal Cornea Eyes									
0-2 mm Ring Average	81	725	50.75	0.74	2.07	1.46	1.14	3.19	2.24
2-5 mm Ring Average	81	725	50.64	0.68	1.90	1.34	0.99	2.77	1.96
2-5 mm Ring Nasal	81	725	51.03	0.87	2.43	1.70	1.13	3.16	2.21
2-5 mm Ring Superior Nasal	81	725	50.42	0.84	2.34	1.66	1.13	3.16	2.24
2-5 mm Ring Superior	81	725	49.65	0.90	2.52	1.82	1.27	3.56	2.56
2-5 mm Ring Superior Temporal	81	725	49.81	0.89	2.49	1.79	1.11	3.11	2.23
2-5 mm Ring Temporal	81	725	49.82	0.92	2.59	1.85	1.16	3.23	2.32
2-5 mm Ring Inferior Temporal	81	725	50.81	0.86	2.42	1.70	1.13	3.16	2.22
2-5 mm Ring Inferior	81	725	51.74	0.91	2.54	1.75	1.28	3.57	2.47
2-5 mm Ring Inferior Nasal	81	725	51.86	0.99	2.77	1.91	1.33	3.71	2.56
5-7 mm Ring Average	81	725	50.40	0.72	2.02	1.43	0.95	2.66	1.89
5-7 mm Ring Nasal	81	725	50.79	0.97	2.71	1.91	1.28	3.59	2.53
5-7 mm Ring Superior Nasal	81	725	50.07	0.99	2.78	1.98	1.27	3.56	2.54
5-7 mm Ring Superior	81	725	48.48	1.09	3.04	2.24	1.37	3.83	2.82
5-7 mm Ring Superior Temporal	81	725	49.13	1.14	3.18	2.31	1.29	3.62	2.63
5-7 mm Ring Temporal	81	725	50.04	0.99	2.78	1.98	1.19	3.33	2.37
5-7 mm Ring Inferior Temporal	81	725	51.55	1.20	3.37	2.34	1.39	3.89	2.70
5-7 mm Ring Inferior	81	725	51.61	1.19	3.33	2.31	1.40	3.92	2.71
5-7 mm Ring Inferior Nasal	81	725	51.39	1.18	3.31	2.30	1.47	4.13	2.87
7 mm Zone Minimum	81	725	39.98	1.72	4.81	4.30	1.82	5.10	4.56
7 mm Zone Maximum	81	725	60.60	1.93	5.39	3.18	2.18	6.11	3.60
2-4 mm Ring Average	81	725	50.50	0.69	1.92	1.36	1.00	2.81	1.99
4-6 mm Ring Average	81	725	50.70	0.70	1.95	1.37	0.98	2.74	1.93
6-7 mm Ring Average	81	716	50.20	0.76	2.13	1.51	0.97	2.72	1.94
7 mm Zone Average	81	725	50.56	0.66	1.86	1.31	0.94	2.62	1.85
2-7 mm Ring Superior	81	725	49.76	0.72	2.02	1.45	0.95	2.67	1.92
2-7 mm Ring Inferior	81	725	51.26	0.75	2.09	1.46	1.02	2.85	1.99

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Per study protocol, each operator had a maximum number of 9 attempts to acquire 3 acceptable scans (i.e., theoretically, 3 repeated scans from each of the 3 operator/device pairs for a total of 9 scans for each study eye). In the study, 79 Abnormal Cornea population study eyes (22 Keratoconus, 20 Contact Lens Wearer, 18 Post-Keratorefractive Surgery, and 19 Dry Eye Disease) had 3 acceptable scans from each of the 3 operator/device pairs; 1 Keratoconus eye had 6 acceptable scans (one operator/device pair did not have any acceptable scans), and 1 Keratoconus eye had 8 acceptable scans. Therefore, a total of $9 \times 79 + 6 \times 1 + 8 \times 1 = 725$ scans were included in the analysis for all parameters, except for 6-7 mm Ring Average which had missing values for 9 acceptable scans (6 Keratoconus, 2 Contact Lens Wearer, and 1 Dry Eye Disease; i.e., $725 - 9 = 716$).
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.

Table 3 provides the results of the repeatability and reproducibility analyses for the ANTERION for corneal epithelial thickness measurements for the Keratoconus Eyes subgroup.

Table 3 Repeatability and Reproducibility of ANTERION Corneal Epithelial Thickness Measurements Precision Analysis Population of Keratoconus Eyes

Eye Population Parameter (µm)	# of Eyes	# of Scans	Intercept	Repeatability			Reproducibility		
				SD	Limit	CV%	SD	Limit	CV%
Keratoconus Eyes									
0-2 mm Ring Average	24	212	48.18	0.86	2.42	1.79	1.36	3.82	2.83
2-5 mm Ring Average	24	212	49.15	0.82	2.30	1.67	1.22	3.42	2.48
2-5 mm Ring Nasal	24	212	50.41	1.06	2.98	2.11	1.33	3.72	2.64
2-5 mm Ring Superior Nasal	24	212	50.16	1.01	2.81	2.00	1.44	4.05	2.88
2-5 mm Ring Superior	24	212	49.63	1.11	3.12	2.25	1.76	4.93	3.55
2-5 mm Ring Superior Temporal	24	212	49.70	1.13	3.15	2.26	1.43	3.99	2.87
2-5 mm Ring Temporal	24	212	47.08	1.21	3.39	2.57	1.54	4.32	3.27
2-5 mm Ring Inferior Temporal	24	212	46.78	1.08	3.02	2.30	1.38	3.85	2.94
2-5 mm Ring Inferior	24	212	48.86	1.09	3.07	2.24	1.53	4.28	3.13
2-5 mm Ring Inferior Nasal	24	212	50.53	1.06	2.98	2.10	1.44	4.04	2.86
5-7 mm Ring Average	24	212	49.79	0.85	2.37	1.70	1.08	3.03	2.17
5-7 mm Ring Nasal	24	212	49.98	1.07	2.98	2.13	1.39	3.89	2.78
5-7 mm Ring Superior Nasal	24	212	49.40	1.20	3.35	2.42	1.53	4.27	3.09
5-7 mm Ring Superior	24	212	48.86	1.25	3.51	2.57	1.76	4.92	3.59
5-7 mm Ring Superior Temporal	24	212	50.01	1.47	4.12	2.94	1.69	4.73	3.38
5-7 mm Ring Temporal	24	212	49.08	1.14	3.20	2.33	1.47	4.13	3.00
5-7 mm Ring Inferior Temporal	24	212	49.37	1.59	4.46	3.23	1.81	5.07	3.67
5-7 mm Ring Inferior	24	212	50.52	1.52	4.25	3.01	1.63	4.57	3.23
5-7 mm Ring Inferior Nasal	24	212	50.99	1.20	3.37	2.36	1.38	3.86	2.71
7 mm Zone Minimum	24	212	34.68	2.03	5.68	5.85	2.12	5.93	6.10
7 mm Zone Maximum	24	212	64.82	2.32	6.50	3.58	2.48	6.94	3.82
2-4 mm Ring Average	24	212	48.65	0.79	2.20	1.62	1.21	3.38	2.48
4-6 mm Ring Average	24	212	49.93	0.82	2.31	1.65	1.14	3.19	2.28
6-7 mm Ring Average	24	206	49.56	0.86	2.42	1.74	1.03	2.87	2.07
7 mm Zone Average	24	212	49.43	0.80	2.24	1.62	1.11	3.12	2.25
2-7 mm Ring Superior	24	212	49.52	0.90	2.51	1.81	1.21	3.39	2.44
2-7 mm Ring Inferior	24	212	49.45	0.83	2.32	1.67	1.12	3.13	2.26

