1 TITLE/SIGNATURE PAGE

STATISTICAL ANALYSIS PLAN

Protocol Number: 916

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Sponsor: Bausch & Lomb Incorporated

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2 TABLE OF CONTENTS

2.1 Table of Tables

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3 LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Terms or Abbreviations	Definitions
ADE	Adverse Device Effect
AE	Adverse Event
ASADE	Anticipated Serious Adverse Device Effect
ATC	Anatomical Therapeutic Chemical
BSCVA	Best Spectacle Corrected Visual Acuity
D	Diopter
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
ePRO	Electronic Patient-Reported Outcomes
FAS	Full Analysis Set
GP	Gas Permeable
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ID	Identification
logMAR	Logarithm of the Minimum Angle of Resolution
MedDRA	Medical Dictionary for Regulatory Activities
OD	Right Eye
OS	Left Eye
OU	Oculi Unitas; Both eyes used together
PMMA	Polymethylmethacrylate
PT	Preferred Term
SAE	Serious Adverse Event
SOC	System Organ Class
TEAE	Treatment-Emergent Adverse Event
USADE	Unanticipated Serious Adverse Device Effect
US	United States
VA	Visual Acuity
WHO DDE	World Health Organization Drug Dictionary Enhanced

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4 INTRODUCTION

This is a single-treatment study evaluating the product performance of a new silicone hydrogel multifocal daily disposable contact lens.

Approximately 300 subjects (600 eyes) will be enrolled in this 3-week, single-arm, bilateral, open-label study at approximately 20 investigative sites in the United States (US).

The study is designed to include habitual wearers of multifocal lenses. All subjects will be seen for a Screening/Dispensing Visit, at which time informed consent will be obtained and eligibility will be assessed.

All consented subjects will be assigned a subject identification (ID) number in sequential order by the Electronic Data Capture (EDC) system. At the Screening/Dispensing Visit, all eligible subjects will receive study contact lenses to wear on a daily disposable basis for approximately 3 weeks, with scheduled in-office follow-up visits at 1 week and 3 weeks.

No interim analyses are planned.

5 STUDY OBJECTIVES

The objective of this study is to evaluate the product performance of a new silicone hydrogel daily disposable multifocal contact lens, the Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens, when worn by current soft contact lens wearers on a daily disposable wear basis.

6 INVESTIGATIONAL PLAN

6.1 Overall Study Design

Subjects will be fitted for their study multifocal lenses at a Dispensing Visit on study Day 1, at which screening procedures will also be performed. Subjects will return for a follow-up visit at 1 week and 3 weeks. At the 3-Week Follow-up Visit, subjects will be exited from the study.

The complete schedule of assessments in provided in Table 1.

Table 1. Schedule of Assessments

PROCEDURE/ASSESSMENTS	Screening/ Dispensing Visit Day 1	1-Week Follow-Up Visit Day 8	3-Week Follow-Up Visit Day 23	Unscheduled Visit	Exit Visit
		Day 6-10 (5-9 days after V1)	Day 20-26 (19-25 days after V1)		
Informed consent/HIPAA authorization	X				
Demographics	X				
Contact lens use history and contact lens use (e.g., average daily wear time, number of days worn, lens brand, lens wear modality, lens care system brand, product use history)	X (Habitual)	X[a]	X[a]		
Ocular medical history and concomitant medications	X				
Changes in ocular medical history and concomitant medications		X	X	X	X
Eligibility	X				
Lens fitting	X	X[b]			
Dispense study materials	X	X		X[b]	
Collect worn /unworn lenses, blister foils and study materials		X	X	X[b]	X
Adverse events	X	X	X	X	X
Symptoms/Complaints Form	X (Habitual)	X	X	X	
Subject-completed forms/surveys					
Baseline Questionnaire	X				
Lens Performance Rating Scales (after 10 minutes of lens settling & adaptation, if just inserted) [d]	X[c]	X	X		
Instruct subject to complete Online Consumer Survey at least 7 days after the 1-Week Follow-Up Visit but before the 3-Week Follow-Up Visit		X			
Confirm Visit in ePRO (triggers survey and reminders)		X			
Confirm Subject has completed surveye			X		
With habitual lenses					
High-contrast distance logMAR lens VA (OU)	X				
Intermediate lens VA (OU)	X				
Near lens VA (OU)	X				
Without lenses					
Spherocylindrical refraction	X				X
Near add power	X				
High-contrast distance logMAR BSCVA (OD/OS/OU)	X				X
High-contrast intermediate logMAR BSCVA (OU w/near add)	X				
High-contrast near logMAR BSCVA (OU w/near add)	X				

PROCEDURE/ASSESSMENTS	Screening/ Dispensing Visit Day 1	1-Week Follow-Up Visit Day 8	3-Week Follow-Up Visit Day 23	Unscheduled Visit	Exit Visit
Pupil measurement	X				
Keratometry	X				X
Slit lamp exam	X	X	X	X	
With dispensed study lenses/With WORN study lenses					
High-contrast distance logMAR lens VA (OU)	X	X	X	X	X
High-contrast intermediate logMAR lens VA (OU)	X	X	X	X	X
High-contrast near logMAR lens VA (OU)	X	X	X	X	X
Lens wettability	X	X	X	X	X
Lens deposits (type, percent, and degree)		X	X	X	X
Lens centration	X	X	X	X	X
Lens movement	X	X	X	X	X
Compare distance lens VA to screening/dispensing BSCVA	X	X	X	X	X
Investigator-completed forms					
Investigator questionnaire					X

[a] Collect only study lens wear at follow-up visits (average daily wear time, number of days worn, rewetting drop use, if a habitual rewetting drop user).
[b] If the subject requires a change to their study lens power, adjust the fit and dispense study lenses with the appropriate power according to the Fitting Guide.
[c] All Lens Performance ratings will be collected on habitual lenses at Screening. Abbreviated Lens Performance ratings will be collected once the study lenses are dispensed and adapted on the eye. Use provided rating scales (separate document).
[d] At dispensing allow 10 minutes from insertion for lens settling & adaptation before performing assessments.
[e] If subject has not completed survey, they should complete at this visit.

Note: All VA measurements MUST be made using a phoropter.
Note: If this is an Exit Visit, also perform the procedures listed under the Exit Visit column.

6.2 Selection of Study Population

To be eligible for entry into the study, the subject must meet the following inclusion criteria:

1. Subjects must be age 40 years or older on the date the ICF is signed and have the capacity to provide voluntary informed consent.
2. Subjects must be willing and able to comply with all treatment and follow-up/study procedures, as well as willing and able to refrain from using any contact lenses other than those provided for the duration of the study.
3. Subjects must be correctable through spherocylindrical refraction to 42 letters (0.1 logMAR) or better (distance, high contrast) in each eye.
4. Subjects must have clear central corneas and be free of any anterior segment disorders.
5. Subject must wear their current lenses for a minimum of 12 hours per day at least four days per week.

6. Subjects must habitually wear a multifocal lens in each eye.
7. Subjects must be an adapted multifocal soft contact lens wearer for a minimum of 6 months.
8. Subjects must require distance lens correction from +3.00 to -6.00 D in each eye.
9. Subjects must be presbyopic and require near add correction from +0.75 to +2.50 D in each eye.
10. Subjects must have access to an internet connection to complete an online survey and be able to receive text message.

The subject is not eligible to participate in the study if the subject meets any of the following exclusion criteria:

1. Subjects participating in any drug or device clinical investigation within 30 days prior to entry into this study and/or plan to do so during the period of study participation.
2. Subjects who are women of childbearing potential (those who are not surgically sterilized or postmenopausal) are excluded from participation in the investigation if they meet any one of the following conditions:
   - She is currently pregnant
   - She plans to become pregnant during the study
   - She is breastfeeding
3. Subjects with any systemic disease currently affecting ocular health or that, in the Investigator's opinion, may have an effect on ocular health during the course of the study.
4. Subjects with an active ocular disease.
5. Subjects who have had any corneal surgery (e.g., refractive surgery).
6. Subjects who have worn gas-permeable (GP) contact lenses within the last 30 days or who have worn polymethylmethacrylate (PMMA) lenses within the last 3 months.
7. Subjects who currently wear monovision or toric contact lenses.
8. Subjects who are not correctable to 32 letters (0.3 logMAR) with bilateral soft multifocal contact lenses.
9. Subjects with an ocular astigmatism >1.00 D in either eye.
10. Subjects with anisometropia (spherical equivalent) >2.00 D.
11. Subjects with any Grade ≥2 finding during the slit lamp examination. Subjects with corneal infiltrates of ANY GRADE are not eligible.
12. Any "Present" finding during the slit lamp examination that, in the Investigator's opinion, interferes with contact lens wear.
13. Any scar or neovascularization within the central 6 mm of the cornea. Subjects with minor peripheral corneal scarring (that does not extend into the central area) that, in the Investigator's opinion, does not interfere with contact lens wear are eligible for this study.

14. Subjects who are amblyopic.
15. Subjects using any systemic or topical ocular medication that will, in the Investigator's opinion, affect ocular physiology or lens performance.
16. Subjects who are allergic to any component in the study care products.

