

# Johnson & Johnson Vision Care, Inc.

## Clinical Study Protocol

Clinical Evaluation of 3 Contact Lens Materials with 3 Solution Types

Protocol: CR-6012

Version: 2.0

Date: 08 January 2018

Investigational Products: RevitaLens® Multi-Purpose Disinfecting Solution, CLEAR CARE® Contact Lens Solution, and OPTI-FREE® Puremoist® Multi-Purpose Contact Lens Solution.

Key Words: RevitaLens® Multi-Purpose Disinfecting Solution, CLEAR CARE® Contact Lens Solution, and OPTI-FREE® Puremoist® Multi-Purpose Contact Lens Solution, ACUVUE® 2, ACUVUE® OASYS®, ACUVUE Vita, and 1-DAY ACUVUE MOIST, etafilcon A, senofilcon A, senofilcon C, daily disposable, dispensing.

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

This trial will be conducted in compliance with the protocol, ISO 14155,<sup>1</sup> the International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP),<sup>2</sup> the Declaration of Helsinki,<sup>3</sup> and all applicable regulatory requirements.

**Confidentiality Statement:**

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**PROTOCOL TITLE, NUMBER, VERSION**

Title: Clinical Evaluation of 3 Contact Lens Materials with 3 Solution Types

Protocol Number: CR-6012

Version: 2.0

Date: 08 January 2018

**SPONSOR NAME AND ADDRESS**

Johnson & Johnson Vision Care, Inc. (JJVC)

7500 Centurion Parkway

Jacksonville, FL 32256

**MEDICAL MONITOR**

Name: Meredith Bishop, OD, MS, FAAO

Title: Principal Research Optometrist

Address: 7500 Centurion Parkway, Suite 100; Jacksonville, FL 32256

[REDACTED]

Email: mbishop4@its.jnj.com

[REDACTED]

The Medical Monitor must be notified by the clinical institution/site by e-mail, fax, 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 signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations,<sup>4</sup> ICH guidelines,<sup>2</sup> ISO 14155,<sup>1</sup> and the Declaration of Helsinki.<sup>3</sup>

Author/Study  
Responsible  
Clinician

**See Electronic Signature Report**

Meredith Bishop, OD, MS, FAAO  
Principal Research Optometrist

\_\_\_\_\_  
DATE

Clinical Operations  
Manager

**See Electronic Signature Report**

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DATE

Biostatistician

**See Electronic Signature Report**

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Data Management

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Fellow Reviewer

**See Electronic Signature Report**

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Approver

**See Electronic Signature Report**

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## CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Date
1.0	Meredith Bishop, OD, MS, FAAO	Original Protocol	03Nov2017
2.0	Meredith Bishop, OD, MS, FAAO	Updated lens case preparation work aid	08Jan2018

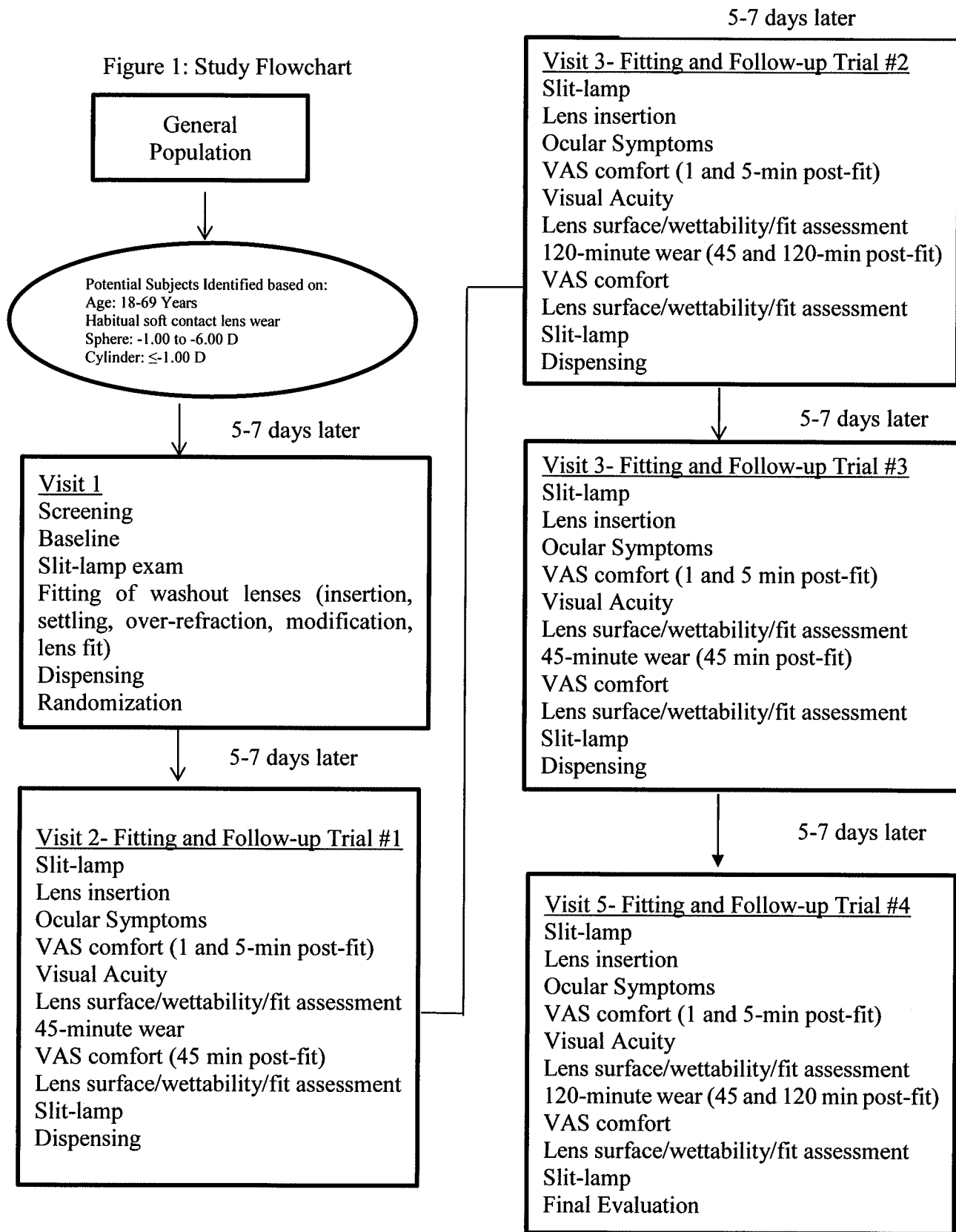
## SYNOPSIS

Protocol Title	Clinical Evaluation of 3 Contact Lens Materials with 3 Solution Types
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Phase 4 Post Market Study
Trial Registration	This study will be registered on ClinicalTrials.gov based on the following: this is a post-market study with approved products.
Test Article(s)	<p><u>Lens Care Solutions:</u>  Test: RevitaLens® Multi-Purpose Disinfecting Solution  Control 1: CLEAR CARE® Contact Lens Solution  Control 2: OPTI-FREE® Puremoist® Multi-Purpose Contact Lens Solution</p> <p><u>Soft Contact Lenses:</u>  ACUCUE® 2 (etafilcon A), ACUVUE® OASYS® (senofilcon A), ACUVUE Vita (senofilcon C), and 1-DAY ACUVUE MOIST (etafilcon A).</p>
Wear and Replacement Schedules	Wear Schedule: Daily Disposable Replacement Schedule: Daily Disposable
Objectives	The primary objective of this study is to gain clinical insights of the study lenses and solutions with respect to comfort.
Study Endpoints	Primary endpoint: subjective assessment of initial comfort using Visual Analog Scale (VAS) Other Endpoints: Expanded corneal staining, ocular physiology, subject's reported ocular symptoms, and ocular adverse events.
Study Design	<p>This is a multi-site, randomized, double-masked, contralateral, 2 treatment x 2 period crossover, dispensing, five-visit study.</p> <p>See the flow chart at the end of the synopsis table for the schematic of the study visits and procedures of main observations (Figure 1).</p>
Sample Size	Up to 120 subjects are targeted to be enrolled and approximately 90 subjects are targeted to complete the study.
Study Duration	The study will last approximately 4 months and include a 2-month enrollment period.

Anticipated Study Population	Up to 120 healthy subjects ages 18-69 years that are current soft contact lens wearers will be recruited for this clinical study.
Eligibility Criteria	<p>Potential subjects must satisfy all of the following criteria to be enrolled in the study:</p> <ol style="list-style-type: none"> <li>1. Subjects must be 18-69 years of age (inclusive)</li> <li>2. Subjects must be habitual disposable hydrogel or silicone hydrogel (1-day, 2-week, or monthly replacement schedule) soft lens wearer in both eyes. Habitual is defined as at least one (1) month of contact lens wear where the lenses are worn for a minimum of six (6) hours per day and a minimum of five (5) days per week</li> <li>3. Subjects must have best corrected visual acuity of 20/25 (Snellen or equivalent) or better in each eye</li> <li>4. The subject's refractive sphere (vertexed) must be between -1.00 and -6.00 D in each eye.</li> <li>5. The subject's refractive cylinder must be less than or equal to -1.00 D in each eye</li> <li>6. The subject must have normal eyes (i.e., no ocular medications or infections of any type)</li> <li>7. Subjects must possess a functional/usable pair of spectacles and bring them to the visit (only if applicable - to the investigators discretion)</li> <li>8. Subjects must read, understand, and sign the Statement of Informed Consent</li> <li>9. Subjects must appear able and willing to adhere to the instructions set forth in this clinical protocol.</li> </ol> <p>Potential subjects who meet any of the following criteria will be excluded from participating in the study:</p> <ol style="list-style-type: none"> <li>1. Currently pregnant or breast-feeding</li> <li>2. Diabetes</li> <li>3. Any ocular or systemic allergies or disease which may interfere with contact lens wear (at the discretion of the investigator)</li> <li>4. Any systemic disease, autoimmune disease, or use of medication which may interfere with contact lens wear (at the discretion of the investigator)</li> <li>5. Any infectious diseases (e.g. hepatitis, tuberculosis) or a contagious immunosuppressive disease (eg, HIV), by self-report</li> <li>6. Current habitual use of Restasis, Xiidra, ocular steroids, or any medication (RX or OTC) that may interfere with contact lens wear (at the discretion of the investigator)</li> <li>7. Grade 2 or greater corneal staining or conjunctival injection on the FDA scale</li> </ol>

	<ol style="list-style-type: none"> <li>8. Clinically significant (Grade 3 or greater on the FDA scale) corneal edema, corneal vascularization, or any other abnormalities of the cornea (excluding corneal staining) which would contraindicate contact lens wear</li> <li>9. Clinically significant (Grade 3 or greater on the FDA scale) tarsal abnormalities which might interfere with contact lens wear</li> <li>10. Any active ocular abnormalities/conditions that may interfere with contact lens wear (at the discretion of the investigator)</li> <li>11. Any corneal distortion due to previous rigid gas permeable lens wear, surgery or pathology</li> <li>12. History of any ocular or corneal surgery (eg, RK, PRK, LASIK)</li> <li>13. Habitual contact lens wear modality as extended wear</li> <li>14. Participation in any pharmaceutical or medical device related clinical trial within 7 days prior to study enrollment</li> <li>15. History of binocular vision abnormality or strabismus</li> <li>16. Habitual wearers of rigid gas permeable lens within the past 3 months</li> <li>17. Employees of investigational clinic (investigator, coordinator, and technician etc.) or family members of employees of the investigational clinic by self-report.</li> </ol>
Disallowed Medications/Interventions	Current habitual use of Restasis, Xiidra, ocular steroids, or any medication (RX or OTC) that may interfere with contact lens wear (at the discretion of the investigator)
Measurements and Procedures	Safety parameters (slit lamp findings, adverse events), subject reported symptoms, comfort rating (VAS) and lens fit.
Microbiology or Other Laboratory Testing	None
Study Termination	The occurrence of one or more Unanticipated Adverse Device Effect (UADE), or any SAE where relationship to study agent cannot be ruled out, will result in 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	Lacri-pure, EyeCept re-wetting drops, Opti-Free, ClearCare, slit lamp, Snellen VA chart, fluorescein, auto-refractors, phoropters
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 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
CTP	Clinical Technical Procedure
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 Council for 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 <sup>®</sup>	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**

Reusable soft contact lenses require regular cleaning and disinfection to prevent lens deposits and infections. Multi-purpose care solution is the most commonly used lens care system. They are designed to rinse, disinfect, clean, and store soft lenses. The purpose of this study is to evaluate the subjective comfort of 3 ACUVUE® brand contact lenses with 2 multi-purpose solutions (Test and Control) and one peroxide solution (Control) when lenses are worn for 45 minutes and 2 hours.

### **1.1. Name and Descriptions of Investigational Products**

The investigational products in this study are 3 lens care solutions: RevitaLens® Multi-Purpose Disinfecting Solution (Test), CLEAR CARE® Contact Lens Solution (Control 1), and OPTI-FREE® Puremoist® Multi-Purpose Contact Lens Solution (Control 2). Their evaluation will be performed on 3 reusable soft contact lenses: ACUVUE® 2, ACUVUE® OASYS®, ACUVUE Vita using a crossover design. The 1-DAY ACUVUE MOIST, a daily disposable lens, will be worn during the washout period between solution use including habitual lens care solution at baseline.

All contact lens and lens care solutions used in this study are FDA approved and marketed products.

### **1.2. Intended Use of Investigational Products**

The proposed use of the contact lens care products is to clean and disinfect contact lenses as indicated on-label.

### **1.3. Summary of Findings from Nonclinical Studies**

Not Applicable - Marketed products 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:

- There may be less comfort than when the lens was first placed on the eye.
- 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, photo-phobia, 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 out contact lenses and contact lens care products. The information from this study will aid in the further development and design of new contact lenses.

For the most comprehensive clinical information regarding the contact lenses and care products refer to the package inserts (Appendix C).

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

All lenses and care products are FDA approved and marketed products. Refer to package inserts (Appendix C) for additional information.

## **2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES**

### **2.1. Objectives**

The primary objective of this study is subjective assessment of initial comfort of 3 reusable ACUVUE Brand Contact Lenses (ACUVUE® 2, ACUVUE® OASYS®, ACUVUE Vita soaked) soaked in the 3 study lens care solutions (Test: RevitaLens®, Control 1: CLEAR CARE®, and Control 2: OPTI-FREE® Puremoist®) for 16-28 hours each. Initial comfort will be assessed at 1-min, 5-min, 45-min and 2 hours of lens wear.

### **2.2. Endpoints**

#### Primary Endpoint(s):

Subjective assessment of initial comfort will be conducted using Visual Analogue Scale (VAS) of comfort. VAS of comfort consists of a vertical line which represents continuous scale from 0 (extremely uncomfortable) to 100 (extremely comfortable). VAS comfort will be administered at 1-min, 5-min, 45-min and 2-hours post-fit.

#### Other Endpoints:

- Expanded corneal staining [REDACTED]
- Slit-Lamp findings [REDACTED]
- Subject's reported ocular symptoms [REDACTED]
- Lens fitting assessment [REDACTED]
- Lens deposit characteristics [REDACTED]
- Lens wettability characteristics [REDACTED]
- Adverse events

### **2.3. Hypotheses**

The test solution will be similar to the control solutions with respect to initial comfort at 1-min, 5-min, 45-min and 2 hours post-fit of pre-soaked lenses.

This is a pilot study and all the hypothesis are exploratory in nature.

## **3. TARGETED STUDY POPULATION**

### **3.1. General Characteristics**

The study populations will be healthy spherical habitual contact lens wearers between 18-69 years of age.

### **3.2. Inclusion Criteria**

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

1. Subjects must be 18-69 years of age (inclusive)
2. Subjects must be habitual disposable hydrogel or silicone hydrogel (1-day, 2-week, or monthly replacement schedule) soft lens wearer in both eyes. Habitual is defined as at least one (1) month of contact lens wear where the lenses are worn for a minimum of six (6) hours per day and a minimum of five (5) days per week
3. Subjects must have best corrected visual acuity of 20/25 (Snellen or equivalent) or better in each eye
4. The subject's spherical refraction (vertexed) must be between -1.00 and -6.00 D in each eye
5. The subject's refractive cylinder must be less than or equal to -1.00 D in each eye
6. The subject must have normal eyes (i.e., no ocular medications or infections of any type)
7. Subjects must possess a functional/usable pair of spectacles and bring them to the visit (only if applicable - to the investigators discretion)
8. Subjects must read, understand, and sign the Statement of Informed Consent
9. Subjects must appear able and willing to adhere to the instructions set forth in this clinical protocol.

### **3.3. Exclusion Criteria**

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

1. Currently pregnant or breast-feeding
2. Diabetes
3. Any ocular or systemic allergies or disease which may interfere with contact lens wear (at the discretion of the investigator)
4. Any systemic disease, autoimmune disease, or use of medication which 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 (eg, HIV), by self-report
6. Current habitual use of Restasis, Xiidra, ocular steroids, or any medication (prescription or over-the-counter) that may interfere with contact lens wear (at the discretion of the investigator)
7. Grade 2 or greater corneal staining or conjunctival injection on the FDA scale
8. Clinically significant (Grade 3 or greater on the FDA scale) corneal edema, corneal vascularization, or any other abnormalities of the cornea (excluding corneal staining) which would contraindicate contact lens wear
9. Clinically significant (Grade 3 or greater on the FDA scale) tarsal abnormalities which might interfere with contact lens wear
10. Any active ocular abnormalities/conditions that may interfere with contact lens wear (at the discretion of the investigator)
11. Any corneal distortion due to previous rigid gas permeable lens wear, surgery or pathology
12. History of any ocular or corneal surgery (eg, RK, PRK, LASIK)
13. Habitual contact lens wear modality as extended wear
14. Participation in any pharmaceutical or medical device related clinical trial within 7 days prior to study enrollment
15. History of binocular vision abnormality or strabismus
16. Habitual wearers of rigid gas permeable lens within the past 3 months
17. Employees of investigational clinic (investigator, coordinator, and technician etc.) or family member of an employee of the clinic by self-report.

### **3.4. Enrollment Strategy**

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

## **4. STUDY DESIGN AND RATIONALE**

### **4.1. Description of Study Design**

This is a multi-site, randomized, double-masked, contralateral (i.e. exposure to different lens care solutions in either eye), 2-treatment x 2-period crossover, dispensing (washout lenses only), five-visit study. Here we define treatment as a pair of a control solution (CLEAR CARE or OPTI-FREE) and a test solution (RevitaLens).

Each subject will be randomly assigned to wear either ACUVUE 2, ACUVUE OASYS or ACUVUE Vita throughout the study. Subjects will then be randomly assigned to wear in a random sequence two pairs of lenses soaked in control solutions and test solution. Over the course of the study, subjects will be exposed to control solutions in one eye and to test solution in the contralateral eye for 2 hours using pre-soaked contact lenses. A washout period will be incorporated between each exposure where subjects will be wearing 1-Day ACUVUE Moist, a daily disposable lens, for 5 to 7 days.

The study begins with an Initial Visit (Visit 1) where subjects will be consented and screened for eligibility criteria. Subjects who found to be eligible will be fit and dispensed with 1-DAYACUVUE® MOIST® for 5 to 7 days as a washout period (subjects will wear these lenses during all washout periods). Subjects will then return for Visit 2 where they will be fit with their first pair of soaked lenses based on the randomization scheme. After 45 min of lens wear, subjects will be scheduled for a follow-up visit (Visit 3) 5-7 days later. Visit 3 will follow the same procedures as Visit 2, but with a 2-hour wear period. A washout period of 5-7 between Visit 3 and Visit 4 will occur. Following the washout period, subjects will be fit with the second pair of pre-soaked lenses at Visit 4. After 45 min of lens wear, subjects will be scheduled for a follow-up visit (Visit 5) 5-7 days later (see below for more details).

#### Visit 1:

Visit 1 (Baseline/Fitting/Washout): Baseline CLDEQ-8, eligibility, fitting of 1-DAY ACUVUE® MOIST (washout lenses) (Insertion, ocular symptoms, visual acuity, lens fit, dispensing), randomization.

Washout (Subject wears 1-DAY ACUVUE® MOIST) 5-7 days

#### Period 1: Solution 1 and Solution 2 soaked lenses

Visit 2 (Baseline/Fitting/45 min Follow-up): Modified CLDEQ-8, slit-lamp eligibility, fitting of lens pair #1 (Insertion, ocular symptoms, VAS comfort rating, visual acuity, lens fit, surface characteristics). 45 minutes of lens wear. Follow-up on lens pair #1 (ocular symptoms, VAS comfort rating, visual acuity, lens fit, surface characteristics, slit-lamp).

Washout (subject wears 1-DAY ACUVUE® MOIST) 5-7 days

Visit 3 (Fitting/120 min Follow-up/Washout): Modified CLDEQ-8, slit-lamp eligibility, fitting of lens pair #2 (Insertion, ocular symptoms, VAS comfort rating, visual acuity, lens fit, surface characteristics). 120 minutes of lens wear. Follow-up on lens pair #2 (ocular symptoms, VAS comfort rating, visual acuity, lens fit, surface characteristics, slit-lamp).

Washout (subject wears 1-DAY ACUVUE® MOIST) 5-7 days

#### Period 2: Solution 1 and Solution 3 soaked lenses

Visit 4 (Baseline/Fitting/45 min follow-up): Modified CLDEQ-8, slit-lamp eligibility/fitting of lens pair #3 (Insertion, ocular symptoms, VAS comfort rating, visual acuity, lens fit, surface characteristics). 45 minutes of lens wear/Follow-up on lens pair #3 (ocular symptoms, VAS comfort rating, visual acuity, lens fit, surface characteristics, slit-lamp).

Visit 5 (Fitting/120 min Follow-up): Modified CLDEQ-8, slit-lamp eligibility, fitting of lens pair #4 (Insertion, ocular symptoms, VAS comfort rating, visual acuity, lens fit, surface characteristics). 120 minutes of lens wear. Follow-up on lens pair #4 (ocular symptoms, VAS comfort rating, visual acuity, lens fit, surface characteristics, slit-lamp).  
Final evaluation.

#### 4.2. Study Design Rationale

This is a contralateral 2x2 crossover trial with primary objective to evaluate initial comfort at 1-min, 5 min, 45 min and 2-hours post-fit of 3 reusable contact lenses soaked in 3 lens care solutions. This design was considered because patient-specific factors that might affect initial comfort such as tear film quality and burning/stinging tolerance level are well controlled. A washout period of 5-7 days was implemented between each exposure, including exposure to habitual solution, to reduce any potential carry-over effect that may bias the results. However, this design is not optimal for any potential bias associated with dominant eye effect, inter-eye interactions. Another limitation is associated with compliance problems such as subjects mixing up which eye each lens is in.

#### 4.3. Enrollment Target and Study Duration

A total of up to 120 subjects (i.e. 40 per study lens) will be enrolled (informed consent signed). The goal is for a sample size of approximately 90 subjects (i.e. 30 per study lens) after subjects who withdraw or are lost to follow-up.

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

The number of subjects targeted for randomization and completion are as follows:

Table 1: Target number of subjects by arm and site

	ACUVUE 2	OASYS	Vita	Total
Randomization	36	36	36	108
Completion	30	30	30	90
Number of sites				4
Number of subjects/site Min-Max	25-35	25-35	25-35	90-120

The study will last approximately four weeks for each subject and the entire study duration will be approximately 4 months and include a 2-month enrollment period.

Once the informed consent has been signed the subject will be considered enrolled.

## 5. TEST ARTICLE ALLOCATION AND MASKING

### 5.1. Test Article Allocation

Subjects, in blocks of three, will be first randomly assigned to one of the three study lens types to wear throughout the study (ACUVUE 2, ACUVUE OASYS, ACUVUE Vita). Within each study lens, a contralateral 2-treatment x 2-period crossover design will be used to randomly assign subjects to wear 2 pair of lenses soaked in control solutions (CLEAR CARE and Opti-Free) and test solution (RevitaLens). Subjects in block of two will be randomized to one of the following sequences:

Sequence	Period 1	Period 2
Sequence 1	OPTI-FREE - RevitaLens	CLEAR CARE – RevitaLens
Sequence 2	CLEAR CARE – RevitaLens	OPTI-FREE - RevitaLens

At each period, subjects will be exposed to a control solution (OPTI-FREE or CLEAR CARE) in one eye and to a test solution (RevitaLens) in the contralateral eye for 2 hours using pre-soaked contact lenses. The test and control solutions will be randomly assigned to left and right eyes. A washout period will be incorporated between lens wear periods where subjects will be wearing 1-Day ACUVUE Moist, a daily disposable lens, for 5 to 7 days.

The randomization will be stratified by site and each site will receive separate randomization scheme. The study site will follow the randomization scheme provided and will complete enrollment according to the randomization list and will not pre-select or assign subjects. The assignment of the subjects must be performed at the first baseline visit (Visit 1). 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

The randomization scheme will be generated using the PROC PLAN procedure from the SAS Software Version 9.4 or higher (SAS Institute, Cary, NC).