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Per study protocol, each operator had a maximum number of 9 attempts to acquire 3 acceptable scans (i.e., theoretically, 3 repeated scans from each of the 3 operator/device pairs for a total of 9 scans for each study eye). In the study, 22 Keratoconus population study eyes had 3 acceptable scans from each of the 3 operator/device pairs, one study eye had 6 acceptable scans (one operator/device pair did not have any acceptable scans) and one study eye had 8 acceptable scans. Therefore, a total of $9 \times 22 + 6 \times 1 + 8 \times 1 = 212$ scans were included in the analysis for all parameters, except for 6-7 mm Ring Average which had missing values for 6 acceptable scans (i.e., 212 – 6 = 206).
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.

Table 4 below provides the results of the repeatability and reproducibility analyses for the ANTERION for corneal epithelial thickness measurements for the Contact Lens Wearer subgroup.

Table 4 Repeatability and Reproducibility of ANTERION Corneal Epithelial Thickness Measurements Precision Analysis Population of Contact Lens Wearer

Eye Population	# of	# of		Repeatability			Reproducibility		
Parameter (µm)	Eyes	Scans	Intercept	SD	Limit	CV%	SD	Limit	CV%
Contact Lens Wearer									
0-2 mm Ring Average	20	180	50.06	0.79	2.21	1.58	1.07	3.01	2.15
2-5 mm Ring Average	20	180	49.67	0.71	1.99	1.43	1.04	2.92	2.10
2-5 mm Ring Nasal	20	180	50.02	0.89	2.49	1.78	1.26	3.52	2.52
2-5 mm Ring Superior Nasal	20	180	49.14	0.80	2.25	1.63	1.11	3.12	2.27
2-5 mm Ring Superior	20	180	48.17	0.95	2.66	1.97	1.15	3.23	2.39
2-5 mm Ring Superior Temporal	20	180	48.09	0.83	2.32	1.73	1.02	2.85	2.11
2-5 mm Ring Temporal	20	180	49.06	0.85	2.38	1.73	1.04	2.91	2.12
2-5 mm Ring Inferior Temporal	20	180	50.63	0.87	2.44	1.72	1.09	3.04	2.14
2-5 mm Ring Inferior	20	180	51.32	0.92	2.59	1.80	1.31	3.65	2.54
2-5 mm Ring Inferior Nasal	20	180	50.99	1.10	3.07	2.15	1.55	4.34	3.04
5-7 mm Ring Average	20	180	50.24	0.79	2.21	1.57	1.08	3.01	2.14
5-7 mm Ring Nasal	20	180	50.77	0.97	2.71	1.91	1.45	4.06	2.86
5-7 mm Ring Superior Nasal	20	180	49.77	1.02	2.85	2.05	1.33	3.73	2.68
5-7 mm Ring Superior	20	180	48.17	1.18	3.31	2.46	1.34	3.76	2.79
5-7 mm Ring Superior Temporal	20	180	48.47	0.99	2.77	2.04	1.13	3.17	2.34
5-7 mm Ring Temporal	20	180	49.80	1.02	2.85	2.04	1.12	3.14	2.25
5-7 mm Ring Inferior Temporal	20	180	51.61	1.04	2.91	2.01	1.18	3.31	2.29
5-7 mm Ring Inferior	20	180	51.91	1.20	3.37	2.32	1.54	4.31	2.96
5-7 mm Ring Inferior Nasal	20	180	51.37	1.23	3.45	2.40	1.78	4.99	3.47
7 mm Zone Minimum	20	180	43.23	1.55	4.33	3.58	1.74	4.86	4.01
7 mm Zone Maximum	20	180	57.68	1.96	5.49	3.40	2.37	6.63	4.11
2-4 mm Ring Average	20	180	49.58	0.79	2.20	1.58	1.05	2.95	2.12
4-6 mm Ring Average	20	180	49.92	0.77	2.16	1.54	1.08	3.03	2.17
6-7 mm Ring Average	20	178	50.44	0.88	2.48	1.75	1.14	3.20	2.27
7 mm Zone Average	20	180	49.99	0.74	2.08	1.48	1.04	2.91	2.08
2-7 mm Ring Superior	20	180	48.91	0.80	2.23	1.63	0.99	2.78	2.03
2-7 mm Ring Inferior	20	180	51.01	0.82	2.29	1.60	1.17	3.27	2.29

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Per study protocol, each operator had a maximum number of 9 attempts to acquire 3 acceptable scans (i.e., theoretically, 3 repeated scans from each of the 3 operator/device pairs for a total of 9 scans for each study eye). In the study, all 20 Contact Lens Wearer population study eyes had 3 acceptable scans from each of the 3 operator/device pairs. Therefore, a total of 9 × 20 = 180 scans were included in the analysis for all parameters, except for 6-7 mm Ring Average which had missing values from two acceptable scans (i.e., 180 – 2 = 178).
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.

Table 5 below provides the results of the repeatability and reproducibility analyses for the ANTERION for corneal epithelial thickness measurements for the Post Keratorefractive Surgery Eyes subgroup.

Table 5 Repeatability and Reproducibility of ANTERION Corneal Epithelial Thickness Measurements Precision Analysis Population of Post Keratorefractive Surgery Eyes

