Clinical Study Protocol
Johnson & Johnson Vision Care, Inc.

Protocol Title
Evaluating visual acuity and initial fit performance of two soft contact lenses

Protocol CR-6441

Version: 2.0

Date: 06 May 2021

Investigational Products:
Daily disposable soft contact lenses made in senofilcon A material.
Test Lens: EMO-200
Control Lens: EMO-118

Key Words: myopia, soft contact lens, non-dispensing, daily wear, daily disposable, senofilcon A, logMAR visual acuity, lens fit, pediatric population

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

Confidentiality Statement:

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PROTOCOL TITLE, NUMBER, VERSION

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SPONSOR NAME AND ADDRESS

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

MEDICAL MONITOR

[redacted]

[redacted]

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

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

AUTHORIZED SIGNATURES

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

Author/Study Responsible Clinician	**See Electronic Signature Report** [redacted]	DATE
Clinical Operations Manager	**See Electronic Signature Report** [redacted]	DATE
Biostatistician	**See Electronic Signature Report** [redacted]	DATE
Data Management	**See Electronic Signature Report** [redacted]	DATE
Medical Safety Officer	**See Electronic Signature Report** [redacted]	DATE
Reviewer – Fellow	**See Electronic Signature Report** [redacted]	DATE

Reviewer – Biostatistician	**See Electronic Signature Report** [redacted]	DATE
Approver	**See Electronic Signature Report** [redacted]	DATE
Approver	**See Electronic Signature Report** [redacted]	DATE

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Date
1.0	[redacted]	Original Protocol	28 April 2021
2.0	[redacted]	Corrected numbering errors in Section 3.3	06 May 2021

SYNOPSIS

Protocol Title	Evaluating visual acuity and initial fit performance of two soft contact lenses
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Clinical trial phase: confirmatory Design control phase: confirmatory phase, phase 3
Trial Registration	The study will be registered on clinicaltrial.gov by the Sponsor.
Test Article(s)	Investigational Products: • Test: EMO-200 • Control: EMO-118 Both lenses are Daily disposable soft contact lenses (SCL) made in senofilcon A material.
Wear and Replacement Schedules	Wear Schedule: Daily wear Replacement Schedule: Daily disposable This is a non-dispensing study. Subjects will wear both test articles during one visit. The order of contact lens type received will be randomized.
Objectives	To compare visual acuity and lens fit performance of EMO-200 with EMO-118 lens. **Primary Objective:** To demonstrate that visual acuity of EMO-200 lens is non-inferior to EMO-118 lens. **Secondary Objective:** To demonstrate that lens fit performance of EMO-200 lens is non-inferior to EMO-118 lens.
Study Endpoints	**Primary endpoint:** • Monocular distance (4 m) logMAR visual acuity under bright lighting conditions with a high luminance, high contrast chart (bright HLHC), measured per [redacted] and [redacted] **Secondary endpoints:** • Lens fit acceptance, measured per [redacted] **Other endpoints:** • Monocular distance (4 m) logMAR visual acuity under dim lighting conditions with a low luminance, high contrast chart (dim LLHC), measured per [redacted] and [redacted] • Monocular distance (4 m) logMAR visual acuity under bright lighting conditions with a high luminance, low contrast chart (bright HLLC), measured per [redacted] and [redacted]

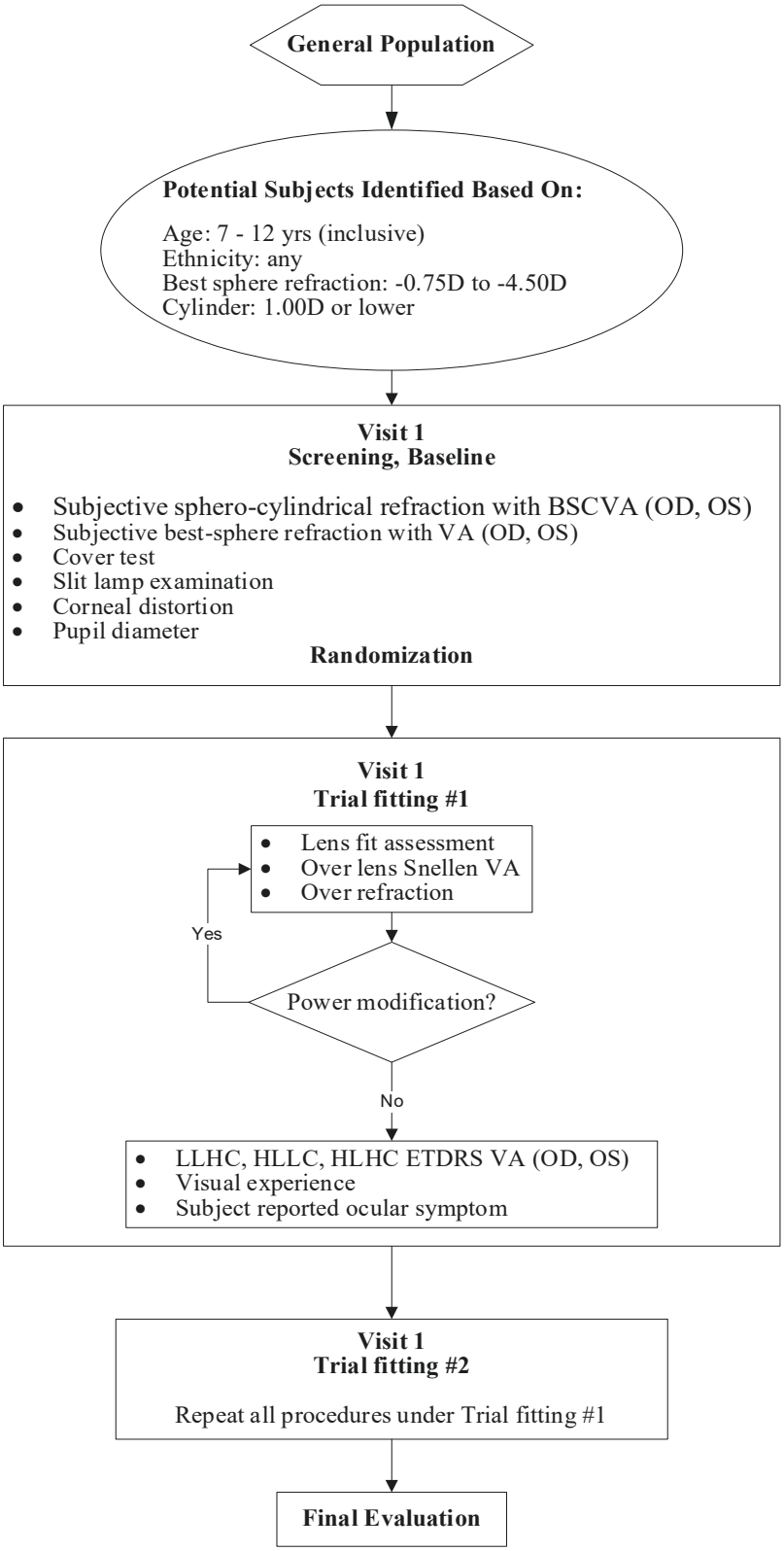
	• Lens centration and movement characteristics, measured per [redacted] • Slit lamp findings, measured per [redacted] • Subject reported ocular symptoms, measured per [redacted] • Pupil diameter (mm), measured per [redacted]
Study Design	This is a multi-center, randomized, controlled, double-masked, 2x2 cross-over, non-dispensing study. Each subject will be bilaterally fitted with one of the two test articles in each of the two periods during a single visit, which includes: Visit 1: Subject screening, baseline evaluation, randomization, lens fit #1 and #2, and final evaluation See the flow chart at the end of the synopsis table for the schematic of the study visits and procedures of main observations (Figure 1).
Sample Size	Approximately 67 subjects will be enrolled in the study with a minimum of 56 subjects targeted to complete the study.
Study Duration	The total duration of the study (anticipated first subject first visit and last subject last visit) is maximal 10 weeks, including up to 10 weeks of enrollment period.
Anticipated Study Population	Healthy male and female children between 7 and 12 years of age (inclusive) with non-vertex corrected best sphere refraction between -0.75 D and -4.50 D (inclusive), with 1.00 D or less astigmatism in each eye. Potential subjects can be spectacle lens wearers, current soft lens wearers, or symptomatic myopes (e.g., with complaints of blurry vision) currently without correction. There are no restrictions as to race/ethnicity of the subject.
Eligibility Criteria – Inclusion	Potential subjects must satisfy all of the following criteria to be enrolled in the study: **Inclusion Criteria following Screening:** The subject must: 1. The subject's parents or legal guardians must read, understand, and sign the STATEMENT OF INFORMED CONSENT (Parental Permission Form and Authorization to Use and Disclose Medical Information). The subject must read (or be read to) and sign the CHILDREN'S ASSENT (Information and Assent Form) and receive a fully executed copy of the form. 2. Appear able and willing to adhere to the instructions set forth in this clinical protocol. 3. Between 7 and 12 (inclusive) years of age at the time of screening. 4. Have normal eyes (i.e., no ocular medications or infections of any type). **Inclusion Criteria following Baseline Evaluation:**

	5. Have non-vertex corrected subjective spherical distance refraction in the range of -0.75 D to -4.50 D (inclusive) in each eye. 6. Have refractive cylinder in the range of 0.00 D to -1.00 D (inclusive) in each eye with any degree of axis, by subjective sphero-cylindrical refraction. 7. Have sphero-cylindrical best-corrected visual acuity of 0.04 logMAR ($20/20^{-2}$) or better in each eye, and the difference of sphero-cylindrical best-corrected visual acuity between the two eyes is less than 0.20 logMAR (2 lines). 8. Have < 1.50 D difference in subjective best-sphere refraction between the two eyes.
Eligibility Criteria – Exclusion	Potential subjects who meet any of the following criteria will be excluded from participating in the study: **Exclusion Criteria following Screening:** The subject must not: 1. Currently pregnant or lactating. 2. Have any systemic disease (e.g., Sjögren's Syndrome), allergies, infectious disease (e.g., hepatitis, tuberculosis), contagious immunosuppressive diseases (e.g., HIV), autoimmune disease (e.g., rheumatoid arthritis), any underlying medical condition that makes subjects at risk of severe COVID complications, or other diseases, by parent of legal guardian's self-report, which are known to interfere with contact lens wear and/or participation in the study. 3. Use of systemic medications (e.g., chronic steroid use) that are known to interfere with contact lens wear and/or participation in the study. See section 9 for additional details regarding excluded systemic medications. 4. Any current use of ocular medication (occasional use of re-wetting drops is allowed). 5. Any previous or planned (during the course of the study) ocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.). 6. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment. 7. Current or recent (within 60 days from enrollment) wear of orthokeratology lenses. 8. Current or recent (within 30 days from enrollment) rigid lens wearers. 9. Immediate family member of an employee of clinical site (e.g., Investigator, Coordinator, Technician).

