Clinical Study Protocol
Johnson & Johnson Vision Care, Inc.

Protocol Title: Pilot Dispensing Study of Two Marketed Daily Disposable Multifocal Contact Lenses

Protocol CR-6612

Version: 3.0

Date: 17 July 2025

Test Articles:

Control: Approved Product ACUVUE® OASYS MAX 1-Day Multifocal Contact Lens

Test Product: Approved Product INFUSE® One Day Multifocal

Commercially Available Product Lots: ACUVUE® OASYS MAX 1-Day Multifocal Contact Lens and INFUSE® One Day Multifocal

Keywords: ACUVUE® OASYS MAX 1-Day Multifocal Contact Lens, INFUSE® One Day Multifocal, presbyopia platform, senofilcon A, kalifilcon A, dispensing, daily wear, daily disposable, logMAR acuity

Statement of Compliance to protocol, GCP and applicable regulatory guidelines:

This clinical trial will be conducted in compliance with ISO 14155[1], Declaration of Helsinki[2], United States (US) Code of Federal Regulations (CFR)[3], and International Council for Harmonization Good Clinical Practice E6(R2) (ICH GCP)[4].

Confidentiality Statement:

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PROTOCOL TITLE, NUMBER, VERSION AND DATE

Protocol Title: Pilot Dispensing Study of Two Marketed Daily Disposable Multifocal Contact Lenses
Protocol Number: CR-6612
Version: 3.0
Date: 17 July 2025

SPONSOR NAME AND ADDRESS

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

[redacted]

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 the assigned clinical research associate.

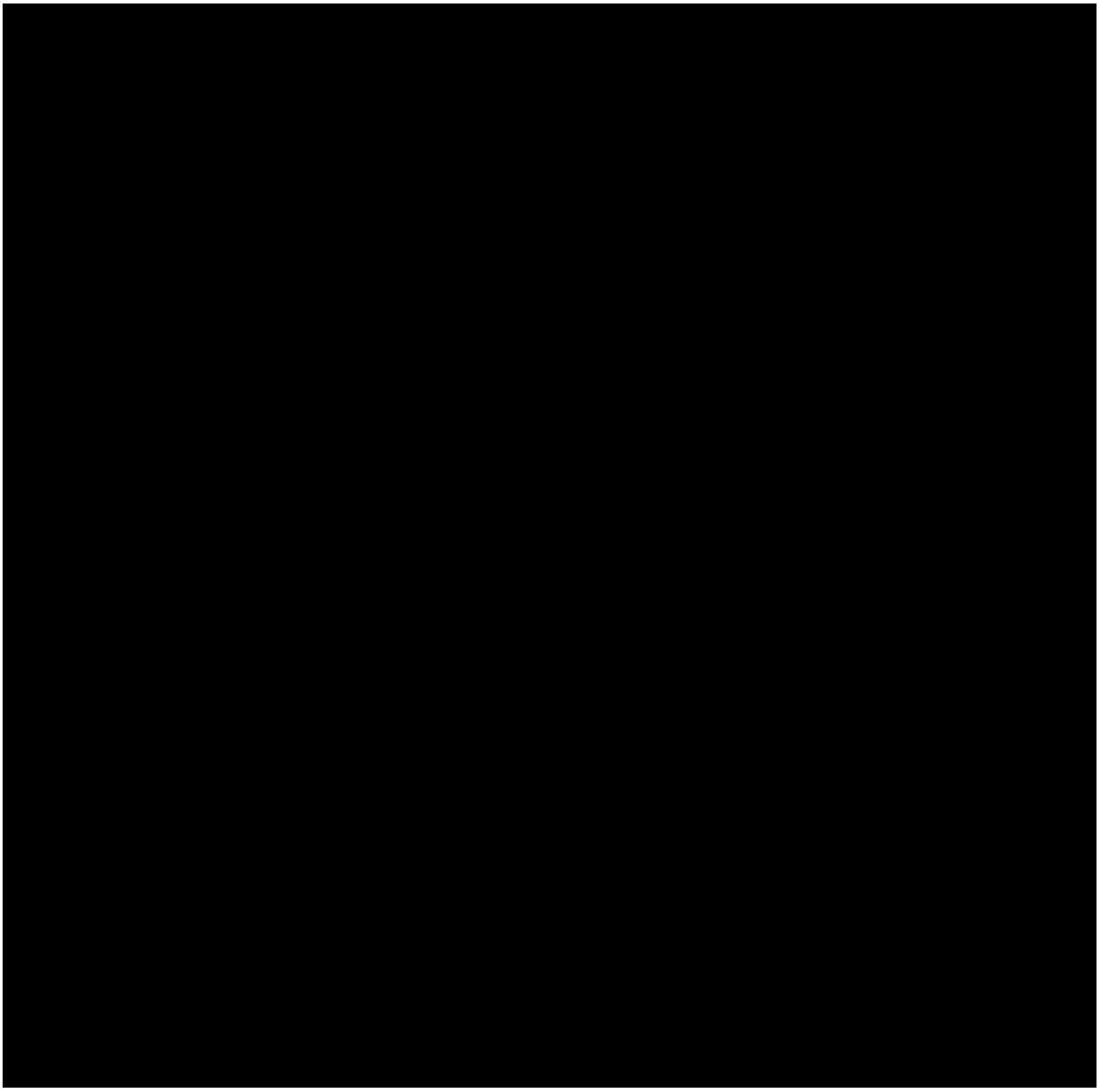
The Medical Monitoring Plan is maintained as a separate document and included in the Trial Master File.

AUTHORIZED SIGNATURES

The signatures below constitute 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, ISO 14155[1], Declaration of Helsinki[2], and the United States (US) Code of Federal Regulations (CFR)[3], and International Council for Harmonization Good Clinical Practice E6(R2) (ICH GCP)[4].

Author & Study Responsible Clinician	*See Electronic Signature Report* [redacted]	DATE
Clinical Operations Manager	*See Electronic Signature Report* [redacted]	DATE
Biostatistician	*See Electronic Signature Report* [redacted]	DATE
Data Management	*See Electronic Signature Report* [redacted]	DATE
Medical Safety Officer	*See Electronic Signature Report* [redacted]	DATE
Medical Monitor	*See Electronic Signature Report* [redacted]	DATE
Platform Lead/Project Lead/Director	*See Electronic Signature Report* [redacted]	DATE

[redacted]



SYNOPSIS

Protocol Title	Pilot Dispensing Study of Two Marketed Daily Disposable Multifocal Contact Lenses
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Clinical trial phase: Post Market [redacted]
Trial Registration	This study will be registered on ClinicalTrials.gov.
Test Article(s)	Test Lens: INFUSE® One Day Multifocal Control Lens: ACUVUE® OASYS MAX 1-Day Multifocal Contact Lens
Wear and Replacement Schedules	Wear Schedule: Daily wear Replacement Schedule: Daily disposable
Objectives	Primary Objectives: The primary objective of this study is to evaluate the Test lens compared to the Control lens after approximately 1-week of optimized lens wear with respect to high luminance high contrast binocular distance (4m), intermediate (64cm), and near (40cm) visual acuity. Secondary Objectives: Not Applicable Exploratory Objectives: Not Applicable
Study Endpoints	Co-Primary Efficacy Endpoints: 1. Binocular High Luminance, High Contrast (HLHC) logMAR Visual Acuity at Distance (4 m) 2. Binocular HLHC logMAR Visual Acuity at Intermediate (64 cm) 3. Binocular HLHC logMAR Visual Acuity at Near (40 cm) Secondary Efficacy Endpoints: Not Applicable Exploratory Efficacy Endpoints: Not Applicable Safety Endpoint: Not Applicable.
Study Design	This is a 6-visit, single-masked, multi-site, 2×3 crossover, randomized-controlled, dispensing clinical trial. Up to 70 subjects will be enrolled with the aim of approximately 60 subjects to complete. At the initial visit (Visit 1), if subjects meet all eligibility criteria, they will be randomized to one of two lens wear sequences (Test/Control/Control or Control/Test/Test) in a bilateral fashion. If the subject is dispensed study lenses at the initial visit, five additional visits will be conducted. The first follow-up visit (Visit 2) will be 3±1 days after the initial visit. At Visit 2, subjects will undergo lens optimization, if necessary. Subjects will wear the study lenses for 7±1 days and then return for their second follow-up at Visit 3. At Visit 3, subjects will be dispensed their second study lens, per the randomization schedule. Subjects will return for their follow-up visit in the second lens type (Visit 4) 3±1 days after Visit 3. It will be determined if the subject needs optimization and the lenses will be dispensed with subjects returning for their second follow-up visit 7±1 days after Visit 4. At Visit 5, subjects

