BAUSCH + LOMB

Protocol ID: 916

Protocol Title: A Study to Evaluate the Product Performance of a New Silicone Hydrogel Multifocal Contact Lens

Sponsor: Bausch & Lomb Incorporated

[redacted]

BAUSCH + LOMB

[redacted]

A Study to Evaluate the Product Performance of a New Silicone Hydrogel Multifocal Contact Lens

PROTOCOL/CLINCIAL INVESTIGATION PLAN

STUDY # 916

Sponsor: Bausch & Lomb Incorporated

This clinical investigation is being conducted in accordance with 21 CFR Parts 11, 50, 54, 56 and 812; 42 CFR Part 11 – Clinical Trials Registration and Results Information Submission; EN ISO 14155:2020 *Clinical investigation of medical devices for human subjects – Good clinical practice*; Medical Device Regulation (MDR) 2017/745; International Council for Harmonisation (ICH) Good Clinical Practice; the Declaration of Helsinki and applicable local regulations. Additional information on the investigational test article(s) is presented in the Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens Investigator's Brochure[1].

Revision Chronology:

Amendment 1	**29 NOVEMBER 2022**
Original	21 SEPTEMBER 2022

Key design elements of this protocol will be registered on www.clinicaltrials.gov as required by current regulations and, if applicable, other public databases as required by local country regulations. In addition, results of this study will be made publicly available on www.clinicaltrials.gov regardless of outcome as required by current regulations and, if applicable, in other public databases as required by local country regulations. The identity of the subjects who participated in the study will be maintained confidential.

INVESTIGATOR STATEMENT OF APPROVAL

A Study to Evaluate the Product Performance of a New Silicone Hydrogel Multifocal Contact Lens

STUDY # 916

I have read this clinical study protocol and concur that it contains all information necessary to conduct the study and agree to abide by all provisions set forth therein.

I agree to conduct this study in accordance with 21 CFR Parts 11, 50, 54, 56 and 812; 42 CFR Part 11 – Clinical Trials Registration and Results Information Submission; EN ISO 14155:2020 *Clinical investigation of medical devices for human subjects – Good clinical practice*; Medical Device Regulation (MDR) 2017/745; International Council for Harmonization (ICH) Good Clinical Practice; the Declaration of Helsinki and applicable local regulations.

I will not initiate the study until I have obtained written approval by the appropriate IRB/EC and have complied with all financial and administrative requirements of the governing body of the clinical institution and the Sponsor. I agree to obtain written informed consent from each study subject prior to performing any study specific procedures.

I understand my obligation as the Principal Investigator to supervise all testing of the investigational products used in this study involving human subjects and to ensure that the investigational product is dispensed as per protocol.

I understand my obligation as the Principal Investigator to ensure that all study personnel assisting in the conduct of the study are qualified and are properly trained to conduct their assigned tasks and obligations during the entire course of the trial. I agree to maintain adequate and accurate records in accordance with government regulations and to make those records available for inspection.

I testify that I have never been disqualified as an Investigator by any Regulatory Authority, and have never been involved in a study or other research that was terminated due to misconduct or fraudulent activity

I understand that my signature on this document indicates my agreement to this Clinical Investigational Plan/Protocol and to review and, if appropriate, sign the clinical study report. I understand that my signature on electronic case report forms indicates that the data therein has been reviewed and accepted by me.

I understand that this document and related information is subject to confidentiality terms found in my signed Confidentiality or Clinical Services Agreement. I agree to protect the confidentiality of my patients when allowing the Sponsor of this clinical investigation, and/or relevant regulatory authorities and IRBs, direct access to my medical records for study subjects.

_____

Principal Investigator, Printed Name

_____ _____

Principal Investigator, Signature Date

Address of Principal Investigator

_____

_____

PERSONNEL RESPONSIBLE FOR CONDUCTING THE STUDY

Function	Organization
Study Sponsor: protocol, investigational product supply and distribution, safety monitoring and reporting to FDA, study oversight, regulatory, and auditing	Bausch & Lomb Incorporated 1400 North Goodman Street Rochester, NY 14609 USA Main telephone number: 585-338-5306
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

SYNOPSIS

Name of Sponsor/ Company:
Bausch & Lomb Incorporated

Study:
#916

Name of Investigational Product:
Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens

Title of Study:
A Study to Evaluate the Product Performance of a New Silicone Hydrogel Multifocal Contact Lens

Number of Clinical Centers:
Approximately 18 to 20 investigative sites in the United States

Objective:
The objective of this study is to evaluate the product performance of a new silicone hydrogel daily disposable multifocal contact lens, the Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens, when worn by current soft contact lens wearers on a daily disposable wear basis.

Methodology:
This is a single-treatment study evaluating the product performance of a new silicone hydrogel multifocal daily disposable contact lens.

- Approximately 300 subjects (600 eyes) will be enrolled in this 3-week, single-arm, bilateral, open-label study at approximately 20 investigative sites in the United States.
- Habitual wearers of multifocal soft contact lenses will be required to wear dispensed study lenses on a daily disposable basis for approximately 3 weeks, with scheduled in-office follow-up visits at 1 week and 3 weeks

Number of Subjects Planned:
Approximately 300 subjects (600 eyes), with at least 270 subjects expected to complete the study.

Diagnosis and Main Criteria for Inclusion:

1. Subjects must be age 40 years or older on the date the ICF is signed and have the capacity to provide voluntary informed consent
2. Subjects must be willing and able to comply with all treatment and follow-up/study procedures, as well as willing and able to refrain from using any contact lenses other than those provided for the duration of the study
3. Subjects must be correctable through spherocylindrical refraction to 42 letters (0.1 logMAR) or better (distance, high contrast) in each eye
4. Subjects must have clear central corneas and be free of any anterior segment disorders
5. Subject must wear their current lenses for a minimum of 12 hours per day at least four days per week
6. Subjects must habitually wear a multifocal lens in each eye
7. Subjects must be an adapted multifocal soft contact lens wearer for a minimum of 6 months
8. Subjects must require distance lens correction from +3.00 to -6.00 D in each eye
9. Subjects must be presbyopic and require near add correction from +0.75 to +2.50 D in each eye
10. Subjects must have access to an internet connection to complete an online survey and be able to receive text message

Exclusion Criteria:

1. Subjects participating in any drug or device clinical investigation within 30 days prior to entry into this study and/or plan to do so during the period of study participation
2. Subjects who are women of childbearing potential (those who are not surgically sterilized or postmenopausal) are excluded from participation in the investigation if they meet any one of the following conditions:
   - She is currently pregnant
   - She plans to become pregnant during the study
   - She is breastfeeding
3. Subjects with any systemic disease currently affecting ocular health or that, in the Investigator's opinion, may have an effect on ocular health during the course of the study
4. Subjects with an active ocular disease
5. Subjects who have had any corneal surgery (e.g., refractive surgery)
6. Subjects who have worn gas-permeable (GP) contact lenses within the last 30 days or who have worn polymethylmethacrylate (PMMA) lenses within the last 3 months
7. Subjects who currently wear monovision or toric contact lenses

8. Subjects who are not correctable to 32 letters (0.3 logMAR) with bilateral soft multifocal contact lenses
9. Subjects with an ocular astigmatism >1.00 D in either eye
10. Subjects with anisometropia (spherical equivalent) >2.00 D
11. Subjects with any Grade ≥2 finding during the slit lamp examination. Subjects with corneal infiltrates of ANY GRADE are not eligible
12. Any "Present" finding during the slit lamp examination that, in the Investigator's opinion, interferes with contact lens wear
13. Any scar or neovascularization within the central 6 mm of the cornea. Subjects with minor peripheral corneal scarring (that does not extend into the central area) that, in the Investigator's opinion, does not interfere with contact lens wear are eligible for this study
14. Subjects who are amblyopic
15. Subjects using any systemic or topical ocular medication that will, in the Investigator's opinion, affect ocular physiology or lens performance
16. Subjects who are allergic to any component in the study care products

Investigational Product, Dosage and Mode of Administration:

The Test lens to be used in this study is the Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens, manufactured by Bausch & Lomb Incorporated, Rochester, NY. The description of the Test lens is as follows:

- Sphere power: +3.00 to -6.00
- Add: Low and High
- Diameter: 14.2 mm
- Base curve: 8.6 mm
- Material: kalifilcon A
- Packaging solution: phosphate-buffered solution

The Investigator or designee will instruct all subjects that they must comply with the Subject Instructions provided to them.

Subjects will be instructed that other contact lenses (other than the assigned study lenses) and contact lens care products (other than any eye drops provided) are not allowed to be used during the study.

Study Duration of Treatment:

Approximately 3 weeks

Criteria for Evaluation:

- The primary endpoint is the proportion of subjects agreeing with the statement "Clear vision: near, far, and in-between"

Statistical Methods:

Continuous variables will be summarized using the sample size, mean, standard deviation, median, minimum, and maximum. Categorical variables will be summarized using frequencies and percentages.

The responses to the primary endpoint statement will be summarized using categorical summary statistics (strongly agree, agree, slightly agree, neither agree nor disagree, slightly disagree, disagree, strongly disagree).

Responses of strongly agree, agree, and slightly agree will be coded to a category "Agree." Responses of strongly disagree, disagree, and slightly disagree will be coded to a category "Disagree." The trichotomized responses will be summarized categorically (agree, neither agree nor disagree, disagree).

Neutral responses (i.e., "neither agree nor disagree") will not be included in the primary statistical analysis. The non-neutral responses used for the analysis will be presented using categorical summary statistics (agree, disagree). An exact 95% confidence interval around the proportion of subjects agreeing with the statement will be presented along with the p-value from a one-sided exact binomial test of the alternative hypothesis is that the proportion of subjects agreeing is greater than 0.5.

Sample Size Calculations:

Approximately 300 subjects will be enrolled. Allowing for up to 10% losses, power calculations were completed for 270 completed subjects. An exact binomial test with a nominal 5% one-sided significance level will have 93% power to detect the difference between the Null hypothesis proportion, π_0 of 0.5 and the Alternative proportion, π_1, of 0.6 when the sample size is 270.

TABLE OF CONTENTS

PAGE

1.0 INTRODUCTION 14

2.0 BACKGROUND, RATIONALE AND OBJECTIVES 14

2.1 Intended Purpose of Device 14
2.2 Target Population 14
2.3 State of the Art 14
2.4 Objective of Study 14
2.5 Minimization of Bias and Confounding Factors 14

3.0 STUDY DESIGN 15

3.1 Description of Study Design 15
3.2 Informed Consent Process 15
3.3 Selection of Study Population 15
3.3.1 Eligibility 16
3.3.2 Subject Completion 17
3.3.3 Subject Discontinuation 17
3.3.4 Lost to Follow-up 18
3.4 Investigators 19
3.5 Finances 19
3.6 Study Duration 19

4.0 STUDY MATERIALS 19

4.1 Description of Investigational Test Article (Test) 20
4.2 Description of Control Product (Comparator) 20
4.3 Instructions for Use and Administration 20
4.3.1 Storage Requirements 20
4.3.2 Subject Instructions 20
4.3.3 Fitting Guide 21
4.4 Packaging and Labeling 21
4.5 Other Materials 21
4.6 Product Replacement 21
4.7 Accountability and Traceability 21
4.8 Masking/Unmasking 22
4.9 Product Risk Assessment 22

5.0 STUDY METHODS 22

5.1 Study Visits 22
5.1.1 Screening/Dispensing Visit 23
5.1.2 1-Week Follow-up Visit 25
5.1.3 3-Week Follow-up 26
5.1.4 Exit Visit 28
5.1.5 Unscheduled Visits 28
5.1.6 Missed Visits 30
5.1.7 Product Dispensing Only Visit 30
5.1.8 Post Study Follow-up 30
5.2 Questionnaires and Surveys 31
5.2.1 Baseline Questionnaire 31
5.2.2 Online Consumer Survey 31
5.2.3 Investigator Survey 31
5.3 Study Completion / Early Study Terminations / Suspensions 31
5.3.1 Study Completion 31
5.3.2 Early Study Termination/Suspension 32
5.4 Concomitant Medications/Therapy 32
5.5 Treatment Compliance 32
5.6 Protocol Deviations 32

6.0 ADVERSE EVENTS 32

6.1 INTRODUCTION TO ADVERSE EVENT DEFINITIONS 32
6.1.1 Serious Adverse Event (SAE) Definitions 33
6.1.2 Significant Non-Serious Adverse Event Definitions 34
6.1.3 Non-Significant Non-Serious Adverse Events Definitions 34
6.1.4 Adverse Device Effect (ADE) Definitions 34
6.1.5 Relationship Definition: Study Device and/or Other Study Materials 35
6.1.6 Severity Definitions 35
6.2 PROCEDURES FOR EVALUATING ADVERSE EVENTS 36
6.2.1 Procedures for Reporting Serious or Significant Adverse Events 36
6.2.2 Procedures for Reporting Off-Site Unanticipated Serious Adverse Device Effects 37
6.2.3 Device Deficiencies: Definition and Reporting Procedures 37
6.2.4 Procedures for Culturing of Corneal Ulcer or Suspected Ocular Infection 38
6.2.5 Guidelines for Reporting Pregnancies 38

