Johnson & Johnson Vision Care
7500 Centurion Parkway
Jacksonville, FL 32256

Clinical Study Protocol

Evaluation of Astigmatic Contact Lenses

Protocol Number: CR-5871

Version: 4.0

Date: 14 March 2017

Distribution:

C. Davis
J. Tokarski

Key Words:

Monthly Replacement
Subjective Responses
Physiological
Response Dispensing
Astigmatism

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1.1 PROTOCOL TITLE, NUMBER, DATE

TITLE: Evaluation of Astigmatic Contact Lenses

PROTOCOL NUMBER: CR-5871

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1.2 NAME AND ADDRESS OF SPONSOR

Johnson & Johnson Vision Care

7500 Centurion Parkway, Jacksonville, FL 32256

1.3 AUTHORIZED SIGNATURES

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations, ICH guidelines, and the Declaration of Helsinki.

Author:	**See Electronic Signature Report** Name: Kristy Canavan, O.D. FAAO Title: Principal Research Optometrist	DATE
Biostatistician:	**See Electronic Signature Report** Name: Borm Kim Little, M.S. Title: Biostatistician II	DATE
Clinical Data Manager:	**See Electronic Signature Report** Name: Randall Paulk Title: Clinical Project Mgr.-Data & Systems	DATE
Reviewed:	**See Electronic Signature Report** Name: Noel Brennan Title: Research Fellow/ Platform Lead Myopia	DATE
Clinical Operations:	**See Electronic Signature Report** Name: Margaret Balsamo, C.C.R.A. Title: Clinical Operations Manager	DATE
Approver:	**See Electronic Signature Report** Name: Giovanna Olivares, O.D., F.A.A.O. Title: Global Platform Director, R&D Astigmatism	DATE

1.4 MEDICAL MONITOR

Primary Medical Monitor

NAME: Kristy Canavan, O.D.

TITLE: Principal Research Optometrist

ADDRESS: 7500 Centurion Parkway, Suite 100, Jacksonville, FL 32256

24 HOUR CONTACT TELEPHONE #: [redacted]

The Medical Monitor should be notified by the clinical site in writing and by telephone within 24 hours of learning of a Serious Adverse Event. The Medical Monitor may be contacted during business hours for adverse event questions. General study related questions should be directed towards your assigned clinical research associate.

The Medical Monitor should be notified by the clinical site in writing and by telephone within 24 hours of learning of a Serious Adverse Event (SAE).

Detailed Instructions for Review of Adverse Events

Notes:

1. Refer to Sections 8.1 through 8.5 of the study protocol for safety parameters and adverse event definitions.
2. The CTMS adverse event reports are entitled Serious Adverse Events, but the reports include all Adverse Events.

AE Forms (initial report and follow-up)		Look for or consider
Review THIS section…	**…And cross-check with THESE**	
AE Description and AE Diagnosis	• Onset • Severity • Outcome • AE Category • Copies of relevant information provided by site (e.g., hospital reports, labs, etc.)	• Medically consistent/logical?
Relationship to Test Article (AE Categories: not related, doubtful, possible, probable and very likely)	• Onset • Study Agent(s) and Dosing	• Medically logical/possible?
Outcome (resolved, ongoing, not resolved, resolved sequelae, fatal, resolving & unknown)	• AE Description • AE Category • Study Agent(s) and Dosing • Copies of relevant information provided by site (e.g., hospital reports, labs, etc.)	• Medically consistent/logical?
AE Category	• AE Description • AE Diagnosis • Outcome • Copies of relevant information provided by site (e.g., hospital reports, labs, etc.)	• Medically consistent/logical?

1.5 INVESTIGATOR(S) SIGNATURE PAGE

The Principal Investigator is responsible for ensuring that all study site personnel, including sub-investigators and other staff members, adhere to all ICH regulations and GCP guidelines regarding clinical trials during and after study completion.

I have read and understand the protocol specified above and agree on its content. I agree to conduct this study according to this protocol and GCP and ICH guidelines, the Declaration of Helsinki, and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. I shall not disclose the information contained in this protocol or any results obtained from this study without written authorization.

Principal Investigator: _____ _____

Signature Date

_____

Name (Printed)

Institution Name _____

1.6 ESTIMATED REPORT DATE

Approximately 60 days post data hard lock.

1.7 CHANGE HISTORY

Document Change History			
Version	**Originator**	**Description of Change(s)**	**Date**
1.0	Kristy Canavan	New Protocol	08 December 2016
2.0	Kristy Canavan	PRO version 3.0 (Section 16.1)	09 January 2017
3.0	Kristy Canavan	Protocol date updated	18 January 2017
4.0	Kristy Canavan	1. Section 3.1: Old Text "when worn for 30 (-2/±6) days on daily wear modality" replaced by "when worn for approximately 30 days". 2. Section 4.7.1, Treatment 1, Assignment 1 updated from "rules" to "guide" and the instruction to "choose the least minus sphere" was removed. 3. [redacted] added to the appendix.	14 March 2017

1.8 PROTOCOL SYNOPSIS

Protocol Number and Title: CR-5871 Evaluation of Astigmatic Contact Lenses

Sponsor: JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256

Investigational Product: senofilcon C toric contact lenses and Air Optix for Astigmatism

Regimen and Dosing: Subjects will be assigned to wear one of two study lenses bilaterally for approximately 30 days in a daily wear, monthly replacement modality.

Phase or Type of Study: Design validation study

Study Objectives: To demonstrate that the senofilcon C toric in its final lens design meets the design validation requirements related to corneal staining, lens fitting characteristics, visual acuity and rotational performance of senofilcon C toric contact lenses as well as subjective comfort and handling.

Other Endpoints/Observations:

- Subjective CLUE vision
- GSI Questionnaire
- Lens deposits

Study Design: This is a randomized, double-masked, bilateral dispensing parallel group design study. Subjects will be assigned to wear one of two study lenses bilaterally for approximately 30 days in a daily wear, monthly replacement modality.

Sample Size: Approximately 270 eligible subjects will be enrolled and a minimum of 230 are targeted to complete the study (115 subjects per arm). A replacement subject may be enrolled if a subject discontinues from the study prematurely. The decision to enroll replacement subjects will be made by the joint agreement of the Investigator and Sponsor.

Eligibility Criteria:

Subjects must meet all study Inclusion Criteria as outlined below:

1) Healthy adult males or females age ≥18-40 years of age with signed informed consent.
2) The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
3) Subject must be a habitual soft toric contact lens wearer. Habitual wearer is defined as someone who wears contact lenses for at least 6 hours a day, 5 days a week for the past 30 days.
4) Subject's vertex corrected spherical component of their distance refraction must be between -1.00 to -4.75D (inclusive) in each eye.
5) Subject's vertex corrected refractive cylinder must be between -0.75 and -1.50DC (inclusive) in each eye.
6) Subject's refractive cylinder axis must be 180±25 and 90±15 in each eye.
7) The subject must have visual acuity best correctable to 20/25 or better for each eye
8) The subject must read and sign the Informed Consent form.

Subjects meeting any of the following Exclusion Criteria will not be eligible to participate in the study:

1) Women who are pregnant or breastfeeding
2) Any ocular or systemic allergies or diseases that may contraindicate contact lens wear.
3) Any ocular medications use within the last one month.
4) Any systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear.
5) Any infectious disease (e.g., hepatitis, tuberculosis) or a contagious immunosuppressive disease (e.g., HIV), by self-report.
6) Habitual wearer of extended wear contact lenses.
7) Known sensitivity to Revitalens OcuTec®
8) Any previous history of ocular and/or refractive surgery (e.g., radial keratotomy, PRK, LASIK, etc.).
9) A clinical finding or history of entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or moderate or above corneal distortion, by self-report.
10) History of binocular vision abnormality or strabismus, by self-report.
11) Habitual wearer of rigid gas permeable (RGP) lenses, orthokeratology lenses, or hybrid lenses (e.g. SynergEyes, SoftPerm) within the past 6 months.
12) Employee of investigational clinic (e.g., Investigator, Coordinator, Technician).
13) Participation in any contact lens or lens care product clinical trial within 14 days prior to study enrollment.
14) Clinically significant (grade 3 or higher) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities, bulbar injection or any other abnormalities which would contraindicate contact lens wear.
15) Any history of a contact lens-related corneal inflammatory event within the past year that may contraindicate contact lens wear.
16) Any active ocular infection.
17) Any corneal distortion resulting from previous hard or rigid gas permeable contact lens wear.
18) Any fluctuations in vision due to clinically significant dry eye or other ocular conditions.

Disallowed Medications: Use of any prescription or over-the-counter (OTC) medications that may affect contact lens wear from 24 hours prior to receiving the study product throughout study participation.

2.1 NAME AND DESCRIPTION OF INVESTIGATIONAL PRODUCTS

The following contact lenses will be used in this study:

	LENSES	
Test Article Form	Test	Control
Design / Description	senofilcon C toric	Air Optix for Astigmatism
Lot Number or Other Identifier e.g., Compass Protocol Number or Lens ID Code	[redacted]	[redacted]
Manufacturer	JJVC	Alcon
Packaging Form	Blister	Blister
Nominal Distance Powers (D)	-1.00 to -4.50 in 0.25 steps	-1.00 to -4.50 in 0.25 steps
Nominal Cylinder Powers (D)	-0.75, -1.25	-0.75, -1.25
Nominal Base Curve @ 22 oC	8.5/14.5	8.7/14.5
Material	senofilcon C	lotrafilcon B
Cylinder Axis (°)	80, 90, 100, 10, 20, 160, 170, 180	80, 90, 100, 10, 20, 160, 170, 180
Overall Diameter (mm)	14.5	14.5

The following solutions will be used in this study:

	SOLUTIONS
Solution Name / Description	Revitalens OcuTec®Multi-Purpose Disinfecting Solution
Manufacturer	Abbott Medical Optics

2.2 SUMMARY OF FINDINGS FROM NONCLINICAL STUDIES

[redacted]

2.3 SUMMARY OF KNOWN RISKS AND BENEFITS TO HUMAN SUBJECTS

See [redacted]

2.4 DESCRIPTION OF TRIAL TREATMENTS

The test lens is senofilcon C formulated using the same monomeric components for currently marketed senofilcon A, in different ratios. The control lens is Alcon Air Optix® for Astigmatism which is currently marketed as a monthly replacement. The study lenses will be worn in a bilateral and random fashion using a parallel group design. Using a computer-generated randomization scheme, each subject will randomly be assigned to one of two lenses in a 1:1 ratio. The test and control lenses will be worn as daily wear for approximately thirty days.

2.5 STATEMENT OF COMPLIANCE TO PROTOCOL, GCP, AND APPLICABLE REGULATORY GUIDELINES

This trial will be conducted in compliance with the protocol, the International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP), the Declaration of Helsinki, and all applicable regulatory requirements.

2.6 DESCRIPTION OF POPULATION TO BE STUDIED, ENROLLMENT TARGETS, AND STUDY DURATION

Approximately 270 eligible subjects will be enrolled and a minimum of 230 are targeted to complete the study (115 subjects per arm). Subjects will be ≥18 and ≤40 years of age. Enrolled subjects must be habitual wearers of soft toric contact lenses in both eyes.

Approximately 50% of study subjects will be habitual monthly replacement modality toric wearers including Air Optix for Astigmatism and Biofinity Toric. Habitual is defined as at least one month of lens wear where the lenses are worn a minimum of six hours per day and a minimum of five days per week. Subject participation is expected to be approximately 30 days.

2.7 RELEVANT LITERATURE REFERENCES AND PRIOR DATA

See [redacted]

3.1 DESCRIPTION OF OBJECTIVES AND PURPOSE

The objectives of this study are to evaluate corneal staining, lens fitting characteristics, visual acuity, rotational performance, and the subjective comfort of senofilcon C toric contact lens compared to Air Optix for Astigmatism when worn for approximately 30 days.

The following will be monitored and evaluated:

1. Adverse events
2. Lens fit characteristics
3. Vision characteristics
4. Physiological characteristics
5. Ocular symptoms
6. Lens deposits
7. Average wear time
8. Reasons for discontinuation
9. Lens damage

4.1 PRIMARY AND SECONDARY ENDPOINTS

The primary endpoints for this study are:

- Monocular distance visual acuity 20/40 or better,
- Contact lens related corneal staining,
- Lens fitting acceptability,
- Absolute rotation
- Stability with blink.

Monocular visual acuity (VA) will be assessed with the study lenses using a Snellen distance VA chart at an optical distance of 20 feet throughout the study. Observed monocular VA collected during planned visits will be dichotomized whether VA was '20/40 or better' or 'worse'. VA of 20/40 with a negative modifier will be considered to be worse than 20/40. Additionally, observed monocular VA will be dichotomized whether VA was '20/20 or better' or 'worse' at fitting using the same logic as the previous VA category.

Contact lens related corneal staining will be assessed via slit lamp throughout the study. Corneal staining will be graded using a 5-level scale; 0=no staining, 1=trace, 2=mild, 3=moderate and 4=severe. Observed corneal staining collected during planned and unscheduled visits will be dichotomized whether the corneal staining is 'grade 2 or lower' or 'Grade 3 or higher'.

Lens fit characteristics will be assessed via slit lamp in terms of lens position, movement and tightness. Each lens fit collected at fitting will be judged as being either 'acceptable' or 'unacceptable' based on the static and dynamic fit characteristic.

Lens rotation will be assessed via slit lamp with beam that can be rotated. The rotational error (assume shortest distance) and direction (base towards the nose or based towards temple]) will be calculated. Absolute rotation will be dichotomized whether rotation was '> 10-degree' or 'worse' upon 15 minute post insertion at fitting.

Rotational stability with blink will be assessed via slit lamp with beam that can be rotated. The stability of the scribe mark rotational position during a series of normal (unforced) blinks will be observed. Observed rotational stability with blink will be dichotomized whether stability was '> 5-degree' or 'worse' at fitting.

The secondary endpoints are:

- Monocular distance visual acuity 20/20 or better,
- Subjective CLUE comfort score, and
- Subjective CLUE handling score

Subjective CLUE comfort and handling score will be assessed using the Contact Lens User ExperienceTM (CLUE) questionnaire. CLUE is a validated patient-reported outcomes (PRO) questionnaire to assess patient-experience attributes of soft contact lenses (comfort, vision, handling, and packaging) in a contact-lens wearing population in the US, ages 18-65. Derived CLUE scores using Item Response Theory (IRT) follow a normal distribution with a population average score of 60 (SD 20), where higher scores indicate a more favorable/positive response. A 5 point increase in an average CLUE score translates into 10% shift in the distribution of scores for population of soft disposable contact lens wearers.

The following primary and secondary hypotheses will be tested throughout the study using a gate keeping strategy. The secondary hypotheses will be tested only if all primary hypotheses are met. Otherwise, no secondary hypotheses testing will be performed.

