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

Clinical Study Protocol

Long-term Evaluation of [redacted] UV Blocker

Protocol Number: CR-5638
Version: 6.0, Amendment 5.0
Date: 13 October 2016

Distribution
Ms. Leilani Sonoda

Key Words
senofilcon
Photochromic
Physiological Response
Subjective Performance
Fitting Characteristics
Dispensing
Daily Wear

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1.1 PROTOCOL TITLE, NUMBER, DATE

TITLE: Long-term Evaluation of [redacted] UV Blocker
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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: John R. Buch, O.D., M.S., F.A.A.O. Title: Principal Research Optometrist	DATE
Biostatistician:	**See Electronic Signature Report**	
	Name: Jessica Cannon, M.S. Title: Biostatistician II	DATE
R&D Platform Lead:	**See Electronic Signature Report**	
	Name: Zohra Fadli, Ph.D. Title: Principal Scientist, Platform Lead	DATE
Clinical Operations:	**See Electronic Signature Report**	
	Name: Hongzhi Guo Title: Clinical Operations Manager	DATE
Reviewer :	**See Electronic Signature Report**	
	Name: Randy Paulk Title: Clinical Project Manager, Data and System	DATE

1.4 MEDICAL MONITOR

NAME: John R. Buch, O.D., M.S., F.A.A.O.
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 clinical site may be supplied an Adverse Event form to complete regarding the adverse event evaluation.

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

The clinical study report is expected within 90 days after hard data lock.

1.7 CHANGE HISTORY

Revision	Originator	Description of Change(s)	Date
1.0	John R. Buch	New Protocol	09 September 2016
2.0	John R. Buch	Section 1.4, removed medical monitoring plan (will be provided separately) Section 4.7.1, removed GSI questionnaire from visit 3, visit 4, visit 5 and visit 6	14 September 2016
3.0	John R. Buch	Moved Inclusion criteria #1 to instruction	19 September 2016
4.0	John R. Buch	Section 4.7.1, visit 1, baseline, slit lamp step 9, change to 'Grade 2 or greater'. Section 4.7.1, visit 1, baseline refraction step 12, change to '20/25+3 or better'.	23 September 2016
5.0	John R. Buch	Section 1.8 & 4.2, Inclusion critiera #5, changed cylinder to ≤1.00 Section 4.7.1 changed the Slit Lamp Findings instructions at Visits 2-8 Section 4.7.1, changed Dispensing Note 2 in Visits 1, 3, 4 & 5 in the dispensing step from 'cannot be worn at any time…' to 'cannot be worn until during Visit 6.' Section 4.7.1, added that lenses can be stored at room temperature in Dispensing Note 3 in Visits 4 and 5 Section 4.7.1, Visit 6, step 21 moved to after step 18 and re-numbered Section 4.7.1, Visit 6, Habitual Lens Release #1, language changed from 'dispense' to 'worn.'	04 October 2016
6.0	Jessica Cannon	Section 1.8 was updated to included eyestrain as an efficacy primary parameter. Section 4.1 updated both Primary Efficacy Hypotheses and the secondary efficacy hypothesis to be assessed at 2-, 4-, 8- and 12-week follow-ups Section 7.1 was updated, this section included endpoints that were not listed in the hypotheses section. Section 4.7.1, Vist 7, step 18 and Vist 8, step 17, changed the Slit Lamp findings instructions. CTP[redacted] added to Protocol.	13 October 2016

1.8 PROTOCOL SYNOPSIS

Protocol Number and Title: 5638 – Long-term Evaluation of [redacted] UV Blocker
Sponsor: JJVCI, 7500 Centurion Parkway, Jacksonville, FL 32256
Investigational Product: Senofilcon-based contact lens containing [redacted] UV blocker in 1% concentration throughout the entire lens.
Ancillary Supplies: Optifree PureMoist

Randomization and Dispensing: Subjects will be randomly fit with either the investigational lenses on both eyes, or the control lens on both eyes. After three months of wearing the study lenses, all subjects will return to their habitual lenses for two weeks.
Principal Investigators: TBD
Study Sites: External, U.S.
Microbiology or Other Testing Laboratory: NA
Phase or Type of Study: Feasibility B
Primary Endpoint: The primary endpoints are the safety and efficacy of the investigational product measured every 2 or 4 weeks over a 12 week period. • Safety: Biomicroscopy findings • Efficacy: Distance monocular logMAR acuity • Efficacy: Eyestrain caused by glare **Secondary Endpoint**: The secondary endpoints are the safety and efficacy of the investigational product measured every 2 or 4 weeks over a 12 week period • Safety: Ocular symptoms • Efficacy: Wearing time **Other Observations:** • Subjective performance as measured by the [redacted] and lens Preference
Study Design: This study is a randomized, 8-visit, partially subject-masked (Control arm only), 14-weeks dispensing trial. The study lenses will be worn as daily wear (DW) for a period of 12 weeks, with follow-up visits occurring after 1, 2, 4, 8 and 12 weeks. Afterwards, the habitual lenses will be worn for a period of two weeks with weekly visits. The lenses are expected to be worn at least five (5) days per week for at least six (6) hours per day worn.
Sample Size: Approximately 60 test subjects and approximately 60 control subjects will be enrolled with the intent of completing with 50 cohorts in each group. A replacement subject may be enrolled if a subject discontinues from the study prematurely; the decision whether to enroll replacement subjects will be made by the joint agreement of the Investigator and Sponsor.
Screening: Healthy male and female volunteers (≥18 years) will be screened as per criteria outlined below.

Qualification, Dispensing and Follow-Up Procedures:

Screening: Subjects will complete informed consent. Demographics and medical history will be reviewed. Subjects must meet all of the study inclusion criteria to continue in the study.

Study Product: Approximately 50% of the subjects will be assigned an investigational lens with a new UV blocker on both eyes, while the remaining ~50% of the subjects will be assigned a control lens on both eyes.

Study Dispensing Procedures: Lenses must display 20/30 visual acuity or better OD and OS, an acceptable lens fit OD and OS, and the approval of the investigator.

Follow-up Visits: All volunteers will return to the clinic based on the following schedule:

Visit #	Follow-up Visit Title	Visit Window
2	7 days after visit 1	±1 day
3	7 days after visit 2	±1 day
4	14 days after visit 3	±2 days
5	28 days after visit 4	±4 days
6	28 days after visit 5, Return to habitual lenses	±4 days
7	7 days after visit 6	±1 day
8	7 days after visit 7	±1 day

Adverse event and concomitant medication reporting and study completion will be recorded.

Study Population Characteristics: Participant subjects will be at least 18 years of age or older who fulfill the following inclusion/exclusion criteria: Subjects should meet all study Inclusion Criteria as outlined below:

1. The subject must read and sign the Informed Consent form.
2. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. Healthy adult males or females age ≥ 18 years of age with signed informed consent. Eligible presbyopes will be those that wear full distance contact lenses in both eyes, then wear reading glasses over them.
4. The subject's optimal vertexed spherical equivalent distance correction must be between -1.00 and – 6.00D.
5. The subject's refractive cylinder must be ≤ 1.00D in each eye.
6. The subject must have visual acuity best correctable to 20/25+3 or better for each eye.
7. Subjects should own a wearable pair of spectacles.
8. The subject is a current spherical soft contact lens wearer (defined as a minimum of 6 hours of DW per day, at least 5 days per week, for a minimum of 1 month prior to the study) and willing to wear the study lenses on a similar basis.
9. Subjects must be able and willing to wear the study lenses at least 6 hours a day, a minimum of 5 days per week
10. The subject must have normal eyes (i.e., no ocular medications or infections of any type).

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

1. Currently pregnant or lactating (subjects who become pregnant during the study will be discontinued).
2. Any systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear. This may include, but not be limited to, diabetes, hyperthyroidism, recurrent herpes simplex/zoster, Sjögren's syndrome, xerophthalmia, acne rosacea, Stevens-Johnson syndrome, and immunosuppressive diseases or any infectious diseases (e.g. hepatitis, tuberculosis).
3. Use of any of the following medications within 1 week prior to enrollment: oral retinoid isotretinoin (e.g. Accutane), oral tetracyclines, topical scopolamine, oral (e.g. Seldane, Chlor-Trimeton, and Benadryl) and ophthalmic antihistamines, oral phenothiazines (e.g., Haldol, Mellaril, Thorazine, Elavil, Pamelor, Compazine), oral and ophthalmic Beta-adrenergic blockers (e.g., Propranolol, Timolol, and Practolol), systemic steroids, and any prescribed or over the counter (OTC) ocular medication.
4. Entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or moderate or above corneal distortion by keratometry.
5. Any previous, or planned, ocular or interocular surgery (e.g.., radial keratotomy, PRK, LASIK, etc.).
6. Any grade 2 or greater slit lamp findings (e.g.., edema, corneal neovascularization, corneal staining, tarsal abnormalities, conjunctival injection) on the FDA classification scale, any previous history or signs of a contact lens-related corneal inflammatory event (e.g.., past peripheral ulcer or round peripheral scar), or any other ocular abnormality that may contraindicate contact lens wear.
7. Any known hypersensitivity or allergic reaction to Optifree®Puremoist® multi-purpose care solution or Eye-Cept® rewetting drop solution
8. Any ocular infection, allergy or clinically significant ocular disease (e.g. corneal edema, uveitis, severe keratoconjunctivitis sicca, ocular hypertension), or ocular conditions (e.g. strabismus), which might interfere with the study.
9. Any corneal distortion resulting from previous hard or rigid gas permeable contact lens wear.
10. Toric, extended wear, monovision or multi-focal contact lens correction.
11. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.
12. History of binocular vision abnormality or strabismus.
13. Employee or relative of employees of sponsor or investigational clinic (e.g., Investigator, Coordinator, Technician)

Schedule of Events:

Procedure	Baseline	Trial Fit & Dispense	Follow-up 1, 2, 3, 4, 5, 6, 7	Unsched	Exit
Visit	1	1	2, 3, 4, 5, 6, 7, 8	PRN	8
Informed consent	✓	-	-	-	-
Eligibility screening	✓	-	-	-	-
PRO Baseline Questionnaires	✓	-	-	-	-
Subject demographics	✓	-	-	-	-
General health and medication history	✓	-	-	-	-
Subject's own contact lens information	✓	-	-	-	-
Habitual lens care	✓	-	-	-	-
Visual acuity (Snellen)	✓	-	-	-	✓
Spherocylindrical refraction and BVA	✓	-	-	✓	✓
Slit lamp biomicroscopy	✓	-	✓	✓	-
Keratometry	✓	-	-	-	✓
Trial fitting lens information	-	✓	-	-	-
Lens Damage	-	✓	-	-	-
Distance spherical over-refraction	-	✓	✓	-	-
Lens modification	-	✓	-	-	-
Symptoms	-	✓	✓	✓	-
PRO dispensing questionnaires	-	✓	-	-	-
Visual acuity (logMAR)	-	✓	✓	✓	-
Lens fitting assessment	-	✓	✓	*	-
Lens dispensing information and criteria	-	✓	-	-	-
Patient instructions	-	✓	-	-	-
Lens information	-	-	✓	✓	-
Compliance	-	-	✓	✓	-
Wearing times	-	-	✓	✓	-
PRO follow-up questionnaires	-	-	✓	*	-
Surface characteristics	-	-	✓	*	-
Chief complaint, diagnosis, treatment	-	-	-	✓	-

* If wearing lenses

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 through the study period of ~14 weeks. Habitual medications taken by successful soft contact lens wearers are considered acceptable. Note that habitual medications should be taken throughout the study period.

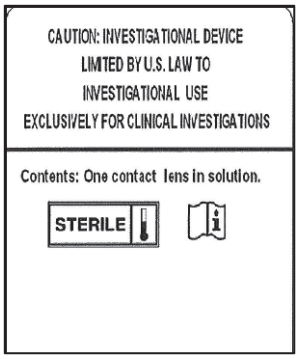
Stopping Rules:

The occurrence of one or more Unanticipated Adverse Device Effect (UADE), or any SAE where relationship to study agent cannot be ruled out, will result in prompt investigation and possible stopping of further dispensing investigational product. In the event of a UADE or SAE, the Sponsor Medical Monitor may unmask the treatment regimen of subject(s) and may discuss this with the Investigator before any further subjects are enrolled.

Clinical Safety: Assessments by the Investigator will occur at all study visits and will include review of Adverse Events and Concomitant Medications. A Safety Review Board (SRB) will be formed in association with this study. The SRB will include the medical monitor and clinical research manager (CRM). The medical monitor and CRM will review and evaluate all events and will determine if the remaining subjects assigned to that treatment group may proceed with treatment.
Laboratory Review: The collection of samples is not required in this study.
Safety Review Board: A Safety Review Board (SRB) will be formed in association with this study. The SRB will include the medical monitor and clinical research manager (CRM). The medical monitor and CRM will review and evaluate all events and will determine if the remaining subjects assigned to that treatment group may proceed with treatment.
Statistical Methods: All data summaries and statistical analyses will be performed using the SAS software Version 9.4 or higher (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 analysis.

2.1 NAME AND DESCRIPTION OF INVESTIGATIONAL PRODUCTS

The following contact lenses will be used in this study:

	Control (Oasys)	Test
Manufacturer	JJVCI	JJVCI
Lens Design	PHN130	ECL100
Production Run Number	Varies	[redacted]
Packaging Form	Sterile blister pack	Sterile blister pack
Nominal Water Content	38	38
Nominal Dk (edge corrected)	103	103
Nominal Modulus	101	101
Inversion Indicator	123	123
Nominal Base Curve/Diameter @ 22 °C (mm)	8.4 / 14.0	8.4 / 14.0
Nominal Center Thickness @ -3.00 D (mm)	0.070	0.085
Nominal Powers (D)	-1.00 to -6.00 in 0.25 steps	-1.00 to -6.00 in 0.25 steps
Norbloc UV Blocker	Yes	Yes
[redacted] UV Blocker	No	Yes
Example of Foil		

The following solutions will be used in this study:

SOLUTIONS	
Solution Name / Description	Opti-Free® PureMoist®
Lot Number or Other Identifier	Varies
Manufacturer	Alcon Laboratories, Fort Worth, TX
Maximum Preservative	0.001% polyquaternium-1, 0.0006% myristamidopropyl dimethylamine

Additional Supplies: Preservative free rewetting drops/artificial tears will be supplied for use as needed. Opti-Free® PureMoist® multipurpose solution will be used for storing lenses between insertions.

2.2 SUMMARY OF FINDINGS FROM NONCLINICAL STUDIES

All previous pre-clinical findings were deemed satisfactory to proceed with clinical trial on humans. For most comprehensive nonclinical information regarding the Test lens, refer to the Investigator's Brochure.

2.3 SUMMARY OF KNOWN RISKS AND BENEFITS TO HUMAN SUBJECTS

The risks of wearing soft contact lenses are well known and are described in the [redacted] and Informed Consent. Of interest to this study are the relatively unfamiliar risks involved with bothersome light. Glare affects all individuals and can be more than just an occasional annoyance. The Automobile Association in the UK estimates that glare was responsible for 36 deaths and nearly 3,000 car accidents in 2013 (Massey 2013)[1]. This type of glare is often called disability glare since it disables a person from performing a task. Less obtrusive is discomfort glare. Discomfort glare is the sensation of annoyance or even pain induced by overly bright sources. This can be an immediate sensation such as having a computer screen in front of a bright window. It can also be a delayed response. This type of delayed, bothersome light is present as a form of light pollution and generally becomes noticeable when it is removed (e.g., shielding your eyes from overhead office lights). The eyestrain that is produced by glare can cause ocular redness, lacrimation, pain, fatigue, blurred vision, and headache (Sheedy, Hayes et al. 2003)[2]. The potential benefits to human subjects for a contact lens that reduces eyestrain caused by glare is evident.

2.4 DESCRIPTION OF TRIAL TREATMENTS

The lenses are described in section 2.1 and in the [redacted]. The lenses will be worn in a bilateral fashion using a 2-arm parallel group design.

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 60 test subjects and approximately 60 control subjects will be enrolled with the intent of completing approximately 50 cohorts in each group. Enrolled subjects will be habitual wearers of spherical contact lenses worn on a daily wear basis. All subjects will be ≥ 18 years of age. Subjects will wear the study contact

[1] Massey, R. (2013). The dazzling sunsets that kill 36 drivers in 12 months: Glare contributes to 3,000 accidents and is particularly dangerous at this time if year. The Daily Mail.

[2] Sheedy, J. E., et al. (2003). "Is all asthenopia the same?" Optometry & Vision Science **80**(11): 732-739.

lenses for approximately 12 weeks on a daily wear (DW) basis, then wear their habitual lenses for approximately 2 weeks, for a total study duration of approximately 14 weeks (98 days) per subject.