Eye Population	# of	# of		Repeatability			Reproducibility		
Parameter (µm)	Eyes	Scans	Intercept	SD	Limit	CV%	SD	Limit	CV%
Post Keratorefractive Surgery									
0-2 mm Ring Average	18	162	55.02	0.67	1.87	1.21	1.04	2.90	1.88
2-5 mm Ring Average	18	162	54.10	0.59	1.66	1.10	0.93	2.62	1.73
2-5 mm Ring Nasal	18	162	53.73	0.80	2.24	1.49	1.03	2.89	1.92
2-5 mm Ring Superior Nasal	18	162	53.10	0.76	2.12	1.43	1.00	2.79	1.88
2-5 mm Ring Superior	18	162	52.52	0.73	2.04	1.39	1.00	2.80	1.90
2-5 mm Ring Superior Temporal	18	162	53.19	0.70	1.97	1.32	0.93	2.61	1.75
2-5 mm Ring Temporal	18	162	54.49	0.70	1.97	1.29	0.96	2.68	1.76
2-5 mm Ring Inferior Temporal	18	162	55.65	0.70	1.96	1.25	1.15	3.21	2.06
2-5 mm Ring Inferior	18	162	55.30	0.81	2.26	1.46	1.26	3.53	2.28
2-5 mm Ring Inferior Nasal	18	162	54.84	1.06	2.98	1.94	1.33	3.73	2.43
5-7 mm Ring Average	18	162	51.81	0.61	1.72	1.18	0.91	2.55	1.76
5-7 mm Ring Nasal	18	162	51.90	1.05	2.93	2.01	1.29	3.61	2.49
5-7 mm Ring Superior Nasal	18	162	51.36	0.94	2.62	1.82	1.21	3.38	2.35
5-7 mm Ring Superior	18	162	49.90	0.98	2.76	1.97	1.22	3.42	2.45
5-7 mm Ring Superior Temporal	18	162	50.56	0.97	2.71	1.92	1.09	3.06	2.16
5-7 mm Ring Temporal	18	162	51.88	0.83	2.32	1.60	1.03	2.89	1.99
5-7 mm Ring Inferior Temporal	18	162	53.27	0.96	2.69	1.80	1.20	3.35	2.25
5-7 mm Ring Inferior	18	162	52.75	0.96	2.68	1.81	1.25	3.51	2.38
5-7 mm Ring Inferior Nasal	18	162	52.50	1.46	4.07	2.77	1.72	4.80	3.27
7 mm Zone Minimum	18	162	41.75	1.63	4.56	3.90	1.68	4.71	4.03
7 mm Zone Maximum	18	162	60.77	1.71	4.78	2.81	1.98	5.54	3.26
2-4 mm Ring Average	18	162	54.34	0.62	1.75	1.15	1.00	2.79	1.83
4-6 mm Ring Average	18	162	53.12	0.61	1.70	1.15	0.95	2.67	1.80
6-7 mm Ring Average	18	162	51.06	0.67	1.88	1.31	0.98	2.74	1.92
7 mm Zone Average	18	162	53.07	0.55	1.54	1.04	0.88	2.45	1.65
2-7 mm Ring Superior	18	162	51.99	0.57	1.59	1.09	0.82	2.30	1.58
2-7 mm Ring Inferior	18	162	53.78	0.76	2.12	1.41	1.05	2.95	1.96

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Per study protocol, each operator had a maximum number of 9 attempts to acquire 3 acceptable scans (i.e., theoretically, 3 repeated scans from each of the 3 operator/device pairs for a total of 9 scans for each study eye). In the study, all 18 Post Keratorefractive Surgery population study eyes had 3 acceptable scans from each of the 3 operator/device pairs. Therefore, a total of 9 × 18 = 162 scans were included in the analysis for all parameters.
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.

Table 6 below provides the results of the repeatability and reproducibility analyses for the ANTERION for corneal epithelial thickness measurements for the Dry Eye Disease subgroup.

Table 6 Repeatability and Reproducibility of ANTERION Corneal Epithelial Thickness Measurements Precision Analysis Population of Dry Eye Disease

Eye Population	# of	# of		Repeatability			Reproducibility		
Parameter (µm)	Eyes	Scans	Intercept	SD	Limit	CV%	SD	Limit	CV%
Dry Eye Disease									
0-2 mm Ring Average	19	171	50.68	0.56	1.56	1.10	0.98	2.74	1.93
2-5 mm Ring Average	19	171	50.27	0.50	1.40	1.00	0.59	1.64	1.17
2-5 mm Ring Nasal	19	171	50.34	0.60	1.67	1.19	0.73	2.05	1.45
2-5 mm Ring Superior Nasal	19	171	49.54	0.70	1.95	1.41	0.75	2.11	1.52
2-5 mm Ring Superior	19	171	48.53	0.68	1.89	1.39	0.83	2.32	1.71
2-5 mm Ring Superior Temporal	19	171	48.56	0.77	2.16	1.59	0.90	2.51	1.85
2-5 mm Ring Temporal	19	171	49.67	0.75	2.11	1.52	0.84	2.36	1.69
2-5 mm Ring Inferior Temporal	19	171	51.51	0.68	1.92	1.33	0.76	2.12	1.47
2-5 mm Ring Inferior	19	171	52.43	0.69	1.93	1.31	0.84	2.36	1.61
2-5 mm Ring Inferior Nasal	19	171	51.63	0.65	1.83	1.27	0.80	2.25	1.56
5-7 mm Ring Average	19	171	50.01	0.55	1.53	1.09	0.61	1.72	1.23
5-7 mm Ring Nasal	19	171	50.77	0.74	2.06	1.45	0.89	2.49	1.75
5-7 mm Ring Superior Nasal	19	171	49.98	0.69	1.93	1.38	0.85	2.38	1.70
5-7 mm Ring Superior	19	171	46.99	0.81	2.27	1.72	0.90	2.52	1.92
5-7 mm Ring Superior Temporal	19	171	47.36	0.93	2.60	1.96	1.04	2.92	2.20
5-7 mm Ring Temporal	19	171	49.75	0.90	2.52	1.81	0.98	2.75	1.98
5-7 mm Ring Inferior Temporal	19	171	52.60	1.00	2.80	1.90	1.14	3.20	2.17
5-7 mm Ring Inferior	19	171	51.58	0.87	2.43	1.68	1.01	2.83	1.96
5-7 mm Ring Inferior Nasal	19	171	50.85	0.73	2.04	1.43	0.85	2.37	1.67
7 mm Zone Minimum	19	171	41.61	1.55	4.33	3.72	1.64	4.60	3.95
7 mm Zone Maximum	19	171	58.17	1.49	4.17	2.56	1.72	4.82	2.96
2-4 mm Ring Average	19	171	50.18	0.45	1.27	0.90	0.61	1.70	1.21
4-6 mm Ring Average	19	171	50.18	0.49	1.37	0.98	0.60	1.69	1.20
6-7 mm Ring Average	19	170	49.96	0.54	1.51	1.08	0.66	1.84	1.31
7 mm Zone Average	19	171	50.22	0.46	1.28	0.91	0.56	1.57	1.12
2-7 mm Ring Superior	19	171	48.85	0.50	1.40	1.03	0.60	1.69	1.24
2-7 mm Ring Inferior	19	171	51.43	0.52	1.45	1.01	0.59	1.66	1.15

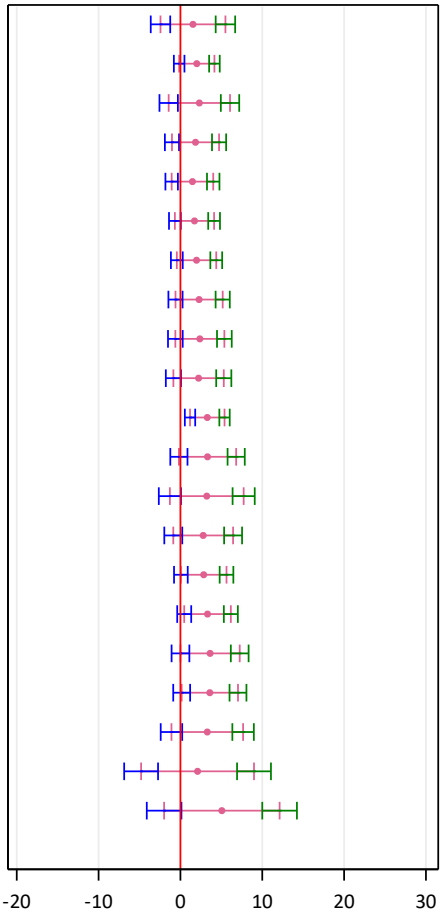
All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye. Per study protocol, each operator had a maximum number of 9 attempts to acquire 3 acceptable scans (i.e., theoretically, 3 repeated scans from each of the 3 operator/device pairs for a total of 9 scans for each study eye). In the study, all 19 Dry Eye Disease population study eyes had 3 acceptable scans from each of the 3 operator/device pairs. Therefore, a total of 9 × 19 = 171 scans were included in the analysis for all parameters, except for 6-7 mm Ring Average which had missing values for one acceptable scan (i.e., 171 – 1 = 170).
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.

