Johnson & Johnson Vision Care, Inc.

Clinical Study Protocol

Protocol Title: Clinical Comparison of Two Marketed Reusable Cosmetic Contact Lenses

Protocol: CR-6286

Version: 3.0

Date: 20 December 2018

Investigational Products: ACUVUE® 2 DEFINE™ Vivid Style contact lens, LACELLE™ Contact Lenses in Sparkling Brown

Key Words: ACUVUE® 2 DEFINE™ Vivid Style contact lens, LACELLE™ Contact Lenses, reusable, Etafilcon A, Hefilcon A, dispensing, logMAR visual acuity, subjective vision

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

Confidentiality Statement:

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

PROTOCOL TITLE, NUMBER, VERSION

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SPONSOR NAME AND ADDRESS

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

MEDICAL MONITOR

Name: Brian Pall, OD, MS, FAAO
Title: Director, Clinical Sciences
Address: 7500 Centurion Parkway, Suite 100
[redacted]
Email: bpall@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,[4] ICH guidelines,[2] ISO 14155,[1] and the Declaration of Helsinki.[3]

Author/Study Responsible Clinician	**See Electronic Signature Page** Brian Pall, OD, MS, FAAO Director, Clinical Sciences, R&D	DATE
Clinical Operations Manager	**See Electronic Signature Page** [redacted] Clinical Operations Manager, Clinical Operations	DATE
Biostatistician	**See Electronic Signature Page** [redacted] Biostatistician II, R&D	DATE
Data Management	**See Electronic Signature Page** [redacted] Clinical Project Manager, Data and Systems, R&D	DATE
Reviewer	***Fellow review is NOT required*** [redacted] Clinical Research Fellow	DATE
Approver	**See Electronic Signature Page** [redacted] Director, Beauty Platform and External Innovation, R&D	DATE

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Date
1.0	Meredith Bishop	Original Protocol	06 June 2018
2.0	[redacted]	Addition of labeling protocol number, addition of LogMAR step at Visit 1to confirm dispensing criteria, updated control lens variant	13 July 2018
3.0	[redacted]	Updated Medical Monitor information, and updated procedures for returning lenses following the study close out visit.	20 December 2018

SYNOPSIS

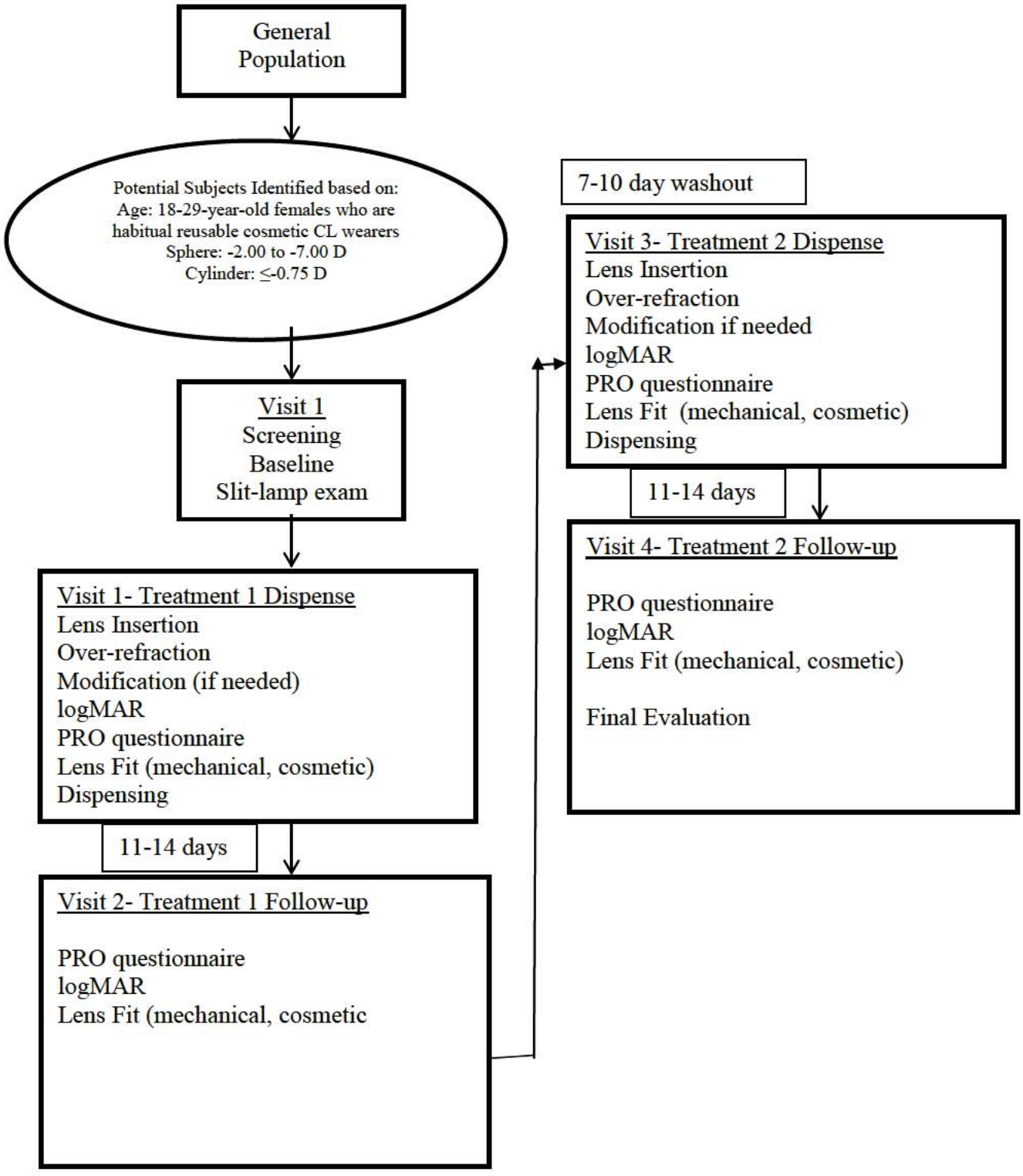
Protocol Title	Clinical Comparison of Two Marketed Reusable Cosmetic Contact Lenses
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Exploratory phase, Phase 2
Trial Registration	This study will be registered on ClinicalTrials.gov by the Sponsor.
Test Article(s)	Marketed Products: ACUVUE® 2 DEFINE™ Vivid Style contact lens, LACELLE™ Sparkling Brown
Wear and Replacement Schedules	Wear Schedule: Daily Wear Replacement Schedule: Two weeks
Objectives	The purpose of this study is to evaluate the Objective Vision Logarithm of Minimal Angle of Resolution (logMAR) visual performance of two brands of marketed cosmetic contact lenses.
Study Endpoints	Primary endpoint: logMAR visual performance Other observations: lens fit, and CLUE vision, comfort, and handling, Hula Hoop assessment, and ocular physiology.
Study Design	This will be a 4-visit, multi-site, randomized, brand-masked, bilateral, 2×2 Williams' crossover study. Subjects will wear each study treatment for a period of 11-14 days with a 7-10 days washout between treatments. Visit 1: Baseline and eligibility, insert treatment #1, logMAR vision, post fit questionnaire, lens fit assessment. Dispense treatment #1 for 11-14 days Visit 2: Follow up on treatment #1: Subjective questionnaire, logMAR vision, lens fit, and physiology assessment. Washout 7-10 days

	Visit 3: Reconfirm eligibility, insert treatment #2, logMAR vision, post fit questionnaire, lens fit assessment. Dispense treatment #2 for 11-14 days Visit 4: Follow up on treatment #2: Subjective questionnaire, logMAR vision, lens fit, and physiology assessment. Final evaluation. See the flow chart (Figure 1) at the end of the synopsis table for the schematic of the study visits and procedures of main observations.
Sample Size	Up to 50 female subjects will be enrolled with the aim of approximately 40 subjects completing.
Study Duration	The study is expected to last up to 3 months. The enrollment period will also be up to 2 months.
Anticipated Study Population	We will aim to recruit up to 50 female subjects, ages 18 to 29 years (inclusive). Subject must be habitual reusable cosmetic contact lens wearers.
Eligibility Criteria	Potential subjects must satisfy all of the following criteria to be enrolled in the study: 1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form 2. Appear able and willing to adhere to the instructions set forth in this clinical protocol (ie, willing to wear only the study lenses and not use habitual lenses during the study) 3. Females between 18 and 29 (inclusive) years of age at the time of screening 4. The subject's vertex corrected spherical equivalent distance refraction must be in the range of -2.00 D to -7.00 D (inclusive) in each eye 5. The subject's refractive cylinder must be less than or equal to 0.75 D (inclusive) in each eye 6. Have spherical best corrected logMAR visual acuity (VA) of 0.18 or better in each eye 7. Be a current soft contact lens wearer in both eyes with a minimum of 6 hours/day and 5 days/week over the last month by self-report 8. Must be habitual reusable (2 week, or monthly), cosmetic contact lenses wearers. 9. The subject must be willing to be photographed and/or video-taped

Eligibility Criteria	Potential subjects who meet any of the following criteria will be excluded from participating in the study: 1. Currently pregnant or lactating 2. Any systemic disease (eg, Sjögren's Syndrome), allergies, infectious disease (eg, hepatitis, tuberculosis), contagious immunosuppressive diseases (eg, HIV), autoimmune disease (eg rheumatoid arthritis), or other diseases, by self-report, which are known to interfere with contact lens wear and/or participation in the study (at the investigators discretion) 3. Use of systemic medications (eg, chronic steroid use) that are known to interfere with contact lens wear (at the investigators discretion) 4. Any previous, or planned (during the study) ocular surgery (eg, radial keratotomy, PRK, LASIK, etc.) 5. Participation in any contact lens or lens care product clinical trial within seven (7) days prior to study enrollment 6. Employee or family members of clinical site (eg, Investigator, Coordinator, Technician) Exclusion Criteria after Baseline 7. Any ocular allergies, infections or other ocular abnormalities that are known to interfere with contact lens wear and/or participation in the study. This may include, but not be limited to entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or corneal distortion (at the investigators discretion) 8. Clinically significant (Grade 3 or 4 on FDA scale) tarsal abnormalities, bulbar injection, corneal edema, corneal vascularization, corneal staining, or any other abnormalities of the cornea which would contraindicate contact lens wear.
Disallowed Medications/Interventions	None
Measurements and Procedures	logMAR VA, PRO questionnaires (comfort, vision, and handling), lens fit assessment, and safety parameters (slit lamp findings, entrance/exit VA).
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	EyeCept (Optics Laboratory, Inc.), LacriPure (Menicon), Blink Revitalens (Johnson & Johnson Vision), Fluorescein (Akorn, Inc.) or other Sponsor-approved supplies
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
[redacted]	[redacted]
D	Diopter
DMC	Data Monitoring Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	Intent-to-Treat
JJVC	Johnson & Johnson Vision Care, Inc.
LC	Limbus Center
LogMAR	Logarithm of Minimal Angle of Resolution
MedDRA©	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NIH	National Institutes of Health
OD	Right Eye
OHRP	Office for Human Research Protections
OHSR	Office for Human Subjects Research
OS	Left Eye
OU	Both Eyes
PD	Protocol Deviation
PHI	Protected Health Information
PI	Principal Investigator
PIG	Patient Instruction Guide

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

1. INTRODUCTION AND BACKGROUND

Cosmetic contact lenses can have patterns of varying size and opacities. When designing new cosmetic patterns, it is important to test the performance in a clinical study. The ACUVUE® 2 DEFINE™ Vivid Style contact lens is a marketed contact lens formulated using etafilcon A and the intended use is to correct vision. The ACUVUE® 2 DEFINE™ Vivid Style contact lens contains a cosmetic pattern, so it also affects the visual appearance of the eye. Hence, the present study was designed to evaluate the objective vision Objective Vision Logarithm of Minimal Angle of Resolution (logMAR) high illuminance/high contrast of two brands of marketed cosmetic contact lens.

1.1. Name and Descriptions of Investigational Products

This study will include two marketed contact lenses. Further details about the test articles are found in Section 6 of this protocol.

1.2. Intended Use of Investigational Products

The intended use of the investigational products is to correct vision. During this dispensing study, each lens type will be worn for approximately 2 weeks.

1.3. Summary of Findings from Nonclinical Studies

Not Applicable - Marketed Product Only

1.4. Summary of Known Risks and Benefits to Human Subjects

The following risks/adverse events can be associated with wearing soft contact lenses in general:

- The eyes may burn, sting and/or itch.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion.
- There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal

abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.

- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor VA, 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.
- Due to the reduction in light transmittance with cosmetically tinted lenses, some patients may experience visual symptoms while wearing the Study Contact Lenses. In addition, some patients may experience reduced peripheral awareness due to the opaque iris pattern.

There is no direct benefit to the subjects for participating in the study, although they will be able to try out marketed contact lenses. The information from this study will aid if the further development and assessment of new potential contact lenses.

For the most comprehensive clinical information regarding the marketed contact lenses refer to the package inserts (APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

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

For the most comprehensive clinical information regarding the marketed contact lenses refer to the package insert (APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT).

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

Primary Objective:
The primary objective of this study is to evaluate the logMAR high illuminance/high contrast of one brand of marketed contact lens.

2.2. Endpoints

Primary Endpoint:

LogMAR objective vision (high illumination/high contrast) at lens fit.

Other Observations:

Overall quality of vision, overall comfort and handling scores will be assessed using the Contact Lens User Experience (CLUE)™ questionnaire. CLUE is a validated patient-reported outcomes questionnaire to assess patient-experience attributes of soft, disposable contact lenses (comfort, vision, handling, and packaging) in a contact-lens wearing population in the US, ages 18-65. Scores follow a normal distribution with a population average score of 60 (SD 20), where higher scores indicate a more favorable/positive response.

LogMAR objective vision (high illumination/low contrast, low illumination/high contrast)
Mechanical Lens Fit
Cosmetic Lens Fit
Hula Hoop Assessment
Ocular Physiology

2.3. Hypotheses

Due to the exploratory nature of this pilot study, there will be no planned hypotheses. Instead, descriptive summaries (ie, tables and figures) of study endpoints will be provided for each lens type.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

Females aged 18 to 29 years (inclusive) who are habitual reusable (2 week or monthly) soft cosmetic contact lens wearers will be recruited for this clinical study. Subjects must meet all the inclusion and none of the exclusion criteria listed in Section 3.2.

3.2. Inclusion Criteria

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

1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form
2. Appear able and willing to adhere to the instructions set forth in this clinical protocol (ie, willing to wear only the study lenses and not use habitual lenses during the study)
3. Females between 18 and 29 (inclusive) years of age at the time of screening
4. The subject's vertex corrected spherical equivalent distance refraction must be in the range of -2.00 D to -7.00 D (inclusive) in each eye
5. The subject's refractive cylinder must be less than or equal to 0.75 D (inclusive) in each eye
6. Have spherical best corrected logMAR VA of 0.18 or better in each eye
7. Be a current soft contact lens wearer in both eyes with a minimum of 6 hours/day and 5 days/week over the last month by self-report
8. Must be habitual reusable (2 week, or monthly), cosmetic contact lenses wearers.
9. The subject must be willing to be photographed and/or video-taped

3.3. Exclusion Criteria

Exclusion Criteria after Screening:

1. Currently pregnant or lactating
2. Any systemic disease (eg, Sjögren's Syndrome), allergies, infectious disease (eg, hepatitis, tuberculosis), contagious immunosuppressive diseases (eg, HIV), autoimmune disease (eg rheumatoid arthritis), or other diseases, by self-report, which are known to interfere with contact lens wear and/or participation in the study (at the investigators discretion)

3. Use of systemic medications (eg, chronic steroid use) that are known to interfere with contact lens wear (at the investigators discretion)
4. Any previous, or planned (during the study) ocular surgery (eg, radial keratotomy, PRK, LASIK, etc.)
5. Participation in any contact lens or lens care product clinical trial within seven (7) days prior to study enrollment
6. Employee or family members of clinical site (eg, Investigator, Coordinator, Technician)

Exclusion Criteria after Baseline

7. Any ocular allergies, infections or other ocular abnormalities that are known to interfere with contact lens wear and/or participation in the study. This may include, but not be limited to entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or corneal distortion (at the investigators discretion)
8. Clinically significant (Grade 3 or 4 on Food and Drug Administration [FDA] scale) tarsal abnormalities, bulbar injection, corneal edema, corneal vascularization, corneal staining, or any other abnormalities of the cornea which would contraindicate contact lens wear.

3.4. Enrollment Strategy

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

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

This will be a 4-visit, multi-site, randomized, brand-masked, bilateral, 2×2 Williams' crossover study.

The study begins with an initial visit (Visit 1). If a subject is found to meet all eligibility criteria, they will be random to one of two lens wear sequences (Test/Control or Control/Test).

If the subject is dispensed study lenses at the initial visit, 3 follow-up visits will be conducted. Visit 2 will occur approximately 2 weeks after the initial visit. At the end of visit 2, subjects will be instructed to wear their habitual contact lenses or spectacles for 7-10 days. Subjects will then return for visit 3 to receive their second study treatment. Visit 4 will occur approximately 2 weeks after visit 3. Unscheduled follow-up visits may occur during the study, if needed. Subjects will be advised to wear the study lenses at least six (6) hours per day for a period of 11-14 days each. Lens replacement is scheduled at Visit 3.

4.2. Study Design Rationale

Crossover designs are a well-established study design in which subjects are exposed to multiple treatments during different time periods. This design was considered since the study period is relatively short the design can be cost effective.

4.3. Enrollment Target and Study Duration

Approximately 50 female subjects ages 18 to 29 years (inclusive) who are habitual reusable soft cosmetic contact lens wearers will be enrolled in this 4-visit, two-site clinical study. The study will last approximately 3 months with a 2-month enrollment period.

Enrollment is defined as execution of the informed consent and/or assent form.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

Use of the test articles will be randomized using a randomization scheme supplied by the study biostatistician.

A block size of two (2) sequences will be utilized. A computer-generated randomization scheme will be used to randomly assign subjects, in blocks of 2, to one of the two possible lens wear sequences (TEST/CONTROL or CONTROL/TEST). The randomization scheme will be generated by site using the PROC PLAN procedure from Statistical Analysis System (SAS) Software Version 9.4 or higher (SAS Institute, Cary, NC).

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

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

5.2. Masking

Due to visible difference between the lenses, it is difficult to complete mask subject, however subjects will be masked to the lens type and brand. Investigators will not be masked.

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

record. The Investigator is also advised not to reveal the study treatment assignment to the clinical site or Sponsor personnel.