### 5.2. Masking

This is a double masked study where subjects and investigators are masked to the identity of the study lenses and lens care solutions. Every attempt will be made to keep the personnel involved in the data collection unaware of the identity of study lenses and solutions.

The identity of lens care solutions will be not masked due to the differences in shape and color of the bottles. To maintain the masking of lens care solutions two investigator designees (i.e. sub-investigator and clinical coordinator) who are not involved in data collection will be responsible for soaking the lenses in the solutions per the randomization scheme and putting them in lens cases and handing them over to subjects for insertion.

The identity of the study lenses will be masked by over labeling the blister packs with a label containing the study number, lot number, sphere power, expiration date and the

randomization codes. Only the personnel involved in the over labeling and the Statistician generating the randomization scheme will have access to the decode information translating the randomization codes into test and control groups. The medical monitor will also have access to the decode information in case breaking the mask is necessary for the urgent medical treatment of a subject.

### **5.3. Procedures for Maintaining and Breaking the Masking**

Under normal circumstances, the mask should not be broken until all subjects have completed the study and the database is finalized. Otherwise, the mask should be broken only if specific emergency treatment/course of action would be dictated by knowing the treatment status of the subject. In such cases, the Investigator may, in an emergency, contact the medical monitor. In the event the mask is broken, the Sponsor must be informed as soon as possible. The date, time, and reason for the unmasking must be documented in the subject record. The Investigator is also advised not to reveal the study treatment assignment to the clinical site or Sponsor personnel.

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

1. Investigator 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 designee will record the subject's number on the appropriate line of the randomization scheme
3. Investigator 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 lens will be used in this study:

Table 2: Test Article

	Washout Lens	Randomization lens Arm 1	Randomization lens Arm 2	Randomization lens Arm 3
Name	1-DAY ACUVUE® MOIST	ACUVUE® 2	ACUVUE® OASYS®	ACUVUE® Vita®
Manufacturer	Johnson and Johnson Vision Care, Inc.	Johnson and Johnson Vision Care, Inc.	Johnson and Johnson Vision Care, Inc.	Johnson and Johnson Vision Care, Inc.
Compass Protocol(s)	17CP1339	17CP1339	17CP1339	17CP1339
Lens Material	Etafilcon A	Etafilcon A	Senofilcon A	Senofilcon C
Nominal Base Curve @ 22°C	8.5	8.3	8.4	8.4
Nominal Diameter @ 22°C	14.2	14.0	14.0	14.0
Nominal Distance Powers (D)	-1.00 to -6.00D	-1.00 to -6.00D	-1.00 to -6.00D	-1.00 to -6.00D
Modality in Current Study	Daily	Daily	Daily	Daily
Replacement Frequency in Current Study	Daily	Daily	Daily	Daily
Packaging Form (vial, blister, etc.)	Blister	Blister	Blister	Blister

All Subjects will wear Moist and will be randomized into one of the other lens types. Each subject will wear approximately fifty 1-DAY ACUVUE® MOIST® and eight of the other lens type.

The following lens care systems will be used in this study:

Table 3: Lens Care Systems

	Test	Control 1	Control 2
Solution Name/Description	Revitalens®	OPTI-FREE PureMoist	Clear Care
Manufacturer	Johnson & Johnson, Inc	Alcon, Inc	Alcon, Inc

Lenses will be soaked in the appropriate solution by an unmasked staff member at the site and transferred to the investigator in an unmarked lens case for lens insertion by the subject.

## **6.2. Ancillary Supplies/Products**

The following solutions will be used in this study:

Table 4: Ancillary Supplies

Solution Name/Description	Solution		
	EyeCept	Lacripure	Fluorescein
Manufacturer	Optics Laboratory, Inc.	Menicon	Akorn, Inc.
Preservative	None	None	None
Other distinguishing items (dye, packaging, approval status, etc.	NA	NA	D&C Yellow No. 8, 0.6 mg



## **6.3. Administration of Test Articles**

Washout study lenses will be dispensed to subject 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 can be replaced at the discretion of the Investigator and/or the Sponsor. Subjects will wear only the washout study lenses between visits.

Following each washout period, subjects will return to the clinic and will be dispensed a pair of lenses pre-soaked in the lens solution in accordance with the randomization scheme. These lenses will be worn for 45 or 120 minutes and the staining assessments procedures will be conducted.

## **6.4. Packaging and Labeling**

The study lenses will be packaged in blisters as the primary packaging. The study lenses will be over-labeled to mask the subject to the identity of the lens. The study lenses will be in investigational cartons sealed with a tamper evident seal, commercial cartons, or in plastic bags as the secondary packaging form. Sample labels for the primary and secondary packages are provided below:

<i>Primary Label</i>	<i>Secondary Package</i>
	<p>CAUTION: INVESTIGATIONAL DEVICE LIMITED BY U.S. LAW TO <b>INVESTIGATIONAL USE</b> EXCLUSIVELY FOR CLINICAL INVESTIGATIONS For Use in Clinical Study CR-</p> <hr/> <p>Contents: Six contact lenses in solution. Sponsored by: Johnson &amp; Johnson Vision Care, Inc. Jacksonville, FL 32256, USA Lenses should be stored away from light.</p> <p><b>STERILE</b>  </p>

The identity of lens care solutions will be not masked due to the differences in shape and color of the bottles. To maintain the masking of lens care solutions two investigator designees (i.e. sub-investigator and clinical coordinator) who are not involved in data collection will be responsible for soaking the lenses in the solutions per the randomization scheme and putting them in lens cases and handing them over to subjects for insertion.

#### **6.5. Storage Conditions**

Study lenses and solutions will be maintained at ambient temperatures at the clinical site. All lenses and solutions must be kept under secure conditions.

#### **6.6. Collection and Storage of Samples**

When possible, any lens associated with an Adverse Events 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 back to JJVC. Any solution associated with an Adverse Events and/or a Product Quality Complaint must be retained and quarantined from the site inventory 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 lenses, solutions, and supplies to complete the investigation. The Investigator is asked to retain all shipment documentation for the test article accountability records.

Study lenses and solutions 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 study lenses and solutions must be accounted. This includes:

1. Study lenses dispensed for the subject for trial fitting, to wear out of the office, or issued for the subject to replace appropriately between visits
2. Study lenses returned to the Investigator unused

3. The number and reason for unplanned replacements
4. Study lenses that undergo the soaking process
5. Empty bottles of solutions used during the study

The Investigator will collect all unused study lenses 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 study lenses, and must be labeled with the subject number and date of return. Following final reconciliation of study lenses and solutions by the monitor, the Investigator or monitor will return all unused study lenses and solutions to JJVC.

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

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

## 7. STUDY EVALUATIONS

### 7.1. Time and Event Schedule

Table 5: Time and Events

Visit Information	Visit 1 Baseline, Dispense Washout lenses	Visit 2 Study lens pair #1 fitting and follow-up after 45 min	Visit 3 Study lens pair #2 fitting and follow-up after 2 hours	Visit 4 Study lens pair #3 fitting and follow-up after 45 min	Visit 5 Study lens pair #4 fitting and follow-up after 2 hours
Time Point		5-7 days after V1	5-7 days after V2	5-7 days after V3	5-7 days after V4
Estimated Visit Duration	2 hours	2 hours	3 hours	2 hours	3 hours
Study Informed Consent	X				
Inclusion/Exclusion Screening Criteria	X				
Demographics	X				
Medical History & medication review	X	X	X	X	X
Modified CLDEQ-8	X	X	X	X	X
Habitual Lens Info	X				
Keratometry	X				
Subjective Refraction	X				
Eye Dominance	X				
Baseline Biomicroscopy	X	X	X	X	X
Baseline expanded corneal staining	X	X	X	X	X
Eligibility	X				

Visit Information	Visit 1 Baseline, Dispense Washout lenses	Visit 2 Study lens pair #1 fitting and follow-up after 45 min	Visit 3 Study lens pair #2 fitting and follow-up after 2 hours	Visit 4 Study lens pair #3 fitting and follow-up after 45 min	Visit 5 Study lens pair #4 fitting and follow-up after 2 hours
Time Point		5-7 days after V1	5-7 days after V2	5-7 days after V3	5-7 days after V4
Estimated Visit Duration	2 hours	2 hours	3 hours	2 hours	3 hours
Randomization	X				
Washout Lens fitting	X				
Lens pair #1 fitting (Washout)		X			
Lens pair #2 fitting			X		
Lens pair #3 fitting				X	
Lens pair #4 fitting					X
Snellen VA	X	X	X	X	X
Ocular Symptoms	X	X	X	X	X
Post fit VAS comfort	X				
1 min post fit VAS comfort		X	X	X	X
5 min post fit VAS comfort		X	X	X	X
45 min post fit VAS comfort			X		X
Lens Fit Assessment	X	X	X	X	X
Lens Surface Assessment	X	X	X	X	X
Lens Deposits Assessment	X	X	X	X	X
Lens Dispensing & Instruction	X	X	X	X	
Wear Time		X	X	X	X
45-minute follow-up VAS comfort		X		X	
120-minute follow-up VAS comfort			X		X
Follow-up Ocular symptoms		X	X	X	X
Follow-up lens fit		X	X	X	X
Follow-up lens surface assessment		X	X	X	X
Exit Slit-lamp		X	X	X	X
Exit Expanded Corneal staining		X	X	X	X
Adverse Event Review		X	X	X	X
Final Evaluation					X

## 7.2. Detailed Study Procedures

### VISIT 1

The subjects must present to Visit 1 wearing their spectacles (if applicable), having not worn lenses that day.

Visit 1: Screening			
Step	Procedure	Details	
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.  <b>Note:</b> The subject must be provided a signed copy of this document.	
1.2	Demographics	Record the subject's date of birth, gender, race and ethnicity.	
1.3	Medical History and Concomitant Medications	Questions regarding the subjects' medical history and concomitant medications.	
1.4	Habitual Lenses and care solutions	Questions regarding the subject's habitual lens type/parameters and care solutions.	
1.5	Eligibility after Screening	All responses to Screening Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria must be answered "no" for the subject to be considered eligible.	

Visit 1: Baseline			
Step	Procedure	Details	
1.6	Baseline modified CLDEQ-8 Questionnaires	The subject will respond to the Baseline modified CLDEQ-8 Questionnaires. Note: instruct the patient to think about how their habitual contact lenses feel on an average day in the last week and answer the questions based on this level of comfort.	Appendix A
1.7	Entrance Visual Acuity	Record the distance Snellen visual acuity (OD, OS, and OU) to the nearest letter with their habitual spectacle correction in place. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	

Visit 1: Baseline			
Step	Procedure	Details	
1.8	Keratometry	Record the keratometry readings OD and OS in diopters. This can come from any appropriate instrument so long as the same instrument is used at the Final Evaluation.	
1.9	Subjective Sphero-cylindrical Refraction	Complete subjective spherocylindrical refraction and record the resultant distance visual acuity (OD, OS, and OU) to the nearest letter.	
1.10	Eye dominance	The dominant eye will be measured using the +1.00 lens blur method. If there is no obvious dominant eye with the +1.00 lens method neither will be recorded in the EDC and the sighting ocular dominance will be performed and recorded.	Ocular Dominance Test work aid
1.11	Slit Lamp Biomicroscopy	<p>FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility.</p> <p>If there are any Grade 2 or higher corneal staining or conjunctival injection, or Grade 3 or higher other slit-lamp findings, the subject is ineligible to continue at this time, but may return up to one additional time to determine eligibility. If discontinued a final examination must be completed.</p> <p><u>Note 1:</u> The following [REDACTED] will be used to assess specific ocular physiology in greater detail:</p> <ul style="list-style-type: none"> <li>• [REDACTED] Limbal and conjunctival redness</li> <li>• [REDACTED] Expanded Corneal staining</li> <li>• [REDACTED] Conjunctival staining</li> </ul> <p>If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.</p>	
1.12	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.	

Visit 1: Washout Lens Fitting			
Step	Procedure	Details	
1.13	Lens Selection	All subjects will be fit in 1-DAY ACUVUE® MOIST as a washout lens. Subjects will be corrected for distance vision only.	
1.14	Lens Insertion	The subject inserts the study lenses. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses, if applicable.	
1.15	Lens Settling	Allow the study lenses to settle for a minimum of 5 minutes.	
1.16	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.	
1.17	Subjective Best Sphere Over Refraction	Perform a distance spherical over-refraction OD and OS using any acceptable means (i.e., phoropter, trial lenses, flipper bars) in normal room illumination and record the resultant distance Snellen visual acuity OD and OS. A plano spherical over-refraction must be achieved.	
1.18	Lens Power Modification (if applicable)	Adjust the lens power if the subject's best sphere over-refraction is outside of plano. For each power modification, remove the lens, assign the new lens power, and repeat steps (1.15-1.19). Record the resultant distance Snellen visual acuity OD and OS. Up to <u>two</u> power modifications are allowed.	
1.19	Post-Fit VAS Questionnaire	The subject will respond to the Post-Fit VAS Questionnaire.	
1.20	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
1.21	Subjective Lens Fit Assessment	<p>Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics.</p> <p>An unacceptable fit is deemed by one of the following criteria:</p> <ul style="list-style-type: none"> <li>limbal exposure at primary gaze or with extreme eye movement</li> </ul>	

Visit 1: Washout Lens Fitting			
Step	Procedure	Details	
		<ul style="list-style-type: none"> <li>• edge lift</li> <li>• excessive movement in primary and up gaze</li> <li>• insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up</li> </ul> <p><b>Note:</b> if lens fit is unacceptable subject will be discontinued from the study.</p>	
1.22	White Light Lens Surface Wettability	Record the white light lens wettability of both lenses.	
1.23	Surface Deposits	Record any front and back surface lens deposits.	
1.24	Continuance	<p>For the subject to continue in the study, they must meet all three of the following criteria:</p> <ul style="list-style-type: none"> <li>• Visual acuity is 20/30 or better OD and OS</li> <li>• The lens fit is acceptable OD and OS</li> <li>• Investigator approval.</li> </ul> <p>If the Investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.</p>	
1.25	Dispense	<p>The lenses will be dispensed for a 5-7 day wearing period</p> <ul style="list-style-type: none"> <li>• Dispense enough lenses to last the subject to their scheduled follow-up visit. Do not dispense extras*.</li> <li>• The lenses will be dispensed with right and left eye designation.</li> <li>• The lenses will be worn as daily disposable only.</li> <li>• Study approved rewetting drops are permitted if needed.</li> <li>• No other contact lenses should be worn during the wear period (spectacles may be worn)</li> <li>• No solutions or care products should be used</li> </ul>	

Visit 1: Washout Lens Fitting			
Step	Procedure	Details	
		<ul style="list-style-type: none"> <li>Subjects may use reading glasses over study contact lenses as needed</li> <li>A patient instruction guide will be provided.</li> <li>Subjects will be scheduled for Visit 2 in approximately 5-7 days.</li> </ul> <p><b>* Note:</b> 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, if applicable. The lens will be stored in labeled vial with study provided solution, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.</p>	
1.26	Randomization	Subjects will be randomized to a contact lens arm and a solution order. The same power lenses as fit in Visit 1 will be used in all remaining visits. (this will allow time for lenses to be soaked 16-28 hours)	

**Prior to Visit 2, randomized lenses will be prepared.**

Sixteen to twenty-eight hours prior to Visit 2, the subject's lenses will be soaked in the test solutions in the sponsor provided lens cases. (See work aid for lens preparation instructions)

**VISIT 2**

The subjects must present to Visit 2 wearing their habitual spectacles (if applicable) having not worn any lenses or used any artificial tears that day.

Visit 2: Follow-up of Washout lenses			
Step	Procedure	Details	
2.1.	Adverse Events and Concomitant Medications Review	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	
2.2.	Compliance	Confirm compliance with the dispensed Washout lenses.	

Visit 2: Follow-up of Washout lenses			
Step	Procedure	Details	
2.3.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
2.4.	Follow-Up modified CLDEQ-8 Questionnaires	The subject will respond to the Follow-Up modified CLDEQ-8 Questionnaires. Note: instruct the patient to think about how their wash-out contact lenses feel on an average day and answer the questions based on this level of comfort.	Appendix A
2.5.	Visual Acuity	Record the distance Snellen visual acuity with their habitual spectacles (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	
2.6.	Slit Lamp Biomicroscopy	<p>FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility.</p> <p>If there are any Grade 2 or higher corneal staining or conjunctival injection, or Grade 3 or higher other slit-lamp findings, the subject is ineligible to continue at this time, but may return up to one additional time to determine eligibility. If discontinued a final examination must be completed. All adverse events must be followed to resolution.</p> <p><u>Note 1:</u> The following [REDACTED] will be used to assess specific ocular physiology in greater detail:</p> <ul style="list-style-type: none"> <li>• [REDACTED] Limbal and conjunctival redness</li> <li>• [REDACTED]: Expanded Corneal staining</li> <li>• [REDACTED] Conjunctival staining</li> </ul> <p>If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.</p>	
2.7.	Confirm Eligibility	Confirm subject is still eligible to continue	

Visit 2: Lens pair #1 Fitting			
Step	Procedure	Details	
2.8.	Lens Selection	Following the randomization scheme, lenses will be selected. The same lens power as worn in V1 will be used. Lenses will have been soaked for 16-28 hours in	

Visit 2: Lens pair #1 Fitting			
Step	Procedure	Details	
		the study solution as specified by randomization scheme. The investigator must inspect the lenses and lens case for damage prior to the subject inserting the lenses. (See work aid for lens preparation instructions)	
2.9.	Lens Insertion	The subject inserts the study lenses. Check for lens damage under the slit lamp before proceeding with lens settling. If the lens is damaged, the visit will be stopped, an exit slit lamp and visual acuity will be completed and the subject will be discontinued from the study.	
2.10.	1-minute Post-Fit VAS Questionnaire	The subject will respond to the Post-Fit VAS Questionnaire.	
2.11.	5-minute Post-Fit VAS Questionnaire	The subject will respond to the Post-Fit VAS Questionnaire.	
2.12.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
2.13.	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.	
2.14.	Subjective Lens Fit Assessment	<p>Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics.</p> <p>An unacceptable fit is deemed by one of the following criteria:</p> <ul style="list-style-type: none"> <li>• limbal exposure at primary gaze or with extreme eye movement</li> <li>• edge lift</li> <li>• excessive movement in primary and up gaze</li> <li>• insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up</li> </ul> <p><b>Note:</b> if lens fit is unacceptable subject will be discontinued from the study.</p>	
2.15.	White Light Lens Surface Wettability	Record the white light lens wettability of both lenses.	

Visit 2: Lens pair #1 Fitting			
Step	Procedure	Details	
2.16.	Surface Deposits	Record any front and back surface lens deposits.	
2.17.	Continuance	<p>For the subject to continue in the study, they must meet all three of the following criteria:</p> <ul style="list-style-type: none"> <li>• Visual acuity is 20/30 or better OD and OS</li> <li>• The lens fit is acceptable OD and OS</li> <li>• Investigator approval.</li> </ul> <p>If the Investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.</p>	
2.18.	Wear time - 45 minutes	<p>Subjects will wear the study lenses (in office) for 45 minutes.</p> <p>During this time, no rewetting drops are permitted.</p> <p>Note: no lenses will be replaced during the wear time. If a new lens is needed, the visit will be stopped, an exit slit lamp and visual acuity will be completed and the subject will be discontinued from the study.</p>	

Visit 2: Lens Pair # 1 Follow-Up			
Step	Procedure	Details	
2.19.	Compliance	Confirm compliance with the prescribed wear schedule.	
2.20.	45-minute Follow-Up VAS Questionnaires	The subject will respond to the Follow-Up VAS Questionnaires.	
2.21.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
2.22.	Visual Acuity	Record the distance Snellen visual acuity with the study CLs (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	
2.23.	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics.	

Visit 2: Lens Pair # 1 Follow-Up			
Step	Procedure	Details	
		<p>An unacceptable fit is deemed by one of the following criteria:</p> <ul style="list-style-type: none"> <li>• limbal exposure at primary gaze or with extreme eye movement</li> <li>• edge lift</li> <li>• excessive movement in primary and up gaze</li> <li>• insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up</li> </ul> <p><u>Note:</u> if lens fit is unacceptable subject will be discontinued from the study.</p>	
2.24.	White Light Lens Surface Wettability	Record the white light lens wettability of both lenses.	
2.25.	Surface Deposits	Record any front and back surface lens deposits.	
2.26.	Remove lenses	Lenses will be removed and discarded	
2.27.	Slit Lamp Biomicroscopy	<p>FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility.</p> <p>Any adverse events must be followed to resolution.</p> <p><u>Note 1:</u> The following [REDACTED] will be used to assess specific ocular physiology in greater detail:</p> <ul style="list-style-type: none"> <li>• [REDACTED] Limbal and conjunctival redness</li> <li>• [REDACTED]: Expanded Corneal staining</li> <li>• [REDACTED]: Conjunctival staining</li> </ul> <p><u>Note 2:</u> Each eye should be photo-documented if significant (Grade 2 or more) fluorescein corneal staining noted. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.</p>	[REDACTED] [REDACTED] [REDACTED] [REDACTED]
2.28.	Visual Acuity	Record the distance Snellen visual acuity with their habitual spectacles (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	

Visit 2: Lens Pair # 1 Follow-Up			
Step	Procedure	Details	
2.29.	Dispense	<p>The washout lenses, 1-DAY ACUVUE® MOIST will be dispensed for a 5-7 day wearing period</p> <ul style="list-style-type: none"> <li>• Dispense enough lenses to last the subject to their scheduled follow-up visit. Do not dispense extras*.</li> <li>• The lenses will be dispensed with right and left eye designation.</li> <li>• The lenses will be worn as daily disposable only.</li> <li>• Study approved rewetting drops are permitted if needed.</li> <li>• No other contact lenses should be worn during the wear period (spectacles may be worn)</li> <li>• No solutions or care products should be used</li> <li>• Subjects may use reading glasses over study contact lenses as needed</li> <li>• A patient instruction guide will be provided.</li> <li>• Subjects will be scheduled for Visit 2 in approximately 5-7 days.</li> </ul> <p><b>* Note:</b> 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, if applicable. The lens will be stored in labeled vial with study provided solution, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.</p>	

Prior to Visit 3, randomized lenses will be prepared.

Sixteen to twenty-eight hours prior to Visit 3, the subject's lenses will be soaked in the test solutions in the sponsor provided lens cases. (See work aid for lens preparation instructions)

### VISIT 3

The subjects must present to Visit 3 wearing their habitual spectacles (if applicable) having not worn contact lenses the day of the visit.

Visit 3: Confirm Baseline			
Step	Procedure	Details	
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.	
3.2.	Compliance	Confirm compliance with the dispensed Washout lenses.	
3.3.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
3.4.	Follow-Up modified CLDEQ-8 Questionnaires	The subject will respond to the Follow-Up modified CLDEQ-8 Questionnaires. Note: instruct the patient to think about how their wash-out contact lenses feel on an average day and answer the questions based on this level of comfort.	Appendix A
3.5.	Visual Acuity	Record the distance Snellen visual acuity with their habitual spectacles (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	
3.6.	Slit Lamp Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. If there are any Grade 2 or higher corneal staining or conjunctival injection, or Grade 3 or higher other slit-lamp findings, the subject is ineligible to continue at this time, but may return up to one additional time to determine eligibility. If discontinued a final examination must be completed. Any adverse events must be followed to resolution.  <u>Note 1:</u> The following CTP's will be used to assess specific ocular physiology in greater detail:	

Visit 3: Confirm Baseline			
Step	Procedure	Details	
		<ul style="list-style-type: none"> <li>• [REDACTED] Limbal and conjunctival redness</li> <li>• [REDACTED] Expanded Corneal staining</li> <li>• [REDACTED] Conjunctival staining</li> </ul> <p>If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.</p>	
3.7.	Confirm Eligibility	Confirm subject is still eligible to continue	

Visit 3: Lens pair #2 Fitting			
Step	Procedure	Details	
3.8.	Lens Selection	Following the randomization scheme, lenses will be selected. The same lens power as worn in V1 will be used. Lenses will have been soaked for 16-28 hours in the study solution as specified by randomization scheme. (See work aid for lens preparation instructions)	
3.9.	Lens Insertion	The subject inserts the study lenses. Check for lens damage under the slit lamp before proceeding with lens settling. If the lens is damaged, the visit will be stopped, an exit slit lamp and visual acuity will be completed and the subject will be discontinued from the study.	[REDACTED]
3.10.	1-minute Post-Fit VAS Questionnaire	The subject will respond to the Post-Fit VAS Questionnaire.	
3.11.	5-minute Post-Fit VAS Questionnaire	The subject will respond to the Post-Fit VAS Questionnaire.	
3.12.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[REDACTED]
3.13.	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]
3.14.	Subjective Lens Fit Assessment	<p>Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics.</p> <p>An unacceptable fit is deemed by one of the following criteria:</p>	[REDACTED]

Visit 3: Lens pair #2 Fitting			
Step	Procedure	Details	
		<ul style="list-style-type: none"> <li>• limbal exposure at primary gaze or with extreme eye movement</li> <li>• edge lift</li> <li>• excessive movement in primary and up gaze</li> <li>• insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up</li> </ul> <p><b>Note:</b> if lens fit is unacceptable subject will be discontinued from the study.</p>	
3.15.	White Light Lens Surface Wettability	Record the white light lens wettability of both lenses.	
3.16.	Surface Deposits	Record any front and back surface lens deposits.	
3.17.	Continuance	<p>For the subject to continue in the study, they must meet all three of the following criteria:</p> <ul style="list-style-type: none"> <li>• Visual acuity is 20/30 or better OD and OS</li> <li>• The lens fit is acceptable OD and OS</li> <li>• Investigator approval.</li> </ul> <p>If the Investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.</p>	
3.18.	Wear time- 120 minutes	<p>Subjects will wear the study lenses (in office) for 120 minutes.</p> <p>During this time, no rewetting drops are permitted.</p> <p>Note: no lenses will be replaced during the wear time. If a new lens is needed, the visit will be stopped, an exit slit lamp and visual acuity will be completed and the subject will be discontinued from the study.</p>	
3.19.	45-minute Post-Fit VAS Questionnaire	The subject will respond to the Post-Fit VAS Questionnaire.	