2.7 RELEVANT LITERATURE REFERENCES AND PRIOR DATA

See [redacted]

3.1 DESCRIPTION OF OBJECTIVES AND PURPOSE

The purpose of this investigation is to evaluate the safety and efficacy of the JJVCI Investigational Contact Lens with new UV blocker by comparison with the otherwise similar ACUVUE® OASYS® when worn for as daily wear with lens replacement every two weeks for 12 weeks.

This is a pilot study and all primary and secondary hypotheses are exploratory in nature.

4.1 PRIMARY AND SECONDARY ENDPOINTS

4.1.1 Primary Efficacy and Safety Endpoints:

The co-primary endpoints for efficacy evaluations are:

1. Eyestrain caused by glare score. This will be assessed using eyestrain patient reported outcomes.
2. Monocular distance visual acuity on LogMAR scale using ETDRS charts.

The primary endpoint for safety evaluation is physiological findings (grade 3 or higher) using slit lamp. The measures include edema, corneal neovascularization, corneal staining, conjunctival injection, tarsal abnormalities, and other complications using the FDA slit lamp grading scale 0 to 4, where 0 = none, 1 = trace, 2 = Mild, 3 = moderate and 4 = severe.

4.1.2 Secondary Efficacy and Safety Endpoints:

The secondary endpoints are average daily wear time (in hours) and presence of ocular symptom (yes/no).

Both primary and secondary endpoints will be evaluated at each follow-up visit.

The subject's adverse events, keratormety changes, lens deposit, reasons for discontinuation, lens damage, number and reasons for unscheduled lens replacement, overall comfort, overall vision and overall handling will be monitored at the follow-up visits.

4.1.3 Primary Hypotheses:

1. Efficacy (Eyestrain caused by glare): Subjects wearing the JJVCI Investigational Test contact lenses on a daily wear basis report eyestrain caused by glare that is, on average, significantly lower to that of subjects wearing ACUVUE® OASYS® contact lenses on a daily wear basis. The assessments will be made at the 2-, 4-, 8- and 12-week follow-up visits.

2. Efficacy (Visual Acuity): Subjects wearing the JJVCI Investigational Test contact lenses on a daily wear basis report an average distance monocular logMAR visual acuity that is statistically no different to that of subjects wearing ACUVUE® OASYS® contact lenses on a daily wear basis. The assessments will be made at the 2-, 4-, 8- and 12-week follow-up visits.

3. Safety (Slit Lamp Findings): Subjects wearing the JJVCI Investigational Test contact lenses on a daily wear basis have a percentage of grade 3 or higher slit lamp findings that is statistically no different to that of

subjects wearing ACUVUE® OASYS® Contact Lenses on a daily wear basis. The assessments will be made at each follow-up visit.

4.1.4 Secondary Hypotheses:

1. Efficacy (Average Wear Time): Subjects wearing the JJVCI Investigational Test contact lenses on a daily wear basis report an average daily wear time that is statistically no different to that of subjects wearing ACUVUE® OASYS® contact lenses on a daily wear basis. The assessments will be made at the 2-, 4-, 8- and 12-week follow-up visits.

2. Safety (Symptoms): Subjects wearing the JJVCI Investigational Test contact lenses on a daily wear basis have a percentage of reported symptoms, problems, or complaints (Yes or No) that is statistically no different to that of subjects wearing ACUVUE® OASYS® contact lenses on a daily wear basis. The assessments will be made at each follow-up visit.

4.2 INCLUSION CRITERIA

Potential subjects must satisfy all of the following criteria to be enrolled in the study:
Subjects should meet all study Inclusion Criteria as outlined below:

1. The subject must read and sign the Informed Consent form.
2. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. Healthy adult males or females age ≥ 18 years of age with signed informed consent. Eligible presbyopes will be those that wear full distance contact lenses in both eyes, then wear reading glasses over them.
4. The subject's optimal vertexed spherical equivalent distance correction must be between -1.00 and – 6.00D.
5. The subject's refractive cylinder must be ≤ 1.00D in each eye.
6. The subject must have visual acuity best correctable to 20/25+3 or better for each eye.
7. Subjects should own a wearable pair of spectacles.
8. The subject is a current spherical soft contact lens wearer (defined as a minimum of 6 hours of DW per day, at least 5 days per week, for a minimum of 1 month prior to the study) and willing to wear the study lenses on a similar basis.
9. Subjects must be able and willing to wear the study lenses at least 6 hours a day, a minimum of 5 days per week
10. The subject must have normal eyes (i.e., no ocular medications or infections of any type).

4.3 EXCLUSION CRITERIA

Potential subjects who meet any of the following criteria will be excluded from participating in the study:

1. Currently pregnant or lactating (subjects who become pregnant during the study will be discontinued).
2. Any systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear. This may include, but not be limited to, diabetes, hyperthyroidism, recurrent herpes simplex/zoster, Sjögren's syndrome, xerophthalmia, acne rosacea, Stevens-Johnson syndrome, and immunosuppressive diseases or any infectious diseases (e.g. hepatitis, tuberculosis).
3. Use of any of the following medications within 1 week prior to enrollment: oral retinoid isotretinoin (e.g. Accutane), oral tetracyclines, topical scopolamine, oral (e.g. Seldane, Chlor-Trimeton, and Benadryl) and ophthalmic antihistamines, oral phenothiazines (e.g., Haldol, Mellaril, Thorazine, Elavil, Pamelor, Compazine), oral and ophthalmic Beta-adrenergic blockers (e.g., Propranolol, Timolol, and Practolol), systemic steroids, and any prescribed or over the counter (OTC) ocular medication.
4. Entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or moderate or above corneal distortion by keratometry.
5. Any previous, or planned, ocular or interocular surgery (e.g.., radial keratotomy, PRK, LASIK, etc.).

6. Any grade 2 or greater slit lamp findings (e.g.., edema, corneal neovascularization, corneal staining, tarsal abnormalities, conjunctival injection) on the FDA classification scale, any previous history or signs of a contact lens-related corneal inflammatory event (e.g.., past peripheral ulcer or round peripheral scar), or any other ocular abnormality that may contraindicate contact lens wear.
7. Any known hypersensitivity or allergic reaction to Optifree®Puremoist® multi-purpose care solution or Eye-Cept® rewetting drop solution
8. Any ocular infection, allergy or clinically significant ocular disease (e.g. corneal edema, uveitis, severe keratoconjunctivitis sicca, ocular hypertension), or ocular conditions (e.g. strabismus), which might interfere with the study.
9. Any corneal distortion resulting from previous hard or rigid gas permeable contact lens wear.
10. Toric, extended wear, monovision or multi-focal contact lens correction.
11. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.
12. History of binocular vision abnormality or strabismus.
13. Employee or relative of employees of sponsor or investigational clinic (e.g., Investigator, Coordinator, Technician).

4.4 STUDY DESIGN, TIME AND EVENTS SCHEDULE, FLOWCHART

This is a randomized, partially subject masked (control arm only), controlled, 2-arm parallel group, multi-site, 3-month dispensing study of JJVCI Investigational Contact Lens (Test). Approximately 120 subjects will be screened and enrolled to ensure that at least 60 subjects are randomly assigned to either JJVCI Investigational contact lens (Test) or ACUVUE® OASYS® contact lens (Control). The goal is for a sample size of 100 after subjects who withdraw or are lost-to-follow-up.

The study will begin with an Initial Visit (Visit 1 = Day 0). If a subject is found to meet all eligibility criteria (see section 4.3), they will be randomized and fit with either Test or Control lens in both eyes. Otherwise the subject will be deemed ineligible for this study.

If the subject is dispensed at the Initial Visit, then the five follow-up visits will be conducted. The follow-up visits will occur approximately at 1-, 2-, 4-, 8- and 12-week after the Initial Visit. Unscheduled follow-up visits may occur during the study. Subjects will be advised to wear the study lenses at least 6 hours a day, a minimum of 5 days per week and wear the study lenses to the follow-up visit. Both the Test and Control lenses will be worn as a daily wear with lens replacement every two weeks including at the 2-, 4-, 8-week follow-up visits.

The Investigator is responsible for ensuring that all subjects entering the study conform to subject selection criteria. The number of subjects targeted for randomization and completion are as follows:

	Target to complete
Subjects	120 subjects (60 Test and 60 Control)
Sites	6
Subject/site	15 (minimum) 25 (maximum)
Randomization of less than the minimum will require Sponsor notification as soon as possible.	

Visit	Description	≈ Duration
1	Informed consent, eligibility criteria, baseline data. Subjects will be fit with test lenses or control lenses on both eyes.	2.0 hours
2	7-days (±1 days) from visit 1. First follow-up for the test lens, subjective responses including **preferences**, VA, fitting characteristics, surface characteristics, physiology. Same study lenses to be worn for approximately one more week.	1.0 hours
3	7-days (±1 days) from visit 2. Second follow-up for the test lens, subjective responses, VA, fitting characteristics, surface characteristics, physiology. New lenses of the same power and type will be dispensed for approximately 2 weeks.	1.5 hours
4	14-days (±2 days) from visit 3. Third follow-up for the test lens, subjective responses, VA, fitting characteristics, surface characteristics, physiology. Four new lenses of the same power and type will dispensed for approximately 4 weeks (biweekly replacement).	1.5 hours
5	28-days (±4 days) from visit 4. Fourth follow-up for the test lens, subjective responses, VA, fitting characteristics, surface characteristics, physiology. Four new lenses of the same power and type will dispensed for approximately 4 weeks (biweekly replacement).	1.5 hours
6	28-days (±4 days) from visit 5. Fifth follow-up for the test lens, subjective responses, VA, fitting characteristics, surface characteristics, physiology. **Subjects will be placed back into their habitual lenses.**	1.5 hours
7	7-days (±1 days) from visit 6. First follow-up for the habitual lens, subjective responses including **preferences**, VA, fitting characteristics, surface characteristics, physiology. Same habitual lens type to be worn approximately one more week.	1.5 hours
8	7-days (±1 days) from visit 7. Second follow-up for the habitual lens, subjective responses, VA, fitting characteristics, surface characteristics, physiology. **Final Evaluation.**	1.0 hours

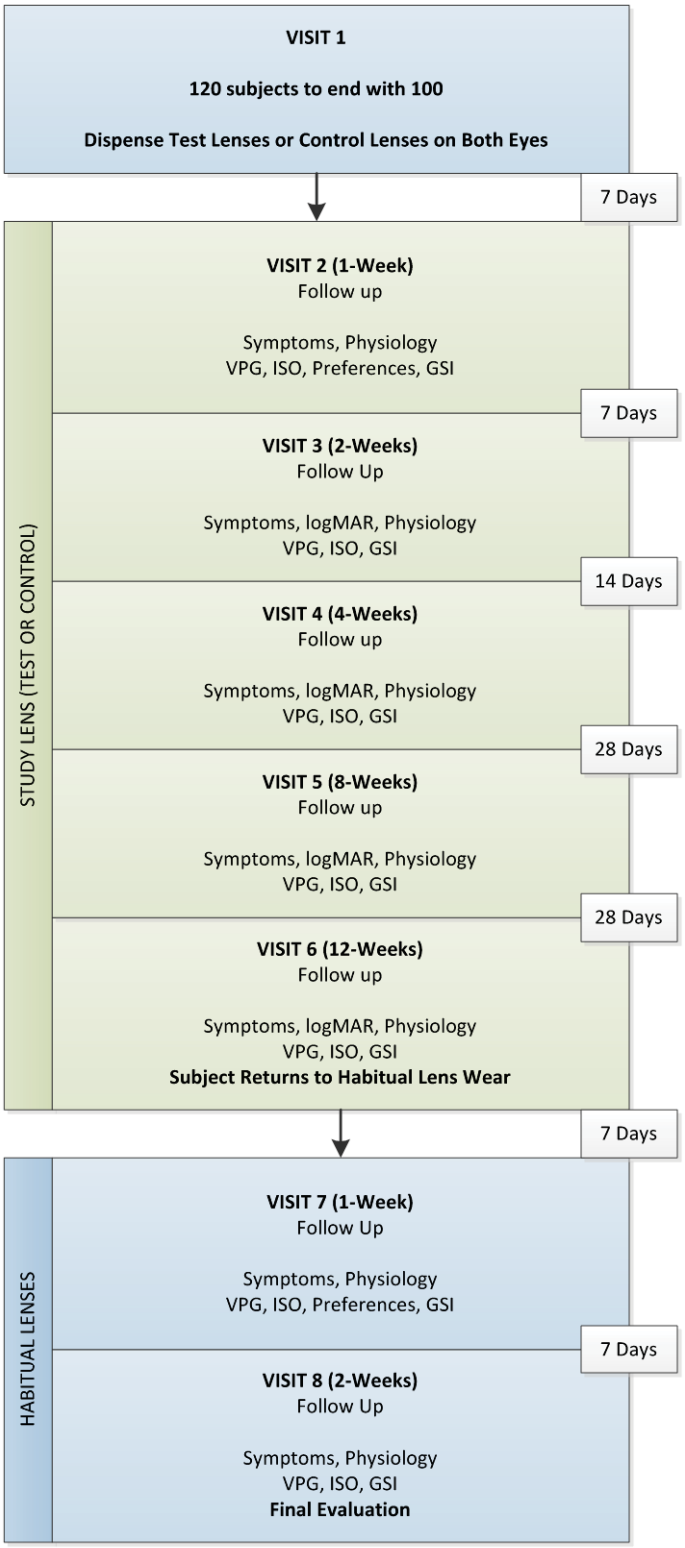
4.4.1 TIME AND EVENT SCHEDULE

Procedure	Baseline	Trial Fit & Dispense	Follow-up 1, 2, 3, 4, 5, 6, 7	Unsched	Exit
Visit	1	1	2, 3, 4, 5, 6, 7, 8	PRN	8
Informed consent	✓	-	-	-	-
Eligibility screening	✓	-	-	-	-
PRO Baseline Questionnaires	✓	-	-	-	-
Subject demographics	✓	-	-	-	-
General health and medication history	✓	-	-	-	-
Subject's own contact lens information	✓	-	-	-	-
Habitual lens care	✓	-	-	-	-
Visual acuity (Snellen)	✓	-	-	-	✓
Spherocylindrical refraction and BVA	✓	-	-	✓	✓
Slit lamp biomicroscopy	✓	-	✓	✓	-
Keratometry	✓	-	-	-	✓
Trial fitting lens information	-	✓	-	-	-
Lens Damage	-	✓	-	-	-
Distance spherical over-refraction	-	✓	✓	-	-
Lens modification	-	✓	-	-	-
Symptoms	-	✓	✓	✓	-
PRO dispensing questionnaires	-	✓	-	-	-
Visual acuity (logMAR)	-	✓	✓	✓	-
Lens fitting assessment	-	✓	✓	*	-
Lens dispensing information and criteria	-	✓	-	-	-
Patient instructions	-	✓	-	-	-
Lens information	-	-	✓	✓	-
Compliance	-	-	✓	✓	-
Wearing times	-	-	✓	✓	-
PRO follow-up questionnaires	-	-	✓	*	-
Surface characteristics	-	-	✓	*	-
Chief complaint, diagnosis, treatment	-	-	-	✓	-

* If wearing lenses

Each lens type must be worn for approximately 14 days. ENTER "P" FOR STUDY PROCEDURE DATA SUPPORTING PRIMARY ENDPOINT.

4.4.2 OPTIONAL FLOWCHART



4.5 RANDOMIZATION AND MASKING

Subjects will be randomly assigned to either JJVCI Investigational Contact Lens (Test) or ACUVUE OASYS (Control) groups based on a computer-generated randomization schedule prepared before the study by the sponsor Biostatiscian. The randomization will be stratified by study site and randomly permuted blocks of 4 assignments will be used to achieve 1:1 Test versus Control lens type ratio within each study site.

The study site must follow the randomization scheme provided and complete enrollment according to the randomization list and not pre-select or assign subjects. The randomized assignment of subjects will be performed at the first visit prior to the first fitting. The following must have occurred prior to randomization:

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

This is a partially subject masked study. The dynamic nature (variable shade) of the Test lens makes full masking impossible. However, the identity of the Control lenses will be masked to the subject by way of investigational foil. This will reduce the likelihood that habitual wearers of ACUVUE OASYS recognize the Control lens and increase the likelihood that questionnaires will be answered unbiasedly.

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

Wear Schedule: Daily wear
Replacement Schedule: 2 week
Test Article Packaging Description: Blister packaging in sterile packing solution
Labeling: Investigational

4.7 DETAILED STUDY PROCEDURES

4.7.1 SEQUENCE OF EVENTS

Habitual	Subjects must enter the study wearing their habitual hydrogel lenses for the purposes of accurately responding to the Baseline Questionnaires.

VISIT 1: SCREENING			**Day 0**
The following information will be recorded:			
Step		**Details**	[redacted]
1	Statement of Informed Consent	Each subject must read, understand and sign the Statement of Informed Consent before being enrolled in the study (attached separately). A witness must also sign the form. Note: The subject must be provided with a signed copy of this document.	
2	Demographics	Date of birth, gender, race, ethnicity, and global ID.	

