Johnson & Johnson Vision Care
7500 Centurion Parkway
Jacksonville, FL 32256

Clinical Study Protocol

Evaluation Of The Effects Of A Black Annulus Within A Hydrogel Contact Lens On Visual Performance

Protocol: CR-5856

Version: 2.0, Amendment 1.0

Date: 22 SEP 2016

Distribution:

Marina Archer (DHF)

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Non-dispensing
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1.1 PROTOCOL TITLE, NUMBER, DATE

TITLE: Evaluation Of The Effects Of A Black Annulus Within A Hydrogel Contact Lens On Visual Performance

PROTOCOL NUMBER: CR-5856

VERSION: 2.0, Amendment 1.0

DATE: September 22, 2016

1.2 NAME AND ADDRESS OF SPONSOR

Johnson & Johnson Vision Care

7500 Centurion Parkway, Jacksonville, FL 32256

1.3 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, ICH guidelines, and the Declaration of Helsinki.

Author: _____ 22nd Sept 2016.
Name: [redacted]
Title: Director of Clinical Operations, OTG-i
DATE

R&D Clinical Lead: **See Electronic Signature Report** _____
Name: [redacted]
Title: Principal Research Optometrist
DATE

Biostatistician: **See Electronic Signature Report** _____
Name: [redacted]
Title: Biostatistician II
DATE

Clinical Operations: **See Electronic Signature Report** _____
Name: [redacted]
Title: Clinical Operations Manager
DATE

Reviewer: **See Electronic Signature Report** _____
Name: [redacted]
Title: Biostatistician Manager
DATE

Reviewer: **See Electronic Signature Report** _____
Name: [redacted]
Title: Clinical Project Manager-Data & Systems
DATE

Reviewer: **See Electronic Signature Report** _____
Name: [redacted]
Title: Platform Lead
DATE

1.4 MEDICAL MONITOR

NAME: Mr. Ali A. Mearza MB BS, FRCOphth

TITLE: Consultant Ophthalmologist

ADDRESS: 22 Wimpole Street, London W1G 8GQ, UK

E-MAIL: [redacted]

[redacted]

The Medical Monitor should be notified by the clinical site in writing and by 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.

1.5 INVESTIGATOR(S) SIGNATURE PAGE

The Principal Investigator is responsible for ensuring that all study site personnel, including sub-investigators and other staff members, adhere to all ICH regulations and GCP guidelines regarding clinical trials during and after study completion.

I have read and understand the protocol specified above and agree on its content. I agree to conduct this study according to this protocol and GCP and ICH guidelines, the Declaration of Helsinki, and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. 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 (Printed)

Institution Name _____

1.6 ESTIMATED REPORT DATE

November 2016

1.7 CHANGE HISTORY

Document Change History			
Version	**Originator**	**Description of Change(s)**	**Date**
1.0	K. Dumbleton	New Protocol	17 MAY 2016
2.0	R. Franklin	Corrected error in Lens Fit Assessment section at Visit 1. Changed lens material to methafilcon A and supplier to No7 Contact Lenses. Changed intermediate peripheral acuity eccentricity from 12.5° to 10° to avoid blind spot. Clarified visual acuity procedures in section 4.7.1 to be consistent with objectives section.	22 SEPT 2016

1.8 PROTOCOL SYNOPSIS

Protocol Number and Title: CR-5856 Evaluation Of The Effects Of a Black Annulus Within a Hydrogel Contact Lens on Visual Performance
Sponsor: JJVCI, 7500 Centurion Parkway, Jacksonville, FL 32256
Test Articles: Custom made CE marked commercially available hydrogel contact lenses with 1mm wide black annulus and 6mm inner diameter made from methafilcon A material by No7 Contact Lenses (Test). CE marked hydrogel contact lenses made from methafilcon A material by No7 Contact Lenses (Control). The design of the control contact lens is identical to the test contact lens, except that the test lens has the black annular ring.
Regimen and Dosing: At the fitting visit (Visit 1), up to two pairs of Fitting lenses will be trialled for approximately 20 to 30 minutes each for the purposes of determining the optimum study lens parameters and familiarization with the study procedures. Subjects will wear 2 of 2 study contact lenses (Test/Control or Control/Test per the randomization scheme) for a wearing time of approximately three to four hours at each of the two measurement visits (Visits 2 and 3), with the subjects remaining at the clinical site for the duration of the visits.
Phase or Type of Study: Pilot Study

Primary Objective:

The primary objective of the study will be to measure the binocular functional visual performance of the test and control contact lenses under distance day time conditions (250 cd/m2) for centrally presented high contrast (HC) time controlled visual acuity (TCVA) targets.

Secondary Objective:

The secondary objectives of the study will be to measure the binocular functional visual performance of the test and control contact lenses for the following conditions:

i. Distance night time conditions (2.5 cd/m2) for centrally presented HC TCVA targets;
ii. Intermediate vision indoor conditions (50cd/m2) for centrally presented HC TCVA targets.

Additional Measurements:

In addition to the primary and secondary objectives, the following will be measured:

i. Monocular functional visual performance for centrally presented high contrast (HC) time controlled visual acuity (TCVA) targets.
    a. Distance day time conditions (250 cd/m2)
    b. Distance night time conditions (2.5 cd/m2)
    c. Intermediate vision indoor conditions (50cd/m2)
ii. Distance monocular and binocular functional visual performance of the test and control contact lenses under night time conditions (2.5 cd/m2) for HC TCVA targets presented at 5° eccentricity;
iii. Intermediate vision monocular and binocular functional visual performance of the test and control contact lenses under indoor conditions (50cd/m2) for HC TCVA targets presented at 5° eccentricity;
iv. Distance monocular and binocular functional visual performance of the test and control contact lenses under night time conditions (2.5 cd/m2) for decreasing contrast targets presented at 20° eccentricity;
v. Intermediate vision monocular and binocular functional visual performance of the test and control contact lenses under indoor conditions (50cd/m2) for decreasing contrast targets presented at 10° eccentricity;
vi. Monocular and binocular horizontal visual fields when wearing the test and control contact lenses with an Esterman perimetry test.
vii. Subjective rating of performance following driving simulation while wearing test and control contact lenses under night time conditions;
viii. Subjective rating of performance following PC based reaction time game while wearing test and control contact lenses.

Study Design: The study will be a bilateral, subject-masked, randomized, 2x2 cross-over, non-dispensing pilot study involving three clinic visits. Investigators who collect measurements for primary and secondary endpoints will also be masked to the identity of the study lenses. Each subject will be assigned to a unique sequence of the lens types per the randomization scheme (Test/Control or Control/Test). Lenses will be worn for approximately three to four hours each with a 2-14 day washout period in between lenses.

Sample Size: A minimum of 20 eligible subjects are targeted to complete the study as the cohort population. Subjects who are found to be ineligible, or who are discontinued or incomplete, will be classified as the non-cohort population. The total number of subjects enrolled may not exceed 25 subjects,

except by joint agreement of the Investigator and Sponsor.

Eligibility Criteria:

Subjects should meet all study Inclusion Criteria as outlined below:

1) Healthy adult males or females 35 to 42 years of age (inclusive) with signed informed consent.
2) The subject is a current spherical soft contact lens wearer (defined as a minimum of 6 hours of DW for a minimum of 1 month prior to the study).
3) The subject's optimal vertexed spherical equivalent distance correction must be between -6.00 and +4.00 D (inclusive).
4) Any cylinder power must be ≤ 0.75D.
5) The subject must have visual acuity best correctable to 20/30 or better for each eye.
6) The subject must read and sign the Informed Consent form.
7) The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.

Subjects meeting any of the following Exclusion Criteria will not be eligible to participate in the study:

1) Currently pregnant or lactating,
2) Any ocular or systemic allergies or diseases that may interfere with contact lens wear.
3) Any infectious disease (e.g., hepatitis, tuberculosis) or a contagious immunosuppressive disease (e.g., HIV) by self-report).
4) Clinically significant (grade 3 or 4) corneal edema, corneal vascularization, corneal staining, or any other abnormalities of the cornea which would contraindicate contact lens wear.
5) Clinically significant (grade 3 or 4) tarsal abnormalities or bulbar injection which might interfere with contact lens wear.
6) Any ocular infection.
7) Any previous, or planned, ocular or intraocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.).
8) Any corneal distortion resulting from previous hard or rigid gas permeable contact lens wear.
9) Habitual contact lens type is toric, bifocal, in monovision contact lens wear, or is worn as extended wear.
10) Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.
11) Employee of investigational clinic (e.g., Investigator, Coordinator, Technician)

Stopping Rules:

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 Investigator before any further subjects are enrolled.

2.1 NAME AND DESCRIPTION OF TEST ARTICLES

The following contact lenses will be used in this study:

	LENSES		
Test Article Form	Fitting Lenses	Test	Control
Design / Description	CE marked hydrogel contact lenses	Custom made, CE marked, commercially available hydrogel contact lenses with 1mm wide black annulus and 6mm inner diameter	CE marked hydrogel contact lenses
Lot Number or Other Identifier	N/A	N/A	N/A
Manufacturer	No7 Contact Lenses	No7 Contact Lenses	No7 Contact Lenses
Packaging Form	Vial	Vial	Vial
Nominal Distance Powers (D)	-6.00DS to +4.00DS	-6.00DS to +4.00DS	-6.00DS to +4.00DS
Nominal Base Curve @ 22°C	7.70, 8.00, 8.30, 8.60, 8.90, 9.20, 9.50 mm	7.70, 8.00, 8.30, 8.60, 8.90, 9.20, 9.50 mm	7.70, 8.00, 8.30, 8.60, 8.90, 9.20, 9.50 mm
Nominal Diameter @ 22°C	13.5, 14.0, 14.5 mm	13.5, 14.0, 14.5 mm	13.5, 14.0, 14.5 mm
Material	methafilcon A	methafilcon A	methafilcon A

Fitting lenses used at Visit 1 will be selected from a pre-ordered trial set, and will be disposed of after use. The Test and Control lenses used at Visits 2 and 3 are custom-ordered for each participant, and will be disposed of after use.

2.2 SUMMARY OF FINDINGS FROM NONCLINICAL STUDIES

See package insert (Appendix B).

2.3 SUMMARY OF KNOWN RISKS AND BENEFITS TO HUMAN SUBJECTS

See package insert (Appendix B).

2.4 DESCRIPTION OF TRIAL TREATMENTS

The study will be a bilateral, subject-masked, randomized 2x2 cross-over, non-dispensing pilot study involving three clinic visits. Investigators who collect measurements for primary and secondary endpoints will also be masked to the identity of the study lenses. The subjects will attend a first Enrolment / Fitting visit to initially obtain their informed consent and evaluate the potential participants suitability to take part in the investigation. If they fulfill the investigation's inclusion and exclusion criteria, they will be enrolled, fitted with the study contact lens type to ensure than a clinically acceptable fit is achieved and trained into the testing procedures. At the completion of the visit the test and control contact lenses will be ordered. When the study contact lenses become available the subjects will then attend two test visits during which one of the study contact lens will be tested each time. The order of testing the test or control contact lens will be randomized. The participants will attend the visits not wearing contact lenses and not having worn contact lenses that day.

2.5 STATEMENT OF COMPLIANCE TO PROTOCOL, GCP, AND APPLICABLE REGULATORY GUIDELINES

This trial will be conducted in compliance with the protocol, the International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP), the Declaration of Helsinki, and all applicable regulatory requirements.

2.6 DESCRIPTION OF POPULATION TO BE STUDIED, ENROLLMENT TARGETS, AND STUDY DURATION

The prospective subjects will all be subjects registered with the sites as potential study participants. They will initially be contacted by telephone, the investigation will be explained in detail and if interested an Enrolment / Fitting / Measurement visit will be scheduled. The subjects fulfilling the criteria for inclusion and exhibiting none of the exclusion criteria will be invited in a random fashion to participate in the study until the test population is achieved. Up to 25 subjects may be enrolled in order to achieve a cohort population of 20 subjects. The study is anticipated to last for approximately 4 months with each subject being involved for a period of up to 1 to 2 months, dependent upon the length of time that is required to manufacture their study lenses.

2.7 RELEVANT LITERATURE REFERENCES AND PRIOR DATA

See package insert (Appendix B).

3.1 DESCRIPTION OF OBJECTIVES AND PURPOSE

Johnson & Johnson Vision Care (JJVCI) are interested in evaluating the effects of incorporating a black annulus within a hydrogel contact lens, on functional visual performance. The black annulus is designed to mimic the performance of a similar design. The research aims to determine whether this black annulus is likely to have any detrimental effect on vision for the wearer. This pilot study will compare the central and peripheral visual performance, including functional assessment of vision, of a test contact lens incorporating a black annulus with that of a control clear contact lens.

The primary objective of the study will be to measure the binocular functional visual performance of the test and control contact lenses under distance day time conditions (250 cd/m2) for centrally presented high contrasts (HC) time controlled visual acuity (TCVA) targets.

The secondary objectives of the study will be to measure the binocular functional visual performance of the test and control contact lenses for the following conditions:

i. Distance night time conditions (2.5 cd/m2) for centrally presented HC TCVA targets;
ii. Intermediate vision indoor conditions (50cd/m2) for centrally presented HC TCVA targets.

The additional study measurements will be:

i. Monocular functional visual performance for centrally presented high contrast (HC) time controlled visual acuity (TCVA) targets.
    a. Distance day time conditions (250 cd/m2)
    b. Distance night time conditions (2.5 cd/m2)
    c. Intermediate vision indoor conditions (50cd/m2)
ii. Distance monocular and binocular functional visual performance of the test and control contact lenses under night time conditions (2.5 cd/m2) for HC TCVA targets presented at 5° eccentricity;
iii. Intermediate vision monocular and binocular functional visual performance of the test and control contact lenses under indoor conditions (50cd/m2) for HC TCVA targets presented at 5° eccentricity;
iv. Distance monocular and binocular functional visual performance of the test and control contact lenses under night time conditions (2.5 cd/m2) for decreasing contrast targets presented at 20° eccentricity;
v. Intermediate vision monocular and binocular functional visual performance of the test and control contact lenses under indoor conditions (50cd/m2) for decreasing contrast targets presented at 10° eccentricity.
vi. Monocular and binocular horizontal visual fields when wearing the test and control contact lenses with an Esterman perimetry test.
vii. Subjective rating of performance following driving simulation while wearing test and control contact lenses under night time conditions;
viii. Subjective rating of performance following PC based reaction time game while wearing test and control contact lenses.

4.1 PRIMARY AND SECONDARY ENDPOINTS

The primary endpoint will be measurements of binocular functional visual performance under distance day time conditions (250 cd/m^2) for centrally presented high contrasts (HC) time controlled visual acuity (TCVA) targets.