Visit 3: Lens Pair # 2 Follow-Up			
Step	Procedure	Details	
3.20.	Compliance	Confirm compliance with the prescribed wear schedule.	
3.21.	120-minute Follow-Up VAS Questionnaires	The subject will respond to the Follow-Up VAS Questionnaires.	
3.22.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
3.23.	Visual Acuity	Record the distance Snellen visual acuity with the study CLs (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	
3.24.	Subjective Lens Fit Assessment	<p>Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics.</p> <p>An unacceptable fit is deemed by one of the following criteria:</p> <ul style="list-style-type: none"> <li>• limbal exposure at primary gaze or with extreme eye movement</li> <li>• edge lift</li> <li>• excessive movement in primary and up gaze</li> <li>• insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up</li> </ul> <p><u>Note:</u> if lens fit is unacceptable subject will be discontinued from the study.</p>	
3.25.	White Light Lens Surface Wettability	Record the white light lens wettability of both lenses.	
3.26.	Surface Deposits	Record any front and back surface lens deposits.	
3.27.	Remove lenses	Lenses will be removed and discarded	
3.28.	Slit Lamp Biomicroscopy	<p>FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility.</p> <p>Any adverse events must be followed to resolution.</p>	

Visit 3: Lens Pair # 2 Follow-Up			
Step	Procedure	Details	
		<p><u>Note 1:</u> The following [REDACTED] will be used to assess specific ocular physiology in greater detail:</p> <ul style="list-style-type: none"> <li>• [REDACTED] Limbal and conjunctival redness</li> <li>• [REDACTED] Expanded Corneal staining</li> <li>• [REDACTED] Conjunctival staining</li> </ul> <p><u>Note 2:</u> Each eye should be photo-documented (if significant (Grade 2 or more) fluorescein corneal staining noted.</p> <p>If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.</p>	
3.29.	Visual Acuity	Record the distance Snellen visual acuity with their habitual spectacles (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	[REDACTED]
3.30.	Dispense	<p>The washout lenses, 1-DAY ACUVUE® MOIST will be dispensed for a 5-7 day wearing period</p> <ul style="list-style-type: none"> <li>• Dispense enough lenses to last the subject to their scheduled follow-up visit. Do not dispense extras*.</li> <li>• The lenses will be dispensed with right and left eye designation.</li> <li>• The lenses will be worn as daily disposable only.</li> <li>• Study approved rewetting drops are permitted if needed.</li> <li>• No other contact lenses should be worn during the wear period (spectacles may be worn)</li> <li>• No solutions or care products should be used</li> <li>• Subjects may use reading glasses over study contact lenses as needed</li> <li>• A patient instruction guide will be provided.</li> <li>• Subjects will be scheduled for Visit 2 in approximately 5-7 days.</li> </ul>	

Visit 3: Lens Pair # 2 Follow-Up			
Step	Procedure	Details	
		<p><b>* Note:</b> 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, if applicable. The lens will be stored in labeled vial with study provided solution, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.</p>	

Prior to Visit 4, randomized lenses will be prepared.

Sixteen to twenty-eight hours prior to Visit 4, the subject's lenses will be soaked in the test solutions in the sponsor provided lens cases. (See work aid for lens preparation instructions)

#### VISIT 4

The subjects must present to Visit 4 wearing their habitual spectacles (if applicable) having not worn any lenses that day.

Visit 4: Confirm Baseline			
Step	Procedure	Details	
4.1.	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.	
4.2.	Compliance	Confirm compliance with the dispensed Washout lenses.	
4.3.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
4.4.	Follow-Up modified CLDEQ-8 Questionnaires	<p>The subject will respond to the Follow-Up modified CLDEQ-8 Questionnaires.</p> <p>Note: instruct the patient to think about how their washout contact lenses feel on an average day and answer the questions based on this level of comfort.</p>	Appendix A
4.5.	Visual Acuity	Record the distance Snellen visual acuity with their habitual spectacles (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	

Visit 4: Confirm Baseline			
Step	Procedure	Details	
4.6.	Slit Lamp Biomicroscopy	<p>FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility.</p> <p>If there are any Grade 2 or higher corneal staining or conjunctival injection, or Grade 3 or higher other slit-lamp findings, the subject is ineligible to continue at this time, but may return up to one additional time to determine eligibility. If discontinued a final examination must be completed. Any adverse events must be followed to resolution.</p> <p><u>Note 1:</u> The following [REDACTED] will be used to assess specific ocular physiology in greater detail:</p> <ul style="list-style-type: none"> <li>• [REDACTED]: Limbal and conjunctival redness</li> <li>• [REDACTED] Expanded Corneal staining</li> <li>• [REDACTED] Conjunctival staining</li> </ul> <p>If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.</p>	[REDACTED] [REDACTED] [REDACTED] [REDACTED]
4.7.	Confirm Eligibility	Confirm subject is still eligible to continue	

Visit 4: Lens pair #3 Fitting			
Step	Procedure	Details	
4.8.	Lens Selection	Following the randomization scheme, lenses will be selected. The same lens power as worn in V1 will be used. Lenses will have been soaked for 16-28 hours in the study solution as specified by randomization scheme. The investigator must inspect the lenses and lens case for damage prior to the subject inserting the lenses. (See work aid for lens preparation instructions)	[REDACTED]
4.9.	Lens Insertion	The subject inserts the study lenses. Check for lens damage under the slit lamp before proceeding with lens settling. If the lens is damaged, the visit will be stopped, an exit slit lamp and visual acuity	[REDACTED]

Visit 4: Lens pair #3 Fitting			
Step	Procedure	Details	
		will be completed and the subject will be discontinued from the study.	
4.10.	1-minute Post-Fit VAS Questionnaire	The subject will respond to the Post-Fit VAS Questionnaire.	
4.11.	5-minute Post-Fit VAS Questionnaire	The subject will respond to the Post-Fit VAS Questionnaire.	
4.12.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
4.13.	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.	
4.14.	Subjective Lens Fit Assessment	<p>Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics.</p> <p>An unacceptable fit is deemed by one of the following criteria:</p> <ul style="list-style-type: none"> <li>• limbal exposure at primary gaze or with extreme eye movement</li> <li>• edge lift</li> <li>• excessive movement in primary and up gaze</li> <li>• insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up</li> </ul> <p><b>Note:</b> if lens fit is unacceptable subject will be discontinued from the study.</p>	
4.15.	White Light Lens Surface Wettability	Record the white light lens wettability of both lenses.	
4.16.	Surface Deposits	Record any front and back surface lens deposits.	
4.17.	Continuance	<p>For the subject to continue in the study, they must meet all three of the following criteria:</p> <ul style="list-style-type: none"> <li>• Visual acuity is 20/30 or better OD and OS</li> <li>• The lens fit is acceptable OD and OS</li> <li>• Investigator approval.</li> </ul>	

Visit 4: Lens pair #3 Fitting			
Step	Procedure	Details	
		If the Investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.	
4.18.	Wear time- 45 minutes	Subjects will wear the study lenses (in office) for 45 minutes. During this time, no rewetting drops are permitted. Note: no lenses will be replaced during the wear time. If a new lens is needed, the visit will be stopped, an exit slit lamp and visual acuity will be completed, and the subject will be discontinued from the study.	

Visit 4: Lens Pair # 3 Follow-Up			
Step	Procedure	Details	
4.19.	Compliance	Confirm compliance with the prescribed wear schedule.	
4.20.	45-minute Follow-Up VAS Questionnaires	The subject will respond to the Follow-Up VAS Questionnaires.	
4.21.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
4.22.	Visual Acuity	Record the distance Snellen visual acuity with the study CLs (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	
4.23.	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: <ul style="list-style-type: none"> <li>limbal exposure at primary gaze or with extreme eye movement</li> <li>edge lift</li> <li>excessive movement in primary and up gaze</li> <li>insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up</li> </ul>	

Visit 4: Lens Pair # 3 Follow-Up			
Step	Procedure	Details	
		<b>Note:</b> if lens fit is unacceptable subject will be discontinued from the study.	
4.24.	White Light Lens Surface Wettability	Record the white light lens wettability of both lenses.	
4.25.	Surface Deposits	Record any front and back surface lens deposits.	
4.26.	Remove lenses	Lenses will be removed and discarded	
4.27.	Slit Lamp Biomicroscopy	<p>FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility.</p> <p>Any adverse events must be followed to resolution.</p> <p><b>Note 1:</b> The following [REDACTED] will be used to assess specific ocular physiology in greater detail:</p> <ul style="list-style-type: none"> <li>• [REDACTED] Limbal and conjunctival redness</li> <li>• [REDACTED] Expanded Corneal staining</li> <li>• [REDACTED] Conjunctival staining</li> </ul> <p><b>Note 2:</b> Each eye should be photo-documented if significant (Grade 2 or more) fluorescein corneal staining noted.</p> <p>If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.</p>	[REDACTED] [REDACTED] [REDACTED] [REDACTED]
4.28.	Visual Acuity	Record the distance Snellen visual acuity with their habitual spectacles (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	
4.29.	Dispense	<p>The washout lenses, 1-DAY ACUVUE® MOIST will be dispensed for a 5-7 day wearing period</p> <ul style="list-style-type: none"> <li>• Dispense enough lenses to last the subject to their scheduled follow-up visit. Do not dispense extras*.</li> <li>• The lenses will be dispensed with right and left eye designation.</li> <li>• The lenses will be worn as daily disposable only.</li> </ul>	

Visit 4: Lens Pair # 3 Follow-Up			
Step	Procedure	Details	
		<ul style="list-style-type: none"> <li>• Study approved rewetting drops are permitted if needed.</li> <li>• No other contact lenses should be worn during the wear period (spectacles may be worn)</li> <li>• No solutions or care products should be used</li> <li>• Subjects may use reading glasses over study contact lenses as needed</li> <li>• A patient instruction guide will be provided.</li> <li>• Subjects will be scheduled for Visit 2 in approximately 5-7 days.</li> </ul> <p><b>* Note:</b> 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, if applicable. The lens will be stored in labeled vial with study provided solution, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.</p>	

Prior to Visit 5, randomized lenses will be prepared.

Sixteen to twenty-eight hours prior to Visit 5, the subject's lenses will be soaked in the test solutions in the sponsor provided lens cases. (See work aid for lens preparation instructions)

## VISIT 5

The subjects must present to Visit 5 wearing their habitual spectacles (if applicable) having not worn contact lenses the day of the visit.

Visit 5: Confirm Baseline			
Step	Procedure	Details	
5.1.	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.	

Visit 5: Confirm Baseline			
Step	Procedure	Details	
5.2.	Compliance	Confirm compliance with the prescribed wear schedule.	
5.3.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
5.4.	Follow-Up modified CLDEQ-8 Questionnaires	The subject will respond to the Follow-Up modified CLDEQ-8 Questionnaires. Note: instruct the patient to think about how their washout contact lenses feel on an average day and answer the questions based on this level of comfort.	Appendix A
5.5.	Visual Acuity	Record the distance Snellen visual acuity with their habitual spectacles (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	
5.6.	Slit Lamp Biomicroscopy	<p>FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility.</p> <p>If there are any Grade 2 or higher corneal staining or conjunctival injection, or Grade 3 or higher other slit-lamp findings, the subject is ineligible to continue at this time, but may return up to one additional time to determine eligibility. If discontinued a final examination must be completed. Any adverse events must be followed to resolution.</p> <p><u>Note 1:</u> The following [REDACTED] will be used to assess specific ocular physiology in greater detail:</p> <ul style="list-style-type: none"> <li>• [REDACTED] Limbal and conjunctival redness</li> <li>• [REDACTED]: Expanded Corneal staining</li> <li>• [REDACTED] Conjunctival staining</li> </ul> <p>If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.</p>	
5.7.	Confirm Eligibility	Confirm subject is still eligible to continue	

Visit 5: Lens pair #4 Fitting			
Step	Procedure	Details	
5.8.	Lens Selection	Following the randomization scheme, lenses will be selected. The same lens power as worn in V1 will be used. Lenses will have been soaked for 16-28 hours in the study solution as specified by randomization scheme. The investigator must inspect the lenses and lens case for damage prior to the subject inserting the lenses. (See work aid for lens preparation instructions)	
5.9.	Lens Insertion	The subject inserts the study lenses. Check for lens damage under the slit lamp before proceeding with lens settling. If the lens is damaged, the visit will be stopped, an exit slit lamp and visual acuity will be completed and the subject will be discontinued from the study.	C [REDACTED]
5.10.	1-minute Post-Fit VAS Questionnaire	The subject will respond to the Post-Fit VAS Questionnaire.	
5.11.	5-minute Post-Fit VAS Questionnaire	The subject will respond to the Post-Fit VAS Questionnaire.	
5.12.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[REDACTED]
5.13.	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]
5.14.	Subjective Lens Fit Assessment	<p>Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics.</p> <p>An unacceptable fit is deemed by one of the following criteria:</p> <ul style="list-style-type: none"> <li>• limbal exposure at primary gaze or with extreme eye movement</li> <li>• edge lift</li> <li>• excessive movement in primary and up gaze</li> <li>• insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up</li> </ul>	[REDACTED]

Visit 5: Lens pair #4 Fitting			
Step	Procedure	Details	
		<b>Note:</b> if lens fit is unacceptable subject will be discontinued from the study.	
5.15.	White Light Lens Surface Wettability	Record the white light lens wettability of both lenses.	
5.16.	Surface Deposits	Record any front and back surface lens deposits.	
5.17.	Continuance	<p>For the subject to continue in the study, they must meet all three of the following criteria:</p> <ul style="list-style-type: none"> <li>• Visual acuity is 20/30 or better OD and OS</li> <li>• The lens fit is acceptable OD and OS</li> <li>• Investigator approval.</li> </ul> <p>If the Investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.</p>	
5.18.	Wear time- 120 minutes	<p>Subjects will wear the study lenses (in office) for 120 minutes.</p> <p>During this time, no rewetting drops are permitted.</p> <p>Note: no lenses will be replaced during the wear time. If a new lens is needed, the visit will be stopped, an exit slit lamp and visual acuity will be completed and the subject will be discontinued from the study.</p>	
5.19.	45-minute Post-Fit VAS Questionnaire	The subject will respond to the Post-Fit VAS Questionnaire.	

Visit 5: Lens Pair # 4 Follow-Up			
Step	Procedure	Details	
5.20.	Compliance	Confirm compliance with the prescribed wear schedule.	
5.21.	120-minute Follow-Up VAS Questionnaires	The subject will respond to the Follow-Up VAS Questionnaires.	
5.22.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
5.23.	Visual Acuity	Record the distance Snellen visual acuity with the study CLs (OD, OS, and OU) to the nearest letter. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	

Visit 5: Lens Pair # 4 Follow-Up			
Step	Procedure	Details	
5.24.	Subjective Lens Fit Assessment	<p>Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics.</p> <p>An unacceptable fit is deemed by one of the following criteria:</p> <ul style="list-style-type: none"> <li>• limbal exposure at primary gaze or with extreme eye movement</li> <li>• edge lift</li> <li>• excessive movement in primary and up gaze</li> <li>• insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up</li> </ul> <p><u>Note:</u> if lens fit is unacceptable subject will be discontinued from the study.</p>	<div></div> <div></div>
5.25.	White Light Lens Surface Wettability	Record the white light lens wettability of both lenses.	<div></div>
5.26.	Surface Deposits	Record any front and back surface lens deposits.	<div></div>
5.27.	Remove lenses	Lenses will be removed and discarded	
5.28.	Slit Lamp Biomicroscopy	<p>FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility.</p> <p>Any adverse events must be followed to resolution.</p> <p><u>Note 1:</u> The following <div></div> will be used to assess specific ocular physiology in greater detail:</p> <ul style="list-style-type: none"> <li>• <div></div> Limbal and conjunctival redness</li> <li>• <div></div> Expanded Corneal staining</li> <li>• <div></div> Conjunctival staining</li> </ul> <p><u>Note 2:</u> Each eye should be photo-documented if significant (Grade 2 or more) fluorescein corneal staining noted.</p>	<div></div> <div></div> <div></div> <div></div>

Visit 5: Lens Pair # 4 Follow-Up			
Step	Procedure	Details	
		If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	

## FINAL EVALUATION

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

Final Evaluation			
Step	Procedure	Details	
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 Distance Visual Acuity	Record the exit distance visual acuity OD, OS, OU with the subject's spectacles or the same method used in Baseline entrance distance visual acuity.	

### 7.3. Unscheduled Visits

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

- Chief complaint prompting the visit. If the reason is an adverse event, the applicable eCRF for the adverse event 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 (when applicable)

Unscheduled Visit			
Step	Procedure	Details	
U.1	Chief Complaints	Record the subject's chief complaints for reasons for the unscheduled visit.	
U.2	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.	
U.3	Entrance VA	Record the entrance distance visual acuity (OD, OS and OU) to the nearest letter.	
U.4	Subjective Sphero-cylindrical Refraction	Perform bare-eye subjective sphero-cylindrical 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 <u>distance</u> visual acuity to the nearest letter (OD, OS, and OU).	
U.5	Dispensing	Dispensing of 1-DAY ACUVUE® MOIST washout lenses	
U.6	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 may be instilled.	
U.7	Exit Visual Acuity	Record the subject's exit distance visual acuity (OD, OS, and OU) to the nearest letter.	

#### 7.4. Laboratory Procedures

Not applicable.

### 8. SUBJECTS COMPLETION/WITHDRAWAL

#### 8.1. Completion Criteria

Subjects are considered to have completed the study if they:

- Provided informed consent;
- They are eligible;
- Completed all study visits;
- Have not withdrawn/discontinued from the study for any reason described in Section 8.2

## **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 the study protocol including study lens wear schedule
- 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 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

An additional subject may 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: Current habitual use of 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: Current habitual use of Restasis, Xiidra, ocular steroids, or any medication (RX or OTC) that may interfere with contact lens wear (at the discretion of the investigator)

## **10. DEVIATIONS FROM THE PROTOCOL**

Investigator will notify study sponsor upon identification of a protocol deviation. Major 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 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.

## **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 (Refer to Form [REDACTED] [REDACTED] for test article return instructions)

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 1 to entry:* This definition includes events related to the investigational medical device or the comparator.

*Note 2 to entry:* This definition includes events related to the procedures involved.

*Note 3 to entry:* For users or other persons, this definition is restricted to events related to investigational medical devices.”<sup>1</sup>

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
3. 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 untoward medical occurrence that:

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

Diagnoses and conditions that are considered 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
- Hyphema
- Penetration of Bowman's Membrane
- Persistent Epithelial Defect
- Limbal cell Damage leading to Conjunctivalization

**Significant Adverse Events** – Those events that are usually symptomatic and warrant discontinuation (temporary or permanent) of the test article (excluding Serious Adverse Events).

Diagnoses and conditions that are considered 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** – Those conditions that are usually asymptomatic and usually do not warrant discontinuation (temporary or permanent) of the test article. However, the Investigator may choose to treat as a precautionary measure.

Diagnoses and conditions that are considered 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 to entry:* 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 to entry: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.”<sup>1</sup>*

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

### **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; 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; severe for all events - see definition in Section 13.2.2)
- Outcome – not recovered or not resolved; recovering or resolving; recovered or resolved with sequelae; recovered or resolved; death related to adverse event; unknown
- Actions Taken – none; temporarily discontinued; permanently discontinued; 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, possibly 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) begins 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. He/she will 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, including concomitant medications prescribed, in accordance with applicable licensing requirements
- Any referral to another health care provider if needed
- Outcome, ocular damage (if any)

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

In addition, if an infiltrate(s) is present, 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 or not 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, fax, or telephone, but no later than 24 hours following discovery of the event. The Investigator is obligated to pursue and obtain information requested by the Sponsor in addition to that information reported on the eCRF. All subjects experiencing a serious/significant adverse event must be followed up and all outcomes must be reported.

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

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

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

#### **Unanticipated (Serious) Adverse Device Effect (UADE)**

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

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

#### **Non-Serious Adverse Events**

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

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

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

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

#### **13.4.3. Event of Special Interest**

None.

#### **13.5. Reporting of Pregnancy**

Subjects reporting pregnancy (by self-report) during the course of 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. At the Investigator's discretion, the study participant may be followed by the Investigator through

delivery. However, this data will not be collected as part of the clinical study database. Pregnant participants are not discontinued from contact lens or solution related studies for safety concerns, but due to general concerns relating to pregnancy and contact lens use. Specifically, pregnant women are discontinued due to fluctuations in refractive error and/or visual acuity that occur secondary to systemic hormonal changes, and not due to unforeseen health risks to the mother or fetus.

## **14. STATISTICAL METHODS**

### **14.1. General Considerations**

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

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

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

Summaries will be presented by study solution, by lens type and across all lens types.

### **14.2. Sample Size Justification**

This is a pilot study and the sample size was not based on any empirical power calculation. The collected data will be used to design future clinical evaluation.

### **14.3. Analysis Populations**

#### **Safety Population:**

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

#### **Intent-to-Treat (ITT) Population:**

All randomized subjects regardless of actual treatment and subsequent withdrawal from study or deviation from 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%.

#### 14.5. Primary Analysis

Initial comfort scores at 1-min, 5-min, 45-min and 2-hour post-fit will be analyzed using a multivariate hierarchical Bayesian model for repeated measures to test for the difference between the test solution and control solutions at 1-min, 5-min, 45-min and 120-min. The regression model will include sequence, period, solution, lens and lens by solution interaction as fixed effects. Investigational site, subjects and eye nested within subjects will be included as random effect factors.

##### The Model:

Let  $y_{ijk} = (y_{1ijk}, y_{2ijk}, y_{3ijk}, y_{4ijk})$  denote the initial comfort scores for the  $i^{\text{th}}$  eye of the  $j^{\text{th}}$  subject, from  $k^{\text{th}}$  site at 1-min, 5-min, 45-min and 2-hour post fit. The likelihood of  $y_{ijk}$  is constructed as follow:

$$y_{ijk} \sim N(\mu, \Sigma),$$

where  $\mu = (\mu_1, \mu_2, \mu_3, \mu_4)^T$  and  $\Sigma$  is a 4x4 variance-covariance matrix. Here  $\mu_1, \mu_2, \mu_3$  and  $\mu_4$  are given by:

$$\mu_i = \mu_0 + \beta_1 \text{sequence} + \beta_2 \text{period} + \beta_3 i \text{lens} + \beta_4 i \text{solution} + \beta_5 i \text{lens} * \text{solution} + \delta_{i(jk)} + \delta_{j(k)} + \delta_k,$$

where  $\delta_{i(jk)} \sim N(0, \sigma_{\text{eye}}^2)$ ,  $\delta_{j(k)} \sim N(0, \sigma_{\text{subj}}^2)$ ,  $\delta_k \sim N(0, \sigma_{\text{site}}^2)$ . Other baseline characteristics such as age, gender and CLDEQ-8 score will also be included as fixed effects when appropriate.

Non-informative prior distributions will be used for the coefficients in the models as well as for the error terms: Independent vague normal  $N(0, 1000)$  priors for the regression coefficients ( $\mu_0$  and  $\beta$ ), inverse gamma  $IG(0.001, 0.001)$  for  $\sigma_{\text{eye}}^2$ ,  $\sigma_{\text{subj}}^2$ ,  $\sigma_{\text{site}}^2$  and inverse Wishart  $IW(R, 4)$  for  $\Sigma$ .  $R$  is determined by  $S = E[\Sigma] = 4R$  where  $S$  is the sample variance-covariance matrix of the  $y_{ijk}$ . The Metropolis sampler algorithm as implemented in the MCMC Procedure (SAS 9.4, SAS Institute, Cary, NC) will be used to estimate the posterior distributions of the unknown parameters. Inferences will be made based on a posterior credible interval for the relevant parameters. Results will be reported as regression coefficient mean estimates with 95% credible intervals.

#### 14.6. Secondary Analysis

Not applicable.

#### 14.7. Other Exploratory Analyses

Further exploratory analysis will be conducted on corneal staining, subjects reported ocular symptoms and ocular adverse events at the discretion of the Study Responsible Clinician.