Primary Study Hypotheses	
1	At least 80% of eyes in the Test group will have monocular visual acuity of 20/40 or better throughout the wear period.
2	The incidence rate of observing contact lens related corneal staining grade 3 or higher for the Test lens will be no different or better than that of the Control lens throughout the wear period.
3	At least 80% of lens fits in the Test group will have acceptable fit at fitting.
4	At least 80% of lens fits in the Test group will have absolute rotation ≤ 10 degrees upon 15 minutes post insertion at fitting..
5	At least 80% of lens fits in the Test group will have rotational stability with blink ≤ 5 degrees at fitting.
Secondary Study Hypotheses	
1	The proportion of eyes with visual acuity 20/20 or better in the Test group will be non-inferior to that of the Control group at fitting (a non-inferiority margin of 10% will be used).
2	The overall CLUE comfort score assessed throughout the study for the Test lens will be non-inferior to that of the Control lens. A non-inferiority margin of -5 will be used.
3	The overall CLUE handling score assessed throughout the study for the Test lens will be superior to 50 CLUE handling score.

4.2 INCLUSION CRITERIA

Subjects must meet all study Inclusion Criteria as outlined below:

1) Healthy adult males or females age ≥18-40 years of age with signed informed consent.
2) The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
3) Subject must be a habitual soft toric contact lens wearer. Habitual wearer is defined as someone who wears contact lenses for at least 6 hours a day, 5 days a week for the past 30 days.
4) Subject's vertex corrected spherical component of their distance refraction must be between -1.00 to -4.75D (inclusive) in each eye.
5) Subject's vertex corrected refractive cylinder must be between -0.75 and -1.50DC (inclusive) in each eye.
6) Subject's refractive cylinder axis must be 180±25 and 90±15 in each eye.
7) The subject must have visual acuity best correctable to 20/25 or better for each eye
8) The subject must read and sign the Informed Consent form.

Subjects meeting any of the following Exclusion Criteria will not be eligible to participate in the study:

1) Women who are pregnant or breastfeeding,
2) Any ocular or systemic allergies or diseases that may contraindicate contact lens wear.
3) Any ocular medications use within the last one month.
4) Any systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear.
5) Any infectious disease (e.g., hepatitis, tuberculosis) or a contagious immunosuppressive disease (e.g., HIV), by self-report.
6) Habitual wearer of extended wear contact lenses.
7) Known sensitivity to Revitalens OcuTec®
8) Any previous history of ocular and/or refractive surgery (e.g., radial keratotomy, PRK, LASIK, etc.).
9) A clinical finding or history of entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or moderate or above corneal distortion, by self-report.
10) History of binocular vision abnormality or strabismus, by self-report.
11) Habitual wearer of rigid gas permeable (RGP) lenses, orthokeratology lenses, or hybrid lenses (e.g. SynergEyes, SoftPerm) within the past 6 months.
12) Employee of investigational clinic (e.g., Investigator, Coordinator, Technician).
13) Participation in any contact lens or lens care product clinical trial within 14 days prior to study enrollment.

14) Clinically significant (grade 3 or higher) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities, bulbar injection or any other abnormalities which would contraindicate contact lens wear.
15) Any history of a contact lens-related corneal inflammatory event within the past year that may contraindicate contact lens wear.
16) Any active ocular infection.
17) Any corneal distortion resulting from previous hard or rigid gas permeable contact lens wear.
18) Any fluctuations in vision due to clinically significant dry eye or other ocular conditions.

4.4 STUDY DESIGN, TIME AND EVENT SCHEDULE, FLOWCHART

The study is a multi-site, 5-visit dispensing, bilateral two arm parallel group design, double-masked clinical trial. Approximately 270 eligible subjects will be enrolled and a minimum of 230 are targeted to complete the study.

Description of study timing:

Visit	Description	≈ Duration
1	Enrollment visit: Informed consent, eligibility criteria, baseline data, trial fitting, dispensing, and visual performance.	2.5 hours
2	6-9 days from Visit 1: Follow-up visit for the study lens: Subjective responses, VA, fitting characteristics, surface characteristics, physiology.	1.0 hour
3	6-9 days from Visit 2: Follow-up visit for the study lens: Subjective responses, VA, visual performance, fitting characteristics, surface characteristics, physiology.	1.5 hours
4	6-9 days from Visit 3: Follow-up visit for the study lens: Subjective responses, VA, fitting characteristics, surface characteristics, physiology.	1.0 hour
5	6-9 days from Visit 4: Follow-up visit for the study lens: Subjective responses, VA, visual performance fitting characteristics, surface characteristics, physiology.	1.5 hours

4.4.1 TIME AND EVENT SCHEDULE

Event	Visit 1 Day 0 (Consent, Baseline, Study Lens Dispense)	Visit 2 6-9 days after Visit 1 (Study Lens Follow-Up)	Visit 3 6-9 days after Visit 2 (Study Lens Follow-Up)	Visit 4 6-9 days after Visit 3 (Study Lens Follow-Up)	Visit 5 6-9 days after Visit 4 (Study Lens Follow-Up; Final Evaluation)
Study Informed Consent	X				
Demographics	X				
Medical History	X	X	X	X	X
Contact Lens History	X				
Inclusion/Exclusion Criteria	X				
PRO Questionnaire	X	X	X	X	X
Ocular Symptoms	X	X	X	X	X
Subjective Refraction	X				
Slit Lamp Findings	X	X	X	X	X
Lens (test article) Fitting	X				
Spherical Over-Refraction	X				X
Snellen Visual Acuity	X	X	X	X	X
Visual Performance (ETDRS)	X		X		X
Lens Fit Assessment	X	X	X	X	X
Lens Surface Evaluation	X	X	X	X	X
Lens Wettability	X	X	X	X	X
Lens Removal		X	X	X	X
Lens Insertion	X	X	X	X	
Dispense Lens	X				
Compliance / Wear Time		X	X	X	X
Final Evaluation Form					X
Adverse Event Review	X	X	X	X	X
Concomitant Medication Review	X	X	X	X	X
Study Completion					X

4.5 RANDOMIZATION AND MASKING

This study is a randomized, double-masked parallel group design. Each subject will be randomized to wear one of two study lenses during the study in a ratio of 1:1 following the randomization scheme provided by the JJVC biostatistician. The randomization assignment will be performed at the first visit prior to the first fitting.

The following must have occurred prior to assignment:

- Informed consent has been obtained
- Subject meets all the inclusion / exclusion criteria
- Subject history and baseline information has been collected

This will be a double masked study. The identity of the study lenses will be masked to not only the subject but also investigators involved in the data collection.

There is an inherent potential risk for unmasking. However, masking will be maintained as much as is logistically feasible. Under normal circumstances, the mask should not be broken until all subjects have completed the study and the database is finalized. Otherwise, the mask should be broken only if specific emergency treatment/course of action would be dictated by knowing the treatment status of the subject. In such cases, the investigator may, in an emergency, contact the medical monitor. In the event the mask is broken, the sponsor must be informed as soon as possible. The date, time, and reason for the unmasking must be documented in the subject record.

Subjects who have had their treatment assignment unmasked are expected to return for all remaining scheduled evaluations. A replacement subject may be enrolled if a subject discontinues from the study prematurely. The decision to enroll replacement subjects will be made by the joint agreement of the Investigator and Sponsor.

4.6 WEAR AND REPLACEMENT SCHEDULES, INCLUDING FORM, PACKAGING AND LABELING

Wear Schedule: Daily Wear, Monthly replacement

Test Article Packaging Description: Blister packaging in sterile packing solution

Labeling: Investigational

4.7 DETAILED STUDY PROCEDURES

4.7.1 SEQUENCE OF EVENTS

Visit 1: Enrollment Visit, Baseline Evaluation and Dispensing Trial 1
Subjects should present to Visit 1 wearing their habitual contact lenses

SCREENING INFORMATION			
Step	**Descriptor**	**Details**	**or Appendix**
1.	Statement of Informed Consent	Each subject must read, understand and sign the Statement of Informed Consent before being enrolled in the study. The Principal Investigator or designee conducting the informed consent discussion must also sign the consent form. *Note: The subject must be provided with a signed copy of this document.*	
2.	Demographics	Age, gender, race and ethnicity	
3.	Case History	Record the subject's medical and ocular history and concomitant medications.	
4.	Activity History	Record the subject's responses to questions regarding his/her daily activities, device usage and lifestyle.	
5.	Habitual Contact Lens Type	Record the following information with regard to the subject's habitual contact lenses: • Lens type • Base curve, diameter, and power • Lens care regimen • Modality • Approximate prescription date	
6.	Wear Time	Record the subject's average wear time (WT) and comfortable wear time (CWT).	
7.	Eligibility at Screening	All responses to Inclusion Criteria questions must be answered "yes," and all responses to Exclusion Criteria questions must be answered "no" for the subject to be considered eligible.	

BASELINE INFORMATION			
Step	**Descriptor**	**Details**	**or Appendix**
1.	Baseline CLUE	Subject will complete the baseline CLUE questionnaire regarding their own contact lens experience.	
2.	GSI Background Questionnaire	Subject will complete GSI questions regarding their experiences with their habitual lenses.	
3.	Distance visual acuity	Record the distance Snellen visual acuity for OD, OS, OU. Subject must keep reading smaller lines until less than half of the letters are correctly identified.	[redacted]
4.	Subject-Reported Ocular Symptoms	Record Subject Reported Ocular Symptoms or Problems	[redacted]
5.	Subjective spherocylinder refraction	Perform binocular subjective best spherocylinder refraction and record the best corrected visual acuity for OD, OS, OU. Subject must keep reading smaller lines until less than half the letters are correctly identified.	[redacted]
6.	Biomicroscopy	Slit Lamp Classification Scale (2018) will be used to grade the findings. The following [redacted] will be used to assess specific ocular physiology in greater detail: (0.50 steps) [redacted]: Limbal and conjunctival redness : Corneal staining : Conjunctival staining	[redacted]
7	Eligibility after Baseline Examination	All responses to Inclusion Criteria questions must be answered "yes," and all responses to Exclusion Criteria questions must be answered "no" for the subject to be considered eligible.	

VISIT 1: TREATMENT 1 - ASSIGNMENT 1			
Step	**Descriptor**	**Details**	**or Appendix**
1.	Lens Information	Select lens type based on Randomization scheme Select the lens powers based on the following guide: • The cylinder & axis are as close as possible to the vertex corrected refraction • Do not over-correct cylinder power • **The best spherical equivalent of the toric contact lens** should be as close as possible to the spherical equivalent (SE) of the subject's vertexed refraction *For example :* *Subject's refraction: -2.00-1.00 x180 (SE -2.50DS)* *Lens choice A: -2.00-0.75 x 180 (SE -2.37)* *Lens choice B: -2.25-0.75x180 (SE -2.62)* *Lens choice A should be chosen in this example*	

Step	Descriptor	VISIT 1: TREATMENT 1 - FITTING 1 Details	or Appendix
1.	Right Lens Insertion	The investigator or subject will place the lens on eye. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. If lens damage is present, complete the Product Quality Complaint Form and return the lens to the Sponsor. The lens will be stored in labeled vial with unpreserved saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.	
2.	Timed settling for right lens	The investigator will start a stopwatch or timer as soon as the right lens is inserted. **Note: Study lenses have scribe marks at either 6 o'clock and 12 o'clock positions or 3, 6, 9 o'clock positions. Rotation measurements are made relative to a vertical reference line. Record base nasal or base temporal to the nearest degree.** At one (1) minute after insertion: Record the rotational position to the nearest degree At three (3) minutes after insertion: Record the rotational position to the nearest degree	
3.	Left lens insertion	The investigator or subject will insert the left lens. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. If lens damage is present, complete the Product Quality Complaint Form and return the lens to the Sponsor. The lens will be stored in labeled vial with unpreserved saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor	
4.	Timed settling for left lens	The investigator will note the time on the stopwatch or timer as soon as the left lens is inserted. At one (1) minute after insertion: Record the rotational position to the nearest degree. At three (3) minutes after insertion: Record the rotational position to the nearest degree.	
5.	Lens settling	Allow a minimum of 10 minutes of lens settling time.	

6.	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable Toric lens fit will be unacceptable if lenses rotated more than 20 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, proceed to final evaluation.	[redacted]
7.	Subjective spherical over refraction	Perform subjective spherical refraction over the study contact lens and record the result in visual acuity for OD, OS. Plano or +0.25D must be achieved to continue.	
8.	Lens modification (if needed)	Select the reason(s) for lens change (select all that apply): • The settled lens rotation is such that one of the other available lens cylinder axis would be better (use LARS rule to determine the replacement lens cylinder axis) • The over-refraction is not plano or +0.25 in both eyes • Other (specify reason) If one or both lenses are modified, repeat steps 1 through 7 for one or both eyes as appropriate. * If plano over-refraction cannot be achieved, the final sphere should be the most plus/least minus possible for best vision. A maximum of two lens modifications is allowed. If these conditions are not met, proceed to final evaluation.	
9.	ETDRS Visual performance	Under high illumination and high chart luminance, record the distance high contrast visual acuity for OD, OS, OU using ETDRS charts at 4 meters.	[redacted]
10.	CLUE Post-Fit Questionnaire	Subject will complete the CLUE Questionnaire regarding vision and comfort.	
11.	GSI Questionnaire	Subject will complete GSI questions regarding their experiences with the study lenses.	
12.	Subject-Reported Ocular Symptoms	Record Subject Reported Ocular Symptoms or Problems	[redacted]

13.	Lens Fit Assessment	The general lens fit characteristics will be recorded for both study lenses. These include lens position (centration, limbal exposure, edge lift), and movement (primary and up gaze as well as push-up). Fit acceptability is defined as: • No limbal exposure (presence of clear cornea) in primary gaze or with extreme eye movements. • No edge Lift • No insufficient/excessive, unacceptable movement in all three movement assessments (Primary Gaze, Upgaze and Josephson Push-up). If lens movement is insufficient and unacceptable in primary gaze and upgaze but is acceptable with the Josephson Push-up technique, the fit will be deemed acceptable. *Note: If the lens fit is deemed unacceptable, discontinue the subject and proceed to final evaluation.	[redacted]
14.	Lens Deposits	Front and Back Surface Lens Deposits Back Trapped Debris and Mucin Plugs Lens damage	[redacted]
15.	Lens Wettability	Subjective Lens Surface Wettability	[redacted]

The study lenses being worn will be dispensed.

Step	Descriptor	VISIT 1: TREATMENT 1 - DISPENSING 1 Details	[redacted] or Appendix
1.	Distance visual acuity	Record the distance Snellen visual acuity for OD, OS, OU. Subject must keep reading smaller lines until less than half of the letters are correctly identified Subject must be 20/30 or better OD and OS to continue.	[redacted]
2.	Dispensing eligibility	Lenses may be dispensed if these conditions are satisfied: • The quality of vision is acceptable to the subject • The lens fit was found to be acceptable.	
3.	Patient Instruction Guide	Confirm that the subject has received a Patient Instruction Guide. Eye-Cept® rewetting drops may be used as needed by the subjects if lenses become dry during use.	
4.	Lens Care Regimen	Revitalens Ocutec ® will be the multipurpose solution for the study. The multipurpose solution is used to rub, rinse and store the lenses when they are not being worn.	
5.	Follow-up visit scheduling	An appointment for the next visit should be made for approximately 1 week (6 to 9 days) after the dispensing visit. Subjects should be advised to wear the study lenses eight hours each day and to the follow-up visit, after a **minimum of 8 hours wear that day**.	