VISIT 1: SCREENING			Day 0
The following information will be recorded:			
Step		**Details**	[redacted]
3	Case History	Questions regarding the subject's general health and medical history, including concomitant medications. Habitual medications taken by successful soft contact lens wearers are considered acceptable. Note that habitual medications should be continued throughout the study period.	
4	Habitual Contact Lens Type	Questions regarding the subject's habitual contact lens, including: lens name, base curve, diameter, power, and lens wearing modality.	
5	Current Contact Lens Wear Times	Record the habitual wear time (WT) and comfortable wear time (CWT).	
6	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.	

VISIT 1: BASELINE INFORMATION			Day 0
The following information will be recorded:			
Step		**Details**	[redacted]
1	Spherical Over-refraction	Perform a spherical over-refraction OD and OS. **The over-refraction of their habitual lenses must be within ±0.25 D OD and OS.** Subjects outside of this range will not be allowed to participate in the study.	
2	Glare Questionnaire	The subject will respond to the Eyestrain Caused by Glare Questionnaire in regards to their habitual lenses.	[redacted]
3	Project-Specific Questionnaire	The subject will respond to the Project-Specific Questionnaire	
4	CLUE Baseline Questionnaire	The subject will respond to the CLUE Baseline Questionnaire	
5	GSI Background Questionnaire	The subject will respond to the GSI Background Questionnaire	
6	Activity History Questionnaire	The subject will respond to the Activity History Questionnaire	

VISIT 1: BASELINE INFORMATION			Day 0
The following information will be recorded:			
Step		**Details**	[redacted]
7	Visual Acuity	Record the distance Snellen visual acuity with the habitual lenses (OD, OS, and OU) to the nearest letter. Smaller lines must be shown until the subject incorrectly identifies at least 50% of the letters.	[redacted]
8	Remove Habitual Lens	The subject's habitual lenses will be removed and stored in their own lens case. If they forgot to bring their lens case, one will be provided to them.	
9	Slit Lamp Findings	FDA Slit Lamp Classification Scale [redacted]) will be used to grade the findings and will be used to determine eligibility. Record only whole numbers. If any of these slit lamp findings are grade 2 or higher, the subject is ineligible to continue; complete the Final Evaluation.	[redacted]
10	Iris Color	The investigator will record the subject's iris color based on the scale provided (Appendix B).	
11	Keratometry	Record the keratometry readings OD and OS in diopters. This can come from any appropriate instrument so long as the same instrument is used at the Final Evaluation.	[redacted]
12	Subjective Refraction	The investigator will complete a subjective refraction (sphere and cylinder) and record the resultant distance visual acuity OD, OS, and OU to the nearest letter. Best corrected Snellen distance visual acuity (BVA) must be 20/25+3 or better in each eye.	[redacted]
13	Eligibility at Baseline	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.	
14	Eye Rinse	The study coordinator, investigator, or technician will rinse the subject's eyes thoroughly with saline.	

VISIT 1: Lens Assignment #1			Day 0
The following information will be collected:			
Steps		**Details**	[redacted]
1	Lens Information	The Lens Randomization Table will be used to determine which study lens is worn. The lens powers are based on the vertexed (12mm), spherical equivalent subjective refraction (Appendix A). The investigator or subject will place the lenses on. Quickly check for any lens damage and replace if necessary.	

VISIT 1: Lens Assignment #1			Day 0
The following information will be collected:			
Steps		**Details**	[redacted]
2	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the Product Quality Complaint form and save lens in vial with saline.	

VISIT 1: FITTING #1			Day 0
The following information will be collected:			
Steps		**Details**	[redacted]
1	Time Interval	Please wait at least 5 minutes before continuing.	
2	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS. A 0.00 D spherical over-refraction must be achieved to continue.	
3	Lens Modification Criteria	The lens power will be modified if the over-refraction is ±0.25 D or more in either eye. One modification attempt is allowed.	

VISIT 1: TRIAL FITTING LENS MODIFICATION			(If needed, one modification is allowed)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Lens Information	The lens power will be chosen based on the over-refraction results from the first trial lenses.	
2	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the Product Quality Complaint form and save lens in vial with saline.	
3	Time Interval	Please wait at least 5 minutes before continuing.	
4	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS. If a 0.00 D spherical over-refraction OD and OS is not demonstrated, the subject is terminated from the study; complete the Final Evaluation.	

VISIT 1: FITTING #1, CONTINUED			Day 0
The following information will be collected:			
Steps		**Details**	[redacted]
1	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]
2	Dispensing Questionnaire	Subjects will respond to the Dispensing Questionnaire for initial comfort and vision (ID: ISOC0001, ISOV0001)	
3	GSI Post-Fit Questionnaire	Subjects will respond to the GSI Post-Fit Questionnaire.	
4	LogMAR (ETDRS) Visual Acuity	Using the Sekonic light meter with ISO1 setting of 125 under high illumination (>7.3 EV) and high chart luminance (9.9-10.7 EV) record the distance ETDRS high contrast: 1. OD: Chart HC1 2. OS: Chart HC2 3. OU: Chart HC3	[redacted]
5	Lens Fit Assessment:	The fit of the lens is judged by the investigator as pass or fail based on the criteria below. If the fit of the lens is judged as a failure, the subject is terminated from the study. To be judged as a failure, the lens must display one or more of the following: 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
6	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
7	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]
8	Continuance	For the subject to continue in the study, they must meet all three of the following criteria: 1. Visual acuity is 0.17 logMAR (20/30) or better OD and OS. 2. The lens fit is acceptable OD and OS 3. Investigator approval. If the investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.	

VISIT 1: DISPENSING #1			Day 0
The following information will be collected:			
Steps		**Details**	[redacted]
1	Dispense	The lenses will be dispensed for 6-8 days. 1. The subjects should wear their lenses similar to the inclusion criteria: ≥ 6 hours per day, ≥ 5 days per week. 2. The lenses will be worn as daily wear only. 3. All subjects will be provided Opti-Free PureMoist to be used in a rub regime. 4. Preservative-free rewetting drops are permitted if needed. 5. A patient instruction booklet will be provided. 6. The lenses must be stored in the supplied case out of direct sunlight. Note 1: In the event a lens is lost or damaged, the subject will return to the investigator site for replacement (extra lenses cannot be given at the dispensing visit). Note 2: The subject's habitual contact lenses cannot be worn until during Visit 6 when they are placed back into their habitual lenses.	
2	Follow-up Visit Scheduling	An appointment for the next visit should be made for approximately 7 days (range 6-8 days) after Visit 1. Subjects should be advised to wear the study lenses at least 6 hours a day, and a minimum of 5 days per week. The study lenses must be worn into the Follow-up Visit.	

VISIT 2: 7-DAY FOLLOW-UP			(Follow-up #1, 6-8 days after Visit 1)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Concomitant Medications and Medical History Review	Record the concomitant medications and review the subject's medical history, specifically noting any changes from baseline.	
2	Wearing Time	Record the average wearing time and comfortable wearing time.	
3	Compliance	Confirm compliance with the prescribed wear schedule, including adherence to the rub regime.	
4	Use of Lens Rewetting Drops	The subjects will record the approximate daily use of lens rewetting drops (i.e., how many times per day on average).	
5	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]

VISIT 2: 7-DAY FOLLOW-UP		(Follow-up #1, 6-8 days after Visit 1)	
The following information will be collected:			
Steps		**Details**	[redacted]
6	Glare Questionnaire	The subject will respond to the Eyestrain Caused by Glare Questionnaire in regards to their study lenses.	[redacted]
7	Project-Specific Questionnaire	The subject will respond to the Project-Specific Questionnaire	
8	CLUE Follow-up Questionnaire	The subject will respond to the CLUE Follow-up Questionnaire	
9	Patient Reported Outcomes	Subjects will respond to the following individual questions. 1. Subjective Comfort (Item ID: ISOC0001) 2. Subjective Vision (Item ID: ISOV0001) 3. Subjective Handling (Item ID: ISOH0001)	
10	Lens Preferences	Subjects will respond to preference questions relating back to their habitual lenses.	
11	GSI Product Performance Questionnaire	Subjects will respond to the GSI Product Performance Questionnaire.	
12	Entrance Visual Acuity	Record the distance visual acuity with the study contact lenses (OD, OS, and OU) to the nearest letter. Smaller lines must be shown until the subject incorrectly identifies at least 50% of the letters.	[redacted]
13	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS.	
14	Lens Fit Assessment:	Subjective Assessment of the Lens Fit. If the fit is graded as unacceptable based on the criteria below, then the subject is discontinued from the study and will not be replaced. 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
15	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
16	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]

VISIT 2: 7-DAY FOLLOW-UP		(Follow-up #1, 6-8 days after Visit 1)	
The following information will be collected:			
Steps		**Details**	[redacted]
17	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the Product Quality Complaint form and save lens in vial with Optifree PureMoist or saline.	
18	Temporary Lens Removal & Storage	The lenses will be removed and temporarily stored in suitable lens case with Opti-Free PureMoist or saline. The lenses should not be rubbed and will be reinserted in step 21.	
19	Slit Lamp Findings	Slit Lamp Classification Scale [redacted] will be used to grade the findings. Record only whole numbers. Note: Subject must be free of any FDA grade 3 or greater slit lamp findings with no active ocular infection/inflammation.	[redacted]
20	Eye Rinse	The study coordinator, investigator, or technician will rinse the subject's eyes thoroughly with saline.	
21	Lens Re-Insertion	The same lenses removed in step 18 will be placed back on the eyes and worn for an additional 6-8 days.	
22	Exit Visual Acuity	Record the distance Snellen visual acuity with the study lenses (OD, OS, and OU) to the nearest letter. Smaller lines must be shown until the subject incorrectly identifies at least 50% of the letters.	[redacted]
23	Follow-up Visit Scheduling	An appointment for the next visit should be made for approximately 7 days (range 6-8 days) after Visit 2. Subjects should be advised to wear the study lenses at least 6 hours a day, and a minimum of 5 days per week. The study lenses must be worn into the Follow-up Visit.	

VISIT 3: 14-DAY FOLLOW-UP		(Follow-up #2, 6-8 days after Visit 2)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Concomitant Medications and Medical History Review	Record the concomitant medications and review the subject's medical history, specifically noting any changes from baseline.	
2	Wearing Time	Record the average wearing time and comfortable wearing time.	
3	Compliance	Confirm compliance with the prescribed wear schedule, including adherence to the rub regime.	

VISIT 3: 14-DAY FOLLOW-UP		(Follow-up #2, 6-8 days after Visit 2)	
The following information will be collected:			
Steps		**Details**	[redacted]
4	Use of Lens Rewetting Drops	The subjects will record the approximate daily use of lens rewetting drops (i.e., how many times per day on average).	
5	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]
6	Glare Questionnaire	The subject will respond to the Eyestrain Caused by Glare Questionnaire in regards to their study lenses.	[redacted]
7	Project-Specific Questionnaire	The subject will respond to the Project-Specific Questionnaire	
8	CLUE Follow-up Questionnaire	The subject will respond to the CLUE Follow-up Questionnaire	
9	Patient Reported Outcomes	Subjects will respond to the following individual questions. 1. Subjective Comfort (Item ID: ISOC0001) 2. Subjective Vision (Item ID: ISOV0001) 3. Subjective Handling (Item ID: ISOH0001)	
10	GSI Product Performance Questionnaire	Subjects will respond to the GSI Product Performance Questionnaire.	
11	Entrance Visual Acuity	Record the distance visual acuity with the study contact lenses (OD, OS, and OU) to the nearest letter. Smaller lines must be shown until the subject incorrectly identifies at least 50% of the letters.	[redacted]
12	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS.	
13	LogMAR (ETDRS) Visual Acuity	Using the Sekonic light meter with ISO1 setting of 125 under high illumination (>7.3 EV) and high chart luminance (9.9-10.7 EV) record the distance ETDRS high contrast: 1. OD: Chart HC1 2. OS: Chart HC2 3. OU: Chart HC3	[redacted]

VISIT 3: 14-DAY FOLLOW-UP		(Follow-up #2, 6-8 days after Visit 2)	
The following information will be collected:			
Steps		**Details**	[redacted]
14	Lens Fit Assessment:	Subjective Assessment of the Lens Fit. If the fit is graded as unacceptable based on the criteria below, then the subject is discontinued from the study and will not be replaced. 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
15	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
16	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]
17	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the Product Quality Complaint form and save lens in vial with Optifree PureMoist or saline.	
18	Lens Removal & Storage	The worn lenses will be removed, stored in the following manner, and returned to the Sponsor: 1. OD and OS lens stored wet in a labeled vial with Opti-Free PureMoist. The lenses should not be rubbed. 2. The lenses will be stored and shipped cold (refrigerated or frozen).	
19	Slit Lamp Findings	Slit Lamp Classification Scale [redacted] will be used to grade the findings. Record only whole numbers. Note: Subject must be free of any FDA grade 3 or greater slit lamp findings with no active ocular infection/inflammation.	[redacted]
20	Eye Rinse	The study coordinator, investigator, or technician will rinse the subject's eyes thoroughly with saline.	

VISIT 3: LENS ASSIGNMENT #2			(6-8 days after Visit 2)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Lens Information	The same lens type and power of the previous study lens must be chosen. The investigator or subject will place the lenses on. Quickly check for any lens damage and replace if necessary.	
2	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the [redacted] form and save lens in vial with saline.	

VISIT 3: FITTING #2			(6-8 days after Visit 2)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Time Interval	Please wait at least 5 minutes before continuing.	
2	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS. A 0.00 D spherical over-refraction must be achieved to continue.	
3	Lens Modification Criteria	The lens power will be modified if the over-refraction is ±0.25 D or more in either eye. One modification attempt is allowed.	

VISIT 3: TRIAL FITTING LENS MODIFICATION			(If needed, one modification is allowed)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Lens Information	The lens power will be chosen based on the over-refraction results from the first trial lenses.	
2	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the [redacted] form and save lens in vial with saline.	
3	Time Interval	Please wait at least 5 minutes before continuing.	

VISIT 3: TRIAL FITTING LENS MODIFICATION		(If needed, one modification is allowed)	
The following information will be collected:			
Steps		**Details**	[redacted]
4	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS. If a 0.00 D spherical over-refraction OD and OS is not demonstrated, the subject is terminated from the study; complete the Final Evaluation.	

VISIT 3: FITTING #2, CONTINUED		(6-8 days after Visit 2)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]
2	Dispensing Questionnaire	Subjects will respond to the Dispensing Questionnaire for initial comfort and vision (ID: ISOC0001, ISOV0001)	
3	LogMAR (ETDRS) Visual Acuity	Using the Sekonic light meter with ISO1 setting of 125 under high illumination (>7.3 EV) and high chart luminance (9.9-10.7 EV) record the distance ETDRS high contrast: 1. OD: Chart HC1 2. OS: Chart HC2 3. OU: Chart HC3	[redacted]
4	Lens Fit Assessment:	The fit of the lens is judged by the investigator as pass or fail based on the criteria below. If the fit of the lens is judged as a failure, the subject is terminated from the study. To be judged as a failure, the lens must display one or more of the following: 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
5	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
6	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]

VISIT 3: FITTING #2, CONTINUED			(6-8 days after Visit 2)
The following information will be collected:			
Steps		**Details**	[redacted]
7	Continuance	For the subject to continue in the study, they must meet all three of the following criteria: 1. Visual acuity is 0.17 logMAR (20/30) or better OD and OS. 2. The lens fit is acceptable OD and OS 3. Investigator approval. If the investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.	

VISIT 3: DISPENSING #2			(6-8 days after Visit 2)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Dispense	The lenses will be dispensed for 12-16 days. 1. The subjects should wear their lenses similar to the inclusion criteria: ≥ 6 hours per day, ≥ 5 days per week. 2. The lenses will be worn as daily wear only. 3. All subjects will be provided Opti-Free PureMoist to be used in a rub regime. 4. Preservative-free rewetting drops are permitted if needed. 5. The lenses must be stored in the supplied case out of direct sunlight. Note 1: In the event a lens is lost or damaged, the subject will return to the investigator site for replacement (extra lenses cannot be given at the dispensing visit). Note 2: The subject's habitual contact lenses cannot be worn until during Visit 6 when they are placed back into their habitual lenses.	
2	Follow-up Visit Scheduling	An appointment for the next visit should be made for approximately 14 days (range 12-16 days) after Visit 3. Subjects should be advised to wear the study lenses at least 6 hours a day, and a minimum of 5 days per week. The study lenses must be worn into the Follow-up Visit.	

