1. TITLE PAGE

Protocol Title:	Clinical Pilot Study to Provide Research Data for TONOREF III Tested to ANSI Z80.10-2014
Protocol Number:	NIDEK-TONOREF-PILOT-0002
Product Name:	Auto ref/kerato/tono/pachymeter TONOREF III
Proposed Indications for use:	The auto ref/kerato/tono/pachymeter TONOREF III is a medical device which measures objective refractive errors, corneal curvature radius, intraocular pressure and corneal thickness of the patient's eye.
Site/Investigators:	2 Investigative Sites in the U.S.
Name of Sponsor:	NIDEK CO., LTD.
Address of Sponsor:	34-14 Meahama, Hiroishi-cho, Gamagori, Aichi, 443-0038, Japan
NCT Number:	NCT07152808
Original Protocol (Version 1):	August 3, 2022
Version 2	May 16, 2023

2. STUDY PROTOCOL

This was a prospective clinical study to be conducted at two investigative sites located in the United States. The specific objective of the study was to assess the tonometer function and performance of the TONOREF III to the GAT. [redacted] TONOREF III and [redacted] GAT were used during study procedures. Investigators assessed IOP and remained masked to the results of the IOP measurement.

This was an open-label study, meaning all study staff and subjects were aware of which devices were being used. The GAT, and TONOREF III were used in accordance with this clinical protocol and Operator's Manual for each device.

Each subject was evaluated initially for suitability as a candidate for this study. Informed consent was obtained from each candidate prior to any study specific measurements not routinely performed,

including measurements with the investigational device. Subjects that were candidates for enrollment were asked their willingness to participate in this study and underwent the required screening for the confirmation of compliance with inclusion and exclusion criteria.

[redacted]

[redacted] had to meet all inclusion and none of the exclusion criteria in order for the subject to be enrolled in the study. [redacted] eyes were selected as the study eye(s).

Subjects were selected in accordance with the inclusion and exclusion criteria. Up to [redacted] subjects were enrolled to provide approximately [redacted] evaluable subjects (approximately [redacted] eligible subjects per [redacted]).

3. STATISTICAL ANALYSIS PLAN

Analysis of Study Endpoints

For the study eye(s), the IOP value measured with [redacted] minus the IOP value measured with [redacted] equals the difference between the test and predicate tonometer.

For [redacted] will be used for the analysis.

For [redacted] will be used for the analysis. Otherwise, [redacted] will be used.

The difference between [redacted] and [redacted] will be analyzed in the following [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

The data analysis will include a comparison of the frequencies of all AEs, and ADEs (including subject complaints and corneal abrasions for the test device and reference tonometer).

The report of clinical agreement results will include the following presentation of results and analyses:

a) Scatter plot of measured IOP values, with [redacted] on the y-axis versus [redacted] on the x-axis, using the same scale for the x and y axes.

b) Similar to the Bland-Altman plot, the difference ([redacted] minus [redacted]) versus [redacted] results will be plotted with the mean difference and the 95% and 99% LOAs indicated.

Analysis of Safety Endpoints

The data analysis will include a comparison of the frequencies of all AEs and ADEs. AEs reported will be listed by subject and subject complaints and corneal abrasions for the test and reference devices will be specified.