If a subject meets all the inclusion criteria and does not exhibit any of the exclusion criteria, the subject is eligible for entry into the study. Ineligible subjects MUST NOT be enrolled in this study. Any subject enrolled in the study who later is found to have not met the eligibility criteria at entry will be discontinued.

6.3 Treatments

Subjects will be assigned to the Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens, manufactured by Bausch & Lomb Incorporated, Rochester, NY.

The description of the Test lens is as follows:

- Sphere power: -6.00 D to +3.00 in steps of 0.25 D
- Add: High and Low
- Diameter: 14.2 mm
- Base curve: 8.6 mm
- Material: kalifilcon A
- Packaging solution: phosphate-buffered saline solution

6.4 Efficacy and Safety Variables

6.4.1 Efficacy Variables

The primary endpoint will be assessed as the proportion of subjects agreeing with the statement "Clear vision: near, far, and in-between" in the online consumer survey, which is completed at least 7 days after the 1-Week Follow-Up Visit but before the 3-Week Follow-Up Visit.

Supportive effectiveness will include the following:

- Consumer survey
- Investigator questionnaire
- Number of visits to achieve a successful fit
- Number of lenses to achieve a successful fit
- Contact lens visual acuity (VA) in logarithm of the minimum angle of resolution (logMAR) units
- Contact lens VA in Snellen equivalent units
- Lens performance rating scales
- Lens deposits

- Lens characteristics
  - Wettability
  - Centration
  - Movement

6.4.2 Safety Variables

The following variables will be used to evaluate safety:

- Adverse events (AEs)
- Clinical safety examinations
  - Symptoms/complaints
  - Slit lamp examination
  - Best spectacle corrected visual acuity (BSCVA) in logMAR units
  - BSCVA in Snellen equivalent units
  - Spherocylindrical refraction
  - Keratometry

6.5 Statistical Methods

6.5.1 Data Sets Analyzed

The Full Analysis Set (FAS) will consist of all eligible, dispensed subjects or eyes. If only one eye is dispensed, the subject will be included in the FAS for subject level analyses, but only the dispensed eye will be included in the FAS for eye level analyses. The FAS will be used for all efficacy analyses in subject level and eye level data.

The Safety Analysis Set will consist of all dispensed subjects or eyes. If only one eye is dispensed, the subject will be included in the Safety Analysis Set for subject level summaries, but only the dispensed eye will be included in the Safety Analysis Set for eye level summaries. All safety analyses and summaries will be based on the Safety Analysis Set.

6.5.2 Endpoints at Scheduled and Unscheduled Visits

Efficacy and safety assessments conducted at unscheduled visits will be assigned to a corresponding scheduled visit if they occurred in a scheduled visit window (Table 1) and will be summarized by visit and visit type (scheduled or unscheduled). If subjects/eyes have multiple assessments at a given visit and visit type, each subject will be counted once for the worst case value for that visit and visit type. The exception to this rule is for continuous efficacy endpoints (including binocular lens VA in logMAR units and lens performance ratings), where the average over all of the multiple assessments for the visit and visit type will be summarized. A total column will be displayed to summarize data over unscheduled and scheduled visits using the same rule.

Assessments done at unscheduled visit which occurs out of scheduled visit windows will only be included in the summary of all follow-up visits or all assessments; these data will not be windowed into a scheduled visit summary. Each subject will only be counted once in any given summary.

Data listings will present data from all visits.

Online consumer survey, investigator questionnaire, and treatment compliance will only be summarized using data from scheduled visits.

6.5.3 Disposition of Subjects

Disposition summaries will be presented for all enrolled subjects. These summaries will include an accountability of subjects, summarizing the number and percentage of subjects in the following categories: active subjects, eligible at the Screening Visit, and ineligible at the Screening Visit. A subject is considered active once enrolled until completing or discontinuing from the study. In addition, within the eligible and ineligible at baseline categories, the number and percentage of subjects who have completed the study and discontinued the study will be presented. Lens dispensation status will be presented for discontinued subjects. All percentages will be based on the number of subjects enrolled, except that dispensation status percentages will be based on the number of discontinued subjects. Subject status will also be summarized by investigational site.

Subjects and eyes in the Full Analysis Set and the Safety Analysis Set will be summarized as well, with percentages based on all enrolled subjects/eyes.

The reasons for study discontinuation will also be summarized for each eye. Only the primary reason for study discontinuation will be recorded. Percentages will be based on the number of eyes for all enrolled subjects.

Details of discontinued eyes and ineligible subjects will be presented separately. Subject listings will also be provided for disposition data, as well as analysis sets and inclusion/exclusion criteria.

6.5.4 Demographic and Other Baseline Characteristics

Demographic summaries will be presented for the FAS. Demographic characteristics including age (years), sex, ethnicity, and race will be summarized at the subject level. Age will also be summarized in the following categories: 40 – 49, 50 – 59, 60 – 69, 70+. Subjects reporting more than one race will be summarized as “Multiple.” Sex, ethnicity, and race will

be summarized as categorical variables, while age will be summarized as a continuous variable.

Baseline eye characteristic summaries will be presented as continuous statistics summary for the FAS. Diagnostic refraction sphere (diopters), cylinder (diopters) and add power (diopters) will be summarized at the eye level using minus cylinder notation. Positive cylinder will be converted to minus cylinder format by adding the cylinder power to the sphere power, changing the cylinder power sign from '+' to '-', and changing the axis by 90 degrees (adding 90 degrees if axis < 90 and subtracting 90 degrees if axis > 90). The mean refractive spherical equivalent (MRSE) (diopters) will be summarized as a continuous measure. MRSE is calculated after converting the sphere and cylinder to minus cylinder notation as MRSE = sphere measurement +1/2 of cylinder measurement. Axis (degrees) will also be summarized by frequency and percentages in category groups (0, 1 to 30 or 150 to 180, 31 to 59 or 121 to 149, 60 to 120). Pupil size (mm) will be collected at the Screening/Dispensing Visit and summarized continuously as well.

Subject listings for demographic and baseline eye characteristic data will also be presented.

6.5.5 Baseline Questionnaire

Each eligible subject will complete a questionnaire prior to study lens insertion. Responses will be regarding current habitual lens wear. The categorical responses will be summarized by frequency and percentage for the FAS. The denominator will be the number of subjects who have non-missing responses for each question in the baseline questionnaire. The numerical responses will be summarized continuously. In addition, the categories used for subgroup analysis will be presented together, refer to Section 6.5.11.5. Subject listings of responses will be presented.

6.5.6 Ocular Medical History and Lens/Lens Care History

Ocular Medical history and lens/lens care history will be collected at the Screening Visit.

The Medical Dictionary for Regulatory Activities (MedDRA) Version 25.1 will be used to code reported medical history terms. Ocular medical history will be presented in subject listings at the subject, eye, and event level by System Organ Class (SOC) and Preferred Term (PT).

Lens/lens care history will be assessed using collected data regarding subjects' most recent contact lens wear experience. Average number of days per week worn, average daily wear time, average hours of comfortable wear per day, and average number of times used

rewetting drops per day for habitual rewetting drop users will be summarized at the subject level, and hours Lenses Worn on the Day of Screening/Dispensing Visit, if subject comes in to the study visit wearing a lens, will be summarized at the eye level using continuous summary statistics. A categorical summary of habitual rewetting drop users and non-users will be conducted with rewetting drop users defined as having an average number of times used rewetting drops per day collected at baseline > 0. Habitual lens sphere (diopters) will be summarized continuously at the eye level. In addition, routinely used pre-study contact lens care system will be summarized categorically at the subject level. Percentages will be based on the number of subjects with responses. The most recent lens correction brand will be summarized similarly by eye (OD, OS). Lens/lens care history data will also be presented in subject listings.

6.5.7 Concomitant Medications

All concomitant medications (ocular, systemic or topical) that have been taken in the past 30 days before signing the Informed Consent Form (ICF) and during the course of the study will be collected.

Medications will be coded using World Health Organization Drug Dictionary (WHO Drug Global C3, September 1, 2022) and presented using the therapeutic drug class (Anatomical Therapeutic Chemical (ATC) 4 classification) and preferred name. If the ATC 4 classification is not provided, the next lowest classification that is provided in the coding dictionary will be used. The preferred name will be defined as the active ingredient; if the active ingredient is not provided or includes more than two ingredients (e.g., multivitamins) then the drug name will be presented as the preferred name. Any uncoded terms will be presented with the ATC classification and preferred name of “Uncoded”.

Reported and coded terms (ATC class and preferred name) will be presented in subject listings.

6.5.8 Measurements of Treatment Compliance

Treatment compliance will be assessed using lens wear parameter data.

Average number of days per week worn, average daily wearing time (hours), average hours of comfortable wear, and hours worn on the day at visit are collected at follow-up visits and summarized continuously at the eye level. Average number of days per week worn will also be summarized categorically at the eye level: 0, 1, 2, 3, 4, 5, 6, 7. Percentages will be based on the number of eyes with non-missing responses. Rewetting drop use (average number of times per day rewetting drops were used) will be collected and summarized continuously at

the subject level for subjects who used rewetting drops at baseline only. Subjects who are habitual rewetting drop users with an on-treatment value of "not applicable" will be summarized as using 0 rewetting drops per day. In addition, the number and percentage of subjects who used rewetting drops at baseline will be presented.