VISIT 4: 28-DAY FOLLOW-UP		(Follow-up #3, 12-16 days after Visit 3)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Concomitant Medications and Medical History Review	Record the concomitant medications and review the subject's medical history, specifically noting any changes from baseline.	
2	Wearing Time	Record the average wearing time and comfortable wearing time.	
3	Compliance	Confirm compliance with the prescribed wear schedule, including adherence to the rub regime.	
4	Use of Lens Rewetting Drops	The subjects will record the approximate daily use of lens rewetting drops (i.e., how many times per day on average).	
5	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]
6	Glare Questionnaire	The subject will respond to the Eyestrain Caused by Glare Questionnaire in regards to their study lenses.	[redacted]
7	Project-Specific Questionnaire	The subject will respond to the Project-Specific Questionnaire	
8	CLUE Follow-up Questionnaire	The subject will respond to the CLUE Follow-up Questionnaire	
9	Patient Reported Outcomes	Subjects will respond to the following individual questions. 1. Subjective Comfort (Item ID: ISOC0001) 2. Subjective Vision (Item ID: ISOV0001) 3. Subjective Handling (Item ID: ISOH0001)	
10	GSI Product Performance Questionnaire	Subjects will respond to the GSI Product Performance Questionnaire.	
11	Entrance Visual Acuity	Record the distance visual acuity with the contact lenses (OD, OS, and OU) to the nearest letter. Smaller lines must be shown until the subject incorrectly identifies at least 50% of the letters.	[redacted]
12	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS.	

VISIT 4: 28-DAY FOLLOW-UP		(Follow-up #3, 12-16 days after Visit 3)	
The following information will be collected:			
Steps		**Details**	[redacted]
13	LogMAR (ETDRS) Visual Acuity	Using the Sekonic light meter with ISO1 setting of 125 under high illumination (>7.3 EV) and high chart luminance (9.9-10.7 EV) record the distance ETDRS high contrast: 1. OD: Chart HC1 2. OS: Chart HC2 3. OU: Chart HC3	[redacted]
14	Lens Fit Assessment:	Subjective Assessment of the Lens Fit. If the fit is graded as unacceptable based on the criteria below, then the subject is discontinued from the study and will not be replaced. 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
15	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
16	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]
17	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the Product Quality Complaint form and save lens in vial with Optifree PureMoist or saline.	
18	Lens Removal & Storage	The worn lenses will be removed, stored in the following manner, and returned to the Sponsor: 1. OD and OS lens stored wet in a labeled vial with Opti-Free PureMoist. The lenses should not be rubbed. 2. The lenses will be stored and shipped cold (refrigerated or frozen).	
19	Slit Lamp Findings	Slit Lamp Classification Scale [redacted]) will be used to grade the findings. Record only whole numbers. Note: Subject must be free of any FDA grade 3 or greater slit lamp findings with no active ocular infection/inflammation.	[redacted]
20	Eye Rinse	The study coordinator, investigator, or technician will rinse the subject's eyes thoroughly with saline.	

VISIT 4: Lens Assignment #3			(12-16 days after Visit 3)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Lens Information	The same lens type and power of the previous study lens must be chosen. The investigator or subject will place the lenses on. Quickly check for any lens damage and replace if necessary.	
2	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the Product Quality Complaint form and save lens in vial with saline.	

VISIT 4: FITTING #3			(12-16 days after Visit 3)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Time Interval	Please wait at least 5 minutes before continuing.	
2	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS. A 0.00 D spherical over-refraction must be achieved to continue.	
3	Lens Modification Criteria	The lens power will be modified if the over-refraction is ±0.25 D or more in either eye. One modification attempt is allowed.	

VISIT 4: TRIAL FITTING LENS MODIFICATION			(If needed, one modification is allowed)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Lens Information	The lens power will be chosen based on the over-refraction results from the first trial lenses.	
2	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the Product Quality Complaint form and save lens in vial with saline.	
3	Time Interval	Please wait at least 5 minutes before continuing.	

VISIT 4: TRIAL FITTING LENS MODIFICATION		(If needed, one modification is allowed)	
The following information will be collected:			
Steps		**Details**	[redacted]
4	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS. If a 0.00 D spherical over-refraction OD and OS is not demonstrated, the subject is terminated from the study; complete the Final Evaluation.	

VISIT 4: FITTING #3, CONTINUED		(12-16 days after Visit 3)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]
2	Dispensing Questionnaire	Subjects will respond to the Dispensing Questionnaire for initial comfort and vision (ID: ISOC0001, ISOV0001)	
3	LogMAR (ETDRS) Visual Acuity	Using the Sekonic light meter with ISO1 setting of 125 under high illumination (>7.30 EV) and high chart luminance (9.9-10.7 EV) record the distance ETDRS high contrast: 1. OD: Chart HC1 2. OS: Chart HC2 3. OU: Chart HC3	[redacted]
4	Lens Fit Assessment:	The fit of the lens is judged by the investigator as pass or fail based on the criteria below. If the fit of the lens is judged as a failure, the subject is terminated from the study. To be judged as a failure, the lens must display one or more of the following: 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
5	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
6	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]

VISIT 4: FITTING #3, CONTINUED		(12-16 days after Visit 3)	
The following information will be collected:			
Steps		**Details**	[redacted]
7	Continuance	For the subject to continue in the study, they must meet all three of the following criteria: 1. Visual acuity is 0.17 logMAR (20/30) or better OD and OS. 2. The lens fit is acceptable OD and OS 3. Investigator approval. If the investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.	

VISIT 4: DISPENSING #3		(12-16 days after Visit 3)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Dispense	The lenses will be dispensed for 24-32 days. 1. The subjects should wear their lenses similar to the inclusion criteria: ≥ 6 hours per day, ≥ 5 days per week. 2. The lenses will be worn as daily wear only. 3. All subjects will be provided Opti-Free PureMoist to be used in a rub regime. 4. Preservative-free rewetting drops are permitted if needed. 5. The lenses must be stored in the supplied case out of direct sunlight. Note 1: In the event a lens is lost or damaged, the subject will return to the investigator site for replacement (extra lenses cannot be given at the dispensing visit). Note 2: The subject's habitual contact lenses cannot be worn until during Visit 6 when they are placed back into their habitual lenses. Note 3: The subject will leave with the pair of study lenses that they have on their eyes, and with one additional pair to replace in approximately 14 days. The worn lenses will both be stored dry at room temperature at home in a labeled container and brought with them to visit 5.	
2	Follow-up Visit Scheduling	An appointment for the next visit should be made for approximately 28 days (range 24-32 days) after Visit 4. Subjects should be advised to wear the study lenses at least 6 hours a day, and a minimum of 5 days per week. The study lenses must be worn into the Follow-up Visit.	

VISIT 5: 56-DAY FOLLOW-UP		(Follow-up #4, 24-32 days after Visit 4)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Concomitant Medications and Medical History Review	Record the concomitant medications and review the subject's medical history, specifically noting any changes from baseline.	
2	Wearing Time	Record the average wearing time and comfortable wearing time.	
3	Compliance	Confirm compliance with the prescribed wear schedule, including adherence to the rub regime.	
4	Use of Lens Rewetting Drops	The subjects will record the approximate daily use of lens rewetting drops (i.e., how many times per day on average).	[redacted]
5	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]
6	Glare Questionnaire	The subject will respond to the Eyestrain Caused by Glare Questionnaire in regards to their study lenses.	[redacted]
7	Project-Specific Questionnaire	The subject will respond to the Project-Specific Questionnaire	
8	CLUE Follow-up Questionnaire	The subject will respond to the CLUE Follow-up Questionnaire	
9	Patient Reported Outcomes	Subjects will respond to the following individual questions. 1. Subjective Comfort (Item ID: ISOC0001) 2. Subjective Vision (Item ID: ISOV0001) 3. Subjective Handling (Item ID: ISOH0001)	
10	GSI Product Performance Questionnaire	Subjects will respond to the GSI Product Performance Questionnaire.	
11	Entrance Visual Acuity	Record the distance visual acuity with the contact lenses (OD, OS, and OU) to the nearest letter. Smaller lines must be shown until the subject incorrectly identifies at least 50% of the letters.	[redacted]
12	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS.	

VISIT 5: 56-DAY FOLLOW-UP		(Follow-up #4, 24-32 days after Visit 4)	
The following information will be collected:			
Steps		**Details**	[redacted]
13	LogMAR (ETDRS) Visual Acuity	Using the Sekonic light meter with ISO1 setting of 125 under high illumination (>7.3 EV) and high chart luminance (9.9-10.7 EV) record the distance ETDRS high contrast: 1. OD: Chart HC1 2. OS: Chart HC2 3. OU: Chart HC3	[redacted]
14	Lens Fit Assessment:	Subjective Assessment of the Lens Fit. If the fit is graded as unacceptable based on the criteria below, then the subject is discontinued from the study and will not be replaced. 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
15	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
16	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]
17	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the Product Quality Complaint form and save lens in vial with Optifree PureMoist or saline.	
18	Lens Removal & Storage	The worn lenses will be removed, stored in the following manner, and returned to the Sponsor: 1. OD and OS lens stored wet in a labeled vial with Opti-Free PureMoist. The lenses should not be rubbed. 2. The lenses will be stored and shipped cold (refrigerated or frozen).	
19	Slit Lamp Findings	Slit Lamp Classification Scale [redacted] will be used to grade the findings. Record only whole numbers. Note: Subject must be free of any FDA grade 3 or greater slit lamp findings with no active ocular infection/inflammation.	[redacted]
20	Eye Rinse	The study coordinator, investigator, or technician will rinse the subject's eyes thoroughly with saline.	

VISIT 5: Lens Assignment #4			(24-32 days after Visit 4)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Lens Information	The same lens type and power of the previous study lens must be chosen. The investigator or subject will place the lenses on. Quickly check for any lens damage and replace if necessary.	
2	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the [redacted] form and save lens in vial with saline.	

VISIT 5: FITTING #4			(24-32 days after Visit 4)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Time Interval	Please wait at least 5 minutes before continuing.	
2	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS. A 0.00 D spherical over-refraction must be achieved to continue.	
3	Lens Modification Criteria	The lens power will be modified if the over-refraction is ±0.25 D or more in either eye. One modification attempt is allowed.	

VISIT 5: TRIAL FITTING LENS MODIFICATION			(If needed, one modification is allowed)
The following information will be collected:			
Steps		**Details**	[redacted]
1	Lens Information	The lens power will be chosen based on the over-refraction results from the first trial lenses.	
2	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the [redacted] form and save lens in vial with saline.	
3	Time Interval	Please wait at least 5 minutes before continuing.	

VISIT 5: TRIAL FITTING LENS MODIFICATION		(If needed, one modification is allowed)	
The following information will be collected:			
Steps		**Details**	[redacted]
4	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS. If a 0.00 D spherical over-refraction OD and OS is not demonstrated, the subject is terminated from the study; complete the Final Evaluation.	

VISIT 5: FITTING #4, CONTINUED		(24-32 days after Visit 4)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]
2	Dispensing Questionnaire	Subjects will respond to the Dispensing Questionnaire for initial comfort and vision (ID: ISOC0001, ISOV0001)	
3	LogMAR (ETDRS) Visual Acuity	Using the Sekonic light meter with ISO1 setting of 125 under high illumination (>7.3 EV) and high chart luminance (9.9-10.7 EV) record the distance ETDRS high contrast: 1. OD: Chart HC1 2. OS: Chart HC2 3. OU: Chart HC3	[redacted]
4	Lens Fit Assessment:	The fit of the lens is judged by the investigator as pass or fail based on the criteria below. If the fit of the lens is judged as a failure, the subject is terminated from the study. To be judged as a failure, the lens must display one or more of the following: 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
5	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
6	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]

VISIT 5: FITTING #4, CONTINUED		(24-32 days after Visit 4)	
The following information will be collected:			
Steps		**Details**	[redacted]
7	Continuance	For the subject to continue in the study, they must meet all three of the following criteria: 1. Visual acuity is 0.17 logMAR (20/30) or better OD and OS. 2. The lens fit is acceptable OD and OS 3. Investigator approval. If the investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.	

VISIT 5: DISPENSING #4		(24-32 days after Visit 4)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Dispense	The lenses will be dispensed for 24-32 days. 1. The subjects should wear their lenses similar to the inclusion criteria: ≥ 6 hours per day, ≥ 5 days per week. 2. The lenses will be worn as daily wear only. 3. All subjects will be provided Opti-Free PureMoist to be used in a rub regime. 4. Preservative-free rewetting drops are permitted if needed. 5. The lenses must be stored in the supplied case out of direct sunlight. Note 1: In the event a lens is lost or damaged, the subject will return to the investigator site for replacement (extra lenses cannot be given at the dispensing visit). Note 2: The subject's habitual contact lenses cannot be worn until during Visit 6 when they are placed back into their habitual lenses. Note 3: The subject will leave with the pair of study lenses that they have on their eyes, and with one additional pair to replace in approximately 14 days. The worn lenses will both be stored dry at room temperature at home in a labeled container and brought with them to visit 6. Note 4: The subjects need to be reminded to bring their habitual contact lenses with them to their next visit.	
2	Follow-up Visit Scheduling	An appointment for the next visit should be made for approximately 28 days (range 24-32 days) after Visit 5. Subjects should be advised to wear the study lenses at least 6 hours a day, and a minimum of 5 days per week. The study lenses must be worn into the Follow-up Visit.	

VISIT 6: 84-DAY FOLLOW-UP		(Follow-up #5, 24-32 days after Visit 5)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Concomitant Medications and Medical History Review	Record the concomitant medications and review the subject's medical history, specifically noting any changes from baseline.	
2	Wearing Time	Record the average wearing time and comfortable wearing time.	
3	Compliance	Confirm compliance with the prescribed wear schedule, including adherence to the rub regime.	
4	Use of Lens Rewetting Drops	The subjects will record the approximate daily use of lens rewetting drops (i.e., how many times per day on average).	[redacted]
5	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]
6	Glare Questionnaire	The subject will respond to the Eyestrain Caused by Glare Questionnaire in regards to their study lenses.	[redacted]
7	Project-Specific Questionnaire	The subject will respond to the Project-Specific Questionnaire	
8	CLUE Follow-up Questionnaire	The subject will respond to the CLUE Follow-up Questionnaire	
9	Patient Reported Outcomes	Subjects will respond to the following individual questions. 1. Subjective Comfort (Item ID: ISOC0001) 2. Subjective Vision (Item ID: ISOV0001) 3. Subjective Handling (Item ID: ISOH0001)	
10	GSI Product Performance Questionnaire	Subjects will respond to the GSI Product Performance Questionnaire.	
11	Entrance Visual Acuity	Record the distance visual acuity with the contact lenses (OD, OS, and OU) to the nearest letter. Smaller lines must be shown until the subject incorrectly identifies at least 50% of the letters.	[redacted]
12	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS.	

VISIT 6: 84-DAY FOLLOW-UP		(Follow-up #5, 24-32 days after Visit 5)	
The following information will be collected:			
Steps		**Details**	[redacted]
13	LogMAR (ETDRS) Visual Acuity	Using the Sekonic light meter with ISO1 setting of 125 under high illumination (>7.3 EV) and high chart luminance (9.9-10.7 EV) record the distance ETDRS high contrast: 1. OD: Chart HC1 2. OS: Chart HC2 3. OU: Chart HC3	[redacted]
14	Lens Fit Assessment:	Subjective Assessment of the Lens Fit. If the fit is graded as unacceptable based on the criteria below, then the subject is discontinued from the study and will not be replaced. 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
15	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
16	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]
17	Lens Damage	Lens damage (draw in source document and describe). Replace lens if damaged and complete the Product Quality Complaint form and save lens in vial with Optifree PureMoist or saline.	
18	Lens Removal & Storage	The worn lenses will be removed, stored in the following manner, and returned to the Sponsor: 1. OD and OS lens stored wet in a labeled vial with Opti-Free PureMoist. The lenses should not be rubbed. 2. The lenses will be stored and shipped cold (refrigerated or frozen).	
19	End of study treatment time	The supplied test and control lenses will no longer be in use.	
20	Slit Lamp Findings	Slit Lamp Classification Scale [redacted]) will be used to grade the findings. Record only whole numbers. Note: Subject must be free of any FDA grade 3 or greater slit lamp findings with no active ocular infection/inflammation.	[redacted]
21	Eye Rinse	The study coordinator, investigator, or technician will rinse the subject's eyes thoroughly with saline.	

VISIT 6: 84-DAY FOLLOW-UP		(Follow-up #5, 24-32 days after Visit 5)	
The following information will be collected:			
Steps		**Details**	[redacted]

VISIT 6: HABITUAL LENS ASSIGNMENT #1		(24-32 days after Visit 5)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Lens Information	The subject or investigator will place the subject's habitual lenses on both eyes.	

