Clinical Study Protocol
Johnson & Johnson Vision Care, Inc.

Evaluation of Dryness in a Silicone Hydrogel Daily Disposable Contact Lens

Protocol CR-6388

Version: 3.0

Date: 07 April 2021

Investigational Products: Alcon DAILIES® Aqua Comfort Plus® (nelfilcon A), Alcon DAILIES TOTAL1® (delfilcon A), CooperVision® clariti® 1 day (somofilcon A), CooperVision® MyDay® (stenfilcon A), Johnson & Johnson 1-Day ACUVUE® Moist (etafilcon A), and Johnson and Johnson ACUVUE OASYS®1-Day with HydraLuxe™ Technology (senofilcon A) are daily disposable marketed and FDA approved contact lenses which will be worn in daily disposable modality

Keywords: Alcon DAILIES® Aqua Comfort Plus® (nelfilcon A), Alcon DAILIES TOTAL1® (delfilcon A), CooperVision® clariti® 1 day (somofilcon A), CooperVision® MyDay® (stenfilcon A), Johnson & Johnson 1-Day ACUVUE® Moist (etafilcon A), and Johnson and Johnson ACUVUE OASYS®1-Day with HydraLuxe™ Technology (senofilcon A), habitual lens, daily disposable, daily wear, dispensing, symptomatic, CLDEQ-8, CLUE

Statement of Compliance to protocol, GCP and applicable regulatory guidelines:
This trial will be conducted in compliance with the protocol, ISO 14155,[1] the International Council for Harmonization Good Clinical Practice E6(R2) (ICH GCP),[2] the Declaration of Helsinki,[3] and all applicable regulatory requirements.

Confidentiality Statement:
This document contains confidential information, which should not be copied, referred to, released or published without written approval from Johnson & Johnson Vision Care, Inc. The information may not be disclosed to others except to the extent necessary to obtain Institutional Review Board/Independent Ethics Committee approval and informed consent, or as required by International, Federal and State Laws, as applicable. Persons to whom this information is disclosed must be informed that this information is privileged and confidential and that it should not be further disclosed without the written permission of Johnson & Johnson Vision Care, Inc. Any supplemental information that may be added to this document is also confidential and proprietary to Johnson & Johnson Vision Care, Inc. and must be kept in confidence in the same manner as the contents of this document.

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PROTOCOL TITLE, NUMBER, VERSION AND DATE

Title: Evaluation of Dryness in a Silicone Hydrogel Daily Disposable Contact Lens
Protocol Number: CR-6388
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SPONSOR NAME AND ADDRESS

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

MEDICAL MONITOR

[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 your assigned clinical research associate.

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

AUTHORIZED SIGNATURES

The signatures below constitutes the approval of this protocol and the attachments and provide the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations,[4] ISO 14155,[1] ICH guidelines,[2] and the Declaration of Helsinki.[3]

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
Biostatistics Reviewer	**See Electronic Signature Report** [redacted]	DATE
Data Management	**See Electronic Signature Report** [redacted]	DATE
Medical Safety Officer	**See Electronic Signature Report** [redacted]	DATE
Fellow Reviewer	**See Electronic Signature Report** [redacted]	DATE
Approver	**See Electronic Signature Report** [redacted]	DATE

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Date
1.0	[redacted]	Original Protocol	10 MAR 2020
2.0	[redacted]	1. Update to new protocol template 2. Add pre-screening questions appendix 3. Removed pre-screen questionnaire related inclusion criteria. 4. Add COVID-19 Work Instruction in the Appendix of this protocol 5. Update preference question response set 6. Updated Biostatistics Reviewer to Senior Biostatistician 7. Updated section 4 to clarification the description of the study design and the study design rationale. 8. Updated section 5.1 to clarification the randomization instructions to the clinical sites on use of the randomization scheme. 9. Updated section 8.2 to clarify that subjects are to be discontinued if they miss any scheduled study visits. 10. Updated section 14.2 to include sample size calculations for CLUE endpoints . 11. Updated section 14.5, 14.6 and 14.7 to correct statisitical analysis plan details. 12. Author / study responsible clinician / medical monitor updated from [redacted]	25 MAR 2021
3.0	[redacted]	13. Updated typo "R stasis" to "Restasis" for exclusion #12 in section 3.3 14. Removed verbiage "(for subjects that are discontinued early)" in step F3.	07 APR 2021

SYNOPSIS

Protocol Title	Evaluation of Dryness in a Silicone Hydrogel Daily Disposable Contact Lens
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Marketing claims, Phase 4
Trial Registration	This study will be registered on ClinicalTrials.gov based on the following: this study utilized a marketed product
Test Article(s)	Test: Johnson and Johnson ACUVUE OASYS®1-Day with HydraLuxe™ Technology (Senofilcon A) (AO1D) Control: Subject's habitual lens, including: - Alcon DAILIES® Aqua Comfort Plus® (nelfilcon A) (DACP) - Alcon DAILIES TOTAL1® (delfilcon A) (DT1) - CooperVision® clariti® 1 day (somofilcon A) (Clariti) - CooperVision® MyDay® (stenfilcon A), (MyDay) - Johnson & Johnson 1-Day ACUVUE® Moist (etafilcon A) (Moist)
Wear and Replacement Schedules	Wear Schedule: Daily Replacement Schedule: Daily
Objectives	Primary Objective: The primary objective of this study is to demonstrate that AO1D is non-inferior to habitual lenses with respect to subjective comfort from baseline to 2-week follow-up in a population of symptomatic daily disposable contact lens wearers. Secondary Objectives: The secondary objectives of this study are to demonstrate that AO1D is non-inferior with respect to (1) change in contact lens related dry eye symptoms from baseline to 2-week follow-up, (2) subjects' habitual lenses with respect to contact lens related dry eye symptoms and (3) subjective comfort at 2-week follow-up in a population of symptomatic daily disposable contact lens wearers.

Study Endpoints	Primary Endpoint: 1. Change in the CLUE comfort score from baseline at 2-week follow-up Secondary Endpoints: 1. Change in the CLDEQ-8 total score from baseline at 2-week follow-up 2. CLDEQ-8 total score at 2-week follow-up 3. CLUE comfort score at 2-week follow-up Tertiary Endpoints 1. CLDEQ-8 Individual Questions: • During a typical day in the past 2 weeks, how often did your eyes feel discomfort while wearing your contact lenses? • When your eyes felt discomfort with your contact lenses, how intense was this feeling of discomfort (on a scale of 1-5) at the end of your wearing time? • During a typical day in the past 2 weeks, how often did your eyes feel dry? • When your eyes felt dry, how intense was this feeling of dryness (on a scale of 1-5) at the end of your wearing time? 2. CLUE Comfort Individual Questions: • These contact lenses were very comfortable (C001_2) • I could wear these contact lenses comfortably for as long as I wanted to (C008_1) • These lenses were very comfortable at the end of the day (C020_2) • My eyes felt very dry at the end of the day (C021_2) • My eyes felt dry all day (C022_1) • My eyes felt dry at the end of the day (C023_1) • I have experienced dry eyes (C041_1) • The comfort of these lenses decreased throughout the day (C061_1) 3. CLUE Vision Individual Questions: • I had very good vision at the end of the day (V004_2) • I experienced fluctuations in the quality of my vision (V009_1) • I was very satisfied with the quality of my vision in dim lighting (V013_2)

	• I was satisfied with the quality of my vision at night (V014_1) • I was very satisfied with the clarity of distant objects (V034_2) • I was satisfied with the clarity of near objects (V035_1) • I was very satisfied by the clarity of my vision at the end of the day (V037_2) • My vision with these lenses was exceptional (V124_3) 4. MRD Questions: • These lenses help to reduce the feeling of dryness at the end of the day (MIS01977) • I would recommend them to people who experience dryness with their own contact lenses (P3_0021_p10) • Have you been able to use these lenses for 8 hours or more with digital devices? (MIS01978) Please think about your experience with your current contact lenses / the study contact lenses. Please indicate how you would rate the contact lenses on each of the following characteristics. • Not making your eyes feel dry throughout the day (P3_0006_p38) • Keeping your eyes from feeling dry at the end of the day (P3_0006_p39) Please indicate how often, if ever, you experienced the following sensations when you wore your current contact lenses/ the study contact lenses. • Burning (P3_0023_p01) • Dryness (P3_0023_p02) • Grittiness (P3_0023_p03) 5. Preference Questions: • Thinking about the last two lenses you tried, which lens did you prefer overall? (PREF1) • Overall Comfort (PREF10_3) • Comfort at the end of the day (PREF10_5) • Overall vision (PREF10_7) • Keeping your eyes from feeling dry (PREF10_14)

	Other Endpoints: Average Wear Time / Comfortable Wear Time Safety Endpoints: Adverse events, lens fitting characteristics, slit lamp findings, entrance/exit visual acuity, subject reported ocular symptoms
Study Design	This is a multi-site, randomized, bilateral, dispensing, parallel design study with two arms (ARM 1 and ARM 2). Subjects may be pre-screened for contact lens related dryness symptoms via phone or email prior to entrance to the study. Subjects in ARM 1 will be fitted into AO1D and followed up after 2 weeks of wear. Subject will be masked to the identity of the lens assigned. There will be 2 visits as follows: • Pre-screen questions via phone or email • Visit 1: Screening, baseline evaluation, fitting AO1D • Visit 2: 2-week follow up and final evaluation Subjects in ARM 2 will be first fitted into their habitual lenses and dispensed for 2 weeks. At the follow-up visit, subjects will be fitted into AO1D and followed up after 2 weeks of wear. Subjects will not be masked to their habitual lens (open label), but they will be masked to the identity of AO1D during the second period of wear. There will be 3 visits as follows: • Pre-screen questions via phone or email • Visit 1: Screening, baseline evaluation, fitting habitual lens • Visit 2: 2-week habitual lens follow up; fitting AO1D • Visit 3: 2-week AO1D follow up and final evaluation See the flow chart at the end of the synopsis table for the schematic of the study visits and procedures of main observations.
Sample Size	Approximately 112 potential subjects will be enrolled via. pre-screening, and approximately 80 subjects (40 per arm) are targeted to complete the study.
Study Duration	The study will last approximately 4 months and include approximately a 3-month enrollment period.

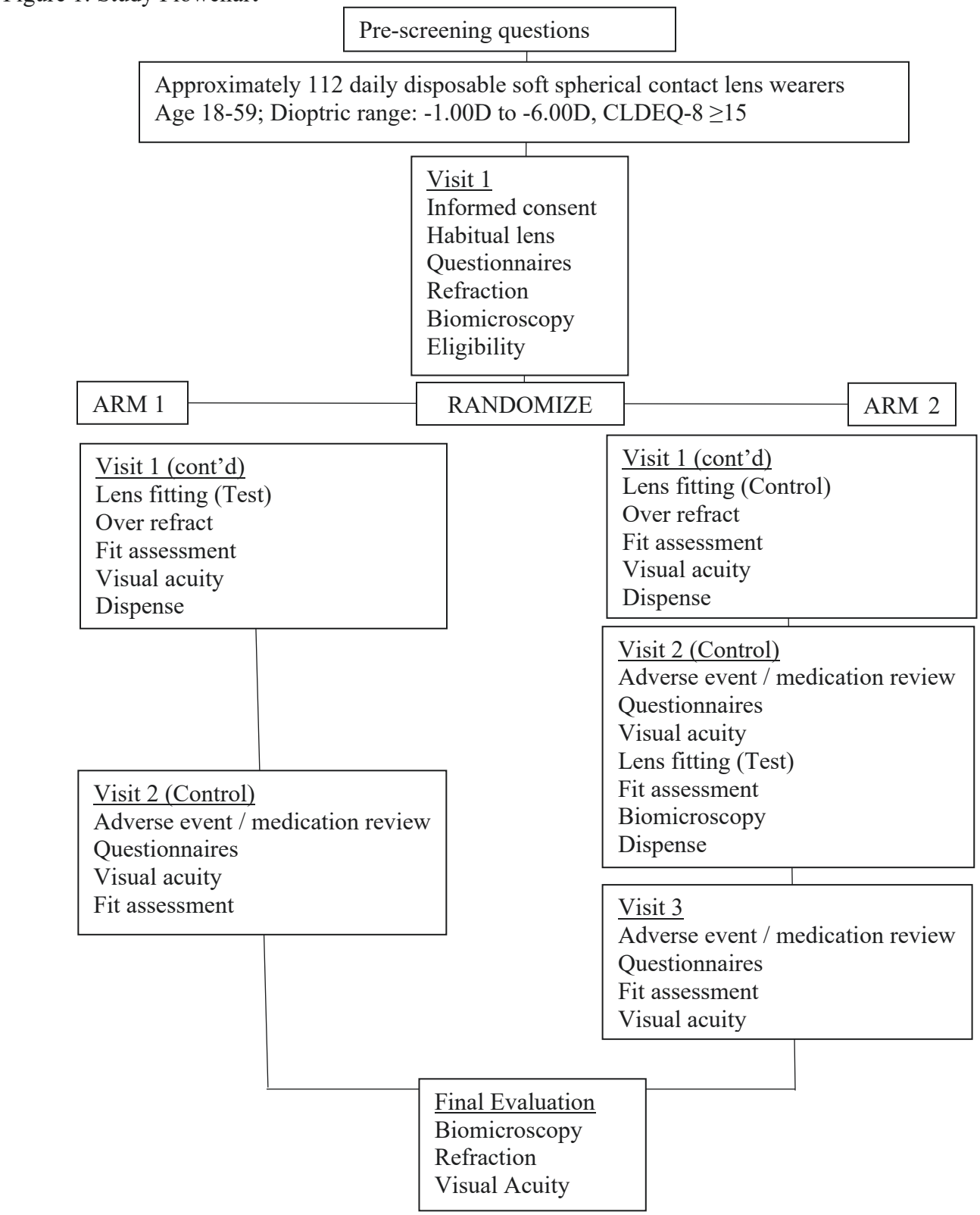
Anticipated Study Population	Subjects, ages 18-59 that are current daily disposable spherical soft contact lens wearers are to be enrolled in this clinical study. Across sites, approximately 112 potential subjects will be enrolled via pre-screening, and approximately 80 subjects (40 per arm) are targeted to complete the study. Subjects will be pre-screened via phone or email to determine symptomatology and targeted for enrollment with a questionnaire to identify contact lens related dry eye symptoms. Upon enrollment, eligible subjects will have a CLDEQ-8 score of 15 or greater. Subjects who habitually use ACUVUE OASYS®1-Day will not be eligible. Recruitment will aim to enroll subjects evenly by habitual lens type by site. Considering subject availability and regional differences as potential barriers to the exact proportion of 20% per lens type by site, the maximum for each habitual lens type will be capped at 40% per lens type by site.

Eligibility Criteria - Inclusion	Potential subjects must satisfy all of the following criteria to be enrolled in the study: Inclusion Criteria after Screening: 1. The subject must 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. Between 18 and 59 (inclusive) years of age at the time of screening. 4. Be a daily disposable current soft contact lens wearer in both eyes with a minimum of 6 days/week wear time over the last 1 month by self-report. 5. Have a CLDEQ-8 score of 15 or greater with the habitual lens. 6. Subjects must possess a pair of spectacles for distance correction. 7. Subject's habitual lens must be the following lens types: Alcon DAILIES® Aqua Comfort Plus®, Alcon DAILIES TOTAL1®, CooperVision® clariti® 1 day, CooperVision® MyDay®, or Johnson & Johnson 1-Day ACUVUE® Moist Inclusion Criteria after Baseline 8. The subject's vertex corrected spherical distance refraction must be in the range of -1.00 D to -6.00 D (inclusive) in each eye. 9. The magnitude of subject's vertex corrected refractive cylinder must be less than 1.00 diopter in each eye. 10. Have spherical best corrected visual acuity of 20/25 or better in each eye.

Eligibility Criteria – Exclusion	Potential subjects who meet any of the following criteria will be excluded from participating in the study: Exclusion Criteria after Screening: 1. Subject's habitual lens is ACUVUE OASYS®1-Day. 2. Currently pregnant or lactating, by self-report. 3. Any ocular or systemic allergies, disease or use of medication which may interfere with contact lens wear (at the discretion of the investigator). 4. Any active ocular abnormalities/conditions that may interfere with contact lens wear (at the discretion of the investigator). 5. Any infectious diseases (e.g. hepatitis, tuberculosis) or a contagious immunosuppressive disease (e.g. HIV), by self-report. 6. Any corneal distortion resulting from previous hard or rigid gas permeable contact lens wear. 7. Habitual contact lens wear modality as extended wear (≥1 night per month of extended wear). 8. Habitual contact lens is rigid gas permeable, toric, monovision or multi-focal 9. Any previous, or planned (during the course of the study) ocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.). 10. Participation in any contact lens or lens care product clinical trial within 2 weeks prior to study enrollment. 11. Employee or employee's immediate family member of clinical site (e.g., Investigator, Coordinator, Technician). 12. Current habitual use of Restasis, Xiidra, ocular steroids, or any medication (Rx or over the counter (OTC)) that may interfere with contact lens wear (at the discretion of the investigator). Exclusion Criteria after Baseline 13. Any ocular allergies, infections or other ocular abnormalities that are known to interfere with contact lens wear and/or participation in the study. This may include, but not be limited to entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or corneal distortion. 14. Any Grade 3 or greater biomicroscopy findings (this includes, corneal edema, corneal staining, corneal vascularization, conjunctival injection, tarsal abnormalities, bulbar injection) on the FDA classification scale [redacted]
Disallowed Medications/Interventions	Current habitual use of Restasis, Xiidra, ocular steroids, or any medication (Rx or over the counter (OTC)) that may interfere with contact lens wear (at the discretion of the investigator)

Measurements and Procedures	PRO questionnaires (comfort, vision, and dryness), lens fit assessment, and safety parameters (slit lamp findings, entrance/exit visual acuity).
Microbiology or Other Laboratory Testing	None
Study Termination	The occurrence of an Unanticipated Adverse Device Effect (UADE) or Serious Adverse Event (SAE) for which a causal relationship to a test article cannot be ruled out, will result in stopping further dispensing investigational product. In the event of a UADE or SAE, the Sponsor Medical Monitor may unmask the treatment regimen of subject(s) and may discuss this with the Principal Investigator before any further subjects are enrolled.
Ancillary Supplies/ Study-Specific Materials	Non-preserved saline, sodium fluorescein
Principal Investigator(s) and Study Institution(s)/Site(s)	A full list of Principal Investigators, clinical sites, and institutions is kept separately from the Study Protocol and is included in the study Trial Master File.

Figure 1: Study Flowchart



COMMONLY USED ABBREVIATIONS, ACRONYMS AND DEFINITIONS OF TERMS

ADD	Plus Power Required For Near Use
ADE	Adverse Device Effect
AE	Adverse Event/Adverse Experience
BCVA	Best Corrected Visual Acuity
BSCVA	Best Spectacle Corrected Visual Acuity
CFR	Code of Federal Regulations
CLUE	Contact Lens User Experience
COAS	Complete Ophthalmic Analysis System
COM	Clinical Operations Manager
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
CT	Center Thickness
[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
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	Intent-to-Treat
JJVC	Johnson & Johnson Vision Care, Inc.
LC	Limbus Center
LogMAR	Logarithm of Minimal Angle of Resolution
MedDRA©	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NIH	National Institutes of Health
OD	Right Eye
OHRP	Office for Human Research Protections
OHSR	Office for Human Subjects Research
OS	Left Eye
OU	Both Eyes
PD	Protocol Deviation
PHI	Protected Health Information

PI	Principal Investigator
PIG	Patient Instruction Guide
PQC	Product Quality Complaint
PRO	Patient Reported Outcome
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
VA	Visual Acuity

1. INTRODUCTION AND BACKGROUND

Dryness and discomfort are frequent complaints of contact lens wearers. Modern contact lens products, such as ACUVUE OASYS®1-Day may provide relief to subjects who experience symptoms of dryness related to contact lens wear. This study will evaluate contact lens related dry eye symptoms and subjective comfort in ACUVUE OASYS® 1-Day and subject's habitual daily disposable contact lenses.

1.1. Name and Descriptions of Investigational Products

This study will evaluate the commercially available marketed products (ACUVUE OASYS® Brand Contact Lenses 1-Day with HydraLuxe™ Technology). Further details about the test articles are found in Section 6 of this protocol.

1.2. Intended Use of Investigational Products

The intended use of the investigative product is for correcting myopia. During the study, each test article will be worn bilaterally in daily wear, daily disposable modality for at least 8 hours per day for approximately two weeks.

1.3. Summary of Findings from Nonclinical Studies

Not Applicable – marketed product only.

1.4. Summary of Known Risks and Benefits to Human Subjects

The following risks/adverse events can be associated with wearing soft contact lenses in general:
• The eyes may burn, sting and/or itch.
• There may be a feeling of something in the eye (foreign body, scratched area).
• There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion.

• There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
• There may be excessive watering, unusual eye secretions, or redness of the eye.
• Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

There is no direct benefit to the subject for participating in the study, although they will be able to try marketed contact lenses and may find improvement in symptoms of dryness and discomfort related to contact lens wear.

For the most comprehensive clinical information regarding marketed lenses: Alcon DAILIES® Aqua Comfort Plus® (nelfilcon A), Alcon DAILIES TOTAL1® (delfilcon A), CooperVision® clariti® 1 day (somofilcon A), CooperVision® MyDay® (stenfilcon A), Johnson & Johnson 1-Day ACUVUE® Moist (etafilcon A), and Johnson and Johnson ACUVUE OASYS®1-Day with HydraLuxe™ Technology (senofilcon A), refer to the latest version of the associated package insert (APPENDIX C: PACKAGE INSERTS).

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

Symptoms of dryness related to contact lens wear will be evaluated for study inclusion by the Contact Lens Dry Eye Questionnaire (CLDEQ-8). The CLDEQ-8 is a validated outcome measure for soft contact lenses wearers to evaluate the status of and change in overall opinion of soft contact lenses, as seen in Figure 2.[7] It has been highly correlated with habitual baseline status and change in overall opinion when subjects are refit with contact lenses.[5] A CLDEQ-8 score of ≥12 is proposed to identify contact lens wearers who could benefit from clinical management of their CL- related symptoms.[6] A three point change in CLDEQ-8 scores has also been shown to be clinically important.[6] For this study, to ensure that symptomatic subjects are being recruited, the inclusion criteria will have a CLDEQ cut off of ≥15.

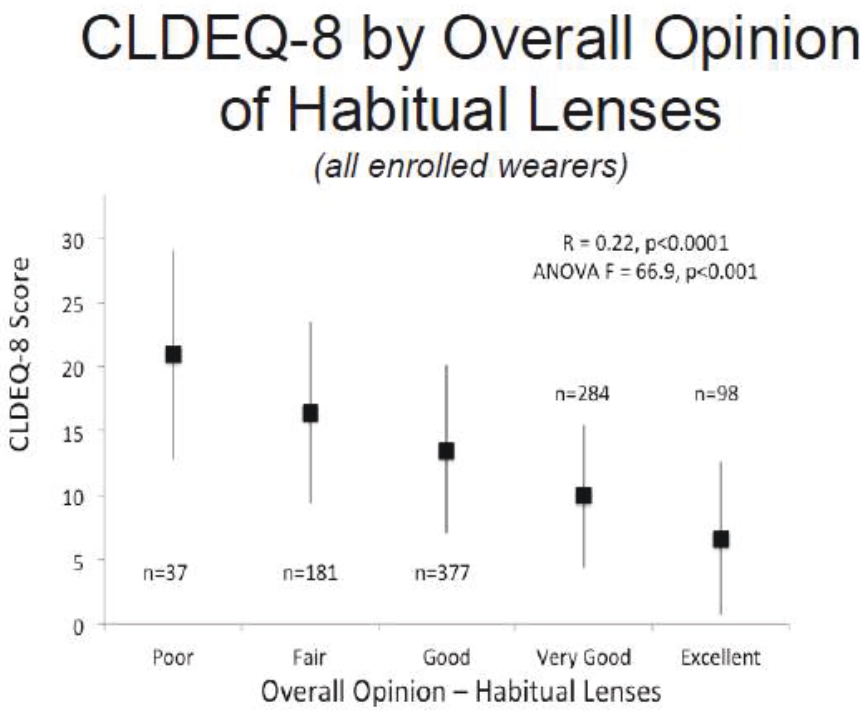


Figure 2: CLDEQ-8 by Overall Opinion of Habitual Lenses[7]

For the most comprehensive clinical information regarding marketed lenses: Alcon DAILIES® Aqua Comfort Plus® (nelfilcon A), Alcon DAILIES TOTAL1® (delfilcon A), CooperVision® clariti® 1 day (somofilcon A), CooperVision® MyDay® (stenfilcon A), Johnson & Johnson 1-Day ACUVUE® Moist (etafilcon A), and Johnson and Johnson ACUVUE OASYS®1-Day with HydraLuxe™ Technology (senofilcon A), refer to the latest version of the associated package insert. (APPENDIX C: PACKAGE INSERTS).