	10. Children who are wards of the State or any other agency, institution, or entity. **Exclusion Criteria following Baseline:** 11. Any ocular allergies, infections or other ocular abnormalities that are known to interfere with contact lens wear and/or participation in the study. This may include, but not be limited to entropion, ectropion, extrusions, chalazia, recurrent styes, ocular hypertension, glaucoma, history of recurrent corneal erosions, aphakia, uveitis, severe keratoconjunctivitis sicca, keratoconus, keratoconus suspect, and pellucid marginal degeneration. 12. Grade 3 or greater palpebral conjunctival observations or any other Grade 2 or greater slit lamp findings (e.g., edema, corneal neovascularization, corneal staining, conjunctival injection) on the ISO 11980 classification scale. 13. Any previous history or signs of a contact lens-related corneal inflammatory event (e.g., past peripheral ulcer or round peripheral scar), or any other ocular abnormality that may contraindicate contact lens wear or subjects' participation in the study. 14. Any central corneal scar. 15. Any corneal distortion resulting from ocular diseases or previous hard or rigid gas permeable contact lens wear. 16. Binocular vision abnormality, intermittent strabismus or strabismus. 17. Pupil diameter under bright illumination is less than 2 mm in either eye.
Disallowed Medications/Interventions	Disallowed medications for this study include: Any medication and therapies that would normally contraindicate contact lens wear or have ocular side effects that would affect vision assessment. Concomitant therapies that are disallowed include: 1. Contact lens corneal reshaping/CRT/orthokeratology 2. Any vision training/vision therapy/orthoptics/patching 3. Any therapies that the investigator feels would be contraindicated in contact lens wear or would affect vision assessment. See section 9.1 for details regarding disallowed systemic medications.
Measurements and Procedures	• ETDRS logMAR distance visual acuity under dim LLHC, bright HLLC and bright HLHC conditions (OD, OS) • Subjective lens fit assessment (OD, OS) • Pupil diameter (OD, OS) • Subject's reported ocular symptoms (OD, OS)

	• Slit lamp examination per the ISO 11980 grading scale (OD, OS)
Microbiology or Other Laboratory Testing	None.
Study Termination	The occurrence of an Unanticipated Adverse Device Effect (UADE) or Serious Adverse Event (SAE) for which a causal relationship to a test article cannot be ruled out, will result in stopping further fitting 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	• Precision Vision® distance (4-meter) high (Charts 1 – 4) and low (Chart 1 and 2) contrast ETDRS logMAR visual acuity charts. • Precision Vision® LED Illuminator Cabinet • Precision Vision® large mesopic filter for ETDRS Illuminator Cabinet • Sekonic light meter • Eye-Cept® Rewetting Drops by Optics® Laboratories • Fluorescein GloStrips® 0.6 mg or equivalent
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
AL	Axial Length
BCVA	Best Corrected Visual Acuity
BSCVA	Best Spectacle Corrected Visual Acuity
CFR	Code of Federal Regulations
COM	Clinical Operations Manager
CRA	Clinical Research Associate
CRF	Case Report Form
CI	Confidence Interval
CLWT	Cumulative Lens Wear Time
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
LSM	Least-square mean
MedDRA©	Medical Dictionary for Regulatory Activities
MK	Microbial Keratitis
MOP	Manual of Procedures
MPMVA	Maximum Plus to Maximum Visual Acuity
NIH	National Institutes of Health
OD	Right Eye
OHRP	Office for Human Research Protections
OHSR	Office for Human Subjects Research
OS	Left Eye

OU	Both Eyes
PD	Protocol Deviation
PHI	Protected Health Information
PI	Principal Investigator
PIG	Patient Instruction Guide
PQC	Product Quality Complaint
PRO	Patient Reported Outcome
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SECAR	Spherical Equivalent Cycloplegic Auto Refraction
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 Care (JJVC) has developed a soft contact lens prototype (EMO-118) for the purpose of controlling myopia progression in pediatric populations. A six-month dispensing clinical trial ([redacted]) was conducted, which indicated that EMO-118 lens was efficacious in slowing myopia progression in children between 7 and 12 years of age after 6 months of wear. [5] The EMO-118 lens is further evaluated in a longer-term, pivotal study ([redacted]) for the purpose of demonstrating the safety and efficacy of the lens meeting specific requirements from heath authorities. [redacted] study is currently on-going.

The EMO-200 lens is a "re-design" of EMO-118 for supporting market launch. Both EMO-118 and EMO-200 lenses have the same geometry and optical design, and are in the same senofilcon A material. The "re-design" was driven by upgrades to the lens design system to enable metrology of the complex optics on the lens plastic molds. In other words, the EMO-118 lens design was "re-generated" using the upgraded lens design system and was given a new lens design code of EMO-200. As documented in [redacted], the two lens designs are equivalent. Based on the thorough comparison between the EMO-118 and EMO-200 lenses with considerations of equivalency of lens design, product specifications, test methods, raw materials, and/or manufacturing process, it is determined that it is prudent to confirm the clinical performance of the EMO-200 lens in a sample of pediatric patients that the lens is intended to be used.

The purpose of the study is to demonstrate that the redesigned EMO-200 lens is non-inferior to the EMO-118 with regards to visual performance and lens fit acceptance. These two endpoints are selected as surrogate assessments of the optics introduced to the eye that drives myopia control.

1.1. Name and Descriptions of Investigational Products

The two investigative lenses of the study are EMO-200 (Test lens) and EMO-118 (Control lens). Both the Test and Control lenses are made of the same materials using the same manufacturing process as the ACUVUE OASYS® Brand Contact Lenses with HydraLuxe™ Technology (cleared by FDA under K042275). Both lenses have the same optical design intended for controlling the progression of myopia through introducing relative plus powers to the lens, and both lenses have the same diameter and base curve. As specified in the technical report ([redacted]), the two lens designs are equivalent. Further details about the test articles are found in Section 6 of this protocol.

1.2. Intended Use of Investigational Products

The intended use of the investigational soft contact lenses (Test: EMO-200, Control: EMO-118) is for correcting myopia and slowing axial elongation and myopia progression in children. Both lenses are intended to be worn in daily disposable modality. During this study, each subject will wear both test articles once within one study visit (one lens type in each of the two periods). Each lens type will be worn by the subject binocular for up to 2 hours. This is a non-dispensing study; no study lenses will be dispensed to the subjects to take home to wear.

1.3. Summary of Findings from Nonclinical Studies

All previous pre-clinical findings were deemed satisfactory prior to proceeding with clinical trials on humans. For the most comprehensive nonclinical information regarding the investigational lens refer to the latest version of the Investigator's Brochure for EMO Design Family Lenses.[6]

1.4. Summary of Known Risks and Benefits to Human Subjects

The benefit of controlling myopia progression is considered to be substantial[7] as the prevalence of myopia has been increasing over the past few decades.[8-10] Because myopia increases the risk of diseases such as cataract, glaucoma, peripheral retinal degeneration, retinal detachment, and myopic macular degeneration,[11] myopia is likely to become a leading cause of permanent sight-loss.[12-14] Research has shown that early onset of myopia and moderate amount of myopia at young age are risk factors for future high degrees of myopia,[15] while "slowing myopia by 1 diopter should reduce the likelihood of a patient developing myopic macular degeneration by 40%".[16] As such, it can be considered most advantageous to control the progression of myopia and start treatment at an early age when myopia is at a low level.[17]

The risks associated with the wear of contact lenses for myopia control include 1) contact lens risks in the general population; 2) contact lens risks in a pediatric population; and 3) risks specifically associated with EMO family of lenses, such as potential sub-optimal visual performance and long-term physiological and/or neurological impact.

Assessments regarding contact lens risks in general and in the pediatric population concluded that the risks associated with the EMO investigational lenses are expected to be the same as those normally attributed to the wear of soft hydrophilic contact lenses on a daily wear basis. The daily disposable modality of the investigational lenses further reduces risks associated with lens care and the use of care products (e.g., cleaning, disinfecting, rinsing and storage, etc.). Anticipated adverse reactions with these lenses are the same as any other soft contact lens as listed in this study protocol Section 13.1. In addition, the most recent review of the safety of contact lens wear in children concluded that "the incidence of corneal infiltrative events in children is no higher than in adults, and in the youngest age range of 8 to 11 years, it may be markedly lower".[18] In addition, in all JJVC-sponsored prospective, pediatric soft contact lens trials for myopia control to date, which involves 920 patient-years of daily disposable soft contact lens wear in children (aged 7 – 15 years at baseline), there have been no serious or significant ocular adverse events (AE) reported.[5,19] The rates of contact lens related non-significant ocular AEs were found to be consistent with those reported in the literature and are similar to, if not less than, the rate for adults, supporting the conclusion that children can safely wear daily disposable soft contact lenses.

Due to the unique optical design of the EMO lenses, visual performance of these lenses may not be equivalent to that of lenses with a conventional spherical lens design. To manage the risk, special attention will be paid to visual acuity, visual complaints (e.g., blurry vision or

visual artifacts such as ghosting or haloes, etc.), and subjective visual acceptance while fitting the study lenses. In addition, the study lens power may be modified based on visual acuity and refraction over the study lens. There has been no evidence in the literature suggesting any long-term physiological or neurological risks associated with children being exposed to chronic myopic defocus (e.g., due to under correction) or to multi-focal optical interventions. For example, there have been no reports of loss of best corrected visual acuity in published pediatric clinical trials utilizing various methods for myopia control purposes or in any prior JJVC conducted myopia control trials.[5,20-26] Because the current study is a non-dispensing study and the maximum lens exposure time for each subject is 4 hours in total, contact lens risks in pediatric population and potential long-term physiological/neurological impact are not applicable.