7.0 STATISTICAL METHODS 39

7.1 ASSESSMENT OF EFFECTIVENESS 39
7.1.1 Primary Effectiveness Endpoints 39
7.1.2 Secondary Effectiveness Endpoints 39
7.1.3 Supportive Effectiveness 39
7.1.4 Statistical Hypothesis Testing and Control of Multiplicity 40
7.1.5 Descriptive Statistics 41
7.1.6 Pooling Analysis 41
7.1.7 Missing Effectiveness Data 41
7.1.8 Effectiveness Sensitivity Analysis 41
7.1.9 Subject Self-Assessments 41
7.2 ASSESSMENT OF SAFETY 41
7.2.1 Adverse Events 41
7.2.2 Clinical Safety Examinations 42
7.2.3 Concomitant Medications 42
7.3 SUBJECT DISPOSITION 42
7.4 DEMOGRAPHICS AND BASELINE CHARACTERISTICS 42
7.5 PROTOCOL DEVIATIONS 42
7.6 COMPLIANCE 43
7.7 INTERIM ANALYSES 43
7.8 ADDITIONAL STATISTICAL CONSIDERATIONS 43
7.8.1 Analysis Populations 43
7.8.2 Sample Size Determination 43
7.8.3 Handling of Missing Data 43
7.8.4 Multicenter Issues 43
7.8.5 Multiplicity Issues 43

8.0 DATA QUALITY ASSURANCE 43

8.1 SUBJECT CONFIDENTIALITY 43
8.2 STUDY MONITORING 44
8.3 SOURCE DOCUMENTATION 45
8.4 ELECTRONIC CASE REPORT FORMS AND DATA VERIFICATION 45
8.5 RECORDING OF DATA AND RETENTION OF DOCUMENTS 46
8.6 AUDITING PROCEDURES 46
8.7 INSTITUTIONAL REVIEW BOARD 47
8.8 PUBLICATION OF RESULTS 47

9.0 REFERENCES 48

APPENDICES

APPENDIX A: SCHEDULE OF VISITS AND PARAMETERS 49

APPENDIX B: METHODS OF CLINICAL EVALUATION 51

APPENDIX C: SUBJECT INSTRUCTIONS 69

APPENDIX D: FITTING GUIDE 76

GLOSSARY OF TERMS

Adverse Device Effect (ADE)	Adverse event related to the use of an investigational medical device. Note 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. Note 2: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.
Adverse Event (AE)	Untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated. Note 1: This definition includes events related to the investigational medical device. Note 2: This definition includes events related to the procedures involved. Note 3: For users or other persons, this definition is restricted to events related to the use of investigational medical devices.
Anticipated Serious Adverse Device Effect (ASADE)	Anticipated serious adverse device effect is an effect which by its nature, incidence, severity or outcome has been identified in the risk assessment.
Device Deficiency	Inadequacy of a medical device with respect to its identity, quality, durability, reliability, usability, safety or performance. Note 1: Device deficiencies include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling. Note 2: This definition includes device deficiencies related to the investigational medical device.
Investigational Medical Device	A medical device being assessed for clinical performance, effectiveness, or safety in a clinical investigation Note 1: This includes medical devices already on the market that are being evaluated for new intended uses, new populations, new materials or design changes. Note 2: This includes medical devices already on the market that are being evaluated within their intended use in a post-market clinical investigation (interventional or non-interventional). Note 3: The terms “investigational medical device” and “investigational device” are used interchangeably.
Life-threatening adverse event	An adverse event is considered “life-threatening” if, in the view of either the investigator or Sponsor, its occurrence places the patient or subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more

	severe form, might have caused death.
Malfunction	Failure of a medical device to perform in accordance with its intended purpose when used in accordance with the instructions for use or clinical investigation plan.
Medical Device	An instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; control of conception; disinfection of medical devices; providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.
Serious Adverse Device Effect (SADE)	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Serious Adverse Event (SAE)	An adverse event that led to any of the following outcomes: a) Death b) Serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following: 1) a life-threatening illness or injury, or 2) a permanent impairment of a body structure or a body function including chronic diseases, or 3) in-patient or prolonged hospitalization, or 4) medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure or a body function, c) Fetal distress, fetal death, a congenital abnormality, or birth defect including physical or mental impairment.

Serious Health Threat	Signal from any adverse event or device deficiency that indicates an imminent risk of death or a serious deterioration in the health in subjects, users or other persons, and that requires prompt remedial action for other subjects, users or other persons. Note 1: This would include events that are of significant and unexpected nature such that they become alarming as a potential serious health hazard or possibility of multiple deaths occurring at short intervals.
Treatment-Emergent Adverse Event	A treatment-emergent adverse event is defined as any event not present prior to the initiation of the treatments or any event already present that worsens in either intensity or frequency following exposure to the treatments.
Unanticipated Adverse Device effect (UADE) or Unanticipated Serious Adverse Device Effect (USADE)	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. [FDA, 21CFR 812.3] USADE: Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current risk assessment. [EN ISO 14155:2020]
Unanticipated Serious Adverse Device Effect (USADE)	Unanticipated adverse device effect is a serious adverse event caused by or related to use of a medical device not previously identified in nature, severity, or degree of incidence in the current risk assessment, or any unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
Use Error	User action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user. Note 1: Use errors includes slips, lapses and mistakes. Use error includes the inability of the user to complete a task. Note 2: Use errors can result from a mismatch between the characteristics of the user, user interface, task or use environment. Note 3: Users might be aware or unaware that a use error has occurred. Note 4: An unexpected physiological response of the patient is not by itself considered a use error. Note 5: A malfunction of a medical device that causes an unexpected result is not considered a use error.
Vulnerable Subject	Individuals who are unable to fully understand all aspects of the investigation that are relevant to the decision to participate, or who could be manipulated or unduly influenced as a result of a compromised position, expectation of benefits or fear of retaliatory response.

LIST OF ACRONYMS and ABBREVIATIONS

Abbreviation /Acronym	Term
ADE	Adverse Device Effect
AE	Adverse Event
ASADE	Anticipated Serious Adverse Device Effect
BSCVA	Best Spectacle-corrected Visual Acuity
CFR	Code of Federal Regulations
D	Diopter
eCRF	Electronic Case Report Form
EC	Ethics Committee
EDC	Electronic Data Capture
FDA	United States Food and Drug Administration
GCPs	Good Clinical Practice
GP	Gas Permeable
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
ID	Identification
IRB	Institutional Review Board
ISO	International Organization for Standardization
logMAR	Logarithm of the Minimum Angle of Resolution
MDR	Medical Device Regulation
mm	Millimeter
OD	Right Eye
OS	Left Eye
OU	*Oculi Unitas*; Both eyes used together
PMMA	Polymethylmethacrylate
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TEAE	Treatment-Emergent Adverse Event
USADE	Unanticipated Serious 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).***

1.0 INTRODUCTION

Bausch & Lomb Incorporated ("Bausch + Lomb") is evaluating the product performance of a new silicone hydrogel daily disposable multifocal contact lens. The Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens is indicated for correcting the effects of refractive ametropia, including myopia, hyperopia, and presbyopia. The kalifilcon A material is a hydrophilic, silicone hydrogel with 55% water and high oxygen permeability to promote acceptable eye health and favorable wear experience. The lens is supplied sterile in a plastic package containing phosphate-buffered saline solution with potassium chloride, poloxamine, poloxamer 181, glycerin, and erythritol to promote a favorable wear experience**.**

2.0 BACKGROUND, RATIONALE AND OBJECTIVES

2.1 Intended Purpose of Device

The Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens is intended for use for the correction of refractive ametropia (myopia and hyperopia) and presbyopia.

2.2 Target Population

The Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens is for use by patients prescribed the correction of refractive ametropia, (including myopia and hyperopia), and presbyopia by means of soft contact lenses, regardless of gender, age, or ethnicity, and who do not have contraindications for the device.

2.3 State of the Art

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**.**

2.4 Objective of Study

The objective of this study is to evaluate the product performance of a new silicone hydrogel daily disposable multifocal contact lens, the Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens, when worn by current soft contact lens wearers on a daily disposable wear basis.

2.5 Minimization of Bias and Confounding Factors

The Sponsor will avoid improper influence on any parties participating in, or contributing to, the clinical investigation or the induction thereof. The selection and treatment of subjects and evaluation of clinical investigation data are potential sources of bias. Methods that are incorporated within the clinical investigation design to minimize potential bias include, but are not limited to, screening subjects to confirm eligibility with defined inclusion/exclusion criteria prior to enrollment; maintaining a log of all subjects screened and enrolled; collecting demographics and medical ocular history at baseline to later assess possible characteristics that may influence endpoints; standardizing data collection requirements and clinical investigation procedures; requiring a Financial Disclosure by Investigators; using standardized training materials for all trial personnel; and by

scheduling regular monitoring visits to be conducted to verify adherence to the clinical investigation plan and source data.

3.0 STUDY DESIGN

3.1 Description of Study Design

The is a single-treatment study evaluating the product performance of a new silicone hydrogel multifocal daily disposable contact lens.

Approximately 300 subjects (600 eyes) will be enrolled in this 3-week, single-arm, bilateral, open-label study at approximately 20 investigative sites in the United States.

The study is designed to include habitual wearers of multifocal lenses. All subjects will be seen for a Screening/Dispensing Visit, at which time informed consent will be obtained and eligibility will be assessed.

All consented subjects will be assigned a subject identification (ID) number in sequential order by the Electronic Data Capture (EDC) system. At the Screening/Dispensing Visit, all eligible subjects will receive study contact lenses to wear on a daily disposable basis for approximately 3 weeks, with scheduled in-office follow-up visits at 1 week and 3 weeks.

3.2 Informed Consent Process

Voluntary written informed consent must be obtained from every subject prior to the initiation of any study-related activities. The Investigator must have a defined process for obtaining consent. Subjects must be given ample time to read, understand, and ask questions, in order to consider voluntary participation. The subject must indicate voluntary consent by providing a written signed and dated informed consent form (ICF). A copy of the signed and dated ICF must be provided to the subject, and the original document must be filed in the subject's study records.

The ICF must meet all applicable local laws and be written in language that the subject understands. Subjects must be informed that their participation in the study is voluntary and that their decision to withdraw from participation at any time during the study will not impact any aspect of their standard care. Subjects will be provided with contact information for the appropriate individuals should questions or concerns arise after signing the ICF during the clinical study.

Subjects must also be informed that their records may be accessed by appropriate authorities and Sponsor-designated personnel. The Investigator must ensure all procedures and practices are in place to protect the privacy and the best interest of the subject.

3.3 Selection of Study Population

Recruitment for the study may start at any point after the Investigator agrees, in writing, to participate in the study. Written informed consent, including Health Insurance Portability and Accountability Act (HIPAA), enrollment in the study, or dispensing of study products cannot begin until the Investigator has received Institutional Review Board (IRB) and Sponsor 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 or not they participate in the study. The Sponsor will record information for each potential study subject who signs an ICF.

Once a potential subject is consented, their information will be recorded on the screening log and the Investigator should proceed with screening procedures.

Potential subjects will be classified as eligible or "Screen Failures." A subject deemed a Screen Failure cannot participate in the study since he/she has not met the study inclusion criteria or has met the exclusion criteria. Electronic case report forms (eCRFs) must be completed for screen failure subjects and a copy of their signed ICF, and any information collected as part of screening (e.g., source documents, etc.) must be kept in their permanent records.

Once a subject is enrolled (i.e., a subject ID number is assigned), a subject is considered active and must be accounted for at every visit until exited (completed or discontinued) from the study, even if they are not dispensed study materials. Refer to Section 3.3.4 for subjects determined to be lost to follow-up.

3.3.1 Eligibility

3.3.1.1 Inclusion Criteria

1. Subjects must be age 40 years or older on the date the ICF is signed and have the capacity to provide voluntary informed consent
2. Subjects must be willing and able to comply with all treatment and follow-up/study procedures, as well as willing and able to refrain from using any contact lenses other than those provided for the duration of the study
3. Subjects must be correctable through spherocylindrical refraction to 42 letters (0.1 logMAR) or better (distance, high contrast) in each eye
4. Subjects must have clear central corneas and be free of any anterior segment disorders
5. Subject must wear their current lenses for a minimum of 12 hours per day at least four days per week
6. Subjects must habitually wear a multifocal lens in each eye
7. Subjects must be an adapted multifocal soft contact lens wearer for a minimum of 6 months
8. Subjects must require distance lens correction from +3.00 to -6.00 D in each eye
9. Subjects must be presbyopic and require near add correction from +0.75 to +2.50 D in each eye
10. Subjects must have access to an internet connection to complete an online survey and be able to receive text message

3.3.1.2 Exclusion Criteria

1. Subjects participating in any drug or device clinical investigation within 30 days prior to entry into this study and/or plan to do so during the period of study participation
2. Subjects who are women of childbearing potential (those who are not surgically sterilized or postmenopausal) are excluded from participation in the investigation if they meet any one of the following conditions:
   - She is currently pregnant

- She plans to become pregnant during the study
- She is breastfeeding

3. Subjects with any systemic disease currently affecting ocular health or that, in the Investigator's opinion, may have an effect on ocular health during the course of the study
4. Subjects with an active ocular disease
5. Subjects who have had any corneal surgery (e.g., refractive surgery)
6. Subjects who have worn gas-permeable (GP) contact lenses within the last 30 days or who have worn polymethylmethacrylate (PMMA) lenses within the last 3 months
7. Subjects who currently wear monovision or toric contact lenses
8. Subjects who are not correctable to 32 letters (0.3 logMAR) with bilateral soft multifocal contact lenses
9. Subjects with an ocular astigmatism >1.00 D in either eye
10. Subjects with anisometropia (spherical equivalent) >2.00 D
11. Subjects with any Grade ≥2 finding during the slit lamp examination. Subjects with corneal infiltrates of ANY GRADE are not eligible
12. Any "Present" finding during the slit lamp examination that, in the Investigator's opinion, interferes with contact lens wear
13. Any scar or neovascularization within the central 6 mm of the cornea. Subjects with minor peripheral corneal scarring (that does not extend into the central area) that, in the Investigator's opinion, does not interfere with contact lens wear are eligible for this study
14. Subjects who are amblyopic
15. Subjects using any systemic or topical ocular medication that will, in the Investigator's opinion, affect ocular physiology or lens performance
16. Subjects who are allergic to any component in the study care products

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

3.3.2 Subject Completion

The subject has completed the study after completion of the Exit Visit procedures at the 3-Week Follow-Up Visit. Subjects who require further follow-up for an adverse event (AE) will be followed according to Section 5.1.8.