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

5.3. Procedures for Maintaining and Breaking the Masking

The Clinical Supply Unit will generate a unique code for all study lenses. The test articles mask shall not be broken unless information concerning the lens type is necessary for the urgent medical treatment of a subject. The Sponsor must be notified before the mask is broken.

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 1: Test Articles

	Test	Control
Name	ACUVUE® 2 DEFINE™ Vivid Style	LACELLE™ Sparkling Brown
Manufacturer	Johnson & Johnson	Bausch and Lomb
[redacted]	[redacted]	[redacted]
Lens Material	Etafilcon A	Hefilcon A
Nominal Base Curve @ 22°C	8.3 mm	8.6 mm
Nominal Diameter @ 22°C	14.0 mm	14.0 mm
Nominal Distance Powers (D)	-2.00 to -7.00 D	-2.00 to -7.00 D
Modality in Current Study	Reusable	Reusable
Replacement Frequency	Two Week	Monthly
Packaging Form (vial, blister, etc.)	Blister	Blister

Each subject will wear approximately 2 of the lenses.

6.2. Ancillary Supplies/Products

The following supplies, or Sponsor-approved alternatives, will be used in this study:

Table 2: Ancillary Supplies

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

6.3. Administration of Test Articles

Test articles 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 may be replaced at the discretion of the Investigator and/or the Sponsor.

6.4. Packaging and Labeling

The test articles will be packaged in blisters as the primary packaging. The test article will be over-labeled to mask the subject/Investigators to the identity of the lens. The test articles will be in plastic bags as the secondary packaging form. The sample study label is shown below:

6.5. Storage Conditions

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

6.6. Collection and Storage of Samples

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

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

6.7. Accountability of Test Articles

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

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

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

The Investigator will collect all unused test articles from the subjects at the end of the subject's participation. Subject returned unused test articles must be separated from the clinical study inventory of un-dispensed test articles, and must be labeled with the subject number and date of return. Following final reconciliation of test articles by the monitor, the Investigator or monitor will return all unused test articles to JJVC or a designated third party storage depot, or will instruct the site staff to destroy the lenses on site. More detailed instructions will be provided prior to the Close-out Visit.

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

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

7. STUDY EVALUATIONS

7.1. Time and Event Schedule

Table 3: Time and Events

Visit Information	Visit 1 Screening, Baseline, Dispense Treatment 1	Visit 2 Treatment 1 Follow-up,	Visit 3 Screening, Baseline, Dispense Treatment 2	Visit 4 Treatment 2 Follow-up, Final Evaluation
Time Point	Day 0	11-14 days after V1	7-10 days after V2	11-14 days after V3
Estimated Visit Duration	2 hours	1 hour	1.5 hours	1 hour
Study Informed Consent	X			
Inclusion/Exclusion Screening Criteria	X			
Demographics	X			
Medical History & medication review	X	X	X	X
Habitual Lens Info	X			
PRO Baseline CLUE	X			
Iris color	X			
HVID	X			
Keratometry	X			
Subjective Refraction	X			
Biomicroscopy	X	X	X	X
Subject Reported Ocular Symptoms	X	X	X	X
Eligibility after baseline exam	X			
Randomization	X			
Lens Fitting #1	X			
Lens Fitting #2			X	
PRO Post Fit (CLUE)	X		X	
PRO Follow Up (CLUE)		X		X
Over refraction	X		X	
LogMAR VA	X	X	X	X
Cosmetic Lens Fit	X	X	X	X
Hula Hoop Assessment	X	X	X	X
Lens Fit Assessment	X	X	X	X
Wettability Characteristics	X	X	X	X

Visit Information	Visit 1 Screening, Baseline, Dispense Treatment 1	Visit 2 Treatment 1 Follow-up,	Visit 3 Screening, Baseline, Dispense Treatment 2	Visit 4 Treatment 2 Follow-up, Final Evaluation
Time Point	Day 0	11-14 days after V1	7-10 days after V2	11-14 days after V3
Estimated Visit Duration	2 hours	1 hour	1.5 hours	1 hour
Lens Surface Assessment	X	X	X	X
Lens Dispensing & instruction	X		X	
Adverse Event Review		X	X	X
Final Evaluation				X

7.2. Detailed Study Procedures

VISIT 1

The subjects must present to Visit 1 wearing their habitual contact lenses.

Visit 1: Screening			
Step	Procedure	Details	[redacted]
1.1	Statement of Informed Consent	Each subject must read, understand, and sign the Statement of Informed Consent before being enrolled into the study. The Principal Investigator or his/her designee conducting the informed consent discussion must also sign the consent form. **Note**: The subject must be provided a signed copy of this document.	
1.2	Demographics	Record the subject's year of birth, gender, race and ethnicity.	
1.3	Medical History and Concomitant Medications	Questions regarding the subjects' medical history and concomitant medications.	
1.4	Habitual Lenses	Questions regarding the subject's habitual lens type and parameters.	
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	[redacted]
1.6	PRO Baseline Questionnaire	The subject will respond to the PRO Baseline (CLUE) Questionnaire	Appendix A
1.7	Entrance Visual Acuity	Record the distance logMAR VA (OD, OS) to the nearest letter with their habitual contact lens correction in place under high illumination and high chart luminance. Record the distance (4 meter) ETDRS high contrast VA twice OD (HC1-HC2) and twice OS (HC3-HC4). Subjects must attempt each line after identifying the starting line until 3 or more letters are missed.	[redacted]
1.8	Remove Habitual Contact Lenses	The subject's habitual lenses will be removed and stored in their own lens case. If they forgot to bring their lens case, one will be provided to them.	
1.9	Iris Color	Record iris color in both eyes (self-reported)	
1.10	Horizontal visible iris diameter (HVID)	Measure the horizontal visible iris diameter for each eye separately using a pd stick in normal room illumination. Measure from the edge of the iris nasally to the edge of the iris temporally. Record in mm to one decimal place.	
1.11	Keratometry	Record the keratometry readings OD and OS.	[redacted]
1.12	Subjective Sphero-cylindrical Refraction	Complete subjective spherocylindrical refraction and record the resultant distance VA (OD, OS and OU) to the nearest letter. Note: The subjects contact lens powers based on the vertexed (12 mm), spherical equivalent must be between -2.00 and -7.00 D.	[redacted]
1.13	Slit Lamp Findings	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. If any of these slit lamp findings are Grade 3 or higher, the subject may not continue at this time, but may return up to one additional time to determine eligibility. If discontinued a final examination must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
1.14	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: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
1.15	Randomization	Once eligibility is confirmed, consult the randomization scheme for the correct lens code and randomization ID.	
1.16	Lens Selection	Assign the study lens based on the randomization scheme. Select the contact lens power based on the vertexed (12 mm), spherical equivalent subjective refraction.	
1.17	Lens Insertion	The Subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable. **Note 1:** Designated site staff should observe the insertion process. If it appears that the subject attempts to insert a lens that is "inside-out", they should interfere to avoid incorrect insertion. **Note 2:** If the lens moves excessively on the eye after insertion, ask the subject to remove the lens, confirm lens is not inverted (correct if it is) and reinsert.	
1.18	Lens Settling	Allow the study lenses to settle for a minimum of 5 minutes.	
1.19	Subjective Best Sphere Over Refraction	Perform subjective best sphere refraction over the study lenses with a phoropter (adopt the maximum plus to maximum VA (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the best corrected distance VA to the nearest letter (OD, OS, OU).	[redacted]
1.20	Lens Power Modification (if applicable)	Adjust the lens power if the subject's best sphere over-refraction is not plano. For each power modification, repeat steps (1.16 to 1.19). Two power modifications are allowed.	

1.21	Distance ETDRS LogMAR Visual Acuity	Per [redacted] please confirm room illuminance and chart luminance are within acceptable ranges for both high/low contrast VA testing. 1. Under high illumination and high chart luminance, record the distance (4 meter) ETDRS high contrast VA twice OD (HC1-HC2) and twice OS (HC3-HC4). 2. Under high illumination and high chart luminance, record the distance (4 meter) ETDRS low contrast VA twice OD (LC1-LC2) and twice OS (LC3-LC4). 3. With the goggles on, under normal illumination and chart luminance, record the distance (4 meter) ETDRS high contrast VA twice OD (HC5-HC6 and twice OS (HC7-HC8). Allow subject to adjust to dim condition for 3 minutes. Letter-by-letter results will be recorded into the electronic data capture form, which will calculate the visual performance score for each chart read.	[redacted]
1.22	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
1.23	Post-Fit Questionnaire	The subject will respond to the CLUE Post-Fit Questionnaire	[redacted] Appendix A
1.24	Cosmetic Lens Fit Assessment (without slit-lamp)	The Cosmetic Lens Assessment will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	Appendix D
1.25	Hula Hoop Assessment (without slit-lamp)	The Hula Hoop Assessment will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	Appendix D

1.26	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable/unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit will be any one or more of the following criteria: • Presence of limbal exposure (appearance of clear cornea) in any gaze; • Presence of edge lift; • Presence of unacceptable movement (excessive or insufficient) in <u>all three</u> of the following conditions: primary gaze, up gaze, and Josephson push up. Note: if lens fit is unacceptable subject will be discontinued from the study.	[redacted]
1.27	Wettability Characteristics	Record the white light lens wettability of both lenses.	[redacted]
1.28	Surface Deposits	Record any front and back surface lens deposits.	[redacted]
1.29	LogMAR Visual Acuity	Record the logMAR distance visual acuity (OD and OS) with the study contact lens correction in place.	[redacted]
1.30	Continuance	For the subject to continue in the study, they must meet all three of the following criteria: • logMAR VA is 0.18 or better OD and OS (high illumination/high contrast) • The lens fit is acceptable OD and OS • Investigator approval. If the Investigator does not approve the dispensing of the first study lens, then the subject should be discontinued and the final evaluations completed.	
1.31	Dispense	The lenses will be dispensed for a 11-14 day wearing period. • Subject is willing to wear the lenses for the dispensing period for 6 hours per day each day, and will not wear their habitual lenses during the dispensing period. • The lenses will be worn as daily wear only. • Subjects will be given Revitalens	

		solution, or Sponsor-approved alternative. • Rewetting drops are permitted if needed. • A patient instruction booklet will be provided. • Subjects will be scheduled for their 11-14 day follow-up visit, ensuring that they wear the study lens at least 6 hours on the day of the follow-up visit. * Note: In the event a lens is lost or damaged, the subject will return to the clinical site for replacement. As much as reasonably possible, a damaged lens and packaging should be returned to the clinical site (wet, if possible) and then returned to the Sponsor. If lens damage is present, complete the PQC Form. The lens will be stored in labeled vial with saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.	

VISIT 2

The subjects must present to Visit 2 wearing test article for at least six (6) hours on the day of the visit. They will be asked to bring their spectacles to this visit (if applicable).

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

2.6.	Distance ETDRS LogMAR Visual Acuity	Per [redacted] please confirm room illuminance and chart luminance are within acceptable ranges for both high/low contrast VA testing. 1. Under high illumination and high chart luminance, record the distance (4 meter) ETDRS high contrast VA twice OD (HC1-HC2) and twice OS (HC3-HC4). 2. Under high illumination and high chart luminance, record the distance (4 meter) ETDRS low contrast VA twice OD (LC1-LC2) and twice OS (LC3-LC4). 3. With the goggles on, under normal illumination and chart luminance, record the distance (4 meter) ETDRS high contrast VA twice OD (HC5-HC6) and twice OS (HC7-HC8). Allow subject to adjust to dim condition for 3 minutes. Letter-by-letter results will be recorded into the electronic data capture form, which will calculate the visual performance score for each chart read.	[redacted]
2.7.	Cosmetic Lens Fit Assessment (without slit-lamp)	The Cosmetic Lens Assessment will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	Appendix D
2.8.	Hula Hoop Assessment (without slit-lamp)	The Hula Hoop Assessment will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	Appendix D
2.9.	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit will be any one or more of the following criteria: • Presence of limbal exposure (appearance of clear cornea) in any gaze; • Presence of edge lift; • Presence of unacceptable movement	[redacted]

		(excessive or insufficient) in <u>all three</u> of the following conditions: primary gaze, up gaze, and Josephson push up. **<u>Note</u>**: if lens fit is unacceptable subject will be discontinued from the study.	
2.10.	Wettability Characteristics	Record the white light lens wettability of both lenses.	[redacted]
2.11.	Surface Deposits	Record any front and back surface lens deposits.	[redacted]
2.12.	Remove lenses	The lenses will be removed and discarded.	
2.13.	Exit Slit Lamp Biomicroscopy	FDA Slit Lamp Classification Scale will be complete. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
2.14.	Exit Visual Acuity	Record the distance logMAR VA (OD, OS) to the nearest letter with their habitual spectacle correction, or trial frame, in place under high illumination and high chart luminance. Record the distance (4 meter) ETDRS high contrast VA twice OD (HC1-HC2) and twice OS (HC3-HC4). Subjects must attempt each line after identifying the starting line until 3 or more letters are missed.	[redacted]
2.15	Washout	Subject will be instructed to wear their habitual contact lenses as they normally do for the 7-10 days between Visit 2 and Visit 3.	

VISIT 3

The subjects must present to Visit 3 wearing their habitual spectacles (if applicable).

Visit 3: Eligibility			
Step	Procedure	Details	[redacted]
3.1	Adverse Events and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit. Record any adverse events or medical history changes from the previous study visit.	
3.2	Entrance Visual Acuity	Record the distance logMAR VA (OD, OS) to the nearest letter with their habitual spectacle correction in place under high illumination and high chart luminance. Record the distance (4	[redacted]

		meter) ETDRS high contrast VA twice OD (HC1-HC2) and twice OS (HC3-HC4). Subjects must attempt each line after identifying the starting line until 3 or more letters are missed.	
3.3	Slit Lamp Findings	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. If any of these slit lamp findings are Grade 3 or higher, the subject may not continue at this time, but may return up to one additional time to determine eligibility. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
3.4	Confirm Eligibility	Confirm subjects is eligible to continue.	

Visit 3: Treatment 2 Lens Fitting			
Step	Procedure	Details	[redacted]
3.5	Lens Selection	Assign the study lens. Select the contact lens power based on the vertexed (12 mm), spherical equivalent subjective refraction.	
3.6	Lens Insertion	The Subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable. **Note 1:** Designated site staff should observe the insertion process. If it appears that the subject attempts to insert a lens that is "inside-out", they should interfere to avoid incorrect insertion. **Note 2:** If the lens moves excessively on the eye after insertion, ask the subject to remove the lens, confirm lens is not inverted (correct if it is) and reinsert.	
3.7	Lens Settling	Allow the study lenses to settle for a minimum of 5 minutes.	

3.8	Subjective Best Sphere Over Refraction	Perform subjective best sphere refraction over the study lenses with a phoropter (adopt the maximum plus to maximum VA (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the best corrected distance VA to the nearest letter (OD, OS, OU).	[redacted]
3.9	Lens Power Modification (if applicable)	Adjust the lens power if the subject's best sphere over-refraction is not plano. For each power modification, repeat steps (3.6 to 3.9). Two power modifications are allowed.	
3.10	Distance ETDRS LogMAR Visual Acuity	Per [redacted] please confirm room illuminance and chart luminance are within acceptable ranges for both high/low contrast VA testing. 1. Under high illumination and high chart luminance, record the distance (4 meter) ETDRS high contrast VA twice OD (HC1-HC2) and twice OS (HC3-HC4). 2. Under high illumination and high chart luminance, record the distance (4 meter) ETDRS low contrast VA twice OD (LC1-LC2) and twice OS (LC3-LC4). 3. With the goggles on, under normal illumination and chart luminance, record the distance (4 meter) ETDRS high contrast VA twice OD (HC5-HC6 and twice OS (HC7-HC8). Allow subject to adjust to dim condition for 3 minutes. Letter-by-letter results will be recorded into the electronic data capture form, which will calculate the visual performance score for each chart read.	[redacted]
3.11	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
3.12	Post-Fit Questionnaire	The subject will respond to the CLUE Post-Fit Questionnaire	[redacted] Appendix A
3.13	Cosmetic Lens Fit Assessment (without slit-lamp)	The Cosmetic Lens Assessment will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	Appendix D

3.14	Hula Hoop Assessment (without slit-lamp)	The Hula Hoop Assessment will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	Appendix D
3.15	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable/unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit will be any one or more of the following criteria: • Presence of limbal exposure (appearance of clear cornea) in any gaze; • Presence of edge lift; • Presence of unacceptable movement (excessive or insufficient) in <u>all three</u> of the following conditions: primary gaze, up gaze, and Josephson push up. Note: if lens fit is unacceptable subject will be discontinued from the study.	[redacted]
3.16	Wettability Characteristics	Record the white light lens wettability of both lenses.	[redacted]
3.17	Surface Deposits	Record any front and back surface lens deposits.	[redacted]
3.18	LogMAR Visual Acuity	Record the logMAR distance visual acuity (OD and OS) with the study contact lens correction in place.	[redacted]
3.19	Continuance	For the subject to continue in the study, they must meet all three of the following criteria: • LogMAR VA is 0.18 or better OD and OS (high illumination/high contrast) • The lens fit is acceptable OD and OS • Investigator approval. If the Investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject.	
3.20	Dispense	The lenses will be dispensed for a 11-14 day wearing period. • Subject is willing to wear the lenses for the dispensing period for 6 hours per day each day, and will not wear their habitual lenses during the dispensing period.	

		• The lenses will be worn as daily wear only. • Subjects will be given Revitalens solution, or Sponsor-approved alternative. • Rewetting drops are permitted if needed. • Subjects will be scheduled for their 11-14 day follow-up visit, ensuring that they wear the study lens at least 6 hours on the day of the follow-up visit. * Note: In the event a lens is lost or damaged, the subject will return to the clinical site for replacement. As much as reasonably possible, a damaged lens and packaging should be returned to the clinical site (wet, if possible) and then returned to the Sponsor. If lens damage is present, complete the PQC Form. The lens will be stored in labeled vial with saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.	

VISIT 4

The subjects must present to Visit 4 wearing test article for at least six (6) hours on the day of the visit. They will be asked to bring their spectacles to this visit (if applicable).