VISIT 6: HABITUAL LENS FITTING #1		(24-32 days after Visit 5)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Time Interval	Please wait at least 5 minutes before continuing.	
2	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS.	
3	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]
4	Dispensing Questionnaire	Subjects will respond to the Dispensing Questionnaire for initial comfort and vision (ID: ISOC0001, ISOV0001)	
5	LogMAR (ETDRS) Visual Acuity	Using the Sekonic light meter with ISO1 setting of 125 under high illumination (>7.3 EV) and high chart luminance (9.9-10.7 EV) record the distance ETDRS high contrast: 1. OD: Chart HC1 2. OS: Chart HC2 3. OU: Chart HC3	[redacted]

VISIT 6: HABITUAL LENS FITTING #1		(24-32 days after Visit 5)	
The following information will be collected:			
Steps		**Details**	[redacted]
6	Lens Fit Assessment:	The fit of the lens is judged by the investigator as pass or fail based on the criteria below. If the fit of the lens is judged as a failure, the subject is terminated from the study. To be judged as a failure, the lens must display one or more of the following: 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
7	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
8	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]

VISIT 6: HABITUAL LENS RELEASE #1		(24-32 days after Visit 5)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Habitual Lens Release	The subject's habitual lenses will be worn for 6-8 days. 1. The subjects should wear their lenses similar to the inclusion criteria: ≥ 6 hours per day, ≥ 5 days per week. 2. The lenses will be worn as daily wear only. 3. All subjects will be provided Opti-Free PureMoist to be used in a rub regime. 4. Preservative-free rewetting drops are permitted if needed. Note: Daily disposable wearers do not need to adhere to the Optifree PureMoist solution and rub regime.	
2	Follow-up Visit Scheduling	An appointment for the next visit should be made for approximately 7 days (range 6-8 days) after Visit 6. Subjects should be advised to wear their habitual lenses at least 6 hours a day, and a minimum of 5 days per week. Their habitual lenses must be worn into the Follow-up Visit.	

VISIT 7: 7-DAY FOLLOW-UP HABITUAL LENS		(Follow-up #1, 6-8 days after Visit 6)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Concomitant Medications and Medical History Review	Record the concomitant medications and review the subject's medical history, specifically noting any changes from baseline.	
2	Wearing Time	Record the average wearing time and comfortable wearing time.	
3	Compliance	Confirm compliance with the prescribed wear schedule, including adherence to the rub regime.	
4	Use of Lens Rewetting Drops	The subjects will record the approximate daily use of lens rewetting drops (i.e., how many times per day on average).	
5	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]
6	Glare Questionnaire	The subject will respond to the Eyestrain Caused by Glare Questionnaire in regards to their habitual lenses.	[redacted]
7	Project-Specific Questionnaire	The subject will respond to the Project-Specific Questionnaire	
8	CLUE Follow-up Questionnaire	The subject will respond to the CLUE Follow-up Questionnaire	
9	Patient Reported Outcomes	Subjects will respond to the following individual questions. 1. Subjective Comfort (Item ID: ISOC0001) 2. Subjective Vision (Item ID: ISOV0001) 3. Subjective Handling (Item ID: ISOH0001)	
10	Lens Preferences	Subjects will respond to preference questions relating back to their habitual lenses.	
11	GSI Product Performance Questionnaire	Subjects will respond to the GSI Product Performance Questionnaire.	
12	Entrance Visual Acuity	Record the distance visual acuity with the habitual contact lenses (OD, OS, and OU) to the nearest letter. Smaller lines must be shown until the subject incorrectly identifies at least 50% of the letters.	[redacted]

VISIT 7: 7-DAY FOLLOW-UP HABITUAL LENS		(Follow-up #1, 6-8 days after Visit 6)	
The following information will be collected:			
Steps		**Details**	[redacted]
13	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS.	
14	Lens Fit Assessment:	Subjective Assessment of the Lens Fit. If the fit is graded as unacceptable based on the criteria below, then the subject is discontinued from the study and will not be replaced. 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
15	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
16	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]
17	Temporary Lens Removal & Storage	The lenses will be removed and temporarily stored in suitable lens case with Opti-Free PureMoist or saline. The lenses will be reinserted in step 20.	
18	Slit Lamp Findings	Slit Lamp Classification Scale [redacted] will be used to grade the findings. Record only whole numbers. Note: Subject must be free of any FDA grade 3 or greater slit lamp findings with no active ocular infection/inflammation.	[redacted]
19	Eye Rinse	The study coordinator, investigator, or technician will rinse the subject's eyes thoroughly with saline.	
20	Lens Re-Insertion	The same lenses removed in step 17 will be placed back on the eyes and worn for an additional 6-8 days.	
21	Exit Visual Acuity	Record the distance Snellen visual acuity with their habitual lenses (OD, OS, and OU) to the nearest letter. Smaller lines must be shown until the subject incorrectly identifies at least 50% of the letters.	[redacted]
22	Follow-up Visit Scheduling	An appointment for the next visit should be made for approximately 7 days (range 6-8 days) after Visit 7. Subjects should be advised to wear their habitual lenses at least 6 hours a day, and a minimum of 5 days per week. The habitual lenses must be worn into the Follow-up Visit.	

VISIT 8: 14-DAY FOLLOW-UP HABITUAL LENS		(Follow-up #2, 6-8 days after Visit 7)	
The following information will be collected:			
Steps		**Details**	[redacted]
1	Concomitant Medications and Medical History Review	Record the concomitant medications and review the subject's medical history, specifically noting any changes from baseline.	
2	Wearing Time	Record the average wearing time and comfortable wearing time.	
3	Compliance	Confirm compliance with the prescribed wear schedule, including adherence to the rub regime.	
4	Use of Lens Rewetting Drops	The subjects will record the approximate daily use of lens rewetting drops (i.e., how many times per day on average).	[redacted]
5	Subject-reported Ocular Symptoms	The subject will respond to a Symptoms Questionnaire.	[redacted]
6	Glare Questionnaire	The subject will respond to the Eyestrain Caused by Glare Questionnaire in regards to their habitual lenses.	[redacted]
7	Project-Specific Questionnaire	The subject will respond to the Project-Specific Questionnaire	
8	CLUE Follow-up Questionnaire	The subject will respond to the CLUE Follow-up Questionnaire	
9	Patient Reported Outcomes	Subjects will respond to the following individual questions. 1. Subjective Comfort (Item ID: ISOC0001) 2. Subjective Vision (Item ID: ISOV0001) 3. Subjective Handling (Item ID: ISOH0001)	
10	GSI Product Performance Questionnaire	Subjects will respond to the GSI Product Performance Questionnaire.	
11	Entrance Visual Acuity	Record the distance visual acuity with the habitual contact lenses (OD, OS, and OU) to the nearest letter. Smaller lines must be shown until the subject incorrectly identifies at least 50% of the letters.	[redacted]
12	Spherical Over-refraction	Perform a spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS.	

VISIT 8: 14-DAY FOLLOW-UP HABITUAL LENS		(Follow-up #2, 6-8 days after Visit 7)	
The following information will be collected:			
Steps		**Details**	[redacted]
13	Lens Fit Assessment:	Subjective Assessment of the Lens Fit. If the fit is graded as unacceptable based on the criteria below, then the subject is discontinued from the study and will not be replaced. 1. Limbal exposure in any gaze 2. Edge lift 3. Insufficient and/or excessive movement in all three movement categories	[redacted]
14	Lens Deposits	Record the front and back surface deposits of the lenses.	[redacted]
15	Lens Wettability	Record the white light lens wettability of both lenses.	[redacted]
16	Temporary Lens Removal & Storage	The lenses will be removed and temporarily stored in suitable lens case with Opti-Free PureMoist or saline until the completion of the visit.	
17	Slit Lamp Findings	Slit Lamp Classification Scale [redacted] will be used to grade the findings. Record only whole numbers. Note: Subject must be free of any FDA grade 3 or greater slit lamp findings with no active ocular infection/inflammation.	[redacted]
18	Eye Rinse	The study coordinator, investigator, or technician will rinse the subject's eyes thoroughly with saline.	

VISIT 8: FINAL EVALUATION		(Normally 6-8 days after Visit 7)	
The final evaluation will ordinarily take place after Visit 8 is completed. It may also take place at any point the subject discontinues the study or is terminated from the study.			
Step		**Details**	[redacted]
1	Final Exam Form	Indicate if the subject completed the study successfully or not. If subject discontinued, indicate the reason.	
2	Keratometry	Record the keratometry readings OD and OS in diopters. This should be captured with the same instrument used at baseline.	[redacted]
3	Best-corrected Distance Visual Acuity	Record the subject's best corrected distance visual acuity with refraction OD, OS, and OU.	[redacted]

VISIT 8: FINAL EVALUATION		(Normally 6-8 days after Visit 7)	
The final evaluation will ordinarily take place after Visit 8 is completed. It may also take place at any point the subject discontinues the study or is terminated from the study.			
Step		**Details**	[redacted]
4	Comments and Signature	Record any additional information on the page provided and sign the paper copy if applicable.	

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 the IRB/IEC, if applicable*] 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 STUDY ARTICLES

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 provide the subject additional lenses when a lens is damaged or lost between visits. Subjects must return to the investigational site for a replacement lens.

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 or issued for the subject to replace appropriately between visits, 2) what was returned to the Investigator unused, 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.

Please reference APPENDIX C: TEST ARTICLE ACCOUNTABILITY IN THE EDC SYSTEM for instructions on the Lens Depot.

The following table summarizes all documentation of receipt, usage, and return.

	Documentation	Description
Prior to Study Beginning	Test Article Shipped Form / Order Receipt Record	Confirms shipment contents. Two representatives from the site must sign the TAS form accepting and confirming the quantity and condition of the Test Articles received. If a discrepancy exists, contact the Sponsor immediately to launch an investigation. If warranted, a corrected TAS form will be sent to the site. The original TAS form will be maintained at the site in the study files, a copy confirming receipt will be sent back to the Sponsor.
	EDC Lens Depot / Receiving Test Articles in the EDC.	Confirms shipment contents in the EDC. Must be completed prior to dispensing. A site representative will log into the EDC accepting receipt of each Test Article lot. If a discrepancy exists, contact the Sponsor immediately to launch an investigation, only accept the quantity that is physically in the shipment. **Refer to Appendix C for complete instructions on how to Receive, Dispense, and Return Test Articles in the EDC.**
During Study Dispensing	Contact Lens Dispensing Log	Accounts for all test articles issued, used and returned by each study subject, as well as any unplanned replacements
	Subject Record	Test article distribution information in the subject record must correspond with the Lens Accountability Log and the corresponding CRF
Study Conclusion/ Close-Out	Return Sheet	Requested by the Site, during Study Conclusion/Close-Out. Accompanies unused product for return to Sponsor. The Sponsor Monitor must sign the Return Sheet Prior to the Site shipping the Test Articles to JJVCI. The original Return Sheet will be maintained at the site in the study files, a copy confirming receipt will be sent back to the Sponsor.
	EDC Lens Depot / Returning Test Articles in the EDC.	Confirms return shipment contents back to JJVCI in the EDC. Must be completed prior to shipping Test Articles back to JJVCI. A site representative will log into the EDC, entering in the return amount of each Test Article lot. **Refer to Appendix C for complete instructions on how to Receive, Dispense, and Return Test Articles in the EDC.**
	Lens Reconciliation	The monitor will review all the lens accountability records and attempt to reconcile. **Explanation will be needed for any unaccounted test articles.**

Note: If there is a discrepancy between the shipment sheet and contents, *contact the study monitor immediately.*

4.10 PROCEDURES FOR MAINTAINING AND BREAKING RANDOMIZATION CODES

Each type of test article except for the subject's habitual spectacles is assigned and labeled with a unique lens ID code (also serves as the randomization code). The identity of the control lens type (Oasys) will be masked to subjects.

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. The designee (documented on the delegation log) will consult the randomization scheme to obtain the study test article assignment for that subject prior to dispensing.

2. The designee will record the subject's number on the appropriate line of the randomization scheme.

The 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.

4.11 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 [redacted] or electronic equivalent).

For each complaint, the following minimum information shall be recorded by the CRA/COM on the [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 [redacted] for test article return instructions)

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

[redacted]

5.1 WITHDRAWAL CRITERIA

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

- Lost to follow-up
- Withdrawal of consent
- Death

- Subject was randomized but did not satisfactorily complete the fitting process,
- A scheduled visit is missed,
- Subject no longer met eligibility criteria (i.e. subject became pregnant during the study),
- Discontinuation of study treatment as a result of the investigator's belief that for safety reasons (e.g., adverse event) it is in the best interest of the subject to stop treatment.
- Non-compliance to the protocol.

For discontinued subjects, the Investigator will:

- Update the enrollment log to document reason for discontinuation and provide to CRA
- 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.

Investigators may be asked to replace discontinued subjects if the minimum target number of total subjects across all sites may otherwise not be met.

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. Disallowed medications for this study include those medications new to the subject within the past month and pose a threat to safe and comfortable contact lens wear.

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 wellbeing 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

A separate monitoring plan will be provided.

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 EFFICACY ASSESSMENTS

7.1 EFFICACY PARAMETERS

The primary safety parameters in this study are Biomicroscopy findings and the primary efficacy parameters are visual acuity (LogMAR) and Eyestrain caused by glare. The secondary safety parameter in this study is ocular symptoms and the efficacy parameter is average wear time. Other observations are subjective performance measured by GSI, CLUE and Lens Preference.

7.2 METHODS FOR ASSESSING, RECORDING, AND ANALYZING EFFICACY

Refer to Section 4.1 (Primary and Secondary Endpoints) and Section 9 (Statistical Analysis).

8 SAFETY ASSESSMENTS

8.1 SAFETY PARAMETERS

All subjects randomized and treated will be in the safety analyses. All reported AEs will be summarized. All safety data will be listed by subject. The following safety parameters will be monitored and evaluated:

- Adverse events
- Ocular physiology (corneal staining, limbal and bulbar conjunctival redness)
- Ocular symptoms
- Slit Lamp Findings
- Lens Deposits
- Reasons for discontinuation

- Lens damage
- Reason for unplanned lens replacement
- Snellen VA

8.2 ADVERSE EVENTS

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 48 hours 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
- Hyphemia
- 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 $\geq$ 2 Lines of BSCVA
- Other grade 3 or higher corneal findings, such as abrasions or edema
- Any corneal event which necessitates temporary lens discontinuation $\geq$ 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 8.3).
- 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 patient 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 events 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

This section is a general outline of the statistical methods that will be implemented in this clinical trial. For more details, refer to the stand-alone Statistical Analysis Plan (SAP) of this clinical study.

General Considerations:
Statistical programming and analyses will be performed using SAS (SAS Institute, Cary, NC)5 Version 9.4 or higher. Throughout the analysis of data, the results for each eye will be used when available for summarization and statistical analysis.

Descriptive statistics will be reported at baseline and each post fit time period for all safety and efficacy variables as appropriate. Unless otherwise noted, continuous variables will be summarized using descriptive statistics: number of non-missing values (N), mean (Mean), standard deviation (SD), median (Median), minimum (Min), and maximum (Max); and categorical variables will be summarized using the frequency count (N) and the percentage (%) of subjects or eyes in each category.

Summaries will be presented by study article type (Test or Control) and will be performed separately by completion status (completed or discontinued). See Section 9.7 for additional details regarding subject completion status. The denominator for percentages of counts will be the same for each visit on the summary tables and will equal the final number of subjects or eyes in the group under consideration. Unscheduled visits will be summarized separately and will be excluded from efficacy analysis.

Analysis Population Sets:

Efficacy analyses will be performed on all randomized subjects who completed the study and did not substantially deviate from the protocol as determined by the trial cohort review committee prior to database hard lock (Per-Protocol Population). Justification of excluding subjects with protocol deviations in the per-protocol population set will be documented in a memo to file. Additional post-hoc analyses may be conducted by including all randomized subjects who have been successfully dispensed and have at least one follow-up visit. Refer to section 9.7 Evaluable Subjects for more details.

Safety analyses will be performed on the safety population, which will be comprised of all randomized subjects who have been successfully dispensed at least one study lens.

Unless otherwise specified, all statistical tests will be 2-sided and conducted at the 0.05 level of significance.

Efficacy Analysis:
Visual Acuity
Contact lens monocular distance best-corrected visual acuity (BCVA) on logMAR scale will be analyzed using a linear mixed model to test for the differences between the Test and Control group at each follow-up visit. Lens group, time (1-, 2-, 4-, 8- and 12-week) and the lens group by time interaction will be included as fixed effects in the model; and investigator site, subject and eye nested within subject as random effects when appropriate.

