Clinical Study Protocol
Johnson & Johnson Vision

The Effects of Contact Lenses With UV/HEV-Filter on Visual Function

Protocol CR-6480

Version: 5.0

Date: 12 June 2023

Investigational Products: senofilcon A with new ultraviolet (UV) and high energy visible (HEV) light filter

Keywords: Sphere R&D platform, Presbyopia R&D Platform, Astigmatism R&D Platform, ACUVUE® OASYS MAX 1-Day, ACUVUE® OASYS MAX 1-Day Multifocal, ACUVUE® OASYS 1-DAY, ACUVUE® OASYS Multifocal, ACUVUE® OASYS 1-Day for Astigmatism, senofilcon A, UV/HEV-filter, daily wear, daily disposable, non-dispensing, psychometric evaluation, visual range, brightness perception, motion detection.

Statement of Compliance to protocol, GCP and applicable regulatory guidelines:
This trial will be conducted in compliance with the protocol, ISO 14155:2020,[1] the Declaration of Helsinki,[2] and all applicable regulatory requirements.

Confidentiality Statement:

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PROTOCOL TITLE, NUMBER, VERSION AND DATE

Title: The Effects of Contact Lenses With UV/HEV-Filter on Visual Function
Protocol Number: CR-6480
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SPONSOR NAME AND ADDRESS

Johnson & Johnson Vision Care, Inc. (JJVC)
7500 Centurion Parkway
Jacksonville, FL 32256

MEDICAL MONITOR

The Medical Monitor must be notified by the clinical institution/site by e-mail or telephone within 24 hours of learning of a Serious Adverse Event. The Medical Monitor may be contacted during business hours for adverse event questions. General study related questions should be directed towards your assigned clinical research associate.

The Medical Monitoring Plan is maintained as a separate document and included in the Trial Master File.

AUTHORIZED SIGNATURES

The signatures below constitutes the approval of this protocol and the attachments and provide 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,[3] ISO 14155:2020,[1] and the Declaration of Helsinki.[2]

Author / Study Responsible Clinician	*See Electronic Signature Report*	DATE
Co-author		DATE
Co-author		DATE
Clinical Operations Manager	*See Electronic Signature Report*	DATE
Biostatistician	*See Electronic Signature Report*	DATE
Biostatistical Review	*See Electronic Signature Report*	DATE
Data Management	*See Electronic Signature Report*	DATE
Medical Safety Officer	*See Electronic Signature Report*	DATE
Approver	*See Electronic Signature Report*	DATE

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Justification for Change	Date
1.0	[redacted]	Original Protocol	N/A	06 October 2022
2.0	[redacted]	Added AVO MAX 1-Day to list of Keywords on Cover Page Updated Test Article section of Synopsis with correct product names. Section 7.2-V1 Step 1.14 removed wording regarding age of subject as factor in Lens Design Assignment	Accuracy	12 October 2022
3.0	[redacted]	Removed the word 'approximately' and the '~' symbol when referencing the total number of subjects for Phase 2. Updated Phase I and Phase II to Phase 1 and Phase 2 throughout for consistency. Updated EDC system name to Clario.	Accuracy	24 October 2022
4.0	[redacted]	Increased the planned sample size for Phase 1. Added objective and sample size justification for Phase 1. Clarified sample size calculation for Phase 2 using the data collected from Phase 1.	To update the planned sample size for Phase 1 and to improve clarity for Phase 2 sample size calculation.	17 March 2023

5.0	[redacted]	Updated endpoints in Section 2.2.	Based on decision from platform leads based on sample size calculations from Phase 1.	12 June 2023
		Updated hypotheses in Section 2.3	Based on decision from platform leads based on sample size calculations from Phase 1.	
		Updated statistical Sections 14.2, 14.5, 14.6, and 14.7	Based on decision from platform leads based on sample size calculations from Phase 1.	
	[redacted]	Updated Phase 2 sample size in Section 4.3 to match synopsis.	Accuracy	
		Updated Section 6.1 CLIFT test article quantities to reflect updated sample size.	Accuracy	

SYNOPSIS

Protocol Title	The Effects of Contact Lenses With UV/HEV-Filter on Visual Function
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Clinical trial phase: Feasibility Design control phase: 3
Trial Registration	This study will be registered on ClinicalTrials.gov by the Sponsor.
Test Article(s)	Investigational Products: senofilcon A-based contact lens (toric) with new UV/HEV filter Approved Products: ACUVUE® OASYS MAX 1-Day (sphere, multifocal), ACUVUE® OASYS 1-Day (sphere, toric), ACUVUE® OASYS Multifocal
Wear and Replacement Schedules	Wear Schedule: Daily wear Replacement Schedule: Daily
Objectives	The objectives of this study are to objectively measure potential benefits of a new UV/HEV filter using psychophysical testing techniques.
Study Endpoints	Primary endpoint(s): visual range Secondary endpoint(s): brightness perception, motion detection Other observations: Ocular physiology.
Study Design	This is a 2-phase, single-site, non-dispensing, randomized, controlled, double-masked, 2x2 crossover study. There will be 2 subject groups (sphere wearers and multifocal wearers) in Phase 1 and 3 subject groups (sphere wearers, multifocal wearers, and toric wearers) in Phase 2. Each subject will be bilaterally fitted with one of the two test articles in each of the two periods within each study phase. There will be a total of 2 visits in each phase of the study: 1. Visit 1: Screening, baseline evaluation, lens fit #1 and psychophysical evaluation 2. Visit 2: Baseline evaluation, lens fit #2, psychophysical evaluation, and final evaluation. See the flow chart at the end of the synopsis table for the schematic of the study visits and procedures of main observations (Figure 1).

Sample Size	Phase 1 will pilot the procedures and will enroll approximately 24 subjects, with a target of at least 20 to complete (~10 spherical wearers and ~10 multifocal wearers). Data from Phase 1 will be used for sample size estimation for Phase 2. Subjects in Phase 1 will not participate in Phase 2. Phase 2 will execute the same procedures as Phase 1 with a different sample size. Phase 2 sample size will be calculated based on data collected from Phase 1. The total sample size for Phase 2 will be approximately 135 subjects (45 per subject group to enroll and 40 to complete) due to resources and study timing.
Study Duration	There are two study visits in each phase that will last approximately 2.5-3 hours each and will be separated by 1-14 days. • The study enrollment period for Phase 1 will be approximately 2 weeks, making the duration of Phase 1 approximately 4 weeks. • Up to 2 weeks will be allotted for statistical analyses. • The study enrollment period for Phase 2 will be approximately 12 weeks, making the duration of Phase 2 approximately 14 weeks. • The total study duration is expected to last about 20 weeks.
Anticipated Study Population	All subjects will be healthy adult male and female volunteers of any race and ethnicity that satisfy the inclusion criteria. All subjects must habitually wear one of three soft contact lenses within the power ranges available for this study: 1. Spherical 2. Multifocal 3. Toric (astigmatism)

Eligibility Criteria - Inclusion	Potential subjects must satisfy all of the following criteria to be enrolled in the study: Inclusion Criteria following Screening The subject must: 1. Read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form. 2. Appear able and willing to adhere to the instructions set forth in this clinical protocol. 3. Be between 18 and 70 (inclusive) years of age at the time of screening. 4. By self-report, habitually wear soft contact lenses (sphere, multifocal, toric) in both eyes in a daily reusable or daily disposable wear modality (i.e. not extended wear modality). Habitual wear is defined as a minimum of 6 hours of wear per day, for a minimum of 5 days per week during the past 30 days. Inclusion Criteria at Baseline Evaluation 5. If applicable, those subjects receiving the spherical lenses will need a vertex-corrected distance refraction within the range of -1.00 through -6.00 DS 6. If applicable, those subjects receiving the multifocal lenses will need a vertex-corrected distance refraction within the range of -1.00 through -6.00 DS 7. If applicable, those subjects receiving the toric lenses will need a vertex-corrected distance refraction within the range of -1.50 through -4.00 DS, -0.625 through -1.625 DC, and cylinder axes: 80/90/100, 170/180/10 8. The best corrected, monocular, distance visual acuity must be 20/25 or better in each eye.

Eligibility Criteria – Exclusion	Potential subjects who meet any of the following criteria will be excluded from participating in the study: Exclusion Criteria following Screening The subject must not: 1. Be currently pregnant or lactating. 2. Be currently using any ocular medications or have any ocular infection of any type. 3. By self-report, have any ocular or systemic disease, allergies, infection, or use of medication that the investigator believes might contraindicate or interfere with contact lens wear, or otherwise compromise study endpoints, including infectious disease (e.g., hepatitis, tuberculosis), contagious immunosuppressive disease (e.g., Human Immunodeficiency Virus [HIV]), autoimmune disease (e.g. rheumatoid arthritis, Sjögren's syndrome), or history of serious mental illness or seizures. See section 9.1 for additional details regarding excluded systemic medications. 4. Have habitually worn rigid gas permeable (RGP) lenses, orthokeratology lenses, or hybrid lenses (e.g. SynergEyes, SoftPerm) within the past 6 months. 5. Be currently wearing lenses in an extended wear modality. 6. Have participated in a contact lens or lens care product clinical trial within 14 days prior to study enrollment. 7. Be an employee (e.g., Investigator, Coordinator, Technician) or immediate family member of an employee (including partner, child, parent, grandparent, grandchild or sibling of the employee or their spouse) of the clinical site. 8. (Phase 2 only): Have participated in Phase 1 of the study. Exclusion Criteria at Baseline Evaluation The subject must not: 9. Have clinically significant (grade 3 or higher on the FDA grading scale) slit lamp findings (e.g., corneal edema, neovascularization or staining, tarsal abnormalities or bulbar injection) or other corneal or ocular disease or abnormalities that the investigator believes might contraindicate contact lens wear or may otherwise compromise study endpoints (including entropion, ectropion, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, moderate or above corneal distortion, herpetic keratitis). 10. Have a history of strabismus or amblyopia.

	11. Have fluctuations in vision due to clinically significant dry eye or other ocular conditions. 12. Have had or have planned (within the study period) any ocular or intraocular surgery (e.g., radial keratotomy, PRK, LASIK, iridotomy, retinal laser photocoagulation, etc.).
Disallowed Medications/Interventions	No ocular medications. See section 9.1 for details regarding disallowed systemic medications.
Measurements and Procedures	The new UV/HEV-filter has the potential to provide visual benefits that go beyond the correction of ametropia. To evaluate some of these benefits, various laboratory equipment will be used to measure visual range, brightness perception, and motion detection in accordance with published literature and established psychometric and psychophysical principles.
Microbiology or Other Laboratory Testing	None
Study Termination	The occurrence of an Unanticipated Adverse Device Effect (UADE) or Serious Adverse Event (SAE) for which a causal relationship to a test article cannot be ruled out, will result in stopping 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 Principal Investigator before any further subjects are enrolled.
Ancillary Supplies/ Study-Specific Materials	Optical device for measuring visual range; light track for motion detection, projected optics for measuring brightness perception.
Principal Investigator(s) and Study Institution(s)/Site(s)	A full list of Principal Investigators, clinical sites, and institutions is kept separately from the Study Protocol and is included in the study Trial Master File.

Figure 1: Study Flowchart: Phase 1

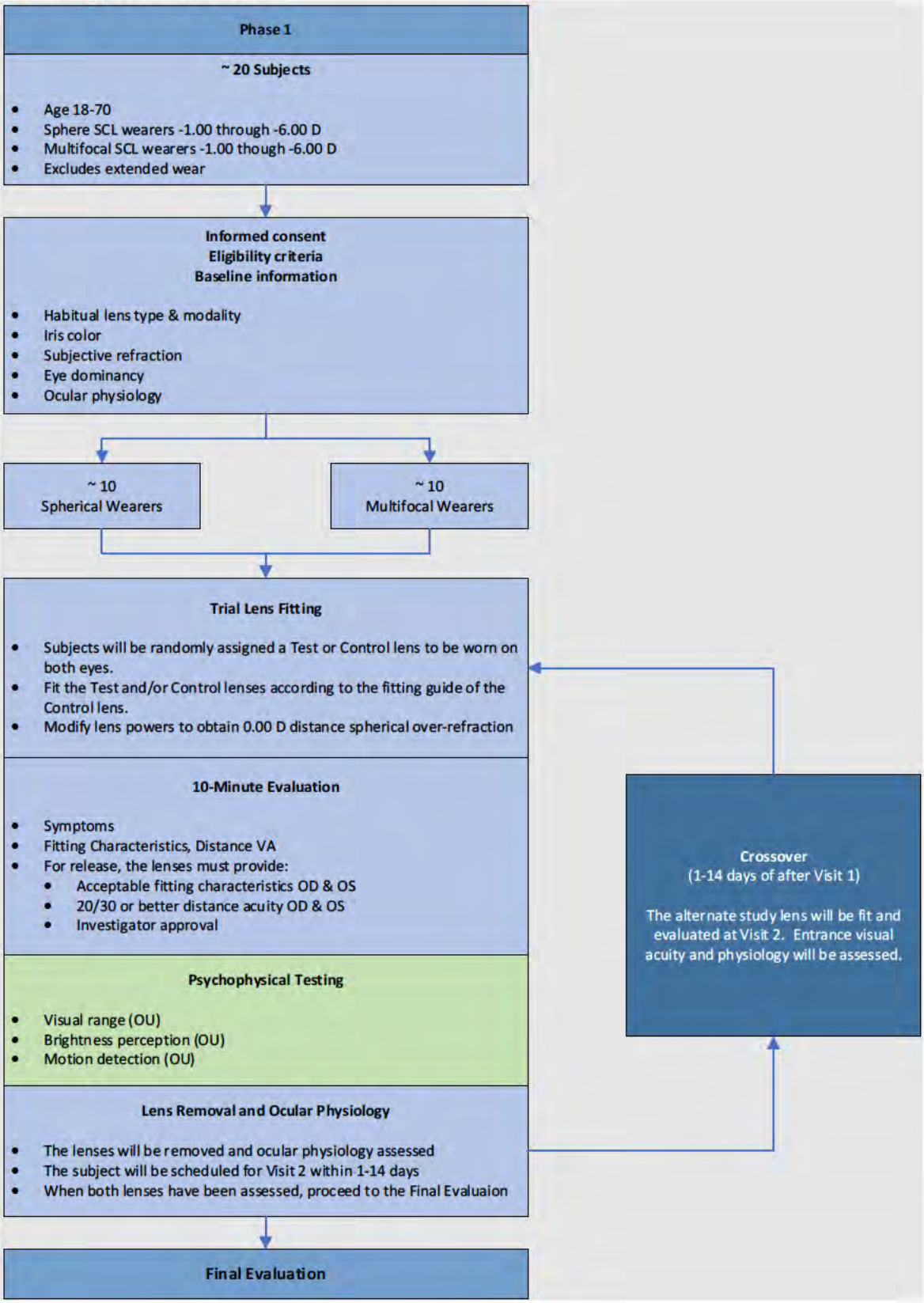
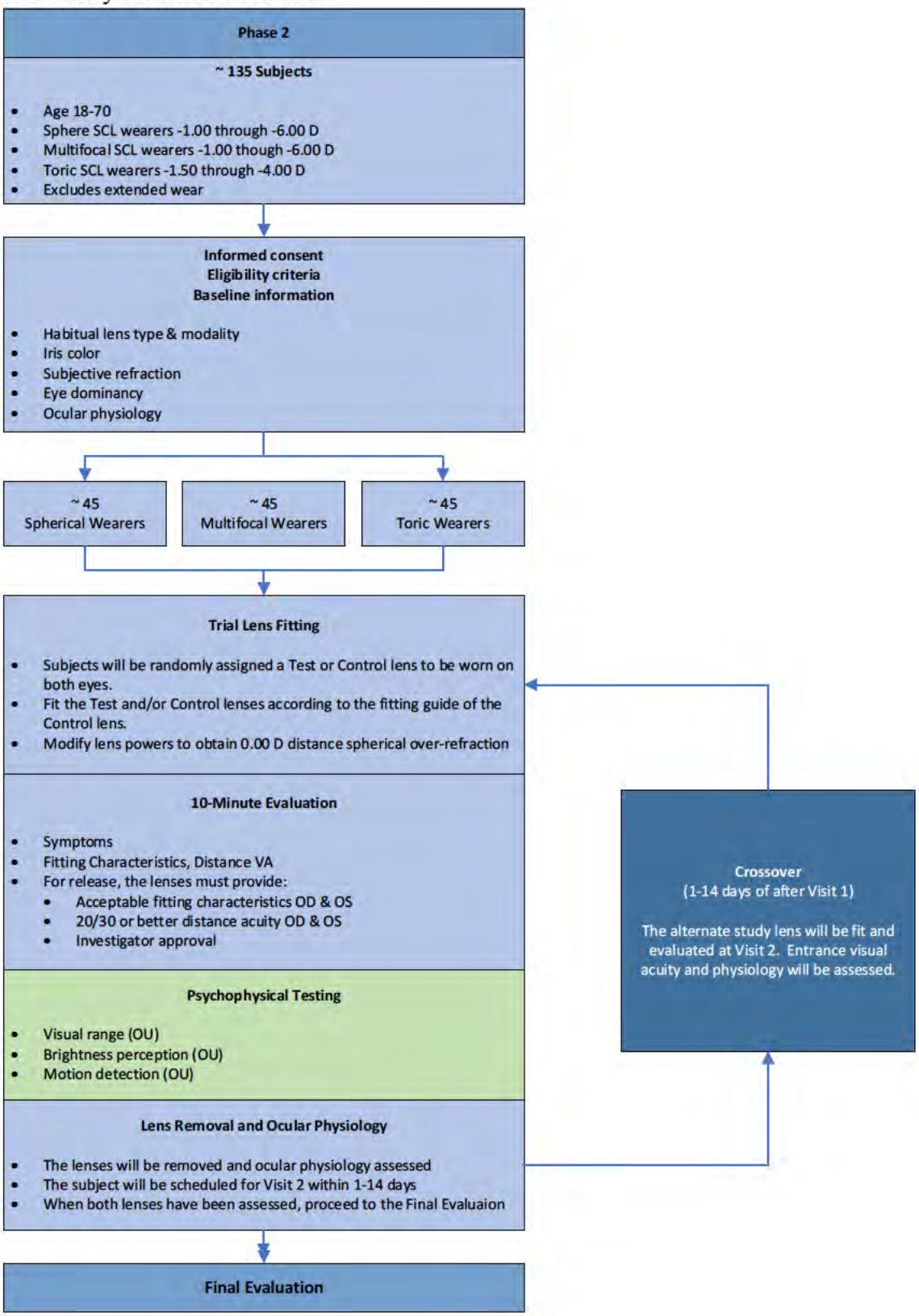


Figure 2: Study Flowchart: Phase 2



COMMONLY USED ABBREVIATIONS, ACRONYMS AND DEFINITIONS OF TERMS

ADD	Near addition; the additional power required for near vision correction
ADE	Adverse Device Effect
ADHD	Attention Deficit Hyperactivity Disorder
AE	Adverse Event/Adverse Experience
AO1DfA	ACUVUE OASYS® 1-DAY with HydraLuxe™ TECHNOLOGY for ASTIGMATISM
BSCVA	Best Spectacle Corrected Visual Acuity
CFR	Code of Federal Regulations
CLUE	Contact Lens User Experience
COM	Clinical Operations Manager
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
[redacted]	[redacted]
D	Diopter
DMC	Data Monitoring Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
ESD	Eyelid Stabilized Design
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HEV	High Energy Visible
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
IB	Investigator's Brochure
ICH	The International Council for Harmonization
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	Intent-to-Treat
JJVC	Johnson & Johnson Vision Care, Inc.
LASIK	Laser-Assisted in Situ Keratomileusis
LRE	Log-Relative Energy
OD	Right Eye
OS	Left Eye
OU	Both Eyes
PIG	Patient Instruction Guide
PQC	Product Quality Complaint
PRK	Photorefractive Keratectomy
PRO	Patient Reported Outcome
QA	Quality Assurance
SAE	Serious Adverse Event/Serious Adverse Experience
SAP	Statistical Analysis Plan

SAS	Statistical Analysis System
SD	Standard Deviation
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
UGA	University of Georgia
UV	Ultraviolet
VA	Visual Acuity

1. INTRODUCTION AND BACKGROUND

A. Visibility (a.k.a. visual range, contrast sensitivity function under emulated blue haze)

Bennett in 1930 defined "visibility" as "the clearness with which objects in the atmosphere stand out from their surroundings." In Wooten and Hammond (2012) the authors provided a detailed overview of the atmospherics optics and visual issues that are involved. A few basic ideas were explored:

A.1. Rayleigh's and Mie's scatter equations

Essentially, short-wave (SW) visible light (blue appearing) scatters significantly more than other wavelengths. Hence, a clear sky is blue, correlating with the predominance of SW energy that is scattered into our eyes. Note that violet wavelengths are scattered more than blue, yet we perceive a blue sky and not a violet sky. This is because the sun emits more blue light than violet, and our eyes are more sensitive to blue than to violet. When particle diameter is greater than about 0.1λ, Rayleigh's theory does not explain the scattering. Larger particles scatter more and show a more complex spatial pattern and wavelength dependency (smaller particles converge on Rayleigh's theory, larger, like fog droplets, simpler geometrical optics).

A.2. Haze aerosols

Pure air, consisting of only gas molecules, is so rare as to be only of theoretical interest. Ground fog is unusual, but not rare. Between these two extremes exists a range of conditions called aerosols that constitute the overwhelmingly predominant set of factors that largely determine the quality of vision in the atmosphere. The wavelength dependency of haze aerosols was first presented by Middleton (1952): $\beta_{sc} = c\lambda^{-\upsilon}$. This formula, combined with extensive observations, show that scatter in haze aerosols varies from slightly blue to very blue.

A.3. Visual range

Aside from the optical and neural aspects of the human observer, scatter in the aerosol haze is the primary determinant of visual discrimination and range in the outdoors. As we look out over the landscape from an elevated location or from an airplane, we notice that the more and more distant elements of the scene become lighter in tone, until sometimes the most distant objects are indiscernible from the horizon. Frequently, the scene seems tinged with a distinctly blue hue. Artists call this phenomenon "aerial prospective" and use it as a depth cue in paintings. Atmospheric physicists call it air light. It is this air light that forms a SW dominant veiling illuminance over visual objects in the distance.

