BAUSCH + LOMB

1 -Week Dispensing Evaluation of kalifilcon A Toric Daily Disposable Contact Lenses Compared to Ultra for Astigmatism Contact Lenses

CLINICAL INVESTIGATIONAL PLAN
STUDY: ROC2-21-013
[redacted]

PROJECT NAME: [redacted]

Sponsor: Bausch + Lomb Incorporated

This study is being conducted in accordance with 21CFR Parts 11, 50, 54, 56 and 812; 42 CFR Part 11 – Clinical Trials Registration and Results Information Submission; ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good Clinical Practice; International Council for Harmonization (ICH) Good Clinical Practice (GCP) - Declaration of Helsinki and applicable local regulations.

Revision Chronology:

Version 1.0 **January 28, 2022**

The information in the following document is confidential. The information contained herein will not be disclosed to others without written authorization from Bausch + Lomb Incorporated.

[redacted]

TABLE OF CONTENTS

LIST OF ABBREVIATIONS 5
INVESTIGATIONAL SITE AND STUDY PERSONNEL 6
SYNOPSIS 7
1.0 INTRODUCTION 11
2.0 OBJECTIVE 11
3.0 STUDY DESIGN 11
3.1 Description of Study Design 11
3.2 Selection of Study Population 12
3.2.1 Eligibility 12
3.2.1.1 Inclusion Criteria 12
3.2.1.2 Exclusion Criteria 13
3.2.2 Point of Enrollment and Randomization 13
3.2.3 Subject Completion 13
3.2.4 Lost to Follow-up 14
3.3 Investigators 14
3.4 Study Duration 14
3.5 Protocol Changes and Amendments 14
4.0 STUDY MATERIALS 14
4.1 Description of the Test Article(s) 14
4.2 Description of Comparator Product(s) 15
4.3 Instructions for Use and Administration 15
4.3.1 Storage Requirements 15
4.3.2 Subject Instructions 15
4.4 Other Study Materials 16
4.5 Packaging and Labeling 16
4.6 Accountability 16
4.7 Masking 16
4.8 Product Replacement 17
4.9 Risk Assessment 17
4.9.1 Risk Related to Subject 17
4.9.2 Risk Related to Data Management 17
4.10 Relevance of Clinical Investigation 18
5.0 STUDY METHODS 18

5.1 Study Visits 18
5.1.1 Methodology: 18
5.1.2 Unscheduled Visits 21
5.1.3 Missed Visits 21
5.1.4 Post-Study Follow-up Visit 21
5.2 Study Completion 21
5.2.1 Study Termination/Suspension 21
5.2.2 Study Termination Procedure 22
5.3 Concomitant Medications/Therapy 22
5.4 Protocol Deviations 22
6.0 ADVERSE EVENTS 22
6.1 Adverse Event Definitions 23
6.1.1 Adverse Event (AE) 23
6.1.2 Serious Adverse Event (SAE) 23
6.1.3 Serious Adverse Ocular Event 23
6.1.4 Significant, Non-Serious Adverse Event 24
6.1.5 Non-significant, Non-serious Adverse Event 24
6.1.6 Adverse Device Effect (ADE) 24
6.1.6.1 Anticipated Serious Adverse Device Effect (ASADE) 25
6.1.6.2 Unanticipated Serious Adverse Device Effect (USADE) 25
6.1.7 Device Deficiency 25
6.2 Adverse Event Treatment and Culturing 25
6.3 Adverse Event Identification and Evaluation 26
6.4 Adverse Event Collection and Reporting 27
6.5 Reporting Device Deficiencies 28
6.6 Emergency Contact Details for Reporting Serious Adverse Events and Adverse Device Effects: 28
7.0 STATISTICAL METHODS 29
7.1 Study Endpoints 29
7.2 Hypothesis 29
7.3 Sample Size 29
7.4 Randomization 29
7.5 Study Populations 30
7.6 Statistical Analysis 30

7.6.1 Pass/Fail Criteria 30
7.6.2 Interim Analyses 30
7.6.3 Exploratory/Sensitivity Analysis 30
7.6.4 Deviations 30
8.0 DATA QUALITY ASSURANCE 30
8.1 Study Monitoring 31
8.1.1 Monitoring Subject Risk 31
8.1.2 Monitoring the Informed Consent Process 31
8.1.3 Data Verification 31
8.1.3.1 Direct Entry with Verification 32
8.1.3.2 Double Entry of Data 32
8.1.3.3 The Data Management Summary (DMS) 33
8.1.4 Annual Research Clinic Monitoring Plan 33
8.1.4.1 Monitoring Procedure 33
8.1.4.2 Site Performance Evaluation & Monitoring Report 34
8.2 Auditing Procedures 34
8.3 Source Documentation 34
8.4 Maintaining Subject Privacy 34
8.5 Locking the Database 35
8.6 Retention of Documents 35
8.7 Clinical Quality Assurance 35
8.8 Institutional Review Board 35
8.9 Statements of Compliance 36
8.10 Informed Consent Process 36
8.10.1 Vulnerable Population 36
8.11 Publication of Results 37
9.0 BIBLIOGRAPHY 37
APPENDIX A: METHODS OF CLINICAL EVALUATION 38
APPENDIX B: SUBJECT INSTRUCTIONS FOR USE 44

LIST OF ABBREVIATIONS

Abbreviation/Acronym	Term
AE	Adverse Event
ADE	Adverse Device Effect
ASADE	Anticipated Serious Adverse Device Effect
B+L	Bausch + Lomb
BSCVA	Best Spectacle-Corrected Visual Acuity
CFR	Code of Federal Regulations
CRT	Clinical Research Technician
CRF/e-CRF	Case Report Form / Electronic Case Report Form
D	Diopter
DOB	Date of Birth
EDC	Electronic Data Capture
EC	Ethics Committee
FDA	United States Food and Drug Administration
GCPs	Good Clinical Practices
GPRM	Global Pharmacovigilance and Risk Management
GPS	Global Product Surveillance
GSSP	Global Safety Surveillance and Pharmacovigilance
HIPAA	Health Insurance Portability and Accountability Act
HCHI	High Contrast High Illumination
IB	Investigator's Brochure
IDE	Investigational Device Exemption
ICF	Informed Consent Form
IOP	Intraocular Pressure
ID	Identification
IRB	Institutional Review Board
ISO	International Organization for Standardization
PI	Principal Investigator
SAE	Serious Adverse Event
TMF	Trial Master File
USADE	Unanticipated Serious Adverse Device Effect
US	United States
USC	United States Code
VA	Visual Acuity

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

INVESTIGATIONAL SITE AND STUDY PERSONNEL

The Investigators are Optometrists employed by Bausch + Lomb and determined to be suitably qualified by training and experience to conduct this study. There are not any external organizations involved in the clinical investigation. Each Investigator may participate in all components of study execution. The study is paid for entirely by Bausch + Lomb. It will only be conducted at one site.

Sponsor:	**Investigational Site:**
Bausch + Lomb Incorporated	Bausch + Lomb Incorporated
1400 North Goodman Street	1400 North Goodman Street
Rochester, NY 14609	Rochester, NY 14609

Principal Investigator	**Clinical Affairs**
[redacted]	[redacted]

Clinical Investigator	
[redacted]	

SYNOPSIS

Study Title	1-Week Dispensing Evaluation of kalifilcon A Daily Disposable Toric Contact Lenses Compared to Ultra for Astigmatism Contact Lenses
Sponsor	Bausch + Lomb Incorporated, 1400 N. Goodman St. Rochester, NY 14609
Number of Sites	One Investigational Site, Bausch + Lomb Incorporated, Rochester, NY 14609
Clinical Phase	Confirmatory
Trial Registration	This study will be registered on clinicaltrials.gov.
Test Article(s)	**Test Lenses:** T01: kalifilcon A Daily Disposable Toric Contact Lenses L[redacted] **Control Lenses:** C01: Ultra for Astigmatism Contact Lenses
Wear and Replacement Schedules	Wear Schedule: Daily Wear Replacement Schedule: Daily replacement
Objective	The objective of this study is to evaluate the visual performance of kalifilcon A Daily Disposable Toric contact lenses compared to commercially available Ultra for Astigmatism contact lenses.
Ethical Considerations	Written approval of the protocol and informed consent will be provided to Bausch + Lomb by the IRB prior to initiation of the study. Investigators are not to deviate from the study protocol except when necessary for the protection of the subject's health, safety, or welfare. Before any study-specific procedures are performed, the Investigator (or designee) will explain to the purpose of the study, the associated procedures, and any anticipated effects or adverse reactions to the subject. The subject will be given sufficient time and opportunity to ask questions regarding any aspect of the study and to decide whether or not to participate in the study. Once the Investigator (or designee) is assured the subject understands the implications of study participation, the subject will be asked to give consent to participate in the study by signing and dating the ICF.
Study Design	Experienced soft contact lens wearing subjects will be enrolled in this 1-week, confirmatory, randomized, bilateral, 2-way crossover, double masked (subject and investigator), repeated measures, dispensing study. All subjects will be seen for a Screening/Baseline Visit at which informed consent will be obtained and eligibility will be assessed. [redacted]