Lens wear parameters will be presented in a data listing.

6.5.9 Protocol Deviations

Protocol deviation will be recorded throughout the study. Major deviations will be defined as any protocol deviations that could have an impact on the validity of the key outcomes in the study. Major protocol deviations will be identified in a review of the deviations by the study team prior to database lock. Major protocol deviations will be summarized in total for the Full Analysis Set. Subjects are only counted once under each protocol deviation category if more than one deviation occurred. A data listing of all protocol deviations will be provided.

6.5.10 Analysis of Efficacy

6.5.10.1 Descriptive Statistics

Analyses of effectiveness outcomes will be completed using the Full Analysis Set.

In general, data will be summarized by visit as appropriate. Data will be summarized separately at the subject and eye levels. For lens performance rating endpoints at the subject level, the worst case over both eyes will be derived and summarized for categorical variables.

Summaries for continuous variables will include the sample size (n), mean, standard deviation, median, minimum, and maximum. Means and medians will be presented with one more decimal place than the recorded raw data. Standard deviations will be presented with two more decimal places than the recorded raw data. Minima and maxima will be presented with the same number of decimal places as the recorded raw data. Values with magnitude less than one will be presented with a leading zero to the left of the decimal (e.g., 0.123 or -0.123).

Categorical data will be summarized using frequencies and percentages. Percentages will be presented with one decimal place. Percentages may not be presented when the count is zero. Unless otherwise specified, the denominator for percentages will be the number of non-missing values within the group being presented.

6.5.10.2 Primary Efficacy

The primary effectiveness analysis will be performed based on the FAS. The primary endpoint is evaluated as the responder status based on subjects' responses to the statement "Clear vision: near, far, and in-between' in the online consumer survey, where a "responder" is defined as a participant agrees the statement. For the primary endpoint, the null hypothesis (H0) is that the proportion of subjects agreeing with the statement (π) is less than or equal to 0.5. The alternative hypothesis (H1) is that the proportion of subjects agreeing is greater than 0.5.

$$H_0: \pi \leq 0.5$$
$$H_1: \pi > 0.5$$

The responses to the primary endpoint statement will be summarized using categorical summary statistics (strongly agree, agree, slightly agree, neither agree nor disagree, slightly disagree, disagree, strongly disagree).

Responses of strongly agree, agree, and slightly agree will be coded to a category "Agree." Responses of strongly disagree, disagree, and slightly disagree will be coded to a category "Disagree." The trichotomized responses will be summarized categorically (agree, neither agree nor disagree, disagree).

Neutral responses (i.e., "neither agree nor disagree") will not be included in the primary statistical analysis. The non-neutral responses used for the analysis will be presented using categorical summary statistics (agree, disagree). An exact 95% confidence interval (Clopper-Pearson test) around the proportion of subjects agreeing with the statement will be presented along with the p-value from a one-sided exact binomial test of the alternative hypothesis is that the proportion of subjects agreeing is greater than 0.5.

6.5.10.3 Sensitivity Analyses

Sensitivity to missing primary endpoint data will be evaluated using best-case imputation, worst-case imputation, and tipping point analysis.

6.5.10.4 Secondary Efficacy

There are no predefined secondary effectiveness endpoints.

6.5.10.5 Supportive Effectiveness Endpoints

6.5.10.5.1 Consumer Survey

Agreement with statements in the online consumer survey will be analyzed using the same method described for primary endpoint.

Subject listings for online consumer survey responses will be presented.

6.5.10.5.2 Investigator Questionnaire

The investigator questionnaire is collected at the Exit Visit. The responses to each statement in the investigator questionnaire will be summarized using categorical summary statistics and the percentages will be based on the number of subjects for whom there are non-missing responses.

The following investigator questionnaire items will also be evaluated using one-sided exact binomial test of the alternative hypothesis that the proportion of subjects for whom the investigators agreed is greater than 0.5.

- The proportion of subjects for whom the investigator was completely, very satisfied, or somewhat satisfied with the use of the contact lenses by the subject
- The proportion of subjects for whom the investigator agrees that the lens was easy to fit for the subject
- The proportion of subjects for whom the investigator agrees that the lenses deliver clear vision for the subject
- The proportion of subjects for whom the investigator agrees that the lens helps maintain a smooth, wettable surface for the subject
- The proportion of subjects for whom the investigator reports that it was extremely simple, simple, or somewhat simple to successfully fit the contact lens for the subject
- The proportion of subjects for whom the investigator agrees that the fitting process for the lens was straightforward for the subject
- The proportion of subjects for whom the investigator reports that it was extremely easy, easy, or somewhat easy to successfully fit the lens during the first visit for the subject

Subject listings for investigator questionnaire responses will be presented.

6.5.10.5.3 Number of Visits to Achieve a Successful fit

Study lens dispensation will be collected at the Screening/Dispensing Visit and 1-Week Follow-up Visit at the eye level. Subjects may require a change to their study lens power at the 1-Week Follow-up Visit. The total number of visits required to achieve a successful lens fit will be summarized for the FAS using continuous summary statistics.

In addition, unscheduled lens replacements will be summarized categorically by replacement reason for completed eyes and discontinued eyes. Subject listings for visit accountability and unscheduled visits will be presented.

6.5.10.5.4 Number of Refinements to Achieve a Successful Fit

The number of refinements completed will be collected at Screening/Dispensing Visit and 1-Week Follow-up Visit (if subject requires a change to their study lens power at this visit) at eye level. Data will be summarized for the FAS as continuous summary statistics at the eye level. Refinements at the Screening/Dispensing Visit and the 1-Week Follow-up Visit will be summarized separately, and a combination of the two visits will be summarized as well.

The number of lens refinements at the Screening/Dispensing Visit will be summarized by baseline add groups using categorical summary statistics for the following categories: 1, 2, 3, >3 refinements. The summary will be at the eye level. Baseline add group is defined based on the add power obtained at the Screening/Dispensing Visit (> 1.50D as High Add, <= 1.50D as Low Add). A total column combining low add and high add will be summarized. Eyes with missing add will not be included in this analysis.

Starting lens sphere and add as well as final lens sphere and add for dispensed lenses at the Screening/Dispensing Visit will also be summarized by baseline add groups. If the subjects achieve plano status with their starting sphere and add for an eye, no final sphere and add will be collected and the starting sphere and add will be summarized as their final sphere and add.

If the subject requires a change to their study lenses at the 1-Week Follow-up Visit, then the final sphere and add at the Screening/Dispensing Visit and 1-Week Follow-up Visit will be summarized. An additional summary of final add on both eyes will be conducted by the following categories: Low add – Low add, Low add – None, Low add – High add, High add – High add, High add –None. Percentages will be based on the number of subjects with non-missing responses for both eyes at each visit. Final sphere and add for this analysis are the final dispensed lens power that can provide satisfactory vision after the fitting procedure (final sphere and add for subjects whose starting sphere and add cannot achieve satisfactory vision and starting sphere and power for subjects who have satisfactory vision with starting lens power).

For eyes that require a change to their lenses, continuous summary statistics will be provided for sphere change and categorical summary statistics will be provided for add change using the following categories: Low Add to None, Low Add to High Add, None to Low Add, None to High Add, High Add to None, High Add to Low Add. The percentage of each add change

category will be based on the number of eyes that require an add change. The lens change summary will be performed at the eye level for eyes that have: sphere change only, add change only, and both sphere and add change, and at subject level for subjects who have: sphere change only in both eyes, sphere change only in either eye, add change only in both eyes, add change only in either eye, sphere and add change in both eyes, sphere change in one eye and add change in the other eye, and sphere and add change in either eye. In addition, a shift table will be provided for subjects who have an add change in either eye, at the subject level.

A data listing for the number of refinements for each eye at each visit will also be presented.

6.5.10.5.5 Contact Lens Visual Acuity

Binocular distance, intermediate, and near high contrast lens VA (letters correct) with habitual lenses will be obtained at the Screening/Dispensing Visit. The binocular distance, intermediate, and near high contrast lens VA will be obtained for dispensed study lenses at the Screening/Dispensing Visit, and with worn study lenses (if the subject comes in wearing study lenses) or for dispensed study lenses (if the subject requires a change to their study lenses at 1-Week Follow-up Visit) at all follow-up visits. 90% High Contrast logMAR charts with Sloan Letters from Precision Vision, Inc. will be used for distance, intermediate, and near lens VA assessments.

For distance VA, letter scores obtained with distance VA chart (CAT. NO. 2103-2) will be converted to the logMAR scales using the following algorithm and rounding to two decimals:

If $X \geq 7$ then logMAR = 0.8 – (0.02*[X – 7]);
Else if $X < 3$ then logMAR = 1.0 – 0.0333*X;
Else if $3 \leq X < 7$ then logMAR = 0.9 – (0.025*[X – 3]);
Where X = the number of letters entered on the case report form.