Figure 3: Visual range illustration

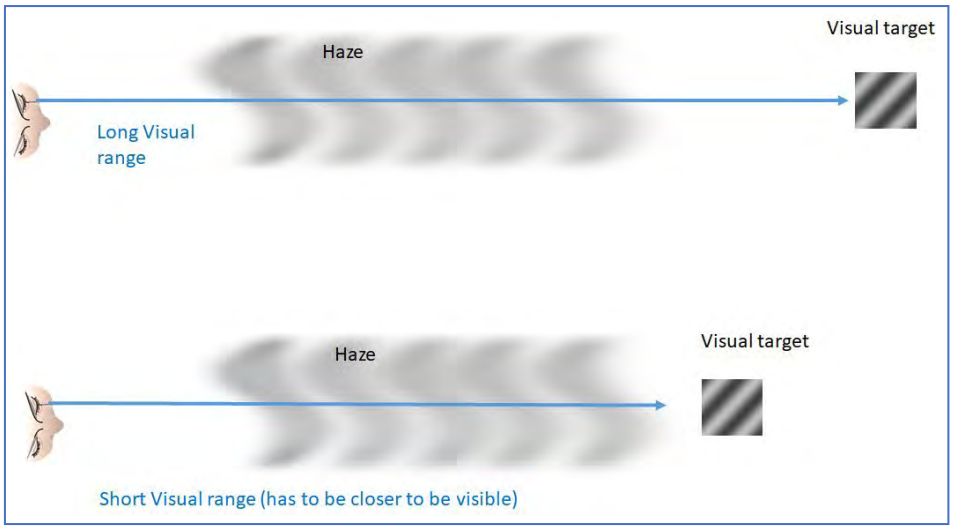
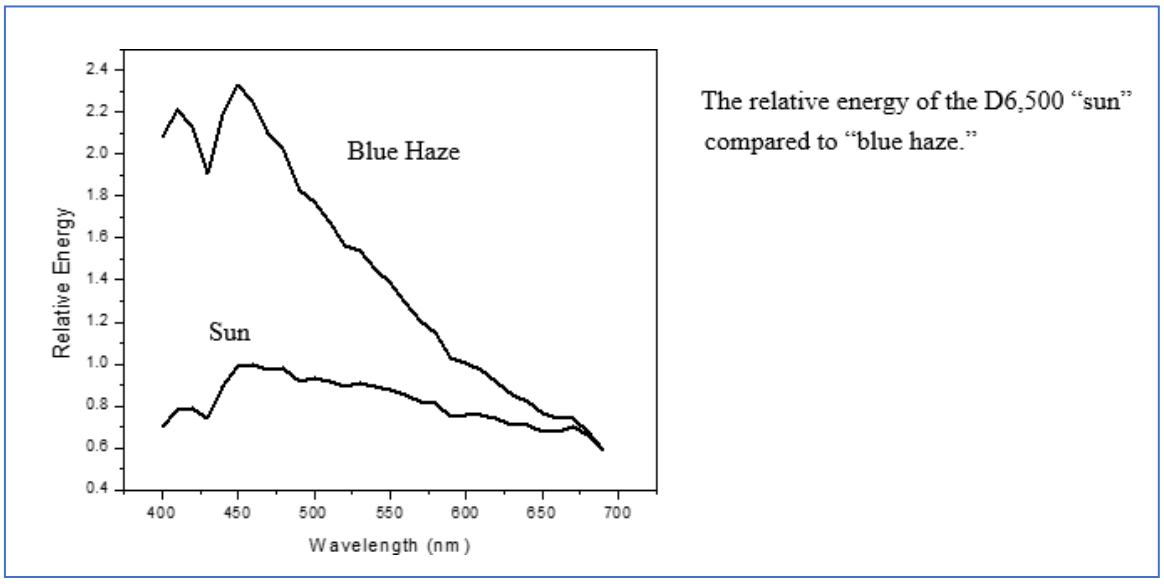


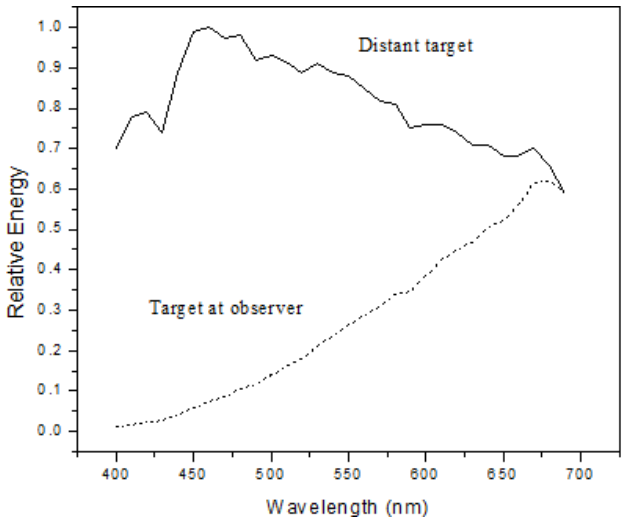
Figure 4: Energy of blue haze versus sunlight



A.4. Targets and backgrounds (air light):

Non-image forming air light acts as a background or veiling luminance with respect to targets seen through it. Furthermore, the background luminance increases and becomes increasingly short-wave dominant (blue haze) as the viewing distance increases. The luminance of a target, on the other hand, decreases and becomes increasingly short-wave deficient as the viewing distance increases.

Figure 5: Wavelength versus relative energy of D6500 illuminant



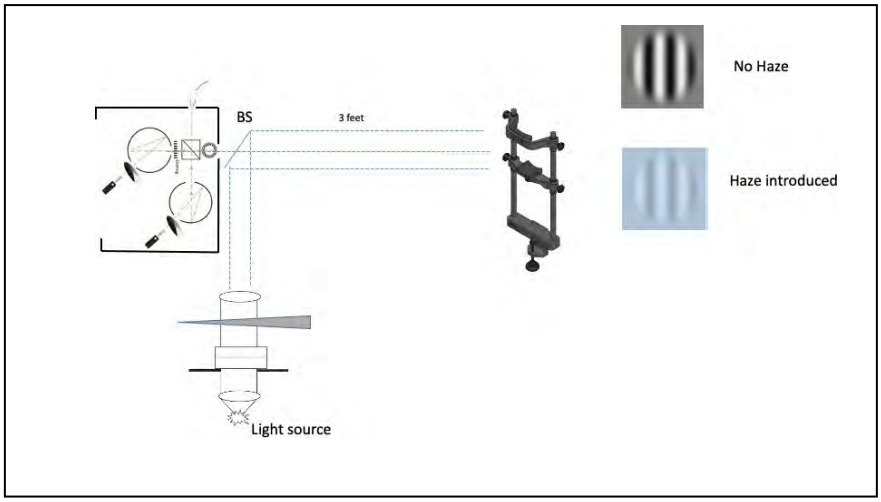
Solid curve shows the spectral energy of a D6500 illuminant that is reflected from a spectrally flat target; the dashed curve shows the spectral energy of this same light after it has passed through the intervening atmosphere where $\beta = c\lambda^{-2.0}$.

A short-wave absorbing filter would have a quantitatively different effect on the luminance of a background and a target. A SW filter would improve contrast for a target in an aerosol haze by attenuating the air light luminance (background) more than the target luminance

A.5 The conceptual design of the visibility apparatus:

In the proposed study, the plan is to use a system that is based on the systems that previously used and published, testing the ideas expounded in the Visibility Hypothesis (Hammond et al., 2012, Fletcher et al., 2014).

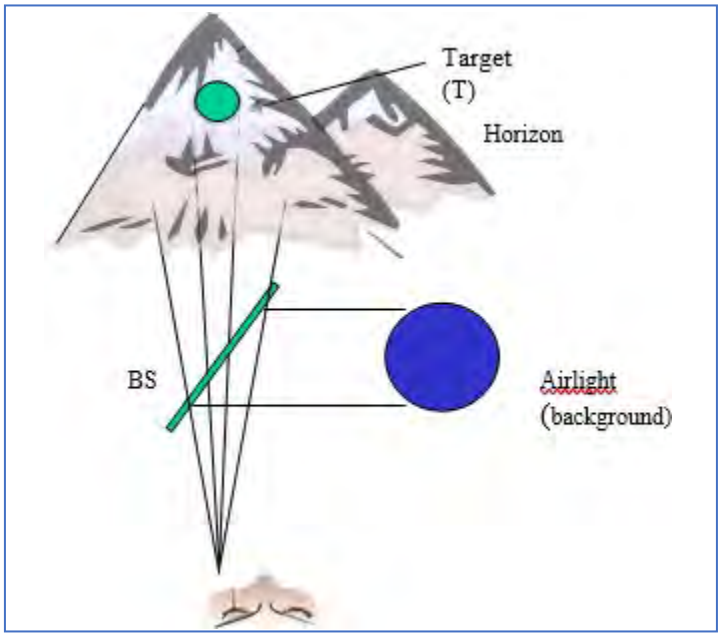
Figure 6: Schematic of visual range set up.



Contrast sensitivity is measured using a series of sine-wave gratings on glass (back illuminated with broad-band light). Blue Haze is brought in from a different optical channel and imposed

between the eye and the grating target. At the plane of the eye, it can be made to exactly mimic the optics of a natural scene.

Figure 7: Visual range set up emulates natural scene



A.6. Details of the method

The determination of contrast sensitivity requires an apparatus that provides for the careful, calibrated variation of sine-wave gratings with respect to spatial frequency and contrast. In most vision experiments, these features are achieved with a CRT oscilloscope or computer monitor (or even less precisely, with wall charts like the CSV-1000), which allows relatively simple electronic control of both spatial frequency and contrast. However, absolute energy and the spectral energy distributions of the available phosphors are not appropriate for the experiments that we would like to conduct. The need for brighter light in some of the assessments rules out oscilloscopic displays because of their relatively low energy. Also, as noted, we need broad-band light that is close in spectral energy to natural phases of daylight. This can be achieved with a combination of integrating spheres and laser light sources; it cannot be done with CRTs. The challenge for our proposal is how to generate and control sine-wave gratings in a way that allows a wide range of control of the spectral energy distributions. CRTs, computer monitors, wall charts, etc., will not work. Consequently, the previously validated apparatus used in other clinical studies, such as [redacted] can be adapted for testing visual range under simulated haze conditions, as shown in Figure 7 above.

To measure visual range, participants will view a highly calibrated 0.5 cycles per mm grating, which when placed in the apparatus with the participant at the appropriate test distance produces contrast at 8 cycles per degree of visual angle. Participants will view the grating first with no simulated haze interposed. The researcher will gradually introduce haze that increases

intensity, until the haze is sufficient to reduce contrast to the point that a participant is unable to resolve the grating.

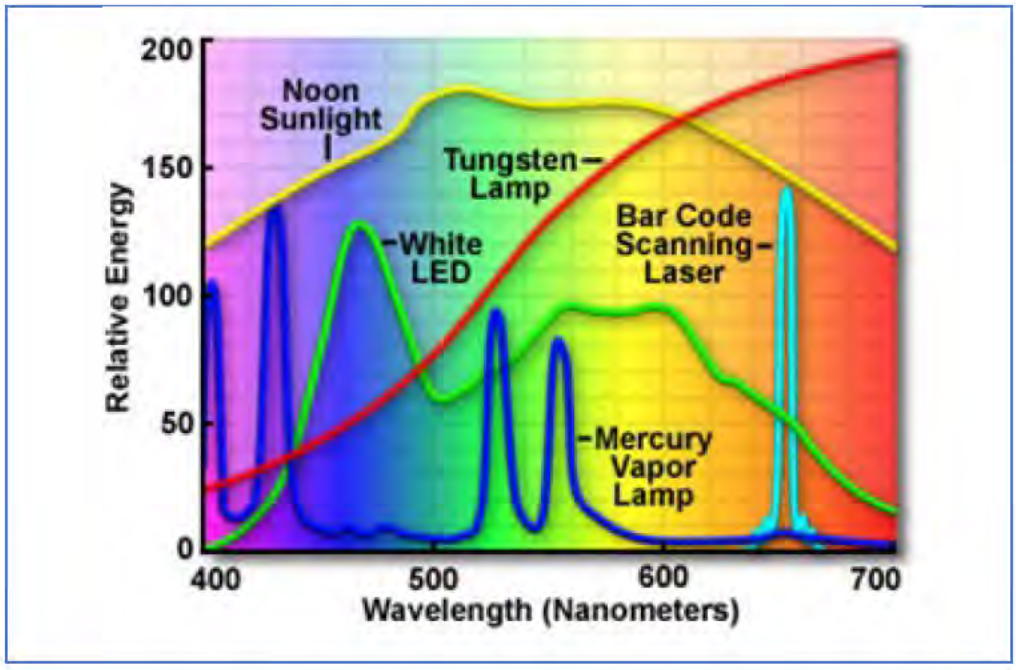
B. Brightness perception

There is a long history (reviewed in Hammond, 2012) of using yellow-tinted lenses to improve visual function outdoors. In addition to visibility effects outlined above they also tend to reduce the deleterious effects of very bright light (glare). Human vision, however, must operate over a very large range. Hence, a corollary question has also been asked: how the pigments (yellow filters) enhance vision in normal and low-light conditions. Many have observed that yellow goggles, for example, tend to enhance the perception of brightness in a normal lit scene (Kelly, 1990). Probably the most popular physiological explanation for this effect is akin to the Purkinke effect: selectively absorbing some SW energy causes a small amount of rods to come "online" and boost the overall brightness signal (Kelly, 1990).

The original experiment was done by Kelly (1990). Kelly measured brightness using the magnitude estimation technique. Kelly exposed subjects to a series of targets (small, 5deg and large 15deg) and subjects estimated their brightness relative to a standard. Subjects who wore yellow-tinted goggles perceived the targets "up to 40% brighter" than subjects who wore non-tinted control goggles.

The biggest problem with Kelly's experiment was simply that the stimuli were simple and non-chromatic. Basically, she used flat gray neutral density filters illuminated with a tungsten-halogen projector. This type of stimulus would bear very little resemblance to a scene in real life (and be minimally absorbed by a SW filter).

Figure 8: Relative Energy of Various Light Sources



The lack of SW energy in Tungsten-Halogen would have minimized any direct filtering effects in Kelley's study.

Details of the method
The evaluation will involve simple tests of stimulus brightness based on brightness matching: in essence, the investigators will set the scene at a moderate brightness and the subject will adjust the standard (now the dependent outcome) to match. A projector with a high-intensity xenon source will be used to project natural scenes for binocular viewing. A total of five scenes will be selected that vary in their short- mid- and long-wave composition. Participants will adjust a neutral density wedge that controls the intensity of a light stimulus presented next to the natural scene. The log-relative energy at which the standard and scene match to the observer will be recorded.

C. Motion perception (a.k.a. peripheral glare displacement threshold)

There are many definitions of motion perception, but some distinctions should be made up front. In past studies we have measured temporal vision (like CFF or the temporal contrast sensitivity function) but this is not motion per se. Motion implies movement across space and typically includes both speed/velocity and direction. In a real-world setting, motion perception also includes input from not just visual but also vestibular and proprioceptive inputs. Most basic motion experiments tend to keep stimulus exposure (duration) and head position constant while varying the velocity (isochronal thresholds).

The underlying biology of motion perception is well-known and distinct. Retinal ganglion cells that act as motion detectors have been identified, as well as the primary visual pathways (primarily magnocellular) and extrastriate cortical areas specialized for motion (like V5). This biology itself could likely be influenced by tinted contact lenses. For example, the wavelength content of stimuli have been used to bias information transmission down the magno vs the parvocellular pathways. The magnocellular system (unlike parvocellular neurons) does not respond to stimuli varying only in hue. This is the scientific justification behind used colored filters (like Irlen filters) for disorders that reflect parvo-magno imbalances (like dyslexia and schizophrenia; although the state of the evidence for using these kinds of filters is pretty controversial; Miyasaka et al., 2019).

Leibowitz et al. (1972) performed the study that was both foundational and is likely the best option for beginning studies in this area. Liebowitz first showed that much of the variance in peripheral motion perception is caused by optical factors. The basic result is shown below:

Figure 9: Motion threshold versus stimulus eccentricity

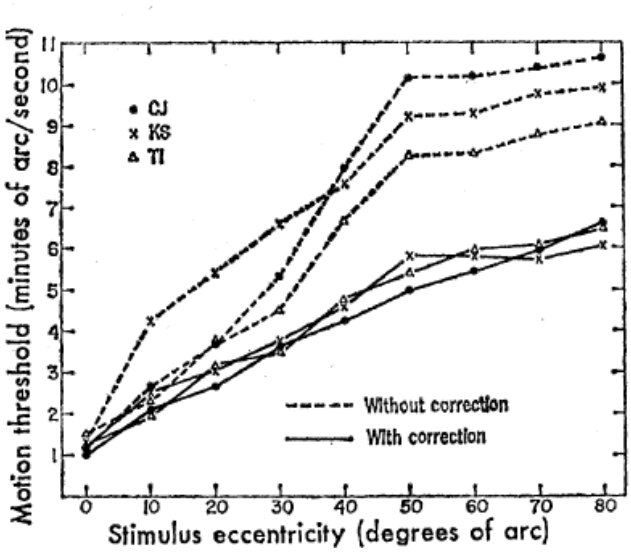


Fig. 1. Motion thresholds as a function of stimulus eccentricity with and without correction for peripheral refractive errors. *CJ*, *KS*, and *TI* refer to subjects.

As shown in the figure, whereas motion thresholds change for all subjects with eccentricity, the worsening was much greater for subjects whose refractive condition was not corrected. The testing scheme that Leibowitz used can be used in this study to emphasize different optical factors (he tested mostly blur) while measuring small changes in isochronal thresholds.

Details of the method

Leibowitz used only three male graduate students. While a subject maintained monocular fixation with his dominant eye, thresholds for motion perception were determined for the temporal visual field for a one-second exposures at eccentric angles ranging from 0° to 80° in 10° steps. The stimulus was a white (high reflectance, 80%) square, 1.3 cm on a side, with luminance 4.3 mlam, viewed against a black (low reflectance, less than one percent) background at a distance of 78.7 cm. Subjects report whether the stimuli moved to the left of right (forced choice, with thresholds defined psychometrically). In our application, we will select points that are in the area of the curve most affected by optical correction (40-80 degrees, randomly presented). A xenon source will be channeled through a fiber optic light guide affixed to an automated, motor-driven positioning slide that moves left and right on fixed increments. Participants will view a centrally located fixation point. The fiber optic test light will be presented in the periphery. Participants will judge which direction the test light moved from its starting point, either to the left (towards the fixation point) or to the right (away from the fixation point). The essential idea is that the poorer optics results in more aberrated the light, the less the subject will be able to correctly indicate the direction of motion. The distance necessary for a participant to reliably detect that movement has occurred will be recorded.

1.1. Name and Descriptions of Investigational Products

This study will test three (3) senofilcon A designs (two of which are commercially available: ACUVUE OASYS MAX 1-Day and ACUVUE OASYS MAX 1-Day Multifocal) that each contain a new UV/HEV filter against three (3) commercially available products that don't contain the new UV/HEV-filter (ACUVUE® OASYS 1-Day, ACUVUE® OASYS Multifocal, and ACUVUE® OASYS 1-Day for Astigmatism). Further details about the test articles are found in Section 6 of this protocol.

1.2. Intended Use of Investigational Products

The intended use of the investigative product is for correcting myopia and for improving the visual experience by improving contrast in an HEV environment. During the study, each test article will be worn bilaterally in daily wear, daily disposable modality for 2.5-3 hours. The subject will wear both test articles in a cross-over study design.

1.3. Summary of Findings from Nonclinical Studies

All previous pre-clinical findings were deemed satisfactory prior to proceeding with clinical trials on humans. For the most comprehensive nonclinical information regarding senofilcon A lens with new UV/HEV filter, refer to the latest version of the Investigator's Brochure.[10]

1.4. Summary of Known Risks and Benefits to Human Subjects

The risks of wearing soft contact lenses are well known and are described in the Investigator's Brochure and Informed Consent. The material safety testing/lens release criteria was determined based on the Risk Assessment. Benefits to the subjects include the correction of their refractive error with the potential of improved contrast in HEV environments.

For the most comprehensive risk and benefit information regarding the senofilcon A with new UV/HEV-filter, refer to the latest version of the Investigator's Brochure or the package insert of the marketed products.

1.5. Relevant Literature References and Prior Clinical Data Relevant to Proposed Clinical Study

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Additional information about the toric Test lens can be found in the Investigator Brochure. Additional information about the other Test lenses and the Control lenses can be found in their Package Insert (Appendix C).

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

The purpose of this investigation is to evaluate the short-term, clinical psychophysical performance of contact lenses with a new UV/HEV-filter.

Primary Objective(s)
The primary objective of Phase 1 study is to collect clinical data to estimate the required Phase 2 sample size for achieving the primary objective with adequate statistical power given the prespecified primary hypotheses testing.

The primary objective of the Phase 2 study is to objectively measure potential benefits of a new UV/HEV filter using psychophysical testing techniques.

The results from this study may be used to support marketing claims or help understand market readiness of the Test lenses that contain the UV/HEV filter.

2.2. Endpoints

The investigational lens has the potential to improve how far the subject can see through blue atmospheric haze (visual range), improve how well they can perceive motion, and positively influence how bright an image appears compared to the control lens. In this study, the investigators will evaluate these parameters using controlled laboratory systems.

Primary Endpoints for Sphere and Multifocal wearers:

1. Visual Range (tested binocularly at 8 cycles per degree). Visual range is defined as the log relative energy of simulated haze needed to obscure an otherwise high contrast grating target. Better visual range is indicated by a higher log-relative energy (LRE) of simulated haze (more haze) to obscure an otherwise highly visible target.

Secondary Endpoints:

1. For Spherical wearers - Motion Detection (tested binocularly). Motion detection is defined as the distance needed (in mm) to determine that a test light has moved from a standard position. Better motion detection is indicated by a smaller distance needed to detect that movement has occurred.

2. For Multifocal wearers - Brightness Perception Score (tested binocularly). Brightness perception is defined as the log- relative energy needed to match a standard stimulus to a natural scene, across 10 different projected scenes. The perception of brighter image is indicated by a higher log-relative energy (LRE) needed to match the initially dim standard to the target. The top 5 scenes will be averaged for each subject.

