NCT:NCT03681808

Clinical Study Protocol

Biotrue ONEday for Astigmatism Soft Contact Lens

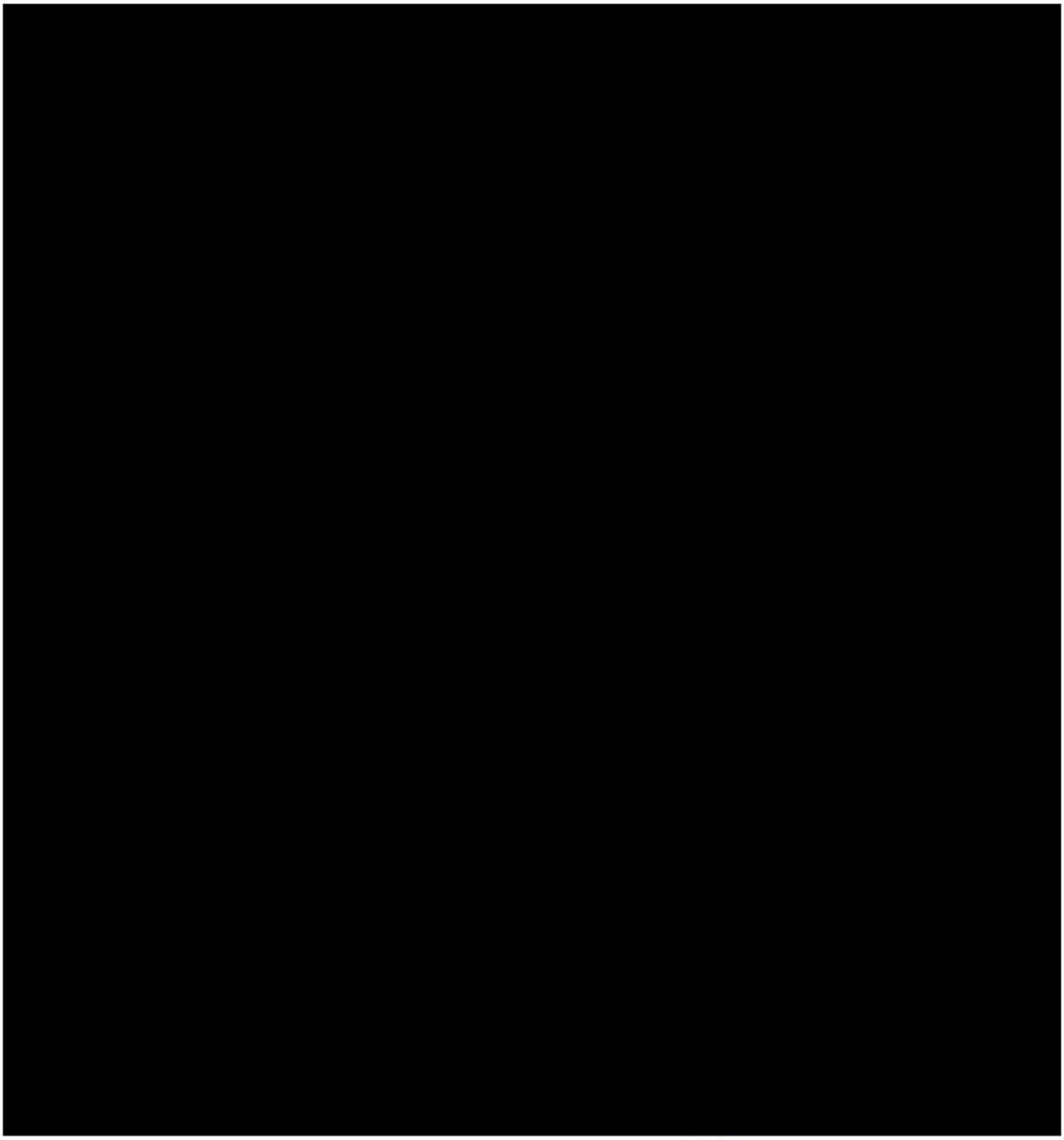
Protocol 885

A Study to Evaluate the Safety and Effectiveness of the Biotrue ONEday for Astigmatism Soft Contact Lens When Worn on a Daily Basis

Developmental phase of study:	Pivotal Trial
Study design	Investigator/Sponsor masked, randomized, open-label, parallel-group, multicenter study
Date:	23-Aug-2018
Sponsor representative	[redacted] Clinical Trial Manager [redacted]
Sponsor	Bausch & Lomb Inc., a Division of Valeant Research and Development, a subsidiary of Valeant Pharmaceuticals North America, LLC 400 Somerset Corporate Blvd. Bridgewater, NJ 08807 [redacted]

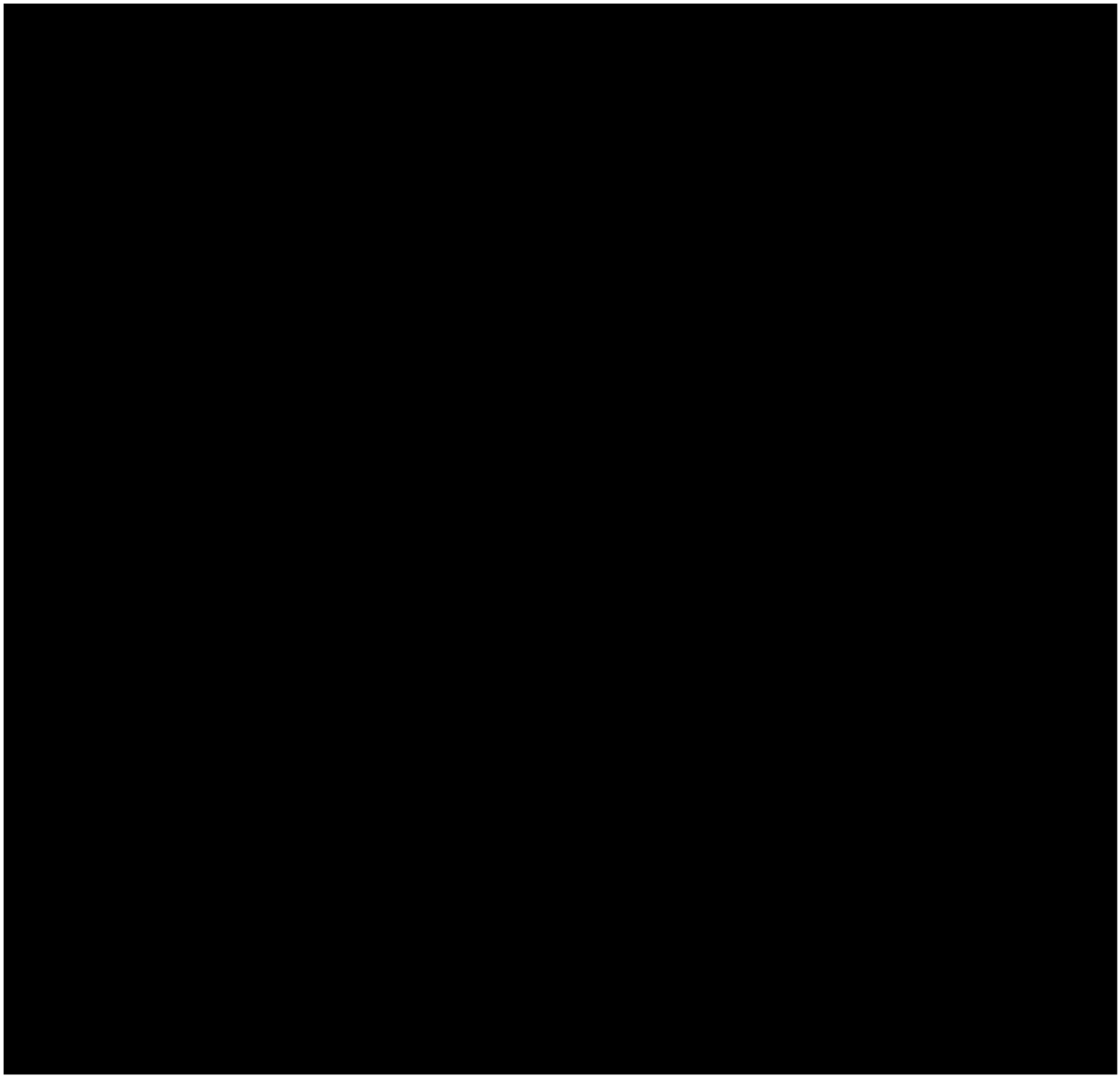
Protocol Review and Approvals

A Study to Evaluate the Safety and Effectiveness of the Biotrue ONEday for Astigmatism Soft Contact Lens When Worn on a Daily Basis



Personnel Responsible for Conducting the Study

A Study to Evaluate the Safety and Effectiveness of the Biotrue ONEday for Astigmatism Soft Contact Lens When Worn on a Daily Basis



Principal Investigator Protocol Agreement Page

I agree:

- To assume responsibility for the proper conduct of this clinical study at this site and to conduct the study in compliance with this protocol, any future amendments, and with any other study conduct procedures provided by the Sponsor.
- That I am aware of, and will comply with, the internationally recognized code of Good Clinical Practices (GCP) and all other applicable regulatory requirements to obtain written and dated approval from the Institutional or Central Review Board (IRB) or Independent Ethics Committee (IEC) for the study protocol, written informed consent, consent form updates, subject-recruitment procedures (eg, advertisements), and any other written information to be provided to the subjects, before initiating this clinical study.
- Not to implement any changes to, or deviations from the protocol without prior agreement from the Sponsor and review and documented approval from the IRB/IEC, except to eliminate an immediate hazard to the study subjects, or when change(s) involves only logistical or administrative aspects of the clinical study.
- To permit direct monitoring and auditing by the Sponsor or Sponsor's representatives and inspection by the appropriate regulatory authority(ies).
- That I am thoroughly familiar with the appropriate use of the investigational products(s), as described in this protocol, and any other information provided by the Sponsor or designee, including, but not limited to, the current Investigator Brochure or equivalent document and approved product label (if applicable).
- To provide sufficient time, and adequate numbers of qualified staff and facilities for the foreseen duration of the clinical study to conduct the study properly, ethically, and safely.
- To ensure all persons assisting in this study are adequately informed about the protocol, investigational product(s), and their clinical study-related duties and functions.

_____

Principal Investigator (print name)

_____ _____

Principal Investigator (signature) Date

2 Synopsis

Name of Sponsor/Company: Bausch & Lomb Inc., a Division of Valeant Research and Development, a subsidiary of Valeant Pharmaceuticals North America, LLC
Name of Investigational Product: Biotrue ONEday For Astigmatism Soft Contact Lens
Name of Active Ingredient: nesofilconA
Title of Study:.A Study to Evaluate the Safety and Effectiveness of the Biotrue ONEday for Astigmatism Soft Contact Lens When Worn on a Daily Basis
Number of Clinical Centers: 13
Objectives: The objective of this study is to evaluate the safety and effectiveness of the Biotrue ONEday for Astigmatism Soft Contact Lens when worn on a daily basis by currently adapted soft contact lens wearers in a population including Chinese ancestry.
Methodology: This is a multicenter, randomized 1:1, parallel-group, bilateral, Investigator-masked study at 13 investigative sites in the United States (US) in a population including Chinese subjects (maternal and paternal grandparents born in China), comparing Biotrue ONEday for Astigmatism Soft Contact Lens (Test) to 1-Day Acuvue Moist for Astigmatism contact lenses (Control). Approximately 244 subjects will be randomized in this 3-month, parallel-group, bilateral, Investigator-masked study at 13 investigative sites in the US enrolling approximately 50% Chinese subjects. In order for submission of this study to the Chinese Regulatory Authorities, approximately 244 subjects will be enrolled and randomized, including those of Chinese descent (both maternal and paternal grandparents born in China, with a documented family tree worksheet kept with the subjects source documents). At the Screening Visit, approximately half of the eligible subjects will be randomized to receive Biotrue ONEday for Astigmatism Soft Contact Lenses (Test) and the other eligible half will be randomized to receive 1-Day Acuvue Moist for Astigmatism contact lenses (Control). Both groups will wear their assigned lenses on a daily wear basis throughout the study with visits planned for Screening (Visit 1), Dispense (Visit 2), 1 week (Visit 3), 1 Month (Visit 4), 3 Months (Visit 5), and/or a final Exit Visit. Subjects will be randomized sequentially. Subjects will be dispensed product according to the treatment arm corresponding to their randomization and will be unmasked. Subjects will be instructed to use their habitual rewetting drops as needed during the study. Subjects will be provided with Test lenses or Control lenses as part of the dispensing package and instructions for the use and care for the test articles. Subjects will also be required to complete a paper diary on a weekly basis. Subjects will be provided with a reminder at every visit to complete the diary to capture wear experience on a weekly basis until they exit the study.
Number of Subjects Planned: 244
Diagnosis and Main Criteria for Inclusion: The Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, astigmatism) in aphakic or nonaphakic persons with non-diseased eyes, exhibiting astigmatism of 5.00 diopters or less, that does not interfere with visual acuity (VA). The lens may be prescribed in spherical powers ranging from +4.00D to -9.00D. The lens has been prescribed for single-use disposable wear. No lenses should be disposed of. All lenses, worn or unworn, will be returned to the Sponsor. To be eligible for entry into the study, the subject must meet the following inclusion criteria: • Subject must be of legal age (at least 18 or as defined by state law) on the date the informed consent form (ICF) is signed and have the capacity to provide voluntary informed consent. • Subject must be able to read, understand and provide written informed consent on the IRB approved ICF and provide authorization as appropriate for local privacy regulations.

- Subject must have physiologically normal anterior segments not exhibiting clinically significant biomicroscopy findings (greater than Grade 1 and/or presence of infiltrates) and have clear central 6 mm corneas.
- Subject must be an adapted wearer of soft contact lenses, wear a lens in each eye, and each lens must be of the same manufacture and brand.
- Subject must have vision correctable through spherocylindrical refraction to 45 letters (0.04 logMAR) or better (distance, high contrast) in each eye. Visual acuity of 0.04 logMAR is the acuity where an individual subject would be given credit for reading logMAR 0.0 and logMAR 0.0 is equivalent to Chinese logarithmic visual acuity chart value of 5.0.
- Subject must be myopic or hyperopic and require lens correction from +4.00 diopter (D) to -9.00 D in both eyes.
- Subject must be a habitual wearer of toric soft contact lenses.
- Subject must be able to be fit in both the Test and Control lenses in the listed parameters.
- Subject have no active ocular disease or allergic conjunctivitis.
- Subject must not be using any topical ocular medications.
- Subject must agree to wear their study lenses on a daily wear basis for the duration of the study.
- Subject must be willing and able to follow the visit schedule and follow instructions for use of the study products.

Key exclusion criteria:

The subject is not eligible to participate in the study if the subject meets any of the following exclusion criteria:

- Subject has worn gas permeable (GP) contact lenses within last 30 days or polymethylmethacrylate (PMMA) lenses within last 3 months.
- Subject has systemic disease affecting ocular health.
- Subject is using any systemic or topical medications that will affect ocular physiology or lens performance.
- Subject has an active ocular disease (for example but not limited to papillary conjunctivitis, any conjunctivitis: viral, bacterial, allergic), any corneal infiltrative response or are using any ocular medications.
- Subject has any "Present" finding during the slit lamp examination that, in the Investigator's judgment, interferes with contact lens wear.
- Subject has any scar or neovascularization within the central 6 mm of the cornea. Minor peripheral corneal scarring (that does not extend into the central 6 mm of the cornea), that in the Investigator's judgment, does not interfere with contact lens wear, are eligible for this study.
- Subject has anisometropia (spherical equivalent) of greater than 2.00 D based on spherocylindrical refraction.
- Subject is aphakic.
- Subject is amblyopic.
- Subject has had any corneal surgery (eg, refractive surgery).
- Subject is participating in a conflicting study (or actively participating within another active cohort of this study).
- Subject has participated in any drug or device clinical investigation (within 14 days) prior to entry into this study and/or during the period of study participation.
- Subject is a woman of childbearing potential if one of the following: pregnant, plans to become pregnant during study or is breast feeding.
- Subject meets any of the following criteria:
  - Ophthalmologist, OD, Optician, Ophthalmologist's Assistant/Technician

- employee of a market research firm
- employee of manufacturer of contact lens or contact lens care products
- employee of the investigational site

- Subject wears monovision or multifocal contact lenses.
- Subject is considered by the Investigator to not be a suitable candidate for participation.

Investigational Product, Dosage and Mode of Administration (Test Article):

The Test Product in this case is the Biotrue ONEday for Astigmatism Soft Contact Lens. The description is as follows:

Diameter: 14.5 mm
Base Curve: 8.4 mm
Material: nesofilcon A

Spherical Power: Plano to –6.00D (in 0.25D steps);

Cylinder Powers; -.75, -1.25, -1.75

Axis: 10°, 20°, 60°,70°, 80°, 90°, 100°, 110°, 120°,160°, 170°, 180° (12 axes)

Cylinder Powers; -2.25

Axis 20°, 90°, 160°, 180° (4 axes)

Spherical Power: -6.50 to -9.00 (in 0.50D Steps);

Cylinder Powers; -.75, -1.25, -1.75

Axis: 10°, 20°,70°, 80°, 90°, 100°, 110°, 160°, 170°, 180° (10 axes)

Spherical Power: +0.25D to +4.00D (in 0.25D steps);

Cylinder Powers: -0.75D, -1.25D, -1.75D

Axis: 20°, 70°, 90°, 110°, 160°, 180° (6 axes)

Orientation Mark at 6 o'clock

Duration of Treatment:

Duration of clinical trial per subject: 3 months

Visits scheduled at Screening (Visit 1), Dispense (Visit 2), 1 week (Visit 3), 1 month (Visit 4), 3 months (Visit 5), and/or a final Exit Visit.

Reference Therapy, Dosage and Mode of Administration:

The Control Product in this case is the 1-Day Acuvue Moist for Astigmatism contact lenses with the following description:

Diameter: 14.5 mm
Base Curve: 8.5 mm
Material: etafilcon A

Spherical Power: Plano to –6.00D (in 0.25D steps);

Cylinder Powers; -.75, -1.25, -1.75

Axis: 10°, 20°, 60°,70°, 80°, 90°, 100°, 110°, 120°,160°, 170°, 180° (12 axes)

Cylinder Powers; -2.25

Axis 20°, 90°, 160°, 180° (4 axes)

Power: -6.50 to -9.00 (in 0.50D Steps);
Cylinder Powers; -.75, -1.25, -1.75
Axis: 10°, 20°,70°, 80°, 90°, 100°, 110°, 160°, 170°, 180° (10 axes)

Spherical Power: +0.25D to +4.00D (in 0.25D steps);
Cylinder Powers: -0.75D, -1.25D, -1.75D
Axis: 20°, 70°, 90°, 110°, 160°, 180° (6 axes)
Orientation Marks at 3 and 9 o'clock

Criteria for Evaluation:

The primary effectiveness endpoint is the proportion of subjects achieving a contact lens corrected distance logMAR VA of 0.04 or better in both eyes, evaluated at the 1-Week Follow-up Visit. Visual acuity of 0.04 logMAR is the acuity where an individual subject would be given credit for reading logMAR 0.0 and logMAR 0.0 is equivalent to Chinese logarithmic visual acuity chart value of 5.0.

Other performance criteria for evaluation will be summarized descriptively.

Effectiveness:

1 Visual acuity
   - optimal corrected distance BSCVA measured with the phoropter
   - contact lens corrected distance VA

Safety:

1 Eye condition

Eye condition criteria include the following, which will be summarized descriptively.
   - Slit lamp findings
   - Dilated fundus exam findings
   - Intraocular pressure

2 Lens Suitability
   - Centration
   - Wettability
   - Movement

3 Lens Status
   - Deposits

4 Visual acuity
   - uncorrected distance VA

5 Change in manifest refraction between the Screening and Exit Visits

6 Change in corneal curvature between the Screening and Exit Visits

Statistical Methods:

General Statistical Methods

In general, data will be summarized by treatment group and visit as appropriate. Data will be summarized separately at the subject and eye levels. Subject level summaries will summarize the average of the subject's 2 eyes for continuous variables and the worst case over both eyes for categorical variables.

Summaries for continuous variables will include the sample size, mean, standard deviation, median, minimum, and maximum. Means and medians will be presented with one more decimal place than the recorded raw data. Standard deviations will be presented with 2 more decimal places than the recorded raw data. Minima and maxima will be presented with the same number of decimal places as the

recorded raw data. Values with magnitude less than 1 will be presented with a leading zero to the left of the decimal (eg, 0.123 or -0.123).

Categorical data will be summarized using frequencies and percentages. Percentages will be presented with one decimal place. Percentages may not be presented when the count is zero. Unless otherwise specified the denominator for percentages will be the number of non-missing values within the group being presented.

Primary Effectiveness Analysis

At the 1-Week Follow-up Visit, subjects with non-missing logMAR acuities 0.04 or better in both eyes will be classified as "0.04 or Better." Subjects with at least one logMAR acuity > 0.04 at the visit will be classified as "Worse than 0.04." Subjects with at least one missing value at the visit will not be classified and their classification value will be assigned as missing.

The summaries and analyses of the primary effectiveness endpoint will be at the subject level.

Use of the Intention-to-Treat (ITT) Population and imputation of missing values are not conservative practices in non-inferiority analyses. Consequently, the Per Protocol Population will be used for the primary analysis without imputation of missing data.

VA Effectiveness will be summarized categorically (0.04 or Better, Worse than 0.04) by treatment group at the 1-Week Follow-up Visit for the Per Protocol (PP) Population in a table. Missing data will not be imputed for this primary analysis of the PP Population. The denominator for percentages will be the number of non-missing values.

The difference between treatment groups (Test minus Control) in the proportion of subjects classified as "0.04 or Better" will be estimated. An asymptotic Wald non-inferiority test (without continuity correction; using the sample variance; alpha risk = 0.025) and the associated two–sided 95% confidence interval will be used to test the statistical hypothesis. The difference between treatment groups (in percentage units), the asymptotic standard error for the difference (in percentage units), the associated Z value, the p-value for the non-inferiority test, and a two–sided 95% confidence interval (in percentage units) around the difference will be presented. [redacted]

Sample Size Calculations:

Primary Effectiveness Endpoint

The null hypothesis is that the difference in the proportion of subjects with both eyes "0.04 or Better" between the test group (π_T) and the control group (π_C) is less than or equal to the negative value of the non-inferiority margin ($-\delta$). The alternative hypothesis is that the difference in proportions is greater than the negative value of the non-inferiority margin.

$H_0: \pi_T - \pi_C \leq -\delta$

$H_1: \pi_T - \pi_C > -\delta$

In a previous evaluation of Biotrue ONEday for Astigmatism Soft Contact Lenses, 92.5% of subjects with baseline logMAR BSCVA of 0.04 or better achieved the primary effectiveness endpoint of this study at the follow-up visit. Consequently 92.5% is the expected percentage of subjects "0.04 or Better" in the Test and Control groups. [redacted]

A one-sided alpha risk of 0.025 (eg, a two-sided 95% confidence interval) will be used to test the hypothesis.

When the sample size in each group is 109 subjects, a two-group large-sample normal approximation test of proportions with a one-sided 0.025 significance level will have 80% power to reject the null hypothesis that the test is inferior to the control [redacted] in favor of the alternative hypothesis that the test lens is non-inferior, assuming that the expected difference in proportions is 0.000 and the proportion in the standard group is 0.923.

Overall Power and Sample Size

In order to allow for dropouts of up to 10%, at least approximately 109/(1-0.1) ≈ 122 subjects will be enrolled in each treatment group for a total enrollment of approximately 244 subjects.