Visit 2: Treatment 1 Follow-Up			
Step	Procedure	Details	[redacted]
4.1.	Adverse Events and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit. Record any adverse events or medical history changes from the previous study visit.	
4.2.	Wearing Time	Record the average wearing time and comfortable wearing time.	
4.3.	Compliance	Confirm compliance with the prescribed wear schedule.	
4.4.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
4.5.	Follow-Up Questionnaire	The subject will respond to the CLUE Follow-Up Questionnaire	[redacted] Appendix A
4.6.	Distance ETDRS LogMAR Visual Acuity	Per [redacted] please confirm room illuminance and chart luminance are within acceptable ranges for both high/low contrast VA testing.	[redacted]

		1. Under high illumination and high chart luminance, record the distance (4 meter) ETDRS high contrast VA twice OD (HC1-HC2) and twice OS (HC3-HC4). 2. Under high illumination and high chart luminance, record the distance (4 meter) ETDRS low contrast VA twice OD (LC1-LC2) and twice OS (LC3-LC4). 3. With the goggles on, under normal illumination and chart luminance, record the distance (4 meter) ETDRS high contrast VA twice OD (HC5-HC26 and twice OS (HC7-HC8). Allow subject to adjust to dim condition for 3 minutes. Letter-by-letter results will be recorded into the electronic data capture form, which will calculate the visual performance score for each chart read.	
4.7.	Cosmetic Lens Fit Assessment (without slit-lamp)	The Cosmetic Lens Assessment will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	Appendix D
4.8.	Hula Hoop Assessment (without slit-lamp)	The Hula Hoop Assessment will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	Appendix D
4.9.	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit will be any one or more of the following criteria: • Presence of limbal exposure (appearance of clear cornea) in any gaze; • Presence of edge lift; • Presence of unacceptable movement (excessive or insufficient) in <u>all three</u> of the following conditions: primary gaze, up gaze, and Josephson push up. **<u>Note</u>**: if lens fit is unacceptable subject will be discontinued from the study.	[redacted]

4.10.	Wettability Characteristics	Record the white light lens wettability of both lenses.	[redacted]
4.11.	Surface Deposits	Record any front and back surface lens deposits.	[redacted]
4.12.	Remove lenses	The lenses will be removed and discarded.	

FINAL EVALUATION

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

Final Evaluation			
Step	Procedure	Details	[redacted]
F.1	Final Exam Form	Indicate if the subject completed the study successfully. If subject discontinued from the study, indicate the reason.	
F.2	Exit Slit Lamp Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
F.3	Exit Visual Acuity	Record the distance logMAR VA (OD, OS) to the nearest letter with their habitual spectacle correction, or trial frame, in place under high illumination and high chart luminance. Record the distance (4 meter) ETDRS high contrast VA twice OD (HC1-HC2) and twice OS (HC3-HC4). Subjects must attempt each line after identifying the starting line until 3 or more letters are missed.	[redacted]

7.3. Unscheduled Visits

If, during the investigation, a subject requires an unscheduled visit to the clinical site, the following information will be collected 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 ie, beyond licensure is required, the subject will be referred to the appropriate health care provider.

The following information may be collected during an unscheduled visit.

Unscheduled Visit			
Step	Procedure	Details	[redacted]
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 logMAR distance visual acuity (OD and OS) with the subject's habitual spectacle correction, trial frame or unaided.	[redacted]
U.4	Subjective Sphero-cylindrical Refraction	Perform bare-eye subjective spherocylindrical refraction with a phoropter (adopt the maximum plus to maximum VA (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the best corrected distance VA to the nearest letter (OD, OS, and OU).	[redacted]
U.5	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.	[redacted]
U.6	Dispensing (if applicable)	Additional lenses may be dispensed.	
U.7	Exit Visual Acuity	Record the subject's exit distance VA (OD, OS, and OU) to the nearest letter.	[redacted]

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 and/or assent;
- they are eligible;
- Completed all three phases of testing;
- 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 protocol
- Subject lost to follow-up
- Subject no longer meets eligibility criteria (eg 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)

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 VA
- 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: Not applicable.
Concomitant therapies that are disallowed include: Not applicable.

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

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 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 PQCs:

- 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 (ie, tears, rips, etc.), only in situations where there is no deficiency alleged by the subject

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

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

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

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

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

13. ADVERSE EVENTS

13.1. Definitions and Classifications

Adverse Event (AE) – An AE is "any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device.
Note 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."[1]

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

1. Was not present prior to the study, but appeared or reappeared following initiation of the study
2. Was present prior to the study, but worsened during the study. This would include any condition resulting from concomitant illnesses, reactions to concomitant medications, or progression of disease states
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 VA equivalent to 2 acuity lines or greater
- Central Corneal Opacity
- Central Corneal Neovascularization

- Uveitis
- Endophthalmitis
- Hypopyon
- Hyphemia
- Penetration of Bowman's Membrane
- Persistent Epithelial Defect
- Limbal cell Damage leading to Conjunctivalization

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

Diagnoses and conditions that are considered 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."[1]

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 (IB) 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 – ie, 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, possible requiring additional therapy, and may interfere with the subject's daily activities
- Severe – Event is intolerable, necessitates additional therapy or alteration of therapy and interferes with the subject's daily activities

13.3. Documentation and Follow-Up of Adverse Events

The recording and documenting of adverse events (ocular and non-ocular) 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 VA 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 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 the written guidelines, including reporting timelines.

13.4.3. Event of Special Interest

Not applicable.

13.5. Reporting of Pregnancy

Subjects reporting pregnancy (by self-report) during the study will be discontinued after the event is recorded as an Adverse Event. Once discontinued, pregnant participants and their fetuses will not be monitored for study related purposes. 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 VA 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 study biostatistician. 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 (SAS Institute, Cary, NC). Throughout the analysis of data, the results for each subject/eye will be used when available for summarization. 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.

Further exploratory analysis can be undertaken, if necessary, at the discretion of the clinical project leader.

14.2. Sample Size Justification

This pilot study is not powered to test for any planned hypotheses. Hence, the sample size was chosen based on availability of time and resources. Targeting 20 subjects to complete the study will be sufficient to evaluate descriptive summaries of study endpoints.

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

Not applicable.

14.5. Primary Analysis

The primary endpoint will be descriptively summarized by lens type.

14.6. Secondary Analysis

Not applicable.

14.7. Other Exploratory Analyses

All observations will be descriptively summarized by lens type.

14.8. Interim Analysis

Not applicable.

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 Express 5.5). 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.[1]

15.2. Subject Record

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

- subject identification
- eligibility
- study identification
- study discussion
- provision of and date of informed consent
- visit dates
- results of safety and efficacy parameters as required by the protocol
- a record of all adverse events
- follow-up of adverse events
- medical history and concomitant medication
- test article receipt/dispensing/return records
- date of study completion
- reason for early discontinuation of test article or withdrawal from the study, if applicable

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

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

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),[2] and applicable regulatory requirements. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles of the Declaration of Helsinki 64th WMA General Assembly 2013[3] and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with Section 8 of the ICH E6 guidelines on Good Clinical Practice (GCP),[2] and applicable regulatory requirements.

18.3. Independent Ethics Committee or Institutional Review Board (IEC/IRB)

Before the start of the study, the Investigator (or Sponsor when applicable) will provide the IEC/IRB with current and complete copies of the following documents (where applicable):

- Final protocol 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,[3] current ICH[2] and ISO 14155[1] guidelines, applicable regulatory requirements, and Sponsor Policy.

Before entry into the study, the Investigator or an authorized member of the clinical site personnel must explain to potential subject the aims, methods, reasonably anticipated benefits, and potential hazards of the study, and any discomfort it may entail. Subjects will be informed that their participation is voluntary and that they may withdraw consent to participate at any time.

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

18.5. Privacy of Personal Data

The collection, processing and disclosure of personal data and medical information related to the Study Subject, and personal data related to Principal Investigator and any clinical site personnel (e.g., name, clinic address and phone number, curriculum vitae) is subject to compliance with the Health Information Portability and Accountability Act (HIPAA) in the United States[5] and other applicable personal data protection and security laws and regulations. Appropriate measures will be employed to safeguard these data, to maintain the confidentiality of the person's related health and medical information, to properly inform the concerned persons about the collection and processing of their personal data, to grant them reasonable access to their personal data and to prevent access by unauthorized persons.

All information obtained during the course of the investigation will be regarded as confidential. All personal data gathered in this trial will be treated in strictest confidence by Investigators, monitors, Sponsor's personnel and IEC/IRB. No data will be disclosed to any third party without the express permission of the subject concerned, with the exception of Sponsor personnel (monitor, auditor), IEC/IRB and regulatory organizations in the context of their investigation related activities that, as part of the investigation will have access to the CRFs and subject records.

The collection and processing of personal data from subjects enrolled in this study will be limited to those data that are necessary to investigate the efficacy, safety, quality, and utility of the investigational product(s) used in this study.

These data must be collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data privacy protection laws and regulations. The Sponsor ensures that the personal data will be:

- processed fairly and lawfully
- collected for specified, explicit, and legitimate purposes and not further processed in a way incompatible with these purposes
- adequate, relevant, and not excessive in relation to said purposes
- accurate and, where necessary, kept current

Explicit consent for the processing of personal data will be obtained from the participating subject before collection of data. Such consent should also address the transfer of the data to other entities and to other countries.

The subject has the right to request through the Investigator access to his personal data and the right to request rectification of any data that are not correct or complete. Reasonable steps should be taken to respond to such a request, taking into consideration the nature of the request, the conditions of the study, and the applicable laws and regulations.

Appropriate technical and organizational measures to protect the personal data against unauthorized disclosures or access, accidental or unlawful destruction, or accidental loss or alteration must be put in place. Sponsor personnel whose responsibilities require access to personal data agree to keep the identity of study subjects confidential.

19. STUDY RECORD RETENTION

In compliance with the ICH/GCP guidelines,[2] the Investigator/Institution will maintain all CRFs and all subject records that support the data collected from each subject, as well as all study documents as specified in ICH/GCP[2] and all study documents as specified by the applicable regulatory requirement(s). The Investigator/Institution will take measures to prevent accidental or premature destruction of these documents.

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

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

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

20. FINANCIAL CONSIDERATIONS

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

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

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

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

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

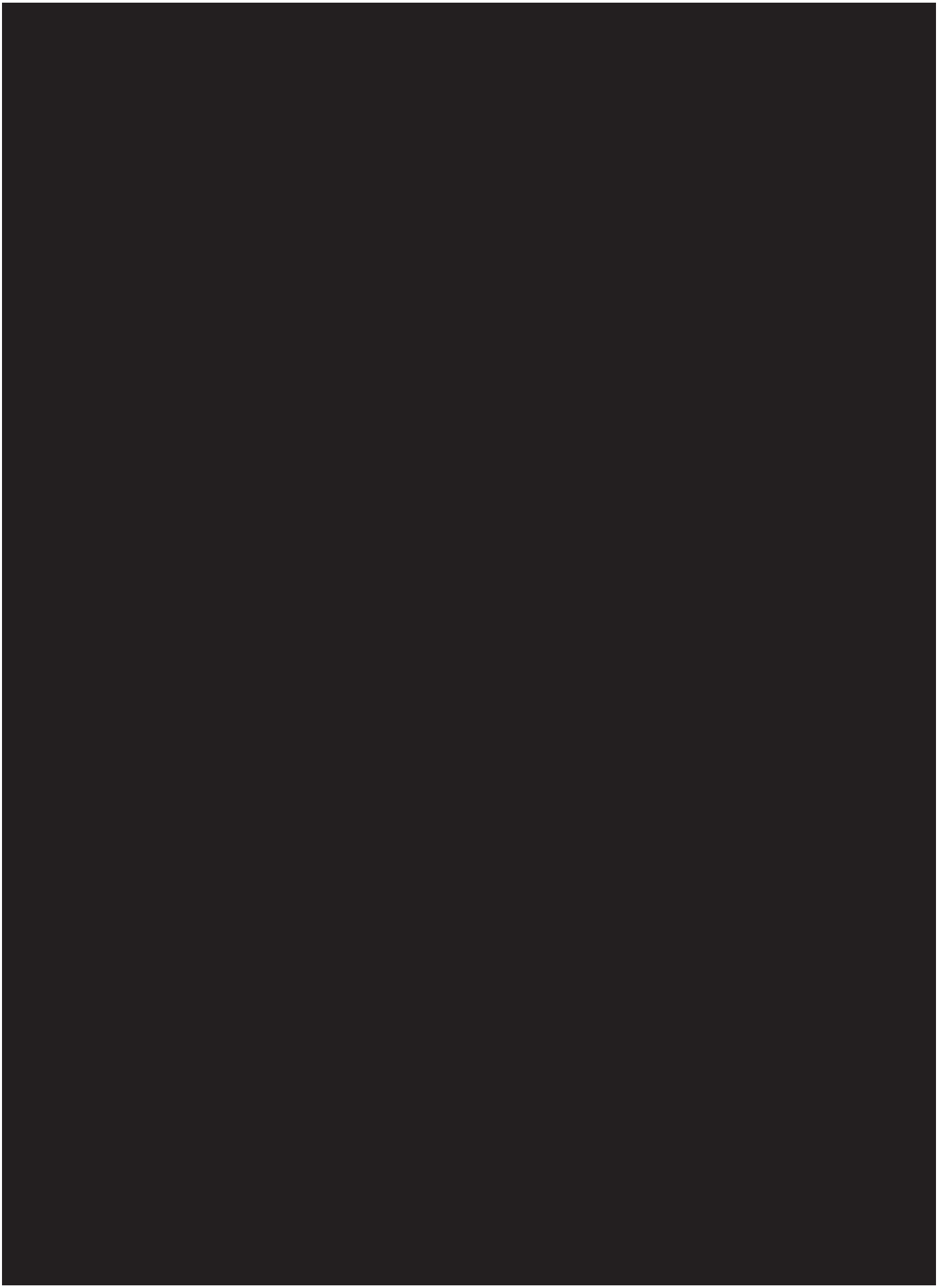
21. PUBLICATION

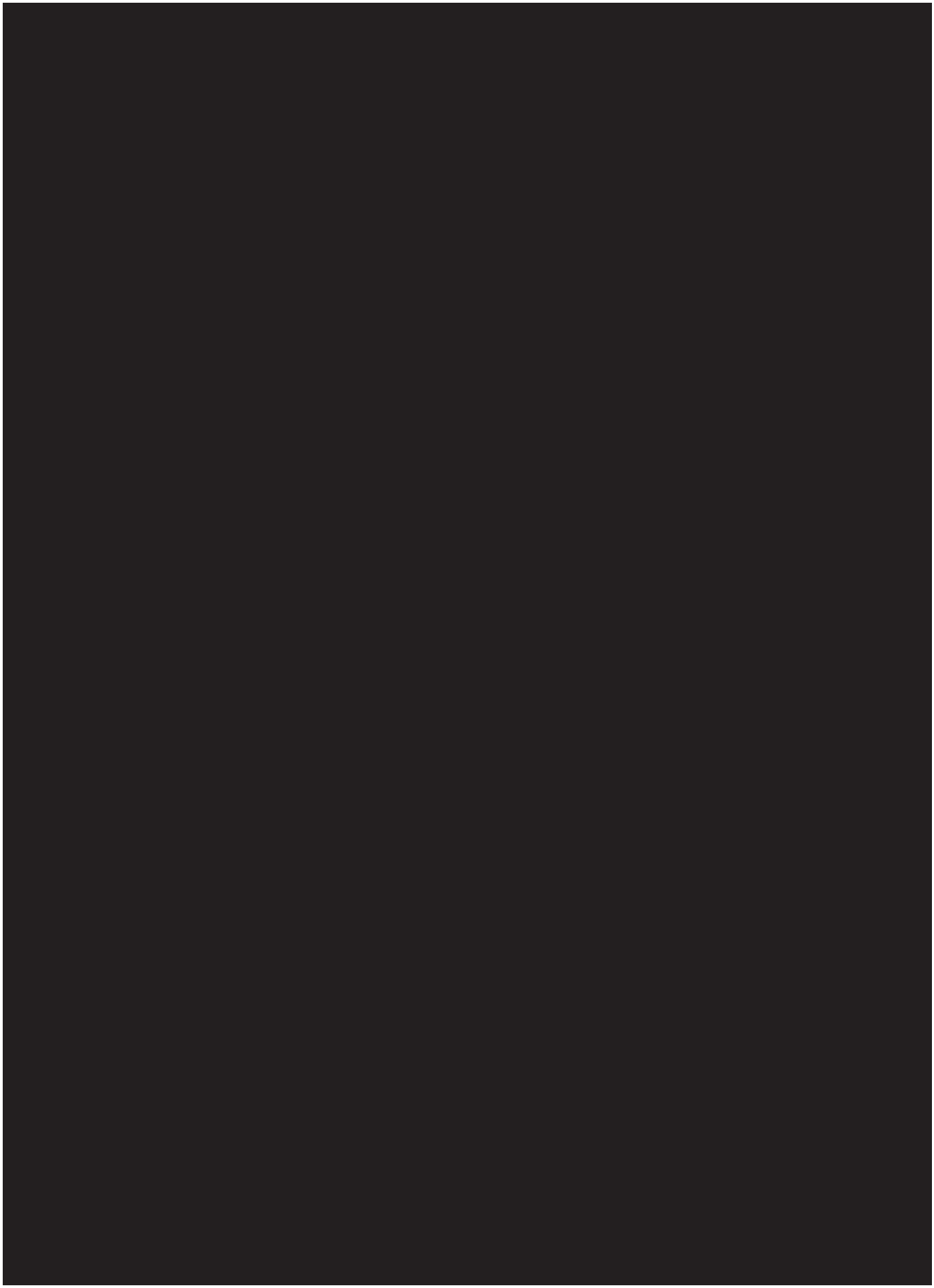
This study will be registered on ClinicalTrials.gov by the Sponsor.