Exploratory Endpoints:

1. For Spherical wearers – brightness perception
2. For Multifocal wearers – motion detection
3. For Toric wearers – visual range, motion detection, and brightness perception
4. Biomicroscopy (all contact lens wearers)

2.2. Hypotheses

Phase 1

No Hypotheses will be tested in Phase 1. Data obtained from Phase 1 will be used to calculate the sample size required for yielding adequate statistical power in testing the planned primary hypotheses in Phase 2. See Section 14.8 for further details.

Primary Hypotheses - Phase 2

The statistical hypotheses to meet the primary study objective of Phase 2 will be defined on the basis of the Phase 1 clinical results to make the adequate efficacy assumptions to power the Phase 2 of the study appropriately.

1. Subjects wearing the Test lens will have statistically significantly improved visual range than the Control lens among spherical wearers.

2. Subjects wearing the Test lens will have statistically significantly improved visual range than the Control lens among multifocal wearers.

Secondary Hypotheses - Phase 2

1. Subjects wearing the Test lens will have statistically significantly improved motion detection than the Control lens among spherical wearers.

2. Subjects wearing the Test lens will perceive an image statistically significantly brighter than the Control lens among multifocal wearers.

Exploratory Hypotheses - Phase 2

1. Subjects wearing the Test lens will have statistically significantly improved visual range than the Control lens among Toric wearers.

2. Subjects wearing the Test lens will perceive an image statistically significantly brighter than the Control lens among Toric wearers.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

This study will enroll healthy adult subjects of any gender, race, and ethnicity that satisfy the eligibility criteria.

3.2. Inclusion Criteria

Potential subjects must satisfy all of the following criteria to be enrolled in the study:

Inclusion Criteria following Screening
The subject must:

1. Read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form.

2. Appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. Be between 18 and 70 (inclusive) years of age at the time of screening.
4. By self-report, habitually wear soft contact lenses in both eyes in a daily reusable or daily disposable wear modality (i.e. not extended wear modality). Habitual wear is defined as a minimum of 6 hours of wear per day, for a minimum of 5 days per week during the past 30 days.

Inclusion Criteria at Baseline Evaluation

5. If applicable, those subjects receiving the spherical lenses will need a vertex-corrected distance refraction within the range of -1.00 through -6.00 DS
6. If applicable, those subjects receiving the multifocal lenses will need a vertex-corrected distance refraction within the range of -1.00 through -6.00 DS
7. If applicable, those subjects receiving the toric lenses will need a vertex-corrected distance refraction within the range of -1.50 through -4.00 DS, -0.625 through -1.625 DC, and cylinder axes: 80/90/100, 170/180/10
8. The best corrected, monocular, distance visual acuity must be 20/25 or better in each eye

3.3. Exclusion Criteria

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

Exclusion Criteria following Screening
The subject must not:

1. Be currently pregnant or lactating.
2. Be currently using any ocular medications or have any ocular infection of any type.
3. By self-report, have any ocular or systemic disease, allergies, infection, or use of medication that the investigator believes might contraindicate or interfere with contact lens wear, or otherwise compromise study endpoints, including infectious disease (e.g., hepatitis, tuberculosis), contagious immunosuppressive disease (e.g., Human Immunodeficiency Virus [HIV]), autoimmune disease (e.g. rheumatoid arthritis, Sjögren's syndrome), or history of serious mental illness or seizures. See section 9.1 for additional details regarding excluded systemic medications.
4. Have habitually worn rigid gas permeable (RGP) lenses, orthokeratology lenses, or hybrid lenses (e.g. SynergEyes, SoftPerm) within the past 6 months.
5. Be currently wearing lenses in an extended wear modality.
6. Have participated in a contact lens or lens care product clinical trial within 14 prior to study enrollment.
7. Be an employee (e.g., Investigator, Coordinator, Technician) or immediate family member of an employee (including partner, child, parent, grandparent, grandchild or sibling of the employee or their spouse) of the clinical site.
8. (Phase 2 only): Have participated in Phase 1 of the study.

Exclusion Criteria at Baseline Evaluation
The subject must not:

9. Have clinically significant (grade 3 or higher on the FDA grading scale) slit lamp findings (e.g., corneal edema, neovascularization or staining, tarsal abnormalities or bulbar injection) or other corneal or ocular disease or abnormalities that the investigator believes might contraindicate contact lens wear or may otherwise compromise study endpoints (including entropion, ectropion, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, moderate or above corneal distortion, herpetic keratitis).
10. Have a history of strabismus or amblyopia.
11. Have fluctuations in vision due to clinically significant dry eye or other ocular conditions.
12. Have had or have planned (within the study period) any ocular or intraocular surgery (e.g., radial keratotomy, PRK, LASIK, iridotomy, retinal laser photocoagulation, etc.).

3.4. Enrollment Strategy

Study subjects will be recruited from the Institution/clinical site's subject database and/or utilizing Independent Ethics Committee (IEC) or Institutional Review Board (IRB) approved materials.

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

The study is a 2-phase, single-site, non-dispensing, controlled, randomized, double-masked, 2x2 crossover (2 study lenses x 2 wearing periods) design where one of the study lenses will be worn bilaterally for 2.5-3 hours on Visit 1 and the other study lens worn bilaterally for 2.5-3 hours on Visit 2. At study closure, participants will have no further access to the study lenses.

It is important that the subjects wear the same type of lens on both eyes (i.e., both eyes wear spherical, both eyes wear multifocal, or both eyes wear toric). All lenses will be fit for distance vision OD and OS according to the fitting guides located in the appendices, which largely follow the Fitting Guide of the control lenses.

Non-presbyopes (age 18 through 39) may wear either a spherical lens or a toric lens on both eyes. The Fitting Guide for spherical products extends to 1.00 D of refractive cylinder, while the Fitting Guide for toric products starts at 0.75 D of refractive cylinder. The investigator will therefore use her / his experience in deciding whether the subject will be best fit in a spherical or toric lens on each eye. If fitting the toric lens, the refractive cylinder power should be suitable to be fit with either the 0.75 D or 1.25 D cylinder lens.

Presbyopes (age 40-70) will be fit with a multifocal lens on both eyes. Note that the multifocal lenses, particularly the higher ADD powers, are likely to over-refract needing more minus. This is normal and will not follow the same 0.00 D over-refraction requirement as the spherical and toric designs.

4.2. Study Design Rationale

The purpose of this study is to evaluate the performance of a new UV/HEV-filter in a 2x2 crossover design for three different subject groups (i.e., sphere wears, multifocal wears, and toric wears). Crossover designs are a well-established study design in which subjects are exposed to multiple treatments during different time periods. This design is cost effective and more efficient since it eliminates part of the inter-subject variability from the treatment comparisons. Subjects will be randomized into the two lens wear sequences: Test/Control or Control/Test. Randomization eliminates selection bias and balances both the known and unknown confounding factors that may affect the study outcomes. A potential limitation of crossover design is the carry-over effect from the previous treatment. The 2 study periods (visits) will be separated by 1-14 days and the wearing time of 2.5-3 hours in each period is considered effectively short to minimize the presence of the carry-over effect in the psychometric tests of interest. Rest period between trials within a single measurement type and between different measurement types is incorporated to eliminate the impact of any previous testing.

- Within a single measurement type (e.g., visual range), a minimum of 30-seconds will be taken between trials.
- Between measurement types (e.g., when switching from visual range to measuring brightness perception), a 5-minute break will be taken.
- Participants will be given a 15-minute break after every 45 minutes of visual function testing.

4.3. Enrollment Target and Study Duration

Phase 1

Phase 1 will have an enrollment target of 24 subjects, with a target of at least 20 to complete. Approximately 10 subjects will wear spherical soft contact lenses and approximately 10 subjects will wear multifocal soft contact lenses. The study will be conducted at a single clinical site. A subject will be considered enrolled upon signing the informed consent form.

There will be 2 visits in total per subject separated by 1-14 days. The enrollment period is 2 weeks making the duration of Phase 1 approximately 4 weeks. If subjects discontinue prior to the final evaluation, then additional subjects may be enrolled at the discretion of the study sponsor to maintain sample size requirements.

Phase 2

Phase 1 results are used to estimate the number of subjects required for Phase 2. However, the total sample size for Phase 2 will be approximately 135 subjects due to resources and study timing. The study will be conducted at a single clinical site. A subject will be considered enrolled upon signing the informed consent form. Phase 1 subjects will not be Phase 2 subjects.

There will be 2 visits in total per subject separated by 1-14 days. The enrollment period is 12 weeks making the duration of Phase 2 approximately 14 weeks. If subjects discontinue prior to the final evaluation, then additional subjects may be enrolled at the discretion of the study

sponsor to maintain sample size requirements. The investigation will end at the time that the study data is hard locked.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

This is a two phase, 2x2 crossover study within each phase. Both study lenses will be worn in a bilateral and randomized fashion. Randomly-permuted block randomization will be used to avoid bias in the assignment of subjects to treatment and to enhance the validity of statistical comparisons across treatment groups. A computer-generated randomization scheme will be used to randomly assign subjects to one of the two possible lens wear sequences (Test/Control or Control/Test) within each study phase. The randomization will be stratified by subject group within each phase. The random scheme will be generated by the unmasked biostatistician using the PROC PLAN procedure in Statistical Analysis System (SAS) Software Version 9.4 or higher (SAS Institute, Cary, NC).[5]

Randomization will be performed at Visit 1. The following must have occurred prior to randomization:

- Informed consent must have been obtained.
- The subject must have met all eligibility criteria.
- The subject's screening and baseline information must have been collected.

5.2. Masking

This is a double-masked study. Subjects will be unaware of the identity of the investigational product. The investigator conducting the psychophysical testing will also not be informed. Instead, lens type will be identified by code only, and the link between the code and the lens type will not be revealed to the investigator conducting the psychophysical testing until after the database has been locked. The clinician fitting the lenses will not be masked as to the identity of the investigational products and may be able to tell the difference between the Test and Control lenses based on color differences between the lenses.

5.3. Procedures for Maintaining and Breaking the Masking

Every attempt will be made to keep the clinical trial personnel involved in the study (e.g. data management, study lead biostatistician and clinical operations) unaware of the identity of the assigned study lenses. The identity of the study lenses will be masked by having the blister packs labeled with the study number, lot number, sphere power, expiration date and the randomization codes. Only the unmasked biostatistician generating the lens fitting schedule will have access to the decode information that allows matching of the randomization codes to the test articles. The medical monitor will also have access to the decode information in case breaking the mask is necessary for the urgent medical treatment of a subject.

Under normal circumstances, the mask should not be broken until all subjects have completed the study and the database is finalized. Otherwise, the mask should be broken only if specific

emergency treatment/course of action would be dictated by knowing the treatment status of the subject. In such cases, the investigator may, in an emergency, contact the medical monitor. In the event the mask is broken, the sponsor must be informed as soon as possible. The date, time, and reason for the unmasking must be documented in the subject record. The investigator is also advised not to reveal the study treatment assignment to the clinical site or sponsor personnel.

Subjects who have had their treatment assignment unmasked are expected to return for all remaining scheduled evaluations.

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 1: Test Articles

	Test - Sphere	Test - Multifocal	Test - Astigmatism
Name	ACUVUE® OASYS MAX 1-Day	ACUVUE® OASYS MAX 1-Day Multifocal	TRA
Manufacturer	JJVC	JJVC	JJVC
[redacted]	[redacted]	[redacted]	[redacted]
Lens Material	senofilcon A	senofilcon A	senofilcon A
Nominal Base Curve @ 22°C	8.5	8.3	8.5
Nominal Diameter @ 22°C	14.3	14.3	14.3
Nominal Distance Powers (D)	-1.00 through -6.00 in 0.25 steps	-1.00 through -6.00 in 0.25 steps	-1.50 through -4.00 in 0.25 steps
Nominal ADD Powers	NA	Low, Med, High	NA
Nominal Cylinder Powers (D)	NA	NA	-0.75, -1.25
Nominal Cylinder Axes (degrees)	NA	NA	10, 80, 90, 100, 170, 180
Water Content *(Optional)*	38	38	38
Oxygen Permeability (Dk)	103	103	103
Wear Schedule in Current Study	Daily	Daily	Daily
Replacement Frequency	Daily	Daily	Daily
Packaging Form (vial, blister, etc.)	Blister	Blister	Blister
New UV/HEV-filter	Yes	Yes	Yes

Table 2: Control Articles

	Control - Sphere	Control - Multifocal	Control - Astigmatism
Name	ACUVUE® OASYS 1-Day	ACUVUE® OASYS Multifocal	ACUVUE® OASYS 1-Day for Astigmatism
Manufacturer	JJVC	JJVC	JJVC
[redacted]	[redacted]	[redacted]	[redacted]
Lens Material	senofilcon A	senofilcon A	senofilcon A
Nominal Base Curve @ 22°C (mm)	8.5	8.4	8.5
Nominal Diameter @ 22°C (mm)	14.3	14.3	14.3
Nominal Distance Powers (D)	-1.00 through -6.00 in 0.25 steps	-1.00 through -6.00 in 0.25 steps	-1.50 through -4.00 in 0.25 steps
Nominal ADD Powers	NA	Low, Med, High	NA
Nominal Cylinder Powers (D)	NA	NA	-0.75, -1.25
Nominal Cylinder Axes (degrees)	NA	NA	10, 80, 90, 100, 170, 180
Water Content *(Optional)*	38	38	38
Oxygen Permeability (Dk)	103	103	103
Wear Schedule in Current Study	Daily	Daily	Daily
Replacement Frequency	Daily	Daily	Daily
Packaging Form (vial, blister, etc.)	Blister	Blister	Blister
New UV/HEV-filter	Yes	Yes	Yes

Based on estimates from the CLIFT program, this study will utilize a minimum of 36 lenses per SKU for sphere, a minimum of 14 lenses per SKU for multifocal, and a minimum of 20 lenses per SKU for astigmatism.

6.2. Ancillary Supplies/Products

The following solutions will be used in this study:

Table 3: Ancillary Supplies

	Solutions			
Solution Name/Description	Acuvue™ RevitaLens Multipurpose Solution	Single use Eye-Cept® Rewetting Drops	LacriPure Saline Solution	ScleralFil Preservative Free Saline Solution
Manufacturer	Johnson & Johnson Vision	Optics Laboratory	Menicon	Bausch & Lomb
Preservative	alexidine dihydrochloride 0.00016% and polyquaternium-1 0.0003%	None	None	None

Lens cases and fluorescein strips (either 0.6 mg or 1.0 mg) will be supplied for use as needed.

6.3. Administration of Test Articles

Test articles will be dispensed to subjects meeting all eligibility requirements, including any dispensing requirements set forth in this clinical protocol. Subjects will be dispensed an adequate supply of test articles to complete the study. Lost or damaged test articles may be replaced at the discretion of the investigator and/or the sponsor.

6.4. Packaging and Labeling

The test articles will be packaged in blisters as the primary packaging. The test article will be over-labeled to mask the subject and investigators to the identity of the lens. The test articles will be in investigational cartons sealed with a tamper evident seal plastic bags as the secondary packaging form. Sample labels for each lens type are shown below. The information represented on the labels below are sample information only and are not representative of the actual study lens information.

Table 4: Sample Labels

Sphere Label	Multifocal Label	Astigmatism Label	Secondary Label (Sphere, Multifocal, and Astigmatism)
CAUTION: INVESTIGATIONAL DEVICE LIMITED BY U.S. LAW TO INVESTIGATIONAL USE EXCLUSIVELY FOR CLINICAL INVESTIGATIONS Contents: One contact lens in solution. STERILE LOT C7VN01 SPH -1.25 ADD HGH EXP 2025/08/01 CR-6480 RC P	CAUTION: INVESTIGATIONAL DEVICE LIMITED BY U.S. LAW TO INVESTIGATIONAL USE EXCLUSIVELY FOR CLINICAL INVESTIGATIONS Contents: One contact lens in solution. STERILE LOT C7M101 SPH -1.00 EXP 2023/03/15 CR-6480 RC P	CAUTION: INVESTIGATIONAL DEVICE LIMITED BY U.S. LAW TO INVESTIGATIONAL USE EXCLUSIVELY FOR CLINICAL INVESTIGATIONS Contents: One contact lens in solution. STERILE LOT C7G201 SPH -4.00 CYL -0.75 AXIS 180 EXP 2023/03/15 CR-6480 RC P	Sponsored By/Parrainé par: Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, FL 32256, USA Contents/Contenu: Contact Lenses in Solution Lentilles cornéennes dans une solution

6.5. Storage Conditions

Test articles will be maintained at ambient temperatures at the clinical site. Test articles must be kept under secure conditions.

6.6. Collection and Storage of Samples

When possible, any lens or test article associated with an Adverse Event and/or a Product Quality Complaint must be retained and stored in a glass vial with moderate solution pending directions from the sponsor for potential return to JJVC.

6.7. Accountability of Test Articles

JJVC 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.

Test articles must be kept in a locked storage cabinet, accessible only to those assigned by the Investigator for dispensing. The Investigator may delegate this activity to authorized study site personnel listed on the Site Delegation Log. All test articles must be accounted. This includes:

1. What was dispensed for the subject for trial fitting, to wear out of the office, or issued for the subject to replace appropriately between visits.
2. What was returned to the Investigator unused, including expired or malfunctioning product.
3. The number and reason for unplanned replacements.

The Investigator will collect all unused test articles from the subjects at the end of the subject's participation. Subject returned unused test articles must be separated from the clinical study inventory of un-dispensed test articles and must be labeled with the subject number and date of return. Following final reconciliation of test articles by the monitor, the Investigator or monitor will return all unused test articles to JJVC.

If there is a discrepancy between the shipment documents and the contents, contact the study monitor immediately.

[redacted]

7. STUDY EVALUATIONS

7.1. Time and Event Schedule

Table 5: Time and Events: Phase 1 and Phase 2

Visit Information	Visit 1 Screening, Baseline, Treatment 1 Fit and Evaluation	Visit 2 Treatment 2 Fit and Evaluation, Final Evaluation
Time Point	Day 0	1-14 days following Visit 1
Minimum lens wear time immediately prior to visit	NA	NA
Estimated Visit Duration	3.0 hours	2.5 hours
Statement of Informed Consent	x	
Demographics	x	
Medical History/Concomitant Medications	x	x
Habitual Contact Lens Information	x	
Eligibility Following Screening	x	
Entrance Visual Acuity	x	
Subjective Sphero-Cylindrical Refraction and best-corrected VA	x	
Entrance Slit Lamp Biomicroscopy	x	x
Eligibility Following Baseline Evaluation	x	
Lens Selection	x	
Lens Insertion & Settling	x	
Visual Acuity and Over Refraction	x	x
Lens Power Modification (if applicable)	x	
Subject Reported Ocular Symptoms	x	x
General Fit Assessment	x	x
Toric Fit Assessment (if applicable)	x	
Psychophysical Testing: Visual Range	x	x
Psychophysical Testing: Brightness Perception	x	x

Visit Information	Visit 1 Screening, Baseline, Treatment 1 Fit and Evaluation	Visit 2 Treatment 2 Fit and Evaluation, Final Evaluation
Time Point	Day 0	1-14 days following Visit 1
Minimum lens wear time immediately prior to visit	NA	NA
Estimated Visit Duration	3.0 hours	2.5 hours
Psychophysical Testing: Motion Detection	x	x
Exit Slit Lamp Examination	x	x
Exit Snellen Distance Visual Acuity	x	x
Final Evaluation		x

7.2. Detailed Study Procedures

VISIT 1

Subjects will enter Visit 1 wearing their own form of vision correction.

Visit 1: Screening			
Step	Procedure	Details	[redacted]
1.1	Statement of Informed Consent	Each subject must read, understand, and sign the Statement of Informed Consent before being enrolled into the study. The Principal Investigator or his/her designee conducting the informed consent discussion must also sign the consent form. **Note:** The subject must be provided a signed copy of this document.	
1.2	Demographics	Record the subject's year of birth, age, gender, race and ethnicity.	
1.3	Medical History and Concomitant Medications	Record the subject's medical history and concomitant medications.	
1.4	Habitual Lenses and Habitual Wear Time	Record the subject's habitual lens type, parameters, lens care solution, wear modality, approximate prescription date, and duration of lens wear.	

Visit 1: Screening			
Step	Procedure	Details	[redacted]
1.5	Eligibility after Screening	All responses to Screening Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria must be answered "no" for the subject to be considered eligible. *If subject is deemed to be ineligible after screening, proceed to Final Evaluation and complete Subject Disposition. Refraction and Biomicroscopy forms do not need to be completed as part of Final Evaluation.*	

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.6	Entrance Visual Acuity	Record the distance Snellen visual acuity (OD, OS, and OU) to the nearest letter with their habitual correction in place. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	
1.7	Remove Habitual Lens	If applicable, the subject's habitual contact 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.	
1.8	Subjective Sphero-cylindrical Refraction	Complete subjective spherocylindrical refraction and record the resultant distance visual acuity (OD, OS, and OU) to the nearest letter. Refractive cylinder guidelines: • For sphere: 0.00 through 1.00 DC • For multifocal: 0.00 through 0.75 DC • For toric: 0.75 through 1.75 DC	[redacted]
1.9	ADD Power Determination (if applicable)	The near reading addition will be determined using the binocular crossed cylinder technique (BCC) at 40 cm.	[redacted]
1.10	ADD Power Refinement (if applicable)	Place the BCC result in the trial frame and refine the near prescription with trial lenses (or flippers) under binocular conditions. Subjects with at least a +0.75 D ADD will be fit with multifocal lenses. Otherwise fit with spherical lenses.	[redacted]

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.11	Eye Dominancy	The investigator will determine eye dominancy of the subject by first using the +1.00 blur test. If this fails to determine dominancy, then the sighting test will be used. See Appendix E.	Appendix E
1.12	Iris Color	The investigator will record the subject's iris color based on the scale provided.	Appendix F
1.13	Slit Lamp Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings. If any of these slit lamp findings are grade 3 or higher, the subject may not continue at this time, but may return up to one additional time to determine eligibility. If discontinued a final examination must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
1.14	Lens Design Assignment	Based on their subjective refraction, the investigator will note whether the subject will receive a spherical lens on both eyes (Phase 1 and 2), a multifocal lens on both eyes (Phase 1 and 2), or a toric lens on both eyes (Phase 2 only). See section 4.1.	
1.15	Eligibility after 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. *If subject is deemed to be ineligible after baseline, proceed to Final Evaluation and complete Subject Disposition. Refraction and Biomicroscopy forms do not need to be completed as part of Final Evaluation.*	

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.16	Lens Design Fitting Steps	Please jump to the appropriate fitting section in the protocol depending on the lens design: • For spherical lenses, proceed to step 1.17. • For multifocal lenses, proceed to step 1.25 • For toric lenses, proceed to step 1.32	

Visit 1: Spherical Lens Fitting: Phase 1 and 2			
Step	Procedure	Details	[redacted]
1.17	Lens Selection	Assign the study lens (Test or Control) according to the randomization scheme provided by the biostatistician. Select the contact lens power based on the vertex-corrected refraction. Record the test condition.	
1.18	Lens Insertion	The Investigator or the subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable. Ensure the subject is given a Clinic-only Wear Patient Instruction Guide.	
1.19	Lens Settling 1	Allow the study lenses to settle for a minimum of 5 minutes.	
1.20	Subjective Best Sphere Over Refraction	Perform subjective best sphere refraction over the study lenses with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach) and record the best corrected distance visual acuity to the nearest letter (OD, OS, and OU).	[redacted]
1.21	Lens Power Modification (if applicable)	Adjust the lens power if the subject's best sphere over-refraction is not plano. For each power modification, select the adjusted fitting lens power as appropriate and repeat steps 1.17 through 1.19. Up to two power modifications are allowed.	