3.3.3 Subject Discontinuation

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 Grade 3 or 4 slit lamp findings
- Persistent study-related symptoms/complaints
- Unacceptable contact lens visual acuity (VA)
- Unacceptable contact lens centration
- Unacceptable contact lens movement
- Failure to follow study procedures

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
- Lost to follow-up (Section 3.3.4)
- Either eye is discontinued
- Becomes pregnant during the study

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 retrieve all study materials. Adverse events will be followed as described in Section 6.0.

Subject discontinuations must 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 who voluntarily withdraw from the study are not required to provide a reason for their decision but should be encouraged to share this information. Subjects who are discontinued from the study following enrollment will not be replaced.

Exit Visit assessments should be completed for early discontinued subjects, if possible.

At the final study visit, all study subjects who are discontinuing should be examined to ensure that their ocular health is consistent with pre-study, baseline conditions. Any adverse effects determined to have been reasonably caused by participation in the study will be followed per the standard of care. Participation in the study will not impact post-study choices of study subjects for correcting their vision using marketed products (e.g., contact lenses and contact lens care solutions).

Whether a subject completes or is discontinued from the study, they will be directed by the Investigator to resume their habitual method of vision correction.

3.3.4 Lost to Follow-up

Subjects who did not return for scheduled follow-up visits, as defined by the visit window, and could not be contacted via 2 telephone calls and 1 letter with delivery confirmation, 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. If the Investigator determines that a subject has been lost to follow-up, the "study exit date" should be recorded as the last successful contact or the date a certified

letter was sent. Just prior to database lock, the database will be reviewed for all lost to follow-up entries to confirm, once again, that contact with the subject was never made. A study subject may withdraw from the study at any time for any reason.

3.4 Investigators

The study will be conducted at approximately 20 investigative site(s) located in the US by Investigators who are determined by Bausch + Lomb to be suitably qualified by training and experience to conduct this study. This will include appropriate current state licensing and study-specific training. Principal Investigators will sign the Device Investigator Agreement Form prior to the start of the study. Investigators will be compensated for their services with appropriate standard professional rates. Compensation will not be dependent on the study outcomes.

Each Investigator will enroll approximately 15 subjects (30 eyes). 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.

3.5 Finances

The study will be financed through Bausch & Lomb Corporate Research & Development. A Clinical Trial Agreement will be executed between Bausch + Lomb and each Investigator prior to their participation in the clinical trial. The agreement will include the responsibilities of each party, payment and reimbursement procedures and requirements, intellectual property and publication terms, insurance and indemnification, coverage for subject injury. Investigator and subject compensation are outlined in the Investigator's Clinical Trial Agreement.

3.6 Study Duration

Investigators will have 4 weeks from the enrollment start date communicated by the Sponsor to conduct the Screening/Dispensing Visit.

Subjects will be followed for approximately 3 weeks (unless discontinued or lost to follow-up) from the initial Screening/Dispensing Visit and must adhere to the following schedule:

SCHEDULED FOLLOW-UP VISITS		
Visit	**Target**	**Acceptable Visit Range**
V1: Screening/Dispensing Visit	Day 1	Not applicable
V2: 1-Week Follow-Up Visit	Day 8	Day 6-10 (5-9 days after V1)
V3: 3-Week Follow-Up Visit	Day 23	Day 20-26 (19-25 days after V1)

A visit scheduling table will be provided in the initial study shipment to aid the Investigator in scheduling follow-up visits.

4.0 STUDY MATERIALS

Bausch + Lomb will provide all study materials at no charge to the Investigator. Sites will be provided with fit sets and dispensing sets for the Bausch + Lomb (kalifilcon A) Daily

Disposable Multifocal Contact Lenses and dispensing sets for the Bausch + Lomb INFUSE® Contact Lenses. All other materials will be provided to the site prior to the start of the study. Refer to Section 4.6 for ordering replacement test lenses in the case of loss or damage.

Subjects will be provided with lens cases in which to dry stack their used lenses. All used and unused lenses will be returned to the Sponsor at end of the study.

Subjects must use only study-supplied lenses. Use of other contact lenses is not allowed and will be considered a protocol deviation.

4.1 Description of Investigational Test Article (Test)

The Test lens to be used in this study is the Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens, manufactured by Bausch & Lomb Incorporated, Rochester, NY. The description of the Test lens is as follows:

- Sphere power: -6.00 D to +3.00 in steps of 0.25 D
- Add: High and Low
- Diameter: 14.2 mm
- Base curve: 8.6 mm
- Material: kalifilcon A
- Packaging solution: phosphate-buffered saline solution

The investigational test article(s) for this study are manufactured and verified under a controlled process according to the applicable regulations. With regard to those aspects, every precaution has been taken to protect the health and safety of study participants. per B&L SOP TD-GEN-FRM-039 Clinical Scorecard Evaluation[4]

4.2 Description of Control Product (Comparator)

Not applicable; this is a single-treatment study evaluating the product performance of a new silicone hydrogel multifocal daily disposable contact lens.

4.3 Instructions for Use and Administration

Each enrolled subject will be assigned a subject number. Each eligible subject will be issued a supply of study contact lenses and will wear these lenses on a daily disposable wear basis for the duration of the study. The Investigator or designee will instruct all subjects to adhere to the Subject Instructions provided (Appendix C).

Note: Subjects may continue to use their habitual rewetting drops as needed.

4.3.1 Storage Requirements

All study lenses provided by the Sponsor must be stored in a secure location accessible only to study personnel and maintained at ambient room temperature.

4.3.2 Subject Instructions

a) All must be given Subject Instructions for the use of the study lenses (Appendix C). Subjects must comply with the instructions provided to them. Subject Instructions will be supplied to the Investigator by Bausch & Lomb (or CRO) for distribution to the subject.

b) The Investigator or other designee must 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 Sponsor's or Investigator's opinion, jeopardizes the subject's well-being or the validity of the study should be discontinued.

4.3.3 Fitting Guide

The Investigator will be supplied with a Fitting Guide for fitting the study lenses (Appendix D).

4.4 Packaging and Labeling

The study lenses will be provided by Bausch + Lomb and will be packaged in a blister pack with an investigational label. The label will contain the following information at minimum:

- Lens power
- Base curve
- Diameter
- ADD power
- Lot number
- Expiration date
- Manufacturer's name
- Manufacturer's place of business
- Caution statement

4.5 Other Materials

All subjects will be dispensed lens cases for return of dry-stacked worn study lenses to the Investigator during the study. Subjects that habitually use rewetting drops may continue to use their drops. ***OTHER CONTACT LENS CARE PRODUCTS ARE NOT ALLOWED TO BE USED.***

Investigators will return all worn and unworn study lenses to the Sponsor at the end of the study.

4.6 Product Replacement

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

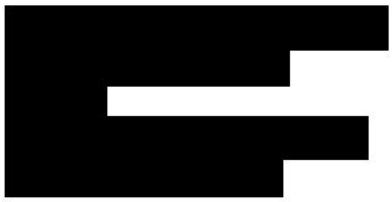
Should the site's inventory be low or depleted, additional inventory of lenses can and must be ordered from Bausch & Lomb Clinical Supply Chain by sending a Stock Material Order Form for Study 916 to email: [redacted]

4.7 Accountability and Traceability

Designated site staff will be responsible to keep current and accurate records of study materials during the study. The records will include receipt and acknowledgement of all study lenses. The disposition of study lenses dispensed and returned by the subjects will be recorded on study product accountability logs. The study lenses are to be dispensed only to subjects enrolled in the study, in accordance with the conditions specified in this protocol.

Upon completion of the study, a Clinical Monitor will review and verify the Investigator's accountability logs.

Following verification, and as directed by the Sponsor, all used and unused study supplies (study lenses) must be returned to the Sponsor at the address below:



4.8 Masking/Unmasking

This is an open-label study.

4.9 Product 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.

5.0 STUDY METHODS

5.1 Study Visits

Refer to Appendix A for a schedule of visits and parameters and Appendix B for 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. Both the Investigator and subject must keep the signed ICF document. The Investigator should retain the signed original document in the subject's record and provide a copy to the subject. In addition, the applicable privacy regulation requirements must be met.

Eligible subjects will be required to complete and initial the subject-completed forms while at the visits listed below. The data will then be transcribed into eCRFs by qualified site personnel. The original subject-completed forms will be retained by the site in the study files.

Visit Name	Subject-Completed Forms
Screening/Dispensing Visit	• Informed Consent • Initial Lens Performance Rating Scales (Habitual Lenses) • Baseline Questionnaire • Abbreviated Lens Performance Rating Scales (Study lenses)

Visit Name	Subject-Completed Forms
1-Week Follow-up Visit	• Lens Performance Rating Scales (Study Lenses)
At least 7 days after the 1-Week Follow-Up Visit but before the 3-Week Follow-Up Visit	• Online Consumer Survey
3-Week Follow-up Visit	• Lens Performance Rating Scales (Study Lenses)

Note: If the subject returns for an Unscheduled Visit, Symptoms and Complaints should be assessed.

5.1.1 Screening/Dispensing Visit

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

A Screening Log will be provided by the Sponsor to track all consented subjects who 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 HIPAA authorization.

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

Screening/Dispensing will proceed as follows:

a. Enter the subject information on the next available line of the Screening Log:
   - Subject initials
   - Subject date of birth
   - Screening date

b. Collect demographic and the following habitual contact lens use history information and record in the subject's source document:
   - Over the last week, Average number of days per week worn
   - Over the last week, Average daily wearing time, hours per day
   - Over the last week, Average hours of comfortable wear per day
   - Over the last week, Average number of times used rewetting drops per day
   - Hours lenses worn on the day of this visit
   - Current lens brand
   - Current lens care products

c. Collect ocular medical history (within 1 year of signing the ICF) and concomitant medications. Concomitant medications (as defined for this study) include any medications for ocular conditions taken within 30 days of signing the ICF.

d. Have the participant complete the Lens Performance Rating Scales for habitual lenses using the 0-100 rating scales provided by the Sponsor.

e. Have the participant complete the Symptoms/Complaints Form for habitual lenses

f. Perform the following baseline assessments (with habitual lenses) and record in the subject's source document:

- Distance, intermediate, and near lens VA (OU) with a high contrast logMAR visual acuity chart

g. Perform the following baseline assessments (without lenses) and record in the subject's source document:

- Spherocylindrical refraction
- Add power
- High-contrast distance BSCVA (OD, OS, and OU logMAR)
- High-contrast intermediate logMAR BSCVA (OU w/near add)
- High-contrast near logMAR BSCVA (OU w/near add)
- Keratometry

h. Pupil measurement

i. Perform a slit lamp examination. 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 corneal scars
- Any corneal staining
- Any corneal infiltrate
- Any other graded slit lamp findings Grade >2

j. Assess eligibility. Indicate on the Screening Log whether the subject is a "Screen Pass" or "Screen Fail." "Screen Fail" subjects are ineligible and cannot be enrolled 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.

k. Administer the Baseline Questionnaire.

l. Dispense 10 study contact lenses per eye according to the Fitting Guide and dispense all study materials.

- **The subject MUST insert the study lenses at this visit**.

Note: Study lenses should be allowed to equilibrate a minimum of <u>10 minutes</u> on the eye. Subjects should be encouraged to walk around, read, and/or look outside while the lens is equilibrating. If the vision is unsatisfactory, the lenses should be refined by adding add power according to the fitting guide to achieve acceptable vision. Number of refinements completed to achieve satisfactory vision in each eye will need to be collected.

- **Order remaining study contact lenses on Stock Material Order Form.**

m. For the dispensed lenses, perform the following assessments:

- Dispensed lens sphere power
- Dispensed lens add power (high, low, or none)
- Distance (OU), intermediate (OU), and near (OU) lens VA
- Lens wettability
- Lens centration
- Lens movement

n. Compare the high-contrast OU distance lens VA to the high-contrast OU distance BSCVA obtained at this visit. If the VA has decreased by ≥10 letters, explain.

o. Have the subject complete the abbreviated Lens Performance Rating Scales for study lenses using the 0-100 rating scales provided by the Sponsor.

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

q. Provide instructions for study contact lens wear to the subject and instruct the subject to wear their study lenses to the 1-Week Follow-Up Visit.

r. Register subject information in ePRO system **while subject is in office**. This should be done only for eligible, dispensed subjects. Subject data to be entered for registration:

- Subject number
- Date of birth
- Subject phone number (text capability)
- Screen date

s. After registration, the subject will log into the ePRO Portal with their User ID and Temporary Password. After initial login, they will be prompted to update their password, create a security question, confirm consent, and complete a quick training session of the use of the ePRO system. Once all these steps are done at the screening visit, the subject is considered "active" in the ePRO system.

t. Provide subject with Online Consumer Survey Instructions.

u. Complete the Screening/Dispensing Visit eCRFs. If the subject is discontinued or exited at this visit, complete Exit Visit eCRFs.