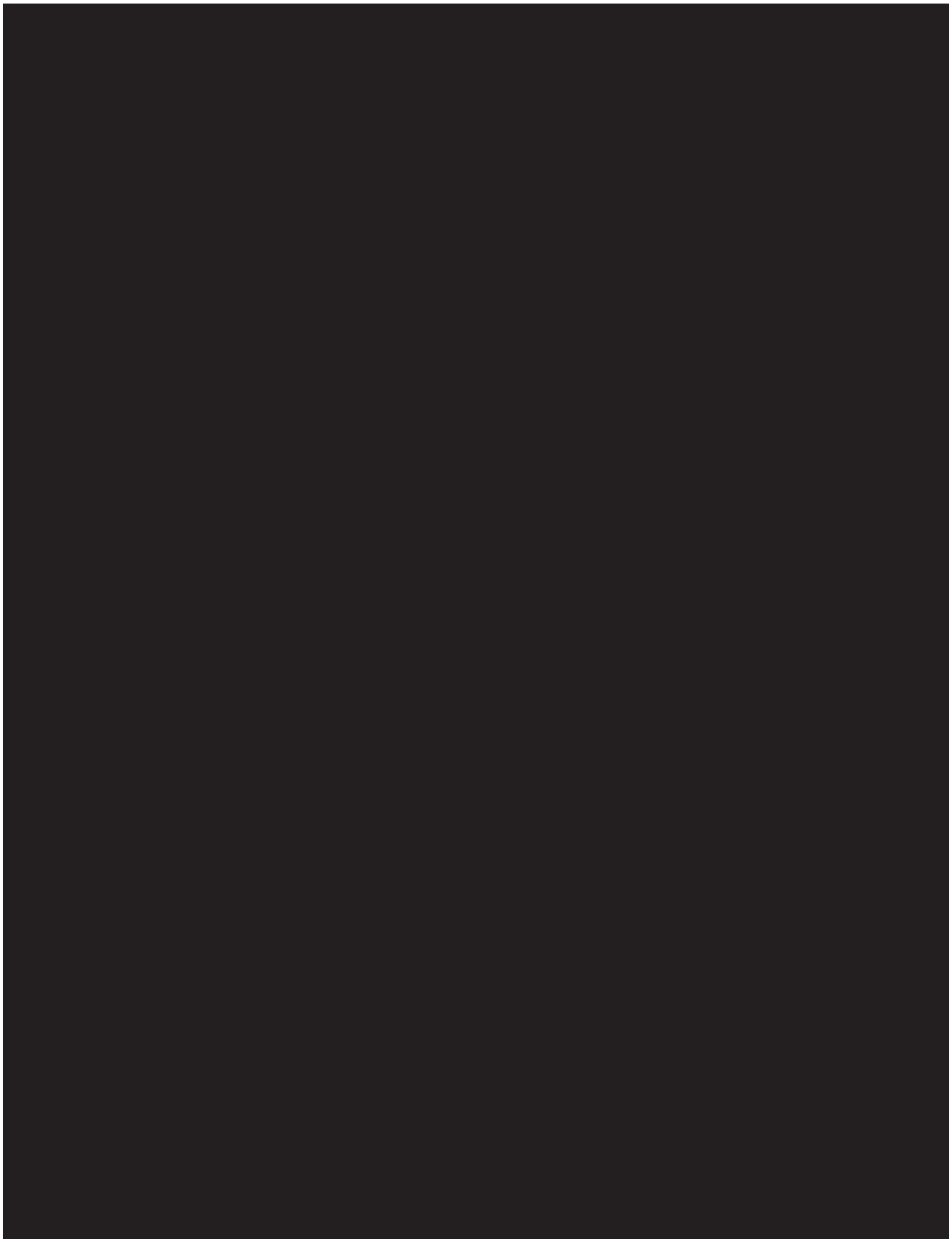
22. REFERENCES

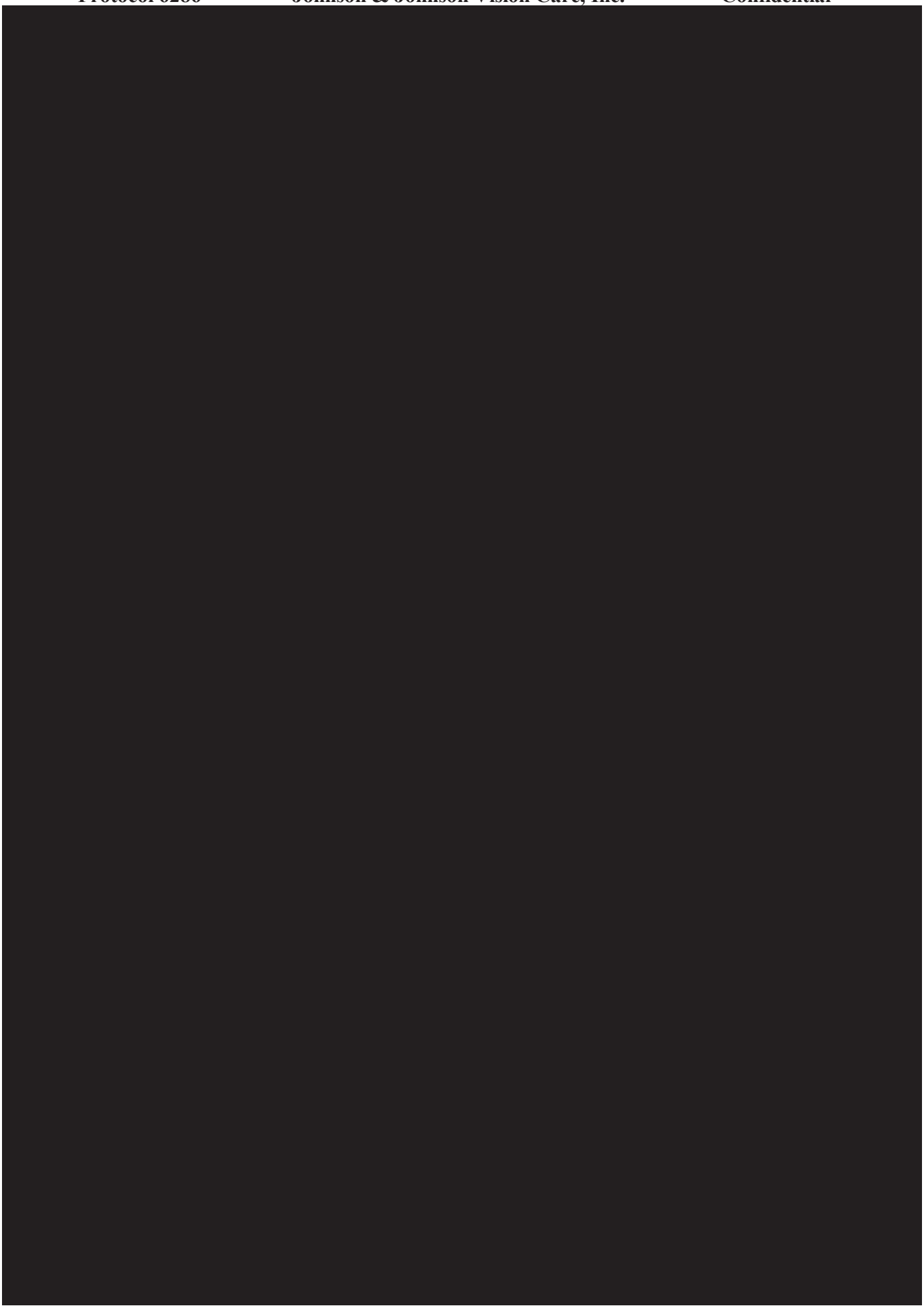
1. ISO 14155:2011: Clinical Investigation of Medical Devices for Human Subjects — Good Clinical Practice. Available at: https://www.iso.org/standard/45557.html
2. International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP). Available at: http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
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

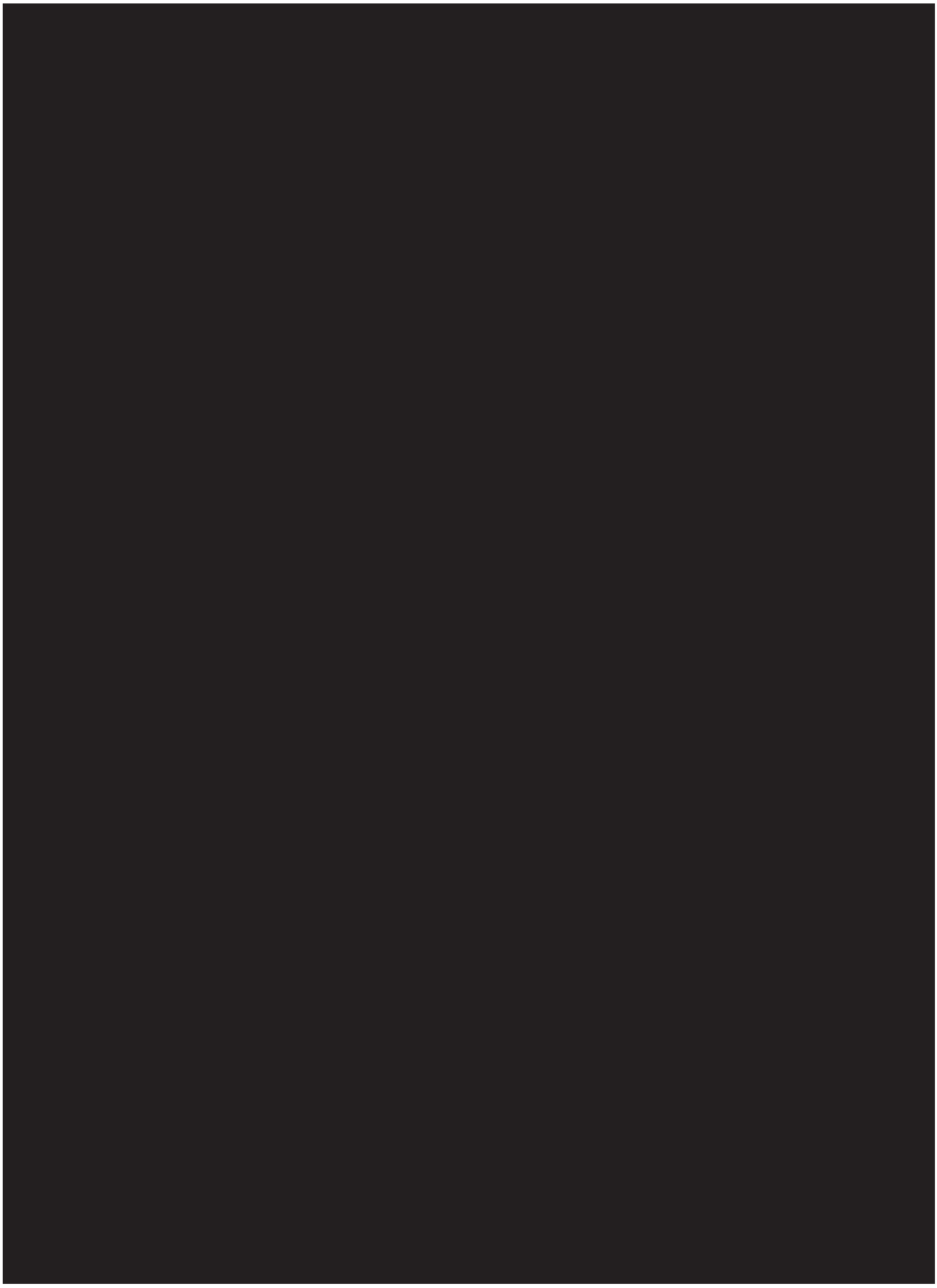
APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)











APPENDIX B: PATIENT INSTRUCTION GUIDE

Patient Instruction Guide (PIG) will be provided separately.

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

ACUVUE® 2 DEFINE™ Vivid Style & LACELLE™ Sparkling Brown

软性角膜接触镜(商品名：美瞳两周)

使用说明书

【注册号】国食药监械（进）字2014第3224697号
【产品名称】软性角膜接触镜
【商品名称】美瞳两周
【英文名称】ACUVUE® 2 DEFINE™ Brand Contact Lenses
【型号、规格】无
【说明书批准及修改日期】20140930修1-20161101

【警示】

- **本产品直接接触角膜，若不遵守使用方法或相关注意事项，则可能造成多种眼疾，甚至失明。使用前请务必认真阅读本说明书，遵从医嘱，按照正确的使用方法使用。**
- **建议经眼科医生检查评估后，再决定是否配戴本产品。配戴本产品，应由眼视光专业人士进行验配。**
- **由于配戴本品可使配戴者发生角、结膜损害危险性增高，甚至出现角膜炎、角膜溃疡等眼部疾病，因此当出现眼分泌物增加、眼红、眼痛、畏光、异物感、流泪、视力下降等异常现象时，应立刻中止配戴，并尽快去医院接受眼科医师的检查，延误治疗可能会发生永久性视力损害。**
- **即使正确使用本产品，由于存在个体差异仍可能产生如角膜内皮细胞减少、角膜新生血管形成等改变。**
- **平光装饰性镜片，不具矫正屈光不正功能，但与矫正功能镜片具有同样的风险，应谨慎使用。**
- **严格按【配戴时间表】配戴。日戴镜片不能用于睡眠配戴。临床已经证明：日戴镜片睡眠配戴，发生严重不良事件的危险性将大幅提高。**
- **初次戴镜者应在配镜后第1天、第1周、第1月、第3月定期到医院复查，随后即使无任何不适亦建议定期(或遵医嘱)去医院进行眼部检查。**
- **已灭菌，开封前确认包装是否破损。如包装破损，请勿使用本产品。**
- **配戴者必须遵循眼视光专业人员的指导及产品使用说明，使用已取得医疗器械注册证的软性角膜接触镜护理产品。禁用洗涤液、肥皂等其他代用品清洁镜片，禁用酒精等其他代用品消毒镜片。**
- **本品属于医疗器械，购买使用前请确认产品标签上是否印有医疗器械注册号。**
- **防紫外线软性角膜接触镜并不能替代紫外线防护镜和太阳眼镜，因为软性角膜接触镜并不完全遮盖眼部及周围组织，所以建议您仍应该坚持使用紫外线护具。**

【禁忌】

- 患有各种眼部疾患：如眼部急性或慢性炎症、青光眼、角膜知觉异常、角膜上皮缺损、角膜内皮细胞减少、干眼症等，经眼视光专业人员判断不能配戴。
- 患有可能影响眼部的全身性疾病，经眼视光专业人员判断不能配戴。
- 有接触镜过敏史或接触镜护理产品过敏史。
- 生活或工作环境不适宜配戴软性角膜接触镜,例如空气中弥散粉尘、药品、气雾剂（如发胶、挥发性化学物）、灰尘等。
- 不能按要求使用软性角膜接触镜者。
- 不能定期进行眼部检查者。
- 个人卫生条件不具备配戴软性角膜接触镜所必需的卫生条件者。

【适用范围】
用于矫正有晶体和无晶体的无疾病眼的屈光不正（近视和远视）,1.00D以下散光患者配戴不影响视敏度，可增强或改变虹膜颜色。请根据专业人士的建议定期更换您的镜片。该产品适用于日戴，更换周期为2周。

【注意事项】

- 镜片置于指尖，观察侧面，如果镜片呈自然的弯曲的碗形，则为正面。如果镜片的边缘外翻，则为反面。另一种区别方法是用食指和拇指轻挤镜片，边缘应当往内翻，如果镜片反了，边缘会轻度外翻。
- 初次配戴软性角膜接触镜在最初的1～2周内可能有轻微的镜片移动感或不适感，一般可以自行消失。如果异物感较为明显，或者出现视物模糊、眼红、畏光、流泪等刺激症状则应及时摘下镜片寻找原因。
  导致上述问题的可能原因有：
  ①镜片未居眼角膜中央；②镜片污浊破损；③左右戴反；④其他原因。若症状持续，应及时去医院接受眼科医师检查。
- 本产品严禁加热或冰冻。
- 戴镜期间如需使用药品尤其是滴眼液，须咨询医生。
- 如处于孕期、哺乳期或近期计划怀孕者请慎用，并须咨询医生。
- 如有角膜塑形镜配戴史，配戴软性角膜接触镜前请咨询医生。
- 配戴软性角膜接触镜进行洗浴、游泳及冲浪等水上或潜水活动时，软性角膜接触镜有可能脱落，同时眼部感染的风险可能增高，因此不建议配戴。或如有必要，建议选择使用日抛型软性角膜接触镜。
- 在患病期间如感冒、发热和过度疲劳等情况下，谨慎配戴软性角膜接触镜。
- 请先戴上镜片后再上妆，先取下镜片后再卸妆。
- 如配戴软性角膜接触镜时使用定型水、香水等喷雾剂，请小心使用并且紧闭双眼至烟雾消失,避免进入眼内。
- 请完全适应配戴软性角膜接触镜后再从事机动车驾驶等操作。
- 不得与他人共用镜片。
- 放置于远离儿童可触及的地方。
- 镜片未配戴时，务必始终将镜片完全浸润在推荐的保存液中。长时间处于干燥状态会降低镜面恢复可湿状态的能力。如果镜片从眼内取出并在空气中暴露较长时间，其表面将变得干燥并会逐渐脱水。这时，应该将镜片丢弃，换用新镜片。
- 在配戴期间请勿从事剧烈的碰撞性及身体对抗性运动。

【配戴时间表】
日戴。初次配戴软性角膜接触镜可能会有不同程度的异物感，参照以下时间表进行配戴，可以使眼睛逐步适应软性角膜接触镜。

配镜的天数	每天戴镜的小时
第一天	6-8 小时
第二天	8-10 小时
第三天	10-12小时
第四天及以后	不超过12小时

- 遵守配戴时间。初戴或长时间停戴后再戴者，从每天戴6-8小时开始，每天增加2小时。日戴镜片勿戴镜睡眠。建议一次配戴最长不超过12小时。配戴时间因人而异，不要超时配戴。
- 如果一天之中间歇配戴，建议一天累计配戴时间不超过12个小时。
- 镜片实际使用寿命建议遵照眼科医生建议。

【性能结构及组成】
该产品为球面单焦设计，镜片材料为etafilcon A水凝胶，铝箔盖塑料包装，镜片可着棕褐色、黑灰色、黑绿色；含水量：59±2%，折射率：1.400，透氧系数：21.4×10^{-11} (cm²/s)[mLO_2/(mL x mmHg))]（Fatt 边缘矫正，35° C）；
透氧量：25.5×10^{-9}(cm/s)[mLO_2/(mL x mmHg)]（- 3.00 D），对可见光谱（380nm～780nm）透射率应为不小于90%，具有紫外线防护功能，对UV-B段（280nm～315nm）光谱透射率平均应<5%；对UV-A段（316nm ～380nm）光谱透射率平均应<30%。
镜片中心厚度见【后顶焦度与中心厚度对比表】。

【包装内部件】
无菌包装使用铝箔封塑料包装（PP杯），内含一片镜片。

【护理液使用注意事项】
使用适用于软性角膜接触镜的护理液。

- 请严格按照不同类型护理液的说明书使用，使用顺序不得颠倒，不同的护理液不得混合或者替代使用。
- 护理液须在货架有效期及开瓶有效期内使用，过期后必须丢弃。
- 手指、镜片或镜片盒等外界污物勿触及瓶口。打开瓶盖后，瓶盖内口向上放置。
- 常温、避光、干燥环境下保存。
- 护理液在正常使用期间发生混浊，或者使用过程中出现眼部不适，例如眼红、流泪等应立即停止使用，并须咨询医生。
- 已经接触过镜片的护理液需抛弃禁止重复使用。