Visit 1: Spherical Lens Fitting: Phase 1 and 2			
Step	Procedure	Details	[redacted]
1.22	Lens Settling 2	Please wait a total of 10 minutes from final lens insertion to continue.	
1.23	Visual Acuity	Record the best corrected Snellen distance visual acuity to the nearest letter (OD, OS, and OU). Subjects must read the smallest line until at least 50% of the letters are read incorrectly. Visual acuity with the study contact lenses must be 20/30 or better OD, OS and OU.	[redacted]
1.24	General Lens Fit Assessment	Evaluate lens centration, movement on blink, and push-up test for each eye. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement. • edge lift. • excessive movement in primary and up gaze. • insufficient movement in all three of the following conditions: primary gaze, up gaze, and push-up test. Note: if lens fit is unacceptable for either eye, the subject will be discontinued from the study.	[redacted]

Visit 1: Multifocal Lens Fitting: Phase 1 and 2			
Step	Procedure	Details	[redacted]
1.25	Lens Selection	Assign the study lens (Test or Control) according to the randomization scheme provided by the biostatistician. Select the contact lens power based on the vertex-corrected refraction. Record the test condition.	

Visit 1: Multifocal Lens Fitting: Phase 1 and 2			
Step	Procedure	Details	[redacted]

	ADD							
	+0.75	+1.00	+1.25	+1.50	+1.75	+2.00	+2.25	+2.50
Dominant Eye	LOW	LOW	LOW	MID	MID	MID	MID	MID
Non Dominant Eye	LOW	LOW	LOW	MID	MID	HGH	HGH	HGH

1.26	Lens Insertion	The Investigator or the subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable. Ensure the subject is given a Clinic-only Wear Patient Instruction Guide.	
1.27	Lens Settling 1	Allow the study lenses to settle for a minimum of 5 minutes.	
1.28	Subjective Best Sphere Over Refraction	Perform subjective best sphere refraction over the study lenses with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach) and record the best corrected distance visual acuity to the nearest letter (OD, OS, and OU).	[redacted]
1.29	Lens Settling 2	Please wait a total of 10 minutes from final lens insertion to continue.	
1.30	Visual Acuity	Record the best corrected Snellen distance visual acuity to the nearest letter (OD, OS, and OU). Subjects must read the smallest line until at least 50% of the letters are read incorrectly. Visual acuity with the study contact lenses must be 20/30 or better OD, OS and OU.	[redacted]

Visit 1: Multifocal Lens Fitting: Phase 1 and 2			
Step	Procedure	Details	[redacted]
1.31	General Lens Fit Assessment	Evaluate lens centration, movement on blink, and push-up test for each eye. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement. • edge lift. • excessive movement in primary and up gaze. • insufficient movement in all three of the following conditions: primary gaze, up gaze, and push-up test. **Note:** if lens fit is unacceptable for either eye, the subject will be discontinued from the study.	

Visit 1: Toric Lens Fitting: Phase 2			
Step	Procedure	Details	[redacted]
1.32	Lens Selection	Assign the study lens (Test or Control) according to the randomization scheme provided by the biostatistician. Select the contact lens power based on the vertex-corrected refraction. Record the test condition.	
1.33	Lens Insertion	The Investigator or the subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable. Ensure the subject is given a Clinic-only Wear Patient Instruction Guide.	
1.34	Lens Settling 1	Allow the study lenses to settle for a minimum of 5 minutes. For toric lenses, ensure the lens orientation has stabilized before continuing.	

Visit 1: Toric Lens Fitting: Phase 2			
Step	Procedure	Details	[redacted]
1.35	Subjective Best Sphere Over Refraction	Perform subjective best sphere refraction over the study lenses with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach) and record the best corrected distance visual acuity to the nearest letter (OD, OS, and OU).	[redacted]
1.36	Lens orientation	Measure the lens orientation in each eye.	[redacted]
1.37	Lens Power Modification (if applicable)	Adjust the lens power if the subject's best sphere over-refraction is not plano. Additionally, for toric lenses, adjust the lens axis parameter if the settled lens orientation is such that a different axis would be more appropriate (use the LARS rule to determine the replacement lens axis). For each power modification, select the adjusted fitting lens power as appropriate and repeat steps 1.33 through 1.36. Up to two power modifications are allowed.	
1.38	Lens Settling 2	Please wait a total of 10 minutes from final lens insertion to continue.	
1.39	Visual Acuity	Record the best corrected Snellen <u>distance</u> visual acuity to the nearest letter (OD, OS, and OU). Subjects must read the smallest line until at least 50% of the letters are read incorrectly. Visual acuity with the study contact lenses must be 20/30 or better OD, OS and OU.	[redacted]

Visit 1: Toric Lens Fitting: Phase 2			
Step	Procedure	Details	[redacted]
1.40	General Lens Fit Assessment	Evaluate lens centration, movement on blink, and push-up test for each eye. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement. • edge lift. • excessive movement in primary and up gaze. • insufficient movement in all three of the following conditions: primary gaze, up gaze, and push-up test. Note: if lens fit is unacceptable for either eye, the subject will be discontinued from the study.	
1.41	Toric Fit Assessment (toric lenses only)	Record for each eye: 1. The rotational position to the nearest degree 2. Lens stability with blinks 3. Toric fit acceptability. The toric lens fit will be designated as 'unacceptable' if either: a. The lens ABSOLUTE ROTATION is greater than 20 degrees b. The LENS STABILITY WITH BLINK is greater than 5 degrees If one or both lenses demonstrate an unacceptable toric fit, the subject will be discontinued (proceed to final evaluation).	[redacted]

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
1.42	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
1.43	Continuance	For the subject to continue in the study, they must meet all three of the following criteria: • Distance visual acuity is 20/30 or better OD and OS. • The lens fit is acceptable OD and OS. • Investigator approval. If the Investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.	
1.44	Lenses Worn in Clinic	The lenses will be released for approximately 2.5 hours for psychometric testing. 1. The subjects must wear both study lenses the entire time. 2. The lenses will be worn as daily wear only. 3. Rewetting drops are permitted if needed. **Note**: In the event a lens is lost or damaged, it will be replaced immediately.	
1.45	Psychophysical Testing Sequence	The following psychophysical tests will be performed in any order: 1. Visual range (OU) at approximately 8 cpd a. Units: log relative energy b. Range / decimal places: 0.00-10.00 2. Brightness perception (OU) a. Units: log relative energy b. Range / decimal places: 0.00 to 10.00 3. Motion detection (OU) a. Units: mm b. Range / decimal places: 0.00 – 700.00 Following the psychophysical testing by the principal investigator, the subject will return to the sub-investigator.	
1.46	Lens Removal	The worn study lenses will be removed and discarded.	

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
1.47	Exit Slit Lamp Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings. If the subject has a Grade 3 slit lamp finding, it will be recorded as an Adverse Event and the subject will be monitored as per the guidelines given in section 13. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be instilled.	
1.48	Exit VA	Record the subject's distance visual acuity, OD, OS, and OU, to the nearest letter with their habitual correction in place.	
1.49	Schedule next visit	Schedule the follow-up visit to occur within 14 days (counting the day of this visit as day 0, the subject may return on day 1 through 14).	

VISIT 2

Subjects will enter Visit 2 wearing the same form of habitual vision correction that they entered Visit 1.

Visit 2: Treatment 2 Baseline			
Step	Procedure	Details	[redacted]
2.1	Adverse Events and Concomitant Medications Review	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	
2.2	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
2.3	Visual Acuity	Record the distance Snellen visual acuity with the contact lenses (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly. • Note: Entrance visual acuity must be within 1 line of Visit 1 to continue. Otherwise, determine if there is an adverse event.	[redacted]
2.4	Slit Lamp Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings. If the subject has a Grade 3 slit lamp finding, it will be recorded as an Adverse Event and the subject will be monitored as per the guidelines given in section 13. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be instilled.	[redacted]
2.5	Continuance	Verify that the subject is eligible to continue in the study. : Next step based on lens design: • For spherical lenses, proceed to step 2.6. • For multifocal lenses, proceed to step 2.14. • For toric lenses, proceed to step 2.21.	

Visit 2: Spherical Lens Fitting: Phase 1 and 2			
Step	Procedure	Details	[redacted]
2.6	Lens Selection	Assign the study lens (Test or Control) according to the randomization scheme provided by the biostatistician. Select the contact lens power based on the vertex-corrected refraction or the final powers from Visit 1. Record the test condition.	
2.7	Lens Insertion	The Investigator or the subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable. Ensure the subject is given a Patient Instruction Guide.	
2.8	Lens Settling 1	Allow the study lenses to settle for a minimum of 5 minutes.	
2.9	Subjective Best Sphere Over Refraction	Perform subjective best sphere refraction over the study lenses with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach) and record the best corrected distance visual acuity to the nearest letter (OD, OS, and OU).	[redacted]
2.10	Lens Power Modification (if applicable)	Adjust the lens power if the subject's best sphere over-refraction is not plano. For each power modification, select the adjusted fitting lens power as appropriate and repeat steps 2.6 through 2.9. Up to two power modifications are allowed.	
2.11	Lens Settling 2	Please wait a total of 10 minutes from final lens insertion to continue.	
2.12	Visual Acuity	Record the best corrected Snellen distance visual acuity to the nearest letter (OD, OS, and OU). Subjects must read the smallest line until at least 50% of the letters are read incorrectly. Visual acuity with the study contact lenses must be 20/30 or better OD, OS and OU.	[redacted]

Visit 2: Spherical Lens Fitting: Phase 1 and 2			
Step	Procedure	Details	[redacted]
2.13	General Lens Fit Assessment	Evaluate lens centration, movement on blink, and push-up test for each eye. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement. • edge lift. • excessive movement in primary and up gaze. • insufficient movement in all three of the following conditions: primary gaze, up gaze, and push-up test. Note: if lens fit is unacceptable for either eye, the subject will be discontinued from the study.	

<table>
<tr><th colspan="4">Visit 2: Multifocal Lens Fitting: Phase 1 and 2</th></tr>
<tr><th>Step</th><th>Procedure</th><th>Details</th><th>[redacted]</th></tr>
<tr><td>2.14</td><td>Lens Selection</td><td>Assign the study lens (Test or Control) according to the randomization scheme provided by the biostatistician.
Select the contact lens power based on the vertex-corrected refraction or the final powers from Visit 1.

Record the test condition.</td><td></td></tr>
<tr><td colspan="4">
<table>
<tr><td></td><td>ADD</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>+0.75</td><td>+1.00</td><td>+1.25</td><td>+1.50</td><td>+1.75</td><td>+2.00</td><td>+2.25</td><td>+2.50</td></tr>
<tr><td>Dominant Eye</td><td>LOW</td><td>LOW</td><td>LOW</td><td>MID</td><td>MID</td><td>MID</td><td>MID</td><td>MID</td></tr>
<tr><td>Non Dominant Eye</td><td>LOW</td><td>LOW</td><td>LOW</td><td>MID</td><td>MID</td><td>HGH</td><td>HGH</td><td>HGH</td></tr>
</table>
</td></tr>
<tr><td>2.15</td><td>Lens Insertion</td><td>The Investigator or the subject inserts the study lenses. Record the time of lens insertion.
Check for lens damage under the slit lamp before proceeding with lens settling.
Replace damaged lenses if applicable.
Ensure the subject is given a Patient Instruction Guide.</td><td></td></tr>
<tr><td>2.16</td><td>Lens Settling 1</td><td>Allow the study lenses to settle for a minimum of 5 minutes.</td><td></td></tr>
<tr><td>2.17</td><td>Subjective Best Sphere Over Refraction</td><td>Perform subjective best sphere refraction over the study lenses with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach) and record the best corrected <u>distance</u> visual acuity to the nearest letter (OD, OS, and OU).</td><td>[redacted]</td></tr>
<tr><td>2.18</td><td>Lens Settling 2</td><td>Please wait a total of 10 minutes from final lens insertion to continue.</td><td></td></tr>
<tr><td>2.19</td><td>Visual Acuity</td><td>Record the best corrected Snellen <u>distance</u> visual acuity to the nearest letter (OD, OS, and OU). Subjects must read the smallest line until at least 50% of the letters are read incorrectly. Visual acuity with the study contact lenses must be 20/30 or better OD, OS and OU.</td><td>[redacted]</td></tr>
</table>

Visit 2: Multifocal Lens Fitting: Phase 1 and 2			[redacted]
Step	Procedure	Details	
2.20	General Lens Fit Assessment	Evaluate lens centration, movement on blink, and push-up test for each eye. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement. • edge lift. • excessive movement in primary and up gaze. • insufficient movement in all three of the following conditions: primary gaze, up gaze, and push-up test. **Note:** if lens fit is unacceptable for either eye, the subject will be discontinued from the study.	

Visit 2: Toric Lens Fitting: Phase 2			[redacted]
Step	Procedure	Details	
2.21	Lens Selection	Assign the study lens (Test or Control) according to the randomization scheme provided by the biostatistician. Select the contact lens power based on the vertex-corrected refraction or the final powers from Visit 1. Record the Test condition.	
2.22	Lens Insertion	The Investigator or the subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable. Ensure the subject is given a Patient Instruction Guide.	

Visit 2: Toric Lens Fitting: Phase 2			
Step	Procedure	Details	[redacted]
2.23	Lens Settling 1	Allow the study lenses to settle for a minimum of 5 minutes. For toric lenses, ensure the lens orientation has stabilized before continuing.	
2.24	Subjective Best Sphere Over Refraction	Perform subjective best sphere refraction over the study lenses with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach) and record the best corrected distance visual acuity to the nearest letter (OD, OS, and OU).	[redacted]
2.25	Lens orientation (toric lenses only)	If fitting toric lenses, measure the lens orientation in each eye.	[redacted]
2.26	Lens Power Modification (if applicable)	Adjust the lens power if the subject's best sphere over-refraction is not plano. Additionally, for toric lenses, adjust the lens axis parameter if the settled lens orientation is such that a different axis would be more appropriate (use the LARS rule to determine the replacement lens axis). For each power modification, select the adjusted fitting lens power as appropriate and repeat steps 2.24 through 2.27. Up to two power modifications are allowed.	
2.27	Lens Settling 2	Please wait a total of 10 minutes from final lens insertion to continue.	
2.28	Visual Acuity	Record the best corrected Snellen distance visual acuity to the nearest letter (OD, OS, and OU). Subjects must read the smallest line until at least 50% of the letters are read incorrectly. Visual acuity with the study contact lenses must be 20/30 or better OD, OS and OU.	[redacted]

Visit 2: Toric Lens Fitting: Phase 2			
Step	Procedure	Details	[redacted]
2.29	General Lens Fit Assessment	Evaluate lens centration, movement on blink, and push-up test for each eye. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement. • edge lift. • excessive movement in primary and up gaze. • insufficient movement in all three of the following conditions: primary gaze, up gaze, and push-up test. Note: if lens fit is unacceptable for either eye, the subject will be discontinued from the study.	
2.30	Toric Fit Assessment (toric lenses only)	Record for each eye: 1. The rotational position to the nearest degree 2. Lens stability with blinks 3. Toric fit acceptability. The toric lens fit will be designated as 'unacceptable' if either: a. The lens ABSOLUTE ROTATION is greater than 20 degrees b. The LENS STABILITY WITH BLINK is greater than 5 degrees If one or both lenses demonstrate an unacceptable toric fit, the subject will be discontinued (proceed to final evaluation).	[redacted]

Visit 2: Treatment 2 Lens Fitting and Assessment			
Step	Procedure	Details	[redacted]
2.31	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	

Visit 2: Treatment 2 Lens Fitting and Assessment			
Step	Procedure	Details	[redacted]
2.32	Continuance	For the subject to continue in the study, they must meet all three of the following criteria: • Visual acuity is 20/30 or better OD and OS. • The lens fit is acceptable OD and OS. • Investigator approval. If the Investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.	
2.33	Lenses Worn in Clinic	The lenses will be released for approximately 2.5 hours for psychometric testing. 1. The subjects must wear both study lenses the entire time. 2. The lenses will be worn as daily wear only. 3. Rewetting drops are permitted if needed. **Note**: In the event a lens is lost or damaged, it will be replaced immediately.	
2.34	Psychophysical Testing Sequence	The following psychophysical tests will be performed in any order: 1. Visual range (OU) at approximately 8 cpd a. Units: log relative energy b. Range / decimal places: 0.00-10.00 2. Brightness perception (OU) a. Units: log relative energy b. Range / decimal places: 0.00 to 10.00 3. Motion detection (OU) a. Units: mm b. Range / decimal places: 0.00 – 700.00 Following the psychophysical testing by the principal investigator, the subject will return to the sub-investigator.	
2.35	Lens Removal	The worn study lenses will be removed and discarded.	

FINAL EVALUATION

The final evaluation will ordinarily take place immediately following the last scheduled follow-up visit per the study protocol. It may also take place at any point the subject discontinues the study or is terminated from the study.

Final Evaluation			
Step	Procedure	Details	[redacted]
F.1	Final Exam Form	Indicate if the subject completed the study successfully. If subject discontinued from the study, indicate the reason.	
F.2	Exit Refraction	Perform bare-eye subjective spherocylindrical refraction with a phoropter and record the best-corrected distance visual acuity (OD, OS, and OU) to the nearest letter. **Note**: This step is not necessary if the subject was exited due to screen failure.	[redacted]
F.3	Exit Slit Lamp Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled. This step is not necessary if the subject was exited due to screen failure. **Note**: This step is not necessary if the subject was exited due to screen failure, or if biomicroscopy was performed as part of the final follow-up visit procedures (i.e., immediately prior to the final evaluation).	[redacted]

7.3. Unscheduled Visits

If, during the investigation, a subject requires an unscheduled visit to the clinical site, the following information will be collected, as appropriate:

- Chief complaint prompting the visit. If the reason is an adverse event, the applicable eCRF for the adverse event must be completed and subject record 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 test article dispensed or collected from the subject, if applicable.
- 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 record must be completed documenting the date and primary reason for withdrawal and the study CRA notified.

Any ocular and non-ocular Adverse Events that are ongoing at the time of the study visit will be followed by the Investigator, within licensure, until they have resolved, 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.

The following information will be collected during an unscheduled visit.

Unscheduled Visit			
Step	Procedure	Details	[redacted]
U.1	Reason for unscheduled visit	Indicate if the only reason for the visit is that the subject requires additional test articles. If the reason is other than resupply of previously dispensed lenses, specify the reason for the visit.	
U.2	Chief Complaints (if applicable)	Record the subject's chief complaints for reasons for the unscheduled visit.	
U.3	Adverse Events and Concomitant Medications Review (if applicable)	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	
U.4	Entrance VA (if applicable)	Record the entrance distance visual acuity (OD, OS, and OU) to the nearest letter.	[redacted]
U.5	Subjective Sphero-cylindrical Refraction (if applicable)	Perform bare-eye subjective spherocylindrical refraction with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the best corrected distance visual acuity to the nearest letter (OD, OS, and OU).	[redacted]
U.6	Slit Lamp Biomicroscopy (if applicable)	FDA Slit Lamp Classification Scale will be used to grade the findings. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be instilled.	[redacted]
U.7	Dispensing (if applicable)	If the subject requires additional lenses to complete the wear period and is eligible to do so, provide additional lenses per the dispensing instructions given in the detailed study procedures.	

Unscheduled Visit			
Step	Procedure	Details	[redacted]
U.8	Exit Visual Acuity (if applicable)	Record the subject's exit distance visual acuity (OD, OS, and OU) to the nearest letter.	

NOTE: If the only reason for the unscheduled visit is that the subject requires additional test articles, only the dispensing information needs to be recorded.

7.4. Laboratory Procedures

None

8. SUBJECTS COMPLETION/WITHDRAWAL

8.1. Completion Criteria

Subjects are considered to have completed the study if they:

- provided informed consent.
- they are eligible.
- have not withdrawn/discontinued from the study for any reason described in section 8.2.
- completed all visits through the final visit 2.
- If all visits were completed but an additional visit is considered necessary for subject care, follow the requirements for unscheduled visits in section 7.3.

8.2. Withdrawal/Discontinuation from the Study

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

- Subject withdrawal of consent.
- Subject not compliant to protocol (e.g., follow-up 2 or more days out of window).
- Subject lost to follow-up.
- Subject no longer meets eligibility criteria (e.g. the subject becomes pregnant).
- Subject develops significant or serious adverse events necessitating discontinuation of study lens wear
- Subjects who have experienced a Corneal Infiltrative Event (CIE).
- Investigator's clinical judgment regarding the subject safety reasons (that it is in the best interest of the subject to stop treatment).
- Subject not successfully 'dispensed' due to lack of efficacy and safety including poor vision, poor comfort or unacceptable fit.

For discontinued subjects, the Investigator will:

- Complete the current visit (scheduled or unscheduled).
- Complete the Final Evaluation, indicating the reason that the subject was discontinued from the study.
- Record the spherocylindrical refraction with best corrected distance visual acuity.

- Collect used test article(s) (worn or brought to the visit) from the subject and discard them, unless otherwise stated in section 7.2.
- Collect all unused test article(s) from the subject.
- Make arrangements for subject care, if needed, due to their study participation

Additional subjects will be enrolled if a subject discontinues from the study prematurely.

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 (or equivalent) as the final attempt.