3 Table of Contents

LIST OF TABLES

4 List of Abbreviations and Definitions of Terms

Abbreviation or specialist term	Definition or Explanation
ADE	Adverse device effect
AE	Adverse event
BSCVA	Best spectacle-corrected visual acuity
CFR	Code of Federal Regulations
CRA	Clinical research associate
CRF	Case report form
CTM	Clinical trial materials
D	Diopter
FDA	US Food and Drug Administration
GCP	Good clinical practice
GP	Gas permeable
HIPAA	Health Insurance Portability Accountability Act
ICF	Informed consent form
ICH	International Conference on Harmonisation
ID	Identification
IEC	Independent Ethics Committee
IOP	Intraocular pressure
IRB	Institutional review board
ITT	Intent-to-treat
logMAR	Logarithm of the minimum angle of resolution
MCMC	Markov chain Monte Carlo
MedDRA	Medical Dictionary for Regulatory Activities
MPS	Multi-purpose solution
OD	Doctor of optometry
PMMA	Polymethylmethacrylate
PP	Per protocol
PT	Preferred term
SAE	Serious adverse event
SOC	System organ class
SOP	Standard operating procedure
SUSAR	Suspected unexpected serious adverse reaction
TEAE	Treatment-emergent adverse event
UADE	Unanticipated adverse device effect
US	United States
VA	Visual acuity

NOTE: The first occurrence of some abbreviations is not spelled out in the document (eg, units of measure).

5 Introduction and Rationale

5.1 Introduction

The Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of astigmatism. The lens is prescribed for single-use disposable wear, and is to be discarded after each removal.

5.2 Rationale

5.2.1 Study Rationale

The rationale for the study is to evaluate this lens in a population including currently adapted soft contact lens wearers of Chinese ancestry.

5.2.2 Design Rationale and Risk Assessment

The assessments required for the study are routinely performed and are standard of care for contact lens wearers. The subjects will be informed of any potential study specific risks in the informed consent form (ICF) or if new risks become apparent during the study.

6 Study Objectives and Purpose

6.1 Objective

The objective of this study is to evaluate the safety and effectiveness of the Biotrue ONEday for Astigmatism Soft Contact Lens when worn on a daily basis by currently adapted soft contact lens wearers in a population including Chinese ancestry.

7 Investigational Plan

7.1 Description of the Protocol

This is a multicenter, randomized 1:1, parallel-group, bilateral, Investigator-masked study at 13 investigative sites in the United States (US) on a population including approximately 50% Chinese subjects (maternal and paternal grandparents born in China), comparing Biotrue ONEday for Astigmatism Soft Contact Lens (Test) to 1-Day Acuvue Moist for Astigmatism contact lens (Control).

Approximately 244 subjects will be randomized in this 3 month, parallel-group, bilateral, Investigator-masked study at 13 investigative sites in the US enrolling Chinese subjects. In order for submission of this study to the Chinese Regulatory Authorities, approximately 244 randomized subjects will be enrolled, including those of Chinese origin with 2nd generation Chinese ancestry with both sets of grandparents being of Chinese origin, with a documented family tree worksheet kept with the subject's source documents.

A person with Chinese ancestry would be defined as a subject with both sets of grandparents born in China. A person with 3 Chinese grandparents and one grandparent of full Chinese ancestry who was not born in China will be defined as "Non-Chinese".

At the Screening Visit, approximately half of the subjects will be randomized to receive Biotrue ONEday for Astigmatism Soft Contact Lenses (Test) and the other half will be randomized to receive 1-Day Acuvue Moist for Astigmatism contact lenses (Control). Both groups will wear their assigned lenses on a daily wear basis throughout the study with visits planned for Screening (Visit 1), Dispense (Visit 2), 1 week (Visit 3), 1 Month (Visit 4), 3 Months (Visit 5), and/or a final Exit Visit.

Subjects will be randomized sequentially. Subjects will be dispensed product according to the treatment arm corresponding to their randomization and will be unmasked.

Subjects will be instructed to use their habitual rewetting drops as needed during the study. Subjects will be provided with study lenses as part of the dispensing package and instructions for the use and care for the test articles.

Subjects will also be required to complete a paper diary. Subjects will be provided with a reminder to complete the diary to capture wear experience on a weekly basis until they exit the study.

7.2 Duration of Study Participation

7.2.1 Duration of Study Participation for Each Subject

Investigators will have up to 3 weeks between the Screening and Dispensing Visit.

Subjects will be followed for 3 months (unless discontinued or lost to follow-up) and must adhere to the following schedule:

Visit	Target	Acceptable Visit Range
V1: Screening Visit	None	Day -21 to Day -14
V2: Dispensing Visit	Day 1	NA
V3: 1-Week Follow-up Visit	Day 8	Day 6 – 10
V4: 1-Month Follow-up Visit	Day 31	Day 28 – 36
V5: 3-Month Follow-up Visit	Day 92	Day 92 – 102

NA = not applicable

Notes: The 3-month follow-up visit must occur no earlier than Day 92. There is no Day 0 in this numbering scheme. The day prior to dispensing is Day-1.

The visit range is based on the date test articles are initially dispensed (Dispensing Visit). A visit scheduling table will be provided in the initial study shipment to aid the Investigator in scheduling Follow-up Visits.

7.2.2 Determination of End of Clinical Trial (All Subjects)

The subject has completed the study when the 3-Month Follow-up visit (Visit 5) is concluded. Subjects who require further follow-up will be followed according to the adverse event (AE) section (Section 11.5.8).

Bausch + Lomb Clinical Operations will notify the Investigator when to contact the IRB to inform them that the study is complete.

If during the study it becomes evident to the Sponsor that the study should be stopped prematurely or placed on hold, appropriate notification will be given to the US FDA, Investigator(s), and IRBs, as applicable. Bausch + Lomb Clinical Operations will instruct the Investigators to stop/restart dispensing study materials and will arrange for study closeout, if applicable, at each site.

7.3 Study Design and Assessments

Study assessments are summarized in Table 1. Methods of clinical evaluation are presented in Appendix A.

Table 1. Study Design and Schedule of Assessments

PROCEDURE/ASSESSMENTS	Visit 1-Screening	Visit 2 Dispense (Day 1)	Visit 3 1-Week Follow-up (Day 6-10)	Visit 4 1-Month Follow-up (Day 28-36)	Visit 5 3-Month Follow-up (Day 92-102[1])	Unscheduled Visit	Exit Visit
Informed Consent/HIPAA Authorization	X						
Demographics/Baseline Eye/Lens Characteristics	X						
Medical History	X						
Eligibility	X						
Randomization	X						
Dispense and/or return study materials		X[4]	X[4]	X[4]	X[4]	X[4]	X[4]
Diary instruction/reminders and return		X	X	X	X	X	X
Symptoms/Complaints (with habitual lenses including rewetting drops usage)	X						
Adverse Events	X	X	X	X	X	X	X
Without Lenses							
Uncorrected distance VA	X						X
Autorefraction	X				X		X
Spherocylindrical Refraction	X	X	X	X	X	X	X
Distance BSCVA	X	X	X	X	X	X	X
Keratometry	X						X
Slit Lamp Exam	X	X	X	X	X	X	
Intraocular Pressure (IOP)	X	X	X	X	X	X	X
Direct Ophthalmoscope (non-dilated) on the crystalline lens, ocular media, macular region and optic nerve head)	X	X	X	X	X	X	X
Dilated Fundus Exam	X						X
With Study Lenses							
Symptoms/Complaints (including rewetting drops usage)	X[6]	X	X	X	X	X[5]	X
Distance high contrast logMAR lens VA		X[2]	X[2,3]	X[2,3]	X[3]	X[2,3]	
Over-refraction and Distance VA		X[2]	X[2,3]	X[2,3]	X[3]	X[2,3]	
VA line change comparison – Dispense Visit to BSCVA		X[2]					
VA line change comparison – Exit BSCVA to Screening BSCVA							X
Keratometry comparison							X

PROCEDURE/ASSESSMENTS	Visit 1- Screening	Visit 2 Dispense (Day 1)	Visit 3 1-Week Follow-up (Day 6-10)	Visit 4 1-Month Follow-up (Day 28-36)	Visit 5 3-Month Follow-up (Day 92-102[1])	Unscheduled Visit	Exit Visit
VA line change comparison – High contrast distance lens VA at Unscheduled Visit to high contrast BSCVA at Dispensing Visit						X	
VA line change comparison – Follow-up visit to Dispense Visit contact lens VA			X	X	X		
Lens Wettability/Centration/Movement/ and Rotation	X	X[2]	X[2,3]	X[2,3]	X[3]	X[2,3]	
Lens Deposits	X	X[2]	X[2,3]	X[2,3]	X[2,3]	X[2,3]	

BSCVA = best spectacle-corrected visual acuity, HIPPA = Health Insurance Portability Accountability Act, VA = visual acuity

[1] The 3-Month Follow-up Visit must occur no earlier than Day 92.

[2] To be assessed for lenses dispensed at this visit if the subject did not wear lenses to the visit.

[3] To be assessed for lenses worn to the visit.

[4] Lenses will be dispensed as a 3 month supply at Visit 2 (or an Unscheduled Visit in the event of lost lenses when a fresh supply is reordered and dispensed). Used lenses will be collected at Visit 3, 4, 5, Exit Visit, and/or Unscheduled Visit (in the event of lost lenses when a fresh supply has to reordered and dispensed which would occur at an Unscheduled Visit).

[5] In the event the subject comes in for an Unscheduled Visit because he is experiencing a problem, Symptoms and Complaints have to be assessed at this time.

[6] Collection of wetting drop usage not required at Visit 1 (Screening).

Note: The Exit Visit will be delayed in the event that there is a complication and the subject needs to be followed up through an Unscheduled Visit.

8 Selection and Withdrawal of Subjects

8.1 Number of Subjects Planned

Approximately 244 subjects will be randomized in this 3-month, parallel-group, bilateral, Investigator-masked study at 13 investigative sites in the US enrolling Chinese subjects.

8.2 Subject Inclusion Criteria

To be eligible for entry into the study, the subject must meet the following inclusion criteria:

1. Subject must be of legal age (at least 18 or as defined by state law) on the date the ICF is signed and have the capacity to provide voluntary informed consent.
2. Subject must be able to read, understand and provide written informed consent on the IRB approved ICF and provide authorization as appropriate for local privacy regulations.
3. Subject must have physiologically normal anterior segments not exhibiting clinically significant biomicroscopy findings (greater than Grade 1 and/or presence of infiltrates) and have clear central 6 mm corneas.
4. Subject must be an adapted wearer of soft contact lenses, wear a lens in each eye, and each lens must be of the same manufacture and brand.
5. Subject must have vision correctable through spherocylindrical refraction to 45 letters (0.04 logMAR) or better (distance, high contrast) in each eye. Visual acuity of 0.04 logMAR is the acuity where an individual subject would be given credit for reading logMAR 0.0 and logMAR 0.0 is equivalent to Chinese logarithmic visual acuity chart value of 5.0.
6. Subject must be myopic or hyperopic and require lens correction from +4.00 diopter (D) to -9.00 D in both eyes.
7. Subject must be a habitual wearer of toric soft contact lenses.
8. Subject must be able to be fit in both the Test and Control lenses in the listed parameters.
9. Subject have no active ocular disease or allergic conjunctivitis.
10. Subject must not be using any topical ocular medications.
11. Subject must agree to wear their study lenses on a daily wear basis for the duration of the study.
12. Subject must be willing and able to follow the visit schedule and follow instructions for use of the study products.

Written informed consent, enrollment in the study, or dispensing of study products cannot begin until the Investigator has received IRB approval to conduct the study. The Sponsor and IRB must approve any advertising used to recruit subjects prior to use of that advertising.

All consented subjects must be accounted for, whether they participate in the study or not. Bausch + Lomb will provide a Screening Log on which to enter information for each subject

who signs an ICF. All screened subjects must be entered onto the Screening Log, in the order in which they were consented, where they will be assigned a sequential subject identification (ID) number. Once a potential subject is consented and their initials are entered onto the Screening Log, the Investigator should proceed with Screening procedures.

Potential subjects are deemed either "Screen Pass" or "Screen Fail." "Screen Fail" subjects have not met the study inclusion criteria or have met the exclusion criteria. "Screen Fail" subjects cannot be randomized. Subjects are considered enrolled when they have signed the ICF. The copy of their signed ICF and any information collected as part of screening (eg, source documents, etc.) must be kept in their medical records.

"Screen Pass" subjects have met all of the study inclusion criteria and have not met any of the exclusion criteria. Only "Screen Pass" subjects can be randomized to receive the study lenses.

Once a subject has signed the ICF, a subject is considered enrolled and must be accounted for at every visit until exited (completed, discontinued, or non-dispensed) from the study, even if they are not dispensed study materials.

8.3 Subject Exclusion Criteria

The subject is *not* eligible to participate in the study if the subject meets any of the following exclusion criteria:

1. Subject has worn gas permeable (GP) contact lenses within last 30 days or polymethylmethacrylate (PMMA) lenses within last 3 months.
2. Subject has systemic disease affecting ocular health.
3. Subject is using any systemic or topical medications that will affect ocular physiology or lens performance.
4. Subject has an active ocular disease (for example but not limited to papillary conjunctivitis, any conjunctivitis: viral, bacterial, allergic), any corneal infiltrative response or are using any ocular medications.
5. Subject has any "Present" finding during the slit lamp examination that, in the Investigator's judgment, interferes with contact lens wear.
6. Subject has any scar or neovascularization within the central 6 mm of the cornea. Minor peripheral corneal scarring (that does not extend into the central 6 mm of the cornea), that in the Investigator's judgment, does not interfere with contact lens wear, are eligible for this study.
7. Subject has anisometropia (spherical equivalent) of greater than 2.00 D based on spherocylindrical refraction.
8. Subject is aphakic.
9. Subject is amblyopic.

10. Subject has had any corneal surgery (eg, refractive surgery).
11. Subject is participating in a conflicting study (or actively participating within another active cohort of this study).
12. Subject has participated in any drug or device clinical investigation (within 14 days) prior to entry into this study and/or during the period of study participation.
13. Subject is a woman of childbearing potential if one of the following: pregnant, plans to become pregnant during study or is breast feeding.
14. Subject meets any of the following criteria:
    - Ophthalmologist, OD, Optician, Ophthalmologist's Assistant/Technician
    - employee of a market research firm
    - employee of manufacturer of contact lens or contact lens care products
    - employee of the investigational site
15. Subject wears monovision or multifocal contact lenses.
16. Subject is considered by the Investigator to not be a suitable candidate for participation.

If a subject meets all the inclusion criteria and does not exhibit any of the exclusion criteria, the subject is eligible to be enrolled into the study. Ineligible subjects MUST NOT be enrolled in this study and are considered a "Screen Fail". Any subject enrolled in the study who later is found to have not met the eligibility criteria at entry will be discontinued.

Note: Any exceptions to the Inclusion and Exclusion criteria must be cleared by the Sponsor.

8.4 Subject Withdrawal Criteria

8.4.1 List of Treatment Withdrawal Criteria

A subject MUST be discontinued prior to the final study visit for any of the following reasons:

- voluntary withdrawal
- death
- Investigator decision that it is not in the best medical interest of the subject to continue participation in the investigation
- ineligible at the Screening Visit - does not meet the eligibility criteria in the protocol
- inability to maintain recommended wearing schedule
- continued failure to follow subject instructions
- misses more than 1 Follow-up Visit, not including the 3-Month Visit

- lack of motivation
- lost to follow-up (see Section 8.4.3)
- instillation of non-medically indicated solution not specified in the protocol
- other eye is discontinued
- becomes pregnant during the study
- 3-month follow-up visit is conducted prior to Day 92

Prior to discontinuing a subject, every effort should be made to contact the subject, schedule a final study visit, obtain as much follow-up data as possible, and to retrieve all study materials. Adverse events will be followed as described in Section 11.5.8. Subject discontinuations will be documented clearly on the source document and applicable eCRF. The Investigator should indicate the PRIMARY (one) reason that the subject was discontinued for each eye. Subjects that are discontinued from the study following randomization will not be replaced.

8.4.2 Reasons for Treatment Withdrawal

A subject MAY be discontinued (at the discretion of the Investigator, the Sponsor, and/or the IRB) prior to the final study visit for a variety of reasons, including, but not limited to:

- an AE occurring during the course of the study, which precludes continued treatment or follow-up
- persistent slit lamp findings (must be reported to the Sponsor within 24 hours) of the following grades:
    - Moderate
    - Severe
- persistent study-related symptoms/complaints
- unacceptable distance lens VA, lens centration, lens movement, or unacceptable lens rotation

8.4.3 Lost to Follow-up

Subjects who do not return for scheduled Follow-up Visits, as defined by the visit window, and cannot be contacted, are to be considered lost to follow-up. All attempts to contact the subject should be documented and kept with the subject's source documentation, and the applicable eCRFs will be completed. The date of exit reported shall be the date of last in-clinic study visit.

8.4.4 Treatment Withdrawal Follow-up Procedure

Exit Visit assessments should be completed for discontinued subjects.

9 Treatment Plan

The study will be conducted at approximately 13 investigative sites located in the US by Investigators who are determined by Bausch + Lomb to be suitably qualified by training and experience to conduct this study. Principal Investigators will be identified on the Device Investigator Agreement Form.

In the event that selected sites do not meet full enrollment, the Sponsor may decide to increase enrollment as needed at other currently active sites and/or additional site(s) may be added to satisfy the enrollment requirements of the study.

9.1 Randomization and Methods of Assigning Subjects to Treatment Groups

Subjects will be randomized to one of 2 treatment arms at a 1:1 ratio, wearing either Test or Control lenses in both eyes for the duration of the study. Randomization will be stratified by site, ancestry (Chinese, Non-Chinese), and sphere power sign (positive, negative).

Subjects will be randomized sequentially.

The randomization scheme will be produced prior to study enrollment by an unmasked statistician not otherwise involved in the trial. An unmasked designee at each site will be responsible for dispensing the study lenses according to the randomized treatment assignments. Lenses will be dispensed directly to the subject by the unmasked designee, thereby maintaining Investigator masking. In an effort to ensure that the Investigator remains masked, the unmasked designee MUST dispense the study lenses and MUST remove foils from their blister packs out of the Investigator's sight immediately prior to dispensing. Unworn (unopened) lenses that are returned by the subject to the site must be returned in a manner so as not to unmask the Investigator and other staff members at the site (ie, returned in an opaque bag or container labeled with subject identifiers). The unmasked designee will be responsible for physically examining the unopened lens blister package labeling to ensure the appropriate lenses were returned, and will document the return of these lenses in the CTM Product Accountability Log. The Investigator should contact the Medical Monitor prior to emergency unmasking of study arm assignment. In an urgent situation, however, where knowledge of the study arm assignment is critical to subject safety, the code may be broken by requesting the allocated treatment for that subject from the unmasked designee.

The Investigator must notify the Sponsor/Medical Monitor and/or Study Manager as soon as possible after emergency unmasking. In addition, the Investigator must record the date, time, and reason for unmasking the study arm assignment in the source documentation.

Study Monitors will become unmasked during site visits as they perform reconciliation activities and/or review randomization assignments, product accountability records, product inventory, and subject records. Study Monitors must take care not to unmask the Study Manager, other Bausch + Lomb staff, Contract Research Organization (CRO) staff, or site staff during the study.

9.2 Concomitant Medications

Subjects will be instructed to use their habitual rewetting drops as needed during the study. Other contact lenses/solutions are not allowed to be used by subjects during the study. All concomitant medications (ocular, systemic or topical) that have been taken in the past 30 days before signing the ICF and during the course of the study will be collected.

In the event that a subject requires medical treatment (prescription medication) for an ocular condition, treat the subject as appropriate to prevent further complications and to potentially resolve the event.

9.3 Treatment Administration and Compliance

The Investigator or other designee will review instructions and warnings for lens wear, lens care, handling, cleaning, and disinfecting with the subject. Any subject who does not follow instructions to a degree that, in the Sponsor or Investigator's opinion, jeopardizes the subject's well-being or the validity of the study, must be discontinued (see Section 8.4).

9.4 Protocol Deviations

The date of and reason for deviations will be documented in all cases. Significant or major protocol deviations impacting the safety of the subject or the integrity of the study must be reported by the Investigator to the IRB immediately. Reporting of all other protocol deviations must adhere to the requirements of the governing IRB.

Subjects may continue to participate until the end of the study, unless the protocol deviations put the subject at risk or the subject's condition requires that they be discontinued from the study.

10 Study Materials and Management

Bausch + Lomb will provide all study materials at no charge to the Investigator. Sites will be provided with dispensing sets for both the Test and Control lenses. All other materials will be provided to the site prior to the start of the study.

Subjects will be given an adequate supply of study lenses to wear on a daily disposable basis for the duration of the study.

Subjects will be provided with lens cases in which to dry stack their used lenses. All used lenses and blister foils will be returned at 1 week (Visit 3), 1 Month (Visit 4), 3 Months (Visit 5), and Exit Visits and all unused lenses will be returned to the Sponsor at end of the study.

Subjects will be instructed to use their habitual rewetting drops as needed during the study. Use of other contact lenses or care products is not allowed.

[redacted]

10.1 Investigational Product, Biotrue ONEday for Astigmatism

The Test Product in this case is the Biotrue ONEday for Astigmatism Soft Contact Lens. The description is as follows:

Diameter: 14.5 mm
Base Curve: 8.4 mm
Material: nesofilcon A

Spherical Power: Plano to –6.00D (in 0.25D steps);
Cylinder Powers; -.75, -1.25, -1.75
Axis: 10°, 20°, 60°,70°, 80°, 90°, 100°, 110°, 120°,160°, 170°, 180° (12 axes)

Cylinder Powers; -2.25
Axis 20°, 90°, 160°, 180° (4 axes)

Power: -6.50 to -9.00 (in 0.50D Steps);
Cylinder Powers; -.75, -1.25, -1.75
Axis: 10°, 20°,70°, 80°, 90°, 100°, 110°, 160°, 170°, 180° (10 axes)

Spherical Power: +0.25D to +4.00D (in 0.25D steps);
Cylinder Powers: -0.75D, -1.25D, -1.75D
Axis: 20°, 70°, 90°, 110°, 160°, 180° (6 axes)

Orientation Mark at 6 o'clock.

10.2 Investigational Control Product, 1-Day Acuvue Moist for Astigmatism Contact Lens

The Control Product in this case is the 1-Day Acuvue Moist for Astigmatism contact lenses with the following description:

Diameter: 14.5 mm
Base Curve: 8.5 mm
Material: etafilcon A

Spherical Power: Plano to –6.00D (in 0.25D steps);
Cylinder Powers; -.75, -1.25, -1.75
Axis: 10°, 20°, 60°,70°, 80°, 90°, 100°, 110°, 120°,160°, 170°, 180° (12 axes)

Cylinder Powers; -2.25
Axis 20°, 90°, 160°, 180° (4 axes)

Spherical Power: -6.50 to -9.00 (in 0.50D Steps);
Cylinder Powers; -.75, -1.25, -1.75
Axis: 10°, 20°,70°, 80°, 90°, 100°, 110°, 160°, 170°, 180° (10 axes)

Spherical Power: +0.25D to +4.00D (in 0.25D steps);
Cylinder Powers: -0.75D, -1.25D, -1.75D
Axis: 20°, 70°, 90°, 110°, 160°, 180° (6 axes)

Orientation Marks at 3 and 9 o'clock.

The Investigator should refer to Appendix C for the fitting guide for the study lenses.

10.2.1 Packaging and Labeling

The Test lenses (Biotrue ONEday for Astigmatism) used in this study will be provided in the currently marketed packaging. The blister label will contain the following information:

- lens power
- base curve
- lens diameter
- lot number
- expiration date
- manufacturers name

The Control lenses (1-Day Acuvue Moist for Astigmatism) used in this study will be provided in the currently marketed packaging. The blister labels will contain the following information:

- lens power

- base curve
- lens diameter
- lot number
- expiration date
- manufacturer's name

The commercial cartons for both Test and Control lenses will contain an additional label: "Study 885 For Clinical Trial Use Only".