This algorithm reflects the distance VA chart being used in this study, starting at the 20/160 Snellen line and with 3 letters on the first line, 4 letters on the second line, and 5 letters on each line thereafter. An example of the chart used for distance VA is as follows:

Figure 1. Distance Visual Acuity (High Contrast) Example Chart

Snellen	logMAR	Chart		Letters Correct
20/160	0.9	S Z N		3
20/125	0.8	R N C V		4
20/100	0.7	K C R H N		5
20/80	0.6	Z K D V C		5
20/63	0.5	H V O R K		5
20/50	0.4	R H S O N		5
20/40	0.3	O K S V Z	K S X R H	4
20/32	0.2	K S N H O	X X K X X	1
20/25	0.1	H O V S N	N D V K O	
20/20	0	V C S Z H	D H O S Z	
20/16	-0.1	C Z D V R	V R N D O	
20/12.5	-0.2	S H R Z C	C Z H K S	
20/10	-0.3	D N O K R	O R Z S K	

TOTAL	32

For intermediate and near VA, logMAR scoring is the same as distance VA but using different charts (CAT. NO. 2105 for intermediate VA and CAT. NO. 2107 for near VA), which both start at the 20/400 Snellen line and with 5 letters on each line. Letter scores obtained with corresponding charts will be converted to the logMAR scales using following algorithm and rounding to two decimals:

logMAR = 1.4 – (0.02*X)
Where X = the number of letters entered on the case report form.

Binocular distance, intermediate, and near high contrast logMAR lens VA will be summarized separately by visit and visit type (unscheduled/scheduled) as continuous summary statistics. Only unscheduled visits in the visit window are included in unscheduled visit type for the corresponding visits. The average for each subject will be summarized if there are multiple unscheduled visits in the same visit window. A Total column will summarize the average for each subject over all scheduled and unscheduled visits. In addition to the summaries provided for each visit, a summary considering all study lens VA scores will be included and will be based on the average of all lens VA assessments for each subject, including VA at scheduled visits and unscheduled visits regardless of whether unscheduled visit happened in the scheduled visit window or not.

Change from binocular high contrast distance lens VA for dispensed study lens obtained at the Screening/Dispensing Visit will also be summarized for binocular high contrast distance

logMAR lens VA at all Follow-up Visits and will be based on the average of all changes for each subject if there are multiple assessments in a visit category, similarly to the summary of binocular high contrast distance lens VA.

Binocular lens VA for habitual lens and study lens will also be summarized categorically (in Snellen equivalent feet) in both mutually exclusive and cumulative categories (ie, summarizing 20/20 or better, 20/25 or better, etc.) by visit. An additional summary of all study lens VA will be provided based on the worst case over all study lens VA assessments. Shift tables will be provided showing change from baseline in Snellen equivalent feet units to the final follow-up lens VA for study lenses.

Subject listings will be presented for binocular high contrast distance, intermediate, near lens VA with habitual lenses and study lenses, including letters correct, VA in logMAR and Snellen equivalent feet units.

6.5.10.5.6 Lens Performance Rating Scales

Lens performance data will be collected at Screening/Dispensing Visit for habitual lenses and at follow-up visits for the study lenses rating from 0 to 100 at the eye level. An abbreviated lens performance assessment for the study lens is conducted at the Screening/Dispensing Visit. Data from the lens performance rating scales will be summarized using continuous summary statistics by visit, including change from habitual lens for follow-up visits at the eye level and subject level. The average of scores for both eyes will be used when summarizing at the subject level. For each lens performance parameter, responses are categorized as favorable if the score >= 50 and as unfavorable if the score < 50. A two-sided 95% confidence interval around the percentage with favorable responses will be presented by conducting a binomial (Clopper-Pearson) test. The p-values will be provided from a two-sided binomial test comparing the percentage of favorable responses to 50%.

Mean change from habitual lens performance ratings for each follow-up visit at the subject level will be compared to zero with an exploratory one-sided one-sample t-test by item. The alternative hypothesis will be that the mean change is greater than zero.

A subject listing of lens performance data for habitual lenses and study lenses will be presented.

6.5.10.5.7 Lens Status – Deposits

Lens deposits, including type, percentage coverage, and degree, will be collected at the eye level for study lenses at all follow-up visits.

Deposit type is identified by the following categories:

- None
- Crystalline deposits
- Crust-like deposits
- Film
- Spots

If deposit existence is confirmed, percentage coverage and degree will be assessed by the below categories:

Percentage Coverage:

- 1 - 25%
- 26 - 50%
- 51 - 75%
- 76 - 100%

Degree:

- Light
- Medium
- Heavy

Lens deposit data will be summarized categorically at the eye and subject level by visit and visit type (unscheduled/scheduled). Eyes/subjects with multiple visits in a visit category will be counted once for the worst category. The Total column will summarize the worst case over scheduled and unscheduled visits for each visit category. In addition, a summary over all follow-up visits for both deposit coverage and degree of deposits will be performed using the worst case over all follow-up visits.

Lens deposit data will be presented in a worn lens evaluation listing.

6.5.10.5.8 Lens Characteristics

Lens characteristics including wettability, centration, and movement will be collected for dispensed study lenses at the Screening/Dispensing Visit and for worn study lenses at other visits. Data will be collected at the eye level. Data will be summarized categorically by visit and visit type (unscheduled/scheduled) at both eye level and subject level. The percentages will be based on the number of eyes/subjects with responses. A total column will be added to summarize the worst case over scheduled and unscheduled visits. In addition, a summary over all follow-up visits will be conducted for study lenses using the worst case over all follow-up visits.

Subject listings will also be presented.

6.5.10.5.8.1 Wettability

Lens wettability will be assessed at each visit on the following scale:

- 100% of anterior lens surface is wettable
- Presence of small (<0.1 mm), individual discrete non-wetting areas
- Presence of single area of non-wetting between 0.1 mm and 0.5 mm in size
- Presence of several areas of non-wetting between 0.1 mm and 0.5 mm in size
- Presence of one or more non-wetting areas greater than 0.5 mm in size

6.5.10.5.8.2 Centration

Lens centration will be assessed at each visit on the following scale:

- Grade 0 (Equal Overlap 360 degrees)
- Grade 1 (Maximum overlap less than or equal to 2/3 in any sector)
- Grade 2 (Maximum overlap greater than 2/3 in any sector)
- Grade 3 (Any Corneal Exposure)

6.5.10.5.8.3 Movement

Lens Movement will be assessed at each visit on the following scale:

- Grade -2 (No observable movement)
- Grade -1 (Minimal; Just observable movement, lens returns to origin)
- Grade 0 (Free movement, lens returns to origin)
- Grade +1 (Substantial movement; but lens does not immediately return to origin)
- Grade +2 (Excessive movement; lens does not return to origin, may result in corneal exposure)

The order of severity for lens movement from worst to best is: -2, +2, -1, +1, 0.

The Josephson Push-Up Test will be used if lens movement is rated as -2 = No observable lens movement and rated as:

- Lens is mobile
- Lens is immobile (the worst case)

6.5.11 Statistical/Analytical Issues

6.5.11.1 Handling of Dropouts or Missing Data

The primary efficacy analysis will be conducted using the FAS and missing values will not be imputed.

Sensitivity to missing primary endpoint data will be evaluated using the following analyses:

- **Best-case analysis:** Subjects with missing responses on the statement of clear vision are imputed as 'Agree.'
- **Worst-case analysis:** Subjects with missing responses on the statement of clear vision are imputed as 'Disagree.'
- **Tipping point analysis:** if the primary efficacy analysis shows statistical significance and the worst-case analysis does not, a tipping point analysis will be performed using the following procedures:
  a. Impute any one missing value as 'Disagree,' and rest of missing value as 'Agree.'
  b. Using the imputed dataset from step a, perform the one-sided exact binomial test and determine statistical significance based on the resulting p-value.
  c. Repeat steps a and b until conclusion reversed or until all data are imputed as 'Disagree.'

Only subjects who did not provide a response to the primary endpoint question, including those who attended the 3-Week Visit but did not fill out the questionnaire, will participate in the sensitivity analyses. Subjects who provided a response of "neither agree nor disagree" will not be included. For Best-case and Worst-case analysis, the number of imputed subjects will be displayed with the number of non-imputed subjects. 95% confidence interval from an exact binomial (Clopper-Pearson) test will be presented with p-value from a one-sided exact binomial test of the alternative hypothesis that the proportion of subjects agreeing is greater than 0.5.

6.5.11.2 Interim Analyses

No interim analyses are planned during the course of the study.

6.5.11.3 Multicenter Studies

The clinical study will be conducted under a common protocol at multiple investigational sites with the intention of pooling the data for analysis. Every effort will be made to promote consistency in study execution at each investigational site. The uniformity of the primary endpoint responses (agree, disagree) among the sites will be evaluated using a chi-square test.

Subjects' responder status to the statement "Clear vision: near, far, and in-between' in the online consumer survey will be summarized categorically at the subject level ('Agree' or 'Disagree') by site for the FAS. The denominator for percentages will be the number of non-missing values. Missing data will not be imputed.

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If any site has fewer than five subjects, that site will be pooled with the site with the fewest subjects, until a pooled site includes at least five subjects.