VISIT 2: Subjects must present to Visit 2 having worn the study lenses for at least 8 hours.

VISIT 2: TREATMENT 1 - FOLLOW-UP 1 (1-WEEK)			
Step	**Descriptor**	**Details**	**or Appendix**
1.	Concomitant Medication and Medical History Review	Record any changes in concomitant medications or health status since the last visit.	
2.	Contact lens wear times	Record the current wear time (WT) and comfortable wear time (CWT).	
3.	Compliance	Record the subject's compliance with wearing the study lenses. Note whether the subject chose to rub the lenses clean after use.	
4.	Subject-reported Ocular Symptoms	Record Subject Reported Ocular Symptoms or Problems	[redacted]
5.	CLUE Questionnaire	Subject will complete the Contact Lens User Experience questionnaire regarding their experiences with the study lenses	
6.	GSI Questionnaire	Subject will complete GSI questions regarding their experiences with the study lenses.	
7.	Distance visual acuity	Record the distance Snellen visual acuity for OD, OS, OU. Subject must keep reading smaller lines until less than half the letters are correctly identified	[redacted]
8.	Toric Fit Evaluation	Record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable Toric lens fit will be unacceptable if lenses rotated more than 20 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, proceed to final evaluation.	[redacted]
9.	Lens Fit Assessment	The general lens fit characteristics will be recorded for both study lenses . These include lens position (centration, limbal exposure, edge lift), and movement (primary and up gaze as well as push-up). Fit acceptability is defined as: • No limbal exposure (presence of clear cornea) in primary gaze or with extreme eye movements. • No edge lift • No insufficient/excessive, unacceptable movement in **all three** movement assessments (Primary Gaze, Upgaze and Josephson Push-up). If lens movement is insufficient and unacceptable in primary gaze and upgaze but is acceptable with the Josephson Push-up technique, the fit will be deemed acceptable. **Note: If the lens fit is deemed unacceptable, discontinue the subject and proceed to final evaluation*	[redacted]

10.	Lens Deposits	Front and Back Surface Lens Deposits Back Trapped Debris and Mucin Plugs Lens damage (draw and describe)	[redacted]
11.	Lens Wettability	Subjective Lens Surface Wettability	[redacted]
12.	Conjunctival Hyperemia	Record Limbal and Bulbar Conjunctival Hyperemia findings	[redacted]
13.	Lens Removal	The subject will remove lenses. Lenses will be saved in lens case with Revitalens OcuTec® *Note: Subject should not rub lenses.*	
14.	Biomicroscopy	Slit Lamp Classification Scale ([redacted] will be used to grade the findings. The following CTP's will be used to assess specific ocular physiology in greater detail: (0.50 steps) • [redacted]: Corneal staining • [redacted]: Conjunctival staining Note: Subject must be free of any FDA grade 3 or greater slit lamp findings with no active ocular infection/inflammation.	[redacted]
15.	Eye Rinse	The investigator or clinical staff will rinse the subject's eyes thoroughly with unpreserved saline.	
16.	Lens Insertion	Subjects will remove the lenses from the lens case and re-insert the lenses.	
17.	Visual Acuity	Record the distance Snellen visual acuity with their **study lenses** correction in place for OD, OS, OU. Subject must keep reading smaller lines until less than half of the letters are correctly identified. Subject must be 20/30 or better OD and OS to continue.	[redacted]
18.	Follow-up visit scheduling	An appointment for the next visit should be made for approximately 1 week (6 to 9 days) after the follow-up visit. Subjects should be advised to wear the study lenses eight hours each day and to the follow-up visit, after a **minimum of 8 hours wear that day.**	

VISIT 3: Subjects must present to Visit 3 having worn the study lenses for at least 8 hours.

VISIT 3: TREATMENT 1- FOLLOW-UP 2 (2-WEEK)			
Step	**Descriptor**	**Details**	**or Appendix**
1.	Concomitant Medication and Medical History Review	Record any changes in concomitant medications or health status since the last visit.	
2.	Contact lens wear times	Record the current wear time (WT) and comfortable wear time (CWT).	
3.	Compliance	Record the subject's compliance with wearing the study lenses. Note whether the subject chose to rub the lenses clean after use..	
4.	Subject-reported Ocular Symptoms	Record Subject Reported Ocular Symptoms or Problems	[redacted]
5.	CLUE Questionnaire	Subject will complete the Contact Lens User Experience questionnaire regarding their experiences with the study lenses.	
6.	GSI Questionnaire	Subject will complete GSI questions regarding their experiences with the study lenses.	
7.	Distance visual acuity	Record the distance Snellen visual acuity for OD, OS, OU. Subject must keep reading smaller lines until less than half the letters are correctly identified	[redacted]
8.	ETDRS Visual performance	Under high illumination and high chart luminance record the distance high contrast visual acuity for OD, OS, OU using ETDRS charts at 4 meters.	[redacted]
9.	Toric Fit Evaluation	Record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable Toric lens fit will be unacceptable if lenses rotated more than 20 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, proceed to final evaluation.	[redacted]

10.	Lens Fit Assessment	The general lens fit characteristics will be recorded for both study lenses. These include lens position (centration, limbal exposure, edge lift), and movement (primary and up gaze as well as push-up). Fit acceptability is defined as: • No limbal exposure (presence of clear cornea) in primary gaze or with extreme eye movements. • No edge lift • No insufficient/excessive, unacceptable movement in **all three** movement assessments (Primary Gaze, Upgaze and Josephson Push-up). If lens movement is insufficient and unacceptable in primary gaze and upgaze but is acceptable with the Josephson Push-up technique, the fit will be deemed acceptable. *Note: If the lens fit is deemed unacceptable, discontinue the subject and proceed to final evaluation.	[redacted]
11.	Lens Deposits	Front and Back Surface Lens Deposits Back Trapped Debris and Mucin Plugs Lens damage (draw and describe)	[redacted]
12.	Lens Wettability	Subjective Lens Surface Wettability	[redacted]
13.	Conjunctival Hyperemia	Record Limbal and Bulbar Conjunctival Hyperemia findings	[redacted]
14.	Lens Removal	The subject will remove lenses. Lenses will be saved in lens case with Revitalens OcuTec® ***Note: Subject should not rub lenses.***	
15.	Biomicroscopy	Slit Lamp Classification Scale ([redacted] will be used to grade the findings. The following [redacted] will be used to assess specific ocular physiology in greater detail: (0.50 steps) • [redacted]: Corneal staining • [redacted]: Conjunctival staining Note: Subject must be free of any FDA grade 3 or greater slit lamp findings with no active ocular infection/inflammation.	[redacted]
16.	Eye Rinse	The investigator or clinical staff will rinse the subject's eyes thoroughly with unpreserved saline.	
17.	Lens Insertion	Subjects will remove the lenses from the lens case and re-insert the lenses.	
18.	Visual Acuity	Record the distance Snellen visual acuity with their **study lenses** correction in place for OD, OS, OU. Subject must keep reading smaller lines until less than half of the letters are correctly identified. Subject must be 20/30 or better OD and OS to continue.	[redacted]
19.	Follow-up visit scheduling	An appointment for the next visit should be made for approximately 1 week (6 to 9 days) after the follow-up visit. Subjects should be advised to wear the study lenses eight hours each day and to the follow-up visit, after a **minimum of 8 hours wear that day.**	

Visit 4: Subjects must present to Visit 4 having worn the study lenses for at least 8 hours.

VISIT 4: TREATMENT 1- FOLLOW-UP 3 (3-WEEK)			
Step	**Descriptor**	**Details**	**or Appendix**
1.	Concomitant Medication and Medical History Review	Record any changes in concomitant medications or health status since the last visit.	
2.	Contact lens wear times	Record the current wear time (WT) and comfortable wear time (CWT).	
3.	Compliance	Record the subject's compliance with wearing the study lenses. Note whether the subject chose to rub the lenses clean after use.	
4.	Subject-reported Ocular Symptoms	Record Subject Reported Ocular Symptoms or Problems	[redacted]
5.	CLUE Questionnaire	Subject will complete the Contact Lens User Experience questionnaire regarding their experiences with the study lenses.	
6.	GSI Questionnaire	Subject will complete GSI questions regarding their experiences with the study lenses.	
7.	Distance visual acuity	Record the distance Snellen visual acuity for OD, OS, OU. Subject must keep reading smaller lines until less than half the letters are correctly identified	[redacted]
8.	Toric Fit Evaluation	Record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable Toric lens fit will be unacceptable if lenses rotated more than 20 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, proceed to final evaluation.	[redacted]
9.	Lens Fit Assessment	The general lens fit characteristics will be recorded for both study lenses. These include lens position (centration, limbal exposure, edge lift), and movement (primary and up gaze as well as push-up). Fit acceptability is defined as: • No limbal exposure (presence of clear cornea) in primary gaze or with extreme eye movements. • No edge lift • No insufficient/excessive, unacceptable movement in **all three** movement assessments (Primary Gaze, Upgaze and Josephson Push-up). If lens movement is insufficient and unacceptable in primary gaze and upgaze but is acceptable with the Josephson Push-up technique, the fit will be deemed acceptable. *Note: If the lens fit is deemed unacceptable, discontinue the subject and proceed to final evaluation.	[redacted]
10.	Lens Deposits	Front and Back Surface Lens Deposits Back Trapped Debris and Mucin Plugs Lens damage (draw and describe)	[redacted] [redacted]

11.	Lens Wettability	Subjective Lens Surface Wettability	[redacted]
12.	Conjunctival Hyperemia	Record Limbal and Bulbar Conjunctival Hyperemia findings	[redacted]
13.	Lens Removal	The subject will remove lenses. Lenses will be saved in lens case with Revitalens OcuTec® ***Note: Subject should not rub lenses.***	
14.	Biomicroscopy	Slit Lamp Classification Scale ([redacted] will be used to grade the findings. The following [redacted] will be used to assess specific ocular physiology in greater detail: (0.50 steps) • [redacted]: Corneal staining • [redacted]: Conjunctival staining Note: Subject must be free of any FDA grade 3 or greater slit lamp findings with no active ocular infection/inflammation.	[redacted]
15.	Eye Rinse	The investigator or clinical staff will rinse the subject's eyes thoroughly with unpreserved saline.	
16.	Lens Insertion	Subjects will remove the lenses from the lens case and re-insert the lenses.	
17.	Visual Acuity	Record the distance Snellen visual acuity with their **study lenses** correction in place for OD, OS, OU. Subject must keep reading smaller lines until less than half of the letters are correctly identified. Subject must be 20/30 or better OD and OS to continue.	[redacted]
18.	Follow-up visit scheduling	An appointment for the next visit should be made for approximately 1 week (6 to 9 days) after the follow-up visit. Subjects should be advised to wear the study lenses eight hours each day and to the follow-up visit, after a **minimum of 8 hours wear that day.**	

Visit 5: Subjects must present to Visit 5 having worn the study lenses for at least 8 hours.

VISIT 5: TREATMENT 1- FOLLOW-UP 4 (4-WEEK)			
Step	**Descriptor**	**Details**	**or Appendix**
1.	Concomitant Medication and Medical History Review	Record any changes in concomitant medications or health status since the last visit.	
2.	Contact lens wear times	Record the current wear time (WT) and comfortable wear time (CWT).	
3.	Compliance	Record the subject's compliance with wearing the study lenses. Note whether the subject chose to rub the lenses clean after use.	
4.	Subject-reported Ocular Symptoms	Record Subject Reported Ocular Symptoms or Problems	[redacted]
5.	CLUE Questionnaire	Subject will complete the Contact Lens User Experience questionnaire regarding their experiences with the study lenses.	
6.	GSI Questionnaire	Subject will complete GSI questions regarding their experiences with the study lenses.	
7.	Distance visual acuity	Record the distance Snellen visual acuity for OD, OS, OU. Subject must keep reading smaller lines until less than half the letters are correctly identified	[redacted]
8.	ETDRS Visual performance	Under high illumination and high chart luminance record the distance high contrast visual acuity for OD, OS, OU using ETDRS charts at 4 meters.	[redacted]
9.	Spherical Over-refraction	Record the spherical over-refraction OD and OS. Record the distance visual acuity with the contact lenses (OD, OS) to the nearest letter.	
10.	Toric Fit Evaluation	Record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable Toric lens fit will be unacceptable if lenses rotated more than 20 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, proceed to final evaluation.	[redacted]

11.	Lens Fit Assessment	The general lens fit characteristics will be recorded for both study lenses. These include lens position (centration, limbal exposure, edge lift), and movement (primary and up gaze as well as push-up). Fit acceptability is defined as: • No limbal exposure (presence of clear cornea) in primary gaze or with extreme eye movements. • No edge lift • No insufficient/excessive, unacceptable movement in **all three** movement assessments (Primary Gaze, Upgaze and Josephson Push-up). If lens movement is insufficient and unacceptable in primary gaze and upgaze but is acceptable with the Josephson Push-up technique, the fit will be deemed acceptable. *Note: If the lens fit is deemed unacceptable, discontinue the subject and proceed to final evaluation..	[redacted]
12.	Lens Deposits	Front and Back Surface Lens Deposits Back Trapped Debris and Mucin Plugs Lens damage (draw and describe)	[redacted]
13.	Lens Wettability	Subjective Lens Surface Wettability	[redacted]
14.	Conjunctival Hyperemia	Record Limbal and Bulbar Conjunctival Hyperemia findings	[redacted]
15.	Lens Removal	All lenses will be retained. Upon removal of the lenses (without gloves), the investigator or clinical staff will store lenses in a clean vial with non- preserved saline with a label detailing the study number, subject number, subject global ID, date, lens type, eye the lens was worn on, and time of lens wear (in days). All lenses will be stored in the refrigerator.	
16,	Biomicroscopy	Slit Lamp Classification Scale ([redacted] will be used to grade the findings. The following [redacted] will be used to assess specific ocular physiology in greater detail: (0.50 steps) • [redacted]: Corneal staining • [redacted]: Conjunctival staining Note: Subject must be free of any FDA grade 3 or greater slit lamp findings with no active ocular infection/inflammation.	[redacted]
17	Eye Rinse	The investigator or clinical staff will rinse the subject's eyes thoroughly with unpreserved saline.	

Final Evaluation: The final evaluation will ordinarily take place after Visit 5 completed. It may also take place at any point the subject discontinues the study or is terminated from the study.

FINAL EVALUATION			
Step	**Descriptor**	**Details**	**or Appendix**
1	Final Exam Form	Indicate if the subject completed the study successfully or not. If subject discontinued, indicate the reason.	
2	Best-corrected Distance Visual Acuity	Record the subject's best corrected distance visual acuity with refraction OD, OS, and OU.	
3	Investigator Signature	Investigator must review and sign the eCRF.	

4.8 DISCONTINUATION CRITERIA

Johnson & Johnson Vision Care, Inc. reserves the right to terminate the study at any time for any reason. Additionally, the IRB/IEC reserves the right to terminate the study if an unreasonable risk is determined. The study may be terminated by the Principal Investigator or Medical Monitor due to specific clinical observations, if in their opinion it would be unwise to continue.