10.2.2 Storage, Handling, and Disposal of Study Lenses

All Test and Control lenses provided by the Sponsor must be stored in a secure location accessible only to study personnel and maintained at room temperature. No lenses should be disposed of. All lenses, worn or unworn, will be returned to the Sponsor.

10.2.3 Study Lens Preparation

The Investigator should refer to the Fitting Guide (see Appendix C) for fitting the Test and Control lenses.

10.2.4 Administration

Test or Control lenses will be worn on a daily disposable wear basis. One hundred twenty (120) new study lenses will be shipped to the site per eye. Up to 110 new study lenses will be dispensed per eye at the Dispensing Visit to provide sufficient quantities to maintain a daily disposable wear modality for at least 102 days. Ten (10) study lenses will remain at the site for all Follow-up Visits.

After contact lens assessments are complete at Follow-up Visits, the Investigator will collect and store worn lenses for subsequent return to the Sponsor.

10.2.4.1 Subject Instructions

All subjects must be given Subject Instructions for the use of study lenses (refer to Appendix B for Subject Instructions). Subjects must comply with the instructions provided to them. Subject Instructions will be supplied to the Investigator by Bausch + Lomb for distribution to the subjects.

All subjects must refer to lens subject instructions for precautions and warnings related to contact lens wear. Subjects should refer to the package insert for precautions and warnings related to the use of this lens care product.

The Investigator or other designee must review, with the subject, the Subject Instructions and the precautions and warnings, as appropriate for the study.

Any subject who does not follow instructions to a degree that, in the Sponsor or Investigator's opinion, jeopardizes the subject's well-being or the validity of the study, should be discontinued.

10.2.4.2 Subject Diary

Subjects will be required to complete a paper diary. Subjects will be provided with a reminder to complete the diary to capture wear experience on a weekly basis until they exit the study. Each enrolled subject will be provided with instructions for completing the diary after 7 days of lens wear. There will be a specified timeframe in which the diary must be completed.

10.3 Study Lens Accountability

The unmasked designee at each site will be responsible for keeping current and accurate records of the amount of study lenses received and dispensed, and their disposition. The study lenses must be stored under the appropriate conditions in a secure area and are to be dispensed only to subjects enrolled in the study, in accordance with the conditions specified in this protocol. During the course of the study, the unmasked designee must maintain an inventory of all study lenses dispensed to or returned by the subject, including subject identifiers. A Clinical Trial Materials (CTM) Product Accountability Log will be provided to the sites to maintain records of the study lenses assigned to each enrolled subject.

At time points throughout the study and/or upon completion of the study, the Sponsor/Sponsor's representative may review the Product Accountability Log to verify the Investigator's accountability records.

The subject will be dispensed up to 110 lenses for the entire study at the Dispense Visit. The subject will drystack up to 10 worn lenses per left eye and 10 worn lenses per right eye in one lens case. The subject will return all blister foils for the worn lenses and the drystack lens cases at each visit. The unmasked designee will collect the lens cases and blister foils, and complete the Product Accountability Log. The drystacked lens cases will be placed in a resealable plastic bag with a 'Worn Lens Label' label adhered to the bag. The resealable bags from each visit will be collected in one white opaque bag per subject. The opaque bag will be labeled with subject ID, Investigator ID, and Investigator name. Do not permanently seal the opaque bag until subject accountability at end of the study. At the end of the study, all unworn/unopened lenses returned by the subject should be in the subject's white opaque bag. Only the unmasked designee will handle the worn and unworn/unopened lens returns and white opaque bags. The unmasked designee must enter all lenses dispensed and returned immediately into the CTM Product Accountability Log. Once the Product Accountability Log has been verified by the study clinical research associate (CRA) (with signature), close and seal each subject's white opaque bag. Following verification, and as directed by the

Sponsor, all subject's sealed opaque bags that include their worn and unworn study lenses must be returned at the end of the study to the Sponsor's CTM Supply Chain at the address listed below. FedEx tags will be provided to the sites for return of subject opaque bags.

10.4 Noninvestigational Products

Subjects will be instructed to use their habitual rewetting drops as needed during the study. The use of other contact lens care products is not allowed.

10.5 Responsibility

Subject data required by this protocol are to be transferred from the source to the eCRFs. The Investigator and his/her study site personnel will be responsible for completing the eCRFs. The Investigator is required to verify that all of the requested information is accurately recorded on the eCRFs by providing an electronic signature. All information requested on the eCRFs needs to be supplied, including subject identification and initials, date(s), assessment values, etc, and any omission or discrepancy will require explanation. All information on eCRFs must be traceable to source documents.

The study monitor will be responsible for reviewing and verifying the data recorded on the eCRFs per the study Monitoring Plan, utilizing the original source documentation and will query discrepant findings. The Investigator and study site personnel will be responsible for answering all queries.

The eCRFs will be submitted to Bausch + Lomb Global Clinical Operations for quality assurance review, data entry, and statistical analysis.

A copy of the eCRFs will be provided to the Investigator at the conclusion of the study, who must ensure that it is stored in a secure place.

11 Study Procedures and Evaluations

NOTE: All VA measurements MUST be made using a phoropter.

NOTE: Use the same keratometer at the Screening and Exit Visits.

11.1 Visit Schedule

11.1.1 Screening Visit

A Screening Log will be provided by the Sponsor to track all consented subjects that the Investigator interviews regarding the study. Once all available lines on the Screening Log have been completed, or the Investigator has fulfilled his/her quota of subjects, the Investigator will sign and date the form to verify that all the subjects who interviewed for the study have provided informed consent and Health Insurance Portability Accountability Act (HIPAA) authorization. The Investigator will send the bottom copy of each Screening Log to the Sponsor as soon as the quota of subjects for his/her site has been enrolled into the study. The Investigator will retain the original document for their records.

After obtaining written informed consent, prospective subjects will be screened to determine whether they meet the entry criteria for the study.

Screening will proceed as follows:

a. Enter the subject information on the next available line of the Screening Log.

b. Collect the following lens history information from the subject: average daily wearing time hours lenses worn on the day of this visit current lens brand and lens wear modality, current lens care products. Collect the relevant medical history for the past 2 years.

c. Collect demographic and baseline information and perform the following baseline/Screening assessments (without lenses) and record in the subject's source document: uncorrected distance VA, autorefraction, spherocylindrical refraction, distance best spectacle-corrected visual acuity (BSCVA), keratometry, intraocular pressure (IOP) using the TonoPen or the Goldmann Applanation Tonometer, dilated fundus exam, direct ophthalmoscope exam (non-dilated).

d. Perform a slit lamp examination (remove the lenses if the subject wore lenses to the visit). Record and diagram the results and findings in the subject's source document and appropriate eCRF:

   - any ungraded finding marked as "PRESENT"
   - any new corneal scars
   - any neovascularization within the central 6 mm of the cornea
   - any corneal staining
   - any corneal infiltrate (record details on the Corneal Infiltrates Evaluation Form [Appendix E])
   - any other graded slit lamp findings Grade 2 or greater

e. If the subject is eligible, collect AE and Symptoms/Complaints information from the subject regarding their habitual lenses.

f. Assign subject numbers to each eligible subject in ascending order. A log will be provided to each site to maintain a record of the subject numbers assigned to each enrolled subject. Record the assigned subject ID on the Screening Log.

g. The unmasked designee will determine the eligible subject's randomized lens type (treatment group).

h. The Screening Visit eCRF should be completed only if the subject is a "Screen Pass."

i. Conduct a diagnostic fitting evaluation for the Test or Control lenses to the lens the subject is randomized to, using the Fitting Sets provided. The prescription determined from this fitting assessment will be used to dispense/order Test or Control lenses according to the lens the subject is randomized to. The Investigator should ensure that the lens was inserted with the toric etch marks roughly at the 6 o'clock positions and /or allow the trial lenses to properly settle on the eye for a minimum of 5 minutes. Collect the following information for both study lenses using the study site's standard diagnostic fitting techniques:

   - Collect Symptoms/Complaints information using the Symptoms/Complaints Rating Scales in Appendix A
   - lens wettability
   - lens centration
   - lens movement
   - lens rotation
   - lens deposits

Record the lens parameters to be dispensed/ordered based on the diagnostic fitting.

j. "Screen Fail" subjects are ineligible and non-dispensed and cannot be enrolled in the study if parameters are unavailable or fit is deemed unacceptable. The reason for screen failure must be documented and maintained with a copy of their ICF.

k. Indicate on the Screening Log whether the subject is a "Screen Pass" or "Screen Fail."

   "Screen Fail" subjects are ineligible and cannot be randomized in the study. The reason for screen failure must be documented on the Screening Log and in the subject record, and maintained with a copy of their ICF.

   Only "Screen Pass" subjects should be randomized in the study.

l. Re-emphasize the exclusion criterion stating that if the subject is a female of child bearing potential and is pregnant and or breast feeding, she is ineligible to be a part of the study.

For each subject, use the Material Order Form for Study 885 to order the appropriate study contact lenses (test or control). Schedule the subject for their Dispensing Visit within 3 weeks as instructed by the Sponsor.

11.1.2 Dispensing Visit

a. Collect/assess all AEs, including serious or significant non-serious AEs

b. Perform a slit lamp examination (remove the lenses if the subject wore lenses to the visit). Record all slit lamp findings and, at a minimum, sketch the following in the subject's source document:

   - any ungraded finding marked as "PRESENT"
   - any new corneal scars
   - any neovascularization within the central 6 mm of the cornea
   - any corneal staining
   - any corneal infiltrate (record details on the Corneal Infiltrates Evaluation Form [Appendix E])
   - any other graded slit lamp findings Grade 2 or greater

c. Perform the following assessments without lenses and record in the subject's source document: spherocylindrical refraction, distance BSCVA, and direct ophthalmoscope exam (non-dilated). IOP will be measured using the TonoPen or Goldmann method.

d. In an effort to ensure the Investigator remains masked, the unmasked designee MUST dispense the lens blister packs. The unmasked designee will dispense110 lenses per eye to sufficiently maintain a daily disposable modality until the 3-Month Follow-up Visit and record in the Product Accountability Log. A 10 day lens supply per eye can be maintained at the office for each subject's visits should the subject forget to wear their lenses to their follow-up office visits.

e. Have the subject insert one pair of the study lenses in their eyes. In an effort to ensure the Investigator remains masked, the subject MUST insert the lenses out of the sight of the Investigator.

   NOTE: Study lenses should be allowed to equilibrate a minimum of 3 minutes on the eye.

   After a minimum of 3 minutes, perform the following assessments and record in the source documentation and applicable eCRF:

   - Collect Symptoms/Complaints information using the Symptoms/Complaints Rating Scales in Appendix A
   - distance high contrast lens VA
   - over-refraction and distance VA
   - lens wettability

- lens centration
- lens movement
- lens rotation
- lens deposits

For each eye, compare the high contrast distance lens VA to the high contrast BSCVA obtained at this visit. If the VA has decreased by 5 letters (0.1 logMAR) or more, explain.

f. Dispense lens cases. Instruct the subject to place all worn lenses in a lens case (up to 10 pairs of lenses per eye per case) with no solution (dry). The subject will return the lens cases and blister labels to the site at the 1-Week Follow-Up Visit.

g. Discuss the diary with instructions to complete on a weekly basis. Subjects will be provided with a reminder at every visit to complete the diary to capture wear experience on a weekly basis until they exit the study.

h. If the subject is discontinued or exited at this visit, complete the Exit Visit eCRF.

i. Re-emphasize the exclusion criterion stating that if the subject is a female of child bearing potential and is pregnant and or breast feeding, she is ineligible to be a part of the study.

11.1.3 1-Week, 1-Month, and 3-Month Follow-up Visits

a. If this is an Exit Visit, indicate that on the eCRF and, in addition to completing the appropriate Follow-Up Visit Form, complete the Exit Visit Form. If a subject misses the scheduled follow-up visit and cannot be seen prior to the start of the visit window for the next scheduled follow-up visit, then the visit is considered missed and it should be recorded as a missed visit in the applicable eCRF.

b. Collect/assess all AEs, including serious or significant non-serious AEs.

c. If the subject did not wear lenses to the visit, the subject can use a pair from the 10 lenses per eye stored in the office to complete the assessment.

d. Collect Symptoms/Complaints information using the Symptoms/Complaints Rating Scales in Appendix A and record them in the source documentation and eCRF.

e. Evaluate the lenses (while on eye) and record the following assessments in the source documentation and eCRF:

- distance high contract lens VA
- over-refraction and distance VA
- lens wettability
- lens centration
- lens movement

- lens rotation
- lens deposits

For each eye, compare the high contrast distance contact lens VA from each respective / current visit (1-Week, 1-Month, 3-Month Follow-up Visits) to the high contrast distance contact lens VA obtained at the Dispensing Visit. If the VA has decreased by 10 letters (0.2 logMAR) or more, record in the subject's source document and explain.

f. Perform a slit lamp examination (remove the lenses if the subject wore lenses to the visit) and record the following assessments in the source documentation and the eCRF. Record all slit lamp findings and, at a minimum, sketch the following in the subject's source document:

- any ungraded finding marked as "PRESENT"
- any new corneal scars
- any neovascularization within the central 6 mm of the cornea
- any corneal staining
- any corneal infiltrate (record details on the Corneal Infiltrates Evaluation Form [Appendix E])
- any other graded slit lamp findings Grade 2 or greater

g. Perform the following assessments without lenses and record in the subject's source document: spherocylindrical refraction, distance BSCVA, and direct ophthalmoscope exam (non-dilated). IOP will be measured using the TonoPen or Goldmann method at all visits. Autorefraction will be measured using the standard autorefractor method at the 3-Month Visit only.

h. The subject will return the worn dry stacked lenses in lens cases and blister foils to the site at each Follow-Up Visit. The unmasked designee will collect the lens cases and put them into the ziploc bag labeled for that visit. The ziploc bag will then be kept in the subject's opaque bag for return to the Sponsor at the end of study. For all visits, except their Exit Visit, dispense lens cases. Instruct the subject to place all worn lenses in a lens case (10 pairs of lenses per eye per case) with no solution (dry) and keep the blister foils to return at their next follow-up visit.

i. Review diary with instructions to complete on a weekly basis. At the 1-Week visit, provide subject with separate diaries for Month 1, Month 2, and Month 3. Collect the previous month's diary at each follow-up visit.

j. Re-emphasize the exclusion criterion stating that if the subject is a female of child bearing potential and is pregnant and or breast feeding, she is ineligible to be a part of the study.

If all scheduled visits are performed on time and the subject completes the 3-Month Visit, the Exit Visit will be done at the same time.

11.1.4 Exit Visit

An Exit Visit should be completed for all subjects who complete the study (3-Month Visit) or discontinued the study early (1-Week, 1-Month Visit, or at an Unscheduled Visit).

The Exit Visit will be delayed in the event that there is a complication and the subject needs to be followed up through an Unscheduled Visit.

a. Indicate status of the subject on the Exit Visit Form. If the status is "Discontinued" or "Non-dispensed," indicate the PRIMARY exit reason for each eye on the Exit Visit Form.

b. Collect/assess all AEs, including serious or significant non-serious AEs.

c. For all dispensed subjects, complete an exit ocular examination without lenses on the eyes. Perform the following assessments: uncorrected distance VA, autorefraction, spherocylindrical refraction, high contrast distance BSCVA, keratometry, dilated fundus exam, and direct ophthalmoscope exam (non-dilated). IOP will be measured using the TonoPen or Goldmann method.

d. For each eye, compare the Exit Visit high contrast distance BSCVA to the high contrast distance BSCVA obtained at the Screening Visit. If the VA has decreased by 10 letters (0.2 logMAR) or more, record in the subject's source document and explain.

e. For each eye, compare the Exit Visit keratometry readings to the Screening Visit keratometry readings. If there is a change of 1.00 D or more, record in the subject's source document and explain.

f. The unmasked CRA must collect all worn and unworn lenses, blister foils, and drystacked lens cases from the subject and record and reconcile in the CTM Product Accountability Log. All subject materials will be kept in the subject's opaque bag to be verified/reconciled by the study monitor before study close out. Once reconciled, the opaque bag can be sealed and returned to Clinical Trial Materials address in Section 10.3.

g. The Exit Visit eCRF should be completed, in addition to the appropriate Follow-Up Visit Form.

NOTE: All unworn, dispensed, non-dispensed study lenses are to be returned to the Sponsor after the study is complete and the lens reconciliation has been finalized. Worn lenses will be dry stacked in lens cases and returned to Bausch and Lomb. All contact lenses must be accompanied by a CTM Product Accountability Log.

11.1.5 Unscheduled Visits

Additional visits may be scheduled, as necessary, to ensure the safety and well-being of subjects. All additional exams should be fully documented in the source documents and on Unscheduled Visit eCRFs, as appropriate. Visits intended to fulfill scheduled visit requirements that fall outside the designated scheduled visit range, are not Unscheduled Visits. In these cases, the visit data will be collected and transcribed to the appropriate scheduled visit eCRF.

If a subject is seen for multiple visits during a given visit timeframe, the data from the visit that is intended to meet the protocol requirements for the scheduled visit should be captured on the visit eCRF. Where such a determination cannot be made, the first visit within the scheduled visit interval will be used for completion of the protocol required scheduled visit eCRF. Data from any additional visits within a scheduled visit interval will be captured on an Unscheduled Visit eCRF.

Product Dispensing Only (Part of the Unscheduled Visit - used only if lens supply is lost)

If a subject is only seen for an unscheduled lens replacement, a complete exam is not required as long as the subject is not experiencing any problems. In an effort to ensure the Investigator remains masked, an unmasked designee MUST dispense the lens(es) to the subject. Record lenses dispensed in the CTM Product Accountability Log. If study lenses are dispensed, collect the following information in the source document and transcribe to the Product Dispensing Only eCRF Form:

- visit date
- subject ID number
- subject initials
- primary reason for lens replacement
- dispensed lens power

If any assessment is performed, then an Unscheduled Visit Form must be completed instead of a Product Dispensing Only Form.

NOTE: All worn study lenses are to be returned to the Sponsor at the end of the study as directed with the materials provided. Worn lenses will be dry stacked in lens cases and returned to Bausch and Lomb. All contact lenses must be accompanied by a CTM Product Accountability Log.

If a subject is experiencing problems, complete the following:

a. Indicate the reason for the Unscheduled Visit.

b. Collect/assess all AEs, including serious or significant non-serious AEs.

c. Collect Symptoms/Complaints information using the Symptoms/Complaints Rating Scales in Appendix A

d. Evaluate the lenses (while on eye) and record the following assessments in the source documentation and eCRF:

   - distance high contrast lens VA
   - over-refraction and distance VA
   - lens wettability
   - lens centration
   - lens movement
   - lens rotation
   - lens deposits

   For each eye, compare the high contrast distance lens VA to the high contrast BSCVA obtained at the Dispensing Visit. If the VA has decreased by 10 letters (0.2 logMAR) or more, record in the subject's source document and explain.

e. Perform the following assessments without lenses and record in the subject's source document: spherocylindrical refraction, distance BSCVA, and direct ophthalmoscope exam (non-dilated). IOP will be measured using the TonoPen or Goldmann method.

f. Perform a slit lamp examination (without lenses). Record all slit lamp findings and, at a minimum, sketch the following in the subject's source document:

   - any ungraded finding marked as "PRESENT"
   - any new corneal scars
   - any neovascularization within the central 6 mm of the cornea
   - any corneal staining
   - any corneal infiltrate (record details on the Corneal Infiltrates Evaluation Form [Appendix E])
   - any other graded slit lamp findings Grade 2 or greater

g. Remind subject to complete the diary on a weekly basis as instructed.

h. Re-emphasize the exclusion criterion stating that if the subject is a female of child bearing potential and is pregnant and or breast feeding, she is ineligible to be a part of the study.

i. The Unscheduled Follow-up Visit eCRF should be completed. If the subject is discontinued or exited at this visit, the Exit Visit Form should also be completed.

11.1.6 Missed Visits

If a subject misses any scheduled follow-up visit and cannot be seen prior to the start of the visit range for the next scheduled follow-up visit, the visit is considered missed.

11.1.7 Study Restrictions

Wearing restrictions are presented in Appendix B.

11.2 Definition of Source Data

All evaluations reported in the eCRF must be supported by appropriately identified source documentation.

11.3 Handling of Subject Withdrawal

No subjects will be replaced on study if a subject withdraws or is removed.

11.4 Evaluation of Effectiveness

11.4.1 Effectiveness Parameters

The primary effectiveness endpoint is the proportion of subjects achieving a contact lens corrected distance logMAR VA of 0.04 or better in both eyes, evaluated at the 1-Week Follow-up Visit.

Other performance criteria for evaluation will be summarized descriptively.

1 Visual acuity

- optimal corrected distance VA measured with the phoropter
- contact lens corrected distance VA

11.5 Evaluation of Safety

11.5.1 Eye Condition

Eye condition criteria include the following, which will be summarized descriptively.

- Slit lamp findings
- Dilated fundus exam findings
- Intraocular pressure

11.5.2 Lens Suitability

- Centration
- Wettability
- Movement

11.5.3 Lens Status

- Deposits

11.5.4 Visual Acuity

- Uncorrected distance VA

11.5.5 Change in Manifest Refraction Between the Screening and Exit Visits

11.5.6 Change in Corneal Curvature Between the Screening and Exit Visits

11.5.7 Adverse Event Definitions

- Adverse Event (AE): any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in a subject, user or other persons, whether or not related to the investigational medical device. This definition includes events related to the investigational medical device, comparator or the procedures involved. For users or other persons, this definition is restricted to events related to investigational medical devices.
- Adverse Device Effect (ADE): an AE related to the use of an investigational medical device. This definition includes AEs resulting from insufficient or inadequate instructions for use; deployment, implantation, installation, or operation; or any malfunction of the investigational medical device. This definition also includes any event resulting from use error or from intentional misuse of the investigational medical device.
- Serious Adverse Event (SAE) is an AE that:
  - led to death;
  - led to serious deterioration in the health of the subject, that resulted in:
    - a life-threatening illness or injury; or
    - a permanent impairment of a body structure or a body function (eg, blindness); or
    - in-patient or prolonged hospitalization; or
    - medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function;
  - led to fetal distress, fetal death, or a congenital abnormality or birth defect.

    NOTE: Planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered an SAE.
- Unanticipated Adverse Device Effect (UADE): any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with a device, if that effect, problem or death was not previously identified in nature, severity or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

11.5.8 Adverse Event

Throughout the course of this study, all efforts will be made to remain alert to possible AEs. The term "AEs" includes both SAEs and Significant Non-Serious Adverse Events. Each are defined below.

If an AE occurs, the first concern will be the safety of the subject and appropriate medical intervention will be made. All AEs (serious AEs and significant non-serious AEs) that occur will be reported in this study.

AEs should be differentiated into device related and non-device related. Any corneal infiltrate, ulcer, neovascularization, etc. shall be presumed to be device related, in the absence of an alternative explanation.

All AEs occurring after signing of informed consent and through the subject's end of participation in the study must be reported. All AEs must be followed until the event resolves or stabilizes.

All AEs should be photo documented and communicated to the CRO and Sponsor in electronic form.

11.5.8.1 Serious Adverse Events

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

Serious adverse events may include any hazardous, **sight-threatening conditions** occurring after exposure to the test article, including the following:

- A presumed infectious ulcer (defined as a progressive erosion of the corneal tissue). For the purposes of reporting:
  - central or paracentral location;
  - penetration of Bowman's membrane;
  - infiltrate ≥2 mm diameter;
  - associated with iritis Grade 2 or greater;
  - associated with any increase in intraocular pressure;
  - culture positive for microorganisms;
  - increasing size or severity at subsequent visits.
- Note: Signs of a presumed infectious corneal ulcer may include irregular focal infiltrates; active lesions with raised edges; significant diffuse infiltration; anterior corneal to

mid-stromal involvement; erosion with overlying staining; conjunctival and lid edema; anterior chamber reaction (iritis); severe bulbar and limbal redness. Symptoms associated with a presumed infectious ulcer (microbial keratitis) may include pain of rapid onset; severe redness; purulent or mucopurulent discharge; tearing; photophobia.