	[redacted] Each type of lenses will be dispensed based on a randomization schedule and they will be worn for a similar period of time. Subjects will wear both test and control lenses as a daily disposable lens.
Study Duration	There are a total of two study lens types (one test lens and one control lens). Subjects will wear each study lens type for approximately one week. Subjects will be dispensed contact lenses to wear for 2 weeks. Subjects may be enrolled in the study for approximately 6 months. The clinical investigation will take approximately 6 months to complete. Screening/Baseline Visit:15 minutes Visit 1: Approximately 45 minutes Visit 2: Approximately 30 minutes Visit 3: Approximately 30 minutes Visit 4: Approximately 30 minutes
Subjects Planned	Approximately 40 contact lens experienced subjects that require astigmatic correction will be enrolled. The target is to have approximately 20 subjects complete the study. Further information regarding the target population can be found in the IB.
Inclusion Criteria	To be eligible for entry into the study, the subject must: 1. Be 18 years or older on the date the Informed Consent Form (ICF) is signed and have the capacity to read, understand and provide written voluntary informed consent. 2. Have physiologically normal anterior segments not exhibiting clinically significant biomicroscopy findings. 3. Have no active ocular disease or allergic conjunctivitis. 4. Not be using any topical ocular medications. 5. Be willing and able to follow instructions. 6. Have signed a statement of informed consent
Exclusion Criteria	The subject is not eligible to participate in the study if the subject is: 1. Participating in a conflicting study in the opinion of the Investigator. 2. Considered by the Investigator to not be a suitable candidate for participation.
Concomitant Medications	Ocular, systemic or topical medications that, in the Investigator's opinion, could potentially affect ocular physiology or lens/solution performance are prohibited.

Investigational Product, Dosage and Mode of Administration	Study lenses will be dispensed to subjects meeting all eligibility requirements including any dispensing requirements in this clinical protocol. Subjects will be dispensed an adequate supply of study lenses to complete the study. Lost or damaged study lenses may be replaced at the discretion of the Investigator. The investigator or designee will instruct all subjects to adhere to the Subject Instructions provided with their study contact lenses. The subjects and investigators will be masked to the study lenses. An unmasked designee at each site will be responsible for all study lens accountability, including dispensing and collecting study supplies to subjects. Subjects will be instructed that other contact lenses (other than the study lenses) are not allowed to be used during the study period. Subjects will wear each of the study lens types in a randomized order for approximately 1 week.
Measurements and Procedures	[redacted]

	o [redacted]
Study Endpoint	The primary endpoint is: 1. Mean Binocular logMAR Visual Acuity
Statistical Methods	Continuous data will be summarized using descriptive statistics: n, mean, standard deviation, median, minimum and maximum. Categorical data will be presented by the total counts for each category and corresponding percentages. Ordinal variables will be reported as either ordinal or categorical variables with the appropriate statistical test being applied. *p*-values ≤ 0.05 will be considered statistically significant.
Sample Size	[redacted]
Hypothesis	[redacted]

Pass/Fail Criteria	There are no pass/fail criteria for the results of the clinical investigation.
Interim Analysis	No interim analyses are planned.
Monitoring Risk	The risks involved with contact lens wear in this study will be minimized because the subjects will be examined frequently and at specified intervals. The risks are further minimized by the study eligibility criteria.
Data Quality Assurance	Edit checks are built into the EDC System to minimize the chance of error. Also, data is collected by using either Direct Entry with Verification or Double Data Entry.

1.0 INTRODUCTION

With Toric contact lenses, the ability of the lens to orient correctly on-eye and to maintain that orientation (i.e., rotational stability) are important aspects of acceptable on-eye performance. Mechanical design features [redacted] are components of Toric contact lens designs that are added to provide acceptable movement, orientation, and rotational stability needed to correct refractive astigmatism. This clinical study aims to confirm that the kalifilcon A Daily Disposable Toric [redacted] contact lens design is providing acceptable vision when compared to Ultra (samfilcon A) for Astigmatism lenses.

2.0 OBJECTIVE

The objective of this study is to evaluate the visual performance of kalifilcon A Daily Disposable Toric contact lenses compared to commercially available Ultra for Astigmatism contact lenses.

3.0 STUDY DESIGN

3.1 Description of Study Design

Approximately 40 experienced soft contact lens wearing subjects that require astigmatic correction will be enrolled in this 1-week, confirmatory, randomized, bilateral, 2-way crossover, double-masked (subject and investigator masked), repeated measures, dispensing study. All subjects will be seen for a Screening/Baseline Visit at which informed consent will be obtained and eligibility will be assessed. [redacted] easurements will be taken at the insertion visit and at the 7 day follow up visit for each lens type.

[redacted]

Each type of lenses will be dispensed based on a randomization schedule and they will be worn for a similar period of time. Subjects will wear both test and control lenses as a daily disposable lens.

The target is to have approximately 20 contact lens experienced subjects complete the study. Further information regarding the target population can be found in the IB.

There are a total of two study lens types (one test lens and one control lens). Subjects will wear each study lens type for approximately one week.

Screening/Baseline Visit: 15 Minutes
Visit 1: Approximately 45 minutes
Visit 2: Approximately 30 minutes
Visit 3: Approximately 30 minutes
Visit 4: Approximately 30 minutes

The clinical investigation will take approximately 6 months to complete.

3.2 Selection of Study Population

Recruitment for this study will target experienced contact lens wearers that have astigmatic refractive error requiring toric contact lens correction. Subjects who have an Rx suitable for the available lens powers will be enrolled in this dispensing study. Due to limited availability of lens powers, it is expected that more subjects may be enrolled and screened at baseline than may be dispensed lenses and/or complete the study. Both the investigational population and the target population are patients prescribed the correction of astigmatism, regardless of gender or ethnicity and who do not have contraindications for the device.

Enrollment will take place during the first month of the study.

Written informed consent, enrollment in the study, or dispensing of study products cannot begin until the Investigator has received Institutional Review Board (IRB)/Ethics Committee (EC) approval to conduct the study.

To reduce the foreseeable factors that could compromise the outcome of the clinical investigation, subjects are targeted who are experienced contact lens wearers. To be eligible to participate, subjects must have physiologically normal anterior segments not exhibiting clinically significant biomicroscopy findings, no active ocular disease or allergic conjunctivitis, not using any topical ocular medications and be willing and able to follow instructions. There are no known or foreseeable factors that may compromise the outcome of this clinical investigation that are not already controlled for by the Inclusion and Exclusion criteria.

3.2.1 Eligibility

3.2.1.1 Inclusion Criteria

To be eligible for entry into the study, the subject must:

1. Be 18 years or older on the date the Informed Consent Form (ICF) is signed and have the capacity to read, understand and provide written voluntary informed consent.
2. Have physiologically normal anterior segments not exhibiting clinically significant biomicroscopy findings.
3. Have no active ocular disease or allergic conjunctivitis.
4. Not be using any topical ocular medications.
5. Be willing and able to follow instructions.
6. Have signed a statement of informed consent.

3.2.1.2 Exclusion Criteria

The subject is not eligible to participate in the study if the subject is:

1. Participating in a conflicting study.
2. Considered by the Investigator to not be a suitable candidate for participation.

3.2.2 Point of Enrollment and Randomization

The study subject and investigator will be masked. An unmasked designee will be responsible for dispensing study products to the subjects according to the randomization schedule. The randomization schedule will be produced prior to study enrollment by Bausch + Lomb's unmasked statistician not otherwise involved in the study.

Randomization will be completed by the unmasked designee. The subjects will be assigned randomization numbers sequentially as they are enrolled. The unmasked designee is responsible for preparing the clinical trial materials according to the randomization schedule. The unmasked designee is also responsible for maintaining study lens inventory, randomization schedule and the Product Accountability Log in a masked fashion.

3.2.3 Subject Completion

The subject will have completed the study when he/she has worn the both the study lens types for approximately 1 week.

Subjects who require further follow-up due to an ongoing Adverse Event will be followed according to the Adverse Event Section 6.0.

The Investigator may discontinue a subject during the study for any reason if, in his or her opinion, it is in the best interest of the subject. Reasons for discontinuation include but are not limited to:

- adverse effects
- other ocular complications
- subject non-compliance
- subject request
- subject found to be ineligible during study participation*

*Any subject enrolled in the study, who later is found to have not met any of the eligibility criteria at entry, will be discontinued at the Sponsor's request.