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

The primary objective of this study is to demonstrate that AO1D is non-inferior to habitual lenses with respect to the change in contact lens subjective comfort from baseline to 2-week follow-up in a population of symptomatic daily disposable contact lens wearers.

The secondary objectives of this study are to demonstrate that AO1D is non-inferior with respect to the (1) change in contact lens related dry eye symptoms, (2) to subjects' habitual lenses with respect to contact lens related dry eye symptoms and (3) subjective comfort at 2-week follow-up in a population of symptomatic daily disposable contact lens wearers.

This study is conducted with the primary intent to support the market claims on the AO1D.

2.2. Endpoints

Primary Endpoint

- Change in CLUE Comfort score from baseline to 2-week follow-up

Subjective overall vision and comfort scores will be assessed using Contact Lens User Experience (CLUE) questionnaire.[8] CLUE is a validated patient-reported outcomes questionnaire to assess patient-experience attributes of soft, disposable contact lenses (comfort, vision, handling, and packaging) in a contact-lens wearing population in the US, ages 18-65. Scores follow a normal distribution with a population average score of 60 (SD 20), where higher scores indicate a more favorable/positive response.[9] A 5-point increase in an average CLUE score translates into 10% shift in the distribution of scores for population of soft disposable contact lens wearers.

Secondary Endpoints

- Change in CLDEQ-8 total score from baseline to 2-week follow-up
- CLDEQ-8 total score at 2-week follow-up
- CLUE Comfort score at 2-week follow-up

The CLDEQ-8 is a validated outcome measure for soft contact lenses wearers. It has been highly correlated with habitual baseline status and change in overall opinion when subjects are refit with contact lenses.[5] A CLDEQ-8 total score of ≥12 is proposed to identify contact lens wearers who could benefit from clinical management of their contact lens related symptoms. A three points change in CLDEQ-8 total scores has also been shown to be clinically important.[6] This study will include the symptomatic subjects who will have a CLDEQ total score of ≥15.

Tertiary Endpoints

1. CLDEQ-8 Questions: CLDEQ-8 individual questions will be analyzed only if primary and/or secondary endpoints are met.
   - During a typical day in the past 2 weeks, how often did your eyes feel discomfort while wearing your contact lenses?
   - When your eyes felt discomfort with your contact lenses, how intense was this feeling of discomfort (on a scale of 1-5) at the end of your wearing time?
   - During a typical day in the past 2 weeks, how often did your eyes feel dry?
   - When your eyes felt dry, how intense was this feeling of dryness (on a scale of 1-5) at the end of your wearing time?

2. CLUE Comfort Questions: CLUE comfort questions will be analyzed only if primary and/or secondary endpoints are met.
   - These contact lenses were very comfortable (C001_2)
   - I could wear these contact lenses comfortably for as long as I wanted to (C008_1)
   - These lenses were very comfortable at the end of the day (C020_2)
   - My eyes felt very dry at the end of the day (C021_2)
   - My eyes felt dry all day (C022_1)
   - My eyes felt dry at the end of the day (C023_1)

- I have experienced dry eyes (C041_1)
- The comfort of these lenses decreased throughout the day (C061_1)

3. CLUE Vision Questions:
   - I had very good vision at the end of the day (V004_2)
   - I experienced fluctuations in the quality of my vision (V009_1)
   - I was very satisfied with the quality of my vision in dim lighting (V013_2)
   - I was satisfied with the quality of my vision at night (V014_1)
   - I was very satisfied with the clarity of distant objects (V034_2)
   - I was satisfied with the clarity of near objects (V035_1)
   - I was very satisfied by the clarity of my vision at the end of the day (V037_2)
   - My vision with these lenses was exceptional (V124_3)

4. MRD Questions:
   - These lenses help to reduce the feeling of dryness at the end of the day (MIS01977)
   - I would recommend them to people who experience dryness with their own contact lenses (P3_0021_p10)
   - Have you been able to use these lenses for 8 hours or more with digital devices? (MIS01978)

Please think about your experience with your current contact lenses/ the study contact lenses. Please indicate how you would rate the contact lenses on each of the following characteristics.
- Not making your eyes feel dry throughout the day (P3_0006_p38)
- Keeping your eyes from feeling dry at the end of the day (P3_0006_p39)

Please indicate how often, if ever, you experienced the following sensations when you wore your current contact lenses/ the study contact lenses.
- Burning (P3_0023_p01)
- Dryness (P3_0023_p02)
- Grittiness (P3_0023_p03)

5. Preference Questions:
   - Thinking about the last two lenses you tried, which lens did you prefer overall? (PREF1)
   - Overall Comfort (PREF10_3)
   - Comfort at the end of the day (PREF10_5)
   - Overall vision (PREF10_7)
   - Keeping your eyes from feeling dry (PREF10_14)

<u>Other Endpoints</u>:
Average Wear Time / Comfortable Wear Time

Safety Endpoints:
Adverse events, lens fitting characteristics, slit lamp findings, entrance/exit visual acuity, subject reported ocular symptoms

2.3. Hypotheses

Primary Hypothesis:

The Primary hypothesis will be evaluated between the two study arms; only the first period will be considered for the second study arm.

Primary Hypotheses	
Endpoint	Hypothesis
CLUE Comfort	The Test lens will be non-inferior to the Habitual lens with respect to the change in CLUE comfort score from baseline at 2-week follow-up. A non-inferiority margin of -5 points on the CLUE scale will be used.

Secondary Hypotheses:

The primary hypothesis must be met in order to test the secondary hypotheses. The secondary hypothesis regarding the change in CLDEQ-8 Scores will be evaluated between the two study arms; only the first period will be considered for the second study arm. The remaining two secondary hypotheses will be evaluated within the second study arm only.

Secondary Hypotheses	
Endpoint	Hypothesis
Change in CLDEQ-8 Total Score	The Test lens will be non-inferior to the Habitual lens with respect to the change in CLDEQ-8 total score from baseline at 2-week follow-up. A non-inferiority margin of 3 points on the CLDEQ-8 scale will be used.
CLDEQ-8 Total Score	The Test lens will be non-inferior to the Habitual lens with respect to CLDEQ-8 total score at 2-week follow-up. A non-inferiority margin of 3 CLDEQ-8 points will be used.
CLUE Comfort	The Test lens will be non-inferior to the Habitual lens with respect to CLUE comfort score at 2-week follow-up. A non-inferiority margin of -5 CLUE points will be used.

The primary hypothesis must be met in order to satisfy the objective of the study.

Tertiary Hypotheses:
Tertiary hypotheses will be evaluated in the following manner.

1. If the primary hypothesis is not met, then the tertiary hypotheses will not be evaluated.

2. If the primary and secondary hypotheses are met: All tertiary hypotheses will be evaluated for both between the study arms and within the second arm.
    a. If the primary and secondary hypotheses regarding CLUE comfort are met then the tertiary hypotheses relevant to this endpoint will be evaluated for both between the study arms and within the second arm.
    b. If only the primary hypothesis for CLUE comfort is met then, then associated tertiary hypotheses relevant to this endpoint will only be evaluated between study arms.
    c. If both secondary hypotheses regarding CLDEQ8-Scores are met, then the tertiary hypotheses relevant to this endpoint will be evaluated for between the study arms only and within the second arm.
    d. If only 1 of the secondary hypotheses regarding CLDEQ8-scores is met, then the associated tertiary hypotheses relevant to this endpoint will be evaluated between study arms.

Tertiary Hypotheses	
Endpoint	Hypothesis
CLDEQ-8 Questions	The Test lens will be non-inferior to the Habitual lens with respect to the following CLDEQ-8 individual questions at 2-week follow-up. An odds ratio margin of 0.67 will be used. 1. During a typical day in the past 2 weeks, how often did your eyes feel discomfort while wearing your contact lenses? 2. During a typical day in the past 2 weeks, how often did your eyes feel dry? 3. When your eyes felt discomfort with your contact lenses, how intense was this feeling of discomfort (on a scale of 1-5) at the end of your wearing time? 4. When your eyes felt dry, how intense was this feeling of dryness (on a scale of 1-5) at the end of your wearing time?

Tertiary Hypotheses	
Endpoint	Hypothesis
CLUE Comfort Questions	The Test lens will be non-inferior to the Habitual lens with respect to the following CLUE comfort individual questions at 2-week follow-up. An odds ratio margin of 0.67 will be used. 1. These contact lenses were very comfortable (C001_2) 2. I could wear these contact lenses comfortably for as long as I wanted to (C008_1) 3. These lenses were very comfortable at the end of the day (C020_2) 4. My eyes felt very dry at the end of the day (C021_2) 5. My eyes felt dry all day (C022_1) 6. My eyes felt dry at the end of the day (C023_1) 7. I have experienced dry eyes (C041_1) 8. The comfort of these lenses decreased throughout the day (C061_1)
CLUE Vision Questions	The Test lens will be non-inferior to the Habitual lens with respect to the following CLUE vision individual questions at 2-week follow-up. An odds ratio margin of 0.67 will be used. 1. I had very good vision at the end of the day (V004_2) 2. I experienced fluctuations in the quality of my vision (V009_1) 3. I was very satisfied with the quality of my vision in dim lighting (V013_2) 4. I was satisfied with the quality of my vision at night (V014_1) 5. I was very satisfied with the clarity of distant objects (V034_2) 6. I was satisfied with the clarity of near objects (V035_1) 7. I was very satisfied by the clarity of my vision at the end of the day (V037_2) 8. My vision with these lenses was exceptional (V124_3)
MRD Questions	The Test lens will be non-inferior to the Habitual lens with respect to the following MRD individual questions at 2-week follow-up. An odds ratio margin of 0.67 will be used. 1. These lenses help to reduce the feeling of dryness at the end of the day (MIS01977) 2. I would recommend them to people who experience dryness with their own contact lenses (P3_0021_p10) 3. Have you been able to use these lenses for 8 hours or more with digital devices? (MIS01978) 4. Not making your eyes feel dry throughout the day (P3_0006_p38) 5. Keeping your eyes from feeling dry at the end of the day (P3_0006_p39) 6. Burning (P3_0023_p01) 7. Dryness (P3_0023_p02) 8. Grittiness (P3_0023_p03)

Tertiary Hypotheses	
Endpoint	Hypothesis
Preference Questions	The Test lens will be superior to the Habitual lens with respect to the preference questions at 2-week follow-up: • Based on your overall opinion of both study lenses, do you prefer one lens more than the other? (PVC015_1) • Overall Comfort (PREF10_3) • Comfort at the end of the day (PREF10_5) • Overall vision (PREF10_7) • Keeping your eyes from feeling dry (PREF10_14)

3. TARGETED STUDY POPULATION

3.1. General Characteristics

Approximately 112 potential subjects will be enrolled via pre-screening, and approximately 80 subjects (40 per arm) are targeted to complete the study. Subjects, ages 18-59 that are current daily disposable spherical soft contact lens wearers are to be enrolled in this clinical study.

Subjects will be pre-screened to determine symptomatology and targeted for enrollment with a \ questionnaire (APPENDIX F). Subjects whose daily disposable lens is the same as the test lens, ACUVUE OASYS®1-Day will not be eligible.
Recruitment will aim to enroll subjects evenly by habitual lens type by site. Considering subject availability and regional differences as potential barriers to the exact proportion of 20% per lens type by site, the maximum for each habitual lens type will be capped at 40% per lens type by site

3.2. Inclusion Criteria

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

Inclusion Criteria after Screening:

1. The subject must 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. Between 18 and 59 (inclusive) years of age at the time of screening.
4. Be a daily disposable current soft contact lens wearer in both eyes with a minimum of 6 days/week wear time over the last 1 month by self-report.
5. Have a CLDEQ-8 score of 15 or greater with the habitual lens.
6. Subjects must possess a pair of spectacles for distance correction.

7. Subject's habitual lens must be the following lens types: Alcon DAILIES® Aqua Comfort Plus® , Alcon DAILIES TOTAL1®, CooperVision® clariti® 1 day, CooperVision® MyDay®, or Johnson & Johnson 1-Day ACUVUE® Moist.

Inclusion Criteria after Baseline:

8. The subject's vertex corrected spherical distance refraction must be in the range of -1.00 D to -6.00 D (inclusive) in each eye.
9. The magnitude of subject's vertex corrected refractive cylinder must be less than 1.00 diopter in each eye.
11. Have spherical best corrected visual acuity of 20/25 or better in each eye.

3.3. Exclusion Criteria

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

Exclusion Criteria after Screening:

1. Subject's habitual lens is ACUVUE OASYS®1-Day.
2. Currently pregnant or lactating, by self-report.
3. Any ocular or systemic allergies, disease or use of medication which may interfere with contact lens wear (at the discretion of the investigator).
4. Any active ocular abnormalities/conditions that may interfere with contact lens wear (at the discretion of the investigator).
5. Any infectious diseases (e.g. hepatitis, tuberculosis) or a contagious immunosuppressive disease (e.g. HIV), by self-report.
6. Any corneal distortion resulting from previous hard or rigid gas permeable contact lens wear.
7. Habitual contact lens wear modality as extended wear (≥1 night per month of extended wear).
8. Habitual contact lens is rigid gas permeable, toric, monovision or multi-focal.
9.. Any previous, or planned (during the course of the study) ocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.).
10. Participation in any contact lens or lens care product clinical trial within 2 weeks prior to study enrollment.
11. Employee or employee's immediate family member of clinical site (e.g., Investigator, Coordinator, Technician).
12. Current habitual use of Restasis, Xiidra, ocular steroids, or any medication (Rx or over the counter (OTC)) that may interfere with contact lens wear (at the discretion of the investigator).

Exclusion Criteria after Baseline:

13. Any ocular allergies, infections or other ocular abnormalities that are known to interfere with contact lens wear and/or participation in the study. This may include, but not be limited to entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or corneal distortion.

14. Any Grade 3 or greater biomicroscopy findings (this includes, corneal edema, corneal staining, corneal vascularization, conjunctival injection, tarsal abnormalities, bulbar injection) on the FDA classification scale [redacted]

3.4. Enrollment Strategy

Study subjects will be recruited from the Institution/clinical site's subject database and/or utilizing Independent Ethics Committee (IEC) or Institutional Review Board (IRB) approved materials. Subjects will be pre-screened via phone or e-mail to determine symptomatology and targeted for enrollment with a CLDEQ-8 questionnaire score of 15 or greater. Recruited subjects will be habitual contact lens wearers of 5 difference lenses; Alcon DAILIES® Aqua Comfort Plus® , Alcon DAILIES TOTAL1®, CooperVision® clariti® 1 day, CooperVision® MyDay®, or Johnson & Johnson 1-Day ACUVUE® Moist. Further details about allocation between habitual lens types within clinical sites is located in Section 4.3.

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

This is a multi-site, randomized, bilateral, dispensing, parallel design study with two arms (ARM 1 and ARM 2). Subjects will be pre-screened for contact lens related dryness symptoms via phone or email prior to enter the study.

Subjects in ARM 1 will be fitted into AO1D and followed up after 2 weeks of wear. Subjects will be masked to the identity of the lens assigned. There will be 2 visits as follows:

- Pre-screen questions via. phone or email
- Visit 1: Screening, baseline evaluation, fitting AO1D
- Visit 2: 2-week follow up and final evaluation

Subjects in ARM 2 will be first fitted into their habitual lenses and dispensed for 2 weeks. At the follow-up visit, subject will be fitted into AO1D and followed up after 2 weeks of where. Subjects will not be masked to their habitual lens (open label), but they will be masked to the identity of AO1D during the second period of wear. There will be 3 visits as follows:

- Pre-screen questions via phone or email
- Visit 1: Screening, baseline evaluation, fitting habitual lens
- Visit 2: 2-week habitual lens follow up; fitting AO1D
- Visit 3: 2-week AO1D follow up and final evaluation

4.2. Study Design Rationale

This study is a parallel design with two arms (ARM 1 and ARM 2). Subjects in the ARM 1 will receive the over labeled AO1D to wear bilaterally for about 2-weeks, while subject in ARM 2 will first receive the open labeled habitual lens to wear bilateral for approximately 2-weeks during the first wear period, then receive the over labeled AO1D in a bilateral fashion for approximately 2-weeks during the second wear period. This design will allow comparison

of the Test lens against subjects' habitual lenses in both between the two study arms and within the ARM 2.The primary endpoints will compare the two study arms in a parallel design setting

The secondary endpoints within ARM 2 are to compare subject's habitual lenses and AO1D lenses. This study design allows efficient comparison of the Test lens compared to subjects' habitual lens with minimal sample size, as well as allows subjects to experience both lens types in efficient comparison.

4.3. Enrollment Target and Study Duration

Approximately 112 potential subjects will be targeted to be enrolled via pre-screening, and approximately 80 subjects (40 per arm) are targeted to complete the study. Subjects will be considered enrolled in the study upon execution of informed consent.

Recruitment will aim to enroll subjects evenly by habitual lens type by site. Considering subject availability and regional differences as potential barriers to the exact proportion of 20% per lens type by site, the maximum for each habitual lens type will be capped at 40% per lens type by site. This will need to be monitored by the clinical site and clinical operations.

Depending on the study arm, there are 2 to 3 planned study visits and the study will last approximately 4 months, including approximately a 4-month enrollment period. Subjects who are discontinued prior to the final evaluation may be replaced at the discretion of the study sponsor.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

This will be a randomized 2-arm study. This study is parallel design with 2 arms such that the first arm (refer as "ARM 1") is designed with 1 lens (the AO1D) while the second arm (refer as "ARM 2") is designed with 2 lenses wearing (habitual lens and AO1D) respectively. Subjects in the ARM 1 will receive the AO1D in a bilateral fashion for approximately 2 weeks, while the subjects in ARM 2 will first receive the open labeled habitual lens to wear bilaterally for approximately 2 weeks during the first wear period and then receive the AO1D to wear bilaterally for approximately 2 weeks during the second wear period.

Subjects will be randomly assigned to either ARM 1 or ARM 2 based on a computer-generated randomization schedule prepared before the study initiation. The randomization scheme will be generated using the PROC PLAN procedure from Statistical Analysis System (SAS) Software Version 9.4 or higher (SAS Institute, Cary, NC)[10] provided by the study biostatistician.

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

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

5.2. Masking

This study will be a subject-masked to the Test lens. Subjects will be unaware of the identity of the Test lens as the Test lens will be over labeled. Due to the nature of the study design, each subject will be aware of the identity of the Control lens as it is her/his habitual lens. Investigators and clinical site personnel involved in the data collection may be aware of the identity of the investigational product.

Subjects who have had their treatment assignment unmasked are expected to return for all remaining scheduled evaluations. If necessary, subjects who are discontinued may be replaced to reach the subject completion target.

5.3. Procedures for Maintaining and Breaking the Masking

One randomization code (alphanumeric character) per test article will be assigned by the study biostatistician using the form [redacted]. For ARM 2, one randomization code will be used for subjects' habitual lens regardless of the lens brand and type. Upon database lock, the study biostatistician will release the randomization codes to the data management.

When dispensing test articles, the following steps should be followed:

1. Investigator or designee (documented on the Delegation Log) will consult the lens fitting schedule/randomization scheme to obtain the test article assignment for that subject prior to dispensing.
2. Investigator or designee will record the subject's number on the appropriate line of the randomization scheme.
3. Investigator or designee will pull the appropriate test articles from the study supply. All test articles that are opened, whether dispensed (placed/fit on eye or dispensed outside the clinical site) or not, must be recorded on the Test Article Accountability Log in the "Dispensed" section.

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 and Description	ACUVUE OASYS®1-Day with HydraLuxe™ Technology	Various US marketed spherical contact lenses

	Test	Control
		(Subjects' own habitual lenses)
Manufacturer	JJVC	Various
[redacted]	[redacted]	[redacted] – MyDay [redacted] – Dailies Total 1 [redacted] – Clariti 1-Day [redacted] – Dailies Aqua Comfort Plus [redacted] – 1-Day Moist
Lens Material	Senofilcon A	Various
Nominal Base Curve @ 22 °C	8.5	Various
Nominal Diameter @ 22 °C	14.3	Various
Nominal Distance Powers (D)	-1.00 to -6.00	-1.00 to -6.00
Nominal Cylinder Powers (D) and Axes	NA	NA
Nominal ADD Powers (D)	NA	NA
Oxygen Permeability (Dk)	103.0	Various
Wear Schedule in Current Study	Daily wear	Daily wear
Replacement Frequency	Daily disposable	Daily disposable
Packaging Form (vial, blister, etc.)	Blister	Various
Detail	JJVC marketed and FDA approved production lenses	US marketed and FDA approved production lenses: Alcon DAILIES® Aqua Comfort Plus®, Alcon DAILIES TOTAL1®, CooperVision® clariti® 1 day, CooperVision® MyDay®, or Johnson & Johnson 1-Day ACUVUE® Moist

The Test lens will be fitted for approximately 40 subjects per study arm, bilaterally in daily disposable modality for up to 16 days (40 subjects × 2 eyes × 16 days × 2 arms). Approximately 2560 Test lenses will be used in this study. The Control lens (i.e., habitual lens) will be fitted for approximately 40 subjects in ARM 2, bilaterally in daily disposably modality for up to 16 days (40 subjects × 2 eyes × 16 days × 1 arm). Approximately 2560 Test lenses (AO1D) will be used in this study. In total, approximately 3840 contact lenses will be used in this study

6.2. Ancillary Supplies/Products

The following supplies will be used in this study:

Table 2: Ancillary Supplies

	Supplies			
Name/Description	EyeCept/ Ophthalmic Saline	LacriPure/ Ophthalmic Saline	ScleralFil/ Ophthalmic Saline	Fluorescein strips (dye)
Manufacturer	Optics Laboratory, Inc.	Menicon	Bausch & Lomb	N/A
Preservative	None	None	None	None
Detail	Unit dose; Sterile; buffered isotonic (0.9% NaCl) aqueous solution	Unit dose; Sterile, isotonic (0.9%NaCl) saline solution	Unit dose; Sterile, buffered, isotonic, saline solution	Diagnostic

6.3. Administration of Test Articles

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

6.4. Packaging and Labeling

The test articles will be packaged in blisters. as the primary packaging. The Test lens will be over labeled to mask the subject to the identity of the lens. The Control lens will be open label. The study articles will be in investigational cartons sealed with a tamper evident seal, commercial cartons, or in plastic bags as the secondary packaging form. The sample study labels are shown below:

6.5. Storage Conditions

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

6.6. Collection and Storage of Samples

No samples will be collected as part of the study procedures.

