Clinical Study Protocol
Johnson & Johnson Vision Care, Inc.

Protocol Title: Evaluation of Visual Acuity with a Reusable Toric Multifocal Contact Lens

Protocol Number: CR-6383

Version: 4.0

Date: 29 October 2021

Test Articles: Bausch + Lomb Ultra® Multifocal for Astigmatism

Key Words: Presbyopia, Multifocal, Astigmatism, Daily Wear, Dispensing, samfilcon A, logMAR visual acuity

Statement of Compliance to protocol, GCP and applicable regulatory guidelines:
This trial will be conducted in compliance with the protocol, ISO 14155:2020,[1] the International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP),[2] the Declaration of Helsinki,[3] and all applicable regulatory requirements.

Confidentiality Statement:

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PROTOCOL TITLE, NUMBER, VERSION AND DATE

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SPONSOR NAME AND ADDRESS

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

MEDICAL MONITOR

[redacted]

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

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

AUTHORIZED SIGNATURES

The signatures below constitutes the approval of this protocol and the attachments and provide the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations,[4] ICH guidelines,[2] ISO 14155:2020,[1] and the Declaration of Helsinki.[3]

Author	See Electronic Signature Page [redacted]	DATE
Clinical Operations Manager	See Electronic Signature Page [redacted]	DATE
Biostatistician	See Electronic Signature Page [redacted]	DATE
Data Management	See Electronic Signature Page [redacted]	DATE
Medical Safety Officer	See Electronic Signature Page [redacted]	DATE
Approver	See Electronic Signature Page [redacted]	DATE

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Date
1.0	[redacted]	Original Protocol	29-Oct-2019
2.0	[redacted]	• Updated lens powers • Adapted to version 11 of protocol template • Updated disallowed medications • Changed lens care solution • COVID-19 appendix added	28-Jan-2021
3.0	[redacted]	• Updated MRD questions • Updated Snellen visual acuity wording throughout Section 7.2 • Changed criteria for unacceptable toric fit in Section 7.2	28-Apr-2021
4.0	[redacted]	• Updated to v13 of protocol template • Increased cylinder eligibility range • Included luminance range in cd/m^2 and illuminance range in lux for logMAR acuity testing at Visits 3 and 4 • Made Visit 1 biomicroscopy consistent with inclusion criteria • Added updated lens label	29-Oct-2021

SYNOPSIS

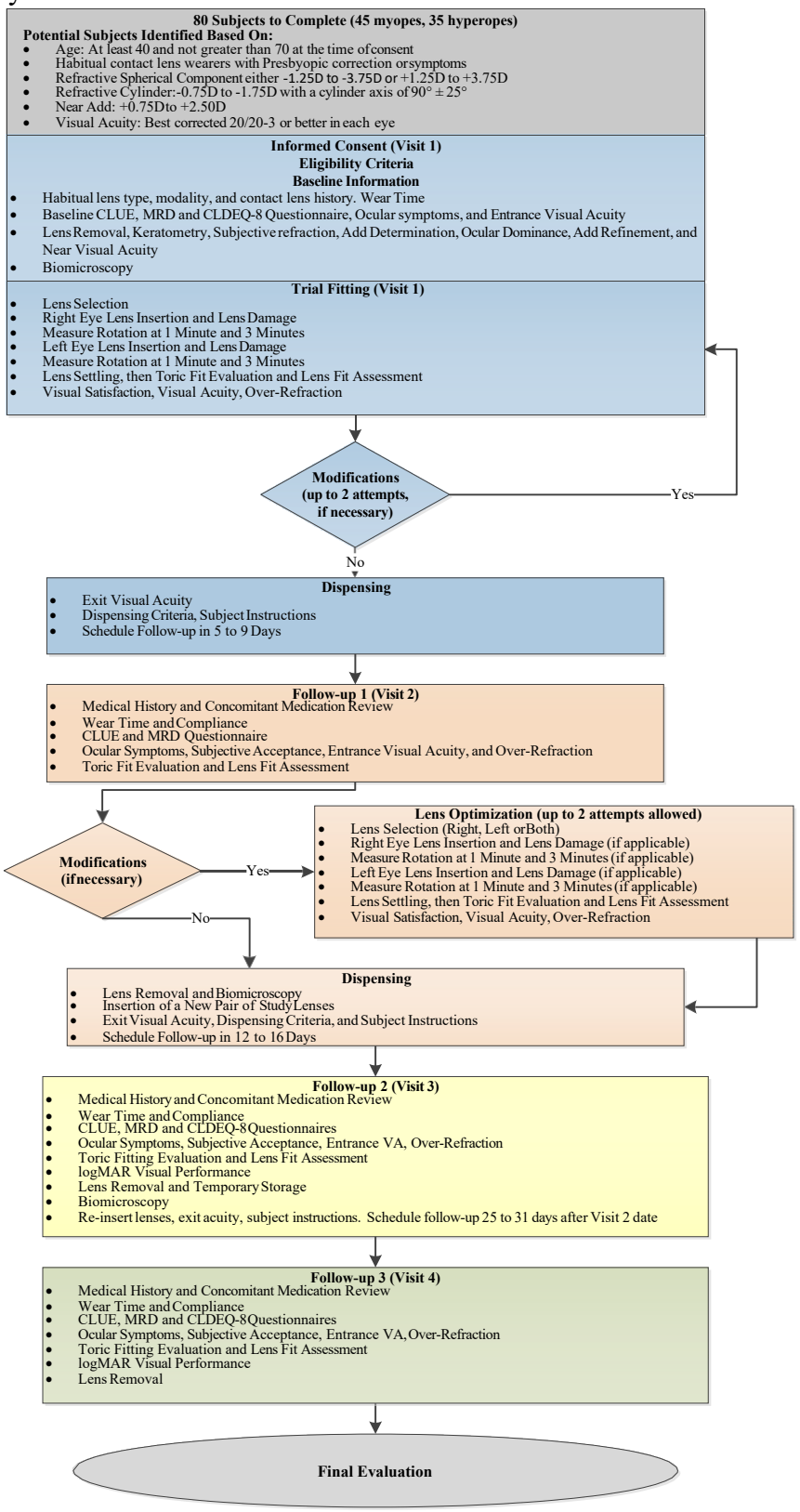
Protocol Title	Evaluation of Visual Acuity with a Reusable Toric Multifocal Contact Lens
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Clinical trial phase: Post-market Design control phase: Not applicable.
Trial Registration	This study will be registered on ClinicalTrials.gov based on the following: The clinical trial is evaluating a U.S. FDA-regulated Device Product
Test Article	Marketed Product: Bausch + Lomb Ultra® Multifocal for Astigmatism contact lens manufactured in samfilcon A material.
Wear and Replacement Schedules	Wear Schedule: The lenses will be used on a daily reusable basis for approximately five weeks (1 week trial followed by 4 week dispense of optimized pair). Replacement Schedule: The lenses will be replaced at the first follow-up visit only.
Objectives	Primary Objective The primary objective of this study is an evaluation of the logMAR visual performance with the study lenses after 4 weeks of wear. Secondary Objective Not applicable. Exploratory Objective Not applicable.
Study Endpoints	Primary endpoints: logMAR visual acuity at distance (4 M), intermediate (64 cm) and near (40 cm).
Study Design	The study is a bilateral, single-masked, single-arm, 4-visit dispensing study. There will be one study treatment, with the subject being in the treatment for approximately five weeks. Approximately 90 eligible subjects will be enrolled, with the aim to complete at least 80 subjects. The subjects will be fit in the study lens and wear the study lenses for 5-9 days then undergo optimization and wear the optimized pair for 4 weeks (25-31 days), with an interim follow-up visit at 2 weeks (12-16 days). The primary endpoint will be logMAR visual performance. 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 50 myopic subjects with against-the-rule astigmatism will be enrolled, with the aim that at least 45 will complete the study. Approximately 40 hyperopic subjects with against-the-rule astigmatism will be enrolled, with the aim that at least 35 will complete the study.
Study Duration	The study will last approximately 2-3 months.
Anticipated Study Population	Healthy male and female volunteers with presbyopia, astigmatism and either myopia or hyperopia will be screened as per criteria outlined below. All volunteers will have baseline measurements taken to ensure eligibility. The baseline procedures will occur after informed consent has been obtained. For a detailed list of procedures see the time and events schedule listed below.
Eligibility Criteria	Potential subjects must satisfy all of the following criteria to be enrolled in the study: Inclusion Criteria following Screening The subject must: 1. Read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form. 2. Appear able and willing to adhere to the instructions set forth in this clinical protocol. 3. Be at least 40 and not more than 70 years of age at the time of screening. 4. Own a wearable pair of spectacles if required for their distance vision. 5. Be an adapted soft contact lens wearer in both eyes (i.e. has worn lenses a minimum of 2 days per week for at least 8 hours per wear day, for the past month). 6. Be an existing wearer of a presbyopic contact lens correction (e.g., reading spectacles over contact lenses, multifocal or monovision contact lenses, etc.) or respond positively to at least one symptom on the “Presbyopic Symptoms Questionnaire”. Inclusion Criteria at Baseline The subject must: 7. Have distance spherical component of refraction in the range of either -1.25 D to -3.75 D or +1.25 to +3.75 D in each eye.

	8. Have refractive cylinder in the range of -0.75 D to -1.75 D in each eye, with their cylinder axis 90°±25°. 9. Have near ADD power requirement in the range of +0.75 D to +2.50 D in each eye. 10. Have best corrected distance visual acuity of 20/20^{-3} or better in each eye. Potential subjects who meet any of the following criteria will be excluded from participating in the study: Exclusion Criteria following Screening The subject must not: 1. Be currently pregnant or lactating. 2. Have any active or ongoing ocular or systemic allergies that may interfere with contact lens wear. 3. Have any active or ongoing systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear. This may include, but not be limited to, diabetes, hyperthyroidism, Sjögren's syndrome, xerophthalmia, acne rosacea, Stevens-Johnson syndrome, and immunosuppressive diseases or any infectious diseases (e.g. hepatitis, tuberculosis). 4. Use systemic medications that may interfere with contact lens wear or cause blurred vision. See section 9.1 for additional details regarding excluded systemic medications. 5. Currently use ocular medication with the exception of rewetting drops. 6. Have any known hypersensitivity or allergic reaction to single use preservative free rewetting drops, sodium fluorescein, or Biotrue® multipurpose solution. 7. Have any previous, or planned, ocular or intraocular surgery (e.g. radial keratotomy, PRK, LASIK, lid procedures, cataract surgery, retinal surgery, etc.). 8. Have a history of amblyopia or strabismus. 9. Have a history of herpetic keratitis. 10. Have a history of irregular cornea. 11. Have a history of pathological dry eye. 12. Have participated in any contact lens or lens care product clinical trial within 14 days prior to study enrollment. 13. Be an employee or immediate family member of an employee of clinical site (e.g., Investigator, Coordinator, Technician). Exclusion Criteria at Baseline

	The subject must not: 14. Have clinically significant (Grade 2 or greater) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities or bulbar injection, or any other corneal or ocular abnormalities which would contraindicate contact lens wear. 15. Have entropion, ectropion, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions. 16. Have any current ocular infection or inflammation. 17. Have any current ocular abnormality that may interfere with contact lens wear
Disallowed Medications/Interventions	Use of any prescription or over-the-counter (OTC) medications that may affect contact lens wear. See section 9.1 for details regarding disallowed systemic medications.
Measurements and Procedures	The key measurements are logMAR visual acuity at distance (4 M), intermediate (64 cm) and near (40 cm) with the study lenses. See Section 7.2 for the detailed procedures.
Microbiology or Other Laboratory Testing	None
Study Termination	The occurrence of one or more Unanticipated Adverse Device Effect (UADE), or any SAE where relationship to study agent cannot be ruled out, may result in stopping further dispensing investigational product. In the event of a UADE or SAE, the Sponsor Medical Monitor may unmask the treatment regimen of subject(s) and may discuss this with the Principal Investigator before any further subjects are enrolled.
Ancillary Supplies/ Study-Specific Materials	Rewetting drops for optional use during lens wear. Biotrue multi-purpose solution for lens care during dispensing period and for worn lens storage. Lens cases will be provided for temporary contact lens storage during study visits and for use during dispensing periods. Stopwatches will be provided to the site for use during visits.
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, ACRONYMS AND DEFINITIONS OF TERMS

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

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

1. INTRODUCTION AND BACKGROUND

Johnson & Johnson Vision launched 1-DAY ACUVUE® MOIST Multifocal in 2015 and ACUVUE® OASYS MULTIFOCAL in 2021. These lenses are recommended for presbyopes who have up to -0.75 D of refractive cylinder. There is a considerable population of presbyopic patients who have greater than -0.75 D of cylinder, in one or both eyes. Currently there are a limited number of soft toric multifocal lenses available. This study will evaluate the visual acuity achieved with one of these marketed lens types (Bausch + Lomb Ultra® Multifocal for Astigmatism).

1.1. Name and Descriptions of Investigational Products

Test Article: Bausch + Lomb Ultra® Multifocal for Astigmatism manufactured in samfilcon A material.
Refer to Table 1: Test Articles in Section 6.1 of the protocol.

1.2. Intended Use of Investigational Products

According to the package insert, the Bausch + Lomb ULTRA® (samfilcon A) Multifocal for Astigmatism Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters (D) and require an add power ranging from +0.75 D to +5.00 D. In this study, a limited range of refractive corrections (spheres, cylinders and axes) will be evaluated (see section 3.2).

1.3. Summary of Findings from Nonclinical Studies

Not applicable for studies of marketed contact lenses.

1.4. Summary of Known Risks and Benefits to Human Subjects

Not applicable for studies of marketed contact lenses.

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

Information about the Bausch + Lomb Ultra® Multifocal for Astigmatism may be found in the package insert (APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT).

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

Primary Objective
The primary objective of this study is to assess the clinical performance of the study lenses with respect to visual acuity (logMAR) after 4-weeks of lens wear.

Secondary Objective
Not applicable.

2.2. Endpoints

Primary Endpoint
Visual Acuity (logMAR)
Multiple assessments of binocular and monocular visual acuity will be made during the study, but the binocular measurements made at the 4-week follow-up evaluation using high contrast letters in bright illuminance conditions will be the primary endpoint. At distance (4 meters), VA is assessed using ETDRS Charts; while near (40 cm) and intermediate (64 cm) assessments will be made using reduced Guillon-Poling charts. Visual acuity will be measured using high and low contrast charts in bright illuminance conditions. Visual acuity will also be measured using high contrast charts in dim illuminance conditions created by the use of goggles. See [redacted] in Appendix G for details regarding the collection of visual acuity (logMAR).

Secondary Endpoint
Not applicable.

Other Exploratory Endpoint
Not applicable.

2.3. Hypotheses

Primary Hypotheses

1. After 25-31 days of wear, the binocular, high-luminance, high-contrast distance (4 M) logMAR visual acuity of the test lens will be statistically better than 0.00 logMAR. This will be determined using ETDRS LogMAR acuity testing charts.

2. After 25-31 days of wear, the binocular, high-luminance, high-contrast intermediate (64 cm) logMAR visual acuity of the test lens will be statistically better than +0.17 logMAR. This will be determined using Guillon/Poling LogMAR acuity testing charts.

3. After 25-31 days of wear, the binocular, high-luminance, high-contrast near (40 cm) logMAR visual acuity of the test lens will be statistically better than +0.17 logMAR. This will be determined using Guillon/Poling LogMAR acuity testing charts.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

The population to be studied will consist of adapted contact lens wearers who have astigmatism in both eyes. Approximately 90 eligible subjects (50 myopes with against-the-rule astigmatism and 40 hyperopes with against-the-rule astigmatism) will be enrolled with at least 80 targeted to complete. Subjects to be enrolled will have -0.75 D to -1.75 D of astigmatism in both eyes with 90°±25° axis.

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. Read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form.
2. Appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. Be at least 40 and not more than 70 years of age at the time of screening.
4. Own a wearable pair of spectacles if required for their distance vision.
5. Be an adapted soft contact lens wearer in both eyes (i.e. has worn lenses a minimum of 2 days per week for at least 8 hours per wear day, for the past month).
6. Be an existing wearer of a presbyopic contact lens correction (e.g., reading spectacles over contact lenses, multifocal or monovision contact lenses, etc.) or respond positively to at least one symptom on the "Presbyopic Symptoms Questionnaire".

Inclusion Criteria at Baseline
The subject must:

7. Have distance spherical component of refraction in the range of either -1.25 D to -3.75 D or +1.25 to +3.75 D in each eye.
8. Have refractive cylinder in the range of -0.75 D to -1.75 D in each eye, with their cylinder axis 90°±25°.
9. Have near ADD power requirement in the range of +0.75 D to +2.50 D in each eye.
10. Have best corrected distance visual acuity of $20/20^{-3}$ or better in each eye.

3.3. Exclusion Criteria

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

Exclusion Criteria following Screening
The subject must not:

1. Be currently pregnant or lactating.
2. Have any active or ongoing ocular or systemic allergies that may interfere with contact lens wear.
3. Have any active or ongoing systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear. This may include, but not be limited to, diabetes, hyperthyroidism, Sjögren's syndrome, xerophthalmia, acne rosacea, Stevens-Johnson syndrome, and immunosuppressive diseases or any infectious diseases (e.g. hepatitis, tuberculosis).
4. Use systemic medications that may interfere with contact lens wear or cause blurred vision. See section 9.1 for additional details regarding excluded systemic medications.
5. Currently use ocular medication with the exception of rewetting drops.

6. Have any known hypersensitivity or allergic reaction to single use preservative free rewetting drops, sodium fluorescein, or Biotrue® multipurpose solution.
7. Have any previous, or planned, ocular or intraocular surgery (e.g. radial keratotomy, PRK, LASIK, lid procedures, cataract surgery, retinal surgery, etc.).
8. Have a history of amblyopia or strabismus.
9. Have a history of herpetic keratitis.
10. Have a history of irregular cornea.
11. Have a history of pathological dry eye.
12. Have participated in any contact lens or lens care product clinical trial within 14 days prior to study enrollment.
13. Be an employee or immediate family member of an employee of clinical site (e.g., Investigator, Coordinator, Technician).