Subject discontinuations will be documented clearly on the applicable case report form. Subjects that are discontinued from the study following randomization will not be replaced.

Exit visits should be completed for early terminated subjects.

The completion of the clinical investigation shall be deemed to coincide with the last visit of the last subject and when follow-up is complete.

3.2.4 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.

3.3 Investigators

The study will be conducted at one investigative site, the Bausch + Lomb Research Clinic in Rochester, NY by Investigators who are employed by Bausch + Lomb. The Investigators are qualified by training and experience to conduct this study. All the study procedures will be performed by Optometrists who are licensed to fit contact lenses.

The assessments required for the study are routinely performed by Optometrists and are standard of care for contact lens wearers. (See Appendix A: Methods of Clinical Evaluation for detailed information about study procedures).

3.4 Study Duration

There are a total of 2 study lens types (one test contact lens and 1 control contact lens). Each study lens type will be worn for approximately 1 week (total of 2 weeks of lens wear). Subjects will be enrolled in the study for approximately 6 months.

The clinical investigation will take approximately 6 months to complete.

3.5 Protocol Changes and Amendments

Changes to the protocol will be approved by the Sponsor. An amendment to the protocol may also require submission and approval from the IRB before implementation. Any amendments to the protocol will be kept in the Trail Master File along with the original version. The Investigator is responsible for the ensuring that staff involved have completed training on the changes before implementing with subjects.

4.0 STUDY MATERIALS

Bausch + Lomb is the manufacturer of the study lenses and will provide all study materials. Subjects must use only study supplied contact lenses during the study.

4.1 Description of the Test Article(s)



Additional contact lens information can be found in the Investigator's Brochure.

Test Lenses (T01): kalifilcon A Daily Disposable Toric [redacted] Lenses in Multiple Powers

4.2 Description of Comparator Product(s)
Control Lenses (C01): Commercially available Ultra for Astigmatism Contact Lenses in Parameter-matched Powers

4.3 Instructions for Use and Administration

Study lenses will be dispensed to subjects meeting all eligibility requirements including any dispensing requirements in this clinical protocol. Subjects will be dispensed an adequate supply of study lenses to complete the study. Lost or damaged study lenses may be replaced at the discretion of the Investigator.

The investigator or designee will instruct all subjects to adhere to the Subject Instructions provided with their study contact lenses.

The subjects and investigators will be masked to the study lenses. An unmasked designee at each site will be responsible for all study lens accountability, including dispensing and collecting study supplies to subjects.

Subjects will be instructed that other contact lenses (other than the study lenses) are not allowed to be used during the study period.

Subjects will wear each of the study lens types in a randomized order for approximately 1 week.

See Appendix B: Subject Instructions for Use

4.3.1 Storage Requirements
All Test and Control lenses provided by the Sponsor must be stored in a secure location accessible only to unmasked study personnel.

4.3.2 Subject Instructions
a) Subject Instructions for the use of study lenses are included in Appendix B, which include precautions and warnings related to contact lens wear. Subjects must comply with the instructions provided to them.

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

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

4.4 Other Study Materials
Worn and unworn study lenses will be returned after the study is complete. No other study materials will be used in this study.

4.5 Packaging and Labeling
Test Lenses: [redacted]. The blisters are sealed with a plastic-coated aluminum foil lid stock, with each blister labeled with the manufacturing lot number of the lens, sphere power, cylinder power, cylinder axis, and expiration date.

Control lenses: The Control contact lenses will be packaged with a Commercial label. The label will contain the following information at minimum:

- lot number
- lens power
- manufacturer's name
- expiration date

4.6 Accountability
The investigational site is 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.

All test materials will be accounted for on the Clinical Trial Materials Form and Lens/Solution Tracking Form. Subjects must return all remaining study materials to the Investigator at the final study visit, or their exit visit if discontinued prior to the final visit.

4.7 Masking
The Investigator and subjects will be masked to the study lenses. Unmasked study personnel will be responsible for dispensing and collecting the study Test and Control lenses and accountability.

The randomization schedule will be created prior to the start of the study by an unmasked statistician not otherwise involved in the study.

In the event that unmasking of a subject's randomly assigned treatment is required, the Investigator (or designee) will reference the subject specific randomization schedule (or login to the EDC System) and unmask the subject.

Whether unmasking occurs inadvertently or intentionally, the Investigator must record the date, time, and reason for unmasking the study treatment in EDC System.

Subjects will be instructed to insert the study lenses out of the sight of the Investigator or site staff other than the unmasked designee. Subjects are not to show the study blister packs and foils to the Investigator or site staff other than the unmasked designee unless instructed to do so.

In order to keep the subjects masked, the study lenses will be dispensed with similar looking labels, that do not identify the lens type.

4.8 Product Replacement

Subjects will be dispensed study lenses for the duration of the study. If additional lenses are necessary, the subject will be instructed to contact the unmasked designee and additional lenses will be dispensed.

4.9 Risk Assessment

Information concerning potential risks associated with the investigational device (as well as possible interactions with concomitant medical treatments and risk-to-benefit ratio) can be found within the Investigator's Brochure. Risks are also summarized within the Informed Consent document. 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 ICF or if new risks become apparent during the study.

4.9.1 Risk Related to Subject

With contact lens wear there may be increased risk of corneal edema (swelling of the cornea) which may temporarily affect vision or comfort, neovascularization (small blood vessels growing into the cornea), giant papillary conjunctivitis (small bumps on the inside of the eyelids), iritis (internal inflammation in the eye), corneal infiltrates (corneal inflammation) and corneal erosion/abrasion or corneal infection, which if untreated may cause ocular problems.

The risks involved in this study will be minimized because the subjects will be examined frequently and at specified intervals. The risks are further minimized by the study eligibility criteria.

The subject may not personally benefit from being in this study other than getting the opportunity to wear different types of contact lenses. However, study results may allow a new or improved product to be marketed in the future giving benefit to other contact lens users.

No clinical benefit is expected from this confirmatory study.

4.9.2 Risk Related to Data Management

The risks involved in this study related to data management will be minimized because the CRT (Clinical Research Technician) will enter the data directly into the Electronic Data Capture (EDC) system. The Primary Investigator or Delegate will visually verify the data as it is entered, except masked information when applicable. If data is not entered directly into the EDC System, the data will be double entered. Then, the two sets of data will be compared to each other and then checked for discrepancies.

Risk of data management is further minimized by edit checks built into the EDC system to

minimize the chance of error. For example, the EDC system does not allow the same lens to be dispensed more than once. Also, the expected ranges of values are specified in the EDC system. If data falls outside of the expected range, the CRT will be prompted to answer a query.

4.10 Relevance of Clinical Investigation

[redacted] This this clinical study aims to confirm whether the kalifilcon A Daily Disposable Toric contact lenses provide comparable vision as the comparator Ultra for Astigmatism lenses.

Further information regarding the relevance of this study in the context of state of the art clinical practice such as background information, summary of relevant literature, mechanism of action, intended clinical performance, and a summary of existing relevant clinical data of the investigational device can be found in the Investigator's Brochure.

