VALEANT
Pharmaceuticals International, Inc.

Clinical Study of Approved Contact Lenses

PROTOCOL STUDY ROC2-17-014

Sponsor:
Bausch + Lomb Incorporated

This clinical investigation is being conducted in accordance with 21CFR Parts 50, 54, 56 and 812, and 42 USC 282(j). The protocol was developed with consideration of the provision in: ISO 14155:2011 Clinical investigation of medical devices for human subjects — Good Clinical Practice; ISO 11980:2012 Ophthalmic Optics – Contact lenses and contact lens care products – Guidance for clinical investigations; ICH GCPs; and applicable local regulations.

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INVESTIGATOR STATEMENT OF APPROVAL

Clinical Study of Approved Contact Lenses

PROTOCOL STUDY ROC2-17-014

I have read the attached document, 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 21CFR Parts 50, 54, 56 and 812, and 42 USC 282(j); the protocol was developed with consideration of the provision in: ISO 14155:2011 Clinical investigation of medical devices for human subjects – Good Clinical Practice; ISO 11980:2012 Ophthalmic Optics - Contact lenses and contact lens care products - Guidance for clinical investigations; ICH GCPs; 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 will obtain written informed consent (and, if applicable, assent for children) from each study subject prior to performing any study specific procedures.

I understand that my signature on this document indicates my agreement to this clinical Investigational Plan/Protocol and, if appropriate, to review and sign the clinical study report.

I understand that my e-signature on a case report form 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 IRB/ECs, direct access to my medical records for study subjects.

_____

Principal Investigator, Printed Name

_____ _____

Principal Investigator, Signature Date

Upon signing, provide a copy of this page to Bausch + Lomb and retain a copy for your files.

PERSONNEL AND FACILITIES

NOTE: The information on this page is subject to change. All changes will be provided under separate cover.

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

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LIST OF ABBREVIATIONS

Abbreviation/Acronym	Term
AE	Adverse Event
ANOVA	Analysis of Variance
BSCVA	Best Spectacle-Corrected Visual Acuity
CFR	Code of Federal Regulations
CRF/e-CRF	Case Report Form / Electronic Case Report Form
D	Diopter
DOB	Date of Birth
EC	Ethics Committee
FDA	United States Food and Drug Administration
GCPs	Good Clinical Practices
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
US	United States
USC	United States Code
VA	Visual Acuity

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

1.0 INTRODUCTION

The aim of this study is to compare the performance of currently marketed Johnson & Johnson Acuvue Vita (senofilcon C) soft contact lenses to the currently marketed Bausch + Lomb Ultra (samfilcon A) soft contact lenses among adapted wearers of Acuvue Oasys soft contact lenses.

2.0 OBJECTIVE

The objective of the study is to evaluate the product performance of currently marketed Acuvue Vita contact lenses (Test) compared to currently marketed Ultra contact lenses (Control).

3.1 STUDY DESIGN

3.2 Description of Study Design

In this randomized, bilateral, double-masked, 1-month study with two parallel groups, approximately 260 subjects (520 eyes) will be enrolled at approximately 10 investigative sites in the United States (US).

Approximately one-half of the subjects (130) will be randomized to receive Test contact lenses and the other half (130) will be randomized to receive Control contact lenses in a 1:1 ratio at the Dispensing Visit. All subjects will be dispensed study lenses according to a unique randomization schedule provided to each site. Both groups will wear the study lenses on a daily wear basis. After two weeks of wearing the study lenses, the subjects will return for an exam, and then continue wearing the same study lenses for the remaining 2 weeks.

Each subject will be required to complete four Take Home Lens Performance Surveys. All take home surveys are required to be completed after a minimum of 5 days of experience with the dispensed study lenses. The first two take home surveys must be returned at the 2-Week Follow-up Visit. The remaining two take home surveys are required to be completed during each of the remaining two weeks (one per week) and must be returned at the final 1-Month Follow-up Visit. All take home surveys will be reviewed by the Investigator for completeness when returned.

Subjects will be required to clean and disinfect their lenses each day using Biotrue™ multi-purpose solution and the contact lens cases provided. The lenses will be worn on a daily wear basis for the entire 1-month study with no scheduled replacement.

3.3 Selection of Study Population

Written informed consent, enrollment in the study, or dispensing of study products cannot begin until the Investigator has received Institutional Review Board (IRB)/Ethics Committee (EC) approval to conduct the study. After receiving IRB approval, recruitment for the study may start at any point after the Investigator agrees, in writing, to participate in the study. The Sponsor and IRB/EC must approve any advertising or other materials used to recruit subjects prior to use of that advertising or material.

Each subject must meet the requirements of the Pre-Screening Tool provided to each site. Each subject will then be assigned a subject identification (ID) number from the Randomization Schedule. Potential subjects are deemed either "Screen Pass" or "Screen Fail." "Screen Fail" subjects have not met the study inclusion criteria or have met the exclusion criteria. "Screen Fail" subjects cannot participate in the study. Case report forms (Electronic CRFs) will be completed for "Screen Fail" subjects, and the 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.