Exclusion Criteria at Baseline
The subject must not:

14. Have clinically significant (Grade 2 or greater) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities or bulbar injection, or any other corneal or ocular abnormalities which would contraindicate contact lens wear.
15. Have entropion, ectropion, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions.
16. Have any current ocular infection or inflammation.
17. Have any current ocular abnormality that may interfere with contact lens wear

3.4. Enrollment Strategy

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

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

The study is a bilateral, single-masked, single-arm, 4-visit dispensing study. Approximately 90 subjects will be enrolled with target completion of at least 80 subjects.
The study begins with an initial visit (Visit 1). If a subject is found to meet all eligibility criteria, they will be dispensed the study lens in a bilateral fashion.

If the subject is dispensed study lenses at the initial visit, then three follow-up visits will occur. The first follow-up visit will occur approximately one week after the initial visit. If necessary, the lens power may be modified at Visit 2, then a new pair of lenses with the final lens power will be dispensed. The second follow-up (Visit 3) will occur approximately 14 days after Visit 2 and the third and final follow-up evaluation (Visit 4) will occur approximately 28 days after Visit 2.

4.2. Study Design Rationale

A single-arm study was chosen to assess the clinical performance with respect to objective vision for the marketed contact lens Bausch + Lomb Ultra® Multifocal for Astigmatism. This study design and the clinical measurements involved are similar to recent studies of a JJVC prototype toric multifocal lens.[6,7] Data from these studies will be compared by creating tables and graphs of aggregate data after the study databases are all hard-locked.

4.3. Enrollment Target and Study Duration

Approximately 50 eligible myopes with against-the-rule astigmatism and 40 eligible hyperopes with against-the-rule astigmatism will be enrolled with at least 80 targeted to complete. The study will last approximately 2-3 months.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

This is a single-arm study. All subjects will be dispensed the study lens in a bilateral fashion.

5.2. Masking

Subjects will be masked to the study lens to help reduce potential bias. Subjects will be unaware of the identity of the investigational product. Investigators and clinical site personnel involved in the data collection will not be masked as to the identity of the investigational product.

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

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

5.3. Procedures for Maintaining and Breaking the Masking

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

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

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

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 1: Test Articles

	Test Lens
Name	Bausch + Lomb Ultra® Multifocal for Astigmatism
Manufacturer	Bausch + Lomb
Lens Material	Samfilcon A
Nominal Base Curve	8.6
Nominal Diameter	14.5
Nominal Distance Powers (D)	-1.00 to -4.00 in 0.25D steps, +1.00 to +4.00 in 0.25D steps
Nominal Cylinder Powers (D)	-0.75, -1.25
Cylinder axes (º)	70, 80, 90, 100, 110
Nominal ADD Power (D)	Low, High
Water Content	46%
Oxygen Permeability (Dk)	114.0
Wear Schedule in Current Study	Daily Reusable
Replacement Frequency	Monthly
Packaging Form (vial, blister, etc.)	Blister

Estimated number of lenses needed = 48 per SKU (90 axis) and 24 per SKU (other axes).

6.2. Ancillary Supplies/Products

The following solutions will be used in this study:

Table 2: Ancillary Supplies

	Single-Use Preservative-Free Rewetting Solutions (any of these three options may be supplied)			Multipurpose Disinfecting and Storing Solution
Solution Name/Description	Eye-Cept® Rewetting Drops	ScleralFil® Preservative Free Saline Solution	LacriPure Saline Solution	Biotrue® multipurpose solution
Manufacturer	Optics Laboratory	Bausch + Lomb	Menicon	Bausch + Lomb
Preservative	Non-Preserved	Non-Preserved	Non-Preserved	Polyquaternium 0.0001% and polyaminopropyl biguanide 0.00013%

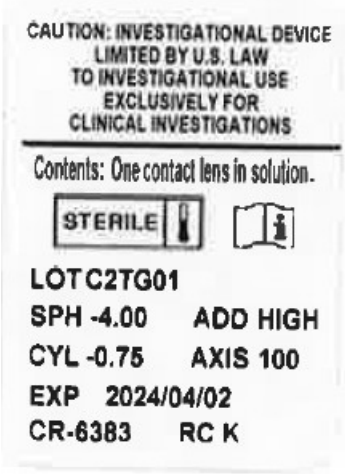
Lens cases which are compatible with Biotrue® multipurpose solution will be provided to participants for temporary storage of contact lenses during Visits 1 and 3 and for use during dispensing periods. Stopwatches will be provided to research sites to help with managing the timing of toric fit assessments and lens settling.

6.3. Administration of Test Articles

Test articles will be dispensed to subjects meeting all eligibility requirements, including any dispensing requirements set forth in this clinical protocol. Subjects will be dispensed an adequate supply of test articles to complete the study. Test articles which are lost or damaged in the period up to and including Visit 2 may be replaced at the discretion of the Investigator and/or the Sponsor.

6.4. Packaging and Labeling

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



6.5. Storage Conditions

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

6.6. Collection and Storage of Samples

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

6.7. Accountability of Test Articles

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

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

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

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

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

[redacted]

7. STUDY EVALUATIONS

7.1. Time and Event Schedule

Table 3: Time and Events

Visit Information	Visit 1 Screening, Baseline, Treatment 1	Visit 2 Treatment 1 Follow-up 1	Visit 3 Treatment 1 Follow-up 2	Visit 4 Treatment 1 Follow-up 3
Time Point	Day 0	7 ± 2 days after Visit 1	14 ± 2 days after Visit 2	28 ± 3 days after Visit 2
Estimated Visit Duration	2.5 hours	1.0 hours	1.0 hours	1.5 hours
Statement of Informed Consent	x			
Demographics	x			
Medical History/Concomitant Medications/Review	x	x	x	x
Current Habitual Correction	x			
Habitual Contact Lens Information	x			
Contact Lens History	x			
Habitual Lens Wear Time	x			
Presbyopic Symptoms Questionnaire	x			
Screening Inclusion/Exclusion Criteria	x			
Ocular Symptoms	x	x	x	x
Entrance Distance and near Visual Acuity	x	x	x	x
Lens Removal	x	x	x	x
Keratometry	x			
Subjective Sphero-Cylindrical Refraction	x			
Near ADD Determination	x			
Ocular Dominance	x			
ADD Refinement	x			
Near Visual Acuity	x			
Slit Lamp Biomicroscopy	x	x	x	x
Baseline Inclusion/ Exclusion	x			
Lens Selection	x	x (if optimized)		
Right Lens Insertion	x	x (if optimized)		
Right Lens 1 Minute and 3 Minute Rotation	x	x (if optimized)		

Visit Information	Visit 1 Screening, Baseline, Treatment 1	Visit 2 Treatment 1 Follow-up 1	Visit 3 Treatment 1 Follow-up 2	Visit 4 Treatment 1 Follow-up 3
Time Point	Day 0	7 ± 2 days after Visit 1	14 ± 2 days after Visit 2	28 ± 3 days after Visit 2
Estimated Visit Duration	2.5 hours	1.0 hours	1.0 hours	1.5 hours
Left Lens Insertion	x	x (if optimized)		
Left Lens 1 Minute and 3 Minute Rotation	x	x (if optimized)		
Lens Settling	x	x (if optimized)		
Toric Fit Assessment	x	x	x	x
Subjective Lens Fit Assessment	x	x		x
Visual Satisfaction	x	x (if optimized)		
Subjective Acceptance		x	x	x
Study Lens Distance and Near Visual Acuity	x	x	x	x
Over Refraction and Visual Acuity	x	x		
Lens Power Modification (if applicable)	x	x		
Determination of Lens Optimization	x	x		
Lens Optimization (if required)	x	x		
Insertion of Study Lenses	x	x		
Exit Snellen Distance and Near Visual Acuity	x	x		
Dispensing Criteria	x	x		
Subject Instructions	x	x		
Instruction Guide	x			
Lens Dispensing	x	x		
Schedule Follow-Up	x	x		
Compliance		x	x	x
Study Lens Wear Time		x	x	x
PRO (CLUE and MRD) Questionnaires	x	x	x	x
CLDEQ-8 Questionnaire	x		x	x
Binocular Over Refraction				x
Distance, Intermediate, and Near ETDRS LogMAR Visual Acuity				x
Final Evaluation				x

7.2. Detailed Study Procedures

VISIT 1

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

Visit 1: Screening			
Step	Procedure	Details	[redacted]
1.1	Statement of Informed Consent	Each subject must read, understand, and sign the Statement of Informed Consent before being enrolled into the study. The Principal Investigator or his/her designee conducting the informed consent discussion must also sign the consent form. **Note**: The subject must be provided a signed copy of this document.	
1.2	Demographics	Record the subject's 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	Habitual Contact Lens Information	Questions regarding the subject's habitual lens type and parameters.	
1.5	Habitual Contact Lens Wear Schedule	Record the duration of wearing this contact lens type and power (number of years and months). During the past month, what is the minimum number of days per week that the subject has worn their lenses for at least 8 hours.	
1.6	Contact Lens History	Record the subject's correction type (i.e. monovision, multifocal, sphere with readers, etc.).	
1.7	Wear time and Comfortable Wear time with Habitual lenses	Record the subjects wear time and comfortable wear time with their habitual contact lenses.	
1.8	Presbyopic Symptoms Questionnaire	Subjects will be asked if they are wearing a presbyopic correction and whether they are experiencing any of five common symptoms of presbyopia.	Appendix D
1.9	Eligibility after Screening	All responses to Screening Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria must be answered "no" for the subject to be considered eligible.	

Visit 1: Screening			
Step	Procedure	Details	[redacted]
		If subject is deemed to be ineligible after screening, proceed to Final Evaluation and complete Subject Disposition. Refraction and Biomicroscopy forms are not required.	

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

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
		equivocal use the sighting dominance test to determine the dominant eye used for the study.	
1.18	ADD Refinement	Place the BCC result in the trial frame and refine the near prescription with trial lenses (or flippers) under binocular conditions.	[redacted]
1.19	Near Visual Acuity	Using the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm. Record the near visual acuity (OD, OS, OU).	
1.20	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. If any of these slit lamp findings are Grade 2 or higher, the subject will be discontinued. If discontinued a final examination must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be instilled.	[redacted]
1.21	Eligibility after Baseline	All responses to Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria questions must be answered "no" for the subject to be considered eligible. *If subject is deemed to be ineligible after baseline, proceed to Final Evaluation and complete all forms.*	

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
1.22	Lens Selection	Select the lens power and axis based on the refraction and fitting guide for each eye. Record the test lens parameters (power and lot number).	Appendix C
1.23	Right Lens Insertion	Subjects will insert the right lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary.	

		Damaged lenses will be stored in labeled vial with Biotrue® multipurpose solution, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
1.24	Timed Settling for Right Lens	The investigator will start a stopwatch as soon as the right lens is inserted. **Note: All lenses in this study have a toric orientation mark at the 6 o'clock position. Rotation measurements are made relative to a vertical reference line**. Record base nasal or base temporal rotation to the nearest degree. At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
1.25	Left Lens Insertion	Subjects will insert the left lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with Biotrue® multipurpose solution, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
1.26	Timed Settling for Left Lens	The investigator will start a stopwatch as soon as the left lens is inserted. **Note: All lenses in this study have a toric orientation mark at the 6 o'clock position. Rotation measurements are made relative to a vertical reference line**. Record base nasal or base temporal rotation to the nearest degree. At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree	

		At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
1.27	Lens Settling	Allow the study lenses to settle for a minimum of 15 minutes.	
1.28	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Toric fit acceptable or unacceptable *Toric lens fit will be unacceptable if lenses rotated more than 30 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, remove, store, and label the lenses, and proceed to final evaluation.*	[redacted]
1.29	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all three</u> movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
1.30	Determine Visual Satisfaction	Determine if the subject's vision is acceptable with the lenses. Allow the subject to look down a hallway or out of a window for distance vision assessments, and for them to read a book, magazine or similar for near vision.	

1.31	Study Lens Distance and Near Visual Acuity	Record the distance and near Snellen visual acuity (OD, OS, OU) to the nearest letter with the study contact lenses in place. *For near measurements use the ETDRS 2000 Series Chart 1 or 2.*	[redacted]
1.32	Distance Over-Refraction and Distance Visual Acuity	Perform a distance over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over-refraction may also be refined under binocular conditions. Record the results. The results of the distance over-refraction may also be checked for the impact on near vision under monocular and/or binocular conditions.	
1.33	Lens Power Modification (if applicable)	If the subject reports unsatisfactory vision, or is unable to obtain 20/30 distance visual acuity OU with the lenses than a modification must be attempted. If the subject reports satisfactory vision with the lenses a modification is not required however may at the Investigators discretion based upon their findings on the measured visual acuity and/or over- refraction. *Note: switching to a non-multifocal lens per section 5 of the Fitting Guide is not an available option in this study.* Select the reason(s) for lens change (select all that apply): • The settled lens rotation is such that one of the other available lens cylinder axis would be better (use LARS rule to determine the replacement lens cylinder axis) • Power Modification needed • Unsatisfactory Vision • Other (specify reason) If one or both lenses are modified, repeat steps **1.22 through 1.32** for one or both eyes as appropriate. A maximum of ***two*** lens modifications are allowed.	Appendix C: Fitting Guide
1.34	Exit Distance and Near Visual Acuity	Record the distance and near Snellen visual acuity (OD, OS, OU) to the nearest letter with the study contact lenses in place.	[redacted]

		For near measurements use the ETDRS 2000 Series Chart 1 or 2.	
1.35	Dispensing Criteria	The lenses may be dispensed for 5-9 days, if the following criteria are met: • Distance Snellen acuity equal to or better than 20/30 OU • Subject must indicate that the vision is acceptable. • Subject must indicate that the comfort of the lenses is acceptable. • Lenses must have an acceptable toric and general lens fit.	
1.36	Subject Instructions	Instruct the Subject on the following: • The lenses will be worn on a daily wear basis. • After each lens removal, use a rub/rinse/soak lens care regimen with Biotrue® multipurpose solution (per manufacturer's instructions). • If determined necessary by the Investigator sterile non-preserved rewetting drops may be dispensed to be used as needed for dryness. • Subjects will be instructed to wear lenses for a minimum of 6 hours a day, every day during the study. One missed day of lens wear per week is acceptable. • Subjects will be instructed to wear their glasses when not wearing the study lenses**.** • A patient instruction booklet will be provided. ***Note:*** *In the event a lens is lost or damaged, the subject will return to the investigator site for a determination of whether the lens will be replaced or if the subject will be discontinued. As much as reasonably possible, a damaged lens should be returned to the investigational site and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial*	

		with Biotrue® multipurpose solution and returned to the Sponsor.	
1.37	Schedule Follow-up	The subject will be scheduled to return for their follow-up appointment in 7±2 days.	

VISIT 2

The subjects must present to Visit 2 wearing the study lenses.

Visit 2: Treatment 1 Follow-Up 1			
Step	Procedure	Details	[redacted]
2.1	Adverse Events and Concomitant Medications Review	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	
2.2	Wear time and Comfortable Wear time (Study Lenses)	Record the average wearing time and comfortable wearing time with the study lenses.	
2.3	Compliance	Confirm compliance with the prescribed wear schedule.	
2.4	PRO (CLUE and MRD) Questionnaires	The subject will respond to the Follow-Up PRO (CLUE and MRD).	
2.5	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
2.6	Subjective Acceptance	Record whether the subject's distance and near vision with the lenses is acceptable.	
2.7	Entrance Distance and Near Visual Acuity	Record the distance and near Snellen visual acuity (OD, OS, OU) to the nearest letter with the study contact lenses in place. *For near measurements use the ETDRS 2000 Series Chart 1 or 2.*	[redacted]
2.8	Distance Over-Refraction and Distance Visual Acuity	Perform a distance over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over-refraction may also be refined under binocular conditions. Record the results. The results of the distance over-refraction may also be checked for the	

Visit 2: Treatment 1 Follow-Up 1			
Step	Procedure	Details	[redacted]
		impact on near vision under monocular and/or binocular conditions.	
2.9	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Toric fit acceptable or unacceptable *Toric lens fit will be unacceptable if lenses rotated more than 30 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, remove, store, and label the lenses, and proceed to final evaluation.*	[redacted]
2.10	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all three</u> movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
2.11	Determination of Lens Optimization	If the subject's vision is unacceptable for at least one distance or the Investigator determines that the visual acuity or over-refraction are not acceptable then a lens modification must be made. *If modifications are not needed, proceed to step 2.23.*	

Visit 2: Treatment 1 Follow-Up 1			
Step	Procedure	Details	[redacted]
		Up to ***two*** attempts at changes are permitted if necessary, in order to achieve an acceptable distance and near binocular performance for the subject. Follow the fitting guide allowing for at least 10 minutes of settling time between lens changes. *Note: switching to a non-multifocal lens per section 5 of the Fitting Guide is not an available option in this study.*	
2.12	Lens Optimization (if required)	Select the reason(s) for lens change (select all that apply): • The settled lens rotation is such that one of the other available lens cylinder axis would be better (use LARS rule to determine the replacement lens cylinder axis). • Power Modification needed • Unsatisfactory Vision • Other (specify reason)	
2.13	Lens Selection (if required)	Select the lens power, based on the Fitting Guide for each eye needing optimization. Record the test lens parameters (power and lot number).	Appendix C
2.14	Lens Insertion (if required)	Subjects will insert the lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with Biotrue® multipurpose solution, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
2.15	Timed Settling for Lens (if required)	The investigator will start a stopwatch as soon as the lens is inserted. **Note: All lenses in this study have a toric orientation mark at the 6 o'clock position. Rotation measurements are made relative to a vertical reference line**. Record base nasal or base temporal rotation to the nearest degree.	