A2D-PIG-012017

【镜片配戴、摘取方法】

1.注意：

- 不要过度用力揉捏、摩擦镜片，以免损坏镜片；
- 应严格依照规定的程序和要求清洁、去蛋白、冲洗、消毒、储存和配戴镜片,各步骤间不能相互替代；
- 镜片在配戴前必须用专用的具有消毒功能的护理液浸泡，具体浸泡时间请参照护理液说明书；
- 镜片较长时间保存未戴，必须重新清洗消毒后方能配戴，请参照护理液说明书操作。

2.准备阶段

- 配戴方法要接受专业人员的具体指导。
- 在每次触摸镜片前，都要用中性肥皂和流动的水充分洗手。
- 保持指甲短而修剪齐整，在软性角膜接触镜配戴、取出及护理的过程中勿使指甲接触镜片。
- 在干净、平整的桌面上护理或摘戴镜片，以免脱落在地上或遗失。
- 养成习惯，始终首先拿取、摘戴同一只镜片以免混淆，建议按先右后左顺序。
- 养成习惯，每次配戴前都要检查镜片外观是否符合要求，确认其湿润、清洁。镜片有斑点、残留杂物、气泡、裂纹、破损等外观出现异常情况时均不得使用。

3.镜片配戴步骤

- 配戴前双手须保持清洁和干燥，将镜片内曲面向上托在指端。
- 认准正反面。
- 用食指或中指按住配戴眼上眼皮边缘，将眼皮向上充分撑开，并按在眉弓上加以固定。用另一手的手指按住配戴眼下眼皮边缘，将下眼皮向下充分撑开。
- 将镜片轻柔地放置在配戴眼暴露的角膜（黑眼球）中央部。
- 轻轻眨眼数次，用纸巾拭去溢出眼外的液体（如有）。按上述方法先右后左依次配戴。在戴镜过程中，若镜片被挤出睑裂或掉落在桌面上，须重新用护理液清洁消毒处理后再戴。

4.镜片摘取步骤：

- 按本节第2条做好准备；
- 如同戴镜时的方法，充分撑开配戴眼的眼皮；
- 用拇指和食指指腹轻捏镜片下部，轻轻摘下镜片。

【后顶焦度与中心厚度对比表】

后顶焦度 (单位:D)	中心厚度标称值 (保留2位小数) （单位:mm）	中心厚度标称值 (出厂3位小数对照) （单位:mm）
0.00D	0.12	0.121
-0.25 to -1.25D	0.12	0.124
-1.50 to -1.75D	0.11	0.114
-2.00 to -2.25D	0.10	0.104
-2.50 to -2.75D	0.09	0.094
-3.00 to -9.00D	0.08	0.084
+0.50D	0.12	0.121
+1.00D	0.13	0.131

【镜片护理与存放】

- 在镜片盒内事先注入2/3容量具消毒贮存功能的护理液。
- 将摘下的镜片放置于手掌心，滴2～3滴推荐的具清洁功能护理液。
- 用食指将镜片的正面和反面轻轻揉搓数次。
- 用推荐的具冲洗功能护理液充分地冲洗镜片。冲洗过程中避免护理液瓶口与软性角膜接触镜接触。
- 将冲洗后的镜片，分别放入各自的镜片盒内，使用具有消毒功能的护理液浸泡，浸泡时间参照护理液说明书。
- 镜片长期不用时，须经严格清洁、冲洗、消毒，并储存在具保存功能的护理液中，需参照护理液说明书定期更换储存液。再次配戴前须按护理液说明书的要求，充分地清洁、冲洗，并浸泡消毒。
- 清洁、去蛋白、冲洗、消毒各步骤不能相互替代。
- 去蛋白酶片（液）清洗能够帮助除去镜片上的蛋白质沉积物。具有去蛋白功能的多功能护理液不能代替去蛋白酶片（液），去蛋白酶片（液）的使用也不能替代常规的清洁和消毒。一般建议每周使用去蛋白酶片（液）处理镜片一次，应认真按照去蛋白酶片（液）说明书进行操作。

【镜片盒的清洁】

- 镜片盒是微生物污染的重要来源。为了防止眼部感染，应每日使用后对镜片盒进行清洁、冲洗、风干。
- 每周用清洁的专用刷将镜片盒的内外按照镜片盒厂家或眼视光专业人士的建议进行清洗并风干，保持镜片盒清洁卫生。
- 应按照镜片盒生产商或眼视光专业人员推荐的时间定期更换镜片盒。

【紧急事件处理】

- 如果镜片粘附（停止活动）或无法取下，应直接滴数滴推荐的润眼液至眼内，待镜片能够在眼表面自由活动后将其取出。如果镜片仍不能取出，应立即到医院就诊。
- 任何类型的化学物质（家用产品、各种溶液、实验室化学物质等）如溅入眼内，应用大量自来水冲洗眼睛，取下镜片，立即到医院就诊。
- 外界环境中的灰尘微粒进入眼内可能引起眼部不适，此时不得揉眼，可滴用润眼液，取出镜片后彻底清洗。如果不适感仍未消失，应立即到医院就诊。
- 如果在配戴过程中镜片移位，可以对照镜子寻找移位的镜片，首先往镜片所在位置的相反方向看，用手指将移位镜片旁的眼皮固定，间接将镜片固定，但不要压住移位的镜片，慢慢往镜片方向看，这样移位的镜片可以重新回到角膜中央。如果上述方法不能使镜片复位，可将镜片取出后重新配戴。

【储存条件、有效期】
避免高温。失效日期及批号见标签。请在无菌包装（或外盒）所示的失效日期前使用。

【图形、符号解释】

符号	定义
	请参阅说明书使用
	制造商或产地
	生产日期
	失效日期
LOT	批号
STERILE	使用蒸汽或干热灭菌
DIA	总直径
BC	基弧半径
D	屈光度
CE	质量体系认证
	防紫外线
	废弃物管理费用
	小心：美国联邦法律规定该器械只能由执业医师或经执业医师允许才能出售。

【执行标准】
YZB/USA 5017-2014《软性角膜接触镜（商品名：美瞳两周）》

【生产企业】
企业名称：Johnson & Johnson Vision Care Inc.
住所：7500 Centurion Parkway Jacksonville, Florida, 32256 USA
生产地址：7500 Centurion Parkway Jacksonville, Florida, 32256 USA
The National Technology Park, Limerick, Ireland
邮政编码：32256
电话号码：001-800-843-2020
传真号码：001-904-443-3442
网　址：www.acuvue.com

【代理人】
企业名称：强生视力健商贸（上海）有限公司
住所及经营地址：上海市闵行区南雅路185号3幢1层B区
经营许可证编号：沪闵食药监械经营许20150142号
邮政编码：200245
消费者服务热线：400-882-3636
经销商服务热线：400-881-7272
传真号码：400-881-7272
网　址：www.acuvue.com.cn

【售后服务机构】
企业名称：强生视力健商贸（上海）有限公司
住所及经营地址：上海市闵行区南雅路185号3幢1层B区
经营许可证编号：沪闵食药监械经营许20150142号
邮政编码：200245
消费者服务热线：400-882-3636
经销商服务热线：400-881-7272
传真号码：400-881-7272
网　址：www.acuvue.com.cn

A2D-PIG-012017

博士伦® BAUSCH+LOMB®

蕾丝炫眸™ LACELLE™ COLORS

博士伦®蕾丝炫眸™

软性亲水接触镜 使用说明书

致配戴者：很高兴您能选择我公司的软性亲水接触镜（以下简称镜片。请您在配戴之前仔细阅读，并按照眼科医生或专业验配师的指导下使用镜片。）

主要结构、性能》产品名称：软性亲水接触镜（无商品名）Ticon Cosmetic Daily Disposable Soft Lens产品型号：彩色日抛Cosmetic Daily Disposable 配戴方式：日戴型，最长配戴时间不超过12名称：Hefilcon A 透氧系数：$11\times10^{-11}cm^2/s\times[mlO_2/(ml\times mmHg)]$等效于$8.3\times10^{-11}(cm^2/s)\times[mlO_2/$ 透氧量：$11\times10^{-9}cm/s\times[mlO_2/(ml\times mmHg)]$或等效于$8.3\times10^{-9}(cm/s)\times[mlO_2/(ml\times hPa)]$ 0mm 基弧半径：8.6mm 含水量：42% 折射率：1.432 后顶焦度范围：0.00D至-12.00D。 .00D为0.13mm；-0.25D至-12.00D为0.10mm 镜片颜色：蓝色、棕色、紫色、灰色、绿色、色 内圈：褐色、橙色 虹彩范围：蓝色、棕色、紫色、灰色、绿色、水兰色、褐色。 注：单色只有虹彩颜色、双色为外圈及虹彩颜色、三色为内、外圈及虹彩颜色。

外线。 有效期：五年。 使用周期：一日。灭菌方法：高温灭菌。 贮存：镜片应贮存于干燥、、无腐蚀气体的室内。室内温度控制在-10℃至40℃。保存液类型：氯化钠、硼酸钠、硼酸及纯水调配。

提示：本产品具备抗UV功能，给保护眼睛多一层保障。可以吸收紫外线的软性亲水接触镜并不可以替代其它必备的防紫外眼部护具（如护目镜或太阳眼镜），因为软性亲水接触镜无法完全遮盖眼睛。

《适用范围》镜片用于因屈光不正患者（无禁忌症、18岁以上）近视的视力矫正。

《配戴与摘取》准备工作：1、健康检查：配戴前，请眼科医生或专业验光师仔细检查眼睛的健康情况。

2、修剪指甲：配戴前修剪指甲，磨光甲缘，以免损伤眼睛和镜片。 3、卫生条件：保持配戴环境清洁卫生，并在操作之前用流动的水和中性肥皂彻底洗净双手，用清洁无絮的毛巾擦干或用干手器烘干。4、检查镜片：配戴前先检查镜片是否清洁、柔软、湿润，如镜片破损则不可使用。

如何区分镜片正反面：

1、观察法：将镜片置于手指前端，举至于眼睛水平高度，从侧面观察镜片。如果是正面，镜片侧面将呈碗状半圆形；如果是反面，镜片边缘将向外弯曲，整体呈碟形。2、挤压法：用拇指及食指轻轻挤捏镜片一侧边缘，如果是正面，镜片其余边缘部分应向内卷曲；如果是反面，则其余边缘部分向外翻开。

戴镜方式：1、洗净双手后取出镜片，将镜片置于食指指尖。2、用双手中指拉开上下眼睑，双眼平视前方或注视偏下方，将镜片轻轻贴于眼球正中。3、移开食指，转动眼球以确定镜片附着于角膜上，双手中指放松上下眼睑，轻轻眨动双眼，镜片将自然定位。

摘镜方式：1、洗净双手，眼睛平视前方或稍向上看，用双手中指拉开上下眼睑。2、用右手拇指和食指指腹轻轻挤捏镜片下边缘，使镜片拱起后将镜片取出。

初次配戴者须知

1、初次配戴隐形眼镜，为使眼睛逐渐适应，请参照右表的时间进行配戴。

开始戴镜天数	1	2	3	4	5	6
戴用时间(小时)	4	6	8	10	12	12

2、请在连续配镜1周、1个月、3个月、半年及一年时回原配镜处定期复查，或到眼科医生或专业验光师处进行复查。

《禁忌症、注意事项、警示及提示性说明》1、患有隐形眼镜禁忌症，或工作、生活环境有酸、碱性挥发物质及严重污染者请勿使用。2、如有化妆需要，请先戴上镜片再化妆，先摘下镜片再卸妆。3、眼部感觉干涩不适时，可滴数滴专用润滑液，但切勿在戴镜同时滴用眼药水，以免缩短镜片使用寿命。4、戴镜时请勿大力揉搓眼睛，以免镜片偏位或脱落。5、建议洗脸时不要戴镜，因环境不允许摘镜则请紧闭眼睛，以免镜片被水冲掉或污染镜片。严禁洗澡及游泳时戴镜。6、为保持眼睛健康，建议软性亲水接触镜与框架眼镜交替使用，切勿配戴镜片过夜睡眠。7、如风沙入眼，请摘掉镜片并使用新鲜护理液冲洗干净后再配戴，切勿混杂沙尘颗粒揉搓镜片。8、为确保镜片质量，请在使用中注意避免以下现象的发生：指甲过长或边缘有毛刺、使用无保护套的尖头镜镊夹持镜片。9、当发现镜片破损或包装破损时，请更换镜片。10、如在戴镜过程中发生眼部不适症状，请立刻到眼科医生或专业验光师处进行检查。11、镜片为日戴型镜片，每一天最长使用时间不超过12小时。

禁忌症

1、眼睑疾病：如麦粒肿、睑缘炎等。2、结膜疾病：如重度结膜炎、重度沙眼等。3、角膜疾病：如各种类型的角膜炎症、若感染。4、泪器疾病：如干眼症、急、慢性泪囊炎等。5、其他疾病：如青光眼、眼部肿瘤等眼部疾病；重症糖尿病、高血压、变态反应性疾病、过敏体质等全身性疾病。6、环境条件：生活环境有严重污染或工作环境有粉尘、酸、碱等挥发性物质，不适合配戴镜片。7、任何角膜感觉失常，敏感度减低。8、眼睛表面或相关组织，对隐形眼镜或保养液过敏。9、眼睛红肿或刺痛感。另外，卫生习惯较差者、精神状况不稳定者、职业环境受限者等顾客配戴隐形眼镜，预计效果可能不佳，需要给予加倍指导。妊娠过程中的妇女如果需要配戴隐形眼镜，请咨询医生意见。在不超过最长配戴时间12小时的前提下，根据医嘱规定确认配戴时间。

《可能风险》

下列因素可能引起眼球损伤。其后果轻则引起一时视力不佳，眼球轻度发炎，严重则眼球永久性损伤或至失明，必须自我防范、警惕。1、镜片配适不良，镜片过松或过紧。2、自我使用不当：例如连续戴镜时间过长，导致角膜缺氧，水肿及至擦伤溃疡。3、蛋白质沉淀过量且腐坏后，可能刺激眼球而发炎、损伤。4、镜片护理液使用不当，或选择不当而引起眼睛刺激，发炎、损伤。5、环境因素：洗漱镜片的水污染，戴镜在游泳、环境空气污染都可能引起眼球发炎。

再次提醒：请按照医生或专业验光师指导下使用本产品。

符号：以下符号可能出现在标签或外包装上。

符号	说明	符号	说明
STERILE	无菌		外盒可回收
⚠	详阅使用说明	合格	合格
DIA($\varnothing_T$)	总直径	PWR(F'_v)	后顶焦度
LOT	批号	BC(r_0)	基弧半径
EXP	失效期	②	禁止二次使用

产品名称：软性亲水接触镜 Ticon Cosmetic Daily Disposable Soft Contact Lens

产品型号：彩色日抛Cosmetic Daily Disposable

生产单位：精华光学股份有限公司

生产单位地址：台湾台北县汐止市大同路一段276-1号1，2，5楼，276号5楼、276-2号3、4、5楼

承 产 者：精华光学股份有限公司汐止二厂

生产地址：台湾台北县汐止市大同路一段306号9楼、306之3号4、7、12楼及306号7楼之二、之三

产 地：台湾

执行标准：YZB/国（台）3909-2011《软性亲水接触镜》

注册证号：国食药监械（许）字2011第3220100号（更）

服务单位：北京博士伦眼睛护理产品有限公司

注册和经营地址：北京市东城区幸福大街37号

电话号码：010-87157192，服务热线：4000609855

APPENDIX D: HULA HOOP AND COSMETIC FIT ASSESSMENT

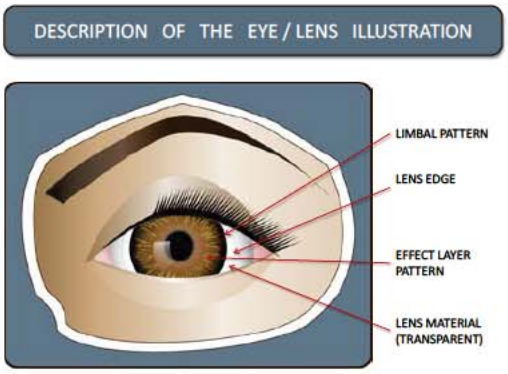
The Cosmetic Lens Acceptance will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).

In this subjective evaluation, the definition of an Acceptable Cosmetic Fit is: **The lens centers well on the eye, and does not provide a level of decentration resulting in undesirable cosmetic effect caused by lens displacement**. Below is description and illustration of acceptable and unacceptable cosmetic lens fit.

Primary gaze: Instruct the subject to look straight ahead. Confirm the subject has proper head and eye alignment (ie, not tilting head or turning eyes). Direct the instrument stand light or similar light onto the subject's face. Next, the study doctor shall orient themselves so they are at the same height / eye level as the subject. With the subject looking directly at the study doctor or at a fixation target level with the study doctor's eyes, the study doctor will evaluate primary gaze cosmetic fit acceptance. Have the subject **blink naturally**. Observe if the limbal ring covers the iris / limbal area completely during the inter-blink period.

Acceptable Cosmetic Lens Fit (Primary Gaze):

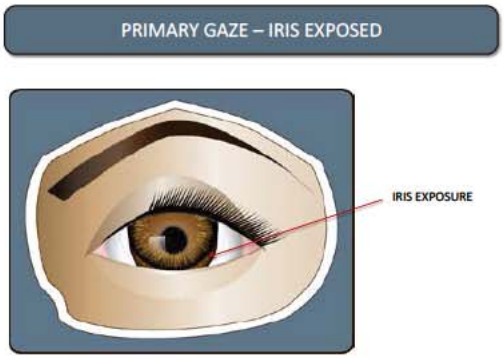
If the **limbal ring** covers the outer iris / limbal area completely during the inter-blink period then this is recorded as an acceptable cosmetic lens fit. Below is an illustration of an acceptable cosmetic fit.



Unacceptable Cosmetic Lens Fit (Primary Gaze):

If the iris is visible outside of the outer limbal ring print or if the sclera is visible inside of the inner limbal ring print (ie, sclera is showing through cosmetic effect layer) during the inter-blink period when the subject is looking in primary gaze then this would be recorded as unacceptable cosmetic fit. If the investigator records an unacceptable cosmetic lens fit acceptance, the investigator will then record the type of the unacceptable cosmetic fit (iris or sclera) and area where it is occurring (inferior, inferior temporal, temporal, etc.). Example: If an unacceptable cosmetic fit is recorded because of inferior iris exposure, the investigator would record iris / inferior. Below is an illustration of an unacceptable cosmetic fit.