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

6.7. Accountability of Test Articles

JJVC will provide the Investigator with sufficient quantities of study articles and supplies to complete the investigation. The Investigator is asked to retain all lens shipment documentation for the test article accountability records.

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

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

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

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

[redacted]

7. STUDY EVALUATIONS

7.1. Time and Event Schedule

Table 3: Time and Events

ARM 1 STUDY PROCEDURES			
Visit Information	Visit 0 Pre-Screening Via Phone or Email (optional)	Visit 1 Screening, Baseline, Randomization, Treatment 1 Fit & Dispense	Visit 2 Treatment 1 Follow-up, Final Evaluation
Time Point	Pre-Visit	Day 0	Day 14 ± 2 after Visit 1
Estimated Visit Duration	15 min	2.0 hours	1.5 hours
Preliminary Subject Identification	x		
Privacy Notice and Disclosure	x		
CLDEQ-8 Questionnaire		x	x
Statement of Informed Consent		x	
Demographics		x	
Medical History/ Concomitant Medications		x	x
Habitual Contact Lens Information	x	x	
Current contact lens wear times		x	x
Inclusion/Exclusion Criteria		x	
Baseline Questionnaires		x	
Contact lens removal		x	x
Entrance Snellen Visual Acuity		x	x
Keratometry		x	
Subjective Sphero-Cylindrical Refraction		x	x
Subjective Best Sphere Refraction		x	
Slit Lamp Biomicroscopy		x	x
Randomization		x	

ARM 1 STUDY PROCEDURES			
Visit Information	Visit 0 Pre-Screening Via Phone or Email (optional)	Visit 1 Screening, Baseline, Randomization, Treatment 1 Fit & Dispense	Visit 2 Treatment 1 Follow-up, Final Evaluation
Time Point	Pre-Visit	Day 0	Day 14 ± 2 after Visit 1
Estimated Visit Duration	15 min	2.0 hours	1.5 hours
Lens Selection		x	
Lens Insertion		x	
Lens Settling		x	
Lens Fit Assessment		x	x
Best Sphere Over Refraction		x	
Lens Power Modification		x	
Subject Reported Ocular Symptoms		x	x
Exit Snellen Visual Acuity		x	
Continuance		x	
Dispense		x	
Dispense Patient Instruction Guide		x	
Subject Instruction		x	
Adverse Events and Concomitant Medications Review			x
Compliance			x
Follow-up questionnaires			x
Final Exam Form			x

ARM 2 STUDY PROCEDURES				
Visit Information	Visit 0 Pre-Screening Via Phone or Email (optional)	Visit 1 Screening, Baseline, Randomization, Treatment 1 Fit & Dispense	Visit 2 Treatment 1 Follow-up, Treatment 2 Fit & Dispense	Visit 3 Treatment 2 Follow-up, Final Evaluation
Time Point	Pre-Visit	Day 0	Day 14 ± 2 after Visit 1	Day 14 ± 2 after Visit 2
Estimated Visit Duration	15 min	2.0 hours	1.5 hours	1.5 hours
Preliminary Subject Identification	x			
Privacy Notice and Disclosure	x			
CLDEQ-8 Questionnaire		x	x	x
Statement of Informed Consent		x		
Demographics		x		
Medical History/ Concomitant Medications		x	x	x
Habitual Contact Lens Information	x	x		
Current contact lens wear times		x	x	x
Inclusion/Exclusion Criteria		x		
Baseline Questionnaires		x		
Contact lens removal		x	x	x
Entrance Snellen Visual Acuity		x	x	x
Keratometry		x		
Subjective Sphero-Cylindrical Refraction		x		x
Subjective Best Sphere Refraction		x		
Slit Lamp Biomicroscopy		x	x	x
Randomization		x		
Lens Selection		x	x	
Lens Insertion		x	x	
Lens Settling		x	x	
Lens Fit Assessment		x	x	x

ARM 2 STUDY PROCEDURES				
Visit Information	Visit 0 Pre-Screening Via Phone or Email (optional)	Visit 1 Screening, Baseline, Randomization, Treatment 1 Fit & Dispense	Visit 2 Treatment 1 Follow-up, Treatment 2 Fit & Dispense	Visit 3 Treatment 2 Follow-up, Final Evaluation
Time Point	Pre-Visit	Day 0	Day 14 ± 2 after Visit 1	Day 14 ± 2 after Visit 2
Estimated Visit Duration	15 min	2.0 hours	1.5 hours	1.5 hours
Best Sphere Over Refraction		x	x	
Lens Power Modification		x	x	
Subject Reported Ocular Symptoms		x	x	x
Exit Snellen Visual Acuity		x	x	x
Continuance		x	x	
Dispense		x	x	
Dispense Patient Instruction Guide		x		
Adverse Events and Concomitant Medications Review			x	x
Compliance			x	x
Follow-up questionnaires			x	x
Preference				x
Final Exam Form				x

7.2. Detailed Study Procedures

PRE-SCREENING:
(via phone or email)

PRE-SCREENING		
Step	Procedure	Details
0.1	Preliminary Subject Identification	The clinical study site will search through their subject database to find potential subjects who may be eligible to participate. Subjects may be contacted by telephone or sent an electronic survey via email.
0.2	Subject's Privacy Notice and	The clinical study site must provide notice to subjects regarding the collection and disclosure of personal

	Disclosure	information. Each subject must provide verbal consent by phone to allow the collection and disclosure of the personal information collected in the screening questionnaire. The verbal consent will be documented in the Screening Questionnaire.
0.3	Habitual Contact Lens Information	Questions regarding the subject's habitual lens type, parameters, wear schedule, and duration.
0.4	Pre-screening Questions	Subject will be contacted by the clinical study site to complete a questionnaire (APPENDIX F) over the phone or via email to determine preliminary eligibility.

VISIT 1

Subjects must present to Visit 1 wearing their habitual contact lens for at least 2 hours. Subjects will be asked to bring their habitual contact lens blisters and/or boxes with them to the visit. Otherwise, subjects may return at another time for Visit 1.

Visit 1: Screening			
Step	Procedure	Details	[redacted]
1.1	Statement of Informed Consent	Each subject must read, understand, and sign the Statement of Informed Consent before being enrolled into the study. The Principal Investigator or his/her designee conducting the informed consent discussion must also sign the consent form. **Note**: The subject must be provided a signed copy of this document.	N/A
1.2	Demographics	Record the subject's year of birth, gender, race and ethnicity.	N/A
1.3	Medical History and Concomitant Medications	Questions regarding the subjects' medical history and concomitant medications.	N/A
1.4	Habitual Contact Lens Information	Collect information regarding the subject's habitual lens type, parameters, wear schedule, and duration.	N/A
1.5	Current contact lens wear times	Record the average of current contact lens wear time (WT) and comfortable wear time (CWT).I'll	N/A
1.6	CLDEQ-8 Questionnaire	The subject will respond to the CLDEQ-8 Questionnaire (Appendix A). Subjects must have a CLDEQ-8 score of 15 or greater to continue in the study.	[redacted]
1.7	Eligibility after Screening	All responses to Screening Inclusion Criteria questions must be answered "yes" and all	N/A

Visit 1: Screening			
Step	Procedure	Details	[redacted]
		responses to Exclusion Criteria must be answered "no" for the subject to be considered eligible. If subject is deemed to be ineligible after screening, proceed to Final Evaluation and complete Subject Disposition. Visual Acuity, Refraction and Biomicroscopy forms are not required.	

Visit 1: Baseline & Randomization			
Step	Procedure	Details	[redacted]
1.8	CLUE and MRD questionnaire	The subject will respond to the CLUE and MRD Baseline Questionnaire (Appendix A)	[redacted]
1.9	Entrance Visual Acuity	Record the distance Snellen visual acuity (OD, OS) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	[redacted]
1.10	Remove Habitual Contact Lenses	The subject will remove their habitual lenses and discarded or store as appropriate.	N/A
1.11	Keratometry	Record the keratometry readings OD and OS in diopters. This can come from any appropriate instrument.	[redacted]
1.12	Subjective Sphero-cylindrical Refraction	Complete subjective spherocylindrical refraction and record the resultant Snellen distance visual acuity (OD, OS) to the nearest letter.	[redacted]

Visit 1: Baseline & Randomization			
Step	Procedure	Details	[redacted]
1.13	Subjective Best Sphere Refraction	Perform subjective best sphere refraction with a phoropter. Confirm spherical endpoints with the duochrome (red-green) test: Neutrality is reached when the letters on both backgrounds appear equally clear/dark. If no neutrality point is obtained, the endpoint will be based on "first green": first report of letters appearing clearer/darker on the green background. If in the investigator's clinical opinion, the subject is not responding well to duochrome, the subjective best sphere refraction endpoint will be recorded. Record the best corrected distance Snellen visual acuity (OD, OS) to the nearest letter.	[redacted]
1.14	Slit Lamp Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. If any of these slit lamp findings are grade 3 or higher, the subject may not continue at this time, but may return up to one additional time to determine eligibility at the investigator's discretion. If discontinued a final examination must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
1.15	Eligibility after Baseline	All responses to Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria questions must be answered "no" for the subject to be considered eligible. If subject is deemed to be ineligible after baseline, proceed to Final Evaluation and complete all forms.	N/A

Visit 1: Baseline & Randomization			
Step	Procedure	Details	[redacted]
1.16	Randomization	Eligible subjects will be randomized to either ARM 1 (single arm) or ARM 2 (crossover), based on the randomization scheme.	N/A
1.17	Lens Selection	Select the contact lens power based on subjective best sphere refraction.	N/A
1.18	Lens Insertion	The subject will insert the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable.	N/A
1.19	Lens Settling	Allow the study lenses to settle for a minimum of 5 minutes.	N/A
1.20	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement. • edge lift. • excessive movement in primary and up gaze. • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up. **NOTE: if lens fit is unacceptable subject will be discontinued from the study.**	[redacted]

Visit 1: Baseline & Randomization			
Step	Procedure	Details	[redacted]
1.21	Subjective Best Sphere Over Refraction	Perform a spherical over-refraction OD and OS using any acceptable means (ie, phoropter, trial lenses, flipper bars) in normal room illumination. Confirm spherical endpoints with the duochrome (red-green) test: Neutrality is reached when the letters on both backgrounds appear equally clear/dark. If no neutrality point is obtained, the endpoint will be based on "first green": first report of letters appearing clearer/darker on the green background. If in the investigator's clinical opinion, the subject is not responding well to duochrome, the subjective best sphere refraction endpoint will be recorded. A plano over refraction must be achieved to continue.	[redacted]
1.22	Lens Power Modification (if applicable)	Adjust the lens power if the subject's best sphere over-refraction is not plano. For each power modification, repeat steps (1.18-1.21). Up *to two power* modifications are allowed.	N/A
1.23	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
1.24	Exit Visual Acuity	Record the distance Snellen visual acuity (OD, OS) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly	[redacted]
1.25	Continuance	For the subject to continue in the study, they must meet all three of the following criteria: • Visual acuity is 20/25 or better OD and OS. • The lens fit is acceptable OD and OS. • Investigator approval. If the Investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.	N/A

Visit 1: Baseline & Randomization			
Step	Procedure	Details	[redacted]
1.26	Dispense	The lenses will be dispensed for a 12-16 day wearing period. During this time, they are required to wear the lenses at least 10 days and at least 8 hours per day that they are worn. • Only study provided contact lenses and saline are permitted during the study. • Dispense enough lenses to last the subject to their scheduled follow-up visit. *Do not dispense extras*. • The lenses will be worn as daily wear/daily disposable only. • Study provided non-preserved ophthalmic saline is permitted for rewetting if needed. Instruct the subject that since the saline is preservative-free, the product is to be disposed after single use due to potential exposure to microbial contamination from re-use of the product. • A patient instruction booklet will be provided. • Subjects will be scheduled for their 2-week follow up visit, ensuring that they wear the study lens at least two (2) hours on the day of the follow-up visit. ***NOTE:** **In the event a lens is lost or damaged, the subject will return to the clinical site for replacement. As much as reasonably possible, a damaged lens and packaging should be returned to the clinical site (wet, if possible) and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.**	N/A
1.27	Subject Instruction	If the subject is randomized to ARM 1, advise them that at their next visit they will need to bring their spectacle or habitual contact lens in hand since the study will be complete.	N/A

If the subject is randomized to ARM 1, proceed to:
ARM 1 STUDY PROCEDURES, Visit 2, Step 2.1.

If the subject is randomized to ARM 2, proceed to:
ARM 2 STUDY PROCEDURES, Visit 2, Step 2.1

ARM 1 STUDY PROCEDURES

VISIT 2 (14 ± 2 days following Visit 1)

Subjects must present with study lenses on eye for at least 2 hours.

ARM 1			
Visit 2: 2-Week Follow-Up			
Step	Procedure	Details	[redacted]
2.1.	Adverse Events and Concomitant Medications Review	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	N/A
2.2.	Wear time	Record the average wear time and comfortable wear time.	N/A
2.3.	Compliance	Confirm compliance with the prescribed wear schedule.	N/A
2.4.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
2.5.	CLDEQ-8 Questionnaire	The subject will respond to the CLDEQ-8 Questionnaire (Appendix A)	[redacted]
2.6.	Follow-up questionnaires	The subject will respond to the CLUE and MRD Follow Up Questionnaire (Appendix A)	[redacted]
2.7.	Entrance Visual Acuity	Record the distance Snellen visual acuity with the contact lenses (OD, OS) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	[redacted]

ARM 1			
Visit 2: 2-Week Follow-Up			
Step	Procedure	Details	[redacted]
2.8.	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement. • edge lift. • excessive movement in primary and up gaze. • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up. **NOTE: if lens fit is unacceptable subject will be discontinued from the study.**	[redacted]
2.9.	Lens Removal and Discard	The lenses will be removed by the subject and discarded. **Proceed to Final Evaluation (Step F.1)**	N/A

ARM 2 STUDY PROCEDURES

VISIT 2 (14 ± 2 days following Visit 1)

Subjects must present with study lenses on eye for at least 2 hours.

ARM 2			
Visit 2: Treatment 1, 2-Week Follow-Up; Treatment 2 Fitting			
Step	Procedure	Details	[redacted]
2.1.	Adverse Events and Concomitant Medications Review	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	N/A
2.2.	Wear Time	Record the average wear time and comfortable wear time.	N/A
2.3.	Compliance	Confirm compliance with the prescribed wear schedule.	N/A
2.4.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]

ARM 2			
Visit 2: Treatment 1, 2-Week Follow-Up; Treatment 2 Fitting			
Step	Procedure	Details	[redacted]
2.5.	CLDEQ-8 Questionnaire	The subject will respond to the CLDEQ-8 Questionnaire (Appendix A). **NOTE**: If subjects no longer meet score criteria of ≥15, the lenses will be removed by the subject and discarded. **The subject will be discontinued and proceed to final evaluation (F.1)**	[redacted]
2.6.	Follow Up questionnaires	The subject will respond to the CLUE and MRD Follow Up Questionnaire (Appendix A)	[redacted]
2.7.	Entrance Visual Acuity	Record the distance Snellen visual acuity with the contact lenses (OD, OS) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	[redacted]
2.8.	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement. • edge lift. • excessive movement in primary and up gaze. • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up. **NOTE: if lens fit is unacceptable subject will be discontinued from the study.**	[redacted]
2.9.	Lens Removal and Discard	The lenses will be removed by the subject and discarded.	[redacted]

ARM 2			
Visit 2: Treatment 1, 2-Week Follow-Up; Treatment 2 Fitting			
Step	Procedure	Details	[redacted]
2.10.	Slit Lamp Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. If the subject has a Grade 3 or higher slit lamp finding, it will be recorded as an Adverse Event and followed per protocol. If discontinued a final examination must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
2.11.	Lens Selection	Assign study lens 2 per the randomization, based on subjective best sphere refraction.	N/A
2.12.	Lens Insertion	The subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable.	N/A
2.13.	Lens Settling	Allow the study lenses to settle for a minimum of 5 minutes.	N/A
2.14.	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement. • edge lift. • excessive movement in primary and up gaze. • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up. **NOTE: if lens fit is unacceptable subject will be discontinued from the study.**	[redacted]

ARM 2			
Visit 2: Treatment 1, 2-Week Follow-Up; Treatment 2 Fitting			
Step	Procedure	Details	[redacted]
2.15.	Subjective Best Sphere Over Refraction	Perform a spherical over-refraction OD and OS using any acceptable means (ie, phoropter, trial lenses, flipper bars) in normal room illumination. Confirm spherical endpoints with the duochrome (red-green) test: Neutrality is reached when the letters on both backgrounds appear equally clear/dark. If no neutrality point is obtained, the endpoint will be based on "first green": first report of letters appearing clearer/darker on the green background. If in the investigator's clinical opinion, the subject is not responding well to duochrome, the subjective best sphere refraction endpoint will be recorded. A plano over refraction must be achieved to continue.	[redacted]
2.16.	Lens Power Modification (if applicable)	Adjust the lens power if the subject's best sphere over-refraction is not plano. For each power modification, repeat steps (2.12-2.15). Up *to two power* modifications are allowed.	N/A
2.17.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
2.18.	Exit Visual Acuity	Record the distance Snellen visual acuity (OD, OS) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	[redacted]
2.19.	Continuance	For the subject to continue in the study, they must meet all three of the following criteria: • Visual acuity is 20/25 or better OD and OS • The lens fit is acceptable OD and OS • Investigator approval	N/A

ARM 2			
Visit 2: Treatment 1, 2-Week Follow-Up; Treatment 2 Fitting			
Step	Procedure	Details	[redacted]
		If the Investigator does not approve the dispensing of the study lens, then the study is terminated for that subject.	
2.20.	Dispense	The lenses will be dispensed for a 12-16 day wearing period. During this time, they are required to wear the lenses at least 10 days and at least 8 hours per day that they are worn. • Only study provided contact lenses and saline are permitted during the study. • Dispense enough lenses to last the subject to their scheduled follow-up visit. *Do not dispense extras*. • The lenses will be worn as daily wear/daily disposable only. • Study provided non-preserved ophthalmic saline is permitted for rewetting if needed. Instruct the subject that since the saline is preservative-free, the product is to be disposed after single use due to potential exposure to microbial contamination from re-use of the product. • Subjects will be scheduled for their 2-week follow up visit, ensuring that they wear the study lens at least two (2) hours on the day of the follow-up visit. ***NOTE:** **In the event a lens is lost or damaged, the subject will return to the clinical site for replacement. As much as reasonably possible, a damaged lens and packaging should be returned to the clinical site (wet, if possible) and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.**	N/A
2.21.	Instruction	Advise the subject that at their next visit they will need to bring their spectacle or habitual contact lens in hand since the study will be complete.	N/A

VISIT 3 (14 ± 2 days following Visit 3)

Subjects must present with study lenses on their eyes for at least 2 hours.

ARM 2			
Visit 3: Treatment 2, 2-Week Follow-Up			
Step	Procedure	Details	[redacted]
3.1.	Adverse Events and Concomitant Medications Review	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	N/A
3.2.	Wear Time	Record the average wear time and comfortable wear time.	N/A
3.3.	Compliance	Confirm compliance with the prescribed wear schedule.	N/A
3.4.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
3.5.	CLDEQ-8 Questionnaire	The subject will respond to the CLDEQ-8 Questionnaire (Appendix A)	[redacted]
3.6.	Follow-up questionnaires	The subject will respond to the CLUE and MRD Baseline Questionnaire (Appendix A)	[redacted]
3.7.	Preference	The subject will respond to the Preference Questionnaire (Appendix A)	[redacted]
3.8.	Entrance Visual Acuity	Record the distance Snellen visual acuity with the contact lenses (OD, OS) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	[redacted]
3.9.	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement. • edge lift. • excessive movement in primary and up gaze. • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up.	[redacted]

ARM 2			
Visit 3: Treatment 2, 2-Week Follow-Up			
Step	Procedure	Details	[redacted]
		NOTE: if lens fit is unacceptable subject will be discontinued from the study.	
3.10.	Lens Removal and Discard	The lenses will be removed by the subject and discarded. **Proceed to Final Evaluation (Step F.1)**	N/A

FINAL EVALUATION (ARM 1 & ARM 2)

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

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

7.3. Unscheduled Visits

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

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

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

Any ocular and non-ocular Adverse Events that are ongoing at the time of the study visit will be followed by the Investigator, within licensure, until they have resolved, returned to pre-treatment status, stabilized, or been satisfactorily explained. If further treatment i.e., beyond licensure is required, the subject will be referred to the appropriate health care provider.

The following information will be collected during an unscheduled visit.

Unscheduled Visit			
Step	Procedure	Details	[redacted]
U.1	Reason for unscheduled visit	Indicate if the only reason for the visit is that the subject requires additional test articles. If the reason is other than resupply of previously dispensed lenses, specify the reason for the visit.	
U.2	Chief Complaints (if applicable)	Record the subject's chief complaints for reasons for the unscheduled visit.	
U.3	Adverse Events and Concomitant Medications Review (if applicable)	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	
U.4	Entrance VA (if applicable)	Record the entrance distance visual acuity (OD, OS) to the nearest letter.	[redacted]
U.5	Subjective Sphero-cylindrical Refraction (if applicable)	Perform bare-eye subjective spherocylindrical refraction with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the best corrected distance visual acuity to the nearest letter (OD, OS).	[redacted]

Unscheduled Visit			
Step	Procedure	Details	[redacted]
U.6	Slit Lamp Biomicroscopy (if applicable)	FDA Slit Lamp Classification Scale will be used to grade the findings. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be instilled.	[redacted]
U.7	Dispensing (if applicable)	If the subject requires additional lenses to complete the wear period and is eligible to do so, provide additional lenses per the dispensing instructions given in the detailed study procedures.	
U.8	Exit Visual Acuity (if applicable)	Record the subject's exit distance visual acuity (OD, OS) to the nearest letter.	[redacted]

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

7.4. Laboratory Procedures

None

8. SUBJECTS COMPLETION/WITHDRAWAL

8.1. Completion Criteria

Subjects are considered to have completed the study if they:

- provide informed consent,
- are eligible to participate the study, and
- completed all study visits.

8.2. Withdrawal/Discontinuation from the Study

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

- Subject death during the study period.
- Subject withdrawal of consent.
- Subject not compliant to protocol.
- Subject lost to follow-up.
- Subject no longer meets eligibility criteria (e.g. the subject becomes pregnant).
- Subject develops significant or serious adverse events causing discontinuation of study lens wear.
- Subjects who have experienced a Corneal Infiltrative Event (CIE).
- Investigator's clinical judgment regarding the subject safety reasons (that it is in the best interest of the subject to stop treatment).
- Subject missed any scheduled study visits.
- Subject not compliant with study lens wear schedule.

- 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

An additional subject will be enrolled if a subject discontinues from the study prematurely.

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

9. PRE-STUDY AND CONCOMITANT INTERVENTION/MEDICATION

Concomitant medications will be documented during screening and updated during the study. Disallowed medications for this study include: Restasis, Xiidra, ocular steroids, or any medication (Rx or OTC) that may interfere with contact lens wear at the discretion of the investigator.

Concomitant therapies that are disallowed include: N/A

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

Or:

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

Subjects with a history of taking medications listed in Table 4 on a long-term, routine basis for less than 6 months will not be allowed to participate in the study.

Table 4: Disallowed systemic medications

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

Examples of disallowed systemic antihistamines are given in Table 5. Subjects with a history of taking systemic antihistamines will be allowed to enroll only if:

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

Or:

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

Table 5: Disallowed systemic antihistamines

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

10. DEVIATIONS FROM THE PROTOCOL

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

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

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

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

Protocol waivers are prohibited.

Table 6 lists examples of deviations that will constitute major and minor protocol deviations for this study.

Table 6: 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 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 at least 6 hours on at least 5 days of a study lens wear period.	Subject does not wear study lenses for at least 1 hour prior to attending a follow-up visit.