Visit 2: Treatment 1 Follow-Up 1			
Step	Procedure	Details	[redacted]
		At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
2.16	Lens Settling (if required)	Allow the study lenses to settle for a minimum of 15 minutes.	
2.17	Toric Fit Evaluation (if required)	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable *Toric lens fit will be unacceptable if lenses rotated more than 30 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, remove, store, and label the lenses, and proceed to final evaluation.*	[redacted]
2.18	Lens Fit Assessment (if required)	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all three</u> movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]

Visit 2: Treatment 1 Follow-Up 1			
Step	Procedure	Details	[redacted]
2.19	Determine Visual Satisfaction (if required)	Determine if the subject's vision is acceptable with the lenses. Allow the subject to look down a hallway or out of a window for distance vision assessments, and for them to read a book, magazine or similar for near vision.	
2.20	Study Lens Distance and Near Visual Acuity (if required)	Record the distance and near Snellen visual acuity (OD, OS, OU) to the nearest letter with the study contact lenses in place. *For near measurements use the ETDRS 2000 Series Chart 1 or 2.*	
2.21	Distance Over-Refraction and Distance Visual Acuity (if required)	Perform a distance over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over-refraction may also be refined under binocular conditions. Record the results. The results of the distance over-refraction may also be checked for the impact on near vision under monocular and/or binocular conditions.	
2.22	Additional Lens Power Optimization (if required)	If the subject reports unsatisfactory vision, or is unable to obtain 20/30 distance visual acuity OU with the lenses than a modification must be attempted. If the subject reports satisfactory vision with the lenses a modification is not required however may at the Investigators discretion based upon their findings on the measured visual acuity and/or over- refraction. *Note: switching to a non-multifocal lens per section 5 of the Fitting Guide is not an available option in this study.* Select the reason(s) for lens change (select all that apply): • The settled lens rotation is such that one of the other available lens cylinder axis would be better (use LARS rule to determine the replacement lens cylinder axis) • Power Modification needed • Unsatisfactory Vision • Other (specify reason)	Appendix C: Fitting Guide

Visit 2: Treatment 1 Follow-Up 1			
Step	Procedure	Details	[redacted]
		If one or both lenses are modified, repeat steps **2.13 through 2.21** for one or both eyes as appropriate.	
2.23	Lens Removal	Have the subject remove the study lenses. Temporarily store the worn lenses until Biomicroscopy has been completed. If no adverse event or PQC was recorded, the worn lenses may be discarded.	
2.24	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
2.25	Insertion of Study Lenses	Provide the subject with a **new** set of lenses that match the power of the lenses that were removed in step 2.23 above.	
2.26	Exit Distance and Near Visual Acuity	Record the distance and near Snellen visual acuity (OD, OS, OU) to the nearest letter with the study contact lenses in place. *For near measurements use the ETDRS 2000 Series Chart 1 or 2.*	[redacted]
2.27	Dispensing Criteria	The lenses will be dispensed for 12-16 days if the following criteria are met: • Distance Snellen acuity equal to or better than 20/30 OU • Subject must indicate that the vision is acceptable. • Subject must indicate that the comfort of the lenses is acceptable. • Lenses must have an acceptable toric and general lens fit.	
2.28	Subject Instructions	Instruct the Subject on the following: • The lenses will be worn on a daily wear basis. • After each lens removal, use a rub/rinse/soak lens care regimen with Biotrue® multipurpose solution (per manufacturer's instructions).	

Visit 2: Treatment 1 Follow-Up 1			
Step	Procedure	Details	[redacted]
		• If determined necessary by the Investigator sterile non-preserved rewetting drops may be dispensed to be used as needed for dryness. • Subjects will be instructed to wear lenses for a minimum of 6 hours a day, every day during the study. One missed day of lens wear per week is acceptable. • Subjects will be instructed to wear their glasses when not wearing the study lenses. • Subjects will be instructed to bring their habitual contacts or spectacles to the next visit. ***Note:*** *In the event a lens is lost or damaged after Visit 2, the subject will return to the investigator site for discontinuation and Final Evaluation. As much as reasonably possible, a damaged lens should be returned to the investigational site and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with Biotrue® multipurpose solution and returned to the Sponsor.*	
2.29	Schedule Follow-up	The subject will be scheduled to return for their follow-up appointment in 14±2 days.	

VISIT 3

The subjects must present to Visit 3 wearing the study lenses.

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

Visit 3: Treatment 1 Follow-Up 2			
Step	Procedure	Details	[redacted]
3.2.	Wear time and Comfortable Wear time (Study Lenses)	Record the average wearing time and comfortable wearing time with the study lenses.	
3.3.	Compliance	Confirm compliance with the prescribed wear schedule.	
3.4.	PRO (CLUE and MRD) and CLDEQ-8 Questionnaires	The subject will respond to the Follow-Up PRO (CLUE and MRD) and Dry Eye Questionnaires.	
3.5.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
3.6.	Subjective Acceptance	Record whether the subject's distance and near vision with the lenses is acceptable.	
3.7.	Entrance Distance and Near Visual Acuity	Record the distance and near Snellen visual acuity (OD, OS, OU) to the nearest letter with the study contact lenses in place. *For near measurements use the ETDRS 2000 Series Chart 1 or 2.*	[redacted]
3.8.	Binocular Distance Over-refraction and Distance Visual Acuity	Perform a binocular over-refraction and record the OD and OS results and distance visual acuity. Note: No lens changes are allowed based on the over-refraction.	Appendix F
3.9.	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Toric fit acceptable or unacceptable *Toric lens fit will be unacceptable if lenses rotated more than 30 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, remove, store, and label the lenses, and proceed to final evaluation.*	[redacted]
3.10.	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the lenses if any of the following is observed:	[redacted]

Visit 3: Treatment 1 Follow-Up 2			
Step	Procedure	Details	[redacted]
		• presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all three</u> movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	
3.11.	Visual Performance Distance (4 M) Intermediate (64 cm) Near (40 cm)	Visual performance will be recorded OD, OS, and OU for the following: **Distance, Bright Illuminance** *ETDRS Charts 4* M-HC#1, HC#2, HC#3 and LC#1, LC#2 and LC#3 **Near, Bright Illuminance** *Reduced Guillon-Poling Charts* High Contrast and Low Contrast Intermediate (64 cm) and Near (40 cm). **Distance, Dim Illuminance (with *<u>Distance</u>* goggles)** *ETDRS Charts 4* M-HC#4, HC#5, HC#6 **Near, Dim Illuminance (with *<u>Near</u>* goggles)** *Reduced Guillon-Poling charts* High Contrast Intermediate (64 cm) and Near (40 cm). **Note:** • **The room illuminance must be between 7.3 and 7.9 EV (or 400 to 600 lux)** • **Distance, HC-1 Chart luminance Acceptable EV Range 10.5-10.7 (or 180 to 210 cd/m^2)** • **Guillon-Poling, Near Chart Luminance Acceptable EV Range 10.8-11.1 (or 220 to 280 cd/m^2)**	[redacted]

Visit 3: Treatment 1 Follow-Up 2			
Step	Procedure	Details	[redacted]
		• **Do not use the Mesopic filter for Dim luminance (Dim luminance will be simulated by using the goggles).**	
3.12.	Lens Removal	Have the subject remove the study lenses and temporarily store them in a lens case with Biotrue® multipurpose solution.	
3.13.	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
3.14.	Insertion of Study Lenses	Have the subject re-insert the lenses which had been removed at step 3.12.	
3.15.	Exit Distance and Near Visual Acuity	Record the distance and near Snellen visual acuity (OD, OS, OU) to the nearest letter with the study contact lenses in place. *For near measurements use the ETDRS 2000 Series Chart 1 or 2.*	[redacted]
3.16.	Subject Instructions	Instruct the Subject on the following: • The lenses will be worn on a daily wear basis. • After each lens removal, use a rub/rinse/soak lens care regimen with Biotrue® multipurpose solution (per manufacturer's instructions). • If determined necessary by the Investigator sterile non-preserved rewetting drops may be dispensed to be used as needed for dryness. • Subjects will be instructed to wear lenses for a minimum of 6 hours a day, every day during the study. One missed day of lens wear per week is acceptable. • Subjects will be instructed to wear their glasses when not wearing the study lenses. • Subjects will be instructed to bring their habitual contacts or spectacles to the next visit.	

Visit 3: Treatment 1 Follow-Up 2			
Step	Procedure	Details	[redacted]
		Note: *In the event a lens is lost or damaged after Visit 3, the subject will return to the investigator site for discontinuation and Final Evaluation. As much as reasonably possible, a damaged lens should be returned to the investigational site and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with Biotrue® multipurpose solution and returned to the Sponsor.*	
3.17.	Schedule Follow-up	The subject will be scheduled to return for their follow-up appointment which should be 25 to 31 days after Visit 2.	

VISIT 4

The subjects must present to Visit 4 wearing the study lenses.

Visit 4: Treatment 1 Follow-Up 3			
Step	Procedure	Details	[redacted]
4.1.	Adverse Events and Concomitant Medications Review	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	
4.2.	Wear time and Comfortable Wear time (Study Lenses)	Record the average wearing time and comfortable wearing time with the study lenses.	
4.3.	Compliance	Confirm compliance with the prescribed wear schedule.	
4.4.	PRO (CLUE and MRD) and CLDEQ-8 Questionnaires	The subject will respond to the Follow-Up PRO (CLUE and MRD) and Dry Eye Questionnaires.	
4.5.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
4.6.	Subjective Acceptance	Record whether the subject's distance and near vision with the lenses is acceptable.	
4.7.	Entrance Distance and Near Visual Acuity	Record the distance and near Snellen visual acuity (OD, OS, OU) to the nearest letter with the study contact lenses in place. *For near measurements use the ETDRS 2000 Series Chart 1 or 2.*	[redacted]

Visit 4: Treatment 1 Follow-Up 3			
Step	Procedure	Details	[redacted]
4.8.	Binocular Distance Over-refraction and Distance Visual Acuity	Perform a binocular over-refraction and record the OD and OS results and distance visual acuity. Note: No lens changes are allowed based on the over-refraction.	Appendix F
4.9.	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Toric fit acceptable or unacceptable *Toric lens fit will be unacceptable if lenses rotated more than 30 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, remove, store, and label the lenses, and proceed to final evaluation.*	[redacted]
4.10.	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all three</u> movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
4.11.	Visual Performance Distance (4M) Intermediate (64 cm) Near (40 cm)	Visual performance will be recorded OD, OS, and OU for the following: **Distance, Bright Illuminance** *ETDRS Charts 4*M-HC#1, HC#2, HC#3 and LC#1, LC#2 and LC#3	[redacted]

Visit 4: Treatment 1 Follow-Up 3			
Step	Procedure	Details	[redacted]
		Near, Bright Illuminance *Reduced Guillon-Poling Charts* High Contrast and Low Contrast Intermediate (64 cm) and Near (40 cm). **Distance, Dim Illuminance (with *Distance* goggles)** *ETDRS Charts 4*M-HC#4, HC#5, HC#6 **Near, Dim Illuminance (with *Near* goggles)** *Reduced Guillon-Poling charts* High Contrast Intermediate (64 cm) and Near (40 cm). **Note:** • **The room illuminance must be between 7.3 and 7.9 EV (or 400 to 600 lux)** • **Distance, HC-1 Chart luminance Acceptable EV Range 10.5-10.7 (or 180 to 210 cd/m^2)** • **Guillon-Poling, Near Chart Luminance Acceptable EV Range 10.8-11.1 (or 220 to 280 cd/m^2)** • **Do not use the Mesopic filter for Dim luminance (Dim luminance will be simulated by using the goggles).**	
4.12.	Lens Removal	Have the subject remove the study lenses. Temporarily store the worn lenses until Biomicroscopy has been completed. If no adverse event or PQC was recorded, the worn lenses may be discarded.	

FINAL EVALUATION

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

Final Evaluation			
Step	Procedure	Details	[redacted]
F.1	Final Exam Form	Indicate if the subject completed the study successfully. If subject discontinued from the study, indicate the reason.	
F.2	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
F.3	Subjective spherocylindrical Refraction	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. Record the refraction and distance visual acuity (OD, OS, OU) to the nearest letter.	[redacted]
F.4	Exit Distance Visual Acuity	Record the distance Snellen visual acuity (OD, OS, OU) to the nearest letter, and the type of visual correction being worn (habitual lenses, distance spectacles or unaided).	[redacted]

7.3. Unscheduled Visits

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

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

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

Any ocular and non-ocular Adverse Events that are ongoing at the time of the study visit will be followed by the Investigator, within licensure, until they have resolved, returned to pre-treatment status, stabilized, or been satisfactorily explained. If further treatment 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	Indicate if the only reason for the visit is that the subject requires additional test articles. If the reason is other than resupply of previously dispensed lenses, specify the reason for the visit.	
U.2	Chief Complaints (if applicable)	Record the subject's chief complaints for reasons for the unscheduled visit.	
U.3	Adverse Events and Concomitant Medications Review (if applicable)	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 (if applicable)	Record the distance Snellen visual acuity (OD, OS, OU) to the nearest letter, and the type of visual correction being worn (study lenses, habitual lenses, distance spectacles or unaided).	[redacted]
U.5	Subjective Sphero-cylindrical Refraction (if applicable)	Perform bare-eye subjective spherocylindrical refraction with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the best corrected distance visual acuity to the nearest letter (OD, OS).	[redacted]
U.6	Slit Lamp Biomicroscopy (if applicable)	FDA Slit Lamp Classification Scale will be used to grade the findings. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be instilled.	[redacted]
U.7	Dispensing (if applicable)	If the subject requires additional lenses to complete the wear period and is eligible to do so, provide additional lenses per the dispensing instructions given in the detailed study procedures.	
U.8	Toric Fit Evaluation (if applicable)	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable *Toric lens fit will be unacceptable if lenses rotated more than 30 degrees, or lens stability is worse than 5 degrees movement*	[redacted]

Unscheduled Visit			
Step	Procedure	Details	[redacted]
		with blink. If toric fit is unacceptable, remove, store, and label the lenses, and proceed to final evaluation.	
U.9	Lens Fit Assessment (if applicable)	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all three</u> movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
U.10	Exit Visual Acuity (if applicable)	Record the distance Snellen visual acuity (OD, OS, OU) to the nearest letter, and the type of visual correction being worn (study lenses, habitual lenses, distance spectacles or unaided).	[redacted]

7.4. Laboratory Procedures

None

8. SUBJECTS COMPLETION/WITHDRAWAL

8.1. Completion Criteria

Subjects are considered to have completed the study if they:

- provided informed consent.
- are eligible.
- completed all visits

8.2. Withdrawal/Discontinuation from the Study

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

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

For discontinued subjects, the Investigator will:

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

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

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

9. PRE-STUDY AND CONCOMITANT INTERVENTION/MEDICATION

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

9.1. Systemic Medications

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 medications is shown

in Table 4. Subjects with a history of taking these medications will be allowed to enroll only if:

- The medications have been taken on a continual or routine basis for at least 6 months and the subject has demonstrated successful contact lens wear during this time.

Or

- The subject previously used these medications on a temporary basis and has ceased that medication at least 1 week prior to signing the informed consent.

Table 4: Disallowed systemic medications

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

10. DEVIATIONS FROM THE PROTOCOL

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

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

If the deviation potentially impacts the safety of patient or changes the technical integrity of the study, then it must be reported to IEC/IRB. This is a "Major Deviation". 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 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
Out-of-window visit	Visit attended 3 or more days out of visit window defined in study procedures	Visit attended 2 or fewer days out of visit window defined in study procedures
Insufficient wear of study lenses	Subject does not wear study lenses for at least 6 hours per day for 3 or more days out of any week through the dispensing period.	Subject does not wear study lenses for at least 6 hours per day for 2 days out of any week through the dispensing period.

11. STUDY TERMINATION

If more than 2 subjects in the investigational soft contact lens group develop serious expected (e.g., definite or probable MK) or unexpected device related adverse events, the study will be suspended. Upon review and consultation with IRB, DMC, and JJVC Safety Review committee, the study may be terminated. This potential stopping rule is established based on our trial involving approximately 200 subjects wearing the investigational soft contact lens for up to 3 years with an assumed MK rate that is below 0.2% per patient-year. The rate of 0.2% per patient year is the established rate for extended wear lenses in adults, which was requested by the FDA as a criterion for evaluating a contact lens for pediatric use in an FDA response to a pre-IDE submission. To be conservative, 200 independent patient years were used in the calculation. The probability of observing 2 cases or more incidents of MK is 0.061, and 3 cases or more incidents of MK is 0.007 (given an MK rate of 0.2% per patient year).

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.

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

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

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

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

- Contact Lens Induced Peripheral Ulcer (CLPU)
- Significant Infiltrative Events (SIE)
- Superior Epithelial Arcuate Lesions (SEALs)
- Any Temporary Loss of > 2 Lines of BSCVA
- Other grade 3 or higher corneal findings, such as abrasions or edema
- Non-contact lens related corneal events - e.g. Epidemic Keratoconjunctivitis (EKC)
- Asymptomatic Corneal Scar
- Any corneal event which necessitates temporary lens discontinuation > 2 weeks

Non-Significant Adverse Events – are defined as those events that are usually asymptomatic and usually do not warrant discontinuation of contact lens wear but may cause a reduction in

wear time. However, the Investigator may choose to prescribe treatment as a precautionary measure.

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

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

Adverse Device Effect (ADE) – An ADE is an "adverse event related to the use of an investigational medical device."
Note 1: 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 13.2).
- 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 to the written guidelines, including reporting timelines.

13.5. Event of Special Interest

None

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

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 Statistical Analysis System (SAS) software Version 9.4 or higher (SAS Institute, Cary, NC). Throughout the analysis of data, the results for each subject/eye will be used when available for summarization and statistical analysis. 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 is a pilot study assessing the clinical performance of a marketed contact lens Bausch + Lomb Ultra® Multifocal for Astigmatism with respect to objective vision. This is the first time the sponsor will be assessing this study lens; therefore, historical data is not available to perform any statistical power calculation. The sample size was chosen by the study responsible clinician and was determined based on previous studies on other multifocal toric contact lenses with similar study endpoints.

14.3. Analysis Populations

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

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

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

14.4. Level of Statistical Significance

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

14.5. Primary Analysis

LogMAR Visual Acuity
Binocular, high luminance, high contrast visual performance on logMAR scale will be analyzed using a linear mixed model. Each model will include the experimental design factors: distance (distance/intermediate/near) as fixed effect. Site will be included as random covariate when appropriate. Other baseline characteristics known of importance such as age, gender and/or add power will be included as fixed covariates when appropriate. The covariance between residual errors from the same subject across different distances will be selected based on the finite-sample corrected Akaike's Information Criterion (Keselman et al. 1998).[8] Covariance structures considered may include: Homogenous compound symmetry (CS) and Unstructured covariance structure (UN). The structure that returns the lowest Akaike Information Criteria Corrected (AICC) will be selected as the structure that best fit the data.

The Kenward and Roger method will be used for the calculation of the denominator of degrees of freedom.[9]

Comparisons will be carried out using 95% confidence intervals constructed of least-square means (LSM) from the linear mixed models. Statistically superiority will be concluded if the upper limits of the confidence intervals are below the thresholds for corresponding distances.