- Any central or paracentral (within 6 mm of cornea) corneal event that results in permanent opacification (such as vascularization);
- Any serious adverse ophthalmic events including hypopyon and hyphema;
- Any neovascularization within the central 6 mm of the cornea;
- Permanent loss of 2 or more lines of BSCVA;
- All cases of iritis.

11.5.8.2 Significant Non-Serious Adverse Events

Significant Non-Serious Adverse Events should include:

- Peripheral non-progressive non-infectious corneal ulcers;
- All symptomatic corneal infiltrative events;
- All cases of corneal staining greater than or equal to Grade 3;
- A temporary loss of 2 or more lines of BSCVA (for greater than or equal to 2 weeks);
- Neovascularization cases equal to Grade 2 or greater;
- Any ocular event that necessitates temporary lens discontinuation of greater than or equal to 2 weeks.

11.5.8.3 Adverse Event Treatment [redacted]

With any AE, treat the subject as appropriate to prevent further complications and to potentially resolve the event consistent with the standard of care.

[redacted]

[redacted]

11.5.8.4 Medical Treatment Including non-Adverse Events

In the event that a subject requires medical treatment (prescription medication) for an ocular condition, treat the subject as appropriate to prevent further complications and to potentially resolve the event.

11.5.8.5 Evaluations

When evaluating AEs, the Investigator must determine if the event is serious (refer to Section 11.5.8.1 for criteria), assess the severity of symptoms and the relationship of the event to the study device using the following guidelines:

a. Severity

- **Mild**: Subject awareness of a sign or symptom that is easily tolerated, requires no treatment, and does not interfere with subject's daily activities.
- **Moderate**: Subject awareness of a sign or symptom which may be a low level of concern to the subject and may interfere with daily activities, but can be relieved by simple therapeutic care.
- **Severe**: A sign or symptom that interrupts the subject's daily activity and requires systemic therapy or other treatment.

b. Relationship to Study Device and/or Rewetting Drops

- **Related:** There is at least a reasonable possibility that the AE/SAE is related to the study device and/or Rewetting Drops Reasonable possibility means that there is evidence to suggest a causal relationship or association between the study device and/or Rewetting Drops and the AE. Also referred to as an ADE.
- **Unrelated:** There is little or no reasonable possibility that the AE/SAE is related to the study device and/or Rewetting Drops. This assessment implies that the AE/SAE has no evidence to suggest either a causal relationship or association to the study device and/or Rewetting Drops and more likely or certain an alternative etiology exists.

11.5.8.6 Procedures for Reporting Adverse Events and Serious Adverse Events

In the case of an AE (Serious and Significant Non-Serious) or Medical Treatment (non-AE), the Investigator must:

- Report the AE or Medical Treatment to the Medical Monitor within 24 hours of knowledge of the event using the Sponsor-provided form (SAE/UDE reporting form) by emailing the completed form to the Medical Monitor

[redacted]

- Indicate on the Initial SAE/UADE reporting form whether the SAE/UADE is presumed to be not study-related, lens-related, solution-related, or both lens/solution related.
- Ensure that the subject's identity is protected and the subject's identifiers in the clinical trial are properly mentioned on the form.
- BEGIN TREATMENT OF THE AE IMMEDIATELY BY A SUITABLY LICENSED EYE CARE PROFESSIONAL.
- Enter the SAE/UADE into the eCRF within 3 business days of submitting the Initial AE/Medical Treatment Notification Form.
- Continue to update the eCRF, if applicable, each time the subject is seen during the management of the incident and at resolution of the incident. Whenever possible, it is suggested that the Investigator take photographs of all AEs and forward them to the Sponsor.
- Cases requiring medical treatment will be evaluated by the Sponsor. Upon review of the medical treatment, Bausch + Lomb Clinical Operations representatives may contact the Investigator to request further information concerning the treatment.
- Submit all bills, prescription receipts, and culture reports/fees related to the AE to Bausch + Lomb Clinical Operations. Expenses incurred for study-related medical treatment will be paid by Bausch + Lomb Clinical Operations.

Guidelines for Reporting Pregnancies

All female subjects of childbearing potential must use an effective method of birth control during the study, to include 2 weeks after last visit, in a manner such that risk of contraceptive failure is minimized. Abstinence is allowed as a birth control method. Before enrolling a female subject of childbearing potential, the Investigator must review the following information about study participation:

- Informed consent requirement
- Contraceptives in use

Following review of this information and appropriate counseling, the Investigator or designee and the subject must sign the informed consent before study enrollment. During the study, all female subjects of childbearing potential should be instructed to contact the Investigator immediately if they suspect they might be pregnant (eg, missed or late menstrual period).

If a subject or Investigator suspects that the subject may be pregnant prior to study enrollment, the study lens must be withheld until the results of laboratory pregnancy testing are available. If pregnancy is confirmed, the subject must not receive study lens and must not be enrolled in the study. If pregnancy is suspected while the subject is receiving study treatment, the study lens must immediately be withheld until the result of pregnancy testing is known. If pregnancy is confirmed, the study lens will be permanently discontinued and the subject will be followed until the pregnancy comes to term. A Pregnancy Report form will be submitted to the Sponsor, initially and at the end of the pregnancy, which includes the outcome of the pregnancy and any complications occurring during the pregnancy or the delivery.

All confirmed pregnancies must be immediately reported to the Medical Monitor within 24 hours of the Investigator's awareness of the pregnancy. All confirmed pregnancies must be reported via confirmed facsimile/email transmission and must be submitted on a Pregnancy Report form within 24 hours of the Investigator's awareness of the pregnancy using the same reporting as procedure for an SAE. Although pregnancy occurring in a clinical study is not considered to be an AE or SAE, any pregnancy complication or elective termination of a pregnancy, for medical reasons, will be recorded as an AE or SAE. Any serious complications or event resulting from the pregnancy should be reported to the Sponsor within 24 hours on a SAE/UADE form along with the Pregnancy Report form.

11.5.9 Obligations of the Sponsor

During the study, the Sponsor will report in an expedited manner:

- All unexpected SAEs possibly related to IMP (SUSAR), to the Health Authorities, as appropriate and to the Investigators.
- All SAEs possibly related to the Test Product, to the IRB/IEC as appropriate and to the Investigators.
- All UADEs related to the Test Product, to Health Authorities, to the IRB/IEC as appropriate and to Investigators.

Any AE not listed as an expected event in the package insert or in this protocol will be considered as unexpected.

The Sponsor will report all safety observations made during the conduct of the trial in the clinical study report.

11.5.10 Reporting Device Deficiencies

A device deficiency is defined as an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Device deficiencies include malfunctions, use errors, and inadequate labeling. All device deficiencies will be reported to the Sponsor and its representatives on a Device Deficiency Report form.

Investigators must evaluate, record, and report via applicable forms any complaints/deficiencies, or malfunctions that could potentially lead to a SAE during this trial to the Sponsor and its representative without unjustified delay. As required, such reports may be provided to the reviewing IRB per their established reporting procedures and the FDA by the Investigator. Upon the Sponsor's request, Investigators must supply any additional information related to the safety reporting of a particular event.

The contact for reporting device deficiencies is:

[redacted]

The Sponsor shall review all device deficiencies and determine and document in writing whether they could have led to a SAE. In the event of a disagreement between the Sponsor and the Investigator(s), the Sponsor shall communicate both opinions to the reviewing IRB per their established reporting procedures and the health authority.

12 Statistics

12.1 Determination of Sample Size

12.1.1 Primary Effectiveness Endpoints

The null hypothesis is that the difference in the proportion of subjects with both eyes "0.04 or Better" between the test group (π_T) and the control group (π_C) is less than or equal to the negative value of the non-inferiority margin (-δ). The alternative hypothesis is that the difference in proportions is greater than the negative value of the non-inferiority margin.

$H_0: \pi_T - \pi_C \leq -\delta$

$H_1: \pi_T - \pi_C > -\delta$

In a previous evaluation of Biotrue ONEday for Astigmatism Soft Contact Lenses, 92.5% of subjects with baseline logMAR BSCVA of 0.04 or better achieved the primary effectiveness endpoint of this study at the follow-up visit. Consequently 92.5% is the expected percentage of subjects "0.04 or Better" in the Test and Control groups. The non-inferiority margin will be set at 10% and the lower confidence limit will be compared to -10%.

A one-sided alpha risk of 0.025 (eg, a two–sided 95% confidence interval) will be used to test the hypothesis.

When the sample size in each group is 109 subjects, a two-group large-sample normal approximation test of proportions with a one-sided 0.025 significance level will have 80% power to reject the null hypothesis that the test is inferior to the control (the difference in proportions, $\pi_T - \pi_C$, is -0.10 or less) in favor of the alternative hypothesis that the test lens is non-inferior, assuming that the expected difference in proportions is 0.000 and the proportion in the standard group is 0.925.

12.1.2 Overall Power and Sample Size

In order to allow for dropouts of up to 10%, at least approximately $109/(1-0.1) \approx 122$ subjects will be enrolled in each treatment group for a total enrollment of approximately 244 subjects.

12.2 Analysis Populations

12.2.1 Intention-to-Treat (ITT) Population

The ITT Population will include all randomized subjects (and both of their eyes) who are deemed eligible based on pre-randomization eligibility assessments. Subjects in the ITT Population will be included in summaries under the lens type to which they were randomized.

12.2.2 Per Protocol Population

The PP Population will include all randomized subjects without major protocol deviations who complete the study through Visit 3 (Days 6 - 10). Major protocol deviations affecting only one eye will result in the exclusion of both eyes from eye level summaries.

12.2.3 Safety Population

The Safety Population will include all dispensed subjects (all subjects fitted with contact lenses). In the Safety Population, subjects will be included in summaries under the lens type actually dispensed and used. If multiple lens types are dispensed and used including the test lens, then the subject will be included in summaries under the test lens treatment group.

12.3 Assessment of Effectiveness

12.3.1 Statistical Analysis

12.3.1.1 Descriptive Statistics

In general, data will be summarized by treatment group and visit as appropriate. Data will be summarized separately at the subject and eye levels. Subject level summaries will summarize the average of the subject's 2 eyes for continuous variables and the worst case over both eyes for categorical variables.

Summaries for continuous variables will include the sample size, mean, standard deviation, median, minimum, and maximum. Means and medians will be presented with one more decimal place than the recorded raw data. Standard deviations will be presented with 2 more decimal places than the recorded raw data. Minima and maxima will be presented with the same number of decimal places as the recorded raw data. Values with magnitude less than 1 will be presented with a leading zero to the left of the decimal (eg, 0.123 or -0.123).

Categorical data will be summarized using frequencies and percentages. Percentages will be presented with one decimal place. Percentages may not be presented when the count is zero. Unless otherwise specified the denominator for percentages will be the number of non-missing values within the group being presented.

12.3.2 Primary Effectiveness Analysis

At the 1-Week Follow-up Visit, subjects with non-missing logMAR acuities 0.04 or better in both eyes will be classified as "0.04 or Better." Subjects with at least one logMAR acuity > 0.04 at the visit will be classified as "Worse than 0.04." Subjects with at least one missing value at the visit will not be classified and their classification value will be assigned as missing. Visual acuity of 0.04 logMAR is the acuity where an individual subject would be given credit for reading logMAR 0.0 and logMAR 0.0 is equivalent to Chinese logarithmic visual acuity chart value of 5.0.

The summaries and analyses of the primary effectiveness endpoint will be at the subject level.

Use of the ITT Population and imputation of missing values are not conservative practices in non-inferiority analyses. Consequently, the PP Population will be used for the primary analysis without imputation of missing data.

Primary Non-Inferiority Analysis with the Per Protocol Population

VA Effectiveness will be summarized categorically (0.04 or Better, Worse than 0.04) by treatment group at the 1-Week Follow-up Visit for the Per Protocol (PP) Population in a table. Missing data will not be imputed for this primary analysis of the PP Population. The denominator for percentages will be the number of non-missing values.

The difference between treatment groups (Test minus Control) in the proportion of subjects classified as "0.04 or Better" will be estimated. An asymptotic Wald non-inferiority test (without continuity correction; using the sample variance; alpha risk = 0.025) and the associated two–sided 95% confidence interval will be used to test the statistical hypothesis. The difference between treatment groups (in percentage units), the asymptotic standard error for the difference (in percentage units), the associated Z value, the p-value for the non-inferiority test, and a two–sided 95% confidence interval (in percentage units) around the difference will be presented. [redacted]

[redacted]

Sensitivity Analysis Using the ITT Population

VA Effectiveness will be summarized categorically (0.04 or Better, Worse than 0.04) by treatment group at the 1-Week follow-up visit for the ITT Population in a table. The denominator for percentages will be the number of non-missing values. Missing data will not be imputed for this categorical summary.

If there are no missing lens VA data at the 1-Week follow-up visit for ITT subjects, then the following will be completed.

- The difference between treatment groups (Test minus Control) in the proportion of subjects classified as "0.04 or Better" will be estimated.

[redacted]

If there are missing lens VA data for ITT subjects at the 1-Week follow-up visit then missing data will be imputed as follows prior to hypothesis testing.

[redacted]

- The difference between treatment groups (Test minus Control) in the proportion of subjects classified as "0.04 or Better" and the asymptotic standard error will be estimated by imputation.
- An estimated difference between treatment groups and two-sided asymptotic Wald 95% confidence interval around the difference will be constructed via combination of the proportion differences and standard errors from the imputations.
- If all of the imputations result in the same estimated difference and confidence interval, then the results of a single imputation may be used.

The estimated difference between treatment groups (Test minus Control) in the percentage of subjects classified as "0.04 or Better" will be presented along with the two-sided asymptotic Wald 95% confidence interval around the difference.

Evaluation of Sensitivity to Missing Data

As an evaluation of sensitivity to missing VA Effectiveness data, a best-case analysis, worst-case analysis, and tipping point analysis will be completed for the ITT Population (Xu et al, 2009). If there are no missing ITT Population data then these analyses will not be completed.

Evaluation of the Influence of Site on the Treatment Effect

VA Effectiveness will be summarized categorically (0.04 or Better, Worse than 0.04) by treatment group and site for the ITT Population in a table. This will be a subject level summary. The denominator for percentages will be the number of non-missing values. Missing data will not be imputed.

A Breslow-Day test for homogeneity of odds ratios will be used to evaluate the consistency of the treatment effect among the sites. If the p-value from this test is less than 0.05 then the difference between sites will be considered to be statistically significant.

Evaluation of the Influences of Age, Sex, and Descent on the Treatment Effect

VA Effectiveness will be summarized categorically (0.04 or Better, Worse than 0.04) by treatment and age group (less than 30, 30 to 39, 40 to 49, 50 or greater) for the ITT Population in a table. The denominator for percentages will be the number of non-missing values. Missing data will not be imputed.

A Breslow-Day test for homogeneity of odds ratios will be used to evaluate the consistency of the treatment effect among the age groups. If the p-value from this test is less than 0.05 then the difference among age groups will be considered to be statistically significant.

VA Effectiveness will be summarized categorically (0.04 or Better, Worse than 0.04) by treatment and sex (Male, Female) for the ITT Population in a table. This will be a subject level summary. The denominator for percentages will be the number of non-missing values. Missing data will not be imputed.

A Breslow-Day test for homogeneity of odds ratios will be used to evaluate the consistency of the treatment effect between the sexes. If the p-value from this test is less than 0.05 then the difference between the sexes will be considered to be statistically significant.

VA Effectiveness will be summarized categorically (0.04 or Better, Worse than 0.04) by treatment and descent (Chinese, Non-Chinese) for the ITT Population in a table. This will be a subject level summary. The denominator for percentages will be the number of non-missing values. Missing data will not be imputed.

A Breslow-Day test for homogeneity of odds ratios will be used to evaluate the consistency of the treatment effect between the descent categories. If the p-value from this test is less

than 0.05 then the difference between the descent categories will be considered to be statistically significant.

VA effectiveness will also be summarized descriptively for each scheduled follow up visit.

12.3.3 Adverse Events

12.3.3.1 Definitions

Adverse events will be coded per the Medical Dictionary for Regulatory Activities (MedDRA). They will be classified into predefined standard categories per chronological criteria:

- Pretreatment AEs: AEs that developed or worsened during the pretreatment phase;
- Treatment-emergent adverse events (TEAEs): AEs that occurred or worsened at any time during the on-treatment phase;
- Post-treatment AEs: AEs that occurred during the post-treatment phase after discontinuation of lens wear.

If the start date (or time) of an AE is incomplete or missing, then the AE will be considered as a TEAE unless a partial date (or time) show it as a pre- or post-treatment event.

All AEs reported in the study will be listed by subject and onset date. Nevertheless, the analyses of the AEs will focus on the treatment-emergent or post-treatment adverse events.

12.3.3.2 Treatment-emergent or Post-treatment Adverse Events

An in-text table of overview of treatment-emergent or post-treatment adverse events subjects with any treatment-emergent or post-treatment AE, subjects with any severe treatment-emergent or post-treatment AE, subjects with any treatment-emergent or post-treatment serious AE, subjects with any treatment-emergent or post-treatment AE leading to permanent treatment discontinuation, or any treatment-emergent or post-treatment AE leading to death (only if death occurred), will be produced by treatment group.

Subjects presenting with treatment-emergent or post-treatment AEs will be listed sorted by treatment group, primary system organ class (SOC), and preferred term (PT).

Treatment-emergent or post-treatment AEs will be summarized by treatment group, tabulating:

- The number and percent of subjects with at least 1 treatment-emergent or post-treatment AE within each and over all SOC(es);
- The number and percent of subjects experiencing each PT in each SOC;
- The number of occurrences of all PT(s) within each and over all SOC(es);
- The number of occurrences of each PT in each SOC.

12.3.3.3 Deaths, Serious and Other Significant Adverse Events

Any deaths and SAEs will be listed.

12.3.3.4 Adverse Events Leading to Treatment Discontinuation

Any TEAE or post-treatment AE leading to permanent treatment discontinuation will be listed.

12.4 Subject Disposition

A detailed description of subject accountability, including number of subjects randomized and receiving Test or Control product, number of subjects who did not complete the study treatment period along with the main reason for permanent treatment discontinuation, and number of subjects who requested treatment discontinuation, will be generated for all subjects.

12.5 Demographics and Baseline Characteristics

12.5.1 Subject Demographic Characteristics, Medical History and Diagnoses

Continuous variables (age) and the qualitative variables (gender, race) will be summarized by descriptive statistics for all subjects for the Safety Population. In the event that more than 10% of subjects discontinue prior to completing the study, separate summaries of demographic characteristics will be provided for the PP Population.

Medical history that is current and relevant for the past 2 years will be collected.

Demographic data will be listed by subject.

12.6 Protocol Deviations

The following protocol deviations will be classified as major deviations when reported in the case report forms.

- Ineligibility
- Non-dispensed subjects
- Misrandomization
- Dispensing or use of the incorrect lens type
- Dispensing of the incorrect lens power, defined as a discrepancy greater than 0.25D in sphere, cylinder, or spherical equivalent
- Non-compliance with the recommended wearing schedule, such as
  - wearing lenses less than 80% of the recommended time, or
  - wearing a lens for multiple days

- Use of medications that could potentially affect ocular physiology or lens performance
- Failure to comply with the procedures used to assess primary effectiveness endpoints, such as missing the assessment or failing to complete the procedure in accordance with the instructions provided by site personnel.

Additional major categories may be added prior to unmasking. Major deviations will be provided in a listing.

12.7 Compliance

Subject compliance will be measured by reviewing diary entries and questioning the subject at each visit.

12.8 Interim Analyses

Not applicable

12.9 Additional Statistical Considerations

12.9.1 Prior/Concomitant Medication/Therapy

Medications will be classified by the latest version of the WHO-DDE dictionary.

13 Quality Control and Quality Assurance

13.1 Study Monitoring

Bausch + Lomb representatives must be allowed to visit all study site locations to assess the data, quality, and study integrity in a manner consistent with applicable health authority regulations and the procedures adopted by Bausch + Lomb.

Prior to the start of the study, member(s) of Bausch + Lomb (or designees) will review the protocol, eCRF, regulatory obligations, and other material or equipment relevant to the conduct of the study with the Investigator/Sub-Investigator and relevant study site personnel.

Monitoring visits and telephone consultations will occur as necessary, or per the Monitoring Plan, during the course of the investigation[redacted]

[redacted]

During the course of the study, if the Sponsor determines that an Investigator is not compliant with the protocol and/or applicable regulatory requirements, the Sponsor will take action to secure compliance. In addition, the Sponsor may terminate the Investigator's participation in the study if appropriate, or if the Investigator remains non-compliant despite the Sponsor's actions.

13.2 Audits and Inspections

Audits of clinical research activities in accordance with the Sponsor's internal Standard Operating Procedures to evaluate compliance with the principles of GCP may take place. A regulatory authority may also wish to conduct an inspection (during the study or after its completion). If an inspection is requested by a regulatory authority and/or IRB, the Investigator must inform the Sponsor immediately that this request has been made.

13.3 Data Quality Assurance

13.3.1 Use and Completion of Case Report Forms (CRFs) and Additional Request

Subject data required by this protocol are to be transferred from the source to the eCRFs. The Investigator and his/her study site personnel will be responsible for completing the eCRFs. The Investigator is required to verify that all of the requested information is accurately recorded on the eCRFs by providing an electronic signature. All information requested on the eCRFs needs to be supplied, including subject identification and initials, date(s), assessment values, etc., and any omission or discrepancy will require explanation. All information on eCRFs must be traceable to source documents.

The study monitor will be responsible for reviewing and verifying the data recorded on the eCRFs per the study Monitoring Plan, utilizing the original source documentation and will query discrepant findings. The Investigator and study site personnel will be responsible for answering all queries.

A copy of the eCRFs will be retained by the Investigator at the conclusion of the study, who must ensure that they are stored in a secure place.

14 Ethics and Administrative Issues

14.1 Ethical Conduct of the Study

This clinical trial will be conducted in accordance with the principles laid down by the World Medical Association – General Assembly (Helsinki, and all applicable amendments) laid down by the World Medical Association general assemblies, and the International Conference on Harmonisation (ICH) guidelines for GCP. This clinical trial will be conducted with all international guidelines, national laws and regulations of the country(ies) in which the clinical trial is performed, as well as any applicable guidelines.

14.2 Ethics Review

As required by local regulation, the Investigator and/or the Sponsor must submit this clinical trial protocol to the appropriate IRB/IEC, and is required to forward to the respective other party a copy of the written and dated approval/favorable opinion of the IRB/IEC (signed by the chairman with IRB/IEC composition).

The clinical trial (study number, clinical trial protocol title and version number), the documents reviewed (clinical trial protocol, ICF, Investigator's Brochure, Investigator's curricula vitae, etc.) and the date of the review should be clearly stated on the written IRB/IEC approval/favorable opinion.

Investigational medicinal product will not be released at the study site and the Investigator will not start the study before the written and dated approval is received by the Investigator and the Sponsor.

During the clinical trial, any amendment or modification to the clinical trial protocol should be submitted to the IRB/IEC before implementation, unless the change is necessary to eliminate an immediate hazard to the subjects, in which case the IRB/IEC should be informed as soon as possible. It should also be informed of any event likely to affect the safety of subjects or the continued conduct of the clinical trial, in particular any change in safety. All updates to the Investigator's Brochure will be sent to the IRB/IEC.

A progress report is sent to the IRB/IEC at least annually and a summary of the trial's outcome at the end of the clinical trial.

14.3 Written Informed Consent

The Investigator (according to applicable regulatory requirements), or a person designated by the Investigator and under the Investigator's responsibility, should fully inform the subject of all pertinent aspects of the clinical trial including the written information giving approval/favorable opinion by the ethics committee (IRB/IEC). All participants should be informed to the fullest extent possible about the study, in language and terms they are able to understand.