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 patient safety or if information indicates the study's results are compromised.

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

JJVC (and the IEC/IRB and DMC, if applicable) will evaluate all adverse events. If it is determined that an adverse event presents an unreasonable risk, the investigation, or that part of the investigation presenting the risk, will be terminated as soon as possible.

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

12. PROCEDURE FOR HANDLING PRODUCT QUALITY COMPLAINTS

A Product Quality Complaint (PQC) refers to any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of test articles after they have been released for clinical trial use.

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

- Subject satisfaction inquiries reported via "Subjective Questionnaires" and "Patient Reported Outcomes (PRO)."
- Clinical test articles that are stored improperly or damaged after receipt at the investigational site.

- Lens replacements that occur due to drops/fall-outs.
- Damage deemed by clinicians or clinical staff to be caused by handling by the user, and not indicative of a quality deficiency (i.e. tears, rips, etc.), only in situations where there is no deficiency alleged by the subject.

Within 24 hours of site personnel becoming aware that a PQC has occurred, the PQC must be recorded in the EDC system, which will trigger an automatic email notification to the appropriate COM/CRA and Clinical QA representative. In cases where the EDC system in use is not configured to send automatic notifications or when an EDC system is not used, the COM/CRA is responsible for notifying Clinical QA upon discovery that a PQC has occurred.

Upon receipt of the EDC notification, the COM/CRA will contact the study site to collect additional information which will include:

- Date the complaint was received/recorded in the EDC System (Date of Sponsor Awareness).
- Who received the complaint.
- Study number.
- Clinical site information (contact name, site ID, telephone number).
- Lot number(s).
- Unique Subject Identifier(s).
- Indication of who first observed complaint (site personnel or subject).
- OD/OS indication, along with whether the lens was inserted.
- Any related AE number if applicable.
- Detailed complaint description (scheduled/unscheduled visit, wear time, symptoms, resolution of symptoms, etc.).
- Eye Care Provider objective (slit lamp) findings if applicable.
- Confirmation of product availability for return (and tracking information, if available), or rationale if product is not available for return [redacted]

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

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

13. ADVERSE EVENTS

13.1. Definitions and Classifications

Adverse Event (AE) – An AE is "any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device."
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
- Any corneal event not explicitly defined as serious or significant adverse event, which necessitates temporary lens discontinuation < 2 weeks

Adverse Device Effect (ADE) – An ADE is an "adverse event related to the use of an investigational medical device."

Note 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.
Note 2: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.[1]

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

13.2. Assessing Adverse Events

In conjunction with the medical monitor, the Investigator will evaluate adverse events to ensure the events are categorized correctly. Elements of categorization will include:

- Seriousness/Classifications (see definition in section 13.1).
- Causality or Relatedness – i.e. the relationship between the test article, study treatment or study procedures and the adverse event (not related, unlikely related, possibly related, or related - see definition in section 13.2.1).
- Adverse Event Severity – Adverse event severity is used to assess the degree of intensity of the adverse event (mild, moderate, or severe - see definition in section 0).
- Outcome – not recovered or not resolved, recovering or resolving, recovered or resolved with sequelae, recovered or resolved, death related to adverse event, or unknown.
- Actions Taken – none, temporarily discontinued, permanently discontinued, or other.

13.2.1. Causality Assessment

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

- Not Related- An adverse event that is not related to the use of the test article, study treatment or study procedures.
- Unlikely Related – An adverse event for which an alternative explanation is more likely, e.g. concomitant treatment, concomitant disease(s), or the relationship of time suggests that a causal relationship is not likely.
- Possibly Related – An adverse event that might be due to the use of the test article, or to the study treatment or study procedures. An alternative explanation, e.g. concomitant treatment, concomitant disease(s), is inconclusive. The relationship in time is reasonable. Therefore, the causal relationship cannot be excluded.
- Related – An adverse event that is listed as a possible adverse effect (device) or adverse reaction (drug) and cannot be reasonably explained by an alternative explanation, e.g.

concomitant treatment of concomitant disease(s). The relationship in time is very suggestive, e.g. it is confirmed by de-challenge and re-challenge.

13.2.2. Severity Assessment

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

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

13.3. Documentation and Follow-Up of Adverse Events

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

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

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

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

- Adverse event (diagnosis not symptom).
- Drawings or photographs (where appropriate) that detail the finding (e.g., size, location, and depth, etc.).
- Date the clinical site was notified.
- Date and time of onset.
- Date and time of resolution.
- Adverse event classification, severity, and relationship to test articles, as applicable.

- Treatment regimen instituted (where appropriate), including concomitant medications prescribed, in accordance with applicable licensing requirements.
- Any referral to another health care provider if needed.
- Outcome, ocular damage (if any).
- Likely etiology.
- Best corrected visual acuity at the discovery of the event and upon conclusion of the event, if the AE is related to the visual system.

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

In addition, if an infiltrate(s) is present, he/she will complete the Corneal Infiltrate Assessment eCRF. Where necessary, a culture of the corneal lesion will be collected to determine if the infection is microbial in nature. If cultures are collected, the date of culture collection and laboratory utilized will be recorded.

Changes in the severity of an AE shall be documented to allow an assessment of the duration of the event at each level of intensity to be performed. Adverse events characterized as intermittent require documentation of the onset and duration of each episode. Changes in the assessment of relationship to the Test Article shall also be clearly documented.

Subjects who present with an adverse event shall be followed by the Investigator, within licensure, until all signs and symptoms have returned to pre-treatment status, stabilized, or been satisfactorily resolved. If further treatment beyond licensure is required, the patient will be referred to the appropriate health care provider. The Investigator will use his/her clinical judgment as to whether a subject reporting with an adverse event will continue in the study. If a subject is discontinued from the study, it will be the responsibility of the Investigator to record the reason for discontinuation. The Investigator will also document the adverse event appropriately and complete the Adverse Event eCRF. Any subjects with ongoing adverse events related to the test article, study treatment or study procedures, as of the final study visit date, should be followed to resolution of the adverse event or until referral to an appropriate health care provider, as recommended by the Investigator. Non-ocular adverse events that are not related to the test article, study treatment, or study procedures may be recorded as "ongoing" without further follow-up.

13.4. Reporting Adverse Events

The Investigator will notify the Sponsor of an adverse event by e-mail, facsimile, or telephone as soon as possible and no later than 24 hours from discovery for any serious /significant adverse events, and 2 days from discovery for any non-significant adverse event. In addition, a written report will be submitted by the Principal Investigator to the IEC/IRB according to their requirements (section 13.4.2). The report will comment whether the adverse event was considered to be related to the test article, study treatment or study procedures.

13.4.1. Reporting Adverse Events to Sponsor

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

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

In the event of a serious/significant adverse event, the Investigator must:

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

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

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

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

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

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

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

13.5. Event of Special Interest

None

13.6. Reporting of Pregnancy

Subjects reporting pregnancy (by self-report) during the study will be discontinued after the event is recorded as an Adverse Event. Once discontinued, pregnant participants and their fetuses will not be monitored for study related purposes. Pregnant participants are not discontinued from contact lens or solution related studies for safety concerns, but due to general concerns relating to pregnancy and contact lens use. Specifically, pregnant women are discontinued due to fluctuations in refractive error and/or visual acuity that occur secondary to systemic hormonal changes, and not due to unforeseen health risks to the mother or fetus.

14. STATISTICAL METHODS

14.1. General Considerations

Statistical Analysis will be undertaken by the sponsor or under the authority of the sponsor. A general description of the statistical methods to be implemented in this clinical trial is outlined below. More details will be included in the stand-alone Statistical Analysis Plan (SAP). The SAP will be developed and finalized prior to database lock.

All data summaries and statistical analyses will be performed using the SAS software Version 9.4 or higher (SAS Institute, Cary, NC).[11] 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) and will be summarized by lens type and ARM (ARM1- AO1D and ARM2 – Subjects' Habitual Lenses and AO1D) Frequency count and percentage of subjects or eyes within each category will be provided for categorical data.

14.2. Sample Size Justification

This study was design and powered to demonstrate non-inferiority of the change from baseline (CFB: 2-Week Follow-up minus baseline) of the Test lens relative to subjects' habitual CLUE comfort scores, a margin of -5 points will be used to test the hypothesis. Additionally, a power analysis for the change from baseline (CFB: 2-week follow-up minus baseline) of the Test lens compared to subjects' habitual lens with respect to CLDEQ-8 total scores was also provided. Table 7 and Table 8 below displays the descriptive statistics for the CLDEQ-8 total scores and CLUE comfort scores, respectively observed from the historical data including [redacted],

[redacted] and [redacted] considering the following 5 habitual lens types: Johnson & Johnson 1-Day ACUVUE® Moist, Alcon DAILIES® Aqua Comfort Plus®, Alcon DAILIES TOTAL1®, Clariti 1-Day and MyDay. Subjects included in Table 7 had a CLDEQ-8 score of 15 or higher at screening.

Table 7 : Historical Descriptive Statistics by Study and Lens Type for CLDEQ-8 Scores

Study	N	Mean (SD)		
		AO1D 2-week	Habitual Baseline	Difference
Overall	24	12.8 (6.35)	20.3 (4.39)	-7.5 (7.17)
[redacted]	11	12.5 (4.37)	19.3 (3.13)	-6.8 (4.77)
[redacted]	5	13.4 (6.27)	18.2 (4.32)	-4.8 (8.04)
[redacted]	8	12.9 (9.06)	22.9 (5.11)	-10.0 (9.30)

Table 8 : Historical Descriptive Statistics by Study and Lens Type for CLUE Comfort Scores

Study	N	Mean (SD)		
		AO1D 2-week	Habitual Baseline	Difference
Overall	24	52.6 (18.78)	37.9 (18.12)	14.72 (25.21)
[redacted]	11	55.0 (16.18)	38.1 (16.47)	16.9 (20.38)
[redacted]	5	52.0 (19.38)	54.8 (21.88)	-2.8 (36.80)
[redacted]	8	49.7 (23.48)	27.1 (8.93)	22.6 (20.60)

Table 9 displays the sample size estimates for the primary endpoint of CLUE Comfort score, and the secondary endpoint of CLDEQ8- Scores for different scenarios of effect sizes. CLDEQ-8 power analysis was provided for informational purposes. All Sample size calculations were performed with 80% power and 2-sided alpha=0.05. With respect to CLDEQ-8 Scores, for ARM1 a standard deviation of 7.17 was utilized (See Table 7), while a standard deviation of 5.0 was utilized for ARM2 in each calculation for the various effect sizes. The different effect sizes for CLDEQ-8 scores were based on the historical effect sizes provided in Table 7. Historically, on average AO1D improved CLEQ8-scores about 7 points after 2-weeks of wear. The power analysis for CLDEQ8-scores is displayed in Table 9 below. With respect to CLUE comfort scores, for ARM1 a standard deviation of 25.21 was used (See Table 8) while, a standard deviation of 18.12 was utilized for ARM2 in the calculation for each scenario. Due to the varying effect sizes displayed in Table 8 above, effect sizes of 3, 5 and 9 were utilized as a more conservative estimate for the sample size calculation since there was a high a difference observed between AO1D and subjects' habitual lenses with respect to CLUE Comfort (22.6 points) in [redacted].

Sample size and power calculations for each endpoint and scenario were calculated using a 2-sided Satterthwaite t-test assuming unequal variances using the POWER[11] procedure in SAS Version 9.4[9].

Table 9 : Sample Size Calculation and Power Analysis required to Test Primary Hypothesis for CLUE Comfort and Secondary hypothesis for CLDEQ8-scores for different Scenarios of Effect Sizes

Endpoint	Endpoint Type	Power	Standard Deviation	Effect Size	Sample Size per Arm	Total Sample Size (Including dropout rate)
Change in CLUE Comfort Scores	Primary	80%	ARM1- 25.21 ARM2 – 18.12	3	120	336
				5	77	216
				9	40	112
Change in CLDEQ-8 Scores	Secondary	80%	ARM1- 7.17 ARM2- 5.00	-3	68	190
				-4	39	110
				-5	26	72

Table 10 contains subject accountability by status for each historical study. As indicated below a total of 65 subjects either failed to meet all eligibility criteria or were discontinued from the study. Based on the information provided in the table below a ~24% ($\frac{65}{265} = 0.245$) was observed in the historical studies. However, due to the ongoing Pandemic of COVID-19 and the stringent enrollment for the 5 habitual lens types, to account for a high number dropouts or screen failures ~40% increase in enrollment is necessary to meet our target subject completion number.

Table 10: Subject Accountability Status by Study

Study	Number Enrolled	Number Assigned not dispensed	Number Screen Failed	Number Dispensed	Number Completed	Number Discontinued
[redacted]	105	1	23	81	73	8
[redacted]	58	0	9	49	39	10
[redacted]	102	0	10	92	87	5
Total	265	1	42	222	199	23

It was determined that a total of 112 subjects will be sufficiently large enough to demonstrate non-inferiority the Test lens compared to subjects' habitual lens with respect to the change in CLUE Comfort scores from baseline to 2-week follow-up considering a ~40% dropout/screen failure rate.

14.3. Analysis Populations

Safety Population:
All subjects who are administered any test article excluding subjects who drop out prior to administering any test article. At least one observation should be recorded.

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

Intent-to-Treat (ITT) Population:
All randomized subjects regardless of actual treatment and subsequent withdrawal from the study or deviation from the protocol. At least one observation should be recorded.

14.4. Level of Statistical Significance

All planned analysis for this study will be conducted with an overall type I error rate of 5%. The study hypotheses will be tested using the following gatekeeping strategy; If the primary hypothesis is met, then the secondary hypotheses will be tested. If the primary and secondary hypotheses are met, all tertiary hypotheses will be evaluated for both between the study arms and within the second arm. If the primary and secondary hypotheses regarding CLUE comfort are met, then the tertiary hypotheses relevant to this endpoint will be evaluated for both between the study arms and within the second arm. If only the primary hypothesis for CLUE comfort is met then, then associated tertiary hypotheses relevant to this endpoint will only be evaluated between study arms. If both secondary hypotheses regarding CLDEQ8-Scores are met, then the tertiary hypotheses relevant to this endpoint will be evaluated for between the study arms only and within the second arm. If only 1 of the secondary hypotheses regarding CLDEQ8-scores is met, then the associated tertiary hypotheses relevant to this endpoint will be evaluated between study arms.

14.5. Primary Analysis

The primary endpoint is the change in CLUE comfort score from baseline to 2-week follow-up. The data from the ARM 1 (Test) will be compared to the first period of the ARM 2 (Control, habitual lens). The primary analyses will be conducted on the Per-Protocol (PP) population. A sensitivity analysis will be conducted on the Intent-to-Treat (ITT) population. Non-inferiority will be assessed on PP population, while superiority will be assessed on ITT population.

Change in CLUE Scores:
The CLUE comfort scores will be analyzed using a linear mixed model to assess the difference between the Test and Control (subjects' habitual lens) lenses. The regression model will include ARM (ARM1 – Test, and ARM 2 – Habitual Lens), time (Baseline and Follow-up evaluation) and ARM by time interaction as fixed effect factors. Baseline characteristics such as age and gender may be included as fixed effect covariates in the model when appropriate. Investigational site will be included as a random effect (G-side). An Unstructured (UN) or compound symmetric (CS) covariance or heterogenous compound symmetry (CSH) structures

will be used to model the residual errors between measurements within the same subject across time (R-side). The log-likelihood ratio test will be used to assess homogeneity between the residual covariance structure across ARM. The Kenward and Roger method[9] will be used to calculate the denominator degree of freedom.

Hypothesis Testing:
The null and alternative hypotheses for non-inferiority of the Test relative to Control are as follows:

$$H_0: \Delta \leq -5$$

$$H_A: \Delta > -5,$$

where Δ is the difference between lens types (Test minus Control) in mean change from baseline at 2-week follow-up. Non-inferiority of the Test lens relative to the Control lens will be based on the LSM difference in the score change from baseline at 2-week follow-up and its corresponding 95% confidence interval from the final model. The lower bound of the 95% CI will be compared to the non-inferiority margin of -5. If the lower bound is greater than -5, the null hypothesis will be rejected, and the Test lens will be considered non-inferior to the Control lens. If non-inferiority of the Test lens over Control lens is met, then superiority test will be also conducted on the ITT population. If the lower bound is greater than 0, then the superiority of the Test lens over the Control lens will be established

14.6. Secondary Analysis

The secondary endpoints are the change in (1) CLDEQ-8 total score from baseline to 2-week, (2) CLDEQ-8 total scores and (3) CLUE comfort scores at 2-week follow-up. For the first secondary endpoint, the data from the ARM 1 (Test) will be compared to the first period of the ARM 2 (Control, habitual lens). The analysis will be conducted on the Per-Protocol (PP) population. A sensitivity analysis will be conducted on the Intent-to-Treat (ITT) population. Non-inferiority will be assessed on PP population, while superiority will be assessed on ITT population. The remaining other secondary analyses will be conducted on the PP population within the ARM 2 only.

Change in CLDEQ-8 Total Scores:
The CLDEQ-8 total scores will be analyzed using a linear mixed model to assess the difference between the Test and Control (subjects' habitual lens) lenses. The regression model will include ARM (ARM1 – Test, and ARM 2 – Habitual Lens), time (Baseline and Follow-up evaluation) and ARM by time interaction as fixed effect factors. Baseline characteristics such as age and gender may be included as fixed effect covariates in the model when appropriate. Investigational site will be included as a random effect (G-side). An Unstructured (UN) or compound symmetric (CS) covariance or heterogenous compound symmetry (CSH) structures will be used to model the residual errors between measurements within the same subject across time (R-side). The log-likelihood ratio test will be used to assess homogeneity between the residual covariance structure across ARM. The Kenward and Roger method[9] will be used to calculate the denominator degree of freedom.

Hypothesis Testing:
The null and alternative hypotheses for non-inferiority of the Test relative to Control are as follows:

$$H_0: \Delta \geq 3$$

$$H_A: \Delta < 3,$$

where Δ is the difference between lens types (Test minus habitual lens) in mean change from baseline at 2-week follow-up. Non-inferiority of the Test lens relative to the Control lens will be based on the least square mean (LS Mean) difference in the score change from baseline at 2-week follow-up and its corresponding 95% confidence interval (CI) from the final model. The upper bound of the 95% CI will be compared to the non-inferiority margin of 3. If the upper bound is less than 3, the null hypothesis will be rejected, and the Test lens will be considered non-inferior to the Control lens. If non-inferiority of the Test lens over Control lens is met, then superiority test will be also conducted on the ITT population. If the upper bound is less than 0, then the superiority of the Test lens over the Control lens will be established.

CLDEQ-8 Total Scores:
The CLDEQ-8 total scores will be analyzed using a linear mixed model to assess the difference between the Test and Control (subjects' habitual lens) lenses within ARM 2. The regression model will include lens type (Habitual lens and AO1D), and baseline score as fixed effect factors. Baseline characteristics such as age and gender may be included as fixed effect covariates in the model when appropriate Investigational site will be included as a random effect.. The correlation measurements from the same subjects across lens type (Habitual and AO1D) will be model using Unstructured (UN) variance-covariance matrix. If the estimation algorithm does not converge, then a Compound Symmetry (CS) or heterogenous compound symmetric (CSH) matrix will be used. The Kenward and Roger method[9] will be used to calculate the denominator degree of freedom.

Hypothesis Testing:
The null and alternative hypotheses for non-inferiority of the Test relative to Control are as follows:

$$H_0: \Delta \geq 3$$

$$H_A: \Delta < 3,$$

where Δ is the difference between lens types at 2-week follow-up (Test (AO1D) minus Control (Habitual Lenses)). Non-inferiority of the Test lens relative to the Control lens will be teste using a 2-sided 95% CI constructed for the LSM difference at 2-week follow-up Non-inferiority will be established if the upper bound of the 95% CI is below 3 CLDEQ-8 points. If non-inferiority of the Test lens over Control lens is met, then superiority test will be also conducted on the ITT population. If the upper bound is less than 0, then the superiority of the Test lens over the Control lens will be established.

CLUE Scores:
The CLUE comfort scores will be analyzed using a linear mixed model to assess the difference between the Test (AO1D) and Control (subjects' habitual lens). The regression model will include lens type and baseline score as fixed effect factors. Baseline characteristics such as age and gender may also be included as fixed effect covariates in the model when appropriate. Investigational site will be included as a random effect. The correlation measurements from the same subjects across lens type will be modeled using UN variance-covariance matrix. If the estimation algorithm does not converge, then a CS or CSH covariance matrix will be used. The Kenward and Roger method[9] will be used to calculate the denominator degree of freedom.

Hypothesis Testing:
The null and alternative hypotheses for non-inferiority of the Test relative to Control are as follows:

$$H_0: \Delta \leq -5$$

$$H_A: \Delta > -5,$$

where Δ is the difference between lens types at 2-week follow-up (Test minus Control). Non-inferiority of the Test lens relative to the Control lens will be test using 2-sided 95% CIs constructed for the LSM difference at 2-week follow-up from the final model. Non-inferiority of the Test relative to the Control (Subjects' habitual lens) will be established is the lower bound of the 95% CI is greater than -5. If non-inferiority of the Test lens over Control lens is met, then superiority test will be also conducted on the ITT population. If the lower bound is greater than 0, then the superiority of the Test lens over the Control lens will be established.

14.7. Other Exploratory Analysis

The following other study endpoints will be assessed in support of primary and secondary endpoints. Exploratory Endpoints will only be tested and analyzed if all primary and secondary hypotheses are met.

1. CLDEQ Questions:
   - During a typical day in the past 2 weeks, how often did your eyes feel discomfort while wearing your contact lenses?
   - When your eyes felt discomfort with your contact lenses, how intense was this feeling of discomfort (on a scale of 1-5) at the end of your wearing time?
   - During a typical day in the past 2 weeks, how often did your eyes feel dry?
   - When your eyes felt dry, how intense was this feeling of dryness (on a scale of 1-5) at the end of your wearing time?

2. CLUE Comfort Questions:
   - These contact lenses were very comfortable (C001_2)
   - I could wear these contact lenses comfortably for as long as I wanted to (C008_1)
   - These lenses were very comfortable at the end of the day (C020_2)
   - My eyes felt very dry at the end of the day (C021_2)

- My eyes felt dry all day (C022_1)
- My eyes felt dry at the end of the day (C023_1)
- I have experienced dry eyes (C041_1)
- The comfort of these lenses decreased throughout the day (C061_1)

3. CLUE Vision Questions:
   - I had very good vision at the end of the day (V004_2)
   - I experienced fluctuations in the quality of my vision (V009_1)
   - I was very satisfied with the quality of my vision in dim lighting (V013_2)
   - I was satisfied with the quality of my vision at night (V014_1)
   - I was very satisfied with the clarity of distant objects (V034_2)
   - I was satisfied with the clarity of near objects (V035_1)
   - I was very satisfied by the clarity of my vision at the end of the day (V037_2)
   - My vision with these lenses was exceptional (V124_3)

4. MRD Questions:
   - These lenses help to reduce the feeling of dryness at the end of the day (MIS01977)
   - Have you been able to use these lenses for 8 hours or more with digital devices? (MIS01978)
   - I would recommend them to people who experience dryness with their own contact lenses (P3_0021_p10)

   - Not making your eyes feel dry throughout the day (P3_0006_p38)
   - Keeping your eyes from feeling dry at the end of the day (P3_0006_p39)
   - Burning (P3_0023_p01)
   - Dryness (P3_0023_p02)
   - Grittiness (P3_0023_p03)

5. Preference Questions:
   - Based on your overall opinion of both study lenses, do you prefer one lens more than the other? (PVC015_1)
   - Overall Comfort (PREF10_3)
   - Comfort at the end of the day (PREF10_5)
   - Overall vision (PREF10_7)
   - Keeping your eyes from feeling dry (PREF10_14)

Tertiary hypotheses will be evaluated in the following manner.