The secondary endpoints will be measurements of binocular functional visual performance measured under the following conditions:

i. Distance night time conditions (2.5 cd/m^2) for centrally presented HC TCVA targets;
ii. Intermediate vision indoor conditions (50cd/m^2) for centrally presented HC TCVA targets.

The following hypotheses will be tested throughout this investigation. This is a pilot study and all the hypotheses are exploratory in nature.

Primary Study Hypothesis	
1	The binocular central distance high contrast, high illumination (250 cd/m^2) TCVA of the test lens is non-inferior to the control lens. The non-inferiority margin will be -0.5 VA units (-10 X logMAR VA).

Secondary Study Hypotheses	
1	The binocular central distance high contrast, low illumination (2.5 cd/m^2) TCVA of the test lens is non-inferior to the control lens. The non-inferiority margin will be -0.75 VA units (-10 X logMAR VA).
2	The binocular central intermediate vision high contrast, medium illumination (50 cd/m^2) TCVA of the test lens is non-inferior to the control lens. The non-inferiority margin will be -0.75 VA units (-10 X logMAR VA).

Other clinical observations:

i. Monocular functional visual performance for centrally presented high contrast (HC) time controlled visual acuity (TCVA) targets.
    a. Distance day time conditions (250 cd/m2)
    b. Distance night time conditions (2.5 cd/m2)
    c. Intermediate vision indoor conditions (50cd/m2)
ii. Distance monocular and binocular functional visual performance of the test and control contact lenses under night time conditions (2.5 cd/m^2) for HC TCVA targets presented at 5° eccentricity;
iii. Intermediate vision monocular and binocular functional visual performance of the test and control contact lenses under indoor conditions (50cd/m^2) for HC TCVA targets presented at 5° eccentricity;
iv. Distance monocular and binocular functional visual performance of the test and control contact lenses under night time conditions (2.5 cd/m^2) for decreasing contrast targets presented at 20° eccentricity;
v. Intermediate vision monocular and binocular functional visual performance of the test and control contact lenses under conditions (50cd/m^2) for decreasing contrast targets presented at 10° eccentricity.
vi. Monocular and binocular horizontal visual fields when wearing the test and control contact lenses with an Esterman perimetry test.
vii. Subjective rating of performance following driving simulation while wearing test and control contact lenses under night time conditions;
viii. Subjective rating of performance following PC based reaction time game while wearing test and control contact lenses.
ix. Biomicroscopy findings;
x. Lens fit characteristics;
xi. Snellen distance visual acuity;
xii. Reasons for discontinuation;
xiii. Reasons for unplanned lens replacement;
xiv. Adverse events;
xv. Lens Damage.

4.2 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) The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
3) The subject must be between 35 and 42 years of age (inclusive).
4) The subject's vertex corrected spherical equivalent distance refraction must be in the range of -6.00D to +4.00D in each eye.
5) The subject's refractive cylinder must be ≤ 0.75D in each eye.
6) The subject must have best corrected visual acuity of 20/30 or better in each eye.
7) The subject must be an adapted soft contact lens wearer in both eyes (defined as a minimum of 6 hours of DW for a minimum of 1 month prior to the study).
8) The subject must have normal eyes (i.e., no ocular medications or infections of any type).

4.3 EXCLUSION CRITERIA

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

1) Currently pregnant or lactating (subjects who become pregnant during the study will be discontinued).
2) Any ocular or systemic allergies or diseases that may interfere with contact lens wear.
3) Any infectious disease (e.g., hepatitis, tuberculosis) or a contagious immunosuppressive disease (e.g., HIV) by self-report.
4) Clinically significant (grade 3 or 4) corneal edema, corneal vascularization, corneal staining, or any other abnormalities of the cornea which would contraindicate contact lens wear.
5) Clinically significant (grade 3 or 4) tarsal abnormalities or bulbar injection which might interfere with contact lens wear.
6) Any ocular infection.
7) Any previous, or planned, ocular or interocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.).
8) Any corneal distortion resulting from previous hard or rigid gas permeable contact lens wear.
9) Habitual contact lens type is toric, bifocal, in monovision contact lens wear, or is worn as extended wear.
10) Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.
11) Employee of investigational clinic (e.g., Investigator, Coordinator, Technician)

4.4 STUDY DESIGN, TIME AND EVENT SCHEDULE, FLOWCHART

The study will be a bilateral, subject-masked, randomized, 2x2 cross-over, non-dispensing pilot study involving three clinic visits. Investigators who collect measurements for primary and secondary endpoints will also be masked to the identity of the study lenses. The study will have two treatments (Test and Control) in two periods (first and second) with two randomization groups (Test/Control or Control/Test).

The participants will attend a first Enrolment / Fitting visit to initially obtain their informed consent and evaluate the potential participant's suitability to take part in the investigation. If they fulfill the investigation's inclusion and exclusion criteria, they will be enrolled, fitted with the study contact lens type to ensure than a clinically acceptable fit is achieved and trained into the testing procedures. This visit will last for approximately three hours. At the completion of the visit the test and control contact lenses will be ordered. When the study contact lenses become available the participants will then attend two test visits during which one of the study contact lens types will be tested each time. The order of testing of the test or control contact lens will be determined at random. The participants will attend the visits not wearing contact lenses and not having worn contact lenses that day. Each measurement visit will last for approximately 4.5 hours.

The participants will not take part in any concomitant investigation of any type or take concomitant medications not allowed by the exclusion criteria.

4.4.1 TIME AND EVENTS SCHEDULE

All study visits are required visits. There are no fixed time intervals between visits; however, it is anticipated that all subjects will complete both measurement visits within a period of no more than one month.

Visit 1 - Enrolment / Fitting Visit
The steps below will be followed:

- Signing of the consent form
- Participant demographics, medical and ocular history questions
- Concomitant treatments questionnaire
- Contact lens history
- Ocular symptoms
- Sphero-cylindrical refraction and BCVA
- Spherical refraction
- Ocular dominance measurement
- Keratometry
- Pupil measurement at 250, 50 & 2.5cd/m2
- HVID
- Biomicroscopy
- Eligibility
- Lens Information
- Lens Damage
- Lens Settling
- Sphero-cylindrical refraction and VA
- Lens fit assessment (including lens fit digital video recording)
- Modification
- Final contact lens prescription
- Familiarization with test measurements
- Lens Removal
- Biomicroscopy
- Sphero-cylindrical refraction and BCVA
- Continuance

Visit 2 – First Measurement Visit
The routine below will be followed:

- Concomitant treatments questionnaire
- Ocular symptoms
- Sphero-cylindrical refraction and BCVA
- Biomicroscopy
- Continuance
- Lens Randomization
- Lens Insertion
- Lens Damage
- Lens Settling
- Spherical over- refraction and VA
- Lens fit assessment (including lens fit digital video recording)
- Visual field measurement, OD, OS, OU
- Vision assessments (according to randomization scheme)
- Lens Removal
- Biomicroscopy
- Sphero-cylindrical refraction and BCVA
- Continuance

Visit 3 – Second Measurement Visit
The steps below will be followed:

- Concomitant treatments questionnaire
- Ocular symptoms
- Sphero-cylindrical refraction and BCVA
- Biomicroscopy
- Continuance
- Lens Randomization
- Lens Insertion
- Lens Damage
- Lens Settling
- Spherical over- refraction and VA
- Lens fit assessment (including lens fit digital video recording)
- Visual field measurement, OD, OS, OU
- Vision assessments (according to randomization scheme)
- Lens Removal

Final Evaluation

- Biomicroscopy
- Snellen VA measurement with spectacle refraction (Sphero-cylindrical)
- Final Evaluation Form

4.5 RANDOMIZATION AND MASKING

The lenses will not be dispensed and will be worn in a bilateral and random fashion using a 2x2 cross-over design. Permuted block randomization will be used to minimize the potential for treatment imbalance. A block size of two (2) will be utilized. A computer-generated randomization scheme will be provided by the study biostatistician to randomly assign subjects to one of two possible lens wear sequences (Test/Control or Control/Test) in a 1:1 manner. The order of applied distance as well as luminance within distance (if applicable) during vision assessments will also be randomized for each subject within lens type. The same orders applied for the first lens type will be used for the second lens type.

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

The study site must follow the randomization scheme provided and complete the enrollment according to the randomization list and not pre-select or assign subjects. The randomized assignment of subjects will be performed at the beginning of Visit 2. 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

This is a subject-masked study. Study participants will be masked with respect to the sequence of study lens wear to which they have been assigned. An unmasked investigator will insert and remove the study lenses so that the subject is not aware of the study lens type. The identity of the study lenses will be unmasked to the investigator who will record the lens fitting measurements. However, the identity of the study lenses will be masked to the investigator who will collect measurements for the study primary and secondary endpoints.

4.6 WEAR AND REPLACEMENT SCHEDULES, INCLUDING FORM, PACKAGING AND LABELING

Wear Schedule: In addition to the trial fitting at the first visit, the study lenses will be worn for a period of approximately three to four hours while attending the study measurement visits.

Replacement Schedule: The study lenses will only be worn once and disposed of after use.

Test Article Packaging Description: Single vials.

Labeling: The study contact lenses are CE marked and marketed in the UK and will carry the approved CE marking.

4.7 DETAILED STUDY PROCEDURES

4.7.1 SEQUENCE OF EVENTS

Visit 1: Enrolment / Fitting			
Step	**Descriptor**	**Details**	**Reference Document**
1.	Statement of Informed Consent	Each subject must read, understand and sign the Statement of Informed Consent before being enrolled in the study. A witness must also sign the form. *Note: The subject must be provided with a signed copy of this document.*	
2.	Demographics	Age, gender, race, and ethnicity,	
3.	Medical History	Questions regarding the subjects' medical history.	
4.	Concomitant Medications/ Treatments	Questions regarding the subjects' medications and/or treatments.	
5.	Contact Lens History	Questions regarding the subjects' habitual contact lenses and wearing patterns.	
6.	Subject Reported Ocular Symptoms	Record any symptoms or problems that the subject may experience with their habitual contact lenses, if applicable. Subject will not be asked about specific categories of complaints, but the severity or frequency will be recorded in the following categories: • Burning/Stinging • Itchiness/Scratchiness • Dryness • Lens Awareness • Grittiness/Foreign Body Sensation • Redness • Irritation/Discomfort • Cloudy/Blurry/Hazy • Variable Vision • Other	[redacted]
7.	Distance Sphero-cylindrical Refraction and Entrance Visual Acuity	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. The distance visual acuity to the nearest letter will be recorded OD, OS and OU. *Note: Best distance visual acuity with sphero-cylindrical refraction must be at least 20/30 in each eye for the subject to enroll in the study.*	Manual of Procedures [redacted]
8.	Best Sphere Refraction	An optimal, distance best sphere refraction will be performed. The distance visual acuity to the nearest letter will be recorded.	Manual of Procedures [redacted]

9.	Ocular Dominance	The distance ocular dominance will be determined with the best distance correction in place using the +1.00 blur test. If the results are equivocal the sighting dominance test will be used to determine the dominant eye for the study.	Manual of Procedures
10.	Keratometry	Keratometry readings will be taken for each eye using an Autokeratometer. Steep and Flat K readings will be recorded in mm and axis.	Manual of Procedures
11.	Pupil size measurement	The measurements will be carried out at three luminance: 250, 50 and 2.5 cd/m2	Manual of Procedures
12.	HVID measurement	Horizontal visible iris diameter will be recorded in millimeters with one decimal place.	Manual of Procedures
13.	Biomicroscopy	Biomicroscopy will be performed OD and OS. Standard Slit Lamp Classification Scales will be used to grade the findings. For the limbal and conjunctival redness, 0.5 unit increments will be used in the grading.	Manual of Procedures [redacted]
14.	Eligibility	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.	
15.	Lens Information	The initial contact lenses will be selected based upon the fitting guide. Place the lenses on the subject's eyes.	Appendix B
16.	Lens Damage	Inspect the lenses on eye with the biomicroscope for damage and if damaged, record the damage and have the subject insert a new lens. Save worn, damaged lenses in sterile saline in the labeled vials provided with the study materials and complete the quality product complaint form.	
17.	Lens Settling	Allow the lenses to settle for at least 15 minutes.	
18.	Spherical Over-Refraction and Visual Acuity	A monocular distance spherical over-refraction will be performed. The distance visual acuity to the nearest letter will be recorded OD, OS and OU.	Manual of Procedures [redacted]
19.	Subjective Lens Fit Assessment	Lens centration, primary gaze movement, upgaze movement and tightness (push-up test) will be evaluated and graded. The subject should not proceed to wear the contact lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in all three	Manual of Procedures [redacted]

		movement categories (primary gaze, upgaze, and push-up).	
20.	Modifications	If the subjects vision is or the Investigator determines that the visual acuity or over-refraction are not acceptable then a lens modification must be made (Repeat Steps 15 to 19). The fitting guide must be followed, allowing for at least 10 minutes settling time between lens changes.	
21.	Final lens parameters	Based on Lens Fit Evaluations, final lens parameters will be recorded.	
22.	Familiarization with visual performance assessment tasks	The subject will undergo familiarization with the study visual performance assessment tasks (time controlled visual acuity, detection tests, driving simulation and computer based reaction time game).	Manual of Procedures
23.	Lens Removal	The contact lenses are removed and discarded.	
24.	Biomicroscopy	Biomicroscopy will be performed OD and OS. Standard Slit Lamp Classification Scales will be used to grade the findings. For the limbal and conjunctival redness, 0.5 unit increments will be used in the grading.	Manual of Procedures [redacted]
25.	Distance Sphero-cylindrical Refraction and Exit Visual Acuity	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. The distance visual acuity to the nearest letter will be recorded OD, OS and OU.	Manual of Procedures [redacted]
26.	Continuance	Indicate whether the subject will continue to the next visit. If not, proceed to Final Evaluation.	
27.	Lens Order	Custom Test and Control lenses will be ordered. Visit 2 will be scheduled once the study lenses are received.	