#### **14.8. Interim Analysis**

No interim analysis is planned.

#### **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.

#### **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 an EDC system (Bioclinica). 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 Date 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. 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.<sup>1</sup>

#### **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.

## **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.

## **17. 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 amendments, 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

guidelines on Good Clinical Practice (GCP),<sup>2</sup> 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 64<sup>th</sup> WMA General Assembly 2013<sup>3</sup> and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with Section 8 of the ICH E6 guidelines on Good Clinical Practice (GCP),<sup>2</sup> 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 and, if applicable, amendments
- Sponsor-approved informed consent form (and any other written materials to be provided to the subjects)
- Investigator's Brochure (or equivalent information) and amendments
- Sponsor-approved subject recruitment materials
- Information on compensation for study-related injuries or payment to subjects for participation in the study
- Investigator's curriculum vitae, clinical licenses, or equivalent information (unless not required, as documented by IEC/IRB)
- Information regarding funding, name of the Sponsor, institutional affiliations, other potential conflicts of interest, and incentives for subjects
- Any other documents that the IEC/IRB requests to fulfill its obligation

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

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

- Protocol amendments
- Revision(s) to informed consent form and any other written materials to be provided to subjects
- If applicable, new or revised subject 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 amendments or new edition(s)
- Summaries of the status of the study (at least annually or at intervals stipulated in guidelines of the IEC/IRB)
- Reports of adverse events that are serious, unanticipated, and associated with the 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 amendments that increase subject risk, the amendment and applicable informed consent form revisions must be submitted promptly to the IEC/IRB for review and approval before implementation of the change(s).

At least once a year, the IEC/IRB will 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 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,<sup>3</sup> current ICH<sup>2</sup> and ISO 14155<sup>1</sup> 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<sup>5</sup> 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,<sup>2</sup> 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<sup>2</sup> 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

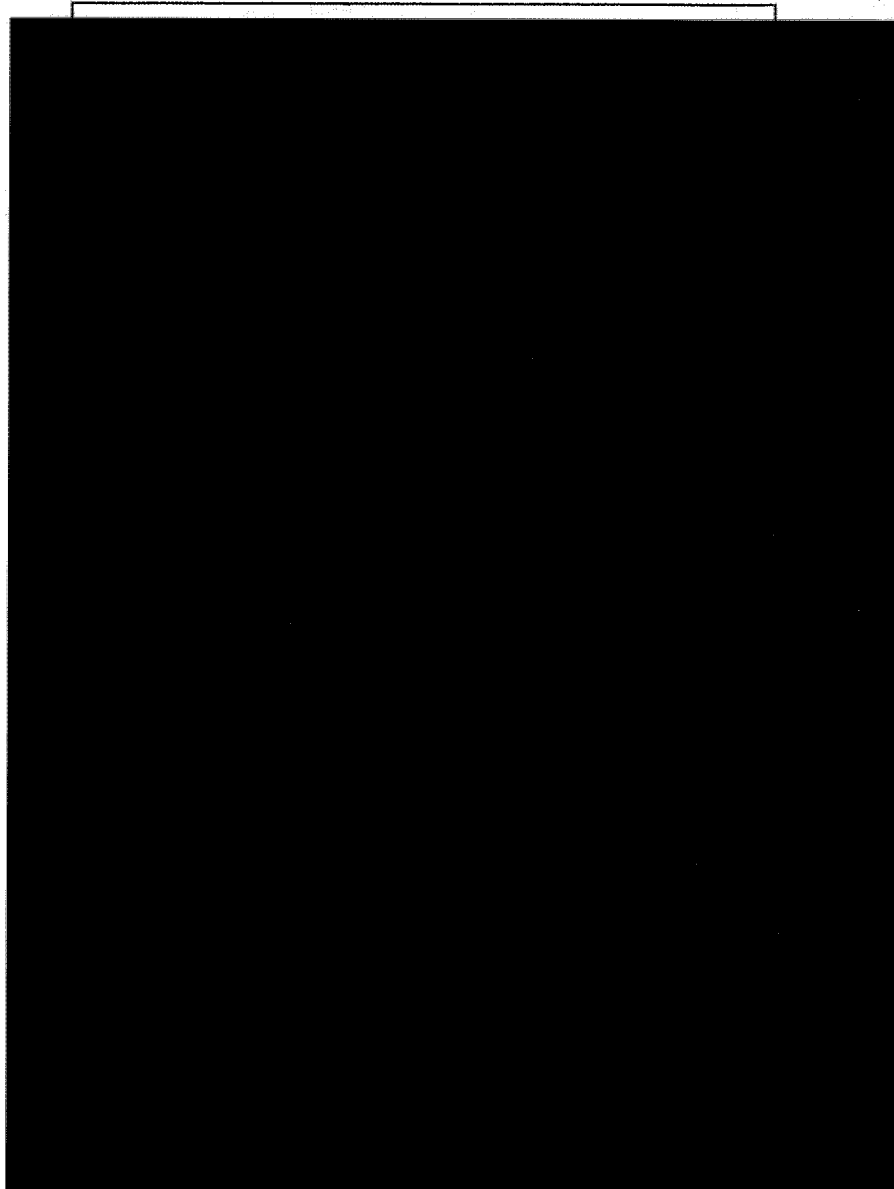
## **21. PUBLICATION**

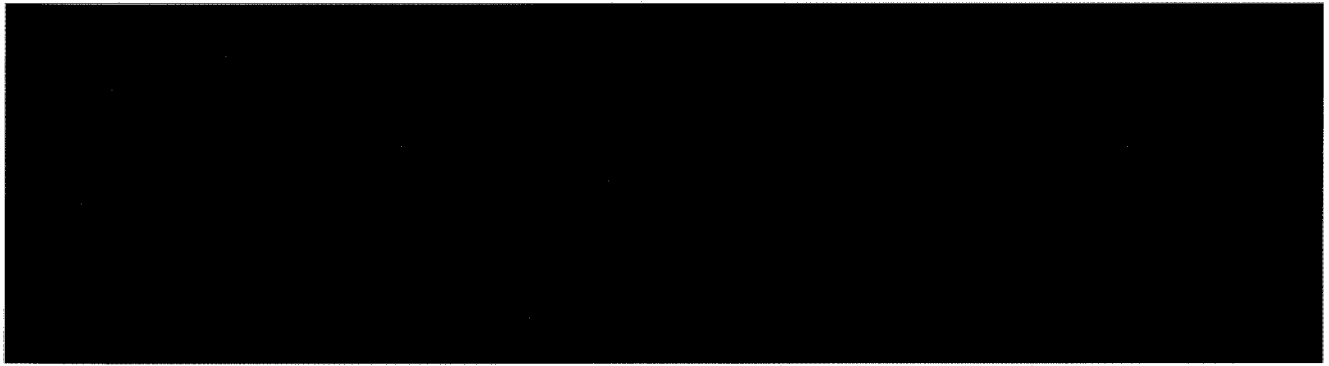
This study will be registered on ClinicalTrials.gov based on the following: This study is a post-market study.

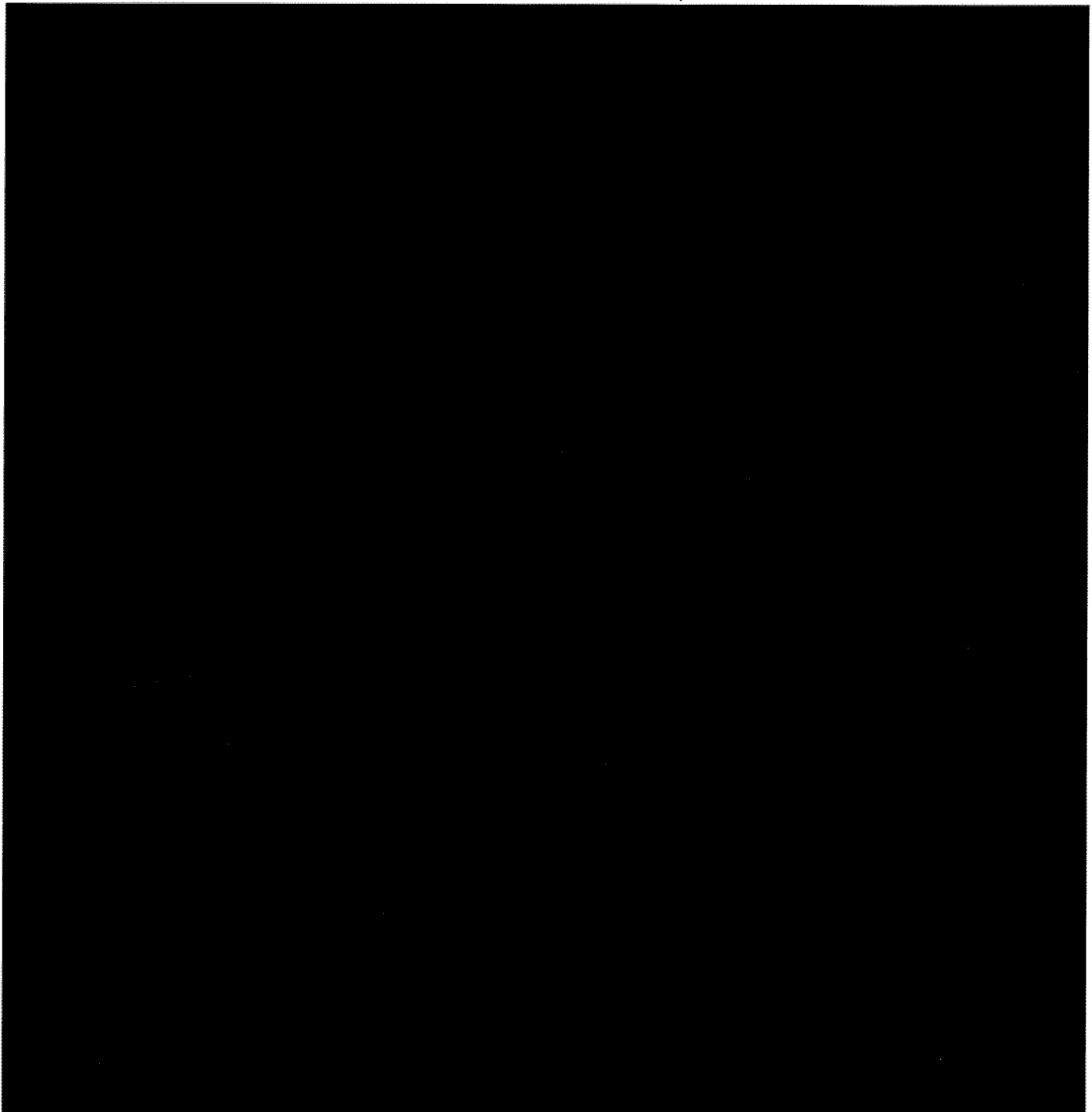
## 22. REFERENCES

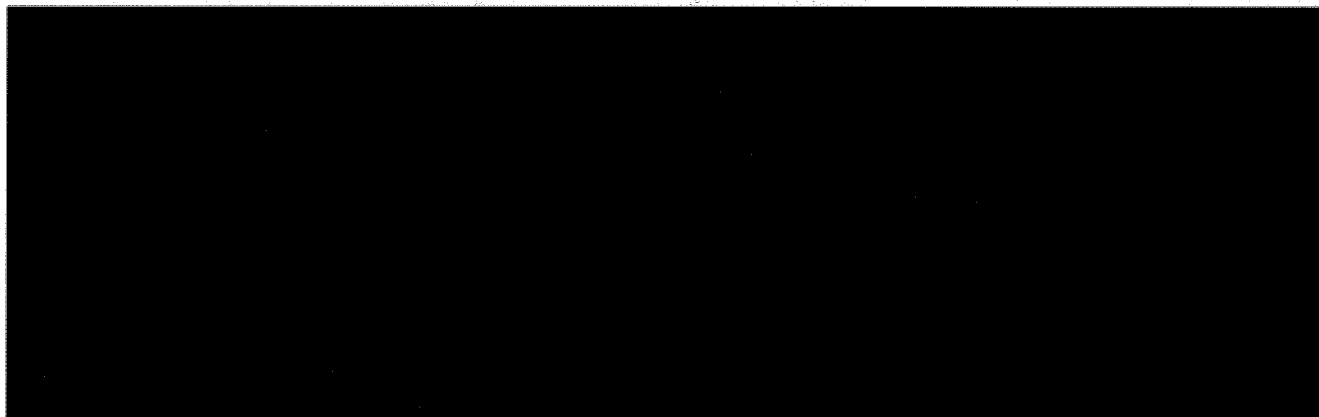
1. ISO 14155:2011: Clinical Investigation of Medical Devices for Human Subjects Good Clinical Practice. Available at: <https://www.iso.org/standard/45557.html>
2. International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP). Available at: <http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html>
3. Declaration of Helsinki - Ethical principles for Medical Research Involving Human Subjects. Available at: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
4. United States (US) Code of Federal Regulations (CFR). Available at: <https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>
5. Health Information Portability and Accountability Act (HIPAA). Available at: <https://www.hhs.gov/hipaa/for-professionals/privacy/index.html>

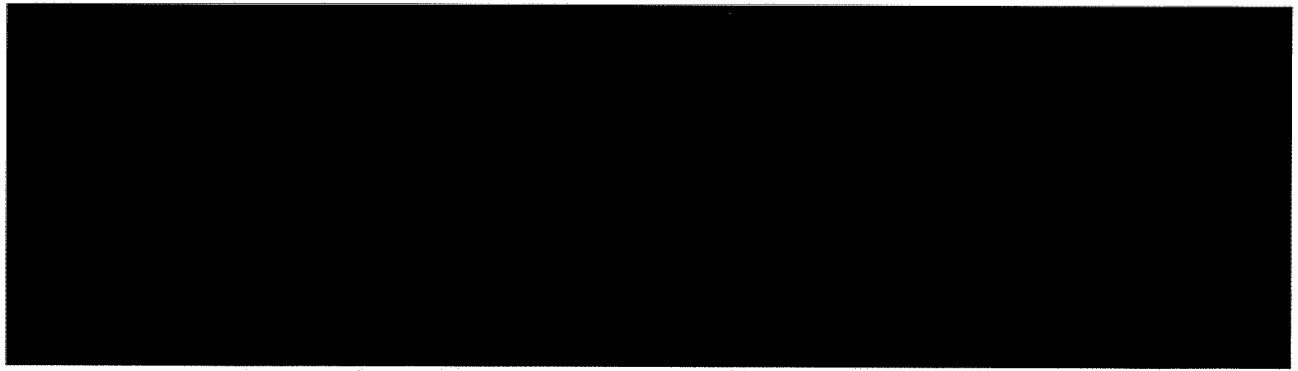
## **APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)**

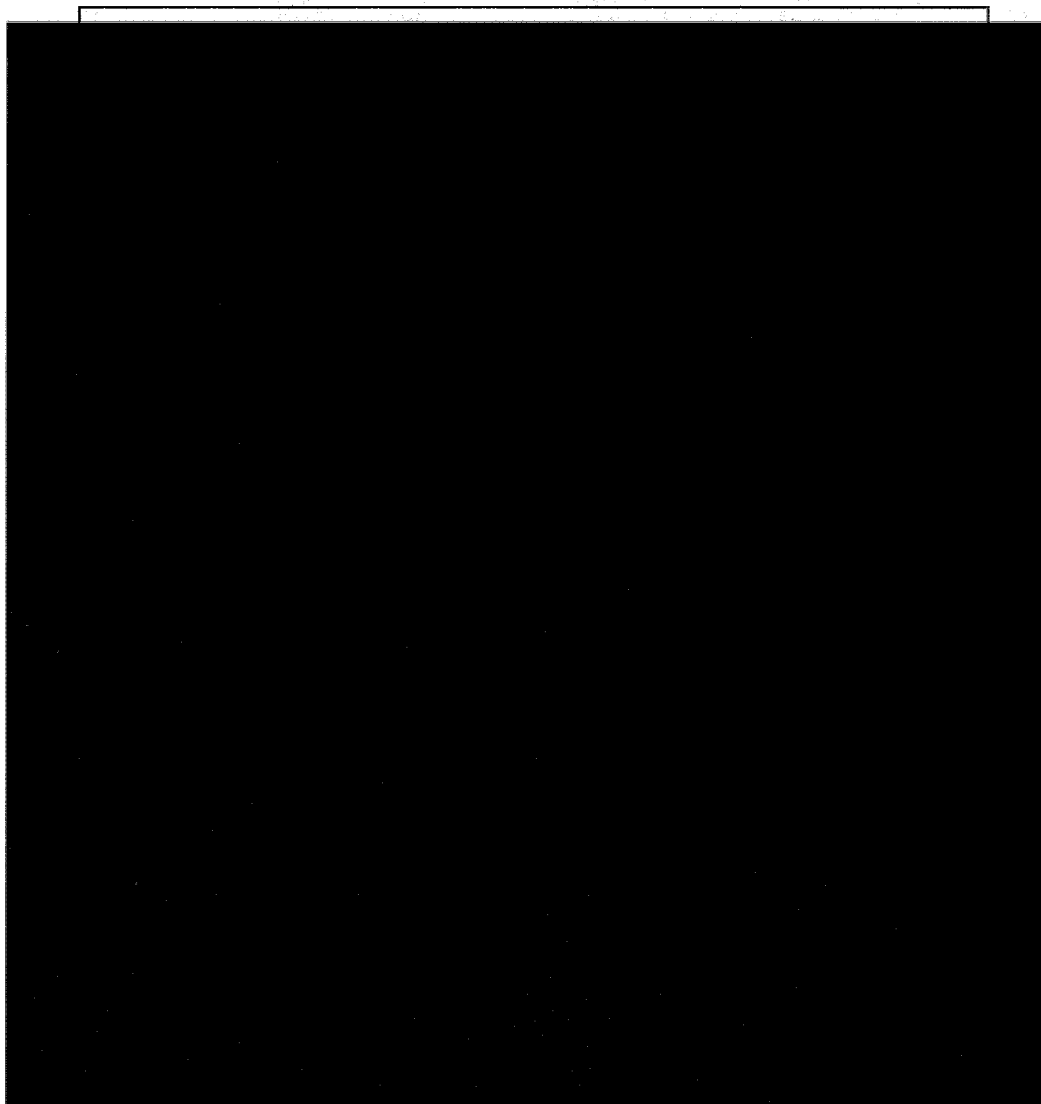












## **APPENDIX B: PATIENT INSTRUCTION GUIDE**

Patient Instruction Guide will be provided separately.

## **APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)**

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- Lens "High" = "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 "ighting 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 (ighting) 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: -0.75 to +1.25 use a "LOW" near ADD lens on each eye
- ADD: +1.50 to +1.75 use a "MID" near ADD lens on each eye
- ADD: -2.00 to +2.50 use a "MID" near ADD on the dominant eye and a "HIGH" near ADD lens on the non-dominant eye

3. Allow the lenses to settle for a minimum of 10 minutes.

4. Assess distance and near vision binocularly and monocularly.

5. Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate, and near.

#### B. 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 unclear lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
- Papillary conjunctival changes may be indicative of an unclear 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 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.

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 dispensing and follow-up information in PATIENT MANAGEMENT).

#### 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 "HIGH" 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.

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.<sup>4</sup>

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.

<sup>4</sup>The OJAO Journal, July 1999, Volume 25, Number 3

#### LENS CARE DIRECTIONS

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

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

**B. Eye Selection**  
Generally, the non-dominant eye is selected for eyes domi-

**1. Ocular Preter**  
Method 1: Determine which eye is the "ighting 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 (ighting) eye.

**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](http://www.acuvue.com).**

#### MONOVISION FITTING GUIDELINES

##### A. Patient Selection

###### Monovision Needs Assessment

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

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

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

###### 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, or progressives). Each patient should understand that monovision, as well as other presbyopic alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. Therefore, caution should be exercised. During the

###### 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 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, lot number, and expiration date

#### REPORT

All serious adverse events should be reported to the manufacturer. For more information, visit [www.acuvue.com](http://www.acuvue.com).



g the Eye Care Professional's office, the patient should be  
ply remove the lenses or should have someone else avail-  
remove the lenses for him or her.

if the sterile blister package is opened or damaged.

and these hands before handling lenses. Do not get  
sions, soaps, creams, deodorants, or sprays in the eyes  
es. It is best to put on lenses before putting on makeup.  
cosmetics are less likely to damage lenses than oil-based

ch contact lenses with the fingers or hands if the hands are  
rein materials, as microscopic scratches of the lenses may  
g distorted vision and/or injury to the eye.

w the handling, insertion, removal, cleaning, disinfecting,  
wearing instructions in the "Patient Instruction Guide" for  
d wearing schedule and those prescribed by the Eye Care

le lenses carefully and avoid dropping them.

ezers or other tools to remove lenses from the lens con-  
specifically indicated for that use. Slide the lens up the side  
ntil it is free of the container.

the lens with fingernails.

Precautions:

ks (slope moving) on the eye, follow the recommended  
"Care for a Sliding (Non-Moving) Lens." The lens should  
in the eye for the continued health of the eye. If non-move-  
are continues, the patient should be instructed to immedi-  
his or her Eye Care Professional.

asses beyond the period recommended by the Eye Care

ould be advised to never allow anyone else to wear their

## LENS CARE DIRECTIONS

re dispensed, the Eye Care Professional should provide  
appropriate and adequate warnings and instructions in  
the individual patient's lens type and wearing schedule.  
Professional should recommend an appropriate care system  
patient's individual requirements.

formation concerning contact lens handling, care, cleaning,  
d storage, refer to the "Patient Instruction Guide" for the  
ring schedule. Copies are available for download at [www.](http://www.)

### lenses Prescribed for Frequent Replacement Wear:

Professional should review with the patient, the lens care  
cleaning, disinfecting, and storing, including both basic lens  
n and specific instructions on the lens care regimen recom-  
patient.

### lenses Prescribed for Disposable Wear:

Professional should review with the patient that no cleaning  
is needed with disposable lenses. Patients should always  
es when they are removed and have spare lenses or spec-  
s. Lenses should only be cleaned, rinsed, and disinfected  
oy basis when replacement lenses or spectacles are not

### ed Out (Dehydrated) Lens

lacement lens is off the eye and exposed to air from  
1 hour or more, its surface will become dry and gradually  
etting. If this should occur, discard the lens and use a new

### iding (Non-Moving) Lenses

s (slope moving), the patient should be instructed to apply

- If steroid 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:

- Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- Always use fresh, unexpired lens care solutions and lenses.
- Do not change solution without consulting with the Eye Care Professional.
- Always follow directions in the package insert for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the contact lenses.
- Sterile unopened solutions, when used, should be discarded after the time specified in the directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions in "Care for A Dehydrated (Dried Out) Lens" if lens surface does become dried out.

## 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

**ACUVUE® ACUVUE® 2, ACUVUE® BIFOCAL, 1-DAY ACUVUE®, and SUREVIEW™ Contact Lenses:**

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. The plastic package is marked with base curve, diopter power, diameter, lot number, and expiration date.

**1-DAY ACUVUE® for ASTIGMATISM Contact Lenses:**

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. The plastic package is marked with base curve, diopter power, axis, cylinder, diameter, lot number, and expiration date.

**ACUVUE® 2 COLOURS Contact Lenses:**

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. The plastic package is marked with base curve, diopter power, diameter, lens color, lot number, and 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, 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.

### occur when wearing contact lenses:

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was fit the eye.
- There may be a feeling of something in the eye (foreign scratched area).
- There may be the potential for some temporary impairment of vision, peripheral inflammation, peripheral corneal ulcers, or corneal staining, infection, tarsal abnormalities, etc., if some of which are clinically acceptable in low as
- There may be excessive watering, unusual eye sore redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos a photophobia, or dry eyes may also occur if the lens continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part ion 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 **IMMEDIATELY REMOVE THE LENS**. If the problem or discomfort should persist, the patient should discard the lens and place a new lens in the eye after inserting the new lens, the problem continues, the patient should be instructed to **IMMEDIATELY REMOVE THE LENS AND CONTACT THEIR EYE CARE PROFESSIONAL**.

## 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](http://www.acuvue.com)

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



©Johnson & Johnson Vision Care, Inc.  
In Canada: Johnson & Johnson Vision Care, division of Johnson  
in USA: Johnson & Johnson

FOCAL	82%	97%
	96%	98%
	98%	99%
COLOURS	81%	97%
UE <sup>a</sup>	82%	97%
UE <sup>a</sup> for ASTIGMATISM	82%	97%
	87%	99%

® 2 COLOURS Brand Contact Lens is indicated for daily and

- | Parameters:              |   |
|--------------------------|---|
| • Diameter Range:        | 12.0 mm to 15.0 mm  |
| • Center Thickness:      | varies with power   |
| • Base Curve Range:      | 7.85 mm to 10.00 mm   |
| • Spherical Power Range: | Daily Wear: -20.00D to +20.00D<br>Extended Wear: -20.00D to +14.00D |

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

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.<sup>3</sup>

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products.

The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.