5.0 STUDY METHODS

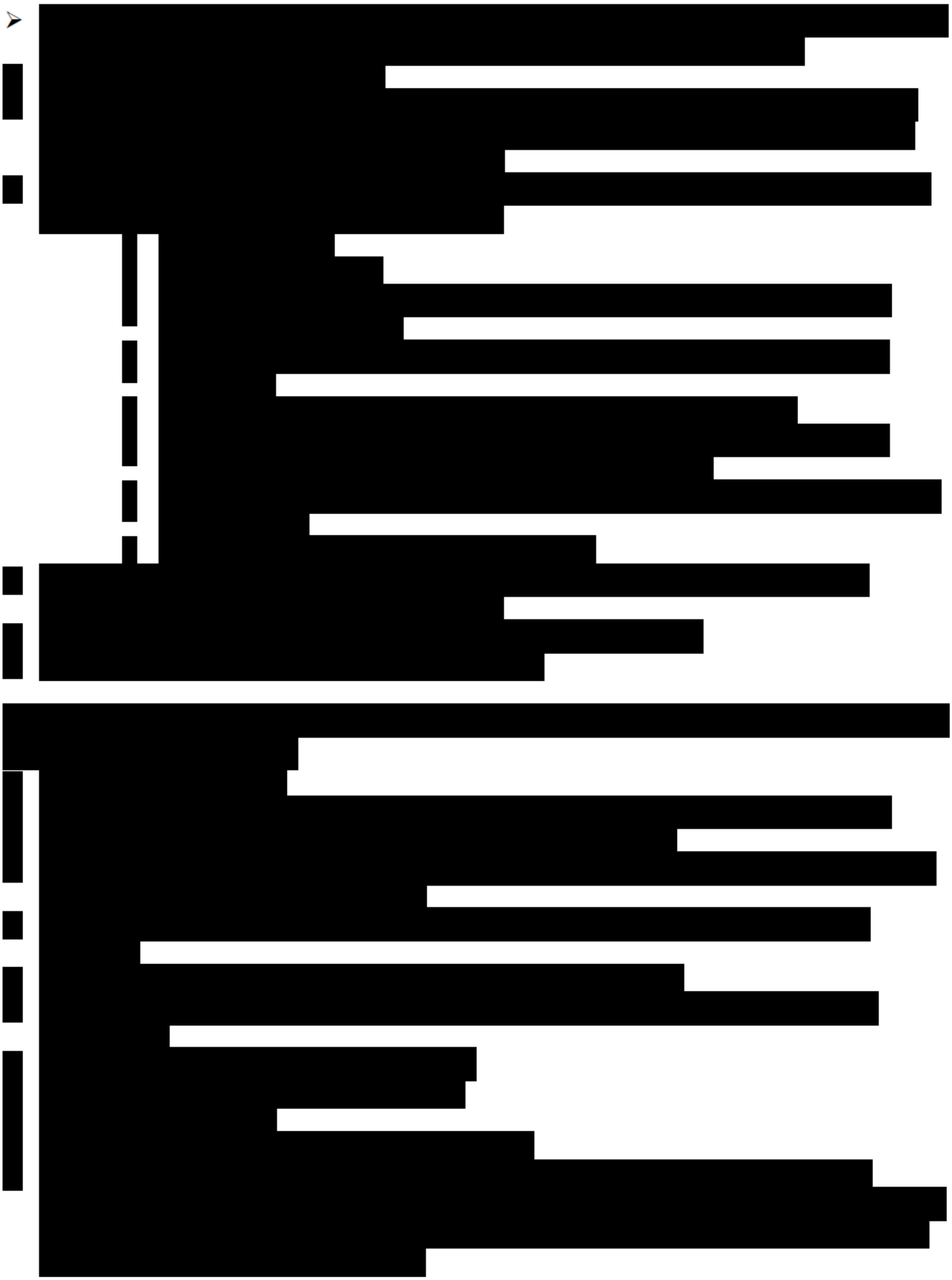
The clinical procedures in this study are part of normal eye examination. There are not any deviations from normal clinical practice. The procedures conducted in the study are outlined below and described in Appendix A Methods of Clinical Evaluation.

Following identification of a potential subject, the Investigator (or designee) will explain the purpose of the study, procedures, risks/benefits, and subject responsibilities to the potential subject. The subject's willingness and ability to meet the follow-up requirements of the study will be determined. If the subject chooses to participate in the investigation, written informed consent will be obtained. The subject and the person obtaining written consent will sign and date the IRB-approved ICF. The Investigator must keep the signed ICF document. The signed original document should be retained in the subject's records, and a copy should be provided to the subject. In addition, the applicable privacy regulation requirements must be met. Additional Informed Consent information is provided in Section 8.10

5.1 Study Visits

5.1.1 Methodology:

[redacted]





- [redacted]

[redacted]

5.1.2 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 on Unscheduled Visit forms as appropriate.

5.1.3 Missed Visits

If a subject misses a Study Visit (and it cannot be rescheduled within the appropriate time frame), the visit is considered missed and the subject must be exited from the study. The Investigator or designee must check the missed visit box on the first page of the applicable e-CRF for that visit.

See Section 3.2.4 Lost to Follow-Up for applicable instructions for subjects who do not return for the final visit.

5.1.4 Post-Study Follow-up Visit

There is no planned follow-up period after the clinical investigation is complete. If a subject requires further follow-up upon discontinuation or completion of the study, the Investigator must schedule post-study follow-up visits, as necessary. The Investigator is required to follow the subject until the condition no longer warrants further follow-up for study purposes. A Post-Study Follow-up Visit e-CRF must be completed for each of these visits.

There will not be any routine eye care provided after the clinical investigation is complete. Subjects should follow-up with their eye care provider every 1-2 years for comprehensive eye care or sooner as recommended by their eye care provider.

5.2 Study Completion

The subject has completed the study when the last visit is completed. Subjects who require further follow-up will be followed according to the Adverse Event or Post- Study Follow-Up Section. There is no planned follow-up period after the clinical investigation is complete.

The completion of the clinical investigation shall be deemed to coincide with the last visit of the last subject and when follow-up is complete

5.2.1 Study Termination/Suspension

If during the study it becomes evident that the study should be stopped prematurely or placed on hold, appropriate notification will be given to the requestor and IRB/ECs, as applicable. Should the Investigator and/or study requester wish to terminate the study, the following Research Clinic procedure will be followed. Any subjects with ongoing Adverse Events at the time of premature

study termination or hold will be followed by the Investigator.

5.2.2 Study Termination Procedure

The decision to terminate a study will be made by the Director of Clinical Affairs and the Principal Investigator (PI). A final slit lamp examination should be performed and adverse events handled accordingly. In the event that a study is suspended or terminated early, the Investigator (or designee) will reference the subject specific randomization schedule (or login to the EDC System) and unmask the subject.

All investigational materials (lenses, solutions, and / or devices) will be retrieved, all subjects will be exited, and the Trial Master File (TMF) will be reconciled. A clinical study report will be written and include the reason for study termination.

5.3 Concomitant Medications/Therapy

Ocular, systemic or topical medications that, in the Investigator's opinion, could potentially affect ocular physiology or lens performance are prohibited.

5.4 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/EC.

Any subject enrolled in the study who later is found to have not met the eligibility criteria at entry will be discontinued. Otherwise, unless the protocol deviations put the subject at risk or the subject's condition requires that they be discontinued from the study, subjects may continue to participate until the end of the study.

All investigators participating in this study agree to conduct the study in accordance with the relevant, current protocol and agree to only make changes in a protocol after being notified by the Sponsor, except when necessary to protect the safety, rights, or welfare of subjects. Under emergency circumstances investigators may proceed without prior approval of the IRB. These deviations will be documented and reported to the IRB as soon as possible.

Corrective Action plans will be developed and completed as deemed necessary for Investigators who deviate from this protocol in a way that adversely affects the rights, safety or well-being of the subject(s) and/or the quality or integrity of data. The Corrective Action Plan will outline the deviation and the site's corrective and/or remedial actions. Decisions regarding critical deviations that merit investigator disqualification and will be documented in the Trial Master File.

6.0 ADVERSE EVENTS

Subjects who experience an Adverse Event (AE) during study participation will be discontinued from study participation but will be followed by the Investigator until resolution of the AE or until the Investigator determines that further improvement is not expected.

6.1 Adverse Event Definitions

For the purposes of this study, reportable AEs include ocular AEs and non-ocular serious adverse events (SAEs). All AEs will be classified first for seriousness and significance and then as to whether or not they are device related or non-device related and if device related, then, if it is an adverse device effect (ADE), an anticipated serious adverse device effect (ASADEs) or an unanticipated serious adverse device effect (USADEs). AEs, ADEs, ASADEs, USADEs, SAEs, Significant Non-Serious AEs and Non-Significant Non-Serious AEs are defined as follows:

6.1.1 Adverse Event (AE)

Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects or users, whether or not related to the investigational medical device. Adverse events should be categorized as device related or non-device related.

Throughout the course of this study all efforts will be made to remain alert to reportable AEs. If an AE occurs, the first concern will be the safety of the subject and appropriate medical intervention will be made.
All reportable AEs occurring after signing of informed consent and through the subject's end of participation in the study must be reported. All reportable AEs must be followed until the event resolves or stabilizes.

6.1.2 Serious Adverse Event (SAE)

An adverse event which:

- 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 (e.g., blindness); or
    - Inpatient 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.

6.1.3 Serious Adverse Ocular Event

Serious Adverse Ocular Event is a serious adverse event that results in, or has 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 require expedited reporting. Serious adverse events include any hazardous, **sight-threatening conditions** occurring after exposure to a test article, including but not limited to the following:

- A presumed infectious ulcer (defined as a progressive erosion of the corneal tissue). For the purposes of reporting, a corneal ulcer which has *any* of the following characteristics should be considered in this category:
    - Central or paracentral location;
    - Penetration of Bowman's membrane;
    - Infiltrate ≥2 mm diameter;

- Associated with iritis;
- Associated with any increase in intraocular pressure;
- Culture positive for microorganisms;
- Increasing size or severity at subsequent visits.

Note: Signs of a presumed infectious 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 corneal scar or 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 (10 letters) of BSCVA.
- All cases of iritis.

