Clinical Study Protocol
Johnson & Johnson Vision Care, Inc.

Protocol Title: Clinical Evaluation of a Daily Wear Reusable Multifocal Optical Design in a Presbyopic Population

Protocol CR-6400

Version: 4.0

Date: 06 August 2020

Investigational Products: JJV Investigational senofilcon A Multifocal Contact Lens

Key Words: Presbyopia, Multifocal, senofilcon A, Daily Wear, Reusable, Dispensing,

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

Confidentiality Statement:

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SPONSOR NAME AND ADDRESS

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The Medical Monitor must be notified by the clinical institution/site by e-mail, fax, or telephone within 24 hours of learning of a Serious Adverse Event. The Medical Monitor may be contacted during business hours for adverse event questions. General study related questions should be directed towards your assigned clinical research associate.

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

AUTHORIZED SIGNATURES

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

Author	*See Electronic Signature Report* Thomas R. Karkkainen, OD, MS, FAAO [redacted]	DATE
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Reviewer	*See Electronic Signature Report* [redacted]	DATE
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Medical Safety Officer	*See Electronic Signature Report* [redacted]	DATE
Approver	*See Electronic Signature Report* [redacted]	DATE

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Date
1.0	Tom Karkkainen	Original Protocol	12-June-2020
2.0	Tom Karkkainen	Throughout document: corrected spelling/grammar errors and updated version number and date. Section1.5: updated information on study [redacted] as CSR has now been completed. Section 4.1: clarified replacement at optimization visit. Section 7.2 & 7.3: biomicroscopy procedure specified to note location of corneal staining. Appendix: Added information regarding COVID-19	22-July-2020
3.0	Tom Karkkainen	Throughout document: updated version number and date. Signature Page: added biostatistician reviewer.	24-July-2020
4.0	Tom Karkkainen	Throughout document: updated version number and date. Section 6.1: added note to lens table that the -3.50 low ADD lens will not be available. Appendix G: Added sphere lenses to table for distance complaint in low ADDs. [redacted]	06-Aug-2020

SYNOPSIS

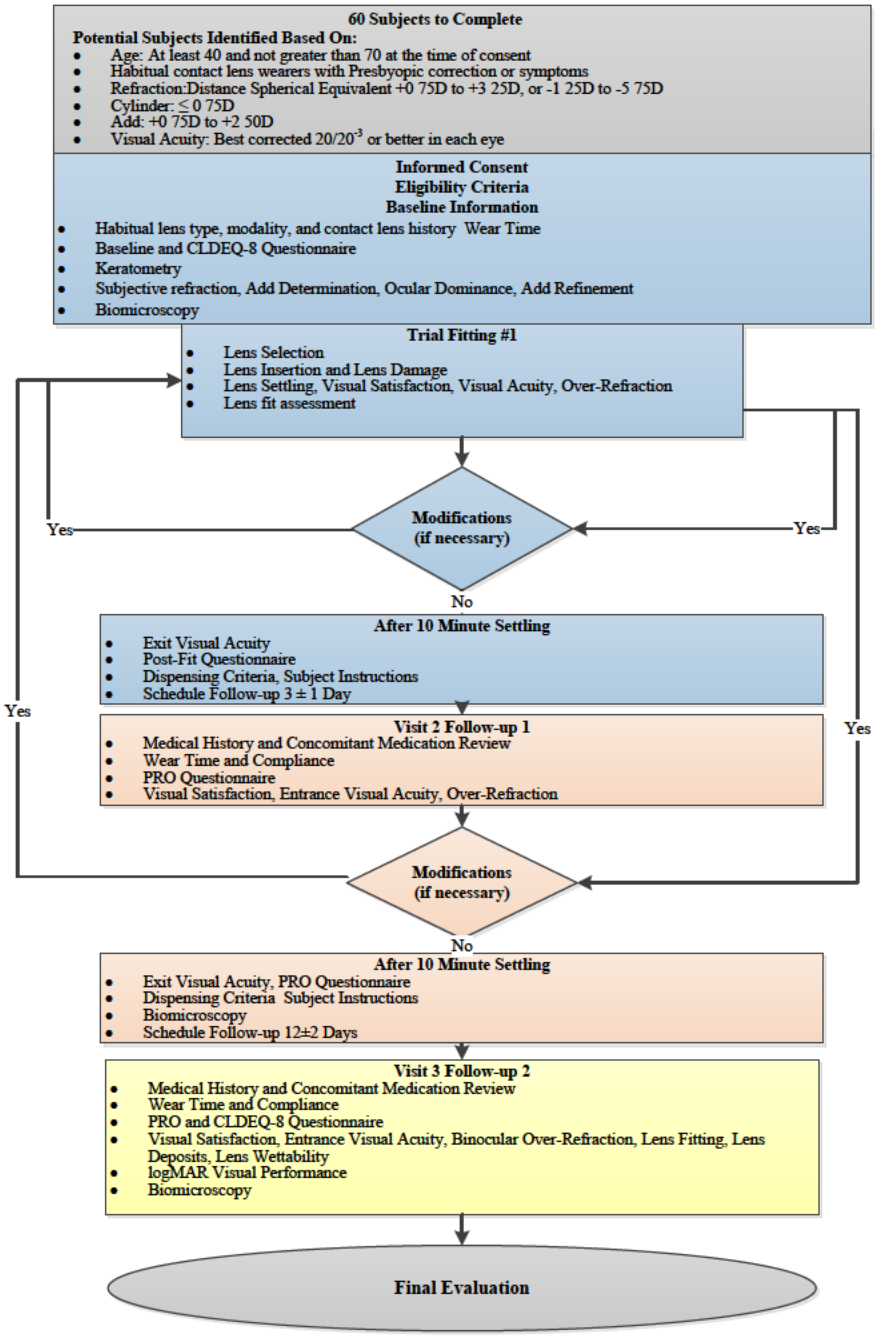
Protocol Title	Protocol Title: Clinical Evaluation of a Daily Wear Reusable Multifocal Optical Design in a Presbyopic Population
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Development phase, Phase 3
Trial Registration	This study will be registered on ClinicalTrials.gov.
Test Article(s)	Investigational Products: JJV Investigational Multifocal Contact Lens manufactured in senofilcon A material.
Wear and Replacement Schedules	Wear Schedule: The Test lenses are used as daily wear reusable. Replacement Schedule: The Test lens will be replaced at the optimization visit. The Test lenses will also be replaced when lost or damaged
Objectives	The purpose of this study is to demonstrate that the JJV Investigational senofilcon A Multifocal Contact Lens in its final lens design FAL100 (low add), FAL101(medium add) and FAL102 (high add), made in the Flexible Manufacturing Platform (FMP) meets the design validation requirements related to vision, eye health and fit acceptance.
Study Endpoints	Primary Endpoints • CLUE vision scores • LogMAR visual acuity scores • Unacceptable lens fit (Yes/No) • Grade 3 or Higher Biomicroscopy Findings (Yes/No) Secondary Endpoints • Number of lenses needed to fit (optimize) the subject's vision Other Endpoints • Lens Deposits • CLUE comfort/handling scores • PRO individual questions

Study Design	This is a single-masked (partial), controlled, dispensing clinical trial. A total of approximately 60 subjects will be targeted to complete with a 1:1 allocation between strata (Hyperopes and Myopes). Subjects will be fit in the study lens for approximately 2-4 days then return to undergo optimization, if required and wear the optimized pair for approximately 2 weeks. The primary endpoints will be CLUE vision scores, logMAR visual acuity, biomicroscopy findings and lens fit. See the flow chart at the end of the synopsis table for the schematic of the study visits and procedures of main observations (Figure 1).
Sample Size	A total of approximately 60 subjects will be targeted to complete.
Study Duration	The study will last approximately 2-3 months.
Anticipated Study Population	Healthy male and female volunteers with presbyopia will be invited to participate in the study. Subjects will be adapted soft contact lens wearers in both eyes. Additional information regarding the eligibility of the population can be found in the inclusion/exclusion criteria outlined below.
Eligibility Criteria	Potential subjects must satisfy all the following criteria to be enrolled in the study Inclusion Criteria after Screening: 1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form. 2. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol. 3. The subject must be at least 40 years of age and not greater than 70 years of age at the time of consent. 4. Subjects must own a wearable pair of spectacles if required for their distance vision. 5. The subject must be an adapted soft contact lens wearer in both eyes (i.e. wears lenses a minimum of 2 days per week for at least 6 hours per wear day, for 1 month of more duration). 6. The subject must either already be wearing a presbyopic contact lens correction (e.g., reading spectacles over contact lenses, multifocal or monovision contact lenses, etc.) or if not respond positively to at least one symptom on the “Presbyopic Symptoms Questionnaire” (Appendix E).

	Inclusion Criteria after Baseline: 7. The subject's distance spherical equivalent refraction (vertex corrected if ≥-4.25 D) must be in the range of -1.25 D to -5.75 D or +0.75 D to +3.25 D in each eye. 8. The subject's refractive cylinder must be ≤0.75 D in each eye. 9. The subject's ADD power must be in the range of +0.75 D to +2.50 D. 10. The subject must have distance best corrected visual acuity of $20/20^{-3}$ or better in each eye. Potential subjects who meet any of the following criteria will be excluded from participating in the study: Exclusion Criteria after Screening: 1. Currently pregnant or lactating. 2. Any active or ongoing ocular or systemic allergies that may interfere with contact lens wear. 3. Any active or ongoing systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear. This may include, but not be limited to, diabetes, hyperthyroidism, Sjögren's syndrome, xerophthalmia, acne rosacea, Stevens-Johnson syndrome, and immunosuppressive diseases or any infectious diseases (e.g. hepatitis, tuberculosis). 4. Any previous, or planned, ocular or intraocular surgery (e.g. radial keratotomy, PRK, LASIK, lid procedures, dacryocystorhinostomy, peripheral iridotomy/iridectomy, cataract surgery, retinal surgery, etc.). 5. A history of amblyopia, strabismus or binocular vision abnormality. 6. History of glaucoma, macular degeneration, recurrent corneal erosions, recurrent styes, herpetic keratitis, irregular cornea or pathological dry eye. 7. Use of any of the following medications within 1 week prior to enrollment: oral retinoids, oral tetracyclines, oral phenothiazines, anticholinergics, corticosteroids. See Section 9.1 for additional information. 8. Use of any ocular medication, with the exception of rewetting drops. 9. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.

	10. Employee or immediate family member of an employee of clinical site (e.g., Investigator, Coordinator, Technician). 11. Any known hypersensitivity or allergic reaction to Optifree®Replenish® multi-purpose care solution, sodium fluorescein or non-preserved rewetting drop solutions. Exclusion Criteria after Baseline: 12. Clinically significant (Grade 2 or greater) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities or bulbar injection, or any other corneal or ocular abnormalities which would contraindicate contact lens wear. 13. Any current ocular infection or inflammation. 14. Any current ocular abnormality that may interfere with contact lens wear.
Disallowed Medications/Interventions	Use of any prescription or over-the-counter (OTC) medications that may affect contact lens wear. See section 9.1 for details regarding disallowed systemic medications.
Measurements and Procedures	See Section 7.2 for the detailed procedures.
Microbiology or Other Laboratory Testing	None
Study Termination	The occurrence of one or more Unanticipated Adverse Device Effect (UADE), or any SAE where relationship to study agent cannot be ruled out, will result in stopping further dispensing of investigational product. In the event of a UADE or SAE, the Sponsor Medical Monitor may unmask the treatment regimen of subject(s) and may discuss this with the Principal Investigator before any further subjects are enrolled.
Ancillary Supplies/ Study-Specific Materials	Rewetting drops, lens cases, glass vials, saline, ETDRS light cabinet, distance (4M) logMAR charts, and Near logMAR charts. Optifree®Replenish® Contact Solution.
Principal Investigator(s) and Study Institution(s)/Site(s)	A full list of Principal Investigators, clinical sites, and institutions is kept separately from the Study Protocol and is included in the study Trial Master File.

Figure 1: Study Flowchart



COMMONLY USED ABBREVIATIONS AND DEFINITIONS OF TERMS

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

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

1. INTRODUCTION AND BACKGROUND

Johnson & Johnson Vision currently markets 1-DAY ACUVUE® Moist Multifocal. The wear modality for the lens is daily disposable. There is a desire to evaluate the same optical design in a reusable modality. The purpose of this study is to evaluate a multifocal optical design manufactured from senofilcon A material.

1.1. Name and Descriptions of Investigational Products

Test Lens: JJV Investigational senofilcon A Multifocal Contact Lens-The lens has the same optical design, diameter, base curve and aspheric back surface design as the 1-Day Acuvue® Moist Brand Multifocal. The lens is manufactured in senofilcon A.

1.2. Intended Use of Investigational Products

The lenses are intended to correct spherical refractive error and presbyopia. The lenses are intended to be used as a 2-week, reusable, daily wear lens and require the use of a care system to clean and disinfect the lenses.

1.3. Summary of Findings from Nonclinical Studies

All previous pre-clinical findings were deemed satisfactory prior to proceeding with clinical trials on humans. [redacted]

1.4. Summary of Known Risks and Benefits to Human Subjects

The Investigational multifocal contact lenses are designed as a continuous asphere providing for the correction of refractive spherical ammetropia and presbyopia. The material is a silicone hydrogel material, senofilcon A.

The intent of the Test lens is daily wear, reusable lens that the subject wears while awake. In this study the lens will not be used for extended wear. Anticipated risks and adverse reactions with this lens are similar to other soft daily wear contact lenses used to correct presbyopia. A listing of examples of adverse reactions is found in the Section 13 of this protocol. The investigator should follow normal clinical guidelines regarding examination and care of subjects who participate in this trial. [redacted]

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

JJV has evaluated the test lenses in the previous clinical studies: [redacted] A summary of the completed studies is listed below.

[redacted] was a dispensing clinical trial with primary end points of logMAR visual acuity at fit and CLUE vision scores at 1 week. The study was a cross-over design with a marketed product serving as the control. There were 32 subjects that completed the study as cohort. The Test lens displayed good visual acuity with the mean distance and intermediate logMAR acuity

better than 0.0 and the mean near logMAR acuity better than +0.1 logMAR. This with true of the acuity at the initial fit as well as the 1 week and 2-week visits in the final lens pair. There were two non-ocular adverse events that occurred during the study that were not related to any of the Test lenses.

[redacted] was a dispensing parallel-ARM study and had a primary endpoint of logMAR visual acuity. There were 149 subjects that completed the study overall with 37 subjects completing in the ARM involving the study lenses that will be used in this study. The lenses displayed clinically acceptable logMAR visual acuity after approximately 2 weeks of wear with the mean bright high contrast binocular logMAR acuity of -0.077, -0.083 and 0.049 for distance, intermediate and near respectively.
[redacted] had four parallel ARMs with one of the ARMs being the test lenses evaluated in this study along with two other investigational test lenses and a control lens. For the ARM with the lenses tested in this study there were no ocular adverse events reported and one non-ocular that was not related to the test article.

[redacted] was a dispensing crossover study on myope subjects and had a primary endpoint of subject vision response. There were 53 subjects that completed the study as cohort. The test lenses displayed clinically acceptable logMAR visual acuity after approximately 2 weeks of wear with the mean bright high contrast binocular logMAR acuity of -0.11, -0.07 and 0.06 for distance, intermediate and near respectively. There was one adverse event in the study that was a non-significant temporal conjunctival hyperemia in the right eye after removal of their lenses. The event resolved without any treatment.

[redacted] was a dispensing crossover study on hyperope subjects and had a primary endpoint of subject vision response. There were 59 subjects that completed the study as cohort. The test lenses displayed clinically acceptable logMAR visual acuity after approximately 2 weeks of wear with the mean bright high contrast binocular logMAR acuity of -0.05, -0.02 and 0.11 for distance, intermediate and near respectively. One subject had a non-ocular serious adverse event of dehydration of moderate severity and received treatment for this event. Although the event was reported as resolved, the subject was permanently discontinued the study. The investigator considered the event to be not related to the study article/study procedure. Three episodes of ocular adverse events were reported. One subject had an ocular AE of non-significant corneal foreign body of mild severity. The subject did not receive any treatment for this event. The event of non-significant corneal foreign body was reported as resolved and no action was taken with the study article. The investigator considered the event to be not related to the study article/study procedure. A second subject had two episodes (one in each eye) of significant infiltrative event (SIE) of moderate severity. The subject received treatment for these events. Although the events were reported as resolved, the subject was permanently discontinued the study. The investigator considered the events to be related to the study article/study procedure.

[redacted] was a dispensing crossover study on hyperope subjects and had a primary endpoint of subject vision response. There were 42 subjects that completed the study as cohort. The test lenses displayed clinically acceptable logMAR visual acuity after approximately 2 weeks of wear with the mean bright high contrast binocular logMAR acuity of -0.025, -0.045 and 0.173

for distance, intermediate and near respectively. There was one adverse event in the study that was a non-significant contact lens acute red eye in the right eye. The event was classified as related to the test article and resolved with treatment.

[redacted] was a dispensing crossover study on hyperope subjects and had a primary endpoint of subject vision response. There were 40 subjects that completed the study as cohort. The test lenses displayed clinically acceptable logMAR visual acuity after approximately 2 weeks of wear with the mean bright high contrast binocular logMAR acuity of -0.12, -0.065 and 0.07 for distance, intermediate and near respectively. There were two adverse events in the study that was a non-significant allergic conjunctivitis that occurred in one subject in both eyes. The event was classified as possibly related to the test article and resolved with treatment.

In addition to the above studies, JJV had tested similar optical designs that have been manufactured in a similar material, however those lenses were worn as daily disposable lenses. The lenses were tested in [redacted]

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

Primary Objective
The primary purpose of this study is to demonstrate that the Multifocal Test lens made with senofilcon A material made from the Flexible Manufacturing Platform (FMP), in its final lens design FAL100, FAL101 and FAL102 (low, mid and high ADD respectively) meets the design validation requirements for CLUE overall quality of vision scores, logMAR visual acuity, ocular physiology and lens fit acceptance.

Secondary Objective
The secondary objective is to evaluate the number of lenses needed to optimize the subject's vision.

2.2. Endpoints

Primary Efficacy Endpoints:

CLUE Overall Quality of Vision
Overall comfort scores will be assessed using the Contact Lens User Experience (CLUE™) questionnaire after approximately 2 weeks of lens wear. CLUE is a validated patient-reported outcomes questionnaire to assess patient-experience attributes of soft, disposable contact lenses (comfort, vision, handling, and packaging) in a contact-lens wearing population in the US, ages 18-65. Derived CLUE™ scores using Item Response Theory (IRT) follow a normal distribution with a population average score of 60 (SD 20), where higher scores indicate a more

favorable/positive response with a range of 0-120. A 5-point increase in an average CLUE™ score translates into 10% shift in the distribution of scores for population of soft contact lens wearers[7].

Visual Acuity (logMAR)

Multiple assessments of binocular and monocular visual acuity will be made during the study, but the binocular measurements made after approximately 2 weeks of lens wear using high contrast letters in bright illuminance conditions will be the primary endpoint. At distance (4 meters), VA is assessed using ETDRS Charts; while near (40 cm) and intermediate (64 cm) assessments will be made using reduced Guillon-Poling charts. Visual acuity will be measured using high and low contrast charts in bright illuminance conditions. [redacted]

Primary Safety Endpoints:

Slit Lamp Findings (SLF)

Slit Lamp Findings (Grade 3 or higher) will be assessed for each subject eye at all study visits (schedule and unscheduled). SLFs will be evaluated and classified using the FDA Grading scale rating from 0 to 4, where Grade 0 represents the absence of findings and 1 to 4 representing successively worse findings (i.e. Grade 1=trace, Grade 2= mile, Grade 3=moderate and Grade 4= severe). The percentage of eyes with Grade 3 or higher slit lamp findings will be analyzed and will include corneal infiltrates. [redacted]

Unacceptable Lens Fit

Unacceptable lens fit will be assessed at all study visits (scheduled and unscheduled) for each subject eye. Unacceptable fit is a binary response where Y=1 if lens fit is unacceptable and Y=0 otherwise. Unacceptable fit was defined as unacceptable if any one of the following criteria:

- limbal exposure at primary gaze or with extreme eye movement;
- edge lift;
- excessive movement in primary up gaze;
- insufficient movement in all three of the following conditions: primary gaze, up gaze, and push up test.

Eyes with multiple unacceptable fitting events was counted only once. [redacted]

Secondary Endpoints

- Summary of lenses needed to fit (optimize) the subject's vision

Other Endpoints

- Lens Deposits
- CLUE comfort/handling scores
- GSI Product Performance ratings

2.3. Hypotheses

All the following co-primary hypotheses must be satisfied in order to meet the study objectives.

Primary Hypotheses:

1. After approximately 2-weeks of wear, the mean overall quality of vision score of the Test lenses will be statistically better than 40 points for the myope population. This will be recorded by the subject using the CLUE Follow-up Questionnaire.

2. After approximately 2-weeks of wear, the mean overall quality of vision score for the Test lenses will be statistically better than 32 points for the hyperope population. This will be recorded by the subject using the CLUE Follow-up Questionnaire.

3. After approximately 2-weeks of wear, the mean distance, binocular, high luminance, high contrast logMAR visual acuity score of the Test lens will be statistically lower than 0.10 logMAR.

4. After approximately 2-weeks of wear, the mean intermediate, binocular, high luminance, high contrast logMAR visual acuity score of the Test lens will be statistically lower than 0.17 logMAR.

5. After approximately 2-weeks of wear the mean near, binocular, high luminance, high contrast logMAR visual acuity score of the Test lens will be statistically lower than 0.17 logMAR.

6. When wearing the Test lenses, the proportion (%) of eyes with at least one reported clinically significant slit-lamp finding (Grade 3 or 4) during the post-fit period will be significantly lower than 5%.

7. When wearing the Test lenses, the proportion (%) of eyes with an unacceptable fit during the study will be statistically less than 5%.

If all the primary hypotheses are met, the following secondary hypothesis will be tested.

Secondary Hypothesis:

1. The proportion of subjects who obtain the optimum lens pair in 4 lenses or less will be at least 90% using a 95% level of confidence.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

Healthy male and female subjects who are habitual soft contact lens wearers will be recruited. Subjects will be at least 40 years of age and not older than 70 years of age at the time of enrolment. They will be myopic or hyperopic and have presbyopia**.**

3.2. Inclusion Criteria

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

Inclusion Criteria after Screening:

1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form.
2. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. The subject must be at least 40 years of age and not greater than 70 years of age at the time of consent.
4. Subjects must own a wearable pair of spectacles if required for their distance vision.
5. The subject must be an adapted soft contact lens wearer in both eyes (i.e. wears lenses a minimum of 2 days per week for at least 6 hours per wear day, for 1 month of more duration).
6. The subject must either already be wearing a presbyopic contact lens correction (e.g., reading spectacles over contact lenses, multifocal or monovision contact lenses, etc.) or if not respond positively to at least one symptom on the "Presbyopic Symptoms Questionnaire" (Appendix E).

Inclusion Criteria after Baseline:

7. The subject's distance spherical equivalent refraction (vertex corrected if ≥-4.25 D) must be in the range of -1.25 D to -5.75 D or +0.75 D to +3.25 D in each eye.
8. The subject's refractive cylinder must be ≤0.75 D in each eye.
9. The subject's ADD power must be in the range of +0.75 D to +2.50 D.
10. The subject must have distance best corrected visual acuity of $20/20^{-3}$ or better in each eye.

3.3. Exclusion Criteria

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

Exclusion Criteria after Screening:

1. Currently pregnant or lactating.
2. Any active or ongoing ocular or systemic allergies that may interfere with contact lens wear.
3. Any active or ongoing systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear. This may include, but not be limited to, diabetes, hyperthyroidism, Sjögren's syndrome, xerophthalmia, acne rosacea, Stevens-Johnson syndrome, and immunosuppressive diseases or any infectious diseases (e.g. hepatitis, tuberculosis).
4. Any previous, or planned, ocular or intraocular surgery (e.g. radial keratotomy, PRK, LASIK, lid procedures, dacryocystorhinostomy, peripheral iridotomy/iridectomy, cataract surgery, retinal surgery, etc.).
5. A history of amblyopia, strabismus or binocular vision abnormality.
6. History of glaucoma, macular degeneration, recurrent corneal erosions, recurrent styes, herpetic keratitis, irregular cornea or pathological dry eye.
7. Use of any of the following medications within 1 week prior to enrollment: oral retinoids, oral tetracyclines, oral phenothiazines, anticholinergics, corticosteroids. See Section 9.1 for additional details.
8. Use of any ocular medication, with the exception of rewetting drops.
9. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.
10. Employee or immediate family member of an employee of clinical site (e.g., Investigator, Coordinator, Technician).
11. Any known hypersensitivity or allergic reaction to Optifree®Replenish® multi-purpose care solution, sodium fluorescein or non-preserved rewetting drop solutions.

Exclusion Criteria after Baseline:

12. Clinically significant (Grade 2 or greater) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities or bulbar injection, or any other corneal or ocular abnormalities which would contraindicate contact lens wear.
13. Any current ocular infection or inflammation.
14. Any current ocular abnormality that may interfere with contact lens wear.

3.4. Enrollment Strategy

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

Table 1: Planned Enrollment by Strata and Site

	Myopes	Hyperopes	Total
Enrollment Target	40	40	80
Randomized	30	30	60
Number of Enrolled per Site (min-max) Target	2-6	2-6	

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

The clinical study is a bilateral, single-masked (partial), single-arm, clinical trial. A total of approximately 60 eligible subjects (30 myopes and 30 Hyperopes) will be targeted to complete the study.

The study begins with an initial visit, Visit 1 (Day 0), if a subject is found to meet all eligibility criteria, they will be fit with the study lens, in both eyes; otherwise the subject will be deemed ineligible and classified as a screen failure.

If a subject is dispensed lenses at the initial visit, then two additional visits will be conducted. Visit 2 will occur 3 ± 1 days after Visit 1. At Visit 2 subjects will undergo lens optimization if the subject reports unsatisfactory vision or is unable to obtain 20/30 binocular distance visual acuity with the study lenses. Subjects will return for Visit 3 (Final Evaluation) after 12±2 days. At the final visit, subjects will undergo subjective and objective assessments of vision.

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

4.2. Study Design Rationale

The study is intended to compare one study lens type and to characterize performance against predefined targets which are set in the Customer Requirements Document. Due to the predefined performance criteria a single-arm study design was chosen. The specifics of the lens design, beyond that the lenses are intended to correct for their distance and near vision, will be masked to the subject. The final optimized lenses are dispensed for approximately 2 weeks of reusable wear which is the intended use cycle of the lens.

4.3. Enrollment Target and Study Duration

A total of approximately 80 eligible subjects will be enrolled with 60 (30 myopes and 30 hyperopes) targeted to complete the study. The study is anticipated to last 2-3 months.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

The study lenses will be worn in a bilateral fashion using a single-arm design. Due to the nature of the design no randomization is required.

5.2. Masking

This is a single arm study and all subjects will be assigned to the same study lens. Subjects will be unaware of the identity of the investigational product. Investigators and clinical site personnel involved in the data collection will not be masked as to the identity of the investigational product.

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

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

5.3. Procedures for Maintaining and Breaking the Masking

The test articles mask shall not be broken unless information concerning the lens type is necessary for the urgent medical treatment of a subject. The Sponsor must be notified before the mask is broken.

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

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 2: Test Articles

	Test Lens	
Name	JJV Investigational Multifocal Contact Lens	ACUVUE OASYS® with HYDRACLEAR® PLUS Sphere*
Manufacturer	Johnson & Johnson® Vision, Inc.	Johnson & Johnson® Vision, Inc.
Build Protocol and/or Lot Number or Other Identifier	[redacted]	N/A
Lens Material	senofilcon A	senofilcon A
Nominal Base Curve	8.35 mm	8.4 mm
Nominal Diameter (mm)	14.3 mm	14.0 mm
Nominal Distance Powers (D)	-1.00 D to -6.00 D** and +0.50 D to +3.50 D in 0.25 D steps	-1.00 D to -6.00 D and +0.50 D to +3.50 D in 0.25 D steps
Nominal Cylinder Powers (D) and Axes	None	None
Nominal ADD Powers (D)	Low, Mid, High	N/A
Water Content	38%	38%
Center Thickness	0.070 mm (-3.00 D)	0.070 mm (-3.00 D)
Oxygen Permeability (Dk)	122.0	122.0
Wear Schedule in Current Study	Daily Wear Reusable	Daily Wear Reusable
Replacement Frequency	Two Weeks	Two Weeks
Packaging Form (vial, blister, etc.)	Blister	Blister

*Note: The spherical test lens is used in the troubleshooting steps only for low ADD subjects who have a distance complaint. Refer to the Fitting Guide in Appendix G for more details.

**Note: There will not be a -3.50 low ADD lens that will be provided.

6.2. Ancillary Supplies/Products

The following solutions will be used in this study:

Table 3: Ancillary Supplies

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

	Solution
Solution Name/Description	OPTI-FREE® Replenish® Multipurpose Disinfecting Solution
Manufacturer	Alcon Laboratories
Preservative	ALDOX® 0.0005%, POLYQUAD® 0.001%

6.3. Administration of Test Articles

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

6.4. Packaging and Labeling

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

6.5. Storage Conditions

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

6.6. Collection and Storage of Samples

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

6.7. Accountability of Test Articles

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

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

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

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

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

[redacted]

7. STUDY EVALUATIONS

7.1. Time and Event Schedule

Table 4: Time and Events

Visit Information	Visit 1 Screening, Baseline, Treatment 1 Fitting	Visit 2 Treatment 1 Follow-up 1 Optimization	Visit 3 Treatment 1 Follow-up 2
Time Point	Day 0	Day 3±1 from V1	Day 12±2 from V2
Estimated Visit Duration	2.5 hours	1.0 hours	1.5 hours
Statement of Informed Consent	x		
Demographics	x		
Medical History/Concomitant Medications	x		
Adverse Events and Concomitant Medications Review		x	x
Compliance		x	x
Habitual Contact Lens Information	x		
Contact Lens History	x		
Wear Time and Comfortable Wear Time with Habitual Lenses	x		
Wear Time and Comfortable Wear Time with Study Lenses		x	x
Screening Inclusion/Exclusion Criteria	x		
Subject Reported Ocular Symptoms	x	x	x
Baseline Questionnaire	x		
CLDEQ-8 Questionnaire	x	x	x

Visit Information	Visit 1 Screening, Baseline, Treatment 1 Fitting	Visit 2 Treatment 1 Follow-up 1 Optimization	Visit 3 Treatment 1 Follow-up 2
Time Point	Day 0	Day 3±1 from V1	Day 12±2 from V2
Estimated Visit Duration	2.5 hours	1.0 hours	1.5 hours
Distance and Near Entrance Visual Acuity	x	x	x
Lens Removal	x	x	x
Keratometry	x		
Subjective Refraction and Distance Visual Acuity	x		
Near ADD Determination	x		
Ocular Dominance	x		
ADD Refinement	x		
Near Visual Acuity	x		
Biomicroscopy	x	x	x
Baseline Inclusion/Exclusion Criteria	x		
Eligibility	x		
Lens Selection	x	x (if modified)	
Lens Insertion	x	x	x
10 Minute Settling	x	x (if modified)	
Visual Satisfaction / Subjective Acceptance	x	x	x
Study Lens Distance and Near Visual Acuity	x	x	x
Distance Over Refraction and Visual Acuity	x	x	
Lens Fit Assessment	x	x	x
Binocular Over Refraction		x	x
Lens Deposits			x
Lens Wettability			x
Visual Performance			x

Visit Information	Visit 1 Screening, Baseline, Treatment 1 Fitting	Visit 2 Treatment 1 Follow-up 1 Optimization	Visit 3 Treatment 1 Follow-up 2
Time Point	Day 0	Day 3±1 from V1	Day 12±2 from V2
Estimated Visit Duration	2.5 hours	1.0 hours	1.5 hours
Modifications	x	x	
Post-Fit GSI Questionnaire	x	x	
Worn Lens Collection		x	x
Study Lens Questionnaire		x	x
Distance and Near Exit Visual Acuity	x	x	
Dispensing Criteria	x	x	
Instructions	x	x	
Schedule Follow-up	x	x	
Final Evaluation			x (or when subject discontinued)

7.2. Detailed Study Procedures

VISIT 1

Subjects must report to the visit wearing their habitual contact lenses to accurately assess baseline questionnaire (CLUE and GSI) performance. If the subject is not wearing their lenses they must be rescheduled.