Agreement results are presented in the figures below:

In the figures below, the summary of Limit of Agreement (LoA) and the corresponding 95% CIs of the lower LoA and upper LoA are shown for Normal Cornea Eyes (Figure 1) and Abnormal Cornea Eyes (Figure 2) populations, as well as stratified into the subgroups Keratoconus Eyes (Figure 3), Contact Lens Wearer (Figure 4), Post- Keratorefractive Surgery Eyes (Figure 5) and Dry Eye Disease (Figure 6). Note that the difference between ANTERION and Cirrus is calculated as ANTERION – Cirrus, where positive differences indicate that ANTERION measures thicker and negative differences indicate that ANTERION measures thinner.

Figure 1 Summary of Limit of Agreement of Corneal Epithelial Thickness Measurements Between ANTERION and Cirrus, Agreement Analysis Population of Normal Cornea Eyes

Parameter (µm)	Mean Bias	Limit of Agreement (LoA)	95% CI of Lower Limit of LoA	95% CI of Upper Limit of LoA
0-2mm Avg	1.53	(-2.44, 5.50)	(-3.63, -1.25)	(4.31, 6.69)
2-5mm Avg	2.00	(-0.16, 4.16)	(-0.80, 0.49)	(3.51, 4.80)
2-5mm Nas	2.31	(-1.44, 6.06)	(-2.56, -0.31)	(4.94, 7.19)
2-5mm S-N	1.84	(-1.03, 4.72)	(-1.90, -0.17)	(3.86, 5.59)
2-5mm Sup	1.47	(-1.07, 4.01)	(-1.83, -0.31)	(3.25, 4.77)
2-5mm S-T	1.72	(-0.68, 4.11)	(-1.40, 0.04)	(3.40, 4.83)
2-5mm Tem	1.97	(-0.44, 4.38)	(-1.16, 0.28)	(3.65, 5.10)
2-5mm I-T	2.28	(-0.60, 5.17)	(-1.47, 0.26)	(4.30, 6.03)
2-5mm Inf	2.38	(-0.62, 5.37)	(-1.52, 0.28)	(4.47, 6.27)
2-5mm I-N	2.22	(-0.86, 5.30)	(-1.78, 0.06)	(4.37, 6.22)
5-7mm Avg	3.28	(1.17, 5.39)	(0.54, 1.81)	(4.76, 6.02)
5-7mm Nas	3.31	(-0.19, 6.81)	(-1.24, 0.86)	(5.76, 7.86)
5-7mm S-N	3.22	(-1.29, 7.73)	(-2.64, 0.06)	(6.37, 9.08)
5-7mm Sup	2.78	(-0.87, 6.44)	(-1.97, 0.22)	(5.34, 7.53)
5-7mm S-T	2.84	(0.06, 5.63)	(-0.78, 0.89)	(4.79, 6.47)
5-7mm Tem	3.31	(0.46, 6.16)	(-0.39, 1.32)	(5.31, 7.02)
5-7mm I-T	3.63	(0.01, 7.24)	(-1.08, 1.09)	(6.16, 8.33)
5-7mm Inf	3.59	(0.15, 7.03)	(-0.88, 1.19)	(6.00, 8.07)
5-7mm I-N	3.28	(-1.10, 7.66)	(-2.41, 0.22)	(6.34, 8.97)
7mm Zone Min	2.09	(-4.80, 8.99)	(-6.87, -2.73)	(6.92, 11.06)
7mm Zone Max	5.06	(-1.99, 12.12)	(-4.11, 0.12)	(10.00, 14.24)



Difference = ANTERION – Cirrus. The 1st acceptable ANTERION scan and 1st acceptable Cirrus scan of each study eye was used to compare the difference (i.e., only one pair per study eye).

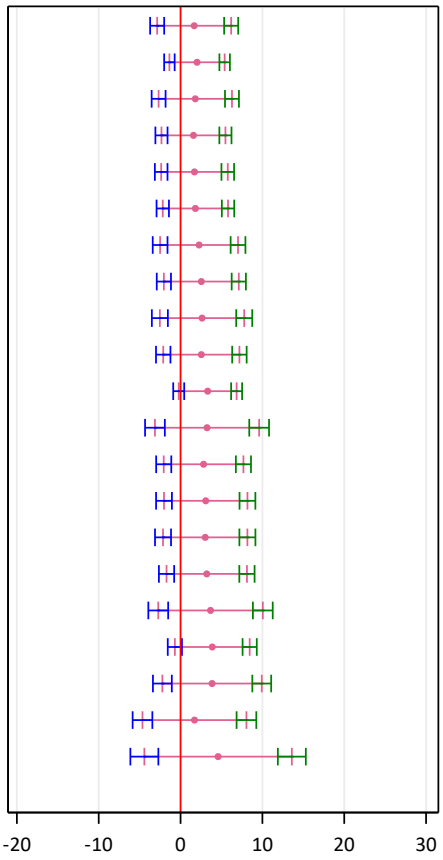
Avg=Average, Nas=Nasal, Tem=Temporal, Sup=Superior, Inf=Inferior

S-N=Superior Nasal, S-T=Superior Temporal, I-N=Inferior Nasal, I-T=Inferior Temporal

95% CI of LoA = LoA ± 1.96 × Sqrt(n/3) × SD of differences, where n = 32, the sample size of differences.