Note: The investigator will only record what they can see without manipulating the eyelids.



Extreme gaze: The study doctor shall orient themselves so they are at the same height / eye level as the subject. Instruct the subject to continue to hold their head in a straight ahead position. Direct the instrument stand light or similar light onto the subject's face. Next, the study doctor will ask the subject to move their eyes in three (3) different gazes (right, left, upgaze) and evaluate the cosmetic fit acceptance in each gaze.

Note 1: After the study doctor has asked the subject to look in a particular gaze (right, left, or upgaze) instruct the subject to blink naturally before evaluating cosmetic acceptance in extreme gaze. Observe if the limbal ring covers the iris / limbal area completely during the inter-blink period.

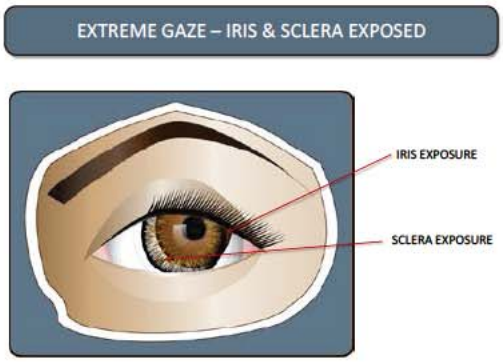
Acceptable Cosmetic Lens Fit (Extreme Gaze):

If the limbal ring covers the outer iris / limbal area during the inter-blink completely then this is recorded as an acceptable cosmetic lens fit.

Unacceptable Cosmetic Lens Fit (Extreme Gaze):

If the iris is visible outside of the outer limbal ring print or if the sclera is visible inside of the inner limbal ring print (ie, sclera is showing through cosmetic effect layer) during the inter-blink period when the subject is looking in extreme gaze then this would be recorded as unacceptable cosmetic fit. If the investigator records an unacceptable cosmetic lens fit acceptance, the investigator shall then record the type of the unacceptable cosmetic fit (iris or sclera) and area where it is occurring (inferior, inferior temporal, temporal, etc...). Example: If an unacceptable cosmetic fit is recorded in extreme left gaze because of nasal sclera exposure and temporal iris exposure, the investigator would record sclera / nasal and iris / temporal. Below is an illustration of an unacceptable cosmetic fit in extreme left gaze.

Note 1: The investigator will only record what they can see without manipulating the eyelids.



HULA HOOP EVALUATION:

Hula hoop is a dynamic evaluation defined as when the subject blinks the amount of lens movement causes the sclera to become more visible (or apparent) inside of the inner limbal ring print. Then, during the inter-blink period, the lens attempts to correctly realign covering the outer iris / limbal area on the subject's eye (or attempts to correctly realign but does not completely center exposing some amount of sclera that is less visible than compared to immediately after the blink). Hula hoop continues to occur with each blink (ie, more sclera is visible just after the blink and then becomes less or completely absent as the lens settles).

APPENDIX E: [redacted]

- [redacted] LENS FITTING CHARACTERISTICS
- [redacted] SUBJECT REPORTED OCULAR SYMPTOMS
- [redacted] FRONT AND BACK SURFACE LENS DEPOSIT GRADING PROCEDURE
- [redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS
- [redacted] BIOMICROSCOPY SCALE
- [redacted] KERATOMETRY PROCEDURE
- [redacted] DISTANCE AND NEAR VISUAL ACUITY EVALUATION
- [redacted] ETDRS DISTANCE VISUAL ACUITY MEASURMENT PROCEDURE
- [redacted] PATIENT REPORTED OUTCOMES
- [redacted] WHITE LIGHT LENS SURFACE WETTABILITY CHARACTERISTICS
- [redacted] VISUAL ACUITY CHART LUMINANCE AND ROOM ILLUMINATION TESTING

[redacted] LENS FITTING CHARACTERISTICS

[redacted] **Lens Fitting Characteristics**

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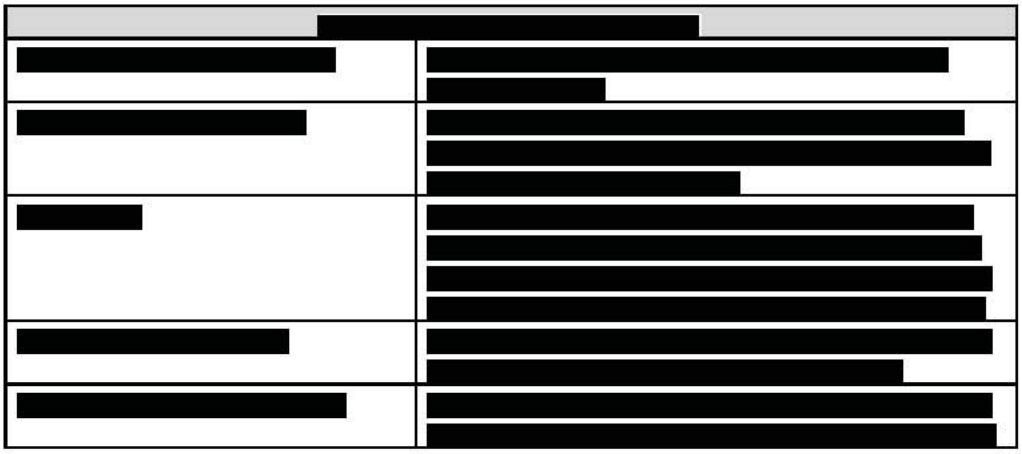
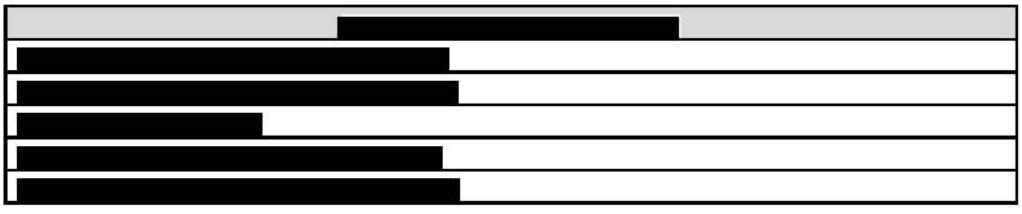
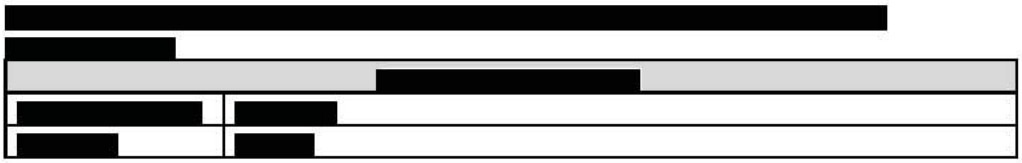
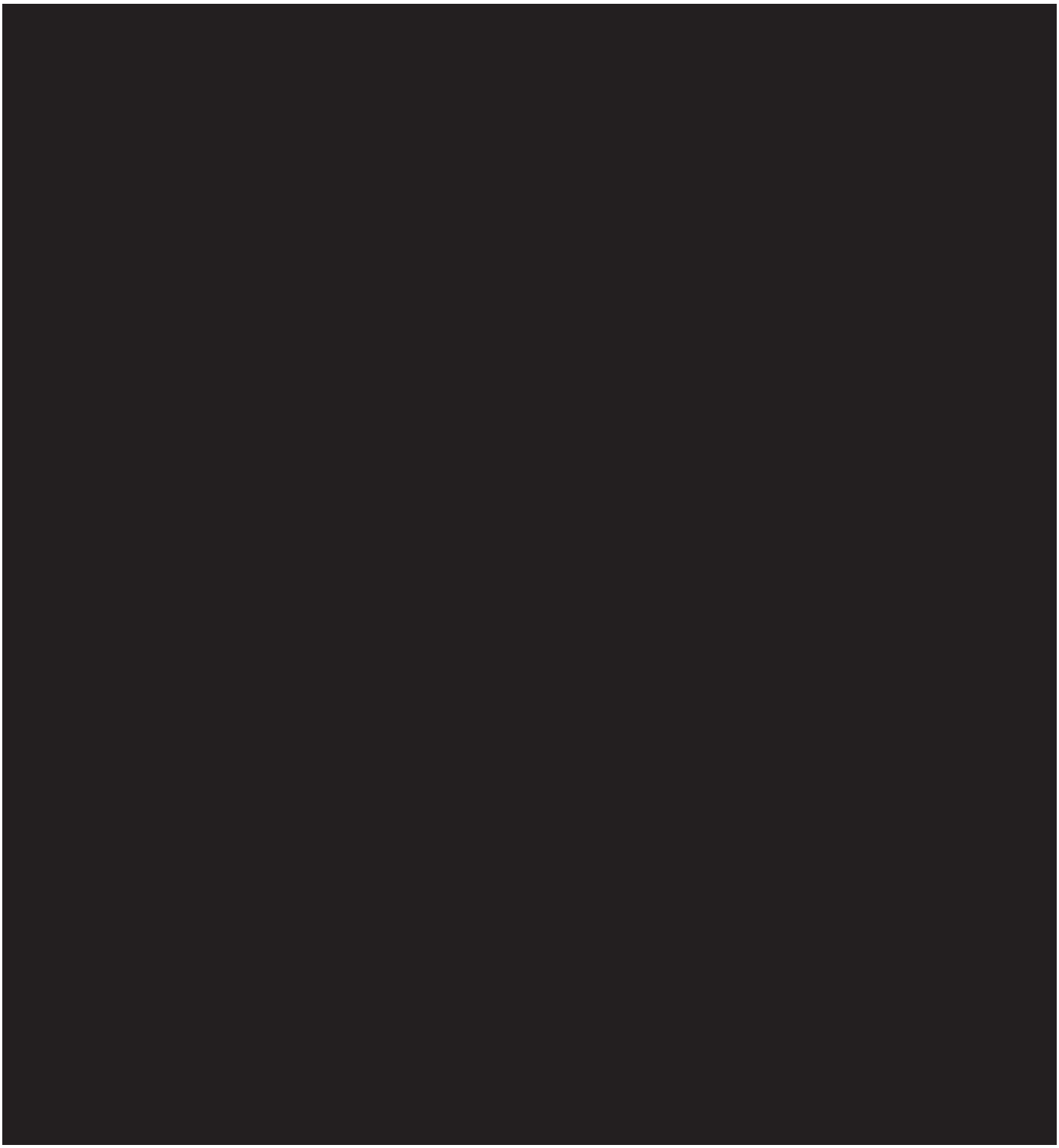
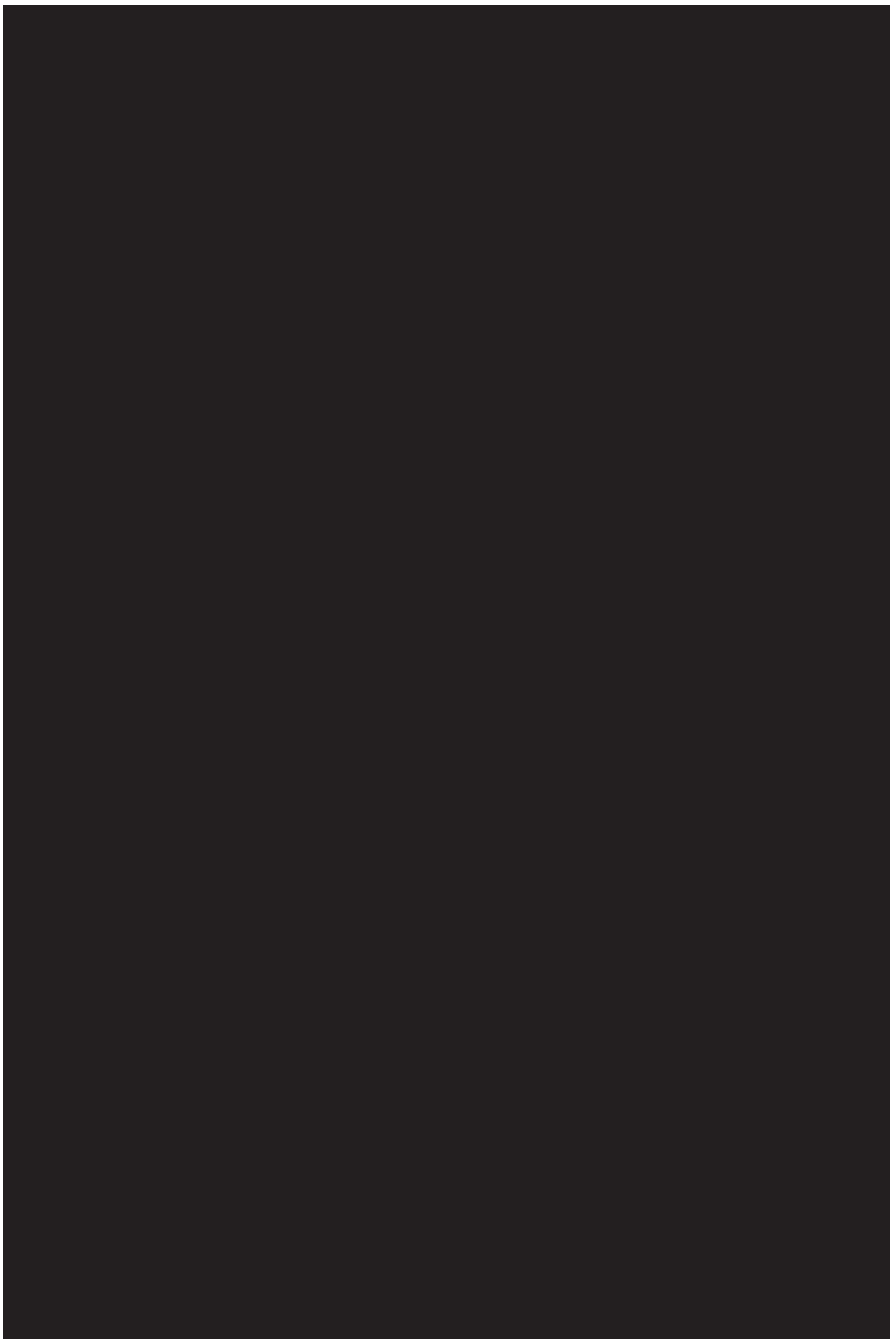
Page 1 of 6











[redacted] **SUBJECT REPORTED OCULAR SYMPTOMS**

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

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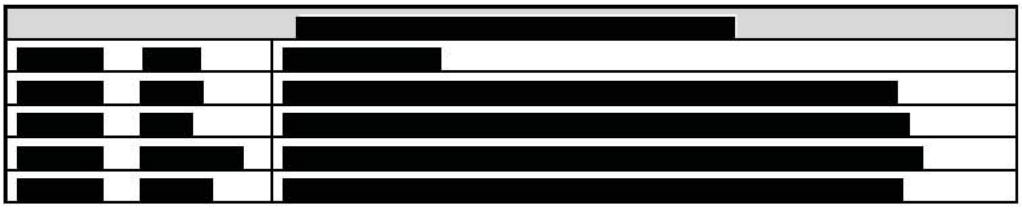
[redacted] **FRONT AND BACK SURFACE LENS DEPOSIT GRADING PROCEDURE**

Front and Back Surface Lens Deposit Grading Procedure



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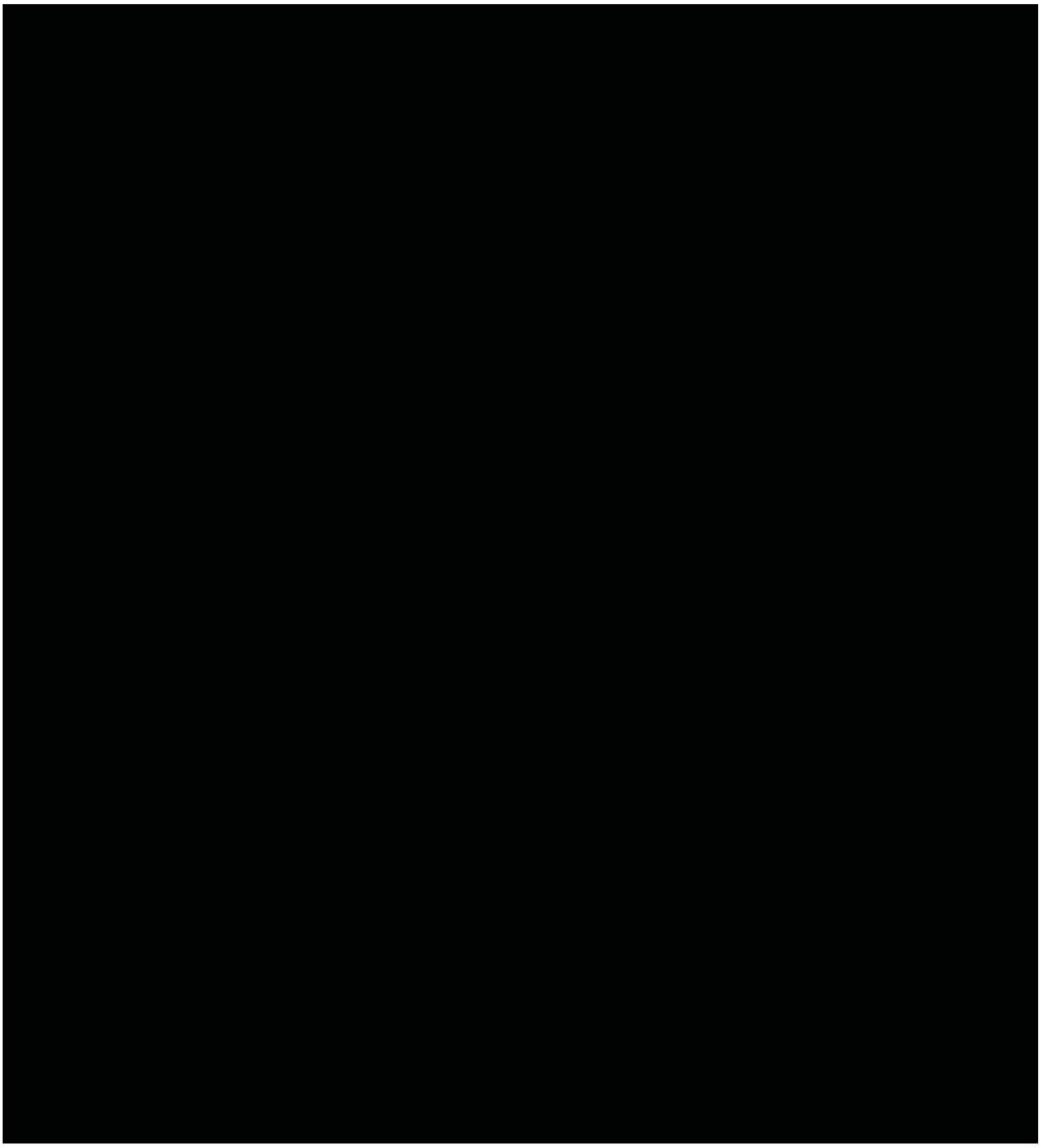

[redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS

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Determination of Distance Spherocylindrical Refractions

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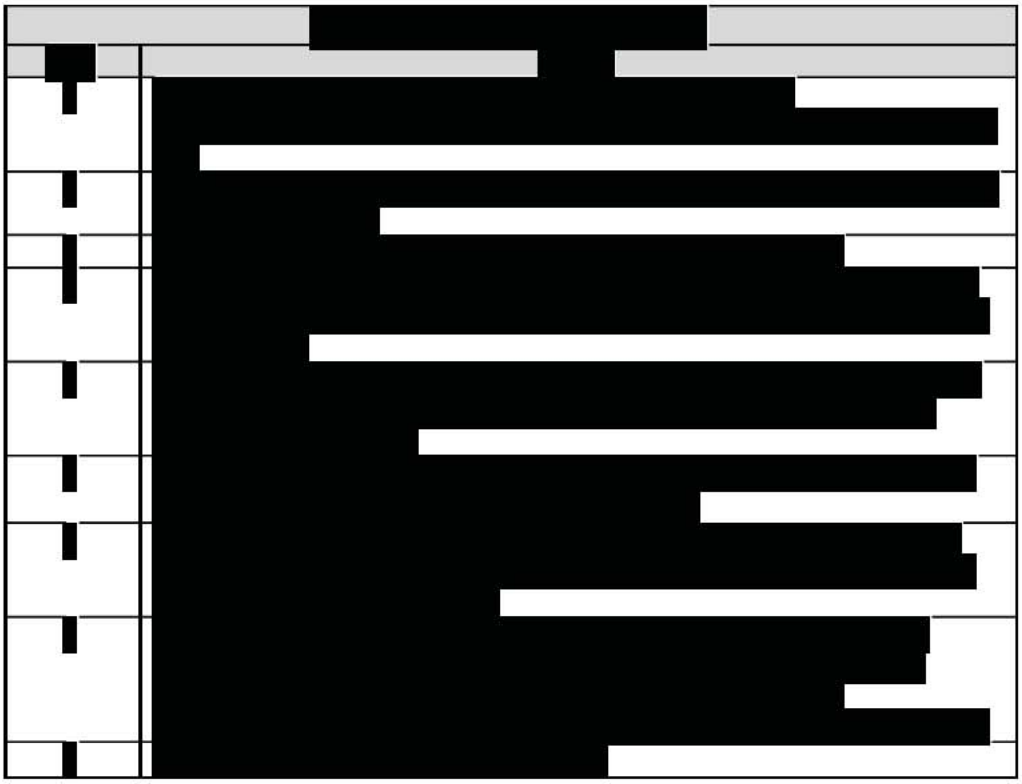
Page 1 of 6



[redacted] **BIOMICROSCOPY SCALE**

[redacted] **Biomicroscopy Scale**

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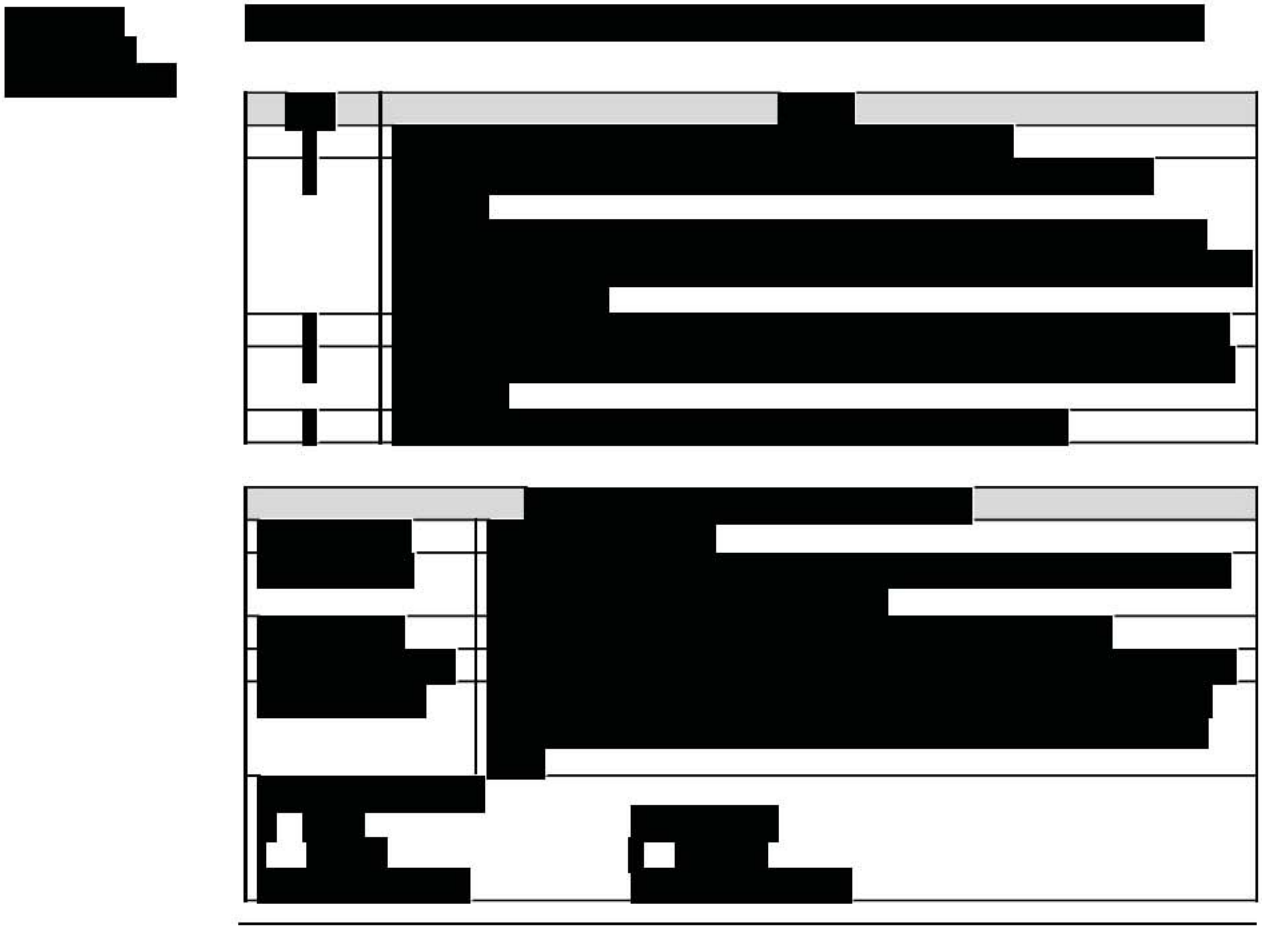

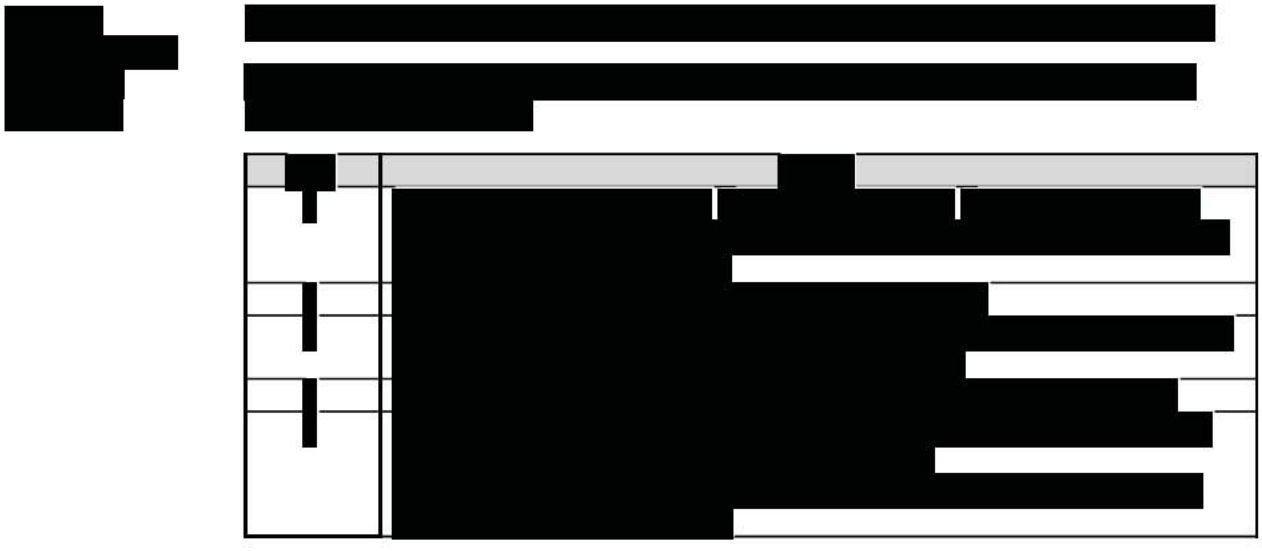

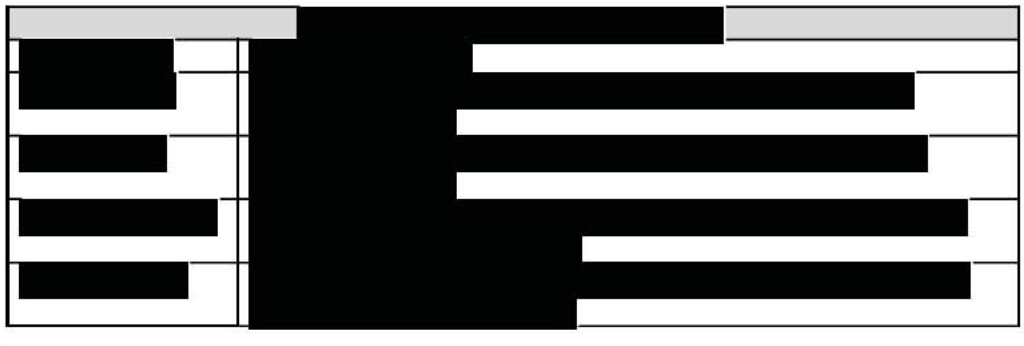

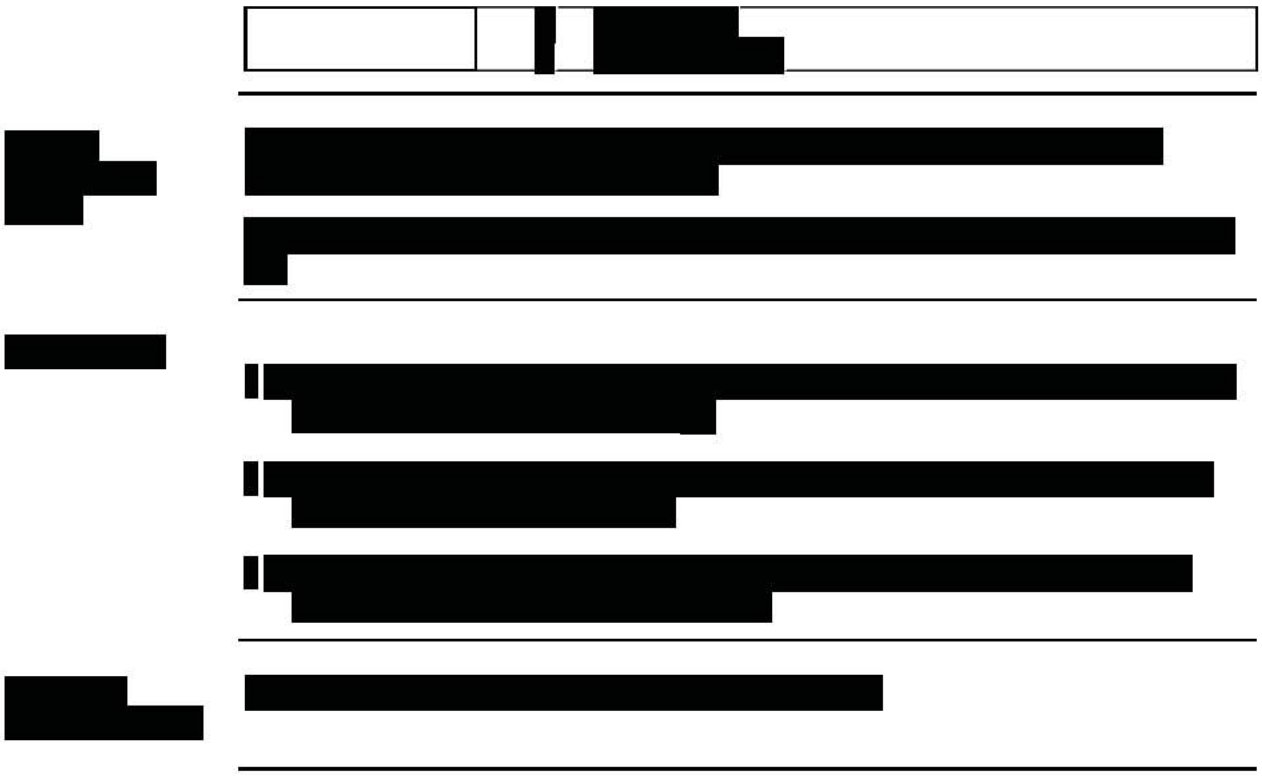

[redacted] **KERATOMETRY PROCEDURE**

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Keratometry Procedure

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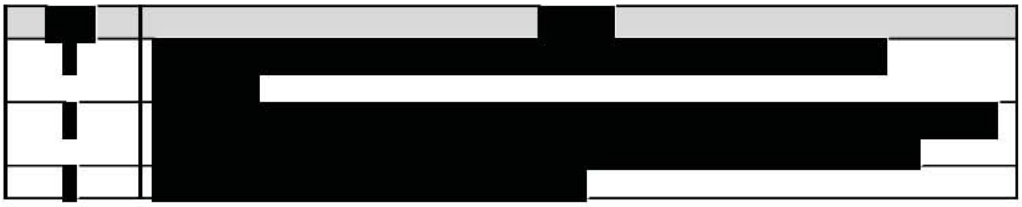

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[redacted] **DISTANCE AND NEAR VISUAL ACUITY EVALUATION**

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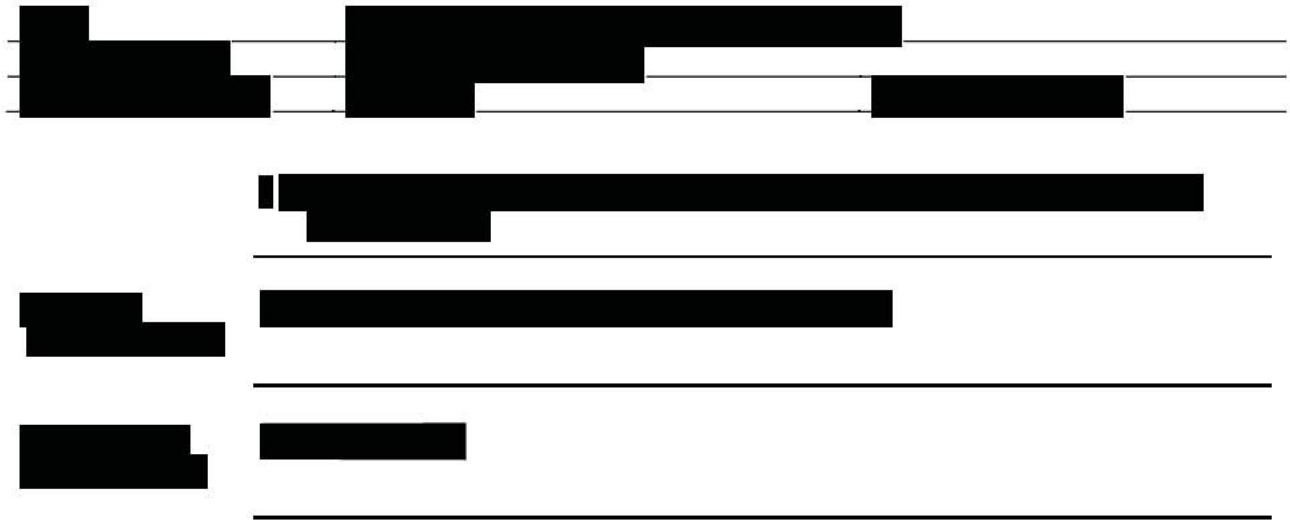