Visit 1: Screening			
Step	Procedure	Details	[redacted]
1.1	Statement of Informed Consent	Each subject must read, understand, and sign the Statement of Informed Consent before being enrolled into the study. The Principal Investigator or his/her designee conducting the informed consent discussion must also sign the consent form. **Note**: The subject must be provided a signed copy of this document.	
1.2	Demographics	Record the subject's age, gender, race and ethnicity.	
1.3	Medical History and Concomitant Medications	Questions regarding the subjects' medical history and concomitant medications.	
1.4	Habitual Lenses	Questions regarding the subject's habitual lens type and parameters.	
1.5	Habitual Lens Duration of Wear/Days per week	Questions regarding the subject's duration of contact lens wear and the minimum number of days they wear their lenses per week.	
1.6	Contact Lens History	Record the subject's correction type (i.e. monovision, multifocal, sphere with readers, etc.).	
1.7	Wear time and Comfortable Wear time with Habitual lenses	Record the subjects wear time and comfortable wear time with their habitual contact lenses.	
1.8	Eligibility after Screening	All responses to Screening Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria must be answered "no" for the subject to be considered eligible.	

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.9	Baseline (CLUE and GSI) and CLDEQ-8 Questionnaires	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of their habitual lenses using the PRO questions.	
1.10	Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
1.11	Entrance Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the subject's habitual contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
1.12	Lens Removal	Have the subject remove their habitual lenses and store in an approved storage solution.	
1.13	Keratometry	Keratometry will be performed OD and OS and the steep and flat dioptric power and corresponding meridians recorded.	[redacted]
1.14	Subjective Refraction and Distance Visual Acuity	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. Record the refraction and distance visual acuity to the nearest letter. *Note: Best distance visual acuity with sphero-cylindrical refraction must be at least 20/20^{-3} in each eye for the subject to be eligible in the study.*	[redacted]
1.15	Near ADD Determination	The near reading addition will be determined using the binocular crossed cylinder technique (BCC) at 40 cm followed by optimization in a trial frame in step 1.17 below.	[redacted]
1.16	Ocular Dominance	Determine the distance ocular dominance with the best distance correction in place using a +1.00-blur test. If the results are equivocal use the sighting dominance test to determine the dominant eye used for the study.	Appendix F
1.17	ADD Refinement	Place the BCC result in the trial frame and refine the near prescription with trial lenses (or flippers) under binocular conditions.	[redacted]

1.18	Near Visual Acuity	Using the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm. Record the near visual acuity OD, OS and OU at 40 cm.	[redacted]
1.19	Biomicroscopy	FDA Slit Lamp Classification Scale* will be used to grade the findings and determine eligibility. *note: for corneal staining note location (nasal, temporal, superior, inferior or central) If any of these slit lamp findings are Grade 2 or higher, the subject will be discontinued. If discontinued a final examination must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be instilled.	[redacted]
1.20	Eligibility after Baseline	All responses to Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria questions must be answered "no" for the subject to be considered eligible. If so, proceed to lens fitting. If not, complete the final evaluation and discharge the subject.	

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
1.21	Lens Selection	The lens powers (distance and ADD) will be selected based upon the calculation provided in EDC. Record the test lens parameters (power and lot number).	
1.22	Lens Insertion	Subjects will insert the lenses themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
1.23	Lens Settling	Allow the study lenses to settle for a minimum of 10 minutes.	
1.24	Determine Visual Satisfaction	Determine if the subject's vision is acceptable with the lenses. Allow the subject to look	

		down a hallway or out of a window for distance vision assessments, and for them to read a book, magazine or similar for near vision.	
1.25	Study Lens Distance and Near Visual Acuity	Measure the distance and near visual acuity OD, OS and OU. Record the results. **Note:** Use the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm to measure the Near visual acuity	[redacted]
1.26	Distance Over-Refraction and Distance Visual Acuity	Perform a distance over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over-refraction may also be refined under binocular conditions. Record the results. The results of the distance over-refraction may also be checked for the impact on near vision under monocular and/or binocular conditions.	
1.27	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the 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 subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
1.28	Modifications	If the subject reports unsatisfactory vision, or is unable to obtain 20/30 distance visual acuity OU with the lenses then a modification must be attempted. If the subject reports satisfactory vision with the lenses a modification is not required, however at the	[redacted]

		Investigator's discretion and based upon their findings on the measured visual acuity and/or over- refraction the investigator may make a modification. Up to two attempts at modification are permitted if necessary, in order to achieve an acceptable distance and near binocular performance for the subject, and to enable them to wear that particular lens type. Follow the fitting guide allowing for at least 10 minutes of settling time between each lens modification attempted. If modifications are required steps 1.21-1.27 will be repeated for each modification.	
1.29	Post-Fit GSI Product Performance Questionnaire	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the GSI questionnaire.	
1.30	Distance and Near Exit Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU. **Note: The distance visual acuity must be at least 20/30 OU for the lenses to be dispensed.**	[redacted]
1.31	Dispensing Criteria	The lenses will be dispensed for 2-4 days. • Distance Snellen acuity equal to or better than 20/30 OU • Subject must indicate that the vision is acceptable. • Subject must indicate that the comfort of the lenses is acceptable. • Lenses must have an acceptable general lens fit.	
1.32	Patient Instructions	Instruct the Subject the following: • The lenses will be worn on a daily wear basis.	

		• OPTI-FREE® Replenish® solution will be used in a rub regime to disinfect and store the lenses each night in the lens case provided. • If determined necessary by the Investigator sterile non-preserved rewetting drops may be dispensed to be used as needed for dryness. • Subjects will be instructed to wear lenses for a minimum of 6 hours a day, every day during the study. • Subjects will be instructed to wear their glasses when not wearing the study lenses. • A patient instruction booklet will be provided. ***Note:*** *In the event a lens is lost or damaged, the subject will return to the investigator site for replacement. As much as reasonably possible, a damaged lens should be returned to the investigational site and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with sterile saline, and returned to the Sponsor.*	
1.33	Schedule Follow-up	The subject will be scheduled to return for their follow-up appointment in 3±1 day. ***Note:*** *To count the follow-up visit as a day of wear the Subject must have worn the study lenses for 6 hours prior to the visit.*	

VISIT 2

The subjects must present to Visit 2 wearing the study lenses. To be counted as a day of wear the lenses need to have been worn for at least six (6) hours prior to the visit.

Visit 2: Treatment 1 Follow-up 1			
Step	Procedure	Details	[redacted]
2.1	Adverse Events and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit.	

		Record any adverse events or medical history changes from the previous study visit.	
2.2	Wear time and Comfortable Wear time with Study lenses	Record the hours the subject has worn the study lenses and the comfortable wear time on the day of follow-up.	
2.3	Compliance	Record the subject's compliance with wearing the study lenses. ***Note:*** *Subjects must have worn lenses for at least 6 hours per day* *To be counted as a day of wear at this visit the Subject must have worn the study lenses for 6 hours prior to the visit.*	
2.4	CLUE Questionnaire	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire.	
2.5	Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
2.6	Subjective Acceptance	Record whether the subject's distance and near vision with the lenses is acceptable.	
2.7	Distance and Near Entrance Visual Acuity	Measure the distance and near visual acuity OD, OS and OU to the nearest letter. Record the results. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
2.8	Distance Over-Refraction and Distance Visual Acuity	Perform a distance over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over-refraction may also be refined under binocular conditions. Record the results and distance visual acuity OD and OS. The results of the distance over-refraction may also be checked for the impact on near vision under monocular and/or binocular conditions.	
2.9	Determination of Lens Optimization	If the subject reports unsatisfactory vision, or is unable to obtain 20/30 distance visual	[redacted]

		acuity OU with the lenses then a modification must be attempted. If the subject reports satisfactory vision with the lenses a modification is not required, however at the Investigator's discretion and based upon their findings on the measured visual acuity and/or over- refraction the investigator may make a modification. Up to two attempts at modification are permitted if necessary, in order to achieve an acceptable distance and near binocular performance for the subject, and to enable them to wear that particular lens type. Follow the fitting guide and steps 1.21-1.27 in Visit 1 Fitting allowing for at least 10 minutes of settling time between each lens modification.	[redacted]
2.10	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the 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 subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
2.12	Lens Removal	The study lenses will be removed and discarded.	
2.13	Biomicroscopy	Perform Biomicroscopy OD and OS. FDA Slit Lamp Classification Scales* will be used to grade the findings. *note: for corneal staining note location (nasal, temporal, superior, inferior or central)	[redacted]

		If any of these slit lamp findings are Grade 3 or higher, an AE must be recorded. All AEs must be followed to resolution. After resolution the subject will be discontinued and Final evaluation completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be instilled.	
2.14	Insertion of Study Lenses	Dispense the subject a new pair of lenses that match the distance and ADD power of the lenses that were removed in Step 2.12 above.	
2.15	PRO (MRD) Questionnaire	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire.	
2.16	Distance and Near Exit Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU. **Note: The distance visual acuity must be at least 20/30 OU for the lenses to be dispensed.**	[redacted]
2.17	Dispensing Criteria	The lenses will be dispensed for 10-14 days. • Distance Snellen acuity equal to or better than 20/30 OU • Subject must indicate that the vision is acceptable. • Subject must indicate that the comfort of the lenses is acceptable. • Lenses must have an acceptable general lens fit.	
2.18	Patient Instructions	Instruct the Subject the following: • The lenses will be worn on a daily wear basis. • OPTI-FREE® Replenish® solution will be used in a rub regime to disinfect and store	

		the lenses each night in the lens case provided. • If determined necessary by the Investigator sterile non-preserved rewetting drops may be dispensed to be used as needed for dryness. • Subjects will be instructed to wear lenses for a minimum of 6 hours a day, every day during the study. • Subjects will be instructed to wear their glasses when not wearing the study lenses. ***Note:*** *In the event a lens is lost or damaged, the subject will return to the investigator site for replacement. As much as reasonably possible, a damaged lens should be returned to the investigational site and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with sterile saline, and returned to the Sponsor.*	
2.19	Schedule Follow-up	The subject will be scheduled to return for their follow-up appointment in 12±2 days. ***Note:*** *To count the follow-up visit as a day of wear the Subject must have worn the study lenses for 6 hours prior to the visit.*	

VISIT 3

The subjects must present to Visit 3 wearing the study lenses. To be counted as a day of wear the lenses need to have been worn for at least six (6) hours prior to the visit.

Visit 3: Treatment 1 Follow-up 2			
Step	Procedure	Details	[redacted]
3.1	Adverse Events and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit. Record any adverse events or medical history changes from the previous study visit.	

3.2	Wear time and Comfortable Wear time with Study lenses	Record the hours the subject has worn the study lenses and the comfortable wear time on the day of follow-up.	
3.3	Compliance	Record the subject's compliance with wearing the study lenses. ***Note:*** *Subjects must have worn lenses for at least 6 hours per day* *To be counted as a day of wear at this visit the Subject must have worn the study lenses for 6 hours prior to the visit.*	
3.4	Follow-up CLUE/ GSI and CLDEQ-8 Questionnaires	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire.	
3.5	Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire	[redacted]
3.6	Subjective Acceptance	Record whether the subject's distance and near vision with the lenses is acceptable.	
3.7	Distance and Near Entrance Visual Acuity	Measure the distance and near visual acuity OD, OS and OU to the nearest letter. Record the results. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
3.8	Visual Performance Distance (4M) Intermediate (64 cm) Near (40 cm)	Visual performance will be recorded OD, OS, and OU for the following: **Distance, Bright Illuminance** *High and Low Contrast ETDRS Charts* 4M- HC#1, HC#2, HC#3 and LC#1, LC#2, LC#3 **Near, Bright Illuminance** *Reduced Guillon-Poling Charts* Intermediate (64 cm) High Contrast and Low Contrast Near (40 cm) High Contrast and Low Contrast **Note:** • **The room illuminance must be between**	[redacted]

		7.3 and 7.9 EV (394-597 lux). • **Distance, HC-1 Chart luminance Acceptable Range 10.5-10.7 EV (181-208 cd/m^2).** • **Guillon-Poling, Near Chart Luminance Acceptable Range 10.8-11.1 EV (223-274 cd/m^2).** •	
3.9	Binocular Distance Over-refraction and Distance Visual Acuity	Perform a binocular over-refraction and record the OD and OS results and distance visual acuity. Note: No lens changes are allowed based on the over-refraction.	Appendix D
3.10	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the 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 subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
3.11	Lens Deposits	Grade and record the amount of front and back surface lens deposits for both eyes.	[redacted]
3.12	Lens Wettability	Grade the wettability of the lenses.	[redacted]
3.13	Lens Removal	Have the subject remove the study lenses and store in saline in a labeled glass vial. **<u>NOTE</u>:** Lenses do not need to be stored in a refrigerator.	
3.14	Biomicroscopy	Perform Biomicroscopy OD and OS. FDA Slit Lamp Classification Scales* will be used to grade the findings.	[redacted]

		*note: for corneal staining note location (nasal, temporal, superior, inferior or central) If any of these slit lamp findings are Grade 3 or higher, an AE must be recorded. All AEs must be followed to resolution. After resolution the subject will be discontinued and Final evaluation completed If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be instilled.	

FINAL EVALUATION

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

Final Evaluation			
Step	Procedure	Details	[redacted]
F.1	Distance Subjective Sphero-cylindrical Refraction and Distance Exit Visual Acuity	Perform bare-eye subjective spherocylindrical refraction with a phoropter and record the best corrected distance visual acuity to the nearest letter (OD, OS, and OU).	
F.2	Subject Disposition	Indicate if the subject completed the study successfully. If subject discontinued from the study indicate the reason.	

7.3. Unscheduled Visits

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

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

If the Investigator withdraws a subject from the study, the final study visit case report forms must be completed indicating the reason(s) why the subject was withdrawn. The subject record

must be completed documenting the date and primary reason for withdrawal and the study CRA notified.

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

The following information will be collected during an unscheduled visit.

Unscheduled Visit			
Step	Procedure	Details	[redacted]
U.1	Chief Complaints	Record the subject's chief complaints for reasons for the unscheduled visit	
U.2	Adverse Events and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit.	
U.3	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
U.4	Entrance VA	Record the entrance distance and near visual acuity (OD, OS and OU). For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
U.5	Subjective Sphero-cylindrical Refraction	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. Record the refraction and distance visual acuity to the nearest letter.	[redacted]
U.6	Biomicroscopy	FDA Slit Lamp Classification Scale* will be used to grade the findings. *note: for corneal staining note location (nasal, temporal, superior, inferior or central) If any of these slit lamp findings are Grade 3 or higher, an AE must be recorded. All AEs must be followed to resolution. After resolution the subject will be discontinued and Final evaluation completed If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be instilled.	[redacted]

Unscheduled Visit			
U.7	Lens Dispensing	Additional study lenses may be dispensed when required.	
U.8	Lens Fit Assessment:	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). The subject should not proceed to wear the 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 subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
U.9	Exit Visual Acuity	Record the subject's exit distance and near visual acuity (OD, OS and OU). For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]

7.4. Laboratory Procedures

Not Applicable

8. SUBJECTS COMPLETION/WITHDRAWAL

8.1. Completion Criteria

Subjects are considered to have completed the study if they:

- provided informed consent
- they are eligible
- completed all study visits

8.2. Withdrawal/Discontinuation from the Study

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

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

For discontinued subjects, the Investigator will:

- Complete the current visit (scheduled or unscheduled)
- Complete the Final Evaluation, indicating the reason that the subject was discontinued from the study
- Record the spherocylindrical refraction with best corrected distance visual acuity
- Collect used test article(s) (worn or brought to the visit) from the subject and discard them, unless otherwise stated in Section 7.2
- Collect all unused test article(s) from the subject

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

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

9. PRE-STUDY AND CONCOMITANT INTERVENTION/MEDICATION

Concomitant medications will be documented during screening and updated during the study. Disallowed medications and therapies are medications or therapies that contraindicate contact lens wear. See the Exclusion criteria for specific details.

9.1. Systemic Medications

The following table lists the medications disallowed in this study.

Table 5: Disallowed systemic medications

Class of Drug	Common Indication(s)	Common Examples
Anticholinergics	Irritable bowel syndrome, Parkinson's disease, peptic ulcer, cystitis, nasal congestion, cold symptoms, overactive bladder, COPD	Bentyl, Spiriva, Atrovent, Hyosyne, Levsin, Symax Fastab, Symax SL, Homax SL, Cogentin, Transderm Scop, etc., …
Oral Phenothiazines	Antipsychotic disorders (schizophrenia, mania)	Compazine, Mellarill, Thorazine, Phenagran, etc.…
Oral Retinoids	Cystic acne	Isotretinoin
Corticosteroids	Arthritis, colitis, asthma, bronchitis, allergic or inflammatory conditions	Cortisone, Prednisone, Hydrocortisone, Medrol, Kenalog etc., …
Oral Tetracycline	Urinary Tract Infection, acne, chlamydia, gonorrhea	Sumcyin, Acitsite, Achromycin V, etc.

10. DEVIATIONS FROM THE PROTOCOL

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

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

If the deviation potentially impacts the safety of patient or changes the technical integrity of the study then it must be reported to IEC/IRB. This is a "Major Deviation" .
Minor deviations have no substantive effect on patient safety or technical integrity of the study. They are often logistical in nature. The informed consent must also not be contradicted by the deviation.

Protocol waivers are prohibited.

11. STUDY TERMINATION

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

The Sponsor will determine when a study will be stopped. The Principal Investigator always has the discretion to initiate stopping the study based on patient safety or if information indicates the study's results are compromised.

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

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

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

12. PROCEDURE FOR HANDLING PRODUCT QUALITY COMPLAINTS

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

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

- Subject satisfaction inquiries reported via "Subjective Questionnaires" and "Patient Reported Outcomes (PRO)."
- Clinical test articles that are stored improperly or damaged after receipt at the investigational site.
- Lens replacements that occur due to drops/fall-outs.
- Damage deemed by clinicians or clinical staff to be caused by handling by the user, and not indicative of a quality deficiency (i.e. tears, rips, etc.), only in situations where there is no deficiency alleged by the subject.

Within 24 hours of site personnel becoming aware that a PQC has occurred, the PQC must be recorded in the EDC system, which will trigger an automatic email notification to the

appropriate COM/CRA and Clinical QA representative. In cases where the EDC system in use is not configured to send automatic notifications or when an EDC system is not used, the COM/CRA is responsible for notifying Clinical QA upon discovery that a PQC has occurred.

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

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

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

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

13. ADVERSE EVENTS

13.1. Definitions and Classifications

Adverse Event (AE) – An AE is “any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device.
This definition includes events related to the investigational medical device or the comparator, and to the procedures involved. For users or other persons, this definition is restricted to events related to investigational medical devices[1]

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

1. Was not present prior to the study, but appeared or reappeared following initiation of the study.
2. Was present prior to the study, but worsened during the study. This would include any condition resulting from concomitant illnesses, reactions to concomitant medications, or progression of disease states.
3. Pregnancy must be documented as an adverse event and must be reported to the clinical monitor and to the Sponsor immediately upon learning of the event.

Serious Adverse Event (SAE) – An SAE is any adverse event that led to any of the following:

- Death
- Serious deterioration in the health of the subject that resulted in any of the following:
- Life-threatening illness or injury
- Permanent or persistent impairment of a body structure or a body function
- Hospitalization or prolongation of patient hospitalization
- Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.
- Chronic disease
- Fetal distress, fetal death or a congenital physical or mental impairment of birth defect.

Diagnoses and conditions that are considered Ocular Serious Adverse Events include, but not limited to:

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

Significant Adverse Events – are defined as events that are symptomatic and warrant discontinuation (temporary or permanent) of the contact lens wear

Diagnoses and conditions that are considered Ocular Significant Adverse Events include, but not limited to the following:

- Contact Lens Induced Peripheral Ulcer (CLPU)
- Significant Infiltrative Events (SIE)
- Superior Epithelial Arcuate Lesions (SEALs)
- Any Temporary Loss of > 2 Lines of BSCVA

- Other grade 3 or higher corneal findings, such as abrasions or edema
- Non-contact lens related corneal events - e.g. Epidemic Keratoconjunctivitis (EKC)
- Asymptomatic Corneal Scar
- Any corneal event which necessitates temporary lens discontinuation > 2 weeks

Non-Significant Adverse Events – are defined as those events that are usually asymptomatic and usually do not warrant discontinuation of contact lens wear but may cause a reduction in wear time. However, the Investigator may choose to prescribe treatment as a precautionary measure.

Diagnoses and conditions that are considered Ocular Non-Significant Adverse Events include, but not limited to the following:

- Non-significant Infiltrative Event (NSIE)
- Contact Lens Papillary Conjunctivitis (CLPC)
- Superficial Punctate Keratitis (SPK)
- Conjunctivitis: Bacterial, Viral, Allergic
- Blepharitis
- Meibomianitis
- Contact Dermatitis
- Localized Allergic Reactions
- Any corneal event not explicitly defined as serious or significant adverse event, which necessitates temporary lens discontinuation < 2 weeks

Adverse Device Effect (ADE) – An ADE is an "adverse event related to the use of an investigational medical device.
NOTE 1: **to entry: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.**
NOTE 2 **to entry: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device."**[1]

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

13.2. Assessing Adverse Events

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

- Seriousness/Classifications (see definition in Section 13.1).

- Causality or Relatedness – i.e. the relationship between the test article, study treatment or study procedures and the adverse event (not related; unlikely related; possibly related; related - see definition in Section 13.2.1).
- Adverse Event Severity – Adverse event severity is used to assess the degree of intensity of the adverse event (mild; moderate; severe for all events - see definition in Section 13.2.2).
- Outcome – not recovered or not resolved; recovering or resolving; recovered or resolved with sequelae; recovered or resolved; death related to adverse event; unknown.
- Actions Taken – none; temporarily discontinued; permanently discontinued; other.

13.2.1. Causality Assessment

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

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

13.2.2. Severity Assessment

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

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

13.3. Documentation and Follow-Up of Adverse Events

The recording and documenting of adverse events (ocular and non-ocular) begin when the subjects are exposed to the test article, study treatment or study procedure. Adverse events

reported before the use of test article, start of study treatment, or study procedures will be recorded as medical history. However, if the condition deteriorates at any time during the study it will be recorded and reported as an AE. Untoward medical events reported after the subject's exit from the study will be recorded as adverse events at the discretion of the Investigator.

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

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

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

- Adverse event (diagnosis not symptom).
- Drawings or photographs (where appropriate) that detail the finding (e.g., size, location, and depth, etc.).
- Date the clinical site was notified.
- Date and time of onset.
- Date and time of resolution.
- Adverse event classification, severity, and relationship to test articles, as applicable.
- Treatment regimen instituted, including concomitant medications prescribed, in accordance with applicable licensing requirements.
- Any referral to another health care provider if needed.
- Outcome, ocular damage (if any).
- Likely etiology.
- Best corrected visual acuity at the discovery of the event and upon conclusion of the event.

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

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

Subjects who present with an adverse event shall be followed by the Investigator, within licensure, until all signs and symptoms have returned to pre-treatment status, stabilized, or been satisfactorily resolved. If further treatment beyond licensure is required, the patient will

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

13.4. Reporting Adverse Events

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

13.4.1. Reporting Adverse Events to Sponsor

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

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

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

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

Unanticipated (Serious) Adverse Device Effect (UADE)
In the event of an Unanticipated (Serious) Adverse Device Effect (UADE), the Investigator will submit a report of the UADE to the Sponsor and IEC/IRB as soon as possible, but no later

than 24 hours after the Investigator first learns of the effect. This report is in addition to the immediate notification mentioned above.

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

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

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

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

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

13.4.3. Event of Special Interest

None

13.5. Reporting of Pregnancy

Subjects reporting pregnancy (by self-report) during the study will be discontinued after the event is recorded as an Adverse Event. Once discontinued, pregnant participants and their fetuses will not be monitored for study related purposes.

Pregnant participants are not discontinued from contact lens or solution related studies for safety concerns, but due to general concerns relating to pregnancy and contact lens use. Specifically, pregnant women are discontinued due to fluctuations in refractive error and/or visual acuity that occur secondary to systemic hormonal changes, and not due to unforeseen health risks to the mother or fetus.

14. STATISTICAL METHODS

14.1. General Considerations

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

All data summaries and statistical analyses will be performed using the Statistical Analysis System (SAS) software Version 9.4 or higher (SAS Institute, Cary, NC). Throughout the analysis of data, the results for each subject/eye will be used when available for summarization and statistical analysis. For efficacy endpoints, unscheduled visits will be summarized separately and will be excluded in the analysis. However, unscheduled visits will be included in the analysis of safety parameters (i.e. Lens Fit and SLFs).

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

Efficacy endpoints will be summarized on both ITT and PP populations, while safety endpoints will be summarized on both safety and PP populations .

14.2. Sample Size Justification

This study was designed and powered to demonstrate that the Multifocal Test lens made with senofilcon A material made from the Flexible Manufacturing Platform (FMP), in its final lens design FAL100, FAL101 and FAL102 (low, mid and high ADD respectively) meets the design validation requirements for the following efficacy and safety endpoints:

- CLUE vision score at 2-week follow-up
- Binocular visual acuity (Distance, Intermediate and Near) at 2-week follow-up
- Proportion of eyes with a significant slit lamp finding (Grade 3 or higher)
- Proportion of eyes with unacceptable lens fitting

The historical data used for the sample size calculation were from 6 JJVC sponsored studies. Table 4 displays the studies, their corresponding study design and the number of subjects enrolled and completed. The investigational product in all these studies was the multifocal Test lens in its' final design (FAL100, FAL101 and FAL102) made from different manufacturing platforms.

Table 6: Historical Studies Utilized for Sample Size Calculation

Study	Study Design	Manufacturing Platform	#Enrolled	#Completed	Population	SKU
[redacted]	Crossover	FMP[1]	46	43	Hyperopes	+1.00 to +4.00
	Crossover	TAM21[2]	71	61	Hyperopes	+1.00 to +4.00
	Crossover	TAM21	63	60	Myopes	-1.00 to-4.00
	Crossover	SCLM[3]	45	45	Hyperopes	+1.00 to +4.00
	Parallel	MCLM[4]	189	168	Myopes	-1.00 to-4.00
	Crossover	SCLM	40	34	Hyperopes	+1.00 to +4.00
Total			454	411		

[1]FMP: Flexible Manufacturing Platform
[2]TAM21: Tokyo Automatic Machinery -3GT (3rd Generation Technology) manufacturing line
[3]SCLM: Single Cavity Lens Machine

[4]MCLM: Multi Cavity Lens Machine

Summaries of efficacy data pooled across all the 6 studies are presented in Table 5. Results showed that near, intermediate and distance VA have similar variation across studies, therefore a 0.11 was utilized for the variation in the power calculation for all positions. Historical data have shown that the average CLUE vision score of Hyperopes is lower that of myopes.

Table 7: Descriptive summary of Efficacy Endpoints Period 1 Only - 2-Week Follow-up

Endpoint	Mean	Median	Standard Deviation	Minimum	Maximum
Distance VA (3m)	-0.077	-0.100	0.1026	-0.320	0.560
Intermediate VA (64cm)	-0.054	-0.060	0.1014	-0.300	0.360
Near VAR (40cm)	0.077	0.060	0.1100	-0.260	0.460
Hyperopes' CLUE Vision score	47.71	48.07	17.514	10.22	93.50
Myopes' CLUE Vision score	56.46	53.37	19.227	21.51	108.04

The proportion of eyes with Grade 3 or higher SLFs and the proportion of eyes with unacceptable lens fittings pooled across all historical studies is presented in the table below. As shown, there was only 1 unacceptable lens fitting in any of the 6 historical study while there have been 5 eyes with reported Grade 3 or higher SLFs.

Table 8: Descriptive Summary of Safety Endpoints All Available Data

Endpoint	Test n(%)
Unacceptable lens fitting	1 (0.2)
SLF Grade 3+	5 (1.4)
Total Eyes (N)	350
Total Subjects	175

%= nx100/N

Safety Analysis

Our plan for safety analysis is to incorporate historical individual subject data from the 6 studies using power prior distributions in a Bayesian framework (see section 14.5). The level of influence of historical data on current is determined by a discounting factor a constrained between 0 and 1 ($0 \leq a_0 \leq 1$). $a_0 = 0$ corresponds to no borrowing of the historical data; while $a_0 = 1$ corresponds to full borrowing (See section 14.5 for more details). For this study we considered a low level of borrowing ranging by 0.1 and 0.30 based on the manufacturing platform where the historical study lens was made from. Table 7 displays the number of subjects and the degrees of borrowing that will be used in the safety analysis. The approved investigational product will be manufactured from the FMP platform; therefore, the borrowing strength is larger to lenses from the FMP platform. Furthermore, the TAM21 platform is considered equivalent with respect to lens performance and lenses from these platforms are

given the same borrowing strength as those from the FMP platform. While all historical studies used the lens in its final design, lenses made from the pilot line are only given a borrowing strength of 10%.

Table 9: Degrees of Borrowing Historical Data by Manufacturing Platform

Manufacturing Platform	Number of Subjects	Level of borrowing (a_0)
FMP	23	0.3
TAM21	66	0.3
Pilot Line (SCLM, MCLM)	86	0.1

We calculated the required sample size with and without borrowing historical data. To achieve a minimum of 80% power with a 2-sided type I error rate of 5%, the required sample size with no borrowing ($a_0 = 0$) was 120 subjects (240 eyes); while the sample size with borrowing was 60 subjects (120 eyes). The sample calculation in each scenario of borrowing was conducted using a Monte Carlo simulation of 1000 trials of samples of size 120 subjects (240 eyes) were drawn from a multivariate binary distribution assuming a compound symmetric (CS) covariance structure between left and right eye from the same subject. Assuming a true proportion of eyes with grade 3 or higher SLFs of p=0.014 and a correlation of ρ=0.70 between left and right eyes. The same approach was considered for the proportion of eyes with unacceptable fitting assuming a true proportion of eyes with unacceptable fit of p=0.01 and a correlation of ρ=0.80 between left and right eyes.

The sample size was mainly driven by safety analysis, the power calculation of the efficacy analysis showed that a sample size of 60 subjects is sufficiently large to test the efficacy hypotheses. No borrowing was considered for the primary efficacy analysis. Table 8 summarize the statistical power of a sample size of 60 subjects (120 eyes) for all endpoints.

Table 10: Power Calculation by Endpoint/Hypothesis Assuming a Sample Size of 60 Subjects

Endpoint	Borrowing	Hypothesis (H_A)	Power (%)
Grade 3 or Higher SLFs	Yes	$p_t < 0.05$	80
Unacceptable lens tit	Yes	$p_t < 0.05$	90
VA Distance	No	$\mu_t < +0.10$	> 99
VA Intermediate	No	$\mu_t < +0.17$	> 99
VA Near	No	$\mu_t < +0.17$	> 99
CLUE Vision (Hyperopes)	No	$\mu_t \geq 32$	99
CLUE Vision (Myopes)	No	$\mu_t \geq 40$	99

The power calculation of the efficacy analyses (CLUE and VA) was conducted using historical data presented in Table 5 above using PROC POWER for one sample means test for equivalence to test each hypothesis.

The plan is to enroll 80 eligible subjects with a target completion of 60 subjects. During the enrollment period, the subject drop-out rate with be closely monitored, if an unexpectedly high

dropout rate is observed, then the targeted total enrollment number maybe be increased accordingly to ensure that a minimum of 60 subjects complete the study.

14.3. Analysis Populations

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

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

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

14.4. Level of Statistical Significance

All planned analysis for this study will be conducted with an overall type I error rate of 5%.

14.5. Primary Analysis

Primary Safety analysis:

Strategy of Incorporating Historical Data:
Safety analysis will be performed by incorporating of historical data from studies: [redacted]. All these studies evaluated the same Test lens that was built in different manufacturing platforms to the same in vitro product requirements and are also considered to be representative of final commercial production. The historical individual data will be incorporated using is the power prior distribution (Ibrahim and Chen; 2000)[11].

Let $(\mathbf{y}, \mathbf{z})$ and $(\mathbf{y_0}, \mathbf{z_0})$ denote the data from current study, and from historical data respectively, p the proportion of eyes with response 1 and ρ the correlation between left and right eyes. To construct a power prior distribution for parameter of interests (p, ρ), we use the formula

$$P(p, \rho \mid \mathbf{y_0}, \mathbf{z_0}, a_0) \propto L(p, \rho \mid \mathbf{y_0}, \mathbf{z_0})^{a0} \pi_0(p, \rho),$$

where $L(p, \rho \mid \mathbf{y_0}, \mathbf{z_0}) \propto P(\mathbf{y_0}, \mathbf{z_0} \mid p, \rho)$ is the likelihood of (p, ρ) based on the historical data and a_0 is a discounting parameter constrained between 0 and 1. This parameter a_0 controls the amount of the historical data we are borrowing: $a_0 = 0$ corresponds to no incorporation of the historical data, while $a_0 = 1$ corresponds to full borrowing of historical data. We set $a_0 = 0.30$ for historical data of the Test lens was made in FMP and TAM21 platforms and $a_0 = 0.10$ for Test lens made in the pilot line.