9. PRE-STUDY AND CONCOMITANT INTERVENTION/MEDICATION

- Concomitant medications will be documented during screening and updated during the study. Disallowed medications for this study include: Any ocular medication. medications that may interfere with contact lens wear (see section 9.1). Habitual medications used by successful soft contact lens wearers are generally considered acceptable.
- Concomitant therapies that are disallowed include: NA

9.1. Systemic Medications

Certain systemic medications are known to have a higher likelihood to interfere with contact lens wear, chiefly by disrupting the tear film.

A summary of disallowed systemic medications is shown in Table 7. Subjects with a history of taking these medications will be allowed to enroll only if:

- The medications have been taken on a continual, routine basis for at least 6 months, and
- The subject has demonstrated successful contact lens wear during this time.

Or:

- The subject was taking the medication on a temporary basis and ceased taking that medication at least 2 weeks prior to signing the informed consent (this is considered sufficient time for the medication to have left the body prior to enrollment).

Subjects with a history of taking medications listed in Table 6 on a long-term, routine basis for less than 6 months will not be allowed to participate in the study.

Table 6: Disallowed systemic medications

Class of Drug	Common Indication(s)	Common Examples
Estrogens (not including contraceptive medication)	Menopause, osteoporosis, vaginitis	Vagifem, Estrace, Climara, Vivelle-Dot, Premarin, Minivelle, etc.
Anticholinergics	Irritable bowel syndrome, Parkinson's disease, peptic ulcer, cystitis, nasal congestion, cold symptoms, overactive bladder, COPD	Bentyl, Spiriva, Atrovent, Hyosyne, Levsin, Symax Fastab, Symax SL, Homax SL, Cogentin, Transderm Scop, etc.
Beta-filters	Hypertension, angina, heart attack, migraine, artrial fibrillation, andrenal cancer, essential tumor, glaucoma	Toprol XL, Lopressor, Tenormin, Propranolol, Timoptic, Trandate, Inderal LA, etc.
Psychotropics	Antipsychotic (schizophrenia, mania), antidepression, antiobsessive, antianxiety, mood stabilizer, stimulants (ADHD)	Zoloft, Celexa, Prozac, Lexapro, Effexor, Cymbalta, Ativan, Xanax, Desyrel, Wellbutrin, etc.
Vitamin A analogs	Cystic acne	Isotretinoin
Analgesics	Urinary tract infection	Phenazopyridine HCL

Examples of disallowed systemic antihistamines are given in Table 7. Subjects with a history of taking systemic antihistamines will be allowed to enroll only if:

- They have taken antihistamines continuously for at least 2 weeks, and
- They have demonstrated successful wear while taking the medication

Or:

- They stopped taking the medication for at least 2 weeks prior to enrollment.

Table 7: Disallowed systemic antihistamines

Class of Drug	Common Indication(s)	Common Examples
Antihistamines	Allergic rhinitis, sedation, hives, allergic conjunctivitis, skin allergy, itching, motion sickness	Hydroxyzine, Promethagan, Phenadoz, Vistaril, Claritin, Zyrtec, Astepro, Astelin, Optivar, Allegra, Benadryl, etc.

10. DEVIATIONS FROM THE PROTOCOL

Investigator will notify study sponsor upon identification of a protocol deviation. Protocol deviations must be reported to the sponsor within 24 hours after discovery of the protocol deviation. The Investigator will report deviations per IRB/IEC requirements. All deviations will be tracked, and corrective actions implemented as appropriate.

If it becomes necessary for the Investigator to implement a deviation in order to eliminate an immediate hazard to the trial subject, the Investigator may implement the deviation immediately without notification to the sponsor. Within 24 hours after the implemented deviation, the Investigator must notify and provide the rationale to the Sponsor and, as required, the IEC/IRB.

If the deviation potentially impacts the safety of patient or changes the technical integrity of the study, then it must be reported to IEC/IRB. This is a "Major Deviation". Deviations that contradict the information contained in the Informed Consent/Assent forms will be considered Major Deviations.

Minor deviations have no substantive effect on patient safety or technical integrity of the study. They are often logistical in nature.

Protocol waivers are prohibited.

Table 8 lists examples of deviations that will constitute major and minor protocol deviations for this study.

Table 8: Examples of major and minor protocol deviations

Deviation category	Major deviation	Minor deviation
Out-of-window visit	Visit attended more than 2 days out of visit window defined in study procedures	Visit attended 2 or fewer days out of visit window defined in study procedures
Insufficient data collection of primary endpoints	Subject does not complete the psychometric evaluations as planned.	NA

In the case of a major protocol deviation, the decision of whether or not the subject will be excluded from the Per-Protocol analysis population will be made at the time of cohort review.

11. STUDY TERMINATION

If more than 2 subjects in the investigational soft contact lens group develop serious expected (e.g., definite or probable MK) or unexpected device related adverse events, the study will be

suspended. Upon review and consultation with IRB, and JJVC Safety Review committee, the study may be terminated.

The occurrence of one or more Unanticipated Serious Adverse Device Effect (USADE), or any SAE where the relationship to study agent cannot be ruled out, may result in stopping further dispensing of test article. In the event of a USADE or SAE, the Sponsor may unmask the treatment regimen for the subject(s) and will discuss this with the Investigator before any further subjects are enrolled.

The Sponsor will 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 are compromised.

JJVC reserves the right to terminate the study at any time for any reason. Additionally, the IEC/IRB reserves the right to terminate the study if an unreasonable risk is determined. The study can be terminated by the Principal Investigator at the individual clinical site due to specific clinical observations, if in their opinion, after a discussion with JJVC, it is determined that it would be unwise to continue at the clinical site.

JJVC (and the IEC/IRB and DMC, 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 IEC/IRB and Regulatory Authority as required by local regulatory requirements.

12. PROCEDURE FOR HANDLING 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.

Potential complaints may come from a variety of sources including but not limited to subjects, clinical research associates (CRA), clinical operations managers (COM), medical monitors, and site personnel, etc. The following are not considered product quality complaints:

- Subject satisfaction inquiries reported via "Subjective Questionnaires" and "Patient Reported Outcomes (PRO)."
- Clinical test articles that are stored improperly or damaged after receipt at the investigational site.
- Lens replacements that occur due to drops/fall-outs.
- Damage deemed by clinicians or clinical staff to be caused by handling by the user, and not indicative of a quality deficiency (i.e. tears, rips, etc.), only in situations where there is no deficiency alleged by the subject.

Within 24 hours of site personnel becoming aware that a PQC has occurred, the PQC must be recorded in the EDC system, which will trigger 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 or when an EDC system is not used, 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 will contact the study site to collect additional information which will include:

- Date the complaint was received/recorded in the EDC System (Date of Sponsor Awareness).
- Who received the complaint.
- Study number.
- Clinical 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 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 [redacted]

Once a complaint is received, it will be assessed by the COM, CRA, or trained site personnel to determine if it is an Adverse Event/Serious Adverse Event (AE/SAE). If the complaint results in an AE/SAE, the COM/CRA, or trained site personnel will follow section 13 of this protocol. If the AE/SAE was potentially the result of a product quality related deficiency, these procedures also applies and will be executed in parallel.

In some cases, a PQC form may be generated in EDC by the site in error. In this event, the PQC forms will be marked “Intentionally Left Blank” or “ILB”. Justification for ILB must be documented.

13. ADVERSE EVENTS

13.1. Definitions and Classifications

Adverse Event (AE) – An AE is “any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated.”

Note: This definition includes events related to the investigational medical device or the comparator, and to the procedures involved. For users or other persons, this definition is restricted to events related to investigational medical devices.[1]

An AE includes any condition (including a pre-existing condition) that:

1. Was not present prior to the study, but appeared or reappeared following initiation of the study.
2. Was present prior to the study but worsened during the study. This would include any condition resulting from concomitant illnesses, reactions to concomitant medications, or progression of disease states.

Note: Pregnancy must be documented as an adverse event and must be reported to the clinical monitor and to the Sponsor immediately upon learning of the event.

Serious Adverse Event (SAE) – An SAE is any adverse event that led to any of the following:

- Death
- Serious deterioration in the health of the subject that resulted in any of the following:
- Life-threatening illness or injury
- Permanent or persistent impairment of a body structure or a body function
- Hospitalization or prolongation of patient hospitalization
- Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.
- Chronic disease
- Fetal distress, fetal death or a congenital physical or mental impairment of birth defect.

Diagnoses and conditions that are considered Ocular Serious Adverse Events include, but not limited to:

- Microbial Keratitis (MK)
- Iritis (including cells in the anterior chamber)
- 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 – are defined as events that are symptomatic and warrant discontinuation (temporary or permanent) of the contact lens wear

Diagnoses and conditions that are considered Ocular Significant Adverse Events include, but not limited to the following:

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

Non-Significant Adverse Events – are defined as those events that are usually asymptomatic and usually do not warrant discontinuation of contact lens wear but may cause a reduction in wear time. However, the Investigator may choose to prescribe treatment as a precautionary measure.

Diagnoses and conditions that are considered Ocular Non-Significant Adverse Events include, but not limited to the following:

- Non-significant Infiltrative Event (NSIE)
- Contact Lens Papillary Conjunctivitis (CLPC)
- Superficial Punctate Keratitis (SPK)
- 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) – An ADE is an "adverse event related to the use of an investigational medical device."
NOTE 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.

NOTE 2: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.[1]

Unanticipated Adverse Device Effect (UADE) – A UADE is 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.

13.2. Assessing Adverse Events

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/Classifications (see definition in section 13.1).
- Causality or Relatedness – i.e., the relationship between the test article, study treatment or study procedures and the adverse event (not related, unlikely related, possibly related, or related - see definition in section 13.2.1).
- Adverse Event Severity – Adverse event severity is used to assess the degree of intensity of the adverse event (mild, moderate, or severe - see definition in section 13.2.2).
- Outcome – not recovered or not resolved, recovering or resolving, recovered or resolved with sequelae, recovered or resolved, death related to adverse event, or unknown.
- Actions Taken – none, temporarily discontinued, permanently discontinued, or other.

13.2.1. Causality Assessment

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, study treatment or study procedures.
- Unlikely Related – 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.
- Possibly Related – An adverse event that might be due to the use of the test article, or to the study treatment or study procedures. 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.
- Related – 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.

13.2.2. Severity Assessment

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, study treatment or study procedure 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.

13.3. Documentation and Follow-Up of Adverse Events

The recording and documenting of adverse events (ocular and non-ocular) begin when the subjects are exposed to the test article, study treatment or study procedure. Adverse events reported before the use of test article, start of study treatment, or study procedures will be recorded as medical history. However, if the condition deteriorates at any time during the study it will be recorded and reported as an AE. Untoward medical events reported after the subject's exit from the study will be recorded as adverse events at the discretion of the Investigator.

Upon finding an adverse event, the Principal Investigator will document the condition in the subject record and in the eCRFs and complete the Adverse Event eCRF.

Complete descriptions of all adverse events must be available in the subject record. All Adverse Events including local and systemic reactions not meeting the criteria for "serious adverse events" shall be captured on the appropriate case report form or electronic data system. All adverse events occurring while the subject is enrolled in the study must be documented appropriately regardless of relationship.

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).
- Drawings or photographs (where appropriate) that detail the finding (e.g., size, location, and depth, etc.).
- Date the clinical site was notified.
- Date and time of onset.
- Date and time of resolution.
- Adverse event classification, severity, and relationship to test articles, as applicable.
- Treatment regimen instituted (where appropriate), 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, if the AE is related to the visual system.

Upon discovery of an AE that is deemed 'possibly related' or 'related' to the test article or study procedures (whether related to the visual system or not), an AE review form [redacted] must be completed. Additional dated and initialed entries should be made at follow-up evaluations. Separate forms must be completed for each eye if the AE is bilateral.

In addition, if an infiltrate(s) is present, he/she will complete the Corneal Infiltrate Assessment 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, the date of culture collection and laboratory utilized will be recorded.

Changes in the severity of an AE shall 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 Test Article shall also be clearly documented.

Subjects who present with an adverse event shall 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 beyond licensure is required, the patient will be referred to the appropriate health care provider. The Investigator will use his/her clinical judgment as to whether a subject reporting with an adverse event will 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 document the adverse event appropriately and complete the Adverse Event eCRF. Any subjects with ongoing adverse events related to the test article, study treatment or study procedures, 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. Non-ocular adverse events that are not related to the test article, study treatment, or study procedures may be recorded as "ongoing" without further follow-up.

13.4. Reporting Adverse Events

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 any serious /significant adverse events, and 2 days from discovery for any non-significant adverse event. In addition, a written report will be submitted by the Principal Investigator to the IEC/IRB according to their requirements (section 13.4.2). The report will comment whether the adverse event was considered to be related to the test article, study treatment or study procedures.

13.4.1. Reporting Adverse Events to Sponsor

Serious/Significant Adverse Events

The Investigator will inform the sponsor of all serious/significant adverse events occurring during the study period as soon as possible by e-mail 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 eCRF. All subjects experiencing a serious/significant 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/significant adverse event, the Investigator must:

- Notify the Sponsor immediately.
- Obtain and maintain in the subject's records all pertinent medical 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 test article.
- Notify the IEC/IRB as required by the IEC/IRB 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 IEC/IRB 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 IEC/IRB and participating Investigators within 10 working days after the Sponsor first receives notification of the effect.

Non-Serious Adverse Events
All non-serious adverse events, including non-serious adverse device effects, will be reported to the sponsor by the Investigator no later than 2 days from discovery.

13.4.2. Reporting Adverse Events to the Responsible IEC/IRB and Health Authorities

Adverse events that meet the IEC/IRB requirements for reporting must be reported within the IEC/IRB's written guidelines. Each clinical site will refer to and follow any guidelines set forth by their Approving IEC/IRB. Each clinical site will refer to and follow any guidelines set forth by their local governing Health Authorities.

The Sponsor will report applicable Adverse Events to the local health authorities according to the written guidelines, including reporting timelines.

13.5. Event of Special Interest

None

13.6. Reporting of Pregnancy

Subjects reporting pregnancy (by self-report) during the study will be discontinued after the event is recorded as an Adverse Event. Once discontinued, pregnant participants and their fetuses will not be monitored for study related purposes. 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.

14. STATISTICAL METHODS

14.1. General Considerations

Statistical Analysis will be undertaken by the sponsor or under the authority of the sponsor. A general description of the statistical methods to be implemented in this clinical trial is outlined below.

All data summaries and statistical analyses will be performed using the Statistical Analysis System (SAS) software Version 9.4 or higher (SAS Institute, Cary, NC).[5] 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 will be excluded from the statistical analysis.

Summary tables (descriptive statistics and/or frequency tables) will be provided for all baseline variables, efficacy variables and safety variables as appropriate. Continuous variables will be summarized with descriptive statistics (n, mean, standard deviation [SD], median, minimum and maximum). Frequency count and percentage of subjects or eyes within each category will be provided for categorical data.

Summaries will be presented separately for each phase and lens type (Test and Control) and will be performed separately by completion status (Safety Population, Per-Protocol Population and Intent-to-Treat Population, when appropriate).

14.2. Sample Size Justification

Sample size for Phase 1 was not determined on the basis of statistical considerations because it is primarily for the collecting clinical data to calculate the required sample size for Phase 2.

Sample size requirements for Phase 2 were based on assumptions derived from the analysis of selected data collected in Phase 1. It was calculated that the total sample size of 120 subjects to complete (40 per group) the study provides at least 90% power to test each primary and secondary hypothesis. The sample size and power calculations were performed using a paired sample *t*-test approach (exact method) in PASS (NCSS, 2021).[6]

A gate-keeping approach will be used to control the study-wise Type I error rate at the one-sided 0.025 level and adjust for multiplicity due to multiple efficacy endpoints of interest in combination of Bonferroni adjustment. The null hypothesis for the primary efficacy endpoints has to be rejected at one-sided alpha level of 0.025 first, in order to propagate the full alpha to the secondary family of hypothesis tests. The Bonferroni approach will apply then to testing the secondary efficacy endpoints.

The sample size estimates for primary endpoints were calculated using 1-sided Type I error rate of 0.025 for each endpoint. The sample size estimates for the two secondary endpoints were adjusted using a Bonferroni adjustment and calculated using a one-sided Type I error rate of 0.0125 (i.e., one-sided 0.025/2).

While no Toric wearers were enrolled in Phase 1, it is anticipated that the multifocal group would require the largest sample due to simultaneous optics of the multifocal lens and the intraocular scattering that naturally occurs with age, which can both compromise and reduce the quality of vision. Hence it is expected that the sample size required to test endpoints for Toric wearers would be no more than the sample size required for Multifocal wearers. As these endpoints did not have data from Phase 1, all hypotheses for the Toric wearers will be exploratory endpoints.

Table 9 displays the statistical power and associated sample sizes estimates derived for the primary and secondary endpoints for Sphere and Multifocal groups, given the assumed treatment effect sizes. Based on the table below, it is planned that Phase 2 will enroll approximately 135 subjects (45 subjects per group) with the target of 120 subjects (40 subjects per group) to complete the study, assuming approximately a 10% drop-out rate.

Table 9: Assumptions for Power and Sample Size Calculations for The Primary and Secondary Endpoints

Endpoint Type	Endpoint (Subject Group)	Standard Deviation of Paired Differences	Effect Size	Alpha	Power	Sample Size Per Group
Primary	Visual Range (Sphere)	0.10	1.83	0.05	0.94	6
	Visual Range (Multifocal)	0.23	0.52	0.05	0.90	41
Secondary	Motion Detection (Sphere)	1.16	0.99	0.03	0.92	16
	Brightness Perception (Multifocal)	0.20	0.70	0.03	0.91	29

14.3. Analysis Populations

Safety Population:
All subjects who are administered any test article excluding subjects who drop out prior to administering any test article.

Per-Protocol (PP) Population:
All subjects who successfully complete all visits and do not substantially deviate from the protocol as determined by the trial cohort review committee prior to database hard lock. Justification for the exclusion of subjects with protocol deviations from the per-protocol population set will be documented in a memo to file.

Intent-To-Treat (ITT Population):
All randomized subjects regardless of actual treatment and subsequent withdrawal from the study or deviation from the protocol.

14.4. Level of Statistical Significance

Although the Test and Control lenses are senofilcon A based lenses with and without the new UV/HEV filter, respectively, the study lenses assigned to each subject group will be different with different optical designs specifically for vision correction of the sphere, multifocal, and toric (astigmatism) lens wearers. Therefore, the planned hypotheses in Phase 2 will be tested separately for each subject group without Type I error adjustment across the three subject groups, due to different optical designs of the study lenses for different groups. The primary hypothesis for each subject group will be tested using a one-sided Type I error rate of 0.025. The secondary hypotheses will be tested only when the primary hypothesis is met for the same subject group. For secondary hypotheses, the Type I error rate will be adjusted using the Bonferroni approach for the two secondary hypotheses and each secondary hypothesis will be tested using the Bonferroni adjusted one-sided Type I error rate 0.0125 (i.e., one-sided 0.025/2).

14.5. Primary Analyses

Phase 1

There is no planned hypothesis testing in Phase 1. Data collected during Phase 1 of the study will be used to power Phase 2 for testing superiority of test lens relative to control lens with respect to the primary endpoint within each subject group. See section 14.8 for details regarding the interim analysis of the Phase 1 data.

Phase 2

Visual Range

The visual range metric will be analyzed separately for two of the three subject groups (i.e., Spherical wearers and Multifocal wearers) using a linear mixed model. The analysis will be conducted on the ITT population. An appropriate distribution from the exponential family (e.g., normal or lognormal) will be considered for the linear mixed modeling based on the distribution of the endpoint. The model will include lens type, lens sequence, and period as fixed effects. Other baseline and subject characteristics such as age, gender, race, and iris color will be included as fixed covariates when appropriate. An unstructured (UN) covariance matrix will be used to model the residual errors among within-subject repeated measures (R-side). If the model fails to converge, a Compound Symmetric (CS) matrix may be considered. The Kenward and Roger method[7] will be used for the denominator degree of freedom.

Hypothesis Testing

The null and alternative hypotheses for testing superiority of the Test relative to the Control with respect to mean visual range within each subject group (Spherical wearers and Multifocal wearers) are as follows:

$$H_0: \mu_T - \mu_C \leq 0$$
$$H_A: \mu_T - \mu_C > 0$$

Where μ_T and μ_C represent mean visual range (i.e., LRE of simulated haze) for the Test and Control lenses, respectively. The one-sided confidence interval for the least-squares (LS) mean difference (Test – Control) and associated p-value will be calculated to test the primary

hypothesis for visual range. Superiority of the Test lens relative to the Control will be declared if the lower confidence limit is greater than 0.

If a significant sequence effect will be observed, only the period 1 data will be analyzed.

14.6. Secondary Analyses

Phase 2

Motion Detection

The motion detection metric will be analyzed for the Spherical wearer subject group only using a linear mixed model. The analysis will be conducted on the ITT population. The model will include lens type, lens sequence, and period as fixed effects. Other baseline and subject characteristics such as age, gender, race, and iris color will be included as fixed covariates when appropriate. An UN covariance matrix will be used to model the residual errors among observations within the same subject at the two study periods (R-side). If the model fails to converge, a CS matrix may be considered. The Kenward and Roger method[7] will be used for the denominator degree of freedom.

Hypothesis Testing

The null and alternative hypotheses for testing superiority of the Test relative to the Control with respect to mean motion detection within the Spherical wearer subject group are as follows:

$$H_0: \mu_T - \mu_C \geq 0$$
$$H_A: \mu_T - \mu_C < 0$$

where μ_T and μ_C represent mean motion detection (i.e., distance needed to detect that movement) for the Test and Control lenses, respectively. The one-sided adjusted confidence interval for the LS mean difference (Test – Control) and associated p-value will be calculated to test statistical superiority. Superiority of the Test lens relative to the Control will be declared if the adjusted upper confidence limit is less than 0.

Brightness Perception

The brightness perception (LRE) will be analyzed for the Multifocal wearers subject group only using a linear mixed model. The analysis will be conducted on the ITT population. The model will include lens type, lens sequence, period, and natural scene as fixed effects. Other subject characteristics such as age, gender, race, and iris color will be included as fixed covariates when appropriate. An UN covariance matrix will be used to model the residual errors of within-subject repeated measures (R-side). If the model fails to converge, a CS matrix may be considered. The Kenward and Roger method[7] will be used for the denominator degree of freedom.

