DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 29, 2015

TopCon Corporation
c/o Mr. Ryan Bouchard
Manager
ORA, Inc.
300 Brickstone Square
Andover, MA 01810

Re: K142417
Trade/Device Name: TopCon SP-1PSpecular Microscope
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: NQE
Dated: April 20, 2015
Received: April 22, 2015

Dear Mr. 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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142417

Device Name
Specular Microscope SP-1P

Indications for Use *(Describe)*
The Specular Microscope SP-1P is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of corneal endothelium and for measurement of the thickness of the cornea.

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

Specular Microscope SP-1P

510(k) Owner
Topcon Corporation
75-1 Hasunuma-Cho
Itabashi-Ku
Tokyo, Japan 174-8580
Phone: (201) 599-5553
Facsimile: (201) 599-5248
Michael Gusel, Manager, Regulatory Affairs and Quality Assurance

Submission Correspondent
Ryan Bouchard
Ora, Inc.
300 Brickstone Square
Andover, MA 01810
Phone: (978) 685-8900
Facsimile: (978) 689-0020

Date Prepared: May 14, 2015

Trade Name of Device
Specular Microscope SP-1P

Common or Usual Name
Microscope, specular

Classification Name
AC-powered slitlamp biomicroscope
21 C.F.R. 886.1850
Class II
Product Code: NQE

Predicate Device
Konan Specular Microscope Xiv Cellchek Plus (K120264)

Device Description
This instrument is a photographic device dedicated to photograph and record corneal endothelial cells as an electronic image without contacting the eye. The Specular Microscope SP-1P also allows for measuring corneal thickness at the same time as corneal endothelial cells photography. The Specular Microscope SP-1P has functions that permit users to analyze photographed corneal endothelial cells and to calculate the area and form of corneal endothelial cells. It automatically performs alignment, photography and analysis. The Specular Microscope SP-1P contains multiple fixation targets, and allows users to photograph both central and peripheral corneal

endothelial cells depending upon which fixation target is used. The Specular Microscope SP-1P has a manual image alignment function which allows the operator to utilize the internal function of the SP-1P to focus on the cornea and obtain the image. The manual image alignment can be utilized in difficult lighting or cases where the subject has a difficult time fixating. The Specular Microscope SP-1P also has a manual editing function which allows the clinician to modify the cells selected on the automatically captured image. Photographed images, images for observation and analysis results are displayed on the color LCD monitor with touch panel. An internal printer allows for printing photographed images and analysis results.

Indications for Use

The Specular Microscope SP-1P is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of corneal endothelium and for measurement of the thickness of the cornea.

Substantial Equivalence

The Specular Microscope SP-1P is substantially equivalent to the Konan Cellchek Plus cleared in K120264. The intended use for the Specular Microscope SP-1P and the identified predicate device is to examine the cornea of the eye, and to measure corneal endothelium and corneal thickness by optical means. In addition, cell counting and analysis programs included with the device enable the user to analyze images of the cell distribution in the eye. Therefore, the Specular Microscope SP-1P may be found to be substantially equivalent to the predicate device.

The Specular Microscope SP-1P and the predicate device are both non-contact ophthalmic microscopes, optical pachymeters, and cameras intended for examination of the corneal endothelium and for measurement of the thickness of the cornea. Both the Specular Microscope SP-1P and the predicate device offer automatic capture. Both devices have a central and peripheral fixation targets. Both the Specular Microscope SP-1P and the predicate device have a built-in CCD camera. Slight differences in flash, illumination for focusing and fixation lamps were evaluated in terms of light safety and found to meet the requirements of ISO 15004-2.

Both the Specular Microscope SP-1P and the predicate device include an optical pachymeter with an accuracy of ±10 microns.

Regarding image analysis, both the Specular Microscope SP-1P and the predicate device offer automatic image analysis while the predicate device also offers manual analysis of images. Clinical performance data is provided which evaluates the precision and accuracy of the automatic analysis performed by the Specular Microscope SP-1P compared to the Center Method for the predicate device. The clinical performance data demonstrates the substantial equivalence of the Specular Microscope SP-1P automatic measurement mode to the predicate device.

The Specular Microscope SP-1P has the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicate. Performance data is provided which further supports substantial equivalence.

Performance Data

The Specular Microscope SP-1P has been tested and found in compliance with the following recognized consensus standards:

> AAMI ANSI ES 60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance;
>
> IEC 60601-1-2: 2007 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance: Collateral Standard: Electromagnetic Capability – Requirements and Tests;
>
> ISO 15004-1:2006 Ophthalmic instruments – Fundamental requirements and test methods – Part 1: General requirements applicable to all ophthalmic instruments;
>
> ISO 15004-2:2007 Ophthalmic Instruments – Fundamental requirements and test methods – Part 2: Light hazard protection;

Both the Specular Microscope SP-1P and the predicate device comply with the following consensus standards: 60601-1, IEC60601-1-2, ISO 15004-1, and ISO 15004 further supporting substantial equivalence.

Summary of the Performance Testing – Clinical

This study is a prospective, open label, randomized, single center study to gather agreement and precision data. This is an open-label study, however, all subject will be randomized to an order of examination on the devices. For non-pathologic subjects, the study eye will be randomly selected if both eyes qualify. For pathologic subjects, the investigator will select the study eye based on presence of qualifying pathology. The clinical study was conducted to assess the accuracy and precision of the Specular Microscope SP-1P by comparing results across three machines/operators to those obtained with a commercially available predicate device, the CellChek XL (Plus), manufactured by Konan Medical, Inc. Machines were tested in three configurations, each with its own operator, in subjects from three eye populations: non-pathologic young adult (NPY; 18-28 years of age) and non-pathologic adult (NPA; 29-80 years of age) subjects and pathologic adult (PA; 29-80 years of age).

A total of 76 subjects were enrolled in the study and comprised the safety population. The effectiveness population comprised 69 subjects. Of the 69 subjects, 21 were in the NPY eye group, 27 were in the NPA eye group and 21 were in the PA eye group. A total of 28 subjects were included in the agreement only cohort and 41 subjects were included in the precision and agreement cohort.

In the effectiveness population, the mean (SD) age was 22.0 (3.06) years for the NPY eye subjects, 52.9 (14.54) years for the NPA eye subjects, and 61.8 (13.71) years for the PA eye

subjects. The overall mean age of all subjects was 46.2 (20.34) years. There were 46 females and 23 males and the majority of subjects were white, non-Hispanic.