The posterior distribution of (p, ρ) given the current and historical data is

$$P(p, \rho \mid \mathbf{y, z, y_0, z_0,}\ a_0) \propto L(p, \rho \mid \mathbf{y, z}) L(p, \rho \mid \mathbf{y_0, z_0})^{a0}\ \pi_0(p, \rho),$$

where $L(p, \rho \mid \mathbf{y, z}) \propto P(\mathbf{y, z} \mid p, \rho)$ is the likelihood of (p, ρ) based on the current data.

Primary Safety Analyses:
Slit lamp finding grade 3 or higher and unacceptable lens fitting responses (yes/no) will be analyzed separately on the safety population using the Bayesian model described below. A sensitivity analysis will be conducted with no borrowing of historical data.

The Model:
Let Y1 and Y2 denote the binary outcomes for the left and right eyes, respectively, when wearing the test lens. Considering the correlation, ρ, between Y1 and Y2, the distribution of the sum Y = Y1 + Y2 is obtained by the mixture of two variables. One of them follow a binomial distribution Bin(2, p) with mixing probability (1-ρ) and the other one follows a modified Bernoulli distribution MBern(p), taking value 0 and 2 rather than conventional 0 and 1, with mixing probability p:

$$P(Y = y \mid p, \rho) = (1- \rho)\text{Bin}(2, p)I_{A1} + \rho\text{MBern}(p)I_{A2};$$

where $I_{A1} = \{0, 1, 2\}$ and $I_{A2} = \{0, 2\}$

To overcome the complexity of the mixture likelihood a latent variable Z_i, i = 1, 2 is introduced in the model to indicate in which component of the model the observation y_i, i=1, 2, belongs to, that is,

$$z_i = \begin{cases} 1, \text{if the observation belong to the MBern}(p), \\ 0, \text{if the observation belong to the Bin}(2, p) \end{cases}$$

The joint distribution of the augmented data (Y_i, Z_i), i=1, 2, is given by

$$P(Y = y_i, Z = z_i \mid p, \rho) = \rho^{z_i} p^{y_i z_i/2} (1-p)^{(2-y_i)z_i/2} (1-\rho)^{1-z_i} \binom{2}{y_i} p^{y_i(1-z_i)} (1-p)^{(2-y_i)(1-z_i)}$$

The posterior distribution of (p, ρ) given (y, z), (y_0, z_0) and a_0 is

$$P\ (p, \rho \mid \mid \mathbf{y, z, y_0, z_0,}\ a_0) = P\ (\mathbf{y, z} \mid p, \rho)\ P\ (\mathbf{y_0, z_0} \mid p, \rho)^{a_0}\ \pi_0(p, \rho)$$

where, π_0 is joint prior distribution of (p, ρ). Here we assume p and ρ to be independent with a prior beta (α, β) for p and uniform (0,1) for ρ. Hence the joint distribution of (p, ρ) is given by π_0 (p, ρ| α, β) $\propto p^{\alpha\ -1}(1-p)^{\beta-1}$. The Metropolis sampler algorithm as implemented in the SAS/STAT MCMC Procedure will be used to estimate the posterior distributions of the parameters (p, ρ). Inferences will be made based on a posterior credible interval for the relevant parameters.

Hypothesis testing for safety endpoints will be conducted as follows:

- Slit Lamp Finding: the Null hypothesis will be rejected if the upper bound of the 2-sided 95% credible interval of the posterior estimate of the proportion of eyes with grade 3 or higher SLFS is below 5%.

- Unacceptable Len Fit: The Null hypothesis will be rejected if the upper bound of the 2-sided 95% credible interval of the posterior estimate of the proportion of eyes with unacceptable lens fitting is below 5%.

If no SLF findings of Grade 3 or higher or unacceptable lens fit is observed, alternative analysis methods will be considered. More details will be provided in the statistical analysis plan.

Primary Efficacy Analyses:
Efficacy analysis will be conducted the Intent-to-Treat Population (ITT) without borrowing from historical data. A sensitivity analysis will be performed by incorporating historical historical data. The level of borrowing used in the safety analysis will be considered. Further sensitivity analyses on the Per-Protocol Population will also be considered.

CLUE Vision
CLUE vision scores will be analyzed using a Bayesian normal random effects model for repeated measures. The model will include baseline clue score, age, add power, gender, timepoint (3-day and 2-week follow-up evaluations) and strata (Hyperopes and Myopes) and the interaction between timepoint and strata as fixed effects. Site will be included as a random effect. An unstructured (UN) covariance structure will be used to model the residual errors from measurements within the same subject across timepoints. Heterogeneous residuals covariance structures (R-side) across strata will be considered when appropriate. Non-informative priors will be used for the unknown parameter. For the β coefficients, independent non-informative priors N(0, 1000) will be used. For the variance of random effect σ^2_{site} an independent non-informative conjugate prior inverse-gamma(0.001, 0.001) will be used. For the residual covariance structure an inverse-Wishart distribution will be used. Inferences will be carried out using the 95% posterior credible intervals for relevant parameters.

Hypothesis testing for CLUE Vision Scores endpoints will be conducted separately for each stratum:

- Hyperopes: The Null hypothesis will be rejected if the lower bound of the 2-sided 95% credible interval of the clue vision posterior mean estimate is above 32.

- Myopes: The Null hypothesis will be rejected if the lower bound of the 2-sided 95% credible interval of the clue vision posterior mean estimate is above 40.

Visual Acuity
Binocular high luminance, high contrast (HLHC) visual acuity (logMAR) at the 2-week follow-up evaluation will be analyzed using a Bayesian normal random-effects model for

repeated measures. The model will include strata (Hyperope and Myope), add power, age, gender, position (40cm, 64cm and 3m) and the interaction between strata and position as fixed effects. Site and will be included as a random effect. An unstructured (UN) covariance structure will be used to model the residual errors from measurements within the same subject across different positions. Heterogeneous residuals covariance structures (R-side) across position will be considered when appropriate. Non-informative priors will be used for the unknown parameter. For the β coefficients, independent non-informative priors N(0, 1000) will be used. For the variance of random effect σ^2_{site} an independent non-informative conjugate prior inverse-gamma(0.001, 0.001) will be used. For the residual covariance structure an inverse-Wishart distribution will be used. Inferences will be carried out using the 95% posterior credible intervals for relevant parameters.

Hypothesis testing for visual acuity (logMAR) endpoints will be conducted separately for each position:

- Distance: The Null hypothesis will be rejected if the upper bound of the 2-sided 95% credible interval the binocular HLHC VA posterior mean estimate is lower than +0.10 logMAR.

- Intermediate: The Null hypothesis will be rejected if the upper bound of the 2-sided 95% credible interval the binocular HLHC VA posterior mean estimate is lower than +0.17 logMAR.

- Near: The Null hypothesis will be rejected if the upper bound of the 2-sided 95% credible interval the binocular HLHC VA posterior mean estimate is lower than +0.17 logMAR.

14.6. Secondary Analysis

The secondary Hypothesis will be conducted on the Intent-to-Treat without borrowing historical data.

Proportion of Subjects with Optimal Lens Pair

The number of lenses used for each subject will be calculated as the original pair (2) plus all the required modifications to reach the optimal pair. In this study the minimum number of lenses per subject used would be 2 where the max would be 6. The data will be dichotomized as 1 if the subject was able to achieve optimal lens pair in 4 lenses or less and 0 otherwise. The binary response will be analyzed using Bayesian logistic regression random-effects model to estimate the proportion of eyes that reached optimal lens pair in 4 lenses or less. The regression model will include strata (Hyperope and Myope), add power, age, gender, event (fitting, optimization, 2-week follow-up) and the interaction between strata by event. Site will be included in the model as a random effect. Non-informative priors will be used for the unknown parameter. For the β coefficients, independent non-informative priors $\mathrm{N}(0, 1000)$ will be used. For the variance of random effects of σ^2_{site} non-informative conjugate prior, inverse-gamma

(0.001, 0.001) will be used. Inferences will be made based on the posterior credible interval for the relevant parameters.

The null hypothesis will be rejected if the lower bound of the 2-sided 95% credible interval the proportion of subjects is above 90%.

14.7. Other Exploratory Analyses

Not Applicable

14.8. Interim Analysis

There will not be an interim analysis performed on this study.

14.9. Procedure for Handling Missing Data and Drop-Outs

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

Subject dropout is expected to be one of the main reasons of missing data in this clinical trial. Past clinical trials don't provide the evidence that subject dropout is systematic or not-at-random. To evaluate the impact of missing data, sensitivity analysis will be conducted using fully Bayesian imputation by imputing missing values.

14.10. Procedure for Reporting Deviations from Statistical Plan

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

15. DATA HANDLING AND RECORD KEEPING/ARCHIVING

15.1. Electronic Case Report Form/Data Collection

The data for this study will be captured on electronic case report forms (eCRFs) using an EDC system EDC system (Bioclinica). An authorized data originator will enter study data into the eCRFs using the EDC system. Data collected on equipment that is not captured in EDC will be formatted to the specification of the JJVC database manager and sent to JJVC for analysis.

External Data Sources for this study include: Not Applicable

The clinical data will be recorded on dedicated eCRFs specifically designed to match the study procedures for each visit. Only specifically delegated staff can enter data on a CRF. Once completed, the eCRFs will be reviewed for accuracy and completeness and signed by the Investigator. The sponsor or sponsor's representatives will be authorized to gain access to the subject recordation for the purposes of monitoring and auditing the study.

Edit checks, electronic queries, and audit trails are built into the system to ensure accurate and complete data collection. Data will be transmitted from the clinical site to a secure central database as forms are completed or updated, ensuring information accuracy, security, and confidentiality. After the final database lock, the Investigator will be provided with Individual Patient Profiles (IPP) including the full audit trail on electronic media in PDF format for all of the study data. The IPP must be retained in the study files as a certified copy of the source data for the study.

The content and structure of the eCRFs are compliant with ISO14155:2011.[1]

15.2. Subject Record

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

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

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

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

15.3ClinicalTrials.gov

Several prior studies have been performed with the investigational lenses therefore this study does not meet the definition of an early feasibility study and is required to be registered on ClinicalTrials.gov.

16. DATA MANAGEMENT

16.1. Access to Source Data/Document

The Investigator/Institution will permit trial-related monitoring, audits, IEC/IRB review and regulatory inspection(s) by providing direct access to source data/documents. Should the

clinical site be contacted for an audit by an IEC/IRB or regulatory authority, JJVC must be contacted and notified in writing within 24 hours.

16.2. Confidentiality of Information

Information concerning the investigational product and patent application processes, scientific data or other pertinent information is confidential and remains the property of JJVC. The Investigator may use this information for the purposes of the study only. It is understood by the Investigator that JJVC will use information developed in this clinical study in connection with the development of the investigational product and therefore may disclose it as required to other clinical investigators and to regulatory agencies. In order to allow the use of the information derived from this clinical study, the Investigator understands that he/she has an obligation to provide complete test results and all data developed during this study to the Sponsor.

16.3. Data Quality Assurance

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

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

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

17. CLINICAL MONITORING

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

- Ensuring that the investigation is being conducted according to the protocol, any subsequent versions, and regulatory requirements are maintained.
- Ensuring the rights and wellbeing of subjects are protected.
- Ensuring adequate resources, including facilities, laboratories, equipment, and qualified clinical site personnel.
- Ensuring that protocol deviations are documented with corrective action plans, as applicable.

- Ensuring that the clinical site has sufficient test article and supplies.
- Clarifying questions regarding the study.
- Resolving study issues or problems that may arise.
- Reviewing of study records and source documentation verification in accordance with the monitoring plan.

18. ETHICAL AND REGULATORY ASPECTS

18.1. Study-Specific Design Considerations

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

18.2. Investigator Responsibility

The Principal Investigator is responsible for ensuring that the clinical study is performed in accordance with the signed agreement, the investigational plan, Section 4 of the ICH E6 guidelines on Good Clinical Practice (GCP),[2] and applicable regulatory requirements. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles of the Declaration of Helsinki 64th WMA General Assembly 2013[3] and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with Section 8 of the ICH E6 guidelines on Good Clinical Practice (GCP),[2] and applicable regulatory requirements.

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

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

- Final protocol.
- Sponsor-approved informed consent form (and any other written materials to be provided to the subjects)
- Investigator's Brochure (or equivalent information).
- Sponsor-approved subject recruitment materials.
- Information on compensation for study-related injuries or payment to subjects for participation in the study.
- Investigator's curriculum vitae, clinical licenses, or equivalent information (unless not required, as documented by IEC/IRB).
- Information regarding funding, name of the Sponsor, institutional affiliations, other potential conflicts of interest, and incentives for subjects.

- Any other documents that the IEC/IRB requests to fulfill its obligation.

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

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

- Protocol revisions
- Revision(s) to informed consent form and any other written materials to be provided to subjects
- If applicable, new or revised subject recruitment materials approved by the Sponsor
- Revisions to compensation for study-related injuries or payment to subjects for participation in the study
- Investigator's Brochure revisions
- Summaries of the status of the study (at least annually or at intervals stipulated in guidelines of the IEC/IRB)
- Reports of adverse events that are serious, unanticipated, and associated with the test articles, according to the IRB's requirements
- New information that may adversely affect the safety of the subjects or the conduct of the study
- Major protocol deviations as required by the IEC/IRB
- Report of deaths of subjects under the Investigator's care
- Notification if a new Investigator is responsible for the study at the clinical site
- Any other requirements of the IEC/IRB

For protocol revisions that increase subject risk, the revisions and applicable informed consent form revisions must be submitted promptly to the IEC/IRB for review and approval before implementation of the change(s).

At least once a year, the IEC/IRB will review and reapprove this clinical study. This request should be documented in writing.

At the end of the study, the Investigator (or Sponsor where required) will notify the IEC/IRB about the study completion. Documentation of this notification must be retained at the clinical site and a copy provided to the CRO or Sponsor as applicable.

18.4. Informed Consent

Each subject or their representative, must give written consent according to local requirements after the nature of the study has been fully explained. The consent form must be signed before performance of any study-related activity. The consent form that is used must be approved by both the Sponsor and by the reviewing IEC/IRB. The informed consent is in accordance with

principles that originated in the Declaration of Helsinki,[3] current ICH[2] and ISO 14155[1] guidelines, applicable regulatory requirements, and Sponsor Policy.

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

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

18.5. Privacy of Personal Data

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

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

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

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

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

- accurate and, where necessary, kept current.

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

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

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

19. STUDY RECORD RETENTION

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

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

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

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

20. FINANCIAL CONSIDERATIONS

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

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

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

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

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

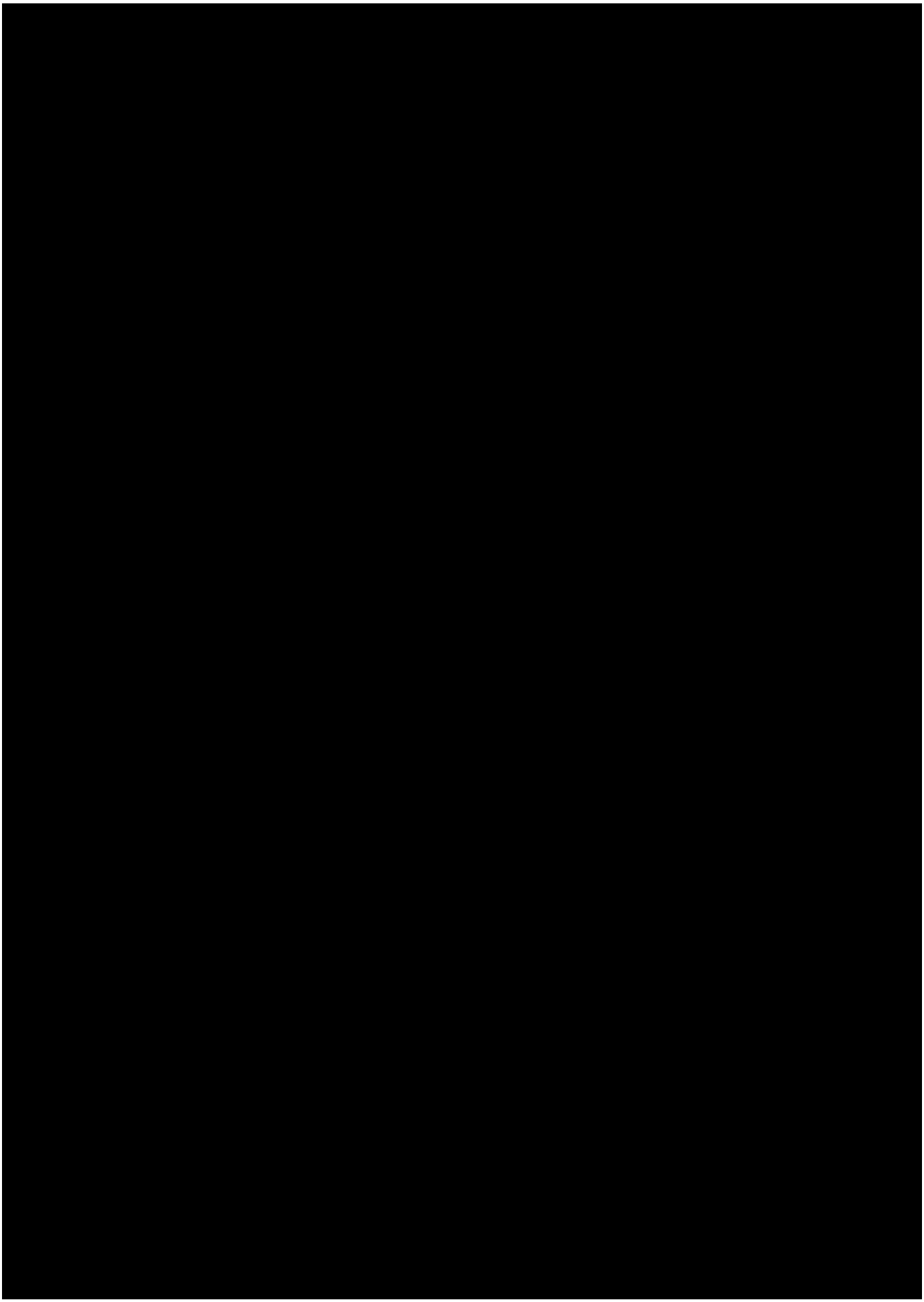
21. PUBLICATION

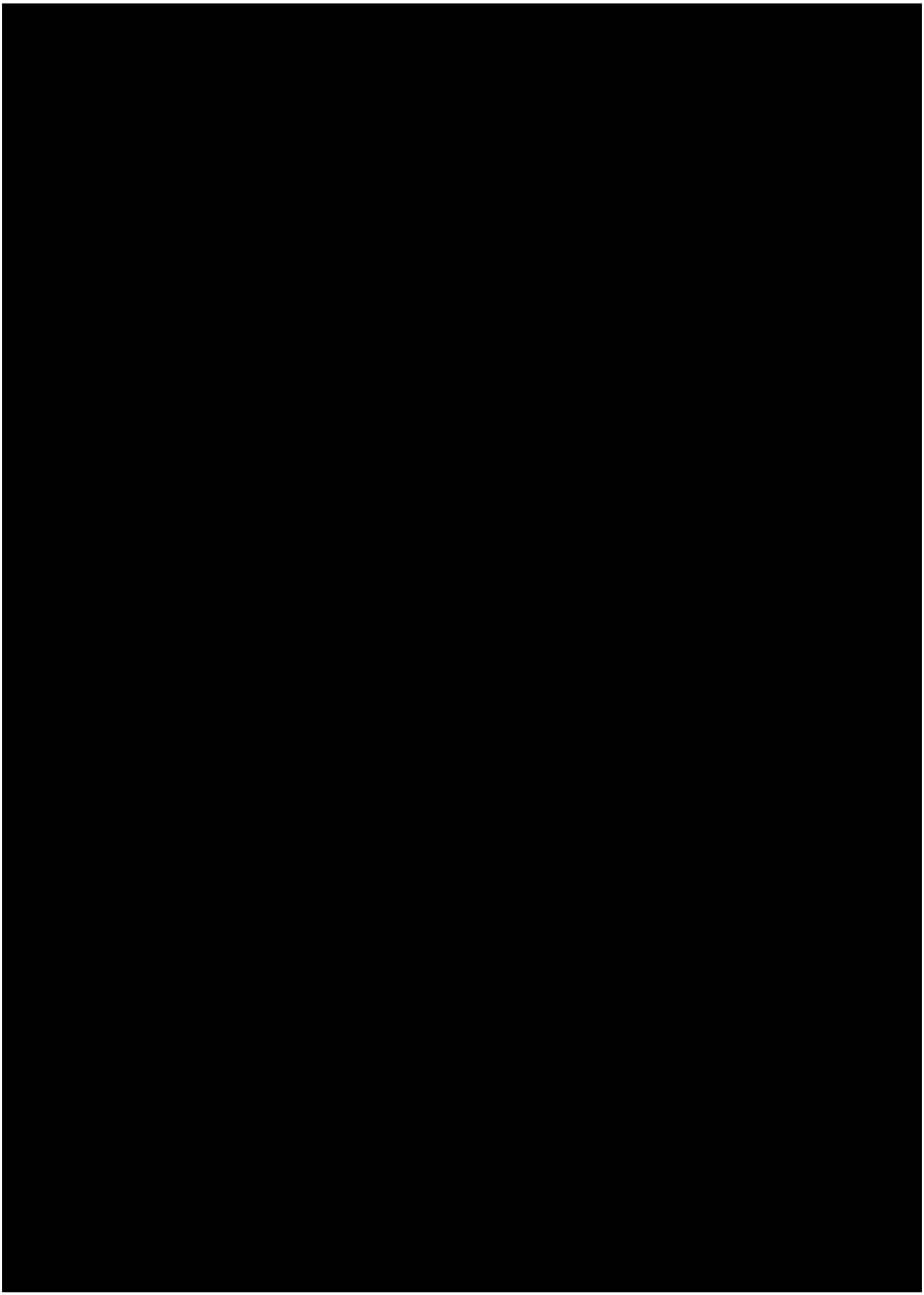
This study will be registered on ClinicalTrials.gov by the Sponsor.

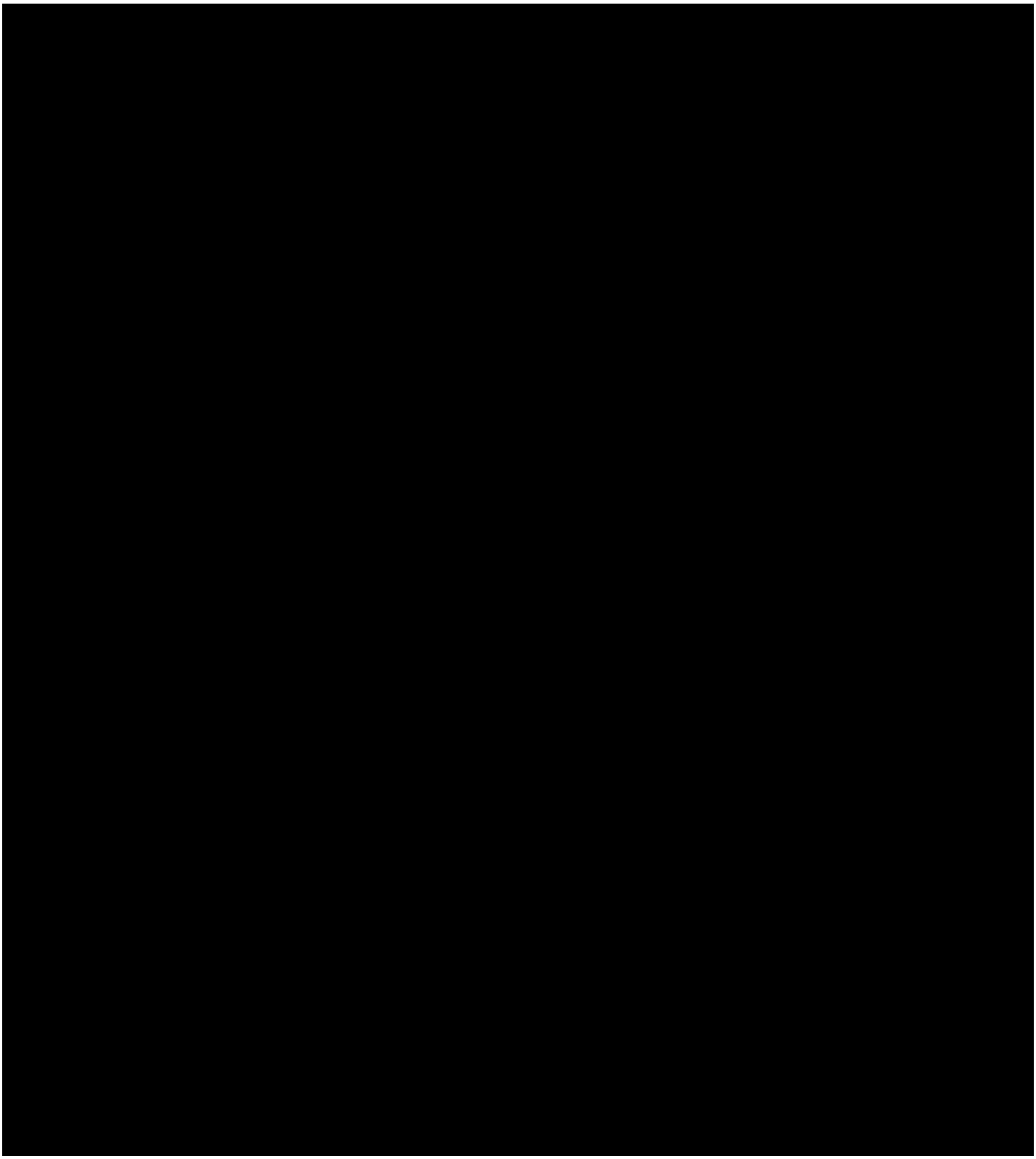
22. REFERENCES

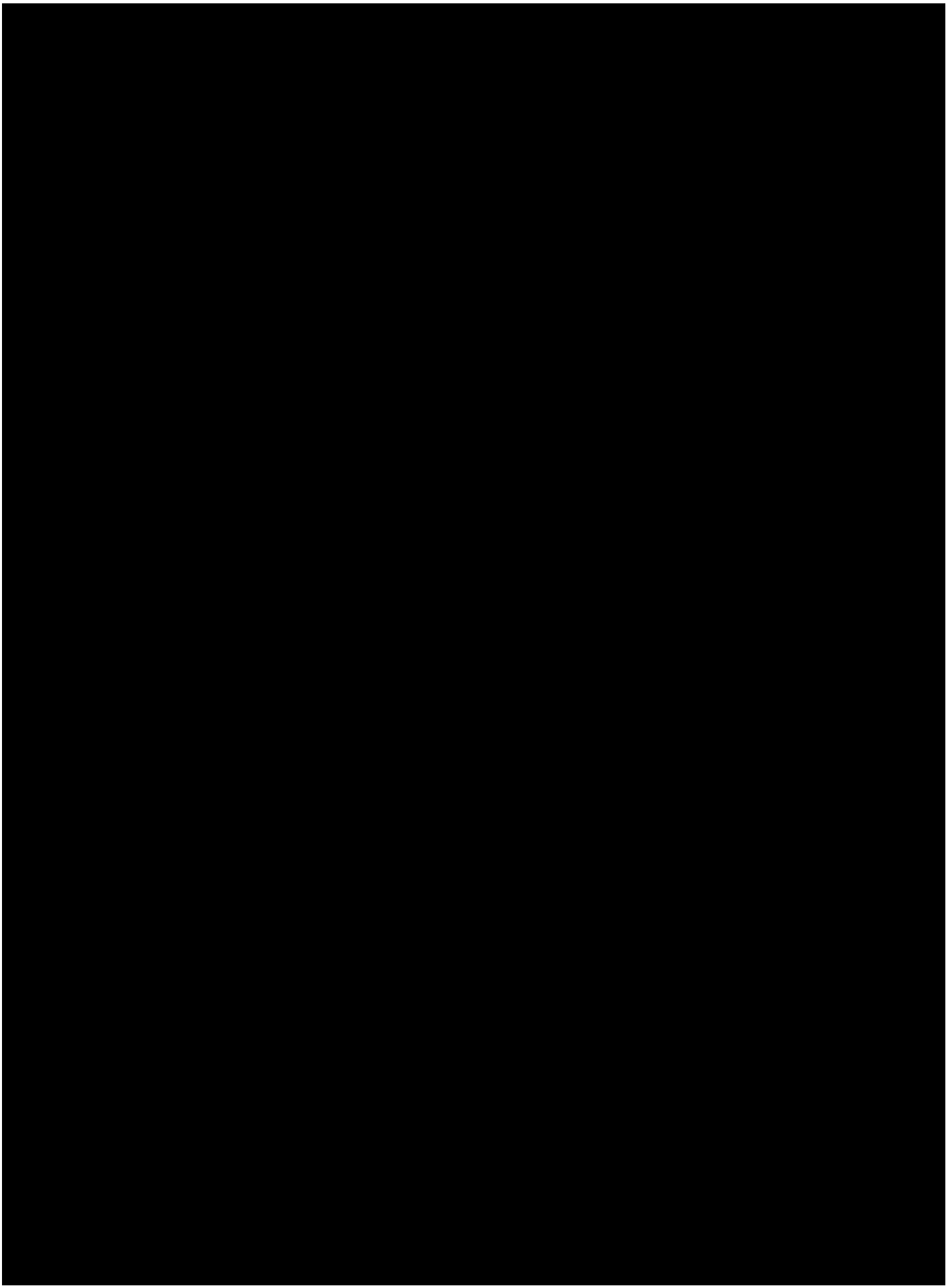
1. ISO 14155:2011: Clinical Investigation of Medical Devices for Human Subjects — Good Clinical Practice. Available at: https://www.iso.org/standard/45557.html
2. International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP). Available at: http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
3. Declaration of Helsinki - Ethical principles for Medical Research Involving Human Subjects. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
4. United States (US) Code of Federal Regulations (CFR). Available at: https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR
5. Health Information Portability and Accountability Act (HIPAA). Available at: https://www.hhs.gov/hipaa/for-professionals/privacy/index.html
6. EU MDR 2017/745
7. Keselman HJ, Algina J, Kowalchuk RK, Wolfinger RD. A Comparison of Two Approaches for Selecting Covariance Structures in the Analysis of Repeated Measures. *Communications in Statistics—Simulation and Computation.* 1998;27:591-604.
8. Kenward MG, Roger JH. Small Sample Inference for Fixed Effects from Restricted Maximum Likelihood. *Biometrics*. 1997;53:983–997.