14.6. Secondary Analysis

Not Applicable

14.7. Other Exploratory Analyses

Not Applicable

14.8. Interim Analysis

An interim analysis will not be 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.

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

Edit checks, electronic queries, and audit trails are built into the system to ensure accurate and complete data collection. Data will be transmitted from the clinical site to a secure central

database as forms are completed or updated, ensuring information accuracy, security, and confidentiality. After the final database lock, the Investigator will be provided with Individual Patient Profiles (IPP) including the full audit trail on electronic media in PDF format for all of the study data. The IPP must be retained in the study files as a certified copy of the source data for the study.

The content and structure of the eCRFs are compliant with ISO14155:2020.[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. Trial Registration on ClinicalTrials.gov

This study will be registered on ClinicalTrials.gov based on the following: The clinical trial is evaluating a U.S. FDA-regulated Device Product.

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

18.2. Investigator Responsibility

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

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

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

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

- Information regarding funding, name of the Sponsor, institutional affiliations, other potential conflicts of interest, and incentives for subjects.
- Any other documents that the IEC/IRB requests to fulfill its obligation.

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

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

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

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

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

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

18.4. Informed Consent

Each subject or their representative, must give written consent according to local requirements after the nature of the study has been fully explained. The consent form must be signed before performance of any study-related activity. The consent form that is used must be approved by

both the Sponsor and by the reviewing IEC/IRB. The informed consent is in accordance with principles that originated in the Declaration of Helsinki,[3] current ICH[2] and ISO 14155:2020[1] guidelines, applicable regulatory requirements, and Sponsor Policy.

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

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

Each subject for this study will complete an assent and a parent or legal guardian must give written informed consent according to local requirements after the nature of the study has been fully explained. The assent and consent forms must be signed before performance of any study-related activity. The assent and consent forms that are used must be approved by both the Sponsor and by the reviewing IEC/IRB. The assent and informed consent forms should be in accordance with principles that originated in the Declaration of Helsinki,[3] current ICH[2] and GCP guidelines, applicable regulatory requirements, and Sponsor policy. Before entry into the study or pre-screening, the Investigator or an authorized member of the clinical site personnel must explain to the potential subject and parent and/or legal guardian the aims, methods, reasonably anticipated benefits, and potential hazards of the study or pre-screening, and any discomfort it may entail. Subjects and parent and/or legal guardian will be informed that their participation is voluntary and that they may withdraw consent to participate at any time. They will be informed that choosing not to participate will not affect the care the subject will receive. Finally, they will be told that the Investigator will maintain a subject identification register for the purposes of long-term follow-up if needed and that their records may be accessed by health authorities and authorized Sponsor personnel without violating the confidentiality of the subject, to the extent permitted by the applicable law(s) or regulations. By signing the assent and informed consent form, the subject is authorizing such access and agrees to be contacted after study completion by health authorities and authorized Sponsor personnel for the purpose of obtaining consent for additional safety evaluations if needed.

18.5. Privacy of Personal Data

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

persons about the collection and processing of their personal data, to grant them reasonable access to their personal data and to prevent access by unauthorized persons.

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

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

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

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

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

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

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

19. STUDY RECORD RETENTION

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

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

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

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

20. FINANCIAL CONSIDERATIONS

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

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

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

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

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

21. PUBLICATION

There is no plan to publish the outcome of this investigation.

22. REFERENCES

1. ISO 14155:2020: Clinical Investigation of Medical Devices for Human Subjects — Good Clinical Practice. Available at: https://www.iso.org/standard/71690.html

2. International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP). Available at: http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
3. Declaration of Helsinki - Ethical principles for Medical Research Involving Human Subjects. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
4. United States (US) Code of Federal Regulations (CFR). Available at: https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR
5. Health Information Portability and Accountability Act (HIPAA). Available at: https://www.hhs.gov/hipaa/for-professionals/privacy/index.html
6. Franklin R. [redacted] *Clinical Study Protocol. Pilot Evaluation of a Silicone Hydrogel Daily Disposable Toric Multifocal Contact Lens.* August 06, 2020.
7. Franklin R. [redacted] *Clinical Study Protocol. Evaluation of Silicone Hydrogel Multifocal Toric Contact Lenses in a Hyperopic Population.* January 11, 2021.
8. Keselman HJ, Algina J, Kowalchuk RK, Wolfinger RD. A Comparison of Two Approaches for Selecting Covariance Structures in the Analysis of Repeated Measures. *Communications in Statistics—Simulation and Computation.* 1998;27(3):591-604.
9. Kenward MG, Roger JH. Small Sample Inference for Fixed Effects from Restricted Maximum Likelihood. *Biometrics*. 1997;53:983-997.

APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

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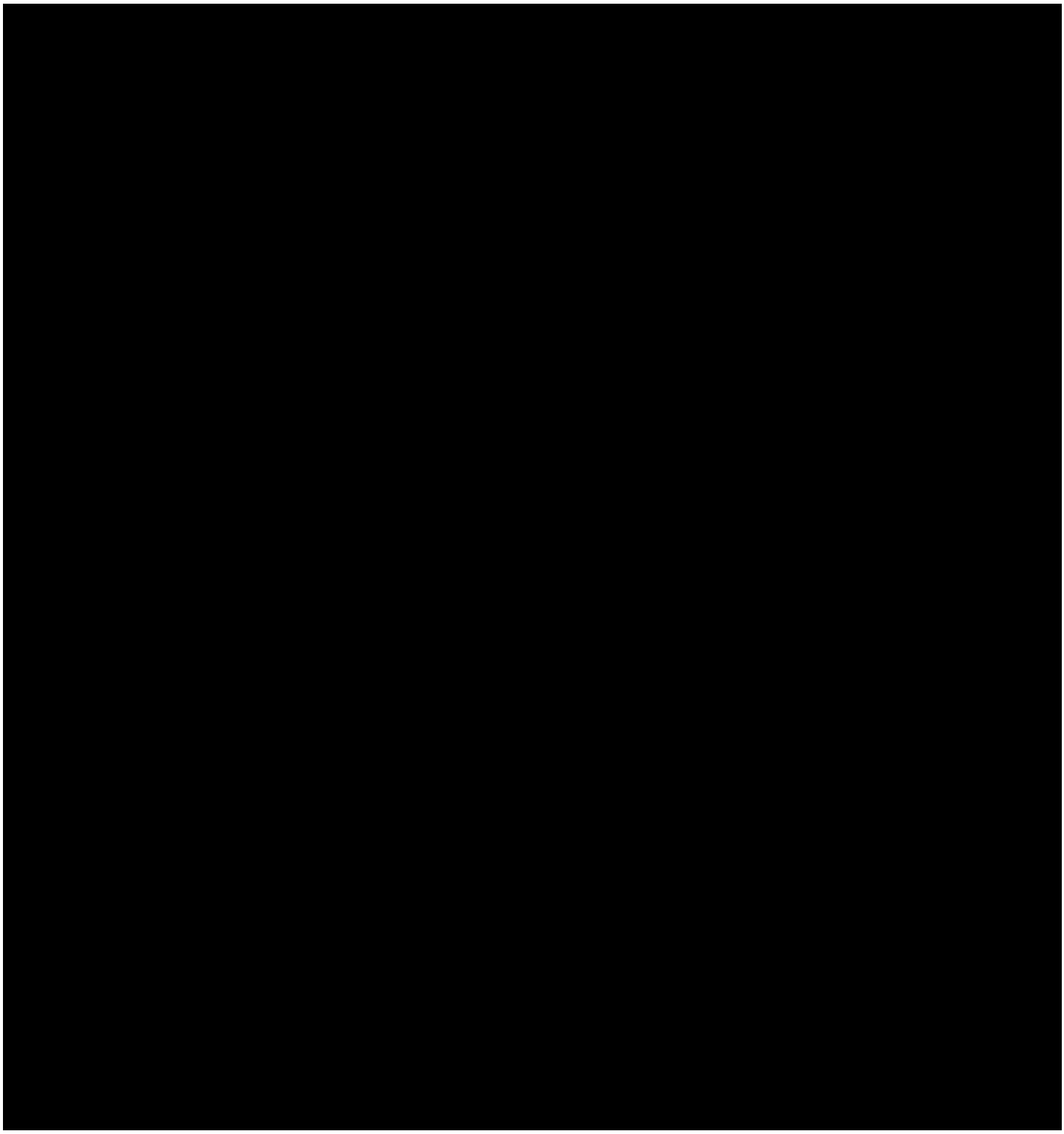

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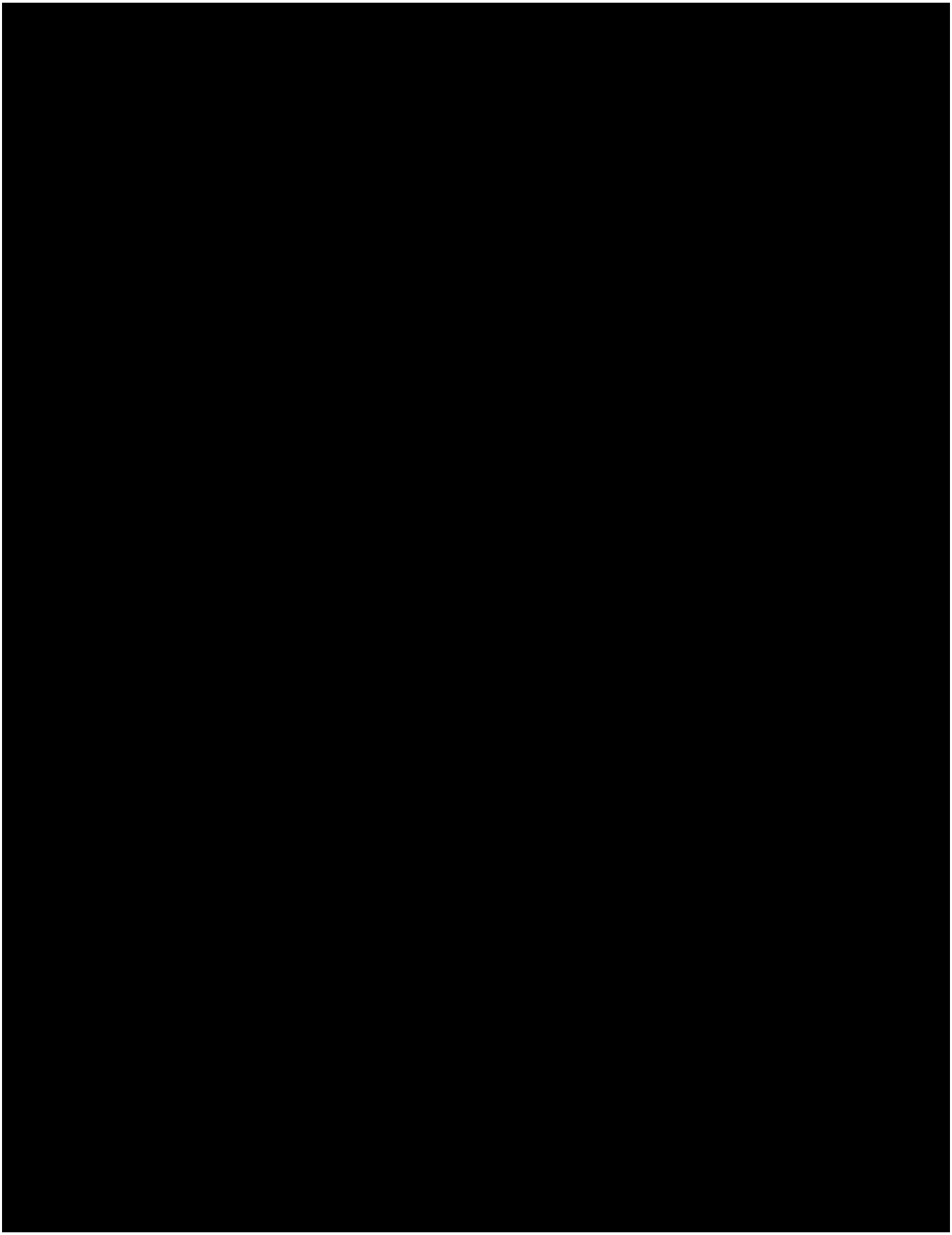

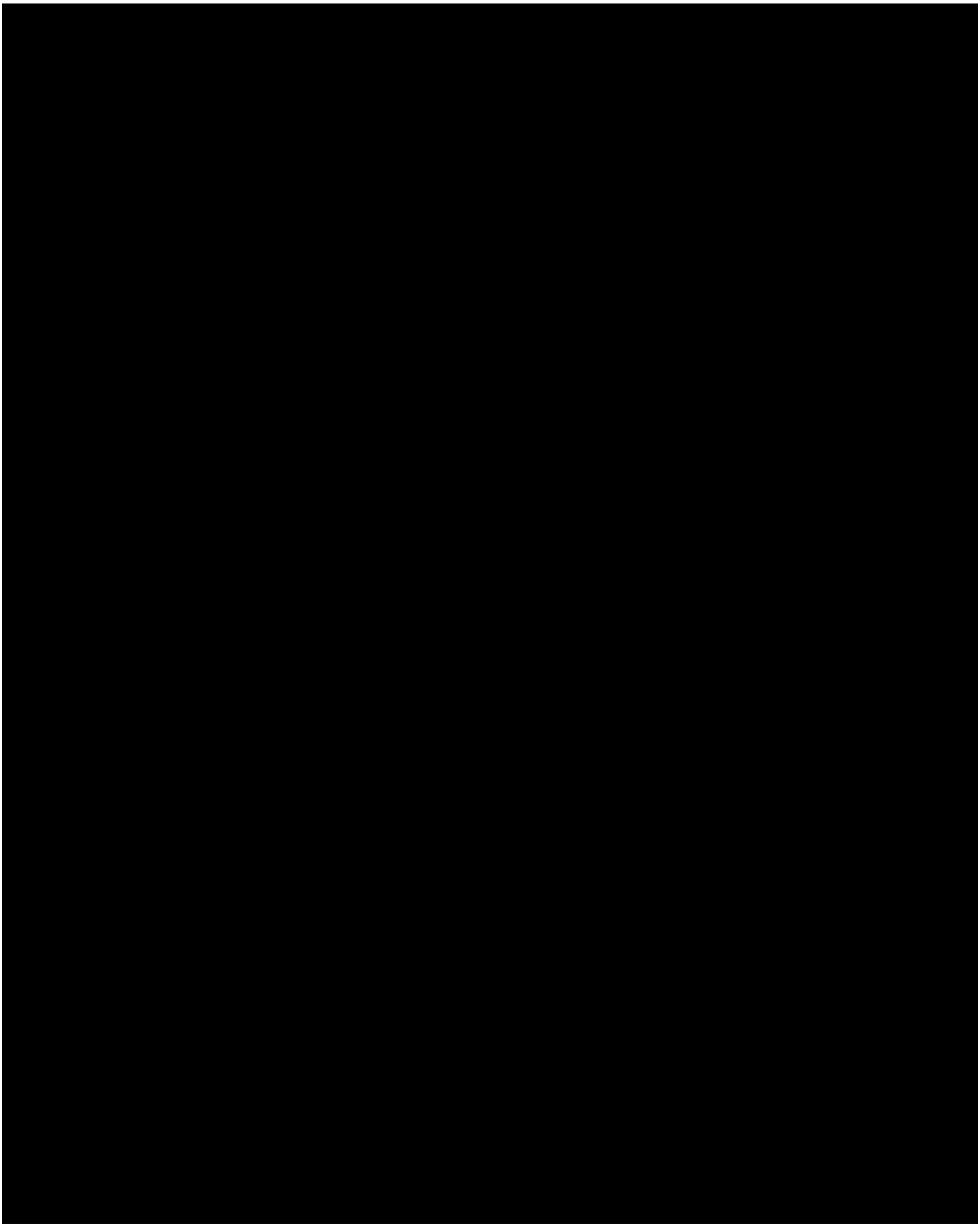

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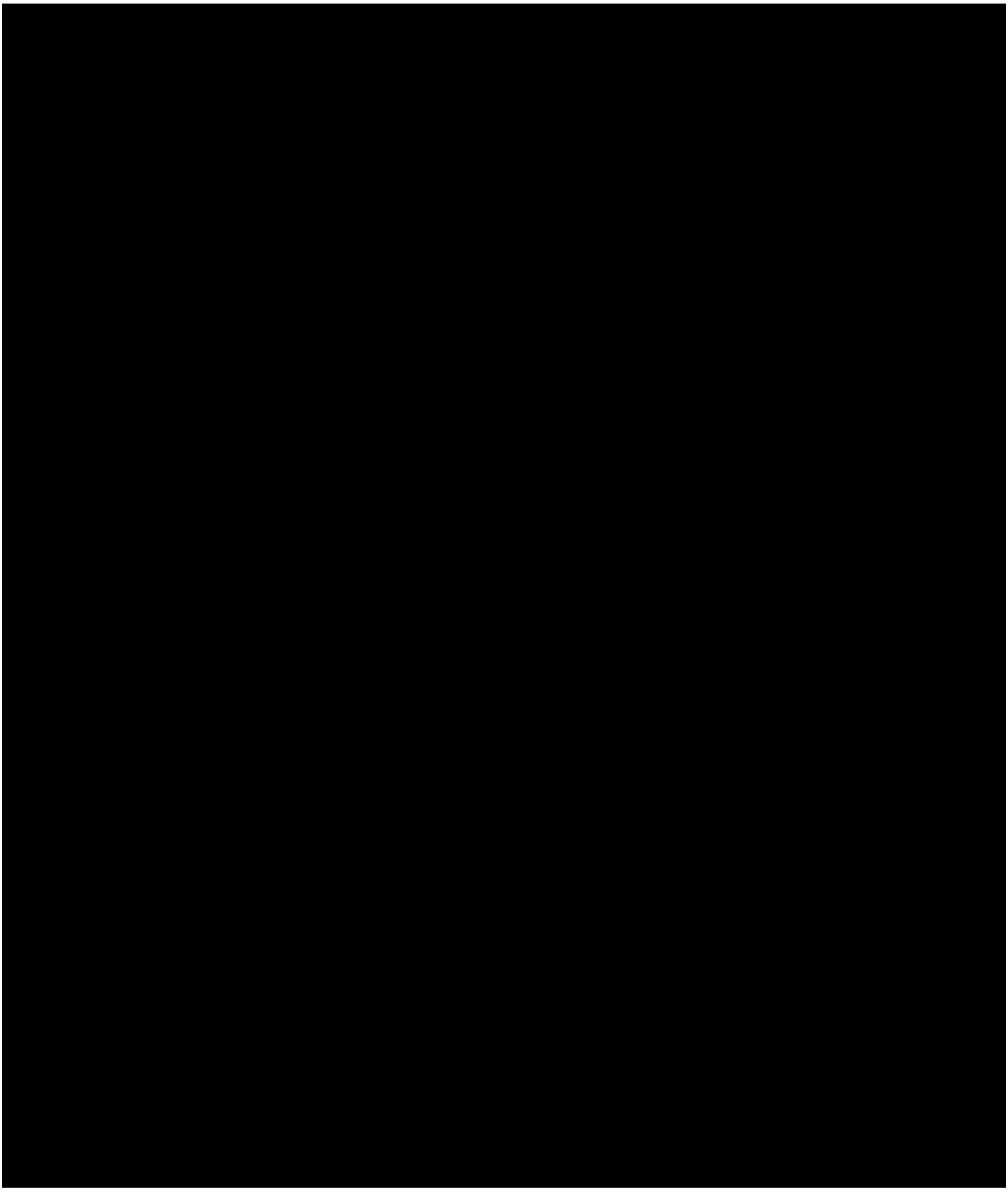