The primary efficacy endpoints are the agreement and precision of the results for the four key variables of Cell Density, Coefficient of Variation, Hexagonality and Central Corneal Thickness. The primary safety endpoint is any adverse events in the study. The discussion of the results by variables for agreement and precision of the measurements with the Topcon SP-1P and the Konan CellChek XL (Plus) follows:

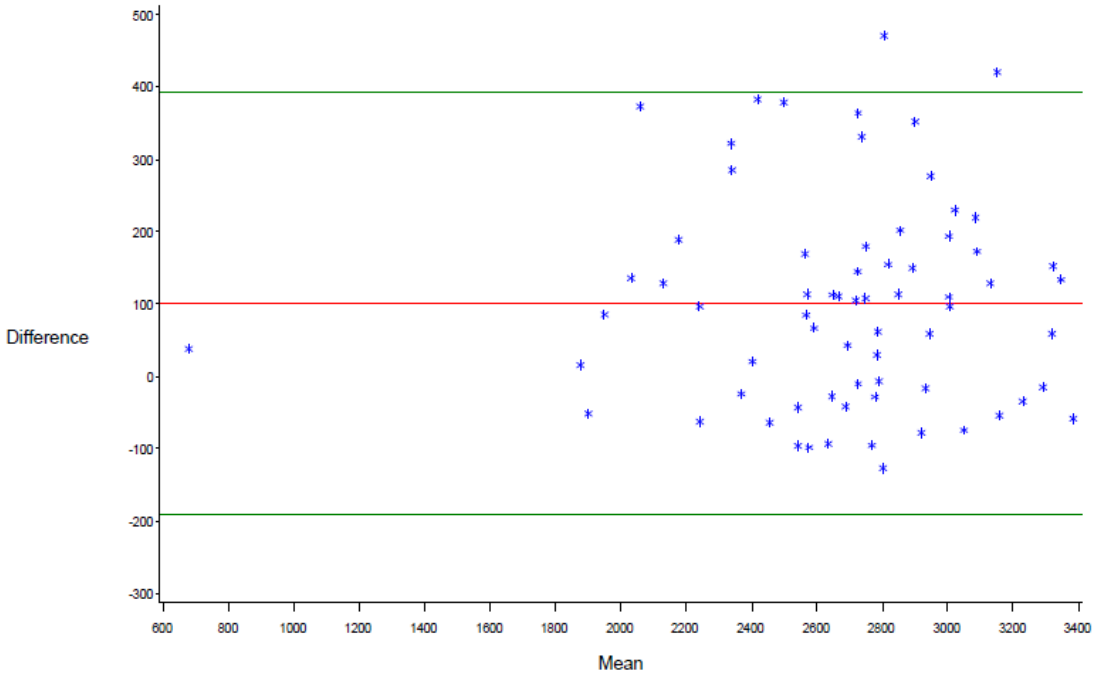
Corneal Endothelial Cell Density

Corneal endothelial cell density as measured with the SP-1P had a mean (SD) of 2737.1 (439.34) compared with 2635.9 (437.48) for the CellChek XL (Plus). The mean (SD) difference was 101.3 (145.68) (Figure 1) with a mean (SD) difference as a percent of the CellChek reading of 4.11% (5.908%).

The 95% LOA intervals included 0 and the Deming regression lines had an associated R^2 value of 0.9448 (Figure 4).

Bland Altman plots with data as a percentage of the mean are presented in Figure 2. Plots of the device difference by the CellChek XL (Plus) value are presented in Figure 3.

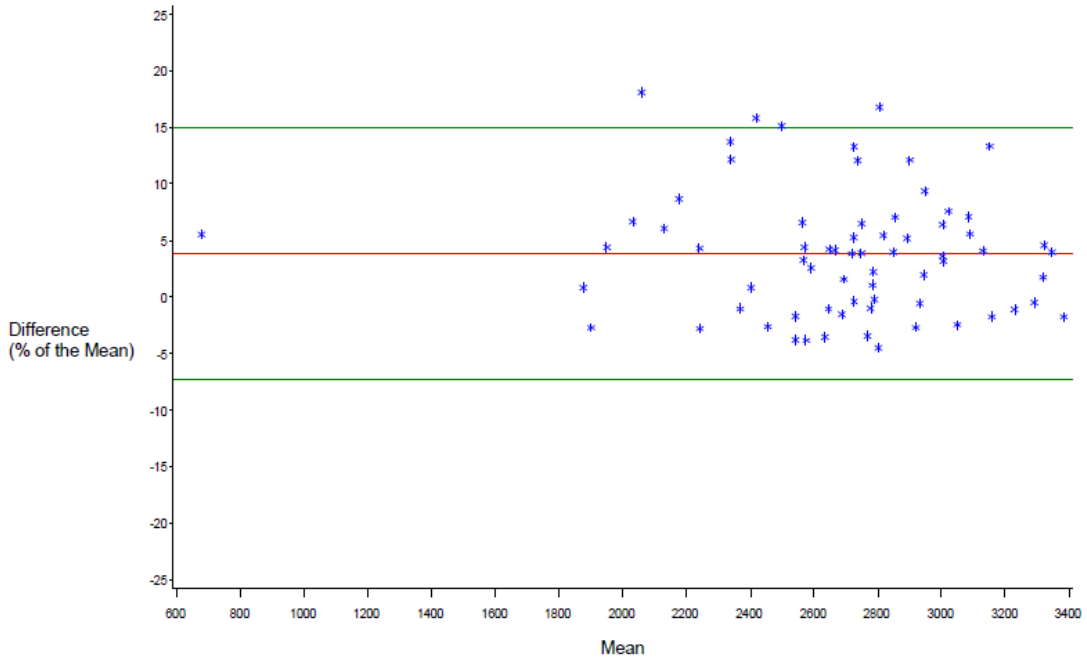
Figure 1: Bland-Altman Plot – Observed Data – Endothelial Cell Density (ECD) – All Subjects – Effectiveness Population



Note: The red line is the mean and the green lines are the Limits of Agreement (LOAs)

The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

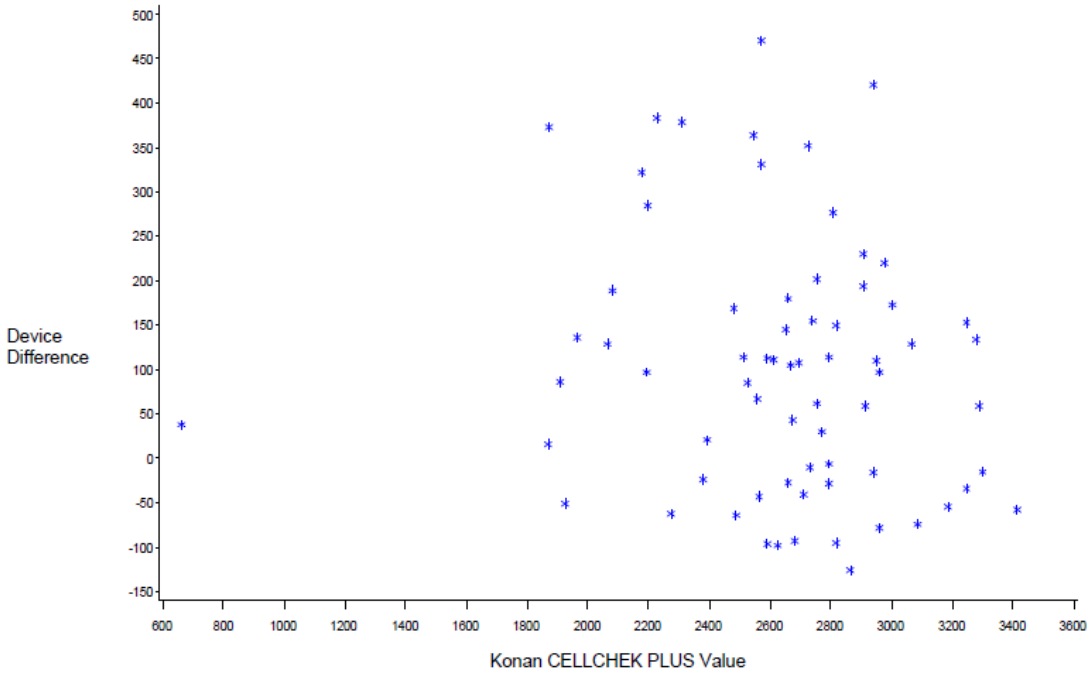
Figure 2: Bland-Altman Plot – Data as a Percentage of the Mean – Endothelial Cell Density (ECD) – All Subjects – Effectiveness Population