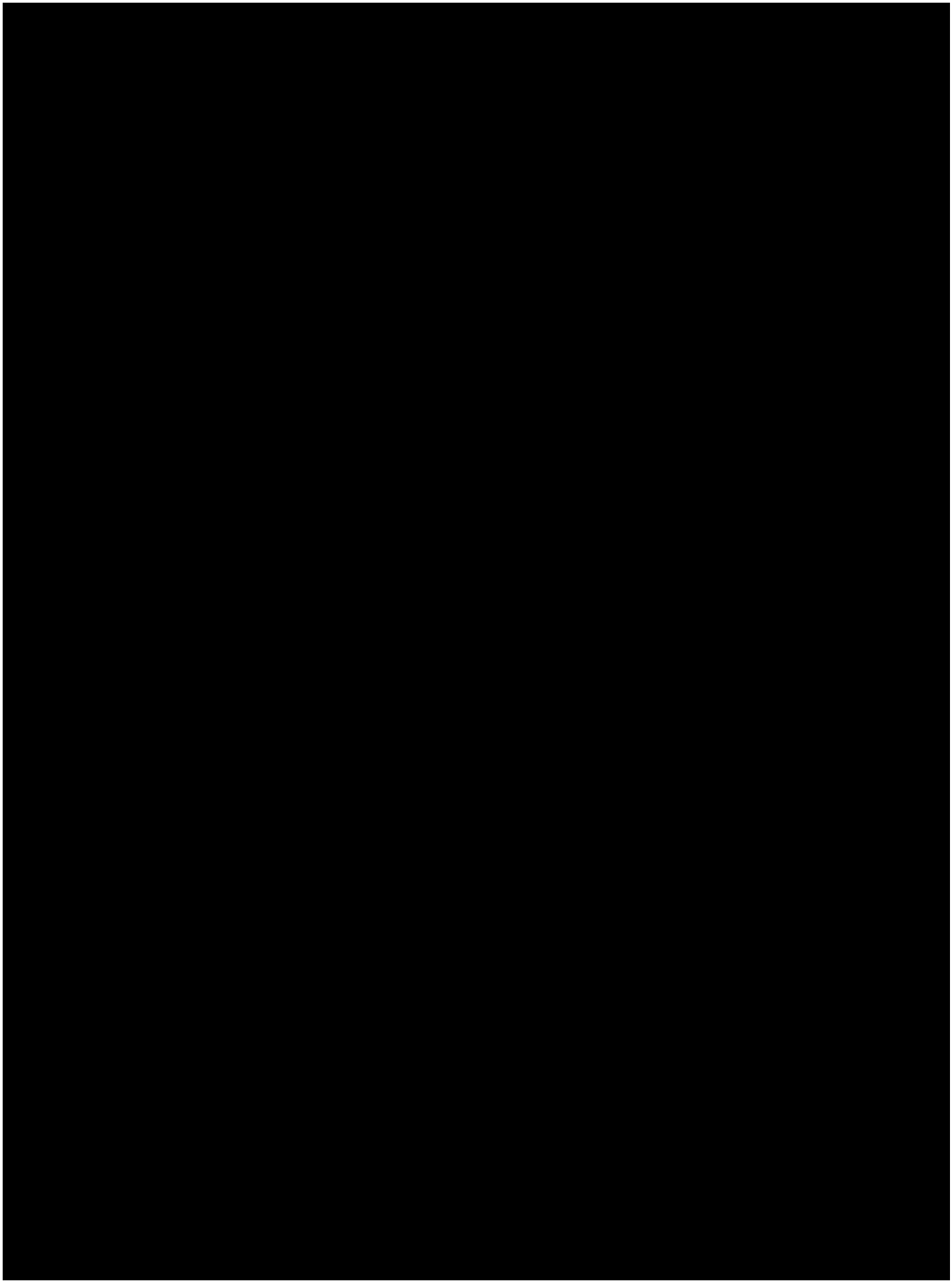
APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

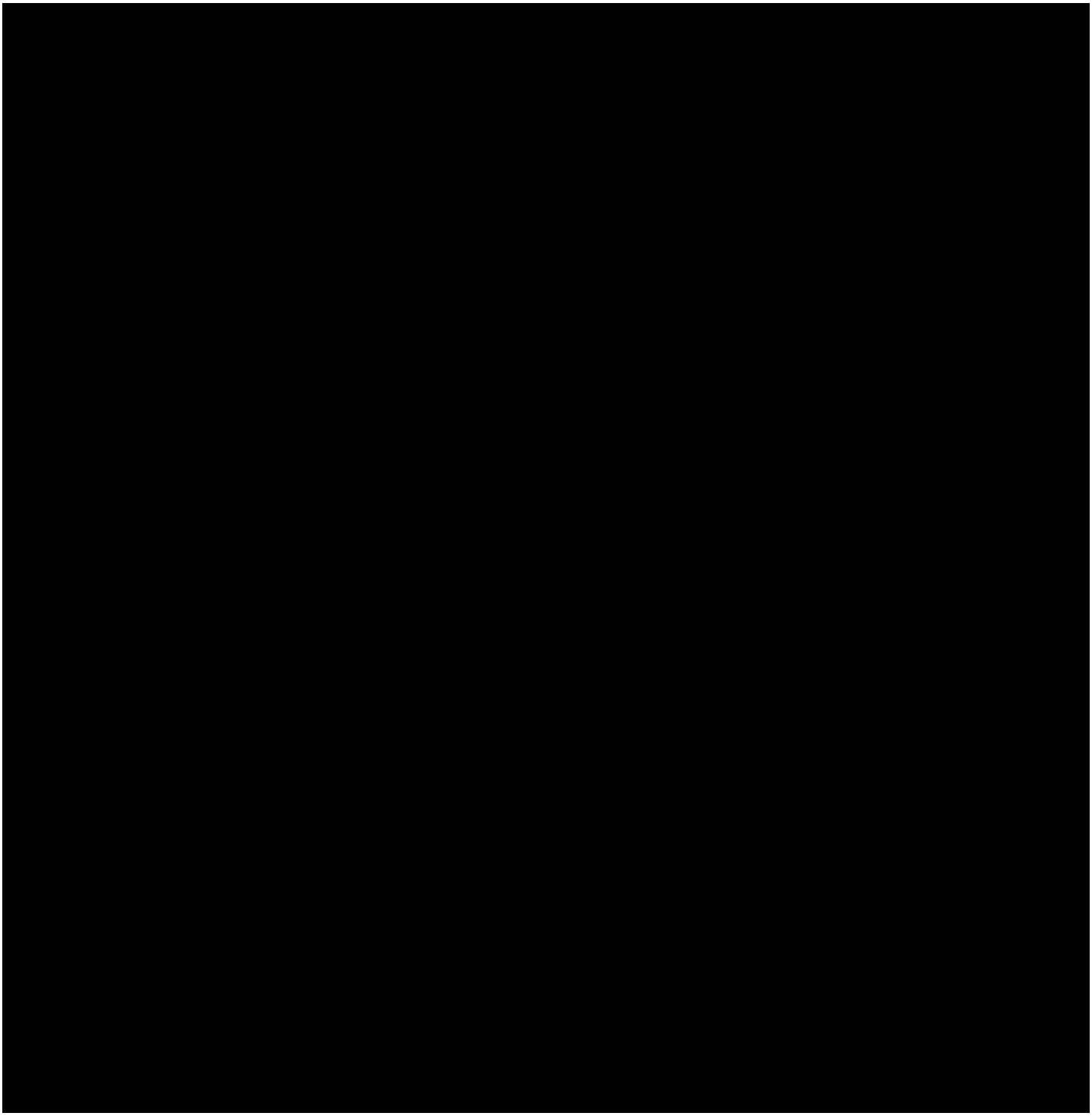


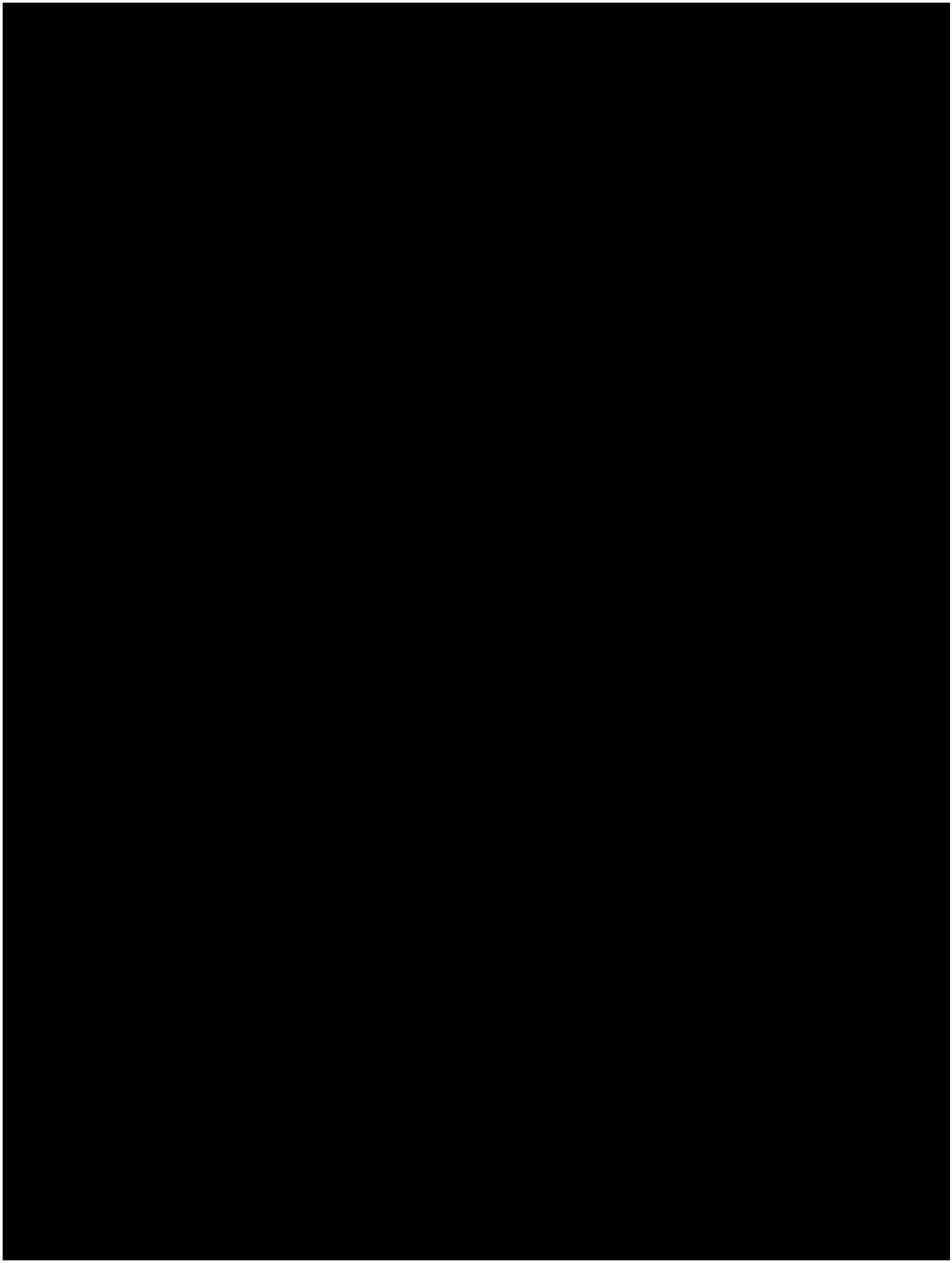


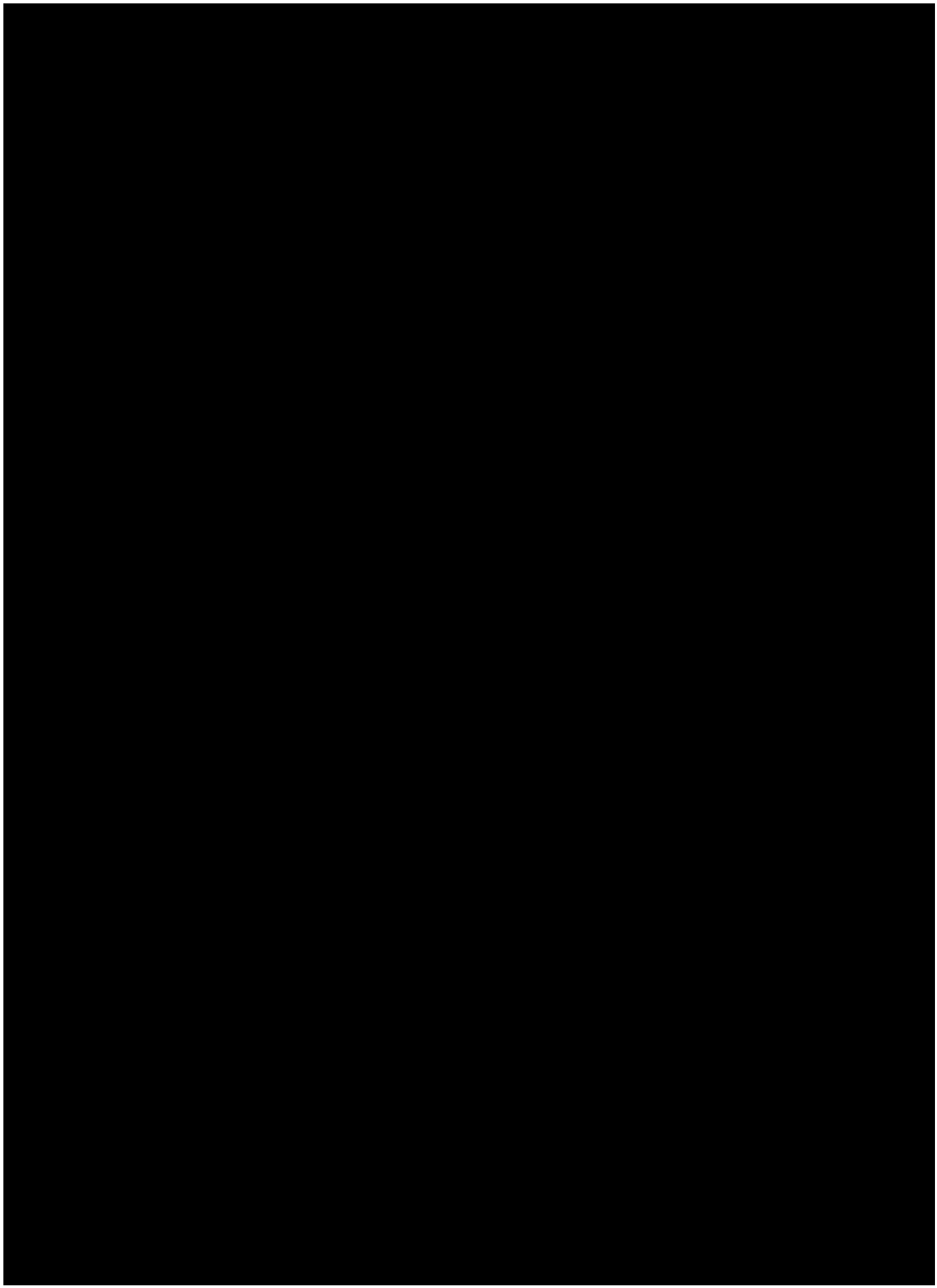


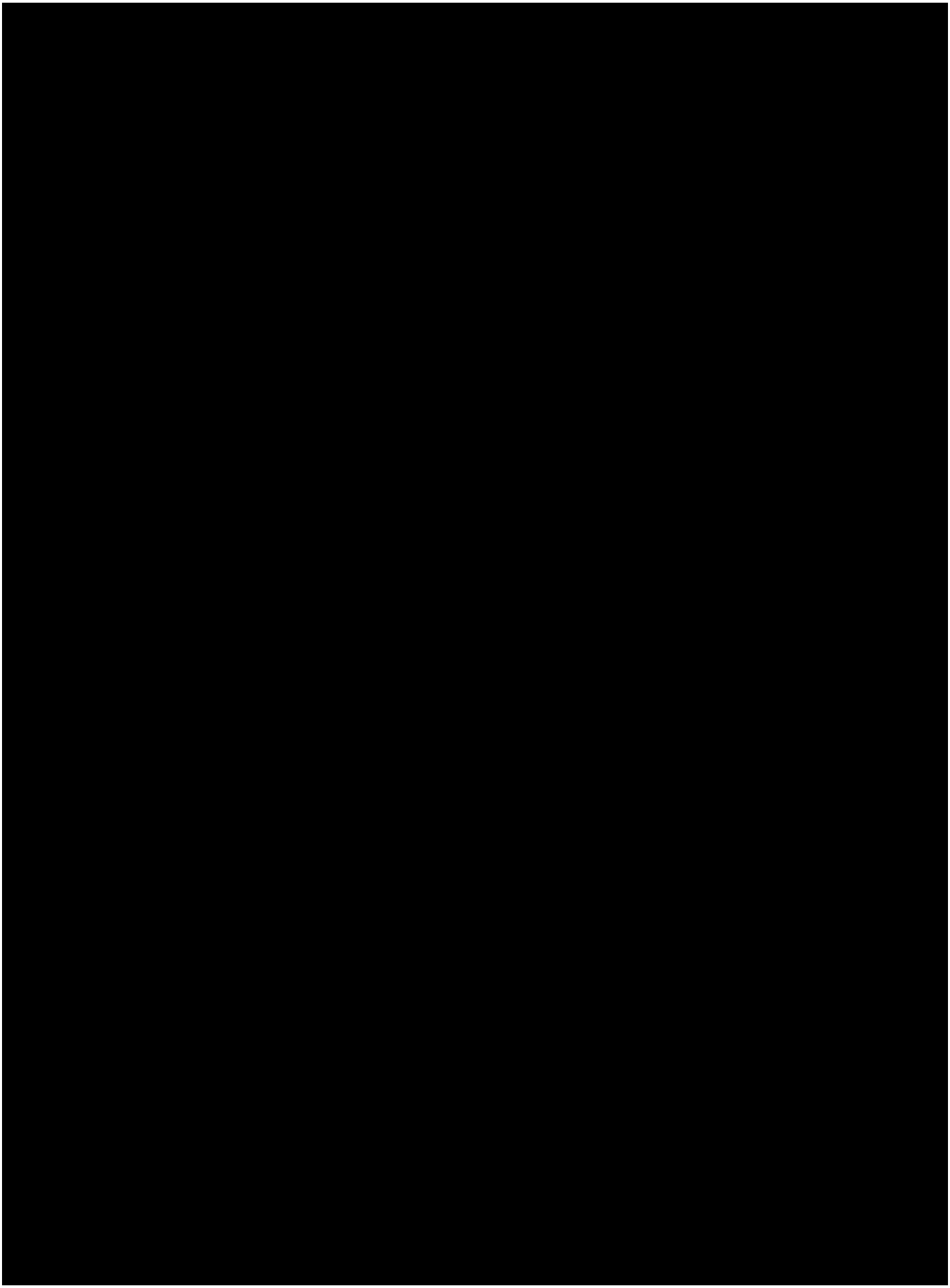


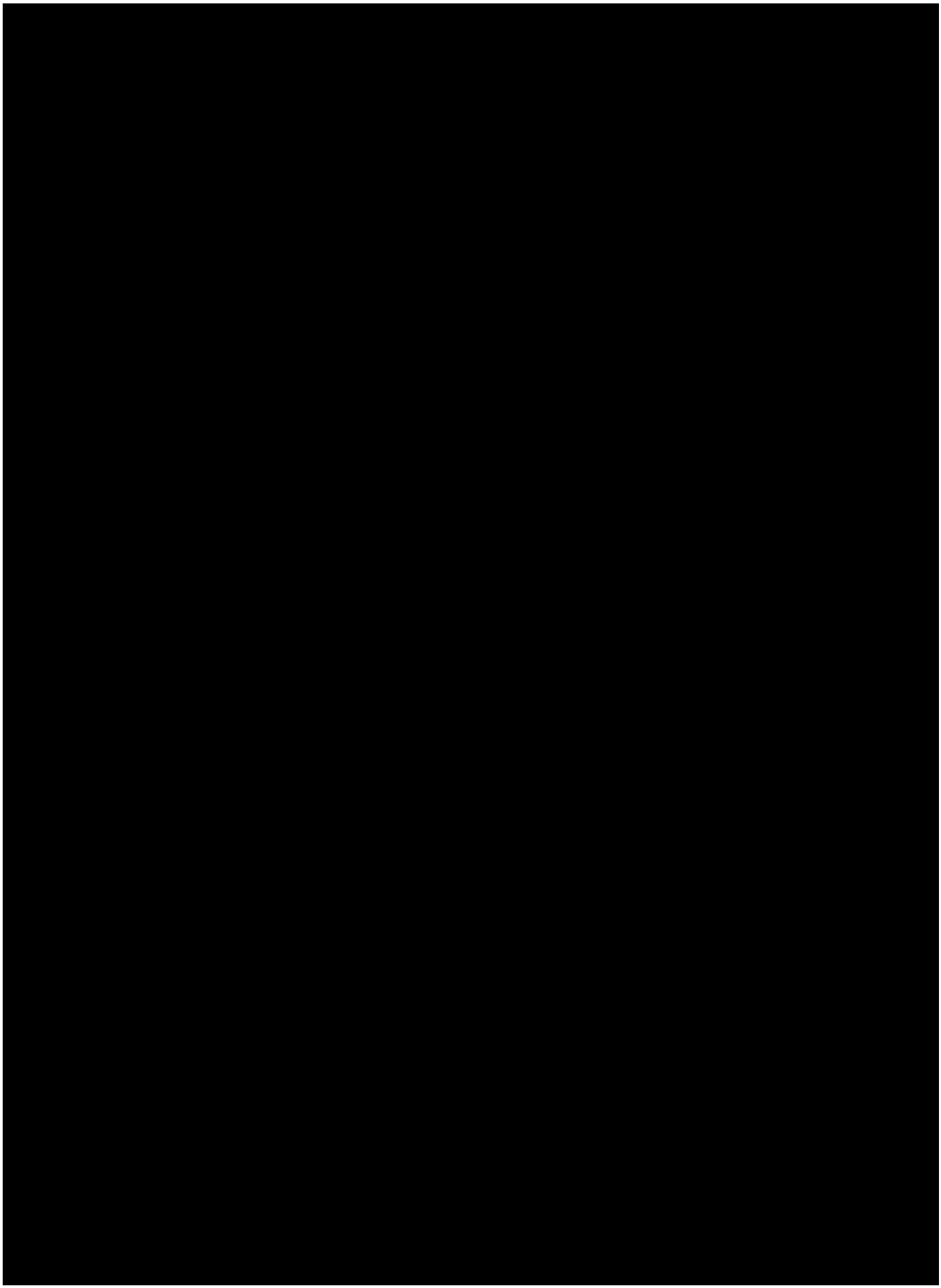


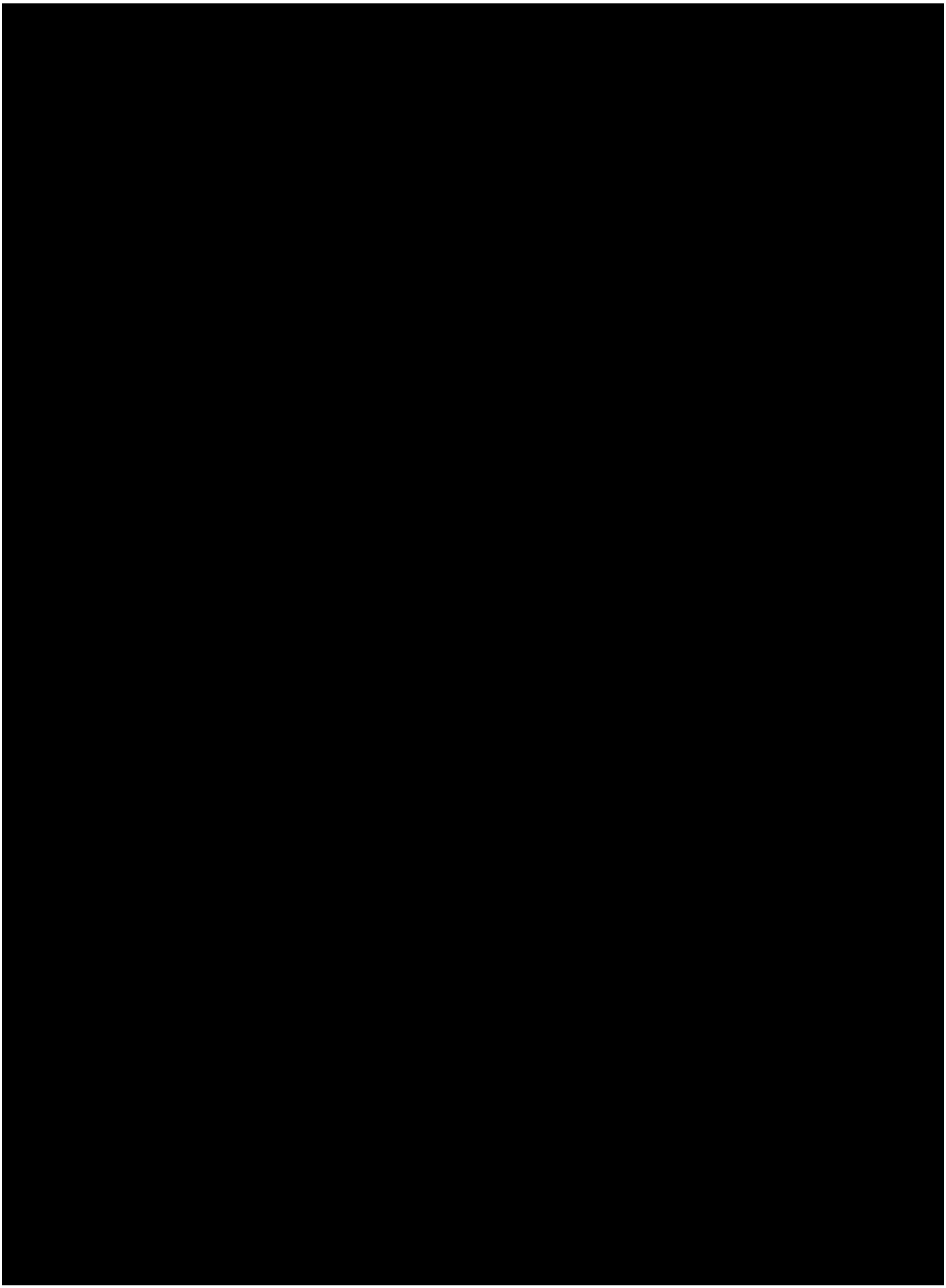


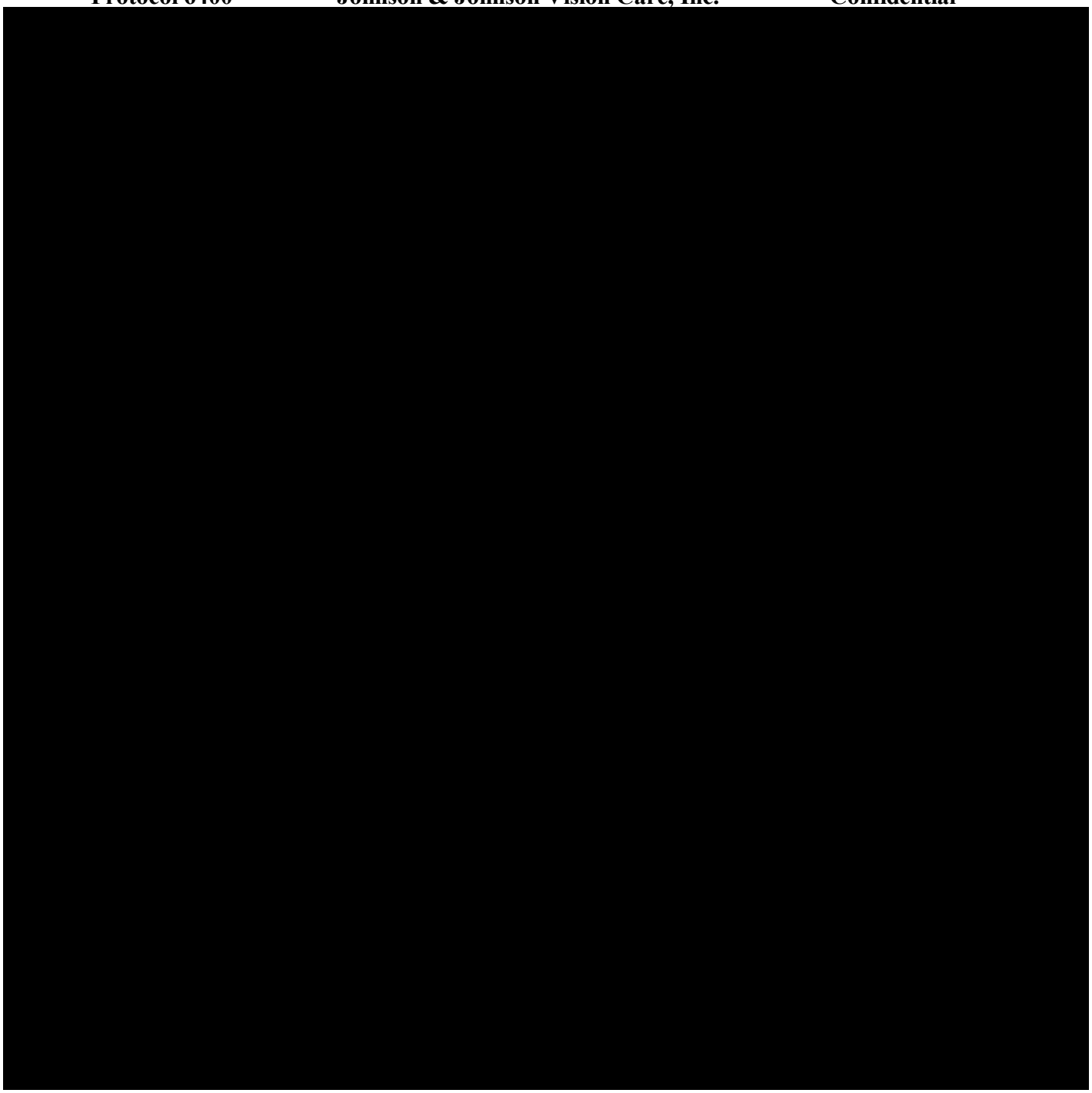


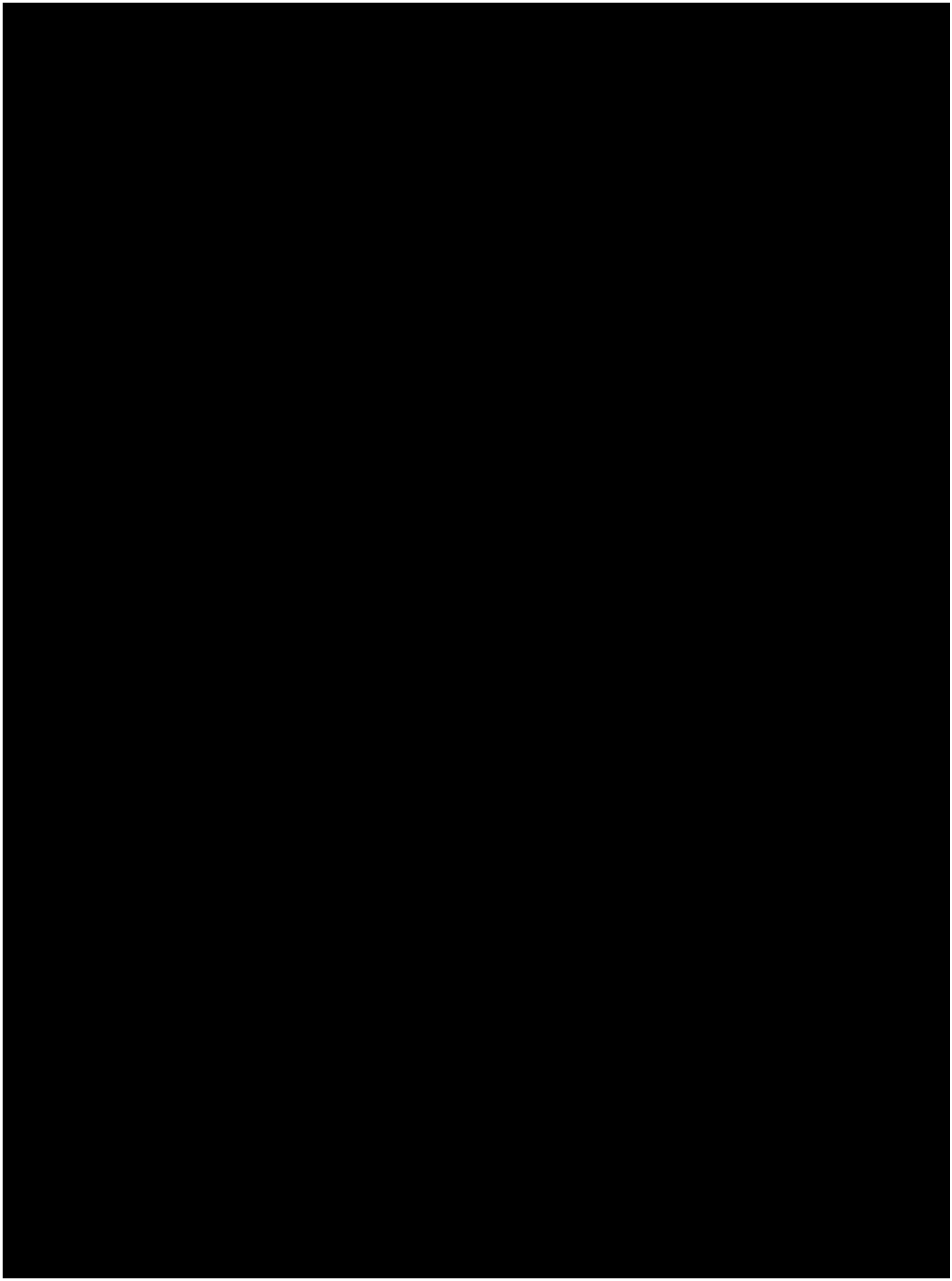












PRO Form Specifications for Forms Used in 6400 Version 1 Final							
Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
COMBOF152	CLUE	V	16.00	V005_2	My vision was very blurry	Agreement	.
COMBOF152	CLUE	V	17.00	V006_1	I was satisfied with my distance vision	Agreement	.
COMBOF152	CLUE	V	18.00	V007_1	I was satisfied with my near vision	Agreement	.
COMBOF152	CLUE	V	19.00	V008_1	I was satisfied with the overall quality of my vision	Agreement	.
COMBOF152	CLUE	V	20.00	V009_1	I experienced fluctuations in the quality of my vision	Agreement	.
COMBOF152	CLUE	V	21.00	V010_1	I was comfortable wearing these lenses while reading a newspaper	Agreement/NA	.
COMBOF152	CLUE	V	22.00	V011_1	My vision deteriorated towards the end of the day	Agreement	.
COMBOF152	CLUE	V	23.00	V013_1	I was satisfied with the quality of my vision in dim lighting	Agreement/NA	.
COMBOF152	CLUE	V	24.00	V014_1	I was satisfied with the quality of my vision at night	Agreement/NA	.
COMBOF152	CLUE	V	25.00	V016_1	I experienced eyestrain when carrying out near activities	Agreement	.
COMBOF152	CLUE	V	26.00	V017_1	I felt the need to squint when looking at distant objects	Agreement	.
COMBOF152	CLUE	V	27.00	V019_1	The clarity of my vision changed throughout the day	Agreement	.
COMBOF152	CLUE	V	28.00	V020_1	My distance vision fluctuated between clear and blurry	Agreement	.
COMBOF152	CLUE	V	29.00	V021_1	My near vision fluctuated between clear and blurry	Agreement	.
COMBOF152	CLUE	V	30.00	V023_1	I noticed a double image around distant objects	Agreement	.
COMBOF152	CLUE	V	31.00	V024_1	I noticed a double image around near objects	Agreement	.
COMBOF152	CLUE	V	32.00	V026_1	I noticed a glare effect (e.g. starburst around a headlight)	Agreement	.
COMBOF152	CLUE	V	33.00	V028_1	I was able to refocus my vision from a distant object to up close	Agreement	.
COMBOF152	CLUE	V	34.00	V028_3	I was able to effortlessly refocus my vision from a distant object to up close	Agreement	.
COMBOF152	CLUE	V	35.00	V031_2	I was able to easily adjust from looking at a near object to far away	Agreement	.
COMBOF152	CLUE	V	36.00	V041_1	I was able to clearly read small print without straining	Agreement/NA	.
COMBOF152	CLUE	V	37.00	V046_1	I was able to clearly view a computer screen	Agreement/NA	.
COMBOF152	CLUE	V	38.00	V054_1	I was able to clearly read car gauges (e.g. speedometer) without straining	Agreement/NA	.
COMBOF152	CLUE	V	39.00	V056_1	My vision was clear enough to allow me to drive at night	Agreement/NA	.