Given the infrequency of adverse events in soft contact lens wearing children and the non-serious nature of the vast majority of these events versus the potential benefit from slowing the progression of myopia, it is proposed that the benefits of slowing myopia progression outweigh the risks associated with daily disposable soft contact lens wear in children. This assessment is supported by Gifford et al., who compared the absolute lifetime risk of vision impairment from myopia to the childhood and lifetime risks of contact lens wear for myopia control. The authors concluded that "The comparative lifetime risks of contact lens wear commenced at age 8 for myopia control are less than the lifetime risks of vision impairment with myopia more than 6D or axial length more than 26 mm. When only childhood CL wear is considered, the risk comparison is clearly skewed towards the positive impact of CL wear, especially in daily disposable wear."[27]

For the most comprehensive risk and benefit information regarding the EMO lenses refer to the latest version of the Investigator's Brochure for EMO Design Family Lenses.[6]

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

The review of the scientific literature examined the current state of published information of contact lens safety and myopia control with soft contact lenses. Potential applicable literature was identified through a literature search on PubMed.org dated since 1980's, as well as through examination of review articles published on the subject. A list of relevant literature references is provided in latest version of the Investigator's Brochure for EMO Design Family Lenses.[6]

To date, there have been five clinical studies involving the EMO-118 lens [redacted] were both non-dispensing pilot studies with a primary objective of evaluating the visual performances of EMO lens design prototypes with [redacted] being conducted in an adult population and [redacted] in a pediatric population. [redacted] was a non-dispensing study including pediatric and your adult subjects for assessing the accommodative response with multiple designs of EMO lenses including EMO-118. [redacted] (on-going) were myopia control clinical trials in 7-12 years old children with the EMO-118 lens dispensed for wear for 6-month and at a

minimum, 3 years, respectively. For detailed information regarding prior clinical data refer to the latest version of the Investigator's Brochure for EMO Design Family Lenses.[6]

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

To compare visual acuity and lens fit performance of EMO-200 with EMO-118 lens.

Primary Objective:
To demonstrate that visual acuity of EMO-200 lens is non-inferior to EMO-118 lens.

Secondary Objective:
To demonstrate that lens fit performance of EMO-200 lens is non-inferior to EMO-118 lens.

2.2. Endpoints

Primary endpoint:

- Monocular distance (4 m) logMAR visual acuity under bright lighting conditions with a high luminance, high contrast chart (bright HLHC), measured per [redacted]

  Monocular distance logMAR visual acuity under bright HLHC conditions will be collected post-lens fitting for each subject eye using the Precision Vision 4-meter high contrast ETDRS charts. One measurement per eye (OD and OS) will be collected. See Sections 7.2 and Appendix D for details regarding primary endpoint data collection.

Secondary endpoints:

- Lens fit acceptance, measured per [redacted]

  Lens fit acceptance will be assessed post lens fitting for each subject eye. Acceptable fit is a binary response where Y=1 if lens fit is deemed acceptable by the investigator and Y=0 otherwise. An unacceptable fit is deemed by one of the following criteria:
  - limbal exposure at primary gaze or with extreme eye movement;
  - edge lift;
  - excessive movement in primary and up gaze; or
  - insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up.

  See Sections 7.2 and Appendix D for details regarding secondary endpoint data collection.

Other endpoints:

- Monocular distance (4 m) logMAR visual acuity under dim lighting conditions with a low luminance, high contrast chart (dim LLHC), measured per [redacted]
- Monocular distance (4 m) logMAR visual acuity under bright lighting conditions with a high luminance, low contrast chart (bright HLLC), measured per [redacted]
- Lens centration and movement characteristics, measured per [redacted]
- Slit lamp findings, measured per [redacted]
- Subject reported ocular symptoms, measured per [redacted]
  Pupil diameter (mm), measured per [redacted]

2.3. Hypotheses

Both the primary and secondary hypotheses must be met in order to satisfy the objective of the study.

Primary Hypothesis:

- After the 10-minute lens settling period, monocular high luminance, high contrast logMAR visual acuity with the Test lens is non-inferior to that of the Control lens with a clinical non-inferiority margin of 0.05 logMAR.

Secondary Hypothesis:

- After the 10-minute lens settling period, the rate of lens fit acceptance with the Test lens is non-inferior to that of the Control lens with a clinical non-inferiority margin of -10%.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

Healthy male and female children between 7 and 12 years of age (inclusive) with non-vertex corrected best sphere refraction between -0.75 D and -4.50 D (inclusive), with 1.00 D or less astigmatism in each eye. Potential subjects can be spectacle lens wearers, current soft lens wearers, or symptomatic myopes (e.g., with complaints of blurry vision) currently without correction. There are no restrictions as to race/ethnicity of the subject.

3.2. Inclusion Criteria

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

Inclusion Criteria following Screening:

The subject must:

1. The subject's parents or legal guardians must read, understand, and sign the STATEMENT OF INFORMED CONSENT (Parental Permission Form and Authorization to Use and

Disclose Medical Information). The subject must read (or be read to) and sign the CHILDREN'S ASSENT (Information and Assent Form) and receive a fully executed copy of the form.
2. Appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. Between 7 and 12 (inclusive) years of age at the time of screening.
4. Have normal eyes (i.e., no ocular medications or infections of any type).

Inclusion Criteria following Baseline Evaluation:

5. Have non-vertex corrected subjective spherical distance refraction in the range of -0.75 D to -4.50 D (inclusive) in each eye.
6. Have refractive cylinder in the range of 0.00 D to -1.00 D (inclusive) in each eye with any degree of axis, by subjective sphero-cylindrical refraction.
7. Have sphero-cylindrical best-corrected visual acuity of 0.04 logMAR (20/20-2) or better in each eye, and the difference of sphero-cylindrical best-corrected visual acuity between the two eyes is less than 0.20 logMAR (2 lines).
8. Have < 1.50 D difference in subjective best-sphere refraction between the two eyes.

3.3. Exclusion Criteria

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

Exclusion Criteria following Screening:

The subject must not:

1. Currently pregnant or lactating.
2. Have any systemic disease (e.g., Sjögren's Syndrome), allergies, infectious disease (e.g., hepatitis, tuberculosis), contagious immunosuppressive diseases (e.g., HIV), autoimmune disease (e.g., rheumatoid arthritis), any underlying medical condition that makes subjects at risk of severe COVID complications, or other diseases, by parent of legal guardian's self-report, which are known to interfere with contact lens wear and/or participation in the study.
3. Use of systemic medications (e.g., chronic steroid use) that are known to interfere with contact lens wear and/or participation in the study. See section 9 for additional details regarding excluded systemic medications.
4. Any current use of ocular medication (occasional use of re-wetting drops is allowed).
5. Any previous or planned (during the course of the study) ocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.).
6. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.
7. Current or recent (within 60 days from enrollment) wear of orthokeratology lenses.
8. Current or recent (within 30 days from enrollment) rigid lens wearers.
9. Immediate family member of an employee of clinical site (e.g., Investigator, Coordinator, Technician).
10. Children who are wards of the State or any other agency, institution, or entity.

Exclusion Criteria following Baseline:

11. Any ocular allergies, infections or other ocular abnormalities that are known to interfere with contact lens wear and/or participation in the study. This may include, but not be limited to entropion, ectropion, extrusions, chalazia, recurrent styes, ocular hypertension, glaucoma, history of recurrent corneal erosions, aphakia, uveitis, severe keratoconjunctivitis sicca, keratoconus, keratoconus suspect, and pellucid marginal degeneration.
12. Grade 3 or greater palpebral conjunctival observations or any other Grade 2 or greater slit lamp findings (e.g., edema, corneal neovascularization, corneal staining, conjunctival injection) on the ISO 11980 classification scale.
13. Any previous history or signs of a contact lens-related corneal inflammatory event (e.g., past peripheral ulcer or round peripheral scar), or any other ocular abnormality that may contraindicate contact lens wear or subjects' participation in the study.
14. Any central corneal scar.
15. Any corneal distortion resulting from ocular diseases or previous hard or rigid gas permeable contact lens wear.
16. Binocular vision abnormality, intermittent strabismus or strabismus.
17. Pupil diameter under bright illumination is less than 2 mm in either eye.

3.4. Enrollment Strategy

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

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

This is a multi-center, randomized, controlled, double-masked, 2x2 cross-over, non-dispensing study. Each subject will be bilaterally fitted with one of the two test articles in each of the two periods during a single visit, which includes:

Visit 1: Subject screening, baseline evaluation, randomization, lens fit #1 and #2, and final evaluation

If a subject meets all edibility criteria, then they will be randomized to one of two lens wear sequences. Subjects will be fitted in a bilateral fashion in their first study lens per the randomization scheme. Study assessments will be performed on the first lens. After undergoing all assessments, the first study lens will be removed, and subjects will have a 15-minute washout period prior to be fit with their second lens per the randomization schedule. Study assessments will be conducted while wearing the 2nd study lens and final evaluations will be performed.

Study participants will have no access to test articles at study closure.

4.2. Study Design Rationale

This study is designed as a confirmatory clinical trial to demonstrate that visual acuity and fit acceptance of the EMO-200 lens is non-inferior to those of the EMO-118 lens using a 2×2 crossover design. Crossover designs are a well-established study design in which subjects are exposed to multiple treatments during different time periods. This design is cost effective and more efficient since it eliminates between-subject variability from the treatment comparisons. Subjects will be randomized into the two lens wear sequences: Test/Control or Control/Test. Randomization removes potential for systematic error or bias and balances both the known and unknown confounding factors that may affect the study outcomes. A potential limitation of crossover design is the carry-over effect from the previous treatment. A washout period of 15 minutes with the subjects wearing their habitual correction before proceeding to Treatment 2 Lens Fitting is considered to minimize the presence of any carry-over effect.

Both EMO-200 and EMO-118 lenses have the same optical design intended for myopia control in pediatric populations. They have the same diameter and base cure and are made in the same material. The EMO-200 lens is manufactured in Ireland for supporting commercialization. It is considered a "re-design" of the EMO-118 lens driven by upgrades to the lens design system to enable metrology of the complex optics on the lens plastic molds. Comparing lenses made under the code name of EMO-200 with those made under the code name of EMO-118, thorough assessments from aspects of lens design, product specifications, test methods, raw materials, and manufacturing process, suggest no reason to believe that the clinical performance of the two lenses would be different. The effectiveness of the optical design in myopia correction and slowing axial elongation and refraction change of the eye has been demonstrated in [redacted] with the EMO-118 lens. Any deviation in the EMO-200 lens from the intended optical and/or mechanical designs, which may lead to the lens potentially being less effective, will be manifested as differences in the lens visual performance and or fit performance, compared to the EMO-118 lens. As such, monocular distance visual acuity and lens fit acceptance of the EMO-200 lens are selected to be the primary and secondary endpoints of this investigation as surrogates in place of assessment of the lens long-term myopia control effect. In addition, subject reported ocular symptoms with the study lenses will be collected.

4.3. Enrollment Target and Study Duration

Approximately 67 subjects will be enrolled in the study with a minimum of 56 subjects targeted to complete the study. The point of study enrollment is defined as the execution of the informed consent and assent at Visit 1.

Approximately 4 – 6 clinical sites in the United States will participate in the study. Each site is expected to screen (enroll) up to 17 subjects with a minimum 10 subjects completing the study. Subjects will be enrolled among participating clinical sites to ensure the target number of completed subjects is met.