Johnson & Johnson Vision Care, Inc. and Sterling IRB will evaluate all adverse events. If it is determined that an adverse event presents an unreasonable risk, the investigation, or that part of the investigation presenting the risk, will be terminated, as soon as possible.

Should the study be terminated (either prematurely or as scheduled), the Investigator will notify the Institutional Review Board (IRB), and Regulatory Authority as required by local regulatory requirements.

4.9 ACCOUNTABILITY PROCEDURES FOR INVESTIGATIONAL PRODUCT AND CONTROL

Johnson & Johnson Vision Care, Inc. will provide the Investigator with sufficient quantities of study articles and supplies to complete the investigation. The Investigator is asked to retain all lens shipment documentation for the test article accountability records. The Investigator may not provide the subject additional lenses in the event a lens is damaged or lost between visits.

Test articles must be kept in a locked storage cabinet, accessible only to those assigned by the Investigator for dispensing. All investigational products must be accounted. This includes 1) what was dispensed for the subject to wear out of the office 2)worn lenses returned to the Investigator and 3) the number and reason for unplanned replacements . The Investigator may delegate this activity to an authorized study site staff member on the Delegation Log.

The Investigator will collect all unused test articles from the subjects at the end of the subject's participation. Following final reconciliation of test articles, the Investigator will package and return all unused study articles to JJVCI.

Reference [redacted] Site Instructions for Test Article Receipt and Test Article Accountability for additional information.

4.10 PROCEDURES FOR MAINTAINING AND BREAKING RANDOMIZATION CODES

The test article mask shall not be broken unless information concerning the lens type is necessary for the urgent medical treatment of a subject. The Sponsor should be notified before the mask is broken.

When dispensing test articles, the following steps should be followed to maintain randomization codes:

1. Investigator will assign an unmasked designee (documented on the Delegation Log) who will consult the randomization scheme to obtain the study test article assignment for that subject prior to dispensing.
2. Designee will record the subject's number on the appropriate line of the randomization scheme.
3. Designee will pull the appropriate test articles from the study supply. All test articles that were opened, whether dispensed or not, must be recorded on the Test Article Accountability Log in the "Dispensed" section.
4. Designee will remove study lenses and packing solution from manufacturer's blister pack and transfer to a lens case (paying particular attention to the study lens to be dispensed OD and OS) prior to entering study examination room for subject fitting.

4.11 REPORTING PRODUCT QUALITY COMPLAINTS

A Product Quality Complaint (PQC) refers to any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of test articles after they have been released for clinical trial use. A PQC) is associated with any investigational product (i.e. product manufactured or supplied specifically for a clinical trial).

Complaint Handling

Once site personnel have become aware that a PQC has occurred, it shall then be recorded in the EDC system, which triggers an automatic email notification to the appropriate COM/CRA and Clinical QA representative. In cases where the EDC system in use is not configured to send automatic notifications, then the COM/CRA is responsible for notifying Clinical QA upon discovery that a PQC has occurred.

Upon receipt of the EDC notification the COM/CRA shall complete the applicable sections of the Product Quality Complaint Form ([redacted] or electronic equivalent).

For each complaint, the following minimum information shall be recorded by the CRA/COM on the Product Quality Complaint Form ([redacted]):

- Date the complaint was received/recorded in the EDC System (Date of Sponsor Awareness)
- Who received the complaint
- Study number
- Investigational site information (contact name, site ID, telephone number)
- Lot number(s)
- Unique Subject Identifier(s)
- Indication of who first observed complaint (site personnel or subject)
- OD/OS indication, along with whether or not the lens was inserted
- Any related AE number if applicable
- Detailed complaint description (scheduled/unscheduled visit, wear time, symptoms, resolution of symptoms, etc.)
- Eye Care Provider objective (slit lamp) findings if applicable
- Confirmation of product availability for return (and tracking information, if available), or rationale if product is not available for return (Refer to Form Control No. [redacted] for test article return instructions)

Clinical QA will assign a unique number to the PQC. Complaint numbering is assigned as follows:

RDTC-XX-001, where RDTC = R&D Technical Complaint, XX = last two digits of the current year, 001 = sequential numbering starting with 001.

5.1 WITHDRAWAL CRITERIA

A subject will be withdrawn from the study for any of the following reasons:

- Lost to follow-up
- Withdrawal of consent
- Death
- Discontinuation of study treatment as a result of the investigator's clinical judgment that for safety reasons (e.g., adverse event) it is in the best interest of the subject to stop treatment.
- The subject becomes pregnant.

For discontinued subjects, the Investigator will:

- Update the enrollment log to document reason for discontinuation
- Complete the "last" Follow-up Visit form (scheduled or unscheduled)
- Complete the Final Evaluation form, indicating the reason that the subject was discontinued from the study
- Record the spherocylindrical refraction with best corrected distance visual acuity
- Collect used study lenses and test articles (worn or brought to the visit) from the subject and discard them
- Collect all unused study lenses and test articles from the subject

Subjects becoming pregnant during the study will be discontinued. Once discontinued, pregnant participants and their fetuses will not be monitored for study related purposes. At the Investigators' discretion, the study participant may be followed by the Investigator through delivery. However, this data will not be collected as part of the clinical study database. Pregnant participants are not discontinued from contact lens or solution related studies for safety concerns, but due to general concerns relating to pregnancy and contact lens use. Specifically, pregnant women are discontinued due to fluctuations in refractive error and/or visual acuity that occur secondary to systemic hormonal changes, and not due to unforeseen health risks to the mother or fetus.

In cases where a subject is lost to follow-up, every possible effort must be made to contact the subject and determine the reason for discontinuation / withdrawal. The measures taken to follow up must be documented including two written attempts and a certified letter as the final attempt.

6.1 PRESTUDY AND CONCOMITANT THERAPY

Concomitant medications will be documented during screening and during the study. Use of any prescription or over-the-counter (OTC) medications that may affect contact lens wear from 24 hours prior to receiving the study product throughout study participation.

6.2 MONITORING TREATMENT COMPLIANCE

Johnson & Johnson Vision Care, Inc. representatives or designees will monitor the study in a manner consistent with ICH GCP E6. The study monitors will maintain close contact with the Principal Investigator and the Investigator's designated staff. The monitor's responsibilities will include:

- Ensuring that the investigation is being conducted according to the protocol
- Ensuring the rights and well-being of subjects are protected
- Ensuring that protocol deviations are documented with corrective action plans, as applicable
- Ensuring that the site has sufficient test article and supplies
- Clarifying questions regarding the study
- Resolving study issues or problems that may arise
- Reviewing the study records to ensure completeness and accuracy
- Study and subject source document records reviewed will include:
    - The Information and Consent Form per 21CFR Parts 50 and 56 and the HIPAA documents
    - Source documentation including consenting and HIPAA process, medical history, concomitant medications, and adverse event information as applicable. The source document should be initialed and dated by the study investigator/s.
    - Investigational product shipping, dispensing, accountability, and return/destruction records
    - Study related Regulatory documents as per ICH E3 section 8

Monitoring for this study will be specified in the monitoring plan which will be provided separately.

6.3 UNSCHEDULED VISITS

If, during the investigation, a subject experiences any investigational device-related difficulties and/or problems requiring an unscheduled visit to the clinic, the following information will be collected at a minimum:

- Chief complaint prompting the visit. If the reason is an adverse event, the applicable eCRF for the adverse event should be completed and source documentation completed as appropriate.
- Date and time of the visit and all procedures completed at the unscheduled visit
- Review of adverse event and concomitant medications
- Documentation of any investigational product dispensed or collected from the subject.
- Slit lamp findings (using the Slit Lamp Classification Scale)

If the Investigator withdraws a subject from the study, the final study visit case report forms must be completed indicating the reason(s) why the subject was withdrawn. The subject enrollment log should be completed documenting the date and primary reason for withdrawal and the study CRA notified.

Any investigational device-related difficulties and/or problems that are ongoing at the time of the final study visit will be followed by the Investigator, within licensure, until they have returned to pre-treatment status, stabilized, or been satisfactorily explained. If further treatment (i.e., beyond licensure) is required, the subject will be referred to the appropriate health care provider.

7.1 EFFICACY PARAMETERS

See section 4.1.

7.2 METHODS FOR ASSESSING, RECORDING, AND ANALYZING EFFICACY

See detailed study procedures in section 4.7 and analysis plans in section 9.1.

8.1 SAFETY PARAMETERS

The safety parameters for this study are:

- Adverse events,
- Biomicroscopy,
- Ocular symptoms,
- Average wear time,
- Reasons for discontinuation, and
- Reasons for unscheduled lens replacement.

Safety parameters will be tabulated using frequency distribution tables or/and descriptive statistics. Adverse events will be listed by subject/eye. There will be separate summary tables for adverse events and infiltrative adverse events. Statistical methods for analyzing safety data, if any, are provided in section 9.

8.2 ADVERSE EVENTS

All Outcome – Resolved, ongoing, not resolved, resolved with sequelae, fatal, resolving, and unknown

Actions Taken – None, temporarily discontinued, permanently discontinued, Other action taken adverse events will be recorded in the subject's source document, documented in the CRF (or appropriate), and evaluated by the Investigator. In addition, a written report will be submitted by the Principal Investigator to the IRB/IEC according to their requirements. Such a report should comment whether or not the adverse event was considered to be related to the test article.

Non-Serious Adverse Events:

All non-serious adverse events, including non-serious adverse device effects, will be reported to the sponsor by the Investigator no later than 2 days from discovery for review by the Medical Monitor.

Serious Adverse Events:

The Investigator will inform the sponsor of all serious adverse events occurring during the study period as soon as possible by e-mail, fax, or telephone, but no later than 24 hours following discovery of the event. The investigator is obligated to pursue and obtain information requested by the Sponsor in addition to that information reported on the CRF. All subjects experiencing a serious adverse event must be followed up and all outcomes must be reported.

When medically necessary, the investigator may break the randomization code to determine the identity of the treatment that the subject received. The Sponsor and study monitor should be notified prior to unmasking the test articles.

In the event of a serious adverse event, the investigator must:

- Notify the Sponsor immediately
- Obtain and maintain in the subject's file all pertinent medical records, information and medical judgment for colleagues who assisted in the treatment and follow-up of the subject
- Provide the Sponsor with a complete case history which includes a statement as to whether the event was or was not related to the use of the investigational test article
- Notify the IRB/IEC as required by the IRB/IEC reporting procedure according to national regulations

Unanticipated (Serious) Adverse Device Effect (UADE):

In the event of an Unanticipated (Serious) Adverse Device Effect (UADE), the Investigator will submit a report of the UADE to the Sponsor and IRB/IEC as soon as possible, but no later than 24 hours after the Investigator first learns of the effect. This report is in addition to the immediate notification mentioned above.

The Sponsor must conduct an evaluation of the UADE and must report the results of the evaluation to FDA, the IRB/IEC and participating investigators within 10 working days after the Sponsor first receives notification of the effect.

8.3 ADVERSE EVENT DEFINITIONS

Adverse Event (AE) – An AE is any untoward (unwanted) medical occurrence in a patient or clinical investigation subject administered a test article whether or not caused by the test article or treatment. An AE can therefore be any unfavorable or unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of the test article whether or not related to the test article.

An AE includes any condition (including a pre-existing condition) that: 1) was not present prior to study treatment, but appeared or reappeared following initiation of study treatment; or 2) was present prior to study treatment, but worsened during study treatment. This would include any condition resulting from concomitant illnesses, reactions to concomitant medications, or progression of disease states. Pregnancy should be documented as an adverse event and should be reported to the clinical monitor and to the Sponsor immediately upon learning of the event.

Serious Adverse Event (SAE) – An SAE is any untoward medical occurrence that:

- Results in death
- Is life threatening
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity (i.e., a significant persistent or permanent change, impairment, damage, or disruption to the subject's body)
- Is a congenital anomaly/birth defect, or
- Requires intervention to prevent permanent damage (the use of the investigational product resulting in a condition which requires medical or surgical intervention to preclude permanent impairment of the body structure or a body function). Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in the above definition.

Diagnoses and conditions that are considered Serious Adverse Events include:

- Microbial Keratitis (MK)
- Iritis
- Permanent decrease in best spectacle corrected visual acuity equivalent to 2 acuity lines or greater
- Central Corneal Opacity
- Central Corneal Neovascularization
- Uveitis
- Endophthalmitis
- Hypopyon
- Hyphema
- Penetration of Bowman's Membrane

- Persistent Epithelial Defect
- Limbal cell Damage leading to Conjunctivalization

Significant Adverse Events – Those events that are usually symptomatic and warrant discontinuation (temporary or permanent) of the test article (excluding Serious Adverse Events). Diagnoses and conditions that are considered Significant Adverse Events include the following:

- Contact Lens Induced Peripheral Ulcer (CLPU)
- Significant Infiltrative Events (SIE)
- Superior Epithelial Arcuate Lesions (SEALs)
- Any Temporary Loss of > 2 Lines of BSCVA
- Other grade 3 or higher corneal findings, such as abrasions or edema
- Any corneal event which necessitates temporary lens discontinuation > 2 weeks
- Non-contact lens related corneal events - e.g. EKC (Epidemic Keratoconjunctivitis)
- Asymptomatic Corneal Scar

Non-Significant Adverse Events – Those conditions that are usually asymptomatic and usually do not warrant discontinuation (temporary or permanent) of the test article. However, the Investigator may choose to treat as a precautionary measure. Diagnoses and conditions that are considered Non-Significant Adverse Events include the following:

- Non-significant Infiltrative Event
- Contact Lens Papillary Conjunctivitis
- Superficial Punctate Keratitis
- Conjunctivitis: Bacterial, Viral, Allergic
- Blepharitis
- Meibomianitis
- Contact Dermatitis
- Localized Allergic Reactions
- Any corneal event not explicitly defined as serious or significant adverse event, which necessitates temporary lens discontinuation < 2 weeks

Adverse Device Effect (ADE) – A sub-set of AEs, and include only those adverse events that are cause by or related to the investigational device or study procedure.

Unanticipated Adverse Device Effect (UADE) – Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, the test article, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan, investigator's brochure or protocol, or any other unanticipated serious problem associated with the test article that relates to the rights, safety and welfare of subjects.

Causality Assessment – A determination of the relationship between an adverse event and the test article. The test article relationship for each adverse event should be determined by the investigator using these explanations:

- Not Related- An adverse event that is not related to the use of the test article.
- Doubtful – An adverse event for which an alternative explanation is more likely, e.g. concomitant treatment, concomitant disease(s), or the relationship of time suggests that a causal relationship is not likely.
- Possible – An adverse event that might be due to the use of the test article. An alternative explanation, e.g. concomitant treatment, concomitant disease(s), is inconclusive. The relationship in time is reasonable. Therefore, the causal relationship cannot be excluded.

- Probable – An adverse event that might be due to the use of the test article. The relationship in time is suggestive (e.g. confirmed by de-challenge). An alternative explanation is less likely, e.g. concomitant treatment or concomitant disease(s).
- Very Likely – An adverse event that is listed as a possible adverse effect (device) or adverse reaction (drug) and cannot be reasonably explained by an alternative explanation, e.g. concomitant treatment of concomitant disease(s). The relationship in time is very suggestive, e.g. it is confirmed by de-challenge and re-challenge.