Note: The red line is the mean and the green lines are the Limits of Agreement (LOAs)

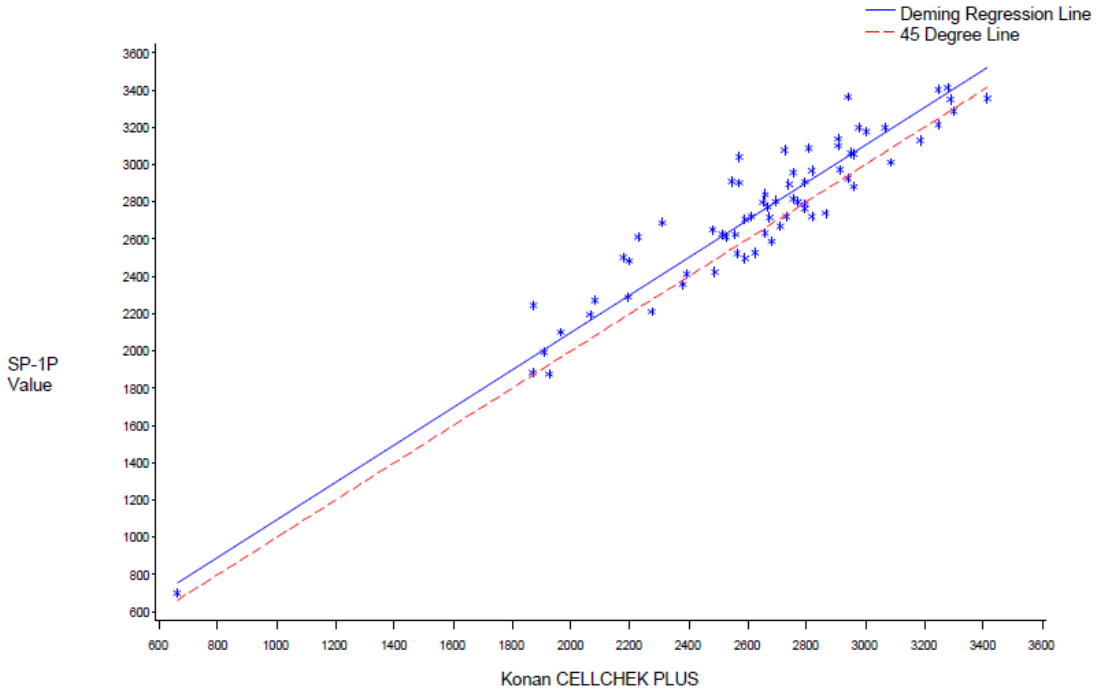
The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

Figure 3: Device Difference by CellChek XL (Plus) Value – Endothelial Cell Density (ECD) – All Subjects – Effectiveness Population



Note: The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

Figure 4: Deming Regression Plot – Topcon SP-1P by CellChek XL (Plus) – Endothelial Cell Density (ECD) – All Subjects – Effectiveness Population



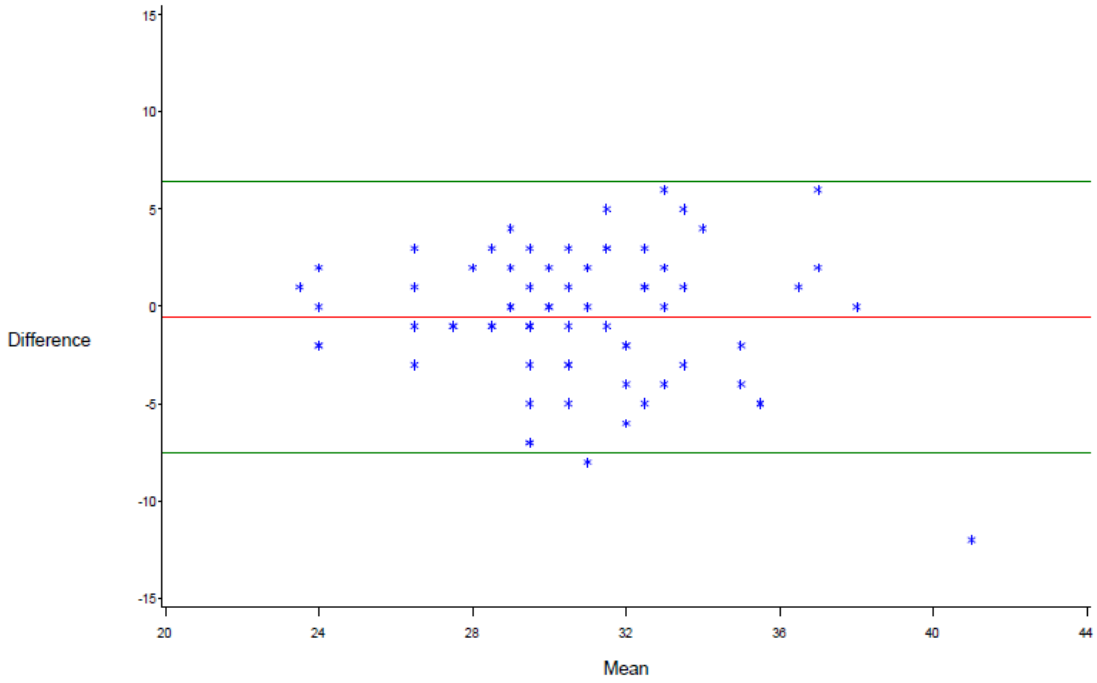
Coefficient of Variation of Endothelial Cell Area

The coefficient of variation of endothelial cell area as measured with the SP-1P had a mean (SD) of 30.5 (3.66) compared with 31.0 (4.04) for the CellChek XL (Plus). The mean (SD) difference was -0.6 (3.47) (Figure 5) with a mean (SD) difference as a percent of the CellChek reading of -1.17% (10.399%).

The 95% LOA intervals included 0 and the Deming regression lines had an associated R^2 value of 0.5961 (Figure 8).

Bland Altman plots with data as a percentage of the mean are presented in Figure 6. Plots of the device difference by the CellChek XL (Plus) value are presented in Figure 7.

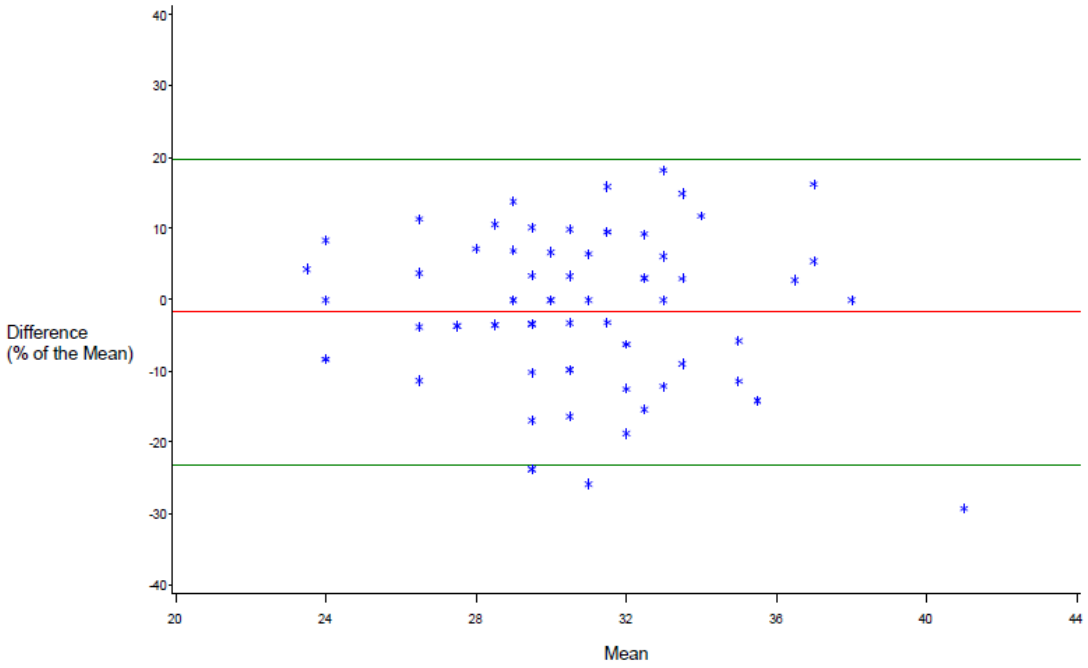
Figure 5 Bland-Altman Plot – Observed Data – Coefficient of Variation Endothelial Cell Area (CV) – All Subjects – Effectiveness Population