Visit 2: First Measurement Visit (2 to 6 weeks after Visit 1)			
Step	**Descriptor**	**Details**	**Appendix**
1.	Concomitant Medications/ Treatments	Questions regarding the subjects' medications and/or treatments.	
2.	Subject Reported Ocular Symptoms	Record any symptoms or problems that the subject may experience with their habitual contact lenses, if applicable. Subject will not be asked about specific categories of complaints, but the severity or frequency will be recorded in the following categories: • Burning/Stinging • Itchiness/Scratchiness	[redacted]

		• Dryness • Lens Awareness • Grittiness/Foreign Body Sensation • Redness • Irritation/Discomfort • Cloudy/Blurry/Hazy • Variable Vision • Other	
3.	Distance Sphero-cylindrical Refraction and Entrance Visual Acuity	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. The distance visual acuity to the nearest letter will be recorded OD, OS and OU.	Manual of Procedures [redacted]
4.	Biomicroscopy	Biomicroscopy will be performed OD and OS. Standard Slit Lamp Classification Scales will be used to grade the findings. For the limbal and conjunctival redness, 0.5 unit increments will be used in the grading.	Manual of Procedures [redacted]
5.	Continuance	Indicate whether the visit needs to be rescheduled.	
6.	Randomization	Study Lens Type will be selected based on the Randomization Scheme	
7.	Study lens insertion	The initial study contact lenses will be selected based upon the randomization schedule. Place the lenses on the subject eyes.	
8.	Lens Damage	Inspect the lenses on eye with the biomicroscope for damage and if damaged, record the damage and have the subject insert a new lens. Save worn, damaged lenses in sterile saline in the labeled vials provided with the study materials and complete the quality product complaint form.	
9.	Lens Settling	Allow the lenses to settle for at least 15 minutes.	
10.	Spherical Over-Refraction and Visual Acuity	A monocular distance spherical over-refraction will be performed. The distance visual acuity to the nearest letter will be recorded OD, OS and OU.	Manual of Procedures [redacted]
11.	Subjective Lens Fit Assessment	Lens centration, primary gaze movement, upgaze movement and tightness (push-up test) will be evaluated and graded. The subject should not proceed to wear the contact lenses if any of the following is observed: • 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> movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the*	Manual of Procedures [redacted]

		subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.	
12.	Visual Field Measurement	Esterman visual fields will be measured OD, OS and OU using a Humphrey perimeter.	Manual of Procedures

13.	Vision Assessments	Time Controlled Visual Acuity (TCVA) Measurements will be made at 4m using 2.5 and 250 cd/m^2 luminance, and at 67cm using 50 cd/m^2 luminance. The luminance requirements will be the same at the target and at the eye. Monocular and binocular visual performance will be measured for the following conditions:
		• Distance 2.5 cd/m^2
		  o Central
		  o 5 degrees eccentricity
		  o 20 degrees eccentricity
		• Distance 250 cd/m^2
		  o Central
		• Intermediate 50 cd/m^2
		  o Central
		  o 5 degrees eccentricity
		  o 10 degrees eccentricity
		The order of luminances tested will be randomized.
		Subjects will undergo a driving simulation test and subsequently make a subjective assessment of their visual performance.
		Subjects will play computer based reaction time games and subsequently make a subjective assessment of their visual performance.
			Manual of Procedures

14.	Lens Removal	The contact lenses are removed and discarded.	

15.	Biomicroscopy	Biomicroscopy will be performed OD and OS. Standard Slit Lamp Classification Scales will be used to grade the findings. For the limbal and conjunctival redness, 0.5 unit increments will be used in the grading.	Manual of Procedures [redacted]
16.	Distance Sphero-cylindrical Refraction and Exit Visual Acuity	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. The distance visual acuity to the nearest letter will be recorded OD, OS and OU.	Manual of Procedures [redacted]
17.	Continuance	Indicate whether the subject will continue to the next visit. If not, proceed to Final Evaluation.	

Visit 3: Second Measurement Visit (2 to 14 days after Visit 2)			
Step	**Descriptor**	**Details**	**/Appendix**
1.	Concomitant Medications/ Treatments	Questions regarding the subjects' medications and/or treatments.	
2.	Subject Reported Ocular Symptoms	Record any symptoms or problems that the subject may experience with their habitual contact lenses, if applicable. Subject will not be asked about specific categories of complaints, but the severity or frequency will be recorded in the following categories: • Burning/Stinging • Itchiness/Scratchiness • Dryness • Lens Awareness • Grittiness/Foreign Body Sensation • Redness • Irritation/Discomfort • Cloudy/Blurry/Hazy • Variable Vision • Other	[redacted]
3.	Distance Sphero-cylindrical Refraction and Entrance Visual Acuity	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. The distance visual acuity to the nearest letter will be recorded OD, OS and OU.	Manual of Procedures [redacted]
4.	Biomicroscopy	Biomicroscopy will be performed OD and OS. Standard Slit Lamp Classification Scales will be used to grade the findings. For the limbal and conjunctival redness, 0.5 unit increments will be used in the grading.	Manual of Procedures [redacted]
5.	Continuance	Indicate whether the visit needs to be rescheduled.	
6.	Randomization	Study Lens Type will be selected based on the Randomization Scheme	
7.	Study lens insertion	The initial study contact lenses will be selected based upon the randomization schedule. Place the lenses on the subject eyes.	
8.	Lens Damage	Inspect the lenses on eye with the biomicroscope for damage and if damaged , record the damage and have the subject insert a new lens. . Save worn, damaged lenses in sterile saline in the labeled vials provided with the study materials and complete the quality product complaint form.	
9.	Lens Settling	Allow the lenses to settle for at least 15 minutes.	
10.	Spherical Over-Refraction and Visual Acuity	A monocular distance spherical over-refraction will be performed. The distance visual acuity to the nearest letter will be recorded OD, OS and OU.	Manual of Procedures [redacted]

11.	Subjective Lens Fit Assessment	Lens centration, primary gaze movement, upgaze movement and tightness (push-up test) will be evaluated and graded. The subject should not proceed to wear the contact lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in all three movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	Manual of Procedures [redacted]
12.	Visual Field Measurement	Esterman visual fields will be measured OD, OS and OU using a Humphrey perimeter.	Manual of Procedures

13.	Vision Assessments	Time Controlled Visual Acuity (TCVA) Measurements will be made at 4m using 2.5 and 250 cd/m^2 luminance, and at 67cm using 50 cd/m^2 luminance. The luminance requirements will be the same at the target and at the eye.
		Monocular and binocular visual performance will be measured for the following conditions:
		• Distance 2.5 cd/m^2
		  ○ Central
		  ○ 5 degrees eccentricity
		  ○ 20 degrees eccentricity
		• Distance 250 cd/m^2
		  ○ Central
		• Intermediate 50 cd/m^2
		  ○ Central
		  ○ 5 degrees eccentricity
		  ○ 10 degrees eccentricity
		The order of luminances tested will be randomized.
		Subjects will undergo a driving simulation test and subsequently make a subjective assessment of their visual performance.
		Subjects will play computer based reaction time games and subsequently make a subjective assessment of their visual performance.
			Manual of Procedures

14.	Lens Removal	The contact lenses are removed and discarded.	

Final Evaluation			
Step	Descriptor	Details	/Appendix
1.	Biomicroscopy	Biomicroscopy will be performed OD and OS. Standard Slit Lamp Classification Scales will be used to grade the findings. For the limbal and conjunctival redness, 0.5 unit increments will be used in the grading.	Manual of Procedures [redacted]
2.	Distance Sphero-cylindrical Refraction and Exit Visual Acuity	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. The distance visual acuity to the nearest letter will be recorded OD, OS and OU.	Manual of Procedures [redacted]
3.	Final Evaluation Form	Indicate the subject completed the study successfully or not. For subjects who discontinue, indicate the reason.	

4.8 DISCONTINUATION CRITERIA

Johnson & Johnson Vision Care, Inc. reserves the right to terminate the study at any time for any reason. Additionally, the IRB/IEC reserves the right to terminate the study if an unreasonable risk is determined. The study may be terminated by the Principal Investigator or Medical Monitor due to specific clinical observations, if in their opinion it would be unwise to continue.

Johnson & Johnson Vision Care, Inc. [*and the IRB/IEC, 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 Institutional Review Board (IRB), and Regulatory Authority as required by local regulatory requirements.

4.9 ACCOUNTABILITY PROCEDURES FOR INVESTIGATIONAL PRODUCT AND CONTROL

The Investigator will retain all lens shipment documentation for the test article accountability records.

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

The Investigator will collect all unused test articles at the end of the subject's participation. Following final reconciliation of test articles, JJVCI will arrange for appropriate return or destruction of unused test articles.

Reference APPENDIX A: SITE INSTRUCTIONS FOR TEST ARTICLE RECEIPT AND TEST ARTICLE ACCOUNTABILITY for instructions on the Lens Depot.

4.10 PROCEDURES FOR MAINTAINING AND BREAKING RANDOMIZATION CODES

Subjects who have had their lens assignment unmasked are expected to return for all remaining scheduled evaluations. A replacement subject may be enrolled if a subject discontinues from the study prematurely (see section 5.1); the decision whether to enroll replacement subjects will be made by the joint agreement of the Investigator and Sponsor.

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

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

There will be an un-masked investigator at the site, therefore no provision is required for breaking randomization codes.

4.11 REPORTING PRODUCT QUALITY COMPLAINTS

A Product Quality Complaint (PQC) refers to any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of test articles after they have been released for clinical trial use. A PQC is associated with any investigational product (i.e. product manufactured or supplied specifically for a clinical trial).

Complaint Handling

Once site personnel have become aware that a PQC has occurred, it shall then be recorded in the EDC system, which triggers 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, then 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 shall complete the applicable sections of the Product Quality Complaint Form [redacted]

For each complaint, the following minimum information shall be recorded by the CRA/COM on the Product Quality Complaint Form [redacted]

- Date the complaint was received/recorded in the EDC System (Date of Sponsor Awareness)
- Who received the complaint
- Study number
- Investigational 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 or not 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]

Clinical QA will assign a unique number to the PQC. Complaint numbering is assigned as follows:

RDTC-XX-001, where RDTC = R&D Technical Complaint, XX = last two digits of the current year, 001 = sequential numbering starting with 001.

5.1 WITHDRAWAL CRITERIA

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

- Lost to follow-up
- Withdrawal of consent
- Death
- Discontinuation of study treatment as a result of the investigator's clinical judgment that for safety reasons (e.g., adverse event) it is in the best interest of the subject to stop treatment.
- The subject becomes pregnant.

For discontinued subjects, the Investigator will:

- Update the enrollment log to document reason for discontinuation
- Complete the "last" Follow-up Visit form (scheduled or unscheduled)
- Complete the Final Evaluation form, indicating the reason that the subject was discontinued from the study
- Record the spherocylindrical refraction with best corrected distance visual acuity
- Collect used study lenses and test articles (worn or brought to the visit) from the subject and discard them
- Collect all unused study lenses and test articles from the subject

Subjects becoming pregnant during the study will be discontinued. Once discontinued, pregnant participants and their fetuses will not be monitored for study related purposes. At the Investigators' discretion, the study participant may be followed by the Investigator through delivery. However, this data will not be collected as part of the clinical study database. Pregnant participants are not discontinued from contact lens or solution related studies for safety concerns, but due to general concerns relating to pregnancy and contact lens use. Specifically, pregnant women are discontinued due to fluctuations in refractive error and/or visual acuity that occur secondary to systemic hormonal changes, and not due to unforeseen health risks to the mother or fetus.

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 as the final attempt.

6.1 PRESTUDY AND CONCOMITANT THERAPY

Concomitant medications will be documented during screening and during the study.

6.2 MONITORING TREATMENT COMPLIANCE

Johnson & Johnson Vision Care, Inc. representatives or designees will monitor the study in a manner consistent with ICH GCP E6. The study monitors will maintain close contact with the Principal Investigator and the Investigator's designated staff. The monitor's responsibilities will include:

- Ensuring that the investigation is being conducted according to the protocol
- Ensuring the rights and well being of subjects are protected
- Ensuring that protocol deviations are documented with corrective action plans, as applicable
- Ensuring that the site has sufficient test article and supplies
- Clarifying questions regarding the study
- Resolving study issues or problems that may arise
- Reviewing the study records to ensure completeness and accuracy
- Study and subject source document records reviewed will include:
    - The Information and Consent Form per 21CFR Parts 50 and 56 and the Data Protection Act
    - Source documentation including consenting, medical history, concomitant medications, and adverse event information as applicable. The source document should be initialed and dated by the study investigator/s.
    - Investigational product shipping, dispensing, accountability, and return/destruction records
    - Study related Regulatory documents as per ICH E3 section 8

6.2.1 MONITORING PLAN

This section of the protocol constitutes the monitoring plan for this study:

At least two monitoring visits will be completed during the study. A combined interim and closure visit may be conducted.

The following data will be reviewed:
1. Incl/Exc-Eligibility
2. Med History
3. Con Meds
4. Demographics
5. Test Article Accountability
6. Test Article Information
7. Primary End Points (PEP)
8. Secondary End Points
9. Protocol Deviations (PD)
10. AE's

11. Product Quality Complaints
12. Compliance
13. Symptoms
14. Comments
15. Intentionally Left Blank (ILB)
16. Unscheduled Visits (UV)
17. Final Evaluation

6.3 UNSCHEDULED VISITS

If, during the investigation, a subject experiences any investigational device-related difficulties and/or problems requiring an unscheduled visit to the clinic, 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 should be completed and source documentation 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 investigational product dispensed or collected from the subject.
- 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 enrollment log should be completed documenting the date and primary reason for withdrawal and the study CRA notified.

Any investigational device-related difficulties and/or problems that are ongoing at the time of the final study visit will be followed by the Investigator, within licensure, until they have returned to pre-treatment status, stabilized, or been satisfactorily explained. If further treatment (i.e., beyond licensure) is required, the subject will be referred to the appropriate health care provider.

7.1 EFFICACY PARAMETERS

The primary efficacy parameters for this study will be measurements of binocular functional visual performance under distance day time conditions (250 cd/m2) for centrally presented high contrasts (HC) time controlled visual acuity (TCVA) targets.

The secondary efficacy parameters for this study will be measurements of binocular functional visual performance of the test and control contact lenses for the following conditions:

i. Distance night time conditions (2.5 cd/m2) for centrally presented HC TCVA targets;
ii. Intermediate vision indoor conditions (50cd/m2) for centrally presented HC TCVA targets.

Other efficacy parameters for this study will be measurements of:

i. Monocular functional visual performance for centrally presented high contrast (HC) time controlled visual acuity (TCVA) targets.
    a. Distance day time conditions (250 cd/m2)
    b. Distance night time conditions (2.5 cd/m2)
    c. Intermediate vision indoor conditions (50cd/m2)
ii. Distance monocular and binocular functional visual performance of the test and control contact lenses under night time conditions (2.5 cd/m2) for HC TCVA targets presented at 5° eccentricity;

iii. Intermediate vision monocular and binocular functional visual performance of the test and control contact lenses under indoor conditions (50cd/m2) for HC TCVA targets presented at 5° eccentricity;
iv. Distance monocular and binocular functional visual performance of the test and control contact lenses under night time conditions (2.5 cd/m2) for decreasing contrast targets presented at 20° eccentricity;
v. Intermediate vision monocular and binocular functional visual performance of the test and control contact lenses under indoor conditions (50cd/m2) for decreasing contrast targets presented at 20° eccentricity.
vi. Horizontal binocular visual field;
vii. Horizontal monocular visual field.
viii. Subjective rating of performance following driving simulation while wearing test and control contact lenses under night time condition (e.g. City Car Driving Simulator / PC game);
ix. Subjective rating of performance following PC based reaction time game while wearing test and control contact lenses.