6.1.4 Significant, Non-Serious Adverse Event

A Significant, Non-Serious Adverse Event is an Adverse Event that does not meet the serious criteria, is considered significant, and requires expedited reporting. These events include (but are not limited to):

- Peripheral non-progressive non-infectious corneal ulcer
- All symptomatic corneal infiltrative events
- All cases of corneal staining severity greater than or equal to Grade 3
- A temporary loss of 2 or more lines (10 or more letters) of BSCVA (for greater than or equal to 2 weeks)
- Increase in neovascularization of 1.5mm or greater.
- Any ocular event that necessitates temporary lens discontinuation of greater than or equal to 2 weeks.

6.1.5 Non-significant, Non-serious Adverse Event

A Non-Significant Non-Serious Adverse Event may include (but are not limited to) and does not require expedited reporting:

- Asymptomatic, peripheral, corneal infiltrative events.
- Bacterial Conjunctivitis
- Viral Conjunctivitis
- Allergic Conjunctivitis
- Corneal Edema
- Contact Lens Related Papillary Conjunctivitis

6.1.6 Adverse Device Effect (ADE)

An ADE is an Adverse Event that is assessed to be related to the use of an investigational medical device. This definition includes Adverse Events resulting from insufficient or inadequate

instructions for use; deployment, implantation, installation, or operation; or any malfunction of the investigational medical device. This definition also includes any event resulting from use error or from intentional misuse of the investigational medical device.

6.1.6.1 Anticipated Serious Adverse Device Effect (ASADE)

An ASADE is an ADE that first meets the serious criteria (see definition above for Serious Adverse Event) or significant, non-serious criteria (see above definition for significant, non-serious AE) and which, by its nature, incidence, severity or outcome, has been previously identified in the investigational plan or application (including a supplementary plan or application) and/or in the risk analysis report. ASADEs include:

- Corneal Ulcer (infectious or non-infectious)
- Keratitis
- Sensitivity to light (photophobia)
- Excessive eye secretions including mucopurulent discharge
- Blurred vision, rainbows or halos around objects
- Poor visual acuity (reduced sharpness of vision)
- Moderate to severe eye pain not relieved by removing the lens

6.1.6.2 Unanticipated Serious Adverse Device Effect (USADE)

An USADE is an ADE that first meets the serious criteria (see definition above for Serious Adverse Event) or significant, non-serious criteria (see above definition for significant, non-serious AE) and has an 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.

6.1.7 Device Deficiency

Inadequacy of an investigational medical device with respect to its identity, quality, durability, reliability, safety, or performance. This includes malfunctions, use errors, inadequate labelling, insufficient or inadequate instructions for use. A Device Deficiency can occur with or without the occurrence of an Adverse Event.

6.2 Adverse Event Treatment and Culturing

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

A culture should be obtained in cases of corneal ulcer or suspected ocular infection, unless medically contraindicated. Cultures should be taken from the cul-de-sac, lower eyelid margin, and the corneal lesion (if applicable). When a culture is obtained, the contact lenses and contact lens cases which were being utilized by the subject at the time of the AE should be collected from the subject (if available at the time of the culture) for culturing and processing by the clinical laboratory designated by the Research Clinic. Microbial data generated from returned subject supplies (e.g., lenses, lens cases and/or lens case solutions) are for information only. Because microbes may be introduced into subject supplies during use, recovery of microbes

from returned subject supplies cannot be presumed to indicate etiology or direction of organism transmission. The ocular cultures, along with the associated contact lenses and contact lens cases, will be sent to the clinical laboratory designated by the Research Clinic for analysis. The clinical laboratory will report the culture results to both the Investigator and to the Research Clinic, the Investigator will record the results in the CRF.

6.3 Adverse Event Identification and Evaluation

Throughout the course of a study all efforts will be made to remain alert to Adverse Events (AEs). If an AE occurs, the first concern will be the safety of the subject and appropriate medical intervention will be made. The associated product should be retained for further analysis, if needed.

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

Identify potential adverse events during a clinical study by using the following sources:

- Direct observation by the Investigator
- Asking the study participant using a non-specific question (i.e. Have you had any problems since the last visit?)
- Unsolicited volunteering of information by the study participant (i.e. Doctor, I have had numerous headaches since I started using this lens)
- Laboratory or test results that meet protocol requirements for classification as an adverse event (i.e. IOP over 30mmHg)

When evaluating AEs, the Investigator should classify the AE based on the following three criteria:

1. **Seriousness and/or significance** (based on the criteria provided in Section 6.1)

   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.

2. The **relationship of the event to the study device** using the following guidelines

- **Related:** There is at least a reasonable possibility that the AE is related to the study device (contact lens) and/or solution or rewetting drops. Reasonable possibility means that there is evidence to suggest a causal relationship or association between the study device and/or solution or rewetting drops and the AE. Also referred to as an ADE.

- **Not Related:** There is little or no reasonable possibility that the AE is related to the study device (contact lens) and/or solution or rewetting drops. This assessment implies that the AE has no evidence to suggest either a causal relationship or association to the study device and/or solution or rewetting drops and a more likely or certain alternative etiology exists.

3. **Expectedness of the event**

- **Unexpected Adverse Event (UAE):** Unexpected Adverse Events must be reported to the IRB within 10 calendar days of discovery.

- **Expected Adverse Event:** An adverse event of which, the nature or severity of which is consistent with the current product labeling, investigator brochure, data sheet, etc.

6.4 Adverse Event Collection and Reporting

The Research Clinic will delegate each function's roles and responsibilities related to adverse event reporting. The Director of Clinical Affairs is responsible for ensuring that all Research Clinic Staff understand their responsibilities for collecting and assessing adverse event information and forwarding applicable adverse event information to the appropriate business function.

Research Clinic Staff are responsible for understanding the procedures for adverse event collection, evaluation, documentation, and reporting.

- Collect and record information about any identified adverse event (including the date of the adverse event, treatment, resolution, assessment of both the seriousness and the relationship to the investigational device and the related procedure) on the Adverse Event form. The Adverse Event Form will be completed each time the subject is seen during the management of the incident and at resolution of the incident.
- If an adverse event is determined to be serious or significant and non-serious, notify the Principal Investigator immediately.
- Report all serious or significant and non-serious adverse events within twenty-four (24) hours to Regulatory Affairs, Global Product Surveillance and/or Global Safety Surveillance and Pharmacovigilance as appropriate for the product being evaluated. Continue to send follow-up information or provide support to the appropriate reporting business function for any serious adverse event as soon as it becomes available.
    - Ensure that the subject's identity is protected and the subject's identifiers in the study are properly documented on the form.
- Report all unexpected adverse device effects to the reviewing Institutional Review Board within 10 business days of discovery. Continue to send follow-up information as soon as it becomes available.
- Report any adverse event resulting from Intentional Misuse of an investigational medical device per the same procedures as above.
- Report any adverse event resulting from a Device Deficiency per the same procedures as above. All Device Deficiencies should be recorded and evaluated for the potential to cause a serious adverse event.

- All appropriate measures will be taken to ensure the safety of the subject. Follow the subject until the adverse event resolves or until an appropriate endpoint is reached. This may imply that follow-up will continue after the subject has left the study.
- A treatment of an AE will depend on the severity of the adverse event. The Principal Investigator will refer the subject to a suitably licensed eye care professional for immediate treatment if necessary.
- Expenses incurred for study-related medical treatment will be paid by Bausch + Lomb. Research Clinic Staff will contact Environmental Health and Safety to initiate the medical payment claims process.
- If it is determined, based on evaluation of any serious adverse event or serious adverse event trending, that the study presents an unreasonable risk, the Research Clinic may choose to terminate the study. Refer to the Study Termination procedures (section 5.2.2) for additional information and relevant periods for terminating a study.
- All adverse events will be documented in the final study report. Adverse Event documentation must be saved in the Trial Master File and in the respective study folder in the electronic repository.

6.5 Reporting Device Deficiencies

- Report to Global Pharmacovigilance and Risk Management (GPRM) and Design Quality within 24 Hours.
- All device deficiencies must be evaluated by the Investigator, and then evaluated by GPRM and Design Quality.
- The Principal Investigator (PI) will record, evaluate, and report via applicable forms any complaints/deficiencies or malfunctions experienced with the study devices using the Device Deficiency form and when applicable, AE form (if AE has occurred). The PI will evaluate the Device Deficiency and record whether an AE occurred related to the device deficiency and also determine the potential of the device deficiency to cause a serious adverse device effect (SADE). The device deficiency form is then sent to GPRM to evaluate as the Sponsor, their independent determination if the device deficiency led to or could have led to a SADE. See ISO 14155:2020 for resolving any discrepancies between the interpretation by the PI and Sponsor on whether the device deficiency could have led to SADE.
    - If there was an Adverse Event that occurred as well as the device deficiency, then it should be reported as both an Adverse Event and a Device Deficiency (both forms should be completed).
    - If the Device Deficiency is unrelated to an Adverse Event, then just the Device Deficiency should be reported on the Device Deficiency form.
- Additionally, the Device Deficiency form will be sent to Bausch + Lomb Design Quality to evaluate whether any updates to Design Records need to be made.