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Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
COMBOF152	CLUE	V	40.00	V096_1	I noticed a halo effect (e.g. rings around lights) during the day	Agreement	.
COMBOF152	CLUE	V	41.00	V097_1	I noticed a halo effect (e.g. rings around lights) in bright light	Agreement	.
COMBOF152	CLUE	V	42.00	V098_1	I noticed a halo effect (e.g. rings around lights) in dim light	Agreement	.
COMBOF152	CLUE	V	43.00	V100_1	I noticed a glare effect during the day	Agreement	.
COMBOF152	CLUE	V	44.00	V101_1	I noticed a glare effect in bright light	Agreement	.
COMBOF152	CLUE	V	45.00	V102_1	I noticed a glare effect in dim light	Agreement	.
COMBOF152	CLUE	H	45.50	H000	The following items will cover your experience Handling these lenses. Please answer all of the items in relation to your experience with the current lenses.		.
COMBOF152	CLUE	H	46.00	H001_1	These lenses were too flexible to be practical	Agreement	.
COMBOF152	CLUE	H	47.00	H014_1	It was easy to insert these lenses	Agreement/NA	.
COMBOF152	CLUE	H	48.00	H015_1	It was easy to determine if these lenses were inside out just by looking	Agreement	.
COMBOF152	CLUE	H	49.00	H018_1	These lenses left my finger and inserted easily into my eye	Agreement	.
COMBOF152	CLUE	H	50.00	H021_1	I had to handle these lenses so much trying to insert them that they got dry	Agreement	.
COMBOF152	CLUE	H	51.00	H022_1	It was easy to pick up these lenses	Agreement/NA	.
COMBOF152	CLUE	H	52.00	H024_1	I was confident these lenses were not inside out when I inserted them	Agreement	.
COMBOF152	CLUE	H	53.00	H025_1	When preparing for insertion, these lenses stood up on my finger	Agreement/NA	.
COMBOF152	CLUE	H	54.00	H027_1	These lenses were too flimsy	Agreement	.
COMBOF152	CLUE	H	55.00	H032_1	It was easy to remove these lenses from my eyes	Agreement	.
COMBOF152	CLUE	H	56.00	H040_1	These lenses seemed too slippery as I tried to remove them from my eyes	Agreement	.

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Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
COMBOF152	MRD	MRD	57.00	P3_0001_p00	Please read the following instructions carefully. .• Your opinion is extremely important to us..• Please complete the following questionnaire based on your experience with the contact lenses you were provided. It is important that your answers be based on your own personal opinion as well as your interpretation of the question. Please do not ask others for direction..• Please make every effort to answer each question to the best of your ability and do not leave any question blank. Please be as honest and sincere as possible. If asked to write in an answer, please be as specific as you can. .• Most questions can be answered by checking the appropriate box. Please pay close attention, though, to any additional instructions relating to individual questions throughout the questionnaire. .• Please note that all your answers will be kept strictly confidential.	INSTRUCT	1
COMBOF152	MRD	MRD	58.00	P3_0002_p00	Thank you for your participation in the study.	INSTRUCT	2
COMBOF152	MRD	MRD	59.00	P3_0003_p00	Considering your experience with the study contact lenses, which statement best describes how you feel about buying these contact lenses, assuming they are offered at an acceptable price?	PurchaseR	3
COMBOF152	MRD	MRD	60.00	P3_0004_p00	Considering your experience with the study contact lenses, which statement best describes your overall opinion of these contact lenses?	ExcellenceR	4
COMBOF152	MRD	MRD	61.00	P3_0006_p00	Please think about your experience with the study contact lenses. Please indicate how you would rate the contact lenses on each of the following characteristics.	INSTRUCT	5
COMBOF152	MRD	MRD	62.00	P3_0006_p01	Overall quality of vision	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	63.00	P3_0006_p04	Clarity of vision during daily activities	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	64.00	P3_0006_p05	Clarity of vision in dim or low lighting conditions	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	65.00	P3_0006_p06	Clarity of vision in bright lighting conditions	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	66.00	P3_0006_p07	Clarity of vision at the end of the day	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	67.00	P3_0006_p08	Clarity of near vision (i.e. looking at things close up, such as reading a book)	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	68.00	P3_0006_p09	Clarity of intermediate vision (i.e. looking at things 2-3 feet away, such as your computer screen)	ExcellenceRNAFirst	5

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Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
COMBOF152	MRD	MRD	69.00	P3_0006_p10	Clarity of distance vision (i.e. looking at things that are more than 5 feet away, such as street signs)	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	70.00	P3_0006_p11	Clarity of vision when reading in bright light	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	71.00	P3_0006_p12	Clarity of vision when reading in dim light (e.g. menu or bill in a restaurant)	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	72.00	P3_0006_p13	Clarity of vision when reading very small print (e.g. medicine bottles)	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	73.00	P3_0006_p14	Clarity of vision when reading your cellphone	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	74.00	P3_0006_p15	Clarity of vision when reading your computer screen	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	75.00	P3_0006_p16	Clarity of vision when driving at night	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	76.00	P3_0006_p17	Clarity of vision when driving during the day	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	77.00	P3_0006_p18	Clarity of vision when watching TV	ExcellenceRNAFirst	5
COMBOF152	MRD	MRD	78.00	P3_0006_p00	Please think about your experience with the study contact lenses. Please indicate how you would rate the contact lenses on each of the following characteristics.	INSTRUCT	6
COMBOF152	MRD	MRD	79.00	P3_0006_p19	Vision not being foggy, cloudy, or filmy	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	80.00	MIS01562	Clarity of peripheral vision	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	81.00	P3_0006_p26	Consistent quality of vision across all distances (near, far, and in-between)	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	82.00	P3_0006_p27	Ease of re-focusing when you look from near to far	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	83.00	P3_0006_p28	Ease of re-focusing when you look from far to near	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	84.00	P3_0006_p29	Ease of judging how far away or close objects are	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	85.00	MIS01563	Uninterrupted vision between and at all distances	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	86.00	P3_0006_p30	Overall comfort	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	87.00	P3_0006_p31	Not stinging or burning your eyes when you first put them in	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	88.00	P3_0006_p32	Comfort immediately when you first put them in	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	89.00	P3_0006_p33	Comfort throughout the day	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	90.00	P3_0006_p34	Comfort each and every day	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	91.00	P3_0006_p36	Comfort at the end of the day	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	92.00	P3_0006_p37	Absence of irritation	ExcellenceRNAFirst	6

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Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
COMBOF152	MRD	MRD	93.00	P3_0006_p46	Keeping your eyes from feeling tired throughout the day	ExcellenceRNAFirst	6
COMBOF152	MRD	MRD	94.00	P3_0006_p00	Please think about your experience with the study contact lenses. Please indicate how you would rate the contact lenses on each of the following characteristics.	INSTRUCT	7
COMBOF152	MRD	MRD	95.00	P3_0006_p43	Feeling fresh and clean everyday	ExcellenceRNAFirst	7
COMBOF152	MRD	MRD	96.00	P3_0006_p44	Feeling clean at the end of each day	ExcellenceRNAFirst	7
COMBOF152	MRD	MRD	97.00	P3_0006_p49	Overall product quality	ExcellenceRNAFirst	7
COMBOF152	MRD	MRD	98.00	P3_0006_p50	Overall ease of handling	ExcellenceRNAFirst	7
COMBOF152	MRD	MRD	99.00	P3_0006_p51	Ease of putting the lenses in your eyes	ExcellenceRNAFirst	7
COMBOF152	MRD	MRD	100.00	P3_0006_p53	Ease of taking the lenses out of your eyes	ExcellenceRNAFirst	7
COMBOF152	MRD	MRD	101.00	P3_0007_p00	Considering everything about the study contact lenses, which of the following phrases best describes how you feel about them? SELECT ONLY ONE	CompareR	8
COMBOF152	MRD	MRD	102.00	P3_0008_p00	Considering everything about the study contact lenses, which of the following phrases best describes how you feel about them in comparison to your current contact lenses, the lenses you wore before the study began? SELECT ONLY ONE	StudyCurrentLensR	9
COMBOF152	MRD	MRD	103.00	P3_0009_p00	How would you describe your awareness of the study contact lenses throughout the day? SELECT ONLY ONE	AwareInEye	10
COMBOF152	MRD	MRD	104.00	P3_0014_p00	In an average day, how many hours did you wear the study contact lenses? ENTER EXACT NUMBER BELOW	HoursPerDay	11
COMBOF152	MRD	MRD	105.00	P3_0015_p00	In an average day, how many hours did you COMFORTABLY wear the study contact lenses? ENTER EXACT NUMBER BELOW	HoursPerDay	12
COMBOF152	MRD	MRD	106.00	P3_0018_p00	Following is a list of words that describe the way contact lenses may feel in your eyes. Please specify how much you agree or disagree with how well these statements describe your experience with the study contact lenses.	INSTRUCT	13
COMBOF152	MRD	MRD	107.00	P3_0018_p06	The study contact lenses feel moist	AgreeDisagreeR	13
COMBOF152	MRD	MRD	108.00	P3_0018_p12	The study contact lenses feel gentle to the eyes	AgreeDisagreeR	13

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Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
COMBOF152	MRD	MRD	109.00	P3_0020_p00	Please describe your vision provided throughout the day by the study contact lenses. SELECT ONE FOR EACH	INSTRUCT	14
COMBOF152	MRD	MRD	110.00	P3_0020_p01	My vision is crisp	AgreeDisagreeR	14
COMBOF152	MRD	MRD	111.00	P3_0020_p02	My vision is clear	AgreeDisagreeR	14
COMBOF152	MRD	MRD	112.00	P3_0020_p03	My vision is comfortable	AgreeDisagreeR	14
COMBOF152	MRD	MRD	113.00	P3_0020_p04	My vision is consistent	AgreeDisagreeR	14
COMBOF152	MRD	MRD	114.00	P3_0020_p05	My vision is dependable	AgreeDisagreeR	14
COMBOF152	MRD	MRD	115.00	P3_0020_p06	My vision is hassle-free	AgreeDisagreeR	14
COMBOF152	MRD	MRD	116.00	P3_0020_p07	My vision is reliable	AgreeDisagreeR	14
COMBOF152	MRD	MRD	117.00	P3_0021_p00	Now that you have worn the study contact lenses, we'd like you to indicate how much you agree or disagree with each of the following statements.	INSTRUCT	15
COMBOF152	MRD	MRD	118.00	P3_0021_p01	They provided crisp vision	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	119.00	P3_0021_p02	They provided clear vision	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	120.00	P3_0021_p03	I would recommend them to others	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	121.00	P3_0021_p04	They allowed me to wear contact lenses longer throughout the day	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	122.00	P3_0021_p05	They were comfortable each and every day I wore them	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	123.00	P3_0021_p06	They felt as natural as my eyes	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	124.00	P3_0021_p07	They maintained my eyes' own natural moisture	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	125.00	P3_0021_p08	They perfectly met the needs of my busy lifestyle	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	126.00	P3_0021_p10	I would recommend them to people who experience dryness with their own contact lenses	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	127.00	P3_0021_p11	They were moist each and every day I wore them	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	128.00	P3_0021_p12	They made me forget that I was wearing contact lenses	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	129.00	P3_0021_p13	They are easy to take care of	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	130.00	P3_0021_p14	They kept my eyes bright and vibrant all day	AgreeDisagreeNAR	15
COMBOF152	MRD	MRD	131.00	P3_0021_p00	Now that you have worn the study contact lenses, we'd like you to indicate how much you agree or disagree with each of the following statements.	INSTRUCT	16
COMBOF152	MRD	MRD	132.00	P3_0021_p15	They made me feel more confident about the long-term health of my eyes	AgreeDisagreeNAR	16

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Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
COMBOF152	MRD	MRD	133.00	P3_0021_p16	They made me feel like I was doing something good for my eyes	AgreeDisagreeNAR	16
COMBOF152	MRD	MRD	134.00	P3_0021_p17	They did not bother my eyes at all throughout the day	AgreeDisagreeNAR	16
COMBOF152	MRD	MRD	135.00	P3_0021_p19	They made my eyes feel healthy	AgreeDisagreeNAR	16
COMBOF152	MRD	MRD	136.00	P3_0021_p20	They allowed me to get the most out of life	AgreeDisagreeNAR	16
COMBOF152	MRD	MRD	137.00	P3_0021_p21	They gave me confidence to do what I wanted, when I wanted	AgreeDisagreeNAR	16
COMBOF152	MRD	MRD	138.00	P3_0021_p28	They kept my eyes looking healthy	AgreeDisagreeNAR	16
COMBOF152	MRD	MRD	139.00	P3_0021_p29	They allowed my eyes to get enough oxygen	AgreeDisagreeNAR	16
COMBOF152	MRD	MRD	140.00	P3_0021_p30	They were perfect for sports and/or exercise	AgreeDisagreeNAR	16
COMBOF152	MRD	MRD	141.00	P3_0021_p32	They allowed me to easily read things with poor contrast, such as black lettering on a dark background	AgreeDisagreeNAR	16
COMBOF152	MRD	MRD	142.00	P3_0021_p00	Now that you have worn the study contact lenses, we'd like you to indicate how much you agree or disagree with each of the following statements.	INSTRUCT	17
COMBOF152	MRD	MRD	143.00	P3_0021_p33	They allowed me to recognize people from across the room	AgreeDisagreeNAR	17
COMBOF152	MRD	MRD	144.00	P3_0021_p34	They allowed me to read traffic signs, street signs or store signs	AgreeDisagreeNAR	17
COMBOF152	MRD	MRD	145.00	P3_0021_p35	They allowed me to see steps, stairs or curbs	AgreeDisagreeNAR	17
COMBOF152	MRD	MRD	146.00	MIS01564	They allow me to feel more productive	AgreeDisagreeNAR	17
COMBOF152	MRD	MRD	147.00	MIS01565	They allow me to return to activities I could do when I was younger but have struggled with lately	AgreeDisagreeNAR	17
COMBOF152	MRD	MRD	148.00	MIS01566	They allow me to work longer on the computer without feeling the need to give my eyes a break	AgreeDisagreeNAR	17
COMBOF152	MRD	MRD	149.00	MIS01567	They allow me to read for longer without feeling the need to give my eyes a break	AgreeDisagreeNAR	17
COMBOF152	MRD	MRD	150.00	MIS01568	I feel years younger wearing these contact lenses	AgreeDisagreeNAR	17
COMBOF152	MRD	MRD	151.00	MIS01569	I feel healthier wearing these contact lenses	AgreeDisagreeNAR	17
COMBOF152	MRD	MRD	152.00	MIS01570	I feel happier wearing these contact lenses	AgreeDisagreeNAR	17
COMBOF152	MRD	MRD	153.00	MIS01571	I am more likely to return to my eye doctor for future check-ups if they prescribed me this contact lens	AgreeDisagreeNAR	17

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Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
COMBOF152	MRD	MRD	154.00	P3_0022_p00	Please indicate how often, if ever, you experienced the following visual issues when you wore the study contact lenses.	INSTRUCT	18
COMBOF152	MRD	MRD	155.00	P3_0022_p01	Blurred vision at close distances (such as reading a book)	FrequencyDKR	18
COMBOF152	MRD	MRD	156.00	P3_0022_p02	Blurred vision at far distances (such as looking at street signs)	FrequencyDKR	18
COMBOF152	MRD	MRD	157.00	P3_0022_p03	Haze/Cloudiness	FrequencyDKR	18
COMBOF152	MRD	MRD	158.00	P3_0022_p05	Eye strain	FrequencyDKR	18
COMBOF152	MRD	MRD	159.00	P3_0022_p09	Fluctuating vision (vision going in and out of focus)	FrequencyDKR	18
COMBOF152	MRD	MRD	160.00	P3_0023_p00	Please indicate how often, if ever, you experienced the following sensations when you wore the study contact lenses.	INSTRUCT	19
COMBOF152	MRD	MRD	161.00	P3_0023_p05	Irritation	FrequencyDKR	19
COMBOF152	MRD	MRD	162.00	P3_0023_p06	Redness	FrequencyDKR	19
COMBOF152	MRD	MRD	163.00	P3_0023_p07	Stinging	FrequencyDKR	19
COMBOF152	MRD	MRD	164.00	P3_0023_p08	Tiredness	FrequencyDKR	19
COMBOF152	MRD	MRD	165.00	P3_0021_p00	Now that you have worn the study contact lenses, we'd like you to indicate how much you agree or disagree with each of the following statements.	INSTRUCT	20
COMBOF152	MRD	MRD	166.00	MIS01992	I am just as satisfied with my vision in these contact lenses as I am with my vision in my glasses.	Agreement	20
COMBOF152	MRD	MRD	167.00	MIS01993	I am more comfortable with my vision in these contact lenses than with my vision in my glasses.	Agreement	20
COMBOF152	MRD	MRD	168.00	MIS01994	I would prefer a vision correction solution that included these contact lenses and my glasses over my prior contact lenses and glasses.	Agreement	20
COMBOF152	MRD	MRD	169.00	MIS01995	I would happily purchase these contact lenses in addition to glasses as an option in the future.	Agreement	20
COMBOF152	MRD	MRD	170.00	MIS01996	I would be more likely to recommend an eye doctor who prescribed these contact lenses to me.	Agreement	20
COMBOF152	MRD	MRD	171.00	MIS01997	I am satisfied with a vision solution that allows me to wear contact lenses 80% of the time, and add glasses as needed.	Agreement	20
COMBOF152	MRD	MRD	172.00	MIS01998	I was able to successfully complete at least 80% of the visual tasks I needed to do with these contact lenses.	Agreement	20

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Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
COMBOF152	MRD	MRD	173.00	P3_0029_p00	If your eye doctor prescribed the study contact lenses to you, please indicate how, if at all, your opinion of your eye doctor would change. SELECT ONLY ONE	ECPOpinionR	21
COMBOF152	MRD	MRD	174.00	MIS01999	Provided that your doctor recommends the study contact lenses, how likely would you be to buy these contact lenses at $97 for a 3-month supply? SELECT ONLY ONE	PurchaseR	22
COMBOF152	MRD	MRD	175.00	MIS02000	Considering the price of $97 for a 3-month supply of the study contact lenses, which statement best describes how you feel about the value of the study contact lenses? SELECT ONLY ONE	ValueR	23
COMBOF152	MRD	MRD	176.00	P3_0032_p00	PLEASE LET THE INVESTIGATOR OR A STAFF MEMBER KNOW WHEN YOU ARE FINISHED WITH THIS QUESTIONNAIRE.	INSTRUCT	24

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Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
MRDD89	MRD	MRD	1.00	P3_0001_p00	Please read the following instructions carefully. .• Your opinion is extremely important to us..• Please complete the following questionnaire based on your experience with the contact lenses you were provided. It is important that your answers be based on your own personal opinion as well as your interpretation of the question. Please do not ask others for direction..• Please make every effort to answer each question to the best of your ability and do not leave any question blank. Please be as honest and sincere as possible. If asked to write in an answer, please be as specific as you can. .• Most questions can be answered by checking the appropriate box. Please pay close attention, though, to any additional instructions relating to individual questions throughout the questionnaire. .• Please note that all your answers will be kept strictly confidential.	INSTRUCT	1
MRDD89	MRD	MRD	2.00	P3_0002_p00	Thank you for your participation in the study.	INSTRUCT	2
MRDD89	MRD	MRD	3.00	P3_0004_p00	Considering your experience with the study contact lenses, which statement best describes your overall opinion of these contact lenses?	ExcellenceR	3
MRDD89	MRD	MRD	4.00	P3_0006_p00	Please think about your experience with the study contact lenses. Please indicate how you would rate the contact lenses on each of the following characteristics.	INSTRUCT	4
MRDD89	MRD	MRD	5.00	P3_0006_p01	Overall quality of vision	ExcellenceRNAFirst	4
MRDD89	MRD	MRD	6.00	P3_0006_p08	Clarity of near vision (i.e. looking at things close up, such as reading a book)	ExcellenceRNAFirst	4
MRDD89	MRD	MRD	7.00	P3_0006_p09	Clarity of intermediate vision (i.e. looking at things 2-3 feet away, such as your computer screen)	ExcellenceRNAFirst	4
MRDD89	MRD	MRD	8.00	P3_0006_p10	Clarity of distance vision (i.e. looking at things that are more than 5 feet away, such as street signs)	ExcellenceRNAFirst	4
MRDD89	MRD	MRD	9.00	P3_0006_p30	Overall comfort	ExcellenceRNAFirst	4
MRDD89	MRD	MRD	10.00	P3_0006_p31	Not stinging or burning your eyes when you first put them in	ExcellenceRNAFirst	4
MRDD89	MRD	MRD	11.00	P3_0006_p32	Comfort immediately when you first put them in	ExcellenceRNAFirst	4
MRDD89	MRD	MRD	12.00	P3_0006_p37	Absence of irritation	ExcellenceRNAFirst	4
MRDD89	MRD	MRD	13.00	P3_0006_p51	Ease of putting the lenses in your eyes	ExcellenceRNAFirst	4

PRO Form Specifications for Forms Used in 6400 Version 1 Final							
Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
MRDD89	MRD	MRD	14.00	P3_0018_p00	Following is a list of words that describe the way contact lenses may feel in your eyes. Please specify how much you agree or disagree with how well these statements describe your experience with the study contact lenses.	INSTRUCT	5
MRDD89	MRD	MRD	15.00	P3_0018_p06	The study contact lenses feel moist	AgreeDisagreeR	5
MRDD89	MRD	MRD	16.00	P3_0018_p12	The study contact lenses feel gentle to the eyes	AgreeDisagreeR	5
MRDD89	MRD	MRD	17.00	P3_0032_p00	PLEASE LET THE INVESTIGATOR OR A STAFF MEMBER KNOW WHEN YOU ARE FINISHED WITH THIS QUESTIONNAIRE.	INSTRUCT	6

PRO Form Specifications for Forms Used in 6400 Version 1 Final							
Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
PROJ50	PROJ	PROJ	1.00	CLDEQ2_1	During a typical day since your last visit, how often did your eyes feel discomfort while wearing your contact lenses?	CLDEQFreq	.
PROJ50	PROJ	PROJ	2.00	CLDEQ3	When your eyes felt discomfort with your contact lenses, how intense was this feeling of discomfort at the end of your wearing time?	CLDEQInt	.
PROJ50	PROJ	PROJ	3.00	CLDEQ5_1	During a typical day since your last visit, how often did your eyes feel dry?	CLDEQFreq	.
PROJ50	PROJ	PROJ	4.00	CLDEQ6	When your eyes felt dry, how intense was this feeling of dryness at the end of your wearing time?	CLDEQInt	.
PROJ50	PROJ	PROJ	5.00	CLDEQ8_1	During a typical day since your last visit, how often did your vision change between clear and blurry or foggy while wearing your contact lenses?	CLDEQFreq	.
PROJ50	PROJ	PROJ	6.00	CLDEQ9	When your vision was blurry, how noticeable was the changeable, blurry, or foggy vision at the end of your wearing time?	CLDEQInt	.
PROJ50	PROJ	PROJ	7.00	CLDEQ10_1	Question about CLOSING YOUR EYES: During a typical day since your last visit, how often did your eyes bother you so much that you wanted to close them?	CLDEQFreq	.
PROJ50	PROJ	PROJ	8.00	CLDEQ11_1	Question about REMOVING YOUR LENSES: How often since your last visit, did your eyes bother you so much while wearing your contact lenses that you felt as if you needed to stop whatever you were doing and take out your contact lenses?	CLDEQFreqRem	.

PRO Form Specifications for Forms Used in 6400 Version 1 Final							
Form (QSSCAT)	Type (QSCAT)	PRO Domain	PRO Sequence	Item ID# (QSTESTCD)	Item Wording	Response Set	Page Number
PROJ85	PROJ	PROJ	1.00	CLDEQ2	During a typical day in the past 2 weeks, how often did your eyes feel discomfort while wearing your contact lenses?	CLDEQFreq	.
PROJ85	PROJ	PROJ	2.00	CLDEQ3	When your eyes felt discomfort with your contact lenses, how intense was this feeling of discomfort at the end of your wearing time?	CLDEQInt	.
PROJ85	PROJ	PROJ	3.00	CLDEQ5	During a typical day in the past 2 weeks, how often did your eyes feel dry?	CLDEQFreq	.
PROJ85	PROJ	PROJ	4.00	CLDEQ6	When your eyes felt dry, how intense was this feeling of dryness at the end of your wearing time?	CLDEQInt	.
PROJ85	PROJ	PROJ	5.00	CLDEQ8	During a typical day in the past 2 weeks, how often did your vision change between clear and blurry or foggy while wearing your contact lenses?	CLDEQFreq	.
PROJ85	PROJ	PROJ	6.00	CLDEQ9	When your vision was blurry, how noticeable was the changeable, blurry, or foggy vision at the end of your wearing time?	CLDEQInt	.
PROJ85	PROJ	PROJ	7.00	CLDEQ10	Question about CLOSING YOUR EYES: During a typical day in the past 2 weeks, how often did your eyes bother you so much that you wanted to close them?	CLDEQFreq	.
PROJ85	PROJ	PROJ	8.00	CLDEQ11	Question about REMOVING YOUR LENSES: How often during the past 2 weeks, did your eyes bother you so much while wearing your contact lenses that you felt as if you needed to stop whatever you were doing and take out your contact lenses?	CLDEQFreqRem	.

PRO Response Option Specifications for Forms Used in 6400 Version 1 Final				
Type (QSCAT)	**Response Set**	**Selections**	**Raw Coding**	**Text Displayed**
CLUE	Agreement	Single	1	Strongly Disagree
			2	Disagree
			3	Neither Agree Nor Disagree
			4	Agree
			5	Strongly Agree
	Agreement/NA	Single	0	Not Applicable
			1	Strongly Disagree
			2	Disagree
			3	Neither Agree Nor Disagree
			4	Agree
			5	Strongly Agree
MRD	AgreeDisagreeNAR	Single	0	Not Applicable
			1	Agree Strongly
			2	Agree Somewhat
			3	Neither Agree nor Disagree
			4	Disagree Somewhat
			5	Disagree Strongly
	AgreeDisagreeR	Single	1	Agree Strongly
			2	Agree Somewhat
			3	Neither Agree Nor Disagree
			4	Disagree Somewhat
			5	Disagree Strongly
	Agreement	Single	1	Strongly Disagree
			2	Disagree
			3	Neither Agree nor Disagree
			4	Agree
			5	Strongly Agree
	AwareInEye	Single	1	I am not aware of them being in my eyes
			2	I am barely aware of them being in my eyes
			3	I am slightly aware of them being in my eyes
			4	I am moderately aware of them being in my eyes
			5	I am very aware of them being in my eyes

PRO Response Option Specifications for Forms Used in 6400 Version 1 Final				
Type (QSCAT)	Response Set	Selections	Raw Coding	Text Displayed
	CompareR	Single	1	The best contact lenses I have ever used or tried
			2	Somewhat better than other contact lenses I have used or tried
			3	About the same as other contact lenses I have used or tried
			4	Somewhat worse than other contact lenses I have used or tried
			5	The worst contact lenses I have ever used or tried
	DAYSPERWK	Single	1	7 days/week
			2	5-6 days/week
			3	3-4 days/week
			4	1-2 days/week
			5	Less often than 1 day/week
	DrynessR	Single	1	Normal
			2	Slightly dry
			3	Dry
			4	Very dry
	ECPOpinionR	Single	1	Much more favorable opinion
			2	Somewhat more favorable opinion
			3	Same opinion
			4	Somewhat less favorable opinion
			5	Much less favorable opinion
	ExcellenceR	Single	1	Excellent
			2	Very Good
			3	Good
			4	Fair
			5	Poor
	ExcellenceRNAFirst	Single	0	Not Applicable
			1	Excellent
			2	Very Good
			3	Good
			4	Fair
			5	Poor
	EyeCondition	Single	1	Healthy, I never have problems with my eyes

PRO Response Option Specifications for Forms Used in 6400 Version 1 Final				
Type (QSCAT)	Response Set	Selections	Raw Coding	Text Displayed
			2	Healthy, but I occasionally have problems with my eyes
			3	I frequently have problems with my eyes
			4	I always have problems with my eyes
	FrequencyDKR	Single	1	Always
			2	Frequently
			3	Occasionally
			4	Rarely
			5	Never
			6	Don't Know
	HoursPerDay	Single	1	hours per day
	INSTRUCT	Single	.	
	Length	Single	1	Less than 1 month
			2	1 month or more but less than 3 months
			3	3 months or more but less than 6 months
			4	6 months or more but less than 1 year
			5	1 year or more but less than 2 years
			6	2 years or more but less than 5 years
			7	5 years or more but less than 10 years
			8	10 years or more
	OpenText	Single	.	
	OptomRel	Single	1	Studying to be an optometrist, ophthalmologist or optician
			2	Work for optometrist, ophthalmologist or optician
			3	Optometrist, ophthalmologist or optician
			4	Employee / Subcontractor for Vistakon
			5	Relative of an employee/subcontractor for Vistakon
			6	Friend of an employee/subcontractor for Vistakon
			7	None of the above
	PresbyVC	Single	1	Non-prescription reading glasses
			2	Prescription reading glasses

PRO Response Option Specifications for Forms Used in 6400 Version 1 Final				
Type (QSCAT)	Response Set	Selections	Raw Coding	Text Displayed
			3	Bifocal/tri-focal glasses
			4	Glasses with progressive lenses (no line bifocals)
			5	Regular contact lenses
			6	Contact lenses for monovision (one lens corrects for up close vision and the other for distance vision)
			7	Soft bifocal/multifocal contact lenses
			8	Other
	PurchaseR	Single	1	Definitely would buy them
			2	Probably would buy them
			3	Might or might not buy them
			4	Probably would not buy them
			5	Definitely would not buy them
	SensitivityR	Single	1	Normal
			2	Slightly sensitive
			3	Sensitive
			4	Very sensitive
	StudyCurrentLensR	Single	1	Much better than my current contact lenses
			2	Somewhat better than my current contact lenses
			3	About the same as my current contact lenses
			4	Somewhat worse than my current contact lenses
			5	Much worse than my current contact lenses
	StudyPar	Single	1	Less than 1 week ago
			2	Between 1 and 2 weeks ago
			3	Between 2 weeks and 1 month ago
			4	Between 1 and 3 months ago
			5	Between 3 and 6 months ago
			6	Over 6 months ago
			7	Never
	ValueR	Single	1	Extremely good value
			2	Very good value
			3	Fairly good value

PRO Response Option Specifications for Forms Used in 6400 Version 1 Final				
Type (QSCAT)	Response Set	Selections	Raw Coding	Text Displayed
			4	Somewhat poor value
			5	Very poor value
	Work	Single	1	At a desk or in an office
			2	In a factory or a production line
			3	Service industry or restaurant
			4	Outside work, for example, landscaping, construction
			5	Homemaker
			6	Other
			7	Retired
			8	Full-time student
			9	Prefer not to answer
	YesNo	Single	1	Yes
			2	No
PROJ	CLDEQFreq	Single	0	Never
			1	Rarely
			2	Sometimes
			3	Frequently
			4	Constantly
	CLDEQFreqRem	Single	1	Never
			2	Less than once a week
			3	Weekly
			4	Several times a week
			5	Daily
			6	Several times a day
	CLDEQInt	Single	0	0 - Never have it
			1	1 - Not at All Intense
			2	2
			3	3
			4	4
			5	5 - Very Intense

APPENDIX B: PATIENT INSTRUCTION GUIDE

To be provided separately.