Prior to a subject's participation in the clinical trial, the written ICF should be signed, name filled in, and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion. A copy of the signed and dated written ICF will be provided to the subject.

The ICF used by the Investigator for obtaining the subject's informed consent must be reviewed and approved by the Sponsor prior to submission to the appropriate IRB/IEC for approval/favorable opinion.

14.4 Subject Data Protection

The subject's personal data, which are included in the Sponsor database, shall be treated in compliance with all applicable laws and regulations.

When archiving or processing personal data pertaining to the Investigator and/or to the subjects, the Sponsor shall take all appropriate measures to safeguard and prevent access to this data by any unauthorized third party.

The Sponsor also collects specific data regarding Investigator as well as personal data from any person involved in the study. This data which may be included in the Sponsor's databases, shall be treated by both the Sponsor and the Investigator in compliance with all applicable laws and regulations.

14.7 Investigator Obligations

The Investigator(s) and delegated Investigator staff undertake(s) to perform the clinical trial in accordance with this clinical trial protocol, ICH guidelines for GCP and the applicable regulatory requirements.

The Investigator is required to ensure compliance with all procedures required by the clinical trial protocol and with all study procedures provided by the Sponsor (including security rules). The Investigator agrees to provide reliable data and all information requested by the clinical trial protocol (from the eCRF, discrepancy resolution form, or other appropriate instrument) in an accurate and legible manner according to the instructions provided and to ensure direct access to source documents to Sponsor representatives.

If any circuits include transfer of data, particular attention should be paid to the confidentiality of the subject's data to be transferred.

The Investigator may appoint such other individuals as he/she may deem appropriate as subinvestigators to assist in the conduct of the clinical trial in accordance with the clinical

trial protocol. All subinvestigators shall be appointed and listed in a timely manner. The subinvestigators will be supervised by and work under the responsibility of the Investigator. The Investigator will provide them with a copy of the clinical trial protocol and all necessary information.

14.7.1 Curriculum Vitae

A current copy of the curriculum vitae describing the experience, qualification and training of each Investigator and sub-investigator will be signed, dated and provided to the Sponsor prior to the beginning of the clinical trial.

14.8 Changes to the Protocol

All appendices attached hereto and referred to herein are made part of this clinical trial protocol.

The Investigator should not implement any deviation from, or changes of the clinical trial protocol. Changes will be implement by the Sponsor and submitted to the IRB/IEC for review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to clinical trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial. Any change agreed upon will be recorded in writing, the written amendment will be signed by the Investigator and by the Sponsor and the signed amendment will be filed with this clinical trial protocol.

Any amendment to the clinical trial protocol requires written approval/favorable opinion by the IRB/IEC prior to its implementation, unless there are overriding safety reasons.

In some instances, an amendment may require a change to the ICF. The Investigator must receive an IRB/IEC written approval/favorable opinion concerning the revised ICF prior to implementation of the change and subject signature should be re-collected if necessary.

14.9 Confidentiality/Publication of the Study

14.9.1 Confidentiality

All information disclosed or provided by the Sponsor (or any company/institution acting on their behalf), or produced during the clinical trial, including, but not limited to, the clinical trial protocol, the eCRFs, the Investigator's Brochure, and the results obtained during the clinical trial, is confidential, prior to the publication of results. The Investigator and any person under his/her authority agree to undertake to keep confidential and not to disclose the information to any third party without the prior written approval of the Sponsor.

However, the submission of this clinical trial protocol and other necessary documentation to the IRB/IEC is expressly permitted, the IRB/IEC members having the same obligation of confidentiality.

The subinvestigators shall be bound by the same obligation as the Investigator. The Investigator shall inform the subinvestigators of the confidential nature of the clinical trial.

The Investigator and the subinvestigators shall use the information solely for the purposes of the clinical trial, to the exclusion of any use for their own or for a third party's account.

Furthermore, the Investigator and the Sponsor agree to adhere to the principles of personal data confidentiality in relation to the subjects, Investigator and its collaborators involved in the study.

14.10 Study Termination

The Sponsor or its representative may terminate the study at any time for scientific or corporate reasons.

If during the study it becomes evident to the Sponsor that the study should be stopped prematurely or placed on hold, appropriate notification will be given to the US FDA, Investigator(s), and IRBs, as applicable. Bausch + Lomb Clinical Operations will instruct the Investigators to stop/restart dispensing study materials and will arrange for study closeout, if applicable, at each site.

15 Data Handling and Record Keeping

15.1 Retention of Records

The Investigator must maintain confidential all study documentation, and take measures to prevent accidental or premature destruction of these documents.

The Investigator should retain the study documents at least 15 years after the completion or discontinuation of the clinical trial.

However, applicable regulatory requirements should be taken into account in the event that a longer period is required.

The Investigator must notify the Sponsor prior to destroying any study essential documents following the clinical trial completion or discontinuation.

If the Investigator's personal situation is such that archiving can no longer be ensured by him/her, the Investigator shall inform the Sponsor and the relevant records shall be transferred to a mutually agreed upon designee.

If the Investigator retires, relocates, or for other reasons withdraws from the responsibility of keeping the study records, custody must be transferred by the Investigator to a person who will accept the responsibility. The Sponsor must be notified in writing by the Investigator of the name and address of the new custodian and receive documented acceptance from the new custodian.

15.2 Clinical Trial Results

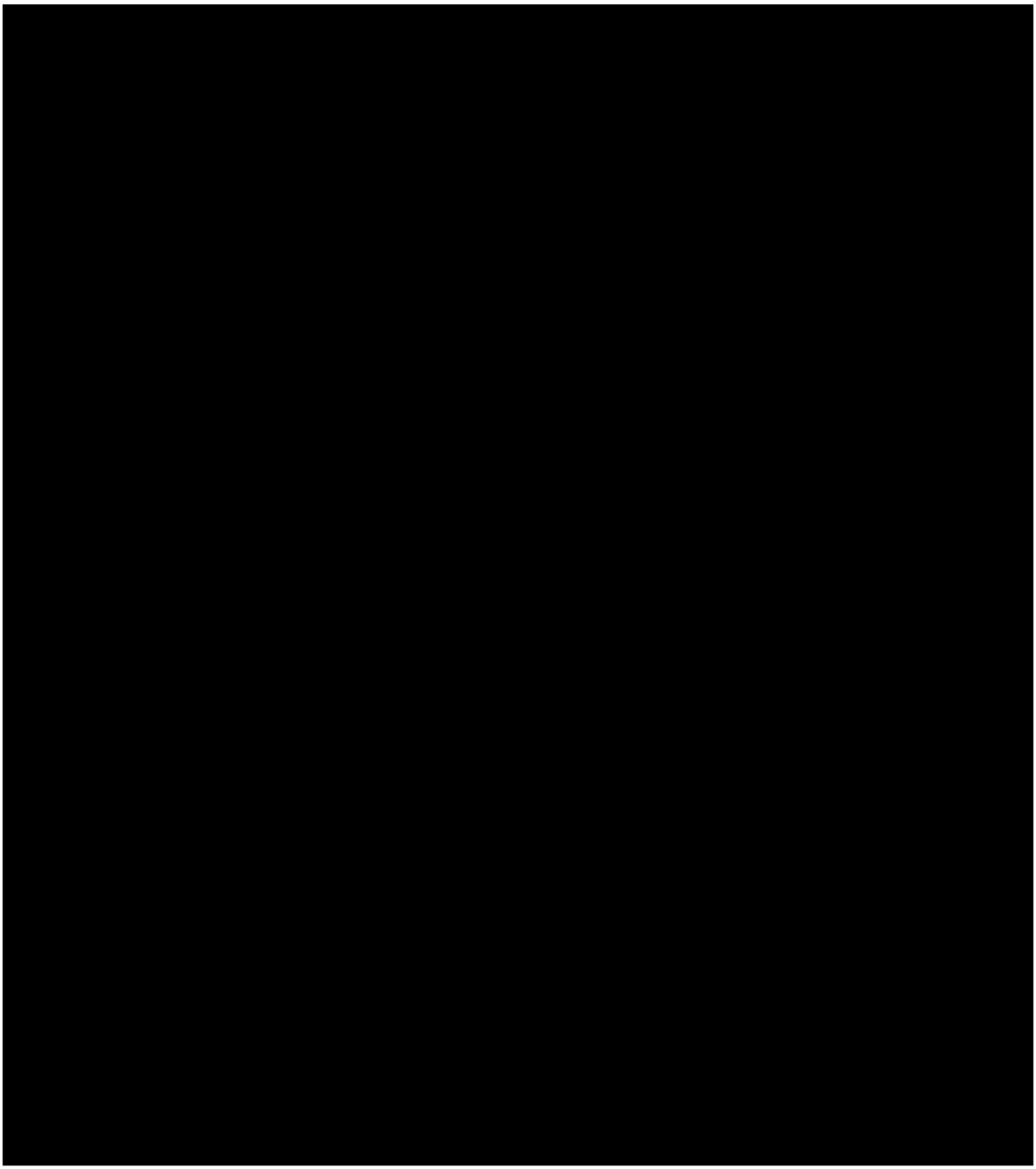
The Sponsor will be responsible for preparing a clinical study report and to provide a summary of study results to the Investigator.

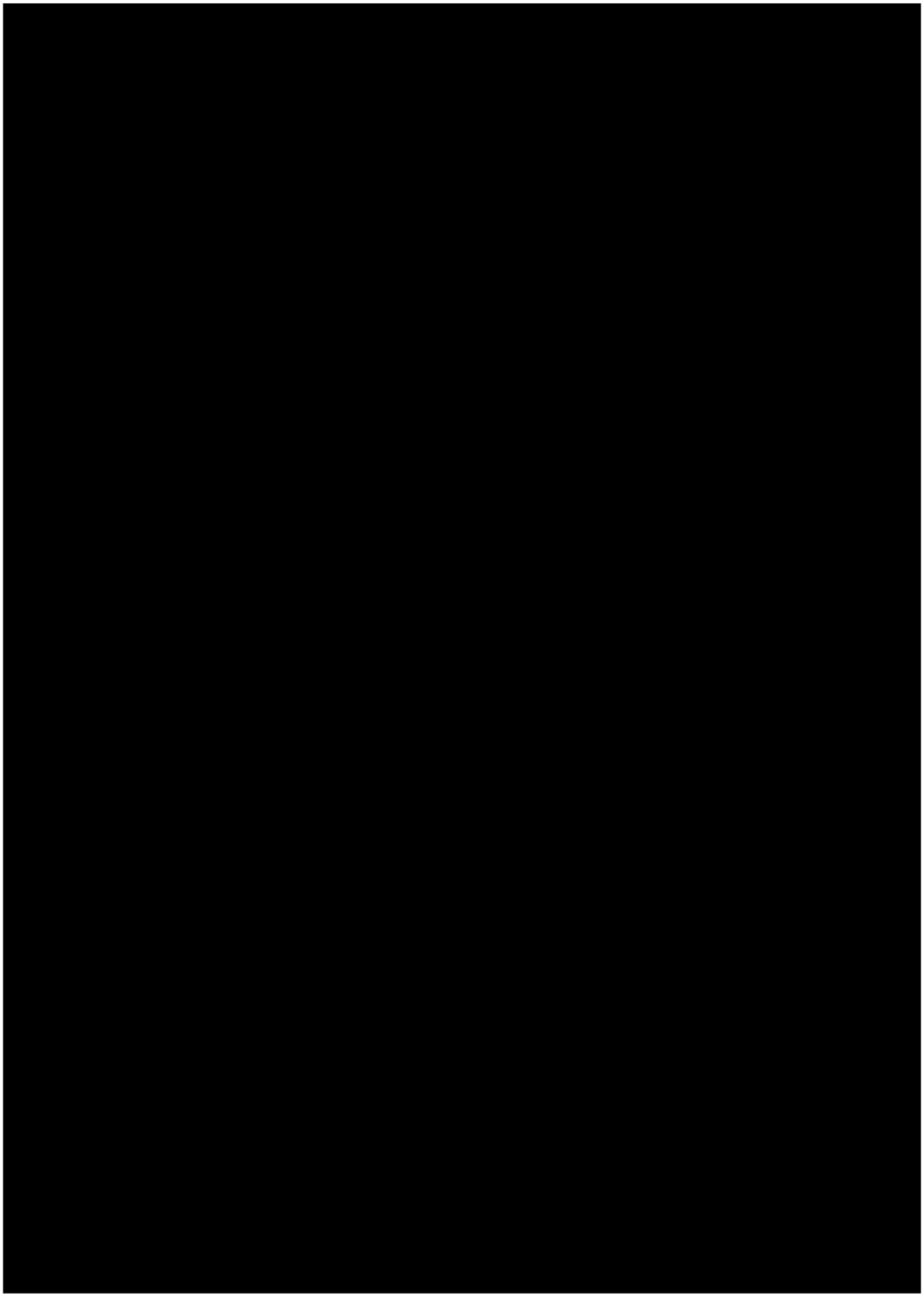
16 References

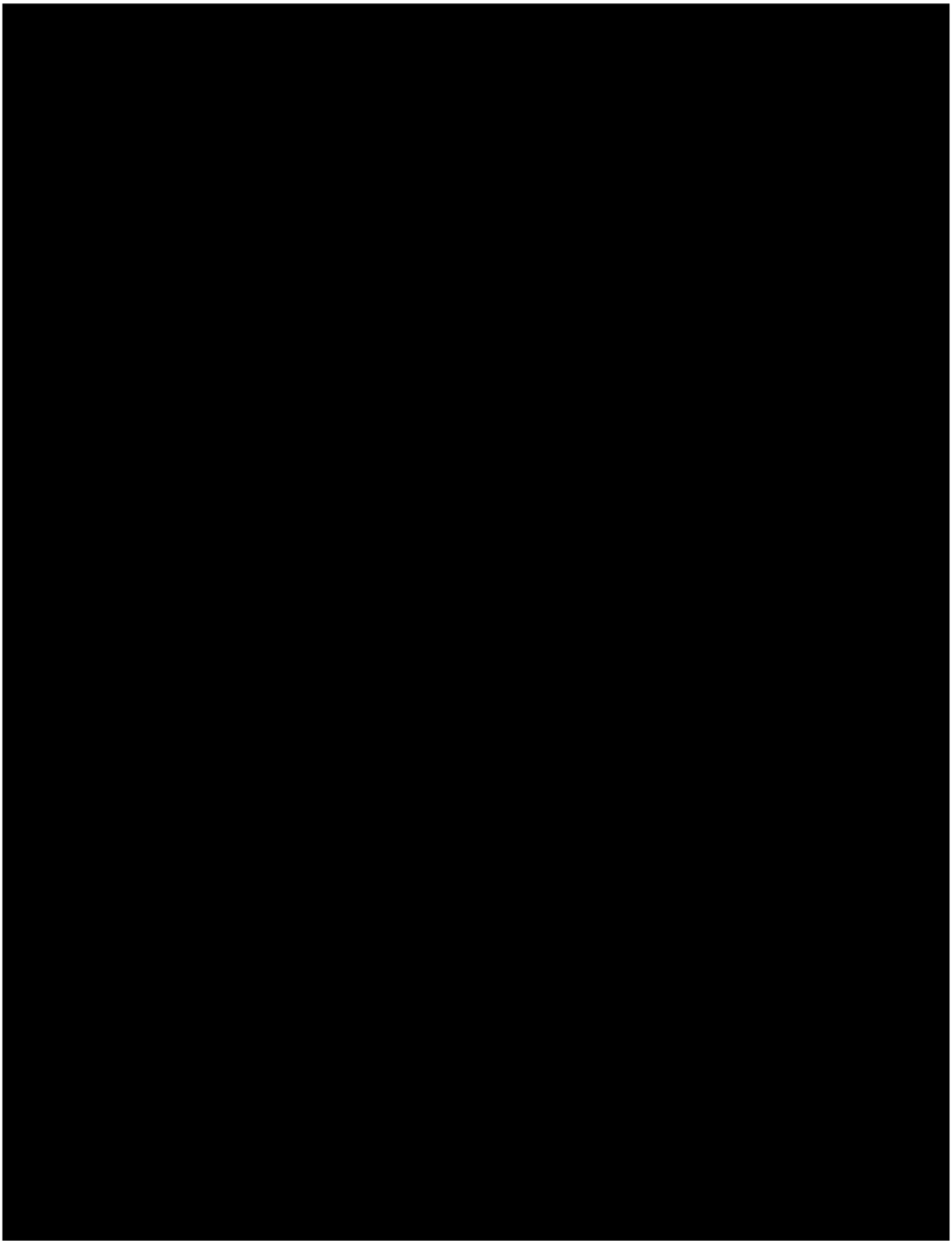
Xu Y, Shiowjen L & Ning L. Missing Data Handling Methods in Medical Device Clinical Trials, Journal of Biopharmaceutical Statistics. 2009; 19:6, 1085-1098.

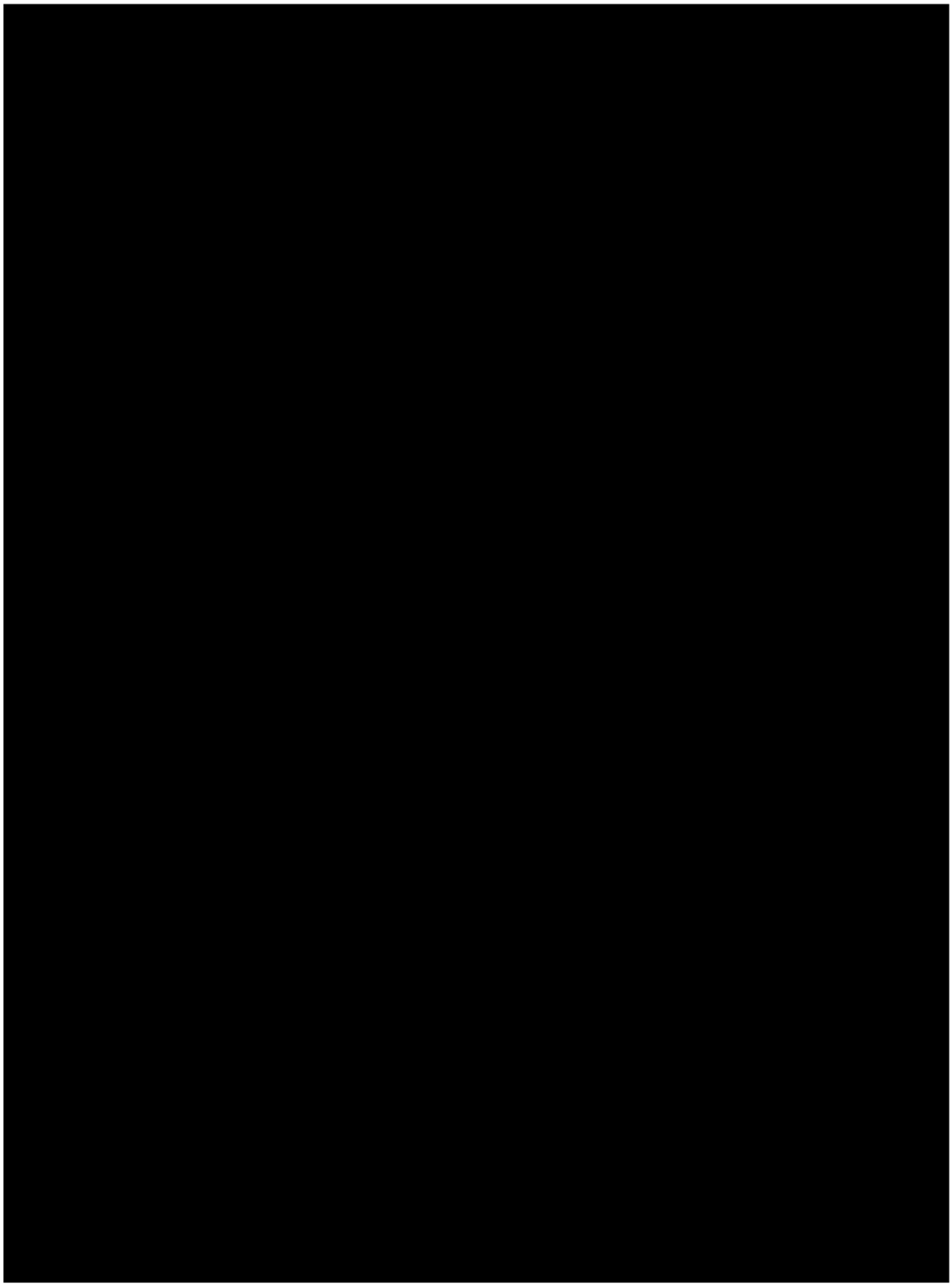
17 Appendices

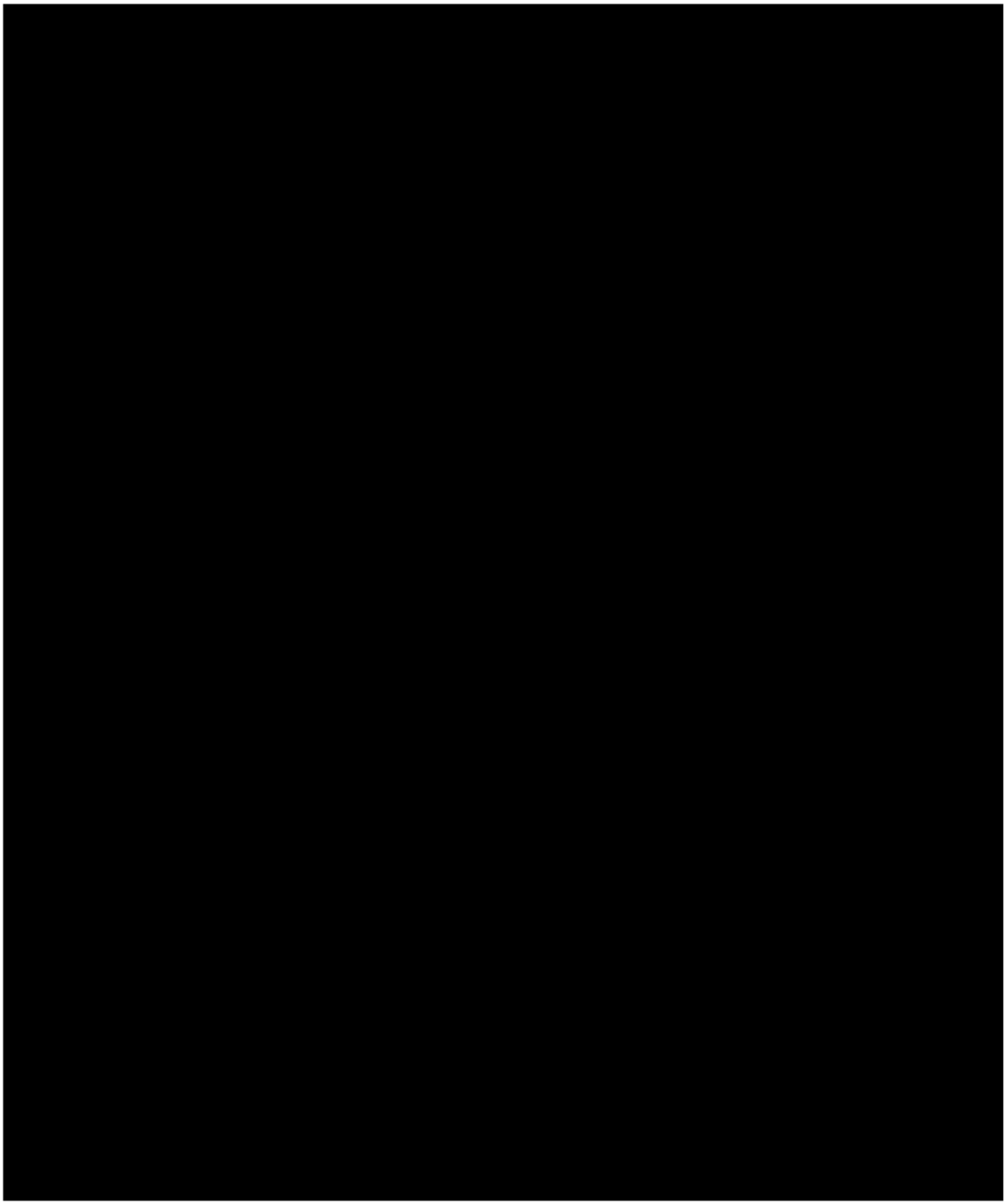
17.1 Appendix A: Methods of Clinical Evaluation