A chi-square test will be used to evaluate the consistency of the primary endpoint responses among the sites after pooling. If 25% or more of the cells have expected counts less than 5, then Fisher's exact test may be used instead. If the p-value from this test is less than 0.05 then the difference between sites will be considered statistically significant.

6.5.11.4 Control of Multiplicity

The primary endpoint is a single test, so multiplicity control is not necessary for this evaluation. The study will require the primary effectiveness endpoint to be statistically significant in order to test other endpoints. Specifically, failure of the primary effectiveness endpoint will invalidate the statistical significance of the supportive effectiveness endpoints.

For the online survey and investigator questionnaire inferential tests on the FAS including all subjects, the risk of type I errors will be controlled as follows:

- These supportive effectiveness outcomes will not be eligible for statistical hypothesis testing unless the null hypothesis is rejected for the primary endpoint.
- The Holm adjustment will be applied. The following tests will be included in the Holm procedure:

  The proportion of subjects agreeing with the statement:

  - Provide effortless vision
  - Provide clear vision from near to far seamlessly throughout the day
  - Provide all-day comfort and continuously clear vision
  - Provide clear vision, even in low light
  - Help reduce stress and tiredness in my eyes
  - Allow me to effortlessly move from various tasks throughout the day
  - Help prevent my eyes from feeling tired and fatigued at the end of the day
  - Help protect against irritation and discomfort
  - Make my eyes feel relaxed Are so breathable, the lenses feel like air

- Provide clear vision when driving at night
- Help my eyes feel healthy
- Feel continuously moist
- Help support changes in my eyes that occur with age
- Give me freedom from reading glasses
- Feel incredibly soft, smooth, and weightless
- Give me the freedom to do more in life
- Provide a new visual experience to see life full of color and vibrancy
- Help me live life to the fullest
- Are comfortable
- Help eyes stay moist
- Provide clear vision
- Prevent blurriness
- Prevent eyes from feeling dry
- Prevent eyes from feeling tired or fatigued

The proportion of subjects for whom the investigator

- was completely, very satisfied, or somewhat satisfied with the use of the contact lenses by the subject
- agrees that the lens was easy to fit for the subject
- agrees that the lenses deliver clear vision for the subject
- agrees that the lens helps maintain a smooth, wettable surface for the subject
- reports that it was extremely simple, simple, or somewhat simple to successfully fit the contact lens for the subject

- agrees that the fitting process for the lens was straightforward for the subject
- reports that it was extremely easy, easy, or somewhat easy to successfully fit the lens during the first visit for the subject

6.5.11.5 Examination of Subgroups

The demographics and baseline characteristics, online consumer survey responses, investigator questionnaire responses, and lens performance rating will also be summarized by the following subgroups.

- Alcon: habitual lens group (including
  Dailies Total® Multifocal,
  Dailies® Aquacomfort Plus® Multifocal,
  Air Optix® Plus Hydraglyde® Multifocal)
- Bausch + Lomb: habitual lens group (including
  Biotrue® ONEday for Presbyopia,
  ULTRA® for Presbyopia,
  PureVision®2 for Presbyopia,
  PureVision for Presbyopia,
  SofLens® Multi-Focal)
- CooperVision: habitual lens group (including
  MyDay® Multifocal,
  Clariti® 1 Day Multifocal,
  Biofinity® Multifocal,
  Proclear 1 Day Multifocal,
  Proclear Multifocal)
- Johnson & Johnson: habitual lens group (including
  Acuvue® Oasys Max 1-Day Multifocal,
  1-Day Acuvue® Moist Brand Multifocal,
  Acuvue® Oasys Multifocal,
  Acuvue® Oasys for Presbyopia)

Habitual lens brand is collected at the eye level. If habitual lens brand for both eyes of the subject are different but belongs to the same manufacturer, then the subject will be counted in that manufacturer category. If the habitual lens brands are from different manufacturers, the subject will be included in the 'Other' lens brand category.

- Subgroups from the baseline questionnaire:
  - Dry Eyes: Very dry or somewhat dry
  - Non-Dry Eyes: Not very dry or not at all dry
  - Tired Eyes: All or most of the time, or quite often
  - Non-Tired Eyes: Now and then, or rarely

- Eye Strain: All or most of the time, or quite often
- Non-Eye Strain: Now and then, or rarely

- Blurry/Fluctuating Vision: All or most of the time, or quite often
- Non-Blurry/Fluctuating Vision: Now and then, or rarely

- Binge Watcher: Frequently or occasionally
- Non-Binge Watcher: Rarely or never

- Computer or Video Gamer: Frequently or occasionally
- Non-Gamer: Rarely or never

- Physically Active: 5+ times per week, or 3-4 times per week
- Non-Physically Active: Once or twice per week or never

- Excessive Digital Device Users – Those with a total of 10 or more hours for a, b, e, g combined.
    a. Work in an office in front of a computer
    b. Work at home in front of a computer
    c. Watch TV
    d. Drive at night (including riding as a passenger)
    e. Use a smartphone or tablet (e.g. iPad)
    f. Study or read from a book, magazine, newspaper etc.
    g. Play electronic games (on any device or system)
    h. Engage in sports/physical activity
- Non-Excessive Digital Device Users – those with a total of less than 10 hours for a, b, e, g combined.

- Subgroups for baseline add power measured at the Screening/Dispensing Visit:
    - High Add (> 1.50D in both eyes)
    - Low Add (≤ 1.50D in both eyes)
    - Mixed Add

Comparisons between subgroup categories from the baseline questionnaire and subgroups of add power (comparing only the high add versus low add) will be made for agreement on each of the statements in the online consumer survey and investigator questionnaire. Analyses comparing these dichotomous subgroups will be conducted using chi-square tests. If 25% or more of the cells have expected counts less than 5, then Fisher's exact test is used instead. Missing data will not be imputed.

6.5.12 Safety Analyses

6.5.12.1 Adverse Events

All adverse events occurring during the study will be recorded and classified to below categories on the basis of MedDRA terminology, the number and percentage of each category will be summarized.

- AEs (NOT Device Related)
- Serious Adverse Events (SAEs) (NOT Device Related)
- Adverse Device Effects (ADE) (Device Related)
- Unanticipated Serious Adverse Device Effects (USADE) (Device Related)
- Anticipated Serious Adverse Device Effects (ASADE) (Device Related)

A treatment-emergent AE (TEAE) is defined as any AE with an onset on or after the date of the first study device use. If the start date of an AE is incomplete or missing, then the AE will be considered as a TEAE unless a partial date shows it as a pre-treatment event. All reported treatment-emergent AEs (TEAEs) will be summarized by the number of subjects reporting AEs, system organ class, preferred term, severity, seriousness, and relationship to study device.

Ocular Adverse events will be summarized as well by the number of subjects/eyes reporting AEs, system organ class, preferred term, severity, and relationship to study device. Ocular adverse events are defined as AEs specified in one or both eyes. Only treatment-emergent adverse events (TEAEs) are included in the summary.

If more than one AE is coded to the same preferred term for a subject, the subject will be counted only once for that preferred term using the most severe and most related occurrence for the severity and relationship to study intervention summaries, respectively.

If the severity of a TEAE is missing, the maximum severity will be assigned to the event for the summaries by severity. The value will be displayed as missing in the data listings.

If the relationship to the study intervention is missing for a TEAE, the event will be considered related to the study intervention for the summaries. The value will be displayed as missing in the data listings.

All information pertaining to AEs noted during the study will be listed by subject, detailing verbatim given by the investigator, preferred term, system organ class, start date, stop date, severity, actions taken, and device relatedness. The AE onset will also be shown relative (in

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number of days) to the day of initial use of the study device. In addition, a list of subjects who experienced SAEs will also be provided.

6.5.12.2 Symptoms/Complaints

Subject symptoms/complaints for each eye will be collected at the Screening/Dispensing Visit and at follow-up visits. Symptoms/complaints collected at the Screening/Dispensing Visit will refer to the habitual lenses; symptoms/complaints collected at follow-up visits will refer to the study lenses. Subjects that experienced any symptoms/complaints will indicate the symptom/complaint level on the following scales:

- 0 - None
- 1 - Slight symptoms. The symptom is felt or noticed occasionally.
- 2 - Mild symptoms. The symptom is noticeable but not irritating or limiting use.
- 3 - Moderate symptoms. The symptom is moderately irritating or annoying; the use of device is limited by <25% (short wear time, etc.).
- 4 - Severe symptoms. The symptom is very irritating or annoying, and the lens cannot be tolerated.

Table 2. Symptoms/Complaint Rating Table

Symptom	OS (left eye)	OD (right eye)
Discomfort	0-4	0-4
Excessive tearing	0-4	0-4
Photophobia	0-4	0-4
Halos	0-4	0-4
Itching/Burning	0-4	0-4
Spectacle Blur	0-4	0-4
Variable Vision	0-4	0-4
Blurred Vision	0-4	0-4
Lens needs cleaning	0-4	0-4
Handling	0-4	0-4

Responses will be summarized for baseline and all follow-up visits with frequencies and percentages. Summary will be displayed by visit type (unscheduled/scheduled) and will include a Total column that will summarize the worst case (over scheduled and unscheduled). An additional summary over all follow-up visits will be performed. Symptoms/Complaints will also be summarized categorically by visit, including all follow-up visits category for whether eyes are experiencing problems at any visit in the study. Results will be dichotomized, with ‘Absent’ if the response is ‘None’ and ‘Present’ if the response is other than ‘None’ for each Symptom.