The covariance between residuals from the same eye and subject at different time points will be selected based on the finite-sample Corrected Akaike's Information Criterion. Covariance structures considered include Compound Symmetry (CS), Heterogeneous Compound Symmetry (CSH), Spatial Power (SP(POW)), *Ante*-dependence (ANTE(1)) and unstructured (UN). For ANTE(1) and SP(POW) structures, site, subject and eye nested within subject will be included as random effects. For the remaining structures only site and subjects will be included as random effects. The covariance structure that returns the lowest Akaike Information Criteria Corrected (AICC) will be selected as the structure that best fit the data. Heterogeneous residuals covariance structures (R-side) across lens groups will be considered when appropriate. The log-likelihood ratio test will be used to test for the homogeneity between the residual covariance structures. The Kenward and Roger method will be used for the denominator degree of freedom.

Comparison between the Test and the Control groups will be conducted at each time point using a t-test on least-square means from the repeated measure analysis. Adjustment for multiple comparisons across time will be performed using Bonferroni's method with alpha equal to 0.01 (0.05/5). The corresponding simultaneous confidence intervals of least-square means differences will be calculated with 99% confidence.

Average Wear Time (AWT)

AWT (in hours) will be analyzed using a linear mixed model to test for difference between the Test and the Control groups. Lens Group, Time (1-, 2-, 4-, 8- and 12-week) and the interaction term the lens group by time will be included as fixed effects in the model; and site as random effect.

The covariance between residuals from the same subject at different time points will be selected based on the finite-sample corrected Akaike's Information Criterion. Covariance structures considered include homogenous compound symmetry (CS), heterogeneous Compound symmetry (CSH), Spatial Power (SP(POW)), *Ante*-dependence (ANTE(1)) and unstructured (UN). For ANTE(1) and SP(POW) structures, site and subject will be included as random effects. For the remaining structures only site will be included as random effect. The covariance structure that returns the lowest AICC will be selected as the structure that best fit the data. Heterogeneous residuals covariance structures (R-side) across lens groups will be considered when appropriate. The log-likelihood ratio test will be used to test for the homogeneity between the residual covariance structures. The Kenward and Roger method will be used for the denominator degree of freedom.

Comparison between the Test and the Control groups will be conducted at each time point using a t-test on least-square means from the repeated measure analysis. Adjustment for multiple comparisons across time will be performed using Bonferroni's method with alpha equal to 0.01 (0.05/5). The corresponding simultaneous confidence intervals of least-square means differences will be calculated with 99% confidence.

Safety Analysis:

Slit Lamp Findings (SLF)

SLF responses will be categorized into a binary outcome as 0 if no Grade 3 or higher SLF or 1 if any Grade 3 or higher SLF. Events occurring during an unscheduled visit will be counted in the subsequent scheduled visit. For example, if a SLF grade 3 or higher occurs between Visit 1 and Visit 2, it will be counted in Visit 2. If there are multiple events at a given time point for one eye, it will be counted only once. The safety endpoint will be analyzed using a Generalized Estimating Equation (GEE) model (Zeger and Liang; 1986)[2] with a binomial distribution and logit link function. The regression model will include terms for lens group, time (1-, 2-, 4-, 8- and 12-week) and the lens group by time interaction (group*time). Appropriate working correlation matrix will be selected to take on consideration the correlation between measurements within each subject using Quasi-likelihood Information Criterion (QIC). Working correlation structures to be considered will include independence (IND), exchangeable (Exch), autoregressive AR(1) and unstructured (UN). The covariance structure that returns the lowest QIC will be selected as the structure that best fit the data. If all model fails to converge, a reduced model will be considered by removing group*time and time from the model.

The odds ratio of outcome 1 between the Test and the Control groups will be calculated with a 95% confidence interval to test for the difference between the Test and Control groups.

If there are no sufficient SLF findings of Grade 3 or higher, analysis will be performed on any SLF grade 2 or higher SLF. Further analyses by subject, visit and/or slit lamp findings category will also be considered if necessary.

Ocular Symptoms, problems or complaints

Reported ocular symptoms, problems or complaints (0 = No, 1 = Yes) at any visit will be analyzed using a GEE model for clustered binary outcome to assess the difference between the Test and Control groups. The regression model will include terms for lens group, time (1-, 2-, 4-, 8- and 12-week) and the lens group by time interaction. Appropriate working correlation matrix will be selected to take on consideration the correlation between measurements within each subject using Quasi-likelihood Information Criterion (QIC). Working correlation structures to be considered will include exchangeable, autoregressive AR(1) and unstructured (UN). Odds ratio of outcome 1 between the Test and the Control groups will be calculated with a 95% confidence interval.

If the interaction lens by time is significant at the 0.15 significance level, the difference between the Test and Control will be assessed for each follow-up visit.

9.2 NUMBER OF SUBJECTS BY SITE AND JUSTIFICATION FOR SAMPLE SIZE

The plan is to enroll 60 eligible subjects per arm with a target completion of 50 subjects per arm. This is a pilot study and the sample size was not based on any empirical calculation. A statistical power analysis for different scenarios of effect size and variance will be provided in the stand alone SAP document.

During the enrollment period, the subject dropout rate will be closely monitored, if unexpectedly high dropout rate is observed in certain arm (s), the targeted total enrollment number will be increased accordingly in order to ensure a minimum of 50 subjects per group to complete the 3-month follow-up. Please refer to the stand alone Statisitical Analysis Plan (SAP).

9.3 LEVEL OF STATISTICAL SIGNIFICANCE

In addition to the unadjusted estimates, adjusted estimates with 5% significance level (type I error rate) will be provided.

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 patient 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. The count of missing values will be included in the summary tables and listings.

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

Subjects will be allocated to one of four mutually exclusive groups:

1. Enrolled, Not Randomized: Subjects are considered to be Enrolled Not Randomized if they were (i) enrolled to the study (provided informed consent) but failed to satisfy the eligibility criteria (inclusion/exclusion criteria) or (ii) were not randomized to study lens for any reason.

2. Randomized, Not Successfully Dispensed: Subjects are considered to be Randomized Not Successfully Dispensed if they are randomized but did not satisfactorily complete the dispensing process. This includes subjects who were dispensed a different type of study lens for each eye or who were dispensed same study lens for both eyes but did not return for any follow-up visits.

3. Successfully Dispensed, Discontinued Subjects: Subjects are considered to have discontinued from the study if they are (i) randomized (ii) Successfully Dispensed and (iii) discontinued because of one of the reasons described in section 5.1.

4. Successfully Dispensed, Completed Subjects: Subjects are considered to have completed the study if they have completed all required visits through Visit 8 (14-week Follow-up Visit).

Safety and efficacy analysis sets will be defined as subsets of successfully dispensed subjects (completed + discontinued).

10.1 ELECTRONIC CASE REPORT FORMS/DATA COLLECTION

The data for this study will be captured on electronic case report forms (eCRFs) using an EDC system (BioClinica), when possible. Designated study site personnel will enter study data into the electronic CRFs (eCRFs) using the EDC system (BioClinica). Data collected on equipment that is not possible to be captured in EDC will be formatted to the specification of the JJVCI database manager and sent to JJVCI 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 JJVCI biostatistician for data analysis in such format.

The clinical data will be recorded on dedicated electronic case report forms (eCRFs) specifically designed to match the testing routine for each visit. Once completed, 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.

BioClinica is compliant with all relevant aspects of ICH/Good Clinical Practices, and 21 CFR Part 11 (Electronic Records & Electronic Signatures) regulations. In addition, the Sponsor and BioClinica are Safe Harbor Certified.

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 PDF 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.

It is recommended that the author of an entry in the source documents 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/DOCUMENTS

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, JJVCI 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 JJVCI. The Investigator may use this information for the purposes of the study only. It is understood by the Investigator that JJVCI 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 JJVCI. JJVCI 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 principle 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 during 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 59th 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 JJVCI 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.

16.1 PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

16.2 CLINICAL TECHNICAL PROCEDURES [redacted]

The [redacted] referenced in this protocol are shown below.

[redacted]	Title	Page
	Limbal and conjunctival (bulbar) redness	103
	Sodium fluorescein corneal staining	111
	Subjective assessment of lens fit	116
	Subject reported ocular symptoms/problems	123
	Front and back surface lens deposits grading procedure	125
	Determination of distance spherocylindrical refractions	131
	Biomicroscopy scale	138
	Distance and near visual acuity evaluation	144
	Distance LogMAR Visual Acuity Measurement Procedure	150
	White Light Lens Surface Wettability	154

[redacted] ***Limbal & Conjunctival (Bulbar) Redness***

[redacted] ***Subject Reported Ocular Symptoms/Problems***

[redacted] ***Biomicroscopy Scale***

[redacted] ***White Light Lens Surface Wettability***

16.3 PATIENT INSTRUCTION GUIDE (INVESTIGATIONAL PRODUCT)

The investigational patient instruction guide will be provided separately.

16.4 PACKAGE INSERT (APPROVED PRODUCT)

IMPORTANT: Please read carefully and keep this information for future use.

This Package Insert and Fitting Guide is intended for the Eye Care Professional, but should be made available to patients upon request.

The Eye Care Professional should provide the patient with the appropriate instructions that pertain to the patient's prescribed lenses. Copies are available for download at www.acuvue.com.

ACUVUE®

OASYS

BRAND CONTACT LENSES

ACUVUE OASYS® Brand Contact Lenses

ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM

ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA

senofilcon A Soft (hydrophilic) Contact Lenses
Visibility Tinted with UV Blocker
for Daily and Extended Wear

Rx Only

CAUTION: U.S. Federal law restricts this device to sale by, or on [redacted] a licensed practitioner.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	Consult Instructions for Use
	Manufactured by or in
	Date of Manufacture
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CYL	Cylinder
AXIS	Axis
MAX ADD	Near ADD
LOW	"Low" Near ADD
MID	"Medium" Near ADD
HGH	"High" Near ADD
CE 0086	Quality System Certification Symbol
	UV-Blocking
	Fee Paid for Waste Management
	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)

DESCRIPTION

The ACUVUE OASYS® Brand Contact Lenses, the ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM, and the ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA are soft (hydrophilic) contact lenses available as spherical, toric, or multifocal lenses and include HYDRACLEAR® PLUS Technology. The lenses are made of a silicone hydrogel material containing an internal wetting agent with visibility tinted UV absorbing monomer.

These lenses are tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling. A benzotriazole UV absorbing monomer is used to block UV radiation.

The transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

Lens Properties:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.42
- Light Transmittance: 85% minimum
- Surface Character: Hydrophilic
- Water Content: 38%
- Oxygen Permeability:

VALUE	METHOD
103 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) @ 35°C	Fatt (boundary corrected, edge corrected)
122 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) @ 35°C	Fatt (boundary corrected, non-edge corrected)

Lens Parameters:

- Diameter Range: 12.0 mm to 15.0 mm
- Center Thickness: varies with power
- Base Curve Range: 7.85 mm to 10.00 mm
- Spherical Power Range: Daily Wear: -20.00D to +20.00D
  Extended Wear: -20.00D to +14.00D
- Multifocal ADD Power Range: +0.25D to +4.00D
- Cylinder Power Range: -0.25D to -10.00D
- Axis Range: 2[redacted]80°

AVAILABLE LENS PARAMETERS

The ACUVUE OASYS® Brand Contact Lenses are hemispherical shells of the following dimensions:

Diameter:	14.0 mm
Center Thickness:	Minus Lens - varies with power (e.g. -4.00D: 0.070 mm) Plus Lens - varies with power (e.g. +4.00D: 0.168 mm)
Base Curve:	8.4 mm, 8.8 mm
Powers:	-0.50D to -6.00D (in 0.25D increments) -6.50D to -12.00D (in 0.50D increments) +0.50D to +6.00D (in 0.25D increments) +6.50D to +8.00D (in 0.50D increments)

The ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM are hemitoric shells of the following dimensions:

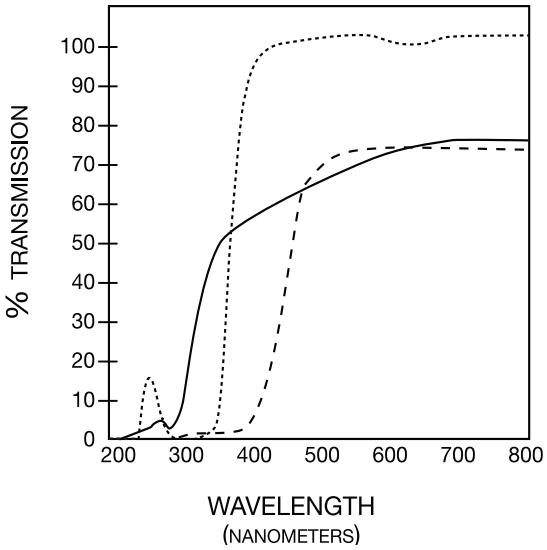
Diameter:	14.5 mm
Center Thickness:	Minus Lens - varies with power (e.g. -4.00D: 0.080 mm) Plus Lens - varies with power (e.g. +4.00D: 0.172 mm)
Base Curve:	8.6 mm
Powers:	plano to -6.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments) +0.25D to +6.00D (in 0.25D increments) Cylinder: -0.75D, -1.25D, -1.75D, -2.25D, -2.75D Axis: 10° to 180° (in 10° increments)

The ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA are hemispherical shells of the following dimensions:

Diameter:	14.3 mm
Center Thickness:	Minus Lens - varies with power (e.g. -4.00D: 0.070 mm) Plus Lens - varies with power (e.g. +4.00D: 0.168 mm)
Base Curve:	8.4 mm
Powers:	-9.00D to +6.00D (in 0.25D increments)
ADD Powers:	+1.25 (LOW), +1.75 (MID), +2.50 (HGH)

TRANSMITTANCE CURVE

ACUVUE OASYS® Brand Contact Lenses vs. 24 yr. old human cornea vs. 25 yr. old human crystalline lens



ACUVUE OASYS®
(senofilcon A)*

24 YR. OLD
HUMAN CORNEA[1]

25 YR. OLD HUMAN
CRYSTALLINE LENS[2]

*The data was obtained from measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-1.00D lens, 0.070 mm center thickness).

1. Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, figure 2-21
2. Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, figure 5

WARNING: UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear, such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. The patient should continue to use UV absorbing eyewear as directed.

ACTIONS

In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina. When hydrated and placed on the cornea for therapeutic use, the contact lens acts as a bandage to protect the cornea.

The transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-Blocking contact lenses help provide protection against harmful UV radiation.

However, clinical studies have not been done to demonstrate that wearing UV-Blocking contact lenses reduces the risk of developing cataracts or other eye disorders. The Eye Care Professional should be consulted for more information.

INDICATIONS (USES)

The ACUVUE OASYS® Brand Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism.

The ACUVUE OASYS® Brand Contact Lens for ASTIGMATISM is indicated for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism.

The ACUVUE OASYS® Brand Contact Lens for PRESBYOPIA is indicated for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D or less of astigmatism.

These lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye Care Professionals may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement (see "REPLACEMENT SCHEDULE"). When prescribed for frequent/planned replacement wear, the lenses may be cleaned and disinfected using a chemical disinfection system only.

These lenses have been approved for daily and extended wear for up to 6 nights/7 days of continuous wear. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Professional.

These lenses are also indicated for therapeutic use as a bandage lens for the following acute and chronic ocular conditions:

- For corneal protection in lid and corneal abnormalities such as entropion, trichiasis, tarsal scars, and recurrent corneal erosion. In addition, they are indicated for protection where sutures or ocular structure malformation, degeneration or paralysis may result in the need to protect the cornea from exposure or repeated irritation.
- For corneal pain relief in conditions such as bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, and post-keratoplasty.
- For use as a barrier during the healing process of epithelial defects such as chronic epithelial defects, corneal ulcer, neurotrophic and neuroparalytic keratitis, and chemical burns.
- For post-surgical conditions where bandage lens use is indicated such as post refractive surgery, lamellar grafts, corneal flaps, and additional ocular

surgical conditions.

- For structural stability and protection in piggy back lens fitting where the cornea and associated surfaces are too irregular to allow for corneal rigid gas permeable (RGP) lenses to be fit. In addition, the use of the lens can prevent irritation and abrasions in conditions where there are elevation differences in the host/graph junction or scar tissue.

Lenses prescribed for therapeutic use may be worn for daily or extended wearing periods.

CONTRAINDICATIONS (REASONS NOT TO USE)

When prescribing contact lens wear for REFRACTIVE AMETROPIA USE, DO NOT USE these lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Severe insufficiency of lacrimal secretion (dry eye)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e., cleaning and disinfecting solutions, rewetting drops, etc.) that contain chemicals or preservatives (such as mercury or Thimerosal, etc.) to which some people may develop an allergic response
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

For THERAPEUTIC USE, the Eye Care Professional may prescribe these lenses to aid in the healing process of certain ocular conditions, which may include those cited above.

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF THE PATIENT EXPERIENCES:

- **Eye Discomfort,**
- **Excessive Tearing,**

- **Vision Changes,**
- **Loss of Vision,**
- **Eye Redness,**
- **Or Other Eye Problems,**

THE PATIENT SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES AND PROMPTLY CONTACT THE EYE CARE PROFESSIONAL.