1. If the primary hypothesis is not met, then the tertiary hypotheses will not be evaluated.

2. If the primary and secondary hypotheses are met: All tertiary hypotheses will be evaluated for both between the study arms and within the second arm.

a. If the primary and secondary hypotheses regarding CLUE comfort are met then the tertiary hypotheses relevant to this endpoint will be evaluated for both between the study arms and within the second arm.
b. If only the primary hypothesis for CLUE comfort is met then, then associated tertiary hypotheses relevant to this endpoint will only be evaluated between study arms.
c. If both secondary hypotheses regarding CLDEQ8-Scores are met, then the tertiary hypotheses relevant to this endpoint will be evaluated for between the study arms only and within the second arm.
d. If only 1 of the secondary hypotheses regarding CLDEQ8-scores is met, then the associated tertiary hypotheses relevant to this endpoint will be evaluated between study arms.

CLUE, MRD and CLDEQ-8 Individual Questions

Each of individual questions (not including preference questions) will be analyzed using a generalized linear mixed model for ordinal data with a multinomial distribution and cumulative logit function as a link function. The model will include lens type as a fixed effect factor and site as a random effect factor. The assumption of proportionality of odds ratio across response categories will be assessed graphically. If this assumption is violated, then the distribution of response will be investigated. If sparse data is observed, then the spare responses may be collapsed to ensure that each response category has sufficient data for the analysis. If the assumption of proportionality of odds is still violated in the collapsed categories, then a partial proportional odds model may be considered. A generalized estimation equation (GEE) may also be considered if necessary. Comparison between the Test and Control lenses at 2-week follow-up will be carried out using 2-sided 95% CI of odds ratio (OR, Test over Control) where the odds ratio represents the odds of having a higher positive rating/experience for the Test lens compared to the Control lens. Non-inferiority will be conducted on the Per-Protocol population. Non-inferiority will be tested by comparing the lower limit of the 95% confidence interval for the odds ratio (Test over Control) to 0.67. If the lower limit is above 0.67 non-inferiority of the Test lens relative to the Control lens will be established. If non-inferiority is met then Superiority will be tested on the ITT population by comparing the lower limit of the 95% CI to 1. The Test lens will be concluded to be superior to the Control lens if the lower limit of the CI is above 1.

Preference Questions

The item responses will be analyzed using a generalized linear mixed model with a multinomial distribution and the generalized logit as the link function. The analysis model may include lens type and other subject characteristics such as gender as fixed covariates when appropriate. Site will be included as a random effect (G-side).

Comparisons between the Test and Control will be constructed using two-sided 95% confidence intervals for the preference ratio (the proportion of subjects preferring the Test lens compared to the Control lens – Test over Control). Superiority will be conducted on the ITT population by comparing the lower limit of the 95% CI to 1. The Test lens will be concluded to be superior to the Control lens if the lower limit of the CI is above 1.

14.8. Interim Analysis

No Interim analysis will be performed on this study.

14.9. Procedure for Handling Missing Data and Drop-Outs

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

Subject dropout is expected to be one of the main reasons of missing data in this clinical trial. Past clinical trials don't provide the evidence that subject dropout is systematic or not-at-random. To evaluate the impact of missing data, sensitivity analysis will be conducted using multiple imputation methods if the proportion of subject dropout is greater than the 15%. The SAS/STAT procedures PROC MI and PROC MIANALYZE will be utilized with a parametric regression method used to make at least 20 imputations.

14.10. Procedure for Reporting Deviations from Statistical Plan

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

15. DATA HANDLING AND RECORD KEEPING/ARCHIVING

15.1. Electronic Case Report Form/Data Collection

The data for this study will be captured on electronic case report forms (eCRFs) using the BioClinica 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 ISO14155:2011.[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.

- The study type is interventional.
- The primary purpose of the clinical trial is other than a feasibility study.
- The clinical trial studies U.S. FDA-regulated Device Product.

At least one facility location is within the United States or one of its territories.

16. DATA MANAGEMENT

16.1. Access to Source Data/Document

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

16.2. Confidentiality of Information

Information concerning the investigational product and patent application processes, scientific data or other pertinent information is confidential and remains the property of JJVC. The Investigator may use this information for the purposes of the study only. It is understood by

the Investigator that JJVC will use information developed in this clinical study in connection with the development of the investigational product and therefore may disclose it as required to other clinical investigators and to regulatory agencies. In order to allow the use of the information derived from this clinical study, the Investigator understands that he/she has an obligation to provide complete test results and all data developed during this study to the Sponsor.

16.3. Data Quality Assurance

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

Training on case report form completion will be provided to clinical site personnel before the start of the study. The Sponsor will review case report forms for accuracy and completeness remotely during the conduct of the study, during monitoring visits, and after transmission to data management. Any data discrepancies will be resolved with the Investigator or designee, as appropriate.

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

16.4. Data Monitoring Committee (DMC)

An independent Data Monitoring Committee (DMC) will be established to oversee the study. Members of DMC must be free of significant conflicts of interest (i.e., financial, intellectual, professional, or regulatory), and are experts in all scientific disciplines needed to interpret the data and ensure study participant safety.
During the conduct of the trial, responsibilities of the DMC will be to periodically review and monitor the incidence of adverse events, determine whether the basic study assumptions remain valid, evaluate whether the overall integrity, scientific merit and conduct of the study remain acceptable, and make recommendations to the Sponsor. DMC meetings will be held quarterly until all subjects have completed the study. The DMC may also meet for an ad hoc review of data in the event that a UADE or other event is reported that may affect the outcome and/or continuation of the study.
The DMC will receive a data review package prior to the scheduled meeting. Data packages will include the following information/listings:

- Subjects enrollment and disposition information, such as
    - Number and Reason for Subject Early Withdrawal
    - Number of subjects screened, randomized, early withdrawal, and complete
    - Number and Reason for Screen Failure

- Medical History
- Concomitant Medications
- Adverse Events
- Protocol Deviations
- Product Quality Complaints

Additional descriptive summary statistics of study endpoints may be provided per the DMC's requests. Unless otherwise specified, the masking of the treatment information will be maintained in the data prepared for the DMC.

Detailed information regarding the roles and responsibilities of the DMC for this study is provided in the Data Monitoring Committee Charter.

17. CLINICAL MONITORING

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

- Ensuring that the investigation is being conducted according to the protocol, any subsequent versions, and regulatory requirements are maintained.
- Ensuring the rights and wellbeing of subjects are protected.
- Ensuring adequate resources, including facilities, laboratories, equipment, and qualified clinical site personnel.
- Ensuring that protocol deviations are documented with corrective action plans, as applicable.
- Ensuring that the clinical site has sufficient test article and supplies.
- Clarifying questions regarding the study.
- Resolving study issues or problems that may arise.
- Reviewing of study records and source documentation verification in accordance with the monitoring plan.

18. ETHICAL AND REGULATORY ASPECTS

18.1. Study-Specific Design Considerations

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

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, section 4 of the ICH E6(R2) guidelines on Good Clinical Practice (GCP),[2] 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[3] and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with section 8 of the ICH E6(R2) guidelines on Good Clinical Practice (GCP),[2] and 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,[3] current ICH GCP[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 subject the aims, methods, reasonably anticipated benefits, and potential hazards of the study, and any discomfort it may entail. Subjects will be informed that their participation is voluntary and that they may withdraw consent to participate at any time.

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

18.5. Privacy of Personal Data

The collection, processing and disclosure of personal data and medical information related to the Study Subject, and personal data related to Principal Investigator and any clinical site personnel (e.g., name, clinic address and phone number, curriculum vitae) is subject to compliance with the Health Information Portability and Accountability Act (HIPAA) in the United States[13] 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 ICH GCP guidelines,[2] 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 ICH GCP[2] and all study documents as specified by the applicable regulatory requirement(s). The Investigator/Institution will take measures to prevent accidental or premature destruction of these documents.

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

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

If it becomes necessary for the Sponsor or the appropriate regulatory authority to review any documentation relating to this study, the Investigator must permit access to such reports.
If the Investigator has a question regarding retention of study records, he/she should contact JJVC.

20. FINANCIAL CONSIDERATIONS

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

JJVC reserves the right to withhold remuneration for costs associated with protocol violations such as:

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

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

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

21. PUBLICATION

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

22. REFERENCES

1. ISO 14155:2011: Clinical Investigation of Medical Devices for Human Subjects — Good Clinical Practice. In. https://www.iso.org/standard/45557.html.

2. International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP). In: http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
3. Declaration of Helsinki - Ethical principles for Medical Research Involving Human Subjects. In. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.
4. United States (US) Code of Federal Regulations (CFR). In: https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR
5. Chalmers RL, Begley CG, Moody K, Hickson-Curran SB. Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) and opinion of contact lens performance. *Optom Vis Sci.* 2012;89(10):1435-1442.
6. Chalmers RL, Keay L, Hickson-Curran SB, Gleason WJ. Cutoff score and responsiveness of the 8-item Contact Lens Dry Eye Questionnaire (CLDEQ-8) in a Large daily disposable contact lens registry. *Contact Lens and Anterior Eye.* 2016;39(5):342-352.
7. Chalmers RL, Hickson-Curran S, Keay L, Gleason B, Albright R. Struggle with Soft Contact Lens Wear is Addressed by Refitting with Daily Disposable Lenses: 4 Month Follow-up from the TEMPO Registry.
8. Wirth RJ, Edwards MC, Henderson M, et al. Development of the Contact Lens User Experience: CLUE Scales. *Optom Vis Sci.* 2016;93(8):801-808.
9. Kenward MG, Roger JH. Small Sample Inference for Fixed Effects from Restricted Maximum Likelihood. *Biometrics.* 1997;53(3):983.
10. SAS Institute Inc. 2016 SAS/STAT® 14.3 User's Guide. Cary NC: SAS Institute Inc.
11. SAS Institute Inc: SAS® 9.4 Statements: Reference TEC, NC: SAS Institute Inc; 2014.
12. Bonferroni C. Calculation of the insurance groups of heads. *Studies in Honour of Professor Salvatore Ortu Carboni.* 1935;Rome: Italy:13-60.
13. Health Information Portability and Accountability Act (HIPAA). In: https://www.hhs.gov/hipaa/for-professionals/privacy/index.html
14. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Available at: http://data.europa.eu/eli/reg/2017/745/2017-05-05

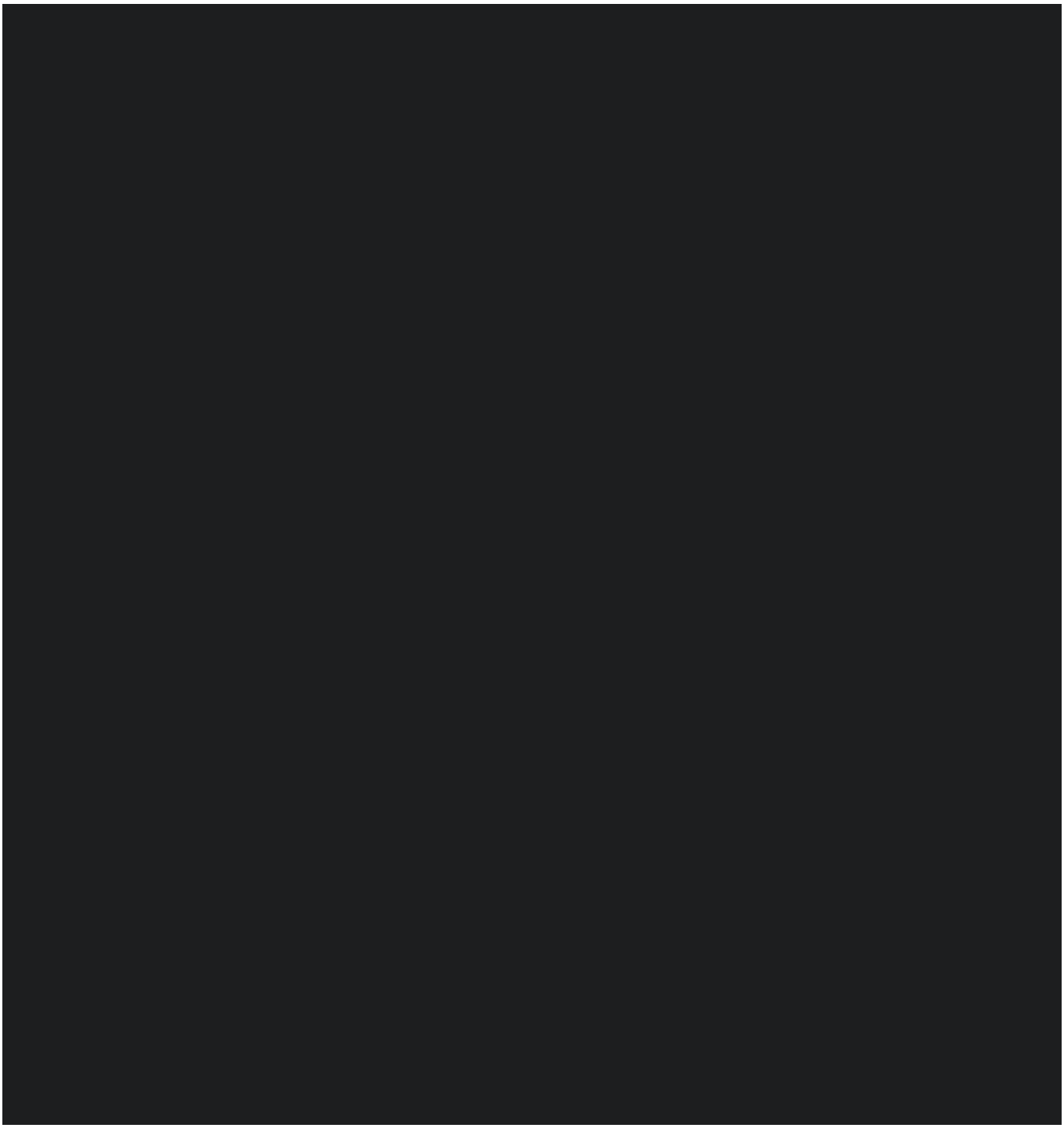
APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

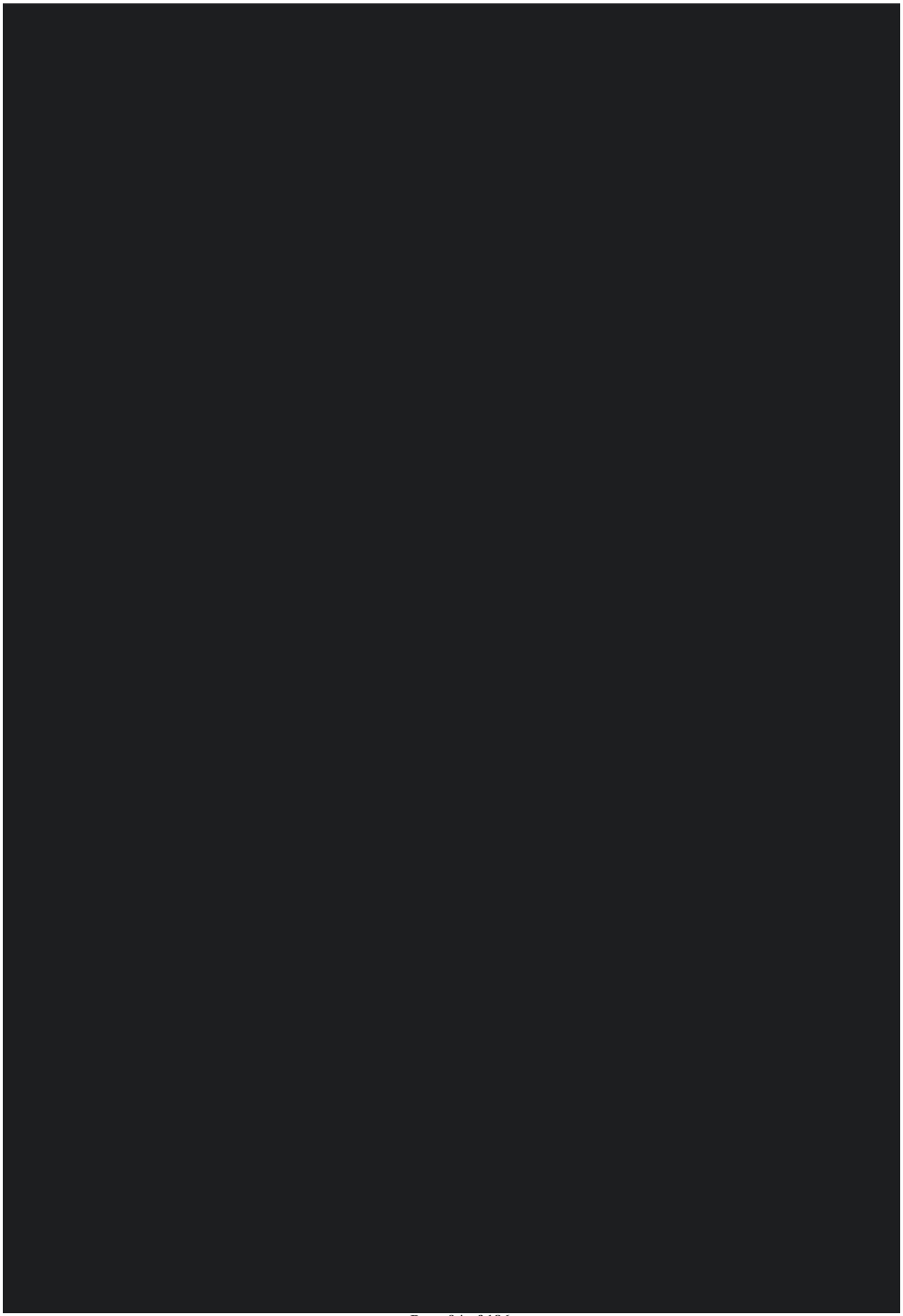
[redacted]

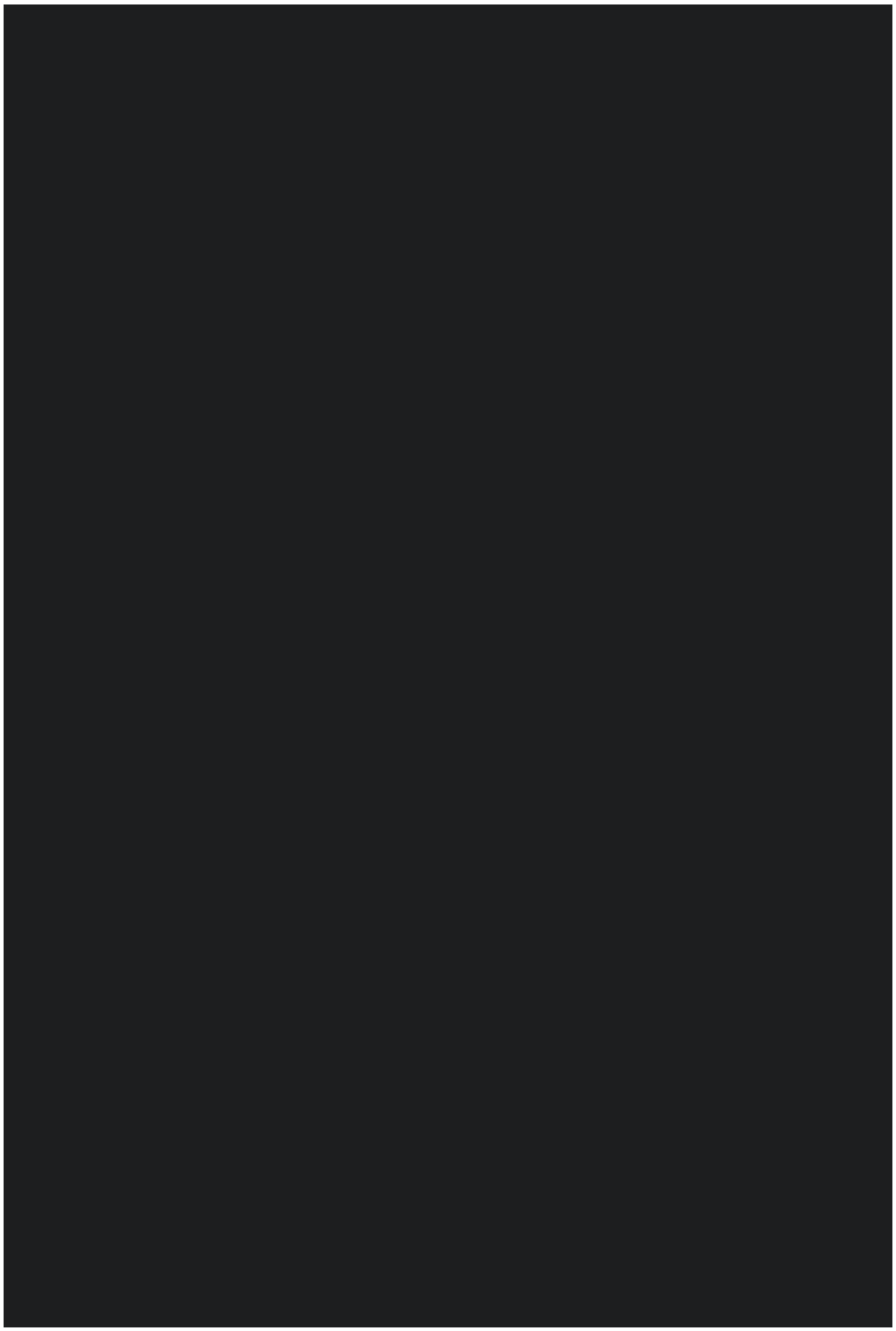
[redacted]

[redacted]

[redacted]







APPENDIX B: PATIENT INSTRUCTION GUIDE

This will be provided separately.

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

Alcon DAILIES® Aqua Comfort Plus® (nelfilcon A)

Alcon®
a Novartis company

FOCUS® DAILIES®, FOCUS® DAILIES® Toric, FOCUS® DAILIES® Progressives, DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric and DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) One-Day Contact Lenses

92024162

IMPORTANT: This package insert is effective as of October, 2013 and supersedes all prior inserts for the product described below. Please read carefully and keep this information for future use. This package insert 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 appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from Alcon by calling Customer Service at 1-800-241-5999 or download from our website at www.alcon.com. In addition a Patient Instruction Booklet is available which is recommended to be given to patients.

Rx only

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL.

DESCRIPTION

FOCUS® DAILIES® and DAILIES® AquaComfort Plus® (nelfilcon A) Soft (hydrophilic) One-Day Contact Lenses are available in a spherical lens design. FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® Toric (nelfilcon A) Soft (hydrophilic) One-Day Contact Lenses are available in a toric design. FOCUS® DAILIES® Progressives and DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) Soft (hydrophilic) One-Day Contact Lenses are available in a multifocal lens design. The lenses are to be prescribed for single use, daily disposable wear.

LENS MATERIAL

The lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide).

- For VISITINT® lenses, the color additive copper phthalocyanine is added to the lens material to create a light blue edge to edge color to make them easier to see when handling.
- Print marks on FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® Toric (nelfilcon A) contact lenses contain the color additive phthalocyanine green.