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

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

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

TORIC FITTING GUIDELINES

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

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

A. How to Determine Lens Cylinder and Axis Orientation

1. Locate the Orientation Marks

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

Figure 1

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

2. Observe Lens Rotation and Stability

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

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

Assessing Rotation

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

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

B. How to Determine the Final Lens Power

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the patient's refractive axis, it is not advisable to over-refract because of the difficulty in computing the resultant power. In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible. So, here is how to determine the final lens power.

For the Sphere:

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

For the Cylinder:

Adjust the axis by the drift angle using LARS. Choose a cylinder that is ≤ 0.25D from the refractive cylinder.

Case Examples:

Example 1
Manifest (spectacle) refraction:
O.D. –2.50 -1.25 x 180 20/20
O.S. –2.00 -1.00 x 180 20/20
Choose a diagnostic lens for each eye with an axis as close to 180° as possible. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens. If the lens has not yet stabilized, recheck until stable.

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

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

Example 2
Manifest (spectacle) refraction:
O.D. –3.00 -1.00 x 90 20/20
O.S. –4.75 -2.00 x 90 20/20

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

The fitting indicates the following:

Right Eye:
Compensate the 10° axis drift by adding it to the manifest refraction axis.
Here is the Rx prescribed:
O.D. –3.00 –0.75 x 100
Left Eye
The lens on the left eye shows good centration, movement and a consistent tendency for the mark to drift right by 10° from the 6 o'clock position following a forced blink. Since the manifest refraction called for a power of –4.75D, adjust for the vertex distance and reduce the sphere by 0.25D and prescribe the –1.75D cylinder. Compensate for the 10° axis drift by subtracting it from the manifest refraction.

Here is the Rx Prescribed:

O.S. –4.50 –1.75 x 80

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

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

MULTIFOCAL FITTING GUIDELINES

A. Presbyopic Needs Assessment & Patient Education

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

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

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

These lenses are available in the following ADD powers:

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

B. Fitting Instructions

1. Determine the following:

- Eye dominance (the methods described in MONOVISION FITTING GUIDELINES may be used)
- Spherical equivalent distance prescription (vertex corrected if necessary and rounded to less minus if between powers)
- Near ADD

2. Select the initial trial lens as follows:

- For each eye select the trial lens distance power that is closest to the patient's distance spherical equivalent.
- Select the near power of the lens based on the patient's ADD range as follows:

  ADD: +0.75 to +1.25 use a "LOW" near ADD lens on each eye

  ADD: +1.50 to +1.75 use a "MID" near ADD lens on each eye

  ADD: +2.00 to +2.50 use a "HGH" near ADD lens on each eye

3. Allow the lens to settle for a minimum 10 minutes.

4. Assess distance and near vision binocularly and monocularly.

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

C. Multifocal Troubleshooting

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

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

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

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

MONOVISION FITTING GUIDELINES

A. Patient Selection

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

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

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

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

B. Eye Selection

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

1. Ocular Preference Determination Methods

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

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

Other methods include the refractive error method and the visual demands method.

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

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

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

C. Special Fitting Characteristics

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

Example: A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without a lens. A presbyopic patient requiring a +1.50D ADD who is –2.50D myopic in the right eye and –1.50D myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

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

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

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

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

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

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

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

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

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

D. Other Suggestions

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

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

Monovision fitting success can be improved by the following suggestions:

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

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

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

PATIENT MANAGEMENT

Dispensing Visit

- PROVIDE THE PATIENT WITH A COPY OF THE PATIENT INSTRUCTION GUIDE FOR THESE LENSES. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE (DISPOSABLE OR FREQUENT REPLACEMENT).
- Recommend an appropriate cleaning and disinfecting system and provide the patient with instructions regarding proper lens care. Chemical or hydrogen peroxide disinfection is recommended.
- Schedule a follow-up examination.

Follow-up Examinations

- Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule, lens replacement schedule, and proper lens care and handling procedures.
- Recommended Follow-up Examination Schedule (complications and specific problems should be managed on an individual patient basis):

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

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

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

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

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

WEARING SCHEDULE

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

For Daily Wear:

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

The maximum suggested wearing time for these lenses is:

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

For Extended Wear:

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

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

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

REPLACEMENT SCHEDULE

For Lenses Prescribed for Frequent Replacement:

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

For Lenses Prescribed for Disposable Wear:

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

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

LENS CARE DIRECTIONS

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

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

For Lenses Prescribed for Frequent Replacement Wear:

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

For Lenses Prescribed for Disposable Wear:

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

Care for a Dried Out (Dehydrated) Lens

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

Care for Sticking (Non-Moving) Lenses

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

EMERGENCIES

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

HOW SUPPLIED

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

- **ACUVUE OASYS®:** base curve, power, diameter, lot number, and expiration date
- **ACUVUE OASYS® for ASTIGMATISM:** base curve, power, diameter, cylinder, axis, lot number, and expiration date
- **ACUVUE OASYS® for PRESBYOPIA:** base curve, power, diameter, ADD, lot number, and expiration date

REPORTING OF ADVERSE REACTIONS

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

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

20400606

In Canada: Johnson & Johnson Vision Care, division of Johnson & Johnson, Inc.
In USA: Johnson & Johnson Vision Care, Inc.
Printed in USA
Revision date: 06/15
Revision number: AO-06-15-01

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

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

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

ACUVUE®
OASYS
BRAND CONTACT LENSES

ACUVUE OASYS® Brand Contact Lenses
ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM
ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA

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

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

SYMBOLS KEY

The following symbols may appear on the label or carton:

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

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

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

Instructions for Use

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

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

WARNING:

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

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

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

- **Rub and Rinse Time**

Instructions for Use

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

WARNING:

– Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections.

– Never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss, or blindness.

- **Lens Case Care**

Instructions for Use

– Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.

– Replace the lens case according to the directions provided by the Eye Care Professional or the manufacturer's labeling that accompanies the case.

– Contact lens cases can be a source of bacterial growth.

WARNING:

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

DESCRIPTION

The ACUVUE OASYS® Brand Contact Lenses, the ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM, and the ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA are soft (hydrophilic) contact lenses available as spherical, toric, or multifocal lenses and include HYDRACLEAR® PLUS Technology. The lenses are made of a silicone hydrogel material containing an internal wetting agent with visibility tinted UV absorbing monomer.

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

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

Lens Properties:

• Specific Gravity (calculated):	0.98 – 1.12
• Refractive Index:	1.42
• Light Transmittance:	85% minimum
• Surface Character:	Hydrophilic
• Water Content:	38%
• Oxygen Permeability:	
VALUE	**METHOD**
103 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) @ 35°C	Fatt (boundary corrected, edge corrected)
122 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) @ 35°C	Fatt (boundary corrected, non-edge corrected)

Lens Parameters:

• Diameter Range:	12.0 mm to 15.0 mm
• Center Thickness:	varies with power
• Base Curve Range:	7.85 mm to 10.00 mm
• Spherical Power Range:	Daily Wear: -20.00D to +20.00D Extended Wear: -20.00D to +14.00D
• Multifocal ADD Power Range:	+0.25D to +4.00D
• Cylinder Power Range:	-0.25D to -10.00D
• Axis Range:	2.5° to 180°

PRECAUTIONS

Special Precautions for Eye Care Professionals:

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

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

- Patients who wear these lenses to correct presbyopia using monovision may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.

- Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.

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

Handling Precautions:

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

Lens Wearing Precautions:

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

Lens Care Precautions:

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

Other Topics to Discuss with Patients:

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

Who Should Know That the Patient is Wearing Contact Lenses?

- Patients should inform all doctors (Health Care Professionals) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require [redacted] nt or may require that the patient not wear c [redacted]

AVAILABLE LENS PARAMETERS

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

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

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

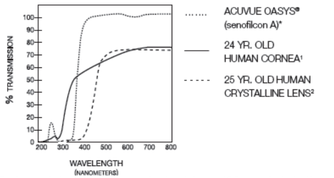
Diameter:	14.5 mm
Center Thickness:	Minus Lens - varies with power (e.g. -4.00D: 0.080 mm) Plus Lens - varies with power (e.g. +4.00D: 0.172 mm)
Base Curve:	8.6 mm
Powers:	plano to -6.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments) +0.25D to +6.00D (in 0.25D increments) Cylinder: -0.75D,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

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

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

TRANSMITTANCE CURVE

ACUVUE OASYS® Brand Contact Lenses vs. 24 yr. old human cornea vs. 25 yr. old human crystalline lens



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

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

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

ACTIONS

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

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

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

However, clinical studies have not been done to demonstrate that wearing UV-Blocking contact lenses reduces the risk of developing cataracts or other eye disorders. The Eye Care Professional should be consulted for more information.

INDICATIONS (USES)

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

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

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

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

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

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

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

- For corneal protection in lid and corneal abnormalities such as entropion, trichiasis, tarsal scars, and recurrent corneal erosion. In addition, they are indicated for protection where sutures or ocular structure malformation, degeneration or paralysis may result in the need to protect the cornea from exposure or repeated irritation.
- For corneal pain relief in conditions such as bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, and post-keratoplasty.
- For use as a barrier during the healing process of epithelial defects such as chronic epithelial defects, corneal ulcer, neurotrophic and neuroparalytic keratitis, and chemical burns.
- For post surgical conditions where bandage lens use is indicated such as post refractive surgery, lamellar grafts, corneal flaps, and additional ocular surgical conditions.
- For structural stability and protection in piggy back lens fitting where the cornea and associated surfaces are too irregular to allow for corneal rigid gas permeable (RGP) lenses to be fit. In addition, the use of the lens can prevent irritation and abrasions in conditions where there are elevation differences in the host/graph junction or scar tissue.

Lenses prescribed for therapeutic use may be worn for daily or extended wearing periods.

CONTRAINDICATIONS (REASONS NOT TO USE)

When prescribing contact lens wear for REFRACTIVE AMETROPIA USE, DO NOT USE these lenses when any of the following conditions exist:

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

For THERAPEUTIC USE, the Eye Care Professional may prescribe these lenses to aid in the healing process of certain ocular conditions, which may include those cited above.

WARNINGS

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

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

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

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

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

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

Specific Instructions for Use and Warnings:

- **Water Activity**

Instructions for Use

Do not expose contact lenses to water while wearing them.

WARNING:

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

- **Soaking and Storing Your Lenses**

Instructions for Use

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

WARNING:

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

ADVERSE REACTIONS

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

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.
- The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:
  - How do the lenses feel on my eyes?
  - How do my eyes look?
  - Have I noticed a change in my vision?

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

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

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

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

GENERAL FITTING GUIDELINES

A. Patient Selection:

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

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

Patients who do not meet the above criteria should not be provided with contact lenses.

B. Pre-fitting Examination:

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription (including determining the preferred reading distance for presbyopes), keratometry and biomicroscopic evaluation.

Based on this evaluation, if it is determined that the patient is eligible to wear these lenses, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

C. Initial Power Determination

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

D. Base Curve Selection (Trial Lens Fitting)

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

- **ACUVUE OASYS®:** 8.4 mm/14.0 mm
- **ACUVUE OASYS® for ASTIGMATISM:** 8.6 mm/14.5 mm
- **ACUVUE OASYS® for PRESBYOPIA:** 8.4 mm/14.3 mm

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

1. Criteria of a Properly Fit Lens

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

2. Criteria of a Flat Fitting Lens

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

3. Criteria of a Steep Fitting Lens

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

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

E. Final Lens Power (Spherical)

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

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

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

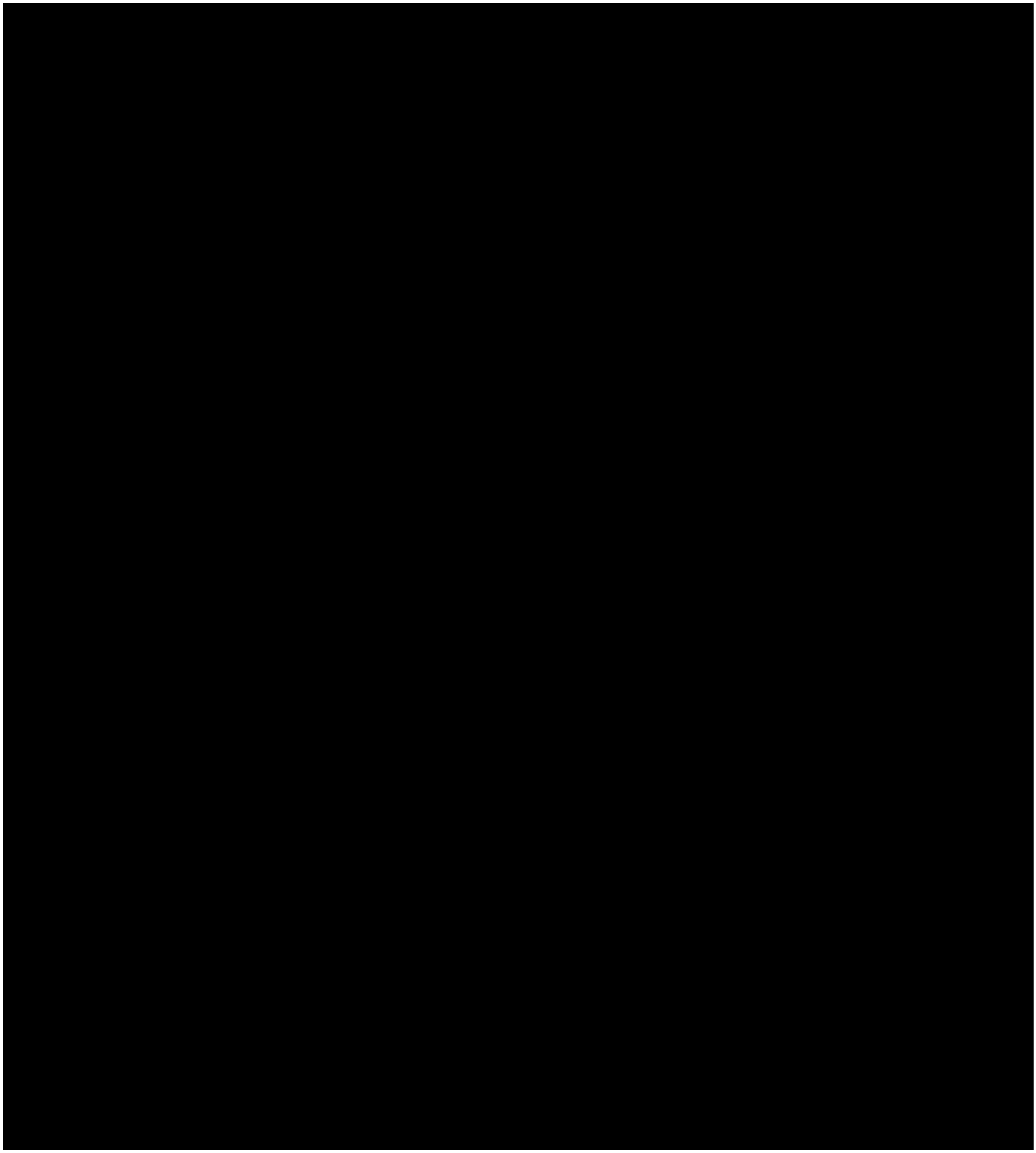
APPENDIX D: BINOCULAR OVER REFRACTION

[redacted]

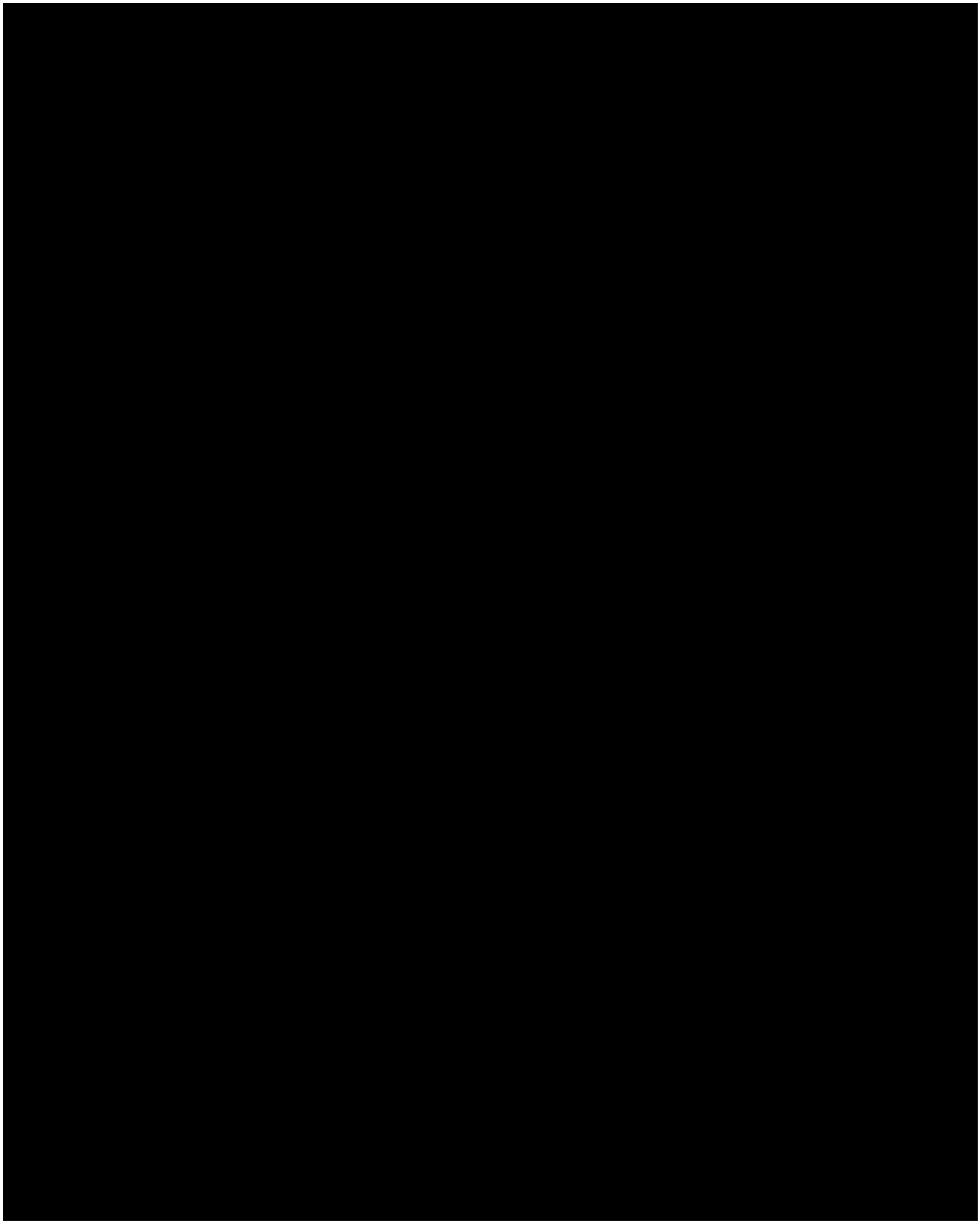
APPENDIX E: PRESBYOPIC SYMPTOMS QUESTIONNAIRE

[redacted]

APPENDIX F: OCULAR DOMINANCE



APPENDIX G: LENS FITTING GUIDE



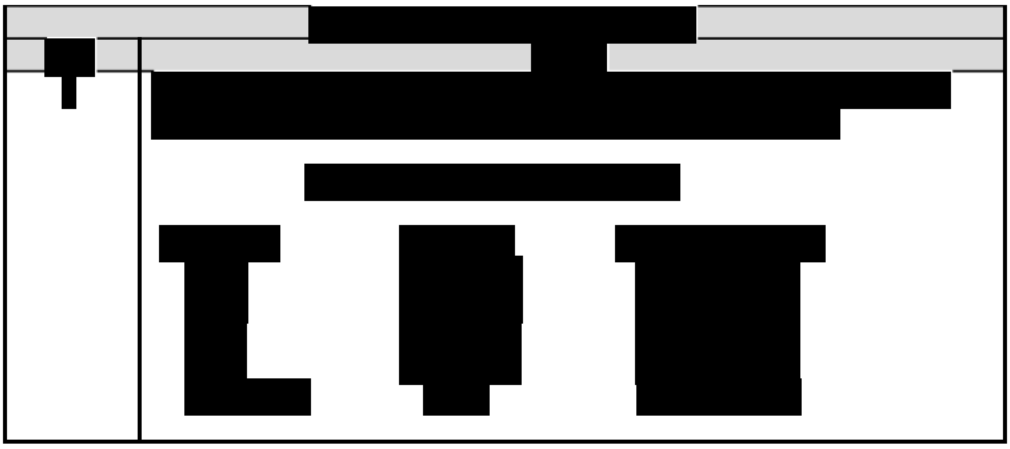
APPENDIX H: [redacted]

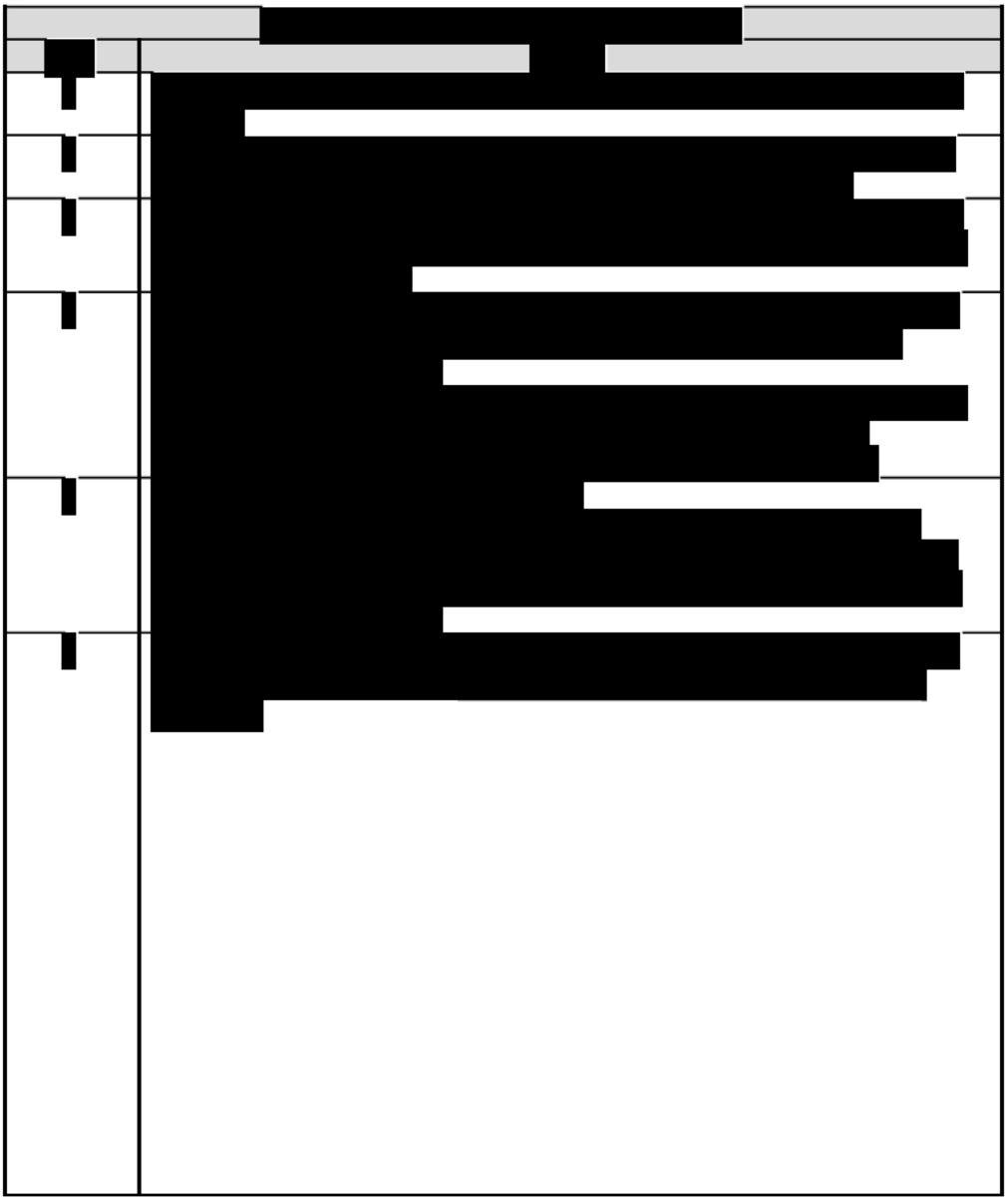
- [redacted] DETERMINATION OF NEAR ADD
- [redacted] NEAR logMAR VISUAL ACUITY MEASUREMENT PROCEDURE
- [redacted] LENS FITTING CHARACTERISTICS
- [redacted] SUBJECT REPORTED OCULAR SYMPTOMS
- [redacted] FRONT AND BACK SURFACE LENS DEPOSIT GRADING PROCEDURE
- [redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL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

[redacted] **DETERMINATION OF NEAR ADD**

[redacted]

[redacted]





[redacted]

[redacted]

<table>
<tr><td>6</td><td>If the tentative ADD is too strong (too much plus), ask the patient to place the near point card at the desired test distance. Place -0.25D in front of both eyes (using +/- 0.25D flippers or loose trial lenses) and ask him/her to compare the tentative ADD with and without the -0.25D. If adding -0.25D does not reduce clarity add the -0.25D to the tentative ADD and repeat the procedure. Continue to add -0.25D until the patient begins to have a reduction in clarity.

With the additional power in place, measure the range of clear focus (i.e., clear focus zone).
<table>
<tr><th>If the desired test distance is…</th><th>Then</th></tr>
<tr><td>Approximately midway within the clear focus zone</td><td>No further adjustments are necessary.</td></tr>
<tr><td>Near the edge of the clear focus zone closest to the patient</td><td>Add -0.25D and measure the range of clear focus again.</td></tr>
<tr><td>Near the edge of the clear focus zone furthest from the patient</td><td>Add +0.25D and measure the range of clear focus again.</td></tr>
</table>
Repeat this step until the near point is approximately midway in the clear zone.</td></tr>
<tr><td>7</td><td>If the tentative ADD is too weak (too much minus), ask the patient to place the near point card at the desired test distance. Place +0.25D in front of both eyes (using +/- 0.25D flippers or loose trial lenses) and ask him/her to compare the tentative ADD with and without the +0.25D. If adding +0.25D improves clarity (visual acuity), add the +0.25D to the tentative ADD and repeat the procedure. Continue to add +0.25D until no more improvement in near visual acuity is achieved at the desired test distance.
NOTE: Be careful to question the patient to ensure that he/she is actually seeing an improvement in visual acuity.
With this in place, measure the range of clear focus for the near point card.
<table>
<tr><th>If the desired test distance is…</th><th>Then</th></tr>
<tr><td>Approximately midway within the clear focus zone</td><td>No further adjustments are necessary.</td></tr>
<tr><td>At the edge of the clear focus zone closest to the patient</td><td>Add -0.25D and measure the range of clear focus again.</td></tr>
<tr><td>At the edge of the clear focus zone furthest from the patient</td><td>Add +0.25D and measure the range of clear focus again.</td></tr>
</table>
Repeat this step until the near point is approximately midway within the clear zone.</td></tr>
</table>

5. GRADING SCALE

- ADD Power: Diopters (0.25D increments)
- Distance tested and range of clear focus: cm (one unit increments)
- Visual Acuity: Snellen

6. REFERENCES

- Carlson, NB, et. al. (1996) Fused Cross Cylinder, in Clinical Procedures for Ocular Examination 2nd ed. (Appleton and Lange, Samford CT): 188-190.
- Grosvenor, TP (1982). The Binocular Vision Examination, Chapter 9 in Primary Care Optometry: A clinical manual. Grosvensor, TP (Professional Press, Chicago):189-200.
- Michaels, DD (1985) Refracting the Aging Eye, Chapter 20 in Visual Optics and Refraction. A clinical approach. Michaels, DD. (Mosby, St.Louis): 414-425.
- Patorgis, CJ (1987). Presbyopia, Chapter 8 in Diagnosis and Management in Vision Care. Amos J (Butterworths, Boston): 226-235.

7. TRAINING REQUIREMENTS

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

CTP-2006, NEAR LOGMAR VISUAL ACUITY MEASUREMENT PROCEDURE

1. OVERVIEW

This document contains the procedure to measure near visual acuity using logMAR visual acuity charts.

2. MATERIALS

- Near visual acuity charts (as specified in the protocol), for example:
  - Guillon-Poling Charts (**NOTE: Guillon-Poling charts are recorded in -10 logMAR**)
  - Precision Vision Sloan ETDRS or landolt C logMAR visual acuity charts
  - Or other equivalent near logMAR visual acuity chart
- Goggles with Neutral Density (ND) filters with 20%-32% transmittance, as specified in the protocol
- Near chart stand or near light box
- Light meters for measuring chart luminance and room illumination

3. SETUP

The following steps are used in the setup of the examination room and equipment prior to evaluation of the subject.

Step	Action
1	Insert visual acuity chart on the illuminator cabinet, chart stand or have subject hold the test card depending on test used and protocol instructions. **NOTE: for tests conducted under low luminance conditions, have the subject wear the goggle labeled as "Near" or "N"**
2	Verify room illumination and chart luminance per protocol requirements with a light meter (reference "Verification of logMAR chart luminance and room illumination" **CTP-2059**). The suggested chart luminance (unless otherwise specified in the clinical study protocol) is: • High luminance: 225 - 275 cd/m^2 (≈10.8-11.1 EV) • Low luminance: 45 – 55 cd/m^2 (≈8.5-8.8 EV)

4. ETDRS VA MEASUREMENT

The following steps are used in the measurement of monocular and/or binocular (as specified in the clinical study protocol) near logMAR visual acuity (VA).

Step	Action
1	Have the subject seated in front of the chart at a recommended distance of 40 cm, unless otherwise stated in the protocol. Position the subject so that the chart is below their line of sight in a comfortable reading position, or as instructed by protocol.
2	Instruct the subject to start with the largest line he/she can easily read the whole line. If the subject… / Then Misses any letter in the first attempted line / Ask the subject to re-start with a line above the line just read until the subject correctly reads all 5 letters of the line or the subject reaches the top line of the chart.

	Is unable to read at least 3 letters on the top line of the chart	Move the subject closer, to 33cm, or further away, to 50cm, from the chart (depending on what improves their vision) and repeat the step 2,, unless the study protocol states that this is not allowed. Record the new test distance in the CRF and proceed to the next step.
	Can't correctly read 3 or more letters after moving the chart to 33 and/or 50 cm test distance, or if moving the chart was not allowed in the protocol	Record the number of letters missed in the top line proceed to step 6. If using EDC, you will need to answer an automated query.
3	It is required that responses are recorded starting from a line where no letters are missed. For lines where no letters are missed, check the "None" box in EDC next to that line of letters (or record "0" missing next to the line if recording on paper). After the subject passes the first attempted line, instruct the subject to continue reading lines down through the chart. For each line read, line through letters that are missed by the subject and record the number of letters missed next to each line. For each subsequent line read, check the box next to each letter missed by the subject, or check the "None" box if no letters are missed. **NOTE: If recording on paper, place a line through each letter missed, or mark a line through the entire row of letters if they are all missed, and then record the number of letters missed (0 to 5) next to each line.**	
4	Encourage the subject to try to continue to read each line. If the subject says he/she cannot see the next line, encourage him/her to take his/her best guess.	
5	Stop the test only when the subject misses three or more letters on a single line. (**NOTE: If the subject misses three letters on a line, and there are still letters that they haven't attempted to read have the subject attempt to read the remaining letters and record the results**.) Otherwise, continue to encourage the subjects to keep reading the next line below till reaching the bottom line. If subjects correctly read all 5 letters on the last line, stop the test and record 0 missing without moving subjects further away from the chart.	
6	Repeat procedure with the same eye or complete the other eye the appropriate number of times, per protocol requirement.	