"Screen Pass" subjects have met all of the study inclusion criteria and have not met any of the exclusion criteria. Only "Screen Pass" subjects are eligible to participate in the study. Subjects who meet all inclusion criteria but are found not to be eligible to participate in the study due to lens fitting characteristics at the Screening/Dispensing Visit will be exited as a non-dispensed subject.

Once a subject passes the initial screening criteria they are considered active and must be accounted for at every visit until exited (completed or discontinued) from the study. Refer to Section 3.3.5 for subjects determined to be lost to follow-up.

3.3.1 Eligibility

3.3.1.1 Inclusion Criteria

1. Subjects must be between the ages of 18 and 40 years old, inclusive, on the date the Informed Consent Form (ICF) is signed and have the capacity to provide voluntary informed consent.
2. Subjects must be able to read, understand and provide written informed consent on the Institutional Review Board (IRB)/Ethics Committee (EC) approved ICF and provide authorization as appropriate for local privacy regulations.
3. Subjects must be willing and able to comply with all treatment and follow-up/study procedures.
4. Subjects must be correctable through spherocylindrical refraction to 32 letters (0.3 logMAR) or better (distance, high contrast) in each eye.
5. Subjects must have clear central corneas and be free of any anterior segment disorders.
6. Subjects must be myopic and require contact lens sphere power correction from -0.50 diopter (D) to -6.00 D (considering vertex distance adjustments in both eyes).
7. Subjects must be habitual wearers of Johnson & Johnson Acuvue Oasys single vision spherical soft contact lenses in each eye.
8. Subjects must use a contact lens care regimen on a routine basis.
9. Subjects must agree to wear their study lenses on a daily wear basis for the duration of the study.

3.3.1.2 Exclusion Criteria

1. Subjects participating in any drug or device clinical investigation within two weeks prior to entry into this study and/or 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 which in the Investigator's opinion may have an effect on ocular health during the course of the study.
4. Subjects using any systemic or topical medications that will, in the Investigator's opinion, affect ocular physiology or lens performance.
5. Subjects with an active ocular disease or who are using any ocular medication.
6. Subjects who are not correctable to 32 letters (0.3 logMAR) in each eye with soft spherical contact lenses.
7. Subjects who currently wear monovision or multifocal contact lenses.
8. Subjects with refractive astigmatism of 0.75 D or greater in either eye.
9. Subjects who are current Acuvue Oasys wearers who have previously been unsuccessful in wearing Acuvue Vita and/or Ultra contact lenses.
10. Subjects with anisometropia (spherical equivalent) of greater than 2.00 D.
11. Subjects with any grade 2 or greater finding during the slit lamp examination (refer to Appendix B for methods of clinical evaluation). Subjects with corneal infiltrates, of ANY GRADE, are not eligible.
12. Subjects with any "Present" finding during the slit lamp examination (refer to Appendix B for methods of clinical evaluation) that, in the Investigator's judgment, interferes with contact lens wear.
13. Subjects with 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 judgment, does not interfere with contact lens wear, are eligible for this study.
14. Subjects who are aphakic.
15. Subjects who are amblyopic.
16. Subjects who have had any corneal surgery (e.g., refractive surgery).
17. Subjects who meet any of the following criteria:
    - the subject is an employee of the investigative site
    - the subject, or a member of the subject's household, is an employee of a marketing research firm
    - the subject, or a member of the subject's household, is an Ophthalmologist, an Optometrist, an Optician, or an Ophthalmic Assistant/Technician
    - the subject, or a member of the subject's household, is an employee of a manufacturer of contact lenses or contact lens care products (e.g., Alcon, Bausch & Lomb, CooperVision, Johnson & Johnson, etc.)

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 when the 1-Month Follow-up Visit is concluded. Subjects who require further follow-up will be followed according to the AE or Post-Study Follow-Up Section.

3.3.3 Subject Discontinuation

A subject MAY be discontinued (at the discretion of the Investigator, the Sponsor, and/or the IRB/EC) 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 (must be reported to the Sponsor within 24 hours)
- persistent study related symptoms/complaints
- unacceptable distance lens visual acuity (VA)
- unacceptable lens centration
- unacceptable lens movement

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

- voluntary withdrawal
- death
- Investigator decision that it is not in the best medical interest of the subject to continue participation in the investigation
- ineligible at baseline- does not meet the eligibility criteria in the protocol
- inability to maintain recommended wearing schedule
- lack of motivation
- continued failure to follow subject instructions
- subject missed the 2-Week Follow-up Visit
- lost to follow-up (refer to Section 3.3.5)
- instillation of non-medically indicated solution not specified in the protocol
- other 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 to retrieve all study materials. Adverse events will be followed as described in Section 6. Subject discontinuations will be documented clearly on the source document and applicable electronic CRF (e-CRF). The Investigator should indicate the PRIMARY (one) reason that the subject was discontinued for each eye. Subjects that are discontinued from the study following randomization will not be replaced.

Exit Visit assessments should be completed for early terminated subjects.