6.6 Emergency Contact Details for Reporting Serious Adverse Events and Adverse Device Effects:

Principal Investigator

[redacted]

[redacted]

7.0 STATISTICAL METHODS

7.1 Study Endpoints

Primary Endpoint:

1. Mean Binocular logMAR Visual Acuity

High Contrast logMAR lens visual acuity was selected as a primary endpoint because it is the standard for measuring visual acuity in contact lens research. It is regarded as the standard because there are an equal number of letters per line, uniform progression in letter size and regular spacing between lines and letters. The final visual acuity measurement is based on the total of all letters read correctly. Visual acuity is measured with logMAR visual acuity charts according to Appendix A.

7.2 Hypothesis

[redacted]

7.3 Sample Size

[redacted]

[redacted]

7.4 Randomization

To minimize or avoid bias, subjects will be assigned randomization numbers as they are enrolled according to unique randomization schedules created for the study. The randomization schedule will be produced prior to study enrollment. Subjects will be receiving each of the study lens

types once, in a randomized order. An effort will be made to conceal the CTM materials from the subject and the investigator throughout the study. Both the study subject and investigator will be masked.

The randomization schedule is verified up to 5 times during the course of the study:
The CRT visually verifies the study material against the randomization schedule during CTM preparation (if applicable) and before dispensing any study materials. The randomization schedule is also verified in EDC after dispensing the CTM. Once the study is complete, randomization is verified again during CTM reconciliation. Upon completion of the study, the EDC programmer also verifies randomization.

7.5 Study Populations
Subjects will be included in all summaries under the treatment that they actually received. Analyses of safety data will include all dispensed subjects. All other summaries will include all eligible, completed subjects.

7.6 Statistical Analysis
Continuous data will be summarized using descriptive statistics: n, mean, standard deviation, median, minimum and maximum. Categorical data will be presented by the total counts for each category and corresponding percentages. The data for each of the ordinal dependent measures (i.e., those assigned a clinical grade) will be analyzed using appropriate nonparametric techniques. Unless otherwise noted, paired t tests will be used to test for differences in means for each of the parametric dependent variables. Differences at the $p \leq 0.05$ level will be considered statistically significant.

7.6.1 Pass/Fail Criteria
There are no pass/fail criteria for the results of the clinical investigation.

7.6.2 Interim Analyses
No interim analyses are planned.

7.6.3 Exploratory/Sensitivity Analysis
There are no planned exploratory or sensitivity analyses for this study.

7.6.4 Deviations
Any deviations from the original statistical analysis plan will be summarized in the Clinical Study Report.

8.0 DATA QUALITY ASSURANCE
Steps will be taken to ensure the accuracy and reliability of data, including the selection of qualified investigators and review of protocol procedures. Prior to the start of the study, member(s) of the Research Clinic and Investigators will review the protocol, e-CRFs, regulatory obligations, and other material or equipment relevant to the conduct of the study.
The Principal Investigator, in turn, must ensure that all Sub-Investigators and clinical personnel are familiar with the protocol and all study-specific procedures and have appropriate knowledge

of the study article. The CRT's are trained on completing case report forms.

The data for this study will be captured on electronic case report forms using an EDC System (Inform). Inform is a fully validated EDC system and is compliant with 21 CFR Part 11. Once the EDC system is installed, test scripts are completed to test the functionality of Inform and ensure the system is complaint. Documentation of compliance with 21 CFR Part 11 is on file with B+L Quality. The clinical data will be recorded on dedicated eCRF's specifically designed to match the study procedures for each visit.

Once completed, the eCRF's will be reviewed for accuracy and completeness and signed by the Investigator. The database will them be locked. Each user has his/her own username and password. Only registered users assigned to the study can login to the clinical study.

Edit checks, electronic queries, and audit trails are built into the EDC system to ensure accurate and complete data collection. Data will be stored in a secure database, ensuring information accuracy, security, and confidentiality.

During the study, if it is determined that an Investigator is not compliant with the protocol and/or applicable regulatory requirements, action will be taken to secure compliance. In addition, the Investigator's participation in the study may be terminated if appropriate, or if the Investigator remains non-compliant.

A data monitoring plan or committee is not needed due to the short duration and/or frequent follow up visits and low risk exposure (daily wear contact lenses).

8.1 Study Monitoring

The monitoring plan for this study includes Informed Consent and Data Verification.

8.1.1 Monitoring Subject Risk

The risks involved with contact lens wear in this study will be minimized because the subjects will be examined frequently and at specified intervals. The risks are further minimized by the study eligibility criteria. The subject population will be restricted to persons who are 18 years of age or older and have full legal capacity to volunteer; no restrictions are made as to gender.

8.1.2 Monitoring the Informed Consent Process

Informed consent forms are verified for all subjects enrolled in each study. Subject and witness signature and date are visually verified by the CRT and then confirmed in the EDC System at the time of enrollment. Informed Consent Form signatures are also verified during study reconciliation by CRT. The signed informed consent forms are kept in the study folder.

8.1.3 Data Verification

Subject data required by this protocol are entered into EDC by the CRT or Delegate using either Direct Entry with Verification or Double Data Entry (outlined in Section 8.1.3.1 and Section 8.1.3.2). The Investigator and the study 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.

The Investigator and study site personnel will be responsible for answering all queries.

Edit checks are built into the EDC System to minimize the chance of error. For example, the EDC System does not allow the same lens to be dispensed more than once. The expected ranges of values are specified in the EDC System. If data falls outside of the expected range, the CRT will be prompted to answer a query. If a value is omitted, the CRT will be prompted to answer a query. The queries are answered in real time.

Data is verified for two randomly selected subjects by the EDC Analyst or designee. After the data is extracted from the EDC System, it is checked for accuracy by comparing the reformat to the data recorded in the EDC System. The data extract is verified by confirming the entered values, study materials, and study eye(s) match. Calculations performed by the EDC System are checked for accuracy. If there is a discrepancy between the values, the EDC Analyst or designee corrects the code to resolve the difference.

8.1.3.1 Direct Entry with Verification

Direct Entry with Verification is the preferred method for entering study data. Data is collected by the CRT or Delegate and entered directly into the EDC System. A second person, typically the Primary Investigator (or Delegate), will visually verify the data as it is entered, except masked information when applicable.

- In the event that the EDC System is unavailable, a paper CRF will be used to collect study data for later entry into the EDC System. After each page of the CRF is entered into the EDC System, the CRT or Delegate will initial the CRF to indicate the data has been entered into the EDC System and visually verified.
- Randomization Verification is required at the conclusion of each study prior to data distribution. The CRT or Delegate will verify each dispensed article against the study randomization and Clinical Trial Material (CTM) label, if applicable. After Randomization Verification of dispensed article, the CRT or Delegate will mark the Verification checkbox in the EDC System to acknowledge completion of dispensed article verification.
- If discrepancies arise during the verification of a paper source, the CRT or Delegate assesses the discrepancy and obtains additional information to determine if the correct entry was made or corrects paper source as appropriate. The CRT or Delegate may consult the Primary Investigator if necessary.
- The data is extracted from the EDC System and checked for accuracy by comparing the extracted data to the data originally recorded in the EDC System. The data extract is checked to confirm the lens reformat codes match the lens key. Calculations performed by the EDC System are checked for accuracy.
- Database Randomization Verification is performed, if applicable, prior to data distribution.

8.1.3.2 Double Entry of Data

If data is not entered directly in the EDC system, the data will be double entered (entered twice)

and the two sets of data will be compared to each other and then checked for discrepancies. When a paper source (i.e. subject questionnaire) is used to collect study data, this method may be used. For example, a subject questionnaire will be entered into two different spreadsheets. The two spreadsheets are then compared to each other.

- If discrepancies arise during the verification of a paper source, the CRT or Delegate assesses the discrepancy and obtains additional information to determine if the correct entry was made or corrects the paper source as appropriate. The CRT or Delegate may consult the Primary Investigator if necessary.
- After the study data from the paper source is entered, each CRT or Delegate entering the data will initial the paper source to indicate that the data has been entered into the EDC System visually verified, and dispensed articles verified against study randomization, prior to data distribution.
- The data is extracted from the EDC System and checked for data accuracy and necessary calculations are performed.

8.1.3.3 The Data Management Summary (DMS)

A Data Management Summary is created after all data has been verified.

8.1.4 Annual Research Clinic Monitoring Plan

[redacted]

8.1.4.1 Monitoring Procedure

[redacted]

2. [redacted]

8.1.4.2 Site Performance Evaluation & Monitoring Report

The Monitor should complete the appropriate Site Performance Evaluation & Monitoring Report within ten business days of the site visit and forward an electronic copy of the completed draft report to the Research Clinic Director or Delegate for review.