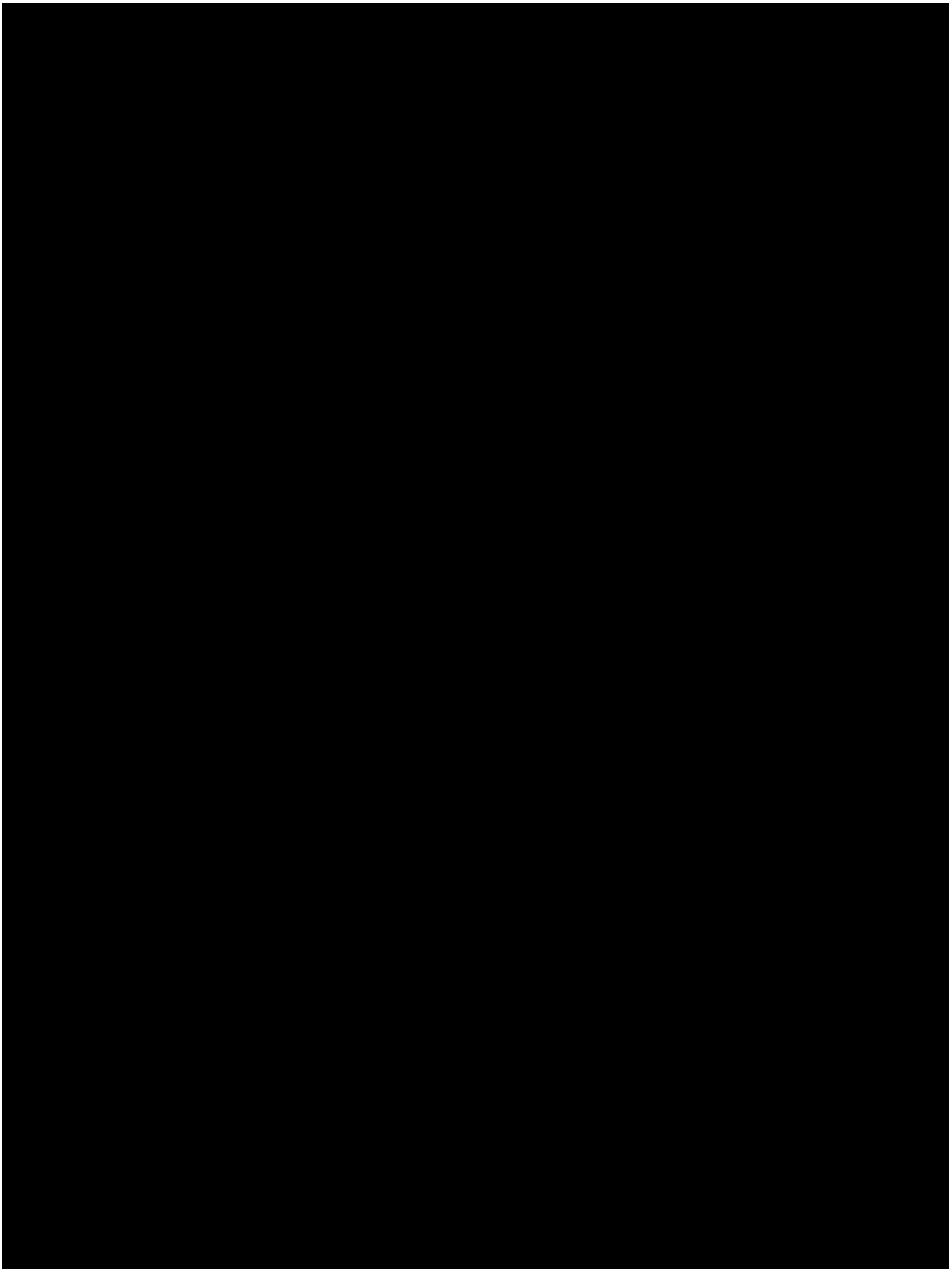

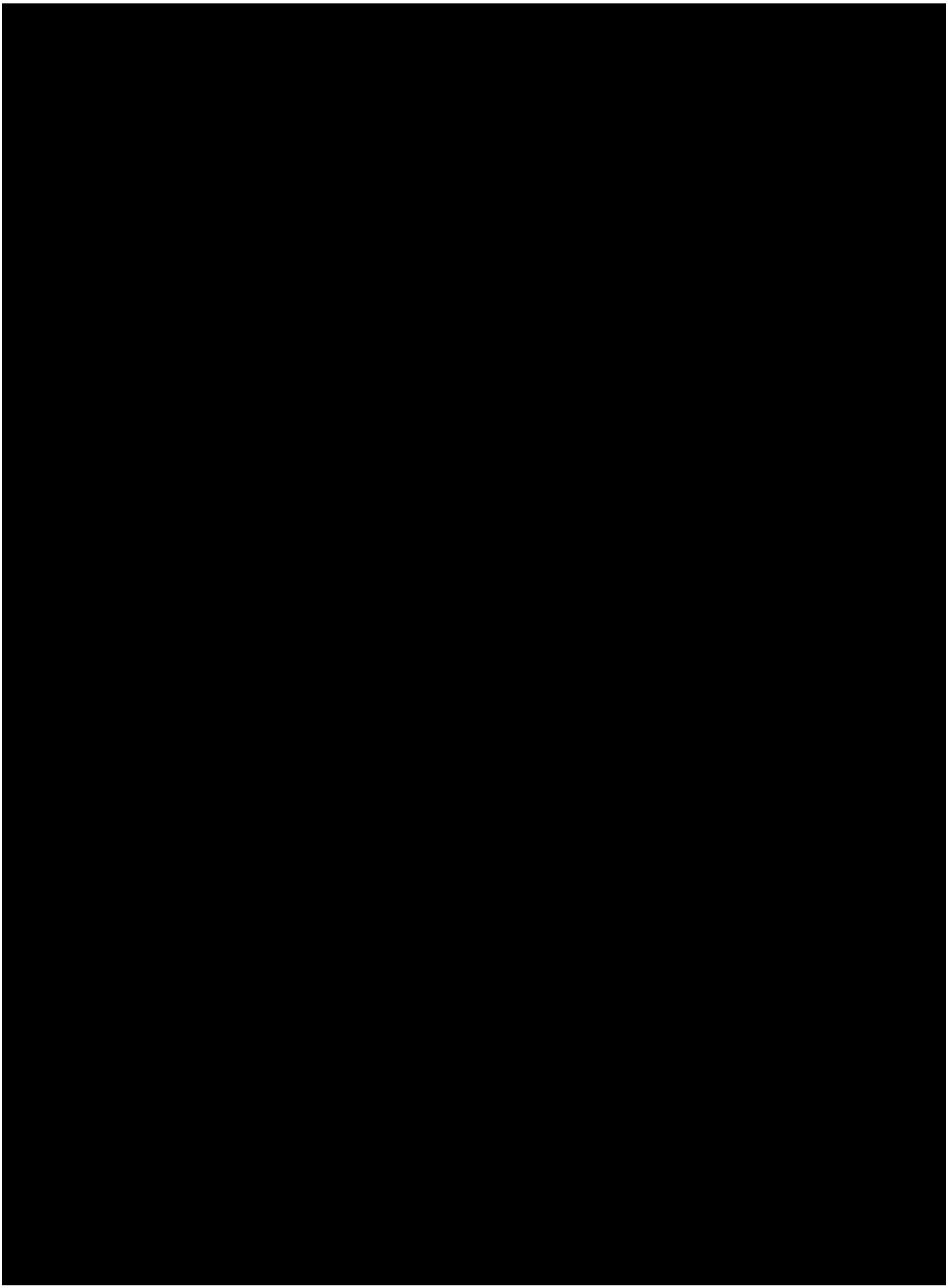

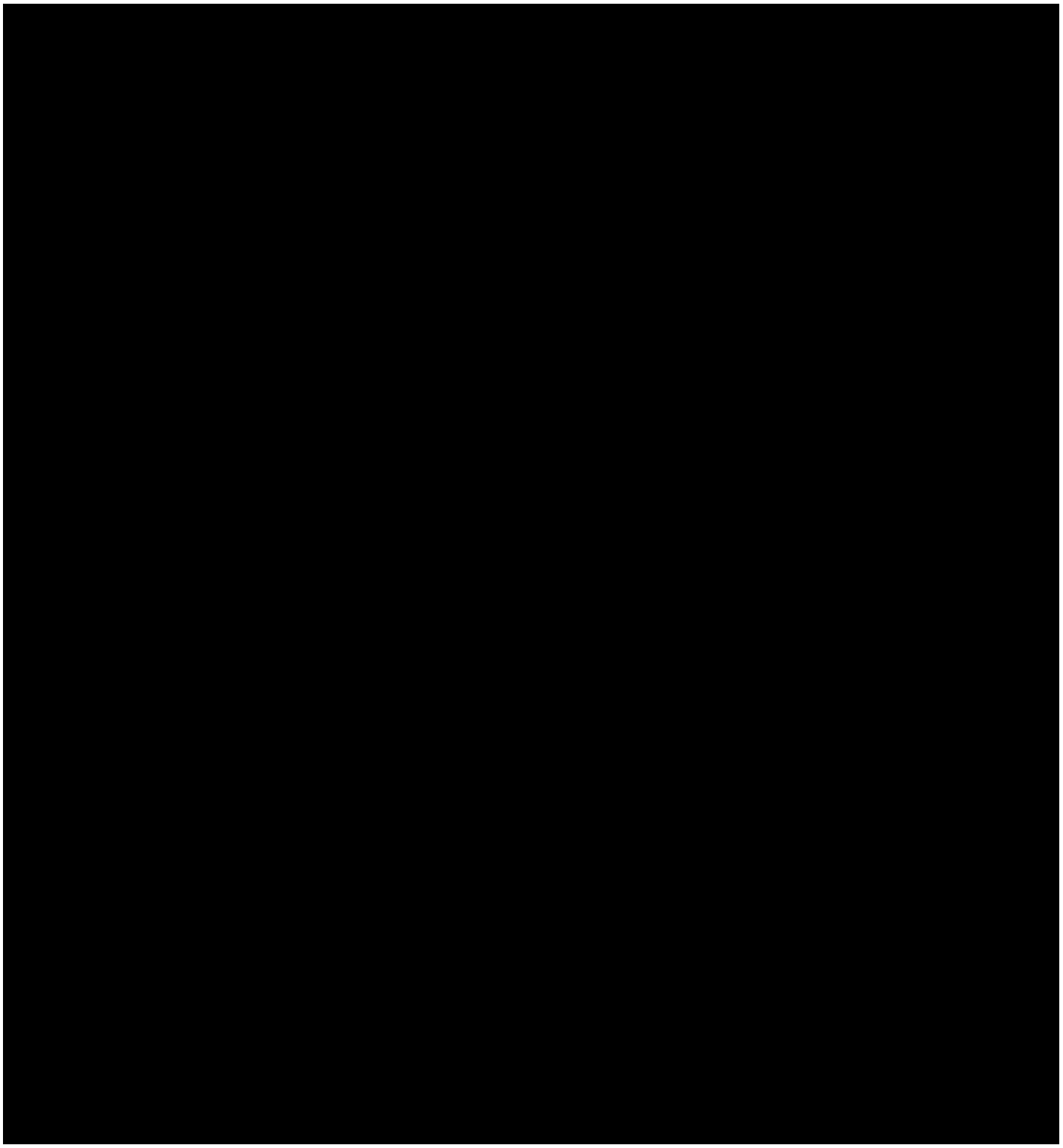

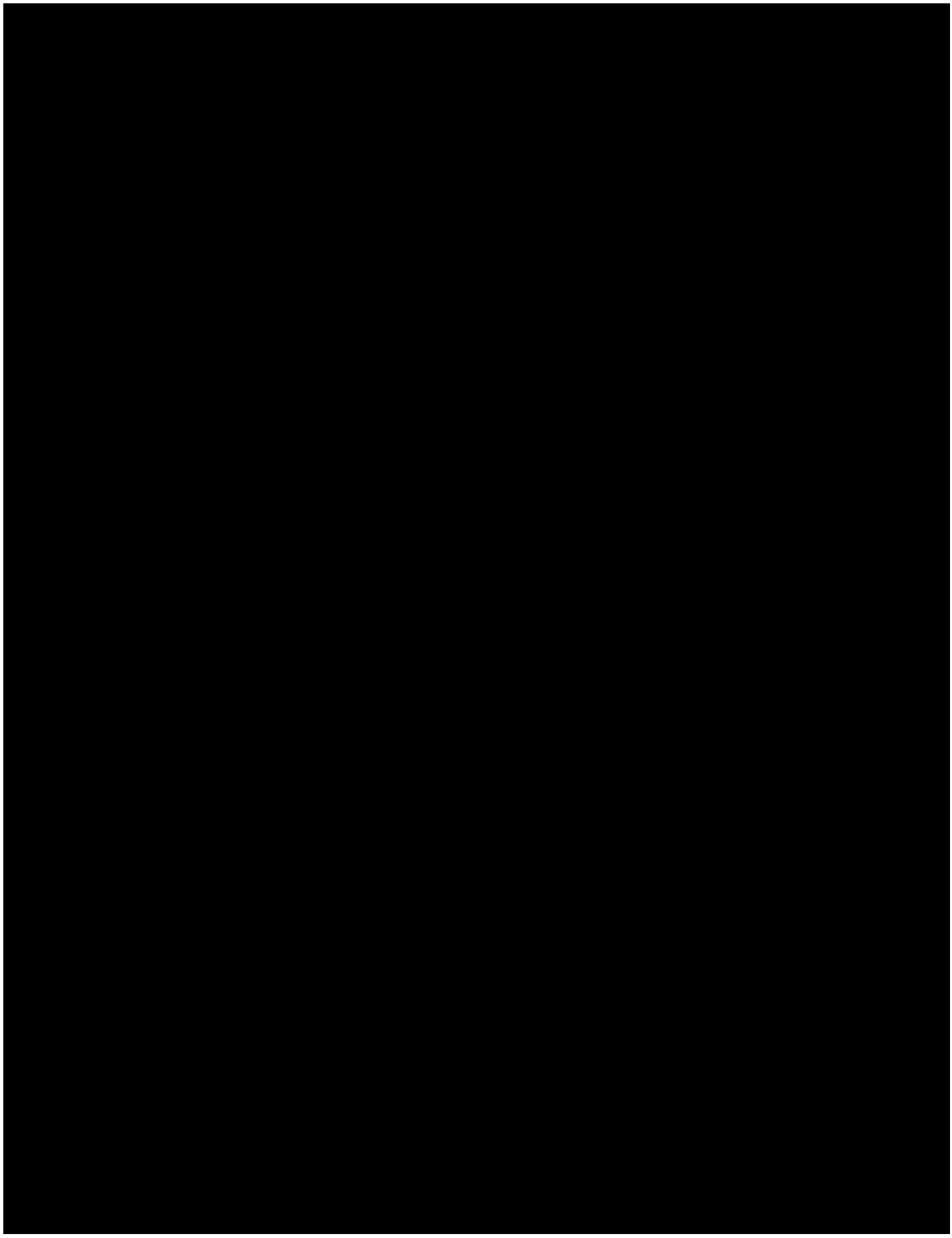

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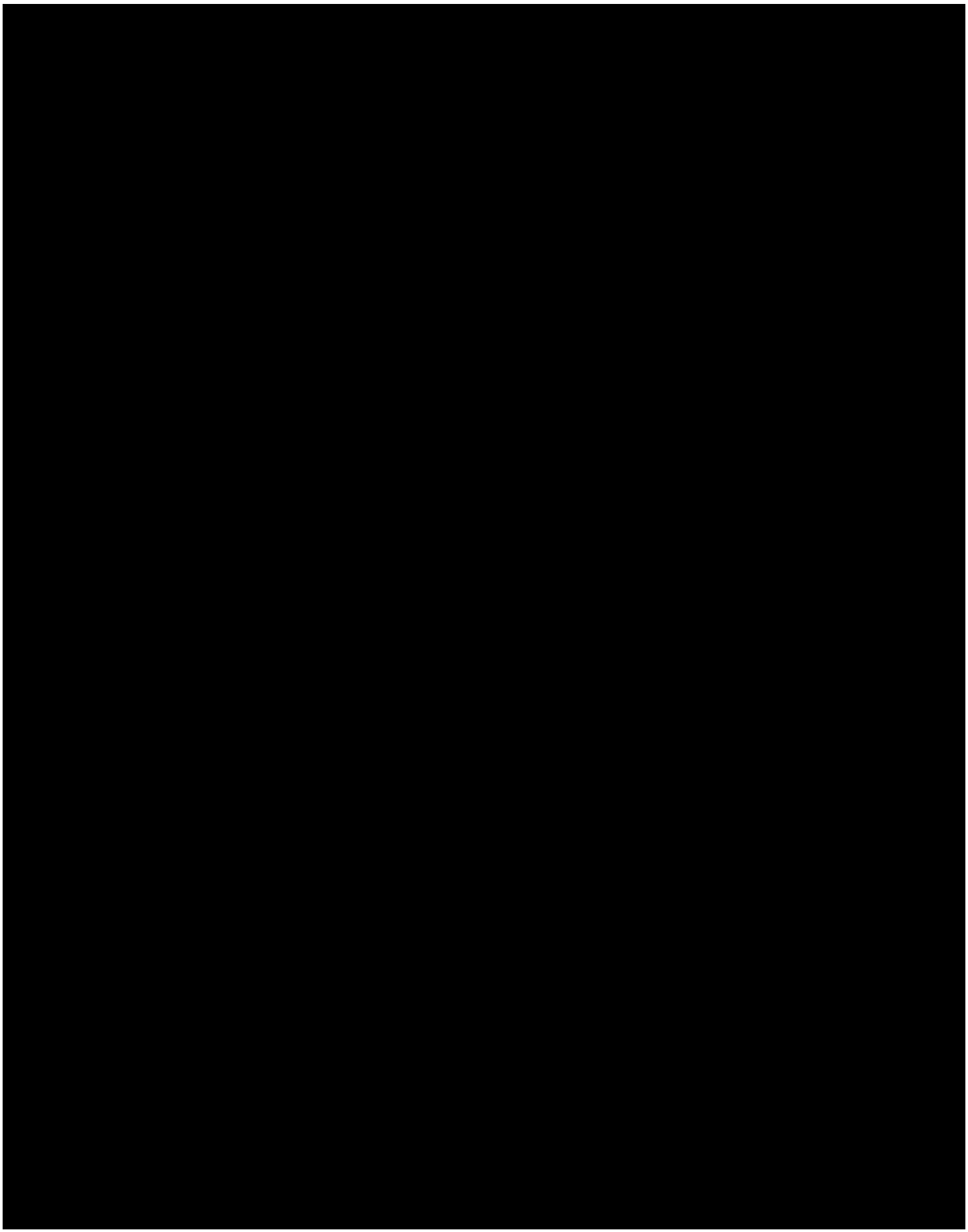