Severity Assessment – A qualitative assessment of the degree of intensity of an adverse event as determined by the investigator or reported to him/her by the subject. The assessment of severity is made irrespective of test article relationship or seriousness of the event and should be evaluated according to the following scale:

- Mild – Event is noticeable to the subject, but is easily tolerated and does not interfere with the subject's daily activities.
- Moderate – Event is bothersome, possible requiring additional therapy, and may interfere with the subject's daily activities.
  Severe – Event is intolerable, necessitates additional therapy or alteration of therapy and interferes with the subject's daily activities.

8.4 METHODS FOR ASSESSING, RECORDING, AND ANALYZING SAFETY

The recording and documenting of adverse events (ocular and non-ocular) begin when the subjects are exposed to the test article or study treatment. Adverse events reported before the use of test article or start of study treatment should be recorded as medical history. Untoward medical events reported after the subject's exit from the study will be recorded as adverse events at the discretion of the Investigator.

All adverse events observed by the Investigator; reported by the subject spontaneously; or in response to direct questioning; will be recorded in the source document. Such documentation will include a description of the adverse event, time of onset, duration of event, treatment regimen instituted, any referral to another health care provider (if needed), any new concomitant medications, outcome, ocular damage (if any), and likely etiology. Best Corrected Visual Acuity (BCVA) should be recorded prior to the report of an adverse event (as part of the baseline evaluation), upon report of the subject's report of the adverse event, and after the adverse event has resolved. All adverse events will be followed in accordance with licensing requirements.

All adverse events will be documented in the appropriate section of the subject's Case Report Form (CRF).

In conjunction with the medical monitor, the Investigator will evaluate adverse events to ensure the events are categorized correctly.

Elements of categorization will include:

Seriousness (see definition in Section 8.3)

Expectedness – i.e. if the event was unexpected or unanticipated in that it was not previously identified in nature, severity, or degree of incidence (see definition in Section 8.3)

Causality or Relatedness – i.e. the relationship between the test article and the adverse event (not related; doubtful; possible; probable; very likely - see definition in Section 8.3)

Adverse Event Intensity or Classification – Adverse event intensity is used to assess the degree of intensity of the adverse event (mild, moderate, severe for all events). In addition Adverse event Classification is used to assess the severity of ocular adverse events (AE not requiring treatment, non-significant or significant see definition in Section 7.4).

Outcome – Fatal, not resolved, resolved, resolved with sequelae, resolving and unknown.

Actions Taken – None, temporarily discontinued, permanently discontinued, Other action taken

Upon finding an adverse event, the Principal Investigator will document the condition on the follow-up visit worksheet source document and in the CRF's using photos or drawings (where appropriate) that detail size, location, and depth. He will also complete the Adverse Event Classification (AEC) Discovery form / eCRF. In addition, if an infiltrate(s) is present, he will complete the Corneal Infiltrate Assessment Form / eCRF. Where necessary, a culture of the corneal lesion will be collected to determine if the infection is microbial in nature. If cultures are collected, a source document note should be completed specifying the date of culture collection and laboratory utilized. An eCRF documenting this should be completed in a comment or unscheduled visit.

Complete description of all adverse events must be available in the source documents. All Adverse Events including local and systemic reactions not meeting the criteria for "serious adverse events" should be captured on the appropriate case report form or electronic data system. Information to be recorded, based on above assessment criteria, includes date site notified, event description, date and time of onset, investigator assessment of severity, relationship to Study Agent(s)/Intervention(s), and time of resolution/stabilization of the event. All adverse events occurring while on study must be documented appropriately regardless of relationship. Define a timeframe for CRF completion and entry of the adverse event information into the database, as applicable.

Any medical condition that is present at the time that the subject is screened should be considered as baseline and not recorded as an AE. However, if the condition deteriorates at any time during the study it should be recorded and reported as an AE.

Changes in the severity of an AE should be documented to allow an assessment of the duration of the event at each level of intensity to be performed. Adverse events characterized as intermittent require documentation of the onset and duration of each episode. Changes in the assessment of relationship to the Study Agent(s)/Interventions should also be clearly documented.

The investigator will notify the Sponsor of an adverse event by e-mail, facsimile, or telephone as soon as possible and no later than 24 hours from discovery for a serious / significant adverse event, and 2 days from discovery for a non-significant adverse event. In addition, a written report will be submitted by the Principal Investigator to the IRB/IEC according to their requirements (Section 1212.3). Such a report should comment whether or not the adverse event was considered to be related to the test article.

8.5 ADVERSE EVENTS FOLLOW-UP

It is the Investigator's responsibility to maintain documentation of each reported adverse event. All adverse events will be followed in accordance with applicable licensing requirements. Such documentation will include the following:

- Adverse Event (Diagnosis not symptom)
- Detailed drawings or photographs, when appropriate
- Date and time of onset
- Date and time of resolution
- Adverse event intensity and classification, as applicable
- Treatment regimen instituted, including concomitant medications prescribed, in accordance with applicable licensing requirements
- Any referral to another health care provider if needed
- Outcome, ocular damage (if any)

- Likely etiology.
- Best corrected visual acuity at the discovery of the event and upon conclusion of the event

In addition, if an infiltrate(s) is present, the Investigator will complete the Corneal Infiltrate Assessment Form / eCRF.

Photographs or video recordings may be collected at the Investigator's discretion for purposes of documenting adverse event findings.

Visual acuity (best corrected) should be recorded prior to the report of an adverse event (as part of the Baseline Evaluation), upon the subject's report of the adverse event, and after the adverse event has resolved.

Subjects who present with an adverse event should be followed by the Investigator, within licensure, until all signs and symptoms have returned to pre-treatment status, stabilized, or been satisfactorily resolved. If further treatment (i.e. beyond licensure) is required, the patient will be referred to the appropriate health care provider. The Investigator should use his/her clinical judgment as to whether or not a subject (eye) reporting with an adverse event should continue in the study. If a subject is discontinued from the study, it will be the responsibility of the Investigator to record the reason for discontinuation. The investigator will also complete the Adverse Event Classification (AEC) Outcome form / eCRF. Any subjects with ongoing adverse events related to the test article as of the final study visit date should be followed to resolution of the adverse event or until referral to an appropriate health care provider, as recommended by the Investigator.

9.1 STATISTICAL METHODS TO BE EMPLOYED

All data summaries and statistical analyses will be performed using the SAS software Version 9.4 or above (SAS Institute, Cary, NC). Throughout the analysis of data, the results for each subject/eye will be used when available for summarization and statistical analysis. Unscheduled visits will be summarized separately and excluded from the statistical analysis.

Summary tables (descriptive statistics and/or frequency tables) will be provided for all baseline, efficacy and safety variables as appropriate. Continuous variables will be summarized with descriptive statistics including n, mean, standard deviation (SD), median, minimum and maximum. Categorical variables will be summarized using frequency count and percentage of subjects or eyes within each category. Summaries will be presented by study lens type and will be performed separately by study population defined in section 9.7.

Safety variables will be summarized descriptively for the safety population. The primary analyses will be conducted on the safety population and the secondary analyses will be conducted on the per protocol population due to nature of the study endpoints (refer to section 9.7). If the dropout rate is higher than 20%, a sensitivity analysis will be conducted for the efficacy endpoints on all randomized subjects who successfully tried at least one study lens.

Monocular Visual Acuity (VA) 20/40 or better Analysis:

Each eye/subject will be categorized into two groups such that 'response=1' if an eye had acceptable VA (i.e., VA 20/40 or better) throughout all planned visits or 'response=0' otherwise. The generalized mixed model will be used to assess the overall acceptable VA for each lens type separately utilizing binomial distribution with logit link function. The model will include lens type as a fixed effect and site, subject and eye nested within subject as random effects. Baseline characteristics such as age and gender may be also included in the model as covariates if appropriate.

The model based proportion of eyes with acceptable VA with its corresponding 95% confidence interval (CI) will be constructed for each lens type from the generalized linear mixed model. Overall acceptable VA will be concluded if the lower limit of the 95% CI is greater than or equal to 0.80 (80%).

Lens Fit Acceptance Analysis:
Lens fit acceptance at fitting will be evaluated by lens type if at least 80% of eyes have acceptable lens fit (response=1) using the generalized mixed model with binomial distribution and logit link function. The model will include lens type as a fixed effect and site, subject and eye nested within subject as random effects. Baseline characteristics such as age and gender may be also included in the model as covariates if appropriate.

The model based proportion of eyes with acceptable lens fit with its corresponding 95% CI will be constructed for each lens type from the generalized linear mixed model. Acceptable lens fit will be concluded if the lower limit of the 95% CI is greater than or equal to 0.80 (80%).

Lens Stability with Blink Analysis:
Observed rotational stability with blink will be dichotomized such that 'response=1' if stability was less than or equal to 5-degree (refer as 'adequate stability') *or* 'response=0' otherwise. The dichotomized stability at fitting will be evaluated by lens type if at least 80% of eyes have adequate stability (response=1). The generalized mixed model will be used to assess adequate stability for each lens type separately utilizing binomial distribution with logit link function. The model will include lens type as a fixed effects and site, subject and eye nested within subject as random effects. Baseline characteristics such as age and gender may be also included as covariates in the model if appropriate.

The model based proportion of eyes with adequate stability with its corresponding 95% CI will be constructed for each lens type from the generalized linear mixed model. Adequate stability will be concluded if the lower limit of the 95% CI is greater than or equal to 0.80 (80%).

Absolute Rotation Analysis:
Absolute rotation will be dichotomized such that 'response=1' if absolute rotation was less than equal to 10-degree (refer as 'acceptable rotation') *or* 'response=0' otherwise. Acceptable absolute rotation upon 15 minute post insertion at fitting will be evaluated by lens type if at least 80% of eyes have acceptable absolute rotation (response=1) using the generalized mixed model with binomial distribution and logit link function. The model will include lens type as a fixed effect; site, subject and eye nested within subject will be considered as random effects. Baseline characteristics such as age and gender may be considered as covariates in the model when appropriate.

The model based proportion of eyes with acceptable absolute rotation with its corresponding 95% confidence interval (CI) will be constructed for each lens type from the generalized linear mixed model. Acceptable absolute rotation will be concluded if the lower limit of the 95% CI is greater than or equal to 0.80 (80%).

Contact Lens Related Corneal Staining (CS) Analysis:
Each eye/subject will be categorized into two groups such that 'response=1' if an eye had acceptable corneal staining (CS) (i.e., CS grade 2 or lower) throughout all planned and unscheduled visits or 'response=0' otherwise. The incidence rate of the Test lens will be compared to the Control lens using a generalized linear mixed model with binomial distribution and logit link function. The model will include lens type as a fixed effect and site, subject and eyes nested within subject as random effects. Baseline characteristics such as age and gender may be considered as covariates in the model when appropriate.

The incidence rate of CS for the Test lens will be compared to the Control lens using the two-sided 95% CI constructed for odds ratios (Test over Control). No difference between Test and Control lenses will be concluded if the 95% CI of the odds ratio contains 1.

Monocular Visual Acuity (VA) 20/20 or better Analysis:
Observed monocular VA will be also dichotomized such that 'response=1' if VA was 20/20 or better (refer as ' suitableVA') *or* 'response=0' otherwise at fitting. Dichotomized VA at fitting will be compared between the Test and Control lenses using a generalized linear mixed model with binomial distribution and logit link function. The

model will include lens type as a fixed effect and site, subject and eyes nested within subject as random effects. Baseline characteristics such as age and gender may be considered as covariates in the model when appropriate.

The model based proportion of eyes with suitable VA at fitting will be compared between the Test and Control lenses using the two-sided 95% CI constructed for odds ratios (Test over Control). Non-inferiority will be concluded if the lower limit of the two-sided 95% CI of the odds ratio is above 0.4. The odds ratio margin of 0.4 corresponds to a 10% difference in proportion between the Test and Control lenses assuming a reference rate of 93%.

CLUE Score Analysis:

CLUE scores including comfort, vision, handling and packaging will be analyzed separately using a linear mixed model adjusting for baseline values as a fixed covariate when appropriate. Each model will include the following experimental design factors: lens type, time event (i.e., fitting, 1-, 2-, 3- and 4-week follow-up), and lens type by time event interaction as fixed effects; and site as a random effect when appropriate. Baseline characteristics such as age and gender may be considered as covariates when appropriate. The covariance between errors from the same subject at different time events will be selected based on the finite-sample corrected Akaike's information Criterion (Keselman et al. 1998).

The following covariate structures will be considered:

- Homogenous compound symmetry (CS)
- Heterogeneous compound symmetry (CSH)
- Variance Components (VC)
- Heterogeneous Variance Component (UN(1))
- Unstructured (UN)
- First order autoregressive (AR(1))
- Spatial Power (SP(POW))

For AR(1), UN(1) and SP(POW) covariance structures, subject will be included as a random effect. For the remaining covariate structures , only site will be included as a random effect. The covariate structure that returns the lowest Akaike Information Criteria Corrected (AICC) will be considered as the structure best fits for the data. Heterogeneous models across the study types may be considered when appropriate. The log-likelihood ratio test will be used to test for homogeneity of variances across lens types.

The overall CLUE comfort scores across all study visits will be compared between the test and control lenses using the two-sided 95% CI constructed for the LS means differences (Test minus Control) from the repeated measures analysis. The non-inferiority will be concluded if the lower limit of the 95% CI for the LS mean difference is greater than -5. If the lower confidence limit is greater than 0, the statistical superiority will be concluded.

The overall CLUE handling scores across all study visits for the Test lens will be assessed whether subjective handling score is adequate using a margin of 50. The adequate subjective handling will be concluded if the lower limit of the 95% CI for the LS mean is greater than 50.

The Kenward and Roger method (Kenward and Roger, 1997) will be used for the calculation of the denominator degree of freedom for the all above statistical models if applicable. If a spatial power covariance structure is selected, the first order option will be used.

In case the statistical model does not converge for any reasons (likely due to small incidence rate) for any of the primary analyses, the 95% CI for the binomial proportions will be constructed using the Agresti-Coull method.

Additional post-hoc analysis may be conducted if necessary at the discretion of the project leader.

9.2 NUMBER OF SUBJECTS BY SITE AND JUSTIFICATION FOR SAMPLE SIZE

Sample size was calculated to attain the optimal number of subjects to demonstrate the statistical acceptance of the primary and secondary hypotheses using the historical data from [redacted] and [redacted]. The incidence rate (%) of the primary endpoints from the historical data are presented in Table below.

Table: Incidence Rate (%) from the Historical Data

Endpoints	***Event***	***Atlas A Rate (%)***	***AOA Rate (%)***
Monocular Visual Acuity 20/40 or better	Overall	100	100
Corneal Staining < Grade 3*	Overall	100	100
Acceptable Lens Fit	Fitting	100	100
Absolute Rotation within 10-degree	15 min	97	96
Stability with Blink within 5-degree	Fitting	100	100

*Corneal staining will be assessed to demonstrate no difference between the Test and Control lenses whereas the other primary endpoints will be assessed to demonstrate satisfying 80% minimum threshold of the Test lens.