5. REFERENCES

- Guillon, M., D.P. Lydon, and R.T. Solman, Effect of target contrast and luminance on soft contact lens and spectacle visual performance. Curr Eye Res, 1988. 7(7): p. 635-48.

6. DATA MANAGEMENT

The electronic data capture system will automatically convert logMAR visual acuity if the chart is used at a distance other than what it was designed for. The formula to compute logMAR score at a different distance other than the chart specified distance is: LogMAR2 = LogMAR1 + log10(D1/D2),

7. TRAINING REQUIREMENT

The training requirement for this document is "Read Only."

CTP-2008, LENS FITTING CHARACTERISTICS

1. OVERVIEW

This document contains instructions for the estimation and recording of lens fitting characteristics including centration, movement upon blink, and tightness (push-up test).

2. DEFINITIONS AND ACRONYMS

The following definitions are provided for clarity.

2.1 **Limbus:** – the transitional zone at the junction of the cornea and sclera.
2.2 **Limbal Exposure** - the presence of clear cornea between the lens edge and the corneal side of the limbus.

3. MATERIALS

Slit Lamb biomicroscope

4. DIRECTIONS

Use low to moderate magnification and diffuse illumination. The right eye should be evaluated first unless observation order is randomized in the study design.

5. LENS CENTRATION

The position of the lens is observed with the subject's eyes in the primary gaze position. Lens centration relative to the cornea is rated as follows and demonstrated in the visual example contained in **Attachment A.**

Lens Centration Grading Scale	
Centered (Optimal)	The lens displays 360° of symmetric corneal overlap.
Slightly decentered	The lens displays a difference in overlap that is 1:2 or less at any point around the cornea.
Substantially decentered	The lens displays a difference in overlap that is greater than 1:2 at any point around the cornea.

NOTE: If the lens is not perfectly centered, the direction of decentration should be recorded on an 8 point directional scale as shown in Attachment A.

6. LIMBAL EXPOSURE

Coverage of the limbus by the lens is evaluated in the primary gaze position and during eye versions. The following scale is used in the grading of limbal exposure.

Limbal Exposure Grading Scale
Full corneal coverage: no exposure of clear cornea in any direction of gaze.
Limbal exposure with extreme eye movements or in upgaze, with or without blinks.
Limbal exposure in primary gaze with or without blinks.

7. EDGE LIFT

The presence of lens edge lift is evaluated and is recorded as either *Present* or *Absent*.

8. EVALUATION OF PRIMARY GAZE MOVEMENT

Without manipulating the subject's lids, observe the vertical movement of the contact lens that occurs with a full blink. The subject's eye is to remain in the primary gaze position. This movement is graded using the following scale and is demonstrated in the visual example contained in **Attachment B**.

Primary Gaze Movement Grading Scale	
Excessive, Unacceptable (+2)	Movement with the blink that typically produces limbal exposure.
Moderate, Acceptable (+1)	Substantial movement with the blink that does not produce limbal exposure, and does not immediately return to its original position.
Optimal (0)	A freely mobile lens that immediately returns to its original position ("freely mobile" defines a lens that moves easily with the blink. Its movement would be considered ideal for a given lens on a given cornea).
Minimal, Acceptable (-1)	Slight movement with the blink, with less movement than a freely mobile lens (less than optimal).
Insufficient, Unacceptable (-2)	No lens movement or just detectable movement. The lens frequently appears adhered to the ocular surface.

9. EVALUATION OF UPGAZE MOVEMENT

Without manipulating the subject's lids, estimate the vertical lens movement observed when the subject looks up and blinks fully. Grade this movement using the following scale.

Upgaze Movement Grading Scale	
Excessive, Unacceptable (+2)	Movement with the blink that typically produces limbal exposure.
Moderate, Acceptable (+1)	Substantial movement with the blink that does not produce corneal exposure, and does not immediately return to its original position.
Optimal (0)	A freely mobile lens that immediately returns to its original position ("freely mobile" defines a lens that moves easily with the blink. Its movement would be considered ideal for a given lens on a given cornea).
Minimal, Acceptable (-1)	Slight movement with the blink, with less movement than a freely mobile lens (less than optimal).
Insufficient, Unacceptable (-2)	No lens movement or just detectable movement. The lens frequently appears adhered to the ocular surface.

10. LENS TIGHTNESS (PUSH-UP TEST)

The subject's eyes should be in the primary gaze position. The push-up test consists of a gentle digital push of the lens upwards using the lower lid. The resistance of the lens to upward movement is judged and graded according to the following scale.

Lens Tightness Grading Scale
Excessive, unacceptable movement (+2)
Moderate, but acceptable movement (+1)
Optimal movement (0)
Minimal, but acceptable movement (-1)
Insufficient, unacceptable movement (-2)

11. FIT EVALUATION

Each lens fit is judged as being either *"Acceptable"* or *"Unacceptable"* based on the static and dynamic fit characteristics. Criteria for *"unacceptable"* lens fits can vary depending on individual protocols (e.g., some bifocal studies may require substantially decentered lenses to be classified as *"unacceptable"*). General guidelines for unacceptable lens fits are presented in the following table.

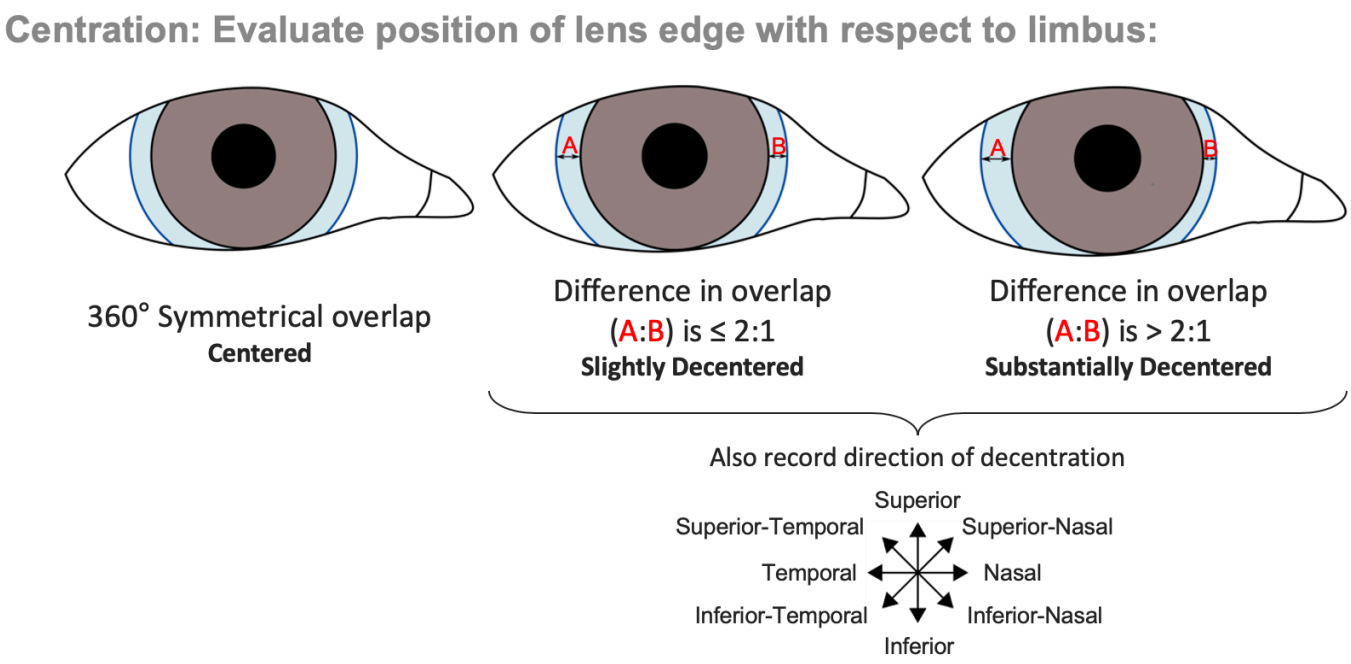
NOTE: The determinants of an unacceptable lens fit may vary by study and are defined in the study protocol.

Fit Evaluation Criteria	
Limbal Exposure	Any gaze
Edge Lift	Present
Insufficient movement	Insufficient movement (grade -2) **in all three movement evaluations** (primary gaze movement on blink, upgaze movement on blink, and push-up test)
Excessive movement	Excessive movement on blink (grade +2) in primary gaze

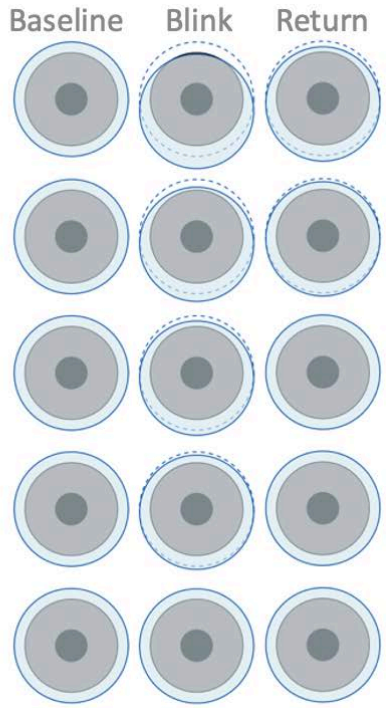
12. TRAINING REQUIREMENTS

The training requirement for this document is "Read Only."

Attachment A Example of Lens Centration Rating



Attachment B Example of Evaluation of Primary Gaze Movement



Excessive, unacceptable (+2): typically produces limbal exposure

Moderate, acceptable (+1): substantial without limbal exposure, does not immediately return to original position

Optimal (0): moves easily, immediately returns to original position

Minimal, acceptable (-1): slight movement, does not move easily

Insufficient, unacceptable (-2): no movement or just detectable movement

CTP-2009, SUBJECT REPORTED OCULAR SYMPTOMS

1. OVERVIEW

This document contains instructions to determine whether or not ocular symptoms and problems are present. If present, this document can be used to determine the characterization of the severity and/or frequency of the reported symptoms or problems.

2. MATERIALS

The appropriate Case Report Form Module.

3. PROCEDURE

The following steps are used in the patient workup and recording of reported symptoms or problems.

Step	Action
1	Following the instruction in the appropriate Case Report Form Module, ask the subject if he/she has experienced any eye symptoms or problems with contact lens wear or the study contact lenses. Read the question(s) provided in the appropriate Case Report Form Module to the subject. Do not guide the subject or read the list of symptoms to the patient.
2	If no symptoms or problems are reported by the subject for one or both eyes, check the "No" box(es). This will close the ability to select and assign a severity grade to the symptoms.
3	If one or more symptoms or problems are reported by the subject for one or both eyes, check the "Yes" box(es) for the appropriate eye(s).
4	Ask the subject to characterize each reported symptom or problem according to the scale provided in the module. For each reported symptom, select the numeric grade that corresponds to the subject's characterization. If the symptom is not listed, select a numeric grade for "Other" and describe the symptom in the associated text box. Select "0" as the severity for any symptoms that were not reported.
5	The investigator should carefully review the reported symptoms to determine whether an adverse event or product quality complaint has occurred.

4. GRADING SCALE

Refer to the appropriate Case Report Form Module.

5. ADDITIONAL INFORMATION

Questions to subject should be modified to reflect the time period of assessment and whether habitual or study lenses are being assessed.

6. TRAINING REQUIREMENTS

The training requirement for this document is "Read Only."

CTP-2011, FRONT AND BACK SURFACE LENS DEPOSIT GRADING PROCEDURE

CTP-2011 (3) Front and Back Surface Lens Deposit Grading Procedure

OVERVIEW

This document contains instructions for the determination of the amount of front and back surface lens deposits while the lens is on the eye.

MATERIALS

Slit Lamp

PROCEDURE

The following steps are used in the grading of front and back surface lens deposits.

NOTES:

- **Deposits may be distinguished from tear film debris and mucin balls by observing the deposits during lens movement. Lens deposits will move with the lens during blink or Josephson Push-up Test while back surface tear debris and mucin balls will not.**

- **Because of the lens-air interface, front surface deposits reflect more light than back surface deposits. If uncertain of the surface, adjust the slit lamp beam to an optic section in order to differentiate if a deposit is adhered to the front or back surface of the lens.**

Step	Action
1	Set the slit beam to a width of approximately 2mm, height of approximately 6mm (approximately 1/2 corneal diameter), and magnification between 16-20X.
2	Scan the entire lens for the presence of any deposits.
3	Grade and record the amount of front and back surface lens deposits. Deposits may be either discrete (e.g., jelly bumps) or appear as a film.
4	Record discrete and film type deposits together as a percentage of the surface area of the front and back lens.
5	Imagine a border enclosing the area of deposition and estimate its size per lens from this perspective. If the deposition is distributed throughout the lens of interest (e.g., in two distinct parts of the region), add the areas of deposition and record the sum (e.g., 10% +20%=30%).

GRADING SCALE

The following scale is used in the grading of front and back surface lens deposits.

Front and Back Surface Lens Deposits		
Grade 0	None	No deposition.
Grade 1	Slight	Deposition which occupies 1-5% of the lens surface area.
Grade 2	Mild	Deposition which occupies 6-15% of the lens surface area.
Grade 3	Moderate	Deposition which occupies 16-25% of the lens surface area.
Grade 4	Severe	Deposition which occupies ≥26% of the lens surface area.

PHOTO-DOCUMENT-ATION

All photodocumentation attachments can be found at the end of this document.

- **Attachment A**: Drawing depicting the grading scale for deposition.

- **Attachment B**: Examples of the deposition grading scale.

REFERENCES

- Mandell, R.B. (1988). Contact Lens Practice. Charles C. Thomas, Springfield, IL, pp 628-643.

- Minno, G.E., Eckel, L., Groemminger, S., Minno, B., & Wrzosek, T. (1991). Quantitative Analysis of Protein Deposits on Hydrophilic Soft Contact Lenses: I. Comparison to Visual Methods of Analysis. II. Deposit Variation among FDA Lens Material Groups. Optometry and Vision Science, 68 (11): 865-872.

TRAINING REQUIRE-MENTS

The training requirement for this document is "Read Only."

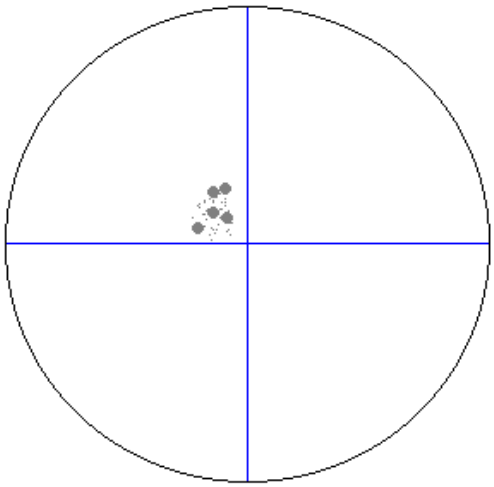
CASE REPORT FORM MODULE

See **Attachment C**

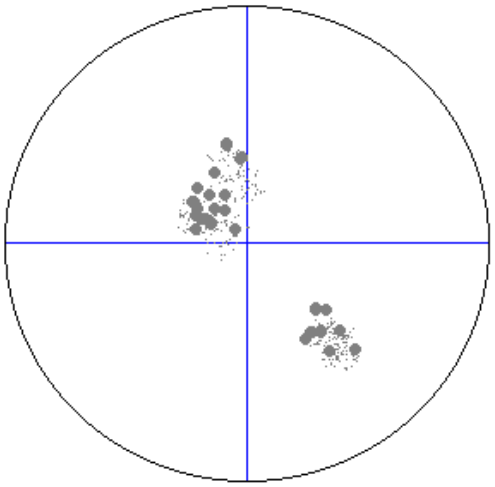
Attachment A

NOTE: The deposition need not be uniform in size. The total area of deposition on the lens is determined by adding all regions with debris together.

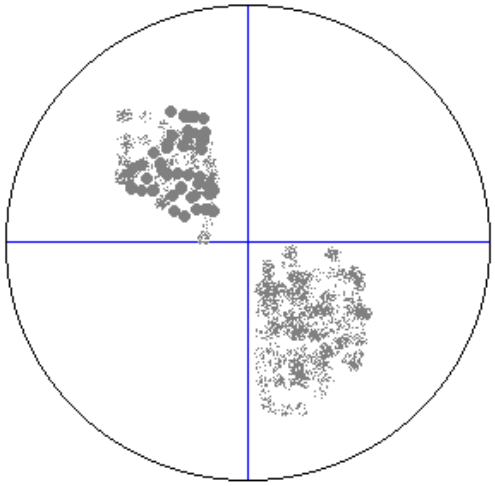
Grade 1 (1 - 5 % lens area)



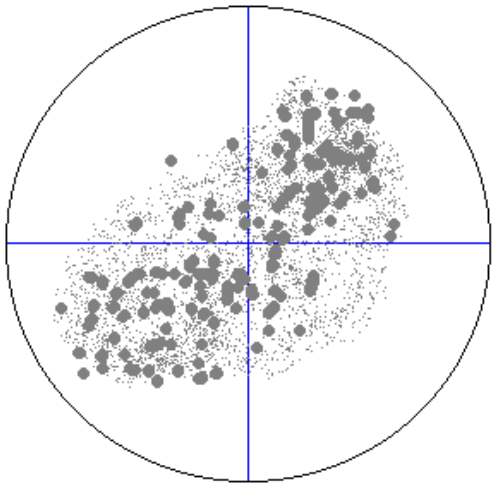
Grade 2 (6 - 15% lens area)



Grade 3 (16 - 25% lens area)

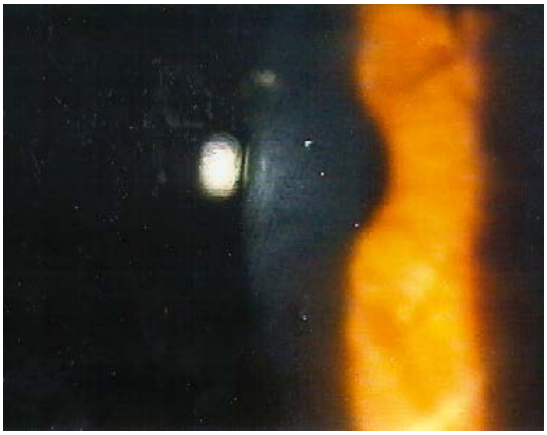


Grade 4 (26% and higher lens area)

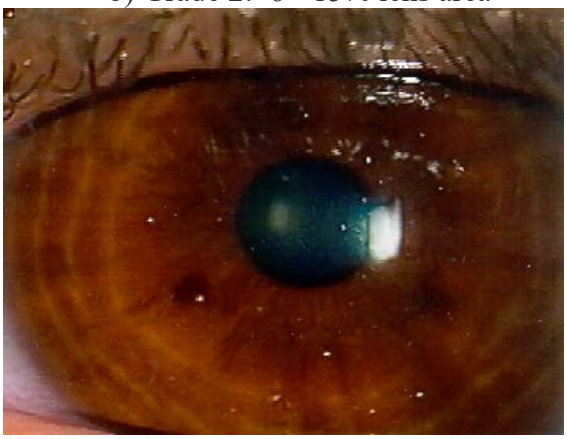


Attachment B

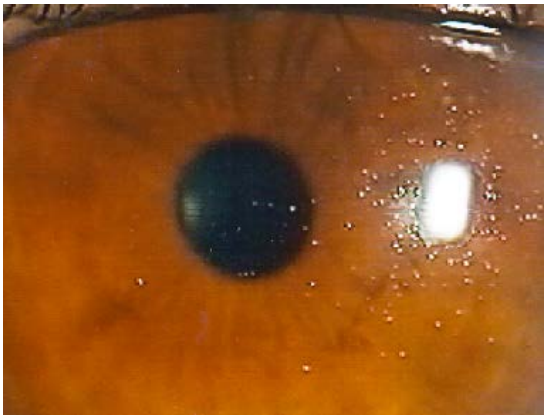
a) Grade 1: 1 – 5% lens area



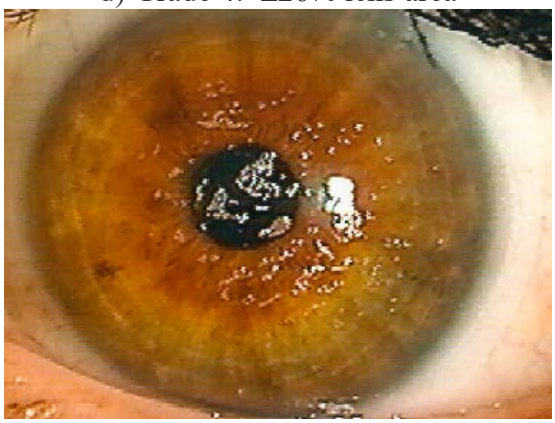
b) Grade 2: 6 - 15% lens area



c) Grade 3: 16 - 25% lens area



d) Grade 4: ≥26% lens area



Attachment C

OD				OS			
SURFACE DEPOSITS:							
1. Front Surface Deposits:							
☐1	None	☐4	Moderate	☐1	None	☐4	Moderate
☐2	Slight	☐5	Severe	☐2	Slight	☐5	Severe
☐3	Mild			☐3	Mild		
2. Back Surface Deposits:							
☐1	None	☐4	Moderate	☐1	None	☐4	Moderate
☐2	Slight	☐5	Severe	☐2	Slight	☐5	Severe
☐3	Mild			☐3	Mild		

Scale:

Grade 0	None	No deposition.
Grade 1	Slight	Deposition, which occupies 1-5% of the lens surface area.
Grade 2	Mild	Deposition, which occupies 6-15% of the lens surface area.
Grade 3	Moderate	Deposition, which occupies 16-25% of the lens surface area.
Grade 4	Severe	Deposition, which occupies 26% of the lens surface area.

CTP-2016, DETERMINATION OF SPHEROCYLINDRICAL REFRACTIONS

CTP-2016 (4) Determination of Distance Spherocylindrical Refractions

OVERVIEW

This document contains guidelines for the determination of the optimum visual acuity (VA) with the most plus/ least minus power.

DEFINITIONS

The following definitions are provided for clarity.

Binocular Balance – a balancing technique that follows monocular subjective refraction with the intention of equalizing the stimulus to accommodation.

Reversal – occurs when the original clearer image becomes more blurred in the measurement of VA.

Binocular Refraction Endpoint – the optimal VA that is easily read with the most plus power binocularly. A final binocular sphere determination should follow the completion of a balance procedure.

Binocular Subjective Refraction – a technique similar to monocular subjective refraction except that both eyes of the subject are open and unoccluded, and view a common distant target. It is used to determine the optimal VA easily read through the most plus/least minus power.

MATERIALS

- Phoropter
- Standard Snellen Visual Acuity Charts or equivalent

MONOCULAR SUBJECTIVE REFRACTION

The following procedures are used in the determination of monocular subjective refraction.

Best Sphere Determination

Step	Action
1	Perform retinoscopy or autorefraction and place the objective finding in the phoropter. Use this measurement as the starting point for the subjective monocular refraction.
2	Use moderate room lighting to obtain maximum contrast on the charts.
3	Place the phoropter in front of the patient and adjust the pupil distance to match the subject's.
4	Occlude the subject's left eye.
5	Check visual acuity of right eye.
6	Add +0.25D sphere and check visual acuity. **If the visual acuity… / Then** Remains unchanged or improved → Repeat Step 6. Decreases → Add minus power in 0.25D increments until the best VA is achieved.
7	Proceed to Cylinder Axis Determination.

Cylinder Axis Determination	
Step	**Action**
1	Have the subject look at a specific line or letter on the chart. Commonly used targets are isolated 20/40 line or an isolated letter of the 20/50 line.
2	Place the optimal refracted sphere and/or the autorefraction cylinder power and axis in the phoropter.
3	Position the cross cylinder lens in front of the subject's right eye.
4	Rotate the cross cylinder lens until the principal meridians of the lens marked by the red and white dots are 45 degrees away from the cylinder axis found on autorefraction.
5	Instruct the subject that the target will be shown with two different lenses and to report through which lens the target appears clearer or whether the two choices appear the same.
6	When asking the question, rotate the cross cylinder lens so that the meridians marked by the red and white dots change positions.
7	Leave the cross cylinder lens in the position at which the subject reports the target as being clearer and turn the correcting cylinder in the refractor toward the red dots on the cylinder lens.
8	Repeat this sequence as many times as necessary until the subject can no longer tell any difference in the appearance of the targets when the cross cylinder is flipped. At this point, both choices will appear equal. This marks the correct cylinder axis and is the end of the test for cylinder axis.
9	Proceed to Cylinder Power Determination.

Cylinder Power Determination	
Step	**Action**
1	Rotate the cross cylinder lens until one of the meridians marked by the red or white dots is directly parallel to the cylinder axis in the refractor.
2	Flip the lens as you ask the subject which target is clearer.
3	Leave the cross cylinder lens in the position at which the subject reports the target as being clearer. **NOTE: If the cylinder is adjusted by 0.50D or more, the sphere needs to be modified inversely by half the cylinder change (e.g., -0.50D increase in cylinder power will require adding +0.25D to the spherical power).**
4	Repeat Step 3 until the subject has no preference between the two choices.
5	The final endpoint or optimal cylinder power is either: 1) the least amount of cylinder power preferred, or 2) the cylinder power currently in the phoropter when the subject cannot distinguish between the two cross cylinder powers presented.
6	Re-check the cylinder axis with the newly refined cylinder power in place.
7	Proceed to Final Monocular Sphere Power Determination.

If the subject prefers the position at which…	Then
The red dots are in line with the correcting cylinder	Increase the cylinder power by -0.25D.
The white dots are in line with the correcting cylinder	Decrease the cylinder power by -0.25D.

Final Monocular Sphere Power Determination	
Step	**Action**
1	Check monocular visual acuity and repeat Step 6 in the Best Sphere Determination procedure. The endpoint is the most plus power that provides the optimal level of visual acuity.
2	Switch occluder to subject's right eye and repeat procedures for monocular subjective refraction for the left eye.

BINOCULAR BALANCE

The following steps are used in binocular balance (alternative techniques may also be used depending on the examiner's preference).

Prism Dissociated Blur Balance

Step	Action
1	Ensure both eyes are unoccluded.
2	Instruct the subject to look at a single line binocularly (e.g., 20/40 line) with the monocular refraction in the phoropter.
3	Add plus in 0.25D increments binocularly until the target is fogged, but legible.
4	Dissociate by presenting 3D prism base up for the right eye and 3D prism base down for the left eye. The subject should see two images; the right eye will see the bottom image and the left eye will see the top image.

If the subject…	Then
Cannot see two distinct images	Increase the prismatic effect with an equal amount of prism power to each eye.
Is still unable to see two images after increasing prismatic effect	An alternative balancing technique should be attempted (the subject is suppressing).

5	Have the patient compare the two images and report which image is clearer, top or bottom.

If the images are…	Then
Equally blurred	Introduce ±0.25D to confirm (See Steps 6-8).
Not equally blurred	Proceed to Step 9.

6	Introduce +0.25D in front of the right eye. The bottom image should become more blurred than the top image.
7	Remove the +0.25D to return to original power.
8	Introduce -0.25D in front of the right eye. The bottom image should become clearer than the top image. If the bottom image is more blurred with +0.25D and clearer with the -0.25D, then the original power is the correct balance.
9	Add plus sphere power in +0.25D steps before the eye with the clearer image until the two images are equally blurred or a reversal occurs. If an additional 0.25D reverses rather than equalizes the preference, the end point of balance is that spherical power which results in the closest acuity match between the eyes, or alternatively to leave the dominant eye with the better acuity (See Ocular Dominance Determination procedure).

10	Proceed to Binocular Refraction Endpoint.

Binocular Refraction Endpoint	
Step	**Action**
1	Present +0.25D to both eyes over the monocular refraction determined. **If the visual acuity…** / **Then** Remains unchanged or improved → Repeat Step 1. Decreases → Add minus power in 0.25D increments until the best visual acuity is achieved. If the letters appear smaller and darker, then the subject is over-minused.
2	Record the refractive power and the monocular / binocular visual acuities.

DUOCHROME TEST

The following steps are used for performing the duo-chrome test, as a monocular end-point test or as a binocular balancing test.

NOTES:

1) The duochrome test must be done in an almost completely darkened room.

2) Some subjects are unresponsive to this test and seem to choose one side or the other, regardless of the lens powers in place. Be alert to this possibility and discontinue the duochrome test, if appropriate.

Monocular Endpoint Test	
Step	**Action**
1	Start with the results of the monocular subjective finding, place +0.50 or +0.75D of spherical power in front of each eye.
2	Display the red/green split chart.
3	Direct the subject's attention to the 20/30 or 20/40 letters (or equivalent) or to the letters one line above his best VA so far.
4	Ask the subject "which of the letters (or circles) – those on the red background or those on the green background - are "sharper, blacker, or more distinct". The subject is expected to report that the letters or circles on the red background are more distinct than those on the green background.
5	Reduce the plus lens power by 0.25D at a time. At some point the subject should report that the letters or circles on the red and green backgrounds are equally distinct. This is typically achieved when all fog has been removed, if the original monocular subjective end point was correct. If an additional 0.25D of plus power is removed, the letters or circles on the green side will appear to be more distinct. The endpoint criterion ordinarily used is the lens power at which the red and green sides of the chart appear to be equally distinct. **NOTE: If the subject's response changes from "red" to "green" with only a 0.25D change in power and no report that the two sides appear to be equally sharp, the refraction endpoint should be the lens power that leave the red chart sharper, or as specified in the study protocol.**

Binocular Balancing Test	
Step	**Action**
1	Start with the results of the monocular subjective finding, place +0.50 or +0.75D of spherical power in front of each eye.
2	Remove occluders from both eyes and place 3Δ prism base-up in front of the right eye, and 3Δ prism base-down in front of the left eye.

3	Call the subject's attention to the lower chart (see by the right eye) and ask the subject to report which of the letters or circles – those on the red side or those on the green side – appear blacker, sharper, or more distinct. The subject is expected to report that it is "the red side"
4	Reduce plus lens power (in front of the right eye only) 0.25D at a time until the patient reports "both the same" and then "the green side". Then add +0.25D to return to the situation in which the two sides are equally distinct. **NOTE: With each lens change, the subject should be reminded to look at the lower chart. The same endpoint criterion as indicated in the above monocular duochrome test should be used.**
5	Call the subject's attention to the upper chart (see by the left eye), and repeat steps 3 and 4.
6	With the lens powers obtained by steps 3 to 5 left in the refractor, the subject is again asked to report, first for the lower chart and then for the upper chart, whether the letters or rings are blacker, sharper, or more distinct on the red side or the green side. **If the subject reports … / Then** "Same" for one chart and "red for the other → Add +0.25D to the eye for which the "same" report was given, with the exception that "red" will be reported. "Same" for one chart and "green" for the other → Add +0.25D to the eye for which the "green" report was given, in the hope that "same" will then be reported. **NOTE: Care must be taken not to add additional minus power at the point, as this may cause the eyes to accommodate, invalidating the test.**

BINOCULAR SUBJECTIVE REFRACTION (HUMPHRISS TECHNIQUE)

The following steps are used in the determination of binocular subjective refraction.

NOTE: This technique is described in detail below utilizing a phoropter, but may also be conducted with hand-held lenses.

Step	Action
1	Place objective refraction in phoropter or trial frame (e.g., retinoscopy or auto-refraction).
2	Place +1.00D in front of the left eye.
3	Present ±0.25D lenses to right eye (present +0.25D first for » 2-3 seconds and -0.25D for only 0.5 seconds) and ask the subject to compare the two lenses. **If the subject… / Then** Immediately reports that -0.25D is clearer. → The patient is not accommodating and is under corrected; therefore, add -0.25D and repeat Step 3. Reports that +0.25D is clearer. → The patient is accommodating; therefore, add +0.25D and repeat Step 3. Hesitates or is unsure about which is clearer. → Do not add any power but proceed to Step 5.
4	Determine cylinder power and axis as described previously in the Cylinder Axis and Cylinder Power Determination procedure tables.
5	Remove +1.00D from the left eye and introduce +1.00D over the right eye.
6	Repeat Steps 3-5 for the left eye.