Note: The red line is the mean and the green lines are the Limits of Agreement (LOAs)

The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

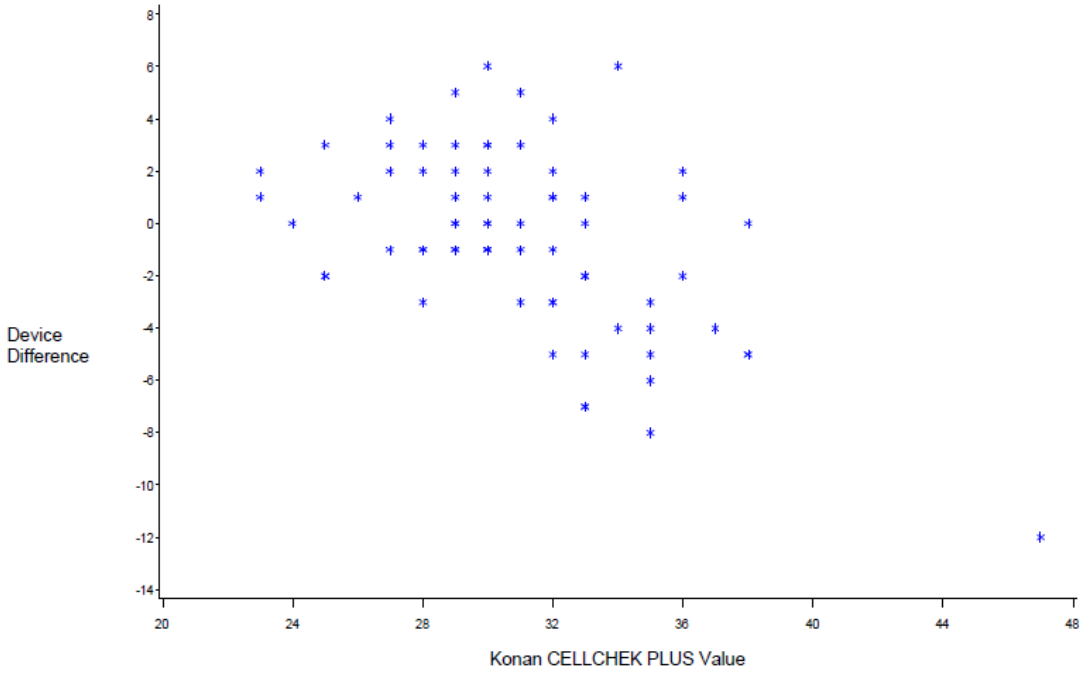
Figure 6 Bland-Altman Plot – Data as a Percentage of the Mean – Coefficient of Variation Endothelial Cell Area (CV) – All Subjects – Effectiveness Population



Note: The red line is the mean and the green lines are the Limits of Agreement (LOAs)

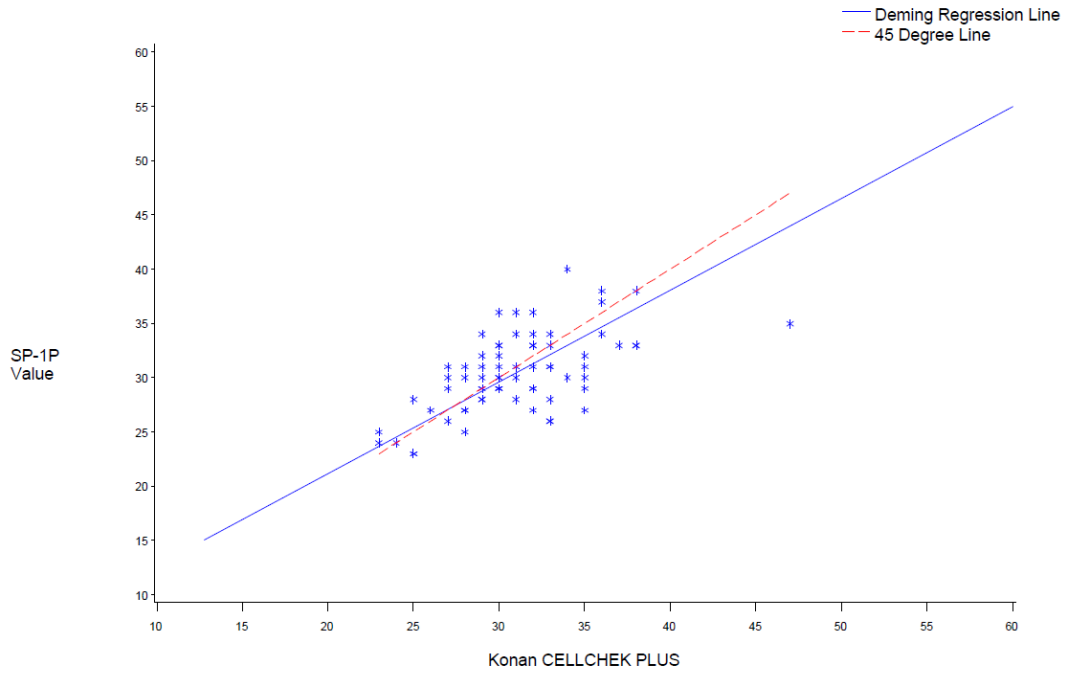
The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

Figure 7 Device Difference by CellChek XL (Plus) Value – Coefficient of Variation Endothelial Cell Area (CV) – All Subjects – Effectiveness Population



Note: The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

Figure 8 Deming Regression Plot – Topcon SP-1P by CellChek XL (Plus) – Coefficient of Variation Endothelial Cell Area (CV) – All Subjects – Effectiveness Population