7.2 METHODS FOR ASSESSING, RECORDING, AND ANALYZING EFFICACY

See detailed study procedures in section 4.7 regarding methods for assessing and recording efficacy.
Statistical methods for analyzing efficacy data are provided in section 9.1 below.

8.1 SAFETY PARAMETERS

The following safety parameters will be monitored and evaluated:

• Ocular physiology characteristics
• Lens fitting characteristics
• Adverse events
• Ocular symptoms
• Snellen distance visual acuity
• Reasons for discontinuation
• Reasons for unplanned lens replacement
• Quality Complaints

Safety parameters will be tabulated using frequency distribution tables and descriptive statistics. Adverse events will be listed by subject/eye. There will be separate summary tables for adverse events and infiltrative adverse events. Statistical methods for analyzing safety data, if any, are provided in section 9.

8.2 ADVERSE EVENTS

All adverse events will be will be recorded in the subject's source document and documented in the appropriate section of the subject's Case Report Form (CRF).

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 (see definition in Section 8.4).
- Expectedness – i.e. if the event was unexpected or unanticipated in that it was not previously identified in nature, severity, or degree of incidence (see definition in Section 8.4).

- Causality or Relatedness – i.e. the relationship between the test article and the adverse event (not related; doubtful; possible; probable; very likely - see definition in Section 8.4).

- Adverse Event Intensity or Classification – Adverse event intensity is used to assess the degree of intensity of the adverse event (mild, moderate, severe for all events). In addition adverse event Classification is used to assess the severity of ocular adverse events (AE not requiring treatment, non-significant or significant see definition in Section 8.4).

- Outcome – Resolved, ongoing, not resolved, resolved with sequelae, fatal, resolving, and unknown.

- Actions Taken – None, temporarily discontinued, permanently discontinued, other action taken.

In addition, a written report will be submitted by the Principal Investigator to the IRB/IEC according to their requirements. Such a report should comment whether or not the adverse event was considered to be related to the test article.

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 for review by the Medical Monitor.

Serious Adverse Events:

The Investigator will inform the sponsor of all serious 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 CRF. All subjects experiencing a serious adverse event must be followed up and all outcomes must be reported.

In the event of a serious adverse event, the investigator must:

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

8.3 ADVERSE EVENT DEFINITIONS

Adverse Event (AE) – An AE is any untoward (unwanted) medical occurrence in a patient or clinical investigation subject administered a test article whether or not caused by the test article or treatment. An AE can therefore be any unfavorable or unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of the test article whether or not related to the test article.

An AE includes any condition (including a pre-existing condition) that: 1) was not present prior to study treatment, but appeared or reappeared following initiation of study treatment; or 2) was present prior to study treatment, but worsened during study treatment. This would include any condition resulting from concomitant illnesses, reactions to concomitant medications, or progression of disease states. Pregnancy should be documented as an adverse event and should 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 (i.e., 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 investigational product 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 Serious Adverse Events include:

- Microbial Keratitis (MK)
- Iritis
- Permanent decrease in best spectacle corrected visual acuity equivalent to 2 acuity lines or greater
- Central Corneal Opacity
- Central Corneal Neovascularization
- Uveitis
- Endophthalmitis
- Hypopyon
- Hyphemia
- Penetration of Bowman's Membrane
- Persistent Epithelial Defect
- Limbal cell Damage leading to Conjunctivalization

Significant Adverse Events – 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 Significant Adverse Events include the following:

- Contact Lens Induced Peripheral Ulcer (CLPU)
- Significant Infiltrative Events (SIE)
- Superior Epithelial Arcuate Lesions (SEALs)
- Any Temporary Loss of $\geq$ 2 Lines of BSCVA
- Other grade 3 or higher corneal findings, such as abrasions or edema
- Any corneal event which necessitates temporary lens discontinuation $\geq$ 2 weeks

- Non-contact lens related corneal events - e.g. EKC (Epidemic Keratoconjunctivitis)
- Asymptomatic Corneal Scar

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 Non-Significant Adverse Events include the following:

- Non-significant Infiltrative Event
- Contact Lens Papillary Conjunctivitis
- Superficial Punctate Keratitis
- 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) – A sub-set of AEs, and include only those adverse events that are cause by or related to the investigational device or study procedure.

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

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.
- Doubtful – 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.
- Possible – An adverse event that might be due to the use of the test article. 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.
- Probable – An adverse event that might be due to the use of the test article. The relationship in time is suggestive (e.g. confirmed by de-challenge). An alternative explanation is less likely, e.g. concomitant treatment or concomitant disease(s).
- Very Likely – An adverse event that is listed as a possible adverse effect (device) or adverse reaction (drug) and cannot be reasonably explained by an alternative explanation, e.g. concomitant treatment of concomitant disease(s). The relationship in time is very suggestive, e.g. it is confirmed by de-challenge and re-challenge.

Severity Assessment – 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 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.

8.4 METHODS FOR ASSESSING, RECORDING, AND ANALYZING SAFETY

The recording and documenting of adverse events (ocular and non-ocular) begin when the subjects are exposed to the test article or study treatment. Adverse events reported before the use of test article or start of study treatment should be recorded as medical history. Untoward medical events reported after the subject's exit from the study will be recorded as adverse events at the discretion of the Investigator.

All adverse events observed by the Investigator; reported by the subject spontaneously; or in response to direct questioning; will be recorded in the source document. Such documentation will include a description of the adverse event, time of onset, duration of event, treatment regimen instituted, any referral to another health care provider (if needed), any new concomitant medications, outcome, ocular damage (if any), and likely etiology. Best Corrected Visual Acuity (BCVA) should be recorded prior to the report of an adverse event (as part of the baseline evaluation), upon report of the subject's report of the adverse event, and after the adverse event has resolved. All adverse events will be followed in accordance with licensing requirements.

All adverse events will be documented in the appropriate section of the subject's Case Report Form (CRF).

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 (see definition in Section 8.3)

Expectedness – i.e. if the event was unexpected or unanticipated in that it was not previously identified in nature, severity, or degree of incidence (see definition in Section 8.3)

Causality or Relatedness – i.e. the relationship between the test article and the adverse event (not related; doubtful; possible; probable; very likely - see definition in Section 8.3)

Adverse Event Intensity or Classification – Adverse event intensity is used to assess the degree of intensity of the adverse event (mild, moderate, severe for all events). In addition Adverse event Classification is used to assess the severity of ocular adverse events (AE not requiring treatment, non-significant or significant see definition in Section 7.4).

Outcome – Fatal, not resolved, resolved, resolved with sequelae, resolving and unknown.

Actions Taken – None, temporarily discontinued, permanently discontinued, Other action taken

Upon finding an adverse event, the Principal Investigator will document the condition on the follow-up visit worksheet source document and in the CRF's using photos or drawings (where appropriate) that detail size, location, and depth. He will also complete the Adverse Event Classification (AEC) Discovery form / eCRF. In addition, if an infiltrate(s) is present, he will complete the Corneal Infiltrate Assessment Form / 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, a source document note should be completed specifying the date of culture collection and laboratory utilized. An eCRF documenting this should be completed in a comment or unscheduled visit.

Complete description of all adverse events must be available in the source documents. All Adverse Events including local and systemic reactions not meeting the criteria for "serious adverse events" should be captured on the appropriate case report form or electronic data system. Information to be recorded, based on above assessment criteria, includes date site notified, event description, date and time of onset, investigator assessment of severity, relationship to Study Agent(s)/Intervention(s), and time of resolution/stabilization of the event. All adverse events occurring while on study must be documented appropriately regardless of relationship. Define a timeframe for CRF completion and entry of the adverse event information into the database, as applicable.

Any medical condition that is present at the time that the subject is screened should be considered as baseline and not recorded as an AE. However, if the condition deteriorates at any time during the study it should be recorded and reported as an AE.

Changes in the severity of an AE should 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 Study Agent(s)/Interventions should also be clearly documented.

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 a serious / significant adverse event, and 2 days from discovery for a non-significant adverse event. In addition, a written report will be submitted by the Principal Investigator to the IRB/IEC according to their requirements (Section 12.3). Such a report should comment whether or not the adverse event was considered to be related to the test article.

8.5 ADVERSE EVENTS FOLLOW-UP

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)
- Detailed drawings or photographs, when appropriate
- Date and time of onset
- Date and time of resolution
- Adverse event intensity and classification, as applicable
- Treatment regimen instituted, including concomitant medications prescribed, in accordance with applicable licensing requirements
- Any referral to another health care provider if needed
- Outcome, ocular damage (if any)
- Likely etiology.
- Best corrected visual acuity at the discovery of the event and upon conclusion of the event

In addition, if an infiltrate(s) is present, the Investigator will complete the Corneal Infiltrate Assessment Form / eCRF.

Photographs or video recordings may be collected at the Investigator's discretion for purposes of documenting adverse event findings.

Visual acuity (best corrected) should be recorded prior to the report of an adverse event (as part of the Baseline Evaluation), upon the subject's report of the adverse event, and after the adverse event has resolved.

Subjects who present with an adverse events should 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 (i.e. beyond licensure) is required, the patient will be referred to the appropriate health care provider. The Investigator should use his/her clinical judgment as to whether or not a subject (eye) reporting with an adverse event should 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 complete the Adverse Event Classification (AEC) Outcome form / eCRF. Any subjects with ongoing adverse events related to the test article 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.

9.1 STATISTICAL METHODS TO BE EMPLOYED

All data summaries and statistical analyses will be performed using either the SAS software Version 9.4 or higher (SAS Institute, Cary, NC) or SPSS software Version 23.0 or higher (IBM Corp, Armonk, NY).

Description of Summary Tables

Summary tables (Descriptive statistics and/or frequency tables) will be provided for all baseline, efficacy and safety variables for each subject/eye 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 variables.

Summaries will be presented by study lens type and will be performed separately by study population defined in section 9.7. Efficacy variables will be summarized descriptively on both the analysis and safety population. Safety variables will be summarized descriptively for the safety population. Unscheduled visits will be summarized separately if applicable. If the difference between the analysis and safety population is higher than 15%, a sensitivity analysis will be conducted on the safety population.

Data summarization will be performed by OTG-i, with oversight by the JJVCI study responsible biostatistician.

Raw data will be provided to OTG-i by JJVCI/Bioclinica in the Study Data Tabulation Model (SDTM) format in conformance to Clinical Data Interchange Standards Consortium (CDISC) standards. OTG-i will be responsible to create CDISC Analysis Data Model (ADaM) datasets as well as the display outputs including tables, listings and figures (TLFs) based on the CDISC ADaM datasets. For more details about CDISC, SDTM and ADaM, please refer to www.cdisc.org.

OTG-i shall follow specifications of ADaM datasets and mock shells of TLFs provided by JJVCI. Sample datasets, ADaM specifications, and mock shells of TLFs may be provided to OTG-i by JJVCI midway through the study if needed.

Description of Analysis Methods

Efficacy Analysis Set

The primary and secondary analysis will be performed on all randomized subjects who successfully completed the study without any protocol deviations that the study responsible clinician documents as impacting the assessment of the hypotheses (i.e. analysis population). Justification of excluding subjects with protocol deviations in the analysis population set will be documented.

Analysis Methods

The binocular central distance high contrast, high illumination (250 cd/m^2) TCVA, the binocular central distance high contrast, low illumination (2.5 cd/m^2) TCVA and the binocular central intermediate vision high contrast, medium illumination (50 cd/m^2) TCVA will be analyzed together using a linear mixed model. The model will include the experimental design factors: sequence of lens wear, period, lens type, condition (determined jointly by distance, illumination and eccentricity) as well as lens type by condition interaction as fixed effects; and subject as a random effect. Other baseline characteristics known of importance such as age, gender and race may be included as fixed covariates when appropriate. The covariance between residual errors from the same subject and period at different conditions will be selected based on the finite-sample corrected Akaike's Information Criterion (Keselman et al., 1998). Covariance structures considered may include:

- Variance Component (VC)
- Homogenous Compound Symmetry (CS),
- Heterogeneous Compound Symmetry (CSH),
- Heterogeneous Variance Component (UN(1))
- Unstructured Covariance Structure (UN).

For UN(1) covariance structures, condition nested within subject and period will be included as an additional random effect. For the remaining structures only subject will be included as a random effect. The improved Kenward and Roger method (Kenward and Roger, 2009) using the KENWARDROGER2 option will be used for the calculation of the denominator degrees of freedom. Heterogeneous models between the study lenses may be considered when appropriate. The log-likelihood ratio test will be used to test for homogeneity of variances between lens types.

Primary Hypothesis Testing:
The null and alternative hypotheses for non-inferiority in the binocular central distance high contrast high illumination TCVA are as follows: H_0: $\mu_1 - \mu_2 \leq -0.5$ v.s. Ha: $\mu_1 - \mu_2 > -0.5$, where μ_1 and μ_2 are the population mean of binocular central distance high contrast high illumination TCVA for the Test lens and the Control lens, respectively. Comparisons between the Test lens and Control lens will be conducted using two-sided 95% confidence intervals constructed for least-square means (LSM) difference (Test - Control) at central distance high contrast high illumination. Non-inferiority will be concluded if the lower limit of the LSM difference is greater than -0.5 VA units.

Secondary Hypothesis Testing:
The null and alternative hypotheses for non-inferiority in each of the secondary endpoints are as follows: H_0: $\mu_1 - \mu_2 \leq -0.75$ v.s. Ha: $\mu_1 - \mu_2 > -0.75$, where μ_1 and μ_2 are the population mean of the corresponding endpoint for the Test lens and the Control lens, respectively. Comparisons between the Test lens and Control lens will be conducted using two-sided 95% confidence intervals constructed for least-square means (LSM) difference (Test - Control) at central distance high contrast low illumination and central intermediate vision high contrast medium illumination, respectively. Non-inferiority will be concluded if the lower limit of the LSM difference is greater than -0.75 VA units.

Bayesian analysis may be considered if the data is not normally distributed.

Further exploratory analysis can be undertaken if necessary at the discretion of the study responsible clinician.

9.2 NUMBER OF SUBJECTS BY SITE AND JUSTIFICATION FOR SAMPLE SIZE

A minimum of 20 subjects are targeted to complete the study as the cohort population. Subjects who are found to be ineligible, or who are discontinued or incomplete, will be classified as the non- cohort population. The total number of subjects enrolled may not exceed 25 subjects, except by joint agreement of the Investigator and Sponsor. Since this is a pilot study and all the hypotheses are exploratory in nature, the sample size was selected by the study responsible clinician and was not based on any empirical power calculation.

9.3 LEVEL OF STATISTICAL SIGNIFICANCE

All planned analysis for this study will be conducted with an overall type I error rate of 5%. Since this study is exploratory in nature, no adjustment for multiple comparisons will be conducted.