- When prescribed for daily wear, patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when lenses are worn overnight, and that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users.[3]
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.

[3] New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

Specific Instructions for Use and Warnings:

- **Water Activity**

  Instructions for Use

  Do not expose contact lenses to water while wearing them.

  WARNING:

  Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If lenses have been submersed in water when participating in water sports or swimming in pools, hot tubs, lakes or oceans, the patient should be instructed to discard them and replace them with a new pair. The Eye Care Professional should be consulted for recommendations regarding wearing lenses during any activity involving water.

- **Soaking and Storing Your Lenses**

  Instructions for Use

  Use only fresh multi-purpose (contact lens disinfecting) solution each time the lenses are soaked (stored).

  WARNING:

  Do not reuse or “top off” old solution left in the lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss, or blindness.

"Topping-Off" is the addition of fresh solution to solution that has been sitting the case.

- **Discard Date on Multi-Purpose Solution Bottle**

  Instructions for Use

  – Discard any remaining solution after the recommended time period indicated on the bottle of multi-purpose solution used for disinfecting and soaking the contact lenses.

  – The Discard Date refers to the time that the patient can safely use contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

  WARNING:

  Using multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss, or blindness.

  – To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.

  – To avoid contaminating the solution, DO NOT transfer to other bottles or containers.

- **Rub and Rinse Time**

  Instructions for Use

  To adequately disinfect the lenses, the patient should rub and rinse the lenses according to the recommended lens rubbing and rinsing times in the labeling of the multi-purpose solution.

  WARNING:

  – Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections.

  – Never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss, or blindness.

- **Lens Case Care**

  Instructions for Use

  – Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.

  – Replace the lens case according to the directions provided by the Eye Care Professional or the manufacturer's labeling that accompanies the case.

– Contact lens cases can be a source of bacterial growth.

WARNING:

Do not store lenses or rinse lens cases with water or any non-sterile solution. Only fresh multi-purpose solution should be used to prevent contamination of the lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss, or blindness.

PRECAUTIONS

Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.

- Patients who wear these lenses to correct presbyopia using monovision may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.

- Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.

Eye Care Professionals should carefully instruct patients about the following care regimen and safety precautions:

Handling Precautions:

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her.

- DO NOT use if the sterile blister package is opened or damaged.

- Always wash and rinse hands [redacted] ndling lenses. Do not get cosmetics, lotions, soaps, creams, deodo[redacted] or sprays in the eyes or on the lenses. It

is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.

- DO NOT touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Instruction Guide for these lenses and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Slide the lens up the side of the bowl until it is free of the container.
- Do not touch the lens with fingernails.
- Close supervision is necessary for the Therapeutic use of these lenses. Ocular medications used during treatment with a bandage lens should be closely monitored by the Eye Care Professional. In certain ocular conditions, only the Eye Care Professional will insert and remove the lenses. In these cases, patients should be instructed not to handle the lenses themselves.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in “Care for Sticking (Non-Moving) Lenses”. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- The patient should be advised to never allow anyone else to wear their lenses. They have been prescribed to fit their eyes and to correct their vision to the degree necessary. Sharing lenses greatly increases the chance of eye infections.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.

Lens Care Precautions:

- Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Chemical disinfection solutions should not be used with heat unless

specifically indicated on product labeling for use in both heat and chemical disinfection.

- Always use fresh, unexpired lens care solutions and lenses.
- Do not change solution without consulting with your Eye Care Professional.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage these lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions in "Care For A Dried Out (Dehydrated) Lens" if lens surface does become dried out.

Other Topics to Discuss with Patients:

- Always contact the Eye Care Professional before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Who Should Know That the Patient is Wearing Contact Lenses?

- Patients should inform all doctors (Health Care Professionals) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require use of [redacted]ction equipment or may require that the patient not wear contact le[redacted]

ADVERSE REACTIONS

The patient should be informed that the following problems may occur when wearing contact lenses:

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.
- The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:
  - How do the lenses feel on my eyes?
  - How do my eyes look?
  - Have I noticed a change in my vision?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS. If the problem or discomfort stops, the patient should discard the lens and place a new fresh lens on the eye.

If after inserting the new lens, the problem continues, the patient should be directed to IMMEDIATELY REMOVE THE LENS AND CONTACT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be instructed NOT to use a new lens as self-treatment for the problem.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

GENERAL FITTING GUIDELINES

A. Patient Selection:

Patients selected to wear these lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear

Patients who do not meet the above criteria should not be provided with contact lenses.

B. Pre-fitting Examination:

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription (including determining the preferred reading distance for presbyopes), keratometry and biomicroscopic evaluation.

Based on this evaluation, if it is determined that the patient is eligible to wear these lenses, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

C. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00D.

D. Base Curve Selection (Trial Lens Fitting)

The following trial lenses should be selected for patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

- **ACUVUE OASYS®**: 8.4 mm/14.0 mm
- **ACUVUE OASYS® for ASTIGMATISM:** 8.6 mm/14.5 mm
- **ACUVUE OASYS® for PRESBYOPIA:** 8.4 mm/14.3 mm

The trial lenses should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. Criteria of a Properly Fit Lens

A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink, and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released.

2. Criteria of a Flat Fitting Lens

A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If the lens is judged to be flat fitting, it should not be dispensed to the patient.

3. Criteria of a Steep Fitting Lens

A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation, and resistance when pushing the lens up digitally with the lower lid. If the lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial trial base curve is judged to be flat or steep fitting, the alternate base curve, if available, should be trial fit and evaluated after the patient has adjusted to the lens. The lens should move freely when manipulated digitally with lower lid, and then return to a properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

E. Final Lens Power (Spherical)

A spherical over-refraction should be performed to determine the final lens power after the lens fit is judged acceptable. The spherical over-refraction should be combined with the trial lens power to determine the final lens prescription. The patient should experience good visual acuity with the correct lens power unless there is excessive residual astigmatism.

Example 1	
Diagnostic lens:	-2.00D
Spherical over-refraction:	-0.25D
Final lens power:	-2.25D

Example 2	
Diagnostic lens:	-2.00D
Spherical over-refraction:	+0.25D
Final lens power:	-1.75D

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow-up information in PATIENT MANAGEMENT).

All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.

TORIC FITTING GUIDELINES

Although most aspects of the fitting procedure are identical for all types of soft contact lenses, including torics, there are some additional steps and/or rules to follow to assure the proper fit of toric lenses.

The only new steps you must follow in prescribing ACUVUE OASYS® for ASTIGMATISM contact lenses are that you must determine the stability, repeatability and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

A. How to Determine Lens Cylinder and Axis Orientation

1. Locate the Orientation Marks

To help determine the proper orientation of the toric lens, you'll find two primary marks about 1 mm from the lens edge representing the vertical position on opposite ends of the lens at 6 and 12 o'clock (Fig. 1). Because of the lens' ballasting system, either mark can represent the vertical position – there is no "top" and "bottom" as in a prism-ballasted lens. You don't need to view both marks to assess orientation; simply look for the 6 o'clock mark as you would with a prism-ballasted lens.

Figure 1

You'll need a biomicroscope and a 1 mm or 2 mm parallelepiped beam to highlight the marks when the lens is fitted to the eye. There are a number of techniques you can use to improve the visibility of the 6 o'clock mark. Using a parallelepiped beam and medium magnification (10x or 15x), slowly pan down the lens, looking just below the direct illumination at the retroilluminated area. Backlighting the mark this way should make it more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark.

2. Observe Lens Rotation and Stability

Observe the position and stability of the "bottom" mark. It usually stabilizes at the 6 o'clock position. If it does, calculation of the lens power will be straightforward. The 6 o'clock position is not a "must"; however, the absolute requirement is that the axis position be stable and repeatable.

The mark may stabilize somewhat left or right (drift) of the vertical meridian and still enable you to fit a toric lens for that eye, as long as the lens always returns to the same “drift axis” position after settling. The deviation can be compensated for in the final prescription. Your objective is to ensure that whatever position the initial lens assumes near 6 o’clock, this position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they must return quickly to the original stable position. If the lens does not return quickly, you may need to select a different lens.

Assessing Rotation

Imagine the eye as a clock dial and every hour represents a 30° interval. If the orientation mark of the initial lens stabilizes somewhat left or right of the vertical position, the final lens will orient on the eye with the same deviation. You can use an axis reticule in the slit lamp or use a line-scribed lens in a spectacle trial frame to measure or estimate the “drift angle” of the cylinder axis.

To compensate for this “drift”, measure or estimate the “drift”, then add or subtract it from the refractive axis to determine the correct cylinder axis. Use the LARS (Left Add, Right Subtract) method to determine which direction to compensate.

B. How to Determine the Final Lens Power

When the diagnostic lens has its axis aligned in the same meridian as the patient’s refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the patient’s refractive axis, it is not advisable to over-refract because of the difficulty in computing the resultant power. In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it’s more practical to prescribe as weak a cylinder as possible.
So, here is how to determine the final lens power.

For the Sphere:

If sphere alone or combined sphere and cylinder Rx >±4.00D, compensate for vertex distance. If sphere alone or combined sphere and cylinder Rx ≤± 4.00D, vertex compensation is not necessary.

For the Cylinder:

Adjust the axis by the drift angle using LARS. Choose a cylinder that is ≤ 0.25D from the refractive cylinder.

Case Examples:

Example 1
Manifest (spectacle) refraction:
O.D. –2.50 -1.25 x 180 20/20
O.S. –2.00 -1.00 x 180 20/20
Choose a diagnostic lens for each eye with an axis as close to 180° as possible. Place the lens on each eye and allow a minimum of 3 minutes for

it to equilibrate, based on the patient's initial response to the lens. If the lens has not yet stabilized, recheck until stable.

Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously. If the lens has not yet stabilized, recheck until stable.

Here is the Rx Prescribed:

O.D. -2.50 -1.25 x 180
O.S. –2.00 -0.75 x 180

Example 2

Manifest (spectacle) refraction:
O.D. –3.00 -1.00 x 90 20/20
O.S. –4.75 -2.00 x 90 20/20

Choose diagnostic lenses of –3.00 –0.75 x 90 for the right eye and –4.50 -1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens. If the lens has not yet stabilized, recheck until stable. The orientation mark on the right lens rotates left from the 6 o'clock position by 10°.

The fitting indicates the following:

Right Eye:
Compensate the 10° axis drift by adding it to the manifest refraction axis. Here is the Rx prescribed:
O.D. –3.00 –0.75 x 100
Left Eye
The lens on the left eye shows good centration, movement and a consistent tendency for the mark to drift right by 10° from the 6 o'clock position following a forced blink. Since the manifest refraction called for a power of –4.75D, adjust for the vertex distance and reduce the sphere by 0.25D and prescribe the –1.75D cylinder. Compensate for the 10° axis drift by subtracting it from the manifest refraction.

Here is the Rx Prescribed:

O.S. –4.50 –1.75 x 80

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in PATIENT MANAGEMENT).

All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.

MULTIFOCAL FITTING GUIDELINES

A. Presbyopic Needs Assessment & Patient Education

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the ACUVUE OASYS® for PRESBYOPIA contact lenses. Wear may not be optimal for activities such as:

1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass their state driver's license requirements with these lenses should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

These lenses are not recommended for patients who have –1.00D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise.

These lenses are available in the following ADD powers:

- Lens “LOW” = “low” near ADD lens (Max +1.25 ADD)
- Lens “MID” = “medium” near ADD lens (Max +1.75 ADD)
- Lens “HGH” = “high” near ADD lens (Max +2.50 ADD)

B. Fitting Instructions

1. Determine the following:

- Eye dominance (the methods described in MONOVISION FITTING GUIDELINES may be used)
- Spherical equivalent distance prescription (vertex corrected if necessary and rounded to less minus if between powers)
- Near ADD

2. Select the initial trial lens as follows:

- For each eye select the trial lens distance power that is closest to the patient's distance spherical equivalent

- Select the near power of the lens based on the patient's ADD range as follows:

  ADD: +0.75 to +1.25 use a “LOW” near ADD lens on each eye

  ADD: +1.50 to +1.75 use a “MID” near ADD lens on each eye

  ADD: +2.00 to +2.50 use a “HGH” near ADD lens on each eye

3. Allow the lens to settle for a minimum 10 minutes.

4. Assess distance and near vision binocularly and monocularly.

- Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near.
- Make adjustments in power as necessary (see Multifocal Troubleshooting below). The use of hand-held trial lenses is recommended.
- If distance and near vision are acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow-up information in PATIENT MANAGEMENT).

C. Multifocal Troubleshooting

Unacceptable Near Vision:
Determine the amount of additional plus, or less minus, over one or both eyes that is acceptable, while checking the effect on distance and near vision. If vision is still not acceptable, change the non-dominant eye to the next highest ADD power.

Unacceptable Distance Vision:
Determine the amount of additional minus, or less plus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable, change the dominant eye to the next lowest ADD power. If the patient is wearing two low ADD lenses, change the dominant eye to a sphere lens with a power equal to the spherical equivalent distance prescription.

Unacceptable Distance and Near Vision:
Determine the amount of additional plus and/or minus over one or both eyes that is acceptable while checking the effect on distance and near vision. If additional plus and/or minus is not required, change the lens power in the dominant eye to the next lowest ADD power and the lens power in the non-dominant eye to the next highest ADD power, if applicable.

All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.

MONOVISION FITTING GUIDELINES

A. Patient Selection

Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.00D) in one eye may not be a good candidate for monovision correction with these lenses.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision correction. Monovision contact lens wear may not be optimal for activities such as:

1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass their state driver's license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with spectacles (multifocal, bifocal, trifocal, readers, progressives). Each patient should understand that monovision, as well as other presbyopic alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments (e.g., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). During the fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision and straight ahead and upward gaze that monovision contact lenses provide.

B. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following two methods for eye dominance can be used.

1. Ocular Preference Determination Methods

Method 1: Determine which eye is the “sighting eye.” Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighti e.

Method 2: Determine which eye will accept the added power with the least reduction in vision. Place a hand-held trial lens equal to the spectacle near ADD in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near ADD lens over the right or left eye.

Other methods include the refractive error method and the visual demands method.

2. Refractive Error Method
For anisometropic correction, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

3. Visual Demands Method
Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction, correct the eye on that side for near.

Example: A secretary who places copy to the left side of the desk will function best with the near lens on the left eye.

C. Special Fitting Characteristics

1. Unilateral Lens Correction
There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may only require a distance lens.

Example: A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without a lens. A presbyopic patient requiring a +1.50D ADD who is –2.50D myopic in the right eye and –1.50D myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

2. Near ADD Determination
Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

3. Trial Lens Fitting
A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the GENERAL FITTING GUIDELINES for base curve selection in this Package Insert.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine the distance correction and the near correction. Next determine the near ADD. With trial lenses of the proper power in place, observe the reaction to [redacted] f correction.

Allow the lenses to settle for about 20 minutes with the correct power lenses in place. Walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tests are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to newsprint and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

4. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

D. Other Suggestions

The success of the monovision technique may be further improved by having the patient follow the suggestions below:

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles [redacted] ver the monovision contact lenses

for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot pass state drivers licensing requirements with monovision correction.

- Make use of proper illumination when carrying out visual tasks.

Monovision fitting success can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of clear near vision and straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the Eye Care Professional in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.

PATIENT MANAGEMENT

Dispensing Visit

- PROVIDE THE PATIENT WITH A COPY OF THE PATIENT INSTRUCTION GUIDE FOR THESE LENSES. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE (DISPOSABLE OR FREQUENT REPLACEMENT).
- Recommend an appropriate cleaning and disinfecting system and provide the patient with instructions regarding proper lens care. Chemical or hydrogen peroxide disinfection is recommended.
- Schedule a follow-up examination.

Follow-up Examinations

- Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule, lens replacement schedule, and proper lens care and handling procedures.
- Recommended Follow-up Examination Schedule (complications and specific problems should be managed on an individual patient basis):
  1. One week from the initial lens dispensing to patient
  2. One month post-dispensing
  3. Every three to six months there

NOTE: More frequent or additional follow-up visits may be recommended for patients on an extended wear schedule.

- Preferably, at the follow-up visits, lenses should be worn for at least six hours. If the lenses are being worn for continuous wear, the examination should be performed as early as possible on the morning following overnight wear.
- Recommended Procedures for Follow-Up Visits:
  1. Solicit and record patient's symptoms, if any.
  2. Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.
  3. Perform an over-refraction at distance and near to check for residual refractive error.
  4. With the biomicroscope, judge the lens fitting characteristics (as described in the GENERAL FITTING GUIDELINES) and evaluate the lens surface for deposits and damage.
  5. Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein (unless contraindicated).
     - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
     - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
     - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
  6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

If any observations are abnormal, use professional judgment to alleviate the problem and restore the eye to optimal conditions. If the criteria for successful fit are not satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and refit the patient.