3.3.4 Screen Failures

Subjects failing to meet subject selection criteria during Visit 1 (Screening/Dispensing) are considered screen failures, and the Investigator should indicate the PRIMARY (one) reason for the screen failure in the study database (i.e., eligibility or lens fitting characteristics). Data for those subjects considered screen failures due to fitting characteristics will be collected on the corresponding e-CRF.

3.3.5 Lost to Follow-up

Subjects who do not return for scheduled follow-up visits, as defined by the visit window and cannot be contacted, are to be considered lost to follow-up. All attempts to contact the subject should be documented and kept with the subject's source documentation, and the applicable e-CRFs will be completed.

3.4 Investigators

The study will be conducted at approximately 10 investigative sites located in the US by Investigators who are determined by Bausch + Lomb to be suitably qualified by training and experience to conduct this study. Principal Investigators will be identified on the Device Investigator Agreement Form.

Each Investigator will enroll approximately 26 subjects, 52 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 study.

3.5 Study Duration

Investigators will have four weeks from the enrollment start date communicated by the Sponsor to conduct the Screening/Dispensing Visit(s).

Subjects will be followed for approximately 1 month (unless discontinued or lost to follow-up) from the Dispensing Visit and must adhere to the following schedule:

Visit	Target	Acceptable Visit Range (from Visit test articles are dispensed)
2-Week Follow-up Visit	14 Days	10-18 Days from Dispensing Visit
1-Month Follow-up Visit	30 Days	26-34 Days from Dispensing Visit

The visit range is based on the date study lenses are dispensed. A visit scheduling table will be provided in the initial study shipment to aid the Investigator in scheduling follow-up visits.

4.1 STUDY MATERIALS

Bausch + Lomb will provide all lenses, lens cases, and Biotrue™ multi-purpose solution. All materials will be provided to the site prior to the Dispensing Visit. Refer to Product Replacement Section 4.9 for ordering replacement Test or Control product in the case of loss or damage.

Use of other contact lenses or contact lens care systems is not allowed. However, the use of habitual rewetting drops is allowed.

4.2 Description of Test Article

The currently marketed Johnson & Johnson Acuvue Vita spherical contact lenses will be dispensed in the standard commercial blister packaging in the following:

- Sphere power: -0.50D to -6.00D.
- Diameter: 14.0 mm
- Base curve: 8.4 mm
- Material: senofilcon C
- Packaging solution: buffered saline solution with methyl ether cellulose

4.3 Description of Comparator Product

The currently marketed Bausch + Lomb Ultra spherical contact lenses will be dispensed in the standard commercial blister packaging in the following:

- Sphere power: -0.50D to -6.00D.
- Diameter: 14.2 mm
- Base curve: 8.5 mm
- Material: samfilcon A
- Packaging solution: 0.5% poloxamine in borate buffered saline

4.4 Instructions for Use and Administration

4.4.1 Subject Instructions

a) All subjects must be given Subject Instructions for the use of study articles (refer to Appendix C for subject instructions) and for precautions and warnings related to contact lens wear. Subjects must comply with the instructions provided to them. Subject Instructions will be supplied to the Investigator by Bausch + Lomb 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 or Investigator's opinion, jeopardizes the subject's well-being or the validity of the study, should be discontinued.

4.4.2 Fitting Guide

The Fitting Guides for the use of the marketed lenses will be provided with the study supplies.

4.5 Other Materials

4.5.1 Care System

Bausch + Lomb Biotrue™ multi-purpose solution will be provided for cleaning, rewetting, disinfecting, and storing lenses. Subjects should refer to the package insert for proper lens care instructions. A lens case will also be provided to the subject.

Subjects will be allowed to use their habitual rewetting drops if needed.

No other care products are allowed to be used during this study.

4.6 Packaging and Labeling

Both the test and control lenses will be in standard commercial blister pack packaging.

4.7 Accountability

The Investigator or designee will be responsible for keeping current and accurate records of the amount of study articles received and dispensed, and its disposition. The test articles must be stored under the appropriate conditions in a secure area and are to be dispensed only to subjects enrolled in the study, in accordance with the conditions specified in this protocol. Applicable e-CRFs will be used to track accountability for the test articles and to maintain records of the study articles assigned to each enrolled subject.

At time points throughout the study and/or upon completion of the study, the Sponsor/Sponsor's representative may review the e-CRFs to verify accountability.

Following verification, and as directed by the Sponsor, study articles must be returned to the Sponsor at the address listed on the Personnel and Facilities page, or with the Sponsor's permission, disposed of at the site in an appropriate manner.

4.8 Masking/Unmasking

Both the Investigator and the subjects will be masked to the study treatment. An unmasked designee at each site will be responsible for dispensing study products to the subjects according to the randomization schedule. The randomization schedule will be produced by the Sponsor statistician not otherwise involved in the study until after the database is locked.