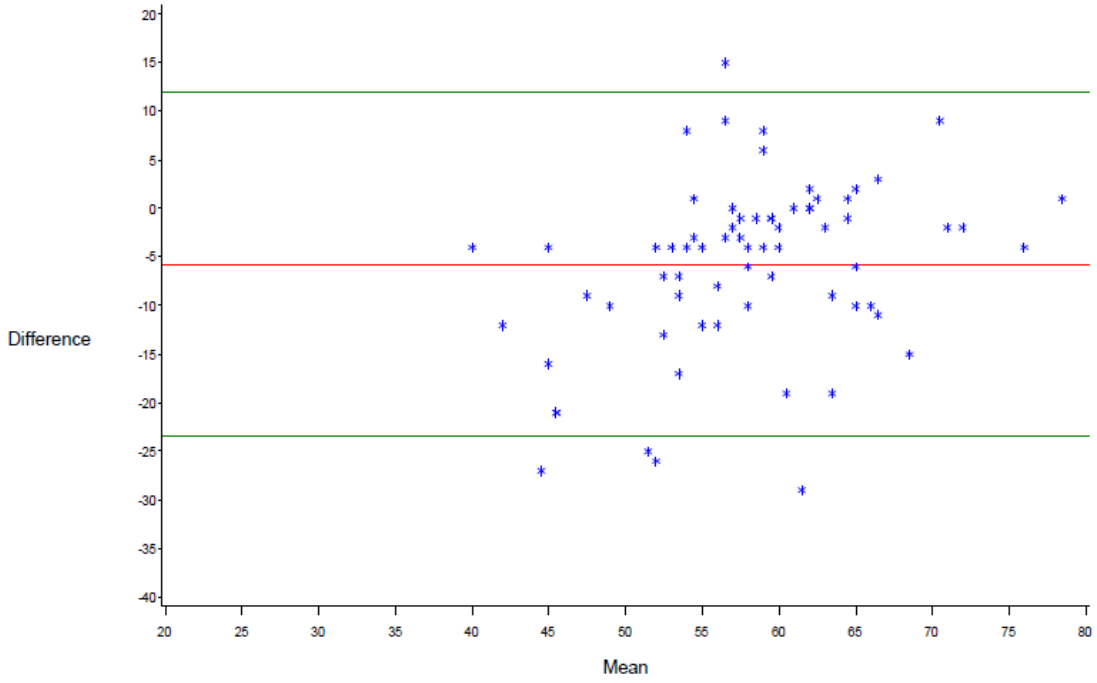
Percent Hexagonality

Percent hexagonality as measured with the SP-1P had a mean (SD) of 55.1 (10.06) compared with 60.9 (7.41) for the CellChek XL (Plus). The mean (SD) difference was -5.8 (8.87) (Figure 9) with a mean (SD) difference as a percent of the CellChek reading of -9.25% (14.579%).

The 95% LOA intervals included 0 and the Deming regression lines had an associated R^2 value was 0.5197 (Figure 12).

Bland Altman plots with data as a percentage of the mean are presented in Figure 10. Plots of the device difference by the CellChek XL (Plus) value are presented in Figure 11.

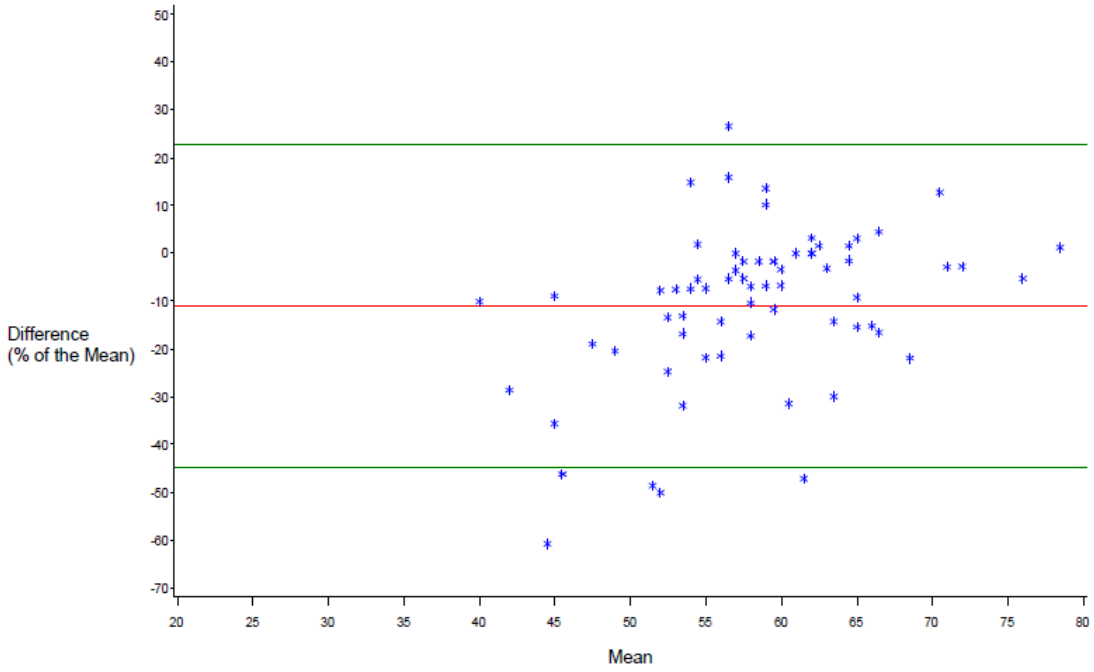
Figure 9Bland-Altman Plot – Observed Data – % Hexagonality (% 6a) – All Subjects – Effectiveness Population



Note: The red line is the mean and the green lines are the Limits of Agreement (LOAs)

The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

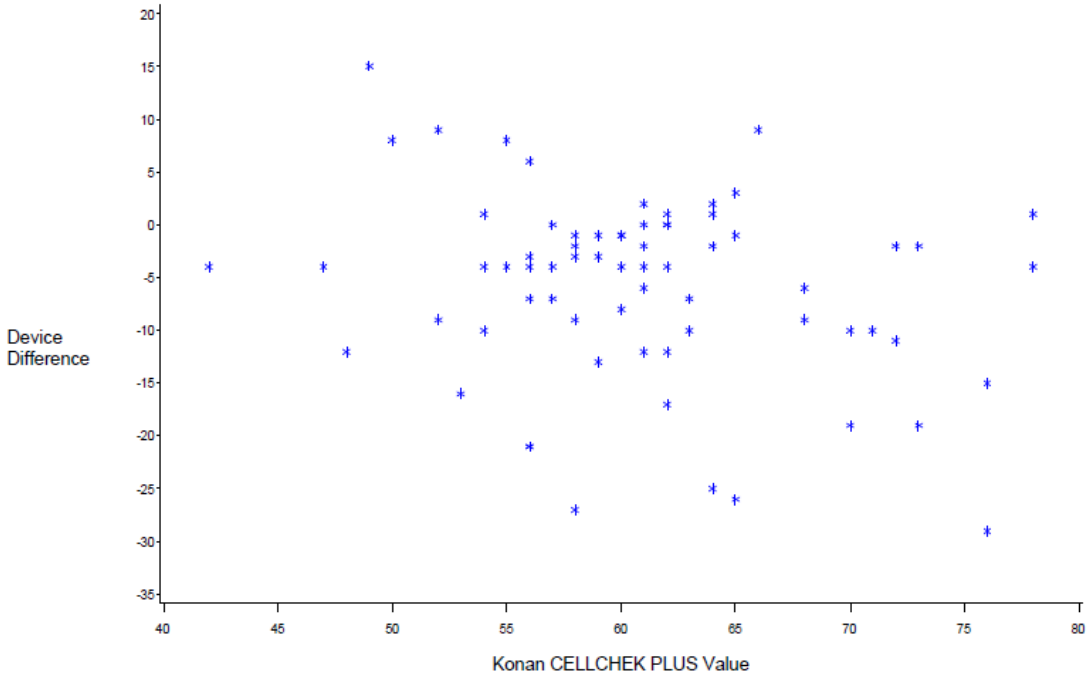
Figure 10 Bland-Altman Plot – Data as a Percentage of the Mean – % Hexagonality (% 6a) – All Subjects – Effectiveness Population