	will be dispensed the same lens type as they wore into Visit 5 and wear the lens for an additional 7±1 days. The final visit will be the follow-up (Visit 6). 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	A total of approximately 70 subjects are targeted to complete. Approximately 60 subjects will be targeted for enrollment. There will be an attempt to recruit approximately equal number of hyperopes and myopes (i.e. 35 per group) into the study.
Study Duration	The study will last approximately 3 to 4 months. The total planned duration of individual participation will be up to 32 days.
Anticipated Study Population	Healthy male and female volunteers who are habitual soft contact lens wearers that have hyperopia or myopia and presbyopia will be screened as per criteria outlined below. The baseline procedures will occur after informed consent has been obtained. Subjects will have medical history recorded and baseline measurements completed to ensure eligibility. See the inclusion/exclusion criteria below for details on eligibility.
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 at least 40 years of age and not greater than 70 years of age at the time of consent. 4. Own a wearable pair of spectacles if required for their distance vision. 5. Be an adapted soft contact lens wearer in both eyes (i.e. worn lenses a minimum of 2 days per week for at least 6 hours per wear day, for 30 days or more duration). 6. Either already be wearing a presbyopic contact lens correction (e.g., reading spectacles over contact lenses, monovision or multifocal contact lenses, etc.) or if not respond positively to at least one symptom on the "Presbyopic Symptoms Questionnaire" (Appendix E). Inclusion Criteria at Baseline Evaluation: 7. The subject's distance spherical equivalent refraction must be in the range of +1.00 to +4.00 or -1.00 D to -4.00 D in each eye. 8. The subject's refractive cylinder must be ≤0.75 D in each eye. 9. The subject's ADD power must be in the range of +0.75 D to +2.50 D. 10. The subject must have distance best corrected visual acuity of $20/20^{-3}$ 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. Have any active or ongoing ocular or systemic allergies that may interfere with contact lens wear. 3. Be diagnosed with diabetes. 4. Have any active or ongoing systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear. This may include, but not be limited to, hyperthyroidism, Sjögren's syndrome, xerophthalmia, acne rosacea, Stevens-Johnson syndrome, and immunosuppressive diseases or any infectious diseases (e.g. hepatitis, tuberculosis). 5. Have any previous, or planned, ocular or intraocular surgery (e.g. radial keratotomy, PRK, LASIK, lid procedures, dacryocystorhinostomy, peripheral iridotomy/iridectomy, cataract surgery, retinal surgery, etc.). 6. Have a history of amblyopia, strabismus or binocular vision abnormality. 7. Use of any of the following medications within 1 week prior to enrollment: oral retinoid, oral tetracyclines, anticholinergics, oral phenothiazines, oral/inhaled corticosteroids. See section 9.1 for further examples. 8. Be currently using any ocular medications with the exception of rewetting drops. 9. Have a history of herpetic keratitis. 10. Have a history of irregular cornea. 11. Have a history of pathological dry eye. 12. Have participated in any contact lens or lens care product clinical trial within 7 days prior to study enrollment. 13. Be an employee (e.g., Investigator, Coordinator, Technician) or immediate family member of an employee (including partner, child, parent, grandparent, grandchild, sibling of the employee or their spouse) of the clinical site. 14. Have any known hypersensitivity or allergic reaction to non-preserved rewetting drop solutions or sodium fluorescein. Exclusion Criteria at Baseline Evaluation: The subject must not: 15. 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 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). 16. Have any current ocular infection or inflammation.
Disallowed Medications/Interventions	No ocular medications are allowed with the exception of rewetting drops. See section 9.1 for details regarding disallowed systemic medications.

[redacted]	[redacted]
Microbiology or Other Laboratory Testing	None
Study Termination	The occurrence of an Unanticipated Adverse Device Effect (UADE), Unanticipated Serious Adverse Device Effect (USADE), or Serious Adverse Event (SAE) for which a causal relationship to a test article cannot be ruled out, may result in stopping further dispensing of the 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	Non-Preserved Rewetting drops, lens cases, glass vials, saline, ETDRS light cabinet, 4 M logMAR charts, and Near logMAR charts.
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.
External Organization(s)	The external organization(s) involved in this study will be listed in the Trial Master File.

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
BSCVA	Best Spectacle Corrected Visual Acuity
CFR	Code of Federal Regulations
CI	Confidence Interval
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
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HEV	High Energy Visible
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HLHC	High Luminance High Contrast
IB	Investigator's Brochure
ICH	The International Council for Harmonization
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	Intention-to-Treat
JJVC	Johnson & Johnson Vision Care, Inc.
LASIK	Laser-Assisted in Situ Keratomileusis
LogMAR	Logarithm of Minimal Angle of Resolution
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
SAS	Statistical Analysis System
SD	Standard Deviation
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
UV	Ultraviolet
VA	Visual Acuity

1. INTRODUCTION AND BACKGROUND

Recently Johnson & Johnson Vision Care launched ACUVUE® OASYS MAX 1-Day Multifocal Contact Lens. In a similar time frame Bausch + Lomb introduced INFUSE® One Day Multifocal in the United States. The primary purpose of this study is to benchmark the performance of these two marketed products with regard to their measured logMAR visual acuity.

1.1. Name and Descriptions of Investigational Products

The study lenses (Test & Control) are marketed products. The Test lens is INFUSE® One Day Multifocal and the control is ACUVUE® OASYS MAX 1-Day Multifocal Contact Lens. Further details about the test articles can be found in section 6 of this protocol.

[redacted]

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

Primary Objectives:
The primary objective of this study is to evaluate the Test lens compared to the Control lens after approximately 1-week of optimized lens wear with respect to high luminance high contrast binocular distance (4m), intermediate (64cm), and near (40cm) visual acuity.

Secondary Objectives:
Not Applicable

Exploratory Objectives:
Not Applicable

2.2. Endpoints

Efficacy Endpoints

Co-Primary Efficacy Endpoints

High Luminance, High Contrast (HLHC) Binocular logMAR Visual Acuity
Visual acuity after approximately 1-week in the optimized lens pair under HLHC illuminance conditions will be evaluated at three different distances. At distance (4 meters), VA will be assessed using ETDRS Charts, while near (40 cm) and intermediate (64 cm) assessments will be made using reduced Guillon-Poling charts. The logMAR visual acuity scores at each distance are continuous co-primary endpoints.

Additional visual acuity will be measured using high and low contrast charts in bright illuminance conditions. Visual acuity will also be measured using high contrast charts in dim illuminance conditions (created using goggles). [redacted]

Secondary Efficacy Endpoints
Not Applicable.

Exploratory Efficacy Endpoints
Not Applicable.

Safety Endpoints

Not applicable.

2.3. Hypotheses

Co-Primary Hypotheses

1. After approximately 1-week of wear in the optimized lenses, the distance, binocular, high luminance, high contrast visual performance of the Test lens will be statistically non-inferior compared to the Control lens. A non-inferiority margin of 0.05 logMAR will be used.

2. After approximately 1-week of wear in the optimized lenses, the intermediate, binocular, high luminance, high contrast visual performance of the Test lens will be statistically non-inferior compared to the Control lens. A non-inferiority margin of 0.05 logMAR will be used.

3. After approximately 1-week of wear in the optimized lenses, the near, binocular, high luminance, high contrast visual performance of the Test lens will be statistically non-inferior compared to the Control lens. A non-inferiority margin of 0.05 logMAR will be used.

2.4. Criteria of Study Success

The Test lens must demonstrate statistically significant non-inferiority relative to that of the Control lens, with respect to binocular HLHC logMAR VA at distance, intermediate, and near to satisfy the primary objective of the study.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

Healthy male and female subjects who are habitual soft contact lens wearers will be recruited. Subjects will be at least 40 years of age and not older than 70 years of age. Subjects enrolled in this study will be myopic or hyperopic and have presbyopia.

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 at least 40 years of age and not greater than 70 years of age at the time of consent.
4. Own a wearable pair of spectacles if required for their distance vision.
5. Be an adapted soft contact lens wearer in both eyes (i.e. worn lenses a minimum of 2 days per week for at least 6 hours per wear day, for 30 days or more duration).
6. Either already be wearing a presbyopic contact lens correction (e.g., reading spectacles over contact lenses, monovision or multifocal contact lenses, etc.) or if not respond positively to at least one symptom on the "Presbyopic Symptoms Questionnaire" (Appendix E).