8.2 Auditing Procedures

Audits of clinical research activities in accordance with Bausch + Lomb'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).

8.3 Source Documentation

Source documentation consists of original subject documents, as well as data and records with information relevant to the subject and his/her participation in the study. The data collected in the e-CRFs at all the visits will be available to the Investigator after the conclusion of the trial.

Examples of source documents include: hospital records, clinical and office charts, laboratory notes, memoranda, signed ICF, evaluation checklists, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, and information initially recorded in an electronic format.

Subject completed forms are also considered to be source data, if applicable to the study. The Investigator or designee should review subject completed forms for completeness and accuracy.

8.4 Maintaining Subject Privacy

Subjects' participation in this study and their study records (including photographs and video/audiotapes) will be held in a way that will protect their privacy, except when ordered by law. It may be necessary for other people to review their records for study reasons. These people may include:

- The Investigator
- The United States Food and Drug Administration (FDA)
- Other state or federal regulatory agencies
- The Institutional Review Board (IRB)
- Contracted monitors or auditors
- Bausch + Lomb personnel associated with the study analysis and reporting

If this occurs, their identity will be protected as legally required. If results of the study are published, subjects will not be identified by name.

The Institutional Review Board and accrediting agencies may inspect and copy subjects' records, which may have the subjects' name on them. Therefore, total confidentiality cannot be

guaranteed. If the study results are presented at meetings or printed in publications, subject names will not be used.

Data pertaining to subjects is only available to Bausch + Lomb personnel. Physical data remains locked and electronic data is password protected. When subjects receive an electronic recruitment invitation, all other potential subjects are blind carbon copied on the invitation to ensure privacy.

Clinical trial data is input into a secure, electronic data capture system in which only relevant study personnel have access. Subject data recorded on e-CRFs during the study will be documented in a coded fashion. The subject will only be identified by the subject number. Confidentiality of subject records must be maintained to ensure subject privacy.

8.5 Locking the Database

After the study is complete, the data is approved by the Principal Investigator via electronic signature. The database is then locked. Any change to the data after database lock will require approval from the EDC Programmer and is documented via electronic audit trail.

8.6 Retention of Documents

Bausch + Lomb will retain essential documents after the completion of the study. The Research Clinic keeps physical study related documents physically on-site for a minimum of 3 years. After 3 years, the documents may be securely stored in an off- site location. Additionally, data is securely stored electronically.

Essential documents include but are not limited to the following:

- IRB approvals for the study protocol, all amendments, ICF(s), and advertisements
- IRB correspondence and reports (e.g., AE reports, protocol deviations, and safety updates)
- regulatory documents
- subject's signed ICF
- accountability records for the test article(s)
- any other documents relevant to the conduct of the study

8.7 Clinical Quality Assurance

Prior to being evaluated clinically, investigational devices such as contact lenses or solutions are analyzed and approved for release by the project manager and design quality at Bausch and Lomb, Rochester, NY. Documentation of pre-clinical testing can be found on the study's clinical scorecard for the relevant products.

8.8 Institutional Review Board

The Investigator should ensure their participation in the study, in addition to the protocol, subject recruitment materials and the ICF to be used in this study are approved by the reviewing IRB prior to entering any subjects in the study. In addition, the Investigator must ensure that the reviewing IRB has provided approval for any protocol amendments prior to implementation. If the amendment necessitates a revision to the ICF, the Investigator should ensure the revised form is also submitted to and approved by the IRB and implemented as directed.

8.9 Statements of Compliance

This study is being conducted in accordance with 21CFR Parts 11, 50, 54, 56 and 812; 42 CFR Part 11 – Clinical Trials Registration and Results Information Submission; ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good Clinical Practice; International Council for Harmonization (ICH) Good Clinical Practice (GCP) - Declaration of Helsinki and applicable local regulations.

This clinical investigation will demonstrate compliance with this document.

The clinical investigation shall not begin until the required approval from the IRB has been obtained. Any additional requirements imposed by the IRB shall be followed.

No insurance will be provided to the subjects.

Bausch + Lomb is financing this clinical investigation. The investigators are paid employees of Bausch + Lomb.

8.10 Informed Consent Process

All subjects will be given a copy of the Informed Consent Form (ICF) to read prior to enrollment. Subjects will have an opportunity to ask questions prior to enrollment and throughout the study. The ICF also contains information on payment for participating in the study. All subjects will need to sign the ICF prior to participation in the study. The person obtaining informed consent will also sign and date the form. The subject's signed informed consent must be obtained before conducting any study related procedures. The original will be retained by the investigative site. A copy of the signed ICF will be given to the subject. If modifications are made to the ICF, the new version must be approved by the IRB. The new version of revised ICF(s) must be reviewed and signed by all active (if required by the IRB) and new subjects at the first opportunity after approval by the IRB.

For this study, subjects will have the capacity to provide written voluntary consent. Emergency treatment is not applicable. No minors or those who cannot speak English or read or write will be recruited for this study.

8.10.1 Vulnerable Population

[redacted]

[redacted]

All subjects will be given a copy of the Informed Consent Form (ICF) to read and will also have an opportunity to ask questions to the Investigator or designee prior to enrollment. All subjects will need to sign the Informed Consent Form prior to participation in the study.

[redacted]

After the study is complete, there is no planned/routine medical follow-up care.

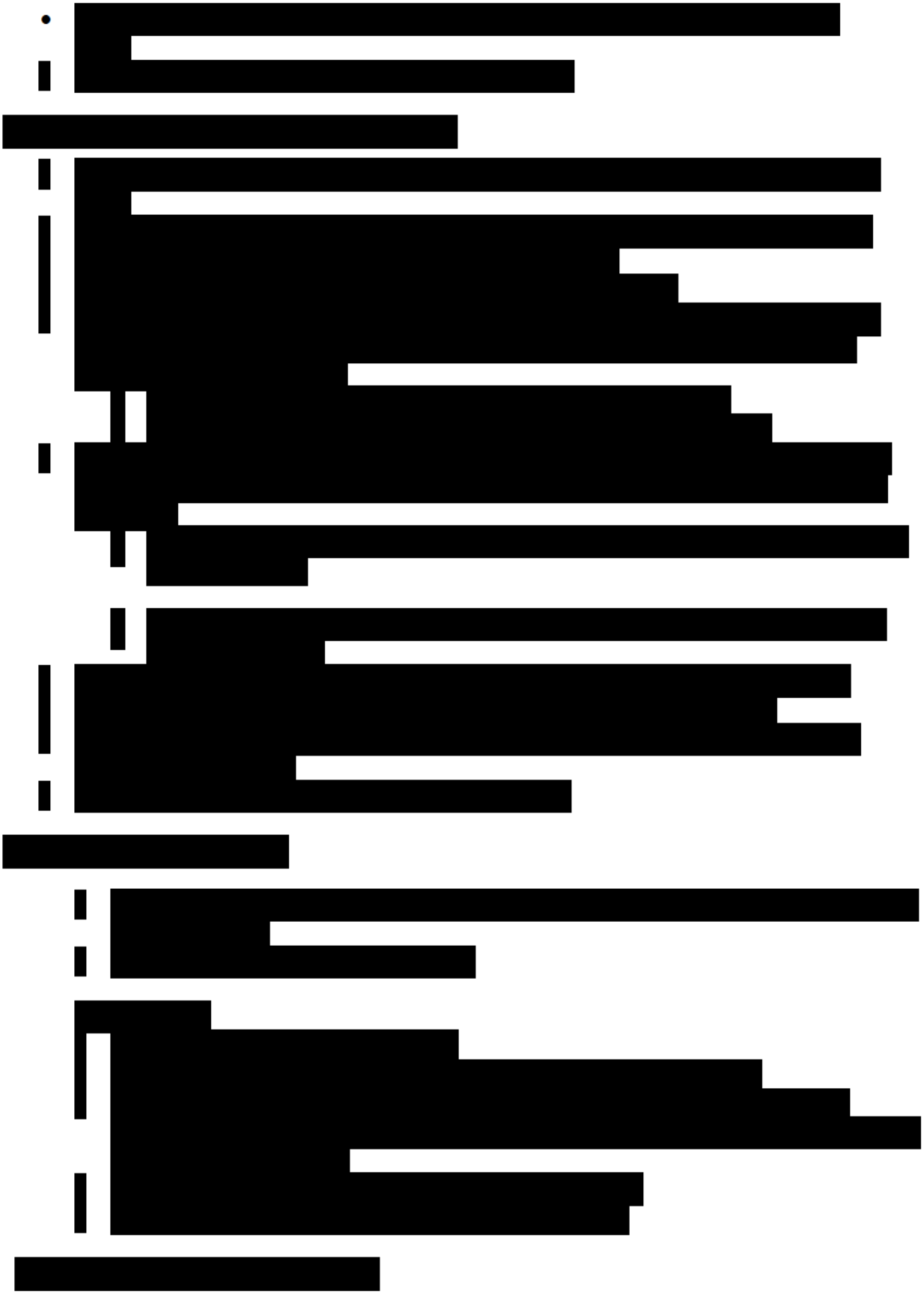
8.11 Publication of Results

All study data generated as a result of this study will be regarded as confidential, until appropriate analysis and review by Bausch + Lomb or its designee and the Investigator(s) are completed. The results of the study may be published or presented by Bausch + Lomb.