Randomization will be completed by the unmasked designee by providing each subject's treatment assignment after the subject has been assigned a subject number (i.e., randomized). The subjects will be assigned randomization numbers sequentially as they are enrolled. The unmasked designee will open the blister packs by removing the foil out of the subject's sight (subject MUST insert lenses). The unmasked designee is also responsible for maintaining study lens inventory, randomization schedule and the Product Accountability Log in a masked fashion.

4.9 Product Replacement

Any additional/replacement (in the case of loss or damage) of Test or Control product must be ordered by fax through Bausch + Lomb Clinical Trial Materials Management, not Customer Service, using the Bausch + Lomb Material Reorder Form.

4.10 Risk Assessment

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

5.1 STUDY METHODS

5.2 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/EC-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 the following at the visits below:

Visit	Item
2-Week Follow-up Visit	Return Take Home Lens Performance Surveys. Subject may complete the second Take Home Lens Performance Survey at this visit, if not completed prior to visit
1-Month Follow-up Visit	Return remaining 2 Take Home Lens Performance Surveys (with study lenses). Subject may complete the final Take Home Lens Performance Survey at this visit, if not completed prior to visit.

5.2.1 Screening Visit

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

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

Screening will proceed as follows:

a. Enter the following information in the e-CRF :
   - subject initials
   - subject date of birth
   - screening date

b. Collect demographic and baseline habitual lens information and record in the e-CRF:
   - The investigator or designees will ask and record the subject's responses to the Lens Performance Survey (100-point scales) regarding their experience with their habitual lens.
   - average daily wearing time
   - confirm current lens brand as Acuvue Oasys
   - current lens care products
   - habitual lens centration
   - habitual lens movement

c. Perform the following baseline assessments (without lenses) and record in the

e-CRF:

- spherocylindrical refraction
- distance best spectacle-corrected visual acuity (BSCVA)
- keratometry

Perform a slit lamp examination (remove the lenses if the subject wore their habitual lenses to the visit). Record the results and findings in the e-CRF.

d. "Screen Fail" subjects are ineligible and cannot continue in the study. The reason for screen failure must be documented and maintained with a copy of their ICF.

e. If the subject is found to be eligible, the Investigator may complete the Dispensing Visit on the same day as the Screening Visit.

f. If lenses need to be ordered record the required information on the Material Reorder Form and schedule the subject for their Dispensing Visit on a separate day as instructed by the Sponsor.

g. The following e-CRF should be completed.

- Screening Visit

If the subject is discontinued or exited at this visit:

- Subject Exit

5.2.2 Dispensing Visit

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

NOTE: Ensure all lenses/lens types for the subject have been received prior to the Dispensing Visit.

NOTE: The Investigator should allow the lenses to properly settle on the eye for a minimum of 5 minutes.

If the Dispensing Visit is occurring on a separate day from the Screening Visit, perform (a) and (b) below, otherwise if the Dispensing Visit occurs on the same day as the Screening Visit, skip to (c).

a. Perform a slit lamp examination (remove the lenses if the subject wore lenses to the visit). Record the results and findings in the e-CRF.

b. Reconfirm subject eligibility. If the subject continues to be eligible, continue the Dispensing Visit. If the subject is determined to be ineligible, they must be discontinued and the reason recorded on the Subject Exit Form.

c. If the subject is eligible, the unmasked designee will dispense 1 pair of the study lenses according to the unique randomization schedule provided to each site. The subject MUST insert the lenses.

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

Record the following into the e-CRF:

- The Investigator or designees will ask and record the subject's responses to the

Lens Performance Survey (100-point scales).
- dispensed lens sphere power, type, and lot number
- distance lens VA
- over-refraction and distance VA
- lens wettability
- lens centration
- lens movement

For each eye, compare the high contrast distance lens VA to the high contrast BSCVA obtained previously in the Screening Visit. If the VA has decreased by 10 letters (0.2 logMAR) or more, explain.

g. The Investigator must assess if the lens fit and VA is acceptable.

   Remind the subjects to complete the first two Take Home Lens Performance surveys after a minimum of 5 days of experience with the study lenses for each week and to return the surveys at their next visit.

h. Subjects who meet all inclusion criteria but are found not to be eligible to participate in the study due to lens fitting characteristics at the Dispensing Visit will be exited as a non-dispensed subject.

i. The following e-CRFs should be completed.
   - Dispensing Visit

   If the subject is discontinued or exited at this visit:

   - Subject Exit

5.2.3 2-Week Follow-up Visit

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

NOTE: If Take-Home Lens Performance Surveys are not completed upon arrival, the second week survey MUST be completed at the visit. The Investigator or designee must review the Surveys for completeness before the subject leaves the office.