Primary Endpoints with 80% Threshold:

The common reference rate of 95% was selected for the sample size calculation as they are binary in nature. Assuming a correlation of 0.8 between eyes, 2000 trials (replicating 2000 trials) were simulated to attain a sample size with a minimum statistical power of 90%.

Primary Endpoints with no difference:

The incidence reference rate of 0.005% was selected for the sample size calculation for no difference between two study lenses on corneal staining grade 3 or higher using the formula given by Diggle et al. (2002) for cluster binary data. The incidence rate of 0.005% was set based on the 5 previous Atlas studies (both sphere and astigmatism) including [redacted], [redacted], CR5726, [redacted] and [redacted]. There were no corneal staining grade 3 or higher throughout all 5 studies so that it was determined that 0.005% is a reasonable assumption.

The number of observations per subject (cluster) was set to 2 (2 eyes per subject) and a correlation of 0.3 between eyes within a subject was assumed to attain a sample size with a minimum statistical power of 80%.

Secondary Endpoint:

Sample size calculation for the overall CLUE comfort was also performed considering the effect size of 5 (Test-Control) to achieve a minimum statistical power of 90%. The 2000 trials were simulated for the repeated measurement from the multivariate normal distribution at a 5% significance level using the following covariances attained from the historical data:

Test :

u11 = 365.99
u21 = 214.84 u22 = 609.18
u31 = 176.06 u32 = 532.54 u33 = 637.19
u41 = 146.71 u42 = 514.08 u43 = 590.60 u44 = 714.34

Control:

u11 = 429.65
u21 = 245.51 u22 = 590.56
u31 = 210.38 u32 = 520.42 u33 = 603.15
u41 = 254.93 u42 = 533.15 u43 = 535.36 u44 = 643.20

It is determined that a total of 270 subjects (135 per arm) will be sufficient to demonstrate statistical acceptance of both primary and secondary hypotheses.

Endpoints	*Power (%)*	*N per Arm*	*Total N*
Monocular Visual Acuity 20/40 or better	90 <	90	207
Corneal Staining < Grade 3	85 <	116	270
Acceptable Lens Fit	90 <	90	207
Absolute Rotation within 10-degree	90 <	90	207
Stability with Blink within 5-degree	90 <	90	207
CLUE comfort	90 <	90	207

* Total N include ~15% Dropout Rate

9.3 LEVEL OF STATISTICAL SIGNIFICANCE

All planned analysis for this study will be conducted with an overall type I error rate of 5%.

The primary analyses (multiple endpoints) will be performed using the intersection-union principal; all primary hypotheses will be simultaneously evaluated using $\alpha = 0.05$. All primary hypotheses must be met in order to claim the success of the study objectives.

The secondary hypotheses will be assessed only if all the primary hypotheses were met using a gate keeping strategy.

Adjustment of multiple pairwise-comparisons between Test and Control across times points for CLUE scores will be conducted using asimulated-based method (Edward and Berry, 1987).

9.4 CRITERIA FOR STUDY TERMINATION

In addition to the stopping rules defined in section 5.1, the occurrence of one or more Serious Unanticipated Adverse Device Effect (USADE), or any SAE where the relationship to study agent cannot be ruled out, may result in stopping further dispensing of investigational product.

In the event of a USADE or SAE, the Sponsor may unmask the treatment regimen for the subject(s) and may discuss this with the Investigator before any further subjects are enrolled.

The sponsor may determine when a study will be stopped. The principal investigator always has the discretion to initiate stopping the study based on subject safety or if information indicates the study's results may be compromised.

9.5 PROCEDURE FOR ACCOUNTING FOR MISSING, UNUSED, AND SPURIOUS DATA

Missing or spurious values will not be imputed.

9.6 PROCEDURE FOR REPORTING DEVIATIONS FROM STATISTICAL PLAN

The analysis will be conducted according to section 9.1. There are no known reasons for which it is planned to deviate from these analysis methods. If for any reason a change is made, the change will be documented in the study report along with a justification for the change.

9.7 EVALUABLE SUBJECTS

Accountability (disposition) of all enrolled subjects will be presented in each of the following status subgroups.

1. Completed: Randomized subjects who are eligible to participate in the study and have successfully completed all required visits including the final visit.
2. Discontinued: Randomized subjects who are prematurely discontinued from the study due to any reasons described in Section 5.1.
3. Total Dispensed: Subjects who administered the test article at least once (i.e. Lens insertion occurred in at least one eye).
4. Enrolled Not Dispensed: Subjects who were (i) enrolled in the study (provided informed consent) but failed to satisfy the eligibility criteria (inclusion/exclusion criteria), (ii) randomized but discontinued or drop out prior to administering the test article, or (iii) not randomized to treatment for any reason.
5. Total enrolled: Subjects who signed the informed consent form (i.e. completed + discontinued + Enrolled not dispensed).

Subjects will be allocated to the following study populations for the analysis purpose.

1. Safety Population: All subjects who are administered the test articles and have at least one observation on any safety or/and efficacy variables.
2. Per-protocol Population: All subjects who have successfully completed all required visits without any major protocol deviations that the cohort review committee documents as impacting the assessment of the hypotheses prior to the data hard-lock.

10.1 ELECTRONIC CASE REPORT FORM/DATA COLLECTION

The data for this study will be captured on electronic case report forms (eCRFs) using an EDC system when possible. Designated study site personnel will enter study data into the electronic CRFs (eCRFs) using the EDC system. Data collected on equipment that is not possible to be captured in EDC will be formatted to the specification of the JJVC database manager and sent to JJVC for analysis. Data generated from post hoc measurements (e.g. Compositional characteristics of contact lens lipid uptake, Measured tear film protective capability, Measured contact lens surface dehydration rate) will be collected on specific Microsoft Office Excel format worksheets at the clinical site and at the completion of the analysis transferred to JJVC biostatistician for data analysis in such format if applicable.

The CRFs will be reviewed for accuracy and completeness and signed by the investigator. Unless otherwise stated, the eCRFs will be considered the source document. The sponsor or sponsor‘s representatives will be authorized to gain access to the source documentation for the purposes of monitoring and auditing the study.

Edit checks, electronic queries, and audit trails are built into the system to ensure accurate and complete data collection. Data will be transmitted from the investigational site to a secure central database as forms are completed or updated, ensuring information accuracy, security, and confidentiality. After the final database lock, the Investigator will be provided with Individual Patient Profiles (IPP) including the full audit trail on electronic media in a non-editable format for all of the study data. The IPP should be retained in the study files as a certified copy of the source data for the study.

The content and structure of the CRFs are compliant with ISO14155:2011 [3].

10.2 SOURCE DOCUMENTATION

At a minimum, source documentation should be available for the following to confirm data collected in the CRF: subject identification, eligibility, and study identification; study discussion, provision of and date of informed consent; visit dates; results of safety and efficacy parameters as required by the protocol; a record of all adverse events; follow-up of adverse events; concomitant medication; investigational product receipt / dispensing / return records; study investigational product administration information; date of study completion; reason for early discontinuation of investigational product or withdrawal from the study, if applicable.

The author of an entry in the source documents must be identifiable. Adverse event notes should be reviewed and initialed by the Investigator.

At a minimum, the type and level of detail of source data available for a study subject should be consistent with that commonly recorded at the site as a basis for standard medical care.
Specific details required as source data for the study will be reviewed with the investigator before the study and will be described in the monitoring guidelines (or other equivalent documents).

10.3 ACCESS TO SOURCE DATA/DOCUMENT

The Investigator(s) / Institution(s) will permit trial-related monitoring, audits, IRB/IEC review and regulatory inspection(s) by providing direct access to source data / documents. Should the clinical site be contacted for an audit by an IRB/IEC or regulatory authority, JJVC should be contacted and notified in writing within 24 hours.

10.4 CONFIDENTIALITY OF INFORMATION

Information concerning the investigational product and patent application processes, scientific data or other pertinent information is confidential and remains the property of JJVC. The Investigator may use this information for the purposes of the study only. It is understood by the Investigator that JJVC will use information developed in this clinical study in connection with the development of the investigational product and therefore may disclose it as required to other clinical investigators and to regulatory agencies. In order to allow the use of the information derived from this clinical study, the Investigator understands that he/she has an obligation to provide complete test results and all data developed during this study to the Sponsor.

The Investigator may not submit for publication or presentation the results of this study without first receiving written authorization from JJVC. JJVC agrees that, before it publishes any results of the study, it shall provide the Investigator with at least 30 days for review of the pre-publication manuscript prior to the submission of the manuscript to the publisher.

11.1 DATA QUALITY ASSURANCE

Steps to be taken to ensure the accuracy and reliability of data include the selection of qualified investigators and appropriate study sites and review of protocol procedures with the principal investigator. The principal investigator, in turn, must ensure that all sub-investigators and study staff are familiar with the protocol and all study-specific procedures and have appropriate knowledge of the study article.

Guidelines for case report form completion will be provided and reviewed with study personnel before the start of the study. The sponsor, Johnson & Johnson Vision Care, Inc. will review case report forms for accuracy and completeness remotely during the course of the study, during on-site monitoring visits and after transmission to data management. Any data discrepancies will be resolved with the investigator or designee, as appropriate.

Quality Assurance representatives from Johnson & Johnson Vision Care, Inc. may visit study sites to review data produced during the study and to access compliance with applicable regulations pertaining to the conduct of clinical trials. The study sites will provide direct access to study-related source data/documents and reports for the purpose of monitoring and auditing by Johnson & Johnson Vision Care, Inc. and for inspection by local and regulatory authorities.

12.1 STUDY-SPECIFIC DESIGN CONSIDERATIONS

Potential subjects will be fully informed of the risks and requirements of the study and, during the study, subjects will be given any new information that may affect their decision to continue participation. They will be told that their consent to participate in the study is voluntary and may be withdrawn at any time with no reason given and without penalty or loss of benefits to which they would otherwise be entitled. Only subjects who are fully able to understand the risks, benefits, and potential adverse events of the study, and provide their consent voluntarily will be enrolled.

12.2 INVESTIGATOR RESPONSIBILITY

The Investigator is responsible for ensuring that the clinical study is performed in accordance with the protocol, Section 4 of the ICH E6 guidelines on Good Clinical Practice (GCP), and applicable regulatory requirements. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects.

Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles of the Declaration of Helsinki 64th WMA General Assembly 2008 and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with Section 8 of the ICH E6 guidelines on Good Clinical Practice (GCP), and applicable regulatory requirements.

12.3 INDEPENDENT ETHICS COMMITTEE OR INSTITUTIONAL REVIEW BOARD (IEC/IRB)

Before the start of the study, the Investigator (or Sponsor when applicable) will provide the IEC/IRB with current and complete copies of the following documents (where applicable):

- Final protocol and, if applicable, amendments
- Sponsor-approved informed consent form (and any other written materials to be provided to the subjects)
- Investigator's Brochure (or equivalent information) and amendments
- Sponsor-approved subject recruitment materials
- Information on compensation for study-related injuries or payment to subjects for participation in the study, if applicable
- Investigator's curriculum vitae, clinical licenses, or equivalent information (unless not required, as documented by IEC/IRB)
- Information regarding funding, name of the Sponsor, institutional affiliations, other potential conflicts of interest, and incentives for subjects
- Any other documents that the IEC/IRB requests to fulfill its obligation

This study will be undertaken only after IEC/IRB has given full approval of the final protocol, amendments (if any), the informed consent form, applicable recruiting materials, and subject compensation programs, and the Sponsor has received a copy of this approval. This approval letter must be dated and must clearly identify the documents being approved.

During the study the Investigator (or Sponsor when applicable) will send the following documents to the IEC/IRB for their review and approval, where appropriate:

- Protocol amendments
- Revision(s) to informed consent form and any other written materials to be provided to subjects
- If applicable, new or revised subject recruiting materials approved by the Sponsor
- revisions to compensation for study-related injuries or payment to subjects for participation in the study, if applicable
- Investigator's Brochure amendments or new edition(s)
- Summaries of the status of the study (at least annually or at intervals stipulated in guidelines of the IEC/IRB)
- Reports of adverse events that are serious, unanticipated, and associated with the investigational product, according to the IRB's requirements
- New information that may adversely affect the safety of the subjects or the conduct of the study
- Major protocol deviations as required by the IEC/IRB
- Report of deaths of subjects under the Investigator's care
- Notification if a new investigator is responsible for the study at the site
- Any other requirements of the IEC/IRB

For protocol amendments that increase subject risk, the amendment and applicable informed consent form revisions must be submitted promptly to the IEC/IRB for review and approval before implementation of the change(s).

At least once a year, the IEC/IRB will be asked to review and reapprove this clinical study. This request should be documented in writing.

At the end of the study, the Investigator (or Sponsor where required) will notify the IEC/IRB about the study completion. Documentation of this notification must be filed in the study Investigator binder and a copy provided to the CRO or Sponsor as applicable.

12.4 INFORMED CONSENT

Each subject must give written consent according to local requirements after the nature of the study has been fully explained. The consent form must be signed before performance of any study-related activity. The consent form that is used must be approved by both the Sponsor and by the reviewing IEC/IRB. The informed consent should be in accordance with principles that originated in the Declaration of Helsinki, current ICH and GCP guidelines, applicable regulatory requirements, and sponsor policy.

Before entry into the study, the Investigator or an authorized member of the investigational staff must explain to potential subject the aims, methods, reasonably anticipated benefits, and potential hazards of the study, and any discomfort it may entail. Subjects will be informed that their participation is voluntary and that they may withdraw consent to participate at any time. They will be informed that choosing not to participate will not affect the care the subject will receive. Finally, they will be told that the Investigator will maintain a subject identification register for the purposes of long-term follow-up if needed and that their records may be accessed by health authorities and authorized sponsor staff without violating the confidentiality of the subject, to the extent permitted by the applicable law(s) or regulations.

By signing the informed consent form the subject is authorizing such access, and agrees to be contacted after study completion, by health authorities and authorized sponsor staff, for the purpose of obtaining consent for additional safety evaluations if needed.

The subject will be given sufficient time to read the informed consent form and the opportunity to ask questions. After this explanation and before entry into the study, consent should be appropriately recorded by means of the subject's dated signature. After having obtained the consent, a copy of the informed consent form must be given to the subject.

> In the event additional investigators / sites are added to the protocol, the informed consent will be modified to include the Investigator's name, address, phone number and 24-hour emergency number.

12.5 PRIVACY OF PERSONAL DATA

The collection, processing and disclosure of personal data and medical information related to the Study Subject, and personal data related to Principal Investigator and any investigational staff (e.g., name, clinic address and phone number, curriculum vitae) is subject to compliance with the Data Protection Act of 1998 and other applicable personal data protection and security laws and regulations. Appropriate measures will be employed to safeguard these data, to maintain the confidentiality of the person's related health and medical information, to properly inform the concerned persons about the collection and processing of their personal data, to grant them reasonable access to their personal data and to prevent access by unauthorized persons.

All information obtained during the course of the investigation will be regarded as confidential. All personal data gathered in this trial will be treated in strictest confidence by investigators, monitors, Sponsors personnel and independent ethics committee. No data will be disclosed to any third party without the express permission of the subject concerned, with the exception of sponsor personnel (monitor, auditor), independent ethics committee and regulatory organizations in the context of their investigation related activities that, as part of the investigation will have access to the CRFs and source documents.