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

- Discard any remaining solution after the recommended use indicated on the bottle of multi-purpose solution used in cleaning and soaking the contact lenses.
- The Discard date refers to the time that the patient can use the contact lens care product after the bottle has been opened.

don must be stable on may use the marks table position. If the flatter lens.

s a 30° interval. If the t or right of the vertical deviation. You can are in a spectacle trial der axis.

drift", then add or at cylinder axis. Use s which direction to a meridian as the n may be performed osed axes, such as 13 refractive axis. It is mputing the resultant be the full power in the ally disturbing to the nder as possible.

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ENT INSTRUC- download at [www.](http://www.)

INSTRUCTION S THE PRESCRIBED LE OR FREQUENT

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l contact lens wear) nagement of specific schedule, lens procedures. ations and specific iat:

previously. If the lens has not yet stabilized, recheck until stable.

Here is the Rx Prescribed:

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

#### Example 2

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

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

The fitting indicates the following:

#### Right Eye:

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

Here is the Rx prescribed:

O.D. -3.00 -0.75 x 100

#### Left Eye

The lens on the left eye shows good centration, movement and a consistent tendency for the mark to drift right by 10° from the 6 o'clock position following a forced blink. Since the manifest refraction called for a power of -4.75D, adjust for the vertex distance and reduce the sphere by 0.25D and prescribe the -1.75D cylinder. Compensate for the 10° axis drift by subtracting it from the manifest refraction.

Here is the Rx Prescribed:

O.S. -4.50 -1.75 x 80

If vision is acceptable, perform a slit lamp examination to assess adequate fit (contraction 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](http://www.acuvue.com).**

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

- Preferably, at the follow-up visits, lenses should be worn for at least six hours. If the lenses are being worn for continuous wear, the examination should be performed as early as possible on the morning following overnight wear.
- Recommended Procedures for Follow-Up Visits:

1. Solicit and record patient's symptoms, if any.
2. Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.
3. Perform an over-refraction at distance and near to check for residual refractive error.
4. With the biomicroscope, judge the lens fitting characteristics (as described in the GENERAL FITTING GUIDELINES) and evaluate the lens surface for deposits and damage.
5. Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein (unless contraindicated).

- The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
- The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
- Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
- 6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

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

## WEARING SCHEDULE

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

**For Daily Wear:**

Delicate-hand to measure the lenses in adults. The Eye Care Professional should

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 if the trial whether this patient can function adequately with the ACUVUE OASYS® for PRESBYOPIA contact lenses. Wear may not be optimal for activities such as:

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

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

These lenses are available in the following ADD powers:

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

## B. Fitting Instructions

1. Determine the following:
  - Eye dominance (the methods described in MONOVISION FITTING GUIDE- LINES may be used)
  - Spherical equivalent distance prescription (vertex corrected if necessary and rounded to less minus if between powers)
- Near ADD

2. Select the initial trial lens as follows:

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

The maximum suggested wearing time for these lenses is:

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

## For Extended Wear:

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

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

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

## REPLACEMENT SCHEDULE

**For Lenses Prescribed for Frequent Replacement:**

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

**For Lenses Prescribed for Disposable Wear:**

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

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

- ADD: +1.50 to +1.75 use a "MID" near ADD lens on each eye
- ADD: +2.00 to +2.50 use a "HIGH" near ADD lens on each eye
3. Allow the lens to settle for a minimum 10 minutes.
4. Assess distance and near vision binocularly and monocularly.

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

## C. Multifocal Troubleshooting

### Unacceptable Near Vision

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

### Unacceptable Distance Vision

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

### Unacceptable Distance and Near Vision

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

**All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at [www.acuvue.com](http://www.acuvue.com).**

## LENS CARE DIRECTIONS

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

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

**For Lenses Prescribed for Frequent Replacement Wear:**

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

**For Lenses Prescribed for Disposable Wear:**

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

### Care for a Dried Out (Dehydrated) Lens

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

### Care for Sticking (Non-Moving) Lenses

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

## EMERGENCIES

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

**Monovision Need**  
For a good prognosis and near visual acuity, significant astigmatism should be corrected. Monovision candidates for non-

1. visually demanding tasks, such as driving a motor vehicle, or if state driver's license requirements are not met.
2. driving automobiles (e.g., driving at night).

**Patient Education**  
All patients do not may not perform a spectacle (multifocal) should understand

can create a vision perception for distance when the patient is with the vision provided 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 if the trial whether this patient can function adequately with the ACUVUE OASYS® for PRESBYOPIA contact lenses. Wear may not be optimal for activities such as:

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

**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](http://www.acuvue.com).**

Each sterile lens is supplied in a saline solution with the following:

- ACUVUE OASYS date
- ACUVUE OASYS cylinder, axis, lot
- ACUVUE OASYS lot number, and

## REPORT

All serious adverse events involving these lenses or ex-

In Canada: Johnson

Brand Contact Lenses  
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make the lenses more  
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VB range of 280 nm to  
380 nm for the entire

following dimensions:

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

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

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

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

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

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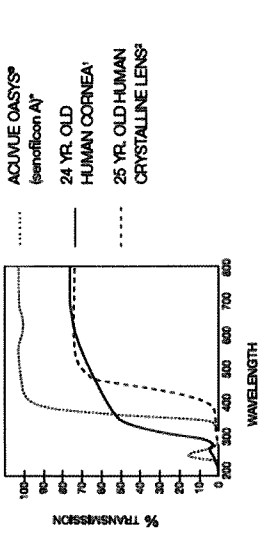
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The data was obtained from measurements taken through the central 3-5 mm portion for the thinnest refracted lens (1.00D lens, 0.070 mm center thickness).

1. Lerman, S. Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, figure 2-24  
2. Weiler, M., Hichins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1988, p. 19, figure 5

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

## ACTIONS

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

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

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

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

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

## Other Topics to Discuss with Patients:

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

## Who Should Know That the Patient is Wearing Contact Lenses?

- Patients should inform all doctors (Health Care Professionals) about being a contact lens wearer.

## INDICATIONS (USES)

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

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

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

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

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

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

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

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

## ADVERSE REACTIONS

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

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, lids and conjunctivitis, some of which are difficultly acceptable in low amounts.
- There may be excessive watering, unusual eye secretions or redness of the eyes.
- 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 ititis may be present. He or she should be instructed to seek immediate professional identification.

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Lenses prescribed for d  
periods.

## CONTRAINDICATIONS

When prescribing contact lenses, the Eye Care Professional should consider the following contraindications:

- Acute or subacute eye
- Any eye disease or eyelids
- Severe insufficiency
- Corneal hypoxia
- Any systemic disease that affects contact lenses
- Allergic reaction generated by wear
- Ocular irritation
- Contact lens side effects (drops, etc.) that Thimerosal, etc.
- Any active condition
- If eyes become

For THERAPEUTIC use aid in the healing process cited above.

Patients should be at lens wear:

**EYE PROBLEMS, INC AND LEAD TO LOSS**

- Eye Discomfort,
- Excessive Tearing

## GENERAL INFORMATION

**A. Patient Selection:** Patients selected to

- Motivation to
- Ability to follow
- General health
- Ability to adapt
- Ability to understand

Patients who do not contact lenses.

**B. Pre-fitting Examination:** Initial evaluation of the patient to determine if there is a case history, the patient as well as an assessment of the initial evaluation should be

Preceding the initial evaluation should be a determination of distant vision (including keratometry and biometry).

Based on this evaluation, the Eye Care Professional should determine if there is a case history, the patient as well as an assessment of the initial evaluation should be

**C. Initial Power Determination:** A spectacle refractive status and fitting instruction on the patient.

**D. Base Curve Selection:** The following trial lens readings. However, the patient should be instructed to seek immediate professional identification.

- ACUVUE OASYS
- ACUVUE OASYS
- ACUVUE OASYS

**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](http://www.acuvue.com).

# ACUVUE® *vita* BRAND CONTACT LENSES

**ACUVUE® VITA Brand Contact Lenses**

**ACUVUE® VITA Brand Contact Lenses for ASTIGMATISM**

**senofilcon C Soft (hydrophilic) Contact Lenses  
Visibility Tinted with UV Blocker  
for Daily Wear Only**



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











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## SYMBOLS KEY

The following symbols may appear on the label or packaging:

SYMBOL	DEFINITION
	Consult Instructions for Use
	Manufactured by or in
	Date of Manufacture
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
1-Month	1-Month Replacement
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)
	Quality System Certification Symbol
	Fee Paid for Waste Management

Visit [www.acuvue.com/guides](http://www.acuvue.com/guides) for additional information about symbols.

## DESCRIPTION

ACUVUE® VITA Brand Contact Lenses and ACUVUE® VITA Brand Contact Lenses for ASTIGMATISM are soft (hydrophilic) contact lenses available as spherical or toric lenses, respectively.

The lenses are made of a silicone hydrogel material containing an internal wetting agent, visibility tint, and UV absorbing monomer.

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: 1.42
- Light Transmittance: 89% minimum
- Surface Character: Hydrophilic
- Water Content: 41%
- Oxygen Permeability (D/k):

VALUE	METHOD
122 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg) at 35°C	Fatt (boundary corrected, non-edge corrected)
103 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg) at 35°C	Fatt (boundary corrected, 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 Range (AXIS): 2.5° to 180°

#### AVAILABLE LENS PARAMETERS

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

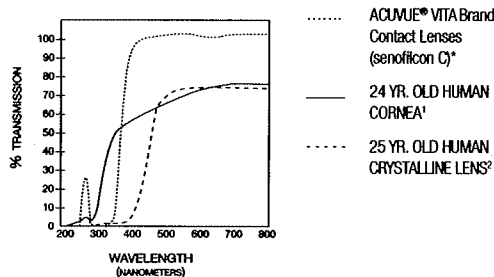
<b>Diameter (DIA):</b>	14.0 mm
<b>Center Thickness:</b>	0.070 mm to 0.217 mm (varies with power)
<b>Base Curve (BC):</b>	8.4 mm, 8.8 mm
<b>Powers (D):</b>	+0.50D to +6.00D (in 0.25D increments) +6.50D to +8.00D (in 0.50D increments) -0.50D to -6.00D (in 0.25D increments) -6.50D to -12.00D (in 0.50D increments)

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

<b>Diameter (DIA):</b>	14.5 mm
<b>Center Thickness:</b>	0.075 mm to 0.172 mm (varies with power)
<b>Base Curve (BC):</b>	8.6 mm
<b>Powers (D):</b>	+0.00D 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 +0.25D to +4.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments) Cylinders (CYL): -0.75D, -1.25D, -1.75D Axis (AXIS): 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°

## TRANSMITTANCE CURVES

ACUVUE® VITA Brand Contact Lenses (senofilcon C) 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 (-1.00D lens, 0.070 mm center thickness).

<sup>1</sup>Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21

<sup>2</sup>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 transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

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

#### INDICATIONS (USES)

ACUVUE® VITA Brand Contact Lenses are indicated for daily 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® VITA Brand Contact Lenses for ASTIGMATISM are indicated for daily 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.

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

These lenses are intended for frequent/planned replacement wear (see **REPLACEMENT SCHEDULE** section). Lenses may be disinfected using a chemical disinfection system only and should be discarded after the recommended wearing period as prescribed by the Eye Care Professional. These lenses are intended for daily wear, monthly replacement.

## 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 (e.g., cleaning and disinfecting solutions, rewetting drops, etc.) that contain chemicals or preservatives (such as mercury, Thimerosal, etc.) to which some people may develop an allergic response.
- Any active corneal infection (bacterial, fungal, protozoal, or viral).
- If eyes become red or irritated.

## WARNINGS

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

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

- **Eye Discomfort,**

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

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

- Patients should be instructed not to wear their lenses while sleeping. Clinical studies have shown that when daily wear users wear their lenses overnight (outside the intended indication), the risk of ulcerative keratitis is greater than among those who do not wear them overnight.<sup>3</sup>
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.

<sup>3</sup> New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

**Specific Instructions for Use and Warnings:**

- **Water Activity**

**Instruction for Use**

Do not expose contact lenses to water while wearing them.

**WARNING:**

Water can harbor microorganisms that can lead to severe

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

- **Soaking and Storing Your Lenses**

**Instruction for Use**

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

**WARNING:**

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

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

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

**Instructions for Use**

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

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

**WARNING:**

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

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

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

- **Rub and Rinse Time**

**Instruction for Use**

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

**WARNING:**

- Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss, or blindness.

- **Lens Case Care**

**Instructions for Use**

- Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry.
- Replace the lens case according to the directions given by the Eye Care Professional or the manufacturer's labeling that accompanies the case.
- Contact lens cases can be a source of bacterial growth.

**WARNING:**

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

## PRECAUTIONS

### Special Precautions for Eye Care Professionals:

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

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

- Patients who wear these lenses to correct presbyopia using monovision may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.

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

**Handling Precautions:**

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her.
- DO NOT use if the sterile blister package is opened or damaged.
- Always wash and rinse hands 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 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, cleaning, disinfecting, storing, 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.
- Always discard lenses worn as prescribed by the Eye Care Professional.

**Lens Care Precautions:**

- Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Do not change solution without consulting with the Eye Care Professional.
- Never use solutions recommended for conventional hard contact lenses only.
- Always use fresh, unexpired lens care solutions and lenses and always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying (e.g., exposing the lens to air for 30 minutes or more) will reduce the ability of the lens surface to return to a wettable state. If the lens surface does become dried out, discard the lens and use a new one.

**Other Topics to Discuss with Patients:**

- Always contact the Eye Care Professional before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- 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 and the lens appears undamaged, the patient should clean and rinse the lens with a recommended soft contact lens care solution, and reinsert the lens. If after reinserting the lens, the problem continues, the patient should discard the lens and place a new fresh lens on the eye.

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

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

## GENERAL FITTING GUIDELINES

### A. Patient Selection

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

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

Patients who do not 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  $\pm 4.00D$ .

#### **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® VITA: 8.4 mm/14.0 mm
- ACUVUE® VITA for ASTIGMATISM: 8.6 mm/14.5 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](http://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® VITA Brand Contact Lenses 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  $\leq \pm 4.00\text{D}$ , 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  $\leq 0.50\text{D}$  from the refractive cylinder.

## 3. Case Examples

### Example 1

Manifest (spectacle) refraction:  
O.D.  $-2.50\text{D} / -1.25\text{D} \times 180^\circ$  20/20  
O.S.  $-2.00\text{D} / -1.00\text{D} \times 180^\circ$  20/20

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

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

Here is the Rx Prescribed:  
O.D.  $-2.50\text{D} / -1.25\text{D} \times 180^\circ$   
O.S.  $-2.00\text{D} / -0.75\text{D} \times 180^\circ$

### Example 2

Manifest (spectacle) refraction:  
O.D.  $-3.00\text{D} / -1.00\text{D} \times 90^\circ$  20/20  
O.S.  $-4.75\text{D} / -2.00\text{D} \times 90^\circ$  20/20

Choose diagnostic lenses of  $-3.00\text{D} / -0.75\text{D} \times 90^\circ$  for the right eye and  $-4.50\text{D} / -1.75\text{D} \times 90^\circ$  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  $-4.75\text{D}$ , compensating for vertex distance the sphere is reduced by  $0.25\text{D}$  to  $-4.50\text{D}$ . The cylinder power will be  $-1.75\text{D}$ . 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](http://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 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 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** section 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 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](http://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](http://www.acuvue.com). REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE (FREQUENT REPLACEMENT).
- Recommend an appropriate cleaning and disinfecting system and provide the patient with instructions regarding proper lens care. Chemical or hydrogen peroxide disinfection is recommended.

## WEARING SCHEDULE

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

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

Studies have not been completed to show that the lens is safe to wear while sleeping.

#### REPLACEMENT SCHEDULE

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

When prescribed for daily wear (frequent replacement), it is recommended that the lenses be discarded and replaced with a new lens each month.

Once removed, it is recommended that the lens remain out of the eye for a period of rest of overnight or longer and be discarded in accordance with the prescribed replacement schedule.

#### LENS CARE DIRECTIONS

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

For complete information concerning contact lens handling, care, cleaning, disinfecting, and storage, refer to the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at [www.acuvue.com](http://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 methyl ether cellulose. The plastic package is marked with the following:

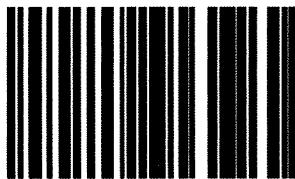
- ACUVUE® VITA: base curve, power, diameter, lot number, and expiration date
- ACUVUE® VITA for ASTIGMATISM: base curve, power, diameter, cylinder, axis, lot number, and expiration date

#### REPORTING OF ADVERSE REACTIONS

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

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

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



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ACUVUE® is a Trademark of Johnson & Johnson Vision Care, Inc.



Multi-Purpose  
Disinfecting Solution

Important—Please read carefully and keep this package insert for future reference

#### Blink RevitaLens® Multi-Purpose Disinfecting Solution

Cleans, Rinses, Disinfects, Removes Protein, Stores, and Conditions soft (hydrophilic) contact lenses, including silicone hydrogel lenses - All Steps in One Bottle.

#### LENS CARE DIRECTIONS

##### RINSE for lens-wearing comfort

When you insert your lenses

1. Wash your hands with soap and water and dry with a lint-free towel prior to handling your lenses.
2. Prior to reapplying lenses, RINSE each side of the lens for 5 seconds with fresh Blink RevitaLens® Multi-Purpose Disinfecting Solution to remove any debris on the lens.

##### RUB, RINSE & SOAK for effective disinfection

When you remove your lenses

1. Wash your hands with soap and water and dry with a lint-free towel prior to handling your lenses.
2. Place 3 or more drops of Blink RevitaLens® Multi-Purpose Disinfecting Solution on one side of the lens surface.
3. RUB your lens gently from the center to the edges for 2 - 4 seconds (never rub in a circular motion, because it may tear the lens and not clean the outer edge surface).
4. Turn the lens over and repeat steps 2 and 3.
5. RINSE each side of the lens for 5 seconds with fresh Blink RevitaLens® Multi-Purpose Disinfecting Solution. Place lenses in clean lens case and fill with Blink RevitaLens® Multi-Purpose Disinfecting Solution. Close lens case tightly.
6. SOAK - Allow lenses to soak for a minimum of six (6) hours for disinfection, cleaning and protein removal.

#### EXTRA CLEANING AND COMFORT

Based on your individual tear chemistry and lens replacement schedule, your eye care professional may recommend additional care procedures. This may be particularly important if lenses are kept longer than 90 days.

#### LENS STORAGE

You may leave your lenses in the unopened lens case containing Blink RevitaLens® Multi-Purpose Disinfecting Solution for up to 30 days continuously. If stored longer than 30 days, your lenses must be cleaned and disinfected again with fresh solution prior to wear.

#### PROTEIN REMOVAL FROM YOUR CONTACT LENSES

Blink RevitaLens® Multi-Purpose Disinfecting Solution removes protein while your lenses are soaking in the lens case. Daily use of Blink RevitaLens® Multi-Purpose Disinfecting Solution eliminates the need for a separate enzymatic cleaner for many lens wearers — check with your eye care professional.

#### DESCRIPTION

Blink RevitaLens® Multi-Purpose Disinfecting Solution is a sterile, buffered aqueous solution with alexidine dihydrochloride 0.00016% and polyquaternium-1 0.0003% as preservatives / disinfectants, boric acid, sodium borate, TETRONIC 904, edetate disodium, sodium citrate, sodium chloride, and purified water.

#### ACTIONS

Blink RevitaLens® Multi-Purpose Disinfecting Solution is formulated with dual disinfection technology designed specifically for soft contact lenses. Dual disinfectants and a surfactant deliver effective cleaning and robust dual disinfection. While the lens is soaking, the surfactant loosens and removes the protein and other deposits that commonly accumulate during lens wear. Dual disinfectants work to destroy microbes on the surface of the lens and provide safe contact lens storage up to 30 days. This formulation conditions the lenses and increases ocular end of day comfort for wearers of most common soft contact lens materials.

#### INDICATIONS (Uses)

Blink RevitaLens® Multi-Purpose Disinfecting Solution is indicated for the care of soft (hydrophilic) contact lenses including silicone hydrogel lenses.

Use this product, as recommended by your eye care professional, to:

- Chemically (NOT HEAT) Disinfect
- Clean
- Rinse
- Store
- Remove Protein
- Condition

#### CONTRAINDICATIONS (Reasons not to use)

Do not use if you are allergic to any ingredient in this product.

#### WARNINGS

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN CORNEAL INFECTION AND/OR ULCERS AND LEAD TO LOSS OF VISION. It is essential that you follow your eye care professional's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case.

You should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect your lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean your lenses.

You should fill your lens case with fresh solution every time you store your lenses and never "top-off" or re-use solution. You should discard your solution immediately after your lenses have been removed from the lens case. You should not expose or store your lenses in or rinse your lens case with any water such as tap, bottled, distilled, or with any non-sterile solution.

Clean, rinse and air dry your lens case each time you remove your lenses. In order to permit excess solution to drain, flip your lens case over and allow it to air dry. Replace your lens case every 1-3 months, depending on hygiene habits.

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Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.

Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule provided by your eye care professional.

Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have also shown that the risk for serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement.

Studies have also shown that smokers had a higher incidence of adverse reactions.

It is recommended that contact lens wearers see their eye care professional at least once each year or, if directed, more frequently.

To avoid contamination, do not touch the tip of the Blink RevitaLens® Multi-Purpose Disinfecting Solution bottle to any surface. Replace cap after using.

#### PRECAUTIONS

- Avoid exposure to water when wearing and caring for your contact lenses.
- Discard any remaining solution in your lens case before re-disinfecting. Always use fresh solution.
- Rinse lens case and caps with fresh solution after each use; dry upside down on a clean towel. Do not use non-sterile water to rinse lens case.
- Always wash your hands, and then dry with a clean, lint-free towel before handling lenses.
- Keep bottle tightly closed when not in use.
- Use the included lens case with the Blink RevitaLens® Multi-Purpose Disinfecting Solution.
- Replace your lens case every 1-3 months.
- Store at room temperature.
- Use before the expiration date marked on the bottle and carton.
- Once bottle is opened, discard any remaining solution after 90 days.
- Never use Blink RevitaLens® Multi-Purpose Disinfecting Solution with a heat disinfection unit.
- Keep out of the reach of children.

#### ADVERSE REACTIONS (Problems and what to do)

The following problems may occur: eyes sting, burn or itch (irritation); comfort is less than when lens was first placed on the eye; feeling of something in the eye (foreign body, scratched area); excessive watering (tearing) of the eye; unusual eye secretions; redness of the eye; reduced sharpness of vision (poor visual acuity); blurred vision; rainbows or halos around objects; sensitivity to light (photophobia); or dry eyes. If you notice any of the above; immediately remove your lenses.

- If the discomfort or problem stops, then look closely at the lens.
  - If the lens is in any way damaged, DO NOT put the lens back on your eye. Place the lens in the lens case and contact your eye care professional.
  - If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens, then reinsert it.
- If the problem continues, IMMEDIATELY consult your eye care professional.

If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

#### GOOD LENS CARE PRACTICES

- Follow your eye care professional's instructions.
- Always wash your hands before handling your lenses.
- Rub, rinse and disinfect your lenses each time you remove them.
- Always handle the same lens, the right or the left, first in order to avoid mix-ups.
- Do not expose lenses or lens case to tap water, bottled water, distilled water, lake or ocean water.
- Do not use saliva or put lenses in your mouth to rewet.
- Do not swim, shower, or use a hot tub while wearing soft contact lenses.
- Do not wear lenses longer than prescribed.
- Do not transfer contact lens solution into smaller travel size containers. The sterility of solutions will be impacted and can lead to serious eye infections.
- Discard any lens that is damaged or dehydrated.
- Avoid using aerosols when wearing contact lenses.
- Discard any remaining solution in your lens case before disinfecting your lenses again.
- See your eye care professional at least once a year.

#### HOW SUPPLIED

Blink RevitaLens® Multi-Purpose Disinfecting Solution is supplied sterile in 2 fl. oz. (60 mL), 10 fl. oz. (300 mL), 12 fl. oz. (360 mL) and 16 fl. oz. (473 mL) plastic bottles. The bottles are marked with lot number and expiration date.

Blink RevitaLens is a trademark owned by or licensed to Abbott Laboratories, its subsidiaries or affiliates.

TETRONIC is a trademark of BASF Corporation.

Abbott Medical Optics Inc.  
Santa Ana, CA 92705 U.S.A.

Questions or comments?  
Please call us at 1-800-347-5005

www.justblink.com  
www.yourhealthyeyes.com

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Revision Date: 08/2015

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## 3% HYDROGEN PEROXIDE Cleaning & Disinfecting Solution

### DESCRIPTION / CONTENTS:

CLEAR CARE® Cleaning & Disinfecting Solution is a sterile solution containing micro-filtered hydrogen peroxide 3%, sodium chloride 0.79%, stabilized with phosphonic acid, a phosphate buffered system, and PLURONIC 17R4† (a cleaning agent).

### GOOD LENS CARE PRACTICES:

To ensure proper disinfection of your lenses you must follow the instructions completely. Do not skip any steps. Always wash and rinse your hands before handling your lenses. This will help prevent eye infections by removing dirt and oils that could get on the lenses.