Inclusion Criteria at Baseline:

7. The subject's distance spherical equivalent refraction must be in the range of +1.00 to +4.00 or -1.00 D to -4.00 D in each eye.
8. The subject's refractive cylinder must be ≤0.75 D in each eye.
9. The subject's ADD power must be in the range of +0.75 D to +2.50 D.
10. The subject must have distance best corrected visual acuity of $20/20^{-3}$ 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. Have any active or ongoing ocular or systemic allergies that may interfere with contact lens wear.
3. Have been diagnosed with diabetes.
4. Have any active or ongoing systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear. This includes, but not be limited to, hyperthyroidism, Sjögren's syndrome, xerophthalmia, acne rosacea, Stevens-Johnson syndrome, and immunosuppressive diseases or any infectious diseases (e.g. hepatitis, tuberculosis).
5. Have any previous, or planned, ocular or intraocular surgery (e.g. radial keratotomy, PRK, LASIK, lid procedures, dacryocystorhinostomy, peripheral iridotomy/iridectomy, cataract surgery, retinal surgery, etc.).
6. Have a history of amblyopia, strabismus or binocular vision abnormality.
7. Use of any of the following medications within 1 week prior to enrollment: oral retinoid, oral tetracyclines, anticholinergics, oral phenothiazines, oral/inhaled corticosteroids. See section 9.1 for further examples.
8. Be currently using any ocular medications with the exception of rewetting drops.
9. Have a history of herpetic keratitis.
10. Have a history of irregular cornea.
11. Have a history of pathological dry eye.
12. Have participated in any contact lens or lens care product clinical trial within 7 days prior to study enrollment.
13. Be an employee (e.g., Investigator, Coordinator, Technician) or immediate family member of an employee (including partner, child, parent, grandparent, grandchild, sibling of the employee or their spouse) of the clinical site.
14. Have any known hypersensitivity or allergic reaction to non-preserved rewetting drop solutions or sodium fluorescein.

Exclusion Criteria at Baseline:
The subject must not:

15. 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 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).
16. Have any current ocular infection or inflammation.

[redacted]

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

This is a 6-visit, single-masked, multi-site, 2×3 crossover, randomized-controlled, dispensing clinical trial. A total of approximately 70 eligible subjects will be enrolled with 60 subjects targeted to complete.

At the initial visit (Visit 1), if subjects meet all eligibility criteria, they will be randomized to one of two lens wear sequences (Test/Control/Control or Control/Test/Test) in a bilateral fashion.

If the subject is dispensed study lenses at the initial visit, five additional visits will be conducted. The first follow-up visit (Visit 2) will be 3±1 days after the initial visit. At Visit 2, subjects will undergo lens optimization, if necessary. Subjects will wear the study lenses for 7±1 days and then return for their second follow-up at Visit 3. At Visit 3, subjects will be dispensed their second study lens, per the randomization schedule. Subjects will return for their follow-up visit in the second lens type (Visit 4) 3±1 days after Visit 3. It will be determined if the subject needs optimization and the lenses will be dispensed with subjects returning for their second follow-up visit 7±1 days after Visit 4. At Visit 5, subjects will be dispensed the same lens type as they wore into Visit 5 and wear the lenses for an additional 7±1 days. The final visit will be the follow-up (Visit 6).

Subjects will be advised to wear the study lenses every day while they are in the study for a minimum of 6 hours per day. The study lenses will be replaced at the optimization visits. In addition, lost or damaged lenses may be replaced when necessary. Unscheduled visit may be conducted.

[redacted]

[redacted]

4.3. Enrollment Target and Study Duration

There will be 6 visits in total per subject; total study duration including the enrollment period is expected to be approximately 3-4 months. The total planned duration for each subject will be approximately 32 days. The investigation will end at the time when all visits have been completed for all enrolled subjects and the final database has been locked.

This study will have an enrollment target of 70 subjects, with a target of at least 60 to complete. There will be an attempt to recruit approximately equal number of hyperopes and myopes (i.e. 35 per group) into the study. The study will be conducted at up to 7 clinical sites, where the enrollment target for each site will be approximately 10 subjects. 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. Subjects will be considered enrolled upon signing of the Informed Consent Form.

The enrollment is open to any sex, race or ethnicity. In addition, subjects must have myopia or hyperopia and presbyopia which is representative of the population that these lenses are used in.

5. TEST ARTICLE ALLOCATION AND MASKING

[redacted]

5.2. Masking

Masking will be used to reduce potential bias. This is a single-masked study. Subjects will be unaware of the identity of the investigational product. However, subjects may observe noticeable differences between study lenses, every effort will be made to maintain the masking. Investigators and clinical site personnel involved in the data collection will not be masked to the identity of the investigational products as they will need to be aware

of the product in order to use the appropriate fitting guides and the test and control lenses may perform differently under monocular visual acuity testing conditions due to the optical designs.

5.3. Procedures for Maintaining and Breaking the Masking

The masking of the subject shall not be broken unless information concerning the lens type is necessary for the medical treatment of a subject. For example, if the subject is being evaluated by medical personnel not associated with the study and it is determined that knowing the type of lens and/or fitting approach they are using during the study would benefit the care of the subject. The Sponsor must be notified before the mask is broken.

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 1: Test Articles

	Test	Control
Name	INFUSE® One Day Multifocal/ INFUSE® One Day Sphere Lenses	ACUVUE® OASYS 1-Day MAX MULTIFOCAL/ ACUVUE® OASYS 1-Day MAX Sphere Contact Lenses
Manufacturer [redacted]	Bausch + Lomb [redacted]	Johnson & Johnson® Vision Care, Inc. [redacted]
Lens Material	kalifilcon A	senofilcon A(C3) with RTY-1 chromophore
Nominal Base Curve	8.6 mm	8.4 mm/8.5(sphere)
Nominal Diameter	14.2 mm	14.3 mm
Nominal Distance Powers (D)	-0.50 D to -4.25 D (0.25 D steps) +0.75 D to +4.50 D (0.25 D steps)	-0.50 D to -4.25 D (0.25 D steps) +0.75 D to +4.50 D (0.25 D steps)
Nominal ADD Powers (D)	LOW, HIGH	LOW, MID, HIGH
Water Content	55%	38%
Center Thickness	Varies with power	Varies with power
Dk (Fatt method, boundary corrected, edge corrected, $\times 10^{-11}$ [cm^2 /sec] [ml O_2/ml × mm Hg] at 35°C)	107	103
Wear Schedule in Current Study	Daily Wear	Daily Wear
Replacement Frequency	Daily disposable	Daily disposable
Packaging Form (vial, blister, etc.)	Blister	Blister

Each subject will wear approximately 40 lenses over approximately 20 days with nominally half off the subjects repeating lens wear, in the test or control, for another 7 days resulting in 14 additional lenses. Therefore, a subject will wear approximately 54 lenses. For 70 subjects enrolled approximately 3,780 lenses will be used.

6.2. Ancillary Supplies/Products

The following solutions will be used in this study:

Table 2: Ancillary Supplies

	Single-Use Preservative-Free Rewetting Solutions (any of these three options may be supplied)		
Solution Name/Description	Eye-Cept® Rewetting Drops	ScleralFil® Preservative Free Saline Solution	LacriPure Saline Solution
Manufacturer	Optics Laboratory	B&L	Menicon
Preservative	Non-Preserved	Non-preserved	Non-preserved

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.

[redacted]

[redacted]

[redacted]

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 (visit 6).
- 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 resulting in a major protocol deviation that is deemed to impact data integrity or safety.
- 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 (subject misses more than 2 days of 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 compliant with study lens wear schedule (i.e. misses more than 2 days of lens wear between follow-up visits).
- 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

If subjects are prematurely discontinued, subject enrollment will continue to meet the intended sample size. Subjects who are discontinued will be replaced.
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 and therapies are medications or therapies that contraindicate contact lens wear. See the Exclusion criteria for specific details as well as Table 4 below.

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 4. Subjects with a history of taking these medications will be allowed to enroll only if:

- The subject was taking the medication on a temporary basis and ceased taking that medication at least 1 week prior to signing the informed consent (this is considered sufficient time for the medication to have left the body prior to enrollment).

Table 4: Disallowed systemic medications

Class of Drug	Common Indication(s)	Common Examples
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., …
Oral Phenothiazines	Antipsychotic disorders (schizophrenia, mania)	Compazine, Mellarill, Thorazine, Phenagran, etc.…
Oral Retinoids	Cystic acne	Isotretinoin
Corticosteroids	Arthritis, colitis, asthma, bronchitis, allergic or inflammatory conditions	Cortisone, Prednisone, Hydrocortisone, Medrol, Kenalog etc., …
Oral Tetracycline	Urinary Tract Infection, acne, chlamydia, gonorrhea	Sumcyin, Acitsite, Achromycin V, etc.

10. DEVIATIONS FROM THE PROTOCOL

Investigators shall not deviate 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, to the IEC/IRB.

If the deviation potentially impacts the safety of subject 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 subject safety or technical integrity of the study. They are often logistical in nature.

Protocol waivers are prohibited.

Table 5 lists examples of deviatoins that will constitute major and minor protocol deviations for this study.

Table 5: 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
Unanswered PRO questions	For questionnaires where data is related to a primary or secondary endpoint, more than 2 PRO questions are unanswered (i.e., left blank).	For questionnaires where data is related to a primary or secondary endpoint, 2 or fewer PRO questions are unanswered (i.e., left blank). For questionnaires where data is not related to a primary or secondary endpoint, any PRO questions are unanswered (i.e., left blank).
Insufficient wear of study lenses	Subject does not wear study lenses for more than 2 days during study lens wear period.	Subject does not wear study lenses for 2 or fewer days during study lens wear period.

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. The list of major deviations with potential impact on the primary endpoint(s) will be flagged separately and used to define the per protocol population.

11. STUDY TERMINATION

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 subject 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 and will follow the internal applicable quality review process and will notify the IEC/IRB. 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.