9.4 CRITERIA FOR STUDY TERMINATION

In addition to the stopping rules defined in section 9.1, the occurrence of one or more Serious Unanticipated Adverse Device Effect (USADE), or any SAE where the relationship to study agent cannot be ruled out, may result in stopping further dispensing of investigational product. In the event of a USADE or SAE, the Sponsor may unmask the treatment regimen for the subject(s) and may discuss this with the Investigator before any further subjects are enrolled.

The sponsor may determine when a study will be stopped. The principal investigator always has the discretion to initiate stopping the study based on subject safety or if information indicates the study's results may be compromised.

9.5 PROCEDURE FOR ACCOUNTING FOR MISSING, UNUSED, AND SPURIOUS DATA

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

9.6 PROCEDURE FOR REPORTING DEVIATIONS FROM STATISTICAL PLAN

The analysis will be conducted according to section 9.1. 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.

9.7 EVALUABLE SUBJECTS

Accountability (disposition) of all enrolled subjects will be presented in each of the following status subgroups.

1. Completed: Randomized subjects who are eligible to participate in the study and have successfully completed all required visits including the final visit.

2. Discontinued: Randomized subjects who are prematurely discontinued from the study due to (i) lost to follow-up, (ii) withdrawal of consent, (iii) death, (iv) unsuccessful dispensing (lack of efficacy or safety), (v) safety reasons at the discretion of the investigator, (vi) dissatisfactory of eligibility criteria (e.g., pregnancy), (vii) noncompliance of the study lens wear schedule.

3. Total Dispensed: Randomized subjects who administered the test article at least once (i.e. lens insertion occurred in at least one eye).

4. Enrolled Not Dispensed: Subjects who were (i) enrolled in the study (provided informed consent) but failed to satisfy the eligibility criteria (inclusion/exclusion criteria), (ii) randomized but discontinued or drop out prior to administering the test article, or (iii) not randomized to treatment for any reason.

5. Total enrolled (i.e. completed + discontinued + Enrolled not dispensed).

Subjects will be allocated to the following study populations. Safety variables will be summarized on the safety population whereas efficacy variables will be summarized on both the analysis and safety population.

1. Safety Population: All subjects who are administered the test article and have at least one observation on any safety or/and efficacy variables.

2. Analysis Population: All subjects who have successfully completed all required visits without any protocol deviations that the study responsible clinician documents as impacting the assessment of the hypotheses.

10.1 ELECTRONIC CASE REPORT FORM/DATA COLLECTION

The data for this study will be captured on electronic case report forms (eCRFs) using an EDC system when possible. Designated study site personnel will enter study data into the electronic CRFs (eCRFs) using the EDC system. Data collected on equipment that is not possible to be captured in EDC will be formatted in conformance to Clinical Data Interchange Standards Consortium (CDISC) standards following JJVCI's specification --i (refer to Section 9.1) for statistical analysis.

The CRFs will be reviewed for accuracy and completeness and signed by the investigator. Unless otherwise stated, the eCRFs will be considered the source document. The sponsor or sponsor‘s representatives will be authorized to gain access to the source documentation 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 investigational 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 a non-editable format for all of the study data. The IPP should be retained in the study files as a certified copy of the source data for the study.

The content and structure of the CRFs are compliant with ISO14155:2011 [3].

10.2 SOURCE DOCUMENTATION

At a minimum, source documentation should be available for the following to confirm data collected in the CRF: subject identification, eligibility, and 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; concomitant medication; investigational product receipt / dispensing / return records; study investigational product administration information; date of study

completion; reason for early discontinuation of investigational product or withdrawal from the study, if applicable.

The author of an entry in the source documents must be identifiable. Adverse event notes should be reviewed and initialed by the Investigator.

At a minimum, the type and level of detail of source data available for a study subject should be consistent with that commonly recorded at the site as a basis for standard medical care. Specific details required as source data for the study will be reviewed with the investigator before the study and will be described in the monitoring guidelines (or other equivalent documents).

10.3 ACCESS TO SOURCE DATA/DOCUMENTS

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

10.4 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 JJVCI. The Investigator may use this information for the purposes of the study only. It is understood by the Investigator that JJVCI will use information developed in this clinical study in connection with the development of an 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.

The Investigator may not submit for publication or presentation the results of this study without first receiving written authorization from JJVCI. JJVCI agrees that, before it publishes any results of the study, it shall provide the Investigator with at least 30 days for review of the pre-publication manuscript prior to the submission of the manuscript to the publisher.

11.1 DATA QUALITY ASSURANCE

Steps to be taken to ensure the accuracy and reliability of data include the selection of qualified investigators and appropriate study sites and review of protocol procedures with the principal investigator. The principal investigator, in turn, must ensure that all sub-investigators and study staff are familiar with the protocol and all study-specific procedures and have appropriate knowledge of the study article.

Guidelines for case report form completion will be included in the eCRF. The sponsor, Johnson & Johnson Vision Care, Inc. will review case report forms for accuracy and completeness remotely during the course of the study, during on-site 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 Johnson & Johnson Vision Care, Inc. may visit study sites to review data produced during the study and to access compliance with applicable regulations pertaining to the conduct of clinical trials. The study sites will provide direct access to study-related source

data/documents and reports for the purpose of monitoring and auditing by Johnson & Johnson Vision Care, Inc. and for inspection by local and regulatory authorities.

12.1 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. They 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.

12.2 INVESTIGATOR RESPONSIBILITY

The Investigator is responsible for ensuring that the clinical study is performed in accordance with the protocol, Section 4 of the ICH E6 guidelines on Good Clinical Practice (GCP), 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 wellbeing of study subjects are protected, consistent with the principles of the Declaration of Helsinki 64th WMA General Assembly 2013 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), and applicable regulatory requirements.

12.3 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, if applicable
- 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 recruiting materials approved by the Sponsor
- Revisions to compensation for study-related injuries or payment to subjects for participation in the study, if applicable
- 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 investigational product, 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 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 be asked to 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 filed in the study Investigator binder and a copy provided to the CRO or Sponsor as applicable.

12.4 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 should be in accordance with principles that originated in the Declaration of Helsinki, current ICH and GCP guidelines, applicable regulatory requirements, and sponsor policy.

Before entry into the study, the Investigator or an authorized member of the investigational staff 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. They will be informed that choosing not to participate will not affect the care the subject will receive. Finally, they will be told that the Investigator will maintain a subject identification register for the purposes of long-term follow-up if needed and that their records may be accessed by health authorities and authorized sponsor staff without violating the confidentiality of the subject, to the extent permitted by the applicable law(s) or regulations. By signing the informed consent form the subject is authorizing such access, and agrees to be contacted after study completion, by health authorities and authorized sponsor staff, for the purpose of obtaining consent for additional safety evaluations if needed.

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.

In the event additional investigators / sites are added to the protocol, the informed consent will be modified to include the Investigator's name, address, phone number and 24-hour emergency number.

12.5 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 investigational staff (e.g., name, clinic address and phone number, curriculum vitae) is subject to compliance with the Data Protection Act of 1998 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, Sponsors personnel and independent ethics committee. 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), independent ethics committee and regulatory organizations in the context of their investigation related activities that, as part of the investigation will have access to the CRFs and source documents.

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.

13.1 DATA HANDLING AND RECORD KEEPING

In compliance with the ICH/GCP guidelines, the Investigator / Institution will maintain all CRFs and all source documents that support the data collected from each subject, as well as all study documents as specified in ICH/GCP Section 8, Essential Documents for the Conduct of a Clinical Trial, 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 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 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 by an agreement with 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 should contact JJVCI Research and Development.

14.1 FINANCIAL CONSIDERATIONS

Remuneration for study services and expenses will be set forth in detail in the Investigator's Research Agreement. The Research Agreement will be signed by the Principal Investigator and a Johnson & Johnson Vision Care management representative prior to study initiation.

Case Report Forms will be completed in real time according to the study procedures specified in the study protocol. Case Report Forms should be completed and reviewed and signed as applicable by the Investigator within 3 days of visit completion. Data queries must be addressed with complete responses within 3 days of generation. Johnson & Johnson Vision Care reserves the right to withhold remuneration until these activities are addressed.

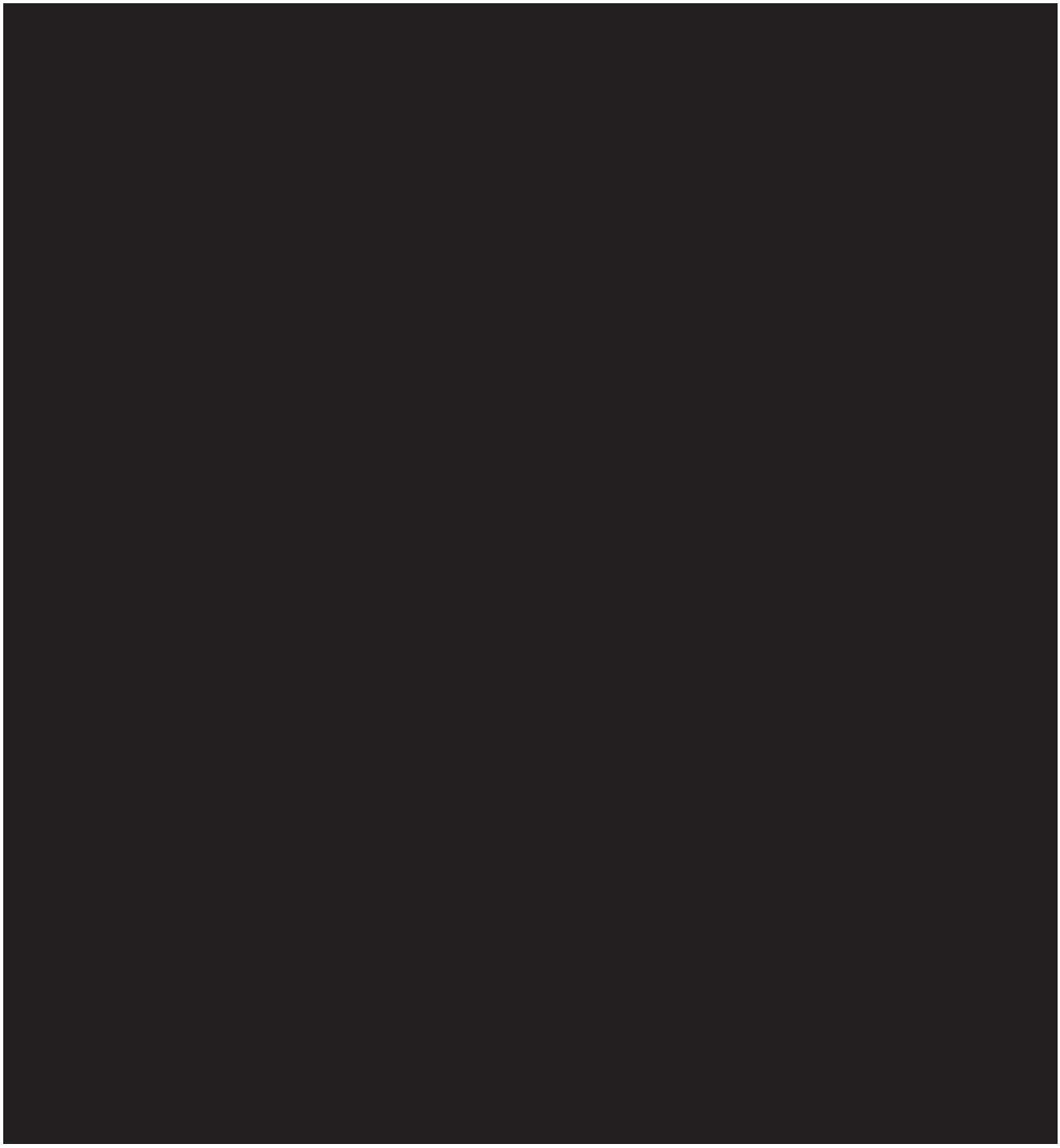
Johnson & Johnson Vision Care reserves the right to withhold remuneration for costs associated with protocol violations such as:

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

15.1 PUBLICATION

This study will be registered on ClinicalTrials.gov.

16.1 PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)



16.2 CLINICAL TECHNICAL PROCEDURES [redacted]

The following [redacted] are included in the Manual of Procedures:

- [redacted] LIMBAL & CONJUNCTIVAL (BULBAR) REDNESS
- [redacted] LENS FITTING CHARACTERISTICS
- [redacted] OCULAR SYMPTOMS
- [redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS
- [redacted] BIOMICROSCOPY SCALE
- [redacted] DISTANCE AND NEAR VISUAL ACUITY EVALUATION

16.3 PATIENT INSTRUCTION GUIDE (APPROVED PRODUCT)

See package insert (Appendix B).

16.4 PACKAGE INSERT

See Appendix B.