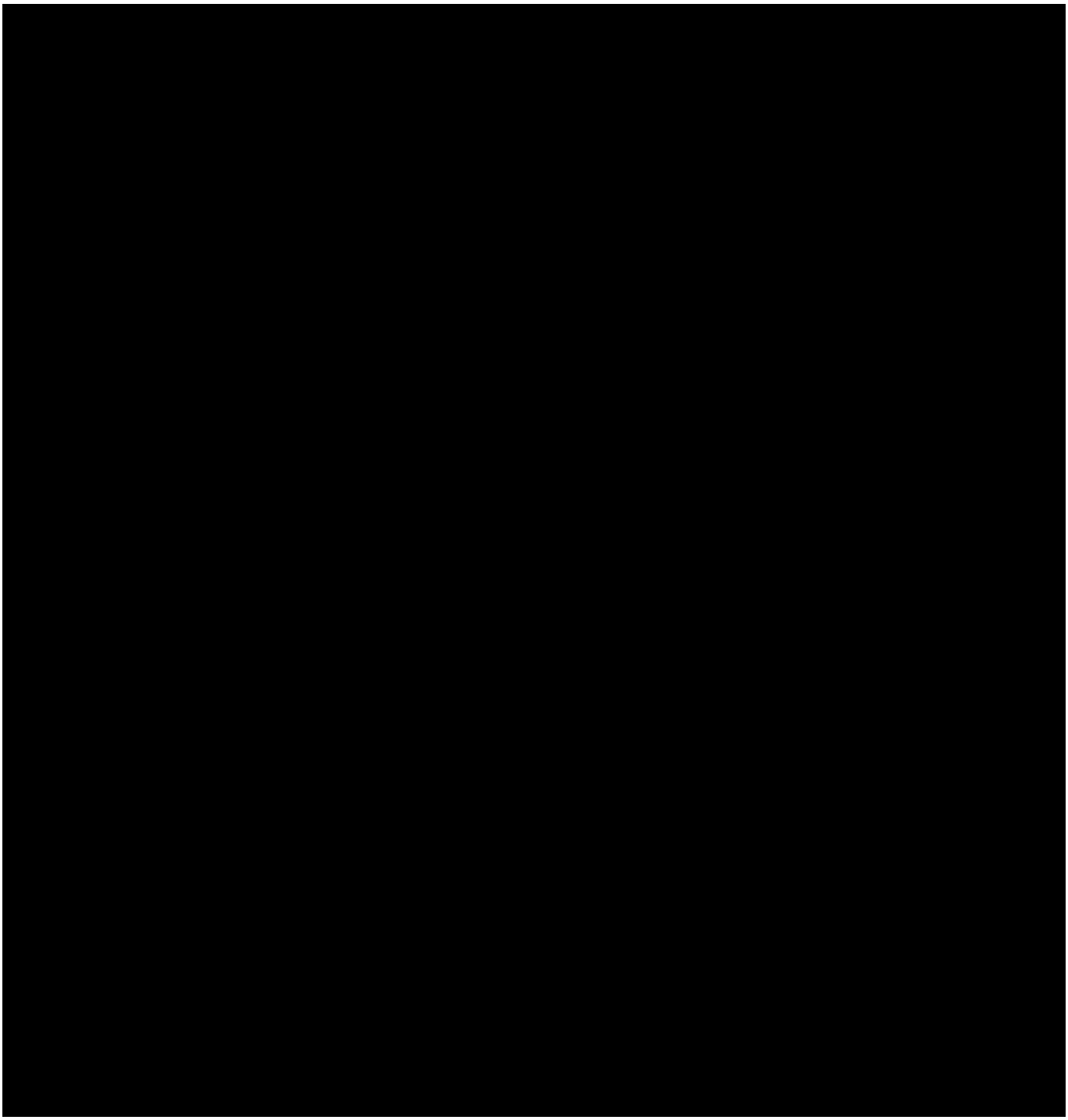

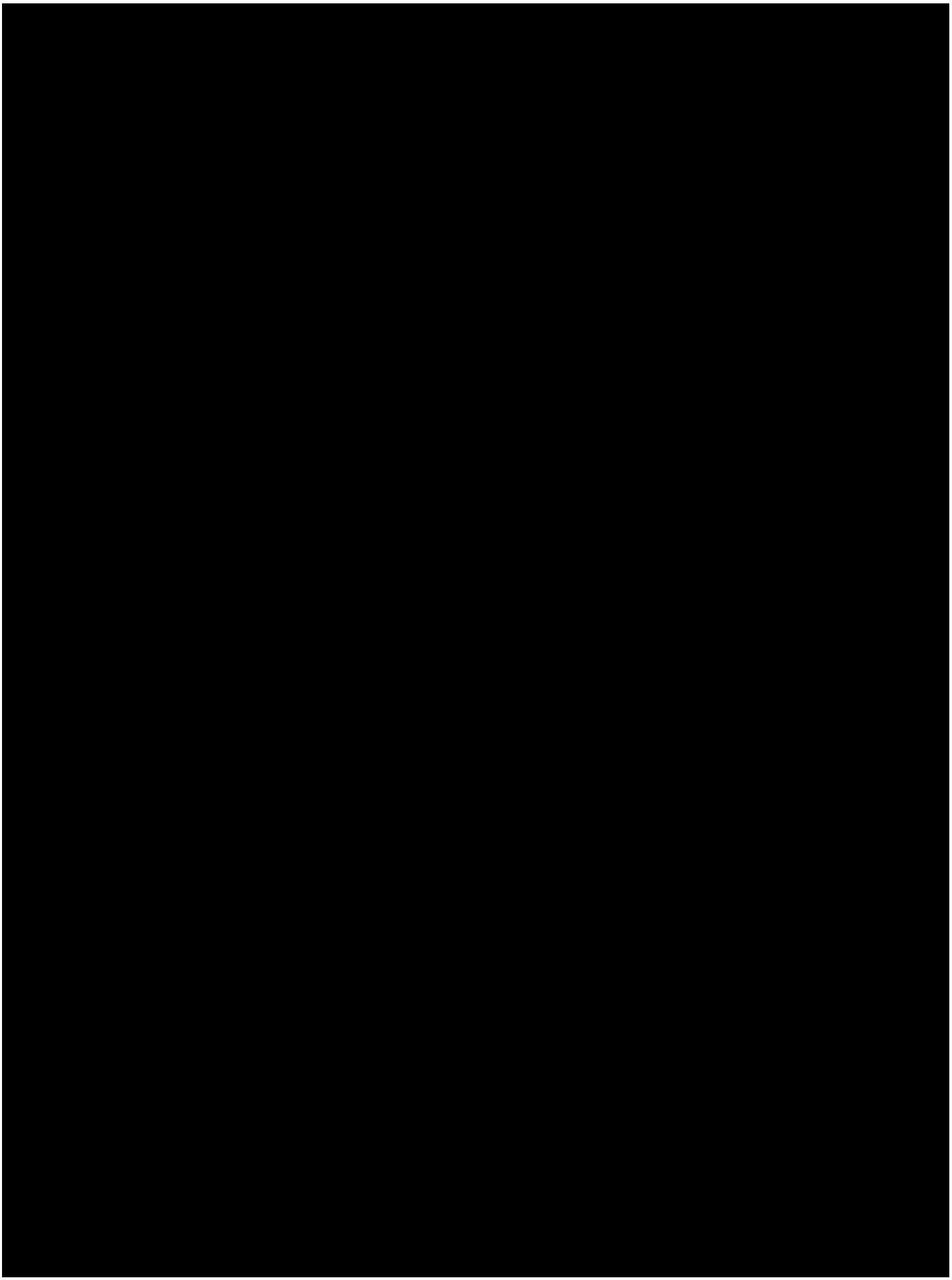

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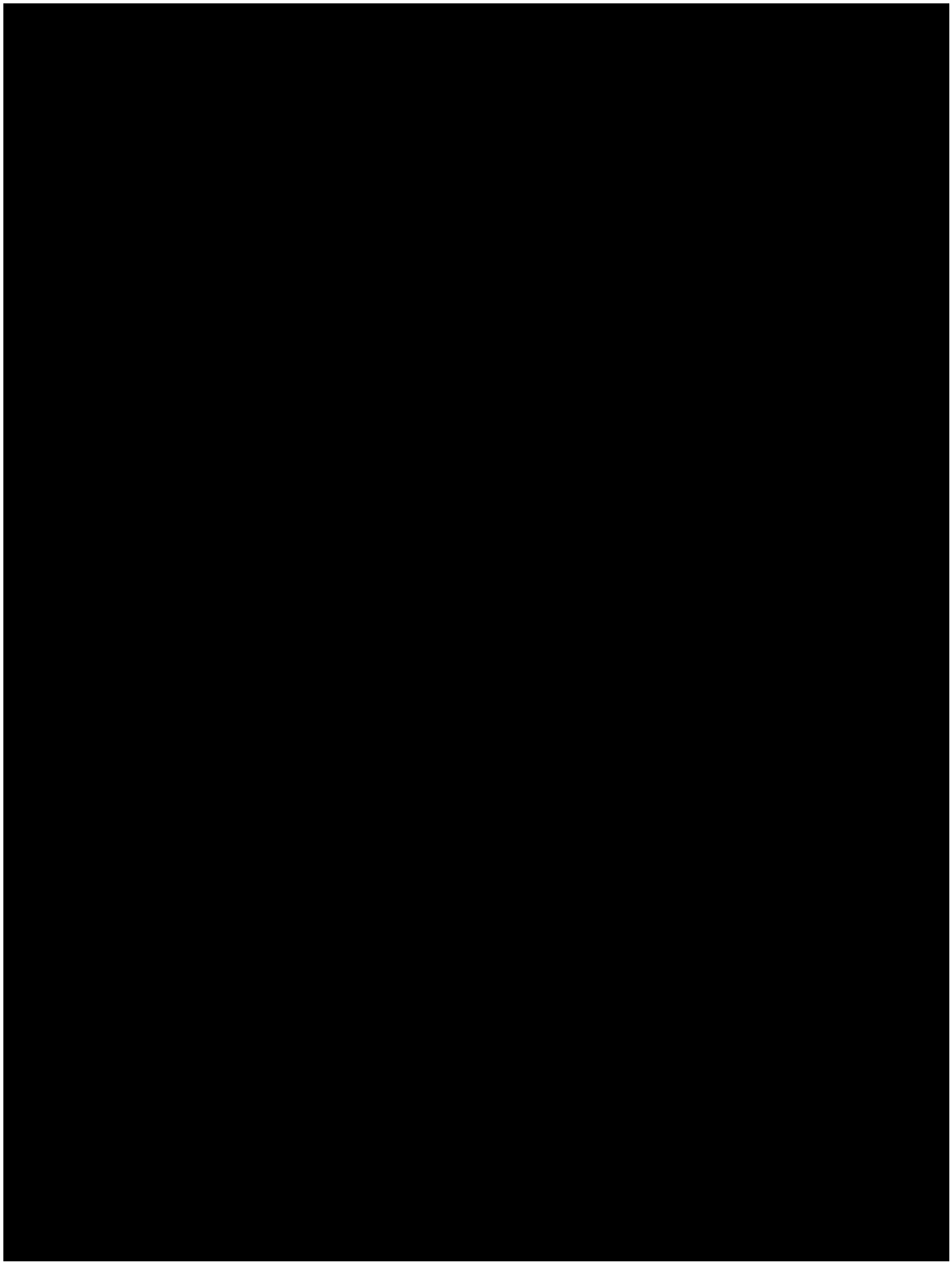

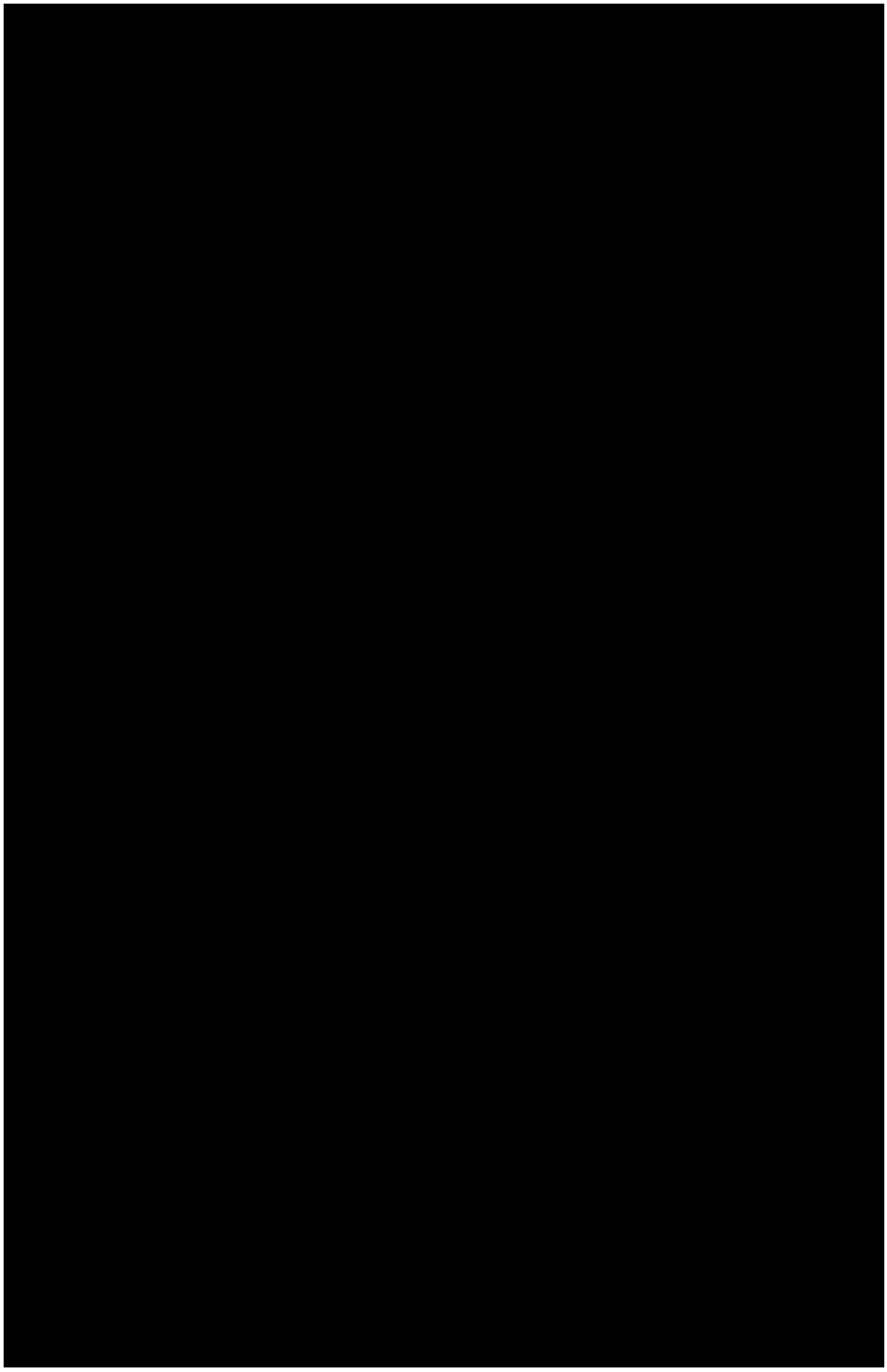

APPENDIX B: PATIENT INSTRUCTION GUIDE

Will be provided separately.

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

BAUSCH Health

DESCRIPTION: UltraMFA DW PIFG Ins / US / FITSET

PART No.: 8184600 **SPEC No. or SPEC DIMENSIONS:** 5573

SPECIAL INSTRUCTIONS: n/a

PRINT SUPPLIERS: Please refer to Bausch Health's *Print Supplier Guidelines*

BLACK	PMS 320						

PACKAGE INSERT / FITTING GUIDE

BAUSCH+LOMB ULTRA® contact lenses

Multifocal for Astigmatism

with MoistureSeal® TECHNOLOGY

℞ ONLY CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA

Printed in the USA

Rev. 2019-02
8184600

SYMBOL REFERENCE GUIDE

For labels and cartons:

	Meets EU Packaging Directive	BC	Base Curve
STERILE	Sterilized Using Steam	SVS	Single Vision Spherical
	Caution	ADD	Add Power
DIA Ø$_T$	Diameter	AX	Cylinder Axis
EXP	Use-By Date	CYL	Cylinder Power
LOT	Batch Code	SPH	Sphere Power
			Temperature Limit
℞ ONLY	Prescription Only (USA)	YYYY-MM-DD	Effective Date
PWR F'_V	Power		Manufacturer

8184600

TABLE OF CONTENTS

CAUTION

Federal law restricts this device to sale by or on the order of a licensed practitioner.