Figure 2 Summary of Limit of Agreement of Corneal Epithelial Thickness Measurements Between ANTERION and Cirrus, Agreement Analysis Population of Abnormal Cornea Eyes

Parameter (µm)	Mean Bias	Limit of Agreement (LoA)	95% CI of Lower Limit of LoA	95% CI of Upper Limit of LoA
0-2mm Avg	1.66	(-2.86, 6.18)	(-3.72, -2.00)	(5.33, 7.04)
2-5mm Avg	2.01	(-1.36, 5.39)	(-2.00, -0.72)	(4.75, 6.03)
2-5mm Nas	1.80	(-2.68, 6.28)	(-3.53, -1.83)	(5.43, 7.13)
2-5mm S-N	1.58	(-2.33, 5.48)	(-3.07, -1.59)	(4.74, 6.22)
2-5mm Sup	1.70	(-2.37, 5.77)	(-3.14, -1.60)	(5.00, 6.54)
2-5mm S-T	1.81	(-2.18, 5.80)	(-2.93, -1.42)	(5.04, 6.56)
2-5mm Tem	2.26	(-2.50, 7.02)	(-3.40, -1.59)	(6.12, 7.93)
2-5mm I-T	2.54	(-2.04, 7.12)	(-2.91, -1.17)	(6.25, 7.98)
2-5mm Inf	2.63	(-2.53, 7.78)	(-3.51, -1.55)	(6.80, 8.76)
2-5mm I-N	2.54	(-2.12, 7.19)	(-3.00, -1.23)	(6.31, 8.08)
5-7mm Avg	3.31	(-0.23, 6.85)	(-0.90, 0.45)	(6.18, 7.52)
5-7mm Nas	3.24	(-3.13, 9.60)	(-4.34, -1.92)	(8.40, 10.81)
5-7mm S-N	2.81	(-2.06, 7.68)	(-2.98, -1.13)	(6.76, 8.61)
5-7mm Sup	3.08	(-2.02, 8.17)	(-2.99, -1.06)	(7.21, 9.14)
5-7mm S-T	3.01	(-2.14, 8.17)	(-3.12, -1.16)	(7.19, 9.15)
5-7mm Tem	3.20	(-1.71, 8.11)	(-2.65, -0.78)	(7.18, 9.05)
5-7mm I-T	3.66	(-2.73, 10.05)	(-3.94, -1.51)	(8.84, 11.26)
5-7mm Inf	3.88	(-0.70, 8.45)	(-1.56, 0.17)	(7.58, 9.31)
5-7mm I-N	3.85	(-2.22, 9.92)	(-3.37, -1.07)	(8.77, 11.07)
7mm Zone Min	1.70	(-4.65, 8.05)	(-5.86, -3.45)	(6.85, 9.26)
7mm Zone Max	4.59	(-4.42, 13.60)	(-6.13, -2.71)	(11.89, 15.31)



Difference = ANTERION – Cirrus. The 1st acceptable ANTERION scan and 1st acceptable Cirrus scan of each study eye was used to compare the difference (i.e., only one pair per study eye).

One Keratoconus population study eye had acceptable ANTERION scans but no acceptable Cirrus scans. This eye was included in the ANTERION precision analysis but excluded from the Agreement Analysis.

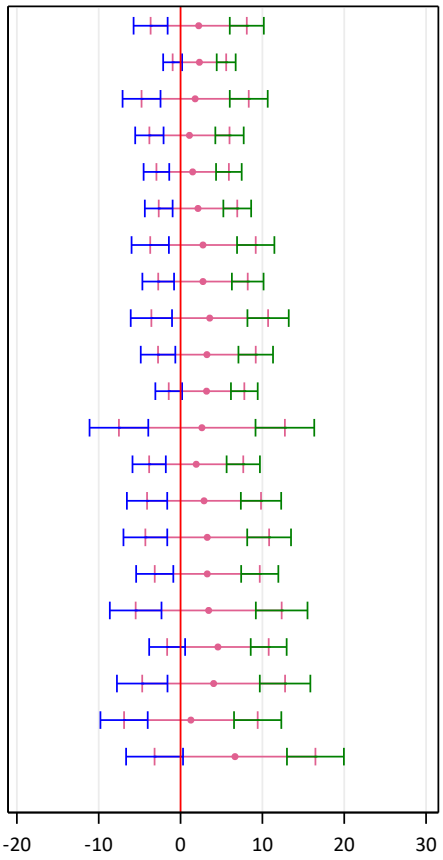
Avg=Average, Nas=Nasal, Tem=Temporal, Sup=Superior, Inf=Inferior

S-N=Superior Nasal, S-T=Superior Temporal, I-N=Inferior Nasal, I-T=Inferior Temporal

95% CI of LoA = LoA ± 1.96 × Sqrt(n/3) × SD of differences, where n = 80, the sample size of differences.

Figure 3 Summary of Limit of Agreement of Corneal Epithelial Thickness Measurements Between ANTERION and Cirrus, Agreement Analysis Population of Keratoconus Eyes

Parameter (µm)	Mean Bias	Limit of Agreement (LoA)	95% CI of Lower Limit of LoA	95% CI of Upper Limit of LoA
0-2mm Avg	2.22	(-3.66, 8.09)	(-5.74, -1.58)	(6.01, 10.17)
2-5mm Avg	2.30	(-0.97, 5.58)	(-2.13, 0.19)	(4.42, 6.73)
2-5mm Nas	1.78	(-4.77, 8.33)	(-7.08, -2.45)	(6.01, 10.65)
2-5mm S-N	1.09	(-3.81, 5.98)	(-5.54, -2.08)	(4.25, 7.72)
2-5mm Sup	1.48	(-2.95, 5.90)	(-4.51, -1.38)	(4.34, 7.47)
2-5mm S-T	2.13	(-2.67, 6.93)	(-4.37, -0.97)	(5.23, 8.63)
2-5mm Tem	2.74	(-3.71, 9.18)	(-5.99, -1.42)	(6.90, 11.46)
2-5mm I-T	2.74	(-2.73, 8.21)	(-4.66, -0.79)	(6.27, 10.14)
2-5mm Inf	3.57	(-3.57, 10.70)	(-6.09, -1.04)	(8.17, 13.22)
2-5mm I-N	3.22	(-2.75, 9.19)	(-4.86, -0.64)	(7.07, 11.30)
5-7mm Avg	3.17	(-1.44, 7.79)	(-3.08, 0.19)	(6.16, 9.43)
5-7mm Nas	2.61	(-7.53, 12.75)	(-11.12, -3.94)	(9.16, 16.34)
5-7mm S-N	1.91	(-3.84, 7.66)	(-5.87, -1.80)	(5.63, 9.70)
5-7mm Sup	2.87	(-4.09, 9.83)	(-6.56, -1.63)	(7.37, 12.30)
5-7mm S-T	3.26	(-4.30, 10.82)	(-6.98, -1.62)	(8.15, 13.50)
5-7mm Tem	3.26	(-3.16, 9.68)	(-5.43, -0.88)	(7.41, 11.95)
5-7mm I-T	3.43	(-5.49, 12.36)	(-8.64, -2.33)	(9.20, 15.51)
5-7mm Inf	4.57	(-1.64, 10.77)	(-3.83, 0.56)	(8.57, 12.96)
5-7mm I-N	4.04	(-4.68, 12.77)	(-7.77, -1.60)	(9.68, 15.86)
7mm Zone Min	1.26	(-6.90, 9.42)	(-9.79, -4.01)	(6.53, 12.31)
7mm Zone Max	6.65	(-3.18, 16.48)	(-6.65, 0.30)	(13.00, 19.96)



Difference = ANTERION – Cirrus. The 1st acceptable ANTERION scan and 1st acceptable Cirrus scan of each study eye was used to compare the difference (i.e., only one pair per study eye).

One Keratoconus population study eye had acceptable ANTERION scans but no acceptable Cirrus scans. This eye was included in the ANTERION precision analysis but excluded from the Agreement Analysis.