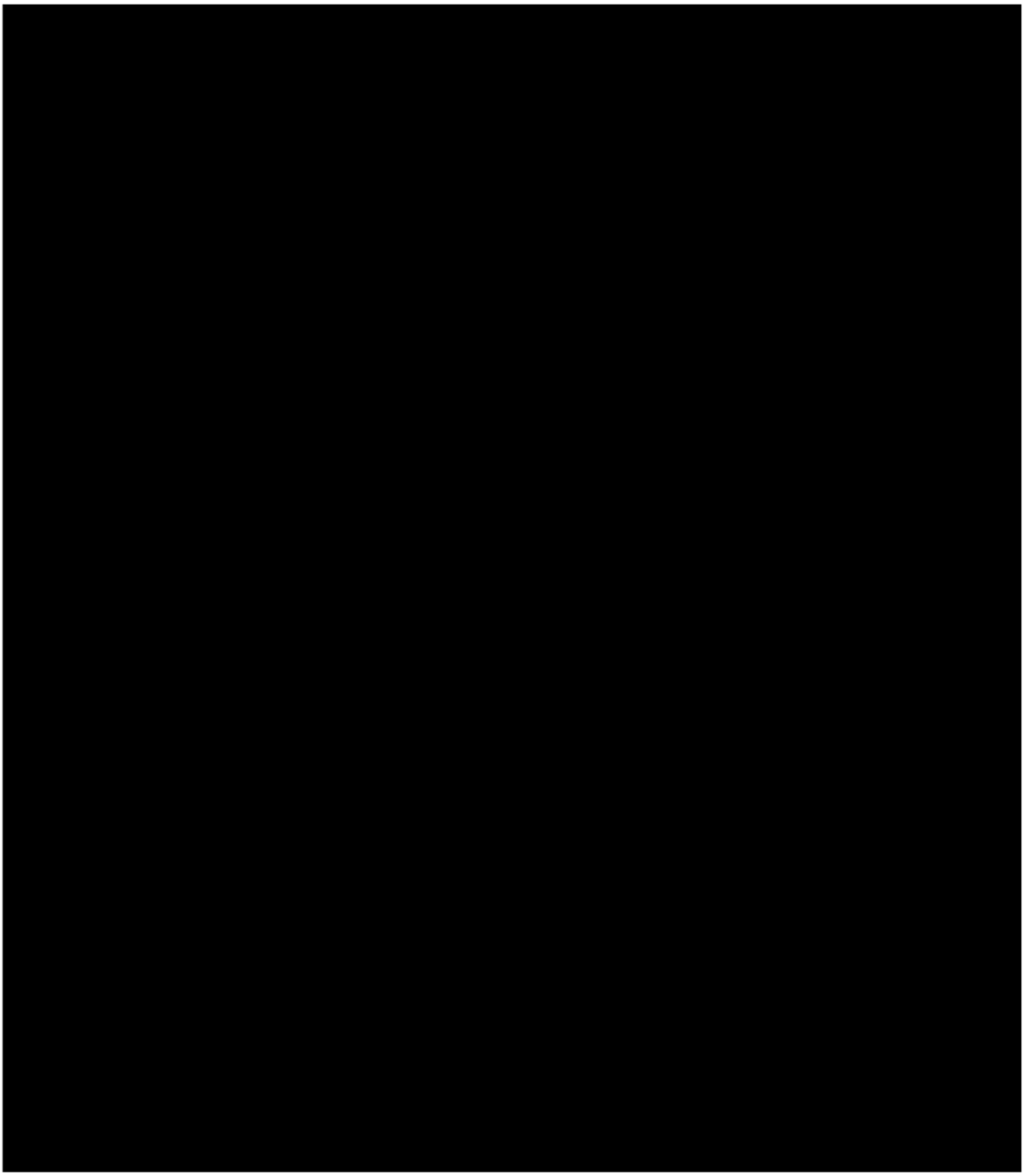


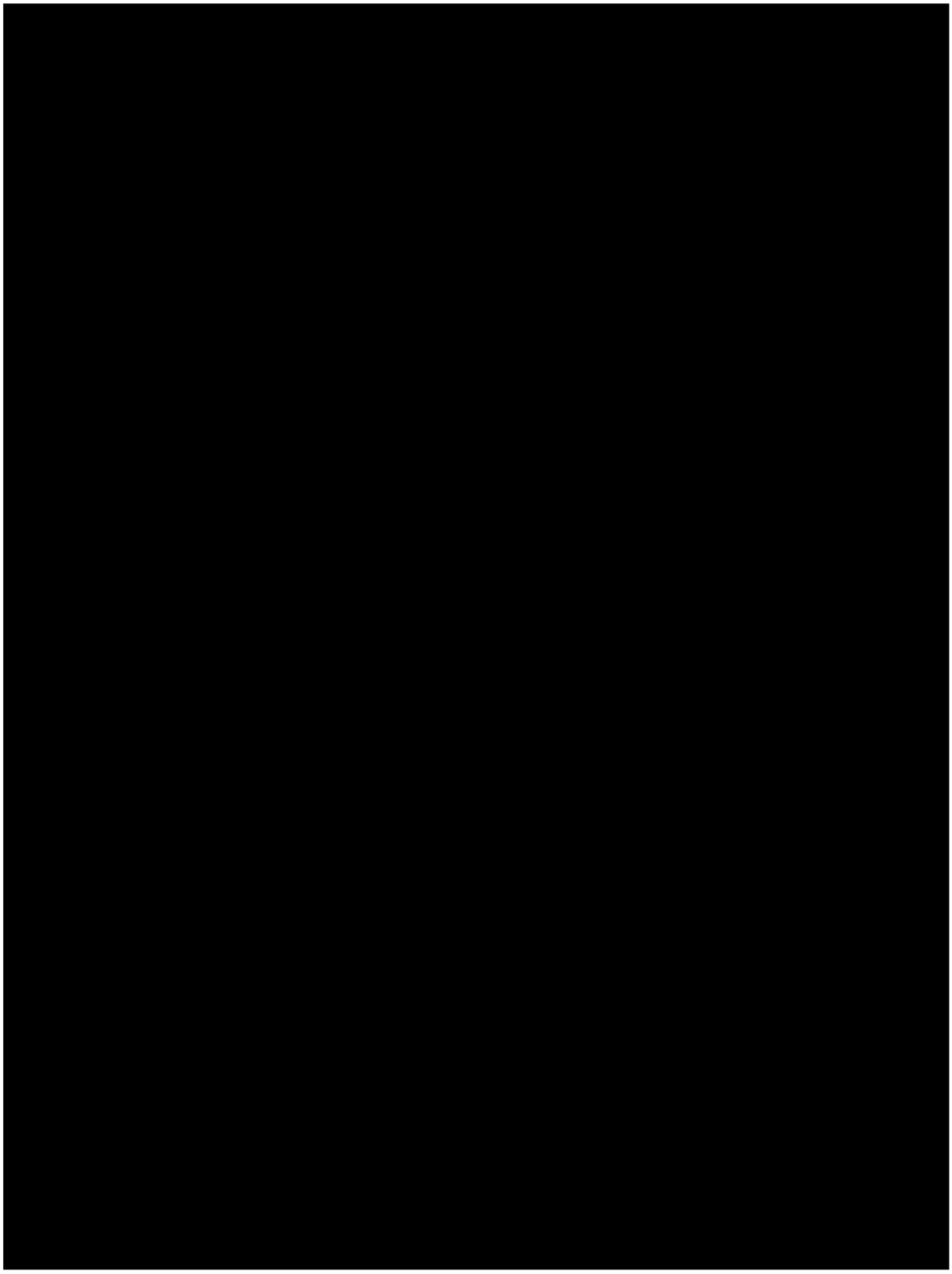


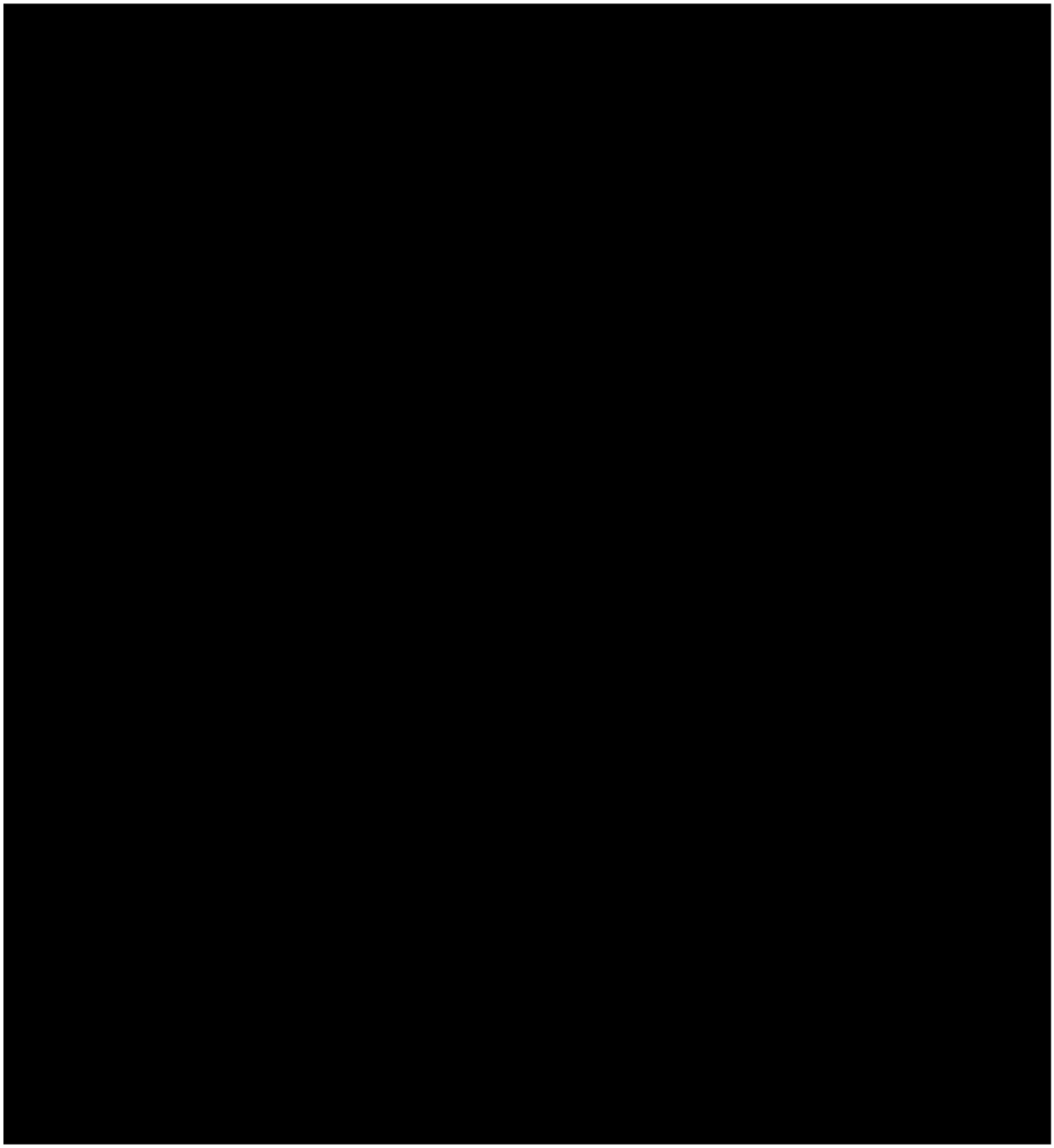


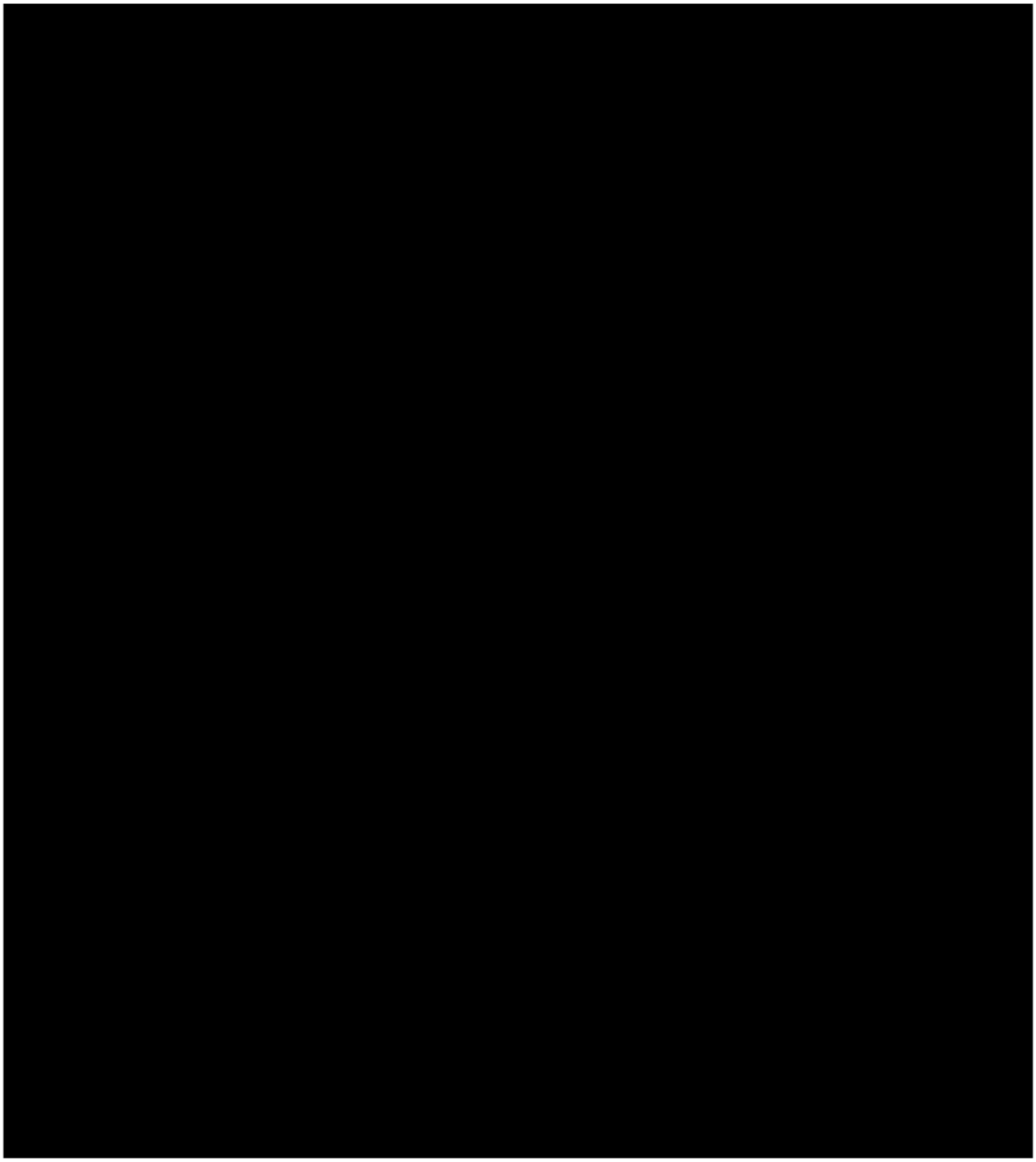


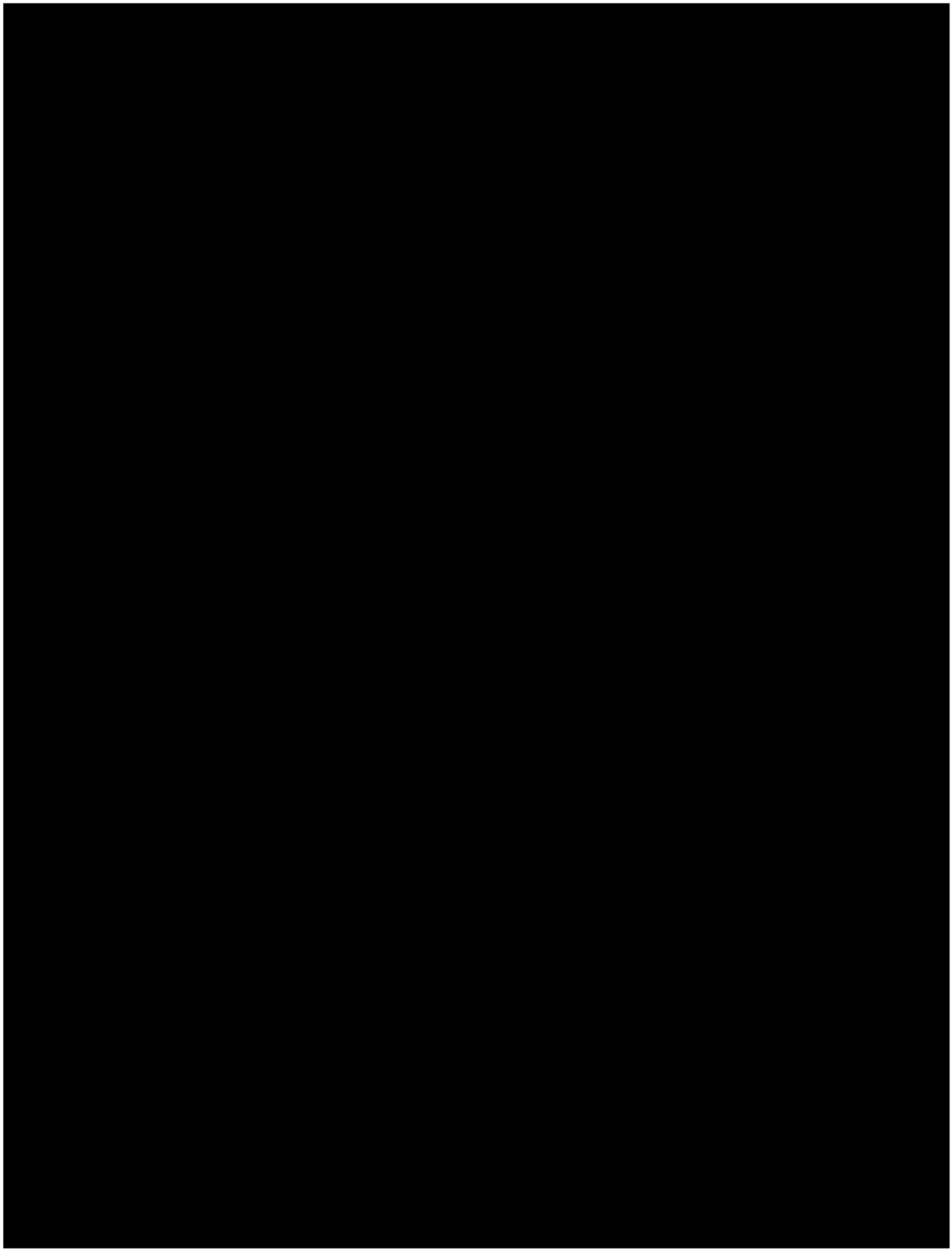


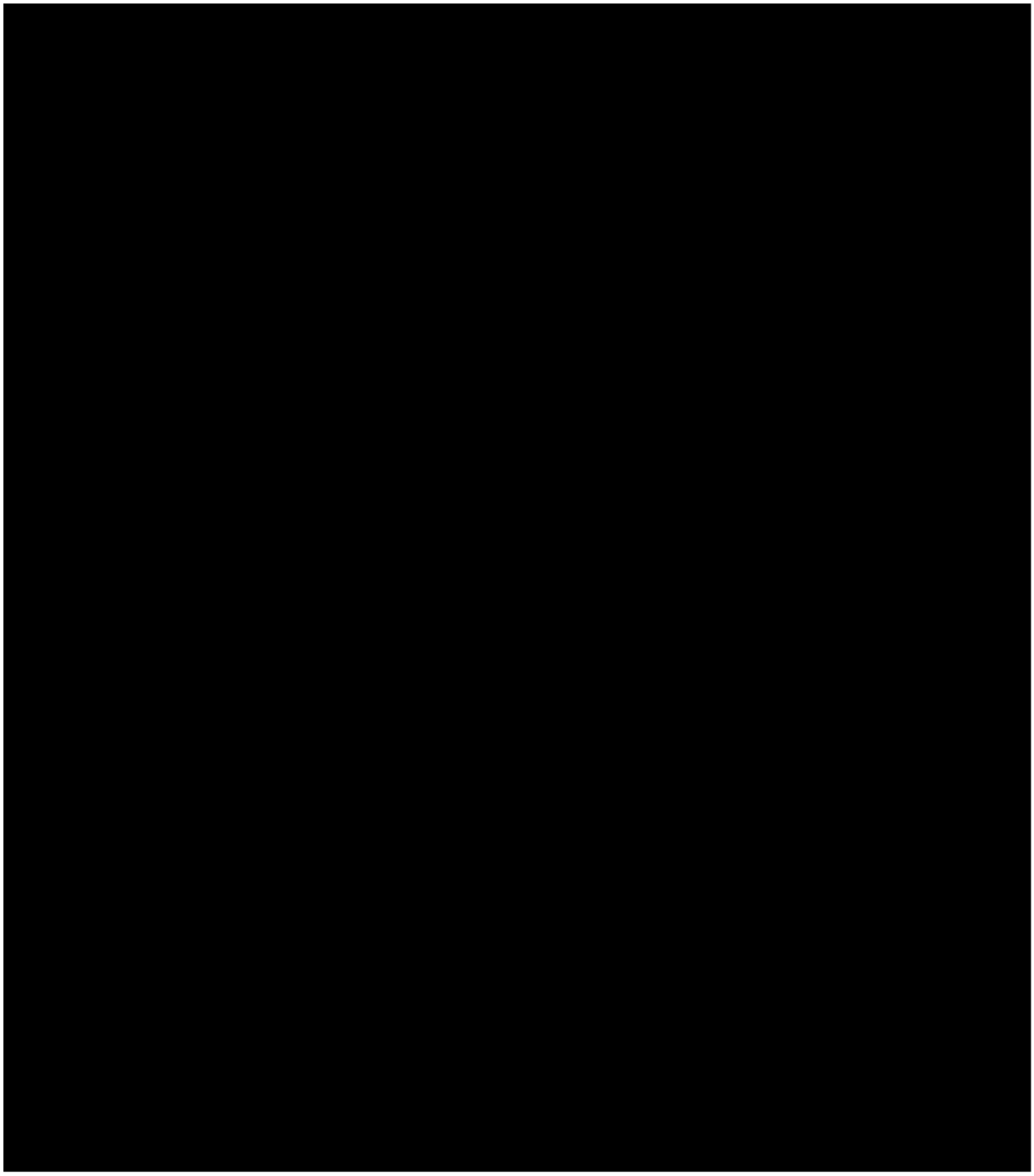


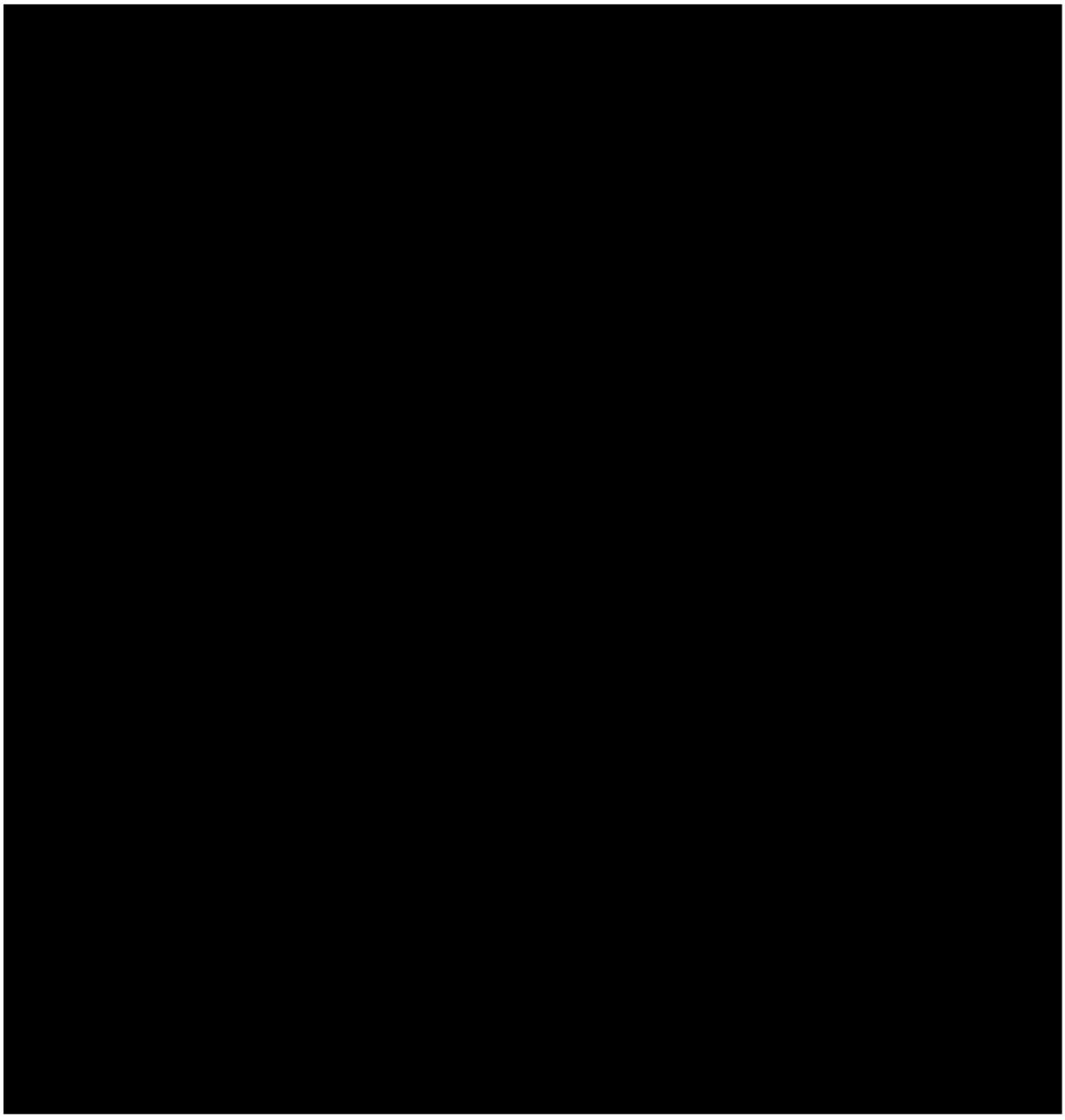


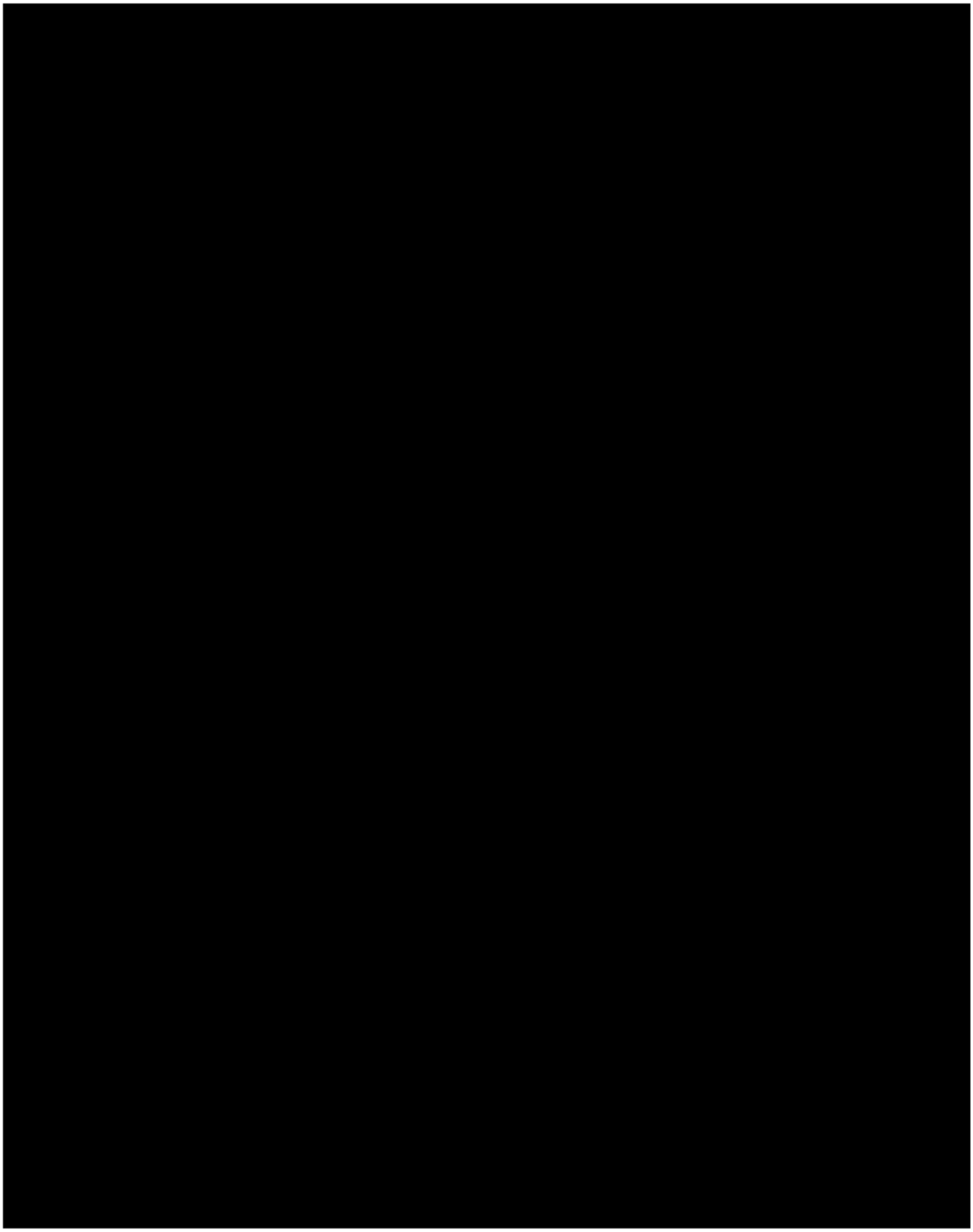












17.2 Appendix B: Subject Instructions

FOR SINGLE-USE DISPOSABLE WEAR

Caution: For clinical trial use only

INTRODUCTION

You will participate in this study designed to evaluate the product performance of Biotrue ONEday for Astigmatism Soft Contact Lenses (Test) when compared to the currently marketed Johnson & Johnson 1-Day Acuvue Moist for Astigmatism contact lens (Control). As a participant in this study, you will be randomly assigned to wear either the Test or Control lenses on a daily disposable basis. Study lenses will be dispensed at the Dispensing Visit. It is very important that you do not use any other contact lenses during the study.

You will wear the lenses on a daily disposable basis. You will replace the lenses daily, and any time you remove your lenses, or when removed from your eyes as indicated by your dispensing eye care professional. All lenses, used and unused, and blister foils must be returned to your eye care professional. It is essential to your safety that you read and understand the information and instructions in these Subject Instructions and have your eye care professional answer any questions, both before and after you receive contact lenses.

Do not discuss or describe your contact lenses with anyone except the person who gave you the study lenses at the Dispensing Visit. You should not show the study blister packs and foils to the Investigator or site staff unless instructed to do so.

Please keep all appointments and follow these instructions thoroughly. If you have any questions or problems, call your eye care professional at _____.

Note:

Please schedule your 1-Week Follow-up, 1-Month Follow-up, and 3-Month Follow-up Visits at the Dispensing Visit.

Visit	Day/Month/Year	Time
1 Week	/ /	_____
1 Month	/ /	_____
3 Month	/ /	_____

Note: Wear your study lenses to each of your Follow-up Visits.

For this study, you will be using the following products:

- Habitual eye drops (to be used if needed).
- Lens cases for storage of worn study lenses (up to 10 pairs of lenses per eye, stacked dry).

GENERAL INFORMATION

Do NOT use any products other than those listed above or dispensed to you by your eye care professional for use in this study.

If problems or symptoms should occur, immediately remove your lenses and follow the steps described in the sections of these instructions entitled ***Warnings*** and ***Adverse Effects***. Prompt attention to problems is essential and may require immediate professional care.

Remember, when wearing contact lenses your eyes should look and feel good and your vision should be clear.

Because they are worn directly on your eyes, contact lenses affect the way in which your eyes function. These effects tend to increase with the length of time the lenses remain on your eyes between removals. Although the great majority of people successfully wear contact lenses without problems, before you decide whether to continue wearing contact lenses for daily disposable wear, you should discuss with your eye care professional the effects of contact lenses on your eyes and the risks associated with wearing contact lenses. You also should read the sections of these instructions entitled "Warnings", "Adverse Reactions", "Precautions", and "Wearing Restrictions and Indications". Ask your eye care professional to explain anything that you do not understand, including any additional restrictions which may be given to you by your eye care professional. These contact lenses have been prescribed for single-use disposable wear, and should be replaced each time lenses are removed from your eyes.

You also need to remember that soft contact lenses, including those covered by these instructions, are made of a type of plastic that absorbs liquids, vapors and small particles, and for some people, may collect deposits from your natural eye fluids. Therefore, you should strictly follow these instructions and any other instructions given to you by your eye care professional. Any failure to follow these instructions and the wearing restrictions will increase the chances of contamination, damage to the lenses, or a buildup of deposits on the lenses, which can lead to serious, sight-threatening eye infections and injuries.

Adherence to your prescribed wearing schedule and regular check-up visits to your eye care professional are also necessary for the proper and safe use of contact lenses. Soft contact lenses generally are comfortable from the beginning. Therefore, be sure to follow the

wearing schedule prescribed for you, and do not over-wear your lenses simply because they remain comfortable and you are not experiencing a problem. Only your eye care professional, through a professional examination, can determine how your eyes are reacting to the contact lenses and whether there are any early signs of possible problems.

Finally, if problems or symptoms should occur, immediately remove your lenses and follow the steps described in the section of these instructions entitled "Warnings and Adverse Reactions." Prompt attention to problems is essential and may require immediately professional care.

Remember, when wearing soft contact lenses your eyes should look and feel good, and your vision should be clear.

1. WEARING RESTRICTIONS and INDICATIONS

The lenses have been prescribed for single-use disposal wear, and will be replaced after each removal.

- Keep a spare pair of lenses available in case you have to remove your lenses immediately upon the appearance of a problem or symptom.
- Avoid rubbing your eyes with the lenses in, which can irritate the eye or dislodge the lens.
- If you get something in your eye, remove the lens immediately. Do not replace with new lens until your eye feels normal.
- Tell your regular physician and every other doctor that you visit, that you wear contact lenses and the type of lenses that you wear. If you are admitted to a hospital, also tell your nurses that you wear contact lenses.
- Do not use any eye drops, ointments, or medicines in your eye unless they are specifically approved by your eye care professional or physician. Some drops, ointments, or medicines will cause injury to the eye if used by a contact lens wearer.
- Ask your eye care professional whether there are any other wearing restrictions that apply to you, write those restrictions in the spaces provided below and follow them carefully.

2. WARNINGS

You should be aware of and fully discuss with your eye care professional the following warnings pertaining to contact lens wear:

- Problems with contact lenses could result in serious injury to your eye. It is essential that you follow your eye care professional's direction and all labeling instructions for proper use of lenses. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Daily disposable lenses are not indicated for overnight wear, and you should not wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when daily disposable lenses are worn overnight.
- Strict compliance with your wearing restrictions, wearing schedule, and follow-up visit schedule should be followed.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should immediately remove lenses and promptly contact your eye care professional.
- Do not expose your contact lenses to water while wearing them.

3. PRECAUTIONS

You should be aware of and fully discuss with your eye care professional the following safety precautions:

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting your lenses.
- If the lens sticks (stops moving) on your eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on your eye for the continued health of your eye. If non-movement of the lens continues, you should immediately consult your eye care professional. Do not attempt to remove the lens, except on the instructions of your eye care professional.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in your eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.

- Be certain that the fingers or hands are free of foreign materials before touching your lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow these handling, insertion, removal and wearing instructions for the daily disposable contact lenses and those instructions prescribed by your eye care professional.
- Never wear lenses beyond the period recommended by your eye care professional.
- Always handle lenses gently and avoid dropping them.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Ask your eye care professional about wearing lenses during water activities and other sports. 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.
- Inform your doctor (health care professional) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with your fingernails.
- Always contact your eye care professional before using any medicine in your eyes.
- Before leaving your eye care professional's office be certain that you are able to remove your lenses promptly or have someone else available to remove them for you.
- Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, Follow-up Visits are necessary to assure the continuing health of your eyes. Your eye care professional should provide you with a recommended follow-up schedule.

4. ADVERSE REACTIONS (Problems And What To Do)

You should be aware 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 VA),
- Blurred vision, rainbows, or halos around objects,
- Sensitivity to light (photophobia),
- Dry eyes.

If you notice any of the above, you should:

- Immediately remove your lenses.
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back in your eye. You should remove the lens and insert a new lens on the eye. If the problem continues, you should immediately remove the lenses and consult your eye care professional.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You should keep the lens off your eye and seek immediately professional identification of the problem and prompt treatment to avoid serious eye damage.

5. PERSONAL CLEANLINESS and LENS HANDLING

Preparing the Lens for Wearing:

It is essential that you learn and use good hygienic methods in the care and handling of the lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

- Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.
- Develop the habit of always working with the same lens first to avoid mix-ups.
- Position the lens on your index finger and examine it to be sure that it is moist, clean, and free of any nicks or tears.
- Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly:
  - Less than usual comfort,
  - The lens may fold on the eye,
  - Excessive lens movement on blink,
  - Blurred vision.

If the lens folds and sticks together: Place the lens in the palm of your hand and wet thoroughly with rewetting solution. Then GENTLY rub the lens between your index finger and palm in a gentle back and forth motion. Replace the lens if it does not unfold.

If the lens flattens or drapes across your finger, the lens or your finger may be too wet. To correct this, dry your finger by transferring the lens several times from one index finger to the other, drying the opposite finger each time.

Placing the Lens on the Eye:

There are other methods of lens placement. If the following methods are difficult for you, your eye care professional will provide you with an alternate method.

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the Lens," next in these instructions).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
  - Cosmetics or oils on the lens (replace the lens),
  - The lens is on the wrong eye,
  - The lens is inside-out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye professional.

The One-Hand Placement Technique