LENS PROPERTIES

- Refractive index: 1.38 (hydrated)
- Light transmittance: VISITINT® ≥ 92% (@ 610 nm)
- Oxygen permeability (Dk): 26 x 10 -11 (cm2/sec) (ml O2 /ml x mm Hg), measured at 35°C (Fatt, edge effect corrected)
- Water content: 69% by weight in normal saline

Approved Power Range: -20.00D to +20.00D

LENS PARAMETERS[1]

FOCUS® DAILIES® (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.6 mm
- Diameter: 13.8 mm
- Powers available: -0.50D to -6.00D (0.25D steps); -6.50D to -10.00D (0.50D steps); +0.50D to +6.00D (0.25D steps)
- Center thickness: 0.10 mm at -3.00D (varies with power)
- Tint: Light blue handling tint

FOCUS® DAILIES® Toric (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.6 mm
- Diameter: 14.2 mm
- Powers available: +4.00D to -6.00D (0.25D steps) -6.50D to -8.00D (0.50D steps) Cylinder: -0.75D, -1.50D Axis: 20°, 70°, 90°, 110°, 160°, 180°
- Center thickness: 0.10 mm at -3.00D (varies with power)
- Tint: Light blue handling tint

FOCUS® DAILIES® Progressives (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.6 mm
- Diameter: 13.8 mm
- Powers available: +5.00D to -6.00D (0.25D steps) Single Progressive Add Effective Range up to +3.00D
- Center thickness: 0.11 mm at -3.00D (varies with power)
- Tint: Light blue handling tint

DAILIES® AquaComfort Plus® (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.7 mm
- Diameter: 14.0 mm
- Powers available: -0.50D to -6.00D (0.25D steps); -6.50D to -10.00D (0.50D steps); +0.50D to +6.00D (0.25D steps)
- Center thickness: (varies with power) 0.10 mm at -3.00D
- Tint: Light blue handling tint

DAILIES® AquaComfort Plus® Toric (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.8 mm
- Diameter: 14.4 mm
- Powers available: +4.00D to -6.00D (0.25D steps); -6.50D to -8.00D (0.50D steps); Cylinder: -0.75D, -1.25D, -1.75D Axis: 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°
- Center thickness: 0.10 mm at -3.00D (varies with power)
- Tint: Light blue handling tint

DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.7 mm
- Diameter: 14.0 mm
- Powers available: +6.00D to -10.00D (0.25D steps); ADD: LO, MED, HI
- Center thickness: 0.10 mm at -3.00D (varies with power)
- Tint: Light blue handling tint

Hereafter, FOCUS® DAILIES®, FOCUS® DAILIES® Toric, FOCUS® DAILIES® Progressives, DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric and DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) One-Day Contact Lenses will be referred to as DAILIES® (nelfilcon A) One-Day Contact Lenses unless product distinction is necessary.

ACTIONS

- When hydrated and placed on the cornea DAILIES® (nelfilcon A) One-Day Contact Lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (Uses)

- FOCUS® DAILIES® and DAILIES® AquaComfort Plus® (nelfilcon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.
- FOCUS® DAILIES® Toric, and DAILIES® AquaComfort Plus® Toric (nelfilcon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes with 6.00 diopters (D) or less of astigmatism.
- FOCUS® DAILIES® Progressives and DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not-aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 1.50 diopters (D) or less of astigmatism that does not interfere with visual acuity.
- DAILIES® (nelfilcon A) One-Day Contact Lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

CONTRAINDICATIONS (Reasons not to use)

Do not use DAILIES® (nelfilcon A) One-Day Contact Lenses when any of the following conditions exists:

- Acute or subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids that may be exacerbated by contact lens wear.
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear.
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may be exacerbated by or interferes with contact lens wear.
- Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exacerbated by the wearing of 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 thimerosal) to which some people may develop an allergic response.
- Any active corneal infection (bacterial, fungal, or viral).
- The use of any medication that is contraindicated or interferes with contact lens wear, including eye medications.
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear.
- If eyes become red or irritated.

WARNINGS

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 professional's directions and all labeling instructions for proper use of their lenses. **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 study results[2] have shown that the risk of ulcerative keratitis is nine times greater for daily wear users who wear their lenses overnight (outside the approved indication) compared to those who do not wear them overnight.
- Studies[2] have shown that contact lens wearers who smoke have an estimated 3 to 8 times greater risk of suffering ulcerative keratitis than those who are nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, redness of the eye, or other problems they should be instructed to immediately remove their lenses and promptly contact their eye care professional. It is recommended that contact lens wearers see their eye care professional regularly as directed.

PRECAUTIONS

Special Precautions for the Eye Care Professional:

Due to the small number [redacted] clinical investigation of lenses, all refractive powers, custom parameters 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, 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.

- 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, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- 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.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continuing health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. Alcon recommends that patients see their eye care professional once each year or as recommended by the eye care professional.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

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

- Carefully follow the handling, insertion, removal, and wearing instructions in the DAILIES® (nelfilcon A) One-Day Contact Lenses Patient Instruction Booklet and any additional instructions provided by the eye care professional.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always keep spare lenses available to avoid reusing the lenses.
- Good hygiene habits help promote safe and comfortable lens wear. Always wash and rinse hands before handling lenses.
- Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pouring the lens onto the palm of your clean hand.
- Never use tweezers or other sharp objects such as fingernails to remove the lens from the container to avoid damaging the lens.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses. If sprays are used, eyes should be kept closed until the spray has settled.
- Always handle lenses carefully. If a lens is dropped, small particles or fibers may adhere to the lens surface which can irritate the eye. Replace with a sterile fresh, new lens.
- Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.
- Consult the eye care professional 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.
- Avoid all harmful or irritating vapors or fumes while wearing lenses.
- Promptly remove a lens to avoid serious injury in the event that dust, a foreign body or other contaminant gets between the lens and the eye.
- Discard any lens which has become dehydrated or damaged. Replace with a sterile fresh, new lens.
- Patients should be instructed to remove their lenses before sleeping.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the section Care for a Sticking Lens. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- Patients should inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or restrict the use of contact lenses in certain work environments.
- Patients should inform their physician that contact lenses are worn and should consult their eye care professional before using any medication in the eye.
- Do not use lenses beyond the expiration date.
- Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. Patients should be informed of these potential conditions and proper remedial treatment should be prescribed if any of these conditions occur. Depending on the severity of the condition appropriate treatment may include the use of rewetting drops intended for use with soft contact lenses or temporary cessation of contact lens wear until the conditions subsides.

It is strongly recommended that patients be provided with a copy of the DAILIES® (nelfilcon A) One-Day Contact Lenses Patient Instruction Booklet available from Alcon Laboratories and understand its contents prior to dispensing the lenses.

ADVERSE REACTIONS

Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:

- Foreign body sensation
- Excessive watering or other unusual eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (sensitivity to light)
- Burning, stinging, itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

If any of the previous signs or symptoms occur:

- **The patient should IMMEDIATELY REMOVE THE LENS(ES). If the discomfort or problem stops, the patient should discard the lens and replace it with a new one. IF THE PROBLEM CONTINUES AFTER INSERTING A NEW LENS, THE PATIENT SHOULD IMMEDIATELY REMOVE THE LENS(ES) AND CONTACT AN EYE CARE PROFESSIONAL AT ONCE**
- Patients should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, infiltrates and bacterial conjunctivitis must be managed and treated early to avoid more serious complications. Additionally, contact lens wear may be associated with ocular changes which require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE REACTION REPORTING

If a patient experiences any serious adverse effects associated with the use of DAILIES® (nelfilcon A) One-Day Contact Lenses, licensed eye care professionals please notify: Alcon Medical Safety in the USA at 1-800-241-7468.

FITTING

For a detailed description of the fitting techniques, refer to the DAILIES® (nelfilcon A) One-Day Contact Lenses Professional Fitting and Information Guide, copies of which are available free of charge from:

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134
1-800-241-5999

REPLACEMENT AND WEAR SCHEDULE

DAILIES® (nelfilcon A) One-Day Contact Lenses are intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a fresh new lens.

WEARING SCHEDULE

- **Daily Wear (less than 24 hours, while awake)**
  The maximum daily wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. There may be a tendency for patients to overwear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that DAILIES® (nelfilcon A) One-Day Contact Lenses are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period. Optimum individual wearing schedule will vary.

CLINICAL DETAILS

- **Seasonal Allergy Wearers**
  A one month subjective trial of contact lens wearers with a history of seasonal allergic conjunctivitis was conducted during a month of expected high pollen count in various US cities. Information was collected about allergy-related symptoms, wear-time and comfort during lens wear. Study results found that these contact lens wearers experienced fewer days of burning and redness when wearing FOCUS® DAILIES® contact lenses as compared to a new pair of their usual lenses. The effects of allergy medications that may have been used during the study were not assessed.

- **All Day Comfort**
  A one month study of 188 subjects was conducted for the purpose of evaluating comfort and wearing time for FOCUS® DAILIES® soft contact lenses. End of day comfort was measured using a 0 to 10 scale where 0 was unacceptable and 10 was excellent. Wearing time was also recorded in hours of wear per day.

Baseline values for end of day comfort and average wearing time with the subject's pre-study lenses were 6.9 out of 10 and 13.5 hours, respectively. Study results found that the average end of day comfort for FOCUS® DAILIES® contact lenses was 7.8 out of 10 with an average wearing time of 14.3 hours. The values for FOCUS® DAILIES® were statistically different compared to the baseline values collected from the pre-study lenses. As in this study, individual results may vary.

Reference: Bauman, E. (1997). Daily Disposables Versus Other Soft Lens Modalities. Optician 214: 33-35, 37.

- **DAILIES® AquaComfort Plus®**
  A one-month study was conducted for the purpose of evaluating the performance for DAILIES® AquaComfort Plus® lenses. Subjective performance measures were evaluated by having the subjects rate these attributes on a scale from 1 to 10, where 1 was "poor/not at all satisfied" and 10 was "excellent/completely satisfied," for both their previous FOCUS® DAILIES® lenses as well as DAILIES® AquaComfort Plus® lenses.

  Subjects rated DAILIES® AquaComfort Plus® contact lenses statistically better for comfort at insertion compared to their own FOCUS® DAILIES® / All Day Comfort lenses. Specifically, average comfort at insertion was 9.0 at baseline with FOCUS® DAILIES® lenses and was 9.5 at one-month with DAILIES® AquaComfort Plus® lenses. Additionally, average overall comfort was 8.8 at baseline with FOCUS® DAILIES® and was 9.1 at one-month with DAILIES® AquaComfort Plus®, while the average comfort at the end of the day was 7.8 at baseline with FOCUS® DAILIES® lenses and was 8.5 at one-month with DAILIES® AquaComfort Plus® lenses (changes not statistically significant).

EMERGENCY LENS CARE

Cleaning and disinfection of the lens is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times.

CARE FOR A STICKING OR TORN LENS

If the lens sticks (stops moving) or cannot be removed from the eye, instruct the patient to apply 1 to 2 drops of a recommended lubricating or rewetting solution in accordance with the manufacturer's instruction for use package labeling. The patient should blink forcefully several times, then while looking up slide the lens down onto the white part of the eye and remove the lens by pinching it between the thumb and forefinger. If the lens continues to stick, the patient should immediately consult the eye care professional.

If the lens tears in your eye it will feel uncomfortable. Advise patients it is not possible to lose a contact lens or part of a contact lens behind the eye and that they should calmly remove the pieces by carefully pinching them as they would do for normal lens removal. If the lens pieces do not seem to remove easily the eye may be rinsed with sterile saline. Excessive pinching should be avoided. If rinsing with saline does not help, instruct patients to contact the eye care professional for assistance. Lenses can be easily located by the eye care professional using fluorescein.

EMERGENCIES

Patients 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 or fresh saline solution, remove and discard the lens, and immediately contact the eye care professional or visit a hospital emergency room without delay.**

Additional information regarding emergency treatment may be provided on the product container label.

HOW SUPPLIED

DAILIES® (nelfilcon A) One-Day Contact Lenses are packaged in strips of five foil sealed blister packs containing phosphate-acetate buffered saline solution and are steam sterilized STERILE. Five blister pack containers are attached to form a single strip. The package storage saline may contain up to 0.05% Poloxamer. In addition, the package storage saline for DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric and DAILIES® AquaComfort Plus® Multifocal One-Day Contact Lenses contains polyethylene glycol (PEG) and hydroxypropyl methylcellulose (HPMC). The package is marked with the base curve, diameter, dioptric power, manufacturing lot number and expiration date.

The following may appear on the labels or cartons:

Symbols/Signs	Description
Rx only	CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.
STERILE	Steam sterilized
EXP	Use by date (Expiry date)
LOT	Batch code
en	Example of two letter language code (English)
Do Not Reuse	Do Not Reuse
DIA	Diameter
BC	Base curve
PWR	Lens power
LO	"Low" near ADD
MED	"Medium" near ADD
HI	"High" near ADD
CE 0086	European conformity sign
	See product instructions
EC REP	Authorized Representative European Community
	Manufacturer
	Packaging waste license sign

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX
76134-2099, USA

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[1]Check for actual product availability as additional powers may be introduced over time.

[2]New England Journal of Me[redacted]21 (12), pp.773-783.

Alcon DAILIES TOTAL1® (delfilcon A)

Alcon	**DAILIES TOTAL1® and DAILIES TOTAL1® Multifocal** (delefilcon A) soft contact lenses for Daily Disposable Wear	W900236420

Important: This package insert is effective as of December 2019 and applicable to the delefilcon A contact lenses described below. Please read carefully and keep this information for future use. This package insert 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 appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from Alcon by calling Customer Service at 1-800-241-5999 or download from our website at www.alcon.com. In addition, a *Patient Instruction Booklet* is available which is recommended to be given to patients.

Rx only

CAUTION: Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.

PRODUCT DESCRIPTION

DAILIES TOTAL1® Multifocal (delefilcon A) soft contact lenses are made from a lens material that is 33% water and 67% (delefilcon A) polymer, a silicone containing hydrogel with added phosphatidylcholine. The core lens material containing 33% water transitions through a water gradient to a hydrogel surface layer that exceeds 80% water. Lenses contain the color additive copper phthalocyanine, a light blue tint, which makes them easier to see when handling.

Lens Properties

- Refractive Index hydrated: 1.42
- Light Transmittance: 93% (@ 610 nm, -1.00 D)
- Oxygen Permeability (Dk): 140 x 10^{-11} (cm^2/sec)(ml O_2 /ml x mm Hg), measured at 35° C (intrinsic Dk-Coulometric method)
- Water Content: 33% by weight in normal saline
- Surface Water Content: ≥ 80%

Lens Parameters

- Diameter Range 13.0 to 15.0 mm
- Spherical Power Range -20.00 to +20.00 D
- Base Curve Range 8.0 to 9.2 mm

Lens Parameters Available[1]

DAILIES TOTAL1® (delefilcon A) spherical contact lenses

- Chord Diameter: 14.1 mm
- Center Thickness: 0.09 mm @ -3.00 D (varies with power)
- Base Curve: 8.5 mm
- Powers: -0.50 to -6.00 D (0.25 D steps)
  -6.50 to -12.00 D (0.50 D steps)
  +0.50 to +6.00 D (0.25 D steps)

DAILIES TOTAL1® Multifocal (delefilcon A) contact lenses

- Chord Diameter: 14.1 mm
- Center Thickness: 0.09 mm @ -3.00 D (varies with power)
- Base Curve: 8.5 mm
- Powers: +6.00 D to -10.00 D (0.25 D steps)
  ADD: LO, MED, HI

NOTE: Hereafter, **DAILIES TOTAL1® spherical contact lenses** and **DAILIES TOTAL1® Multifocal contact lenses** will simply be referred to as delefilcon A contact lenses unless product distinction is necessary.

ACTIONS

When hydrated and placed on the cornea, **delefilcon A** contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (Uses)

DAILIES TOTAL1® (delefilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

DAILIES TOTAL1® Multifocal (delefilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 (D) or less and who may have up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

CONTRAINDICATIONS (Reasons Not To Use)

DO NOT use delefilcon A contact lenses when any of the following exists:

- Inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease which may be exacerbated by or interferes with contact lens wear
- Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exaggerated by the wearing of contact lenses
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear
- If eyes become red or irritated

WARNINGS

Advise patients 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 professional's directions and all labeling instructions for proper use of lenses and lens care products. **Serious 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 study results have shown that the risk of serious adverse reactions is increased when contact lenses are worn overnight[2].
- Studies[2] have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, foreign body sensation, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care professional. It is recommended that contact lens wearers see their eye care professional regularly as directed.

PRECAUTIONS

To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:

Special Precautions for the Eye Care Professional

Due to the small number of patients enrolled in the 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, 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 evaluated on initial dispensing and monitored on an ongoing basis by the prescribing eye care professional.

- Fluorescein, a yellow dye, should not be used while the lenses are on the patient's eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- Patients who wear contact lenses to correct presbyopia may not achieve the best possible 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.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. Alcon recommends that patients see their eye care professional once each year, or more often, as recommended by t[redacted]al.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

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

Handling Precautions

- Be sure that before leaving the eye care professional's office the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear. **Always wash, rinse and thoroughly dry hands with a lint-free towel before handling lenses.**
- **REMOVE A LENS IMMEDIATELY** if an eye becomes red or irritated.
- Always handle lenses carefully. Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use.
- Do not use if blister package is damaged or not sealed completely. This may result in product contamination which can lead to a serious eye infection.
- Ensure that the correct lens for each eye is available. Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pouring the lens onto the palm of your clean hand. Ensure the lens is right side out. Inspect lenses prior to insertion. Do not insert damaged lenses.
- To insert lenses:
  - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses.
  - Place a lens on the tip of your clean and dry right or left index finger, place the middle finger of the same hand close to lower eyelashes and pull down the lower eyelid.
  - Use the fingers of the other hand to lift the upper eyelid.
  - Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
  - Look down and slowly remove the hand, releasing the lower lid.
  - Look straight ahead and slowly remove the other hand, releasing the upper lid.
  - Blink gently.
- To remove lenses:
  - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses. **Make sure hands are clean and completely dry.**
  - Blink fully several times.
  - While looking up, slide the lens down onto the white part of the eye.
  - Remove the lens by pinching gently between the thumb and forefinger. Do not pinch the eye tissue.
  - If the lens is difficult to grasp, dry fingers once more and try again. Do not use rewetting drops in this instance.
- If a lens decenters on the eye, it may be possible to recenter it by:
  - Closing the eye and massaging the lens into place, or
  - Looking in the direction of the lens and blinking gently, or
  - Gently pushing the off-centered lens onto the cornea with light finger pressure on the edge of the upper or lower eyelid.
- If a lens tears in the eye it will feel uncomfortable. Advise wearers it is impossible to lose a contact lens or part of a contact lens behind the eye and to remain calm. Lens pieces may be removed by pinching them as for normal lens removal, carefully avoiding pinching the eye tissue. If the lens pieces do not seem to remove easily, rinsing with saline is recommended. If this does not help, the wearer should contact an eye care professional for assistance.

Lens Wearing Precautions:

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the *Care for a Sticking Lens* section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- The eye care professional should be consulted about wearing lenses during water sports and water related activities. Exposure to water or other non-sterile liquids 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*.
- Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Lenses should be disposed of each day upon removal from the eye.
- Discard any lens which has become dehydrated or damaged. Replace with a sterile, fresh, new lens.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always carry spare lenses with you or have back-up spectacles available.
- Do not share lenses with anyone as this may spread micro-organisms which could result in serious eye health problems.
- Do not use lenses beyond their expiration date.

Other Topics to Discuss with Patients:
- Periodic eye examinations are extremely important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response. Alcon recommends that patients see their eye care professional once each year or as recommended by the eye care professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, and blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such medications accordingly and prescribe proper remedial measures.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Who Should Know that the Patient is Wearing Contact Lenses:
- Patients should inform their health care practitioners that they are wearing contact lenses.
- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn.

It is strongly recommended that patients be provided with a copy of the **DAILIES TOTAL1® and DAILIES TOTAL1® Multifocal** (delefilcon A) Contact Lenses *Patient Instruction Booklet* available from Alcon and understand its contents prior to dispensing the lenses.

WATER ACTIVITIES
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 showering or swimming, discard them and replace with a new pair. Ask the Eye Care Professional for recommendations about wearing lenses during any activity involving water.

ADVERSE EFFECTS
Patients should be instructed to check eyes regularly to make sure they look well, feel comfortable and vision is clear. Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:
- Moderate to severe eye pain not relieved by removing the lens
- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging or itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

WHAT TO DO IF A PROBLEM OCCURS
Patients should be instructed that if any of the above signs or symptoms are noticed, he or she should:
- **IMMEDIATELY REMOVE THE LENSES.**
- **If the discomfort or problem stops,** discard the lens and replace it with a new one.
- **If the discomfort or problem continues after removing lens(es) or upon insertion of a new lens, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**
- **The patient should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.**
- Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE EFFECT REPORTING
If a patient experiences any serious adverse effects associated with the use of **DAILIES TOTAL1®** brand (delefilcon A) contact lenses, please notify: Alcon Medical Safety in the USA at 1-800-757-9780.

FITTING GUIDE AND PATIENT BOOKLET
Conventional methods of fitting contact lenses apply to delefilcon A contact lenses. For a detailed description of the fitting techniques, refer to the **DAILIES TOTAL1®** and **DAILIES TOTAL1® Multifocal** (delefilcon A) Contact Lenses *Professional Fitting and Information Guide*. Both the professional fitting guide and a patient instruction booklet are available free of charge from:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134-2099
1-800-241-5999

LENS WEAR & REPLACEMENT SCHEDULES
DAILY WEAR (less than 24 hours, while awake):
- To avoid tendency of the daily wear patient to over-wear the lenses initially, stress the importance of adhering to a proper, initial wearing schedule. Normal daily wear of lenses assumes a minimum of 6 hours of non lens wear per 24 hour period.
- It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.
- The maximum daily wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. There may be a tendency for patients to over-wear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that delefilcon A contact lenses are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period. Optimum individual wearing schedule will vary.
- Delefilcon A contact lenses are intended to be worn once (daily disposable wear) and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a fresh new lens.

EMERGENCY LENS CARE
Cleaning and disinfection of daily disposable lenses is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times.

CARE FOR A STICKING LENS
If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. It is important that the patient wash and dry their hands thoroughly before removing the lens. If the lens continues to stick, the patient should IMMEDIATELY consult the eye care professional.

IN OFFICE USE OF TRIAL LENSES
Eye care professionals should educate contact lens technicians concerning proper use of trial lenses.
Each contact lens is shipped sterile in a blister pack containing phosphate buffered saline solution. Hands should be thoroughly washed and rinsed and dried with a lint-free towel prior to handling a lens. In [redacted] blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes lenses should be disposed of after a single use and not be re-used from patient to patient.

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 or fresh saline solution and immediately contact the eye care professional or visit a hospital emergency room without delay.

DISPOSAL AND RECYCLING
Dispose of contact lenses and the blister pack lidding in the waste bin, not down the sink or toilet. The carton packaging and the polypropylene (PP) plastic shell of the blister pack should be placed in the waste bin or recycled according to local waste management guidance.

HOW SUPPLIED
Each lens is packaged in a foil-sealed plastic container containing phosphate buffered saline solution with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly(acrylamide-acrylic) acid and is steam sterilized. The package is marked with the base curve, diameter, dioptric power (and ADD power for multifocal lenses), manufacturing lot number, date of manufacture, and expiration date.

The following may appear on the labels or cartons:

Symbol/Abbreviation Description

Rx only	CAUTION: Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.
	Single sterile barrier system
STERILE	Sterilized using steam
EXP	Use-by date (Expiry date)
LOT	Batch code
en	Two letter code for the language (Example shown: English)
	Do not re-use
	Do not use if blister package is damaged
DIA	Diameter
BC	Base curve
PWR	Power
L	Left
R	Right
D	Diopter (lens power)
ADD	Addition power
MAX ADD	Maximum effective addition power
LO	Low
MED	Medium
HI	High
CE	European conformity mark
	Caution
	Consult instructions for use
EC REP	Authorized representative in the European Community
	Manufacturer
	Date of manufacture
MD	Medical device
	Packaging waste license sign

Manufacturer:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134-2099

1-800-241-5999

www.alcon.com

U.S. Pat.: www.alconpatents.com

Alcon

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[1] Check for actual product availability as additional parameters may be introduced over time.
[2] Schein, OD, Glynn RJ, Poggio EC, Seddon JM, Kenyon KR. The Relative Risk of Ulcerative Keratitis Among Users of Daily Wear and Extended Wear Soft Contact lenses. *N Eng J Med*. 1989; 321 (12):773-783.