The null and alternative hypotheses for testing superiority of the Test relative to the Control with respect to mean brightness perception within the Multifocal wearers subject group are as follows:

$$H_0: \mu_T - \mu_C \leq 0$$
$$H_A: \mu_T - \mu_C > 0$$

where μ_T and μ_C represent mean brightness perception (i.e., LRE) for the Test and Control lenses, respectively. The one-sided adjusted confidence interval for the LS mean difference (Test – Control) and associated p-value will be calculated to test statistical superiority. Superiority of the Test lens relative to the Control will be declared if the adjusted lower confidence limit is larger than 0.

If a significant sequence effect was observed, only the period 1 data will be analyzed for the corresponding endpoint.

14.7. Other Exploratory Analysis

For Toric wearers, visual range, and brightness perception will be analyzed and tested in the same manner as described for primary and secondary endpoints.

All other exploratory endpoints will be descriptively summarized

Other exploratory analysis may be conducted at the discretion of the study responsible clinician.

14.8. Interim Analysis

This is a two-phase study. Approximately 20 subjects will be targeted to complete Phase 1. An interim analysis will be performed using data collected from Phase 1 to estimate the required sample size for Phase 2 to achieve at least 80% power for testing the primary hypothesis within each subject group. The total sample size for Phase 2 will be approximately 150 subjects maximum, combining statistical with resources and study timing considerations.

The IA will be conducted at completion of Phase 1. The analyses and statistical power calculation for the determination of the Phase 2 sample size will be conducted by the study unmasked biostatistician. No other team members, nor investigators or subjects will know the Phase 1 results or the Phase 1 lens assignment.

Information about how the sample size calculation for Phase 2 will be conducted is located in Section 14.2. Subject accountability and demographics, and the primary and secondary endpoints data collected from Phase 1 will also be descriptive summarized for the interim analysis.

14.9. Procedure for Handling Missing Data and Drop-Outs

Missing values will not be imputed. The count of missing values will be included in the summary tables and listings.

14.10. Procedure for Reporting Deviations from Statistical Plan

The analysis will be conducted according to that specified in above sections. 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.

15. DATA HANDLING AND RECORD KEEPING/ARCHIVING

15.1. Electronic Case Report Form/Data Collection

The data for this study will be captured first on a paper case report form (CRF) to be stored on the study site, so that the investigator conducting the psychophysical testing may perform necessary calculations. After calculations are performed, the data will be captured on electronic case report forms (eCRFs) using the Clario EDC system. An authorized data originator will enter study data into the eCRFs using the EDC system. Data collected on equipment that is not captured in EDC will be formatted to the specification of the JJVC database manager and sent to JJVC for analysis.

External data sources for this study include: Not Applicable

The clinical data will be recorded on dedicated eCRFs specifically designed to match the study

procedures for each visit. Only specifically delegated staff can enter data on a CRF. Once completed, the eCRFs will be reviewed for accuracy and completeness and signed by the Investigator. The sponsor or sponsor's representatives will be authorized to gain access to the subject recordation for the purposes of monitoring and auditing the study.

Edit checks, electronic queries, and audit trails are built into the system to ensure accurate and complete data collection. Data will be transmitted from the clinical 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 must be retained in the study files as a certified copy of the source data for the study.

The content and structure of the eCRFs are compliant with ISO14155:2020.[1]

15.2. Subject Record

At a minimum, subject record should be available for the following:

- subject identification
- eligibility
- 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
- medical history and concomitant medication
- test article receipt/dispensing/return records
- date of study completion
- reason for early discontinuation of test article or withdrawal from the study, if applicable

The subject record is the eCRF or an external record. The author of an entry in the subject record must be identifiable. The first point of entry is considered to be the source record.

Adverse event notes must be reviewed and initialed by the Investigator.

15.3. Trial Registration on ClinicalTrials.gov

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

16. DATA MANAGEMENT

16.1. Access to Source Data/Document

The Investigator/Institution will permit trial-related monitoring, audits, IEC/IRB review and regulatory inspection(s) by providing direct access to source data/documents. Should the

clinical site be contacted for an audit by an IEC/IRB or regulatory authority, JJVC must be contacted and notified in writing within 24 hours.

16.2. Confidentiality of Information

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

16.3. Data Quality Assurance

Steps will be taken to ensure the accuracy and reliability of data, include the selection of qualified investigators and appropriate clinical sites and review of protocol procedures with the Principal Investigator. The Principal Investigator, in turn, must ensure that all Sub-Investigators and clinical site personnel are familiar with the protocol and all study-specific procedures and have appropriate knowledge of the study article.

Training on case report form completion will be provided to clinical site personnel before the start of the study. The Sponsor will review case report forms for accuracy and completeness remotely during the conduct of the study, 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 JJVC may visit clinical sites to review data produced during the study and to access compliance with applicable regulations pertaining to the conduct of clinical trials. The clinical sites will provide direct access to study-related source data/documents and reports for the purpose of monitoring and auditing by JJVC and for inspection by local and regulatory authorities.

16.4. Data Monitoring Committee (DMC)

Not applicable

17. CLINICAL MONITORING

The study monitors will maintain close contact with the Principal Investigator and the Investigator's designated clinical site personnel. The monitor's responsibilities will include:

- Ensuring that the investigation is being conducted according to the protocol, any subsequent versions, and regulatory requirements are maintained.
- Ensuring the rights and wellbeing of subjects are protected.
- Ensuring adequate resources, including facilities, laboratories, equipment, and qualified clinical site personnel.
- Ensuring that protocol deviations are documented with corrective action plans, as applicable.

- Ensuring that the clinical site has sufficient test article and supplies.
- Clarifying questions regarding the study.
- Resolving study issues or problems that may arise.
- Reviewing of study records and source documentation verification in accordance with the monitoring plan.

18. ETHICAL AND REGULATORY ASPECTS

18.1. 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. Subjects 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. Subjects will only be enrolled if the subject is fully able to understand the risks, benefits, and potential adverse events of the study and provide their consent voluntarily.

18.2. Investigator Responsibility

The Principal Investigator is responsible for ensuring that the clinical study is performed in accordance with the signed agreement, the investigational plan, and applicable regulatory requirements. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles of the Declaration of Helsinki 64th WMA General Assembly 2013[2] and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance applicable regulatory requirements.

18.3. 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.
- Sponsor-approved informed consent form (and any other written materials to be provided to the subjects)
- Investigator's Brochure (or equivalent information).

- Sponsor-approved subject recruitment materials.
- Information on compensation for study-related injuries or payment to subjects for participation in the study.
- 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, 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 revisions
- Revision(s) to informed consent form and any other written materials to be provided to subjects
- If applicable, new or revised subject recruitment materials approved by the Sponsor
- Revisions to compensation for study-related injuries or payment to subjects for participation in the study
- Investigator's Brochure revisions
- 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 test articles, 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 clinical site
- Any other requirements of the IEC/IRB

For protocol revisions that increase subject risk, the revisions 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 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 retained at the clinical site and a copy provided to the CRO or Sponsor as applicable.

18.4. Informed Consent

Each subject or their representative, 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 is in accordance with principles that originated in the Declaration of Helsinki,[2] and ISO 14155:2020[1] guidelines, applicable regulatory requirements, and Sponsor Policy.

Before entry into the study, the Investigator or an authorized member of the clinical site personnel 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.

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.

18.5. 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 clinical site personnel (e.g., name, clinic address and phone number, curriculum vitae) is subject to compliance with the Health Information Portability and Accountability Act (HIPAA) in the United States[8] 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, Sponsor's personnel, and IEC/IRB. 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), IEC/IRB and regulatory organizations in the context of their investigation related activities that, as part of the investigation will have access to the CRFs and subject records.

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.

19. STUDY RECORD RETENTION

In compliance with the ISO 14155:2020,[1] the Investigator/Institution will maintain all CRFs and all subject records that support the data collected from each subject, as well as all study documents as specified in the ISO 14155:2020[1] 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 two (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 two (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 instructed by 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/she should contact JJVC.

20. FINANCIAL CONSIDERATIONS

Remuneration for study services and expenses will be set forth in detail in the Clinical Research Agreement. The Research Agreement will be signed by the Principal Investigator and a JJVC management representative prior to study initiation.

JJVC 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.

JJVC reserves the right to withhold final remuneration until all study related activities have been completed, such as:

- Query resolution.
- Case Report Form signature.
- Completion of any follow-up action items.

21. PUBLICATION

This is a single-site study. The participating institution and Principal Investigator for this study agree that, should this study results be published, the first publication of the results of this study shall be made in conjunction with the presentation of a joint, single-center publication of the study results with the investigators and the institutions contributing data, analyses and comments.

22. REFERENCES

1. ISO 14155:2020: Clinical investigation of medical devices for human subjects — Good clinical practice, Available at: https://www.iso.org/standard/71690.html
2. Declaration of Helsinki – Ethical principles for Medical Research Involving Human Subjects, Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
3. United States (US) Code of Federal Regulations (CFR). Available at: https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR
4. Buch J.Clinical Study Protocol [redacted] *Role of glare and spectral filtering on contrast sensitivity: A pilot study*. November 02, 2022
5. SAS Institute Inc. 2014. SAS/STAT® 13.2 User's Guide. Cary, NC: SAS Institute Inc.
6. PASS. Power Analysis and Sample Size Software. Kaysville, Utah, USA: NCSS, LLC; 2021.
7. Kenward MG RJ. Small Sample Inference for Fixed Effects from Restricted Maximum Likelihood. *Biometrics.* 1997;53(3):983.
8. Health Information Portability and Accountability Act (HIPAA), Available at: https://www.hhs.gov/hipaa/for-professionals/privacy/index.html

APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

Not Applicable.

APPENDIX B: PATIENT INSTRUCTION GUIDE

The Patient Instruction Guide (PIG) will be provided separately.

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

ACUVUE® OASYS MAX 1-Day
ACUVUE® OASYS MAX 1-Day MULTIFOCAL
ACUVUE® OASYS 1-Day with HydraLuxe® Technology
ACUVUE® OASYS 1-Day with HydraLuxe® Technology for ASTIGMATISM
ACUVUE® OASYS MULTIFOCAL with PUPIL OPTIMIZED DESIGN

PACKAGE INSERT & FITTING INSTRUCTION GUIDE

ACUVUE® OASYS MAX 1-Day Contact Lenses

ACUVUE® OASYS MAX 1-Day MULTIFOCAL Contact Lenses

senofilcon A Soft (hydrophilic) Contact Lenses
for Daily Disposable Wear

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.

℞ Only

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DESCRIPTION
	Caution, Consult Instructions for Use
	Date of Manufacture
	Manufacturer
	Use-By Date (expiration date)
	Batch Code
	Sterilized Using Steam Heat
	Indicates a Single Sterile Barrier System
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CE 2797	CE Mark and Identification number of Notified Body
UV BLOCKING	UV Blocking
	Fee Paid for Waste Management
	CAUTION: US 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)
	Authorized Representative in the European Community
	Contains Hazardous Substances
	Do Not Re-Use (Single Use)
	Do Not Use if Package is Damaged
	Medical Device Symbol
	Package Opening Icon (Blister)
	Package Opening Icon (Carton)
L	"Low" near ADD
M	"Medium" near ADD
H	"High" near ADD
MAX ADD	Near ADD

LOW	"Low" near ADD
MID	"Medium" near ADD
HGH	"High" near ADD

Visit www.acuvue.com/guides for additional information about symbols.

DESCRIPTION

ACUVUE® OASYS MAX 1-Day Contact Lenses are soft (hydrophilic) contact lenses available as spherical and multifocal lenses.

These lenses are made of a silicone hydrogel material (senofilcon A) containing an internal wetting agent and are tinted using Reactive Blue Dye #247 to make lenses more visible for handling.

A benzotriazole ultraviolet (UV) absorbing monomer is used to block UV radiation (280 nm – 380 nm) in combination with a novel fused tricyclic chromophore that also blocks UV radiation and partially filters high energy visible radiation (HEV)* in the range of 380 nm to 450 nm. The light transmittance characteristics for these lenses are less than 1% in the UVB range of 280 nm to 315 nm and 10% in the UVA range of 315 nm to 380 nm. The thinnest lenses transmit ≤ 45% of the radiation in the range from 380 nm to 450 nm. Please see HEV filtering NOTE in the ACTIONS section below.

Lens Properties:

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.42
- Visible Light Transmittance: ≥78%
- HEV Light Transmittance*: ≤ 45%
- Surface Character: Hydrophilic
- Water Content: 38%
- Oxygen Permeability (Dk):

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

Lens Parameter Ranges:

- Diameter (DIA): 12.0 mm to 15.0 mm
- Center Thickness: varies with power

- Base Curve (BC): 7.85 mm to 10.00 mm
- Spherical Power (D): -20.00D to +20.00D
- Multifocal ADD Power: +0.25D to +4.00D

Each lens is supplied in a foil-sealed plastic package containing borate buffered saline solution with methyl ether cellulose.

AVAILABLE LENS PARAMETERS

The ACUVUE® OASYS MAX 1-Day Contact Lenses (senofilcon A) are hemispherical shells of the following dimensions:

Diameter (DIA): 14.3 mm

Center Thickness: 0.085 mm to 0.221 mm (varies with power)

Base Curve (BC): 8.5 mm, 9.0 mm

Powers (D): -12.00D to +8.00D

The ACUVUE® OASYS MAX 1-Day MULTIFOCAL Contact Lenses (senofilcon A) are hemispherical shells of the following dimensions:

Diameter (DIA): 14.3 mm

Center Thickness: 0.070 mm to 0.191 mm (varies with power)

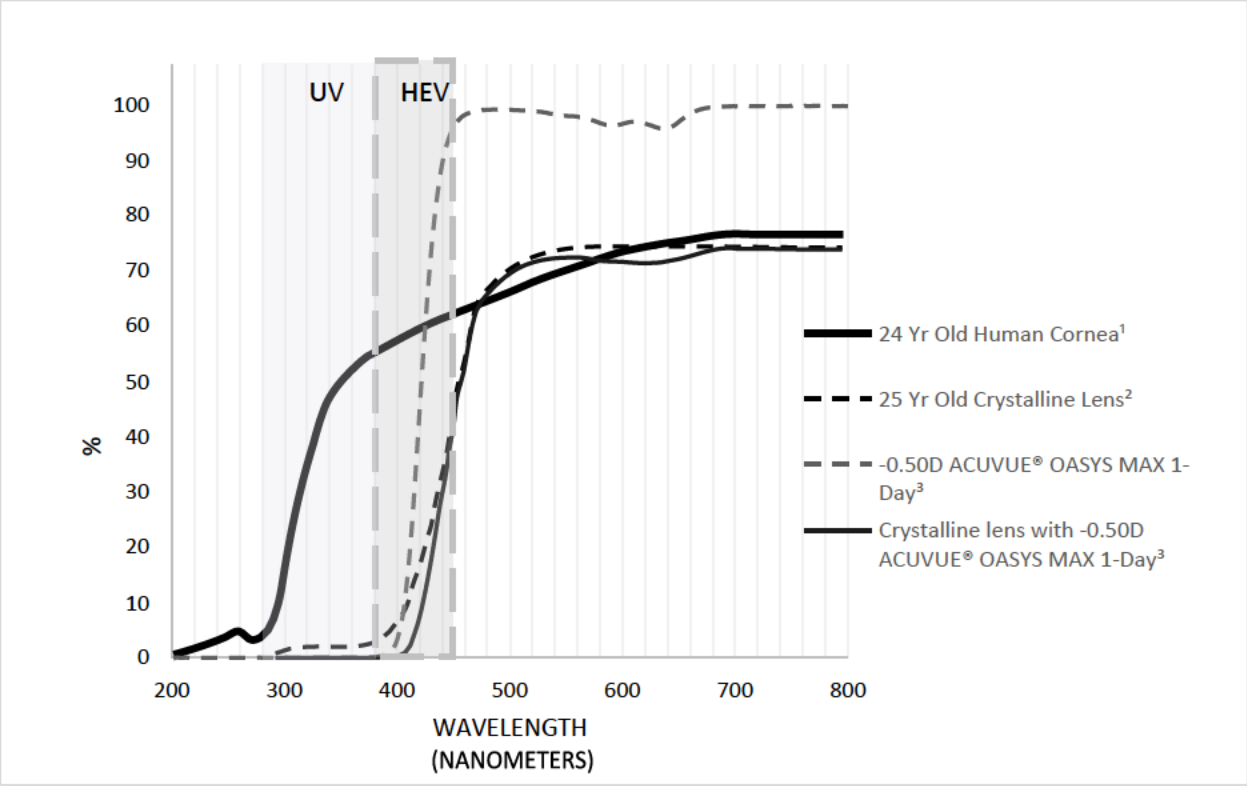
Base Curve (BC): 8.4 mm

Powers (D): -9.00D to +6.00D

ADD Powers (D): +1.25D (LOW), +1.75D (MID), +2.50D (HGH)

TRANSMITTANCE CURVE

ACUVUE® OASYS MAX 1-Day Contact Lenses (senofilcon A) vs. 24 yr. old human cornea and 25 yr. old human crystalline lens.



[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
[3]The data was obtained from measurements taken through the central 6 mm portion for the thinnest single vision lens (-0.50D lens, 0.085mm center thickness).

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.

These lenses contain UV and HEV* light absorbing monomers to help protect against transmission of harmful UV radiation to the cornea and into the eye and reduce transmittance of HEV* light. The light transmittance characteristics for these lenses are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 315 nm to 380 nm for the entire power range. The thinnest lenses transmit ≤ 45% of the radiation across the high energy visible* light wavelength in the range from 380 nm to 450 nm. The visible light transmittance in the range from 380 nm to 780 nm is greater than or equal to 78% depending on the lens thickness.

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. You should continue to use UV absorbing eyewear as directed.

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.

***NOTE: Filtering of HEV light by contact lenses has not been demonstrated to confer any health benefit to the user, including but not limited to retinal protection, protection from cataract progression, reduced eye strain, improved contrast, improved acuity, reduced glare, improved low light vision, or improved circadian rhythm/sleep cycle. The Eye Care Professional should be consulted for more information.**

INDICATIONS (USES)

ACUVUE® OASYS MAX 1-Day Contact Lenses (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are nearsighted (myopic) or farsighted (hyperopic) and may have 1.00D or less of astigmatism that does not interfere with visual acuity.

ACUVUE® OASYS MAX 1-Day MULTIFOCAL Contact Lenses (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are presbyopic and may be nearsighted (myopic) or farsighted (hyperopic) and may have 0.75D or less of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for daily disposable wear. Therefore, no cleaning or disinfection is required. Lenses should be discarded upon removal.

CONTRAINDICATIONS (REASONS NOT TO 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
- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e. rewetting drops) that contain chemicals or preservatives (such as mercury or Thimerosal, etc.) to which some people may develop an allergic response
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses
- Any active corneal infection (bacterial, fungal, protozoal, or viral)
- If eyes become red or irritated

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.

- Patients should be instructed not to wear their 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.[4]
- 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 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.

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

Specific Instructions for Use and Warnings:

- **Water Activity**

  Instruction 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.

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 or multifocal correction 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 unless otherwise indicated. 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 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, rinse, and dry hands before handling lenses. It is best to put on lenses before putting on makeup.

- DO NOT touch contact lenses with 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 ACUVUE® OASYS MAX 1-Day Contact 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. Slide the lens up the side of the bowl until it is free of the container.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in *"Care for a Sticking (Non-Moving) Lens"*. 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. 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.
- Ask the Eye Care Professional about wearing lenses during sporting activities.
- The patient should be advised to never rinse the lenses in water from the tap. Tap water contains many impurities that can contaminate or damage the lenses and may lead to eye infection or injury.

Lens Care Precautions:

- The patient should be informed that no cleaning or disinfection is needed when lenses are worn for daily disposable wear. Patients should always dispose of lenses when removed and have spare lenses or spectacles available.

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.
- Do not change lens type (e.g. brand name, etc.) or parameters (e.g. diameter, base curve, lens power, etc.) without consulting the Eye Care Professional.
- Instruct patients to always confirm the lens parameters printed on the multi-pack and on the individual lens package match their prescription. If there is a mismatch the patient should not use the product.

- 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 eye protection equipment or may require that the patient not wear contact lenses.

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, or 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 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 necessary.

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.

For the Spherical or Multifocal ACUVUE® OASYS MAX 1-Day Contact Lenses, the initial lens should be selected from the currently available base curves.

The trial lens 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 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

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 from 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 MAX 1-Day Multifocal Contact Lenses. Wear may not be optimal for such activities 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. 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 ≥ ±4.00D. Determine the spherical equivalent distance prescription for a multifocal patient. Determine the eye dominance using one of the methods below:

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 (sighting) eye.

Method 2 (preferred): Determine which eye will accept the added power with the least reduction in vision while both eyes are open. Place a hand-held trial lens equal to +1.00D 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 +1.00D lens over the right or left eye, which is the non-dominant eye.

C. Select the Initial Trial Lens

1. For each eye, select the trial lens distance power that is closest to the patient's distance spherical equivalent. Remember to compensate for vertex distance if the refraction is ≥±4.00D.
2. Select the near power of the lens based on the patients 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 "MID" near ADD on the dominant eye and a "HGH" near ADD lens on the non-dominant eye
3. Allow the lenses to settle for a minimum 10 minutes.
4. Assess distance and near vision binocularly and monocularly.
5. Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near.
6. Make adjustments in power as necessary based on the distance over-refraction. The use of hand held trial lenses is recommended. Check the impact on distance and near vision.
7. If vision is still unacceptable, make adjustments in power as necessary (see **"Multifocal Troubleshooting"** below). 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 PATIENT MANAGEMENT section).

D. Multifocal Troubleshooting

Unacceptable Near Vision:
If it has been determined that no change is required based on the over-refraction then add +0.25 D to the spherical power of the non-dominant eye.

Unacceptable Distance Vision:

If it has been determined that no change is required based on the over-refraction then make the changes as listed below:

- If the patient is wearing two "LOW" ADD lenses, change the dominant eye to an ACUVUE® OASYS MAX 1-Day Contact Lens sphere lens with a power equal to the spherical equivalent distance prescription.
- If the patient is wearing two "MID" ADD lenses, change the ADD power in the dominant eye to the "LOW" ADD power.

- If the patient is wearing a "MID" ADD lens in the dominant eye and a "HGH" ADD lens in the non-dominant eye, change the non-dominant eye to a "MID" ADD lens and add +0.25D to the distance power.

Once the changes have been made for the troubleshooting repeat steps 3-6 in section C above ("**Select the Initial Trial Lens")** to assess if the vision is acceptable.