Individual subject responses for symptoms/complaints parameters will also be presented in subject listings.

6.5.12.3 Slit Lamp Examination

Slit lamp examination (without lenses) will be performed at the Screening/Dispensing Visit and at all follow-up visits.

Epithelial Edema, Epithelial Microcysts, Stromal Edema, Endothelial regularity, Corneal Staining, Limbal Injection, Bulbar Injection, Upper Lid Tarsal Conjunctival Abnormalities, Corneal Neovascularization, and Corneal Infiltrates will be assessment on the following scale:

- Grade 0 = None
- Grade 1 = Trace
- Grade 2 = Mild
- Grade 3 = Moderate
- Grade 4 = Severe

Bulbar Conjunctival Lens Compression/Indentation, New Corneal Scar, and Other Slit-Lamp Findings will be assessed as follows:

- Present
- Absent

All slit lamp measures will be assessed for each eye and will be summarized categorically by visit and visit type (unscheduled/scheduled). Eyes/subjects with multiple visits in a visit category will be counted once for the worst case. The Total column will summarize the worst case (from scheduled and unscheduled visits) for each visit category. In addition, a summary of assessment over all follow-up visits will be provided using the worst case.

A listing of eyes with corneal infiltrates and details of the of corneal infiltrate evaluation will be presented.

A listing of eyes with corneal scars and details of follow-up assessments will be presented.

A subject listing of all slit lamp findings data will also be presented.

6.5.12.4 Best Spectacle Corrected Visual Acuity (BSCVA)

Binocular distance, intermediate, and near high contrast BSCVA (letters correct) will be obtained at the Screening/Dispensing Visit. Binocular distance high contrast BSCVA will be obtained at the Exit Visit as well. Binocular BSCVA in logMAR units will be summarized continuously.

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Binocular letter changes from the high contrast distance BSCVA at the Screening/Dispensing Visit to high contrast distance VA for study lenses at all visits will be calculated. Line changes will be summarized categorically using frequencies and percentages. A line change is defined as a change of five letters. Positive line changes reflect improved VA. An additional summary for all study lens assessments will be displayed considering all scheduled visits and unscheduled visit, regardless of the visit window. The worst case will be used for this summary. Details for eyes that decrease two or more lines will be presented. In addition, high contrast distance lens VA will be summarized categorically by visit as to whether the VA is 20/40 or worse in Snellen equivalent units.

Monocular distance high contrast BSCVA will be obtained at the Screening/Dispensing Visit and at the Exit Visit. Monocular BSCVAs will be converted to logMAR score and summarized as continuous statistics at the eye level.

Monocular line changes in BSVCA from baseline to the Exit Visit will be summarized categorically, as well. Details of eyes that decreased two or more lines from the Screening/Dispensing Visit BSCVA to the Exit BSCVA will be tabulated.

Subject listings for binocular and monocular BSCVA will be presented, including letters corrected, VA in logMAR and Snellen equivalent feet unit. In addition, letter changes from baseline BSCVA will also be presented in listings.

6.5.12.5 Exit Eye Examination

Spherocylindrical refraction and keratometry will be assessed at the Screening/ Dispensing and the Exit visit. Spherocylindrical refraction will be measured as sphere (diopters), cylinder (diopters), and axis (degrees) and will be summarized separately as continuous summary statistics in minus cylinder notation (using the same conversion in section 6.5.4), including change from the Screening/Dispensing Visit for sphere and cylinder. The MRSE (diopters) and absolute value of change from baseline will be summarized as continuous measure, and absolute value of change from baseline will also be summarized as a categorical measure using following categories: 0.00-0.99 D, 1.00-1.99 D, 2.00-2.99 D, 3.00-3.99 D, 4.00-4.99 D, and >=5.00 D. MRSE is calculated after converting the sphere and cylinder to minus cylinder notation as MRSE = sphere measurement +1/2 of cylinder measurement. Add power will also be obtained at the Screening/Dispensing Visit and summarized as a continuous measure.

Keratometry will be measured in the horizontal and vertical diopters. The absolute value of keratometry changes collected at the Exit Visit will be summarized both as a continuous and categorical measure, using the following categories: 0.00-0.99 D, 1.00-1.99 D, 2.00-2.99 D,

3.00-3.99 D, 4.00-4.99 D, and ≥5.00 D. The horizontal and vertical changes and the largest change over both results will be included in the summary table.

Subject listings of keratometry and spherocylindrical refractive measures will be presented.

6.5.12.6 Cultures

Cultures will be obtained in cases of corneal ulcer or suspected ocular infection, unless medically contraindicated. Cultures should be taken from the cul-de-sac, lower eyelid margin, and the corneal lesion (if applicable). A listing for culture information will be presented.

6.5.12.7 Pregnancy Status

During the study, all female subjects of childbearing potential should be instructed to contact the Investigator immediately if they suspect they might be pregnant (e.g., missed, or late menstrual period). Female subjects who become pregnant during the study will be followed until completion of pregnancy. Pregnancy itself is not considered an AE. A data listing will be presented for pregnancy status for female subjects.

6.5.13 Determination of Sample Size

Approximately 300 subjects will be enrolled. Allowing for up to 10% losses, power calculations were completed for 270 completed subjects. An exact binomial test with a nominal 5% one-sided significance level will have 93% power to detect the difference between the Null hypothesis proportion, π_0 of 0.5 and the Alternative proportion, π_1, of 0.6 when the sample size is 270.

6.6 Changes in Planned Analyses

The proportion of subjects for whom the investigator agrees with the following statement: "The lens was easy to fit" was removed as an endpoint since this question is not collected in the actual investigator questionnaire.

7 INDEX OF PLANNED TABLES, FIGURES, AND LISTINGS

7.1 Planned Tables

Topline tables are indicated in bold font. Note this table of contents may be updated after the SAP is finalized, to clarify table titles, table numbering, or reformatting of tables.

Table 3. Planned Tables

Table Number	Title	Population
14.1.1.1.1	**Accountability of Subjects Enrolled in the Study and Distribution by Status**	**All Enrolled Subjects**

14.1.1.1.2	**Analysis Sets**	**All Enrolled Subjects**
14.1.1.2	Subject by Subgroups	All Enrolled Subjects
14.1.2	Subject Status by Investigator	All Enrolled Subjects
14.1.3.1	Reasons for Discontinuation by Eye	All Enrolled Eyes
14.1.3.2	Detail of Discontinued Eyes	All Enrolled Eyes
14.1.3.3	Detail of Ineligible Subjects	All Enrolled Subjects
14.1.4.1	**Subject Demographics and Baseline Eye Characteristics**	**Full Analysis Set**
14.1.4.2	Subject Demographics and Baseline Eye Characteristics by Habitual Lens Group	Full Analysis Set
14.1.4.3	Subject Demographics and Baseline Eye Characteristics by Dry Eye Category	Full Analysis Set
14.1.4.4	Subject Demographics and Baseline Eye Characteristics by Tired Eye Category	Full Analysis Set
14.1.4.5	Subject Demographics and Baseline Eye Characteristics by Eye Strain Category	Full Analysis Set
14.1.4.6	Subject Demographics and Baseline Eye Characteristics by Blurry/Fluctuating Vision Category	Full Analysis Set
14.1.4.7	Subject Demographics and Baseline Eye Characteristics by Binge Watcher Category	Full Analysis Set
14.1.4.8	Subject Demographics and Baseline Eye Characteristics by Gamer Category	Full Analysis Set
14.1.4.9	Subject Demographics and Baseline Eye Characteristics by Physically Active Category	Full Analysis Set
14.1.4.10	Subject Demographics and Baseline Eye Characteristics by Add Power Category	Full Analysis Set
14.1.5	**Baseline Questionnaire**	**Full Analysis Set**
14.1.6.1	Baseline Lens/Lens Care History	Full Analysis Set
14.1.6.2	Baseline Lens Brand	Full Analysis Set
14.1.7	Lens Wearing Parameters	Full Analysis Set
14.1.8	Unscheduled Lens Replacements	Full Analysis Set
14.1.9	Major Protocol Deviations	Full Analysis Set
14.2.1.1.1.1	**Online Consumer Survey**	**Full Analysis Set**
14.2.1.1.1.2	Online Consumer Survey by Habitual Lens Group	Full Analysis Set
14.2.1.1.1.3	Online Consumer Survey by Dry Eye Category	Full Analysis Set
14.2.1.1.1.4	Online Consumer Survey by Tired Eye Category	Full Analysis Set
14.2.1.1.1.5	Online Consumer Survey by Eye Strain Category	Full Analysis Set