Note: The red line is the mean and the green lines are the Limits of Agreement (LOAs)

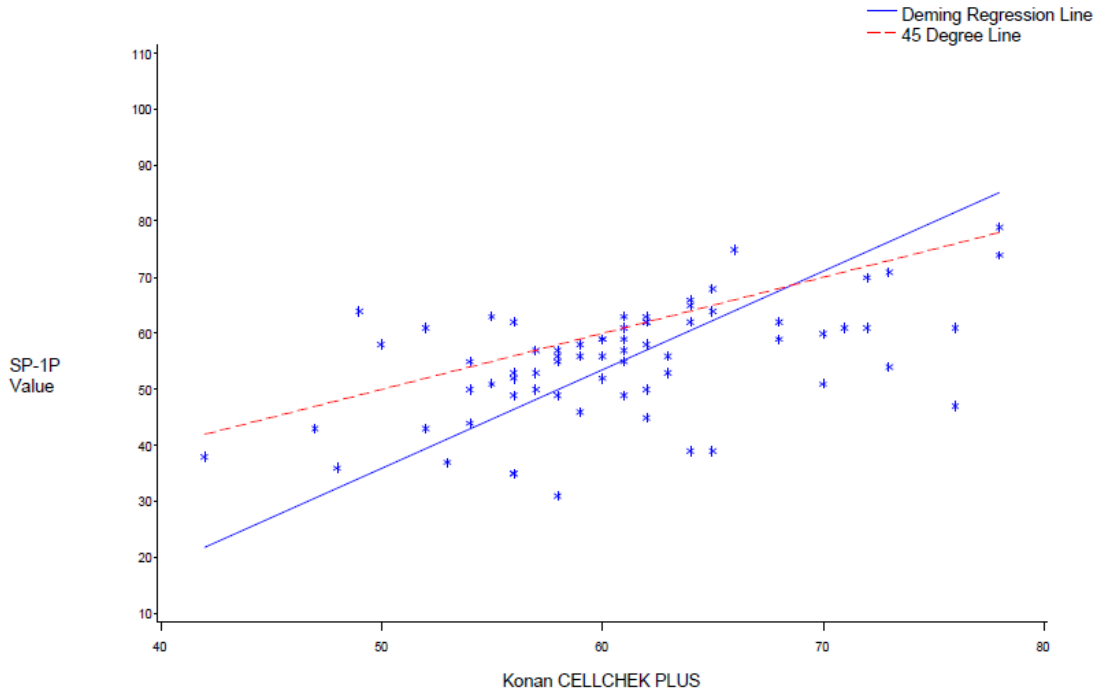
The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

Figure 11 Device Difference by CellChek XL (Plus) Value – % Hexagonality (% 6a) – All Subjects – Effectiveness Population



Note: The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

Figure 12 Deming Regression Plot – Topcon SP-1P by CellChek XL (Plus) – % Hexagonality (% 6a) – All Subjects – Effectiveness Population



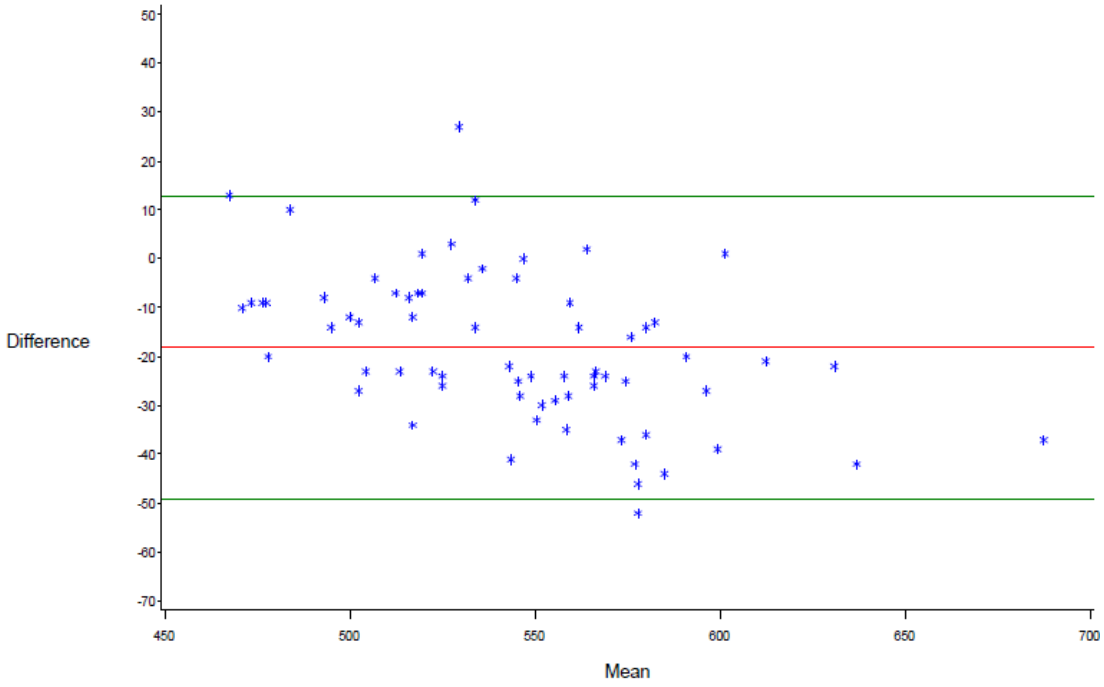
Central Corneal Thickness

Central corneal thickness as measured with the SP-1P had a mean (SD) of 535.5 (39.39) compared with 553.7 (46.83) for the CellChek XL (Plus). The mean (SD) difference was -18.2 (15.47) (Figure 13) with a mean (SD) difference as a percent of the CellChek reading of -3.17% (2.663%).

The 95 % LOA intervals included 0 and the Deming regression lines had an associated R^2 value was 0.9501 (Figure 16).

Bland Altman plots with data as a percentage of the mean are presented in Figure 14. Plots of the device difference by the CellChek XL (Plus) value are presented in Figure 15.

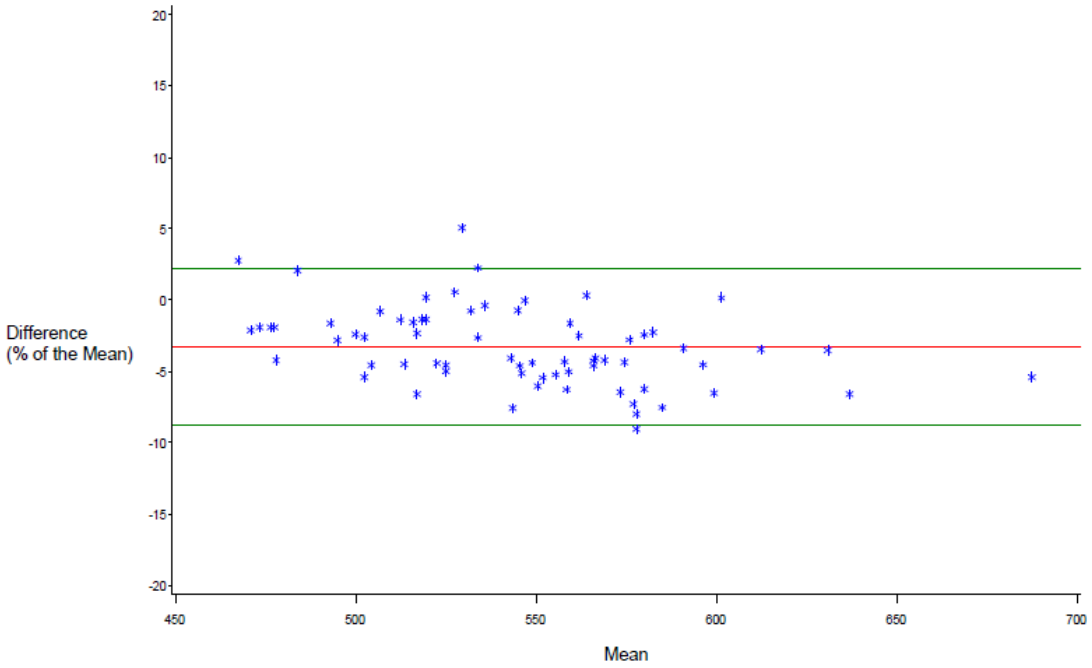
Figure 13 Bland-Altman Plot – Observed Data – Central Corneal Thickness (CCT) – All Subjects – Effectiveness Population