NOTE: If the subject misses this visit, they MUST be discontinued.

a. Collect the following lens information from the subject:
   - average daily wearing time
   - average hours of comfortable wear
   - total number of days of lens wear

b. Complete the Symptoms/Complaints section for the subject's responses **using the Rating Scale included in initial shipment.**

c. If the subject did not come to the visit wearing one or more study lenses, go to step e. Otherwise, evaluate the lenses (while on eye), and record the following assessments:
   - The Investigator or designees will ask and record the subject's responses to the Lens Performance Survey (100-point scales).
   - distance lens VA

- over-refraction and distance VA
- lens wettability
- lens deposits
- lens centration
- lens movement

For each eye, compare the high contrast distance lens VA to the high contrast distance lens VA obtained at the Dispensing Visit. If the VA has decreased by 10 letters (0.2 logMAR) or more, explain.

d. Perform a slit lamp examination (remove the lenses if the subject wore lenses to the visit and place the lenses in a lens case provided filled with Bausch + Lomb Biotrue™ multi-purpose solution). Reconfirm subject eligibility. If eligible, continue the 2-Week Follow-up Visit. If the subject is determined to be ineligible, they must be discontinued and the reason recorded on the Subject Exit Form.

e. If subject is still eligible, the subject will re-insert the study lenses (the same pair initially dispensed).

Provide subjects with the remaining two surveys and remind the subjects to complete the Take Home Lens Performance Surveys each week for the remaining two weeks. These surveys must be completed each week after a minimum of 5 days of experience with the study lenses and be returned at their next visit.

f. If this is an Exit Visit, check the Exit Visit box and complete the Subject Exit Form. If a subject misses this scheduled follow-up visit and cannot be seen prior to the start of the visit window for the next scheduled follow-up visit, then the visit is considered missed. The missed visit box must be checked on the first page of the applicable e-CRF.

g. The following e-CRFs should be completed.
   - 2-Week Follow-up Visit

   If the subject is discontinued or exited at this visit:
   - Subject Exit

5.2.4 1-Month Follow-up Visit

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

NOTE: If the <u>final</u> Take Home Lens Performance Survey is not completed upon arrival, the subject MUST complete this survey before the subject is exited. The Investigator or designee must review both Surveys for completeness before the subject leaves the office.

NOTE: If the subject misses this visit, they MUST be discontinued.

NOTE: All worn and unworn lenses must be collected.

a. Collect the following lens information from the subject:
   - average daily wearing time

- average hours of comfortable wear
- total number of days of lens wear

b. Complete the Symptoms/Complaints section for the subject's responses **using the Rating Scale included in initial shipment**.

c. If the subject did not come to the visit wearing one or more study lenses, go to step e. Otherwise, evaluate the lenses (while on eye), and record the following assessments:
   - The Investigator or designees will ask and record the subject's responses to the Lens Performance Survey (100-point scales).
   - distance lens VA
   - over-refraction and distance VA
   - lens wettability
   - lens deposits
   - lens centration
   - lens movement

   For each eye, compare the high contrast distance lens VA to the high contrast distance lens VA obtained at the Dispensing Visit. If the VA has decreased by 10 letters (0.2 logMAR) or more, explain.

d. Perform a slit lamp examination (remove the lenses if the subject wore lenses to the visit and place the lenses DRY in a lens case provided for return to the Sponsor).

e. Fill out the Investigator Questionnaire.

NOTE: All worn, unworn, dispensed, non-dispensed study lenses are to be returned as directed with the materials provided. Worn lenses will be returned DRY in lens cases.

f. The following E- CRFs should be completed.
   - 1-Month Follow-up Visit
   - Investigator Questionnaire
   - The subject has completed the trial – proceed to Subject Exit.

5.2.5 Exit Visit

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

b. For all subjects, complete an exit ocular examination without lenses on the eyes. Collect the following assessments:
   - spherocylindrical refraction
   - distance BSCVA
   - keratometry

c. For each eye, compare the final visit high contrast distance BSCVA to the high contrast distance BSCVA obtained at the Screening Visit. If the VA has decreased by 10 letters (0.2 logMAR) or more, explain.

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

e. Indicate if a Post-study Follow-up Visit is required and if necessary, schedule the subject accordingly.

f. The following e-CRFs should be completed.
   – Subject Exit

5.2.5.1 Take Home Lens Performance Survey

Each subject will be required to complete four Take Home Lens Performance Surveys. Each enrolled subject will be provided with two surveys at the dispensing of the study lenses. Each subject will complete one survey each week after a minimum of 5 days of wearing the study lenses. Both surveys must be returned to the Investigator at the 2-Week Follow-up Visit and reviewed by the Investigator or designee for completeness. At the 2-Week Follow-up Visit, the subject will be given two additional survey and complete a survey each week after a minimum of 5 days of wearing the study lenses. Both remaining surveys must be returned to the Investigator at the 1-Month Follow-up Visit.

5.2.5.2 Unscheduled Visit

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 subject's record and on Unscheduled Visit e-CRFs, 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 recorded in the appropriate scheduled visit e-CRF.

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 e-CRF. 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 e-CRF. Data from any additional visits within a scheduled visit interval will be captured on an Unscheduled Visit e-CRF.