The total duration of the study enrollment will be approximately 10 weeks, unless otherwise approved by the Sponsor.

There will be one scheduled visit in this study. Eligible subjects will be bilaterally fitted with both test articles within one visit. The total duration of the study is expected to be 12 weeks (including the enrollment period).

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

The study lenses will be worn in a bilateral and random fashion using a 2x2 crossover design with 2 lens types and 2 periods. Two lens types will be fit at one study visit. Using a computer-generated randomization scheme provided by the study biostatistician, each subject will randomly be assigned to one of two unique sequences of the two lens types (Test/Control, or Control/Test).

Permuted block randomization will be used to avoid bias in the assignment of subjects to treatment, and to enhance the validity of statistical comparisons across treatment groups. Each block will contain two different lens trial sequences. The randomization scheme will be generated using the PROC PLAN procedure in Statistical Analysis System (SAS) Software Version 9.4 or higher (SAS Institute, Cary, NC, USA).[32]

The clinical site will follow the randomization scheme provided and will complete enrollment according to the randomization list and will not pre-select or assign subjects.

Randomization shall be performed at Visit 1. The following must have occurred prior to randomization:

- Informed consent must have been obtained.
- The subject must have met all eligibility criteria.
- The subject's screening and baseline information must have been collected.

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

1. Investigator or designee (documented on the Delegation Log) will consult the lens fitting schedule 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 lens fitting schedule.
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.

5.2. Masking

Masking will be used to reduce potential bias. This is a double-masked study where subjects, investigators and clinical site personnel involved in the data collection will be masked to the identity of the assigned study lenses.

5.3. Procedures for Maintaining and Breaking the Masking

Every attempt will be made to keep the clinical trial personnel involved in the study (e.g., Data management, Biostatistician and Clinical Operations) unaware of the identity of the assigned study lenses. The identity of the study lenses will be masked by having the blister packs labeled with the study number, lot number, sphere power, expiration date and the randomization codes. Only the unmasked Biostatistician generating the lens fitting schedule will have access to the decode information that allows matching of the randomization codes to the test articles. The medical monitor will also have access to the decode information in case breaking the mask is necessary for the urgent medical treatment of a subject.

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 before completion of enrollment, with sponsor approval.

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 1: Test Articles

	Test	Control
Design / Description	EMO-200	EMO-118
Manufacturer	JJVC	
Packaging Form	Blister packaging in sterile packing solution	
Packaging Solution	Optimized Borate Buffer (OBB) solution	
[redacted]	[redacted]	[redacted]
Lens Material	Senofilcon A	
Sphere Powers (DS)	-0.75 to -4.75 D in 0.25 D step	
Cylinder Powers (DC)	N/A	
Cylinder Axes (°)	N/A	
ADD Powers (DS)	N/A	

	Test	Control
Nominal Base Curve @ 22 °C	7.9 mm	
Nominal Diameter @ 22 °C	13.8 mm	
Nominal Water Content (%)	38	
Dk (Fatt method, boundary corrected, edge corrected, $\times 10^{-11}$ [cm^2 /sec] [ml O_2/ml × mm Hg] at 35°C)	103	
Wear Schedule in Current Study	Daily wear	
Replacement Frequency	Daily disposable	

Per the study design, each subject will likely use at least one lens (up to 4 lenses) per eye, per each lens type for lens fitting (including lens power modification). Therefore, it is estimated that for each lens type, up to 8 lenses per subject for up to 67 subjects per lens type will be used, which is approximately 536 lenses per each lens type. Each lens type will be worn for up to 2 hours.

6.2. Ancillary Supplies/Products

This is a non-dispensing study with test articles worn during the study visit only. No lens care product will be used. The following solutions will be used in this study as needed:

Table 2: Ancillary Supplies

Solution Name/Description	Eye-Cept® Rewetting Drops
Manufacturer	Optics® Laboratories
Preservative(s)	Preservative free

The following supplies may be provided to the clinical sites as needed:

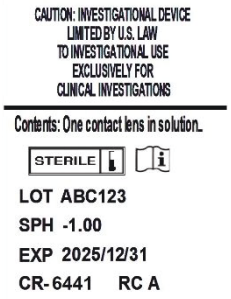
- Precision Vision® distance (4-meter) high (Charts 1 – 4) and low (Chart 1 and 2) contrast ETDRS logMAR visual acuity charts.
- Precision Vision® LED Illuminator Cabinet
- Precision Vision® large mesopic filter for ETDRS Illuminator Cabinet
- Sekonic light meter
- Eye-Cept® Rewetting Drops by Optics® Laboratories
- Fluorescein GloStrips® 0.6 mg or equivalent.

6.3. Administration of Test Articles

Test articles will be fitted to subjects meeting all eligibility requirements during the study visit at the clinical site. No study lenses will be given to subjects to wear out of the office. 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 and investigators to the identity of the lens. The test articles will be in plastic bags as the secondary packaging form. The sample study label is shown below:



6.5. Storage Conditions

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

6.6. Collection and Storage of Samples

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;
2. The number and reason for unplanned replacements.

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

[redacted]

7. STUDY EVALUATIONS

7.1. Time and Event Schedule

Table 3: Time and Events

Visit Information	Visit 1 Screening, Baseline, Len Fitting #1 and #2
Time Point	Day 0
Estimated Visit Duration	3 hours
Statement of Informed Consent and Assent	x
Demographics	x
Medical History/Concomitant Medications	x
Inclusion/Exclusion Criteria	x
Subjective Sphero-Cylindrical Refraction with Best-corrected Distance Visual Acuity	x
Subjective Best-sphere Refraction	x
Subjective Best-sphere Over-refraction	x
Slit Lamp Classification	x
Cover Test	x
Screen for Corneal Distortion	x
Pupil Diameter	x
Lens Assignment	x
Lens Insertion & Settling	x
Lens Fit Assessment	x
Lens-on-Eye Snellen Visual Acuity	x
Lens Power Modification (if applicable)	x
Monocular ETDRS logMAR Distance VA (LLHC, HLLC, and HLHC)	x
Instruct for Vision Experience	x
Subject Reported Ocular Symptoms	x
Habitual Correction Removal and Insertion (if applicable)	x
Study Completion (Final Evaluation)	x

7.2. Detailed Study Procedures

VISIT 1

Subjects should report to the initial visits wearing their habitual correction

Note: verify and document appropriate room and acuity chart lighting levels [redacted] before the visit.

Visit 1: Screening			
Step	Procedure	Details	[redacted]
1.1	Statement of Informed Consent & Children's Assent	Each subject's parent or legal guardian must read, understand, and sign the Statement of Informed Consent (Parental Permission Form and Authorization to Use and Disclose Medical Information), and each subject must read (or be read to), understand and sign the Information and Assent Form before the subject is enrolled into the study. The Principal Investigator or his/her designee conducting the informed consent discussion must also sign the Consent and Assent forms. **Note**: The subject and parent (legal guardian) must be provided a signed copy of both documents.	
1.2	Demographics	Record the subject's year of birth, age, gender, race and ethnicity.	
1.3	Medical History and Concomitant Medications	Questions regarding the subjects' medical history and concomitant medications.	
1.4	Eligibility Following 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. **Note**: If subject is deemed to be ineligible after screening, proceed to Final Evaluation and complete Subject Disposition. Refraction and Biomicroscopy forms are not required.	
1.5	Habitual Contact Lens Removal (if applicable)	If the subject wears habitual soft contact lens to the visit, instruct the subject to remove own lenses and store them temporarily in a lens case (provided by the investigator) with saline.	

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.6	Subjective Sphero-cylindrical Refraction	The investigator will complete subjective (sphero-cylindrical) refraction and record the resultant distance visual acuity (OD and OS) to the nearest letter.	[redacted]
1.7	Subjective Best Sphere Refraction	Perform subjective best sphere refraction with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the resultant distance visual acuity (OD, OS) to the nearest letter. **Note**: The endpoint criterion for the duo-chrome test is the lens power at which the red and green sides of the chart appear to be equally distinct. However, if the subject's response changes from "red" to "green" with only a 0.25 D 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.	[redacted]
1.8	Cover Test	Perform distance and near cover-uncover test to rule out the presence of strabismus.	[redacted]
1.9	Slit Lamp Findings	Slit Lamp Classification Scale per ISO 11980 will be used to grade the findings. **Note**: Except for subjects with Grade 2 palpebral conjunctival observations that are eligible to be enrolled, if any other slit lamp finding (per ISO 11980) is graded as 2 or worse, the subject may not continue at this time, but may return up to one additional time to determine eligibility. If the subject is discontinued from the study, Final Evaluation must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
1.10	Screen for Corneal Distortion	Examine the keratometer mires or corneal topography Placido ring pattern to rule out corneal distortion.	
1.11	Pupil Diameter	Measure pupil diameter under the following two lighting conditions:	[redacted]

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
		• dim illumination (1.4-1.6 lux, or -0.8--0.6 EV), 4 meters away from a low luminance (2.5-2.8 cd/m^2, or 4.3-4.5 EV), high contrast chart (LLHC, with a mesopic filter); • bright illumination (686-788 lux, or 8.1-8.3 EV), 4 meters away from a high luminance (181-208 cd/m^2, or 10.5-10.7 EV), high contrast chart (HLHC). One measurement per eye, per condition. **Note**: Subjects with pupil diameter less than 2mm under the biring illumination in either eye will be discontinued from the study.	
1.12	Eligibility Following Baseline Evaluation	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. **Note**: If subject is deemed to be ineligible after baseline, proceed to Final Evaluation and complete Subject Disposition. Refraction and Biomicroscopy forms do not need to be completed as part of Final Evaluation.	

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
1.13	Lens Selection	Assign the study lens based on the lens fitting schedule. Record the randomization ID. Select the contact lens power based on subjective best sphere refraction.	
1.14	Lens Insertion	The investigator or the subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable. Ensure the subject is given a Patient Instruction Guide.	