IMPORTANT

This package insert and fitting guide has been developed to provide practitioners with information covering characteristics of the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens and to illustrate fitting procedures. It is effective as of revision date on cover and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.

This package insert and fitting guide is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens and the recommended wearing schedule.

DESCRIPTION

The Bausch + Lomb ULTRA® (samfilcon A) Multifocal for Astigmatism Contact Lens material, samfilcon A, is a hydrophilic copolymer of a siloxane methacrylate and N-vinyl pyrrolidone, and is 46% water by weight when immersed in a sterile borate buffered saline with poloxamine solution. This lens is tinted with up to 200 ppm of Reactive Dye 246. The Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lenses utilizes MoistureSeal® Technology which creates a unique material and a hydrophilic surface.

The physical/optical properties of the lens are:

Specific Gravity:	1.048
Refractive Index:	1.411
Light Transmittance:	C.I.E. value—at least 95%
Water Content:	46%
Oxygen Permeability:	114×10^{-11} [$cm^3 O_2$ (STP) x cm]/(sec x cm^2 x mmHg) @ 35°C Polarographic Method (Boundary and Edge Corrected)

The Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens features both a 3-Zone Progressive™ Design and an OpticAlign® Design.

LENS PARAMETERS AVAILABLE

The Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens is a hemispherical shell of the following dimensions:

Diameter:	14.5mm
Center Thickness:	0.05mm to 0.50mm
Base Curve:	8.6mm
Powers:	+4.00D to -6.00D in 0.25D steps
Add Powers:	Low (+0.75D to +1.50D) and High (+1.75D to +2.50D)
Cylinder Powers:	-0.75D, -1.25D and -1.75D
Axis:	10° to 180° in 10° increments

*Additional powers may be introduced overtime, check periodically for product availability.

HOW THE LENS WORKS (ACTIONS)

In its hydrated state, the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

INDICATIONS

Multifocal for Astigmatism Vision Correction

The Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters and require an add power ranging from +0.75D to +5.00D.

Frequent/Planned Replacement Wear

When prescribed for Frequent/Planned Replacement Wear, the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.

Disposable Wear

When prescribed for Disposable Wear, the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens is to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS

After a thorough eye examination, including appropriate medical background, patients should be fully apprised by the prescribing professional of all the risks with contact lens wear. Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of adverse reactions is increased when daily wear lenses are worn overnight.
- When prescribed for Frequent/Planned Replacement Wear, the need for strict compliance with the care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule should be emphasized to the patient.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove the lenses and promptly contact his or her eye care practitioner.

PRECAUTIONS

Special Precautions for Eye Care Practitioners

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers.

  Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the prescribing eye care practitioner should carefully monitor the continuing ocular health of the patient and lens performance on eye.
- Eye care practitioners should instruct the patient to REMOVE A LENS IMMEDIATELY if an eye becomes red or irritated.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with sterile saline solution that is recommended for in-eye use.
- The patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care practitioner.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Aphakic patients should not be fitted with Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lenses until the determination is made that the eye has healed completely.
- Patients who wear aspheric contact lenses, such as the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens, to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Eye care practitioners should carefully instruct patients about the following lens care and safety precautions. It is strongly recommended that patients be provided with a copy of the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens Patient Information Booklet available from Bausch + Lomb and understand its contents prior to dispensing the lenses.

Handling Precautions

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Be sure that before leaving the eye care practitioner's office, the patient is able to remove lenses promptly or have someone else available to remove them.
- Be certain that the fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle lenses carefully and avoid dropping them.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Information Booklet for the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens and those prescribed by the eye care practitioner.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Lens Wearing Precautions

- Never wear lenses beyond the period recommended by the eye care practitioner.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking (Nonmoving) Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Solution Precautions

Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer's labeled lens care instructions with the patient.

- Always use fresh, unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- You should fill your lens case with fresh solution every time you store your lenses and never "top-off" or re-use solution. You should discard your solution immediately after your lenses have been removed from the lens case.
- Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn (stored). Prolonged periods of drying will damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens in the Patient Information Booklet if lens surface does become dried out.
- Do not use saliva or anything other than the recommended solution for lubricating or wetting lenses.
- Tap water, distilled water or homemade saline should not be used as a substitute for any component in the lens care regimen since they have been associated with an *Acanthamoeba* keratitis infection.
- Never use conventional hard contact lens solutions that are not also recommended for use with prescribed lenses.
- Do not mix or alternate lens care systems or solutions unless indicated in the lens care system labeling.
- Do not heat the chemical disinfection solution or lenses.

Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air-dry.
- Lens cases should be replaced at least every three months or as recommended by the lens case manufacturer or eye care practitioner.

Topics to Discuss with the Patient

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the eyes. The patient should be instructed as to a recommended follow-up schedule.
- Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of ocular infection including, but not limited to, *Acanthamoeba* keratitis.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.

Who Should Know That the Patient is Wearing Contact Lenses

- Patients should inform their doctor (health care professional) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you do not wear lenses.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to:

- Immediately remove the lenses.
- If the discomfort or problem stops, the patient should look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should immediately remove the lenses and consult his or her eye care practitioner.

  If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should immediately remove the lenses and contact his or her eye care practitioner or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial staining or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare, and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combination may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

SELECTION OF PATIENTS

The eye care practitioner should not fit patients who cannot or will not adhere to a recommended care or replacement regimen, or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and cleaning instructions could lead to serious eye infections which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also to ensure compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.

Patients selected to wear Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part time), and desired lens usage (reading, recreation or hobbies).

Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear.

If these symptoms persist, the patient should be instructed to contact his or her eye care practitioner.

PRACTITIONER FITTING SETS

Lenses must be discarded after a single use and must not be used from patient to patient.

GENERAL FITTING PROCEDURE

1. Pre-Fitting Examination

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for contact lenses (consider patient hygiene and mental and physical state),
- Make ocular measurements for initial contact lens parameter selection, and
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include spherocylinder refraction and VA, keratometry, and biomicroscopic examination.

2. Lens Power Selection

a. Update spectacle refraction and Add power.
b. Determine ocular dominance.
c. Select toric lens power, adjusting for vertex distance if necessary.
d. Select Add power for both eyes, following the guidance below.
   - Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens Low Add: +0.75D to +1.50D
   - Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens High Add: +1.75D to +2.50D

3. Lens Fitting

a. Allow lens to equilibrate for at least 10 minutes before assessing fit and vision.
b. Confirm axis orientation.
c. Evaluate distance and near vision binocularly in normal room illumination.
d. If vision at distance and near are satisfactory, dispense lenses and schedule follow-up exam within 1-2 weeks.

4. To Refine Near Vision

If patient is wearing two Low Add lenses:

- Refinement 1:
  Place Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens High Add in non-dominant eye while keeping Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens Low Add in dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1:
  Add +0.25D to the non-dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using handheld lenses.

5. To Refine Distance Vision

If patient is wearing two Low Add lenses:

- Refinement 1:
  Fit Bausch + Lomb ULTRA for Astigmatism in dominant eye while keeping Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens Low Add in non-dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, add -0.25D at a time to dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1:
  Fit with Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens Low Add in dominant eye while keeping Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens Add in non-dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, add -0.25D at a time to dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.

6. Patient Education

All patients do not function equally well with multifocal correction. Patients may not perform as well for certain tasks with this correction as they have with multifocal reading glasses. Each patient should understand that multifocal correction can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that multifocal contact lenses provide.

7. Lens Evaluation

a. To determine proper lens parameters, observe the lens relationship to the eye using a slit lamp.
   - Movement: The lens should provide discernible movement with:
     - Primary gaze blink
     - Upgaze blink
     - Upgaze lag
   - Centration: The lens should provide full corneal coverage

b. Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens. If after the lens has settled on the eye, the patient reports lens sensation, or if the lens is moving or decentering excessively, the lens should not be dispensed. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, the lens should not be dispensed.

8. Criteria of a Well-Fitted Lens

If the lens fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient and provides satisfactory visual performance, it is a well-fitted lens and can be dispensed.

9. Characteristics of a Tight (Steep) Lens

A lens which is much too steep may subjectively and objectively cause distortion which will vary after a blink. However, if a lens is only marginally steep, the initial subjective and objective vision and comfort findings may be quite good. A marginally steep lens may be differentiated from a properly fitted lens by having the patient gaze upward. A properly fitted lens will tend to slide downward approximately 0.5mm while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

Toric Lens: With your finger, gently rotate the lens approximately 45˚ to the temporal side. It should reorient with 5 to 10 blinks back to the same stabilized position.

10. Characteristics of a Loose (Flat) Lens

A lens that is too flat will decenter, especially on post-blink, have a tendency to edge lift inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva. A flat fitted lens will have a tendency to be uncomfortable and irritating with fluctuating vision. A flat fitted lens has a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

11. Follow-Up Care

a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, the following schedule is a suggested guideline for follow-up.
   - 24 hours
   - 1 to 2 weeks
   - Every six months thereafter

   At the initial follow-up evaluations the eye care practitioner should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief. Depending on the patient's prior experience with contact lenses and/or continuous wear, the eye care practitioner may consider prescribing a one week period of daily wear adaptation prior to beginning continuous wear.

b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear. If the patient is wearing the lenses for continuous wear, the follow-up examination should be conducted as early as possible the morning after overnight wear.

c. With lenses in place on the eyes, evaluate fitting performance to assure that Criteria of a Well-Fitted Lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

d. After the lens removal, instill sodium fluorescein [unless contraindicated] into the eyes and conduct a thorough biomicroscopy examination.
   1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.
   2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
   3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

   If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the Criteria of a Well-Fitted Lens are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

MONOVISION FITTING GUIDELINES

1. Patient Selection

a. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than one [1] diopter) in one eye may not be a good candidate for monovision with the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lenses.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision.

Monovision contact lens wear may not be optimal for such activities as:

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

b. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

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

a. Ocular Preference Determination Methods
   - Method 1—Determine which eye is the "sighting dominant eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.
   - Method 2—Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

b. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

c. Visual Demands Method

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

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

3. Special Fitting Considerations

Unilateral Lens Correction

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

Example:
A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 diopter lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

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

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines.

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

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

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

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

6. Adaptation

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

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

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

7. Other Suggestions

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

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

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.
- The decision to fit a patient with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering the patient's needs.
- All patients should be supplied with a copy of the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens Patient Information Booklet.

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Regular checkups, as determined by the eye care practitioner, are extremely important.

Daily Wear

There may be a tendency for the daily wear patient to over wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

Disposable Lens Wear

No lens care is needed. The lenses are discarded every time they are removed from the eye. Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

Frequent/Planned Replacement Wear

When removed between replacement periods, lenses must be cleaned and disinfected before reinsertion, or be discarded and replaced with a new lens.

HANDLING OF LENS

Patient Lens Care Directions

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care practitioner should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system selected by the professional, the specific instructions for such products and the particular characteristics of the patient.

Frequent/Planned Replacement Wear

For complete information concerning the care, cleaning and disinfection of contact lenses refer to the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens Patient Information Booklet.

Disposable Wear

For complete information concerning emergency lens care, refer to the Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lens Patient Information Booklet.

a. Soaking and Storing Lenses

Instructions for Use:

Use only fresh contact lens disinfecting solution each time you soak (store) your lenses.

WARNING:

Do not reuse or "top-off" old solution left in lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-off" is the addition of fresh solution to solution that has been sitting in the case.

b. Rub and Rinse Time

Instructions for Use:

Follow the complete recommended lens rubbing and rinsing times in the labeling of the solution used for cleaning, disinfecting and soaking lenses to adequately disinfect lenses and reduce the risk of contact lens infection.

WARNING:

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

c. Lens Case Care

Instructions for Use:

- Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solution/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry.
- Replace lens case at least every three months, or as directed by your eye care practitioner.
- Contact lens cases can be a source of bacterial growth.

WARNING:

Do not store lenses or rinse lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

d. Water Activity

Instructions for Use:

Do not expose contact lenses to water while wearing them.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water when swimming in pools, lakes, or oceans, discard them and replace them with a new pair. Ask your eye care practitioner for recommendations about wearing lenses during any activity involving water.

e. Discard Date on Solution Bottle

Instructions for Use:

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

WARNING:

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

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rewetting solution in their eye. The patient should be instructed to not use plain water, or anything other than the recommended solutions. The patient should be instructed to contact the eye care practitioner if the lens does not begin to move upon blinking after several applications of the solution, and to not attempt to remove the lens except on the advice of the eye care practitioner.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb ULTRA (samfilcon A) Multifocal for Astigmatism Contact Lenses or experienced with the lenses should be reported to:

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, New York 14609 USA
Toll Free Telephone Number
In the Continental U.S., Alaska, Hawaii
1-800-553-5340
In Canada
1-888-459-5000 (Option 1 – English, Option 2 – French)

HOW SUPPLIED

Each sterile lens is supplied in a plastic blister package containing borate buffered saline with poloxamine solution. The container is marked with the manufacturing lot number of the lens, the base curve, sphere, diameter and expiration date.

APPENDIX D: PRESBYOPIC SYMPTOMS QUESTIONNAIRE

[redacted]

APPENDIX E: OCULAR DOMINANCE

[redacted]

APPENDIX F: BINOCULAR OVER REFRACTION

[redacted]

APPENDIX G: [redacted]

- [redacted] DETERMINATION OF NEAR ADDITION
- [redacted] NEAR logMAR VISUAL ACUITY MEASUREMENT PROCEDURE
- [redacted] LENS FITTING CHARACTERISTICS
- [redacted] SUBJECT REPORTED OCULAR SYMPTOMS
- [redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS
- [redacted] BIOMICROSCOPY SCALE
- [redacted] KERATOMETRY
- [redacted] DISTANCE AND NEAR VISUAL ACUITY EVALUATION
- [redacted] TORIC FIT EVALUATION
- [redacted] ETDRS DISTANCE VISUAL ACUITY MEASURMENT PROCEDURE
- [redacted] VISUAL ACUITY CHART LUMINANCE AND ROOM ILLUMINATION TESTING

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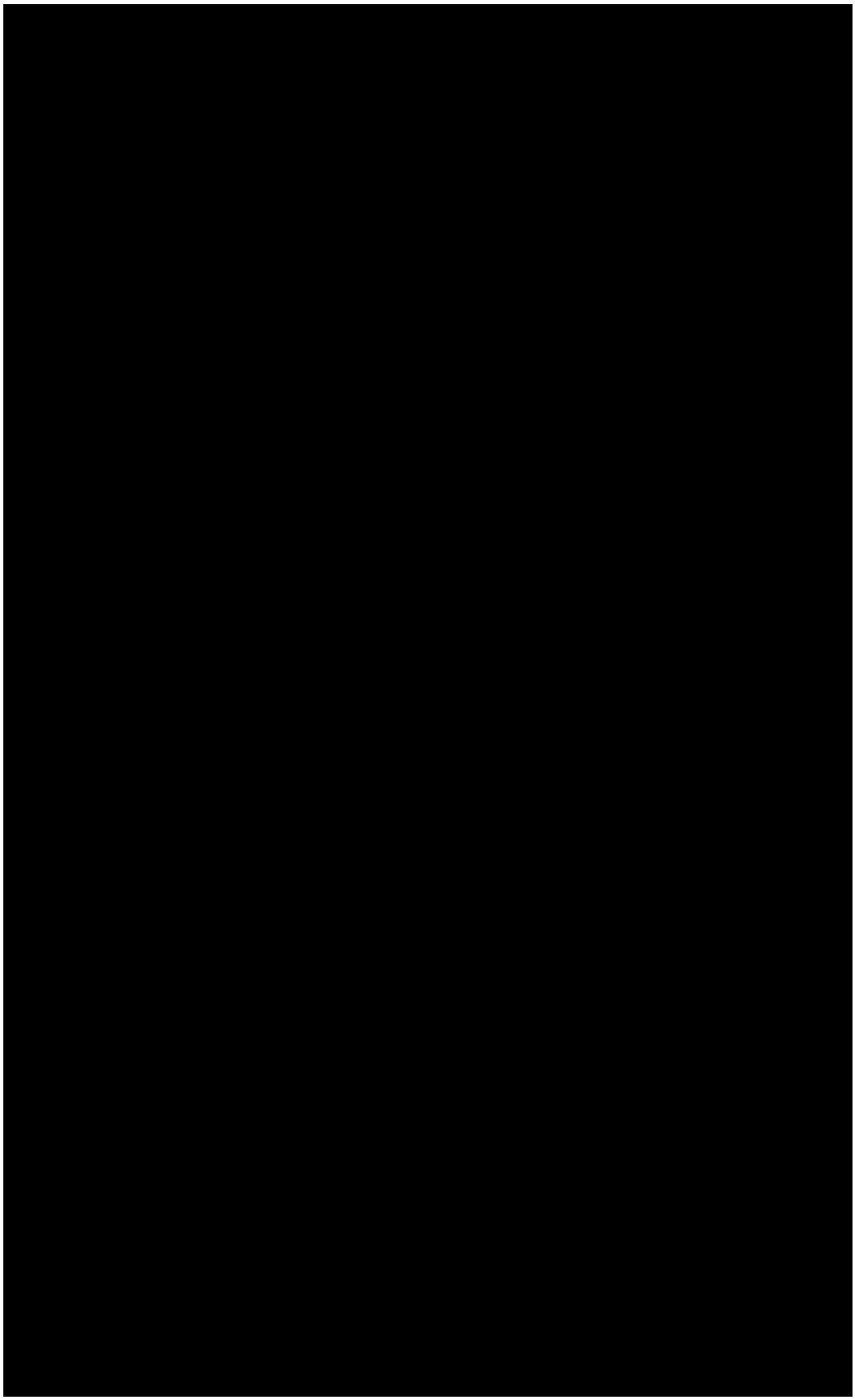