17.1 LIST OF ABBREVIATIONS

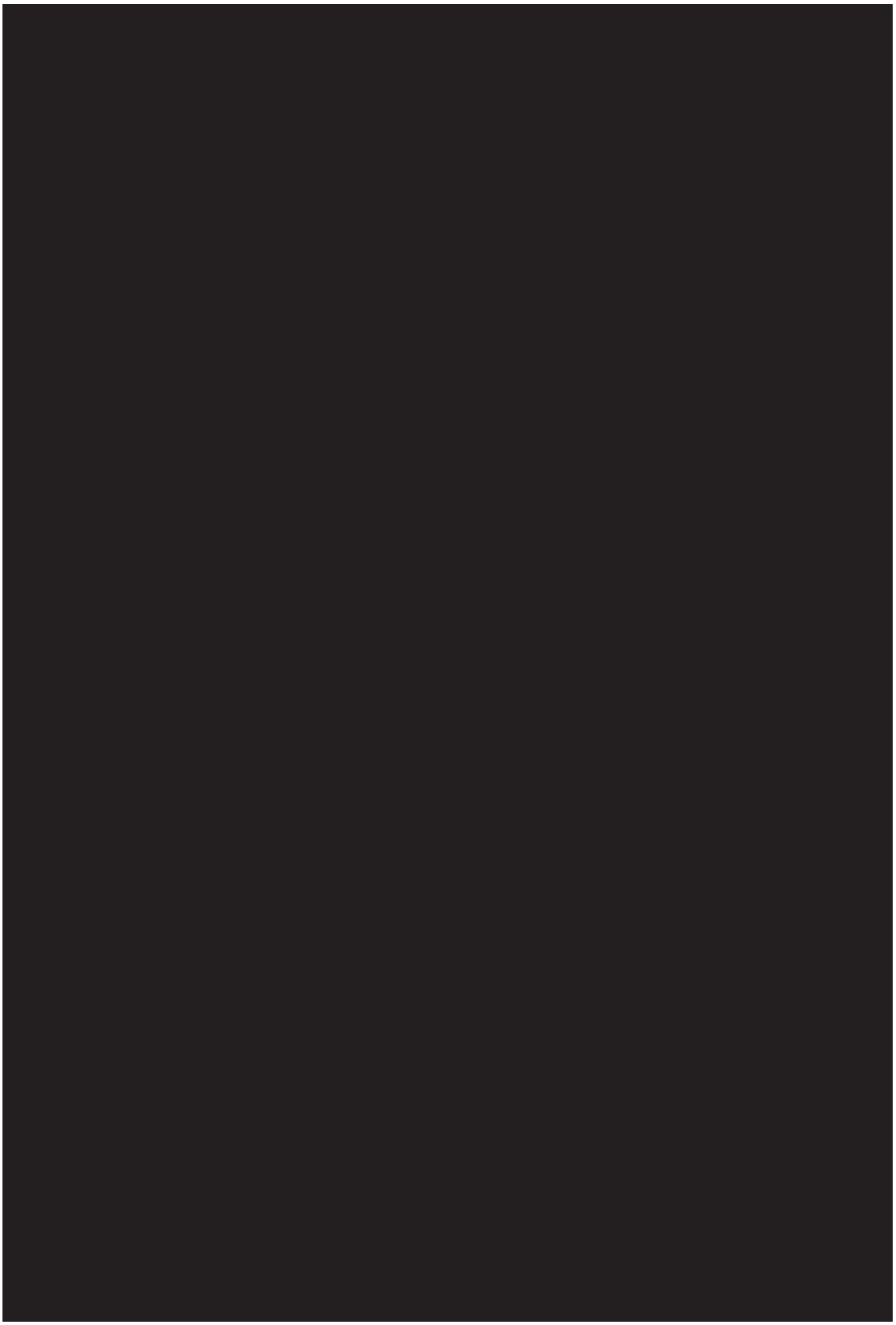
AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CIB	Clinical Investigator's Brochure
CRF	Case Report Form
CRO	Contract Research Organization
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
IRB	Institutional Review Board
MedDRA ©	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
OHSR	Office for Human Subjects Research
PHI	Protected Health Information
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect

APPENDIX A: SITE INSTRUCTIONS FOR TEST ARTICLE RECEIPT AND TEST ARTICLE ACCOUNTABILITY

Part 1 – Overall Test Article Accountability

- Once the test article shipped sheet is completed for the shipment the investigational site must log the shipment into the lens depot in the EDC system.

1. Log into the Study Database in BioClinica Express 5.4



***If Quantity shipped is different from Total Quantity Received, please notify your regional CRA immediately (a query will populate if this occurs to be resolved)**

- At the end of the study you will need to return all unused test article
- At your close out visit your monitor will help you complete a **Test Article Return Worksheet**, documenting how much test article is being returned.
- Once the Test Article Return Worksheet is completed, you will need to enter the quantity of lenses being returned into the lens depot in the EDC system.

6. Enter Total Quantity Returned after the study is completed and lens accountability has

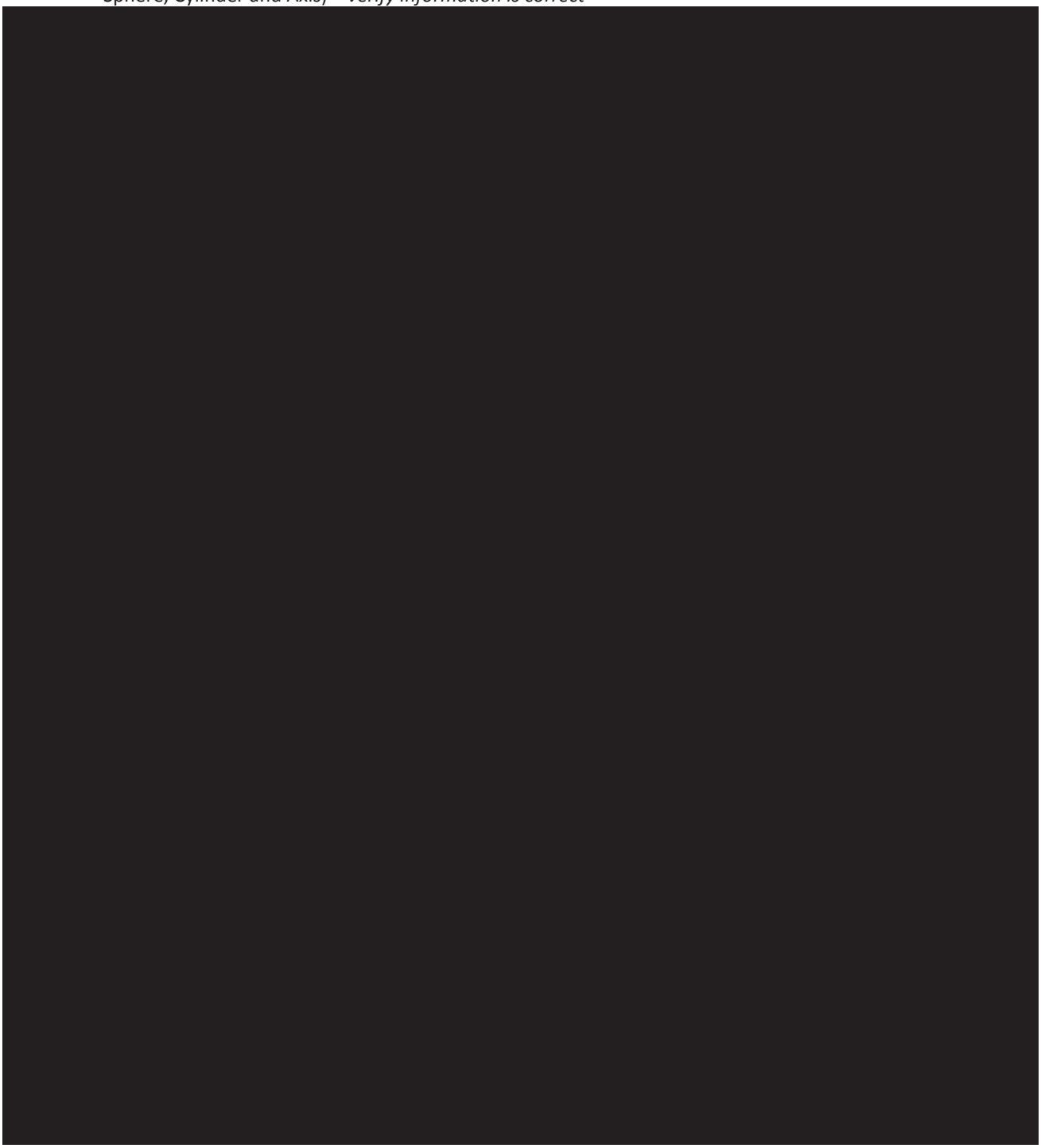
[redacted]

- # Lenses dispensed
- Date dispensed
- Dispenser initials
- Lens count

- The Lens Information eCRF is within the subject's eCRF and is used to record individual lens information.

[redacted]

Once you click the Lot #, all other fields associated with the study are auto populated (e.g. Product Code, Sphere, Cylinder and Axis) – *verify information is correct*



- Once “Yes” is selected and the form is **saved** an additional form will be generated to enter the replacement lens information.

APPENDIX B: LENS PACKAGE INSERT

which may lead to permanent eye damage, for example tap water.
- Never allow saliva to come in to contact with your lens.

If you have not worn your lenses for an extended period of time (several days or more) follow your contact lens care regimen to clean and disinfect the lens prior to insertion.

LONG TERM STORAGE OF CORNEO SCLERAL OR SCLERAL LENSES:
If you are planning to store a lens long term then it is best to store it dry. Disinfect and then wet the lens before use.

DIFFICULTY REMOVING A LENS
If the lens becomes difficult to remove insert a recommended lubricating solution or rewetting solution directly into the eye and wait for five minutes before attempting to remove it. If the problems persist contact your eye care professional.

Occasional dryness may be relieved by the use of lubricating drops which can be prescribed by your eye care professional.

SOFT CONTACT LENS INSTRUCTIONS FOR USE
PRODUCT NAMES:
- Reflex range

MATERIAL:
- GM3 58% Reflex Spherical & Toric, Spherical Toric & Bandage
- GM3 75% Reflex Spherical & Toric,Spherical Toric & Bandage
- SIH Definitive 74% Reflex Range
- Methafilcon 55%
- Contaflex 77%

INDICATIONS (USES):
- Soft lenses are suitable for the optical correction of vision for myopia, hypermetropia, astigmatism and presbyopia. Reflex Kera is suitable for the correction of irregular corneas

CONTRAINDICATIONS:
DO NOT prescribe Reflex lenses in the presence of ocular infection, inflammation or injury, any eye disease, severe dry eyes or corneal hypoaesthesia unless indicated. Or if there is any systemic condition that may affect the eye or cause heightened risk of allergy to contact lens or solution. Or if the patient is taking medication that may interfere with contact lens wear (e.g. preserved eye drops).

RECOMMENDED WEARING SCHEDULE:
- Daily wear - less than 24 hours while awake
- Wearing time should be built up gradually before the maximum is achieved.

REPLACEMENT SCHEDULE:
Reflex lenses should be replaced on a 3 monthly basis or more frequently as recommended by the eye care professional.

WARNINGS:
In order to promote safe use it is essential that the patient follows the manufacturers recommendations for care of contact lenses, use of care products and lens cases.

Patients should be warned that serious adverse reactions such as ulcers or keratitis can arise very quickly and are more likely to occur if the patient does not follow the manufacturers recommendations for wearing times, replacement schedule, use of care products and lens cases. The patient should not wear the lens whilst sleeping, showering or swimming.

The eye care professional must ensure that the patient can remove their lenses before dispensing them and should advise the patient to remove the lenses and contact them immediately if any adverse reaction arises. The patient should attend regular after-care appointments.

Ensure that any sodium fluorescein has dissipated before inserting the lenses, due to lens absorption of the dye and increased infection risk.

IMPORTANT PATIENT INFORMATION

PRECAUTIONS:
DO NOT exceed your recommended wearing time.
DO NOT use the lenses after the recommended replacement date.
DO NOT swim whilst wearing the lenses.
DO NOT sleep whilst wearing the lenses.
DO NOT allow tap water or saliva to come into contact with your lenses.
DO NOT wear your lenses if your eyes are sore and/or red.
DO NOT store lenses in saline only, always use a contact lens solution.
DO NOT use lenses or solutions after their use by date.
DO NOT wear lenses if you are using eye drops unless advised to by your eye care professional.
YOU SHOULD wash and dry hands (with clean lint free tissue or towel) before handling, inserting or removing the lens.
YOU SHOULD rinse your lens case daily with saline or fresh contact lens solution and allow to air dry.
YOU SHOULD replace your lens case on a regular basis.
YOU SHOULD follow your eye care professional's instructions.
YOU SHOULD attend regular after-care appointments with your eye care professional.

LENS CARE DIRECTIONS:
Correct care of your lenses is essential:
- Disinfect your lenses each time they are removed from your eyes to destroy harmful germs and to ensure safe and comfortable contact lens wear
- A separate cleaning and rinsing step may be recommended by your eye care professional to remove contaminants from the lens surface. In addition, your lenses may require periodic enzymatic cleaning to remove protein.
- Your eye care professional should recommend the lens care system most suitable to you.
- Ask your eye care professional before using any alternative lens care products.
- **DO NOT** alternate or mix lens care products from different systems.
- **DO NOT** use heat treatments to disinfect lenses or products recommended for hard or rigid gas permeable contact lenses.
- Never expose contact lenses to any non-sterile water as microbial contamination can occur which may lead to permanent eye damage.

If you have not worn your lenses for an extended period of time (several days or more) follow your contact lens care regimen to clean and disinfect the lens prior to insertion.

CARE FOR A DRIED OUT (DEHYDRATED) LENS:
Rehydrate the lens in a CE marked multipurpose soft lens solution and contact your eye care professional for further advice.

CARE FOR A STUCK (NON-MOVING) LENS:
If the lens sticks to the eye and stops moving, insert a recommended lubricating solution or rewetting solution directly into the eye and wait for the lens to begin moving before attempting to remove it. If the problems persist contact your eye care professional.

Occasional dryness may be relieved by the use of lubricating drops which can be prescribed by your eye care professional.

[redacted]
JJVC Confidential

No7 Contact Lenses

CONTACT LENSES INSTRUCTIONS FOR USE

CE 120

Manufacturer:
No7 Contact Lenses
Hastings East Sussex
TN38 9UB
UK

www.no7contactlenses.com

Issue 5 | September 2016

GENERAL INFORMATION

POTENTIAL ADVERSE REACTIONS:

If you suffer from any of the following reactions associated with your contact lens wear, then discontinue lens wear and contact your eye care professional:

- Red eye
- Foreign body sensation (feeling of something in the eye)
- Sore or painful eye
- Sensitivity to light (photophobia)
- Burning, stinging or itchy eye
- Rainbows or haloes around lights
- Reduced sharpness of vision
- Increased eye secretions
- Severe or persistent dry eyes.

EMERGENCIES:

Sometimes eye infections can be very serious, if your eye is red, very sore and/or vision is reduced contact your eye professional or seek medical advice urgently.

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes or you come into contact with noxious vapours or hazardous environments. ***YOU SHOULD*** remove lenses and flush eyes immediately with saline (preferably) or tap water and immediately contact your eye care professional or seek medical advice.

RGP CONTACT LENSES INSTRUCTIONS FOR USE

PRACTITIONER INFORMATION:

The enclosed rigid lens(es) have been supplied to a design and using a material specified by the practitioner ready for use, soaked in CE marked soaking/wetting solution. Please retain them in their sealed mailer until they are required for fitting. If the lens(es) have not been fitted within 28 days, remove them from their mailer, clean and rinse the lens(es) and mailer and replenish the soaking solution. Repeat the procedure monthly until the lens(es) are used. Lenses should be discarded after the expiry date.

INDICATIONS (USES):

RGP or Rigid Gas Permeable lenses are suitable for the optical correction of vision for myopia, hypermetropia, presbyopia, astigmatism and irregular corneas.

CONTRAINDICATIONS:

DO NOT prescribe RGP lenses in the presence of ocular infection, inflammation or injury, any eye disease, severe dry eyes or corneal hypoaesthesia unless indicated. Or if there is any systemic condition that may affect the eye or cause heightened risk of allergy to contact lens or solution. Or if the patient is taking medication that may interfere with contact lens wear (e.g. preserved eye drops).

RECOMMENDED WEARING SCHEDULE:

- Daily wear - less than 24 hours while awake
- Wearing time should be built up gradually before the maximum is achieved.

REPLACEMENT SCHEDULE:

RGP lenses should be replaced on a yearly basis or more frequently as recommended by the eye care professional.

WARNINGS:

In order to promote safe use it is essential that the patient follows the manufacturers recommendations for care of contact lenses, use of care products and lens cases.