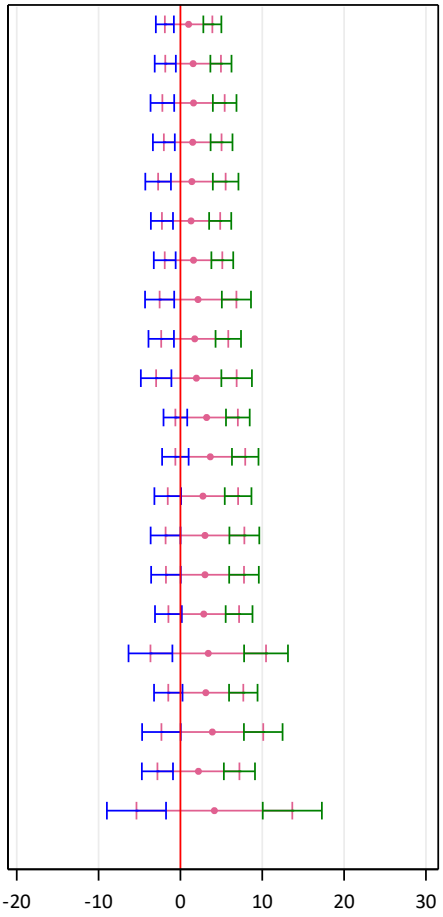
Avg=Average, Nas=Nasal, Tem=Temporal, Sup=Superior, Inf=Inferior

S-N=Superior Nasal, S-T=Superior Temporal, I-N=Inferior Nasal, I-T=Inferior Temporal

95% CI of LoA = LoA ± 1.96 × Sqrt(n/3) × SD of differences, where n = 23, the sample size of differences.

Figure 4 Summary of Limit of Agreement of Corneal Epithelial Thickness Measurements Between ANTERION and Cirrus, Agreement Analysis Population of Contact Lens Wearer

Parameter (µm)	Mean Bias	Limit of Agreement (LoA)	95% CI of Lower Limit of LoA	95% CI of Upper Limit of LoA
0-2mm Avg	1.00	(-1.90, 3.90)	(-3.00, -0.80)	(2.80, 5.00)
2-5mm Avg	1.55	(-1.85, 4.95)	(-3.14, -0.56)	(3.66, 6.24)
2-5mm Nas	1.60	(-2.21, 5.41)	(-3.65, -0.76)	(3.96, 6.85)
2-5mm S-N	1.50	(-2.02, 5.02)	(-3.36, -0.69)	(3.69, 6.36)
2-5mm Sup	1.40	(-2.72, 5.52)	(-4.29, -1.16)	(3.96, 7.09)
2-5mm S-T	1.30	(-2.26, 4.86)	(-3.61, -0.91)	(3.51, 6.21)
2-5mm Tem	1.60	(-1.92, 5.12)	(-3.25, -0.58)	(3.78, 6.45)
2-5mm I-T	2.15	(-2.54, 6.84)	(-4.32, -0.76)	(5.06, 8.62)
2-5mm Inf	1.75	(-2.35, 5.85)	(-3.90, -0.79)	(4.29, 7.40)
2-5mm I-N	1.95	(-2.97, 6.87)	(-4.84, -1.10)	(5.00, 8.74)
5-7mm Avg	3.20	(-0.62, 7.02)	(-2.07, 0.83)	(5.57, 8.47)
5-7mm Nas	3.65	(-0.62, 7.92)	(-2.24, 1.00)	(6.30, 9.54)
5-7mm S-N	2.75	(-1.55, 7.05)	(-3.18, 0.08)	(5.42, 8.68)
5-7mm Sup	3.00	(-1.81, 7.81)	(-3.64, 0.01)	(5.99, 9.64)
5-7mm S-T	3.00	(-1.77, 7.77)	(-3.58, 0.04)	(5.96, 9.58)
5-7mm Tem	2.85	(-1.47, 7.17)	(-3.11, 0.17)	(5.53, 8.81)
5-7mm I-T	3.40	(-3.66, 10.46)	(-6.34, -0.98)	(7.78, 13.14)
5-7mm Inf	3.10	(-1.48, 7.68)	(-3.22, 0.26)	(5.94, 9.42)
5-7mm I-N	3.90	(-2.32, 10.12)	(-4.68, 0.04)	(7.76, 12.48)
7mm Zone Min	2.20	(-2.81, 7.21)	(-4.71, -0.91)	(5.31, 9.11)
7mm Zone Max	4.15	(-5.37, 13.67)	(-8.98, -1.76)	(10.06, 17.28)



Difference = ANTERION – Cirrus. The 1st acceptable ANTERION scan and 1st acceptable Cirrus scan of each study eye was used to compare the difference (i.e., only one pair per study eye).

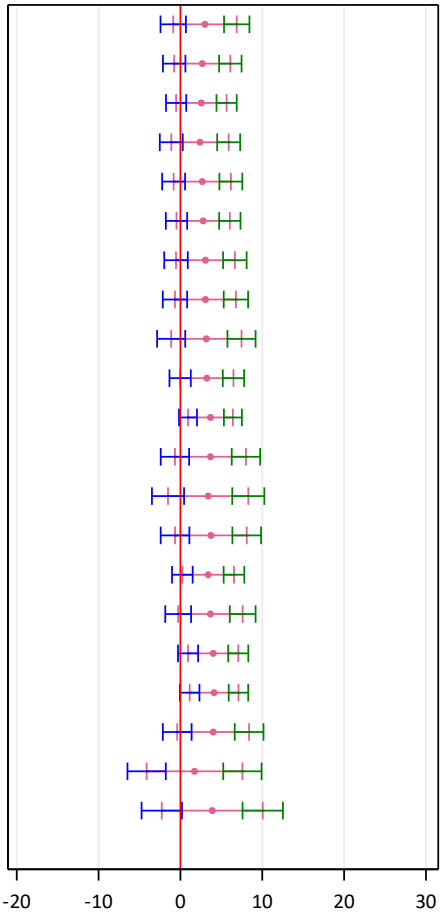
Avg=Average, Nas=Nasal, Tem=Temporal, Sup=Superior, Inf=Inferior

S-N=Superior Nasal, S-T=Superior Temporal, I-N=Inferior Nasal, I-T=Inferior Temporal

95% CI of LoA = LoA ± 1.96 × Sqrt(n/3) × SD of differences, where n = 20, the sample size of differences.