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
1.15	Lens Settling	Allow the study lenses to settle for a minimum of 10 minutes.	
1.16	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement; • edge lift; • excessive movement in primary and up gaze; or • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up. **Note**: if lens fit is unacceptable, the subject will skip Steps 1.17 to 1.22, and proceed with Step 1.23 and Treatment 2 Lens Fitting. The subject will be discontinued after Subjective Lens Fit Assessment for the Treatment 2 has been completed.	[redacted]
1.17	Over the Lens Distance Snellen VA	Record the subject's distance visual acuity to the nearest letter with the study lenses (OD, OS).	[redacted]
1.18	Subjective Best-Sphere Over-refraction	Perform subjective best-sphere refraction over the study lenses with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the best corrected distance visual acuity to the nearest letter (OD and OS). **Note**: The endpoint criterion for the duo-chrome test is the lens power at which the red and green sides of the chart appear to be equally distinct. However, 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.	[redacted]

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
1.19	Lens Power Modification (if applicable)	The subject's best sphere over-refraction **cannot** be positive (>0.00 D) or, in the case of a myopic over-refraction, it **cannot** be -0.50 D or higher (≤-0.50 D). Adjust the study contact lens power when necessary based on the following rules: 1. If subject's best sphere over-refraction is positive, re-refract the subject and adjust the lens power accordingly. 2. If the subject's best sphere over-refraction is plano, continue with the study without lens power modification, regardless of subject's distance VA. 3. If subject's best sphere over-refraction is -0.25 D and distance VA without over refraction is 20/25 (0.10 logMAR) or better, continue with the study without lens power modification. 4. If the subject's spherical over-refraction is -0.25 D and distance visual acuity without over-refraction is worse than 20/25 (0.10 logMAR), and distance visual acuity is 3 or more letters better with over refraction than without over refraction, increase the lens power by -0.25 D and refit the subject to achieve either 20/25 (0.10 logMAR) or better distance VA without over refraction or plano over refraction. 5. If subject's best sphere over-refraction is -0.50 D or more, increase the lens power by -0.25 D each step until the subject's best sphere over refraction is -0.25 D or plano based on the above lens power modification rule #2 - #4. For each study contact lens power modification, record lens information and repeat steps 1.14 – 1.19. Up to three power modifications are allowed.	
1.20	Distance ETDRS LogMAR Visual Acuity	Perform monocular distance ETDRS LogMAR visual acuity test at a 4-meter distance with the subject wearing the study lenses under the following conditions:	[redacted]

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
		1. dim illumination (1.4-1.6 lux, or -0.8--0.6 EV), low luminance (2.5-2.8 cd/m^2, or 4.3-4.5 EV), with high contrast charts (LLHC); 2. bright illumination (686-788 lux, or 8.1-8.3 EV), high luminance (181-208 cd/m^2, or 10.5-10.7 EV) with low contrast charts (HLLC); 3. bright illumination (686-788 lux, or 8.1-8.3 EV), high luminance (181-208 cd/m^2, or 10.5-10.7 EV) with high contrast charts (HLHC); The Precision Vision 4-meter high (Charts 1 – 4) and low contrast (Chart 1 and 2) ETDRS charts will be used. One measurement per condition for OD and OS, respectively.	
1.21	Visual Experience	Encourage the subjects to look at objects at distant and near, and if possible, under bright and dim lighting conditions.	
1.22	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire regarding the study lens.	[redacted]
1.23	Study Contact Lens removal	Subjects remove and discard the study contact lenses.	

Visit 1: Treatment 2 Lens Fitting

Allow 15 minutes of washout period with the subjects wearing their habitual correction before proceeding to Treatment 2 Lens Fitting. If the subject wears habitual soft contact lens to the visit, instruct the subject to remove own lenses and store them temporarily in a lens case (provided by the investigator) with saline before continuing with Treatment 2 Lens Fitting.

Repeat all steps under Treatment 1 Lens Fitting for the second trial lens, per the randomization scheme.

FINAL EVALUATION

The final evaluation will take place immediately following the completion of Visit 1 per the study protocol. It may also take place at any point the subject discontinues the study or is terminated from the study.

In the event of an adverse event, Final Evaluation will be performed after all required follow-up of the adverse event is complete (see Section 13.3 for detailed instructions on follow-up of adverse events).

Final Evaluation			
Step	Procedure	Details	[redacted]
F.1	Final Exam Form	Indicate if the subject completed the study successfully. If subject discontinued from the study, indicate the reason.	
F.2	Exit Refraction	Perform bare-eye subjective spherocylindrical refraction with a phoropter and record the best-corrected distance visual acuity (OD and OS) to the nearest letter. **Note**: This step is not necessary if the subject was exited due to screen failure.	[redacted]
F.3	Exit Slit Lamp Biomicroscopy	Slit Lamp Classification Scale per ISO 11980 will be used to grade the findings. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled. **Note**: This step is not necessary if the subject was exited due to screen failure, or if biomicroscopy was performed as part of the final follow-up visit procedures (i.e., immediately prior to the final evaluation).	[redacted]

7.3. Unscheduled Visits

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

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

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

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

The following information will be collected during an unscheduled visit.

Unscheduled Visit			
Step	Procedure	Details	[redacted]
U.1	Reason for unscheduled visit	Specify the reason for the visit.	
U.2	Chief Complaints	Record the subject's chief complaints for reasons for the unscheduled visit.	
U.3	Adverse Events and Concomitant Medications Review	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	
U.4	Entrance VA	Record the entrance distance visual acuity (OD, OS) to the nearest letter.	[redacted]
U.5	Subjective Sphero-cylindrical Refraction	Perform bare-eye subjective spherocylindrical refraction with a phoropter and record the best-corrected distance visual acuity (OD and OS) to the nearest letter.	[redacted]
U.6	Slit Lamp Biomicroscopy	Slit Lamp Classification Scale per ISO 11980 will be used to grade the findings. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
U.7	Exit Visual Acuity	Record the subject's exit distance visual acuity (OD, OS) to the nearest letter.	[redacted]

7.4. Laboratory Procedures

Not Applicable.

8. SUBJECTS COMPLETION/WITHDRAWAL

8.1. Completion Criteria

Subjects are considered to have completed the study if they:

- provided informed consent;
- are eligible;
- completed the study visit.

8.2. Withdrawal/Discontinuation from the Study

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

- Subject withdrawal of consent.
- Subject not compliant to protocol (e.g., refusing any protocol specified procedure)
- Subject no longer meets eligibility criteria (e.g. the subject becomes pregnant).
- Subject develops significant or serious adverse events, and unable to complete the scheduled visit.
- Subjects who have experienced a Corneal Infiltrative Event (CIE).
- Investigator's clinical judgment regarding the subject safety reasons (that it is in the best interest of the subject to stop treatment).

For discontinued subjects, the Investigator will:

- Complete the current visit (scheduled or unscheduled).
- Complete the Final Evaluation, indicating the reason that the subject was discontinued from the study.
- Record the spherocylindrical refraction with best corrected distance visual acuity.
- Collect used test article(s) (worn during the visit) from the subject and discard them, unless otherwise stated in section 7.2.
- Make arrangements for subject care, if needed, due to their study participation

Additional subjects will be enrolled if a subject discontinues from the study prematurely.

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

9. PRE-STUDY AND CONCOMITANT INTERVENTION/MEDICATION

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

Disallowed medications for this study include:
Any medication and therapies that would normally contraindicate contact lens wear or have ocular side effects that would affect vision assessment.

Concomitant therapies that are disallowed include:

1. Contact lens corneal reshaping/CRT/orthokeratology
2. Any vision training/vision therapy/orthoptics/patching
3. Any therapies that the investigator feels would be contraindicated in contact lens wear or would affect vision assessment.

9.1. Systemic Medications

Certain systemic medications are known to have a higher likelihood to interfere with contact lens wear, chiefly by disrupting the tear film.

A summary of disallowed systemic medications that are typically disallowed in a contact lens research is shown in Table 4. This is especially relevant to subjects with a history of taking medications listed in Table 4 on a long-term, routine basis, but have only used these medications for less than 6 months. However, because this is a one-visit, non-dispensing study, and the subject will only wear the study lenses for up to 4 hours in the investigator's office, subjects with a history of taking these medications will be allowed to enroll only if:

- The medications have been taken on a continual, routine basis for at least 6 months (2 weeks for antihistamines), and
- The subject has demonstrated successful contact lens wear while taking the medication.

Or:

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

Or:

- The subject is a neophyte. Based on the investigator's assessment, the use of these medications will not interfere with the subject's participation in the study or with the assessment of vision and lens fit.

Table 4: Potential Disallowed Systemic Medications

Class of Drug	Common Indication(s)	Common Examples
Estrogens (not including contraceptive medication)	Menopause, osteoporosis, vaginitis	Vagifem, Estrace, Climara, Vivelle-Dot, Premarin, Minivelle, etc.
Antihistamines	Allergic rhinitis, sedation, hives, allergic conjunctivitis, skin allergy, itching, motion sickness	Hydroxyzine, Promethagan, Phenadoz, Vistaril, Claritin, Zyrtec, Astepro, Astelin, Optivar, Allegra, Benedryl, etc.
Anticholinergics	Irritable bowel syndrome, Parkinson's disease, peptic ulcer, cystitis, nasal congestion, cold symptoms, overactive bladder, COPD	Bentyl, Spiriva, Atrovent, Hyosyne, Levsin, Symax Fastab, Symax SL, Homax SL, Cogentin, Transderm Scop, etc.
Beta-blockers	Hypertension, angina, heart attack, migraine, artrial fibrillation, andrenal cancer, essential tumor, glaucoma	Toprol XL, Lopressor, Tenormin, Propranolol, Timoptic, Trandate, Inderal LA, etc.

Class of Drug	Common Indication(s)	Common Examples
Psychotropics	Antipsychotic (schizophrenia, mania), antidepression, antiobsessive, antianxiety, mood stabilizer, stimulants (ADHD)	Zoloft, Celexa, Prozac, Lexapro, Effexor, Cymbalta, Ativan, Xanax, Desyrel, Wellbutrin, etc.
Vitamin A analogs	Cystic acne	Isotretinoin
Human growth hormone products	Short stature of unknown cause as well as poor growth due to a number of medical causes	Genotropin, Nutropin, Saizen, etc.

10. DEVIATIONS FROM THE PROTOCOL

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

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

If the deviation potentially impacts the safety of patient or changes the technical integrity of the study, then it must be reported to IEC/IRB. This is a "Major Deviation". Deviations that contradict the information contained in the Informed Consent/Assent forms will be considered Major Deviations. Minor deviations have no substantive effect on patient safety or technical integrity of the study. They are often logistical in nature. Protocol waivers are prohibited.Table 5 lists examples of deviations that will constitute major and minor protocol deviations for this study.

Table 5: Examples of major and minor protocol deviations

Deviation category	**Major deviation**	**Minor deviation**
Informed Consent/Assent	All deviations related to Informed Consent and Assent other than those specified as minor deviations.	Principal Investigator signed in incorrect place/incorrect time on ICF
Eligibility	Study lenses are fitted to ineligible subjects.	Ineligible subjects are enrolled but are not fitted with study lenses.

Deviation category	Major deviation	Minor deviation
Testing conditions	Mis-randomization	Study procedures are conducted in an order that is different from that specified in the protocol.
Testing procedures	Study procedures related to primary and secondary endpoint assessments are not completed per the protocol specifications.	Other study procedures (not related to primary and secondary endpoint assessments) are not completed per the protocol specifications.
Unanswered PRO questions	N/A	Any number of un-answered PRO questions.