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. If this visit is to dispense study materials only and the subject is not experiencing any problems refer to Section 5.2.6.

b. Collect the following lens information from the subject:
   – average daily wearing time
   – average hours of comfortable wear
   – total number of days of lens wear

c. Complete the Symptoms/Complaints section within the Unscheduled Visit Form **using the Rating Scale included in initial shipment.**

d. If the subject did not come to the visit wearing one or more study lenses, go to step e. Otherwise, evaluate the lenses (while on eye) and record the following assessments:
   - distance lens VA
   - over-refraction and distance VA
   - lens wettability
   - lens deposits
   - lens centration
   - lens movement

   For each eye, compare the high contrast distance lens VA to the high contrast distance lens VA obtained at the visit at which the lenses were dispensed. If the VA has decreased by 10 letters (0.2 logMAR) or more, explain.

e. Perform a slit lamp examination (remove the lenses if the subject wore lenses to the visit and place the lenses in a lens case provided filled with *Bausch + Lomb Biotrue™ multi-purpose solution*).

NOTE: All worn, unworn, dispensed, non-dispensed study lenses are to be returned as directed with the materials provided. Worn lenses will be returned DRY in lens cases.

h. If the subject will continue to wear their original study lenses the subject MUST re-insert the study lenses (the same pair initially dispensed).

f. If lenses are replaced at this visit, collect the following information:
   - primary reason for replacement
   - dispensed lens sphere power, type , and lot number
   - distance lens VA
   - over-refraction and distance VA
   - lens wettability
   - lens centration
   - lens movement

g. The following e-CRFs should be completed.
   - Unscheduled Visit

   If the subject is discontinued or exited at this visit:
   - Subject Exit

5.2.6 Missed Visits

If a subject misses the 2-Week Follow-up Visit and cannot be seen prior to the start of the visit range for the next scheduled follow-up visit, the 2-Week Follow-up Visit is considered missed and the subject must be exited from the study.

The Investigator or designee must check the missed visit box on the first page of the applicable e-CRF for that visit.

See Section 3.3.5 Lost to Follow-Up for applicable instructions for subjects who do not return for the final 1-Month Follow-Up Visit.

5.2.7 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 and record in the Product Dispensing Only e-CRF Form and Product Accountability Log (if applicable):

- visit date
- subject ID number
- subject initials
- primary reason for lens replacement
- dispensed lens sphere power, quantity, type, and lot number

NOTE: All worn, unworn, dispensed, non-dispensed study lenses are to be returned as directed with the materials provided. Worn lenses will be returned DRY in lens cases.

5.2.8 Post-Study Follow-up Visit

If a subject requires further follow-up upon discontinuation or completion of the study, the Investigator must schedule post-study follow-up visits, as necessary.

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 (remove the lenses if the subject wore lenses to the visit). Record the results in the subject's e-CRF.

b) Complete an ocular examination without lenses on the eyes, including spherocylindrical refraction and distance BSCVA.

c) The Investigator is required to follow the subject until the condition no longer warrants further follow-up for study purposes. A Post-Study Follow-up Visit e-CRF must be completed for each of these visits.

d) The following e-CRFs should be completed and submitted.

   – Post-Study Follow-up Visit

5.3 Study Completion

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

5.3.1 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) and IRB/ECs, as applicable. Bausch + Lomb Clinical Affairs 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

Ocular medications or systemic or topical medications that, in the Investigator's opinion, could potentially affect ocular physiology or lens performance are also prohibited, unless medically necessary during the course of the study. If used during the course of the study, these medications must be recorded in the source document and the appropriate e-CRF.

5.5 Protocol Deviations

The date of and reason for deviations will be documented in all cases. Significant or major protocol deviations impacting the safety of the subject or the integrity of the study must be reported by the Investigator to the IRB/EC, CRO and Sponsor, B+L Clinical Affairs immediately. Reporting of all other protocol deviations must adhere to the requirements of the governing IRB/EC.

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

6.1 ADVERSE EVENTS

6.2 Adverse Events

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

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

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

Serious Adverse Events

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

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

- A presumed infectious ulcer (defined as a progressive erosion of the corneal tissue). For the purposes of reporting, a corneal ulcer which has *any* of the following characteristics should be considered in this category:
  - central or paracentral location;
  - penetration of Bowman's membrane;
  - infiltrate ≥2 mm diameter;
  - associated with iritis Grade 2 or greater;
  - associated with any increase in intraocular pressure;
  - culture positive for microorganisms;

- increasing size or severity at subsequent visits.

- Note: Signs of a presumed infectious ulcer may include irregular focal infiltrates; active lesions with raised edges; significant diffuse infiltration; anterior corneal to mid-stromal involvement; erosion with overlying staining; conjunctival and lid edema; anterior chamber reaction (iritis); severe bulbar and limbal redness. Symptoms associated with a presumed infectious ulcer (microbial keratitis) may include pain of rapid onset; severe redness; purulent or mucopurulent discharge; tearing; photophobia.
- Any central or paracentral (within 6mm of cornea) corneal event that results in permanent opacification (such as vascularization).
- Any serious adverse ophthalmic events including hypopyon and hyphema.
- Any neovascularization within the central 6 mm of the cornea.
- Permanent loss of two or more lines of BSCVA.
- All cases of iritis.