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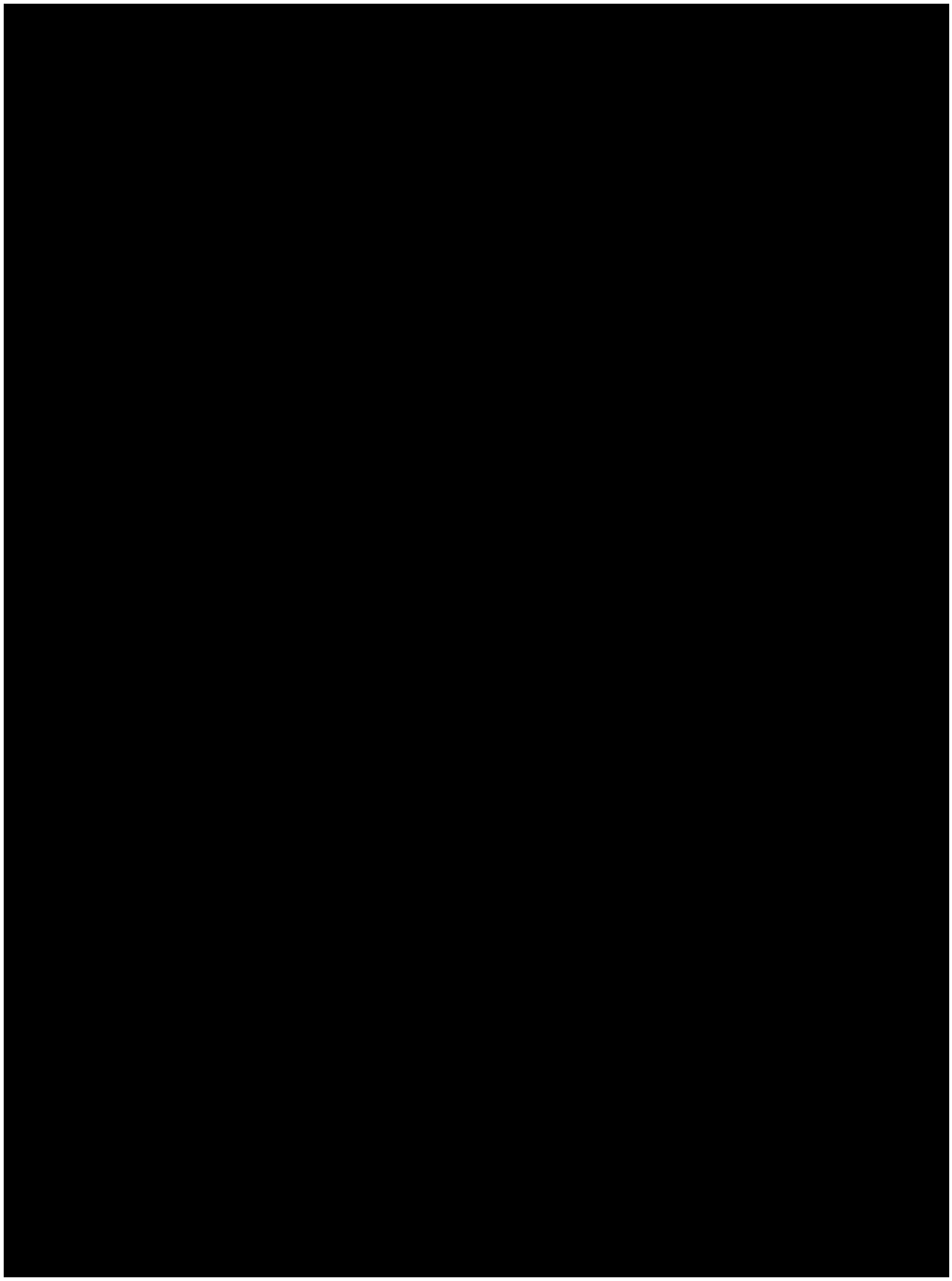

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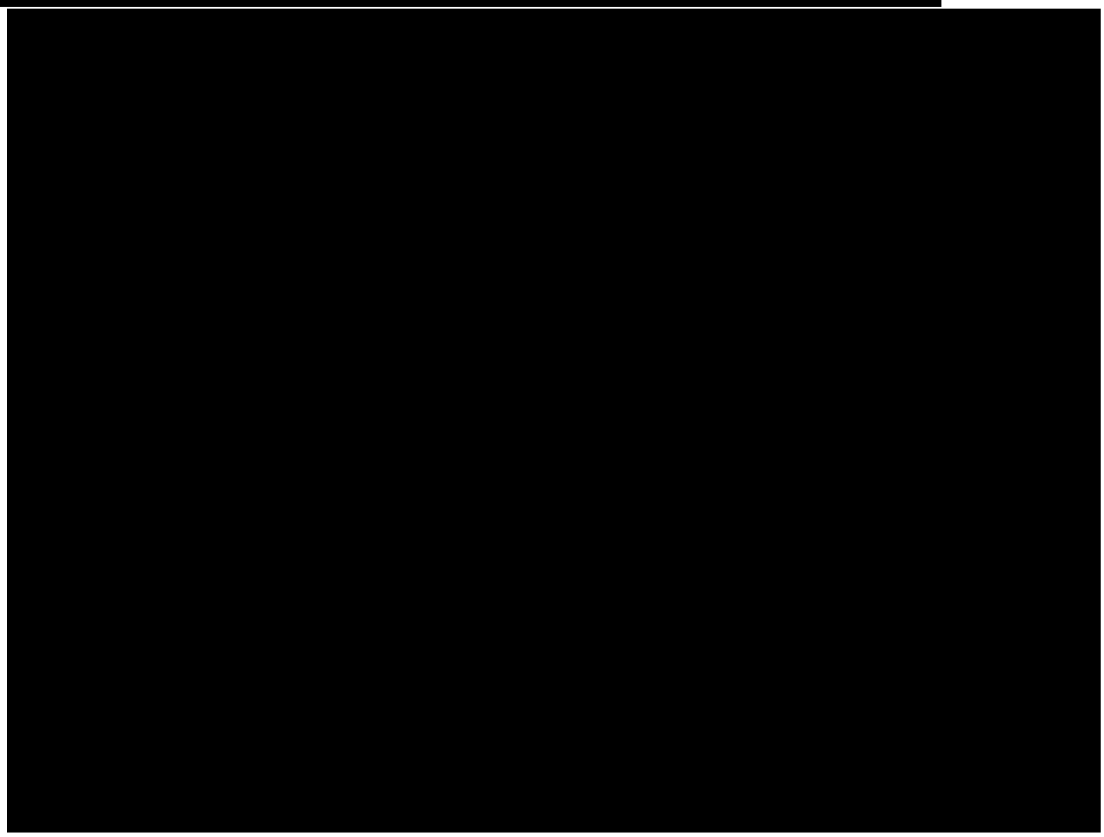

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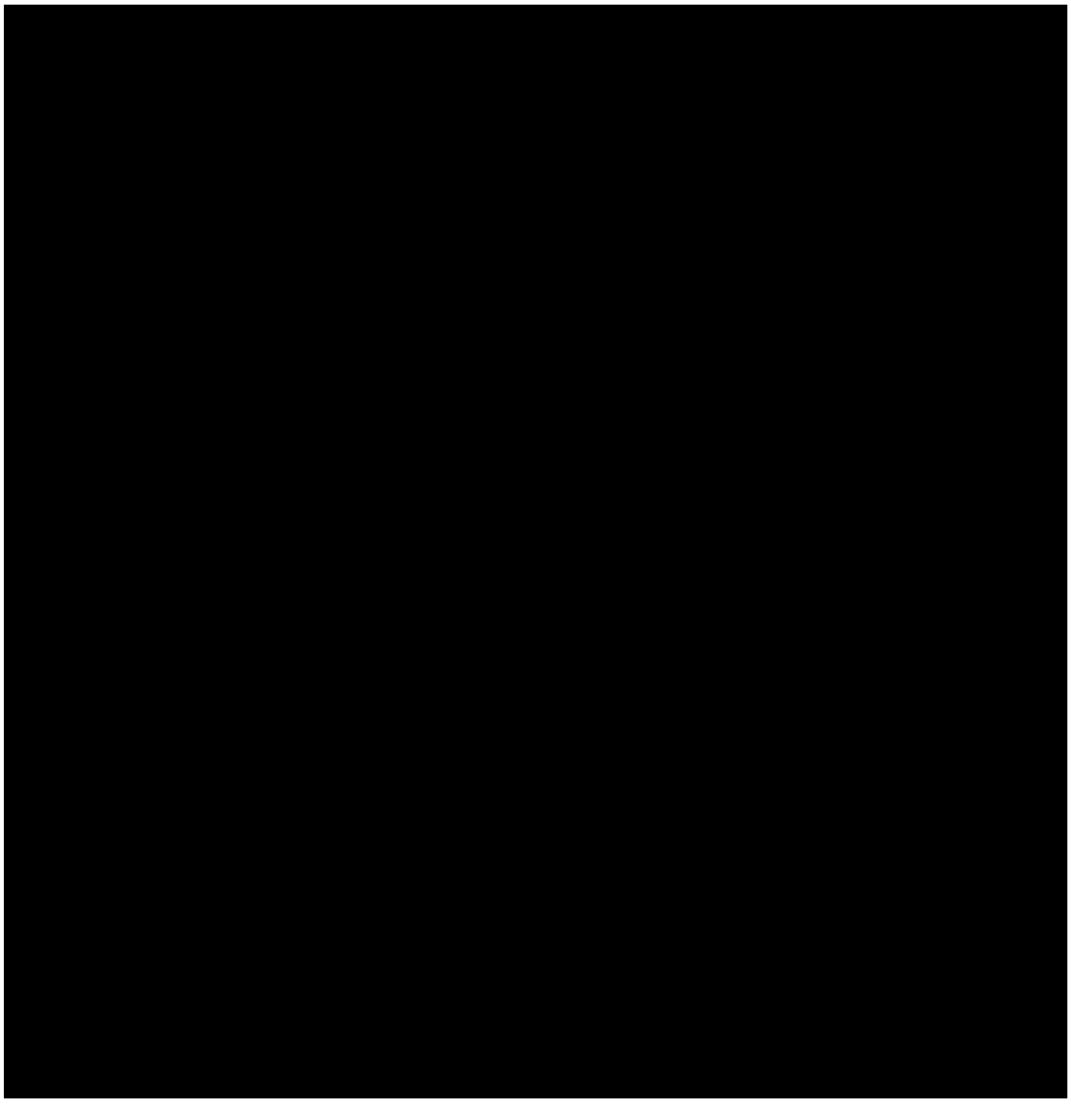

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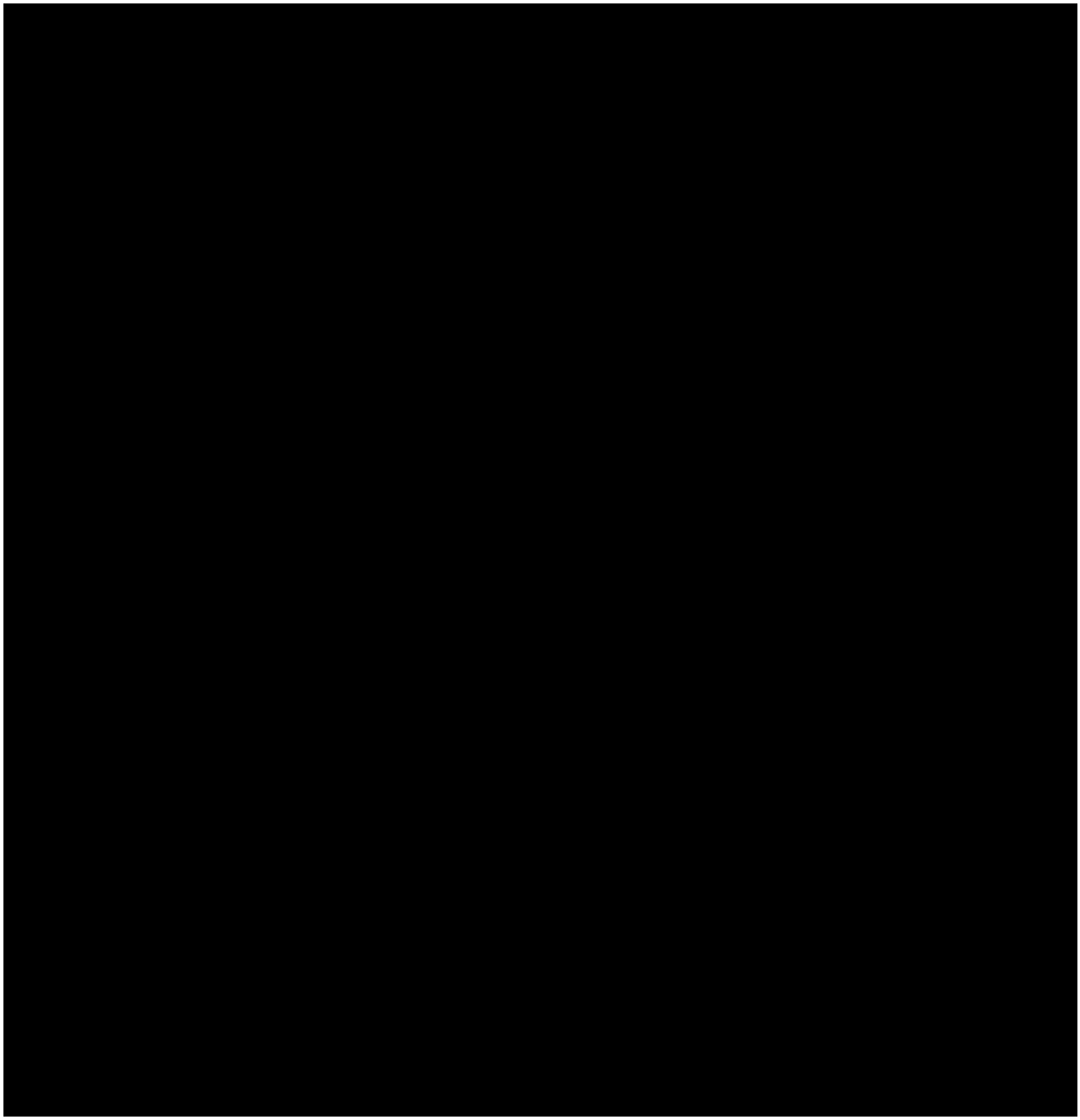

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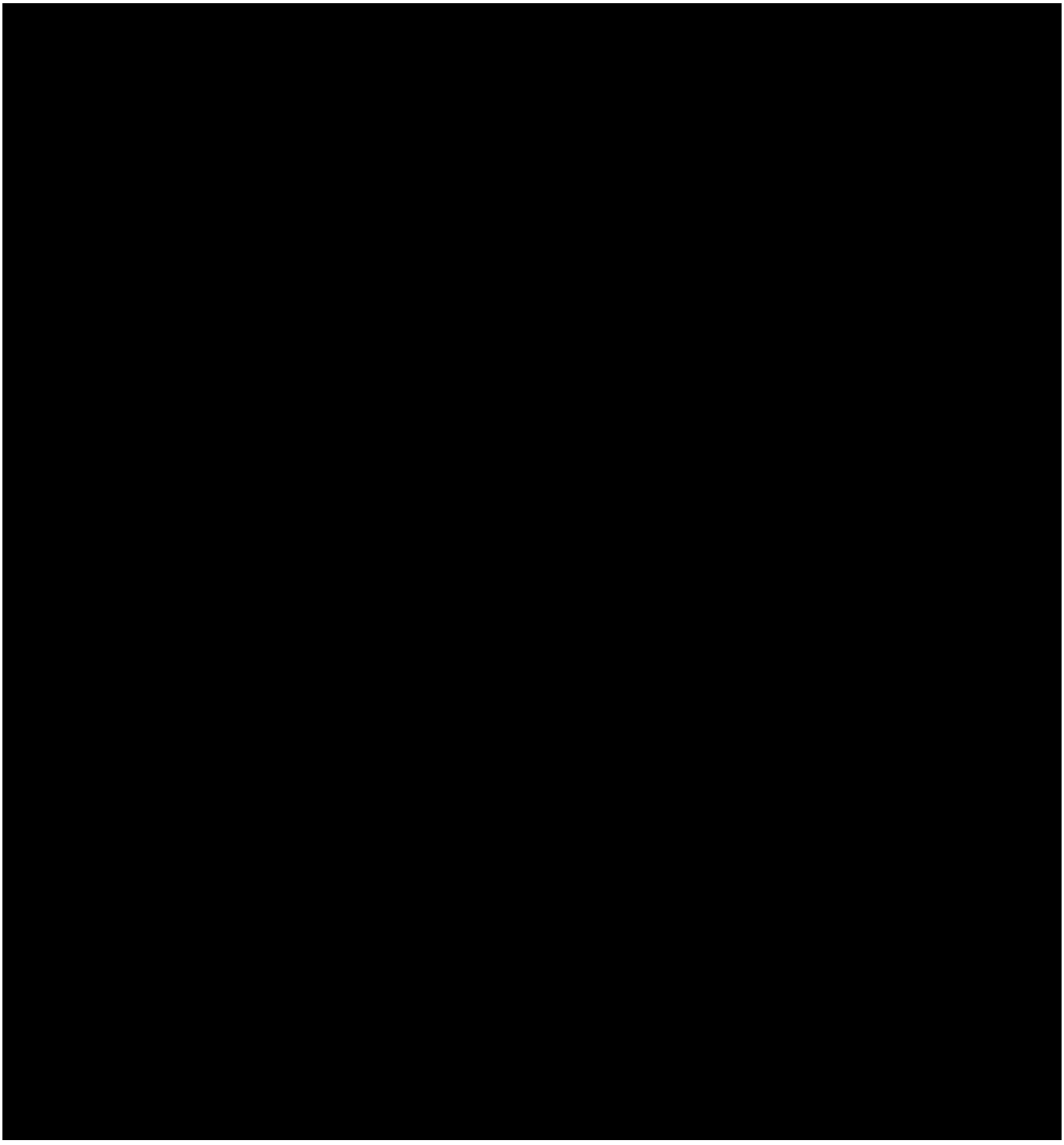

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APPENDIX H: GUIDELINES FOR COVID-19 RISK MITIGATION

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]

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-6383 Evaluation of Visual Acuity with a Reusable Toric Multifocal Contact Lens

Version and Date: 4.0, 29 October 2021

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

I agree to conduct this study according to ISO 14155:2020,[1] GCP and ICH guidelines,[2] the Declaration of Helsinki,[3] United States (US) Code of Federal Regulations (CFR),[4] and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. The Principal Investigator is responsible for ensuring that all clinical site personnel, including Sub-Investigators adhere to all ICH[2] regulations and GCP guidelines regarding clinical trials during and after study completion.

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

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

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

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

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

Principal Investigator: _____

Signature Date

_____

Name and Professional Position (Printed)

Institution/Site: _____

Institution/Site Name

_____

Institution/Site Address