E. 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.

All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download from 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 with significant amounts of uncorrected 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. 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 (sighting) eye.

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 Vision Correction Requirement

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens whereas a bilateral myope would require corrective lenses on both eyes.

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 correction.

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 described in this guide.

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 this mode of 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 news print 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 adaptation 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.

5. Other Suggestions

The success of the monovision technique may be further improved by having your 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 to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet their state driver's license requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Monovision fitting success can be improved with 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 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 from www.acuvue.com.

PATIENT MANAGEMENT

- **Follow the accepted standard of care in fitting and following up with your patient.**
- **Schedule the appropriate follow-up examination.**
- **Preferably, at the follow-up visits, lenses should have been worn for at least six hours.**
- **Provide the patient with a copy of the PATIENT INSTRUCTION GUIDE for these lenses, which can be found at www.acuvue.com. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE (DAILY DISPOSABLE).**

WEARING SCHEDULE

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

Patients tend to over wear 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 condition, 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

REPLACEMENT SCHEDULE

These lenses are indicated for daily disposable wear and should be discarded upon removal.

LENS CARE DIRECTIONS

When lenses are dispensed, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions for daily disposable lens 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 spare lenses or spectacles available.

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Eye Care Professionals may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

Care for a Sticking (Non-Moving) Lens

During removal, if the lens sticks to the eye, 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 consult 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.

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

Revision Date: 02/2022
Revision Number: AO-01-22-03

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 patient instructions that pertain to the patient's prescribed lenses.

ACUVUE OASYS MULTIFOCAL

ACUVUE® OASYS MULTIFOCAL Contact Lenses with PUPIL OPTIMIZED DESIGN

PACKAGE INSERT & FITTING INSTRUCTION GUIDE

ACUVUE® OASYS MULTIFOCAL (senofilcon A) Contact Lens
Soft (hydrophilic) Contact Lenses Visibility Tinted with UV Blocker for Daily & Extended Wear

℞ Only CAUTION: US Federal law restricts this device to sale by or on the order of a licensed practitioner

SYMBOLS KEY

The following symbols may appear on the label or packaging:

Multifocal Lenses For: Presbyopia, Phakic or Aphakic

SYMBOL	DEFINITION
	Caution, Consult Instructions for Use
	Date of Manufacture
	Manufacturer
	Use By Date (expiration date)
	Batch Code
	Sterilized Using Steam Heat
	Indicates a Single Sterile Barrier System
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
	Medical Device Symbol
MAX ADD	Near ADD
LOW	"Low" near ADD
MID	"Medium" near ADD
HGH	"High" near ADD
	CE-mark and **Identification** Number of Notified Body
UV BLOCKING	UV Blocking
	Fee Paid for Waste Management
	CAUTION: US Federal law restricts this device to sale by or on the order of a licensed practitioner

SYMBOL	DEFINITION
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)
EC REP	Authorized Representative in the European Community
	Do not use if package is damaged
	Package Opening Icon
L	"Low" near ADD
M	"Medium" near ADD
H	"High" near ADD

Visit www.acuvue.com/guides for additional information about symbols.

DESCRIPTION

ACUVUE® OASYS MULTIFOCAL (senofilcon A) Soft Contact Lenses are soft (hydrophilic) contact lenses available as multifocal lenses. The lenses are made of a silicone hydrogel material (senofilcon A) containing an internal wetting agent, visibility tint, and UV absorbing monomers.

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

Lens Properties:

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.42

- Light Transmittance: ≥89% minimum
- Surface Character: Hydrophilic
- Water Content: 38%
- Oxygen Permeability (Dk):

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

Lens Parameters Ranges:

The ACUVUE® OASYS MULTIFOCAL (senofilcon A) Soft Contact Lenses are hemispherical or hemitoric shells of the following dimensions:

• Diameter (DIA) :	12.0 mm to 15.0 mm
• Center Thickness:	varies with power
• Base Curve (BC):	7.85 mm to 10.00 mm
• Spherical Power (D):	-20.00D to +20.00D
• Multifocal ADD Power Range:	+0.25D to +4.00D

Each lens is supplied in a foil-sealed plastic package containing borate buffered saline solution with methyl ether cellulose.

AVAILABLE LENS PARAMETERS

The ACUVUE® OASYS MULTIFOCAL (senofilcon A) Soft Contact Lenses 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)

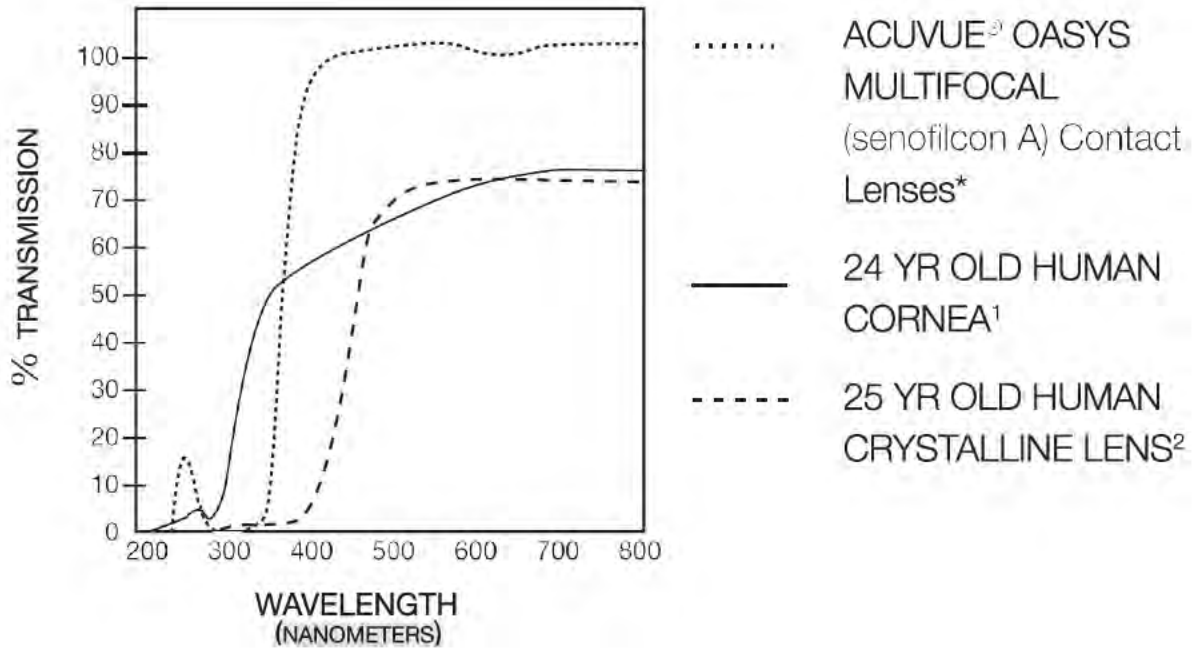
Base Curve: 8.4 mm

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 MULTIFOCAL (senofilcon A) Soft Contact Lenses vs. 24 yr. old human cornea vs. 25 yr. old human crystalline lens.



*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.

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.

These lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye. The light 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 315 nm to 380 nm for the entire power range.

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.

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)

ACUVUE® OASYS MULTIFOCAL (senofilcon A) Contact Lenses are indicated for the correction of vision in presbyopic people with non-diseased eyes who are either presbyopic or are

presbyopic and are also nearsighted (myopic) or farsighted (hyperopic) and may have 0.75D or less of astigmatism.

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 single use disposable wear, no cleaning or disinfection is required. Lenses should be discarded upon removal. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.

These lenses are intended for daily wear for up to 14 days (2 weeks) 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, 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 their lenses while sleeping. Clinical studies have shown that when lenses are worn overnight, the risk of ulcerative keratitis is greater than among those who do not wear them overnight.[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**

Instruction 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**

Instruction 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 in 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 the 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**

Instruction 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 or multifocal correction 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.
- Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.
- Eye Care Professionals should instruct the patient to always have a functional pair of spectacles with a current prescription available to use if the patient becomes unable to wear contact lenses, or in circumstances where contact lens wear is not advised.

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

Handling Precautions:

- DO NOT use if the sterile blister package is opened or damaged.
- Always wash, rinse, and dry hands before handling lenses. It is best to put on lenses before putting on makeup.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient

Instruction Guide for these lenses and those prescribed by the Eye Care Professional.

- Never use tweezers or other tools to remove lenses from the lens container. Slide the lens up the side of the bowl until it is free of the container.
- 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. 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.
- The patient should be advised to never rinse the lenses in water from the tap. Tap water contains many impurities that can contaminate or damage the lenses and may lead to eye infection or injury.

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.
- Do not change solution without consulting with the Eye Care Professional.
- Never use solutions recommended for conventional hard contact lenses only.
- Always use fresh, unexpired lens care solutions and lenses, and always follow directions in the package inserts for the use of contact lens solutions.
- 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 (e.g., exposing the lens to air for 30 minutes or more) will reduce the ability of the lens surface to return to a wettable state. If the lens surface does become dried out, discard the lens and use a new one.

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.

- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- Do not change lens type (e.g. brand name, etc.) or parameters (e.g. diameter, base curve, lens power, etc.) without consulting the Eye Care Professional.
- Instruct patients to always confirm the lens parameters printed on the multi-pack and on the individual lens package match their prescription. If there is a mismatch the patient should not use the product.
- 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 eye protection equipment or may require that the patient not wear contact lenses.

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 and the lens appears undamaged, the patient should clean and rinse the lens with a recommended soft contact lens care solution and reinsert the lens. If after reinserting the lens, the problem continues, 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 the patient regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

- **ACUVUE® OASYS MULTIFOCAL (senofilcon A) Soft Contact Lens:** 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 the lower lid, and then return to a properly centered position when released.

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 MULTIFOCAL (senofilcon A) Soft Contact Lens. Wear may not be optimal for such activities 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. 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. Determine the spherical equivalent distance prescription for a multifocal patient. Determine the eye dominance using one of the methods below:

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 (sighting) eye.

Method 2 (preferred): Determine which eye will not accept added power. Place a +1.00 hand-held trial lens in front of one eye and then the other with the distance refractive error correction is in place for both eyes while the patient is viewing the distance visual acuity chart. The eye that the patient notices the greatest reduction in vision while having the plus over it is determined to be the dominant eye.

C. Select the Initial Trial Lens

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

Remember to compensate for vertex distance if the refraction is greater than ±4.00D.

2. Select the near power of the lens based on the patients 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 "MID" near ADD on the dominant eye and a "HGH" near ADD lens on the non-dominant eye
3. Allow the lenses to settle for a minimum 10 minutes.
4. Assess distance and near vision binocularly and monocularly.
5. Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near.
6. Make adjustments in power as necessary based on the distance over-refraction. The use of hand held trial lenses is recommended. Check the impact on distance and near vision.
7. If vision is still unacceptable, make adjustments in power as necessary (see **"Multifocal Troubleshooting"** below). 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 PATIENT MANAGEMENT section).

D. Multifocal Troubleshooting

Unacceptable Near Vision:

If it has been determined that no change is required based on the over-refraction then add +0.25 D to the spherical power of the non-dominant eye.

Unacceptable Distance Vision:

If it has been determined that no change is required based on the over-refraction then make the changes as listed below:

- If the patient is wearing two "LOW" ADD lenses, change the dominant eye to a ACUVUE® OASYS (senofilcon A) Soft Contact Lens sphere lens with a power equal to the spherical equivalent distance prescription.
- If the patient is wearing two "MID" ADD lenses, change the ADD power in the dominant eye to the "LOW" ADD power.
- If the patient is wearing a "MID" ADD lens in the dominant eye and a "HGH" ADD lens in the non-dominant eye, change the non-dominant eye to a "MID" ADD lens and add +0.25D to the distance power.

Once the changes have been made for the troubleshooting repeat steps 3-6 in section C above (**"Select the Initial Trial Lens"**) to assess if the vision is acceptable.

E. 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 [redacted] 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.

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

- 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 (DAILY DISPOSABLE, EXTENDED WEAR, 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.

WEARING SCHEDULE

The wearing schedule 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 over wear 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

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 are intended 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 Single Use Disposable Wear:

These lenses are indicated for single use disposable wear and should be discarded upon removal.

LENS CARE DIRECTIONS

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 Single Use Disposable Wear:

The Eye Care Professional should review with the patient 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.

Care for a Sticking (Non-Moving) Lens

During removal, if the lens sticks to the eye, 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 MULTIFOCAL : 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

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

Revision date: 08/2020
Revision number: AOMF-08-20-00

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® 1-Day oasys WITH HydraLuxe™ BRAND CONTACT LENSES

ACUVUE OASYS® Brand Contact Lenses 1-Day with HydraLuxe™ Technology

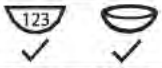
ACUVUE OASYS® Brand Contact Lenses 1-Day with HydraLuxe™ Technology for ASTIGMATISM

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

℞ Only CAUTION: U.S. Federal law restricts this device to sale by or on the order of 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)
LOT	Batch Code
STERILE	Sterile Using Steam or Dry Heat
	Single-Use
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CYL	**Cylinder**
AXIS	Axis
CE 0086	Quality System Certification Symbol
UV Blocking	**UV-Blocking**
	Fee Paid for Waste Management
Rx Only	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)

SYMBOLS KEY

ACUVUE OASYS® Brand Contact Lenses 1-Day and ACUVUE OASYS® Brand Contact Lenses 1-Day for ASTIGMATISM are soft (hydrophilic) contact lenses made with HydraLuxe™ Technology. They are available as spherical or toric lenses respectively.

These lenses are made of a silicone hydrogel material containing an internal wetting agent, visibility tint, and UV absorbing monomer and 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 for these lenses 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:

The physical/optical properties of the lens are:

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

VALUE	METHOD
122×10^{-11} (cm^2/sec) ($ml\ O_2/ml \times mm\ Hg$) at 35°C	Fatt (boundary corrected, non edge corrected)
103×10^{-11} (cm^2/sec) ($ml\ O_2/ml \times mm\ Hg$) at 35°C	Fatt (boundary corrected, 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: -20.00D to +20.00D
- Cylinder Power Range: -0.25D to -10.00D
- Axis Range: 2.5° to 180°

SYMBOLS KEY

ACUVUE OASYS® Brand 1-Day with HydraLuxe™ Technology are hemispherical shells of the following dimensions:

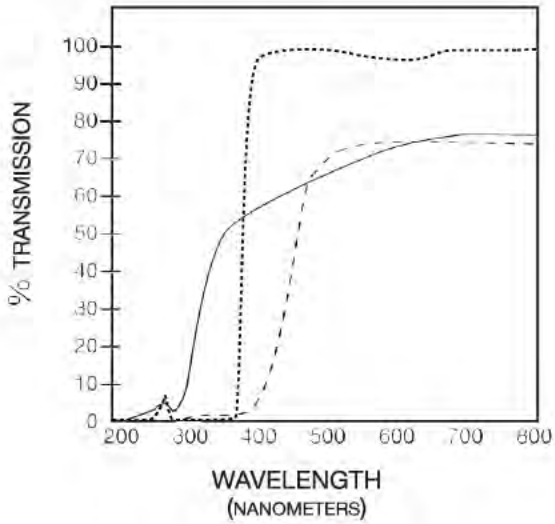
Diameter:	14.3 mm
Center Thickness:	0.085 mm to 0.221 mm (varies with power)
Base Curve:	8.5 mm, 9.0 mm
Powers:	-0.50D to -6.00D (in 0.25D increments) -6.50D to -12.00D (in 0.50D increments) –0.50D to –6.00D (in 0.25D increments) –6.50D to –8.00D (in 0.50D increments)

ACUVUE OASYS® Brand 1-Day with HydraLuxe™ Technology for ASTIGMATISM are hemitoric shells of the following dimensions:

Diameter:	14.3 mm
Center Thickness:	0.075 mm to 0.172 mm (varies with power)
Base Curve:	8.5 mm
Powers:	–0.00D to -6.00D (in 0.25D increments) Cylinders: -0.75D, -1.25D, -1.75D, -2.25D* Axis: 10° to 180° in 10° increments *-2.25D cylinder is availble in 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180° axes only. –0.25D to +4.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments) Cylinders: -0.75D, -1.25D, -1.75D Axis: 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°

SYMBOLS KEY

ACUVUE OASYS® 1-Day with HydraLuxe™ Technology (senofilcon A) Visibility Tinted with UV Blocker vs. 24 yr. old human cornea and 25 yr. old human crystalline lens.



..... ACUVUE OASYS® 1-Day with HydraLuxe™ Technology (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 (-9.00D lens, 0.075 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 onto the retina.

The transmittance characteristics for these lenses 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)

ACUVUE OASYS® Brand Contact Lenses 1-Day with HydraLuxe™ Technology are indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

ACUVUE OASYS® Brand Contact Lenses 1-Day with HydraLuxe™ Technology for ASTIGMATISM are indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 0.50D to 3.00D of astigmatism.

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

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE these contact 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., rewetting drops) that contain chemicals or preservatives (such as mercury, 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.

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 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.

[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.

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 mono-vision 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 the 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 before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, 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 the prescribed

wearing schedule 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.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for a Sticking (Non-Moving) Lens." 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.
- Always discard lenses worn as prescribed by the Eye Care Professional.

Lens Care Precautions:

- The patient should be informed that no cleaning or disinfection is needed when lenses are worn for daily disposable wear. Patients should always dispose of lenses when removed and have spare lenses or spectacles available.

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 eye protection equipment or may require that the patient not wear contact lenses.

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, or 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 risks and benefits of lens wear

Patients who do not satisfy these criteria should not be prescribed 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 vision 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 suitable to wear these lenses, the Eye Care Professional should proceed to the lens fitting instructions as 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. For near vision tasks (or when distance 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® 1-Day: 8.5 mm/14.3 mm
- ACUVUE OASYS® 1-Day for ASTIGMATISM: 8.5 mm/14.3 mm

The trial lens 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 the 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 the fit is acceptable, dispense the lenses and instruct 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 toric lenses, 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® 1-Day for ASTIGMATISM 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 the 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 approximately 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 slit lamp biomicroscope with a 1 to 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.

3. **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. 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 spectacle cylinder axis, it is not advisable to perform a full spherocylindrical over-refraction because of the difficulty in computing the resultant power. A spherical over-refraction without cylinder refraction may be performed.

If the required cylinder correction falls between two available cylinder powers, it is recommended to prescribe the lower cylinder power lens. See below for instructions on how to determine the final lens power.

1. 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.

2. For the Cylinder

Adjust the axis by the drift angle using the LARS method. Choose a cylinder that is ≤ 0.50D from the refractive cylinder.

3. Case Examples

Example 1

Manifest (spectacle) refraction:
O.D. -2.50D / -1.25D x 180° 20/20
O.S. -2.00D / -1.00D x 180° 20/20

Choose a diagnostic lens for each eye with axis 180°. 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. -2.50D / -1.25D x 180°
O.S. -2.00D / -0.75D x 180°

Example 2
Manifest (spectacle) refraction:
O.D. -3.00D / -1.00D x 90° 20/20
O.S. -4.75D / -2.00D x 90° 20/20

Choose diagnostic lenses of -3.00D / -0.75D x 90° for the right eye and -4.50D / -1.75D x 90° for the left eye, the nearest lenses available to the spherical power, cylinder power, and axis needed. For the left eye, since the manifest refraction called for -4.75D, compensating for vertex distance the sphere is reduced by 0.25D to -4.50D. The cylinder power will be -1.75D. 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.

Right Eye

The orientation mark on the right lens rotates left from the 6 o'clock position by 10° and remains stable in this position. Compensation for this rotation should be done as follows:

Compensate the 10° axis drift by adding it to the manifest refraction axis.

Here is the Rx Prescribed:
O.D. -3.00D / -0.75D x 100°

Left Eye

The orientation mark on the left lens rotates right from the 6 o'clock position by 10° and remains stable in this position.

Compensate for the 10° axis drift by subtracting it from the manifest refraction axis.

Here is the Rx Prescribed:
O.S. -4.50D / -1.75D 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.

MONOVISION FITTING GUIDELINES

A. Patient Selection

1. 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:

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

2. 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

1. Ocular Preference Determination Methods

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

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 (sighting) eye.

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.

2. Other Eye Selection Methods

Other methods include the "Refractive Error Method" and the "Visual Demands Method."

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.

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 Vision Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens, whereas a bilateral myope would require corrective lenses on

both eyes.

Examples:

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 correction.

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 described 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 this mode of 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 to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state driver's 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 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

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with methyl ether cellulose. To remove the lens from the container, peel back the foil seal, place a finger on the lens, and slide the lens up the side of the bowl of the lens package until it is free of the container.

- Evaluate the physical fit and visual acuity of the lens on each eye.
- Teach the patient how to apply and remove his or her lenses.
- Explain daily disposable lens wear and schedule a follow-up examination.
- **Provide the patient with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.**

  REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULES.

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, daily disposable modality, and proper lens 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 [illegible]

NOTE: Preferably, at the follow-up visits, lenses should be worn for at least six hours.

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. These 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 schedule should be determined by the Eye Care Professional. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

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 condition, 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

REPLACEMENT SCHEDULE

These lenses are indicated for daily disposable wear and should be discarded upon removal.

LENS CARE DIRECTIONS

When lenses are prescribed for daily disposable wear, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions for daily disposable lens wear at the time they are dispensed.

The Eye Care Professional should review with patients that no cleaning or disinfection is needed with daily disposable lenses. Patients should always dispose of lenses when they are removed and have spare lenses or spectacles available.