CooperVision® clariti® 1 day (somofilcon A)

PACKAGE INSERT

Clariti 1 Day (somofilcon A)
Clariti 1 Day Toric (somofilcon A)
Clariti 1 Day Multifocal (somofilcon A)
Clariti 1 Day Multifocal Toric (somofilcon A)

Soft (hydrophilic**) Contact Lenses for Daily Wear Single Use Only with UV Blocker**

SYMBOLS KEY

The following symbols may appear on the label or carton.

SYMBOL	DEFINITION	Reference
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner	81 FR 38911
	Caution / See Instructions for Wearers	BS EN ISO 15223-1 Table 1, Symbol 5.4.4
	Use by Date (expiration date)	BS EN ISO 15223-1 Table 1, Symbol 5.1.4
	Batch Code	BS EN ISO 15223-1 Table 1, Symbol 5.1.5
	Sterile using Steam Heat	BS EN ISO 15223-1 Table 1, Symbol 5.2.5
	Manufacturer	BS EN ISO 15223-1 Table 1 Symbol 5.1.1
	Authorized representative in the European Community	BS EN ISO 15223-1 Table 1, Symbol 5.1.2
	Do not use if package is damaged	BS EN ISO 15223-1 Table 1, Symbol 5.2.8
	Consult instructions for use / consult electronic instructions for use	BS EN ISO 15223-1 Table 1 Symbol 5.4.3
	Do not re-use	BS EN ISO 15223-1 Table 1, Symbol 5.4.2
	Date of manufacture	BS EN ISO 15223-1 Table 1 Symbol 5.1.3

DESCRIPTION

Clariti 1 Day (somofilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear Single Use are a hydrophilic co-polymer of silicone containing monomers and hydrophilic monomers which is cross-linked with tetraethyleneglycol dimethacrylate and di-functional methacryloxypropyl-terminated poly(dimethylsiloxane).

When hydrated the lens consists of 44.0% somofilcon A and 56.0% water by weight of saline immersed in normal saline. A benzophenone UV absorbing monomer is used in the contact lens to help protect against transmission of harmful UV radiation and Clariti 1 Day (somofilcon A) Soft contact lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

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

The lens has a hemispherical flexible shell, which covers the cornea and a portion of the adjacent sclera, with the following dimensions:

- Chord Diameter: 13.0mm to 15.5mm
- Centre Thickness: 0.03mm to 0.50mm
- Base Curve: 7.5mm to 9.30mm
- Powers: -20.00 DS to +20.00 DS
- Toric Cylinder options: -0.75, -1.25, -1.75 and -2.25
- Toric Axis options: 10^{o} to 180^{o} (10^{o} steps)
- Multifocal Add:

  Lens "LOW" = "low" for spectacle near ADD lens (Max +2.25 ADD)
  Lens "HIGH" = "high" for spectacle near ADD lens (+2.50 ADD or greater)

The physical/optical properties of the lenses are:

- Refractive Index: 1.4003
- %Transmittance @ 590nm: 98.13
- %Transmittance @ 280-315nm: 0.71
- %Transmittance @ 316-380nm: 20.62
- Surface Character: Hydrophilic
- Water Content: 56%
- Oxygen Permeability (DK): 60×10^{-11} (cm^2/sec) (ml O_2/ml x mmHg) at 35^{o}C (Fatt Method for determination of oxygen permeability)
- Specific Gravity: 1.17

LENS PARAMETERS

The lenses are available as follows:

Clariti 1 Day (somofilcon A)

Sphere Powers:	+20.00 to –20.00 DS
Centre Thickness:	varies with power, e.g., 0.07mm (at -3.00 DS)
Diameter:	13.0 through to 15.5mm
Base Curve:	7.50 through to 9.30mm

Clariti 1 Day Toric (somofilcon A)

Sphere Powers:	+20.00 to –20.00 DS
Centre Thickness:	varies with power, e.g., 0.105mm (at -3.00 DS)
Diameter:	13.0 through to 15.5mm
Base Curve:	7.50 through to 9.30mm
Cylinder Options:	-0.75, -1.25, -1.75, -2.25
Axis:	10º to 180º (10º steps)

Clariti 1 Day Multifocal (somofilcon A)

Sphere Powers:	+20.00 to –20.00 DS
Centre Thickness:	varies with power, e.g., 0.07mm (at -3.00 DS)
Diameter:	13.0 through to 15.5mm
Base Curve:	7.50 through to 9.30mm

Add powers are to be prescribed dependent on specific patient requirements as determined by the Eye Care Professional; however, as a guide, the lenses come in the following ADD powers:

Lens “LOW” = “low” for spectacle near ADD lens (Max +2.25 ADD)
Lens “HIGH” = “high” for spectacle near ADD lens (+2.50 ADD or greater)

Clariti 1 Day Multifocal Toric (somofilcon A)

Parameters are the same as above for Clariti 1 Day Multifocal and Toric lenses.

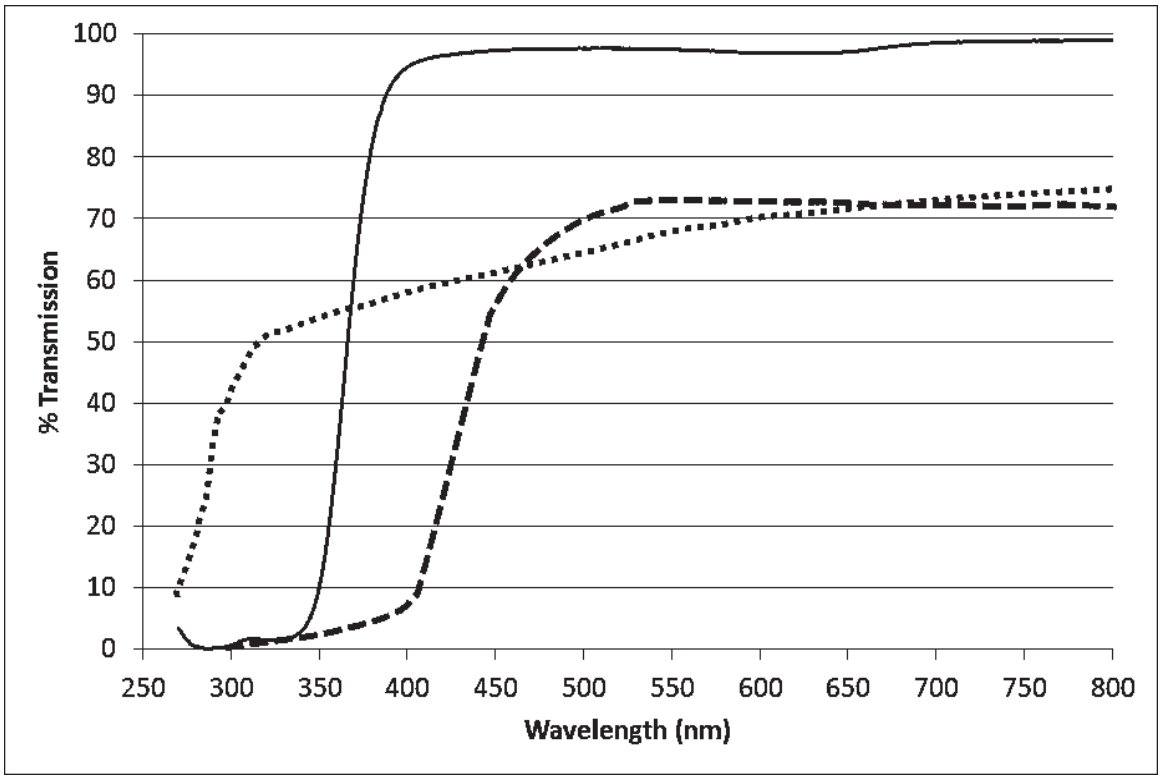
Call our Customer Service Department at (800) 341-2020 for current availability.

ACTIONS

In its hydrated state, Clariti 1 Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker when placed on the cornea acts as a refracting media to focus light rays on the retina.

TRANSMITTANCE CURVES

The transmittance curve below compares Clariti 1 Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker, a 24-yr. old human cornea and 25-yr. old human crystalline lens.



Key:

——— Clariti 1 Day (somofilcon A) Soft (Silicone Hydrogel) Daily Disposable Contact Lens with UV Blocker. The data shown was obtained from measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-6.00DS lens with a centre thickness 0.070 mm).

..... 24 year old human cornea[1]

– – – – – 25 year old crystalline lens[2]

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

WARNING:

UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and the 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. Consult your eyecare practitioner for more information.

INDICATIONS (USES)

The **CLARITI 1 DAY** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The **CLARITI 1 DAY TORIC** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters.

The **CLARITI 1 DAY MULTIFOCAL** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may require a reading addition of +3.00 Diopters or less and may exhibit astigmatism up to 1.50 Diopters or less.

The **CLARITI 1 DAY MULTIFOCAL TORIC** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters and require a reading addition of +3.00 Diopters or less.

The Clariti 1 Day (somofilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE your contact lenses 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
- 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 that may be induced or exaggerated by wearing contact lenses
- Any active corneal infection (bacterial, fungal, protozoal, or viral)
- If the eyes become red or irritated

WARNINGS

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

- Problems with contact lenses or lens care products could result in serious injury to the eye. Proper use and care of your contact lenses and lens care products, including lens cases are essential for the safe use of these products.
- Eye problems, including a sore or lesion on the cornea (corneal ulcers) can develop rapidly and lead to loss of vision.
- The risk of an infected sore or lesion on the cornea (ulcerative keratitis) is greater for people who wear extended wear contact lenses than for those who wear daily wear lenses. Do not wear your lenses while sleeping as the risk of sore or lesion on the cornea (ulcerative keratitis) is greater than among those who do not wear them while sleeping.
- The risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should immediately remove the lenses and promptly contact your eyecare practitioner. It is recommended that you see your eyecare practitioner routinely as directed.

- **Water Activity** – Do not expose your contact lenses to water while you are wearing them.

  Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water when swimming in pools, lakes or oceans, you should discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

PRECAUTIONS

At your initial visit to your eyecare practitioner:

- Be sure you read and understand the full contents of this booklet and discuss it with your eyecare practitioner.

- Give your eyecare practitioner a complete history of your eye health, including any eye injuries, diseases, conditions or other problems you have had with your eyes, even if they seem unimportant to you.

- Tell your eyecare practitioner about your general health, any medicines you are taking, current treatment by a physician, any disease you had or now have and any prior surgery.

- Before leaving the eyecare practitioner's office, you should be able to promptly remove lenses or should have someone else available who can remove the lenses.

Lens Handling Precautions:

- **Always wash and rinse your hands before handling lenses**. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to cause damage to lenses than oil-based products.

- **Do not** touch contact lenses with your fingers or hands if your hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- **Do not** touch the lens with your fingernails.

- **Carefully** follow the handling, insertion, removal and wearing instructions in the Patient Instructions for Clariti 1 Day and those prescribed by your eyecare practitioner.

- **Always** handle lenses gently and avoid dropping them.

- **Never** use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand when removing from lens blister.

Lens Wearing Precautions:

- You should remove your lenses immediately if your eyes become red or irritated.
- **Never** wear lenses beyond the period recommended by your eyecare practitioner.
- **Always** discard lenses worn as prescribed by your eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep **your eyes closed** until the spray has settled.
- **Avoid** all harmful or irritating vapours and fumes while wearing lenses.
- **Avoid** rubbing your eyes with the lenses on; this can irritate your eye or dislodge the lens.
- **Keep** your eyes closed tightly when washing or showering to keep water and soaps out of your eyes; these may cause loss of the senses, contamination or injury to your eyes.
- **Always** contact your eyecare practitioner before using any medicine in the eyes.
- **Ask** your eyecare practitioner whether there are any other wearing restrictions that apply to you.

Follow-up visits to your eyecare practitioner:

- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Be sure to keep your follow-up appointments.
- When you return for follow-up visits, be sure to tell your eye care practitioner if your eyes have felt dry, irritated or anything other than completely comfortable while wearing your contact lenses.
- If there is any question in your mind about your wearing schedule and restrictions, cleaning lens handling procedures, lens replacement program, the condition of your lenses, your follow-up visit schedule, or anything else about contact lens wear, be sure to discuss the subject with your eyecare practitioner, who is there to help you and see you use your contact lenses safely and properly.
- If your eye care practitioner puts a dye or drops in your eyes during the examination, ask when you may reinsert the lenses. The use of most dyes or drops will require a waiting period before the lenses may be reinserted.

Who should know that you are wearing Contact Lenses?

- Inform your doctor (health care professional) about being a contact lens wearer.
- Always inform your 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

Be aware that the following problems may occur when wearing contact lenses:

- Your eyes may sting, burn and/or itch (irritation).
- There may be less comfort than when the lens was first placed on your eye.
- There may be an abnormal feeling of something in the eye (foreign body, scratched area).
- There may be potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion. There may be potential for other physiological observations, such as local or generalized edema, corneal neovascularisation, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering (tearing), unusual secretions or redness of your eyes.
- There may be poor visual acuity, blurred vision, rainbows, or halos around objects, sensitivity to light (photophobia) or dry eyes may also occur if your lenses are worn continuously or for too long a time.

If you notice any of the above symptoms:

- **Immediately remove the lenses**.
- If the discomfort or problem stops, 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 fresh lens on your eye.
- If your lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, you should dispose of the lens and insert a new fresh lens.
- If the problem continues, you should not put the lens back on your eye but immediately consult your eye care professional.
- When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularisation or iritis may be present. **Seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING

Conventional methods of fitting contact lenses apply. For a detailed description of the fitting techniques, refer to the Patient Instructions Guide, copies of which are available from:

CooperVision
Attn: Product Services
711 North Road
Scottsville, New York 14546
(800) 341-2020
www.coopervision.com

WEARING AND APPOINTMENT SCHEDULE

Your eyecare practitioner should prescribe the lenses for daily wear single use only. Your eyecare practitioner will determine your wearing schedule.

The maximum suggested daily wearing time for the lenses is:

Day	Hours
1	(4)
2	(5)
3	(6)
4	(7)
5	(8)
6	(9)
7	(10)
8	(11)
9	(12)
10 and after – all waking hours	

Follow-up examinations are necessary to ensure continued successful contact lens wear and to ascertain the effects of the lenses on the eyes. The following appointment schedule is a suggested guideline:

- 24 hours post-dispensing
- 7 days
- 1 month
- 3 months

Every 6 months thereafter

LENS CARE DIRECTIONS

1. Basic Lens Care Instructions

Eyecare practitioners should review lens care directions with you, including basic lens care information.

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always, wash, rinse and dry your 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 your mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:

    a. Tap water may contain impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
    b. You might lose your lens down the drain.

For Single Use Daily Wear

Remember there is no cleaning or disinfection needed with Clariti 1 Day contact lenses prescribed for daily wear single use wear only. The lenses are to be discarded upon removal and have replacement lenses or spectacles available.

2. Care for a Sticking (Non-Moving) Lens

If the lens stops moving or cannot be removed, you should be instructed to apply a few drops of the recommended lubricating solution directly to your eye and wait until the lens begins to move freely on your eye before removing it. If non-movement of the lens continues, you should immediately consult your eyecare practitioner.

3. Care for a Dehydrated Lens

If a soft, hydrophilic lens is exposed to air while off the eye, it may become dry and brittle. If this happens, dispose of the lens and use a fresh one.

4. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED:

Each lens is supplied sterile in a blister pack containing isotonic saline solution with 0.005% or 0.020% w/v poloxamer 407 added. The blister pack is labelled with the base curve, diopter for spherical lenses or toric power, cylinder and axis for toric lenses, multifocal add for multifocal lenses, diameter, lot number, UV blocker and expiration date of the product.

Do not use if blister pack has been broken or damaged.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients should be reported to:

CooperVision
Attn: Product Services
711 North Road
Scottsville, New York 14546
(800) 341-2020
www.coopervision.com

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed eyecare professional.

CooperVision® MyDay® (stenfilcon A)

CooperVision MyDay Soft (Hydrophilic) Daily Disposable Contact Lenses

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

SYMBOLS KEY:

The following symbols may appear on the label or carton.

SYMBOL	DEFINITION	REFERENCE
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner	81 FR 38911
	Caution / See Instructions for Wearers	BS EN ISO 15223-1 Table 1, Symbol 5.4.4
	Use by Date (expiration date)	BS EN ISO 15223-1 Table 1, Symbol 5.1.4
LOT	Batch Code	BS EN ISO 15223-1 Table 1, Symbol 5.1.5
STERILE	Sterile using Steam Heat	BS EN ISO 15223-1 Table 1, Symbol 5.2.5
	Manufacturer	BS EN ISO 15223-1 Table 1, Symbol 5.1.1
EC REP	Authorized representative in the European Community	BS EN ISO 15223-1 Table 1, Symbol 5.1.2
	Do not use if package is damaged	BS EN ISO 15223-1 Table 1, Symbol 5.2.8
	Consult instructions for use / consult electronic instructions for use	BS EN ISO 15223-1 Table 1, Symbol 5.4.3
	Do not re-use	BS EN ISO 15223-1 Table 1, Symbol 5.4.2
	Date of manufacture	BS EN ISO 15223-1 Table 1, Symbol 5.1.3

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

DESCRIPTION

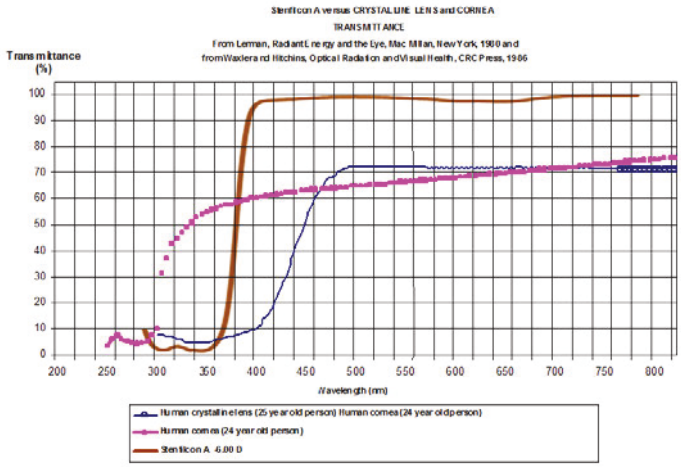
MyDay Contact Lenses are available as an Asphere, Toric, Multifocal, and Multifocal Toric lens designs.

The MyDay material stenfilcon A is primarily a random copolymer of polydimethylsiloxane methacrylate and vinylmethyl acetamide. The UV blocker used is a benzotriazolyl methacrylate. The lenses have a blue tint which is added to make the lens more visible for handling. The lenses also contain a UV absorbing monomer which is used to block UV radiation.

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 the surrounding area. You should continue to use UV-absorbing eyewear as directed.

Long term exposure to the 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 the outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

The MyDay (stenfilcon A) Soft (Hydrophilic) Contact Lens (-6.00 D) blocks 86% of UVA radiation and 97% UVB radiation average across the spectrum. The radiation blockage of the MyDay (stenfilcon A) lens will increase for thicker lenses (Please refer to accompanying transmittance curve graph).



1. Leman, S., *Radiant Energy and the Eye*, MacMillan, New York, 1980, p. 58, figure 2-21. Transmittance profile of the human cornea of a 24-year-old person.
2. Waxler M., and V. M. Hitchins, *Optical Radiation and Visual Health*, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5. Transmittance profile for the human crystalline lens of a 25-year-old person.

MyDay (stenfilcon A) contact lenses parameters:

- Chord Diameter: 13.0 mm to 15.5mm
- Base Curve: 8.4 ± 0.5 mm and 8.7 ± 0.5 mm
- Center Thickness: 0.08 mm to 0.218 mm (varies with power)
- Powers: –20.00D to +20.00D
- Cylinder Powers: -0.25D to -10.00D
- Axis: 0° to 180° in 10° increments
- Add Power Range: +0.50 to +4.00

The physical/optical properties of the lens are:

- Specific Gravity 1.033
- Refractive Index: 1.401
- Light Transmittance: 96%
- Surface Character Hydrophilic
- Water Content 54%
- Oxygen Permeability $80x10^{-11}$ $[(cm^2/sec)x(ml\ O_2)/(ml\ x\ mm\ Hg)]$

Call our Customer Service Department at (800) 341-2020 for current availability.

ACTIONS

When placed on the cornea in its hydrated state, the **MyDay** Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina.

INDICATIONS FOR USE

Aspherical

MyDay ASPHERE Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00D to +20.00D diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

Toric: MyDay (stenfilcon A) Toric Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

Multifocal: MyDay (stenfilcon A) MULTIFOCAL Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

Multifocal Toric: MyDay (stenfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-dieseased eyes who may have -10.00 diopters of astigmatism or less.

CONTRAINDICATIONS (REASONS NOT TO USE):

Do not use the **MyDay** 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), if not aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

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 directions and all labeling instructions for proper use of lenses. 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 these 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 lenses and promptly contact his or her eyecare practitioner.

PRECAUTIONS

Special Precautions for Eye Care Practitioners

- Due to the small numbers 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 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 aspheric 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.
- Aphakic patients should not be fitted with any **MyDay** contact lenses until the determination is made that the eye has healed completely.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb the dye and become discolored. Whenever fluorescein is used in the eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her. Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

Eye care practitioners should carefully instruct patients about the following safety precautions:

- Always discard disposable lenses after the recommended wearing schedule prescribed by the Eye Care Practitioner.
- The compatibility of the lens with lens care regimens has not been evaluated.
- Do not use saliva or any solutions for lubricating or wetting lenses.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking 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.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch the contact lenses with the finger or hands if the hands are not free of foreign materials, as lens damage may occur.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Instructions for **MyDay** contact lenses and those prescr bed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing the lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with fingernails.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Always inform the 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.
- 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.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, or itching (irritation), or other eye pain.
- Comfort is less than when the lens was first placed on the eye.
- Feeling that something is in the eye such as a foreign body or a 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 the problem stops, then look closely at the lens. If the lens is in some way damaged, do not put the lens back on the eye. Place the lens in a storage case and contact the eye care practitioner. Daily disposible lenses should not be reinserted. If the problem continues, the patient should **immediately remove the lenses and consult the eye care practitioner**.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **keep the lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING

Conventional methods of fitting contact lenses apply to all **MyDay** contact lenses. For a detailed description of the fitting techniques, refer to the **MyDay** Professional Fitting and Information Guide, copies of which are available from:

CooperVision, Inc.
www.coopervision.com

WEARING SCHEDULE

The wearing schedule should be determined by the eye care practitioner. Patients tend to over-wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner are also extremely important.

CooperVision recommends that all **MyDay** lenses be discarded and replaced with a new lens on a daily basis.

DAILY DISPOSABLE WEAR: (less than 24 hours, while awake).

The maximum suggested wearing time is 12 hours:

LENS CARE DIRECTIONS

The MyDay (stenfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear single use only.. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

For MyDay contact lenses prescribed for daily wear single use only: The Eye Care Professional should review with patients that no cleaning or disinfection is needed. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

Eye care practitioners should review with the patient lens care directions, including basic lens care information in accordance with patients lens type and wearing schedule.

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or any solutions for lubricating or rewetting. Do not put lenses in the mouth.
- The patient should always have a spare pair of lenses at all times.
- Eye care practitioners may recommend a lubrication/rewetting solution, which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If any **MyDay** lens is exposed to air while off the eye, it may become dry and brittle. In this event, simply dispose of the lens and replace with a fresh one.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply 2 to 3 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 more than 5 minutes, the patient should immediately consult the eye care practitioner.