9.0 BIBLIOGRAPHY

There are no references for this study.

APPENDIX A: METHODS OF CLINICAL EVALUATION





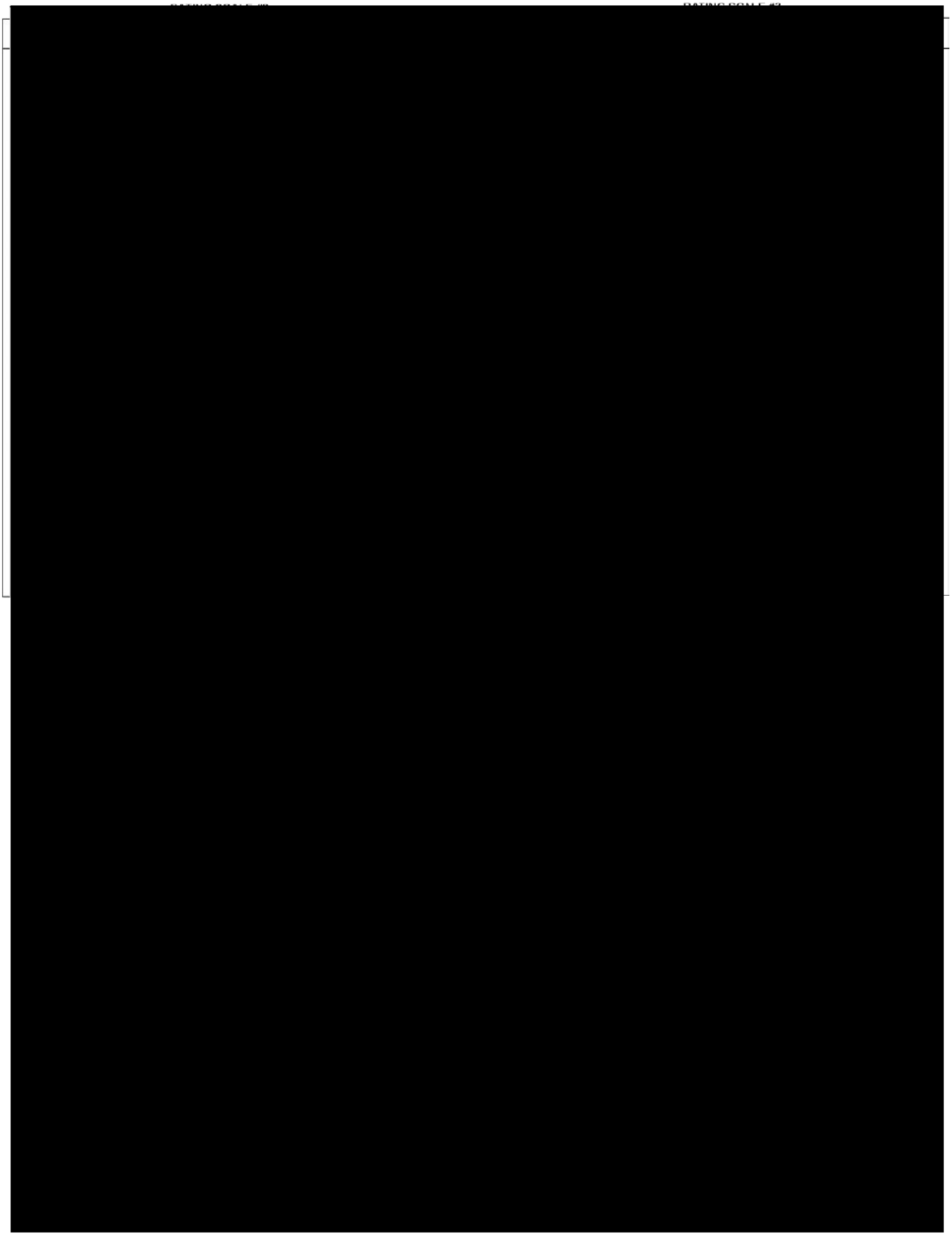


1. [redacted]

3.0 SUBJECTIVE ASSESSMENT RATING SCALES

Subjective Assessment Rating Scales used for collecting subjective data for clinical studies.

[redacted]



APPENDIX B: SUBJECT INSTRUCTIONS FOR USE

CAUTION: Investigational device. Limited by Federal (U.S.A.) Law to investigational use only.

[redacted]

STUDY PRODUCT INFORMATION

[redacted]

[redacted]

[redacted]

[redacted]

All study materials, used and unused, must be returned.

If you have questions or problems, call:

[redacted]

If you require a medical referral for any eye problems experienced during the study, please refer to your informed consent form.

GENERAL INFORMATION

These subject instructions apply to both test and control study materials. For all study lenses, it is essential to your safety that you read and understand the information and instructions in these subject instructions, and have your questions answered before and after you receive contact lenses.

Wearing contact lenses is different from wearing eyeglasses. 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 that 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 begin or to continue wearing contact lenses for daily disposable wear, you should discuss with the study investigator the effects of contact lenses on your eyes and the risks associated with wearing contact lenses. You also should read the sections in these subject instructions entitled "Warnings", "Adverse Reactions", "Precautions", and "Wearing Restrictions and Indications". Ask the investigator to explain anything that you do not understand, including any additional restrictions which may be given to you.

You also need to remember that soft contact lenses, including those covered by these subject 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 the instructions contained in these subject instructions entitled "Personal Cleanliness and Lens Handling", 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 build-up of deposits on the lenses, which can lead to serious, sight-threatening eye infections and injuries.

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

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

WEARING RESTRICTIONS AND INDICATIONS:

Both the Test and Control contact lens designs are intended for the daily disposable wear and correction of refractive error (myopia) in persons with non-diseased eyes

WARNINGS:

You should be aware of and fully discuss with the study investigator 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**.
- Strict compliance with your wearing restrictions, wearing schedule, and follow-up visit schedule must be followed.
- Daily disposable wear 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 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 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.

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

Lens 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 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.
- Always handle your lenses carefully and avoid dropping them.
- Do not touch the lens with your fingernails.
- Carefully follow the handling, insertion, removal, storing and wearing instructions in these subject instructions and those prescribed by the study investigator.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Lens Wearing Precautions

- Never wear your lenses beyond the period recommended by your eye care professional.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking (Nonmoving) Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should **immediately** consult your eye care professional.
- 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.

Topics to Discuss with the Eye Care Professional:

- You should not wear contact lenses during 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 your eye care professional before using any medicine in the eyes.

Who should know that you are wearing contact lenses?

- You may decide to inform your health care professional about being a contact lens wearer.
- Always inform your employer of being a contact lens wearer. Some jobs may require the

use of eye protection equipment or may require that you not wear lenses.

- Ask the study investigator whether there are any other wearing restrictions that apply to you. Write those restrictions in the spaces provided below and follow them carefully:

_____

_____

_____

_____

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 visual acuity)
- 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 on your eye. You should remove the lens and place it in the provided contact lens case dry. Then 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 immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS AND LENS HANDLING:

1. Preparing the Lens for Wearing:

It is essential that you learn and use good hygienic methods in the care and handling of your new 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 a 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.

2. Handling the Lenses:

- 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, clear, 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.
    a) Less than usual comfort,
    b) The lens may fold on the eye,
    c) Excessive lens movement on blink,
    d) Blurred vision.
- If the lens folds and sticks together: Place the lens in the palm of your hand and wet thoroughly with the recommended rinsing or storing solution. Then GENTLY rub the lens between your index finger and palm in a gentle back and forth motion.
- 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.

3. Placing the Lens on the Eye

There are other methods of lens placement. If the following methods are difficult for you, your Study Doctor 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 care professional.

A. **The One-Hand Placement Technique**

- Place the lens on your index finger. 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.

B. **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."





4. 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 towards 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 towards the lens to place it on the center of the eye.

5. Removing the Lens

- Always remove the same lens first.
- Wash, rinse, and dry your hands thoroughly.
- 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.
- Remove the other lens by following the same procedure.
- Follow the required lens care procedures described by your eye care professional.
- NOTE: If this method of removing your lens is difficult for you, your eye care professional will provide you with an alternate method.

6. Return of Your Study Lenses

At each visit, you must return all worn and unworn lenses that were dispensed to you during the designated wear periods.

7. Emergency:

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.