Figure 5 Summary of Limit of Agreement of Corneal Epithelial Thickness Measurements Between ANTERION and Cirrus, Agreement Analysis Population of Post Keratorefractive Surgery Eyes

Parameter (µm)	Mean Bias	Limit of Agreement (LoA)	95% CI of Lower Limit of LoA	95% CI of Upper Limit of LoA
0-2mm Avg	3.00	(-0.88, 6.88)	(-2.43, 0.67)	(5.33, 8.43)
2-5mm Avg	2.67	(-0.76, 6.10)	(-2.14, 0.61)	(4.72, 7.47)
2-5mm Nas	2.56	(-0.53, 5.64)	(-1.76, 0.70)	(4.41, 6.87)
2-5mm S-N	2.39	(-1.12, 5.90)	(-2.52, 0.28)	(4.49, 7.30)
2-5mm Sup	2.67	(-0.83, 6.16)	(-2.23, 0.57)	(4.77, 7.56)
2-5mm S-T	2.78	(-0.48, 6.04)	(-1.78, 0.82)	(4.73, 7.34)
2-5mm Tem	3.06	(-0.54, 6.65)	(-1.98, 0.90)	(5.21, 8.09)
2-5mm I-T	3.06	(-0.67, 6.78)	(-2.16, 0.82)	(5.29, 8.27)
2-5mm Inf	3.17	(-1.13, 7.46)	(-2.85, 0.59)	(5.74, 9.18)
2-5mm I-N	3.22	(-0.04, 6.48)	(-1.34, 1.27)	(5.18, 7.78)
5-7mm Avg	3.67	(0.92, 6.41)	(-0.18, 2.02)	(5.31, 7.51)
5-7mm Nas	3.67	(-0.67, 8.01)	(-2.41, 1.06)	(6.27, 9.74)
5-7mm S-N	3.39	(-1.52, 8.29)	(-3.48, 0.45)	(6.33, 10.26)
5-7mm Sup	3.72	(-0.66, 8.10)	(-2.41, 1.09)	(6.35, 9.86)
5-7mm S-T	3.39	(0.23, 6.54)	(-1.03, 1.50)	(5.28, 7.80)
5-7mm Tem	3.67	(-0.27, 7.61)	(-1.85, 1.30)	(6.03, 9.18)
5-7mm I-T	4.00	(0.93, 7.07)	(-0.30, 2.16)	(5.84, 8.30)
5-7mm Inf	4.11	(1.13, 7.09)	(-0.06, 2.32)	(5.90, 8.29)
5-7mm I-N	4.00	(-0.39, 8.39)	(-2.15, 1.36)	(6.64, 10.15)
7mm Zone Min	1.72	(-4.13, 7.58)	(-6.47, -1.79)	(5.23, 9.92)
7mm Zone Max	3.89	(-2.28, 10.06)	(-4.75, 0.19)	(7.59, 12.53)



Difference = ANTERION – Cirrus. The 1st acceptable ANTERION scan and 1st acceptable Cirrus scan of each study eye was used to compare the difference (i.e., only one pair per study eye).

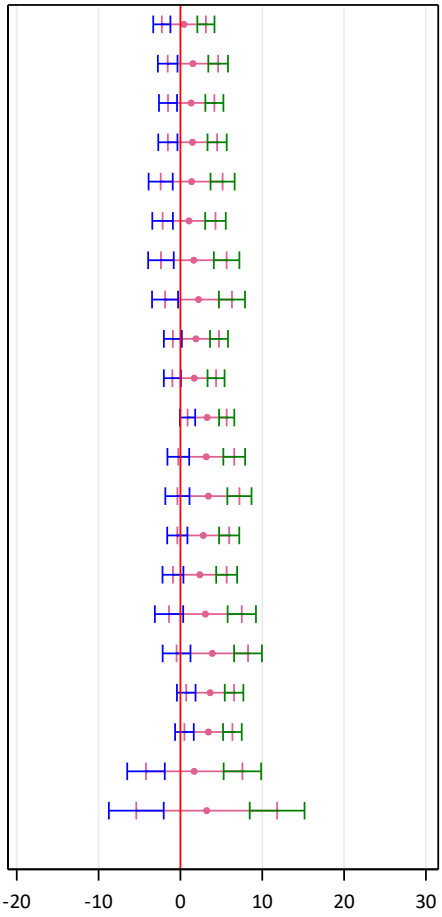
Avg=Average, Nas=Nasal, Tem=Temporal, Sup=Superior, Inf=Inferior

S-N=Superior Nasal, S-T=Superior Temporal, I-N=Inferior Nasal, I-T=Inferior Temporal

95% CI of LoA = LoA ± 1.96 × Sqrt(n/3) × SD of differences, where n = 18, the sample size of differences.

Figure 6 Summary of Limit of Agreement of Corneal Epithelial Thickness Measurements Between ANTERION and Cirrus, Agreement Analysis Population of Dry Eye Disease

Parameter (µm)	Mean Bias	Limit of Agreement (LoA)	95% CI of Lower Limit of LoA	95% CI of Upper Limit of LoA
0-2mm Avg	0.42	(-2.27, 3.11)	(-3.32, -1.22)	(2.07, 4.16)
2-5mm Avg	1.53	(-1.56, 4.61)	(-2.76, -0.36)	(3.41, 5.81)
2-5mm Nas	1.32	(-1.52, 4.15)	(-2.62, -0.41)	(3.05, 5.25)
2-5mm S-N	1.47	(-1.54, 4.48)	(-2.71, -0.36)	(3.31, 5.65)
2-5mm Sup	1.37	(-2.42, 5.15)	(-3.89, -0.94)	(3.68, 6.63)
2-5mm S-T	1.05	(-2.18, 4.28)	(-3.44, -0.92)	(3.02, 5.54)
2-5mm Tem	1.63	(-2.38, 5.64)	(-3.94, -0.82)	(4.08, 7.21)
2-5mm I-T	2.21	(-1.88, 6.30)	(-3.47, -0.28)	(4.71, 7.89)
2-5mm Inf	1.89	(-0.93, 4.71)	(-2.02, 0.17)	(3.62, 5.81)
2-5mm I-N	1.68	(-0.99, 4.36)	(-2.03, 0.05)	(3.32, 5.40)
5-7mm Avg	3.26	(0.87, 5.65)	(-0.06, 1.80)	(4.72, 6.58)
5-7mm Nas	3.16	(-0.26, 6.57)	(-1.59, 1.07)	(5.24, 7.90)
5-7mm S-N	3.42	(-0.37, 7.21)	(-1.84, 1.11)	(5.74, 8.69)
5-7mm Sup	2.79	(-0.38, 5.96)	(-1.61, 0.86)	(4.72, 7.19)
5-7mm S-T	2.37	(-0.91, 5.65)	(-2.19, 0.37)	(4.37, 6.93)
5-7mm Tem	3.05	(-1.39, 7.50)	(-3.12, 0.34)	(5.77, 9.23)
5-7mm I-T	3.89	(-0.47, 8.26)	(-2.17, 1.23)	(6.56, 9.96)
5-7mm Inf	3.63	(0.71, 6.55)	(-0.43, 1.85)	(5.42, 7.69)
5-7mm I-N	3.42	(0.49, 6.35)	(-0.65, 1.63)	(5.21, 7.49)
7mm Zone Min	1.68	(-4.21, 7.57)	(-6.50, -1.91)	(5.28, 9.87)
7mm Zone Max	3.21	(-5.39, 11.81)	(-8.74, -2.04)	(8.46, 15.17)



Difference = ANTERION – Cirrus. The 1st acceptable ANTERION scan and 1st acceptable Cirrus scan of each study eye was used to compare the difference (i.e., only one pair per study eye).