Patients should be warned that serious adverse reactions such as ulcers or keratitis can arise very quickly and are more likely to occur if the patient does not follow the manufacturers recommendations for wearing times, replacement schedule, use of care products and lens cases. The patient should not wear the lens whilst sleeping (unless indicated), showering or swimming.

The eye care professional must ensure that the patient can remove their lenses before dispensing them and should advise the patient to remove the lenses and contact them immediately if any adverse reaction arises. The patient should attend regular after-care appointments.

IMPORTANT PATIENT INFORMATION

PRECAUTIONS:

DO NOT exceed your recommended wearing time.
DO NOT use the lenses after the recommended replacement date.
DO NOT swim whilst wearing the lenses.
DO NOT sleep whilst wearing the lenses unless advised to by your eye care professional.
DO NOT allow tap water or saliva to come into contact with your lenses as this increases your risk of infection.
DO NOT wear your lenses if your eyes are sore and/or red.
DO NOT store lenses in saline only, always use a contact lens solution.
DO NOT use lenses or solutions after their use by date.
DO NOT wear lenses if you are using eye drops unless advised to by your eye care professional.
YOU SHOULD wash and dry hands (with clean lint free tissue or towel) before handling, inserting or removing the lens.
YOU SHOULD rinse your lens case daily with saline or fresh contact lens solution and allow to air dry.
YOU SHOULD replace your lens case on a regular basis.
YOU SHOULD follow your eye care professional's instructions.
YOU SHOULD attend regular after-care appointments with your eye care professional.

LENS CARE DIRECTIONS:

Correct care of your lenses is essential:

- Disinfect your lenses each time they are removed from your eyes to destroy harmful germs and to ensure safe and comfortable contact lens wear.
- A separate cleaning and rinsing step may be recommended by your eye care professional to remove contaminants from the lens surface. In addition, your lenses may require periodic enzymatic cleaning to remove protein.
- Your eye care professional should recommend the lens care system most suitable for you.
- Ask your eye care professional before using any alternative lens care products.
- **DO NOT** alternate or mix lens care products from different systems.
- **DO NOT** expose your lens(es) to hair or cosmetic sprays or excessive heat.
- Never expose contact lenses or your contact lens case to any non-sterile water as microbial contamination can occur which may lead to permanent eye damage, for example tap water.
- Never allow saliva to come in to contact with your lens.

If you have not worn your lenses for an extended period of time (several days or more) follow your contact lens care regimen to clean and disinfect the lens prior to insertion.

LONG TERM STORAGE OF RGP LENSES:

If you are planning to store an RGP lens long term then it is best to store it dry. Disinfect and then wet the lens before use.

CARE FOR A STUCK (NON-MOVING) LENS:

If the lens sticks to the eye and stops moving, insert a recommended lubricating solution or rewetting solution directly into the eye and wait for the lens to begin moving before attempting to remove it. If the problems persist contact your eye care professional.

Occasional dryness may be relieved by the use of lubricating drops which can be prescribed by your eye care professional.

SCLERAL AND CORNEO SCLERAL CONTACT LENSES INSTRUCTIONS FOR USE

PRACTITIONER INFORMATION:

Scleral and corneo scleral lenses are large diameter RGP lenses that extend beyond the cornea. Although supplied clean in CE marked wetting solution, if the lens does not wet well then clean with an alcohol based cleaner.

MATERIAL:

- BOSTON XO
- OPTIMUM EXTRA
- HDS 100 (ICD 16.5)

INDICATIONS (USES):

Corneo Scleral & Scleral lenses are suitable for the optical correction of vision for myopia, hypermetropia, astigmatism, presbyopia and irregular corneas. ICD 16.5 is indicated for the optical correction of irregular corneas and for ocular surface disease.

CONTRAINDICATIONS:

DO NOT prescribe Corneo Scleral & Scleral lenses in the presence of ocular infection, inflammation or injury, any eye disease, severe dry eyes or corneal hypoaesthesia unless indicated. Or if there is any systemic condition that may affect the eye or cause heightened risk of allergy to contact lens or solution. Or if the patient is taking medication that may interfere with contact lens wear (e.g. preserved eye drops).

RECOMMENDED WEARING SCHEDULE:

- Daily wear - less than 24 hours while awake
- Wearing time should be built up gradually before the maximum is achieved.

REPLACEMENT SCHEDULE:

Corneo Scleral & Scleral lenses should be replaced on a yearly basis or more frequently as recommended by the eye care professional.

WARNINGS:

In order to promote safe use it is essential that the patient follows the manufacturers recommendations for care of contact lenses, use of care products and lens cases.

Patients should be warned that serious adverse reactions such as ulcers or keratitis can arise very quickly and are more likely to occur if the patient does not follow the manufacturers recommendations for wearing times, replacement schedule, use of care products and lens cases. The patient should not wear the lens whilst sleeping (unless indicated), showering or swimming.

The eye care professional must ensure that the patient can remove their lenses before dispensing them and should advise the patient to remove the lenses and contact them immediately if any adverse reaction arises. The patient should attend regular after-care appointments.

IMPORTANT PATIENT INFORMATION

PRECAUTIONS:

DO NOT exceed your recommended wearing time.
DO NOT use the lenses after the recommended replacement date.
DO NOT swim whilst wearing the lenses.
DO NOT sleep whilst wearing the lenses
DO NOT allow tap water or saliva to come into contact with your lenses.
DO NOT wear your lenses if your eyes are sore and/or red.
DO NOT store lenses in saline only, always use a contact lens solution.
DO NOT use lenses or solutions after their use by date.
DO NOT wear lenses if you are using eye drops unless advised to by your eye care professional.
YOU SHOULD wash and dry hands (with clean lint free tissue or towel) before handling, inserting or removing the lens.
YOU SHOULD rinse your lens case daily with saline or fresh contact lens solution and allow to air dry.
YOU SHOULD replace your lens case on a regular basis.
YOU SHOULD follow your eye care professional's instructions.
YOU SHOULD attend regular after-care appointments with your eye care professional.

LENS CARE DIRECTIONS:

Correct care of your lenses is essential:

- Disinfect your lenses each time they are removed from your eyes to destroy harmful germs and to ensure safe and comfortable contact lens wear.
- A separate cleaning and rinsing step may be recommended by your eye care professional to remove contaminants from the lens surface. In addition, your lenses may require periodic enzymatic cleaning to remove protein.
- Your eye care professional should recommend the lens care system most suitable for you.
- Ask your eye care professional before using any alternative lens care products.
- **DO NOT** alternate or mix lens care products from different systems.
- **DO NOT** expose your lens(es) to hair or cosmetic sprays or excessive heat.
- Never expose contact lenses to any non-sterile water as microbial contamination can occur

APPENDIX C: [redacted] LIMBAL AND CONJUNCTIVAL (BULBAR) REDNESS

[redacted] Limbal & Conjunctival (Bulbar) Redness

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted]	[redacted]
[redacted]	[redacted]
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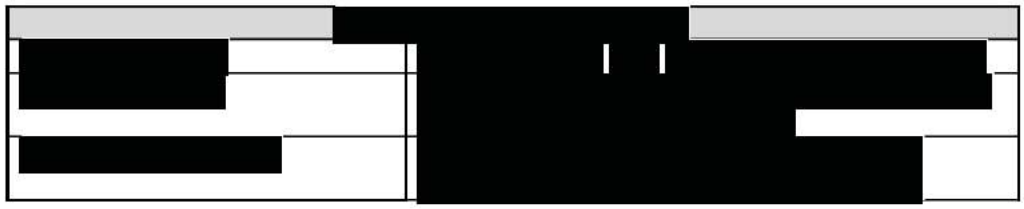
APPENDIX D: [redacted] LENS FITTING CHARACTERISTICS

[redacted] **Lens Fitting Characteristics**

[redacted]



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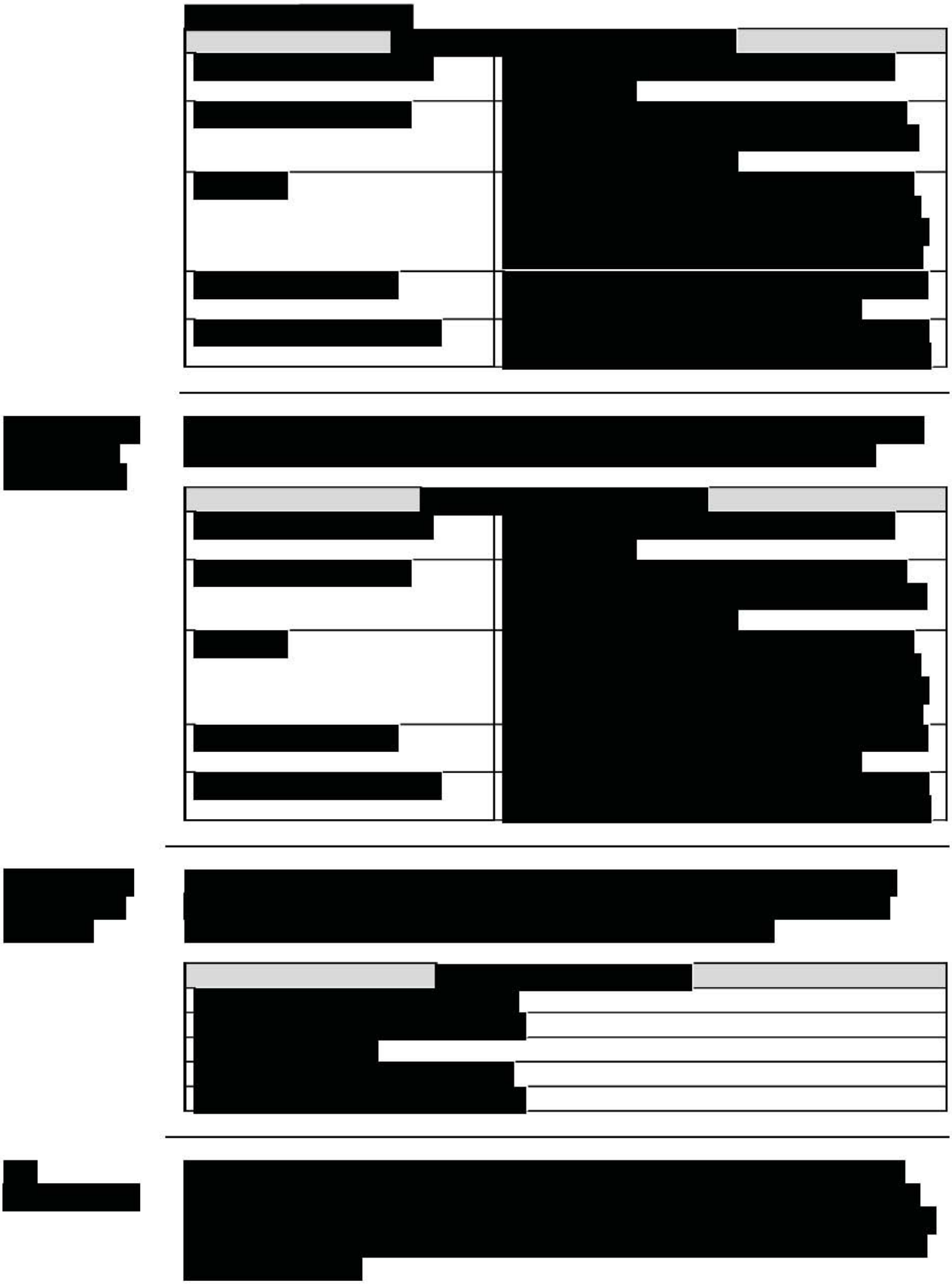