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 apply and will be executed in parallel.

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

13. ADVERSE EVENTS

13.1. Definitions and Classifications

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

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

1. Was not present prior to the study, but appeared or reappeared following initiation of the study.
2. Was present prior to the study but worsened during the study. This would include any condition resulting from concomitant illnesses, reactions to concomitant medications, or progression of disease states.

Note: Pregnancy must be documented as an adverse event and must be reported to the clinical monitor and to the Sponsor immediately upon learning of the event.

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

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

Per ISO 11980, Serious adverse events are those events that result in, or have potential to cause, either permanent impairment of an ocular function or damage to an ocular structure, and may necessitate medical or surgical intervention.

Serious adverse events may include any hazardous, sight-threatening conditions occurring after exposure to test article, including but not limited to the following.

a) A presumed infectious ulcer (defined as a progressive erosion of the corneal tissue). Signs may include irregular focal infiltrates (> 1 mm); active lesions with raised edges; significant diffuse infiltration; anterior corneal to mid-stromal involvement; erosion

with overlying staining; conjunctival and lid edema; anterior chamber reaction (iritis); severe bulbar and limbal redness. Symptoms associated with a presumed infectious ulcer (microbial keratitis) may include pain of rapid onset; severe redness; purulent or mucopurulent discharge; tearing; photophobia. For the purposes of reporting, a corneal ulcer which has *any* of the following characteristics should be considered in this category:

1) central or paracentral location;
2) penetration of Bowman's membrane;
3) infiltrate > 2 mm diameter;
4) associated with iritis ≥ grade 2;
5) associated with any increase in intraocular pressure;
6) culture positive for microorganisms;
7) increasing size or severity at subsequent visits.

b) Any central or paracentral corneal event (such as vascularization) that results in permanent opacification.
c) Any serious adverse ophthalmic events including hypopyon and hyphema.
d) Any neovascularization within the central 6 mm of the cornea.
e) The loss of two or more lines of visual acuity that fail to resolve.
f) All cases of iritis.

Diagnoses and conditions that are considered Ocular Serious Adverse Events that may occur during this study 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 or require medical treatment to maintain normal ocular health.

Per ISO 11980, significant but non-serious adverse events should include, but not be limited to:

– peripheral non-progressive non-infectious ulcers;
– all symptomatic corneal infiltrative events;

- all cases of corneal staining greater than or equal to grade 3;
- a temporary loss of two or more lines of best corrected visual acuity (for greater than or equal to 2 weeks);
- cases greater than or equal to grade 2 neovascularization;
- any ocular event that necessitates temporary lens discontinuation of greater than or equal to 2 weeks.

Diagnoses and conditions that are considered Ocular Significant Adverse Events that may occur during the study 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

In addition to above identified serious and significant adverse events, below are examples of other diagnoses and conditions that may occur during the study. The classification of these adverse events should be based on the above-specified definitions.

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

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

Unanticipated Adverse Device Effect (UADE) – A UADE is any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, the test article, if that effect, problem, or death was not previously identified in nature, severity, or

degree of incidence in the investigational plan, Investigator's Brochure or protocol, or any other unanticipated serious problem associated with the test article that relates to the rights, safety and welfare of subjects.

13.2. Assessing Adverse Events

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

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

13.2.1. Causality Assessment

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

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

13.2.2. Severity Assessment

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

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

13.3. Documentation and Follow-Up of Adverse Events

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

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

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

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

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

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

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

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

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

13.4. Reporting Adverse Events

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

13.4.1. Reporting Adverse Events to Sponsor

Serious/Significant Adverse Events

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

subjects experiencing a serious/significant adverse event must be followed up and all outcomes must be reported.

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

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

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

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

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

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

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

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

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

13.5. Events of Special Interest

None identified.

13.6. Reporting of Pregnancy

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

14. STATISTICAL METHODS

This section is a general outline of the statistical methods that will be implemented in this clinical trial. More details will be included in the stand-alone Statistical Analysis Plan (SAP). The standalone SAP will be finalized and signed prior the database lock and unmasking.

14.1. General Considerations

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

All data summaries and statistical analyses will be performed using the SAS software version 9.4 or higher (SAS Institute, Cary, NC, USA).[32] Throughout the analysis of data, the results for each subject/eye will be used when available for summarization and statistical analysis. Unscheduled visits will be summarized separately and will be excluded from the statistical analysis.

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

14.2. Sample Size Justification

This study was designed and powered to demonstrate non-inferiority of the Test lens (EMO-200) compared to the Control lens (EMO-118) with respect to monocular distance logMAR visual acuity under bright HLHC and lens fit acceptance after 10-minute lens settling period. The ample size was calculated for both the primary and secondary endpoints to achieve a minimum statistical power of 80% using a 2-sided type I error of α=0.05 based on historical data from [redacted] was a 2×2 crossover study with two study lenses (EMO-116 and EMO-118). In [redacted] all eyes had acceptable lens fit. Table 6 below presents the descriptive statistics of monocular logMAR visual acuity under bright HLHC at fitting observed from [redacted].

Table 6: Descriptive Summary of Monocular LogMAR Visual Acuity Post Lens-Fitting from [redacted] – Per Protocol Subjects

	EMO-116	EMO-118
Number of eyes	50	50
Mean (SD)	-0.03 (0.098)	0.01 (0.082)

SD = standard deviation

Monocular Distance logMAR Visual Acuity

The sample size estimate for monocular distance logMAR visual acuity was calculated using a linear mixed model-based power analysis method[33]. The model included lens, period, and lens wear sequence as fixed effects. An unstructured (UN) covariance matrix was used to model the residual errors between measurements within the same subject and eye across study periods. It was assumed there was no difference between the Test and Control lenses since the two study lenses have not been evaluated in the same study previously. Sample size estimation was carried out using an approximation of the power of an F-test derived from the non-centrality parameter calculated from the observed F statistic of the linear mixed model. Below is the variance-covariance matrix used in the sample size calculation for monocular logMAR visual acuity.

Subject intercept: 0.003087

The UN covariance matrix: $\begin{bmatrix} 0.004953 & -0.00076 \\ -0.00076 & 0.005157 \end{bmatrix}$

Lens Fit Acceptance

Acceptable lens fit is a binary response as $Y = 1$ if a subject eye has an acceptable fit and $Y = 0$ otherwise. Indicated by the historical data from [redacted] there was no unacceptable lens fitting for both study lenses. Assuming no difference between study lenses and a correlation of 0.80 between left and right eyes within the same subject and period; and a correlation of 0.50 between measurements within the same subject across periods, a total of 2000 replicating trials were simulated with a reference (Control lens) rate of 95% (worse-case scenario) for lens fit acceptance. Given the rare event binary outcome of fit acceptance (i.e., the number of unacceptable fit is very small), each replicated sample was analyzed using a Bayesian beta-binomial model with correlated binary data (Diniza et al; 2010).[34] Sample size was estimated to achieve a minimal statistical power of 80% with a non-inferiority margin of -10% (Test – Control). Table 7 summarizes the required number of subjects for each of the primary and secondary endpoints to achieve a minimum of 80% statistical power with a 2-sided type I error of 0.05.

Table 7: Sample Size and Power for the Primary and Secondary Endpoints

Endpoints	Test/Margin	Sample size	Power
Monocular LogMAR VA	Non-inferiority (0.05)	28	92%

Lens Fit Acceptance	Non-inferiority (-10%)	56	81%

As indicated in Table 7 above, the sample size chosen for this study was primarily driven by lens fit acceptance in order to achieve a statistical power of at least 80% for both primary and secondary endpoints. The plan is to enroll approximately 67 subjects with a target of 56 to complete the study.

14.3. Analysis Populations

The following analysis populations will be defined and used in the analysis and presentation of the data.

All Enrolled:
All Enrolled Population includes all subjects with recorded data in the electronic Case Report Form (eCRF) database.

Intent-To-Treat (ITT):
Intent-to-treat will include all the subjects who were randomized to study treatment. Subjects will be analyzed as per randomized treatment. At least one observation should be recorded. Subjects with major protocol deviations, including, but not limited to non-compliant to protocol specified lens wear time requirements, ineligible subjects who were inadvertently randomized and primary endpoint measurements collected without or with non-valid device verifications, etc., will be included in the ITT analyses.

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 for safety endpoints should be recorded (e.g., ocular symptom, slit-lamp finding, etc.) on or after treatment start date. Subjects will be analyzed as per treatment received.

Per Protocol (PP)
All subjects who have completed the study and did not substantially deviate from the protocol as determined by the trial cohort review committee prior to database hard lock. Justification of excluding subjects with protocol deviations in the per-protocol population set will be documented in a memo to file. See Section 10 for definition and examples of major deviations.

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

Non-inferiority of Test compared to Control with respect to the primary endpoint of monocular logMAR visual acuity will be assessed on the Per-protocol population (PP).

Monocular Distance logMAR Visual Acuity (VA)

Monocular distance logMAR VA under bright HLHC will be analyzed using a linear mixed model to compare the Test and Control lenses after a 10-minute lens setting period. The model will include lens type, lens sequence, and period as fixed effects. Other subject characteristics such as age, gender and race will be included as fixed covariates when appropriate. Site and subject will be included in the model as random effects (G-side). The covariance of residuals between measurements on the same eye across periods within the same subject (R-side) will be modeled using Unstructured (UN) covariance structure. If the model does not converge, then other covariance structures, such as compound Symmetry (CS) covariance structure, will be considered. The Kenward and Roger method (Kenward & Roger, 1997)[35] will be used for the denominator degree of freedom.

Hypothesis Testing

The null and alternative hypotheses for testing non-inferiority of the Test lens relative to the Control lens with respect to logMAR visual acuity are as follows:

$$H_0\colon\ \mu_T - \mu_C \geq 0.05$$
$$H_A\colon \mu_T - \mu_C < 0.05$$

Where, μ_T represents the mean logMAR VA score for the Test lens and μ_c represents the mean logMAR VA score for the Control lens. Non-inferiority will be declared if the upper bound of the 2-sided 95% confidence interval of the difference (Test – Control) is less than 0.05.

14.6. Secondary Analysis

Non-inferiority of Test compared to Control with respect to the secondary endpoint of lens fit acceptance will be assessed on the safety population.

Let Y_1 and Y_2 denote the binary outcomes of lens fit acceptance (Yes/No) in left and right eyes, respectively, when wearing a study lens. Considering the correlation, ρ, between Y_1 and Y_2, the distribution of the sum $Y = Y_1 + Y_2$ is obtained by the mixture of two variables. One of them follow a binomial distribution $Bin(2,p)$ with mixing probability $(1-\rho)$ 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 ρ:

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

where $I_{A1} = \{0,1,2\}$, $I_{A2} = \{0,2\}$ and p is the probability of success (i.e., acceptable lens fitting).