Sponsor may disqualify a clinical investigator if the clinical investigator has repeatedly or deliberately failed to comply with the protocol, applicable regulatory requirements, or deliberately submitted false information.

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 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 apply 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
- Foetal distress, foetal 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
- Hordeolum
- 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.
NOTE 3: This includes 'comparator' if the comparator is a medical device.

Serious Adverse Device Effect (SADE) - Any adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Unanticipated Serious Adverse Device Effect (USADE): serious adverse device effect (SADE) which by its nature, incidence, severity or outcome has not been identified in the current risk assessment. [USADE is synonymous with UADE below from the United States (US) Code of Federal Regulations (CFR)[3].]
NOTE 1: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk assessment.

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. [UADE is synonymous with USADE above from ISO 14155[1].]

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 this section).
- 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 this section).
- 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.

Causality Assessment

Causality Assessment – A determination of the relationship between an adverse event and the test article, study treatment, or the study procedures. The test article, study treatment, or study procedures 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.

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 subject 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 EDC System, e-mail, 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 listed in this section. The report will comment whether the adverse event was considered to be related to the test article, study treatment or study procedures.

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 EDC System, 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.

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 subject and their fetuses will not be monitored for study related purposes. Pregnant subjects 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 lens type (Test and Control) and time point (baseline, fitting, 1-week follow-up, 1-week follow-up, exit evaluation and unscheduled visits (when applicable)) and will be performed separately by completion status (Safety Population, Per-Protocol Population and Intention-to-Treat, when appropriate).

[redacted]

[redacted]

14.3. Analysis Populations

Safety Population:
All subjects that were administered any study lens. Subjects will be analyzed per actual treatment received.

Per-Protocol Population:
All subjects who have successfully completed all visits and did not substantially deviate from the protocol as determined by the cohort review prior to database lock. Justification of excluding subjects with protocol deviations in the per-protocol population set will be documented in a memo.

Intention-to-Treat (ITT) Population:
All randomized subjects. Subjects will be analyzed per planned randomized treatment.

14.4. Level of Statistical Significance

Co-Primary hypotheses will be tested using a 1-sided Type I error rate of 0.025 for each hypothesis. All co-primary hypotheses are required to demonstrate statistically significant non-inferiority therefore no adjustment for multiple hypotheses was necessary.

14.5. Missing Data Handling Rules

All analyses will be conducted using observed case data. No missing or spurious data will be imputed. The count of missing data will be included in the summary tables and listings.

[redacted]

[redacted]

15. DATA HANDLING AND RECORD KEEPING/ARCHIVING

15.1. Electronic Case Report Form/Data Collection

The data for this study will be captured on electronic case report forms (eCRFs) using a Sitero 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.[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.

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, including 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.
- Ensuring the maintenance and calibration of equipment used per standard equipment requirements.

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 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, according to ISO 14155[1] 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 with 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[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 subjects 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 their 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.

18.4.1. 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)[9] 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[1] guidelines, 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 ISO 14155[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

There is no plan to publish the outcomes of this investigation.



APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

ACUVUE® OASYS MAX 1-Day Multifocal Contact Lens package insert
Bausch + Lomb INFUSE® One Day Multifocal package insert

SYMBOLS KEY

SYMBOL	DESCRIPTION
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LOT	
STERILE	SterfzooUsrigStoornHoot
0	
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UV BLOCKING	INBlod\'1
	FeePa.dforWaste lanagerne\lt
Rx Only	CARDCIN.USFederal\twisrndsth\lid.Meatosalet,.01C<11hal01derafs licensed'.Q..')\i<Iriier
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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.

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NErgar,UdoI.i*nalotMed,\"',September21,fi169;.J:f 1(2).pp. 77 J-783

SpacifiJnstrucionsforUsaandWarnings

WaterActivity

InstrV,CtontorUse

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SpecialPrecautionsforU)ftiCarePrOfessionals:

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SYMBOL	DESCRIPTION
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MD	MedICiJDev,ceSyfltlol
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	"High"nearAOO

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DESCRIPTION

ACUVUE: OASYS IMX1-DayContact,enses are scttl(1-((drcf.hlrd codact lemesvailableasphersk::al,mu!focal,andnuk.focaltoridenses.

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Lens Properties:

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- :"LJecifcGra,ity -
- Aefrac1aehde,: 1.42
- Visible Light Transmittanco .78%
- HEV Light Transmittance*:
- Surface Character: H(Uroph.lc
- WaterContenlt: 38%
- OxygenPermeability(Dk)

VALUE	METHOD
103x\(** mSec) (t=H.),rmLLrm.Hg)@35'C	Fatl(tboondarycmected,edge

LensPa,amete!Ranges:

- Diameter(DIA) 12.0mmtol5.0mm
- Genterlhickness varlesw!thpower
- BaseOJrve(BCI: 7.85rmto10.00rm,
- SphericaJPO' (Di: -20.COOto,20.COO
- C\tfder ID) -0.25Dlo-10.000
- AxisWJ(JSJ
- MLi:focalADDPw.er

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Clinkal Protocol
Johnson & Johnson Vision 01re, Inc.

DESCRIPTION

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CenterThickness:	0.085 mm to 0.221mm i,+ariesw th power)
BaseCurve(BCJ:	8.5mm,9.0mm
Powers(DJ:	-12.0COto.&OCO

TheACINLPOASYSMAX 1-DayMULTFCCALCatact Lenses lsenofitm A) arelherr.sphericalshelsofthefoloMngdmensions

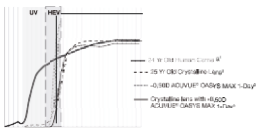
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Centre.Thlekness:	O.O?Ommto0.191 mm!-,.ariesw thpoy,er)
Base Curve (BCJ:	8.4 mm
Powers(DJ:	-9.00!i0.+6.0CO
ADDPowers(DI:	+1.25D(LOW),+1.750(1..1tDi,+2.500l(t;H)

TheACINUE'O'b-SYS /)i_1-Day(AULTIFCCAI.Contactlenses kl ASIK,MATBIA.ker-dicor,Alarsn:rJ.Jist(tlerical oifh tolcwng00Jle!1So,s

Diameter(DIA)	14.3mm
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BaseCurve(BCJ:	8.5mm
Powers(DJ:	-9.00!ro.+6.0CO
Cylinder(Cyl):	+1.00D
Axis:	l07,20°.70',S0°,90',HI0',110',160°,170°,180'
AODPOWtSt(DI:	11.25DtLOW),+1.75D(t;1tD),+2.500l(t;H)

TRANSMITTANCE CURVE

AO..MJE*OASYSIMX 1-dJ;fyCm.actLenses (asnoflw-i A) vs. 24 yr. old lwlocomrrrood25yr.oldrit.mancrystallinelens.



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'WaNn-.M.HtCtFtSS.tM,Cpt,ssROO,at)pc"l<fo1sslaHer:th CRCF,ooa BonREloofDtal.1eCOp,1.9Bfll.-485

'Tha<Ms was ob1Mledlrorn.i'"'"'"'. takenfrOt.9'1'thaoontal 6 mm POhil forthalhn-iestSlftj,a,'lic:;llo>,.s/-(-6.50lloi,,,(0.oc5rrme<>rrlert_,-,).

ACTIONS

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WhoShouldKnowThalthePatientisWearingContactlenses?

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WARNINQ:UVabsorbingcontactlenseesa,eNOTsubstitutesfor protectiveUVabsorbingeyewea1,suchasUVabsorbingpoggles orsunglassesbecauseth.&ydonotcompletelyeoverlheeyeand surroundingarea.YoushouldeontinuetouseUVabsorbingeyewe.ir as directed.

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ACUVUE"D_,IS'(SMAX1-DayContlactlenses(serdlw-vA,lamirdcaledU daiydisposablewearforthecorrectionof"sio,1rlpoople,,,ttnon-diseas.ed eyes«OOareneansi tedi'Th'jOpic)orfars,ghtedil11PeopicJandmayh8,«1.000 orless of tsnimar dd8S not Interfere with sual acwity.

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PatientsshouldbeadvisedoftH11followingwamin9Spertaining1o con1actlenswear.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS,CAN DEVELOP RAPIDLYANDLEAOTOLOSSOFVISION,IFTHEPATIENT EXPERIENCES:

- **EyeOrscomfort.**
- **Excessi•eTtearing,**
- **VisionChanges,**
- **LossofVision.**
- **EyeRedness,or**
- **OtherEyeProblems.**

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

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AlpatientsshouldbesuppliedwlihaeopyolthePATIENT INSTRUCTION,GUIOEfo1theslenses.Copiesa1e11vailablefor download from www.acuvue.com.