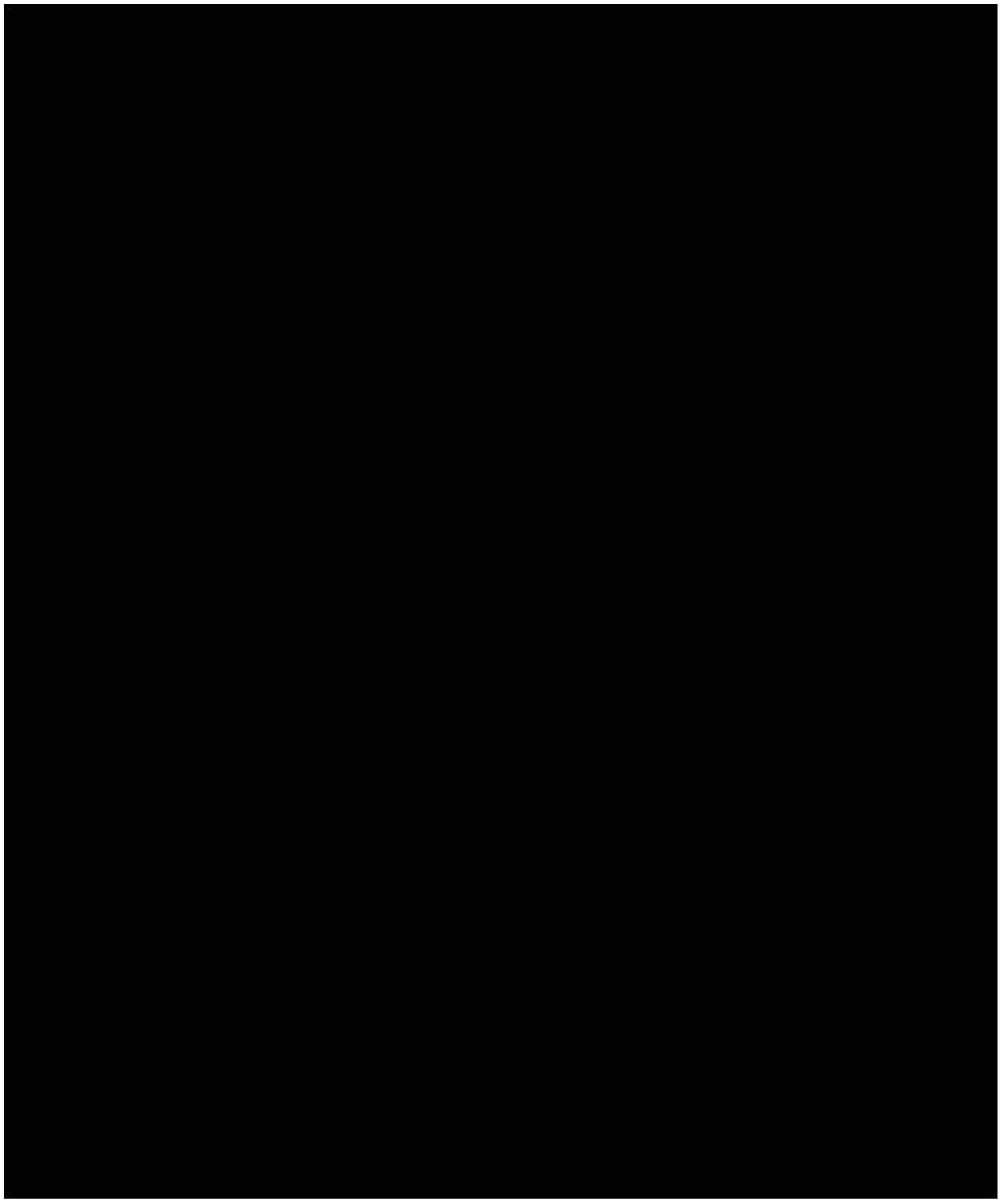

[redacted] EDTRS DISTANCE VISUAL ACUITY MEASURMENT PROCEDURE

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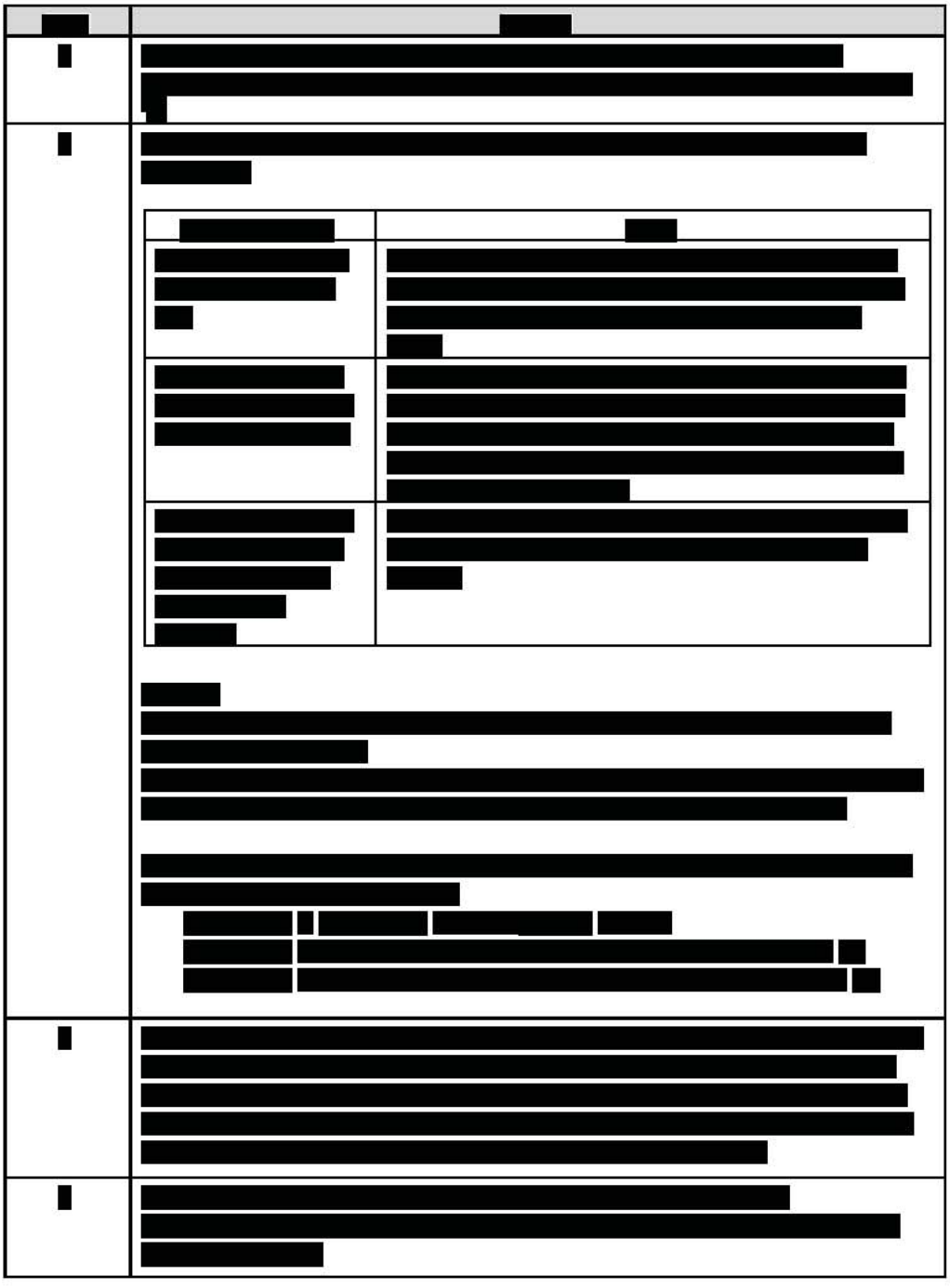

[redacted] **PATIENT REPORTED OUTCOMES**

[redacted]

Patient Reported Outcomes

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

The training requirement for this document is “Read Only.”

[redacted]

[redacted] WHITE LIGTH LENS SURFACE WETTABILITY

[redacted]

White Light Lens Surface Wettability

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
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[redacted]

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[redacted]

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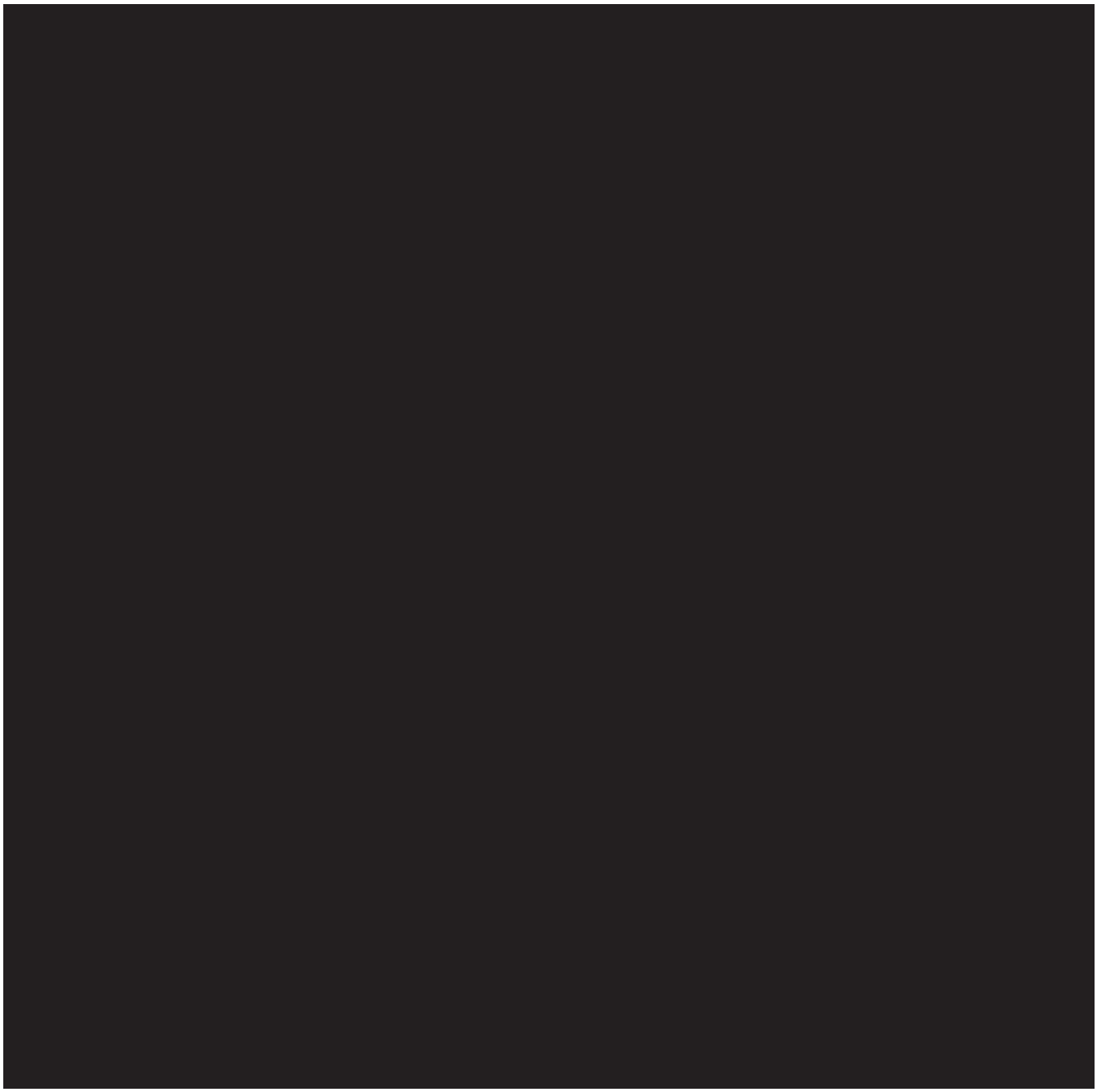
[redacted]

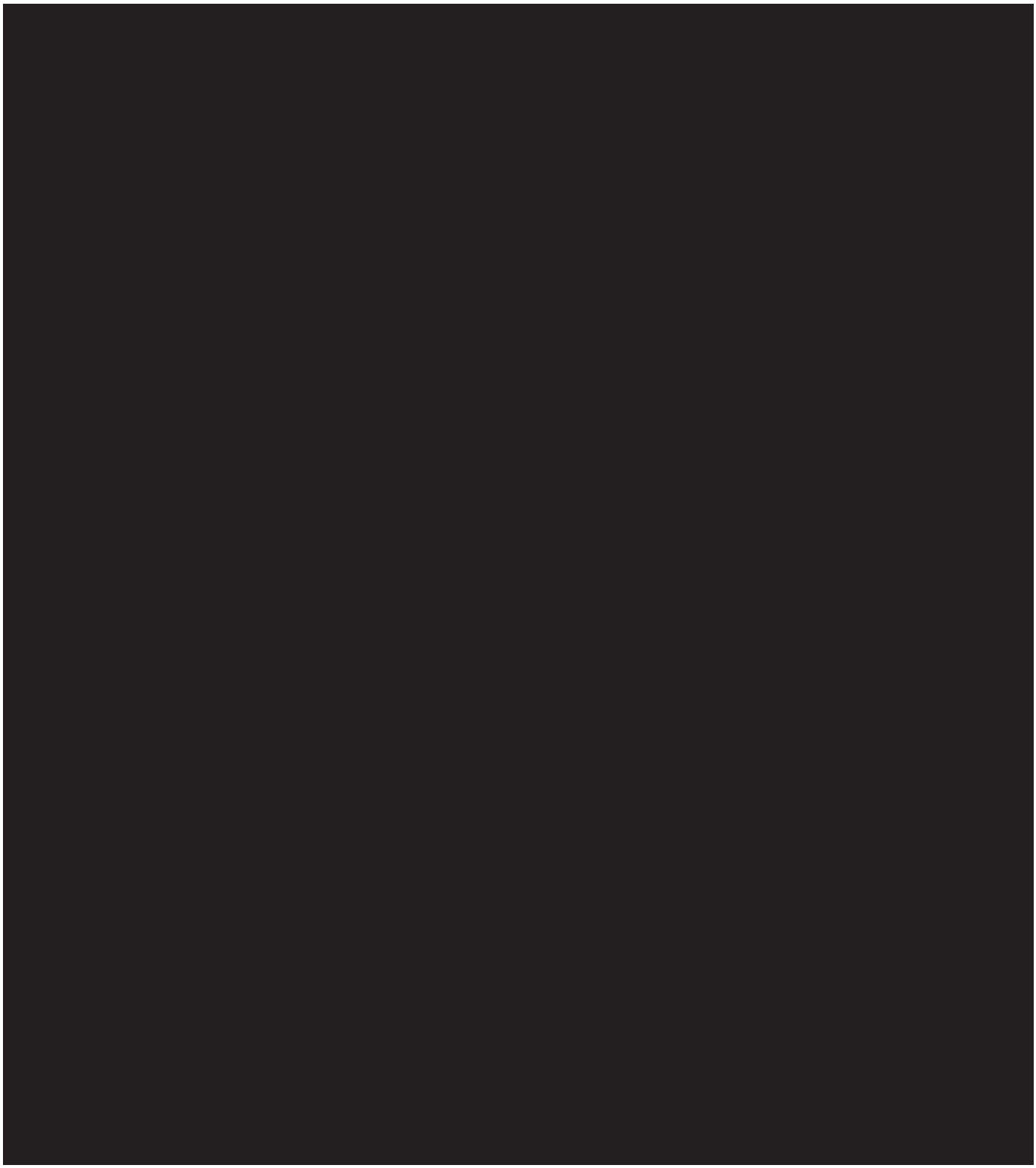
Page 1 of 1

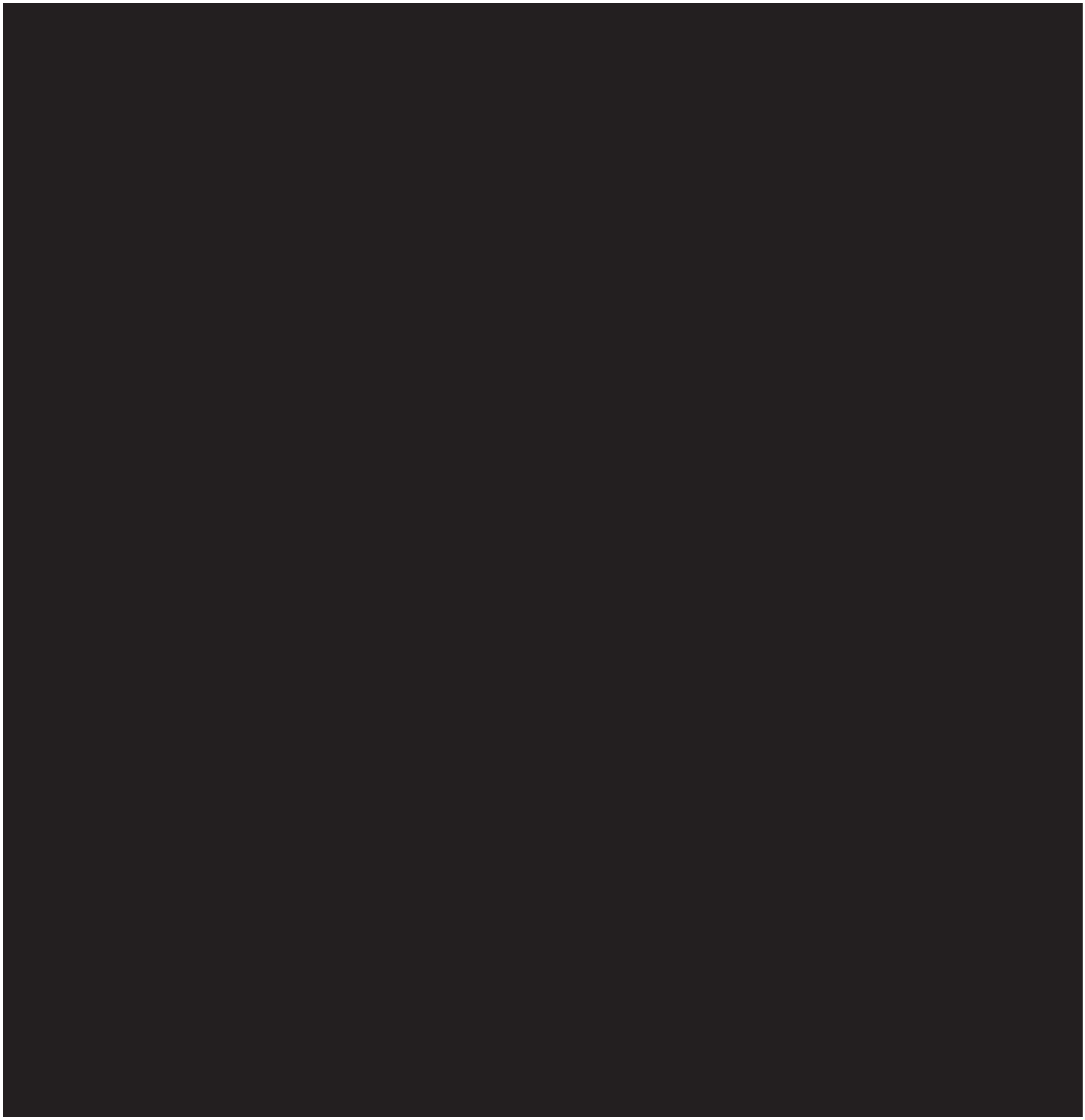
[redacted] VISUAL ACUITY CHART LUMINANCE AND ROOM ILLUMINATION TESTING

[redacted]

[redacted]







PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number/Title: CR-6286 Clinical Comparison of Two Marketed Reusable Cosmetic Contact Lenses

Version and Date: 3.0, 20 December 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,[1] GCP and ICH guidelines,[2] the Declaration of Helsinki,[3] United States (US) Code of Federal Regulations (CFR),[4] and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. The Principal Investigator is responsible for ensuring that all clinical site personnel, including Sub-Investigators adhere to all ICH[2] regulations and GCP guidelines regarding clinical trials during and after study completion.

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

I am responsible for ensuring that all clinical site personnel including Sub-Investigators adhere to all ICH[2] regulations and GCP guidelines regarding clinical trials during and after study completion.

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

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

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

Principal Investigator:

_____

Signature Date

_____

Name and Professional Position (Printed)

Institution/Site:

_____

Institution/Site Name

_____

Institution/Site Address