Significant Non-Serious Adverse Events

Significant Non-Serious Adverse Events should include:

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

Adverse Event Treatment and Culturing

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

For purposes of this study, the Sponsor requests that in the case of suspected bacterial conjunctivitis, corneal ulcer, or ocular infection a culture must be obtained. Appropriate cultures must be taken to identify the pathogenic organism following the Investigator's standard culturing techniques (e.g., lid, cul-de-sac, cornea, lens and lens case with customary growth media). Forward the cultures to your local clinical laboratory for analysis and report culture results to the Sponsor.

Contact Bausch + Lomb Senior Director of Clinical Affairs with questions regarding culturing.

6.3 Medical Treatment (non-Adverse Events)

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

Guidelines for Reporting Adverse Events (Serious and Significant Non-Serious) and Medical Treatments (Non AE)

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

[redacted]

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

6.3.1 Reporting of Complaints for Ancillary Marketed Bausch + Lomb Products

For Bausch + Lomb marketed products used as ancillary products in the study, the Investigators should report any complaints, malfunctions or similar events related to these products as they would in their normal clinical practice and in accordance with reference information as outlined on the commercial packaging.

7.1 Statistical Methods

7.2 Study Endpoints

Primary Effectiveness Endpoints

- For each question on the take home questionnaire at each of four week-long intervals, the proportion of subjects providing a response in the top 3 boxes.
    - Note that these endpoints are not pass/fail criteria for the study. Rather, these are the most important data that will be evaluated.

Secondary Effectiveness Endpoints

- Lens performance survey (100 point scales) questions.

- Comfort upon insertion
- Overall comfort
- Comfort at end of day

Secondary Safety Endpoints

- The proportion of subjects with any slit lamp findings grade 2 or greater at any time.

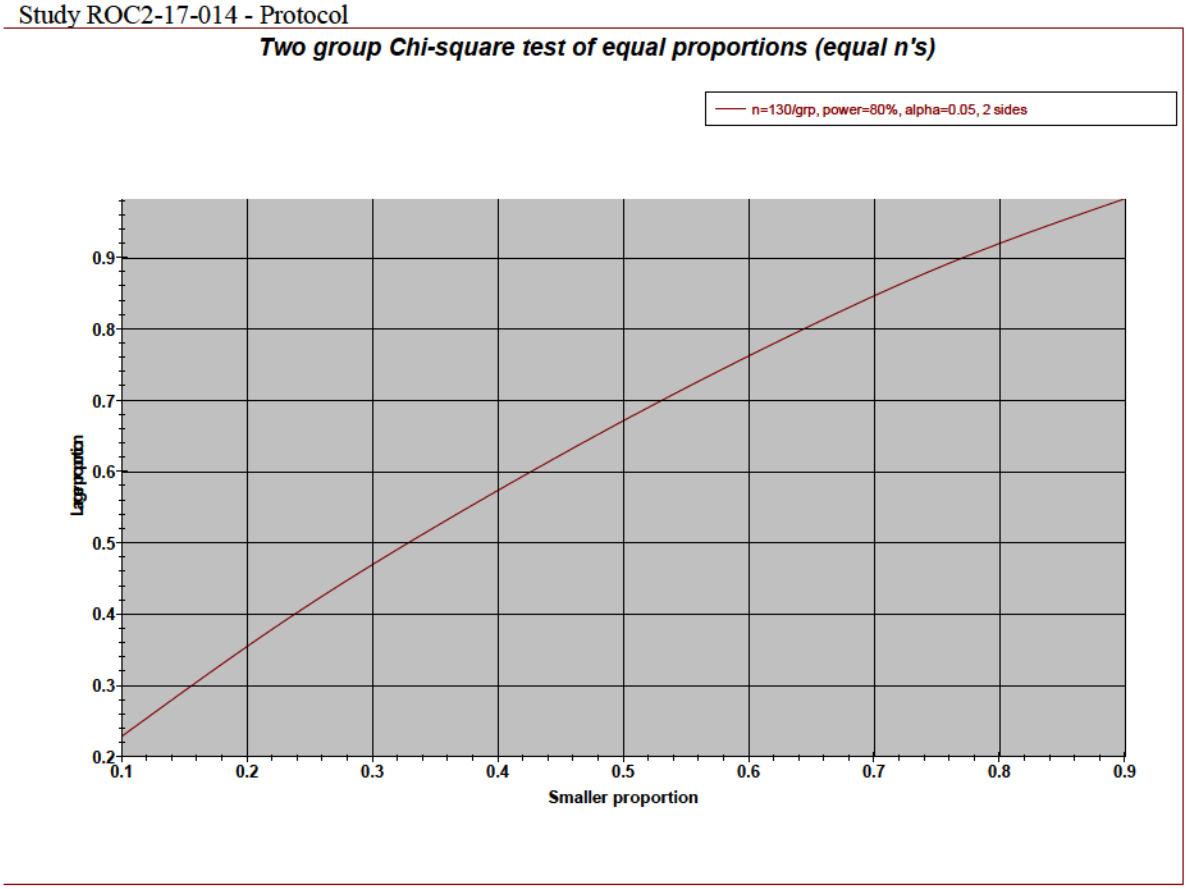
Hypotheses

The following hypotheses will be tested for each question in the take home performance questionnaire at each week.

