1. TITLE PAGE

Protocol Title:	Agreement and Precision Study of the Nidek Mirante OCT Compared to the Optovue RTVue XR Avanti OCT and SLO Image Comparison of the Nidek Mirante and the OPTOS P200DTx
Protocol Number:	Nidek Mirante-001
Protocol Version:	Amendment 2 December 23, 2020
Name of Test Device/ Investigational Device:	Scanning Laser Ophthalmoscope Mirante
Proposed Indication for Use:	The Nidek Mirante, including scanning laser ophthalmoscope function with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus and for axial cross sectional imaging of ocular structures. It is used for in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as an aid in the diagnosis and management of the retinal disease. In addition, the anterior segment adapter (special lens unit) attached over the objective lens of the main body enables non-invasive and non-contact observation of the shape of the anterior segment of the eye such as the cornea or anterior chamber angle.
Investigator:	[redacted]
Clinical site:	Andover Eye Associates
Name of Sponsor:	Nidek Co., Ltd.
Address of Sponsor:	34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, JAPAN
NCT Number	NCT04318132
Original Protocol:	January 10, 2020
Amendment 1:	February 5, 2020
Amendment 2:	December 23, 2020

2. STUDY PROTOCOL

This was a prospective comparative clinical study to be conducted at one clinical site located in the United States. Three Nidek Mirante devices, three Optovue RTVue XR Avanti devices and one OPTOS P200DTx will be used. For agreement and precision analysis of OCT scans and agreement analysis of image quality of OCT ACA scans, each Nidek Mirante device will be paired with one of the Optovue RTVue XR Avanti devices. One device operator will be assigned to each device pair to create three distinct operator/device configurations.

For agreement analysis of SLO image quality, one OPTOS P200DTx will be included in one of three operator/device configurations.

Both eyes of normal subjects must meet all inclusion and none of the exclusion criteria in order for the subject to be enrolled in the study. Eligible subjects will be randomized to testing sequence of devices, the starting device (Nidek Mirante, Optovue RTVue XR Avanti or OPTOS P200DTx) and for the normal subject population, the study eye. For subjects in the glaucoma, retinal disease or corneal groups, the investigator will select the study eye based on presence of qualifying pathology. [redacted].

The Nidek Mirante, Optovue RTVue XR Avanti, and OPTOS P200DTx will be used in accordance with this clinical protocol and each device's User Manual.

Normal, glaucoma, and retinal disease subjects as well as corneal disease subjects enrolled to obtain measurements to demonstrate both agreement and precision will be randomized to the device configuration order and to the starting device within each configuration. Separate randomization schedules will be created for each subject population group (normal, glaucoma, retinal disease and corneal disease).

Corneal disease subjects enrolled to obtain only measurements to demonstrate qualitative agreement will be assessed at configuration 3 (C3) only and randomized using the next available corneal disease group randomization with C3 starting configuration to assign subject ID and starting device.

The device order will be randomly assigned as one of 2 sequences of Device (D), with D1: Test: Nidek Mirante and D2: Control: Optovue RTVue XR Avanti (OCT) and OPTOS P200DTx (SLO).

For the configurations with OPTOS P200DTx, the SLO scans for both devices will be taken after the OCT scans are completed for both devices. The SLO scans will be obtained in the same device order as for OCT.

3. STATISTICAL ANALYSIS PLAN

Analysis of Agreement Endpoints

Analysis of the agreement study endpoints will include measurements from Nidek Mirante and the predicate device. Descriptive statistics of each agreement study endpoint will be provided by subject population for each device. [redacted]

[redacted]

[redacted]

3. [redacted]

Agreement Analysis of Scan Size and Tracing HD Functions

Analysis of the agreement study endpoints of the scan size and tracing HD functions will include measurements from one Nidek Mirante and be analyzed in the same fashion as detailed above.

Analysis of Precision Endpoints

Analysis of the precision study endpoints will include measurements from the Nidek Mirante and predicate device, summarizing the precision results in units measured and as a percentage of the mean across all eyes (% CV). Plots of the within-eye SD for each machine versus the within-eye mean will be provided with different symbols for the two different device types.

[redacted]

Analysis of the Image Quality Assessments

The number of eyes with unacceptable and acceptable image quality will be summarized and compared by device, subject population and for all subjects.

The first acceptable ACA images captured by the Mirante and Optovue RTVue XR Avanti will be compared to assess image quality.

The first acceptable SLO image captured by the Mirante and P200DTx will be compared to assess image quality.

[redacted]

[redacted]

Analysis of Safety Endpoints

Adverse events reported will be listed by subject.