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 THE EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied sterile in a blister containing buffered saline solution. The blister is labeled with the base curve, diameter, dioptic power, manufacturing lot number, and expiration date of the lens.

DO NOT USE IF THE BLISTER IS BROKEN OR THE SEAL HAS BEEN DAMAGED

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing any **MyDay** contact lens or experienced with the lenses should be reported to:

Product Services
(800) 341-2020
www.coopervision.com

CooperVision™

CooperVision, Inc.
6150 Stoneridge Mall Road
Suite 370
Pleasanton, CA 94588

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

This Package Insert and Fitting Instruction 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.

1-DAY ACUVUE® MOIST BRAND CONTACT LENSES

1-DAY ACUVUE® MOIST Brand Contact Lenses

1-DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM

1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses

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

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

SYMBOLS KEY

The following symbols may appear on the label or packaging:

SYMBOL	DEFINITION
	Consult Instructions for Use
	Manufacturer
	Date of Manufacture
	Use By Date (expiration date)
LOT	Batch Code
STERILE	Sterilized Using Steam Heat
	Do Not Re-Use (Single Use)
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)
CE 0086	Quality System Certification Symbol
	Fee Paid for Waste Management
EC REP	Authorized Representative in the European Community

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

DESCRIPTION

1-DAY ACUVUE® MOIST Brand Contact Lenses, 1-DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM, and 1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses are soft (hydrophilic) contact lenses available as spherical, toric, or multifocal lenses, and include LACREON® Technology.

The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1, 1, 1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate.

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

Lens Properties:

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.40
- Light Transmittance: 85% minimum
- Surface Character: Hydrophilic
- Water Content: 58%
- Oxygen Permeability (D/k):

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

Lens Parameters 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 (CYL): -0.25D to -10.00D
- Axis (AXIS): 2.5° to 180°
- ADD Powers: +0.25D to +4.00D

AVAILABLE LENS PARAMETERS

1-DAY ACUVUE® MOIST Brand Contact Lenses are hemispherical shells of the following dimensions:

Diameter (DIA): 14.2 mm
Center Thickness: 0.084 mm to 0.230 mm (varies with power)
Base Curve (BC): 8.5 mm, 9.0 mm
Powers (D): -0.50D to -6.00D (in 0.25D increments)
-6.50D to -12.00D (in 0.50D increments)
+0.50D to +6.00D (in 0.25D increments)

1-DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM are hemitoric shells of the following dimensions:

Diameter (DIA): 14.5 mm
Center Thickness: 0.090 mm to 0.189 mm (varies with power)
Base Curve (BC): 8.5 mm
Powers (D): +0.00 to -6.00D (in 0.25D increments)
Cylinders (CYL): -0.75D, -1.25D, -1.75D, -2.25D*
Axis (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

-6.50D to -9.00D (in 0.50D increments)
Cylinders (CYL): -0.75D, -1.25D, -1.75D, -2.25D*
Axis (AXIS): 10°, 20°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 160°, 170°, 180°
*-2.25D cylinder is available in 20°, 90°, 160°, 180° axes only

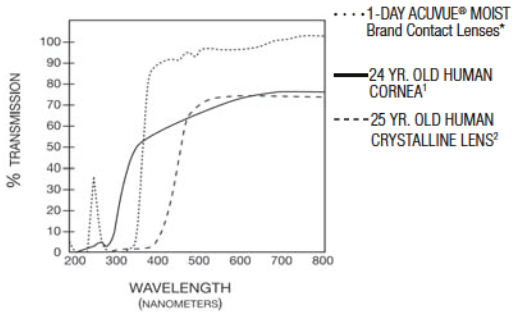
+0.25D to +4.00D (in 0.25D increments)
Cylinders (CYL): -0.75D, -1.25D, -1.75D
Axis (AXIS): 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°

1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses are hemispherical shells of the following dimensions:

Diameter (DIA): 14.3 mm
Center Thickness: 0.084 mm to 0.207 mm (varies with power)
Base Curve (BC): 8.4 mm
Powers (D): +6.00D to -9.00D (in 0.25D increments)
Near ADD Powers (MAX ADD): Low Near ADD (LOW): +1.25D
Medium Near ADD (MID): +1.75D
High Near ADD (HGH): +2.50D

TRANSMITTANCE CURVES

1-DAY ACUVUE® MOIST Brand Contact Lenses (etafilcon A) Visibility Tinted with UV Blocker vs. 24 yr. old human cornea and 25 yr. old human crystalline lens.



*The data are representative measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-3.00D lens, 0.084 mm center thickness).

[1] Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21

[2] Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5

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

ACTIONS

In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The UV Blocking for these lenses averages 97% in the UVB range of 280 nm to 315 nm and 82% in the UVA range of 316 nm to 380 nm for the entire power range.

NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-Blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-Blocking contact lenses reduces the risk of developing cataracts or other eye disorders. The Eye Care Professional should be consulted for more information.

INDICATIONS (USES)

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

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

1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses are indicated for daily disposable wear for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 0.75D or less of astigmatism.

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

When prescribed for daily disposable use, 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.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e., rewetting drops) that contain chemicals or preservatives (such as mercury, Thimerosal, etc.) to which some people may develop an allergic response.
- Any active corneal infection (bacterial, fungal, protozoal, or viral).
- If eyes become red or irritated.

WARNINGS

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

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

- **Eye Discomfort,**
- **Excessive Tearing,**
- **Vision Changes,**
- **Loss of Vision,**
- **Eye Redness, or**
- **Other Eye Problems,**

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

- When prescribed for daily wear, patients should be instructed not to wear their lenses while sleeping. Clinical studies have shown that when lenses are worn overnight, the risk of ulcerative keratitis is greater than among those who do not wear them overnight.[3]
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products are essential for the safe use of these products.

- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care.

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

Specific Instructions for Use and Warnings:

- **Water Activity**
  Instruction for Use
  Do not expose contact lenses to water while wearing them.
  WARNING:
  Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If lenses have been submersed in water when participating in water sports or swimming in pools, hot tubs, lakes, or oceans, the patient should be instructed to discard them and replace them with a new pair. The Eye Care Professional should be consulted for recommendations regarding wearing lenses during any activity involving water.

PRECAUTIONS

Special Precautions for Eye Care Professionals:

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

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.
- Patients who wear these lenses to correct presbyopia using monovision (or modified monovision using 1-DAY ACUVUE® MOIST Brand MULTIFOCAL) may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.

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

Handling Precautions:

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her.
- DO NOT use if the sterile blister package is opened or damaged.
- Always wash and rinse hands 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.
- DO NOT touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Instruction Guide for these lenses and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container. Slide the lens up the side of the bowl until it is free of the container.
- Do not touch the lens with fingernails.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for Sticking (Non-Moving) Lenses." The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.

- The patient should be advised to never allow anyone else to wear their lenses. They have been prescribed to fit their eyes and to correct their vision to the degree necessary. Sharing lenses greatly increases the chance of eye infections.
- If aerosol products, such as hairspray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.

Lens Care Precautions:

- 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.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Who Should Know That the Patient is Wearing Contact Lenses?

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

ADVERSE REACTIONS

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

- The eye may burn, sting, and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, or corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis, and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Have I noticed a change in my vision?

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

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

The patient should be 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
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risks and benefits of lens wear

Patients who do not 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 lens fitting instructions as outlined below.

C. Initial Power Determination

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

D. Base Curve Selection (Trial Lens Fitting)

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

- 1-DAY ACUVUE® MOIST: 8.5 mm/14.2 mm
- 1-DAY ACUVUE® MOIST for ASTIGMATISM: 8.5 mm/14.5 mm
- 1-DAY ACUVUE® MOIST MULTIFOCAL: 8.4 mm/14.3 mm

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

1. Criteria of a Properly Fit Lens

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

2. Criteria of a Flat Fitting Lens

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

3. Criteria of a Steep Fitting Lens

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

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

E. Final Lens Power (Spherical)

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

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

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

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

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

TORIC FITTING GUIDELINES

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

The only new steps you must follow in prescribing 1-DAY ACUVUE® MOIST for ASTIGMATISM are that you must determine the stability, repeatability, and drift angle of the lens axis so that you can prescribe the correct lens axis for the patient.

A. How to Determine Lens Cylinder and Axis Orientation

1. Locate the Orientation Marks

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

Figure 1

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

2. Observe Lens Rotation and Stability

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

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

3. Assessing Rotation

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

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

B. Final Lens Power

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the spectacle cylinder axis, it is not advisable to perform a full spherocylindrical over-refraction because of the difficulty in computing the resultant power. A spherical over-refraction without cylinder refraction may be performed.

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

1. For the Sphere

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

2. For the Cylinder

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

3. Case Examples

Example 1

Manifest (spectacle) refraction:

O.D. -2.50D / -1.25D x 180° 20/20
O.S. -2.00D / -1.00D x 180° 20/20

Choose a diagnostic lens for each eye with axis 180°. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens. If the lens has not yet stabilized, recheck until stable.

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

Here is the Rx prescribed:

O.D. -2.50D / -1.25D x 180°
O.S. -2.00D / -0.75D x 180°

Example 2

Manifest (spectacle) refraction:

O.D. -3.00D / -1.00D x 90° 20/20
O.S. -4.75D / -2.00D x 90° 20/20

Choose diagnostic lenses of -3.00D / -0.75D x 90° for the right eye and -4.50D / -1.75D x 90° for the left eye, the nearest lenses available to the spherical power 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. Compensation for this rotation should be done as follows:

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 **PATIENT MANAGEMENT** section).

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

MULTIFOCAL FITTING GUIDELINES

A. Presbyopic Needs Assessment & Patient Education

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with 1-DAY ACUVUE® MOIST MULTIFOCAL. Wearing these lenses may not be optimal for activities such as:

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

1-DAY ACUVUE® MOIST MULTIFOCAL is not recommended for patients who have -1.00D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise. These lenses are available in the following ADD powers:

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

B. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00D. Determine the spherical equivalent distance prescription for a multifocal patient. Determine the eye dominance using one of the methods below:

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

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

C. Select the Initial Trial Lens

1. For each eye, select the trial lens distance power that is closest to the patient's distance spherical equivalent. Remember to compensate for vertex distance if the refraction is greater than ±4.00D.
2. Select the near power of the lens based on the patients ADD range as follows:
   - ADD: +0.75D to +1.25D use a low near ADD (LOW) lens on each eye
   - ADD: +1.50D to +1.75D use a medium near ADD (MID) lens on each eye
   - ADD: +2.00D to +2.50D use a medium near ADD (MID) on the dominant eye and a high near ADD (HGH) 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 in one week for reassessment (see **PATIENT MANAGEMENT** section).

D. Multifocal Troubleshooting

Unacceptable Near Vision

If it has been determined that no change is required based on the over-refraction, then add +0.25D 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 a 1-DAY ACUVUE® MOIST 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.

E. Adaptation

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

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

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

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

MONOVISION FITTING GUIDELINES

A. Patient Selection

1. Monovision Needs Assessment

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

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

- Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- Driving automobiles (e.g., driving at night). Patients who cannot meet 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.

2. Patient Education

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

B. Eye Selection

1. Ocular Preference Determination Methods

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

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

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

2. Other Eye Selection Methods

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

Refractive Error Method

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

Visual Demands Method

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

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

C. Special Fitting Characteristics

1. Unilateral Vision Correction

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

Examples:

A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without correction.

A presbyopic patient requiring a +1.50D ADD who is -2.50D myopic in the right eye and -1.50D myopic in the left eye may have the right eye corrected for distance and the left eye uncorrected for near.

2. Near ADD Determination

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

3. Trial Lens Fitting

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

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

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

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

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

4. Adaptation

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

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

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

D. Other Suggestions

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

Monovision fitting success can be improved by the following suggestions:

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

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

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

PATIENT MANAGEMENT

- Follow the accepted standard of care in fitting and following up with your patient, e.g., American Optometric Association standard of care.
- 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 SCHEDULES.

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.

When disposed of after a single daily use, these lenses may reduce the risk of developing giant papillary conjunctivitis.[4]

When worn as a daily disposable lens, these lenses may provide improved comfort for many patients who experience mild discomfort and itching associated with allergies during contact lens wear, compared to lenses replaced at intervals of greater than 2 weeks.

Clinical research has shown that when worn on a daily disposable basis, these lenses may provide improved comfort for 2 out of 3 patients who reported suffering from discomfort associated with allergies during contact lens wear.

[4]The CLAO Journal, July 1999, Volume 25, Number 3

LENS CARE DIRECTIONS

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

For complete information concerning contact lens handling and care, refer to the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.

Care for Sticking (Non-Moving) Lenses

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.

HOW SUPPLIED

Each UV-absorbing sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with povidone. The plastic package is marked with the following:

- **1-DAY ACUVUE® MOIST:** base curve, power, diameter, lot number, and expiration date
- **1-DAY ACUVUE® MOIST for ASTIGMATISM:** base curve, power, diameter, cylinder, axis, lot number, and expiration date
- **1-DAY ACUVUE® MOIST MULTIFOCAL:** base curve, power, diameter, ADD power, lot number, and expiration date

REPORTING OF ADVERSE REACTIONS

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

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

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
Tel: 1-800-843-2020
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1-DAY ACUVUE® MOIST and LACREON® are Trademarks of Johnson & Johnson Vision Care, Inc.

Johnson and Johnson ACUVUE OASYS®1-Day with HydraLuxe™ Technology (senofilcon A)

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

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

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

ACUVUE® 1-Day oasys WITH HydraLuxe™ BRAND CONTACT LENSES

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

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

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

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

SYMBOLS KEY

The following symbols may appear on the label or carton:

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

DESCRIPTION

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

These lenses are made of a silicone hydrogel material containing an internal wetting agent, visibility tint, and UV absorbing monomer and are tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling.

A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics for these lenses are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

Lens Properties:

The physical/optical properties of the lens are:

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

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

Lens Parameters:

- Diameter Range: 12.0 mm to 15.0 mm
- Center Thickness: varies with power
- Base Curve Range: 7.85 mm to 10.00 mm
- Spherical Power Range: -20.00D to +20.00D
- Cylinder Power Range: -0.25D to -10.00D
- Axis Range: 2.5° to 180°

AVAILABLE LENS PARAMETERS

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

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

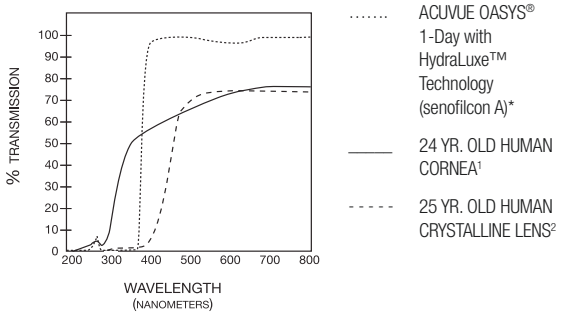
ACUVUE OASYS® Brand 1-Day with HydraLuxe™ Technology for ASTIGMATISM are hemitoric shells of the following dimensions:

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

+0.25D to +4.00D (in 0.25D increments)
-6.50D to -9.00D (in 0.50D increments)
Cylinders: -0.75D, -1.25D, -1.75D
Axis: 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°

TRANSMITTANCE CURVES

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



* The data was obtained from measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-9.00D lens, 0.075 mm center thickness).

[1]Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21

[2]Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5

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

ACTIONS

In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays onto the retina.

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

NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-Blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-Blocking contact lenses reduces the risk of developing cataracts or other eye disorders. The Eye Care Professional should be consulted for more information.

INDICATIONS (USES)

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

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

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

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE these contact lenses when any of the following conditions exist:

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

WARNINGS

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

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

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

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

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

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

Specific Instructions for Use and Warnings:

- **Water Activity**

  Instructions for Use

  Do not expose contact lenses to water while wearing them.

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

PRECAUTIONS

Special Precautions for Eye Care Professionals:

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

- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.
- Patients who wear these lenses to correct presbyopia using mono-vision may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

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

Handling Precautions:

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her.
- DO NOT use if the sterile blister package is opened or damaged.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- DO NOT touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the "Patient Instruction Guide" for the prescribed wearing schedule and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Slide the lens up the side of the bowl until it is free of the container.
- Do not touch the lens with fingernails.

Lens Wearing Precautions:

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

Lens Care Precautions:

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

Other Topics to Discuss with Patients:

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

Who Should Know That the Patient is Wearing Contact Lenses?

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

ADVERSE REACTIONS

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

- The eye may burn, sting, and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, or corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis, and conjunctivitis; some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows, or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Have I noticed a change in my vision?

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

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

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

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

GENERAL FITTING GUIDELINES

A. Patient Selection
Patients selected to wear these lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the 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 lens fitting instructions as outlined below.

C. Initial Power Determination

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

D. Base Curve Selection (Trial Lens Fitting)
The following trial lenses should be selected for patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

- ACUVUE OASYS® 1-Day: 8.5 mm/14.3 mm
- ACUVUE OASYS® 1-Day for ASTIGMATISM: 8.5 mm/14.3 mm

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

1. Criteria of a Properly Fit Lens

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

2. Criteria of a Flat Fitting Lens

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

3. Criteria of a Steep Fitting Lens

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

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

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

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

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

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

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

TORIC FITTING GUIDELINES

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

The only new steps you must follow in prescribing ACUVUE OASYS® 1-Day for ASTIGMATISM are that you must determine the stability, repeatability, and drift angle of the lens axis so that you can prescribe the correct lens axis for the patient.

A. How to Determine Lens Cylinder and Axis Orientation

1. Locate the Orientation Marks

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

Figure 1

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

2. Observe Lens Rotation and Stability

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

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

3. Assessing Rotation

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

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

B. Final Lens Power

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the spectacle cylinder axis, it is not advisable to perform a full spherocylindrical over-refraction because of the difficulty in computing the resultant power. A spherical over-refraction without cylinder refraction may be performed.

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

1. For the Sphere

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

2. For the Cylinder

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

3. Case Examples

Example 1

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

Choose a diagnostic lens for each eye with axis 180°. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens. If the lens has not yet stabilized, recheck until stable.

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

Here is the Rx Prescribed:
O.D. -2.50D / -1.25D x 180°
O.S. -2.00D / -0.75D x 180°

Example 2

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

Choose diagnostic lenses of -3.00D / -0.75D x 90° for the right eye and -4.50D / -1.75D x 90° for the left eye, the nearest lenses available to the spherical power, cylinder power, and axis needed. For the left eye, since the manifest refraction called for -4.75D, compensating for vertex distance the sphere is reduced by 0.25D to -4.50D. The cylinder power will be -1.75D. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens. If the lens has not yet stabilized, recheck until stable.

Right Eye

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

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

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

Left Eye

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

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

Here is the Rx Prescribed:
O.S. -4.50D / -1.75D x 80°

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

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

MONOVISION FITTING GUIDELINES

A. Patient Selection

1. Monovision Needs Assessment

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

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

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

2. Patient Education

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

B. Eye Selection

1. Ocular Preference Determination Methods

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

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

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

2. Other Eye Selection Methods

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

Refractive Error Method

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

Visual Demands Method

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

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

C. Special Fitting Characteristics

1. Unilateral Vision Correction

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

both eyes.

Examples:

A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without correction.

A presbyopic patient requiring a +1.50D ADD who is -2.50D myopic in the right eye and -1.50D myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

2. Near ADD Determination

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

3. Trial Lens Fitting

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

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

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

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

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

4. Adaptation

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

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

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

D. Other Suggestions

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

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state driver's licensing requirements with monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Monovision fitting success can be improved by the following suggestions:

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

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

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

PATIENT MANAGEMENT

Dispensing Visit

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

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

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

Follow-Up Examinations

Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule, daily disposable modality, and proper lens handling procedures.

Recommended Follow-up Examination Schedule (complications and specific problems should be managed on an individual patient basis):

1. One week from the initial lens dispensing to patient
2. One month post-dispensing
3. Every three to six months thereafter

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

Recommended Procedures for Follow-up Visits:

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

If any observations are abnormal, use professional judgment to alleviate the problem and restore the eye to optimal conditions. If

the criteria for successful fit are not satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and refit the patient.

WEARING SCHEDULE

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

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

The maximum suggested wearing time for these lenses is:

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

REPLACEMENT SCHEDULE

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

LENS CARE DIRECTIONS

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

REPORTING OF ADVERSE REACTIONS

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

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

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

Basic Instructions

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

Care for a Sticking (Non-Moving) Lens

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

EMERGENCIES

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

HOW SUPPLIED

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

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

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APPENDIX D: [redacted]

[redacted] LENS FITTING CHARACTERISTICS

[redacted] SUBJECT REPORTED OCULAR SYMPTOMS/PROBLEMS

[redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS

[redacted] BIOMICROSCOPY SCALE

[redacted] KERATOMETRY PROCEDURE

[redacted] DISTANCE AND NEAR SNELLEN VISUAL ACUITY EVALUATION

[redacted] PATIENT REPORTED OUTCOMES

[redacted] LENS INSERTION AND REMOVAL

[redacted] LENS FITTING CHARACTERISTICS

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[redacted] DISTANCE AND NEAR SNELLEN VISUAL ACUITY EVALUATION

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[redacted]PATIENT REPORTED OUTCOMES

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APPENDIX E: [redacted] GUIDELINES FOR COVID-19 RISK MITIGATION

1.0 PURPOSE

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

2.0 SCOPE

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

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

3.0 DEFINITIONS

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

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

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

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

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

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

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

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

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

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

4.0 GUIDANCE FOR STUDY DOCUMENTS

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

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

4.1 Additional Risks Related to the COVID-19 Pandemic:

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

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

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

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

4.1.1 Informed Consent**:**

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

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

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

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

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

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

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

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

4.1.3 Protocol Compliance Investigator(s) Signature Page:

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

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

4.1.4 Study Site Initiation Training Slides:

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

5.0 GUIDANCE FOR REMOTE SUBJECT VISITS

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

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

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

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

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

6.0 STUDY CONDUCT DURING PANDEMIC

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

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

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

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

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

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

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

6.1 Monitoring Visits

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

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

6.1.1 Study Site Initiation:

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

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

6.1.2 Interim Monitoring Visits (if applicable):

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

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

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

6.1.3 Study Site Closure:

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

Attachment A: Study Site Correspondence

XXXX XX, 2020

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

Dear <<Principal Investigator>> and Study Team,

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

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

Protocol:

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

Protocol Signature Page:

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

Informed Consent:

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

COVID-19 Risk Control Checklist for Clinical Studies:

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

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

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

Please file this letter in your site file study correspondence.

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

Study Number
Site Number
Principal Investigator (PI) Name

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

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

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

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

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

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

Principal Investigator Signature and Date

RESOURCE LINKS

US Resource Links

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

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

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

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

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

OUS Resource Links

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

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

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

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

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

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

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

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

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

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

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

APPENDIX F: PRE-SCREENING TELEPHONE SCRIPT WITH QUESTIONS

[redacted]

PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: CR-6388 Evaluation of Dryness in a Silicone Hydrogel Daily Disposable Contact Lens

Version and Date: 3.0 07 April 2021

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] GCP and ICH guidelines,[2] the Declaration of Helsinki,[3] United States (US) Code of Federal Regulations (CFR),[4] and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. The Principal Investigator is responsible for ensuring that all clinical site personnel, including Sub-Investigators adhere to all ICH[2] 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 participants.

I am responsible for ensuring that all clinical site personnel including Sub-Investigators adhere to all ICH[2] regulations and GCP guidelines regarding clinical trials during and after study completion.

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

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

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

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

Principal Investigator: _____ _____

Signature Date

_____

Name and Professional Position (Printed)

Institution/Site: _____

Institution/Site Name

_____

Institution/Site Address