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,

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

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

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

The probability p links to the regression covariates through a logit transformation as follow:

$$\text{logit}(p) = \beta_0 + \beta_1 \text{lens} + \delta + \gamma$$

It is assumed that β_0, β_1 and ρ to be independent with a non-informative prior N(0,1000) for β_0 and β_1, and beta(0.5,0.5) for ρ. δ and γ are the subject-specific and site-specific random effects, respectively. We assume random subject effects are independent and identically distributed as $\delta \sim N(0, \sigma^2_{subj})$ and random site effects are independent and identically distributed as $\gamma \sim N(0, \sigma^2_{site})$. For the variances of random subject and site effects, an independent non-informative conjugate prior inverse-gamma(0.001, 0.001) will be used. The Metropolis sampler algorithm as implemented in the SAS/STAT MCMC Procedure (SAS Institute Inc., 2015)[36] will be used to estimate the posterior distributions of the parameters (β_0, β_1, ρ). Inferences will be made based on a posterior credible interval for the relevant parameters.

Hypothesis Testing

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

$$H_0: p_T - p_C \leq -0.1$$
$$H_1: p_T - p_C > -0.1,$$

where p_T and p_C are the probability of success (i.e., acceptable lens fitting) for Test lens and Control lens, respectively. Non-inferiority will be declared if the posterior probability $p(p_T - p_C > -0.1 | \text{data}) \geq .975$.

In the case of all eyes have an acceptable lens fit (i.e., zero unacceptable lens fit), a Bayesian hierarchical model accounting for zero event problem will be considered (Chen & McGee, 2008).[37] Details of this model will be provided in the stand-along SAP.

14.7. Other Analyses

Summary statistical analysis will be provided for the following other observations:

Other endpoints:

- Monocular distance (4 m) logMAR visual acuity under dim lighting conditions with a low luminance, high contrast chart (dim LLHC), measured per [redacted]
- Monocular distance (4 m) logMAR visual acuity under bright lighting conditions with a high luminance, low contrast chart (bright HLLC), measured per [redacted]

- Lens centration and movement characteristics, measured per [redacted]
- Slit lamp findings, measured per [redacted]
- Subject reported ocular symptoms, measured per [redacted]
- Pupil diameter (mm)

Further exploratory analysis will be considered if necessary, at discretion of the Study Responsible Clinician.

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.

14.10. Procedure for Reporting Deviations from Statistical Plan

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

15. DATA HANDLING AND RECORD KEEPING/ARCHIVING

15.1. Electronic Case Report Form/Data Collection

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

External 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 into the eCRF. 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 record for the purposes of monitoring and auditing the study.

Edit checks, electronic queries, and audit trails are built into the system to ensure accurate and complete data collection. Data will be transmitted from the clinical site to a secure central database as forms are completed or updated, ensuring information accuracy, security, and confidentiality. After the final database lock, the Investigator will be provided with Individual

Patient Profiles (IPP) including the full audit trail on electronic media in PDF format for all of the study data. The IPP must be retained in the study files as a certified copy of the source data for the study.

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

15.2. Subject Record

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

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

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

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

15.3. ClinicalTrials.gov

The study will be registered on clinicaltrial.gov by the Sponsor.

16. DATA MANAGEMENT

16.1. Access to Source Data/Document

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

16.2. Confidentiality of Information

Information concerning the investigational product and patent application processes, scientific data or other pertinent information is confidential and remains the property of JJVC. The

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

16.3. Data Quality Assurance

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

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

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

16.4. Data Monitoring Committee (DMC)

Not applicable.

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 and their parents/legal guardians will be fully informed of the risks and requirements of the study and, during the study, subjects and their parents/legal guardians will be given any new information that may affect their decision to continue participation. Subjects and their parents/legal guardians 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 whose parents are fully able to understand the risks, benefits, and potential adverse events of the study, and provide their consent voluntarily, and subjects who provide their assent will be enrolled.

18.2. Investigator Responsibility

The Principal Investigator is responsible for ensuring that the clinical study is performed in accordance with the signed agreement, the investigational plan, Section 4 of the ICH E6(R2) guidelines on Good Clinical Practice (GCP),[2] and applicable regulatory requirements. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles of the Declaration of Helsinki 64th WMA General Assembly 2013[3] and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with Section 8 of the ICH E6 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):

1. Final protocol.
2. Sponsor-approved informed consent form (and any other written materials to be provided to the subjects)
3. Investigator's Brochure (or equivalent information).
4. Sponsor-approved subject recruitment materials.
5. Information on compensation for study-related injuries or payment to subjects for participation in the study.
6. Investigator's curriculum vitae, clinical licenses, or equivalent information (unless not required, as documented by IEC/IRB).
7. Information regarding funding, name of the Sponsor, institutional affiliations, other potential conflicts of interest, and incentives for subjects.
8. 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 must give written assent and their parents (legal guardians) must give written consent according to local requirements after the nature of the study has been fully explained. The consent and assent forms must be signed before performance of any study-related activity. The consent and assent forms that are used must be approved by both the Sponsor and by the reviewing IEC/IRB. The informed consent and assent are 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 and the parent (legal guardian) the aims, methods, reasonably anticipated benefits, and potential hazards of the study, and any discomfort it may entail. Subjects and their parents (legal guardians) will be informed that their participation is voluntary and that they may withdraw consent to participate at any time.

The subject and parent (legal guardian) will be given sufficient time to read the Information and Assent form and the informed consent form (Parental Permission Form and Authorization to Use and Disclose Medical Information), respectively, and the opportunity to ask questions. After this explanation and before entry into the study, assent and consent should be appropriately recorded by means of the subject's and parent/legal guardian's dated signatures. After having obtained the consent and assent, a copy of the informed consent and assent forms 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,[38] 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 is a multicenter study. The participating institution and Principal Investigations for this study agree that, should this study results be published, the first publication of the results of this study shall be made in conjunction with the presentation of a joint, multicenter publication of the study results with the investigators and the institutions from all appropriate sites contributing data, analyses and comments.

22. REFERENCES

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APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES) AND CONTACT LENS CHECKLIST SPECIFICATIONS

Not Applicable.

APPENDIX B: PATIENT INSTRUCTION GUIDE

This will be provided separately.

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

Not Applicable.

APPENDIX D: [redacted]

- [redacted] Lens Fitting Characteristics
- [redacted] Subject Reported Ocular Symptoms/Problems
- [redacted] Determination of Distance Spherocylindrical Refractive Error
- [redacted] Distance and Near Snellen Visual Acuity Evaluation
- [redacted] Distance LogMAR Visual Acuity Measurement Procedure
- [redacted] Cover-Uncover Test
- [redacted], ISO Biomicroscopy Scale
- [redacted] Measuring Pupil Diameter with NeurOptics VIP-200 Pupillometer and NeurOptics VIP®-300 Pupillometer
- [redacted] Visual Acuity Chart Luminance and Room Illumination Testing

[redacted] LENS FITTING CHARACTERISTICS

[redacted]

[redacted]

[redacted]

[redacted] [redacted]

[redacted]

[redacted]

[redacted] SUBJECT REPORTED OCULAR SYMPTOMS/PROBLEMS

[redacted]

[redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIVE ERROR

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] DISTANCE AND NEAR SNELLEN VISUAL ACUITY EVALUATION

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] DISTANCE LOGMAR VISUAL ACUITY MEASUREMENT PROCEDURE

Title:	**Distance LogMAR Visual Acuity Measurement Procedure**
Document Type:	[redacted]
Document Number:	[redacted] **Revision Number: 4**

[redacted]

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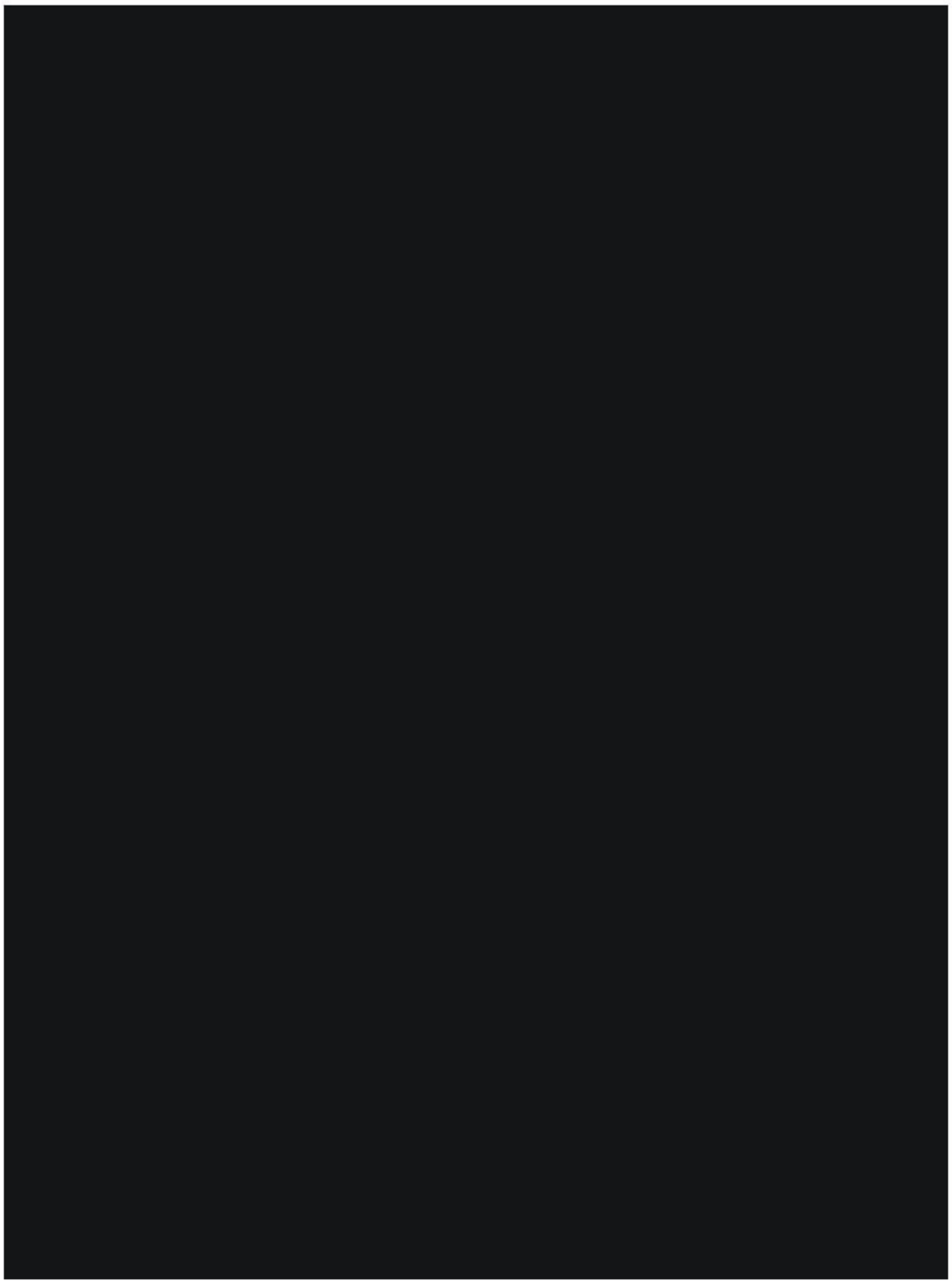