Note: The red line is the mean and the green lines are the Limits of Agreement (LOAs)

The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

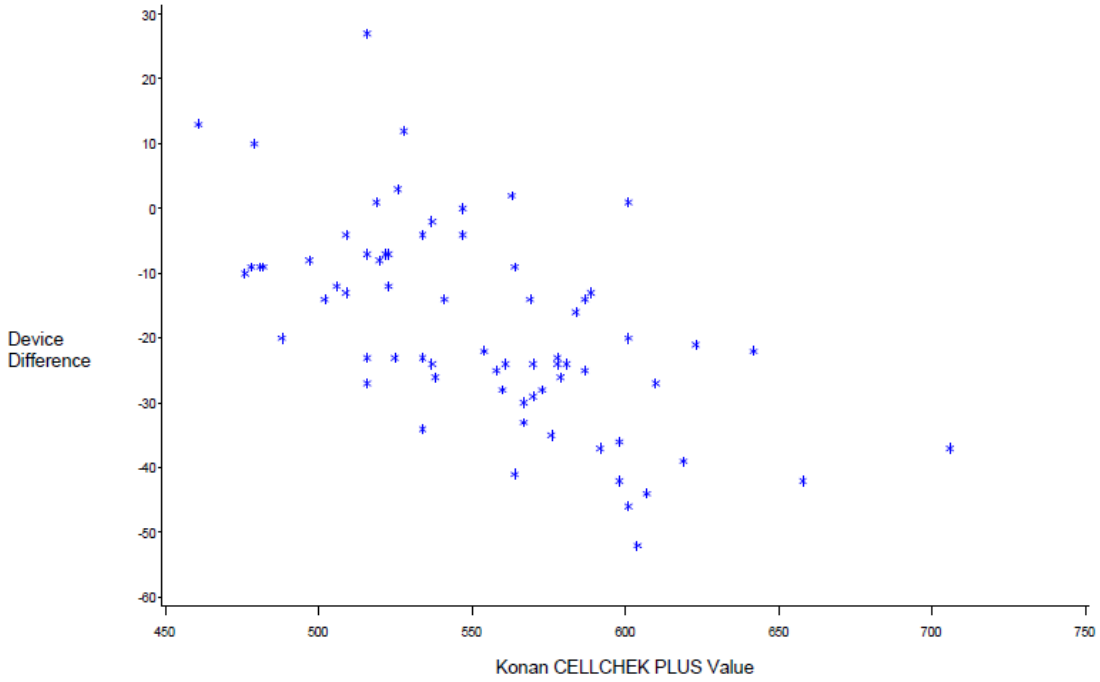
Figure 14 Bland-Altman Plot – Data as a Percentage of the Mean – Central Corneal Thickness (CCT) – All Subjects – Effectiveness Population



Note: The red line is the mean and the green lines are the Limits of Agreement (LOAs)

The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

Figure 15 Device Difference by CellChek XL (Plus) Value – Central Corneal Thickness (CCT) – All Subjects – Effectiveness Population



Note: The differences are calculated as (Topcon SP-1P) – (Konan CellChek XL [Plus])

Figure 16 Deming Regression Plot – Topcon SP-1P by CellChek XL (Plus) – Central Corneal Thickness (CCT) – All Subjects – Effectiveness Population

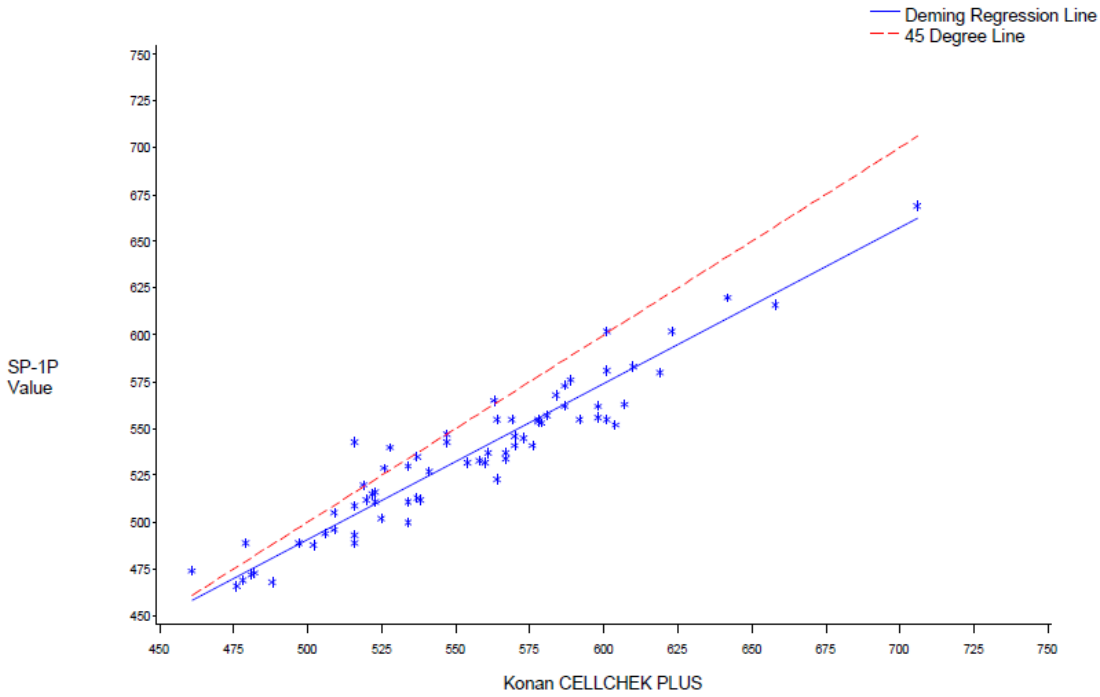


Table 1 provides a summary of the agreement data for all subjects in tabular format as a summary.