Avg=Average, Nas=Nasal, Tem=Temporal, Sup=Superior, Inf=Inferior

S-N=Superior Nasal, S-T=Superior Temporal, I-N=Inferior Nasal, I-T=Inferior Temporal

95% CI of LoA = LoA ± 1.96 × Sqrt(n/3) × SD of differences, where n = 19, the sample size of differences.

B-2020-1 Summary

This study was performed to assess the repeatability and reproducibility of the corneal epithelial thickness parameters of the Heidelberg Engineering ANTERION with Cornea App and compare to those derived from the Zeiss Cirrus HD-OCT 5000 with Anterior Segment Premier Module. In addition, the agreement of the corneal epithelial thickness parameters between the ANTERION and the Zeiss Cirrus 5000 with Anterior Segment Premium Module was assessed.

Rates of acquisition acceptability, as determined by the investigator/operator, were higher for ANTERION Cornea App acquisitions (83.0%) than Cirrus Pachymetry Scans (66.3%) for all eyes. These acceptance rates were similar between the Normal Cornea Eyes and Abnormal Cornea Eyes populations, for both devices.

The repeatability and reproducibility results summarized as SD ratio (i.e., ANTERION SD/Cirrus SD) and analyzed by CV% generally demonstrate similar or better precision on ANTERION than Cirrus for both the Normal Cornea Eyes and Abnormal Cornea Eyes populations.

The agreement results summarized as Limits of Agreement and Deming Regression Coefficient demonstrated general agreement between ANTERION and Cirrus for both the Normal Cornea Eyes and Abnormal Cornea Eyes populations.

Precision

For all populations and subgroups, ANTERION repeatability SD values ranged 0.59µm to 1.59µm, and reproducibility SD values ranged 0.59µm to 1.81µm, except in the 7mm Zone parameters (ranges for repeatability from 1.49µm to 2.32µm and for reproducibility from 1.64µm to 2.48µm).

Comparing to Cirrus, the ANTERION SD values were generally lower (Cirrus repeatability SD range 0.67µm to 2.01µm, reproducibility SD range 0.76µm to 2.24µm, and 7mm Zone range 1.34µm to 2.87µm) for all populations and subgroups.

The repeatability and reproducibility results summarized as SD ratio plots generally demonstrate similar or better precision on ANTERION for both the Normal Cornea Eyes and the Abnormal Cornea Eyes populations. It should be noted that the SD ratio plot findings for the Abnormal Cornea Eyes population applied to all subgroups except the Contact Lens Wearer subgroup. Although a majority of the Contact Lens Wearer subgroup SD ratios were larger than 1—

indicating that Cirrus generally showed better precision in this subgroup— the SD values for ANTERION remained small (repeatability SD values ranged 0.71µm to 1.23µm and reproducibility SD values ranged 1.02µm to 1.78µm, except 7mm Zone Minimum and Maximum for which repeatability SD values were 1.55µm and 1.96µm, respectively, and reproducibility SD values were 1.74µm and 2.37µm, respectively) and comparable to the other subgroups.

The precision results for CV% also generally demonstrate similar or better precision on ANTERION as compared to Cirrus for both the Normal Cornea Eyes and the Abnormal Cornea Eyes populations, with most CV%s for ANTERION within or around 1-4% (range 0.90% to 3.47% for all populations and subgroups except Keratoconus Eyes which ranged up to 3.82%), and most CV%s for Cirrus within or around 1-5% (range 1.29% to 3.63% for all populations and subgroups except Keratoconus Eyes which ranged up to 5.04%). For both devices, the few larger CV%s were typically found for outer zone measurements (7mm Zone Minimum and Maximum).

The CV% results in the outer regions were in general larger compared to the central regions. This finding was observed for both the ANTERION and Cirrus and across all populations/subgroups.

The precision analysis for the areas measured by ANTERION only (i.e., 2-4mm, 4-6mm and 6-7mm Ring Average, 7mm Zone Average, and 2-7mm Superior and Inferior) showed similar standard deviations and CV%s to measurements obtained from the areas measured by both instruments in all populations.

Agreement

ANTERION was observed to measure, in general, slightly thicker values for corneal epithelial thickness compared to the Cirrus for both populations (mean difference 1.3µm to 5.1µm thicker). For the 7mm Zone Minimum and Maximum, the differences between ANTERION and Cirrus are larger than those of other parameters. Nevertheless, for Deming Regression of all parameters, the 95%CI for intercept included 0 and the 95%CI for slope included 1 for all populations and subgroups with exceptions for a few specific parameters in the Keratoconus Eyes, Post Keratorefractive Surgery Eyes and Dry Eye Disease subgroups.

The thicker measurements produced by ANTERION appear to be systematic in nature, where this finding was consistently present for all populations and subgroups with the largest differences found in the Keratoconus Eyes subgroup (1.1µm to 6.7µm thicker) and the smallest differences found in the

Dry Eye Disease subgroup (0.4µm to 3.9µm thicker). This is corroborated by the literature where similar devices from different manufacturers—ANTERION, Avanti and MS-39—were compared for agreement in corneal epithelial thickness measurement and systematic differences were also found. Systematic measurement differences may be attributable to the different measurement strategies and technologies between devices (e.g. ANTERION Cornea App acquires 65 radial scans whereas Cirrus Pachymetry scan acquires 24 radial scans). Due to such device-specific differences, corneal epithelial thickness measurements should not be considered interchangeable.

Similarly to the above discussion of precision analysis for the 7mm Zone parameters, the relatively wider confidence intervals observed in the agreement analysis of 7mm Zone Minimum and Maximum may also be due to the method in which the measurement is produced, i.e. where a single datapoint (minimum or maximum) is obtained from within a large measurement area.

With respect to agreement between devices with a difference in scan patterns, as these single datapoints may not be obtained from the same location, larger differences between devices can occur versus parameters obtained via averaging of many datapoints.

Safety

The secondary objective of this study was to evaluate safety of the ANTERION. No adverse events were reported during the clinical study, thus demonstrating the ANTERION is safe for the intended use.

CONCLUSION

ANTERION (with software version 1.5) has the same intended use/ indications for use, and the same data acquisition modes used by the legally marketed ANTERION (K230897) predicate device identified in this premarket notification. The technological characteristics of the subject ANTERION differ from those of the predicate device, however, the differences do not raise new or different questions of safety or effectiveness.

Results of the non-clinical performance testing demonstrate that the ANTERION with software V.1.5 functions as intended. Results of the clinical performance testing illustrate that ANTERION´s ability to measure parameters of corneal epithelial thickness is similar to CIRRUS HD-OCT 5000. ANTERION was observed to systematically measure slightly thicker values for corneal epithelial thickness compared to the Cirrus. These systematic measurement differences may be attributed to the different measurement strategies and

technologies between devices. Patients should be monitored over time with the same device. Measurements are not interchangeable between devices.

The study results support substantial equivalence of ANTERION and the CIRRUS HD-OCT 5000 in regard to corneal epithelial thickness parameter measurements. The non-clinical and clinical performance testing demonstrate that the device is as safe, as effective, and performs as well or better than the legally marketed predicate.