GENERAL PRESBYOPIC CONTACT LENS NEEDS ASSESSMENT, PATIENT EDUCATION INmAL POWER DETERMINATION, & OCULAR PREFERENCE

A. GeneralPresbyopicContactLensNeedsAssessment&

Patient ducation

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Tose lenses â"eavailable in theIQloMingAOO powers

- Lens"LCM"="low"rtearADDlens(IAax+1.25DADD)
- Lens"IAID" =neoUllnearAOOlens(Max.r1.75DA(q
- Lens"HGH" 'tugh' near AOOie<ls (Max +2.5ODAJ.0)

B. InitialPowerDetermination

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C,OcularPreferenceDetermination

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MULTIFOCAL FITTING GUIDELINES

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[redacted] is should be considered. If ractelerropsia), it should bx ction adequately with mxnic tot be optimal for activities

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deviation. You can use an axis reticule or beam axis dial in the slit lamp o use a line-corbed lens in a spectacle trial frame to measure or estimate the "drift angle" of the cylindor 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 6 ulit Add, Right Subtract method to determine what direction to compensate.

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PACKAGEINSERT &FITTINGINSTRUCTIONGUIDE

ACUVUE OASYS MAX

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IMPORTANT: Please read carefully and keep this infonnationforfutureuse.

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BAUSCH + LOMB

INSERT SPEC DIMENSIONS: Folded: 2.75"x 4.25"
Flat: 11" x 17"

DESCRIPTION: Infuse SVS / Multifocal / Astigmatism PIFG Ins / US / Internal/Web

PART No.: 8191603 **SPEC No. or SPEC DIMENSIONS:** 5573

SPECIAL INSTRUCTIONS: N/A

PRINT SUPPLIERS: Please refer to Bausch + Lomb's *Print Supplier Guidelines*

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BAUSCH+LOMB

INFUSE®

SPHERICAL
(kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses

MULTIFOCAL
(kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses

ASTIGMATISM
(kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses

PACKAGE INSERT / FITTING GUIDE

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

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA

www.bauschinfuse.com

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

IMPORTANT
This Package Insert and Fitting Guide has been developed to provide practitioners with information covering characteristics of the Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, and Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens and to illustrate fitting procedures. It is effective as of revision date on cover and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.

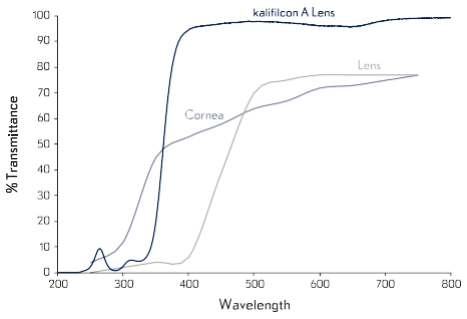
This package insert and fitting guide is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens and the recommended wearing schedule.

DESCRIPTION
The Bausch + Lomb INFUSE® lens material, kalifilcon A, is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-vinylpyrrolidone and is 55% water by weight when immersed in a saline solution. A benzotriazole UV-absorbing monomer is incorporated into the manufacturing process to block Ultraviolet (UV) radiation. The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm. This lens is tinted blue with Reactive Blue Dye 246.

The physical/optical properties of the lens are:

Specific Gravity:	1.029
Refractive Index:	1.4011
Light Transmittance:	C.I.E. Y value - approximately 99%
Water Content:	55%
Oxygen Permeability (Dk):	107 x 10^{-11} [cm^3O_2 (STP) x cm]/(sec x cm^2 x mmHg) @ 35°C (Polarographic Method)

The lens is to be prescribed for single-use disposable wear and is to be discarded after each removal.



Typical transmittance profile of kalifilcon A (55% water) lenses vs a Human Cornea and Human Lens:

1. Human crystalline lens from a 25-year-old person as described in Waxler M., Hitchins V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, fig. 5
2. Human Cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig. 2-21
3. Kalifilcon A (55% water) Soft Contact Lens, -1.00D Power, Nominal Center Thickness 0.08 mm

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

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.

Note:
The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time. 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. Patients should be instructed to consult the eye care practitioner for more information.

CONTACT LENS PARAMETERS AVAILABLE
The Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens is a hemispherical shell of the following dimensions:

Diameter:	14.2mm 14.5mm (Astigmatism)
Center Thickness:	0.05mm to 0.75mm (varies with power)
Base Curve:	8.6mm
Powers (Spherical):	+6.00D to -6.00D in 0.25D steps -6.50D to -12.00D in 0.50D steps
Powers (Presbyopia):	+6.00D to -10.00D in 0.25D steps
Add Powers:	Low (+0.75D to +1.50D) and High (+1.75D to +2.50D)
Powers (Astigmatism):	+4.00D to -6.00D in 0.25D steps -6.50D to -9.00D in 0.50D steps
Cylinder Powers:	-0.75D, -1.25D, -1.75D, -2.25D, and -2.75D
Axis:	0° to 180°

Additional parameters may be introduced over time; check periodically for product availability.

HOW THE LENS WORKS (ACTIONS)
In its hydrated state, the Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, and Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm.

INDICATIONS
SVS
The Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

Presbyopia
The Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in powers ranging from +20.00D to -20.00D with add power ranging from +0.75D to +5.00D.

Astigmatism
The Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters, that does not interfere with visual acuity. The lens may be prescribed in powers ranging from +20.00D to -20.00D.

The lens is to be prescribed for single-use disposable wear and is to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)
DO NOT USE the Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, or Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, when any of the following conditions exist:

- Acute and 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 eyes)
- 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 (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS
After a thorough eye examination, including appropriate medical background, patients should be fully apprised by the prescribing eye care practitioner of all the risks with contact lens wear. Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when daily wear lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove the lenses and promptly contact his or her eye care practitioner.
- Patients should be instructed not to expose their contact lenses to water while wearing them. Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If their contact lenses have been submersed in water when swimming in pools, lakes, or oceans, the contact lenses should be discarded and replaced with a new pair. Recommendations for wearing lenses during any water activity should be discussed with the patient.

PRECAUTIONS
Special Precautions for Eye Care Practitioners
- 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 were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner 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 practitioner.
- Patients who wear contact lenses to correct presbyopia 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 practitioners should instruct the patient to REMOVE THE LENS IMMEDIATELY if the eye becomes red or irritated.
- 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 sterile saline solution that is recommended for in-eye use.
- The patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care practitioner.
- As with any contact lens, follow-up visits are necessary to ensure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Aphakic patients should not be fitted with Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses, Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses, or Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses, until the determination is made that the eye has healed completely.
- The lenses are prescribed for disposable wear and are to be disposed of once they are removed from the patient's eye. It is important that patients be instructed to always have available a pair of replacement lenses. In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens, or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.
- Eye care practitioners should carefully instruct patients about the following safety precautions. It is strongly recommended that patients be provided with a copy of the Patient Information Booklet for Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens/Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens/Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, available from Bausch + Lomb, and understand its contents prior to dispensing the lenses.

Handling Precautions
- 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.
- Be sure that before leaving the eye care practitioner's office, the patient is able to remove lenses promptly or have someone else available to remove them.
- Be certain that the fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Always handle lenses carefully and avoid dropping them.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the Patient Information Booklet for the Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens/Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens/Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens and those prescribed by the eye care practitioner.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Lens Wearing Precautions
- Never wear lenses beyond the period recommended by the eye care practitioner.
- 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 practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Topics to Discuss with the Patient
- As with any contact lens, follow-up visits are necessary to ensure the continuing health of the eyes. The patient should be instructed as to a recommended follow-up schedule.
- Patients should be advised about wearing lenses during sporting and water-related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection including, but not limited to, *Acanthamoeba* keratitis.
- Always contact the eye care practitioner 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 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.

Who Should Know That the Patient is Wearing Contact Lenses
- Patients should inform their doctor (health care professional) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that the patient does not wear lenses.

ADVERSE REACTIONS
The patient should be informed that the following problems may occur:
- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when the lens was first placed on the eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to:
- Immediately remove the lenses.
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on your eye. You should discard the lens and insert a new lens on the eye. If the problem continues, you should immediately remove the lenses and consult your eye care practitioner.
- If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should immediately remove the lens and contact his or her eye care practitioner or physician, who must determine the need for examination, treatment, or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, epithelial staining, or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions
Sight-threatening ocular complications associated with contact lens wear can develop rapidly; therefore, early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare, and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combination may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately, and the lens and/or lens care products retained for analysis and culturing.

SELECTION OF PATIENTS
The eye care practitioner should not fit patients who cannot or will not adhere to a recommended care or replacement regimen or who are unable to place and remove the lenses. Failure to follow handling and cleaning instructions could lead to serious eye infections which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also to ensure compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.

Patients selected to wear Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses, Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses or Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses should be chosen for their motivation to wear contact lenses, general health, and cooperation. The eye care practitioner must take care in selecting, examining, and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part time), and desired lens usage (reading, recreation, or hobbies).

Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry, and slit lamp examination.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes), and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear.

If these symptoms persist, the patient should be instructed to contact his or her eye care practitioner.

PRACTITIONER FITTING SETS
Lenses must be discarded after single-use and must not be used from patient to patient.