Basic Instructions

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Eye Care Professionals may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

Care for a Sticking (Non-Moving) Lens

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 consult 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 UV-blocking 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:

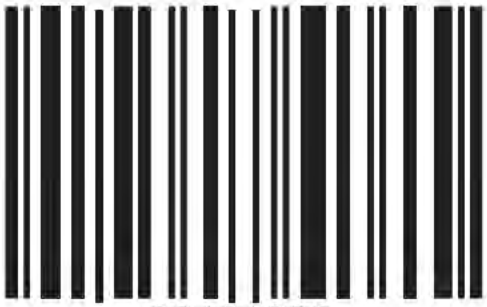
- ACUVUE OASYS® 1-Day: base curve, power, diameter, lot number, and expiration date
- ACUVUE OASYS® 1-Day for ASTIGMATISM: base curve, power, diameter, cylinder, axis, lot number, and expiration date

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing these lenses or experienced with these 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

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



20401080

In Canada: Johnson & Johnson Vision Care, division of Johnson & Johnson, Inc.
In USA: Johnson & Johnson Vision Care, Inc.
Printed in USA.
Revision date: 09/16
Revision number: AO-03-16-13

APPENDIX D: [redacted]

[redacted]
Determination of Near Addition
Lens Fitting Characteristics
Subject Reported Ocular Symptoms/Problems
Determination of Distance Spherocylindrical Refractive Error
Biomicroscopy Scale
Distance and Near Snellen Visual Acuity Evaluation
Toric Fit Evaluation

[redacted] **DETERMINATION OF NEAR ADDITION**

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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[redacted] SUBJECT REPORTED OCULAR SYMPTOMS/PROBLEMS

[redacted]

[redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIVE ERROR

[redacted]

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[redacted]

[redacted] **BIOMICROSCOPY SCALE**

Title:	**Biomicroscopy Scale**	
Document Type:	[redacted]	
Document Number:	[redacted]	**Revision Number: 10**

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[redacted] DISTANCE AND NEAR SNELLEN VISUAL ACUITY EVALUATION

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[redacted]

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[redacted] **TORIC FIT EVALUATION**

[redacted]

[redacted]

[redacted]

[redacted]

APPENDIX E: EYE DOMINANCY

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APPENDIX F: IRIS COLOR SCALE

APPENDIX G: GUIDELINES FOR COVID-19 RISK MITIGATION

1.0 PURPOSE

The purpose of this document is to provide guidelines for the re-opening or initiation of clinical study sites participating in Johnson & Johnson Vision Care, Inc. (JJVCI) clinical studies during the COVID-19 pandemic.

2.0 SCOPE

This document provides guidelines for Johnson & Johnson Vision Care (JJVCI) to address the potential risks from COVID-19 to study subjects, investigators, study site staff, and monitors at study sites. The guidance provided in this document is in effect from the date of approval through the date of retirement of this Work Instruction. At a minimum, this Work Instruction will be reviewed and updated on a quarterly basis, as appropriate.

NOTE: Re-opening of sites outside of the US will be evaluated on a country by country basis subject to local health authority guidance.

3.0 DEFINITIONS

American Academy of Optometry (AAO): The American Academy of Optometry is an organization of optometrists based in Orlando, Florida. Its goal is to maintain and enhance excellence in optometric practice, by both promoting research and the dissemination of knowledge. The AAO holds an annual meeting, publishes a monthly scientific journal, gives credentials to optometrists through the fellowship process and publishes position statements.

American Optometric Association (AOA): The American Optometric Association, founded in 1898, is the leading authority on quality care and an advocate for our nation's health, representing more than 44,000 Doctors of Optometry (O.D.), optometric professionals, and optometry students. Doctor of Optometry take a leading role in patient care with respect to eye and vision care, as well as general health and well-being. As primary health care providers, Doctor of Optometry have extensive, ongoing training to examine, diagnose, treat and manage ocular disorders, diseases and injuries and systemic diseases that manifest in the eye. The American Optometric Association is a federation of state, student, and armed forces optometric associations. Through these affiliations, the AOA serves members consisting of optometrists, students of optometry, paraoptometric assistants and technicians. The AOA and its affiliates work to provide the public with quality vision and eye care.

Centers for Disease Control and Prevention (CDC): The Centers for Disease Control and Prevention is a national public health institute in the United States. It is a United States federal agency, under the Department of Health and Human Services, and is headquartered in Atlanta, Georgia.

COVID-19: Current outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19).

Clinical Study: Voluntary research studies conducted in people and designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments. May also be called clinical trials, studies, research, trials, or protocols.

Clinical Study Site: Location where a clinical study is conducted, such as a doctor’s office, university, or laboratory. Clinical studies are conducted by Investigators who are individual(s) responsible for the conduct of the clinical study at a study site. If a study is conducted by a team of individuals, the Investigator is the responsible leader of the team and may be called the Principal Investigator.

Clinical Operations Manager (COM): The Johnson & Johnson Vision Care (JJVCI) individual responsible for the overall management of a clinical trial.

Monitor: An individual designated to oversee the progress of a clinical study and ensure that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and applicable regulatory requirements.

Medical Safety Officer (MSO): Physician who has primary accountability in their product portfolio for product health and safety, and who serves as an independent medical voice for patient safety.

Safety Management Team (SMT): A cross-functional, collaborative team responsible for review, assessment and evaluation of medical safety data arising from any source throughout the product life cycle.

4.0 GUIDANCE FOR STUDY DOCUMENTS

In alignment with recent health authority guidance, JJVCI is providing recommendations for study-related management in the event of disruption to the conduct of the clinical study. This guidance does not supersede any local or government requirements or the clinical judgement of the investigator to protect the health, safety and well-being of participants and site staff. If, at any time, a participant's safety is considered to be at risk, study intervention will be discontinued, and study follow-up will be conducted as outlined in the protocol.

During the COVID-19 pandemic, the additional risks listed below need to be considered for study participants and study personnel:

4.1 Additional Risks Related to the COVID-19 Pandemic:

- The possible transmission of the Coronavirus infection and consequent complications, beyond the risk of adverse events due to the investigational device and/or procedures.
- The risk may be higher in an optometric clinical study because of the close contact the subject will have with health care professionals during the procedures and assessments (since the investigator must make the measurements close to the subject's face) and, in addition the need for multiple follow-up visits/exams which may expose the subject to other patients and/or healthcare professionals who might be transmitting the virus, even if they do not have symptoms.
- Potential disruptions to the study may be necessary due to current or future pandemic-related emergency restrictions, which may lead to delays in scheduled follow-up visits.
- Subjects experiencing an adverse event related to contact lens wear may receive delayed treatment due to COVID-19 restrictions. In this event, all assessments that can be conducted virtually will be completed by the investigator to determine the best course of treatment for the subject, including an unscheduled visit, up to discontinuation from the study, as appropriate.

If a study subject is found to have contracted COVID-19 during participation in a study, he/she will be discontinued from the study and followed until COVID-19 Adverse Event (AE) resolution.

To help minimize the above potential risks, JJVCI recommend reviewing/complying with local, state, and governmental guidance for COVID-19 risks.

JJVCI will provide the following study specific documents with language pertaining to COVID-19 risks:

4.1.1 Informed Consent:

Will include information concerning the study-associated risks related to the COVID-19 pandemic in bold font and/or boxed on the first page of the Informed Consent document:

STUDY ASSOCIATED RISKS RELATED TO COVID-19 (CORONAVIRUS) PANDEMIC

It is important to note that this study will be conducted, at least in part, during the COVID-19 pandemic. As such, additional risks associated with the infection with COVID-19 exist for you. This is particularly important for this study due, in part, to the closeness of the doctor during the study examinations.

The potential effects of the disease are not fully known, at this time, and may include long-term serious health consequences. In severe cases, this may result in hospitalization and/or death. Based on current knowledge from the Centers for Disease Control and Prevention (CDC), those at high-risk for severe illness from COVID-19 include older adults and people with underlying medical conditions.

During this study, all appropriate measures will be taken to minimize risks including the use of personal protective equipment such as masks and gloves, as well as proper sanitization. This is in conformance to guidance from the CDC, local health departments, and the state and county in which the study doctor's office is located. However, these measures may not completely eliminate the risks associated with contracting COVID-19.

If you are found to have contracted COVID-19 or feel ill with flu-like symptoms during participation in the study, you will not be permitted to continue in-office study follow-up visits, but you will receive instructions and your condition will be monitored by the doctor and/or study staff.

4.1.2 COVID-19 Risk Control Checklist (Attachment-B):

Will include COVID-19 risk control methods that are required by a site to conduct JJVCI clinical studies. The risk controls are consistent with CDC, AOA, AAO Guidance. The Principal Investigator will review/sign the study specific checklist prior to the Site Initiation Meeting.

4.1.3 Protocol Compliance Investigator(s) Signature Page:

Will include a statement indicating that the Principal Investigator (PI) agrees to conduct the study in compliance with all local, state, and governmental guidance's for COVID-19 risk mitigation.

I have read the suggested guidance provided by JJVCI pertaining to the COVID-19 risk mitigation, (COVID-19 Work Instruction in the Appendix of this protocol). I agree to conduct this study in compliance with local, state, governmental guidance for COVID-19 risks.

4.1.4 Study Site Initiation Training Slides:

Will include suggestions to help mitigate potential transmission of COVID-19. Suggestions may include maintaining social distancing in the clinical site by staggered scheduling of study patients, wearing proper PPEs, frequent disinfection, and installing shields on the slit lamp and other applicable equipment.

5.0 GUIDANCE FOR REMOTE SUBJECT VISITS

Potential disruptions to the study may be necessary due to current or future pandemic-related emergency restrictions. Possible disruption of the study as a result of COVID-19 control measures may lead to delays in scheduled follow-up visits.

Subjects may be delayed in being seen for study follow up visit(s), for example due to COVID-19 control measures or due to the subject's concerns or fears about COVID-19 risk. When appropriate, the remote assessment will be conducted to the extent possible. Discussions with the subject during remote assessments may include:

Procedure	Details
Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire regarding the test article when applicable and feasible.
Change of Medical History (Adverse Events) and Concomitant Medications / Therapies Review	Record any adverse events or medical history changes from the previous study visit with the subject/parents. Review the subject's concomitant medications/therapies and record any changes from the previous study visit.
Wearing Time and Compliance	Record the average wearing time (including number of hours per day during weekdays and weekends, and number of days per week). Confirm compliance with the prescribed wear schedule. • Record and discuss the lens wear compliance based on the subject's self-report. For example, the subjects will be asked the time of the day the subject typically puts on the study lenses in the morning and takes off in the evening, the number of days per week lenses were worn, and the number of consecutive days the subject didn't wear the study lenses, etc.

The discussion with the subject will be documented in EDC under Tele-Visit and a minor protocol deviation will be noted. If during the telephone consultation, a subject states he/she wishes to discontinue participating in the study, instruct the subject to stop wearing the study lenses and schedule the subject to return to the clinic for a Final Evaluation at the at earliest possible time. Subjects should return all unused lenses to the clinic at the last visit.

Changes in study visit schedules, missed visits, or participant discontinuations may lead to missing data, including data related to protocol-specified procedures. Case report forms should capture specific information regarding the basis of missing data, including the relationship to the COVID-19 pandemic.

6.0 STUDY CONDUCT DURING PANDEMIC

It is recognized that the Coronavirus Disease 2019 (COVID-19) pandemic may have an impact on the conduct of this clinical study due to, for example, self-isolation/quarantine by participants and study-site personnel; travel restrictions/limited access to public places, including Optometry Clinics; and changes in clinic procedures required to address the COVID-19 challenge.

Every effort should be made to adhere to protocol-specified assessments for study participants, including follow-up. However, if scheduled visits cannot be conducted in person at the study site it is suggested that assessments be performed to the extent possible remotely/virtually or delayed until such time that on-site visits can be resumed in order to continue participant monitoring in accordance with the protocol where possible. At each contact, participants will be interviewed to collect safety data. Key efficacy endpoint assessments should be performed if required and as feasible.

Modifications to protocol-required assessments may be permitted via COVID-19 Appendix after consultation with the participant, investigator, and the sponsor. Missed assessments/visits will be captured in the clinical trial management system for protocol deviations. Interruptions of test article wear or discontinuations of study interventions and withdrawal from the study should be documented with the prefix "COVID-19-related" in the case report form (CRF).

The sponsor will continue to monitor the conduct and progress of the clinical study, and any changes will be communicated to the sites and to the health authorities according to local guidance.

If a participant has tested positive for COVID-19, the investigator should contact the sponsor's responsible medical monitor to discuss initial plans for study intervention and follow-up. The medical monitor will notify the Safety Management Team of any subject(s) that have reported "COVID-19", "Asymptomatic COVID-19", or "Suspected COVID-19" adverse events within 24 hours of the notification.

Modifications made to the study conduct as a result of the COVID-19 pandemic will be summarized in the clinical study report.

COVID-19 screening procedures that may be mandated by local healthcare systems do not need to be reported as an amendment to the protocol even if done during clinical study visits.

6.1 Monitoring Visits

When on-site monitoring by the sponsor is not feasible, the sponsor's site monitor will contact the study site to schedule remote visits. In such cases, on-site monitoring visits will resume when feasible, with increased frequency to address the source data verification backlog.

Even with staffing limitations during this COVID-19 pandemic, all routine operations related to clinical trials should be well-documented and archived as part of standard process. When conditions permit, all parties involved in this clinical trial should communicate relevant information in a timely manner so that all relevant parties remain sufficiently informed.

6.1.1 Study Site Initiation:

During the period that this Work Instruction is in effect, Site Initiation Meetings and training of study site staff will be conducted remotely. The JJVCI study team will conduct training via Skype, Zoom, Microsoft Teams or similar software as well as utilize online training materials, as applicable. Study site training will be documented utilizing Site Initiation Report [redacted] per Study Site Initiation [redacted]

On-site visits may be considered when, for example, hands-on training or evaluation of site facilities is required. While on site, the Clinical Research Associate (CRA) will follow all local, state, and governmental policies for COVID-19 Risk Mitigation, including social distancing, wearing of PPE, etc. as applicable for the location of the study site.

6.1.2 Interim Monitoring Visits (if applicable):

During the period that this Work Instruction is in effect, Interim Monitoring On-site visits will be kept to a minimum and include only those tasks that the CRA cannot perform remotely (e.g., source document verification, test article reconciliation, etc.).

To ensure data integrity during the conduct of all JJVC studies, clinical study teams will follow the study specific Clinical Monitoring Plan [redacted]

While on site, the CRA will follow all local, state, and governmental policies for COVID-19 Risk Mitigation, including social distancing, wearing of PPE, etc. as applicable for the location of the study site.

6.1.3 Study Site Closure:

During the period that this Work Instruction is in effect, the duration of the Study Site Closure Visit will be limited to tasks that the CRA cannot perform remotely (e.g., source document verification, test article final reconciliation and return, etc.).

Attachment A: Study Site Correspondence

XXXX XX, 2020

Re: COVID-19 Mitigation Plan, <<CR-xxxx/protocol title>>

Dear <<Principal Investigator>> and Study Team,

Coronavirus (COVID-19) has impacted several communities and business activities over the past several months. While we work toward the successful conduct of clinical studies, our commitment continues to be the safety of patients, healthcare professionals, and to our communities.

Therefore, we would like to share the following revisions/additions related to the above referenced Johnson & Johnson Vision Care company sponsored clinical trial(s) you are currently working on or considering participation within.

Protocol:

- Guidelines for COVID-19 Risk Mitigation provided in the Appendix section.

Protocol Signature Page:

- Will include a statement indicating the Principal Investigator agrees to conduct the study in compliance with all local, state, and governmental guidelines for COVID-19 risk mitigation.

Informed Consent:

- Will include information concerning the study-associated risks related to the COVID-19 pandemic in bold font and/or boxed on the first page of the Informed consent document.

COVID-19 Risk Control Checklist for Clinical Studies:

- Will include COVID-19 risk control measures that are required to ensure the safety and health of subjects, site staff and monitors during the pandemic.

We want to encourage the need for open lines of communication about potential challenges you may foresee as the result of the current COVID-19 situation. Therefore, we encourage you to regularly connect with your respective Johnson & Johnson clinical study team (Clinical Research Associate (CRA), Lead CRA or Study Managers).

Thank you for your continued engagement, collaboration, and dedication to your study subjects during this challenging time.

Please file this letter in your site file study correspondence.

Attachment B: COVID-19 Risk Control Checklist

Study Number
Site Number
Principal Investigator (PI) Name

The following COVID-19 risk control methods are required to conduct Johnson & Johnson Vison Care clinical studies. Please review the following requirements and Initial each requirement.

PI Initials	General Site Safety Planning Measures
	Signage within site describing Risk Control methods
	Social Distancing practices throughout site (waiting rooms, lobby, exam rooms, etc.)
	Non-contact thermometer available to assess temperatures of staff and patients
	Training on patient flow and physical distancing in waiting room
	Establish longer time frame between patient appointments to reduce persons in the site
	Staff should receive job-specific training on PPE and demonstrate competency with selection and proper use of PPE and wear at all times during interactions with subjects (e.g., putting on and removing without self-contamination)

PI Initials	Site Staff Daily Safety Measures
	As part of routine practice, site staff should regularly monitor themselves for fever and symptoms of COVID-19, including temperature checks
	Any staff member (including non-study clinic staff and Investigators) showing signs of being sick or testing positive for COVID-19 must not be permitted to work on activity that may expose study related staff and subject and the Sponsor shall be informed **NOTE: Inform JJVC in 24 hours of any COVID-19 cases and all potential exposure during the clinical study.**
	Ensure that all staff wear a mask Gloves should be required when working directly with patients and changed between each patient
	Have staff thoroughly wash hands for at least 20 seconds or use an alcohol-based hand sanitizer when they arrive, before and after each patient, before eating and after using the bathroom.
	Cleaning and disinfection procedures for exam rooms and instruments or equipment between patients with gloves.
	Cleaning and disinfection procedures for commonly touched surfaces (doors, chairs, computers, phones, etc.) with gloves.

PI Initials	Before a Patient or Study Visit:
	Patients should be asked prior to entering the site about fever and respiratory illness and whether they or a family member have had contact with another person with confirmed COVID-19 in the past 14 days. Patients exhibiting signs of being sick should be rescheduled when their symptoms resolve.
	Instruct patients that companions should remain outside of the facility and not accompany the patient into the facility unless they are a parent/guardian of the patient or if they are a true caregiver and need to assist the patient
	Request the patient to call or text the office upon arrival so entrance to and movement through facility can be coordinated by site staff

PI Initials	Patients Entering the site:
	Temperature checks utilizing a non-contact thermometer for all patients and companions entering the site.
	All patients and companions must wear cloth or disposable mask at all times in the site
	Maintain social distancing. Waiting rooms or lobbies should be as empty as possible. Advise seated patients to remain at least 6 feet from one another.
	Communal objects in (e.g. toys, reading materials, etc.) should be removed or cleaned regularly.

I certify that I have read and agree to implement all the listed COVID-19 Risk Control Measures required for the conduct of Johnson & Johnson Vision Care studies.

Principal Investigator Signature and Date

RESOURCE LINKS

US Resource Links

- OSHA Training
  https://www.osha.gov/SLTC/covid-19/controlprevention.html

  Personal Protective Equipment (PPE) Training
  CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html

- I&R Training
  ACUVUE® LensAssist: https://www.acuvue.com/lensassist

- Clinic Preparedness Guides
  CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinic-preparedness.html
  AOA: https://aoa.uberflip.com/i/1240437-aoa-guidance-for-re-opening-practices-covid·19/1?m4=
  American Optometric Association: https://www.aoa.org/optometry-practice-reactivation-preparedness- guide

- ln-Office Disinfection of Multi-Patient Use Diagnostic Contact Lenses
  https://www.gpli.info/wp-content/uploads/2020/03/2020-01-15-in-office-disinfecting-of-diagnostic-lenses.pdf

OUS Resource Links

- Updates on local regulations in Hong Kong
  https://www.coronavirus.gov hk/eng/index.html

- Resumption of optical services in England: Letter from Matt Neligan and Poonam Sharma
  https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/04/C0601-reopening-of-optical-services-letter-17-june-2020.pdf

- NHS Optical Letter
  https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/04/C0127-optical-letter-1-april-2020.pdf

- The College of Optometrists primary eye care COVID-19 guidance: Red phase
  https://www.college-optometrists.org/the-college/media-hub/news-listing/coronavirus-covid-19-guidance-for-optometrists.html

- The College of Optometrists COVID-19: College updates
  https://www.college-optometrists.org/the-college/media-hub/news-listing/coronavirus-2019-advice-for-optometrists.html#CollegeGuidelines

- Infection Control Guidelines. (n.d.). Retrieved from Canadian Association Of Optometrists: https://opto.ca/sites/default/files/resources/documents/infection_control_guidelines_2016.pdf

- Infection prevention and control for COVID-19: Interim guidance for outpatient and ambulatory care settings. (2020, May 23 May). Retrieved from Government of Canada: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/interim-guidance-outpatient-ambulatory-care-settings html

- Information for Members On Coronavirus (COVID-19). (n.d.). Retrieved from Canadian Association Of Optometrists: https://opto.ca/sites/default/files/resources/documents/information_for_members_on_coronavirus.pdf

- Coronavirus (COVID-19) resources for health professionals, including aged care providers, pathology providers and health care managers. (2020, September 24). Retrieved from Australian Government Department of Health: https://www.health.gov.au/resources/collections/coronavirus-covid-19-resources-for-health-professionals-including-aged-care-providers-pathology-providers-and-health-care-managers

- Environmental Cleaning and Disinfection Principles for COVID-19. (n.d.). Retrieved from Australian Government Department of Health: https://www health.gov.au/sites/default/files/documents/2020/03/environmental-cleaning-and-disinfection-principles-for-covid-19.pdf

- Infection control guidelines and advice. (n.d.). Retrieved from Optometry Australia : https://www.optometry.org.au/practice-professional-support/coronavirus-covid-19-what-optometrists-need- to-know/covid-19-clinical-advice/infection-control-guidelines-and-advice/

PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: CR-6480 The Effects of Contact Lenses With UV/HEV-Filter on Visual Function

Version and Date: 5.0 12 June 2023

I have read and understand the protocol specified above and agree on its content.

I agree to conduct this study according to ISO 14155:2020,[1] the Declaration of Helsinki,[2] United States (US) Code of Federal Regulations (CFR),[3] and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. The Principal Investigator is responsible for ensuring that all clinical site personnel, including Sub-Investigators adhere to all GCP guidelines regarding clinical trials during and after study completion.

I will assure that no deviation from or changes to the protocol will take place without prior agreement from the Sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants.

All clinical site personnel involved in the conduct of this study have completed Human Subjects Protection Training.

I agree to ensure that all clinical site personnel involved in the conduct of this study are informed about their obligations in meeting the above commitments.

I shall not disclose the information contained in this protocol or any results obtained from this study without written authorization.

I have read the suggested guidance provided by JJVCI pertaining to the COVID-19 risk mitigation, (COVID-19 Work Instruction in the Appendix of this protocol). I agree to conduct this study in compliance with local, state, governmental guidance for COVID-19 risks.

Principal Investigator: _____ _____
Signature Date

_____
Name and Professional Position (Printed)

Institution/Site: _____
Institution/Site Name

_____ _____
Institution/Site Address