14.2.1.1.1.6	Online Consumer Survey by Blurry/Fluctuating Vision Category	Full Analysis Set
14.2.1.1.1.7	Online Consumer Survey by Binge Watcher Category	Full Analysis Set
14.2.1.1.1.8	Online Consumer Survey by Gamer Category	Full Analysis Set
14.2.1.1.1.9	Online Consumer Survey by Physically Active Category	Full Analysis Set
14.2.1.1.1.10	Online Consumer Survey by Add Power Category	Full Analysis Set
14.2.1.1.2.1	**Provide Clear Vision: Near, Far, and In-Between: Number of Participants Agreeing with the Statements**	**Full Analysis Set**
14.2.1.1.2.2	Provide Clear Vision: Near, Far, and In-Between: Number of Participants Agreeing with the Statements with Best Case Imputation	Full Analysis Set
14.2.1.1.2.3	Provide Clear Vision: Near, Far, and In-Between: Number of Participants Agreeing with the Statements with Worst Case Imputation	Full Analysis Set
14.2.1.1.3	Provide Clear Vision: Near, Far, and In-Between Tipping Point Analysis	Full Analysis Set
14.2.1.1.4	Provide Clear Vision: Near, Far, and In-Between by Site	Full Analysis Set
14.2.1.2	**Consumer Survey Responses: Number of Participants Agreeing with the Statements**	**Full Analysis Set**
14.2.1.3.1	**Investigator Questionnaire**	**Full Analysis Set**
14.2.1.3.2	**Investigator Questionnaire: Number of Participants Agreeing with the Statements**	**Full Analysis Set**
14.2.1.4	**Holm Adjustment for Supportive Endpoints**	**Full Analysis Set**
14.2.1.5.1	Online Consumer Survey Comparison of Dry Eye Category	Full Analysis Set
14.2.1.5.2	Online Consumer Survey Comparison of Tired Eye Category	Full Analysis Set
14.2.1.5.3	Online Consumer Survey Comparison of Eye Strain Category	Full Analysis Set
14.2.1.5.4	Online Consumer Survey Comparison of Blurry/Fluctuating Vision Category	Full Analysis Set
14.2.1.5.5	Online Consumer Survey Comparison of Binge Watcher Category	Full Analysis Set
14.2.1.5.6	Online Consumer Survey Comparison of Computer or Video Gamer Category	Full Analysis Set

14.2.1.5.7	Online Consumer Survey Comparison of Physically Active Category	Full Analysis Set
14.2.1.5.8	Online Consumer Survey Comparison of Excessive Digital Device Users Category	Full Analysis Set
14.2.1.5.9	Online Consumer Survey Comparison of Add Power Category	Full Analysis Set
14.2.1.6.1	Investigator Questionnaire Comparison of Dry Eye Category	Full Analysis Set
14.2.1.6.2	Investigator Questionnaire Comparison of Tired Eye Category	Full Analysis Set
14.2.1.6.3	Investigator Questionnaire Comparison of Eye Strain Category	Full Analysis Set
14.2.1.6.4	Investigator Questionnaire Comparison of Blurry/Fluctuating Vision Category	Full Analysis Set
14.2.1.6.5	Investigator Questionnaire Comparison of Binge Watcher Category	Full Analysis Set
14.2.1.6.6	Investigator Questionnaire Comparison of Computer or Video Gamer Category	Full Analysis Set
14.2.1.6.7	Investigator Questionnaire Comparison of Physically Active Category	Full Analysis Set
14.2.1.6.8	Investigator Questionnaire Comparison of Excessive Digital Device Users Category	Full Analysis Set
14.2.1.6.9	Investigator Questionnaire Comparison of Add Power Category	Full Analysis Set
14.2.1.7.1	Summary for Achieving Successful Fits	Full Analysis Set
14.2.1.7.2	Number of Lens Refinements at the Screening/Dispensing Visit	Full Analysis Set
14.2.1.7.3	Lens Power and Add at the Screening/Dispensing Visit	Full Analysis Set
14.2.1.7.4	Dispensed Lens Information for Subjects Require a Change	Full Analysis Set
14.2.1.7.5	Dispensed Lens Add Change for Subjects Require a Change	Full Analysis Set
14.2.2.1.1	Binocular High Contrast Distance logMAR Lens VA	Full Analysis Set
14.2.2.1.2	Binocular High Contrast Intermediate logMAR Lens VA	Full Analysis Set
14.2.2.1.3	Binocular High Contrast Near logMAR Lens VA	Full Analysis Set
14.2.2.1.4	Binocular High Contrast Distance logMAR Lens VA Change from Screening/Dispensing to Each Follow-up Visit	Full Analysis Set

14.2.2.2.1	Binocular High Contrast Distance Snellen Lens VA	Full Analysis Set
14.2.2.2.2	Binocular High Contrast Intermediate Snellen Lens VA	Full Analysis Set
14.2.2.2.3	Binocular High Contrast Near Snellen Lens VA	Full Analysis Set
14.2.2.3.1	Cumulative Binocular High Contrast Distance Snellen Lens VA	Full Analysis Set
14.2.2.3.2	Cumulative Binocular High Contrast Intermediate Snellen Lens VA	Full Analysis Set
14.2.2.3.3	Cumulative Binocular High Contrast Near Snellen Lens VA	Full Analysis Set
14.2.2.4.1	Binocular High Contrast Distance Snellen Lens VA: Screening/Dispensing Visit Versus Final Follow-Up Lens VA	Full Analysis Set
14.2.2.4.2	Binocular High Contrast Intermediate Snellen Lens VA: Screening/Dispensing Visit Versus Final Follow-Up Lens VA	Full Analysis Set
14.2.2.4.3	Binocular High Contrast Near Snellen Lens VA: Screening/Dispensing Visit Versus Final Follow-Up Lens VA	Full Analysis Set
14.2.3.1.1	Lens Performance Rating Scales for Habitual Lenses – Eye Level	Full Analysis Set
14.2.3.1.2	Lens Performance Rating Scales for Habitual Lenses – Subject Level	Full Analysis Set
14.2.3.2.1.1	Lens Performance Rating Scales for Study Lenses – Eye Level	Full Analysis Set
14.2.3.2.1.2	Lens Performance Rating Scales for Study Lenses – Eye Level by Habitual Lens Group	Full Analysis Set
14.2.3.2.1.3	Lens Performance Rating Scales for Study Lenses – Eye Level by Dry Eye Category	Full Analysis Set
14.2.3.2.1.4	Lens Performance Rating Scales for Study Lenses – Eye Level by Tired Eye Category	Full Analysis Set
14.2.3.2.1.5	Lens Performance Rating Scales for Study Lenses – Eye Level by Eye Strain Category	Full Analysis Set
14.2.3.2.1.6	Lens Performance Rating Scales for Study Lenses – Eye Level by Blurry/Fluctuating Vision Category	Full Analysis Set
14.2.3.2.1.7	Lens Performance Rating Scales for Study Lenses – Eye Level by Binge Watcher Category	Full Analysis Set
14.2.3.2.1.8	Lens Performance Rating Scales for Study Lenses – Eye Level by Gamer Category	Full Analysis Set

14.2.3.2.1.9	Lens Performance Rating Scales for Study Lenses – Eye Level by Physically Active Category	Full Analysis Set
14.2.3.2.1.10	Lens Performance Rating Scales for Study Lenses – Eye Level by Add Power Category	Full Analysis Set
14.2.3.2.2.1	Lens Performance Rating Scales for Study Lenses – Subject Level	Full Analysis Set
14.2.3.2.2.2	Lens Performance Rating Scales for Study Lenses – Subject Level by Habitual Lens Group	Full Analysis Set
14.2.3.2.2.3	Lens Performance Rating Scales for Study Lenses – Subject Level by Dry Eye Category	Full Analysis Set
14.2.3.2.2.4	Lens Performance Rating Scales for Study Lenses – Subject Level by Tired Eye Category	Full Analysis Set
14.2.3.2.2.5	Lens Performance Rating Scales for Study Lenses – Subject Level by Eye Strain Category	Full Analysis Set
14.2.3.2.2.6	Lens Performance Rating Scales for Study Lenses – Subject Level by Blurry/Fluctuating Vision Category	Full Analysis Set
14.2.3.2.2.7	Lens Performance Rating Scales for Study Lenses – Subject Level by Binge Watcher Category	Full Analysis Set
14.2.3.2.2.8	Lens Performance Rating Scales for Study Lenses – Subject Level by Gamer Category	Full Analysis Set
14.2.3.2.2.9	Lens Performance Rating Scales for Study Lenses – Subject Level by Physically Active Category	Full Analysis Set
14.2.3.2.2.10	Lens Performance Rating Scales for Study Lenses – Subject Level by Add Power Category	Full Analysis Set
14.2.3.3.1.1	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses - Eye Level	Full Analysis Set
14.2.3.3.1.2	Lens Performance Rating Scales for Study Lenses – Eye Level by Habitual Lens Group	Full Analysis Set
14.2.3.3.1.3	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Eye Level by Dry Eye Category	Full Analysis Set
14.2.3.3.1.4	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Eye Level by Tired Eye Category	Full Analysis Set
14.2.3.3.1.5	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Eye Level by Eye Strain Category	Full Analysis Set