GENERAL FITTING PROCEDURE
1. Pre-Fitting Examination

A pre-fitting patient history and examination are necessary to:
- Determine whether a patient is a suitable candidate for contact lenses (consider patient hygiene and mental and physical state).
- Make ocular measurements for initial contact lens parameter selection.
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include spherocylinder refraction and Visual Acuity (VA), keratometry, and biomicroscopic examination.

2. Initial Lens Power Selection

a. Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.

b. Select the appropriate lens and place on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics.

c. Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. Initial Lens Evaluation

a. To determine proper lens parameters, observe the lens relationship to the eye using a slit lamp.
- Movement: The lens should provide discernible movement with:
  - Primary gaze blink
  - Upgaze blink
  - Upgaze lag
- Centration: The lens should provide full corneal coverage.

b. Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any One-Day Soft lens.

4. Criteria of a Well-Fitted Lens

If the initial lens selection fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient, and provides satisfactory visual performance, it is a well-fitted lens and can be dispensed.

5. Characteristics of a Tight (Steep) Lens

A lens which is much too steep may subjectively and objectively cause distortion which will vary after a blink. However, if a lens is only marginally steep, the initial subjective and objective vision and comfort findings may be quite good. A marginally steep lens may be differentiated from a properly fitted lens by having the patient gaze upward. A properly fitted lens will tend to slide downward approximately 0.5mm, while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

6. Characteristics of a Loose (Flat) Lens

If the lens is too flat, it will:
- Decenter, especially on post-blink.
- Have a tendency to edge lift inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva.
- Have a tendency to be uncomfortable and irritating with fluctuating vision.
- Have a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

7. Follow-Up Care

The wearing and replacement schedules should be determined by the eye care practitioner. Regular check-ups, as determined by the eye care practitioner, are extremely important.

Daily Wear

There may be a tendency for the daily wear patient to over-wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by [redacted] re practitioner. The wearing schedule chosen by the eye care practitioner provided to the patient.

TORIC FITTING GUIDELINES
a. Determine contact lens power. The toric trial lens is used to optimize lens fitting characteristics and determine axis orientation. Lens power is determined by the spectacle refraction. It is preferable to use the spectacle Rx as the basis for the contact lens power. The sphere and cylinder power of the spectacle Rx becomes the closest sphere and cylinder power of the contact lens.

There are two exceptions:

1. If spectacle cylinder power falls between available contact lens cylinder powers, prescribe the lesser contact lens cylinder power. The sphere power can be increased -0.25D to compensate if desired. Of course, this can vary depending on your interpretation of the patient's subjective responses.

   Example: Spectacle Rx: -2.00-1.00 X 180

   Contact Lens Power Ordered: -2.25-0.75 X 180

2. When the spectacle lens power in any principal meridian is greater than 4.00D, the spectacle refraction should be vertexed to the corneal plane. This can affect both the sphere and cylinder powers ordered.

   Example: Spectacle Rx: -5.00-2.75 X 180

   Contact Lens Power Ordered: -4.75-2.25 X 180

b. Determine contact lens axis; the center guide mark should locate at the inferior limbus. Once oriented, rotational rocking should be limited to less than 5°.

c. Allow the lens to settle for at least 3 minutes to achieve a state of equilibrium. Note the orientation of the guide mark relative to the vertical meridian. Regardless of which eye the lens is on, if the rotation is clockwise but stable, note the amount of rotation, add it to the refractive cylinder axis, and order the resulting axis. If the rotation has stabilized counterclockwise, again note the rotation, subtract it from the refractive axis, and order the resulting axis. The guide mark can be used to help you calculate the axis of the desired Rx lens.

   Example: Spectacle Rx: -2.50-1.25 X 80

   Rotation: 20° clockwise

   Final Lens Prescription: -2.50-1.25 X 100

d. Select patient's lenses.

e. Evaluate orientation of final Rx lenses. The orientation of the prescription should be the same as that observed for the trial lenses. For example, if the trial lens rotated clockwise 15°, then the final prescription lens should also rotate clockwise 15°.

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MULTIFOCAL FITTING GUIDELINES

1. Lens Selection

a. Update spectacle refraction and Add power.

b. Determine ocular dominance for distance vision.

c. Select lens distance prescription based upon spherical equivalent from spectacle prescription, adjusted for vertex distance if necessary.

d. Choose trial lenses based upon the above calculation and select Add power.

- Bausch + Lomb INFUSE® Multifocal Low Add: +0.75D to +1.50D
- Bausch + Lomb INFUSE® Multifocal High Add: +1.75D to +2.50D

2. Lens Fitting

a. Allow lens to equilibrate for at least 10 minutes before assessing fit and vision.

b. Evaluate distance and near vision binocularly in normal room illumination.

c. If vision at distance and near is satisfactory, dispense lenses and schedule follow-up exam within 1 to 2 weeks.

3. To Refine Near Vision

If patient is wearing two Low Add lenses:

- Refinement 1: Place Bausch + Lomb INFUSE® Multifocal High Add in non-dominant eye while keeping Bausch + Lomb INFUSE® Multifocal Low Add in dominant eye.
- Refinement 2: If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1: Add +0.25D to the non-dominant eye.
- Refinement 2: If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using handheld lenses.

4. To Refine Distance Vision

If patient is wearing two Low Add lenses:

- Refinement 1: Fit Bausch + Lomb INFUSE® SVS in dominant eye while keeping Bausch + Lomb INFUSE® Multifocal Low Add in non-dominant eye.
- Refinement 2: If vision is still unsatisfactory, add -0.25D at a time to dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1: Fit with Bausch + Lomb INFUSE® Multifocal Low Add in dominant eye while keeping Bausch + Lomb INFUSE® Multifocal High Add in non-dominant eye.
- Refinement 2: If vision is still unsatisfactory, add -0.25D at a time to dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.

5. Patient Education

All patients do not function equally well with multifocal correction. Patients may not perform as well for certain tasks with this correction as they have with multifocal reading glasses. Each patient should understand that multifocal correction can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that multifocal contact lenses provide.

MONOVISION FITTING GUIDELINES

1. Patient Selection

a. *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 one [1] diopter) in one eye may not be a good candidate for monovision with the Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses or Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact 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. Monovision contact lens wear may not be optimal for such activities 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 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.

b. *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 bifocal reading glasses. Each patient should understand that monovision can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

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

a. *Ocular Preference Determination Methods*

- Method 1—Determine which eye is the "sighting dominant 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 trial spectacle near Add lens 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.

b. *Refractive Error Method*

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

c. *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 usually function best with the near lens on the left eye.

3. Special Fitting Considerations

Unilateral Lens Correction

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

Example: A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 diopter lens on the near eye and the other eye left without a lens.

Example: A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. 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.

5. 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 directions in the general fitting guidelines.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next, determine the near add. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Immediately after the correct power lenses are 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 distant objects, observe the reactions. Only after these vision tasks 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.

6. 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.

7. Other Suggestions

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

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having 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 licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision 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 the clear near vision in straight ahead and upward gaze with monovision.
- The decision to fit a patient with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering the patient's needs.
- All patients should be supplied with a copy of the Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens/ Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens/Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens Patient Information Booklet.

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Regular check-ups, as determined by the eye care practitioner, are extremely important.

Daily Wear

There may be a tendency for the daily wear patient to over-wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient. The lens is to be prescribed for single-use disposable wear and is to be discarded after each removal.

HANDLING OF LENSES

Patient Lens Care Directions

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care practitioner should recommend appropriate and adequate procedures for each individual patient in accordance with the particular lens wearing schedule.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rewetting solution in their eye. The patient should be instructed to not use plain water or anything other than the recommended solutions. The patient should be instructed to contact the eye care practitioner if the lens does not begin to move upon blinking after several applications of the solution or drops, and to not attempt to remove the lens except on the advice of the eye care practitioner.

EMERGENCIES

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 THEN REMOVE LENSES PROMPTLY. CONTACT AN EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses, Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses, or Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses or experienced with the lenses, should be reported to:

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA
Toll-Free Telephone Number
In the Continental U.S., Alaska, Hawaii
1-800-553-5340
In Canada
1-888-459-5000

HOW SUPPLIED

Each sterile lens is supplied in a plastic package containing phosphate buffered saline solution with potassium chloride, poloxamine, poloxamer 181, glycerin, and erythritol. Each container is marked with the manufacturing lot number of the lens, diopter power, and expiration date.

SYMBOL GLOSSARY

Comprehensive guide to symbols that may appear on product labels and cartons.