5.1.2 1-Week Follow-up Visit

Note: If the subject does not come to a visit wearing study lenses and is not experiencing any problems, it is preferred if the current visit is rescheduled within the visit window.

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

a. Collect changes in ocular medical history and concomitant medications

b. Collect the following study lens information from the subject:

- Over the last week, Average number of days per week worn
- Over the last week, Average daily wearing time, hours per day
- Over the last week, Average hours of comfortable wear per day
- Hours lenses worn on the day of this visit
- Over the last week, average number of times used rewetting drops per day. (Note: Only to be completed by subjects reporting rewetting drop use with habitual lenses at the Dispensing Visit.)

c. Collect the Lens Performance Ratings for dispensed contact lenses using the 0-100 rating scales provided by the Sponsor.

d. Collect the Symptoms/Complaints for dispensed lenses.

e. If the subject did not come to the visit wearing one or more study lenses, go to step g. Otherwise, evaluate the study lenses (while on eye) and record the following assessments:

- Distance (OU), intermediate (OU), and near (OU) lens VA
- Lens wettability
- Lens deposits (type, percent, and degree)

- Lens centration
- Lens movement

Compare the high-contrast OU distance lens VA to the high-contrast OU distance BSCVA obtained at the Screening/Dispensing visit. If the VA has decreased by ≥10 letters, explain.

f. If the subject requires a change to their study lens power at the 1-Week Follow-Up Visit, collect the worn lenses from the subject, and the unworn lenses for the eye(s) requiring a change, adjust the lens power, dispense study lenses with the appropriate power according to the Fitting Guide, and perform assessment in step e, (with exception of deposits), after an equilibration time of 10 minutes.

Note: Study lenses should be allowed to equilibrate a minimum of 10 minutes on the eye. Subjects should be encouraged to walk around, read, and/or look outside while the lens is equilibrating. If the first set of study lenses is unacceptable to the subject, adjust study lenses according to the Fitting Guide to achieve acceptable vision. Continue to adjust until vision is acceptable. Allow the study lens(es) to equilibrate a minimum of 10 minutes on the eye before conducting the assessments in step e. Number of refinements completed to achieve satisfactory vision in each eye will need to be collected.

g. 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 corneal scars
- Any corneal staining
- Any corneal infiltrate
- Any other graded slit lamp findings Grade >2

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

i. Dispense 20 study contact lenses per eye according to the Fitting Guide.

j. Instruct the subject to wear their study lenses to the 3-Week Follow-Up Visit.

k. Remind the subject to complete Online Consumer Survey at least 7 days after this visit but before the 3-Week Follow-Up Visit.

l. Collect all worn study lenses from the subject.

Note: The Investigator must return all worn study lenses to the Sponsor in the return materials provided. All study contact lenses must be accompanied by a Product Accountability Log.

m. Confirm 1-week visit (V2) in the ePRO system (triggers text reminders for survey completion).

n. Complete the 1-Week Follow-Up Visit eCRF. If the subject is discontinued or exited at this visit, complete Exit Visit eCRFs.

5.1.3 3-Week Follow-up

Note: If the subject does not come to a visit wearing lenses and is not experiencing any problems, it is preferred if the current visit is rescheduled within the visit window.

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

Note: ***The Online Consumer Survey should be completed by the subject before the subject comes into the office for this visit. If it has not been completed prior to coming in, ask subject to complete now.***

a. Collect changes in ocular medical history and concomitant medications

b. Collect the following study lens information from the subject:

- Over the last week, Average number of days per week worn
- Over the last week, Average daily wearing time, hours per day
- Over the last week, Average hours of comfortable wear per day
- Hours lenses worn on the day of this visit
- Over the last week, average number of times used rewetting drops per day (Note: Only to be completed by subjects reporting rewetting drop use with habitual lenses at the Dispensing Visit.)

c. Collect the Lens Performance Ratings for study lenses using the 0-100 rating scales provided by the Sponsor.

d. Collect the Symptoms/Complaints for study lenses.

e. If the subject did not come to the visit wearing one or more study lenses, go to step f. Otherwise, evaluate the lenses (while on eye) and record the following assessments:

- Distance (OU), intermediate (OU), and near (OU) lens VA
- Lens wettability
- Lens deposits (type, percent, and degree)
- Lens centration
- Lens movement

Compare the high-contrast OU distance lens VA to the high-contrast OU distance BSCVA obtained at the Screening/Dispensing visit. If the VA has decreased by ≥10 letters, explain.

f. 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 corneal scars
- Any corneal staining
- Any corneal infiltrate
- Any other graded slit lamp findings Grade >2

g. Collect/assess all AEs/ADEs, including serious or significant non-serious AEs. If subject has an ongoing AE at the time of 3-Week Follow up visit, the subject should not be exited. Unscheduled visit (s) should be scheduled to follow upon the AE(s) until the event resolves or stabilizes. Once event resolves or stabilizes, subject may be exited.

h. Collect all worn and unworn study lenses from the subject.

Note: ***The Investigator must return all worn and unworn study lenses to the Sponsor in the return materials provided. All study contact lenses must be accompanied by a Product Accountability Log.***

i. Complete the 3-Week Follow-Up Visit eCRFs. If the subject is discontinued or exited at this visit, complete Exit Visit eCRFs.

5.1.4 Exit Visit

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

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

b. Collect changes in ocular medical history and concomitant medications

c. For all subjects, complete an exit ocular examination without lenses on the eyes. Collect the following assessments:

- Spherocylindrical refraction
- High-contrast distance (OD, OS, OU) logMAR BSCVA
- Keratometry

Compare the final visit high-contrast distance (OD, OS) BSCVA to the high-contrast distance (OD, OS) BSCVA obtained at the Screening/Dispensing Visit. If the VA has decreased by ≥10 letters, explain.

For each eye, compare the final visit keratometry readings to the Screening/Dispensing Visit keratometry readings. If there is a change of 1.00 D or more, explain.

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

e. Collect all worn and unworn study lenses from the subject.

Note: The Investigator must return all worn and unworn study lenses to the Sponsor in the return materials provided. All study contact lenses must be accompanied by a Product Accountability Log.

f. Complete the Investigator survey following the completion of the subject's final study visit.

g. Complete the Exit visit eCRFs.

5.1.5 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.

If a subject is only seen for replenishment of study lenses, a complete exam is not required, as long as the subject is not experiencing any problems. If study lenses are replaced, record

the eye, dispensed lens sphere power, add power (high, low, none), and primary replacement reason in the Product Dispensing Only eCRF. Collect worn study lenses from the subject. Record the eye, lens type, add power, sphere power, lot number, and quantity dispensed in the Product Accountability Log.

Subjects who require further follow-up on an AE/SAE upon discontinuation or at the conclusion of the 3-Week Follow-Up Visit will be followed according to the Post-study Follow-up Section 3.3.4. At these follow-up visits, the subject should remove contact lenses s/he may be wearing. Assessments will be performed according to the investigator's judgement. The Investigator is required to follow the subject until the condition no longer warrants further follow-up for study purposes.

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

a) Indicate the reason for the Unscheduled Visit.

Note: If the subject is experiencing problems, complete the entire Unscheduled Visit Form.

b) Collect the following information from the subject regarding study lenses:

- Average number of days per week worn
- Average daily wearing time, hours per day
- Average hours of comfortable wear per day
- Hours lenses worn on the day of this visit
- Rewetting drop use.

c) Collect Symptoms/Complaints.

d) If the subject did not come to the visit wearing one or more study lenses, go to step e. Otherwise, evaluate the study lenses (while on eye), and record the following assessments:

- Distance (OU), intermediate (OU), and near (OU) lens VA
- Lens wettability
- Lens deposits
- Lens centration
- Lens movement

Compare the high contrast OU distance lens VA to the high contrast OU distance BSCVA obtained at the Screening/Dispensing Visit. If the VA has decreased by ≥10 letters or more, explain.

e) 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 corneal scars
- Any corneal staining
- Any corneal infiltrate
- Any other graded slit lamp findings Grade >2

f) If an unscheduled lens replenishment for the same lens is required, dispense additional lenses, and collect the following:

- Primary reason for replacement

- Dispensed lens sphere power
- Dispensed lens add power (high, low)
- Distance (OU), intermediate (OU), and near (OU) lens VA
- Lens wettability
- Lens centration
- Lens movement

Note: ***Remember to record replenishment on the Product Accountability Log.***

Note: ***The Investigator must return all worn and unworn study lenses to the Sponsor in the return materials provided. All study contact lenses must be accompanied by a Product Accountability Log.***

g) If an unscheduled lens replacement requires ***a change in lens power for unacceptable vision***, follow steps f, g, h, and i in Section 5.1.2.

h) The Unscheduled Visit eCRFs should be completed.

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

5.1.6 Missed Visits

If a subject misses any scheduled follow-up visit, the visit is considered missed. Indicate a missed visit on the eCRF for that scheduled visit. Schedule the subject for an Exit Visit as soon as possible. If the subject cannot be reached or rescheduled, the subject should be recorded as Lost to Follow-Up.

5.1.7 Product Dispensing Only Visit

If a subject is seen for resupply or replacement of study materials and the subject is not experiencing any problems, a complete exam is not required. If any assessment is performed, then an Unscheduled Visit Form must be completed instead of a Product Dispensing Only Form.

If study lenses are dispensed, collect the following information in the source document for each being dispensed, and transcribe to the Product Dispensing Only eCRF Form:

- Visit date
- Subject ID number
- Primary reason for lens replacement
- Dispensed lens power, add power

Record the sphere power/add, lot number, quantity dispensed, and for which eye the lenses are being dispensed in the Product Accountability Log.

Note: The Investigator must return all worn and unworn study lenses to the Sponsor in the return materials provided. All study contact lenses must be accompanied by a Product Accountability Log.

5.1.8 Post Study Follow-up

If a subject requires discontinuation or is completing the study, but has an ongoing AE, the subject should not be exited until the event resolves or stabilizes. This may imply that follow-up will continue via Unscheduled visits, and that additional evaluations may be requested by the Sponsor.

Investigator must schedule Unscheduled Visits, as necessary.

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

a) Remove any contact lenses the subject may be wearing. Perform a slit lamp examination. Record and sketch the ocular results and findings in the subject's source document

b) Complete an ocular examination without lenses on the eyes, including spherocylindrical refraction and distance (OD, OS, OU) BSCVA

c) The Investigator is required to follow the subject until the condition no longer warrants further follow-up for study purposes. An Unscheduled Visit eCRF must be completed for each of these visits

Once AE has resolved or stabilized, the Investigator may proceed with completing the exit visit

5.2 Questionnaires and Surveys

5.2.1 Baseline Questionnaire

Each eligible subject will complete a questionnaire prior to study lens insertion. Responses will be regarding current habitual lens wear.

5.2.2 Online Consumer Survey

Each subject will be required to complete a Subjective Assessment through an internet survey. Each enrolled subject will be provided with an internet address to access ***at least 7 days after the 1-Week Follow-Up Visit but before the 3-Week Follow-Up Visit***. Each subject will be provided with a confidential unique ID and password (login) in order to access the online survey. If the user forgets their password, there will be a "forgot password" option within the system. The system will send reminders to the subject via email or mobile alerts. The study coordinator will call the subject prior to the visit date to remind the subject to complete the survey.

There will be a specified timeframe in which the survey must be completed. The Investigator will provide the market research firm with the subject's email address. If the subject has not completed the survey during the specified duration, the market research firm may contact that subject by email with a reminder to complete the survey. If the subject has not completed the survey by the time of the 3-Week Follow-Up Visit, the subject may complete it at that time.

5.2.3 Investigator Survey

The Investigator (or designee) will complete a survey to answer questions about each subject's study lens wear at the subject's Exit Visit. This information will be collected within the eCRF system.

5.3 Study Completion / Early Study Terminations / Suspensions

5.3.1 Study Completion

For purposes of the Investigator notifying the IRB, the study is complete when all subjects at the sites have been exited. Sponsor approval is required prior to IRB notification.

5.3.2 Early Study Termination/Suspension

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 Investigator(s) IRBs, and United States Food and Drug Administration (FDA), as applicable. Bausch + Lomb will instruct the Investigators to stop/restart dispensing study materials and will arrange for study closeout, if applicable, at each site.

5.4 Concomitant Medications/Therapy

Other contact lenses are not allowed to be used by subjects during the study.

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

5.5 Treatment Compliance

Treatment compliance will be assessed using lens wear parameter data.

5.6 Protocol Deviations

A deviation from the protocol is an unintended and/or unanticipated departure from the procedures and/or processes approved by the Sponsor and the IRB and agreed to by the Investigator. It is a Sponsor expectation that Investigators will follow the protocol and procedures as written. The Sponsor will not grant protocol waivers for this study. The Investigator may implement a deviation from the protocol to eliminate an immediate hazard to study subjects without prior IRB approval. As soon as possible after such an occurrence, the implemented deviation, as well as the reasons for it should be submitted to the IRB for review and approval. It should also be submitted to the Sponsor for agreement, and to the regulatory authorities, if required.

In the event a protocol deviation occurs, the date of and reason for deviations must be documented in all cases. Significant or major protocol deviations impacting the rights or safety of the subject, or the integrity of the study must be reported by the Investigator to the IRB and Medical Monitor immediately. Reporting of all other protocol deviations must adhere to the requirements of the governing IRB. 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.