14.2.3.3.1.6	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Eye Level by Blurry/Fluctuating Vision Category	Full Analysis Set
14.2.3.3.1.7	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Eye Level by Binge Watcher Category	Full Analysis Set
14.2.3.3.1.8	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Eye Level by Gamer Category	Full Analysis Set
14.2.3.3.1.9	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Eye Level by Physically Active Category	Full Analysis Set
14.2.3.3.1.10	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Eye Level by Add Power Category	Full Analysis Set
14.2.3.3.2.1	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Subject Level	Full Analysis Set
14.2.3.3.2.2	Lens Performance Rating Scales for Study Lenses – Subject Level by Habitual Lens Group	Full Analysis Set
14.2.3.3.2.3	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Subject Level by Dry Eye Category	Full Analysis Set
14.2.3.3.2.4	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Subject Level by Tired Eye Category	Full Analysis Set
14.2.3.3.2.5	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Subject Level by Eye Strain Category	Full Analysis Set
14.2.3.3.2.6	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Subject Level by Blurry/Fluctuating Vision Category	Full Analysis Set
14.2.3.3.2.7	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Subject Level by Binge Watcher Category	Full Analysis Set
14.2.3.3.2.8	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Subject Level by Gamer Category	Full Analysis Set
14.2.3.3.2.9	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Subject Level by Physically Active Category	Full Analysis Set
14.2.3.3.2.10	Lens Performance Rating Scales for Study Lenses Change from Habitual Lenses – Subject Level by Add Power Category	Full Analysis Set

14.2.4.1	Lens Deposits – Eye Level	Full Analysis Set
14.2.4.2	Lens Deposits – Subject Level	Full Analysis Set
14.2.5.1	Lens Wettability – Eye Level	Full Analysis Set
14.2.5.2	Lens Wettability – Subject Level	Full Analysis Set
14.2.6.1	Lens Centration – Eye Level	Full Analysis Set
14.2.6.2	Lens Centration – Subject Level	Full Analysis Set
14.2.7.1	Lens Movement – Eye Level	Full Analysis Set
14.2.7.2	Lens Movement – Subject Level	Full Analysis Set
14.3.1.1.1	**Overall Summary of Ocular Adverse Events**	**Safety Analysis Set**
14.3.1.1.2	**Overall Summary of Adverse Events**	**Safety Analysis Set**
14.3.1.2.1	Ocular Adverse Events	Safety Analysis Set
14.3.1.2.2	Adverse Events	Safety Analysis Set
14.3.1.3	Serious Adverse Events	Safety Analysis Set
14.3.1.4.1	Ocular Adverse Events by Severity	Safety Analysis Set
14.3.1.4.2	Adverse Events by Severity	Safety Analysis Set
14.3.1.5.1	Ocular Adverse Events by Relationship to Study Device	Safety Analysis Set
14.3.1.5.2	Adverse Events by Relationship to Study Device	Safety Analysis Set
14.3.2.1	Symptoms/Complaints - Eye Level	Safety Analysis Set
14.3.2.2	Symptoms/Complaints – Subject Level	Safety Analysis Set
14.3.2.3	Categorical Symptoms/Complaints – Eye Level	Safety Analysis Set
14.3.2.4	Categorical Symptoms/Complaints – Subject Level	Safety Analysis Set
14.3.3.1	Slit Lamp Findings – Eye Level	Safety Analysis Set
14.3.3.2	Slit Lamp Findings – Subject Level	Safety Analysis Set
14.3.4.1	Binocular High Contrast logMAR BSCVA	Safety Analysis Set
14.3.4.2	Binocular High Contrast Distance VA Line Change: Screening/Dispensing Visit BSCVA versus Study Lens VA	Safety Analysis Set
14.3.4.3	Detail of Eyes that Decreased Ten or More Letters Binocular High Contrast Distance: Screening/Dispensing Visit BSCVA versus Follow-Up Lens VA	Safety Analysis Set
14.3.4.4	Binocular High Contrast Distance Snellen Lens VA: Eyes 20/40 or Worse	Safety Analysis Set
14.3.5.1	Monocular High Contrast Distance logMAR BSCVA – Eye Level	Safety Analysis Set
14.3.5.2	Monocular High Contrast Distance VA Line Change: Screening/Dispensing Visit BSCVA versus Exit Visit BSCVA – Eye Level	Safety Analysis Set

14.3.5.3	Detail of Eyes that Decreased Ten or More Letters Monocular High Contrast Distance: Screening/Dispensing BSCVA Visit versus Exit BSCVA	Safety Analysis Set
14.3.6	Spherocylindrical Refraction	Safety Analysis Set
14.3.7.1	Keratometry by Meridian	Safety Analysis Set
14.3.7.2	Detail of Keratometry Changes from Baseline to Exit Visit for Eyes that Changed One or More Diopters	Safety Analysis Set

7.2 Planned Listings

Note this table of contents may be updated after the SAP is finalized, to clarify listing titles, listing numbering, or reformatting of listings.

Table 4. Planned Listings

Listing Number	Title
16.2.1	Subject Disposition (Status of Subject)
16.2.2	Protocol Deviations
16.2.3	Analysis Sets
16.2.4.1	Subject Eligibility
16.2.4.2	Demographics
16.2.4.3.1	Baseline Questionnaire – Part 1
16.2.4.3.2	Baseline Questionnaire – Part 2
16.2.4.4.1	Baseline Lens/Lens Care History
16.2.4.4.2	Ocular Medical History
16.2.4.5	Prior/Concomitant Medications
16.2.4.6.1	Pre-Existing Corneal Scars
16.2.4.6.2	Follow-up on Corneal Scars
16.2.4.7.1	Dispensed Lens Characteristics
16.2.4.7.2	Worn Lens Characteristics
16.2.4.8	Visit Accountability
16.2.4.9	Unscheduled Visits
16.2.5.1	Study Lenses Dispensation/Evaluation
16.2.5.2	Product Dispensing at Unscheduled Visits
16.2.5.3	Lens Wear Parameters
16.2.6.1	Worn Lens Evaluation
16.2.6.2	Online Consumer Survey
16.2.6.3	Investigator Questionnaire
16.2.6.4.1	Exit Exam – Part 1
16.2.6.4.2	Exit Exam – Part 2
16.2.7.1.1	Adverse Events – Part 1
16.2.7.1.2	Adverse Events – Part 2
16.2.7.2.1	Serious Adverse Events – Part 1

16.2.7.2.2	Serious Adverse Events – Part 2
16.2.8	Pregnancy Status for Female Subjects
16.2.9.1.1	Baseline Readings with Habitual Lenses (Screening/Dispensing Visit)
16.2.9.1.2	Baseline Readings without Lenses (Screening/Dispensing Visit)
16.2.9.2	Symptoms/Complaints
16.2.9.3	Lens Performance Assessment
16.2.9.4.1	Slit Lamp Exam – Part 1
16.2.9.4.2	Slit Lamp Exam – Part 2
16.2.9.4.3	Slit Lamp Exam – Part 3
16.2.9.5	Corneal Infiltrates Evaluation
16.2.9.6	Cultures

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Validation Report

1

Subject CN	TAIGLE LLC
Subject DN	EMAILADDRESS=operations@msbdocs.com,CN=TAIGLE LLC,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email	operations@msbdocs.com
Serial #	132378441527873428230597372186267991 46
Issuer DN	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
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15 Feb 2023 15:25:45 (-05:00)	Xiangya Meng UUID : 5e979314-68da-4fc1-bcb2-5fbb58d9760e Email : xiangya.meng@ecrscorp.com		RequestSent	Sign request sent to ePak recipient.
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15 Feb 2023 15:25:45 (-05:00)	Gary Mosehauer UUID : 62625250-9369-4ba9-9669-04c5924e4d82 Email : gary.mosehauer@bausch.com		RequestSent	Sign request sent to ePak recipient.
15 Feb 2023 15:25:46 (-05:00)	Bill Reindel UUID : 5756415f-964d-4d21-8232-b442265bf479 Email : bill.reindel@bausch.com		RequestSent	Sign request sent to ePak recipient.
15 Feb 2023 15:25:53 (-05:00)	Kirk Bateman UUID : 8ce0ee14-a7d2-4faa-9fc2-80dd3ffd4527 Email : kirk.bateman@ecrscorp.com IP Address : 174.26.229.100 OS: Windows, Browser: Chrome, Device: Desktop	Name : BL916 Statistical Analysis Plan Version 1.0.pdf UUID : 3964db6d-4b68-49c3-83a4-b65a8f3f42a7 Document Source : MSB	DocumentViewed	Document viewed by signer.
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16 Feb 2023 13:04:10 (-05:00)	Bill Reindel UUID : 5756415f-964d-4d21-8232-b442265bf479 Email : bill.reindel@bausch.com IP Address : 161.242.10.254 OS: Windows, Browser: Edge, Device: Desktop	Name : BL916 Statistical Analysis Plan Version 1.0.pdf UUID : 3964db6d-4b68-49c3-83a4-b65a8f3f42a7 Document Source : MSB	DocumentViewed	Document viewed by signer.
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