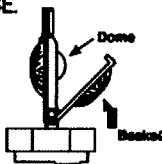
### DIRECTIONS FOR USE - Soft Contact Lenses:

Never put CLEAR CARE Cleaning & Disinfecting Solution on your lenses and insert directly into the eye or burning and stinging will result. If spillage occurs, clean up immediately with a paper towel. Wash and rinse your hands before handling your lenses or touching your eyes.

To clean, disinfect, neutralize, and remove protein from your soft contact lenses:

- Remove and place each lens into the appropriately marked L/R domed lens holder.
- Flip open the snap cap on the CLEAR CARE bottle and bend it back and out of the way.
- Rinse the lenses while on the domed lens holder for 5 seconds.
- Fill the CLEAR CARE lens case to the fill line with CLEAR CARE solution and place the lens holder in the case.
- Tighten the cap on the CLEAR CARE lens case and store lenses for at least 6 hours. DO NOT SHAKE THE CASE.

**NOTE:** To prevent damage to your lens, center the lens on the dome in the lens holder. Be sure the lens does not touch the basket rim, then close the basket lid.



After soaking for six hours, your lenses are ready to wear. No final saline rinse is necessary. Never rinse your lenses with CLEAR CARE Cleaning & Disinfecting Solution prior to insertion or burning and stinging will result. If desired, lenses can be rinsed with sterile saline before inserting.

Discard the used CLEAR CARE solution from the CLEAR CARE lens case. Rinse the lens case with sterile saline or CLEAR CARE solution and allow the case to air dry with the lens holder inverted outside the case. Do not place the lens holder on its side.

### DIRECTIONS FOR USE - RGP Lenses:

Never put CLEAR CARE Cleaning & Disinfecting Solution on your lenses and insert directly into the eye or burning and stinging will result. If spillage occurs, clean up immediately with a paper towel. Wash and rinse your hands before handling your lenses or touching your eyes. To clean, disinfect, neutralize, and remove protein from your RGP lenses:

- Remove and place each lens into the appropriately marked L/R domed lens holder.
- Flip open the snap cap on the CLEAR CARE bottle and bend it back and out of the way.

- Take each lens, one at a time, from the domed lens holder and place it in the palm of your hand. Apply 2 to 4 drops of CLEAR CARE solution and rub. While rubbing RGP lenses with CLEAR CARE solution, some users may experience a mild, temporary skin discoloration (bleaching) of the fingers or hands. Always wash and rinse your hands after rubbing your lenses with the solution.
- Return the lenses to the appropriate holder and close the baskets. Rinse the lenses while on the domed lens holder for 5 seconds.
- Fill the CLEAR CARE lens case to the fill line with CLEAR CARE solution and place the lens holder in the case.
- Tighten the cap on the CLEAR CARE lens case and store lenses for at least 6 hours. DO NOT SHAKE THE CASE.

After soaking for six hours, your lenses are ready to wear. No final saline rinse is necessary. Never rinse your lenses with CLEAR CARE Cleaning & Disinfecting Solution prior to insertion or burning and stinging will result. If desired, lenses can be rinsed with sterile saline before inserting.

Discard the used CLEAR CARE solution from the lens case. Rinse the lens case with sterile saline or CLEAR CARE solution and allow the case to air dry with the lens holder inverted outside the case. Do not place the lens holder on its side.

### STORAGE:

If you do not intend to wear your lenses immediately after disinfection/neutralization, you may store them in the unopened lens case for up to 7 days. Disinfect and neutralize once a week with fresh solution and before wearing your lenses.

### ACTIONS:

When used as directed CLEAR CARE solution provides a unique cleaning action, which removes film and debris from the lens surface. CLEAR CARE solution also helps prevent serious eye infections by killing harmful microorganisms on contact lenses.

### INDICATIONS (Uses):

For simultaneous cleaning, daily protein removal, disinfecting, and storing of soft (hydrophilic) or rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses as recommended by your eye care practitioner.

### CONTRAINDICATIONS (Reasons not to use):

There are no known contraindications for use of CLEAR CARE Cleaning & Disinfecting Solution; however, if you are allergic to any ingredient in this solution, do not use.

### WARNINGS:

Never put CLEAR CARE Cleaning & Disinfecting Solution on your lenses and insert directly into the eye. Lenses must be soaked in the provided lens case for 6 hours (neutralization process) prior to lens insertion. OTHERWISE, BURNING AND STINGING WILL RESULT.

Only use the special CLEAR CARE lens case for disinfection and neutralization. Do not use a flat case.

While rubbing RGP lenses with CLEAR CARE solution, some users may experience a mild, temporary skin discoloration (bleaching) of the fingers or hands. Always wash and rinse your hands after rubbing your lenses with the solution.

NEVER PUT CLEAR CARE SOLUTION THAT HAS NOT BEEN NEUTRALIZED IN YOUR EYES. If unneutralized CLEAR CARE solution gets in your eyes, remove your contact lenses immediately, and flush (wash) your eyes with a large amount of water or sterile saline for a few minutes. If burning or irritation continues, seek immediate assistance from an eye care professional. The red snap cap indicates that CLEAR CARE Cleaning & Disinfecting Solution should never be put directly in your eye.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

Follow your eye care professional's directions and all labeling instructions for proper use and care of your lenses and lens care products, including the lens case. Eye problems, including corneal ulcers and infections, can develop rapidly and lead to loss of vision. Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown the risk of serious adverse reactions is increased when these lenses are worn overnight. Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care professional. Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement. Studies have also shown that smokers have a higher incidence of adverse reactions. If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, immediately remove your lenses and promptly contact your eye care professional. All contact lens wearers should see their eye care professional as directed. Periodic eye exams are extremely important in order to detect and treat problems related to contact lens wear before they cause discomfort or pain.

Close snap cap after using. To avoid contaminating your solution, do not transfer to other bottles or containers.

All contact lens wearers must see their eye care professional regularly and as frequently as directed. If your lenses are for extended wear, your eye care professional may prescribe more frequent visits. Studies have shown that smoking increases the risk of ulcerative keratitis for contact lens users. Do not take CLEAR CARE\* Cleaning & Disinfecting Solution internally or gastric distress will result. Seek professional assistance of physician or a poison control center immediately if taken internally. Keep out of the reach of children.

#### PRECAUTIONS:

- Always wash and dry your hands before handling your lenses.
- Never use this for heat disinfection.
- Never reuse this solution.
- Keep bottle tightly closed when not in use.
- Store at room temperature. (15°C to 30°C / 59°F to 86°F)
- Use before the expiration date marked on the container.
- Once bottle is open, discard any remaining solution after 3 months.

There are no safe, acceptable substitutes for CLEAR CARE Cleaning & Disinfecting Solution components. Do not mix or substitute other lens care hydrogen peroxide products or lens cases. Do not use any other disinfection solutions in the disposable lens case. DO NOT USE OVER-THE-COUNTER GENERIC HYDROGEN PEROXIDE. Generic hydrogen peroxide solutions are not intended for ophthalmic use and may contain ingredients not tested for ocular safety or toxicity. Generic hydrogen peroxide may contain ingredients that cause DISCOLORATION OR DAMAGE YOUR CONTACT LENSES.

#### LENS CASE CARE

To avoid possible damage:

- Do not over tighten the CLEAR CARE lens case (only tighten finger tight).
- Do not use a damaged case.
- Do not fill above the fill line on the case.
- Do not shake the case during disinfection.
- Dispose of your old lens case with each new purchase of CLEAR CARE Cleaning & Disinfecting Solution.

#### ADVERSE REACTIONS (Possible problems and what to do):

The following problems may occur with contact lens wear: eyes sting, burn or itch (irritation), comfort is less than when lens was first placed on the eye, feeling of something in the eye (foreign body, scratched area), excessive watering (tearing) of the eye, unusual eye secretions, redness of the eye, reduced sharpness of vision (poor visual acuity), blurred vision, rainbows or halos around objects, sensitivity to light (photophobia), or dry eyes.

If you notice any of the above, IMMEDIATELY remove your lenses.

- If the problem stops and the lenses appear to be undamaged, repeat the cleaning, disinfection and neutralization process and reinsert them. **NEVER PUT CLEAR CARE\* SOLUTION THAT HAS NOT BEEN NEUTRALIZED IN YOUR EYES or burning and stinging will result.**
- If the lens is in any way damaged, do not put the lens back on your eye. Place the lens in the CLEAR CARE lens case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign body on it, repeat the cleaning, disinfection and neutralization process and reinsert them. **NEVER PUT CLEAR CARE SOLUTION THAT HAS NOT BEEN NEUTRALIZED IN YOUR EYES or burning and stinging will result.**
- If the problem continues IMMEDIATELY remove the lens and consult your eye care professional.

If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

Eye Care Professionals: All adverse reactions observed using CLEAR CARE Cleaning & Disinfecting Solution should be reported to:

Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, Texas 76134  
1-800-757-9195

alcon.medinfo@alcon.com

#### HOW SUPPLIED:

- CLEAR CARE Cleaning & Disinfecting Solution is supplied in sterile 3 fl oz. (90 ml), 12 fl. oz. (355 ml) and 16 fl. oz. (480 ml) plastic bottles. These bottles are marked with lot number and expiration date. A fresh new lens case is supplied with each purchase. For packages with more than 32 oz. of CLEAR CARE solution, an additional lens case is provided.
- TAMPER EVIDENT: Do not use if safety seal around the bottle cap is broken or missing.

For more information regarding this product consult your eye care professional, or write to:

Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, Texas 76134

†PLURONIC is a trademark of BASF.

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\*a trademark of Novartis

Manufactured by:

Alcon Laboratories, Inc.

Fort Worth, Texas 76134, USA

Made in USA



W9011539-0215

PLEASE READ CAREFULLY AND KEEP THIS PACKAGE INSERT FOR FUTURE USE IN CASE YOU HAVE A PROBLEM



Provides comfort and moisture from insertion to removal  
**Cleans, Reconditions, Rinses, Disinfects, Stores**  
 Removes protein deposits  
 Reduces lipid deposition  
 For silicone hydrogel and soft (hydrophilic) contact lenses  
 Sterile

For optimal results, follow these directions for care of your lenses with OPTI-FREE® PUREMOIST® Solution:

- Thoroughly wet each side of the lens with OPTI-FREE PUREMOIST Solution. Rub the lens for 20 seconds.
- Rinse each side of the lens for 10 seconds with a steady stream of OPTI-FREE PUREMOIST Solution.
- Fill your ALCON® Lens Case with fresh OPTI-FREE PUREMOIST Solution.

Store lenses in the closed lens case overnight or at least 6 hours. After soaking, lenses are ready to wear.

If any debris remains on contact lenses, rinse with OPTI-FREE PUREMOIST Solution prior to lens insertion. You may leave your lenses in the unopened lens case containing OPTI-FREE PUREMOIST Solution for up to 30 days. After this time, your lenses must be cleaned and disinfected with OPTI-FREE PUREMOIST Solution prior to wear. Always follow your eye care professional's instructions. Do not change your directions for care of your lenses or your lens care solution without consulting your eye care professional.

#### DESCRIPTION:

OPTI-FREE PUREMOIST Solution is a sterile, buffered, aqueous solution containing sodium citrate, sodium chloride, boric acid, sorbitol, aminomethylpropanol, disodium EDTA, two wetting agents (TETRONIC® 1304† and HydraGlyde® Moisture Matrix [EOBO-41"-polyoxyethylene-polyoxybutylene]) with POLYQUAD® (polyquaternium-1) 0.001% and ALDOX® (myristamidopropyl dimethylamine) 0.0006% preservatives. HydraGlyde® Moisture Matrix is a proprietary multi-functional block copolymer that is primarily designed for wetting and lubricating silicone hydrogel lenses.

#### ACTIONS:

When used as directed OPTI-FREE® PUREMOIST® Solution:

- Cleans by removing protein deposits and reducing lipid deposition from your lenses during disinfection and storage.
- POLYQUAD® and ALDOX® dual disinfectants reduce harmful microorganisms that can cause eye infections.
- Is used to rinse and recondition your silicone hydrogel and soft (hydrophilic) contact lenses.
- Is formulated to disinfect and store lenses for up to 30 days after disinfection.

Do not store your lenses in saline solution in place of OPTI-FREE PUREMOIST Solution. Saline solution will not disinfect lenses.

#### MOISTURE, LUBRICITY, HYDRATING AND CLEANING BENEFITS FOR LENS WEAR

OPTI-FREE PUREMOIST Solution:

- Provides comfort and moisture from insertion to removal. HydraGlyde® Moisture Matrix works independently of your tear film to keep moisture on your lenses.
- Maintains a cushion of moisture that allows your eyelid to glide over the surface of the lens without irritation.
- Keeps the lens hydrated throughout the day.

- Binds to dry areas of the lenses to reduce lipid deposition.
- Reduces lipid deposition and removes protein deposits for clean and fresh lenses.

#### INDICATIONS (USES):

For use in the daily cleaning, reconditioning, rinsing, removing protein deposits, reducing lipid deposition, chemical (not heat) disinfection, and storage of silicone hydrogel and soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

Includes a lens case for storage of silicone hydrogel and soft (hydrophilic) contact lenses during chemical disinfection. Use for storage during chemical disinfection only.

#### CONTRAINDICATIONS (REASONS NOT TO USE):

If you are allergic to any ingredient in this product, do not use.

#### WARNINGS:

Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use and care of your lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown the risk of serious adverse reactions is increased when these lenses are worn overnight. Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care practitioner. Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement. Studies have also shown that smokers have a higher incidence of adverse reactions. If you experience eye discomfort, excessive tearing, vision changes, redness of the eye, immediately remove your lenses and promptly contact your eye care practitioner. It is recommended that contact lens wearers see their eye care practitioner twice each year or, if directed, more frequently.

Lens cases can be a significant source of microbial contamination. To help prevent eye infections, lens cases should be cleaned, rinsed, and air dried every day, and replaced frequently (as recommended by the manufacturer). Use of this lens case with heat may cause warpage. **USE FOR STORAGE DURING CHEMICAL DISINFECTION ONLY. DO NOT USE WITH HEAT.**

Re-use of solution or use of water with lenses may lead to contamination resulting in eye injury and potential loss of vision. See below for additional important safety information.

#### Important Safety Information:

Always follow the product directions for use. Failure to follow product directions may lead to vision loss.

- Visit your eye care practitioner regularly.
- Always wash and dry hands before handling lenses.
- Do not use tap water, bottled water or saliva with lenses or lens case.
- Only use fresh solution to clean and disinfect contact lenses.
- Discard any remaining solution in your lens case after each disinfection cycle. (Never reuse solution).
- Discard any remaining solution six months after first opening.
- Saline or rewetting drops will not disinfect your lenses.
- Always replace your solution and lenses as directed.
- Replace your lens case every one to three months.
- To avoid contamination, do not touch tip of container to any surface. Replace cap after using.
- Not for use with heat (thermal) disinfection.
- Store at room temperature.
- Use before the expiration date marked on the carton and bottle.
- Keep this and all medication out of the reach of children.

#### ADVERSE REACTIONS (POSSIBLE PROBLEMS AND WHAT TO DO):

The following problems may occur: eyes sting, burn or itch (irritation), comfort is less than when lens was first placed on the

eye, feeling of something in the eye (foreign body, scratched area), excessive watering (tearing) of the eye, unusual eye secretions, redness of the eye, reduced sharpness of vision (poor visual acuity), blurred vision, rainbows or halos around objects, sensitivity to light (photophobia), or dry eyes.

If you notice any of the above:

Immediately remove your lenses.

- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, DO NOT put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign body on it, or the problems stop and the lens appears undamaged, thoroughly clean, recondition, rinse, and disinfect the lens, then reinsert it.
- If the problem continues, immediately remove the lens and consult your eye care practitioner.

If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

#### HOW SUPPLIED:

Lens case included. OPTI-FREE® PUREMOIST® Solution is available for purchase in sterile 2 FL OZ (60 mL), 4 FL OZ (118 mL), 10 FL OZ (300 mL), 14 FL OZ (420 mL), and 16 FL OZ (470 mL) plastic bottles. Bottles and cartons are marked with a lot number and expiration date.

†TETRONIC® is a registered trademark of BASF.

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\* trademark of Novartis

U.S. Pat. www.alconpatents.com

Questions or Comments?

Call 1-800-757-9195

alcon.medinfo@alcon.com

www.OPTI-FREE.com

Manufactured by:  
 Alcon Laboratories, Inc.  
 6201 South Freeway  
 Fort Worth, Texas 76134  
 a Novartis company  
 Made in USA

## **APPENDIX D: CLINICAL TECHNICAL PROCEDURES (CTP)**

- [REDACTED] Limbal and Conjunctival (Bulbar) Redness
- [REDACTED] Expanded Sodium Fluorescein Corneal Staining
- [REDACTED] Lens Fitting Characteristics
- [REDACTED] Subject Reported Ocular Symptoms/Problems
- [REDACTED] Front and Back Surface Lens Deposit Grading Procedure
- [REDACTED] Determination of Distance Spherocylindrical Refractions
- [REDACTED] Biomicroscopy Scale
- [REDACTED] Conjunctival Staining
- [REDACTED] Keratometry Procedure
- [REDACTED] Distance and Near Visual Acuity Evaluation
- [REDACTED] Distance LogMAR Visual Acuity Measurement Procedure
- [REDACTED] Patient Reported Outcomes
- [REDACTED] Lens Insertion and Removal
- [REDACTED] White Light Lens Surface Wettability

**██████████ LIMBAL AND CONJUNCTIVAL (BULBAR) REDNESS**

[REDACTED]