Site Corrective Action Plans will be developed and completed as deemed necessary by the Sponsor, Sponsor designee (e.g., CRO) for sites or 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 Site 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 site closure will be made by the Sponsor and documented in the Trial Master File.

6.0 ADVERSE EVENTS

6.1 Introduction to Adverse Event Definitions

Adverse events, serious AEs (SAEs), significant non-serious AEs, non-significant non-serious AEs, adverse device effects (ADEs), anticipated serious adverse device effects

(ASADEs), and unanticipated adverse device effects (UADEs)are defined in this section and in the protocol's glossary.

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

6.1.1 Serious Adverse Event (SAE) Definitions

An AE that (related or not related to the investigational test articles, comparator products or study procedures):

- 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.

Note: A planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered an SAE.

Serious adverse events may include but are not limited to any hazardous, sight-threatening conditions occurring after exposure to the investigational test article or control product 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, this includes:
  - Central or para-central 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 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), and 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, and 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/or hyphema
- Any neovascularization within the central 6 mm of the cornea
- Permanent loss of ≥2 lines of BSCVA
- All cases of iritis.

6.1.2 Significant Non-Serious Adverse Event Definitions

A significant non-serious adverse event is an AE that does not meet the serious criteria, is considered significant by the Sponsor, and requires expedited reporting to the Sponsor (see Section 6.2.1). These events include but are not limited to:

- 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 two or more lines of BSCVA (for greater than or equal to 2 weeks)
- Neovascularization cases Grade 2 or greater (if not within 6 mm of the cornea)
- Any ocular event that necessitates temporary lens discontinuation of greater than or equal to 2 weeks.

6.1.3 Non-Significant Non-Serious Adverse Events Definitions

A non-significant non-serious adverse event may include but are not limited to the following and does not require expedited reporting:

- Bacterial Conjunctivitis;
- Viral Conjunctivitis;
- Allergic Conjunctivitis;
- Corneal Edema;
- Contact Lens Related Papillary Conjunctivitis; and,
- Loss of Contrast Sensitivity

6.1.4 Adverse Device Effect (ADE) Definitions

An adverse device effect is an AE that is assessed to be 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.

6.1.4.1 Anticipated Serious Adverse Device Effect (ASADE) Definition

An anticipated serious adverse device effect (ASADE) is an ADE that first meets the serious criteria (see Section 6.1.1) 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 but are not limited to:

- 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

6.1.4.2 Unanticipated Serious Adverse Device Effect (USADE) Definitions

An unanticipated serious ocular or non-ocular adverse device effect is an adverse event related to the use of an investigational medical device that has resulted in any of the consequences characteristic of a serious adverse event as described in Section 6.1.1 and which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

This definition includes but is not limited to 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. USADEs include but are not limited to

- 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/or hyphema
- Any neovascularization within the central 6 mm of the cornea
- Permanent loss of ≥2 lines of BSCVA
- All cases of iritis.

6.1.5 Relationship Definition: Study Device and/or Other Study Materials

- **Related:** There is at least a reasonable possibility that the AE is related to the study device (study solution) 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.
- **Not related:** There is little or no reasonable possibility that the AE is related to the study device (study solution) and/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 Rewetting Drops and a more likely or certain alternative etiology exists.

6.1.6 Severity Definitions

- **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

6.2 Procedures for Evaluating Adverse Events

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 SAEs, ocular and systemic, must be recorded and reported as required.

All reportable AEs occurring after signing of informed consent and through the subject's end of participation in the study must be reported. If there is an Ongoing AE at the time of subject's discontinuation or at 3-Week Follow up visit, Unscheduled visit(s) must be scheduled to follow up on the AEs until the event resolves or stabilize.

Ocular AEs of possible clinical significance should be photo-documented and shared with the Medical Monitor in electronic form.

When evaluating for reportable AEs, the Investigator should refer to the definitions for AEs to determine:

a) whether the event is serious (refer to Section 6.1.1 and Section 6.1.2)
b) whether the event is severe (refer to Section 6.1.6)
c) whether the event is significant (refer to Section 6.1.2 and Section 6.1.3)
d) whether the event is related to the study device (refer to Section 6.1.5)

6.2.1 Procedures for Reporting Serious or Significant Adverse Events

An AE classified as a SAE or a Significant Non-Serious Ocular AE requires expeditious handling and reporting to the Sponsor to comply with regulatory requirements, as follows:

- To ensure subject safety, all SAEs, regardless of relationship to the IMP, must be immediately (i.e., within a maximum 24 HOURS after becoming aware of the event) reported to the Lexitas and Sponsor. All information relevant to the SAE must be recorded on the Sponsor provided SAE report form signed by the Investigator. Within 24 hours of knowledge of a new SAE, the investigator must enter the SAE information onto the hard copy SAE report form and send the form to the following email distribution:

  [redacted]

- The investigator must verify that the report was received by Lexitas and/or Sponsor. If the investigator is not able to verify it was successfully received by Lexitas and/or Sponsor, the investigator must call the CRO clinical study manager by phone to follow-up. The CRO will forward the documentation to the medical monitor and the sponsor for review.
- Investigators should not wait to receive additional information to fully document the event before initially notifying Lexitas and Sponsor of an SAE or a Significant Non-Serious AE. Additional relevant information such as

hospital records and autopsy reports should be provided to Lexitas and Sponsor as soon as they are available.

- The Investigator should take all appropriate measures to ensure the safety of the subjects: notably, he/she should follow a subject with an SAE or Significant Non-Serious AE until the event has resolved or the condition has stabilized. This may imply that follow-up will continue after the subject has left the study, and that additional evaluations may be requested by the Sponsor.
- 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.
- Continue to update the paper SAE or Significant Non-Serious AE Report Form, if applicable, each time the subject is seen during the management of the event and at resolution of the event. All updated report forms should be submitted by the site to Lexitas and Sponsor within 24 hours. Whenever possible, it is suggested that the Investigator take photographs of all ocular AEs of possible clinical significance and forward them to the Lexitas and Sponsor.
- Events 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.
- Report all USADEs to the reviewing IRB within 10 working days following awareness of the USADE or according to the established reporting procedures of the IRB, whichever is shorter.
- Submit all bills, prescription receipts, and culture reports/fees related to the AE to the Bausch + Lomb Clinical Operations. Expense incurred for study related medical treatment will be paid by Bausch +Lomb Clinical Operations.

6.2.2 Procedures for Reporting Off-Site Unanticipated Serious Adverse Device Effects

When participating in multicenter clinical investigations, Investigators may receive off-site USADE reports. These are Sponsor reports of USADEs which occurred at other clinical sites for the same trial, or in different trials using the same investigational test article or comparator, that met the criteria for reporting to a regulatory agency. These should be reported to the reviewing IRB within 10 working days or per their established reporting procedures, whichever is shorter.

6.2.3 Device Deficiencies: Definition and Reporting Procedures

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.

Investigators must evaluate, record, and report any complaints/ deficiencies or malfunctions experienced with the study solution during this trial to the Medical Monitor

promptly. The Sponsor and Medical Monitor shall review all device deficiencies, and, upon the Sponsor's request, Investigators must supply any additional information related to the safety reporting of a particular event.

Report device deficiencies within 24 hours of knowledge to:

[redacted]

The Medical Monitor will distribute, within 24 hours of knowledge, all device deficiencies to the Sponsor.

The Sponsor shall review all device deficiencies and determine and document in writing whether they could have led to an 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.

6.2.4 Procedures for Culturing of Corneal Ulcer or Suspected Ocular Infection

For purposes of this study, the Sponsor requests that cultures 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). The required culturing techniques are outlined in Appendix B.

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 for culturing and processing by the local clinical laboratory designated by the site.

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 local clinical laboratory designated by the site for analysis. The clinical laboratory will report the culture results to the Investigator who will record the results in the eCRF.

6.2.5 Guidelines for Reporting Pregnancies

During the study, all female subjects of childbearing potential should be instructed to contact the Investigator immediately if they suspect they might be pregnant (e.g., missed, or late menstrual period). Female subjects who become pregnant during the study will be followed until completion of pregnancy. Every effort will be made to obtain the health status of the mother and infant or fetus (in cases of miscarriage or therapeutic abortion) at term. Pregnancy itself is not considered an AE.

All confirmed pregnancies must be reported on a Pregnancy Report and submitted to the Medical Monitor via facsimile or email transmission within 24 hours of the Investigator's awareness of the pregnancy. The Medical Monitor will distribute the completed report to the Sponsor as per the distribution listed below.

All pregnancies will be followed until outcome even after study closure. The outcome of all pregnancies will be reported on a paper Pregnancy Outcome Report and submitted to the Medical Monitor via facsimile or email transmission once the outcome is learned. The Medical Monitor will distribute the completed report to the Sponsor as per the distribution listed below.

Although pregnancy occurring in a clinical study is not considered to be an AE or SAE, any pregnancy complication, spontaneous abortion, or elective termination of a pregnancy, for medical reasons, will be recorded as an SAE. Any serious complication or event resulting from the pregnancy should be reported to the Medical Monitor within 24 hours on the SAE or Significant Non-Serious AE Report Form along with the Pregnancy Report Form.

The contact for reporting pregnancies and pregnancy outcomes are:

[redacted]

7.0 STATISTICAL METHODS

7.1 Assessment of Effectiveness

Analyses of effectiveness outcomes will be completed using the Full Analysis Set.

7.1.1 Primary Effectiveness Endpoints

7.1.1.1 Clear Vision: Near, Far, and In-Between

The primary endpoint will be assessed as part of the online consumer survey. The responses to the primary endpoint statement will be summarized using categorical summary statistics (strongly agree, agree, slightly agree, neither agree nor disagree, slightly disagree, disagree, strongly disagree).

Responses of strongly agree, agree, and slightly agree will be coded to a category "Agree." Responses of strongly disagree, disagree, and slightly disagree will be coded to a category "Disagree." The trichotomized responses will be summarized categorically (agree, neither agree nor disagree, disagree).

Neutral responses (i.e., "neither agree nor disagree") will not be included in the primary statistical analysis. The non-neutral responses used for the analysis will be presented using categorical summary statistics (agree, disagree). An exact 95% confidence interval around the proportion of subjects agreeing with the statement will be presented along with the p-value from a one-sided exact binomial test of the alternative hypothesis is that the proportion of subjects agreeing is greater than 0.5.

7.1.2 Secondary Effectiveness Endpoints

There are no predefined secondary effectiveness endpoints.

7.1.3 Supportive Effectiveness

7.1.3.1 Consumer Survey

Agreement with statements in the online consumer survey will be analyzed using the methods described for the primary endpoint.

7.1.3.2 Investigator Questionnaire

The following investigator questionnaire will also be evaluated using one-sided exact binomial test of the alternative hypothesis is that the proportion of subjects agreeing is greater than 0.5.

- The proportion of subjects for whom the investigator was completely, very satisfied, or somewhat satisfied with the use of the contact lenses by the subject
- The proportion of subjects for whom the investigator rated the fit of the lens as excellent, very good, or good
- The proportion of subjects for whom the investigator agrees that the lenses deliver clear vision for the subject
- The proportion of subjects for whom the investigator agrees that the lens helps maintain a smooth, wettable surface for the subject
- The proportion of subjects for whom the investigator reports that it was extremely simple, simple, or somewhat simple to successfully fit the contact lens
- The proportion of subjects for whom the investigator agrees with the following statement: "The fitting process for the lens is straightforward"
- The proportion of subjects for whom the investigator agrees with the following statement: "The lens was easy to fit"
- The proportion of subjects for whom the investigator reports that it was extremely easy, easy, or somewhat easy to successfully fit the lens during the first visit

7.1.3.3 Number of Visits to Achieve a Successful Fit

The number of visits to achieve a successful fit will be summarized using categorical summary statistics.

7.1.3.4 Number of Lenses to Achieve a Successful Fit

The number of lenses to achieve a successful fit will be summarized using categorical summary statistics.

7.1.3.5 Contact Lens Visual Acuity

Visual acuities will be summarized by visit using continuous summary statistics (logMAR), including change from baseline for follow-up visits.

Acuities will also be summarized categorically (Snellen equivalent feet) in both mutually exclusive and cumulative categories. Shift tables will be provided showing change from baseline in Snellen equivalent feet units by follow-up visit. Line change from baseline will be summarized categorically by follow-up visit.

7.1.3.6 Lens Performance Rating Scales

Data from the lens performance rating scales, including change from baseline for follow-up visits, will be summarized using continuous summary statistics by visit.

7.1.4 Statistical Hypothesis Testing and Control of Multiplicity.

7.1.4.1 Hypotheses

For the primary endpoint, the null hypothesis (H_0) is that the proportion of subjects agreeing with the statement (π) is less than or equal to 0.5. The alternative hypothesis (H_1) is that the proportion of subjects agreeing is greater than 0.5.

$$H_0: \pi \leq 0.5$$

$$H_1: \pi > 0.5$$

7.1.4.2 Control of Multiplicity

The primary endpoint is a single test, so multiplicity control is not necessary for this evaluation. For the online survey and investigator questionnaire inferential tests described in Section 7.1.3.2, the risk of type I errors will be controlled as follows.

- These supportive effectiveness outcomes will not be eligible for statistical hypothesis testing unless the null hypothesis is rejected for the primary endpoint.
- The Holm adjustment will be applied.

7.1.5 Descriptive Statistics

Continuous variables will be summarized using the sample size, mean, standard deviation, median, minimum, and maximum. Categorical variables will be summarized using frequencies and percentages.