The collection and processing of personal data from subjects enrolled in this study will be limited to those data that are necessary to investigate the efficacy, safety, quality, and utility of the investigational product(s) used in this study.

These data must be collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data privacy protection laws and regulations.
The Sponsor ensures that the personal data will be:

- processed fairly and lawfully
- collected for specified, explicit, and legitimate purposes and not further processed in a way incompatible with these purposes
- adequate, relevant, and not excessive in relation to said purposes
- accurate and, where necessary, kept current

Explicit consent for the processing of personal data will be obtained from the participating subject before collection of data. Such consent should also address the transfer of the data to other entities and to other countries.

The subject has the right to request through the Investigator access to his personal data and the right to request rectification of any data that are not correct or complete. Reasonable steps should be taken to respond to such a request, taking into consideration the nature of the request, the conditions of the study, and the applicable laws and regulations.
Appropriate technical and organizational measures to protect the personal data against unauthorized disclosures or access, accidental or unlawful destruction, or accidental loss or alteration must be put in place. Sponsor personnel whose responsibilities require access to personal data agree to keep the identity of study subjects confidential

13.1 DATA HANDLING AND RECORD KEEPING

In compliance with the ICH/GCP guidelines, the Investigator / Institution will maintain all CRFs and all source documents that support the data collected from each subject, as well as all study documents as specified in ICH/GCP Section 8, Essential Documents for the Conduct of a Clinical Trial, and all study documents as specified by the applicable regulatory requirement(s). The Investigator / Institution will take measures to prevent accidental or premature destruction of these documents.

Essential documents must be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents will be retained for a longer period if required by the applicable regulatory requirements or by an agreement with the Sponsor. It is the responsibility of the Sponsor to inform the Investigator / Institution as to when these documents no longer need to be retained.

If the responsible Investigator retires, relocates, or for other reasons withdraws from the responsibility of keeping the study records, custody must be transferred to a person who will accept the responsibility. The Sponsor must be notified in writing of the name and address of the new custodian. Under no circumstance shall the Investigator relocate or dispose of any study documents before having obtained written approval from the Sponsor.

If it becomes necessary for the Sponsor or the appropriate regulatory authority to review any documentation relating to this study, the Investigator must permit access to such reports.

If the Investigator has a question regarding retention of study records, he should contact JJVC Research and Development.

14.1 FINANCIAL CONSIDERATIONS

Remuneration for study services and expenses will be set forth in detail in the Investigator's Research Agreement. The Research Agreement will be signed by the Principal Investigator and a Johnson & Johnson Vision Care management representative prior to study initiation.

Case Report Forms will be completed in real time according to the study procedures specified in the study protocol. Case Report Forms should be completed and reviewed and signed as applicable by the Investigator within 3 days of visit completion. Data queries must be addressed with complete responses within 3 days of generation. Johnson & Johnson Vision Care reserves the right to withhold remuneration until these activities are addressed.

Johnson & Johnson Vision Care reserves the right to withhold remuneration for costs associated with protocol violations such as:

- Continuing an ineligible subject in the study
- Scheduling a study visit outside the subject's acceptable visit range

15.1 PUBLICATION

This study will be registered on ClinicalTrials.gov by the Sponsor

16.1 PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

A summary of the questionnaires are given below.

Study PRO Form Setup For 5871 Version 3 Final					
Study (STUDYID)	Visit (VISITNUM)	Event ([redacted])	Setup Order	Type ([redacted])	Form ([redacted])
5871	1	[redacted]	1	[redacted]	[redacted]
5871	1	[redacted]	2	[redacted]	[redacted]
5871	2	[redacted]	3	[redacted]	[redacted]
5871	3	[redacted]	4	[redacted]	[redacted]
5871	4	[redacted]	5	[redacted]	[redacted]
5871	5	[redacted]	6	[redacted]	[redacted]

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form ([redacted])	Type ([redacted])	PRO Domain	PRO Sequence	Item ID# ([redacted])	Item Wording	Response Set	Page Number
[redacted]					Welcome to CLUE, a Questionnaire designed to help us improve our knowledge of vision correction and how this affects the lives of contact lens wearers. Please take as much time as you need to complete the questionnaire, answering all the questions. Click the box that best corresponds to your answer regarding your current lenses. If you are unsure how to answer an item please give the most applicable answer that you can. All of the information you provide will be kept strictly confidential and used only for the purpose of this study.		.
					The following items will cover your Comfort with these lenses. Please answer all of the items in relation to your experience with the current lenses.		.
					These contact lenses were extremely comfortable	Agreement	.
					These lenses felt very smooth in my eyes	Agreement	.
					I could wear these contact lenses comfortably for as long as I wanted to	Agreement	.
					I am conscious of these lenses at the moment	Agreement	.
					These lenses were comfortable instantly after inserting them	Agreement	.
					These lenses were comfortable at the end of the day.	Agreement	.
					My eyes felt extremely dry part of the day	Agreement	.
					The natural moisture of my eyes was maintained	Agreement	.
					My eyes maintained a feeling of freshness	Agreement	.
					My eyes ached after wearing these lenses	Agreement	.
					My eyes felt tired in the evening	Agreement	.
					I have experienced periods of discomfort that go away after a while	Agreement	.
					The comfort of these lenses decreased throughout the day	Agreement	.
					These lenses were comfortable in dry environments	Agreement/NA	.

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form ([redacted])	Type ([redacted])	PRO Domain	PRO Sequence	Item ID# ([redacted])	Item Wording	Response Set	Page Number
[redacted]					The following items will cover your Vision with these lenses. Please answer all of the items in relation to your experience with the current lenses.		.
					I was very satisfied with my vision	Agreement	.
					I had good vision all day	Agreement	.
					I was satisfied with the overall quality of my vision	Agreement	.
					I experienced fluctuations in the quality of my vision	Agreement	.
					My vision deteriorated towards the end of the day	Agreement	.
					I had difficulty seeing consistently throughout the day	Agreement	.
					My vision was cloudy	Agreement	.
					My vision was crisp	Agreement	.
					I was satisfied with the sharpness of my vision	Agreement	.
					I was satisfied by the clarity of my vision at the end of the day	Agreement	.
					I was satisfied by the clarity of my vision throughout the day	Agreement	.
					The following items will cover your experience Handling these lenses. Please answer all of the items in relation to your experience with the current lenses.		.
					The handling of these lenses was convenient	Agreement	.
					These lenses were folding on my finger when I attempted to insert them	Agreement	.
					It was easy to pick up these lenses	Agreement/NA	.
					When preparing for insertion, these lenses stood up on my finger	Agreement/NA	.
					It was easy to remove these lenses from my eyes	Agreement	.
					These lenses felt as though they were stuck to my eyes when I tried to remove them	Agreement	.
					The handling of these lenses was exceptional	Agreement	.

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form [redacted]	Type [redacted]	PRO Domain	PRO Sequence	Item ID# [redacted]	Item Wording	Response Set	Page Number
[redacted]					Please read the following instructions carefully. .• Your opinion is extremely important to us..• Please complete the following questionnaire based on your experience with your current contact lenses. It is important that your answers be based on your own personal opinion as well as your interpretation of the question. Please do not ask others for direction. .• Please make every effort to answer each question to the best of your ability and do not leave any question blank. Please be as honest and sincere as possible. If asked to write in an answer, please be as specific as you can. .• Most questions can be answered by checking the appropriate box. Please pay close attention, though, to any additional instructions relating to individual questions throughout the questionnaire.. • Please note that all your answers will be kept strictly confidential.	INSTRUCT	1
					Thank you for your participation in the study.	INSTRUCT	1
					How long have you been wearing contact lenses?	Length	2
					On average, how many days per week do you wear your contact lenses?	DAYSPERWK	3
					Considering your experience with your current contact lenses, which statement best describes your overall opinion of these contact lenses?	ExcellenceR	4
					Please think about your experience with your current contact lenses. Please indicate how you would rate the contact lenses on each of the following characteristics.	INSTRUCT	5
					Overall quality of vision	ExcellenceRNAFirst	5
					Clarity of vision during daily activities	ExcellenceRNAFirst	5
					Clarity of vision at the end of the day	ExcellenceRNAFirst	5
					Overall comfort	ExcellenceRNAFirst	5
					Comfort immediately when you first put them in	ExcellenceRNAFirst	5
					Comfort throughout the day	ExcellenceRNAFirst	5
					Comfort each and every day	ExcellenceRNAFirst	5
					Comfort at the end of the day	ExcellenceRNAFirst	5
					Absence of irritation	ExcellenceRNAFirst	5
					Overall ease of handling	ExcellenceRNAFirst	5

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form [redacted]	Type [redacted]	PRO Domain	PRO Sequence	Item ID# [redacted]	Item Wording	Response Set	Page Number
[redacted]					How would you describe your awareness of your current contact lenses throughout the day? SELECT ONLY ONE	AwareInEye	6
					Please indicate how often, if ever, you experience the following visual issues when you wear your current contact lenses.	INSTRUCT	7
					Blurred vision throughout the day	FrequencyDKR	7
					Blurred vision at the end of the day	FrequencyDKR	7
					Eye strain	FrequencyDKR	7
					Please indicate how often, if ever, you experience the following sensations when you wear your current contact lenses.	INSTRUCT	8
					Dryness	FrequencyDKR	8
					Irritation	FrequencyDKR	8
					Lens Awareness (feeling of noticing the lens on your eye).	FrequencyDKR	8
					How would you describe the condition of your eyes?	EyeCondition	9
					How would you describe the sensitivity of your eyes?	SensitivityR	10
					How would you describe the dryness of your eyes?	DrynessR	11
					Have you ever been told by your Eye Care Professional that you have dry eyes?	YesNo	12
					PLEASE LET THE INVESTIGATOR OR A STAFF MEMBER KNOW WHEN YOU ARE FINISHED WITH THIS QUESTIONNAIRE.	INSTRUCT	13

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form [redacted]	Type [redacted]	PRO Domain	PRO Sequence	Item ID# [redacted]	Item Wording	Response Set	Page Number
[redacted]					Welcome to CLUE, a Questionnaire designed to help us improve our knowledge of vision correction and how this affects the lives of contact lens wearers. Please take as much time as you need to complete the questionnaire, answering all the questions. Click the box that best corresponds to your answer regarding your current lenses. If you are unsure how to answer an item please give the most applicable answer that you can. All of the information you provide will be kept strictly confidential and used only for the purpose of this study.		.
					The following items will cover your Comfort with these lenses. Please answer all of the items in relation to your experience with the current lenses.		.
					I am conscious of these lenses at the moment	Agreement	.
					I lost awareness of these lenses instantly after insertion	Agreement	.
					These lenses were very comfortable instantly after inserting them	Agreement	.
					I had to blink more often because these lenses were uncomfortable	Agreement	.
					I felt these lenses when I blinked	Agreement	.
					I experienced a stinging sensation after inserting these lenses	Agreement	.
					I have experienced irritated eyes after inserting these lenses	Agreement	.
					The following items will cover your Vision with these lenses. Please answer all of the items in relation to your experience with the current lenses.		.
					I was satisfied with my vision	Agreement	.
					My vision was blurry	Agreement	.
					I was satisfied with the overall quality of my vision	Agreement	.
					I experienced fluctuations in the quality of my vision	Agreement	.
					My vision took on a foggy appearance	Agreement	.
					I was satisfied with the sharpness of my vision	Agreement	.
					I had to blink more often to clear my vision	Agreement	.

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form [redacted]	Type [redacted]	PRO Domain	PRO Sequence	Item ID# [redacted]	Item Wording	Response Set	Page Number
[redacted]					The following items will cover your experience Handling these lenses. Please answer all of the items in relation to your experience with the current lenses.		.
					The handling of these lenses was convenient	Agreement	.
					It was very easy to insert these lenses	Agreement/NA	.
					These lenses left my finger and inserted into my eye very easily	Agreement	.
					These lenses were folding on my finger when I attempted to insert them	Agreement	.
					When preparing for insertion, these lenses stood up on my finger	Agreement/NA	.
					The handling of these lenses was exceptional	Agreement	.
					Please read the following instructions carefully. .• Your opinion is extremely important to us..• Please complete the following questionnaire based on your experience with the contact lenses you were provided. It is important that your answers be based on your own personal opinion as well as your interpretation of the question. Please do not ask others for direction..• Please make every effort to answer each question to the best of your ability and do not leave any question blank. Please be as honest and sincere as possible. If asked to write in an answer, please be as specific as you can. .• Most questions can be answered by checking the appropriate box. Please pay close attention, though, to any additional instructions relating to individual questions throughout the questionnaire. .• Please note that all your answers will be kept strictly confidential.	INSTRUCT	1
					Thank you for your participation in the study.	INSTRUCT	1
					Considering your experience with the study contact lenses, which statement best describes your overall opinion of these contact lenses?	ExcellenceR	2
					Please think about your experience with the study contact lenses. Please indicate how you would rate the contact lenses on each of the following characteristics.	INSTRUCT	3
					Overall quality of vision	ExcellenceRNAFirst	3
					Clear vision immediately after insertion	ExcellenceRNAFirst	3
					Overall comfort	ExcellenceRNAFirst	3

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form [redacted]	Type [redacted]	PRO Domain	PRO Sequence	Item ID# [redacted]	Item Wording	Response Set	Page Number
[redacted]					Not stinging or burning your eyes when you first put them in	ExcellenceRNAFirst	3
					Comfort immediately when you first put them in	ExcellenceRNAFirst	3
					PLEASE LET THE INVESTIGATOR OR A STAFF MEMBER KNOW WHEN YOU ARE FINISHED WITH THIS QUESTIONNAIRE.	INSTRUCT	4

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form [redacted]	Type [redacted]	PRO Domain	PRO Sequence	Item ID# [redacted]	Item Wording	Response Set	Page Number
[redacted]					Welcome to CLUE, a Questionnaire designed to help us improve our knowledge of vision correction and how this affects the lives of contact lens wearers. Please take as much time as you need to complete the questionnaire, answering all the questions. Click the box that best corresponds to your answer regarding your current lenses. If you are unsure how to answer an item please give the most applicable answer that you can. All of the information you provide will be kept strictly confidential and used only for the purpose of this study.		.
					The following items will cover your Comfort with these lenses. Please answer all of the items in relation to your experience with the current lenses.		.
					These contact lenses were extremely comfortable	Agreement	.
					These lenses felt very smooth in my eyes	Agreement	.
					I could wear these contact lenses comfortably for as long as I wanted to	Agreement	.
					I am conscious of these lenses at the moment	Agreement	.
					These lenses were comfortable instantly after inserting them	Agreement	.
					These lenses were comfortable at the end of the day.	Agreement	.
					My eyes felt extremely dry part of the day	Agreement	.
					The natural moisture of my eyes was maintained	Agreement	.
					My eyes maintained a feeling of freshness	Agreement	.
					My eyes ached after wearing these lenses	Agreement	.
					My eyes felt tired in the evening	Agreement	.
					I have experienced periods of discomfort that go away after a while	Agreement	.
					The comfort of these lenses decreased throughout the day	Agreement	.
					These lenses were comfortable in dry environments	Agreement/NA	.