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the Eye Care Professional. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

For Daily Wear:

Patients tend to overwear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Maximum wearing time should be determined by the Eye Care Professional based upon the patient's physiological eye [redacted] because individual response to contact lenses varies.

The maximum suggested wearing time for these lenses is:

DAY	HOURS
1	6-8
2	8-10
3	10-12
4	12-14
5 and after	all waking hours

For Extended Wear:

It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Professional.

These lenses have been approved for extended wear up to 6 nights/7 days of continuous wear. Not all patients can achieve the maximum wear time.

For Therapeutic lens wear, close supervision by the Eye Care Professional is necessary. These lenses can be worn for extended wear for up to 6 nights/7 days of continuous wear. The Eye Care Professional should determine the appropriate wearing time and provide specific instructions to the patient regarding lens care, insertion, and removal.

REPLACEMENT SCHEDULE

For Lenses Prescribed for Frequent Replacement:

When prescribed for daily wear (frequent replacement), it is recommended that the lenses be discarded and replaced with a new lens every 2 weeks. However, the Eye Care Professional is encouraged to determine an appropriate replacement schedule based upon the response of the patient.

For Lenses Prescribed for Disposable Wear:

When prescribed for disposable wear, the replacement schedule should be determined by the Eye Care Professional based upon the patient's history and their ocular examination, as well as the practitioner's experience and clinical judgment.

Once removed, it is recommended that the lens remain out of the eye for a period of rest of overnight or longer and be discarded in accordance with the prescribed wearing schedule. The Eye Care Professional should examine the patient during the early stages of extended wear.

LENS CARE DIRECTIONS

When lenses are dispensed, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions in accordance with the individual patient's lens type and wearing schedule. The Eye Care Professional should recommend an appropriate care system tailored to the patient's individual requirements.

For complete information concerning contact lens handling, care, cleaning, disinfecting and storage, refer to the Patient Instruction Guide for these lenses. Copies are available for download at www.acuvue.com.

For Lenses Prescribed for Frequent Replacement Wear:

The Eye Care Professional should review with the patient, lens care directions for cleaning, disinfecting and storing, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

For Lenses Prescribed for Disposable Wear:

The Eye Care Professional should review with patients that no cleaning or disinfection is needed with disposable lenses. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available. Lenses should only be cleaned, rinsed, and disinfected on an emergency basis when replacement lenses or spectacles are not available.

Care for a Dried Out (Dehydrated) Lens

If the frequent replacement lens is off the eye and exposed to air from 30 minutes to 1 hour or more, its surface will become dry and gradually become non-wetting. If this should occur, discard the lens and use a new one.

Care for Sticking (Non-Moving) Lenses

If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should **immediately** contact the Eye Care Professional.

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with methyl ether cellulose. The plastic package is marked with the following:

- **ACUVUE OASYS®:** base curve, power, diameter, lot number, and expiration date
- **ACUVUE OASYS® for ASTIGMATISM:** base curve, power, diameter, cylinder, axis, lot number, and expiration date
- **ACUVUE OASYS® for PRESBYOPIA:** base curve, power, diameter, ADD, lot number, and expiration date

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing these lenses or experienced with the lenses should be reported to:

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
Tel: 1-800-843-2020
www.acuvue.com

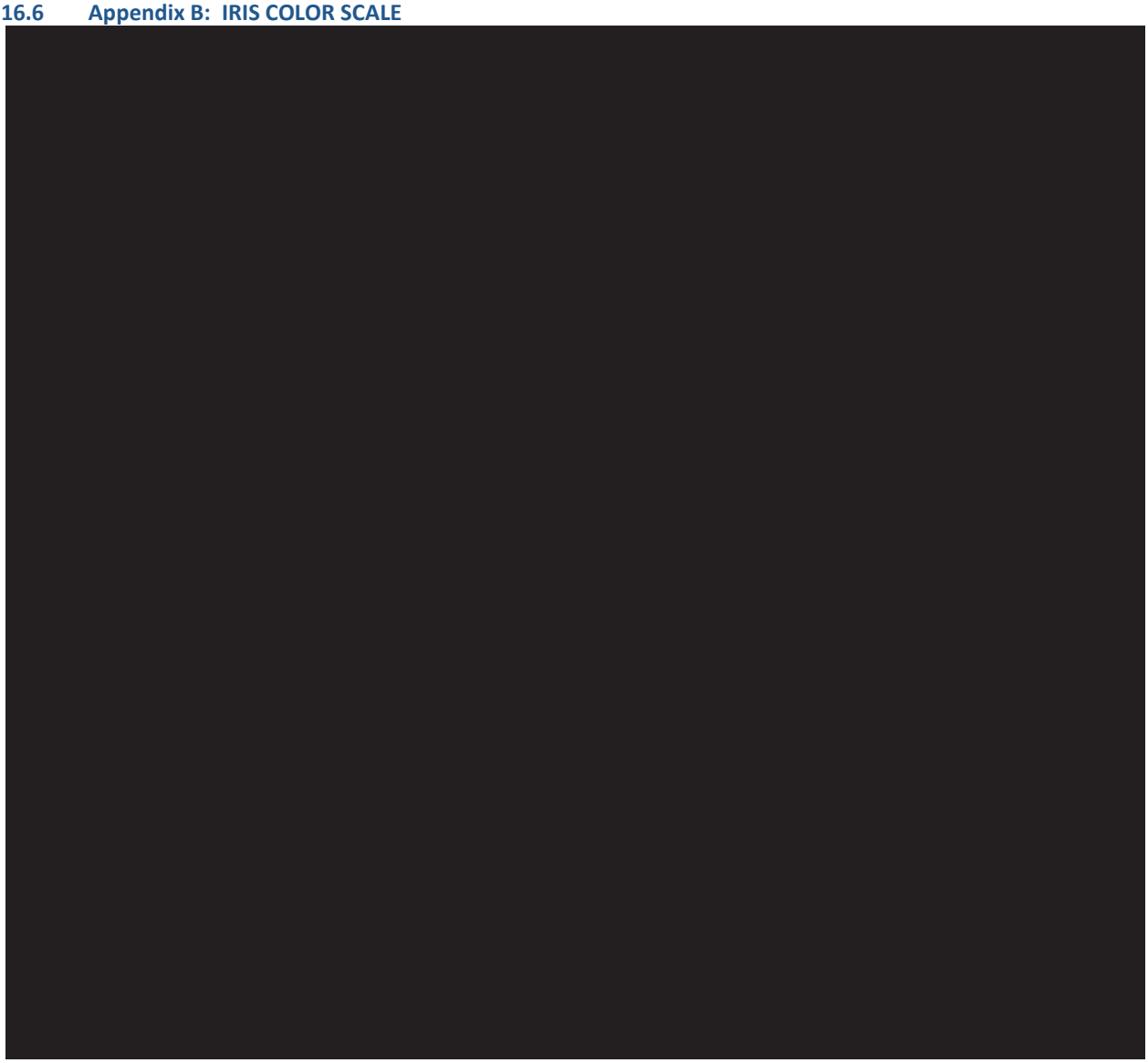
In Canada: Johnson & Johnson Vision Care, division of Johnson & Johnson, Inc.
In USA: Johnson & Johnson Vision Care, Inc.
Printed in USA
Revision date: 06/15
Revision number: AO-06-15-01

16.5 Appendix A: GUIDE TO STARTING CONTACT LENS POWERS

Sphere	Cylinder	Vertexed Sphere	Vertexed Cylinder	Vertexed Sph Equiv	Contact Rx
-0.75	-0.50	-0.743	-0.497	-0.992	-1.00
-0.75	-0.75	-0.743	-0.743	-1.115	-1.00
-0.75	-1.00	-0.743	-0.988	-1.237	-1.25
-1.00	0.00	-0.988	0.000	-0.988	-1.00
-1.00	-0.25	-0.988	-0.249	-1.113	-1.00
-1.00	-0.50	-0.988	-0.497	-1.237	-1.25
-1.00	-0.75	-0.988	-0.743	-1.360	-1.25
-1.00	-1.00	-0.988	-0.988	-1.482	-1.50
-1.25	0.00	-1.232	0.000	-1.232	-1.25
-1.25	-0.25	-1.232	-0.249	-1.356	-1.25
-1.25	-0.50	-1.232	-0.497	-1.480	-1.50
-1.25	-0.75	-1.232	-0.743	-1.603	-1.50
-1.25	-1.00	-1.232	-0.988	-1.726	-1.75
-1.50	0.00	-1.473	0.000	-1.473	-1.50
-1.50	-0.25	-1.473	-0.249	-1.598	-1.50
-1.50	-0.50	-1.473	-0.497	-1.722	-1.75
-1.50	-0.75	-1.473	-0.743	-1.845	-1.75
-1.50	-1.00	-1.473	-0.988	-1.968	-2.00
-1.75	0.00	-1.714	0.000	-1.714	-1.75
-1.75	-0.25	-1.714	-0.249	-1.839	-1.75
-1.75	-0.50	-1.714	-0.497	-1.963	-2.00
-1.75	-0.75	-1.714	-0.743	-2.086	-2.00
-1.75	-1.00	-1.714	-0.988	-2.208	-2.25
-2.00	0.00	-1.953	0.000	-1.953	-2.00
-2.00	-0.25	-1.953	-0.249	-2.078	-2.00
-2.00	-0.50	-1.953	-0.497	-2.202	-2.25
-2.00	-0.75	-1.953	-0.743	-2.325	-2.25
-2.00	-1.00	-1.953	-0.988	-2.447	-2.50
-2.25	0.00	-2.191	0.000	-2.191	-2.25
-2.25	-0.25	-2.191	-0.249	-2.315	-2.25
-2.25	-0.50	-2.191	-0.497	-2.439	-2.50
-2.25	-0.75	-2.191	-0.743	-2.563	-2.50
-2.25	-1.00	-2.191	-0.988	-2.685	-2.75
-2.50	0.00	-2.427	0.000	-2.427	-2.50
-2.50	-0.25	-2.427	-0.249	-2.552	-2.50
-2.50	-0.50	-2.427	-0.497	-2.676	-2.75
-2.50	-0.75	-2.427	-0.743	-2.799	-2.75
-2.50	-1.00	-2.427	-0.988	-2.921	-3.00
-2.75	0.00	-2.662	0.000	-2.662	-2.75
-2.75	-0.25	-2.662	-0.249	-2.787	-2.75
-2.75	-0.50	-2.662	-0.497	-2.911	-3.00
-2.75	-0.75	-2.662	-0.743	-3.034	-3.00
-2.75	-1.00	-2.662	-0.988	-3.156	-3.25
-3.00	0.00	-2.896	0.000	-2.896	-3.00
-3.00	-0.25	-2.896	-0.249	-3.020	-3.00
-3.00	-0.50	-2.896	-0.497	-3.144	-3.25
-3.00	-0.75	-2.896	-0.743	-3.267	-3.25
-3.00	-1.00	-2.896	-0.988	-3.390	-3.50
-3.25	0.00	-3.128	0.000	-3.128	-3.25
-3.25	-0.25	-3.128	-0.249	-3.253	-3.25

Sphere	Cylinder	Vertexed Sphere	Vertexed Cylinder	Vertexed Sph Equiv	Contact Rx
-3.25	-0.50	-3.128	-0.497	-3.377	-3.50
-3.25	-0.75	-3.128	-0.743	-3.500	-3.50
-3.25	-1.00	-3.128	-0.988	-3.622	-3.50
-3.50	0.00	-3.359	0.000	-3.359	-3.25
-3.50	-0.25	-3.359	-0.249	-3.484	-3.50
-3.50	-0.50	-3.359	-0.497	-3.607	-3.50
-3.50	-0.75	-3.359	-0.743	-3.731	-3.75
-3.50	-1.00	-3.359	-0.988	-3.853	-3.75
-3.75	0.00	-3.589	0.000	-3.589	-3.50
-3.75	-0.25	-3.589	-0.249	-3.713	-3.75
-3.75	-0.50	-3.589	-0.497	-3.837	-3.75
-3.75	-0.75	-3.589	-0.743	-3.960	-4.00
-3.75	-1.00	-3.589	-0.988	-4.083	-4.00
-4.00	0.00	-3.817	0.000	-3.817	-3.75
-4.00	-0.25	-3.817	-0.249	-3.941	-4.00
-4.00	-0.50	-3.817	-0.497	-4.065	-4.00
-4.00	-0.75	-3.817	-0.743	-4.188	-4.25
-4.00	-1.00	-3.817	-0.988	-4.311	-4.25
-4.25	0.00	-4.044	0.000	-4.044	-4.00
-4.25	-0.25	-4.044	-0.249	-4.168	-4.25
-4.25	-0.50	-4.044	-0.497	-4.292	-4.25
-4.25	-0.75	-4.044	-0.743	-4.415	-4.50
-4.25	-1.00	-4.044	-0.988	-4.538	-4.50
-4.50	0.00	-4.269	0.000	-4.269	-4.25
-4.50	-0.25	-4.269	-0.249	-4.394	-4.50
-4.50	-0.50	-4.269	-0.497	-4.518	-4.50
-4.50	-0.75	-4.269	-0.743	-4.641	-4.75
-4.50	-1.00	-4.269	-0.988	-4.764	-4.75
-4.75	0.00	-4.494	0.000	-4.494	-4.50
-4.75	-0.25	-4.494	-0.249	-4.618	-4.50
-4.75	-0.50	-4.494	-0.497	-4.742	-4.75
-4.75	-0.75	-4.494	-0.743	-4.866	-4.75
-4.75	-1.00	-4.494	-0.988	-4.988	-5.00
-5.00	0.00	-4.717	0.000	-4.717	-4.75
-5.00	-0.25	-4.717	-0.249	-4.842	-4.75
-5.00	-0.50	-4.717	-0.497	-4.965	-5.00
-5.00	-0.75	-4.717	-0.743	-5.089	-5.00
-5.00	-1.00	-4.717	-0.988	-5.211	-5.25
-6.00	0.00	-5.597	0.000	-5.597	-5.50
-6.00	-0.25	-5.597	-0.249	-5.722	-5.75
-6.00	-0.50	-5.597	-0.497	-5.846	-5.75
-6.00	-0.75	-5.597	-0.743	-5.969	-6.00
-6.00	-1.00	-5.597	-0.988	-6.091	-6.00
-6.25	0.00	-5.814	0.000	-5.814	-5.75
-6.25	-0.25	-5.814	-0.249	-5.939	-6.00
-6.25	-0.50	-5.814	-0.497	-6.062	-6.00
-6.25	-0.75	-5.814	-0.743	-6.186	-6.25
-6.25	-1.00	-5.814	-0.988	-6.308	-6.25
-6.50	0.00	-6.030	0.000	-6.030	-6.00

16.6 Appendix B: IRIS COLOR SCALE



16.7 Appendix C: TEST ARTICLE ACCOUNTABILITY IN THE EDC SYSTEM

Part 1 – Overall Test Article Accountability

- Once the test article shipped sheet is completed for the shipment the investigational site must log the shipment into the lens depot in the EDC system.

1. Log into the Study Database in BioClinica Express 5.4

2. Click on Site Level Data

3. Click on <u>Site Shipment Article Log</u>

- All lenses shipped to the site are listed in the **<u>Site Shipment Article Log</u>**

4. Click on to open <u>each form</u> to receive the lenses.

Lenses MUST be received before the First Subject is seen.

5. Enter <u>Total Quantity Received</u> & save <u>each</u> eCRF.

***If Quantity shipped is different from Total Quantity Received, please notify your regional CRA immediately (a query will populate if this occurs to be resolved)**

- At the end of the study you will need to return all unused test article
- At your close out visit your monitor will help you complete a **Test Article Return Worksheet**, documenting how much test article is being returned.
- Once the Test Article Return Worksheet is completed, you will need to enter the quantity of lenses being returned into the lens depot in the EDC system.

6. Enter Total Quantity Returned after the study is completed and lens accountability has been completed on paper.

Part 2 – Individual Test Article Accountability

- **Individual** subject test article will need to be recorded for all lenses dispensed.
    - All dispensed lenses will be recorded into the EDC system as well as on individual test article accountability logs.
        - What will be recorded:
            - Lot #
            - Subject #

- # Lenses dispensed
- Date dispensed
- Dispenser initials
- Lens count

- The Lens Information eCRF is within the subject's eCRF and is used to record individual lens information.

- The Lot Number field is an Auto Fill field – start to type in the Lot # and the system will complete the field.

Once you click the Lot #, all other fields associated with the study are auto populated (e.g. Product Code, Sphere, Cylinder and Axis) – *verify information is correct*

- If additional lenses are needed, click "Yes" on the eCRF for the "Are additional lenses needed to proceed with fit?" question. ***(Note: this is not for modification of lens power)***

- Once “Yes” is selected and the form is **saved** an additional form will be generated to enter the replacement lens information.

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