7.1.6 Pooling Analysis

The clinical study will be conducted under a common protocol for each investigational site with the intention of pooling the data for analysis. Every effort will be made to promote consistency in study execution at each investigational site. The uniformity of the primary endpoint responses (agree, disagree) among the sites will be evaluated using a chi-square test

7.1.7 Missing Effectiveness Data

Missing data will not be imputed.

7.1.8 Effectiveness Sensitivity Analysis

Sensitivity to missing primary endpoint data will be evaluated using best-case imputation, worst-case imputation, and tipping point analysis.

7.1.9 Subject Self-Assessments

Inferential analyses of the online consumer survey data are described in Section 7.1.1.1 and Section 7.1.3.1. In addition, descriptive statistics will be used to summarize the results of the questionnaire.

7.2 Assessment of Safety

Analyses of safety data will be conducted using the Safety Population.

7.2.1 Adverse Events

All adverse events occurring during the study will be recorded and classified on the basis of MedDRA terminology. Descriptions of AEs will include the date of onset, the date the AE ended, the severity of the AE, the relationship to study device, the action taken to treat the AE, and the outcome. All reported treatment-emergent AEs (TEAEs) will be summarized by the number of subjects reporting AEs, system organ class, severity,

seriousness, and relationship to study medication. TEAEs are those AEs with an onset on or after the date of the first study device use.

Adverse events will be summarized by severity. Each subject will be counted only once within a system organ class or a preferred term by using the adverse events with the highest severity within each category.

Adverse events will be summarized by relationship to study device. Each subject will be counted only once within a system organ class or a preferred term by using the adverse events with the greatest relationship within each category.

All information pertaining to AEs noted during the study will be listed by subject, detailing verbatim given by the investigator, preferred term, system organ class, start date, stop date, severity, actions taken, and drug relatedness. The AE onset will also be shown relative (in number of days) to the day of initial use of the study device.

Serious adverse events (SAEs) will be tabulated by subject.

In addition, a list of subjects who discontinued from the study and a list of subjects who experienced SAEs will also be provided.

7.2.2 Clinical Safety Examinations

Data from the following assessments will be summarized categorically by visit.

- Slit lamp examination
- Symptoms/complaints
- BSCVA in Snellen equivalent units

Data from the following assessments will be summarized using continuous summary statistics.

- Spherocylindrical refraction
- BSCVA in logMAR units

7.2.3 Concomitant Medications

All previous and concomitant medications will be classified based on terminology from the WHO Drug Dictionary. Previous therapies and concomitant medications data will be presented in data listings.

7.3 Subject Disposition

A tabulation of subject disposition will be provided. The tabulation will include the numbers of subjects who enter the study, complete the study, and discontinue the study. The reasons for discontinuation will be included.

7.4 Demographics and Baseline Characteristics

Demographics and baseline characteristics will be summarized using descriptive statistics.

7.5 Protocol Deviations

Protocol deviations will be recorded throughout the study. A tabulation of protocol deviations will be presented in a separate, comprehensive excel tracker.

7.6 Compliance

Subjects will report the average number of days per week that the lenses were worn and their average daily wearing time (hours) at follow-up visits. The data will be summarized by visit.

7.7 Interim Analyses

No interim analyses are planned

7.8 Additional Statistical Considerations

7.8.1 Analysis Populations

- The Full Analysis Set (FAS) will consist of all eligible, dispensed subjects or eyes.
- The Safety Set will consist of all dispensed subjects or eyes.

7.8.2 Sample Size Determination

Approximately 300 subjects will be enrolled. Allowing for up to 10% losses, power calculations were completed for 270 completed subjects. An exact binomial test with a nominal 5% one-sided significance level will have 93% power to detect the difference between the Null hypothesis proportion, π_0 of 0.5 and the Alternative proportion, π_1, of 0.6 when the sample size is 270.

7.8.3 Handling of Missing Data

Missing data will not be imputed.

7.8.4 Multicenter Issues

The study will be conducted at multiple investigational centers in North America with the intention of pooling the results for analysis.

7.8.5 Multiplicity Issues

The overall Type I error will be controlled by requiring the primary effectiveness endpoint to be statistically significant. Specifically, failure of the primary effectiveness endpoint will invalidate the statistical significance of the supportive effectiveness endpoints. See Section 7.1.3 for further detail

8.0 DATA QUALITY ASSURANCE

8.1 Subject Confidentiality

All personal subject data collected and processed for the purposes of this trial will be maintained by the Investigator and his/her staff with adequate precautions as to ensure that the confidentiality of the data is in accordance with local, state, and federal laws and regulations.

Monitors, auditors, and other authorized representatives of CRO, the Sponsor, the IRB approving this trial, the FDA, the Department of Health and Human Services, other domestic government agencies, and other foreign regulatory agencies will be granted direct access to the trial subject's original medical and trial records for verification of the data

and/or clinical trial procedures. Access to this information will be permitted to the aforementioned individuals to the extent permitted by law.

A report of the results of this trial may be published or sent to the appropriate health authorities in any country in which the product may ultimately be marketed, but the subject's identity will not be disclosed in these documents.

Suspected data breaches involving Personal Health Information will be escalated to Bausch + Lomb Data Privacy representative per B+L SOP CLN-035 - Privacy of Clinical Data and Related Protection.[2]

8.2 Study Monitoring

Bausch + Lomb Clinical Operations 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 Clinical Operations.

Prior to the start of the study, member(s) of the Bausch + Lomb Clinical Operations, Clinical Affairs, and Global Regulatory Affairs 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 to verify the following:

- The rights and well-being of subjects are protected
- The conduct of the investigation is in compliance with the currently approved protocol/amendment, 21 CFR Parts 11, 50, 54, 56 and 812; 42 CFR Part 11 – Clinical Trials Registration and Results Information Submission; EN ISO 14155:2020 *Clinical investigation of medical devices for human subjects – Good clinical practice*; Medical Device Regulation (MDR) 2017/745; International Council for Harmonisation (ICH) Good Clinical Practice (GCP); the Declaration of Helsinki and applicable local regulations
- The integrity of the data, including adequate study documentation
- The facilities remain acceptable
- The Investigator and site personnel remain qualified and able to conduct the study
- Investigational test article accountability

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.

Plans for monitoring study sites, designed to ensure compliance with GCPs, study-specific procedures, human rights, and applicable regulations, are described in the Monitoring Plan.[3]

8.3 Source Documentation

All medical information obtained at each study visit must be recorded in the subject's record (source documentation) in real time as it is collected. 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.

Examples of source documents include hospital records, clinical and office charts, laboratory notes, memoranda, signed ICFs, 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. Source documentation worksheets may be provided by the Sponsor to record pertinent information.

Subject-completed forms are also considered to be source data. In no instance should an Investigator or study site personnel record any data or make changes to subject-completed forms. The Investigator or designee should review subject-completed forms during study visits for completeness and accuracy. If an entry is found to be illegible or a mistake is found (e.g., incorrect year was recorded), the subject should be instructed to edit the entry by drawing a single line through the original entry, entering the new information, and dating and initialing the change.

Subjects should be provided the rating scales (separate document) to use while responding to the lens performance assessments being collected. Enter rating from 0 to 100 (e.g., 90).

Source documentation worksheets may be provided by the Sponsor as a tool to record pertinent information. The completed worksheets can then be incorporated into the subject's medical chart. If it is preferred to not use the worksheets in the subject's permanent record, then the worksheets should be used as a reference to determine the type of study data to record in the subject's permanent record. The source document worksheets may be used as a supplement for the subject's medical records.

8.4 Electronic Case Report Forms and Data Verification

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. All information required on the eCRFs needs to be supplied, including subject identification, date(s), assessment values, etc., and any omission or discrepancy will require explanation. All information on eCRFs must be traceable to source documents. Market research data will be collected via ePRO and processed according to the policies and procedures of the ePro vendor. The data will not be included on eCRFs or verified by Bausch + Lomb.

A Clinical Monitor will be responsible for reviewing and verifying 100% of the data recorded on the eCRFs, utilizing the original source documentation, and will query discrepant findings. The Investigator and study site personnel will be responsible for answering all queries.

The eCRF data will be reviewed for completeness, accuracy, consistency, and medical sense. Programmed edit checks will be used to reduce data entry errors and identify unusual data for verification prior to statistical analysis.

A copy of the eCRF data will be retained at the conclusion of the study by the Investigator, who must ensure that it is stored in a secure place.

8.5 Recording of Data and Retention of Documents

Subject data recorded on eCRFs during the study will be documented to maintain subject confidentiality. The subject will only be identified by the subject ID number. Confidentiality of subject's records must be maintained to ensure adherence to applicable local privacy regulations.

The Investigators have to retain records for 2 years after the investigational product is approved by the FDA. The Investigator agrees to adhere to the document retention procedures when signing the protocol Investigator Statement of Approval.

Essential documents include but are not limited to the following:

- Device Investigator Agreement
- Institutional Review Board approvals for the study protocol, all amendments, ICF(s), and advertisements
- Institutional Review Board annual study review
- Institutional Review Board correspondence and reports (e.g., AE reports, protocol deviations, and safety updates)
- Regulatory documents (e.g., financial disclosure and delegation of authority forms or records)
- All source documents
- Electronic CRFs
- Subject's signed ICF (including HIPAA)
- Accountability records for the test article(s)
- Correspondence from and to the Sponsor
- Any other documents relevant to the conduct of the study

In the event that study records are transferred to another location, the Investigator will provide notice of such transfer in writing to Bausch + Lomb Clinical Operations.

8.6 Auditing Procedures

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.

8.7 Institutional Review Board

The Investigator should ensure that the following are approved by their institution's IRB, or if not using their institution's IRB, approved by the reviewing central IRB prior to entering any subjects in the study:

- The protocol
- The Investigator's participation in the study
- Subject recruitment materials (written information or materials including web pages, radio advertisements, television spots, or written text developed to encourage subject enrollment)
- The ICF to be used in this study

Documentation of IRB approval of the study protocol and informed consent must be provided to the Sponsor prior to initiation of 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 Sponsor and the IRB and implemented as directed.

8.8 Publication of Results

All study data generated as a result of this study will be regarded as confidential, until appropriate analysis and review by the Sponsor or its designee and the Investigator(s) are completed. The results of the study may be published or presented by the Investigator(s) after review by, and in consultation and agreement with, the Sponsor, and such that confidential or proprietary information is not disclosed.

Prior to publication or presentation, a copy of the final text should be forwarded by the Investigator(s) to the Sponsor or its designee, for comment. Such comments shall aim to ensure the scientific integrity of the proposed publications and/or presentations and ensure that the data and material referring to Bausch + Lomb products and activities receive fair, accurate, and reasonable presentation.

9.0 REFERENCES

Global and Regional Regulatory References:

- EN ISO 14155:2020 *Clinical investigation of medical devices for human subjects – Good Clinical Practice*
- EN ISO 11980:2012 *Ophthalmic Optics – Contact Lenses and contact lens care products – Guidance for clinical investigations*
- 21 CFR Part 11 – Electronic Records; Electronic Signatures
- 21 CFR Part 50 – Protection of Human Subjects
- 21 CFR Part 54 – Financial Disclosure by Clinical Investigators
- 21 CFR Part 56 – Institutional Review Boards
- 21 CFR Part 812 – Investigational Device Exemptions
- 42 USC 282(j)
- MDR 2017/745 – Regulation of the European Union on the clinical investigation and sale of medical devices for human use

Literature References:

1. Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens Investigator's Brochure
2. B&L SOP No. CLN 035 – Privacy of Clinical Data and Related Information
3. Protocol 916 Monitoring Plan
4. B&L SOP TD-GEN-FRM-039 Clinical Scorecard Evaluation

APPENDIX A: SCHEDULE OF VISITS AND PARAMETERS

All study tasks should be performed by qualified study site personnel as indicated on the delegation of authority log under the supervision of the Principal Investigator. **(Refer to important footnotes at the bottom of the table)**

PROCEDURE/ASSESSMENTS	Screening/ Dispensing Visit Day 1	1-Week Follow-Up Visit Day 8	3-Week Follow-Up Visit Day 23	Unscheduled Visit	Exit Visit
		Day 6-10 (5-9 days after V1)	Day 20-26 (19-25 days after V1)		
Informed consent/HIPAA authorization	X				
Demographics	X				
Contact lens use history and contact lens use (e.g., average daily wear time, number of days worn, lens brand, lens wear modality, lens care system brand, product use history)	X (Habitual)	X[a]	X[a]		
Ocular medical history and concomitant medications	X				
Changes in ocular medical history and concomitant medications		X	X	X	X
Eligibility	X				
Lens fitting	X	X[b]			
Dispense study materials	X	**X**		X[b]	
Collect worn /unworn lenses, blister foils and study materials		X	X	X	X
Adverse events	X	X	X	X	X
Symptoms/Complaints Form	X (Habitual)	X	X	X	
Subject-completed forms/surveys					
Baseline Questionnaire	X				
Lens Performance Rating Scales (after 10 minutes of lens settling & adaptation, if just inserted)	X[c]	X	X		
Instruct subject to complete Online Consumer Survey at least 7 days after the 1-Week Follow-Up Visit but before the 3-Week Follow-Up Visit		X			
Confirm Visit in ePRO (triggers survey and reminders)		X			
Confirm Subject has completed survey[e]			X		
With habitual lenses					
High-contrast distance logMAR lens VA(OU)	X				
Intermediate lens VA (OU)	X				
Near lens VA (OU)	X				
Without lenses					
Spherocylindrical refraction	X				X