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[redacted] COVER-UNCOVER TEST

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[redacted] ISO BIOMICROSCOPY SCALE

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[redacted] MEASURING PUPIL DIAMETER WITH NEUROPTICS VIP-200 PUPILLOMETER AND NEUROPTICS VIP®-300 PUPILLOMETER

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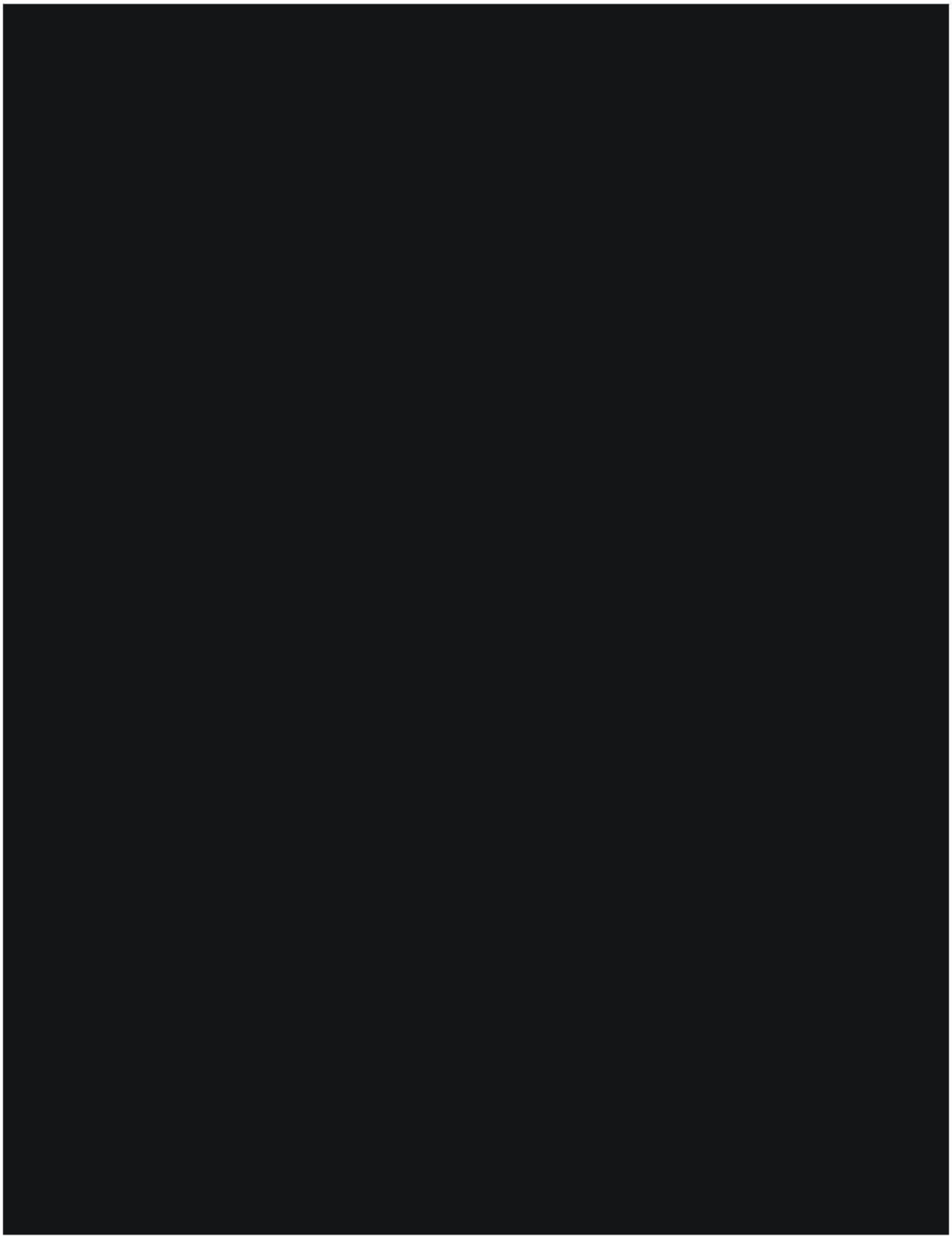

[redacted]

[redacted]

[redacted]VISUAL ACUITY CHART LUMINANCE AND ROOM ILLUMINATION TESTING

[redacted]

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[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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

1.0 PURPOSE

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

2.0 SCOPE

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

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

3.0 DEFINITIONS

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

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

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

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

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

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

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

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

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

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

4.0 GUIDANCE FOR STUDY DOCUMENTS

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

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

4.1 Additional Risks Related to the COVID-19 Pandemic:

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

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

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

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

4.1.1 Informed Consent:

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

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

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

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

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

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

4.1.2 COVID-19 Risk Control Checklist (Attachment-B):

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

4.1.3 Protocol Compliance Investigator(s) Signature Page:

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

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

4.1.4 Study Site Initiation Training Slides:

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

5.0 GUIDANCE FOR REMOTE SUBJECT VISITS

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

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

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

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

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

6.0 STUDY CONDUCT DURING PANDEMIC

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

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

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

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

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

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

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

6.1 Monitoring Visits

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

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

6.1.1 Study Site Initiation:

During the period that this Work Instruction is in effect, Site Initiation Meetings and training of study site staff will be conducted remotely. The JJVCI study team will conduct training via Skype, Zoom, Microsoft Teams or similar software as well as utilize online training materials, as applicable. Study site training will be documented utilizing Site Initiation Report [redacted] per Study Site Initiation [redacted]

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

6.1.2 Interim Monitoring Visits (if applicable):

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

To ensure data integrity during the conduct of all JJVC studies, clinical study teams will follow the study specific Clinical Monitoring Plan [redacted]

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

6.1.3 Study Site Closure:

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

Attachment A: Study Site Correspondence

XXXX XX, 2020

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

Dear <<Principal Investigator>> and Study Team,

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

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

Protocol:

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

Protocol Signature Page:

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

Informed Consent:

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

COVID-19 Risk Control Checklist for Clinical Studies:

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

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

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

Please file this letter in your site file study correspondence.

COVID-19 Risk Control Checklist (Attachment-B):

Study Number
Site Number
Principal Investigator (PI) Name

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

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

PI Initials	Site Staff Daily Safety Measures
	As part of routine practice, site staff should regularly monitor themselves for fever and symptoms of COVID-19, including temperature checks
	Any staff member (including non-study clinic staff and Investigators) showing signs of being sick or testing positive for COVID-19 must not be permitted to work on activity that may expose study related staff and subject and the Sponsor shall be informed **NOTE: Inform JJVC in 24 hours of any COVID-19 cases and all potential exposure during the clinical study.**
	Ensure that all staff wear a mask Gloves should be required when working directly with patients and changed between each patient
	Have staff thoroughly wash hands for at least 20 seconds or use an alcohol-based hand sanitizer when they arrive, before and after each patient, before eating and after using the bathroom.
	Cleaning and disinfection procedures for exam rooms and instruments or equipment between patients with gloves.
	Cleaning and disinfection procedures for commonly touched surfaces (doors, chairs, computers, phones, etc.) with gloves.

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

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

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

Principal Investigator Signature and Date

RESOURCE LINKS

US Resource Links

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

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

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

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

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

OUS Resource Links

- Updates on local regulations in Hong Kong
  https://www.coronavirus.gov hk/eng/index.html

- Resumption of optical services in England: Letter from Matt Neligan and Poonam Sharma
  https://www.england nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/04/C0601-reopening-of-optical-services-letter-17-june-2020.pdf

- NHS Optical Letter
  https://www.england nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/04/C0127-optical-letter-1-april-2020.pdf

- The College of Optometrists primary eye care COVID-19 guidance: Red phase
  https://www.college-optometrists.org/the-college/media-hub/news-listing/coronavirus-covid-19-guidance-for-optometrists.html

- The College of Optometrists COVID-19: College updates
  https://www.college-optometrists.org/the-college/media-hub/news-listing/coronavirus-2019-advice-for-optometrists html#CollegeGuidelines

- Infection Control Guidelines. (n.d.). Retrieved from Canadian Association Of Optometrists: https://opto.ca/sites/default/files/resources/documents/infection_control_guidelines_2016.pdf

- Infection prevention and control for COVID-19: Interim guidance for outpatient and ambulatory care settings. (2020, May 23 May). Retrieved from Government of Canada: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/interim-guidance-outpatient-ambulatory-care-settings html

- Information for Members On Coronavirus (COVID-19). (n.d.). Retrieved from Canadian Association Of Optometrists: https://opto.ca/sites/default/files/resources/documents/information_for_members_on_coronavirus.pdf

- Coronavirus (COVID-19) resources for health professionals, including aged care providers, pathology providers and health care managers. (2020, September 24). Retrieved from Australian Government Department of Health: https://www health.gov.au/resources/collections/coronavirus-covid-19-resources-for-health-professionals-including-aged-care-providers-pathology-providers-and-health-care-managers

- Environmental Cleaning and Disinfection Principles for COVID-19. (n.d.). Retrieved from Australian Government Department of Health: https://www.health.gov.au/sites/default/files/documents/2020/03/environmental-cleaning-and-disinfection-principles-for-covid-19.pdf

- Infection control guidelines and advice. (n.d.). Retrieved from Optometry Australia : https://www.optometry.org.au/practice-professional-support/coronavirus-covid-19-what-optometrists-need-to-know/covid-19-clinical-advice/infection-control-guidelines-and-advice/

PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: CR- 6441 Evaluating visual acuity and initial fit performance of two soft contact lenses

Version and Date: 2.0, 06 May 2021

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

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

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

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

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

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

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

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

Principal Investigator:

_____ _____
Signature Date

_____
Name and Professional Position (Printed)

Institution/Site:

_____
Institution/Site Name

_____
Institution/Site Address