Symbol	Symbol Title	Symbol Description	Standard Reference	Title and Designation Number of the Standard
	Manufacturer	Indicates the medical device manufacturer	5.1.1	ISO 15223-1:2021 Medical device - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Authorized representative in the European Community/European Union	Indicates the authorized representative in the European Community/European Union	5.1.2	
	Date of manufacture	Indicates the date when the medical device was manufactured	5.1.3	
	Use-by date	Indicates the date after which the medical device is not to be used	5.1.4	
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	5.1.5	
	Sterilized using steam	Indicates a medical device that has been sterilized using steam	5.2.5	
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	5.2.8	
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside	5.2.14	
	Do not re-use	Indicates a medical device that is intended for one single use only	5.4.2	
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	5.4.3	
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	5.4.4	
	Medical device	Indicates the item is a medical device	5.7.7	
$DIA\,\varnothing_T$	Total diameter	Indicates total diameter of lens	N/A	N/A
BC	Base curve	Indicates base curve of lens	N/A	N/A
PWR F'_V	Paraxial back vertex power	Indicates lens power in diopters	N/A	N/A
SPH	Sphere power	Indicates spherical power in diopters	N/A	N/A
AX	Cylinder axis	Indicates axis of cylinder power in degrees	N/A	N/A
CYL	Cylinder power	Indicates cylindrical power in diopters	N/A	N/A
ADD	Additional power	Indicates additional power in diopters	N/A	N/A
YYYY-MM	Effective date	Indicates the date in which the insert revision was made effective	N/A	ISO 8601-1:2019 Date and time — Representations for information interchange — Part 1: Basic rules
	Prescription only (USA)	Indicates that federal law (U.S.) restricts this device to sale by or on the order of a licensed practitioner	N/A	21 CFR 801.109
	CE number	Indicates the CE Conformity Marking and the Notified Body Number	N/A	MDR 2017/745, Article 20, 3
	Green dot	Indicates paid fee to meet EU packaging directive	N/A	94/62/EC

APPENDIX G: TEST LENS FITTING GUIDE

BAUSCH + LOMB MULTIFOCAL
2-STEP FITTING GUIDE

INITIAL LENS SELECTION

STEP 1: Update spectacle refraction and ADD power

STEP 2: Select contact lens distance prescription based upon spherical equivalent (or toric lens power, for astigmatic patients) from spectacle Rx. Adjust for vertex if necessary and follow ADD guidance

ADD SELECTION

SPECTACLE ADD	BOTH EYES
+0.75D to +1.50D	Low ADD
+1.75D to +2.50D	High ADD

EVALUATE THE LENS FOR SUCCESS

- **Allow trial lenses to equilibrate** for at least 10 minutes before assessing fit and vision
- **Confirm axis orientation** (for astigmatic patients)
- **Evaluate distance and near vision binocularly** in normal room illumination

If vision at distance and near are satisfactory, dispense lenses and **schedule follow-up exam within 1 to 2 weeks**



REFINE IF NEEDED

Confirm axis orientation (for astigmatic patients) | **Determine eye dominance** | **Follow guidance below**

TO REFINE NEAR VISION

	DOMINANT EYE	NON-DOMINANT EYE
TWO LOW ADDS		
Initial Lens	**Low ADD**	**Low ADD**
Refinement 1	**Low ADD**	**High ADD**
Refinement 2: If vision is still unsatisfactory, make small changes by adding +0.25D at a time to non-dominant eye (wearing High ADD lens) using hand-held lenses, and continue evaluating vision binocularly in normal room illumination. Adjust contact lens power when vision is satisfactory.		
TWO HIGH ADDS		
Initial Lens	**High ADD**	**High ADD**
Refinement 1	**High ADD**	**Add +0.25D to the non-dominant eye**
Refinement 2: If vision is still unsatisfactory, make small changes by adding +0.25D at a time to non-dominant eye using hand-held lenses, and continue evaluating vision binocularly in normal room illumination. Adjust contact lens power when vision is satisfactory.		

TO REFINE DISTANCE VISION

	DOMINANT EYE	NON-DOMINANT EYE
TWO LOW ADDS		
Initial Lens	**Low ADD**	**Low ADD**
Refinement 1	**Single-vision spherical or toric (in case of multifocal for astigmatism) lens**	**Low ADD**
Refinement 2: If vision is still unsatisfactory, make small changes by adding -0.25D at a time to dominant eye using hand-held lenses, and continue evaluating vision binocularly in normal room illumination. Adjust contact lens power when vision is satisfactory.		
TWO HIGH ADDS		
Initial Lens	**High ADD**	**High ADD**
Refinement 1	**Low ADD**	**High ADD**
Refinement 2: If vision is still unsatisfactory, make small changes by adding -0.25D at a time to dominant eye (wearing Low ADD lens) using hand-held lenses, and continue evaluating vision binocularly in normal room illumination. Adjust contact lens power when vision is satisfactory.		

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APPENDIX H: CONTROL LENS FITTING GUIDE

Multifocal Fitting guide located on page 162-164

PACKAGE INSERT & FITTING INSTRUCTION GUIDE



ACUVUE® OASYS MAX 1-Day Contact Lenses

ACUVUE® OASYS MAX 1-Day Contact Lenses for ASTIGMATISM

ACUVUE® OASYS MAX 1-Day MULTIFOCAL Contact Lenses

ACUVUE® OASYS MAX 1-Day MULTIFOCAL Contact Lenses for ASTIGMATISM

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.

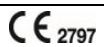
The Eye Care Professional should provide the patient with the appropriate instructions that pertain to the patient's prescribed lenses. Copies are available for download at www.acuvue.com.

℞ 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)
CYL	Cylinder
AXIS	Axis
ASTIGMATISM	Indicates lens(es) for astigmatism
	CE Mark and Identification number of Notified Body
	UK Conformity Assessment Marking 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 (Toric/Astigmatic Lenses)
	Lens Orientation Incorrect (Lens Inside Out) (Toric/Astigmatic Lenses)
	Lens Orientation Correct
	Lens Orientation Incorrect (Inside Out)
	Authorized Representative in the European Community
	Authorized Representative in the United Kingdom
	Contains Hazardous Substances
	Do Not Re-Use (Single Use)
	Do Not Use if Package is Damaged

MD	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
MULTIFOCAL	Indicates “Multifocal Lens(es)”

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, toric, multifocal, and multifocal toric 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
- Cylinder Power (D) -0.25D to -10.00D
- Axis (AXIS) 5˚ to 185˚
- 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 Contact Lenses (senofilcon A) for ASTIGMATISM are hemispherical shells of the following dimensions:

Diameter (DIA): 14.3 mm

Center Thickness: 0.075 mm to 0.193 mm (varies with power)

Base Curve (BC): 8.5 mm

Powers (D): +0.00D to -6.00D (in 0.25D increments)
+0.25D to +4.00D (in 0.25D increments)
-6.50D to -9.00D (in 0.50D increments)

Cylinder (Cyl):	-0.75D, -1.25D, -1.75D, *-2.25D
Axis:	10° to 180° in 10° increments
	*-2.25D cylinder is available in 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180° axes only

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

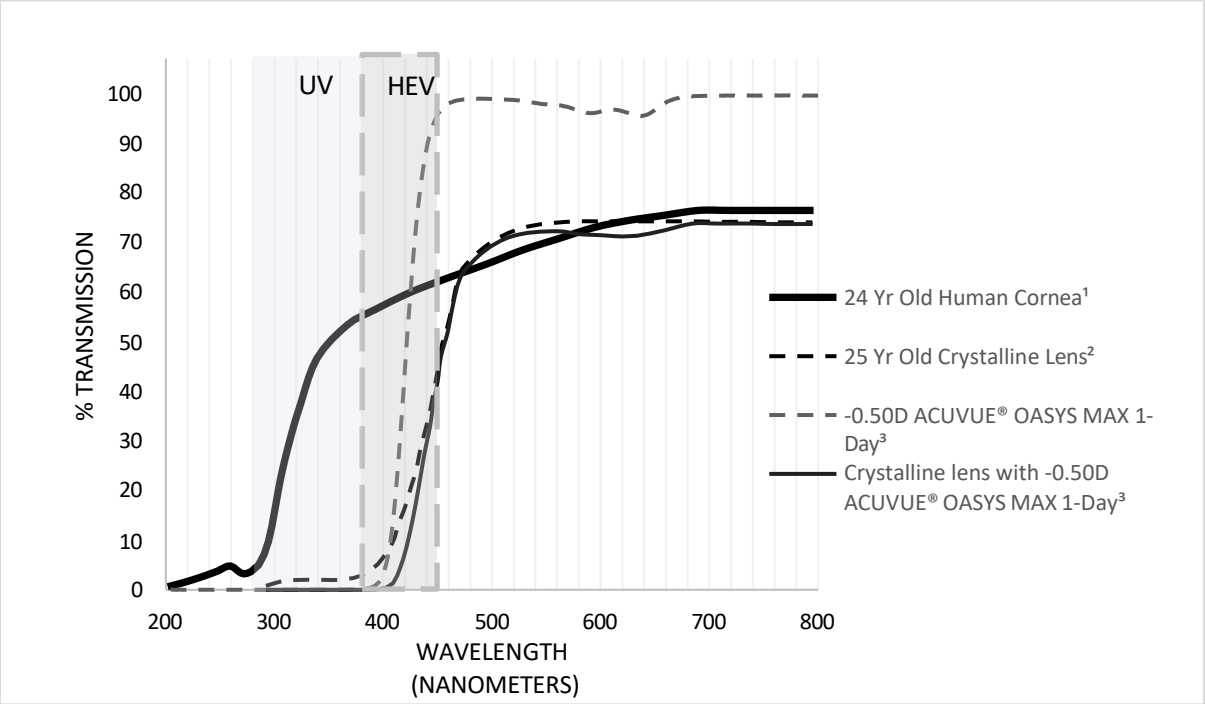
Diameter (DIA):	14.3 mm
Center Thickness:	0.070 mm to 0.191 mm (varies with power)
Base Curve (BC):	8.4 mm
Powers (D):	-9.00D to +6.00D
ADD Powers (D):	+1.25D (LOW), +1.75D (MID), +2.50D (HGH)

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

Diameter (DIA):	14.3 mm
Center Thickness:	0.075 mm to 0.193 mm (varies with power)
Base Curve (BC):	8.5 mm
Powers (D):	-9.00D to +6.00D
Cylinder (Cyl):	-1.00D
Axis:	10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°
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 Contact Lenses for ASTIGMATISM (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who may be nearsighted (myopic) or farsighted (hyperopic) and have 0.50D to 3.00D of astigmatism.