Place the lens on your index finger. With your head up, looking straight ahead, pull down your lower eyelid with the middle finger of your placement hand. Look up steadily at a point above you. Then place the lens on the lower white part of your eye. Remove your index finger and slowly release the lower lid. Look down to position the lens properly. Close your eyes for a moment; the lens will center itself on your eye.

The Two-Hand Placement Technique

With the lens on your index finger, use the middle finger of the other hand to pull the upper lid against the brow. Use the middle finger of your placement hand to pull down the lower lid and then place the lens centrally on your eye. While holding this position, look downward to position the lens properly. Slowly release your eyelids.

If the lens feels uncomfortable, then look in the mirror and gently place a finger on the edge of the contact lens and slowly slide the lens away from your nose while looking in the opposite direction. Then by blinking, the lens will re-center itself. If the lens still feels uncomfortable, follow the steps described in the section of these instructions entitled "Adverse Reactions."

Centering the Lens:

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens, follow one of the procedures below.

Hold the upper and lower eyelids open with your fingers. Then while looking in a mirror, gently place a finger on the contact lens and gently slide the lens toward the center of the eye.

Or

Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, move your eye toward the lens to place it on the center of the eye.

Removing the Lens:

Always remove the same lens first.

1) Wash, rinse, and dry your hands thoroughly.

2) Always be sure that the lens is in the correct position on your eye before you try to remove it (a simple check of your vision, closing one eye at a time, will tell you if the lens is in the correct position). Look up and slowly pull down your lower eyelid with the middle finger of your removal hand and place your index finger on the lower edge of lens. Squeeze the lens

lightly between the thumb and the index finger and remove it. Avoid sticking the edges of the lens together.

3) Remove the other lens by following the same procedure.

Note: If this method of removing your lens is difficult for you, your eye care professional will provide you with an alternate method.

Care for a Sticking (Nonmoving) Lens:

It is important to the health of your eyes that your contact lenses move freely. If a lens sticks (stops moving), put a few drops of your habitual lubricating or rewetting solution into your eye. In this case, do not use plain water or anything other than the recommended solutions. Do not attempt to remove a lens that is sticking, which could damage your eye. If the lens does not begin to move when you blink after several applications of the solution or, contact your eye care professional immediately. Do not attempt to remove the lens except on the advice of your eye care professional.

6. 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 PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

17.3 Appendix C: Fitting Guide

Fit Guide for Biotrue ONEday for Astigmatism

PACKAGE INSERT / FITTING GUIDE

BAUSCH + LOMB

Bio true.

ONEday
(nesofilcon A)
Soft (Hydrophilic)
Contact Lenses

BAUSCH + LOMB

Bio true.

ONEday
for Presbyopia
(nesofilcon A)
Soft (Hydrophilic)
Contact Lenses

BAUSCH + LOMB

Bio true.

ONEday
for Astigmatism
(nesofilcon A)
Soft (Hydrophilic)
Contact Lenses

℞ ONLY

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

Name and Address of Manufacturer:
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, New York, USA 14609

Printed in the U.S.A. 8101903

SYMBOL REFERENCE GUIDE

For label and cartons:

②	Do Not Reuse
	Temperature Limitation
STERILE	Sterile Using Steam or Dry Heat
⚠	See Instruction Leaflet
CE 0050	Indicates the CE Conformity Marking and the Notified Body Number
EC REP	Authorized Representative in European Community
℞ ONLY	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Fee Paid for Waste Management
EXP	Use by Date (Expiration Date)
LOT	Batch Code
DIA $Ø_T$	Diameter
PWR (F'_V)	Diopter (Lens Power)
BC	Base Curve
ADD	Low or High Add Power
SPH	Sphere Power (Diopters)
AX	Cylinder Axis (Degrees)
CYL	Cylinder Power (Diopters)
YYYY-MM-DD	Effective Date

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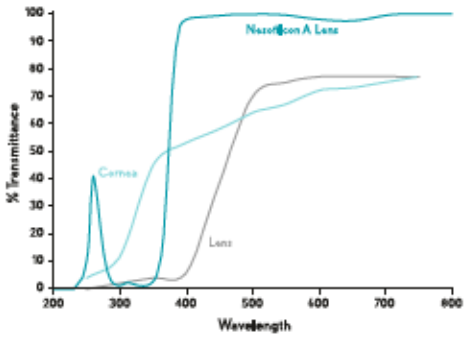

The typical transmittance profile of nesofilcon A lenses vs a Human Cornea and Human Lens:

Nesofilcon A Lens—Nominal Center Thickness 0.1 mm (-1.25D).

Cornea—Human Cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig. 2-21.

Lens—Human crystalline lens from a 25-year-old person as described in Waxler M., Hitchins V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, fig. 5.

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

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

Note
The effectiveness of wearing UV absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduce the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

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LENS PARAMETERS AVAILABLE

The Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens is a hemispherical shell of the following dimensions:

Diameter:	14.2mm 14.5mm (Astigmatism)
Center Thickness:	0.05mm to 0.75mm (varies with power)
Base Curve:	8.6mm 8.4mm (Astigmatism)
Powers (Spherical):	+6.00D to -6.00D in 0.25D steps -6.50D to -9.00D in 0.50D steps
Powers (Presbyopia):	+6.00D to -9.00D in 0.25D steps
Add Powers:	Low (+0.75D to +1.50D) and High (+1.75D to +2.50D)
Powers (Astigmatism):	+4.00D to -6.00D in 0.25D steps
Cylinder Powers:	-0.75D, -1.25D, -1.75D and -2.25D
Axis:	0° to 180°

Additional parameters may be introduced over time, check for product availability.

IMPORTANT

This package insert and fitting guide has been developed to provide practitioners with information covering characteristics of the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens and Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens and to illustrate fitting procedures. It is effective as of May 2016 (2016-05-01) 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 professional, but should be made available to patients upon request. The eye care professional 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 Biotrue® ONEday lens material, Hypergel™ (nesofilcon A), is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone and is 78% water by weight when immersed in a sterile saline solution. A benzotriazole UV-absorbing monomer is incorporated into the manufacturing process to block UV radiation. The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm. This lens is tinted blue with Reactive Blue Dye 246.

The physical / optical properties of the lens are:

Specific Gravity:	1.039
Refractive Index:	1.374
Light Transmittance:	C.I.E. Y value - approximately 99%
Water Content:	78%
Oxygen Permeability (Dk):	42 x 10^{-9} [$cm^2 O_2$(STP)] x cm] / (sec x cm^2 x mmHg) @ 35° C (Polarographic Method)

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

HOW THE LENS WORKS (ACTIONS)

In its hydrated state, the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens and Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm.

INDICATIONS

SVS

The Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

Presbyopia

The Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in powers ranging from +20.00D to -20.00D with add power ranging from +0.75D to +5.00D.

Astigmatism

The Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters, that does not interfere with visual acuity. The lens may be prescribed in powers ranging from +20.00D to -20.00D for daily wear.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) 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
- 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 professional'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 serious adverse reactions is increased when daily wear lenses are worn overnight.
- 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 lenses** and promptly contact his or her eye care professional.
- Patients should be instructed not to expose their contact lenses to water while wearing them.

  Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If their contact lenses have been submersed in water when swimming in pools, lakes or oceans, the contact lenses should be discarded and replaced with a new pair. Recommendations for wearing lenses during any water activity should be discussed with the patient.

PRECAUTIONS

Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on eye should be carefully monitored by the prescribing eye care professional.
- Patients who wear contact lenses 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 professionals 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 professional.
- 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 Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lenses until the determination is made that the eye has healed completely.
- The lenses are prescribed for disposable wear, and are to be disposed of once they are removed from the patient's eye. It is important that patients be instructed to always have available a pair of replacement lenses. In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.
- Eyecare professional should carefully instruct patients about the following safety precautions. It is strongly recommended that patients be provided with a copy of the Patient Information Booklet for Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens/ Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens / Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens, 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-base cosmetics are less likely to damage lenses than oil-base products.
- Be sure that before leaving the eye care professional'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 Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses / Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses / Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lenses and those prescribed by the eye care professional.

- 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.

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.
- Always contact the eye care professional before using any medicine in the eyes.

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, then 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 professional. 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 professional**.
- 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 professional** 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 combinations 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 professional 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. 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 Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care professional 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 professional.

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. Initial Lens Power Selection

a. Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.

b. Select the appropriate lens and place on the eye. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics.

c. Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. Initial 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.

4. Criteria of a Well-Fitted Lens

If the initial lens selection 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.

5. 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.

6. Characteristics of a Loose (Flat) Lens

If the lens is too flat, it 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.
- Have a tendency to be uncomfortable and irritating with fluctuating vision.
- Have a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

7. 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.

- 3-4 days post-dispensing
- 10 days
- 1 month
- 3 months
- Every six months thereafter

At the initial follow-up evaluations the eye care professional should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief.