PROCEDURE/ASSESSMENTS	Screening/ Dispensing Visit Day 1	1-Week Follow-Up Visit Day 8	3-Week Follow-Up Visit Day 23	Unscheduled Visit	Exit Visit
Near add power	X				
High-contrast distance logMAR BSCVA (OD/OS/OU)	X				X
High-contrast intermediate logMAR BSCVA (OU w/near add)	X				
High-contrast near logMAR BSCVA (OU w/near add)	X				
Pupil measurement	X				
Keratometry	X				X
Slit lamp exam	X	X	X	X	
With dispensed study lenses/With WORN study lenses[d]					
High-contrast distance logMAR lens VA (OU)	X	X	X	X	X
High-contrast intermediate logMAR lens VA (OU)	X	X	X	X	X
High-contrast near logMAR lens VA (OU)	X	X	X	X	X
Lens wettability	X	X	X	X	X
Lens deposits (type, percent, and degree)		X	X	X	X
Lens centration	X	X	X	X	X
Lens movement	X	X	X	X	X
Compare distance lens VA to screening/dispensing BSCVA	X	X	X	X	X
Investigator-completed forms					
Investigator questionnaire					X

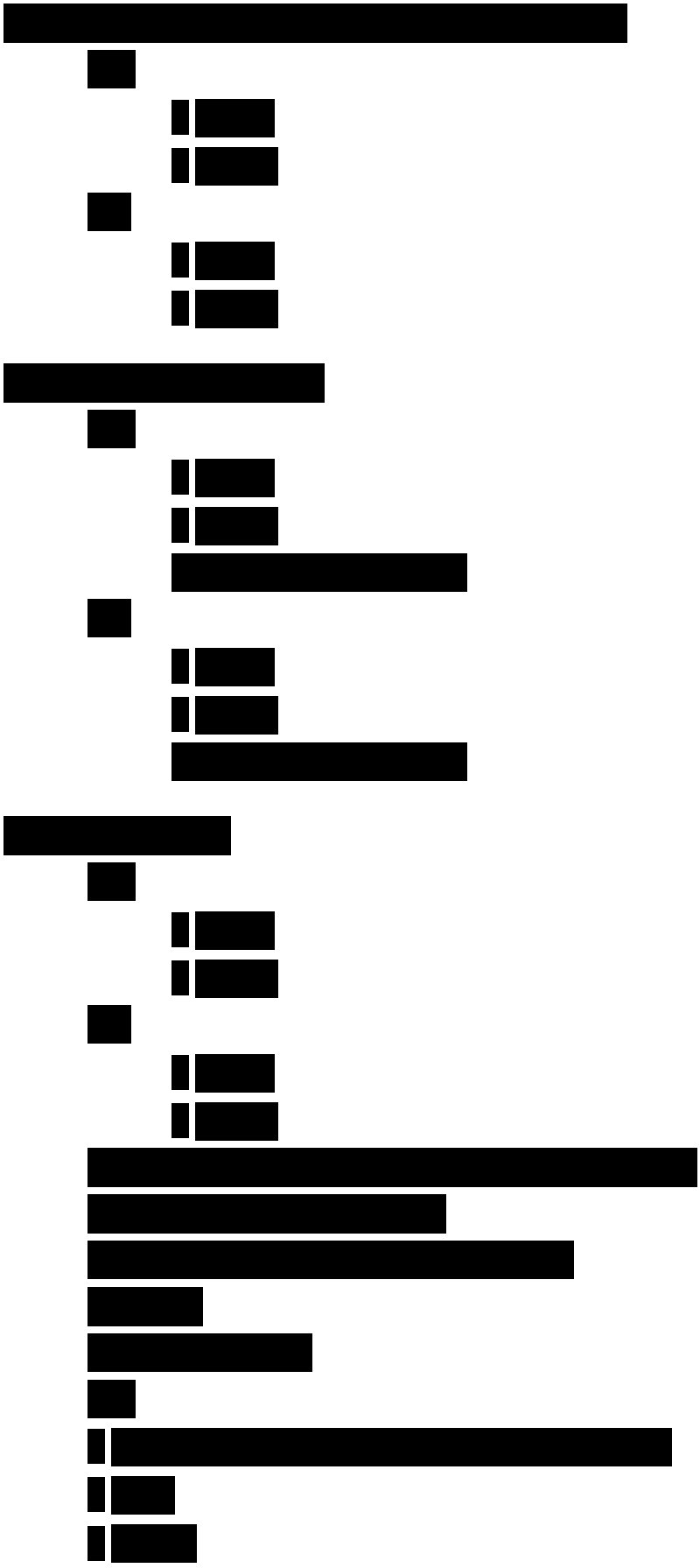
[a] Collect only study lens wear at follow-up visits (average daily wear time, number of days worn, rewetting drop use, if a habitual rewetting drop user).
[b] If the subject requires a change to their study lens power, adjust the fit and dispense study lenses with the appropriate power according to the Fitting Guide.
[c] All Lens Performance ratings will be collected on habitual lenses at Screening. Abbreviated Lens Performance ratings will be collected once the study lenses are dispensed and adapted on the eye. Use provided rating scales (separate document).
[d] At dispensing allow 10 minutes from insertion for lens settling & adaptation before performing assessments.
[e] If subject has not completed survey, they should complete at this visit.

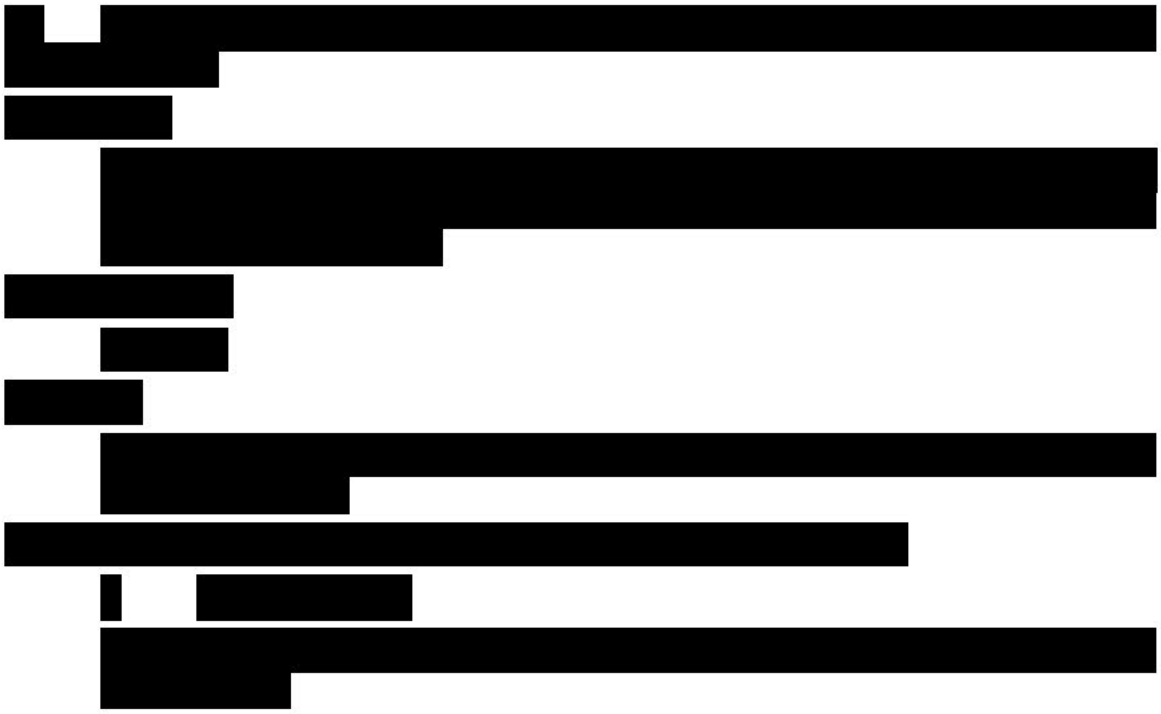
Note: All VA measurements MUST be made using a phoropter.
Note: If this is an Exit Visit, also perform the procedures listed under the Exit Visit column.

[redacted]

[redacted]

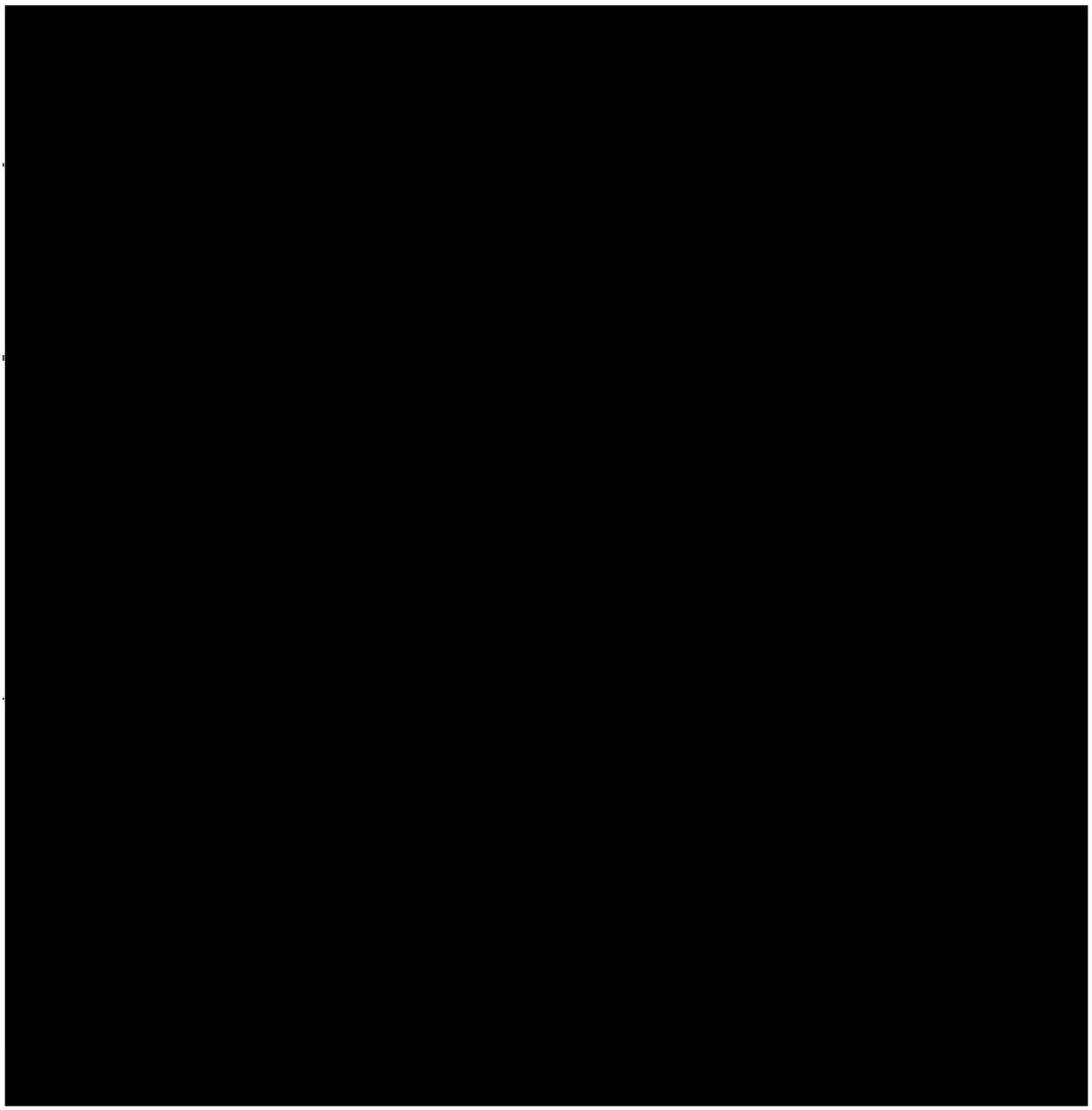
[redacted]



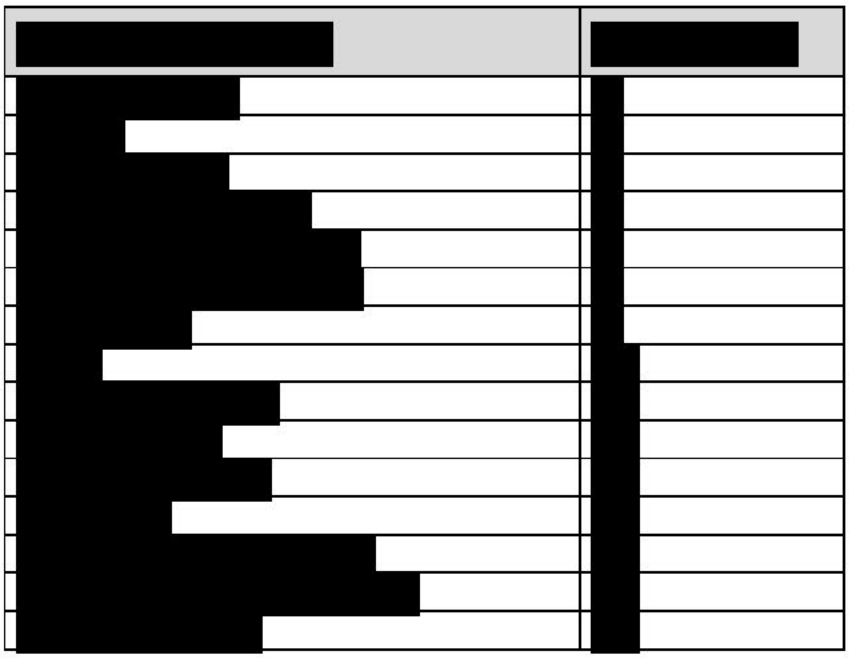


[redacted]

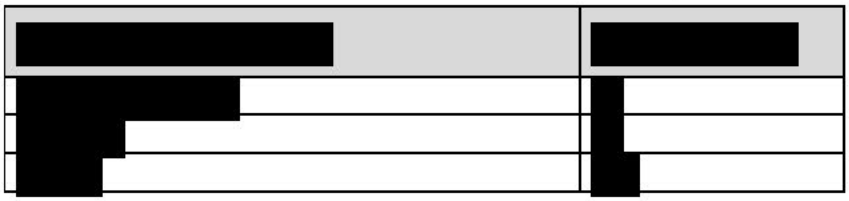
BAUSCH + LOMB™



[redacted]



[redacted]



[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

APPENDIX C: SUBJECT INSTRUCTIONS

FOR SINGLE-USE DISPOSABLE WEAR

CAUTION: Investigational Device. Limited by Federal law (U.S.A.) to investigational use.