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form [redacted]	Type [redacted]	PRO Domain	PRO Sequence	Item ID# [redacted]	Item Wording	Response Set	Page Number
[redacted]					The following items will cover your Vision with these lenses. Please answer all of the items in relation to your experience with the current lenses.		.
					I was very satisfied with my vision	Agreement	.
					I had good vision all day	Agreement	.
					I was satisfied with the overall quality of my vision	Agreement	.
					I experienced fluctuations in the quality of my vision	Agreement	.
					My vision deteriorated towards the end of the day	Agreement	.
					I had difficulty seeing consistently throughout the day	Agreement	.
					My vision was cloudy	Agreement	.
					My vision was crisp	Agreement	.
					I was satisfied with the sharpness of my vision	Agreement	.
					I was satisfied by the clarity of my vision at the end of the day	Agreement	.
					I was satisfied by the clarity of my vision throughout the day	Agreement	.
					The following items will cover your experience Handling these lenses. Please answer all of the items in relation to your experience with the current lenses.		.
					The handling of these lenses was convenient	Agreement	.
					These lenses were folding on my finger when I attempted to insert them	Agreement	.
					It was easy to pick up these lenses	Agreement/NA	.
					When preparing for insertion, these lenses stood up on my finger	Agreement/NA	.
					It was easy to remove these lenses from my eyes	Agreement	.
					These lenses felt as though they were stuck to my eyes when I tried to remove them	Agreement	.
					The handling of these lenses was exceptional	Agreement	.

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form [redacted]	Type [redacted]	PRO Domain	PRO Sequence	Item ID# [redacted]	Item Wording	Response Set	Page Number
[redacted]					Please read the following instructions carefully. .• Your opinion is extremely important to us..• Please complete the following questionnaire based on your experience with the contact lenses you were provided. It is important that your answers be based on your own personal opinion as well as your interpretation of the question. Please do not ask others for direction..• Please make every effort to answer each question to the best of your ability and do not leave any question blank. Please be as honest and sincere as possible. If asked to write in an answer, please be as specific as you can. .• Most questions can be answered by checking the appropriate box. Please pay close attention, though, to any additional instructions relating to individual questions throughout the questionnaire. .• Please note that all your answers will be kept strictly confidential.	INSTRUCT	1
					Thank you for your participation in the study.	INSTRUCT	1
					Considering your experience with the study contact lenses, which statement best describes how you feel about buying these contact lenses, assuming they are offered at an acceptable price?	PurchaseR	2
					Considering your experience with the study contact lenses, which statement best describes your overall opinion of these contact lenses?	ExcellenceR	3
					Please think about your experience with the study contact lenses. Please indicate how you would rate the contact lenses on each of the following characteristics.	INSTRUCT	4
					Overall quality of vision	ExcellenceRNAFirst	4
					Clarity of vision during daily activities	ExcellenceRNAFirst	4
					Clarity of vision at the end of the day	ExcellenceRNAFirst	4
					Clarity of vision when changing head position	ExcellenceRNAFirst	4
					Not seeing distortion in the appearance of things	ExcellenceRNAFirst	4
					Clarity of vision no matter which direction you look	ExcellenceRNAFirst	4
					Please think about your experience with the study contact lenses. Please indicate how you would rate the contact lenses on each of the following characteristics.	INSTRUCT	5

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form [redacted]	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# [redacted]	Item Wording	Response Set	Page Number
[redacted]					Overall comfort	ExcellenceRNAFirst	5
					Comfort immediately when you first put them in	ExcellenceRNAFirst	5
					Comfort throughout the day	ExcellenceRNAFirst	5
					Comfort each and every day	ExcellenceRNAFirst	5
					Comfort at the end of the day	ExcellenceRNAFirst	5
					Absence of irritation	ExcellenceRNAFirst	5
					Not making your eyes feel dry throughout the day	ExcellenceRNAFirst	5
					Keeping your eyes from feeling dry at the end of the day	ExcellenceRNAFirst	5
					Making your eyes feel moist throughout the day	ExcellenceRNAFirst	5
					Feeling free from deposits and build-up	ExcellenceRNAFirst	5
					Please think about your experience with the study contact lenses. Please indicate how you would rate the contact lenses on each of the following characteristics.	INSTRUCT	6
					Overall ease of handling	ExcellenceRNAFirst	6
					Ease of putting the lenses in your eyes	ExcellenceRNAFirst	6
					Ease of taking the lenses out of your eyes	ExcellenceRNAFirst	6
					Not folding in half while handling	ExcellenceRNAFirst	6
					Considering everything about the study contact lenses, which of the following phrases best describes how you feel about them? SELECT ONLY ONE	CompareR	7
					Considering everything about the study contact lenses, which of the following phrases best describes how you feel about them in comparison to your current contact lenses, the lenses you wore before the study began? SELECT ONLY ONE	StudyCurrentLensR	8
					How would you describe your awareness of the study contact lenses throughout the day? SELECT ONLY ONE	AwareInEye	9
					Please describe your vision provided throughout the day by the study contact lenses. SELECT ONE FOR EACH	INSTRUCT	10
					My vision is crisp	AgreeDisagreeR	10
					My vision is clear	AgreeDisagreeR	10

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form [redacted]	Type [redacted]	PRO Domain	PRO Sequence	Item ID# [redacted]	Item Wording	Response Set	Page Number
[redacted]					My vision is dependable	AgreeDisagreeR	10
					My vision is hassle-free	AgreeDisagreeR	10
					My vision is reliable	AgreeDisagreeR	10
					Please describe the comfort the contact study lenses provided.	INSTRUCT	11
					The study contact lenses provided dependable comfort	AgreeDisagreeR	11
					The study contact lenses provided hassle-free comfort	AgreeDisagreeR	11
					The study contact lenses provided reliable comfort	AgreeDisagreeR	11
					The study contact lenses provided long lasting comfort	AgreeDisagreeR	11
					Please indicate how often, if ever, you experienced the following visual issues when you wore the study contact lenses.	INSTRUCT	12
					Blurred vision throughout the day	FrequencyDKR	12
					Blurred vision at the end of the day	FrequencyDKR	12
					Eye strain	FrequencyDKR	12
					Please indicate how often, if ever, you experienced the following sensations when you wore the study contact lenses.	INSTRUCT	13
					Dryness	FrequencyDKR	13
					Irritation	FrequencyDKR	13
					Redness	FrequencyDKR	13
					Lens Awareness (feeling of noticing the lens on your eye).	FrequencyDKR	13
					While wearing the study contact lenses, how many days, if any, did you use rewetting drops? ENTER NUMBER BELOW ..If you did not use rewetting drops while using the study contact lenses, please input "0" in the space below.	RewetDaysStudy	14
					When you used rewetting drops, how many times during a typical day did you apply them when wearing the study contact lenses? ENTER NUMBER BELOW ..Again, if you did not use rewetting drops while using the study contact lenses, please input "0" in the space below.	RewetFreqStudy	15
					While wearing the study contact lenses, how often did you need to blink several times in order to clear your vision?..	BlinkSeveralTimesDays	16

PRO Form Specifications for Forms Used in 5871 Version 3 Final							
Form [redacted]	Type [redacted]	PRO Domain	PRO Sequence	Item ID# [redacted]	Item Wording	Response Set	Page Number
[redacted]					How many times during a typical day did you need to blink several times in order to clear your vision when wearing the study contact lenses? ENTER NUMBER ONLY BELOW ..Again, If you did not need to blink several times in order to clear your vision while using the study contact lenses, please input "0" in the space below.	OpenNum	17
					If your eye doctor prescribed the study contact lenses to you, please indicate how, if at all, your opinion of your eye doctor would change. SELECT ONLY ONE	ECPOpinionR	18
					PLEASE LET THE INVESTIGATOR OR A STAFF MEMBER KNOW WHEN YOU ARE FINISHED WITH THIS QUESTIONNAIRE.	INSTRUCT	19

PRO Response Option Specifications for Forms Used in 5871 Version 3 Final				
Type [redacted]	Response Set	Selections	Raw Coding	Text Displayed
[redacted]	Agreement	Single	1	Strongly Disagree
			2	Disagree
			3	Neither Agree Nor Disagree
			4	Agree
			5	Strongly Agree
	Agreement/NA	Single	0	Not Applicable
			1	Strongly Disagree
			2	Disagree
			3	Neither Agree Nor Disagree
			4	Agree
			5	Strongly Agree
	AgreeDisagreeR	Single	1	Agree Strongly
			2	Agree Somewhat
			3	Neither Agree Nor Disagree
			4	Disagree Somewhat
			5	Disagree Strongly
	AwareInEye	Single	1	I am not aware of them being in my eyes
			2	I am barely aware of them being in my eyes
			3	I am slightly aware of them being in my eyes
			4	I am moderately aware of them being in my eyes
			5	I am very aware of them being in my eyes
	BlinkSeveralTimesDays	Single	1	Never
			2	Rarely
			3	Sometimes
			4	Often
			5	Always
	CompareR	Single	1	The best contact lenses I have ever used or tried
			2	Somewhat better than other contact lenses I have used or tried
			3	About the same as other contact lenses I have used or tried
			4	Somewhat worse than other contact lenses I have used or tried

PRO Response Option Specifications for Forms Used in 5871 Version 3 Final				
Type [redacted]	Response Set	Selections	Raw Coding	Text Displayed
			5	The worst contact lenses I have ever used or tried
	DAYSPERWK	Single	1	7 days/week
			2	5-6 days/week
			3	3-4 days/week
			4	1-2 days/week
			5	Less often than 1 day/week
	DrynessR	Single	1	Normal
			2	Slightly dry
			3	Dry
			4	Very dry
	ECPOpinionR	Single	1	Much more favorable opinion
			2	Somewhat more favorable opinion
			3	Same opinion
			4	Somewhat less favorable opinion
			5	Much less favorable opinion
	ExcellenceR	Single	1	Excellent
			2	Very Good
			3	Good
			4	Fair
			5	Poor
	ExcellenceRNAFirst	Single	0	Not Applicable
			1	Excellent
			2	Very Good
			3	Good
			4	Fair
			5	Poor
	EyeCondition	Single	1	Healthy, I never have problems with my eyes
			2	Healthy, but I occasionally have problems with my eyes
			3	I frequently have problems with my eyes
			4	I always have problems with my eyes
	FrequencyDKR	Single	1	Always
			2	Frequently

PRO Response Option Specifications for Forms Used in 5871 Version 3 Final				
Type [redacted]	Response Set	Selections	Raw Coding	Text Displayed
			3	Occasionally
			4	Rarely
			5	Never
			6	Don't Know
	INSTRUCT	Single	.	
	Length	Single	1	Less than 1 month
			2	1 month or more but less than 3 months
			3	3 months or more but less than 6 months
			4	6 months or more but less than 1 year
			5	1 year or more but less than 2 years
			6	2 years or more but less than 5 years
			7	5 years or more but less than 10 years
			8	10 years or more
	OpenNum	Single	.	
	PurchaseR	Single	1	Definitely would buy them
			2	Probably would buy them
			3	Might or might not buy them
			4	Probably would not buy them
			5	Definitely would not buy them
	RewetDaysStudy	Single	1	# of days used rewetting drops while wearing study contact lenses
	RewetFreqStudy	Single	1	# of times per typical day used rewetting drops while wearing study contact lenses
	SensitivityR	Single	1	Normal
			2	Slightly sensitive
			3	Sensitive
			4	Very sensitive
	StudyCurrentLensR	Single	1	Much better than my current contact lenses
			2	Somewhat better than my current contact lenses
			3	About the same as my current contact lenses
			4	Somewhat worse than my current contact lenses

PRO Response Option Specifications for Forms Used in 5871 Version 3 Final				
Type [redacted]	Response Set	Selections	Raw Coding	Text Displayed
			5	Much worse than my current contact lenses
	YesNo	Single	1	Yes
			2	No

16.2 CLINICAL TECHNICAL PROCEDURES (CTPS)

Applicable	[redacted] Codes	Title
		Pre-Ocular and Pre-Lens Wettability
X		Limbal and Conjunctival (BULBAR) Redness
X		Expanded Sodium Fluorescein Corneal Staining
		Determination of Near Addition
		Near LogMAR Visual Acuity Measurement Procedure
		Contact Lens Centration Measurements with a Slit Lamp Reticle
X		Lens Fitting Characteristics
X		Subjective Report Ocular Symptoms / Problems
X		Trapped Back Surface Debris and Mucin Plug Grading Procedure
X		Front and Back Surface Lens Deposit Grading Procedure
		Cornea Striae and Corneal Folds Grading Procedure
		Corneal Microcyst and Vacuole Grading Procedure
		Evaluation of Corneal Vascularization
X		Determination of Distance Spherocylindrical Refractions
		Visual Symptom Frequency Questionnaire
X		Biomicroscopy Scale
		Video Recording for Soft Contact Lens Fitting Measurements
		Tarsal Roughness and Tarsal Redness
X		Conjunctival Staining
		Keratometry Procedure
X		Distance and Near Visual Acuity Evaluation
X		Toric Fit Evaluation
		Upper Lid Margin Staining
X		Distance LogMAR Visual Acuity Measurement Procedure
		Measurement of COAS Wavefront Aberrations
X		White Light Lens Surface Wettability

16.3 PATIENT INSTRUCTION GUIDE (APPROVED PRODUCT)

A Patient Instruction Guide will be provided separately.

16.4 PACKAGE INSERT

A Package Insert will be provided separately.

17.1 LIST OF ABBREVIATIONS

AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CIB	Clinical Investigator's Brochure
CRF	Case Report Form
CRO	Contract Research Organization
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
IRB	Institutional Review Board
MedDRA ©	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
OHSR	Office for Human Subjects Research
PHI	Protected Health Information
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect

APPENDIX A: [redacted] Limbal & Conjunctival (Bulbar) Redness

[redacted]

Limbal and Bulbar Conjunctival Redness

REDNESS

	OD					OS			
	N	T	I	S		N	T	I	S
Limbal					Limbal				
Bulbar					Bulbar				

LEVEL OF REDNESS: Refer to the Efron Grading Scale

0: Normal 1: Trace 2: Mild 3: Moderate 4: Severe

APPENDIX B: [redacted] Expanded Sodium Fluorescein Corneal Staining

APPENDIX C: [redacted] Lens Fitting Characteristics

APPENDIX D: [redacted] Subject Reported Ocular Symptoms/Problems

APPENDIX E: [redacted] Trapped Back Surface Debris and Mucin Plug Grading Procedure

APPENDIX F: [redacted] Front and Back Surface Lens Deposit Grading Procedure

APPENDIX G: [redacted] Determination of Distance Spherocylindrical Refractions

APPENDIX H: [redacted] Biomicroscopy Scale

APPENDIX I: [redacted] Conjuntival Staining

APPENDIX J: [redacted] Distance and Near Visual Acuity Evaluation

APPENDIX K: [redacted] Toric Fit Evaluation

APPENDIX L: [redacted] Distance LogMAR Visual Acuity Measurement Procedure

APPENDIX M: [redacted] White Light Lens Surface Wettability

APPENDIX N: [redacted] Visual Acuity Chart Luminance and Room Illumination Testing