7	Remove +1.00D from right eye.
8	Follow steps for Binocular Refraction Endpoint (described previously).

OCULAR DOMINANCE

The following steps are used in the determination of ocular dominance.

Step	Action
1	Ask the subject to extend both arms out and use his/her hands to form a triangle.
2	Ask the subject to keep both eyes open, and look through the triangle at a small object on the wall (e.g., a light switch or doorknob).
3	Occlude the subject's left eye, then right eye.
4	While alternating the occluder from the subject's eyes, ask the subject when they see the object.

If the subject sees the object…	Then
When the left eye is covered	The subject is *right eye* dominant.
When the right eye is covered	The subject is *left eye* dominant.
With both eyes	The opening between the hands may be too large. Therefore, ask the subject to make a smaller opening and repeat the procedure.

GRADING SCALE

Refraction: Sphere and Cylinder Power (+20.0 to -20.0D, 0.25D increments).
Cylinder Axis (0-180°, one-degree increments).

Visual acuity should be recorded using the Snellen visual acuity descriptors on the charts. As a minimum, visual acuity should be recorded monocularly. Refer to the current revision of **CTP-2025** for VA recording.

ADDITIONAL INFORMATION

To minimize memorization, all available 20/20 lines on the Snellen charts should be randomly utilized when testing the patient. In addition, the patient can be asked to read the letters in a line in reverse order.

TRAINING REQUIREMENTS

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

CTP-2018, BIOMICROSCOPY SCALE

1.0 PURPOSE

This document contains instructions for the determination of the level of corneal edema, corneal neovascularization, corneal staining, conjunctival injection, tarsal abnormalities, and other complications in each eye.

2.0 DEFINITIONS

The following definitions are provided for clarity.

Limbus – the 1 to 2mm wide zone of conjunctiva and underlying tissue adjacent to where the cornea joins the sclera.

3.0 MATERIALS

- Slit Lamp
- Slit Lamp Findings FDA Classification Scale
- Slit Lamp mounted camera (for photographic record)
- Slit Lamp with a cobalt blue illumination source
- Sodium Fluorescein strips
- Unpreserved, sterile saline
- Yellow filter (e.g., #12 Kodak Wratten filter or integrated yellow filter in slit lamp)

4.0 CORNEAL EDEMA

The following steps are used in the assessment and grading of corneal edema.

Step	Action
1	Set the slit beam to a width of ≈2mm and a height of ≈6mm (approximately 1/2 corneal diameter). The slit lamp magnification should be between 16-20X.
2	Grade and record the amount of corneal edema present in each eye using the Slit Lamp Findings Classification Scale.
3	Use the following scale for corneal edema grading.

Corneal Edema Grading Scale	
Grade 0 None	No edema
Grade 1 Trace	Slight localized or generalized edema a. Dull glass appearance (slight hazy appearance) of the corneal epithelium, or b. Just detectable central corneal clouding (CCC) without distinct borders
Grade 2 Mild	Mild localized or generalized edema a. Less than 15 vacuoles (microcystic), or b. Light density CCC. Borders distinct but visible only against pupil, or c. Corneal striae (one or more)
Grade 3 Moderate	Significant localized or generalized edema a. 15-50 vacuoles (microcysts), or b. Very distinct borders on CCC, or c. Multiple striae including folds in Descemet's membrane (black lines)
Grade 4 Severe	Advanced localized or generalized edema a. More than 50 vacuoles (microcysts) b. Epithelial bullae c. Epithelial sloughing

5.0 CORNEAL NEOVASC-ULARIZATION

The following steps are used in the assessment and grading of corneal neovascularization.

Step	Action
1	Use focal illumination and medium to high magnification.
2	Examine the limbus in all four quadrants (nasal, temporal, superior and inferior). Instruct the subject to direct their gaze in an appropriate direction so that the corneal area of interest can be observed. Manipulate the lids to reveal the limbus wherever necessary.
3	Grade corneal vascularization by assessing any vessels penetrating the limbus.
4	Estimate vessel length. The longest vessel in the cornea is used for the purpose of grading.
5	Use the following scale for corneal neovascularization grading.

Corneal Vascularization Grading Scale	
Grade 0 None	No vascular changes.
Grade 1 Trace	Congestion and dilation of the limbal vessels. Single vessel extension <1.5 mm from the prefitting position.
Grade 2 Mild	Extension of vessels <1.5 mm from the prefitting position.
Grade 3 Moderate	Extension of limbal vessels 1.5 mm - 2.5 mm from prefitting position.
Grade 4 Severe	Segmented or circumscribed extensions of limbal vessels more than 2.5 mm inside the limbus, or extension to within 3.0 mm of corneal apex.
Location (optional): N Nasal I Inferior C Circumferential	 T Temporal S Superior X Other (describe)

6.0 SODIUM FLUORESCEIN CORNEAL STAINING

The following steps are used in the assessment and grading of fluorescein corneal staining.

NOTE: When stated in the protocol, corneal staining may be evaluated without the instillation of fluorescein.

Step	Action
1	Set the slit beam to a width of ≈2mm and a height of ≈6mm (approximately 1/2 corneal diameter). The slit lamp magnification should be between 16-20X with cobalt illumination source.
2	Moisten the fluorescein strip with a few drops of saline.
3	Have the subject look upwards, pull their lower lid down, and lightly touch the subject's inferior palpebral conjunctiva with the strip.
4	Have the subject blink a few times, and discard the used fluorescein strip.
5	Grade and record the epithelial staining of the whole eye using the following grading scale for corneal staining with fluorescein. If the eye has more than one area of staining, grade and record the area with the greatest severity of staining.

Sodium Fluorescein Corneal Staining Grading Scale	
Grade 0 None	No staining
Grade 1 Trace	Minimal superficial staining or stippling a. Central or generalized b. Peripheral including 3-9 o'clock staining, or c. Dimpling associated with bubbles under lens, or d. Trace superficial lens insertion marks or foreign body tracks
Grade 2 Mild	Regional or diffuse punctate staining a. Centralized or generalized, or b. Peripheral including 3-9 o'clock staining, or c. Mild abrasion or foreign body tracks
Grade 3 Moderate	Significant dense coalesced staining, corneal abrasion or foreign body tracks.
Grade 4 Severe	Severe abrasions greater than 2 mm in diameter, ulcerations, epithelial loss, or full thickness abrasion. Diagram and explain.
Location (optional): N Nasal I Inferior C Central	 T Temporal S Superior O 3-9 o'clock

NOTE: It is recommended that sponsors design data collection forms to obtain information concerning the location of corneal staining so that peripheral staining can be differentiated from corneal staining.

7.0 CONJUNCTIVAL INJECTION

The following steps are used in the assessment and grading of conjunctival injection.

Step	Action
1	Assess the ocular vascular response via external examination. Specifically, classify the appearance of injected (dilated) blood vessels within the limbus as well as within the bulbar conjunctivae.
2	Observe limbal region and bulbar conjunctiva with the slit lamp at 5X - 12X.
3	Use the following scale for the grading of conjunctival injection. **NOTE: If the eye has more than one area of injection, grade and record the area with the greatest severity.**

Conjunctival Injection Grading Scale	
Grade 0 None	No injection present.
Grade 1 Trace	Slight limbal (mild segmented), bulbar (mild regional), and/or palpebral injection.
Grade 2 Mild	Mild limbal (mild circumcorneal), bulbar (mild diffuse), and/or palpebral injection.
Grade 3 Moderate	Significant limbal (marked segmented), bulbar (marked regional or diffuse), or palpebral injection.
Grade 4 Severe	Severe limbal (marked circumcorneal), bulbar (diffuse episcleral or scleral), or palpebral injection.

8.0 TARSAL ABNORM-ALITIES

The following steps are used in the assessment and grading of tarsal abnormalities.

Step	Action
1	Instruct the subject to look down during the eversion procedure and advise them that the procedure will not hurt, but they may feel slight discomfort.
2	Evert upper lid.
3	Observe the conjunctiva with the slit lamp at 5X - 12X using white light.
4	Assess the appearance of the palpebral conjunctiva overlying the upper tarsal plate. Specifically, classify the level of redness and the presence and size of papillae (have central tuft of blood vessels) and follicles (have blood vessels encircling their base).
5	Use the following scale for the grading of tarsal abnormalities.
6	Record the maximum clinical grade observed for that eye.

Tarsal Abnormalities Grading Scale	
Grade 0 None	Uniform satin appearance of conjunctiva
Grade 1 Trace	Slight conjunctival injection without texture
Grade 2 Mild	Mild or scattered papillae/follicles less than 1 mm in diameter
Grade 3 Moderate	Significant papillae/follicles less than 1 mm in diameter, and/or marked conjunctival injection
Grade 4 Severe	Localized or generalized papillae/follicles 1 mm or more in diameter with or without marked injection

9.0 OTHER COMPLICATIONS

The following steps are used in the assessment and grading of other complications.

Step	Action
1	Carry out a full biomicroscopic examination that includes staining with sodium fluorescein dye and lid eversion.
2	Record and grade by severity the slit lamp findings that cannot be classified as corneal edema, corneal staining, injection, vascularization, and tarsal abnormalities. Examples include but are not limited to: corneal scar, conjunctival cyst, conjunctival chemosis, cells and flare in anterior chamber.
3	Specify and briefly describe the "other complications" in the "Specify Other" area of the module.

Other Complications Grading Scale	
Grade 0 None	No other significant biomicroscopic findings
Grade 1 Trace	Minimal findings such as tear film abnormality (debris or low tear break up time)
Grade 2 Mild	Mild findings such as: a. Few faint infiltrates b. Lens adhesion
Grade 3 Moderate	Significant findings such as: a. Infiltrates (multiple or dense) b. Iritis with minimal cells or flare c. Conjunctivitis or EKC
Grade 4 Severe	Severe findings such as:

	a. Marked infiltrates with overlying staining [redacted]

[redacted]

[redacted]

[redacted]

[redacted] **KERATOMETRY**

[redacted]

Keratometry Procedure

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

[redacted] DISTANCE AND NEAR VISUAL ACUITY MEASUREMENT PROCEDURE

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[redacted]

[redacted]

[redacted]

[redacted] [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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

- [redacted]

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

[redacted]

[redacted] ETDRS DISTANCE VISUAL ACUITY MEASUREMENT PROCEDURE

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

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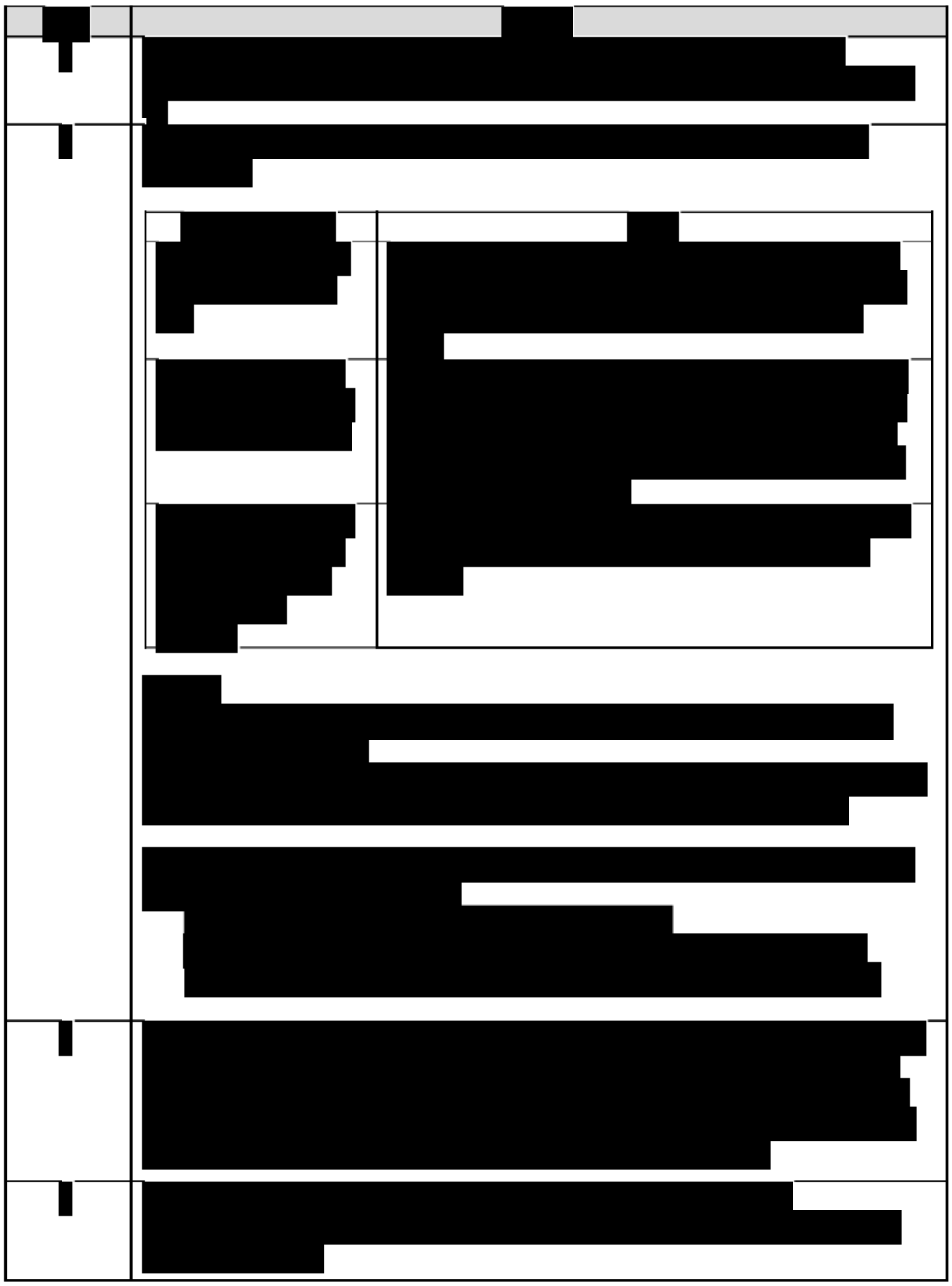
[redacted]



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[redacted] WHITE LIGHT LENS SURFACE WETTABILITY

[redacted] **White Light Lens Surface Wettability**

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[redacted] VISUAL ACUITY CHART LUMINANCE AND ROOM ILLUMINATION TESTING

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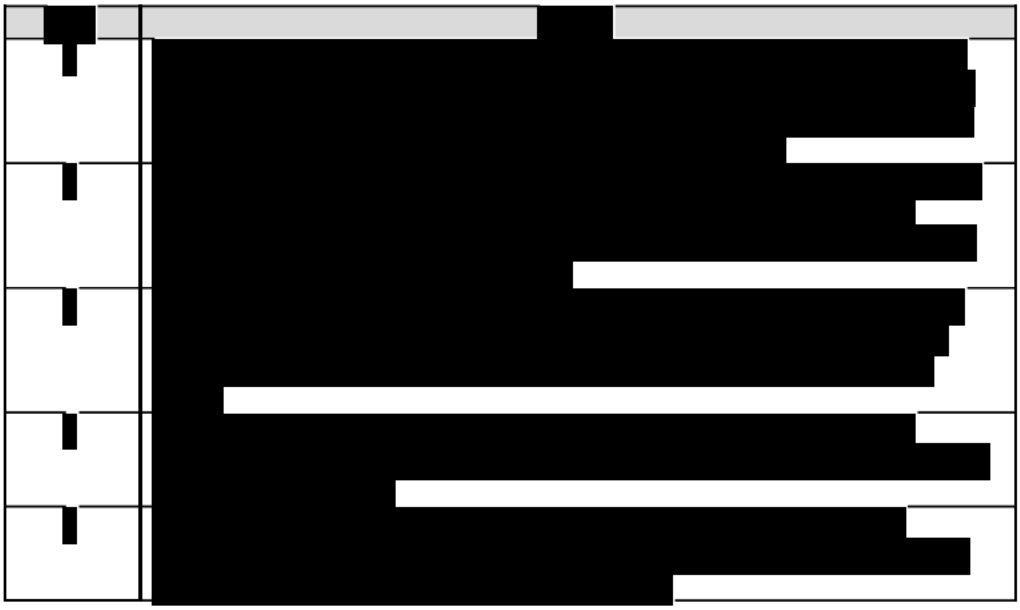

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APPENDIX I: COVID-19 RISK MITIGATION GUIDELINES

1.0 PURPOSE

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

2.0 SCOPE

This document provides guidelines for Johnson & Johnson Vision Care (JJVCI) to address the potential risks from COVID-19 to study subjects, investigators, study site staff, and monitors at study sites in the US. These guidelines do not apply to study sites outside of the US. The guidance provided in this document is in effect from the date of approval through the date of retirement of this Work Instruction. At a minimum, this Work Instruction will be reviewed and updated on a quarterly basis, as appropriate.

NOTE: Sites outside of the US will be evaluated on a site by site basis subject to local health authority guidance.

3.0 DEFINITIONS

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

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

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

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

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

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

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

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

Medical Safety Officer (MSO): Physician who has primary accountability in their product portfolio for product health and safety, and who serves as an independent medical voice for patient safety.

Safety Management Team (SMT): A cross-functional, collaborative team responsible for review, assessment and evaluation of medical safety data arising from any source throughout the product life cycle.

4.0 GUIDANCE FOR STUDY DOCUMENTS

In alignment with recent health authority guidance, JJVCI is providing recommendations for study-related management in the event of disruption to the conduct of the clinical study. This guidance does not supersede any local or government requirements or the clinical judgement of the investigator to protect the health, safety and well-being of participants and site staff. If, at any time, a participant's safety is considered to be at risk, study intervention will be discontinued, and study follow-up will be conducted as outlined in the protocol.

During the COVID-19 pandemic, the additional risks listed below need to be considered for study participants and study personnel:

4.1 Additional Risks Related to the COVID-19 Pandemic:

- The possible transmission of the Coronavirus infection and consequent complications, beyond the risk of adverse events due to the investigational device and/or procedures.
- The risk may be higher in an optometric clinical study because of the close contact the subject will have with health care professionals during the procedures and assessments (since the investigator must make the measurements close to the subject's face) and, in addition the need for multiple follow-up visits/exams which may expose the subject to other patients and/or healthcare professionals who might be transmitting the virus, even if they do not have symptoms.
- Potential disruptions to the study may be necessary due to current or future pandemic-related emergency restrictions, which may lead to delays in scheduled follow-up visits.
- Subjects experiencing an adverse event related to contact lens wear may receive delayed treatment due to COVID-19 restrictions. In this event, all assessments that can be conducted virtually will be completed by the investigator to determine the best course of treatment for the subject, including an unscheduled visit, up to discontinuation from the study, as appropriate.

If a study subject is found to have contracted COVID-19 during participation in a study, he/she will be discontinued from the study and followed until COVID-19 Adverse Event (AE) resolution.

To help minimize the above potential risks, JJVCI recommend reviewing/complying with local, state, and governmental guidance for COVID-19 risks.

JJVCI will provide the following study specific documents with language pertaining to COVID-19 risks:

4.1.1 Informed Consent**:**

Will include information concerning the study-associated risks related to the COVID-19 pandemic in bold font and/or boxed on the first page of the Informed Consent document:

STUDY ASSOCIATED RISKS RELATED TO COVID-19 (CORONAVIRUS) PANDEMIC

It is important to note that this study will be conducted, at least in part, during the COVID-19 pandemic. As such, additional risks associated with the infection with COVID-19 exist for you. This is particularly important for this study due, in part, to the closeness of the doctor during the study examinations.

The potential effects of the disease are not fully known, at this time, and may include long-term serious health consequences. In severe cases, this may result in hospitalization and/or death. Based on current knowledge from the Center for Disease Control (CDC), those at high-risk for severe illness from COVID-19 include older adults and people with underlying medical conditions.

During this study, all appropriate measures will be taken to minimize risks including the use of personal protective equipment such as masks and gloves, as well as proper sanitization. This is in conformance to guidance from the CDC, local health departments, and the state and county in which the study doctor's office is located. However, these measures may not completely eliminate the risks associated with contracting COVID-19.

If you are found to have contracted COVID-19 or feel ill with flu-like symptoms during participation in the study, you will not be permitted to continue in-office study follow-up visits but you will receive instructions and your condition will be monitored by the doctor and/or study staff.

4.1.2 COVID-19 Risk Control Checklist:

Will include COVID-19 risk control methods that are required by a site to conduct JJVCI clinical studies. The risk controls are consistent with CDC, AOA, AAO Guidance. The Principle Investigator will review/sign the study specific checklist prior to the Site Initiation Meeting.

Study Number
Site Number
Principal Investigator (PI) Name

The following COVID-19 risk control methods are required to conduct Johnson & Johnson Vison Care clinical studies. Please review the following requirements and Initial each requirement.

PI Initials	General Site Safety Planning Measures
	Signage within site describing Risk Control methods
	Social Distancing practices throughout site (waiting rooms, lobby, exam rooms, etc.)
	Non-contact thermometer available to assess temperatures of staff and patients
	Training on patient flow and physical distancing in waiting room
	Establish longer time frame between patient appointments to reduce persons in the site
	Staff should receive job-specific training on PPE and demonstrate competency with selection and proper use of PPE and wear at all times during interactions with subjects (e.g., putting on and removing without self-contamination)

PI Initials	Site Staff Daily Safety Measures
	As part of routine practice, site staff should regularly monitor themselves for fever and symptoms of COVID-19, including temperature checks
	Any staff member (including Investigators) showing signs of being sick or testing positive for COVID-19 should not be permitted to work and the Sponsor shall be informed **NOTE: Inform JJVC in 24 hours of any significant impact to the study.**
	Ensure that all staff wear a mask

	Gloves should be required when working directly with patients and changed between each patient
	Have staff thoroughly wash hands for at least 20 seconds or use an alcohol-based hand sanitizer when they arrive, before and after each patient, before eating and after using the bathroom.
	Cleaning and disinfection procedures for exam rooms and instruments or equipment between patients with gloves.
	Cleaning and disinfection procedures for commonly touched surfaces (doors, chairs, computers, phones, etc.) with gloves.

PI Initials	Before a Patient or Study Visit:
	Patients should be asked prior to entering the site about fever and respiratory illness and whether they or a family member have had contact with another person with confirmed COVID-19 in the past 2 to 14 days. Patients exhibiting signs of being sick should be rescheduled when their symptoms resolve.
	Instruct patients that companions should remain outside of the facility and not accompany the patient into the facility unless they are a parent/guardian of the patient or if they are a true caregiver and need to assist the patient
	Request the patient to call or text the office upon arrival so entrance to and movement through facility can be coordinated by site staff

PI Initials	Patients Entering the site:
	Temperature checks utilizing a non-contact thermometer for all patients and companions entering the site
	All patients and companions must wear cloth or disposable mask at all times in the site
	Maintain social distancing. Waiting rooms or lobbies should be as empty as possible. Advise seated patients to remain at least 6 feet from one another.
	Communal objects in (e.g. toys, reading materials, etc.) should be removed or cleaned regularly.

I certify that I have read and agree to implement all the listed COVID-19 Risk Control Measures required for the conduct of Johnson & Johnson Vision Care studies.

Principal Investigator Signature and Date

RESOURCE LINKS

- OSHA Training
  https://www.osha.gov/SLTC/covid-19/controlprevention.html

  Personal Protective Equipment (PPE) Training
  CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html

- I&R Training
  ACUVUE® LensAssist: https://www.acuvue.com/lensassist

- Clinic Preparedness Guides
  CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinic-preparedness html
  AOA: https://aoa.uberflip.com/i/1240437-aoa-guidance-for-re-opening-practices-covid·19/1?m4=
  American Optometric Association: https://www.aoa.org/optometry-practice-reactivation-preparedness-guide

- ln-Office Disinfection of Multi-Patient Use Diagnostic Contact Lenses
  https://www.gpli.info/wp-content/uploads/2020/03/2020-01-15-in-office-disinfecting-of-diagnostic-lenses.pdf

4.1.3 Protocol Compliance Investigator(s) Signature Page:

Will include a statement indicating that the Principal Investigator (PI) agrees to conduct the study in compliance with all local, state, and governmental guidance's for COVID-19 risk mitigation.

I have read the suggested guidance provided by JJVCI pertaining to the COVID-19 risk mitigation, (COVID-19 Work Instruction in the Appendix of this protocol). I agree to conduct this study in compliance with local, state, governmental guidance for COVID-19 risks.

4.1.4 Study Site Initiation Training Slides:

Will include suggestions to help mitigate potential transmission of COVID-19. Suggestions may include maintaining social distancing in the clinical site by staggered scheduling of study patients, wearing proper PPEs, frequent disinfection, and installing shields on the slit lamp and other applicable equipment.

5.0 GUIDANCE FOR REMOTE SUBJECT VISITS

Potential disruptions to the study may be necessary due to current or future pandemic-related emergency restrictions. Possible disruption of the study as a result of COVID-19 control measures may lead to delays in scheduled follow-up visits.

Subjects may be delayed in being seen for study follow up visit(s), for example due to COVID-19 control measures or due to the subject's concerns or fears about COVID-19 risk. When appropriate, the remote assessment will be conducted to the extent possible. Discussions with the subject during remote assessments may include:

Procedure	Details
Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire regarding the test article when applicable and feasible.
Change of Medical History (Adverse Events) and Concomitant Medications / Therapies Review	Record any adverse events or medical history changes from the previous study visit with the subject/parents. Review the subject's concomitant medications/therapies and record any changes from the previous study visit.
Wearing Time and Compliance	Record the average wearing time (including number of hours per day during weekdays and weekends, and number of days per week). Confirm compliance with the prescribed wear schedule. • Record and discuss the lens wear compliance based on the subject's self-report. For example, the subjects will be asked the time of the day the subject typically puts on the study lenses in the morning and takes off in the evening, the number of days per week lenses were worn, and the number of consecutive days the subject didn't wear the study lenses, etc.

The discussion with the subject will be documented in EDC under Tele-Visit and a minor protocol deviation will be noted. If during the telephone consultation, a subject states he/she wishes to discontinue participating in the study, instruct the subject to stop wearing the study lenses and schedule the subject to return to the clinic for a Final Evaluation at the at earliest possible time. Subjects should return all unused lenses to the clinic at the last visit.

Changes in study visit schedules, missed visits, or participant discontinuations may lead to missing data, including data related to protocol-specified procedures. Case report forms should capture specific information regarding the basis of missing data, including the relationship to the COVID-19 pandemic.

6.0 STUDY CONDUCT DURING PANDEMIC

It is recognized that the Coronavirus Disease 2019 (COVID-19) pandemic may have an impact on the conduct of this clinical study due to, for example, self-isolation/quarantine by participants and study-site personnel; travel restrictions/limited access to public places, including Optometry Clinics; and changes in clinic procedures required to address the COVID-19 challenge.

Every effort should be made to adhere to protocol-specified assessments for study participants, including follow-up. However, if scheduled visits cannot be conducted in person at the study site it is suggested that assessments be performed to the extent possible remotely/virtually or delayed until such time that on-site visits can be resumed in order to continue participant monitoring in accordance with the protocol where possible. At each contact, participants will be interviewed to collect safety data. Key efficacy endpoint assessments should be performed if required and as feasible.

Modifications to protocol-required assessments may be permitted via COVID-19 Appendix after consultation with the participant, investigator, and the sponsor. Missed assessments/visits will be captured in the clinical trial management system for protocol deviations. Interruptions of test article wear or discontinuations of study interventions and withdrawal from the study should be documented with the prefix "COVID-19-related" in the case report form (CRF).

The sponsor will continue to monitor the conduct and progress of the clinical study, and any changes will be communicated to the sites and to the health authorities according to local guidance.

If a participant has tested positive for COVID-19, the investigator should contact the sponsor's responsible medical monitor to discuss initial plans for study intervention and follow-up. The medical monitor will notify the Safety Management Team of any subject(s) that have reported "COVID-19", "Asymptomatic COVID-19", or "Suspected COVID-19" adverse events within 24 hours of the notification.

Modifications made to the study conduct as a result of the COVID-19 pandemic will be summarized in the clinical study report.

COVID-19 screening procedures that may be mandated by local healthcare systems do not need to be reported as an amendment to the protocol even if done during clinical study visits.

6.1 Monitoring Visits

When on-site monitoring by the sponsor is not feasible, the sponsor's site monitor will contact the study site to schedule remote visits. In such cases, on-site monitoring visits will resume when feasible, with increased frequency to address the source data verification backlog.

Even with staffing limitations during this COVID-19 pandemic, all routine operations related to clinical trials should be well-documented and archived as part of standard process. When conditions permit, all parties involved in this clinical trial should communicate relevant information in a timely manner so that all relevant parties remain sufficiently informed.

6.1.1 Study Site Initiation:

During the period that this Work Instruction is in effect, Site Initiation Meetings and training of study site staff will be conducted remotely. The JJVCI study team will conduct training via Skype, Zoom, Microsoft Teams or similar software as well as utilize online training materials, as applicable. Study site training will be documented utilizing Site Initiation Report (Form Control No. **VCT-0063**) per Study Site Initiation (Form Control No. **VCCL-0002**).

On-site visits may be considered when, for example, hands-on training or evaluation of site facilities is required. While on site, the Clinical Research Associate (CRA) will follow all local, state, and governmental policies for COVID-19 Risk Mitigation, including social distancing, wearing of PPE, etc. as applicable for the location of the study site.

6.1.2 Interim Monitoring Visits (if applicable):

During the period that this Work Instruction is in effect, Interim Monitoring On-site visits will be kept to a minimum and include only those tasks that the CRA cannot perform remotely (e.g., source document verification, test article reconciliation, etc.).

To ensure data integrity during the conduct of all JJVC studies, clinical study teams will follow the study specific Clinical Monitoring Plan (Form Control No. **VCT-0026**).

While on site, the CRA will follow all local, state, and governmental policies for COVID-19 Risk Mitigation, including social distancing, wearing of PPE, etc. as applicable for the location of the study site.

6.1.3 Study Site Closure:

During the period that this Work Instruction is in effect, the duration of the Study Site Closure Visit will be limited to tasks that the CRA cannot perform remotely (e.g., source document verification, test article final reconciliation and return, etc.).

Attachment A: Study Site Correspondence

XXXX XX, 2020

Re: COVID-19 Mitigation Plan, <<CR-xxxx/protocol title>>

Dear <<Principle Investigator>> and Study Team,

Coronavirus (COVID-19) has impacted several communities and business activities over the past several months. While we work toward the successful conduct of clinical studies, our commitment continues to be the safety of patients, healthcare professionals, and to our communities.

Therefore, we would like to share the following revisions/additions related to the above referenced Johnson & Johnson Vision Care company sponsored clinical trial(s) you are currently working on or considering participation within.

Protocol:

- Guidelines for COVID-19 Risk Mitigation provided in the Appendix section.

Protocol Signature Page:

- Will include a statement indicating the Principle Investigator agrees to conduct the study in compliance with all local, state, and governmental guidelines for COVID-19 risk mitigation.

Informed Consent:

- Will include information concerning the study-associated risks related to the COVID-19 pandemic in bold font and/or boxed on the first page of the Informed consent document.

COVID-19 Risk Control Checklist for Clinical Studies:

- Will include COVID-19 risk control measures that are required to ensure the safety and health of subjects, site staff and monitors during the pandemic.

We want to encourage the need for open lines of communication about potential challenges you may foresee as the result of the current COVID-19 situation. Therefore, we encourage you to regularly connect with your respective Johnson & Johnson clinical study team (Clinical Research Associate (CRA), Lead CRA or Study Managers).

Thank you for your continued engagement, collaboration, and dedication to your study subjects during this challenging time.

Please file this letter in your site file study correspondence.

PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: CR-6400 Protocol Title: Clinical Evaluation of a Daily Wear Reusable Multifocal Optical Design in a Presbyopic Population

Version and Date: 4.0 06 August 2020

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

I agree to conduct this study according to ISO 14155,[1] GCP and ICH guidelines,[2] the Declaration of Helsinki,[3] United States (US) Code of Federal Regulations (CFR),[4] and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. The Principal Investigator is responsible for ensuring that all clinical site personnel, including Sub-Investigators adhere to all ICH[2] regulations and GCP guidelines regarding clinical trials during and after study completion.

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

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

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

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

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

I have read the suggested guidance provided by JJVCI pertaining to the COVID-19 risk mitigation, (COVID-19 Work Instruction in the Appendix of this protocol). I agree to conduct the study in compliance with all local, state, and governmental guidelines for COVID-19 risk mitigation.

Principal Investigator:

_____ _____
Signature Date

_____
Name and Professional Position (Printed)

Institution/Site: _____
Institution/Site Name

_____ _____
Institution/Site Address