Table 1 - Four Corneal Specular Microscopic Variables Assessed with the Two Devices – All Configurations – All Subjects – Effectiveness Population

	ECD	CV	% 6a	CCT
Topcon SP-1P				
N	69	69	69	69
Mean (SD)	2737.1 (439.34)	30.5 (3.66)	55.1 (10.06)	535.5 (39.39)
Median	2772.0	30.0	56.0	537.0
Min-Max	700-3413	23-40	31-79	466-669
Konan CellChek XL (Plus)				
N	69	69	69	69
Mean (SD)	2635.9 (437.48)	31.0 (4.04)	60.9 (7.41)	553.7 (46.83)
Median	2681.0	31.0	61.0	558.0
Min- Max	662-3413	23-47	42-78	461-706
Device Comparisons				
Mean Difference (SD)	101.3 (145.68)	-0.6 (3.47)	-5.8 (8.87)	-18.2 (15.47)
Mean Difference (SD) as a % of the CellChek reading	4.11% (5.908%)	-1.17% (10.399%)	-9.25% (14.579%)	-3.17% (2.663%)
95% LOA	(-190.1, 392.6)	(-7.5, 6.4)	(-23.5, 11.9)	(-49.1, 12.7)
Correlation (R^2)	0.9448	0.5961	0.5197	0.9501
Deming Regression Intercept (95% CI)	89.4 (-100.9, 279.7)	4.2 (-9.0, 17.4)	-52.2 (-95.8, -8.6)	73.9 (41.7, 106.2)
Deming Regression Slope (95% CI)	1.0 (0.9, 1.1)	0.5 (0.4, 0.7)	1.8 (1.1, 2.5)	0.8 (0.7, 0.9)

For subjects in the Precision and Agreement cohort, the measurements from the first acceptable images from each machine within the same configuration are used for the agreement analyses.
The mean differences are calculated as (Topcon SP-1P) - (Konan CellChek XL [Plus]).
The mean differences as a % of the CELLCHECK reading are calculated for each subject first and then summarized.

The precision of the two devices was assessed with repeatability and reproducibility measures: the first within a given subject and the second within and among configurations. Table 2 shows the repeatability and reproducibility data for each of the 4 variables in all subjects.

Table 2 Repeatability/Reproducibility Ratios by Measurement and Subject Population for All Configurations

Parameter	All Subjects	Pathologic Adult	Non Pathologic Adult	Non Pathologic Young
ECD	1.1019/1.1148	1.5159/1.4140	0.9016/0.9263	1.0641/1.1957
CV	0.6984/0.6873	0.8343/0.7698	0.6416/0.5967	0.5884/0.7094
% 6a	1.1369/1.1645	1.4190/1.3395	1.1226/1.1371	0.8849/1.0102
CCT	0.2910/0.3110	0.2727/0.3197	0.2858/0.3075	0.3219/0.3036
The repeatability ratios = Topcon SP-1P/CellChek XL (Plus) NA= not applicable				

Table 3 summarizes the precision analyses for all subjects.

Table 3 Precision Analyses –All Subjects-Effectiveness Population

Variable	Topcon Specular Microscope SP-1P N=41	Konan CellChek XL (Plus) N=41
ECD		
Repeatability SD	70.7	64.1
Repeatability SD as a % of the Mean	2.5%	2.4%
Repeatability Limit	197.9	179.6
Repeatability Ratio [Specular Microscope SP-1P/CellChek XL (Plus)]	1.1019	--
Reproducibility SD	76.6	68.8
Reproducibility SD as a % of the Mean	2.7%	2.5%
Reproducibility Limit	214.6	192.5
Reproducibility Ratio [Specular Microscope SP-1P/CellChek XL (Plus)]	1.1148	--
CV		
Repeatability SD	1.6	2.3
Repeatability SD as a % of the Mean	5.3%	7.2%
Repeatability Limit	4.4	6.3
Repeatability Ratio [Specular Microscope SP-1P/CellChek XL (Plus)]	0.6984	--
Reproducibility SD	1.7	2.4
Reproducibility SD as a % of the Mean	5.5%	7.7%
Reproducibility Limit	4.6	6.7
Reproducibility Ratio [Specular Microscope SP-1P/CellChek XL (Plus)]	0.6873	--

Variable	Topcon Specular Microscope SP-1P N=41	Konan CellChek XL (Plus) N=41
% 6a		
Repeatability SD	4.9	4.3
Repeatability SD as a % of the Mean	8.4%	7.0%
Repeatability Limit	13.7	12.1
Repeatability Ratio [Specular Microscope SP-1P/CellChek XL (Plus)]	1.1369	--
Reproducibility SD	5.2	4.5
Reproducibility SD as a % of the Mean	9.0%	7.3%
Reproducibility Limit	14.7	12.6
Reproducibility Ratio [Specular Microscope SP-1P/CellChek XL (Plus)]	1.1645	--
CCT		
Repeatability SD	3.4	11.8
Repeatability SD as a % of the Mean	0.6%	2.1%
Repeatability Limit	9.6	33.0
Repeatability Ratio [Specular Microscope SP-1P/CellChek XL (Plus)]	0.2910	--
Reproducibility SD	3.9	12.6
Reproducibility SD as a % of the Mean	0.7%	2.3%
Reproducibility Limit	11.0	35.3
Reproducibility Ratio [Specular Microscope SP-1P/CellChek XL (Plus)]	0.3110	--
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (18 total images). The nobound option was used to avoid a negative variance component. The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator+device, operator+device x subject interaction, and residual within subject. **Source:** Table 14.2.2		

Non-Evaluable Images

There were 20 subjects on the SP-1P machine that recorded Non-evaluable results and 4 subjects on the CellChek Plus. A breakdown can be seen in Table 4.

Table 4 Non-Evaluable Results

	Non-Pathologic Young (N=23)	Non-Pathologic Adult (N=27)	Pathologic Adult (N=26)	All Subjects (N=76)
Total Non-Evaluable				
SP-1P	6 (26.1%)	2 (7.4%)	12 (46.2%)	20 (26.3%)
CellChek Plus	1 (4.3%)	0 (0.0%)	3 (11.5%)	4 (5.3%)
Insufficient Number of Cells				

SP-1P	0 (0.0%)	1 (3.7%)	0 (0.0%)	1 (1.3%)
CellChek Plus	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Insufficient Quality				
SP-1P	6 (26.1%)	1 (3.7%)	12 (46.2%)	19 (25.0%)
CellChek Plus	1 (4.3%)	0 (0.0%)	3 (11.5%)	4 (5.3%)
Fair Quality				
SP-1P	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
CellChek Plus	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Poor Quality				
SP-1P	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
CellChek Plus	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Impossible Quality				
SP-1P	6 (26.1%)	1 (3.7%)	12 (46.2%)	19 (25.0%)
CellChek Plus	1 (4.3%)	0 (0.0%)	3 (11.5%)	4 (5.3%)

The high numbers of non-evaluable eyes in the Table 4 is an artifact of the study design and not indicative of the clinical utility of the SP-1P. Any eye that did not have a full dataset available was considered non-evaluable. Subjects participating in the Agreement/Precision Group required 18 acceptable total images and subjects in the Agreement Only Group required 2 acceptable images. Therefore, all subjects that did not meet the minimum number of acceptable images were included in the Non-Evaluable table.

There were 6 times that no images with numerical values were collected for the SP-1P and 4 times for the CellChek. In the cases where no numerical calculation was provided the raw images were available for clinical usability.

There were no AEs in this study in any subject. No safety issues of any kind arose during this study, regardless of the device used. Both instruments were found to be safe and reliable in the assessments of corneal function in all of the eye populations evaluated (NPY, NPA, and PA).

Conclusions

Overall, within-eye/subject variability was acceptable, and similar for both machines. The precision of the two devices was assessed with repeatability and reproducibility measures: the first within a given subject and the second within and among configurations. Repeatability was comparable for ECD, CV and % 6a between the two machines while the SP-1P was better for CCT.

In summary, the agreement and precision of the Topcon SP-1P was found to be substantially equivalent to the Konan CellChek XL (Plus).