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.

ACUVUE® OASYS MAX 1-Day MULTIFOCAL Contact Lenses for ASTIGMATISM (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 have 0.75D to 1.75D of astigmatism.

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, multifocal, or multifocal toric 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 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:

- 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 (including meibomian gland 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. Vertex distance compensation is generally only necessary for refractions ≥ ± 4.00D, but may sometimes also be required for lower refractions in the case of large vertex distances.

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, Toric, Multifocal, or Multifocal Toric 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.

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 MAX 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' symmetrical stabilization design, 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.

   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.

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 generally not necessary, however may be required for larger vertex distances.

For the Cylinder:

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

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 from www.acuvue.com

GENERAL PRESBYOPIC CONTACT LENS NEEDS ASSESSMENT, PATIENT EDUCATION, INITIAL POWER DETERMINATION, & OCULAR PREFERENCE

A. General Presbyopic Contact Lens Needs Assessment & Patient Education

Multifocal and Multifocal toric 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 or ACUVUE® OASYS MAX 1-Day Multifocal for ASTIGMATISM 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.

ACUVUE® OASYS MAX 1-Day Multifocal Contact Lenses are not recommended for patients who may have 1.00D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise.

ACUVUE® OASYS MAX 1-Day Multifocal for ASTIGMATISM Contact Lenses are recommended for patients who have 0.75D to 1.75D refractive cylinder.

These lenses are available in the following ADD powers:

- Lens "LOW" ="low" near ADD lens (Max +1.25D ADD)
- Lens "MID" = "medium" near ADD lens (Max +1.75D ADD)
- Lens "HGH" = "high" near ADD lens (Max +2.50D 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. Vertex distance compensation is generally only necessary for refractions ≥ ± 4.00D, but may sometimes also be required for lower refractions in the case of large vertex distances. Determine the spherical equivalent distance prescription for a multifocal patient.

C. Ocular Preference Determination

The following methods for eye dominance can be used:

Method 1 (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. If the patient indicates that the amount of blur is about the same between the two eyes then try using a +1.50D trial lens. If no difference in blur between eyes is reported, then use Method 2 to determine ocular dominance.

Method 2: 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.

MULTIFOCAL FITTING GUIDELINES

A. 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. Vertex distance compensation is generally only necessary for refractions ≥ ± 4.00D, but may sometimes also be required for lower refractions in the case of large vertex distances. For patients with -0.75D to -1.75D of refractive cylinder, proceed to **"MULTIFOCAL TORIC FITTING GUIDELINES"** section.
2. Select the near power of the lens based on the patients ADD range as follows:
    - ADD: +0.75D to +1.25D use a "LOW" near ADD lens on each eye
    - ADD: +1.50D to +1.75D use a "MID" near ADD lens on each eye
    - ADD: +2.00D to +2.50D 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 of 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 as per standard of care (see **PATIENT MANAGEMENT** section).

B. Multifocal Troubleshooting

Unacceptable Near Vision:
If it has been determined that no change is required based on the over-refraction then add +0.25D 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.

C. 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.

MULTIFOCAL TORIC FITTING GUIDELINES

A. Select the Initial Trial Lens

1. Initial Distance Power Selection
    a. It is very important to determine an accurate distance spectacle Rx; this should be the least minus/most plus power that provides the best corrected binocular and monocular visual acuity. Vertex distance compensation is generally only necessary for refractions ≥ ± 4.00D, but may sometimes also be required for lower refractions in the case of large vertex distances.
    b. The spherical power chosen may include an adjustment to compensate for any under-corrected or over-corrected cylinder power (i.e., if the refraction cylinder power is different to the lens cylinder power).
    c. The lens cylinder axis chosen will be as close as possible to the refraction cylinder axis.
2. Select the near power of the lens based on the patient's ADD range
    - ADD: +0.75D to +1.25D use a "LOW" near ADD lens on each eye
    - ADD: +1.50D to +1.75D use a "MID" near ADD lens on each eye
    - ADD: +2.00D to +2.50D 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 minimum of 10 minutes

4. Determine Lens Cylinder and Axis Orientation

    a. Locate the Orientation Marks

    To help determine the proper orientation of the toric lens, you'll find two primary marks about 1mm 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' symmetrical stabilization design, either mark can represent the vertical position – there is no "top" and "bottom" as in a prismballasted lens. You don't need to view both marks to assess orientation; simply look for the 6 o'clock mark as you would with a prism-ballasted lens.

     **Figure 1**

    You'll need a biomicroscope and a 1mm or 2mm parallelepiped 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.

    b. 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.

    c. 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 or beam axis dial 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.

5. 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.

For the Sphere:

If sphere Rx ≥ ±4.00D, compensate for vertex distance. If sphere Rx < ±4.00D, vertex compensation is generally not necessary, however may be required for larger vertex distances.

For the Cylinder:

Adjust the axis by the drift angle using the LARS method.

Case Examples

Example 1

Manifest (spectacle) refraction:

O.D. -2.50D / -1.75D x 180° 20/20

O.S. -2.00D / -1.00D x 180° 20/20

Because a toric lens with -1.00D cylinder will leave -0.75D of uncorrected cylinder in the right eye, you might choose to add -0.25D sphere to compensate, as shown below. Choose a diagnostic lens for each eye with an axis 180°. Place the lens on each eye and allow a minimum of 10 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, no axis adjustment is needed. If the lens has not yet stabilized, recheck until stable.

Here is the Rx Prescribed:

O.D. -2.75D / -1.00D x 180°

O.S. -2.00D / -1.00D x 180°

Example 2

Manifest (spectacle) refraction:

O.D. -3.00D / -1.00D x 90° 20/20

O.S. -4.75D / -1.25D x 90° 20/20

Since the manifest refraction in the left eye called for a power of -4.75D, compensating for vertex distance the sphere is reduced by 0.25D to -4.50D. Choose a diagnostic lens of -3.00D / -1.00D x 90° for the right eye and -4.50D / -1.00D x 90° for the left eye, the nearest lenses available to the power and axis needed. Place the lens on each eye and

allow a minimum of 10 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 bottom orientation mark on the right lens rotates left from the 6 o'clock position by 10° and remains stable in this position. Compensate the 10° axis drift to the left by adding it to the manifest refraction axis.

Here is the Rx Prescribed:

O.D. -3.00D / -1.00D x 100°

Left Eye

The bottom 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 to the right by subtracting it from the manifest refraction axis.

Here is the Rx Prescribed:

O.S. -4.50D / -1.00D x 80°

6. Allow the lens to settle for a minimum 10 minutes
7. Assess distance and near vision binocularly and monocularly
8. Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near
9. 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.
10. If vision is still unacceptable, make adjustments in power as necessary (see **"Multifocal Toric 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 as per standard of care (see **PATIENT MANAGEMENT** section).

B. Multifocal Toric Troubleshooting

Unacceptable Near Vision:

If it has been determined that no change is required based on the over-refraction, then add +0.25D 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 (“Select the Initial Trial Lens”) to assess if the vision is acceptable.

C. 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 at www.acuvue.com.

MONOVISION FITTING GUIDELINES

A. Patient Selection

Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient 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.

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 10 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



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PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: CR-6612 Pilot Dispensing Study of Two Marketed Daily Disposable Multifocal Contact Lenses

Version and Date: 3.0 17 July 2025

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

I agree to conduct this study according to ISO 14155[1], Declaration of Helsinki[2] , United States (US) Code of Federal Regulations (CFR)[3], and International Council for Harmonization Good Clinical Practice E6(R2) (ICH GCP)[4] and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. I, as the Principal Investigator, am responsible for ensuring that all clinical site personnel, including Sub-Investigators, adhere to all regulations and 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 subjects.

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

I confirm I am licensed, registered, or certified to provide optometric care to subjects in the state or Country of Study Conduct.

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.

Principal Investigator:

_____ _____
Signature Date

_____
Name and Professional Position (Printed)

Institution/Site: _____
Institution/Site Name

_____
Institution/Site Address