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.

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.

PRACTITIONER FITTING SETS

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

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care professional. Regular checkups, as determined by the eye care professional, are 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 professional. The wearing schedule chosen by the eye care professional should be provided to the patient. The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

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 Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) 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 drivers 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 are 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 other 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 professional in conjunction with the patient after carefully considering the patient's needs.**
- **All patients should be supplied with a copy of the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens / Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens / Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens Patient Information Booklet.**

MULTI-FOCAL FITTING GUIDELINES

1. Patient Selection

a. Good motivation

b. Realistic expectations

2. Lens Selection

a. Update spectacle refraction and Add power.

b. Determine ocular dominance for distance vision.

c. Select lens distance prescription based upon spherical equivalent from spectacle prescription, adjusted for vertex distance if necessary.

d. Choose trial lenses based upon the above calculation and select Add power.
   - Low Add: +0.75D to +1.50D
   - High Add: +1.75D to +2.50D

3. Lens Fitting

a. Equilibrate for 10 minutes.

b. Evaluate distance and near vision binocularly in normal room illumination.

c. 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 High Add lens in non-dominant eye while keeping Low Add lens 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 in 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:
  Place SVS lens in dominant eye while keeping Low Add lens in non-dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, add -0.25D at a time to dominant eye using hand held lenses. Adjust contact lens power when vision in satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1:
  Place Low Add lens in dominant eye while keeping High Add lens in non-dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, add -0.25D at a time to dominant eye using hand held lenses. Adjust contact lens power when vision in 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.

HANDLING OF LENSES

Patient Lens Care Direction

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care professional should recommend appropriate and adequate procedures for each individual patient in accordance with the particular lens wearing schedule.

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 professional 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 professional.

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 REMOVED LENSES. PROMPTLY CONTACT YOUR EYE CARE PROFESSIONAL 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 Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens, or experienced with the lenses, should be reported to:

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, New York 14609
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 package containing borate buffered saline solution with poloxamine. Each container is marked with the manufacturing lot number of the lens, diopter power, and expiration date.

Fit Guide for 1-Day Acuvue Moist for Astigmatism

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

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

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

1-DAY ACUVUE® MOIST BRAND CONTACT LENSES

1-DAY ACUVUE® MOIST Brand Contact Lenses

1-DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM

1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses

etafilcon A Soft (hydrophilic) Contact Lenses
Visibility Tinted with UV Blocker
for Daily Disposable Wear

℞ Only

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

SYMBOLS KEY

The following symbols may appear on the label or packaging:

SYMBOL	DEFINITION
	Consult Instructions for Use
	Manufacturer
	Date of Manufacture
	Use By Date (expiration date)
	Batch Code
	Sterilized Using Steam Heat
	Do Not Re-Use (Single Use)
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)
	Quality System Certification Symbol
	Fee Paid for Waste Management
	Authorized Representative in the European Community

Visit www.acuvue.com/guides for additional information about symbols.

DESCRIPTION

1-DAY ACUVUE® MOIST Brand Contact Lenses, 1-DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM, and 1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses are soft (hydrophilic) contact lenses available as spherical, toric, or multifocal lenses, and include LACREON® Technology.

The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1, 1, 1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate.

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

Lens Properties:

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.40
- Light Transmittance: 95% minimum
- Surface Character: Hydrophilic
- Water Content: 58%
- Oxygen Permeability (D/k):

VALUE	METHOD
21.4 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) @ 35°C	Fatt (boundary corrected, edge corrected)
26.0 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) @ 35°C	Fatt (boundary corrected, non-edge corrected)

Lens Parameters Ranges:

- Diameter (DIA): 12.0 mm to 15.0 mm
- Center Thickness: Varies with power
- Base Curve (BC): 7.85 mm to 10.00 mm
- Spherical Power (D): -20.00D to +20.00D
- Cylinder Power (CYL): -0.25D to -10.00D
- Axis (AXIS): 2.5° to 180°
- ADD Powers: +0.25D to +4.00D

AVAILABLE LENS PARAMETERS

1-DAY ACUVUE® MOIST Brand Contact Lenses are hemispherical shells of the following dimensions:

Diameter (DIA): 14.2 mm

Center Thickness: 0.084 mm to 0.230 mm (varies with power)

Base Curve (BC):	8.5 mm, 9.0 mm
Powers (D):	-0.50D to -6.00D (in 0.25D increments) -6.50D to -12.00D (in 0.50D increments) +0.50D to +6.00D (in 0.25D increments)

1-DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM are hemitoric shells of the following dimensions:

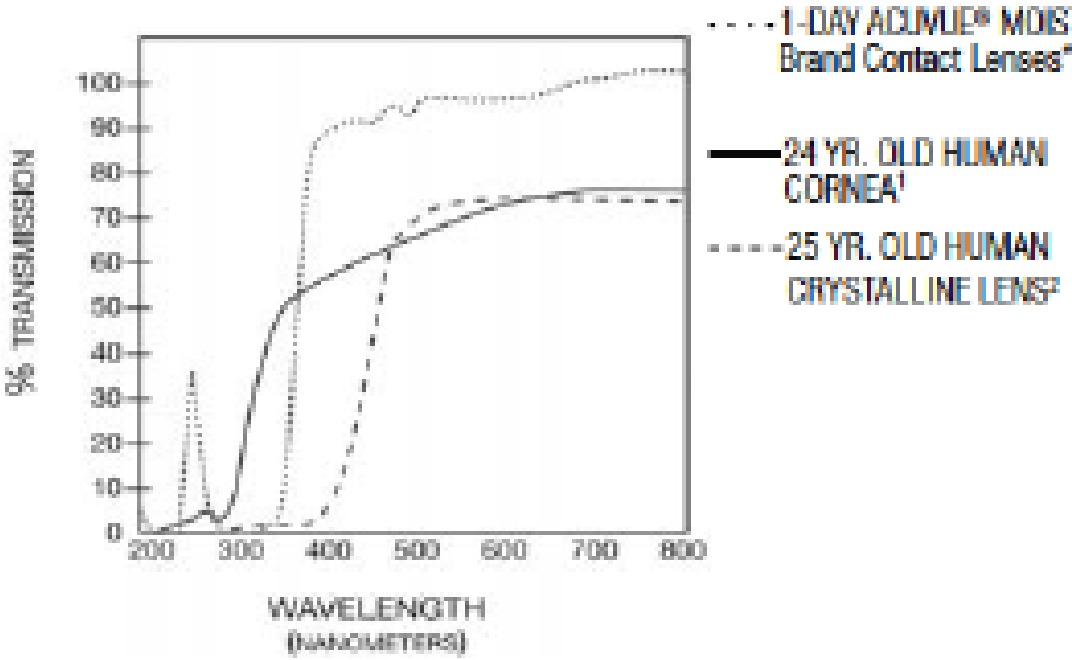
Diameter (DIA):	14.5 mm
Center Thickness:	0.090 mm to 0.189 mm (varies with power)
Base Curve (BC):	8.5 mm
Powers (D):	+0.00 to -6.00D (in 0.25D increments) Cylinders (CYL): -0.75D, -1.25D, -1.75D, -2.25D* Axis (AXIS): 10° to 180° in 10° increments *-2.25D cylinder is available in 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180° axes only -6.50D to -9.00D (in 0.50D increments) Cylinders (CYL): -0.75D, -1.25D, -1.75D, -2.25D* Axis (AXIS): 10°, 20°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 160°, 170°, 180° *-2.25D cylinder is available in 20°, 90°, 160°, 180° axes only +0.25D to +4.00D (in 0.25D increments) Cylinders (CYL): -0.75D, -1.25D, -1.75D Axis (AXIS): 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°

1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses are hemispherical shells of the following dimensions:

Diameter (DIA):	14.3 mm
Center Thickness:	0.084 mm to 0.207 mm (varies with power)
Base Curve (BC):	8.4 mm
Powers (D):	+6.00D to -9.00D (in 0.25D increments)
Near ADD Powers (MAX ADD):	Low Near ADD (LOW): +1.25D Medium Near ADD (MID): +1.75D High Near ADD (HIGH): +2.50D

TRANSMITTANCE CURVES

1-DAY ACUVUE® MOIST Brand Contact Lenses (etafilcon A) Visibility Tinted with UV Blocker vs. 24 yr. old human cornea and 25 yr. old human crystalline lens.



*The data are representative measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-3.000 lens, 0.084 mm center thickness).

[1] Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21

[2] Wacker, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5

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

ACTIONS

In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The UV Blocking for these lenses averages 97% in the UVB range of 280 nm to 315 nm and 82% in the UVA range of 316 nm to 380 nm for the entire power range.

NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-Blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-Blocking contact lenses reduces the risk of developing cataracts or other eye disorders. The Eye Care Professional should be consulted for more information.

INDICATIONS (USES)

1-DAY ACUVUE® MOIST Brand Contact Lenses are indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

1-DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM are indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 0.50D to 3.00D of astigmatism.

1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses are indicated for daily disposable wear for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 0.75D or less of astigmatism.

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

When prescribed for daily disposable use, no cleaning or disinfection is required. Lenses should be discarded upon removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE these lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eye).
- Corneal hypoesthesia (reduced corneal sensitivity).

- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e., rewetting drops) that contain chemicals or preservatives (such as mercury, Thimerosal, etc.) to which some people may develop an allergic response.
- Any active corneal infection (bacterial, fungal, protozoal, or viral).
- If eyes become red or irritated.

WARNINGS

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

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

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

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

- When prescribed for daily wear, patients should be instructed not to wear their lenses while sleeping. Clinical studies have shown that when lenses are worn overnight, the risk of ulcerative keratitis is greater than among those who do not wear them overnight.[3]
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products are essential for the safe use of these products.

- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care.

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

Specific Instructions for Use and Warnings:

- **Water Activity**
  Instruction for Use
  Do not expose contact lenses to water while wearing them.

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

PRECAUTIONS

Special Precautions for Eye Care Professionals:

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

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

- Patients who wear these lenses to correct presbyopia using monovision (or modified monovision using 1-DAY ACUVUE® MOIST Brand MULTIFOCAL) may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.

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

Handling Precautions:

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her.
- DO NOT use if the sterile blister package is opened or damaged.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup.
- DO NOT touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Instruction Guide for these lenses and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container. Slide the lens up the side of the bowl until it is free of the container.
- Do not touch the lens with fingernails.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for Sticking (Non-Moving) Lenses." The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.

- The patient should be advised to never allow anyone else to wear their lenses. They have been prescribed to fit their eyes and to correct their vision to the degree necessary. Sharing lenses greatly increases the chance of eye infections.
- If aerosol products, such as hairspray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.

Lens Care Precautions:

- The patient should be informed that no cleaning or disinfection is needed when lenses are worn for daily disposable wear. Patients should always dispose of lenses when removed and have spare lenses or spectacles available.

Other Topics to Discuss with Patients:

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

Who Should Know That the Patient is Wearing Contact Lenses?

- Patients should inform all doctors (Health Care Professionals) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

ADVERSE REACTIONS

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

- The eye may burn, sting, and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, or corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis, and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Have I noticed a change in my vision?

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

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

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

GENERAL FITTING GUIDELINES

A. Patient Selection

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

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

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

B. Pre-fitting Examination

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

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

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

C. Initial Power Determination

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

D. Base Curve Selection (Trial Lens Fitting)

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

- 1-DAY ACUVUE® MOIST: 8.5 mm/14.2 mm
- 1-DAY ACUVUE® MOIST for ASTIGMATISM: 8.5 mm/14.5 mm
- 1-DAY ACUVUE® MOIST MULTIFOCAL: 8.4 mm/14.3 mm

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

1. Criteria of a Properly Fit Lens

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

2. Criteria of a Flat Fitting Lens

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

3. Criteria of a Steep Fitting Lens

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

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

E. Final Lens Power (Spherical)

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

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

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

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

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

TORIC FITTING GUIDELINES

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

The only new steps you must follow in prescribing 1-DAY ACUVUE® MOIST for ASTIGMATISM are that you must determine the stability, repeatability, and drift angle of the lens axis so that you can prescribe the correct lens axis for the patient.

A. How to Determine Lens Cylinder and Axis Orientation

1. **Locate the Orientation Marks**

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

Figure 1

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

2. Observe Lens Rotation and Stability

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

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

3. Assessing Rotation

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

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

B. Final Lens Power

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the spectacle cylinder axis, it is not advisable to perform a full spherocylindrical over-refraction because of the difficulty in computing the resultant power. A spherical over-refraction without cylinder refraction may be performed.

If the required cylinder correction falls between two available cylinder powers, it is recommended to prescribe the lower cylinder power lens. See below for instructions on how to determine the final lens power.

1. For the Sphere

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

2. For the Cylinder

Adjust the axis by the drift angle using the LARS method. Choose a cylinder that is ≤ 0.50D from the refractive cylinder.

3. Case Examples

Example 1

Manifest (spectacle) refraction:

O.D. -2.50D / -1.25D x 180° 20/20

O.S. -2.00D / -1.00D x 180° 20/20

Choose a diagnostic lens for each eye with axis 180°. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens. If the lens has not yet stabilized, recheck until stable.

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

Here is the Rx prescribed:

O.D. -2.50D / -1.25D x 180°

O.S. -2.00D / -0.75D x 180°

Example 2

Manifest (spectacle) refraction:

O.D. -3.00D / -1.00D x 90° 20/20
O.S. -4.75D / -2.00D x 90° 20/20

Choose diagnostic lenses of -3.00D / -0.75D x 90° for the right eye and -4.50D / -1.75D x 90° for the left eye, the nearest lenses available to the spherical power and axis needed. For the left eye, since the manifest refraction called for -4.75D, compensating for vertex distance the sphere is reduced by 0.25D to -4.50D. The cylinder power will be -1.75D. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens. If the lens has not yet stabilized, recheck until stable.

Right Eye

The orientation mark on the right lens rotates left from the 6 o'clock position by 10° and remains stable in this position. Compensation for this rotation should be done as follows:

Compensate the 10° axis drift by adding it to the manifest refraction axis.

Here is the Rx prescribed:
O.D. -3.00D / -0.75D x 100°

Left Eye

The orientation mark on the left lens rotates right from the 6 o'clock position by 10° and remains stable in this position. Compensation for this rotation should be done as follows:

Compensate for the 10° axis drift by subtracting it from the manifest refraction axis.

Here is the Rx prescribed:
O.S. -4.50D / -1.75D x 80°

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

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

MULTIFOCAL FITTING GUIDELINES

A. Presbyopic Needs Assessment & Patient Education

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with 1-DAY ACUVUE® MOIST MULTIFOCAL. Wearing these lenses may not be optimal for activities such as:

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

1-DAY ACUVUE® MOIST MULTIFOCAL is not recommended for patients who have -1.00D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise. These lenses are available in the following ADD powers:

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

B. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00D. Determine the spherical equivalent distance prescription for a multifocal patient. Determine the eye dominance using one of the methods below:

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

Method 2 Determine which eye does not accept added plus power. Place a +1.00D hand-held trial lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes while the patient is viewing the distance visual acuity chart. The eye with the plus over it that the patient notices the greatest reduction in vision is determined to be the dominant eye.

C. Select the Initial Trial Lens

1. For each eye, select the trial lens distance power that is closest to the patient's distance spherical equivalent. Remember to compensate for vertex distance if the refraction is greater than ±4.00D.
2. Select the near power of the lens based on the patients ADD range as follows:
   - ADD: +0.75D to +1.25D use a low near ADD (LOW) lens on each eye
   - ADD: +1.50D to +1.75D use a medium near ADD (MID) lens on each eye
   - ADD: +2.00D to +2.50D use a medium near ADD (MID) on the dominant eye and a high near ADD (HIGH) lens on the non-dominant eye
3. Allow the lenses to settle for a minimum of 10 minutes.
4. Assess distance and near vision binocularly and monocularly.
5. Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate, and near.
6. Make adjustments in power as necessary based on the distance over-refraction. The use of hand-held trial lenses is recommended. Check the impact on distance and near vision.
7. If vision is still unacceptable, make adjustments in power as necessary (see "Multifocal Troubleshooting" below). If distance and near vision are acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see **PATIENT MANAGEMENT** section).

D. Multifocal Troubleshooting

Unacceptable Near Vision

If it has been determined that no change is required based on the over-refraction, then add +0.25D to the spherical power of the non-dominant eye.

Unacceptable Distance Vision

If it has been determined that no change is required based on the over-refraction, then make the changes as listed below:

- If the patient is wearing two "LOW" ADD lenses, change the dominant eye to a 1-DAY ACUVUE® MOIST sphere lens with a power equal to the spherical equivalent distance prescription.
- If the patient is wearing two "MID" ADD lenses, change the ADD power in the dominant eye to the "LOW" ADD power.
- If the patient is wearing a "MID" ADD lens in the dominant eye and a "HGH" ADD lens in the non-dominant eye, change the non-dominant eye to a "MID" ADD lens and add +0.25D to the distance power.

E. Adaptation

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

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

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

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

MONOVISION FITTING GUIDELINES

A. Patient Selection

1. Monovision Needs Assessment

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

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

- Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- Driving automobiles (e.g., driving at night). Patients who cannot meet 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.

2. Patient Education

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

B. Eye Selection

1. Ocular Preference Determination Methods

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

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

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

2. Other Eye Selection Methods

Other methods include the "Refractive Error Method" and the "Visual Demands Method."

Refractive Error Method

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

Visual Demands Method

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

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

C. Special Fitting Characteristics

1. Unilateral Vision Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens, whereas a bilateral myope would require corrective lenses on both eyes.

Examples:

A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without correction.

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

2. **Near ADD Determination**

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

3. **Trial Lens Fitting**

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

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

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

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

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

4. **Adaptation**

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

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

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

D. Other Suggestions

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

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.
- Have 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 driver's licensing requirements with monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Monovision fitting success can be improved by the following suggestions:

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

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

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

PATIENT MANAGEMENT

- Follow the accepted standard of care in fitting and following up with your patient, e.g., American Optometric Association standard of care.
- Schedule the appropriate follow-up examination.
- Preferably, at the follow-up visits, lenses should have been worn for at least six hours.
- Provide the patient with a copy of the PATIENT INSTRUCTION GUIDE for these lenses, which can be found at www.acuvue.com. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULES.

WEARING SCHEDULE

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

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

The maximum suggested wearing time for these lenses is:

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

REPLACEMENT SCHEDULE

These lenses are indicated for daily disposable wear and should be discarded upon removal.

When disposed of after a single daily use, these lenses may reduce the risk of developing giant papillary conjunctivitis.[4]

When worn as a daily disposable lens, these lenses may provide improved comfort for many patients who experience mild discomfort and itching associated with allergies during contact lens wear, compared to lenses replaced at intervals of greater than 2 weeks.

Clinical research has shown that when worn on a daily disposable basis, these lenses may provide improved comfort for 2 out of 3 patients who reported suffering from discomfort associated with allergies during contact lens wear.

[4] The CLAO Journal, July 1999, Volume 25, Number 3

LENS CARE DIRECTIONS

The Eye Care Professional should review with patients that no cleaning or disinfection is needed with daily disposable lenses. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

For complete information concerning contact lens handling and care, refer to the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.

Care for Sticking (Non-Moving) Lenses

During removal, if the lens sticks to the eye, the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution

directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should **immediately** consult the Eye Care Professional.

EMERGENCIES

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

HOW SUPPLIED

Each UV-absorbing sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with povidone. The plastic package is marked with the following:

- **1-DAY ACUVUE® MOIST**: base curve, power, diameter, lot number, and expiration date
- **1-DAY ACUVUE® MOIST for ASTIGMATISM:** base curve, power, diameter, cylinder, axis, lot number, and expiration date
- **1-DAY ACUVUE® MOIST MULTIFOCAL:** base curve, power, diameter, ADD power, lot number, and expiration date

REPORTING OF ADVERSE REACTIONS

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

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

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
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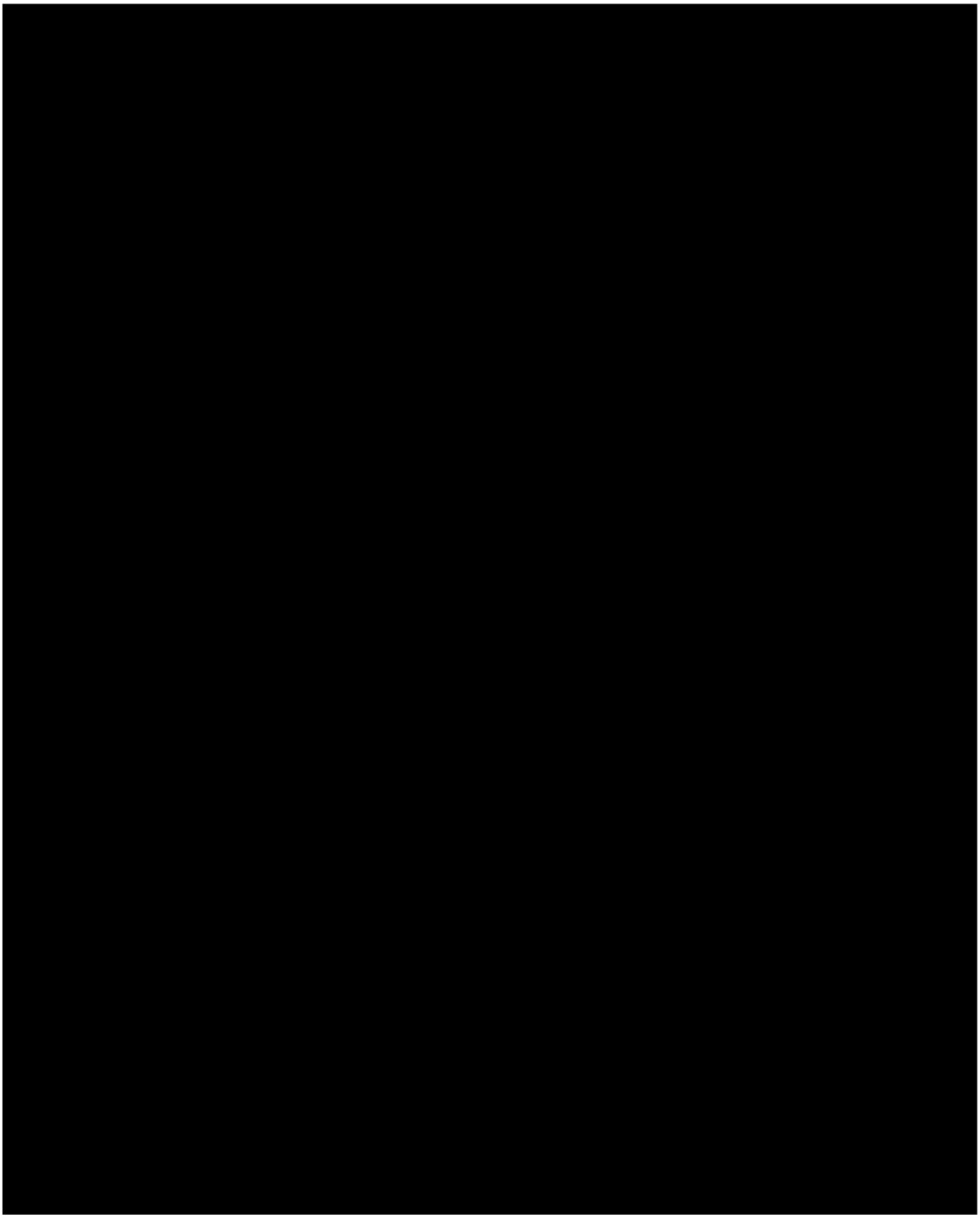
www.acuvue.com

In Canada: Johnson & Johnson Vision Care division of Johnson & Johnson Inc.
In USA: Johnson & Johnson Vision Care, Inc.
Printed in USA
Revision date: 07/17
Revision number: M-07-17-02



17.5 Appendix E: Corneal Infiltrates Evaluation Form