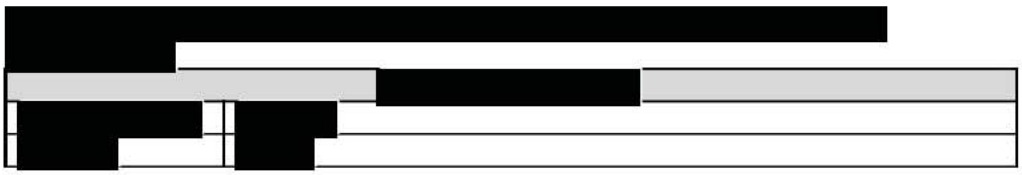

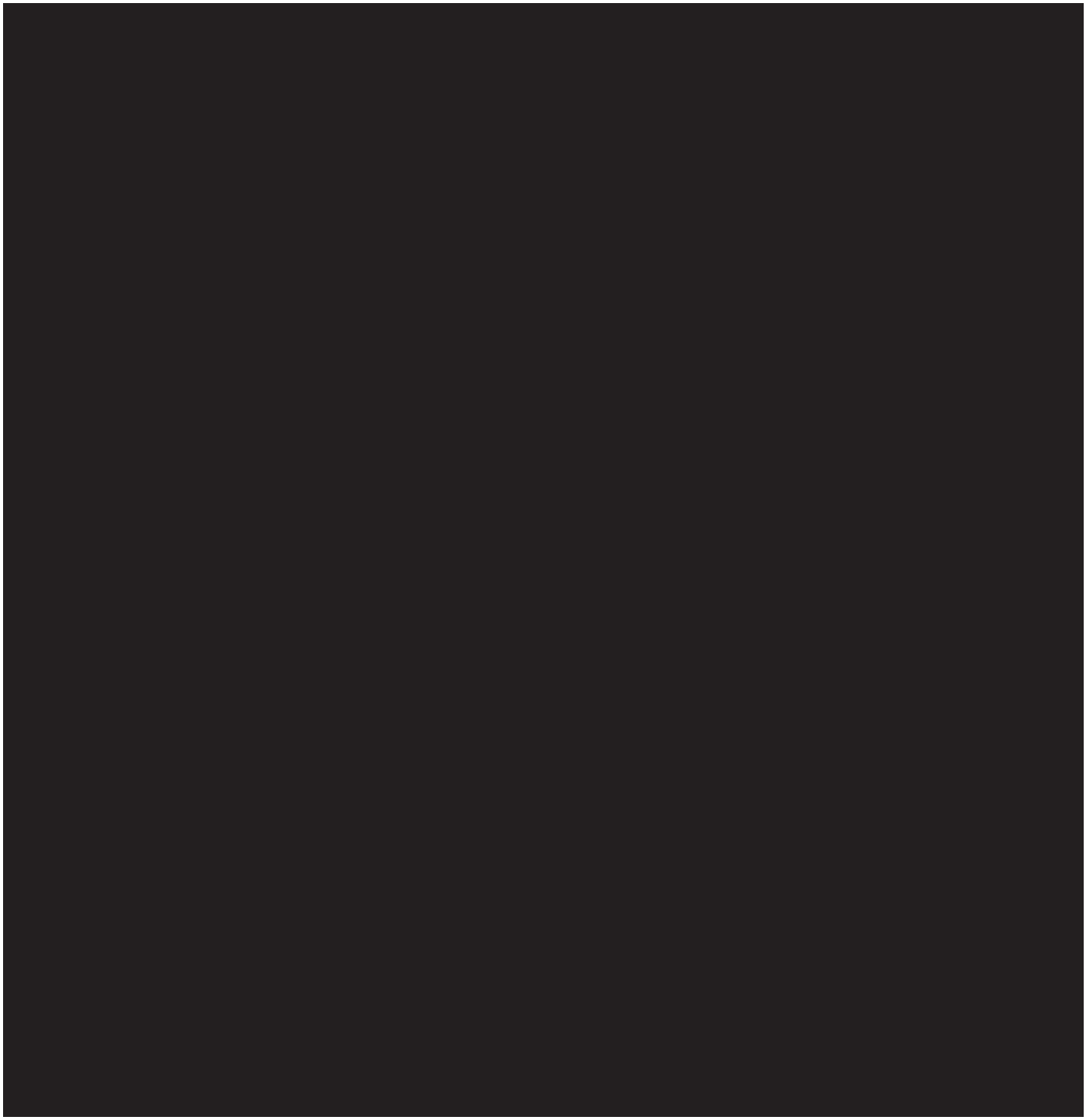

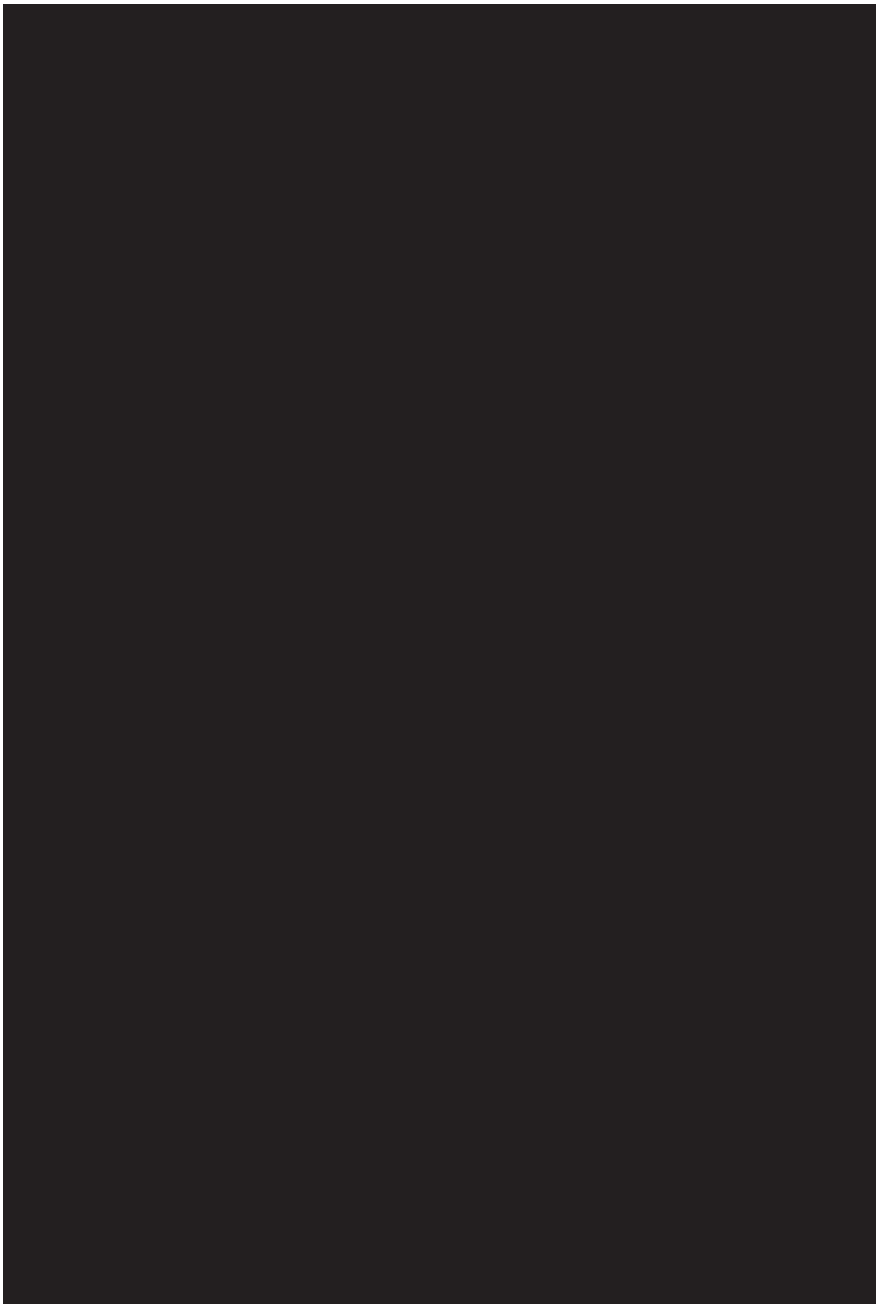

APPENDIX E: [redacted] OCULAR SYMPTOMS

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

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APPENDIX F: [redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS

[redacted] **Determination of Distance Spherocylindrical Refractions**

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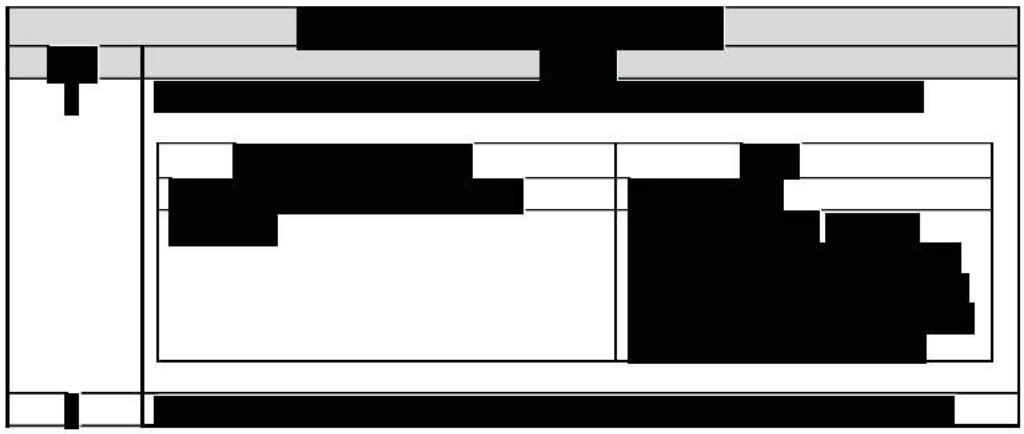

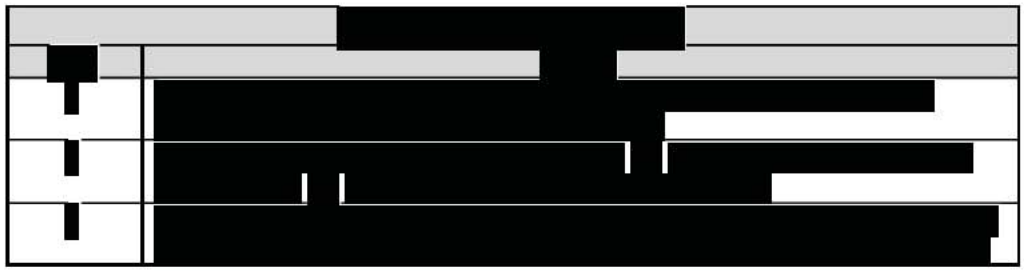

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APPENDIX G: [redacted] BIOMICROSCOPY SCALE

[redacted] **Biomicroscopy Scale**

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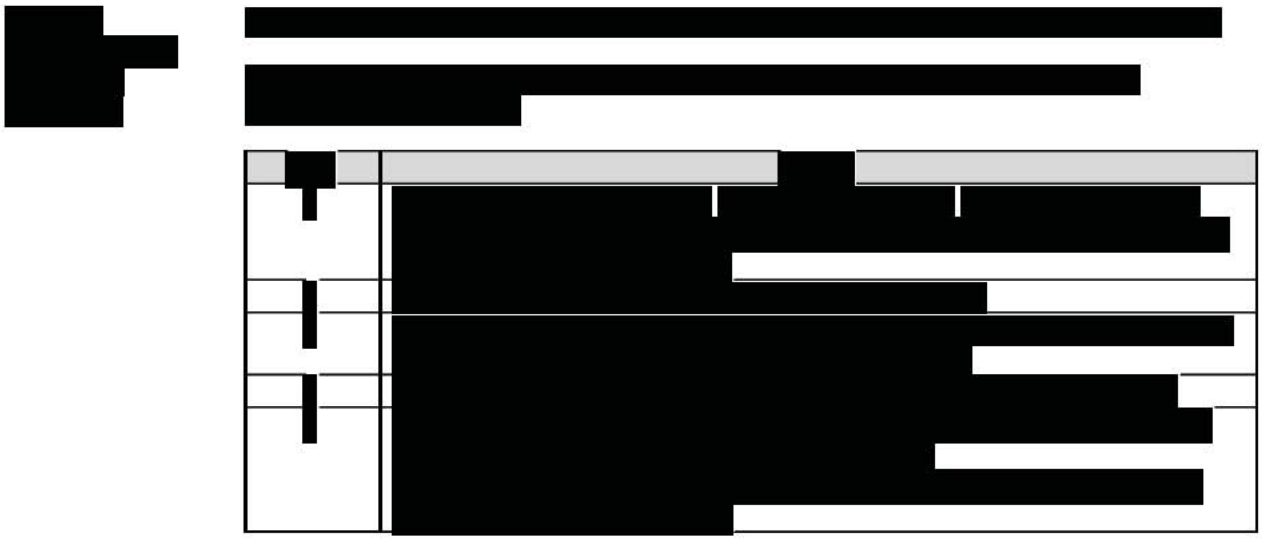

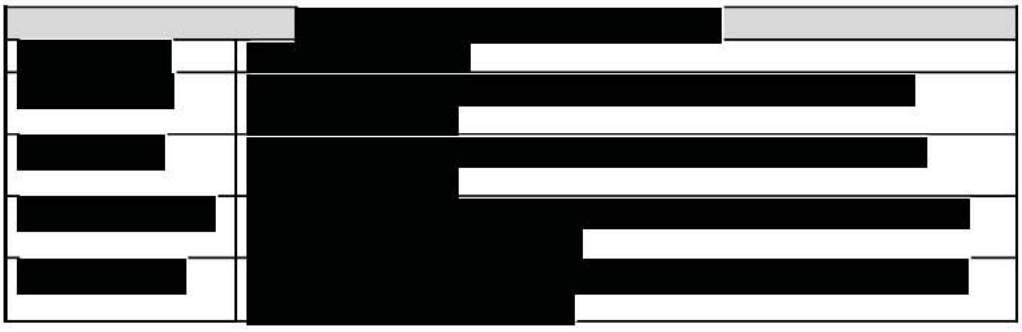

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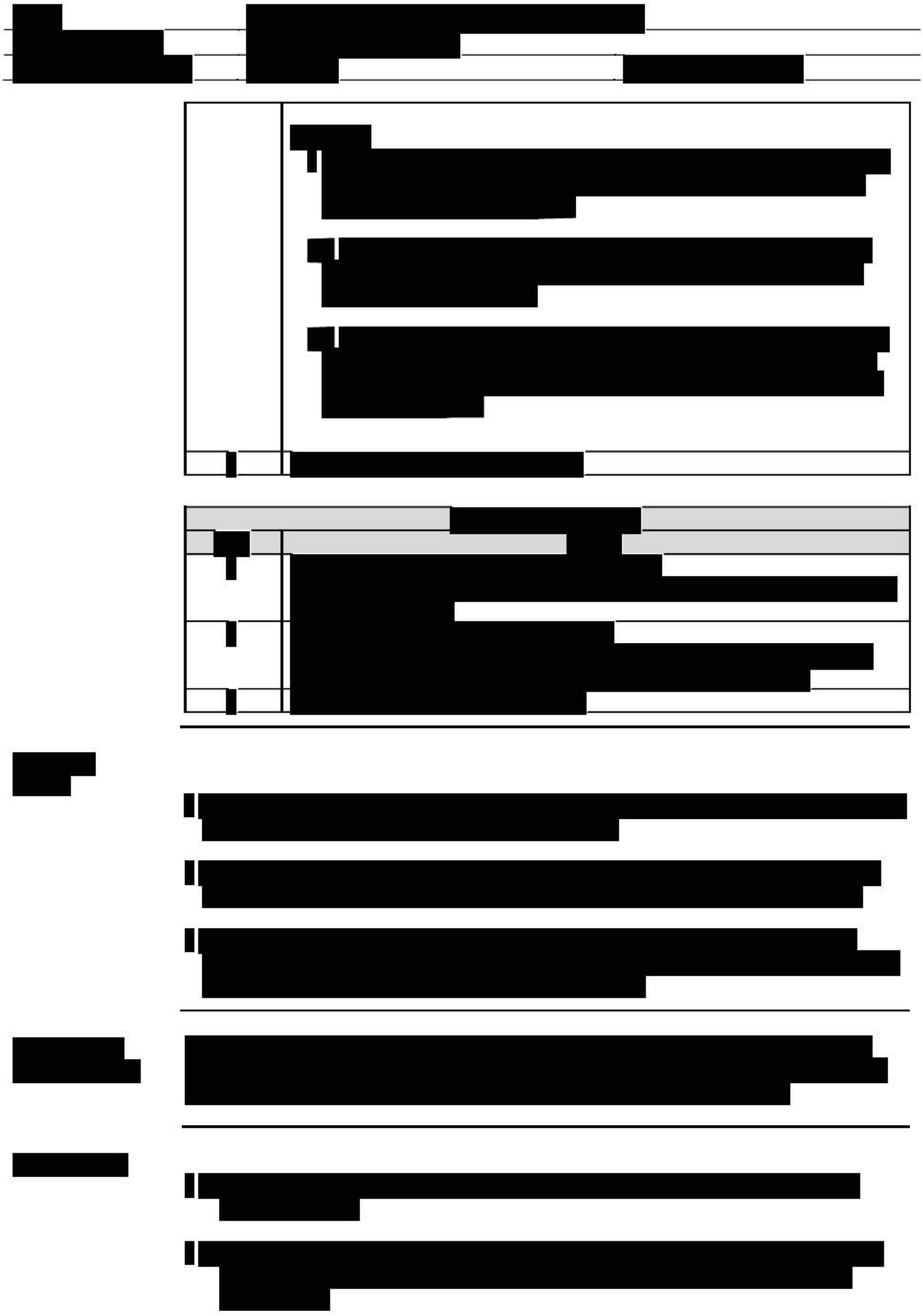
APPENDIX H: [redacted] DISTANCE AND NEAR VISUAL ACUITY EVALUATION

[redacted]



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