**Limbal & Conjunctival (Bulbar) Redness**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

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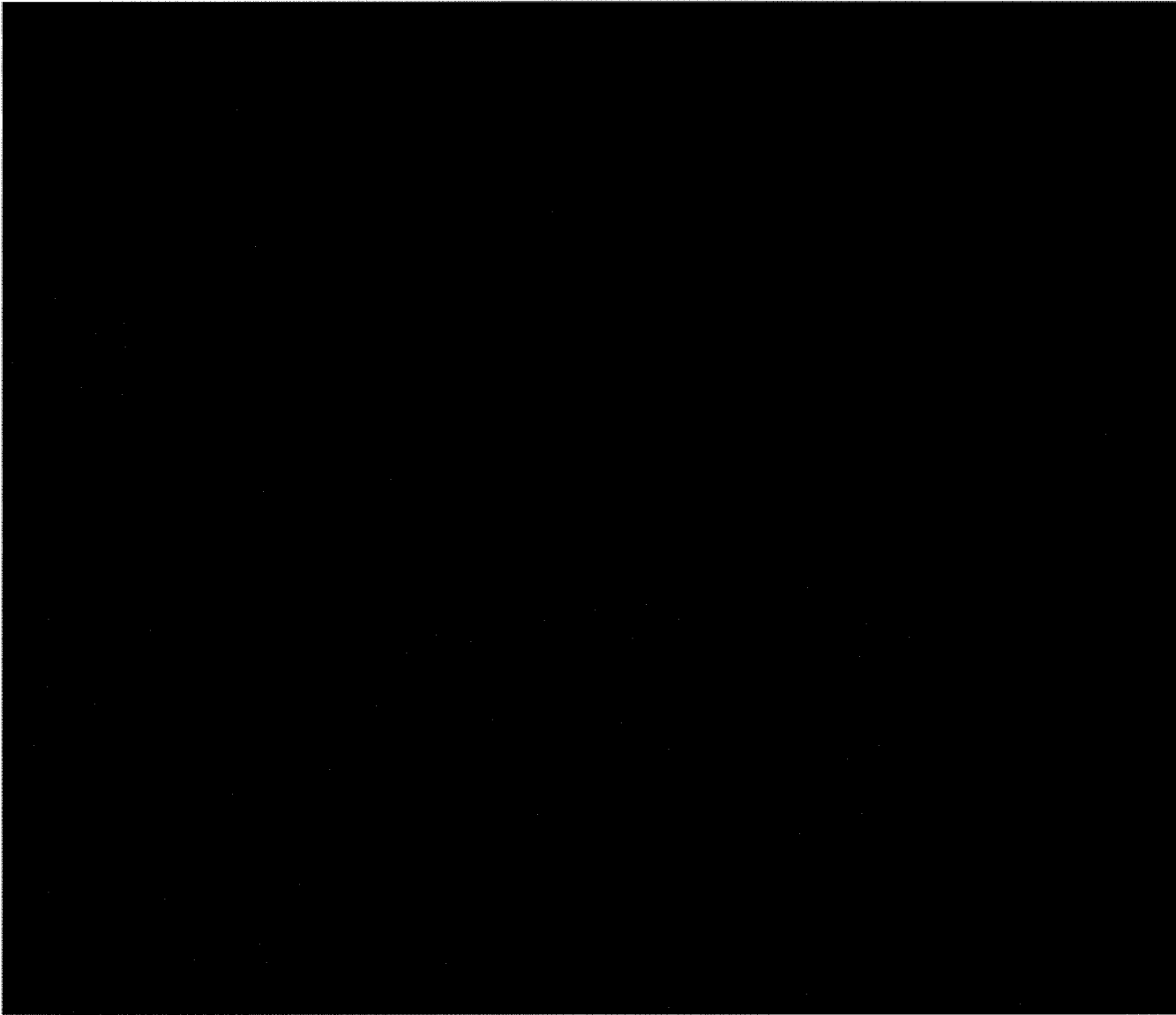
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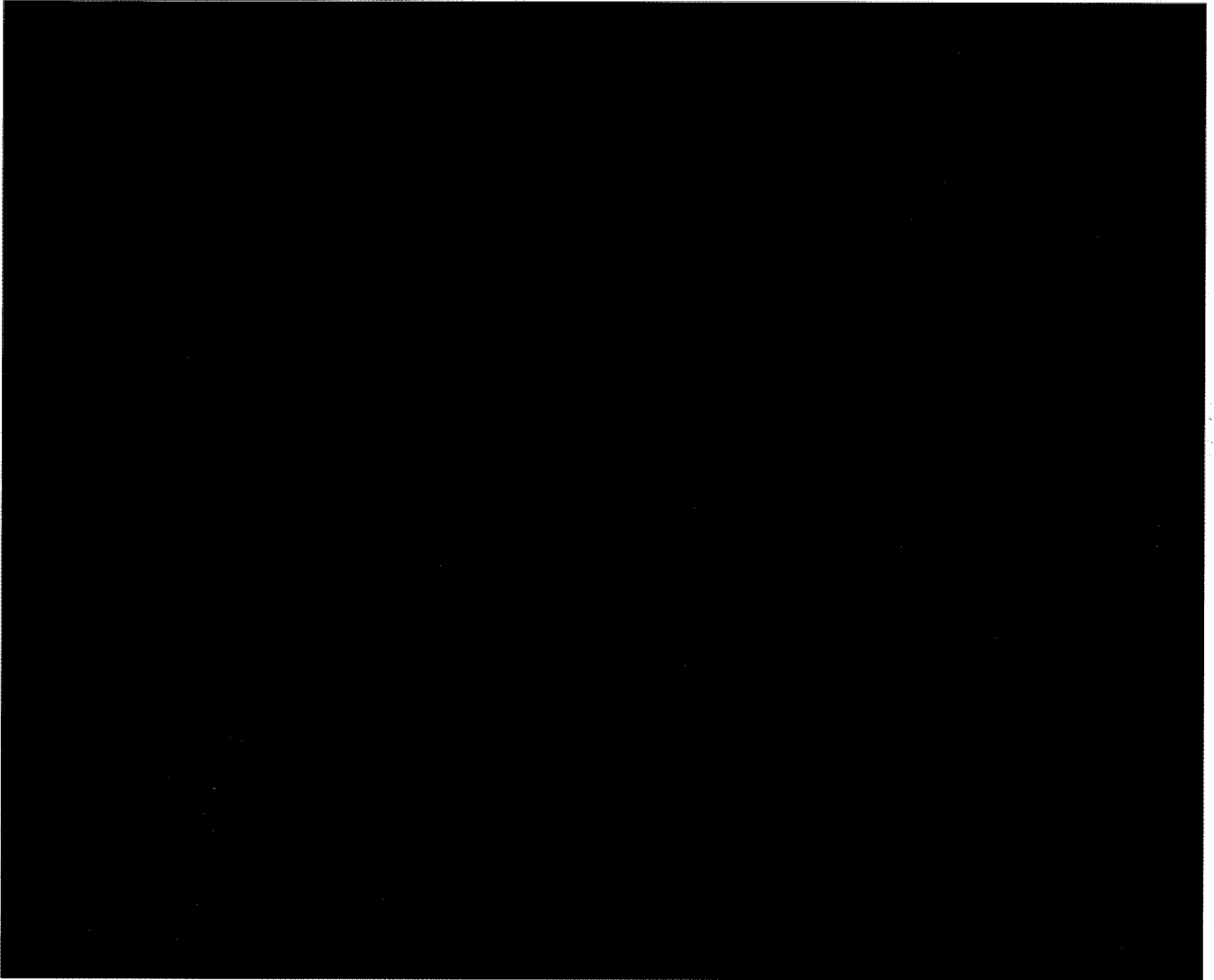
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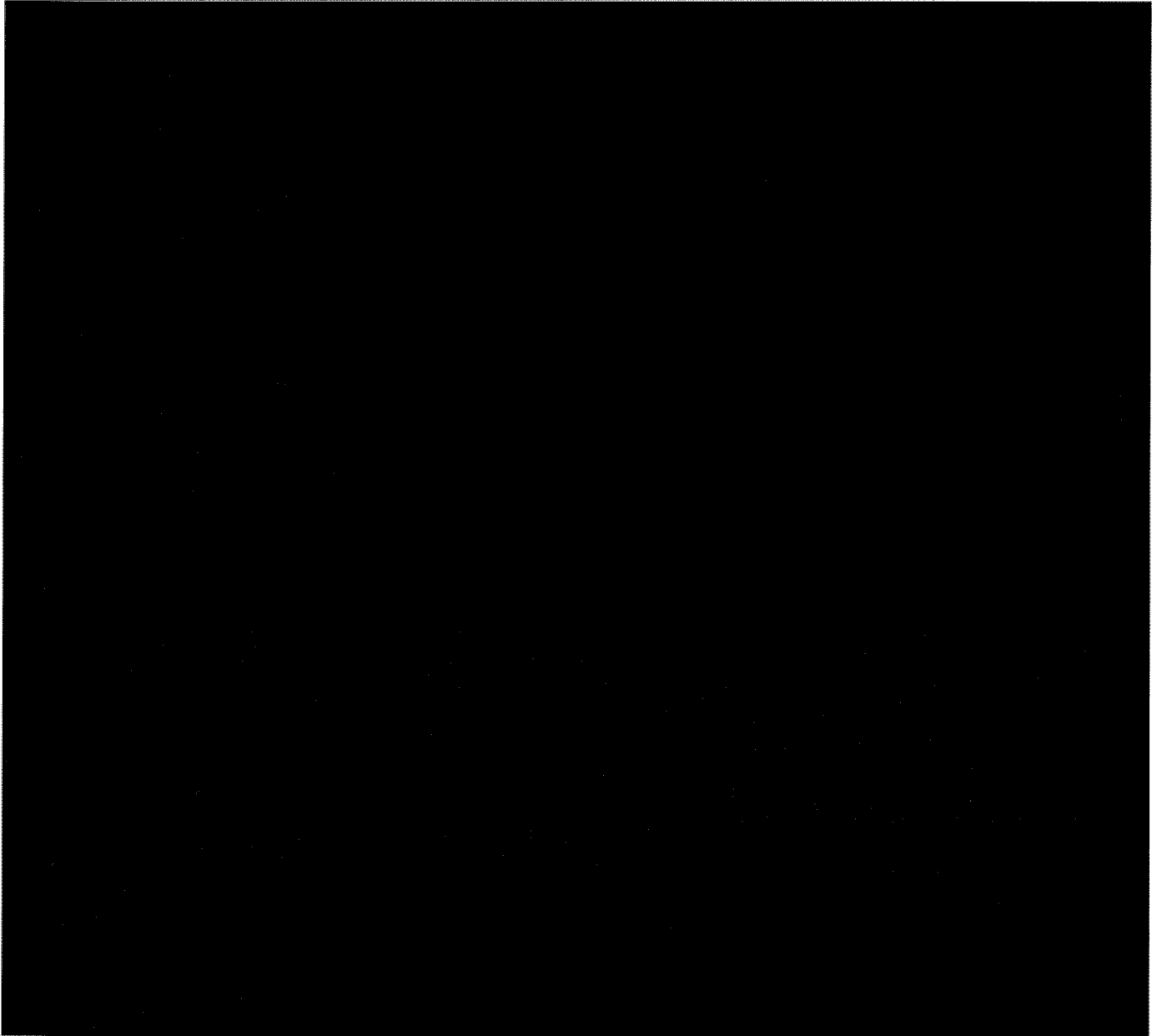
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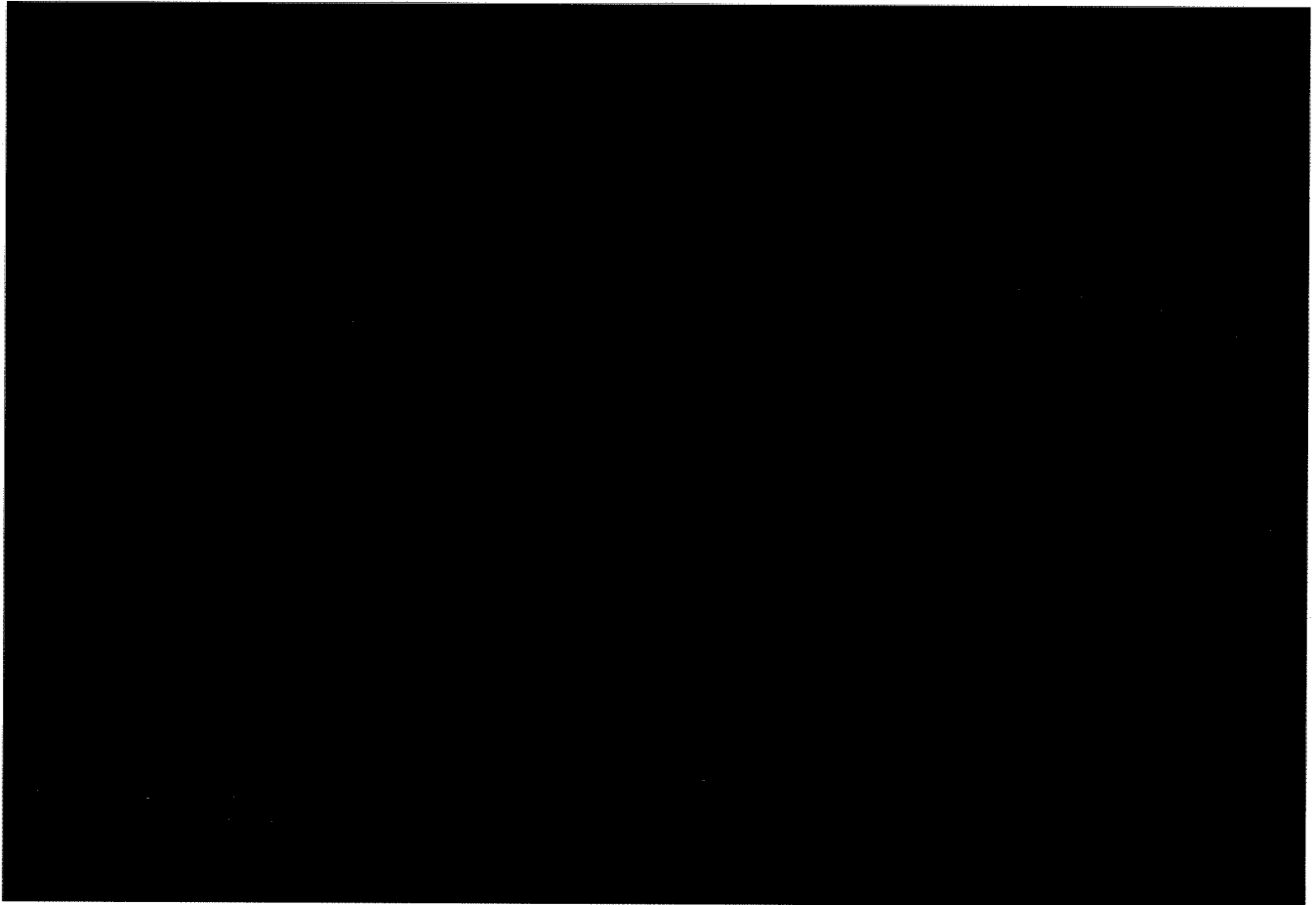
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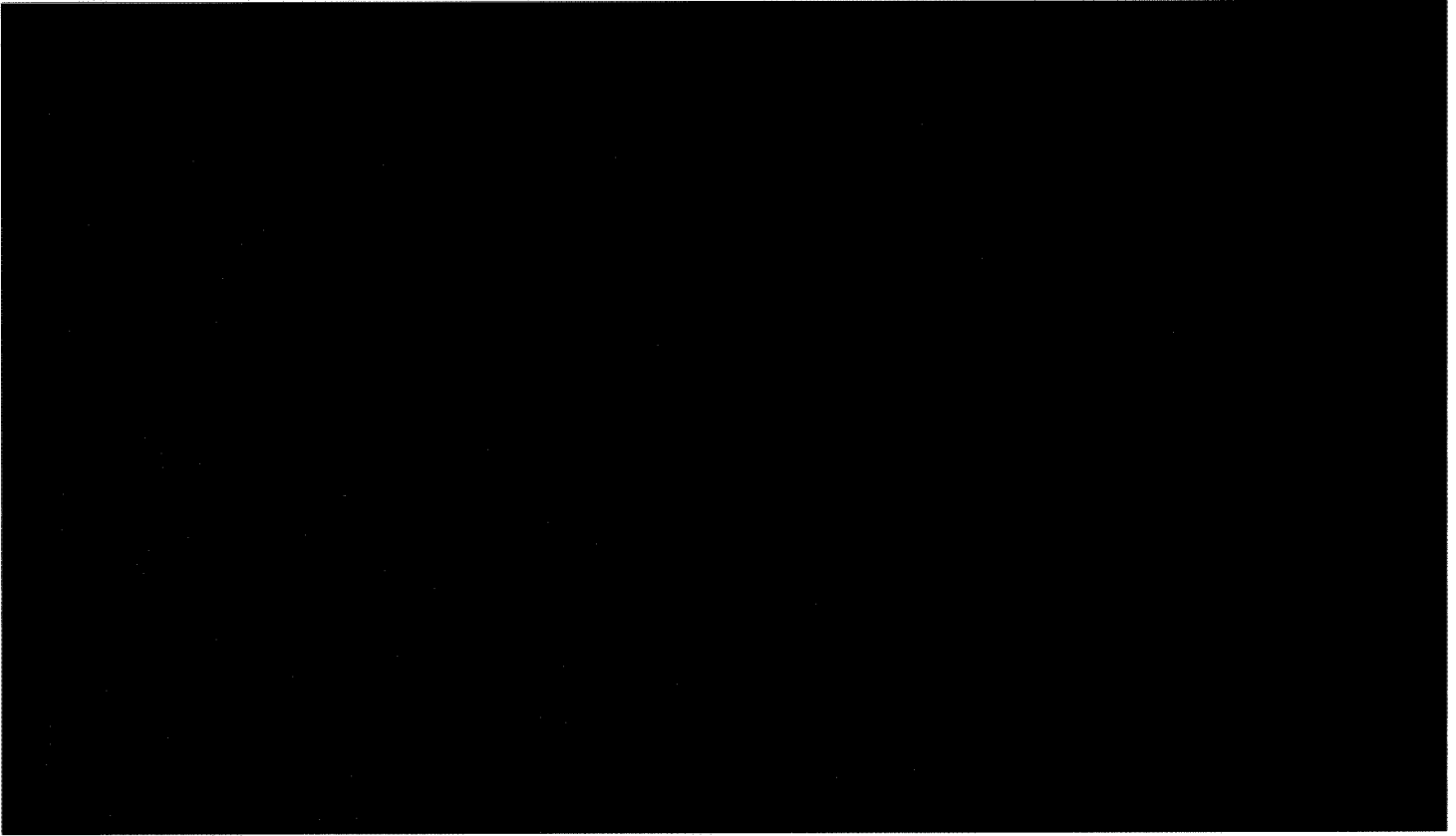
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**EXPANDED SODIUM FLUORESCEIN CORNEAL STAINING**

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1. *Journal of Management Studies*, 1996, 33, 1, 1-15.

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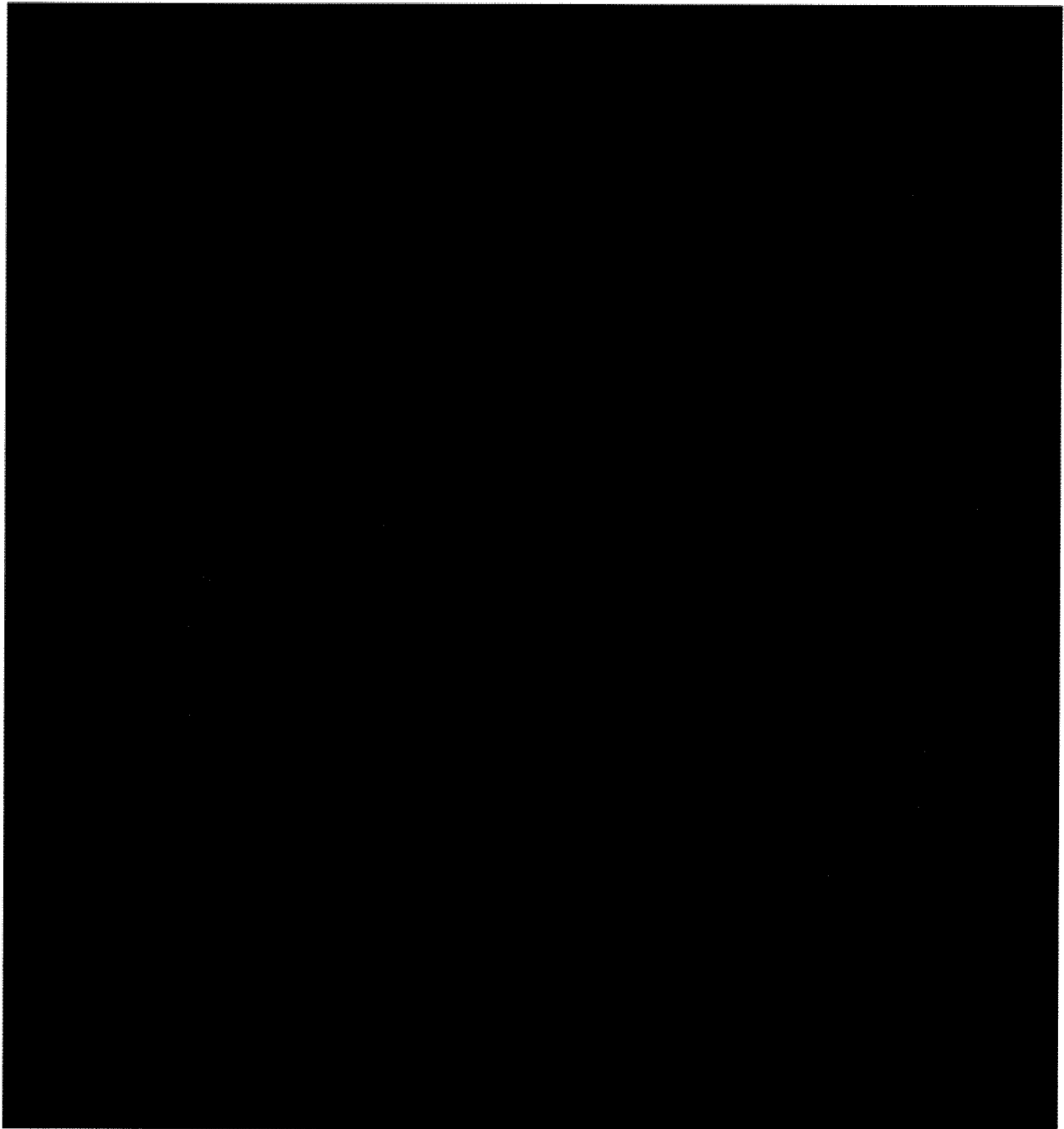
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**FORM MODULE**





**LENS FITTING CHARACTERISTICS**

**[REDACTED] Lens Fitting Characteristics**

**[REDACTED]** [REDACTED]  
[REDACTED]

**[REDACTED]** [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

**[REDACTED]** [REDACTED]

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[REDACTED]

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[REDACTED]	[REDACTED]

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[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
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[REDACTED]  
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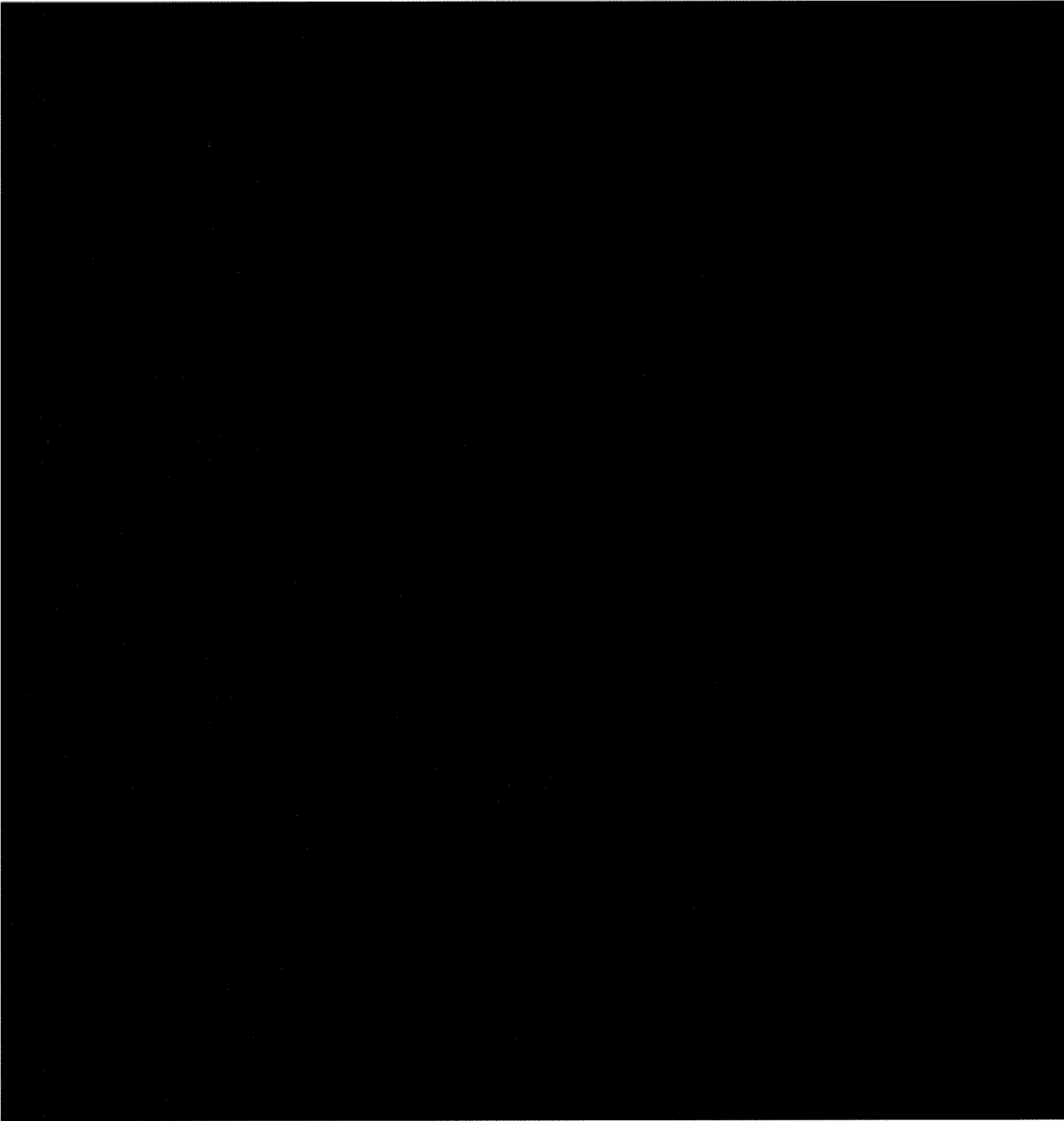
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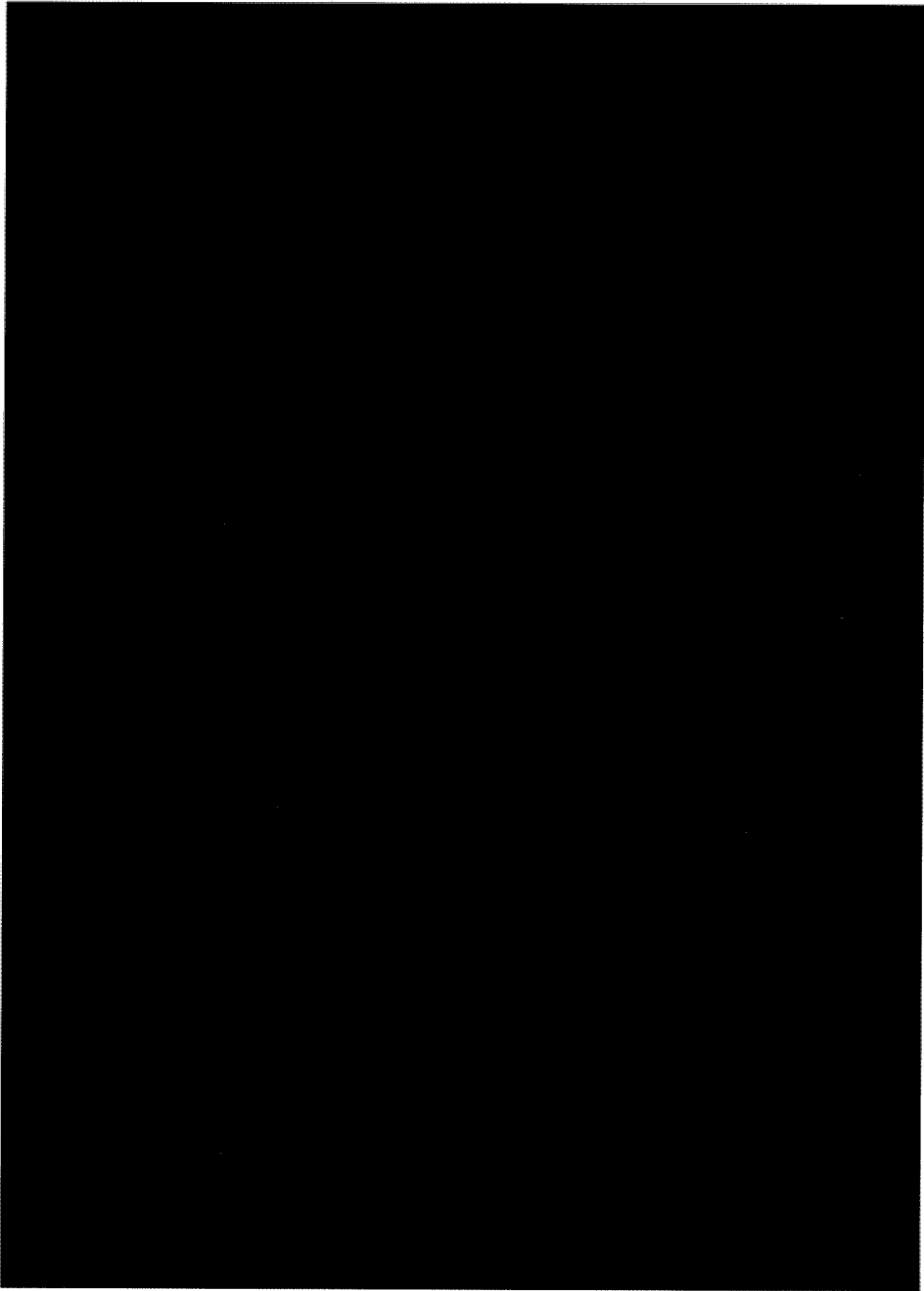
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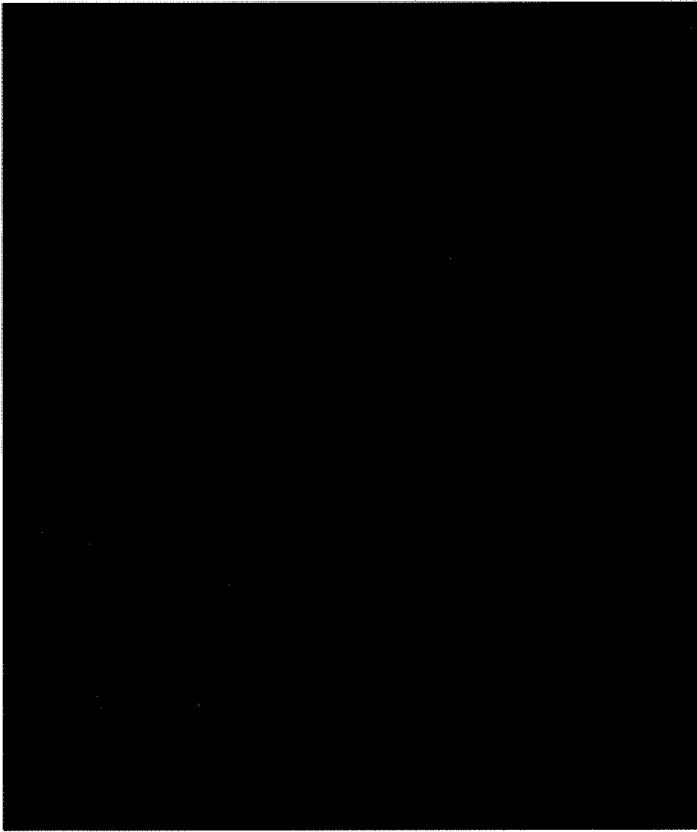
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[REDACTED]