INTRODUCTION

You will participate in this study designed to evaluate the product performance of the investigational Bausch + Lomb (kalifilcon A) Daily Disposable Multifocal Contact Lens (Test). Study lenses will be dispensed at the Screening/Dispensing Visit. **It is very important that you do not use any other contact lenses other than those dispensed to you during the study.**

You will wear the lenses on a daily disposable basis and replace the lenses daily but **do not discard your worn lenses,** as they will be collected at your 1-Week and 3-Week Follow-Up Visits. Throughout the study, place all worn lenses in a study lens case that was provided to you (up to 10 pairs of lenses per case) with no solution (dry). You will return the lens cases to the office at your 1-Week and 3-Week Follow-Up Visits/Exit Visit. Bring all lenses (worn in lens cases and unworn blister packs) and blister foils to the 1-Week and 3-Week Follow-Up Visits/Exit Visit or any unscheduled visit.

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

Note: Please schedule your 1-Week and 3-Week Follow-up Visits at the Screening/Dispensing Visit.

Follow-Up Visit Schedule

Visit	Day/Month/Year	Time
1-Week Follow-Up	/ /	_____
**At the 1-Week Follow-up, you will be provided information regarding an Online Consumer Survey to be completed after at least 7 days of wear after the 1-Week Follow-Up Visit but before the 3-Week Follow-Up Visit.*		
3-Week Follow-Up	/ /	_____

Note: Wear your study lenses to your follow-up visit.

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

- Lens cases for storage of worn study lenses (up to 10 pairs of lenses, stacked dry).

GENERAL INFORMATION

Do NOT use any products other than those dispensed to you by your study doctor for use in this study, with the exception of rewetting drops if you habitually use them.

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 study doctor 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 study doctor to explain anything that you do not understand, including any additional restrictions which may be given to you by your study doctor. 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 study doctor. 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 study doctor 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 study doctor, 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 and a lens case available in case you have to remove your lenses immediately upon the appearance of a problem or symptom.
- Do not use aerosol products such as hair spray while wearing your lenses. The lenses may absorb the spray, resulting in injury to the eye and damage to the lens.
- Avoid wearing the lenses around fumes, irritating vapors, smoky or dusty conditions. The lenses may absorb the chemicals or particles, resulting in injury to the eye.
- 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 study doctor or physician. Some drops, ointments, or medicines will cause injury to the eye if used by a contact lens wearer.
- Ask your study doctor 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 study doctor 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 study doctor'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 study doctor.

3. PRECAUTIONS

You should be aware of and fully discuss with your study doctor 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), you should use a solution intended to lubricate or rewet a contact lens, as recommend by your eyecare practitioner. 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 study doctor. Do not attempt to remove the lens, except on the instructions of your study doctor.

- 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.
- Do not touch contact lenses with your fingers or hands if your hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to your eye.
- Carefully follow these handling, insertion, and wearing instructions for the daily disposable contact lenses and those instructions prescribed by your study doctor.
- Never wear lenses beyond the period recommended by your study doctor.
- Always handle lenses gently and avoid dropping them.
- Ask your study doctor about wearing lenses during water activities and other sports.
- 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 study doctor before using any medicine in your eyes.
- 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 study doctor 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 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 has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, insert a new lens. After insertion of a new lens, if the problem continues, you should immediately remove the lenses and consult your study doctor.

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.
- 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 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 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 professional.

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.

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."

- **<u>Centering the Lens</u>**:

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.

- **<u>Removing the Lens:</u>**

Always remove the same lens first.

1) Always wash your hands thoroughly with mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.

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 study doctor 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), use a solution intended to lubricate or rewet a contact lens, as recommend by your eyecare practitioner. 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 study doctor immediately. Do not attempt to remove the lens except on the advice of your study doctor.

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 STUDY DOCTOR OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY**.

APPENDIX D: FITTING GUIDE

FOR SINGLE-USE DISPOSABLE WEAR

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

IMPORTANT

This Fitting Guide has been developed to provide professionals with information covering characteristics of the investigational daily disposable contact lens and to illustrate fitting procedures. Please read carefully and keep this information for future use. This Fitting Guide is intended for the eye care professional but should be made available to subjects upon request. The eye care professional should provide the subject with the Subject Instructions that pertain to the subject's prescribed lens, and the recommended wearing schedule.

LENS PARAMETERS AVAILABLE (For the study lenses used in this study)

Test Article:

The study lens to be used in this study is the Bausch + Lomb kalifilcon A daily disposable contact lens. The description of the study lens is as follows:

- Sphere Power: -6.00 D to +3.00 in steps of 0.25 D
- ADD: High or Low
- Diameter: 14.2 mm
- Base Curve: 8.6 mm
- Material: kalifilcon A

HOW THE LENS WORKS (ACTIONS)

In their hydrated state, when the contact lens is placed on the cornea, they act as a refracting medium to focus light rays on the retina.

INDICATIONS

The Bausch + Lomb daily disposable contact lens is intended for the daily disposable wear correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 1.00 D or less, that does not interfere with visual acuity. The lenses may be prescribed in spherical powers ranging from +3.00D to -6.00D in steps of 0.25 D with a high or low ADD. The lenses have been prescribed for single-use disposal wear and will be replaced after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb daily disposable 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, subjects should be fully apprised by the prescribing professional of all the risks with contact lens wear. Subjects should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses could result in **serious injury** to the eye. It is essential that subjects follow their 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 subjects should be instructed not to wear lenses while sleeping**. Clinical studies have shown that the risk of serious adverse reactions is increased when daily disposable 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 subject experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the subject 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

Precautions for Eye Care Professionals:

- Due to the small number of subjects 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 subject's ocular health should be carefully weighed against the subject's need for refractive correction; therefore, the continuing ocular health of the subject and lens performance on eye should be carefully monitored by the prescribing eye care professional.

- Subjects 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 subject.
- Eye care professional should instruct the patients to remove the lens immediately if the eye becomes red or irritated.
- Fluorescein should not be used while the subject is wearing the lenses, because the lenses will become discolored. Whenever fluorescein is used, flush the eyes with sterile saline solution. Wait at least 5 minutes before inserting new lenses. If it is not possible to flush the eyes, wait a minimum of 1 hour before inserting new lenses. If inserted too soon, the lenses may absorb residual fluorescein.
- Before leaving the eye care professional's office, the subject should be able to promptly remove lenses.
- The lenses are prescribed for disposable wear and are to be stored for return to the eye care professional once they are removed from the subject's eye. It is important that subjects 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.

Eye care professionals should carefully instruct subjects about the following safety precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the subject should be instructed to **immediately** consult his or her eye care professional. Do not attempt to remove the lens, except on the instructions of the eye care professional.
- 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.
- 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 Subject Instructions and those prescribed by the eye care professional.
- Never wear lenses beyond the period recommended by the eye care professional.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care professional about wearing lenses during water activities and other sports.
- Inform the 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 the hand.

- Do not touch the lens with fingernails.
- Always contact the eye care professional before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the subject not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the subject's eyes. The subject should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

The subject 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 subject notices any of the above, he or she should be instructed to:

- **Immediately remove 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 subject should insert a new lens. After insertion of a new lens, if the problem continues, the subject should **immediately remove the lenses and consult the eye care professional**.

If the above symptoms continue after removal of the lens, or upon insertion of a new lens, the subject 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 stinging 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 subject presenting symptom 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 subject 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 SUBJECTS

Persons who require vision correction and who would not or could not adhere to the replacement regimen for the Bausch + Lomb daily disposable contact lenses or are unable to place and remove the lenses should not be provided with them. Failure to follow handling instructions could lead to serious eye infections, which might result in corneal ulcers.

Subject communication is vital because it relates not only to subject selection but also to ensure compliance. It is also necessary to discuss the information contained in the Subject Instructions with the subject at the time of the initial examination. Subjects selected to wear the Bausch + Lomb daily disposable contact lens 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 subjects. Subject hygiene and willingness to follow eye care professional instructions are essential to their success.

A detailed history is crucial to determining subject needs and expectations. Your subject 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 lens should be preceded by a complete eye examination, including visual acuity, keratometry, and slit lamp examination.

It is normal for the subject 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 subject should be instructed to contact his or her eye care professional.

FITTING PROCEDURE

1. Pre-fitting Examination

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

- determine whether a subject is a suitable candidate for daily disposable contact lenses (consider subject 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 spherocylindrical refraction and VA, keratometry, and biomicroscopic examination.

2. Initial Lens Power Selection

- Lens power is determined from the subject's spherical equivalent prescription corrected to the corneal plane.
- Select the appropriate power lens and place the lens on the eye. Allow the lens to remain on the eye long enough (10 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.
- Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. Initial Lens Evaluation

- 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
    - Up gaze blink
    - Up gaze lag
  - Centration: The lens should provide full corneal coverage.
- Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any daily disposable 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 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 subject gaze upward. A properly fitted lens will tend to slide downward approximately 0.5 mm 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 2.0 mm on up-gaze post-blink.

7. Follow-up Care

- From the day of dispensing, the following schedule is required for this study.
  - 1-Week Follow-Up Visit
  - 3-Week Follow-Up Visit

- Prior to a follow-up examination, the contact lenses should be worn for approximately 1 continuous hour and the subject should be asked to identify any problems which might be occurring related to contact lens wear.
- 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.
- After the lens removal, instill sodium fluorescein (unless contraindicated) into the eyes and conduct a thorough biomicroscopy examination.
    - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.
    - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
    - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens. 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.

MULTIFOCAL FITTING GUIDELINES

1. Lens Selection

- Update spectacle refraction and Add power.
- Determine dominance at distance vision by placing a +1.50 loose handheld trial lens alternatively over each eye binocularly through updated distance correction. The eye for which binocular vision is blurriest through the +1.50 is the dominant eye.
- Select lens distance prescription based upon spherical equivalent from spectacle prescription, adjusted for vertex distance if necessary.
- Choose trial lenses based upon the above calculation and select Add power (Both eyes).
    - Bausch + Lomb INFUSE Multifocal Low Add: +0.75 to +1.50D
    - Bausch + Lomb INFUSE Multifocal High Add: +1.75D to +2.50D

2. Lens Fitting

- Allow lens to equilibrate for at least 10 minutes before assessing fit and vision.
- Evaluate distance and near vision binocularly in normal room illumination.
- If vision at distance and near is satisfactory, dispense lenses.

3. To Refine Near Vision

If patient is wearing two Low Add lenses:

- Refinement 1: Place Bausch + Lomb INFUSE Multifocal High Add in non-dominant eye while keeping Bausch + Lomb INFUSE Multifocal Low Add in dominant eye.
- Refinement 2: If vision is still unsatisfactory, continue adding +0.25 at a time to the non-dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1: Add +0.25D to the non-dominant eye.

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

4. To Refine Distance Vision

If patient is wearing two Low Add lenses:

- Refinement 1: Fit Bausch + Lomb INFUSE SVS in dominant eye while keeping Bausch + Lomb INFUSE Multifocal Low Add in non-dominant eye.
- Refinement 2: If vision is still unsatisfactory, add -0.25D at a time to dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1: Fit with Bausch + Lomb INFUSE Multifocal Low Add in dominant eye while keeping Bausch + Lomb INFUSE Multifocal High Add in non-dominant eye.
- Refinement 2; If vision is still unsatisfactory, add -0.25 at a time to dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.

5. 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 bad 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.

WEARING SCHEDULE

The wearing and daily disposable schedules should be determined by the eye care professional. Regular checkups, as determined by the eye care professional, are extremely important.

Daily Disposable:

There may be a tendency for the daily disposable subject to over-wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily disposable schedule should be stressed to these subjects. 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 subject. The lens is to be prescribed for single-use disposable wear and is to be replaced after each removal.

All subjects should be supplied with a copy of the Subject Instructions.

HANDLING OF LENSES

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

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving), the subject should use a solution intended to lubricate or rewet a contact lens, as recommend by your eyecare practitioner. The subject should be instructed to not use plain water, or anything other than the recommended solutions. The subject 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.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in subjects wearing the Bausch + Lomb daily disposable contact lens should be reported according to the Protocol.

HOW SUPPLIED

The lenses are provided individually in a plastic blister containing sterile packaging solution. Each blister lid stock is marked with the following;

- Lens power
- Base curve
- Diameter
- ADD
- Lot number
- Expiration date
- Manufacturer’s name
- Manufacturer’s place of business
- Caution statement