[REDACTED]

[REDACTED]







**[REDACTED] SUBJECT REPORTED OCULAR SYMPTOMS/PROBLEMS**

**Subject Reported Ocular Symptoms/Problems**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**REQUIREMENTS**

## **████████ FRONT AND BACK SURFACE LENS DEPOSIT GRADING PROCEDURE**

**Front and Back Surface Lens Deposit Grading Procedure**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	
[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]

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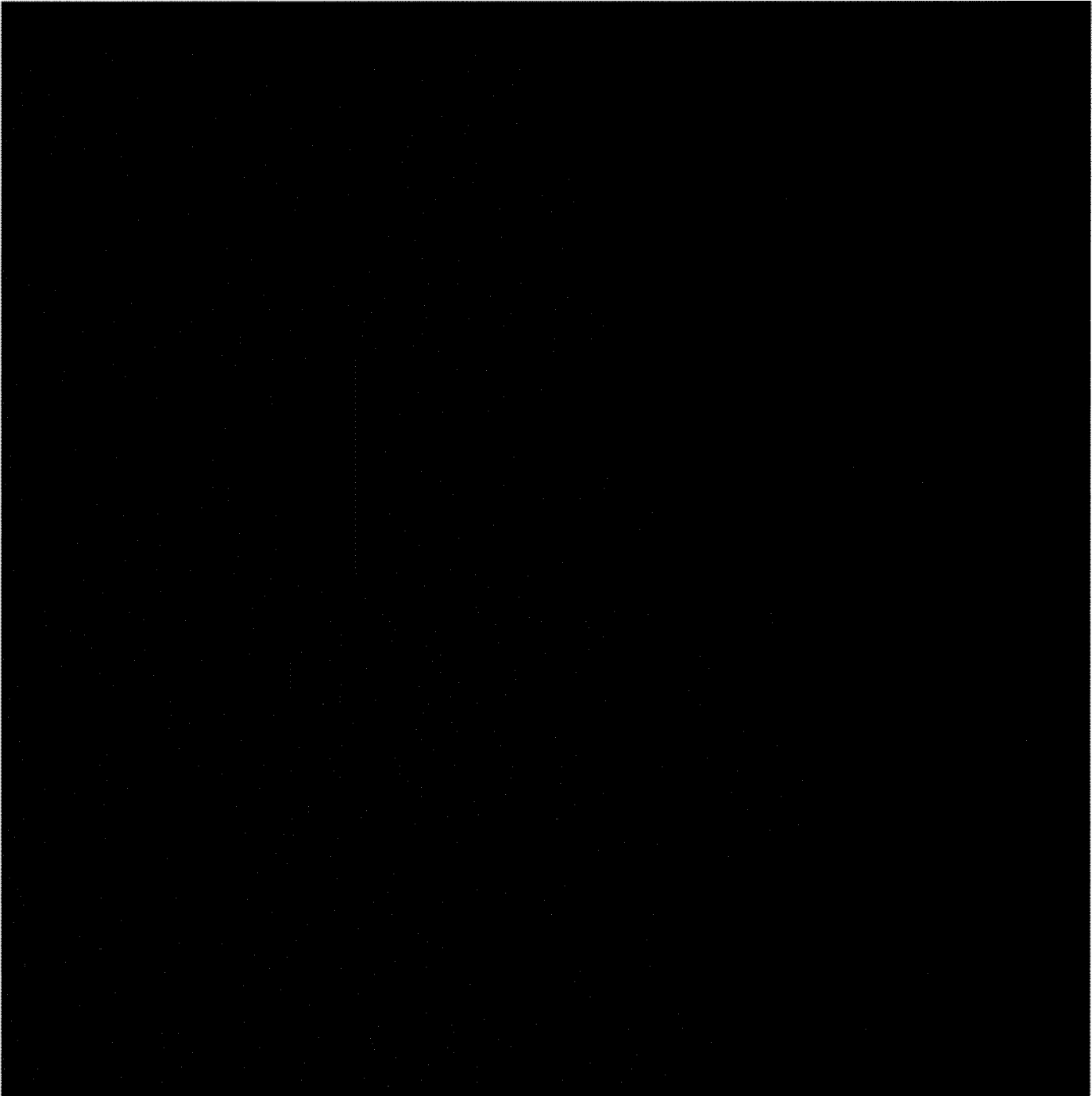
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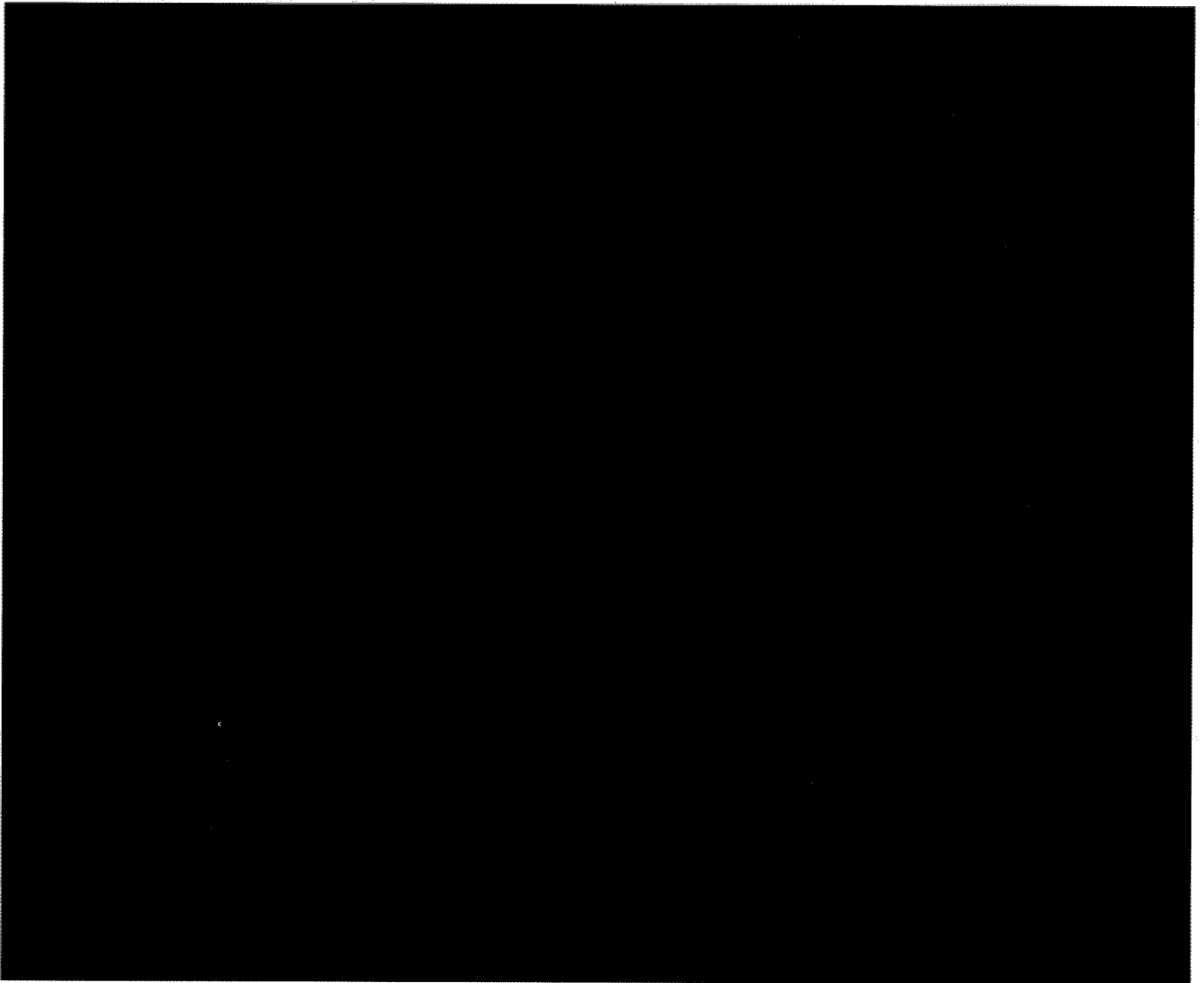
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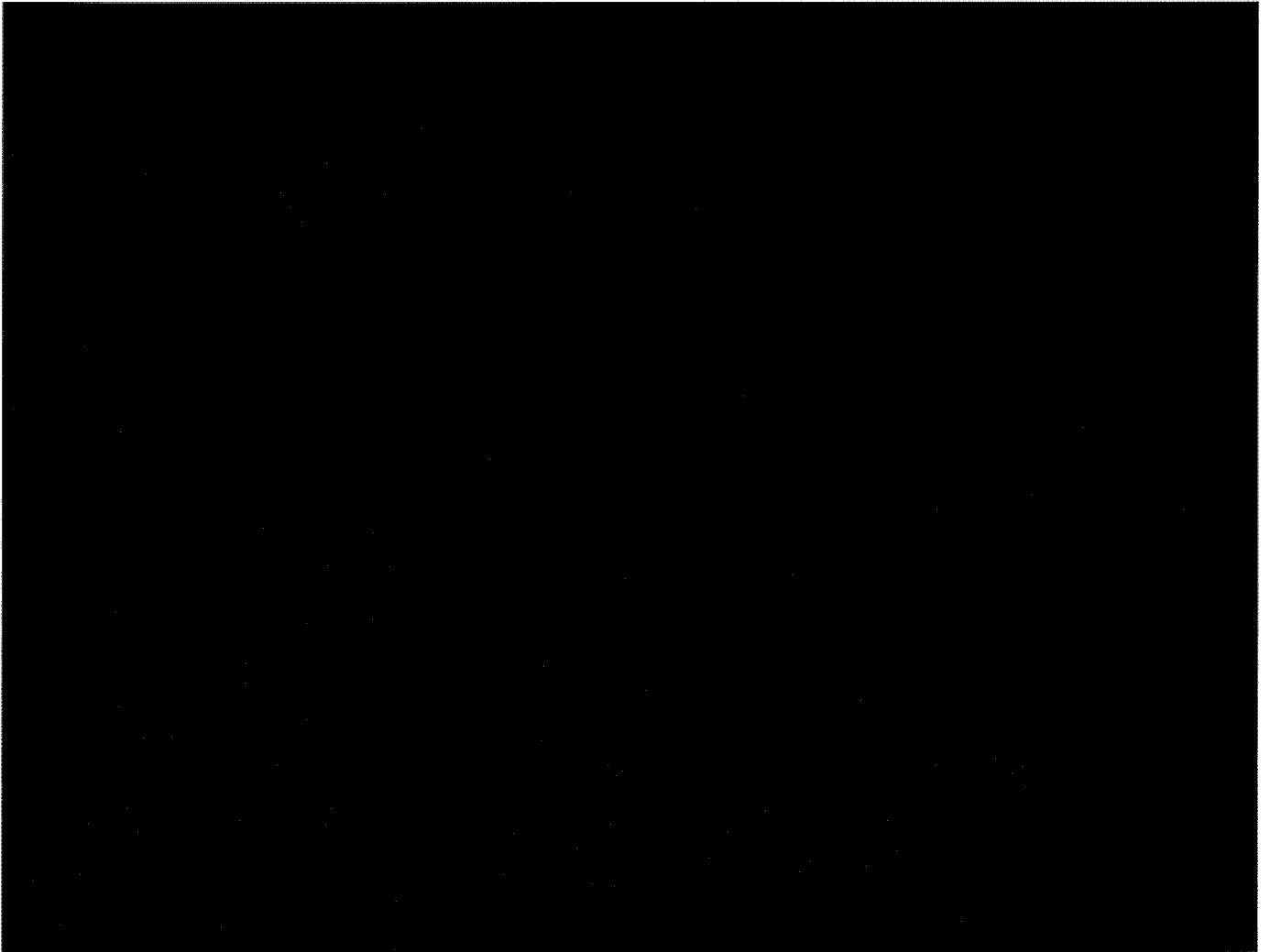
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**██████ DETERMINATION OF DISTANCE SPHEROCYLINDRICAL  
REFRACTIONS**

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15 JULY 2004

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**BIOMICROSCOPY SCALE**

[REDACTED]

## Biomicroscopy Scale

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**CONJUNCTIVAL STAINING**

[REDACTED]

## Conjunctival Staining

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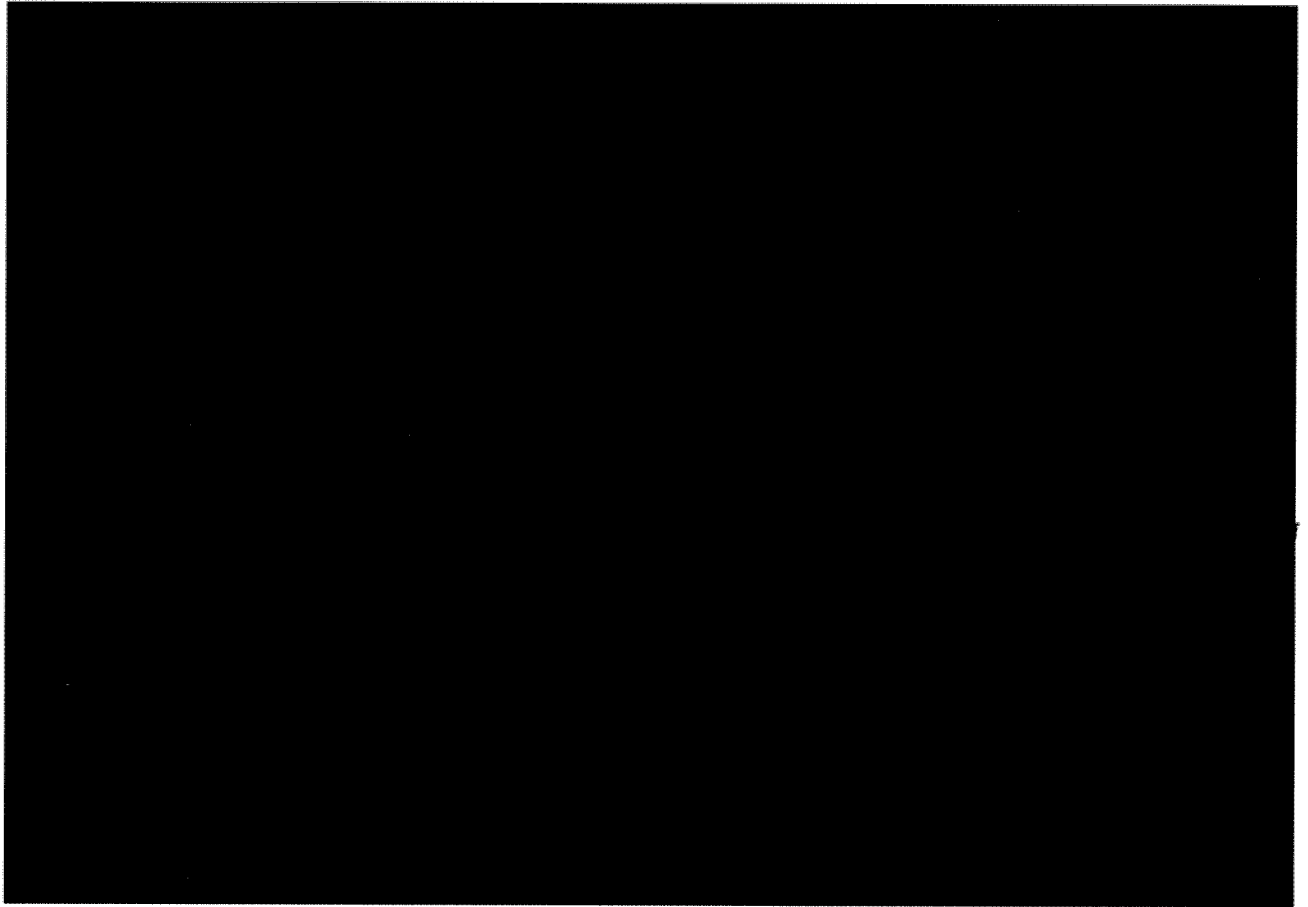
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**[REDACTED] KERATOMETRY PROCEDURE**

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TABLE 1. *Continued*

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**TABLE 1**

[illegible]

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**██████████ DISTANCE AND NEAR VISUAL ACUITY EVALUATION**



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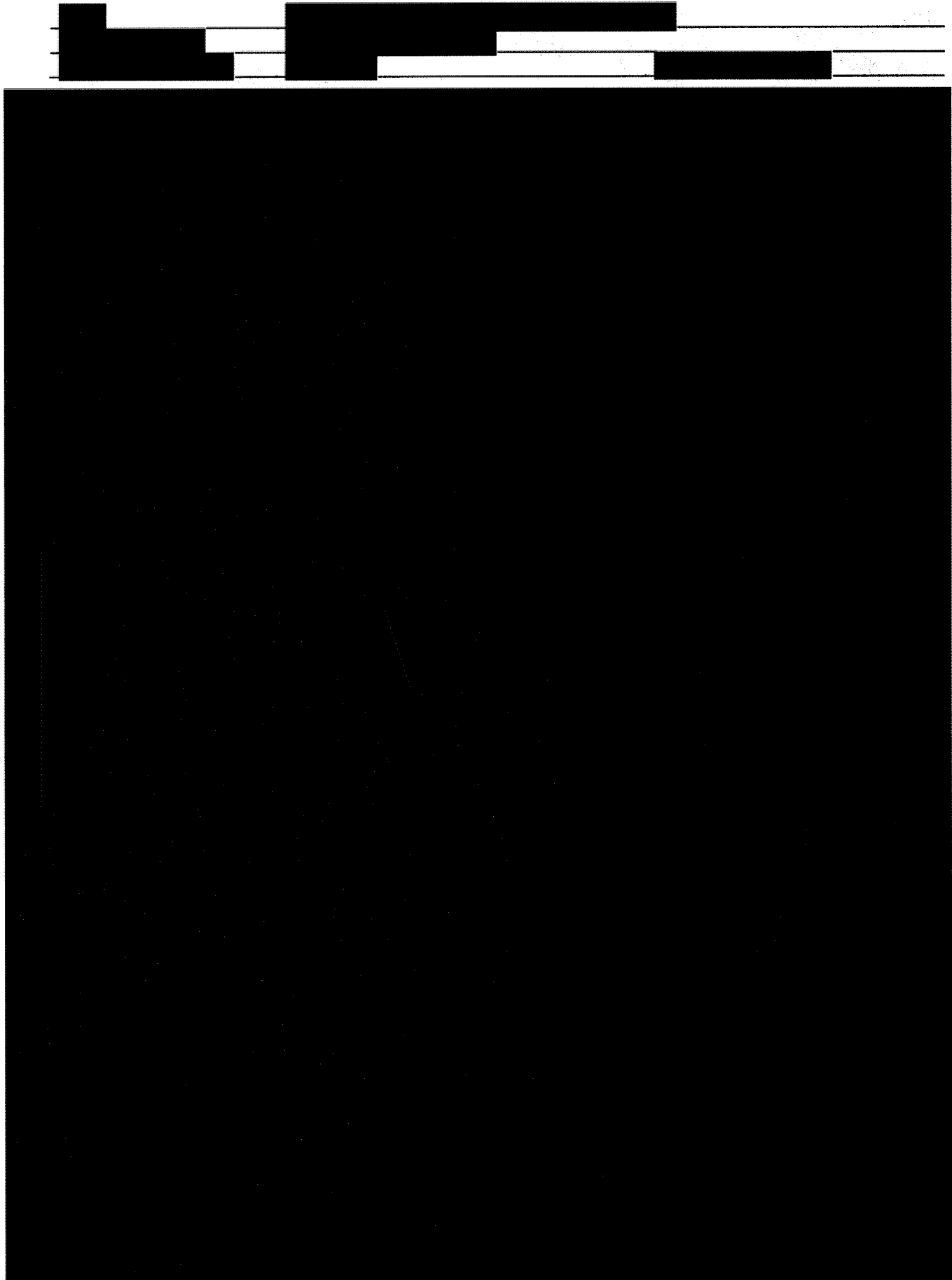
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**██████████, DISTANCE LOGMAR VISUAL ACUITY MEASUREMENT  
PROCEDURE**

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[REDACTED]

Page 2 of 3

[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

**[REDACTED] PATIENT REPORTED OUTCOMES**

**[REDACTED] Patient Reported Outcomes**

[REDACTED] [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

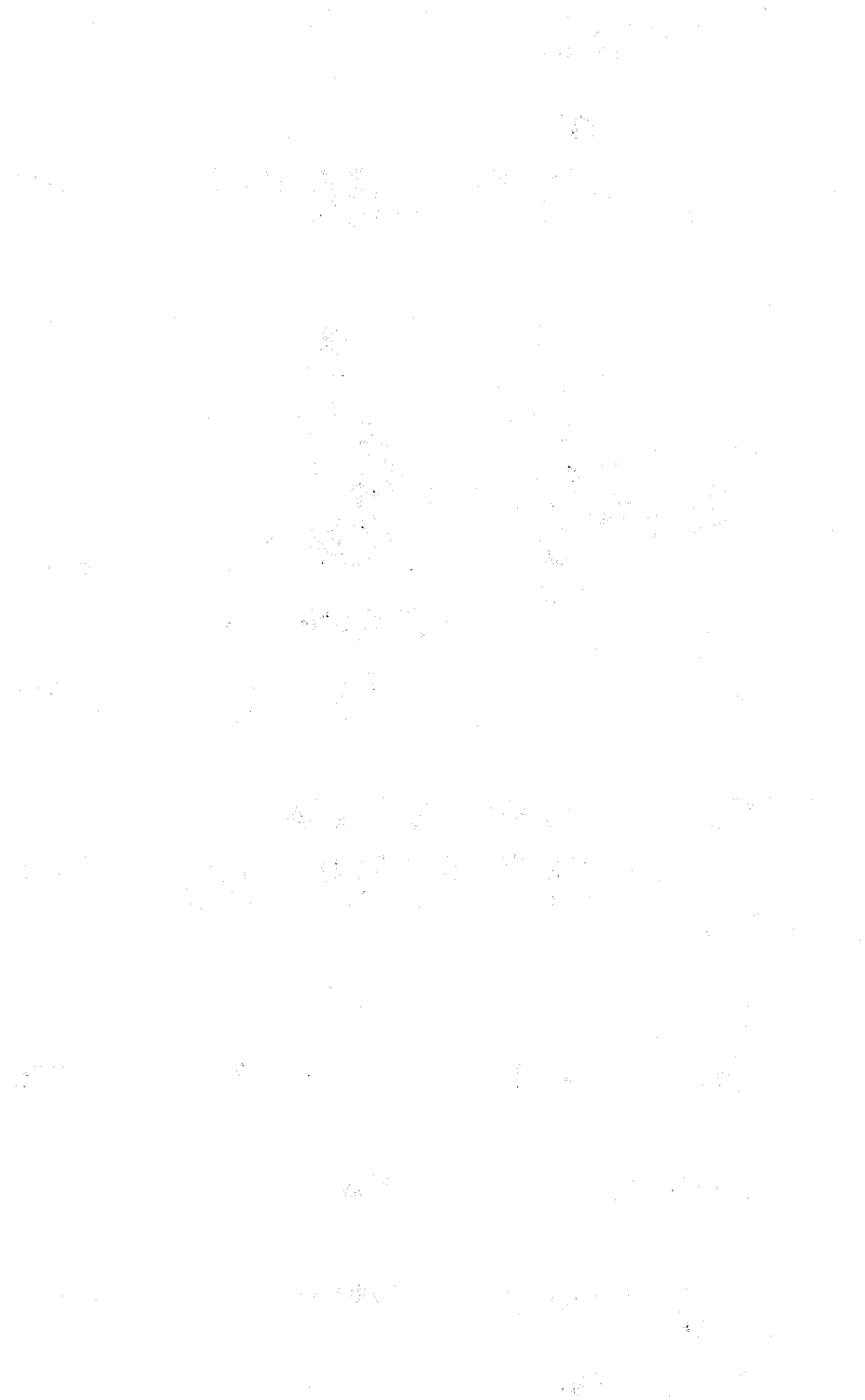
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**██████████, LENS INSERTION AND REMOVAL**



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**1**

\_\_\_\_\_

[REDACTED]

[REDACTED]

---

[REDACTED]

[REDACTED]

[REDACTED]

**WHITE LIGHT LENS SURFACE WETTABILITY**

[REDACTED]

**White Light Lens Surface Wettability**

[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED]	
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]	
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

## **APPENDIX E: LENS PREPARATION WORK AID**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

## PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: CR-6012 Clinical Evaluation of 3 Contact Lens Materials with 3 Solution Types

Version and Date: 2.0 08 January 2018

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

I agree to conduct this study according to ISO 14155,<sup>1</sup> GCP and ICH guidelines,<sup>2</sup> the Declaration of Helsinki,<sup>3</sup> United States (US) Code of Federal Regulations (CFR),<sup>4</sup> 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<sup>2</sup> 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<sup>2</sup> 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.

Principal  
Investigator:

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name and Professional Position (Printed)

Institution/Site:

\_\_\_\_\_  
Institution/Site Name

\_\_\_\_\_  
Institution/Site Address