1. The null hypothesis is that the proportion of subjects providing a response in the top three categories is equal between the treatment groups.
2. The alternative hypothesis is that the proportion of subjects providing a response in the top three categories is not equal between the treatment groups.

7.3 Sample Size

The sample size will be 130 subjects per group, which is the maximum affordable sample size. This sample size will have a varying ability to detect differences between the groups depending on the proportions. For example, a two-group χ^2 test with a 0.050 two-sided significance level will have 80% power to detect the difference between a Smaller proportion, π_1, of 0.500 and a Larger proportion, π_2, of 0.670 when the sample size in each group is 130. Additional cases, assuming the same significance level, power, and sample size are shown in the following figure.



Very few or no dropouts are expected.

7.4 Randomization

Subjects will be randomized to one of two treatments in a 1:1 ratio, receiving either the Test lens or the Control lens for the duration of the study. Within each site and overall, the number of subjects randomized to each treatment will be approximately balanced.

7.5 Study Populations

Subject eyes will be included in all summaries under the treatment that they actually received. Analyses of safety data will include all dispensed subjects. All other summaries will include all eligible, dispensed subjects.

7.6 Statistical Analysis

Primary and secondary analyses will be performed on all eligible, dispensed eyes (completed and discontinued eyes pooled) for efficacy endpoints and for all dispensed eyes (completed and discontinued eyes pooled) for safety endpoints.

Questionnaire responses to the take home questionnaire will be summarized using categorical summary statistics by treatment and week. The proportion of subjects providing a response in the top three categories will be compared between treatments using chi-square tests by week. A Fisher's exact test will be used instead of a chi-square test when any cell in the contingency table has an expected count less than five.

Comfort related lens performance survey question results will be summarized using continuous summary statistics by treatment group and visit. Two-sided two-sample t-tests will be used to compare the treatment groups by visit.

The proportion of subjects with any slit lamp findings grade 2 or greater will be summarized categorically by treatment group and visit. Two-sided Fisher's exact tests will be used to compare the groups by visit.

Missing data will not be imputed.

There will be no adjustments for multiple comparisons.

There are no planned interim analyses.

8.1 DATA QUALITY ASSURANCE

8.2 Study Monitoring plan

Bausch + Lomb representatives and or designees 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 Affairs.

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

The Take Home Lens Performance Surveys do not relate to primary efficacy end points and will not be monitored.

Monitoring, online review and telephone consultations will occur as necessary, during the course of the investigation to verify the following:

- The rights and well-being of subjects are protected
- Completeness and accuracy of the forms
- The conduct of the investigation is in compliance with the currently approved protocol/amendment, 21CFR Parts 50, 54, 56 and 812, and 42 USC 282(j). The protocol was developed with consideration of the provision in: ISO 14155:2011 Clinical investigation of medical devices for human subjects – Good Clinical Practice; ISO 11980:2012 Ophthalmic Optics - Contact lenses and contact lens care products - Guidance for clinical investigations; ICH GCPs; and applicable local regulations.
- The integrity of the data, including adequate study documentation
- The facilities remain acceptable
- The Investigator and site personnel remains qualified and able to conduct the study
- 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.

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. The data collected in the e-CRFs at all the study visits will be provided to the Investigator by the sponsor after the conclusion of the trial.

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

Only subjects are to record information in the Take Home Lens Performance Surveys. **The Investigator or designees should review subject completed home surveys 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. If the survey(s) is not complete at the return visits the Investigator or designees should ensure it is completed prior to the subject's dismissal.

8.4 Case Report Forms and Data Verification

Subject data required by this protocol are to be directly entered into the e-CRFs using single data entry with visual verification. The Investigator and his/her study site personnel will be responsible for completing the e-CRFs. The Investigator is required to verify that all of the requested information is accurately recorded on the e-CRFs. All information requested on the e-CRFs needs to be supplied, including subject identification and initials, date(s), assessment values, etc., and any omission or discrepancy will require explanation. Take Home Lens Performance Survey data will be collected and processed according to the policies and procedures of the CRO, and will not be included on e-CRFs or verified by Bausch + Lomb.

The study monitor will be responsible for reviewing and verifying the data recorded on the e-CRFs per the study Monitoring Plan. The Investigator and study site personnel will be responsible for answering all queries.

A copy of the e-CRFs for each subject will be provided to the Investigator at the conclusion of the study.

8.5 Recording of Data and Retention of Documents

Subject data recorded on e-CRFs during the study will be documented in a coded fashion. The subject will only be identified by the subject number and by their initials if also required. Confidentiality of subject records must be maintained to ensure adherence to applicable local privacy regulations.

The Investigator must retain essential documents indefinitely after the completion of the study, unless otherwise notified by the Sponsor. 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:

- IRB/EC approvals for the study protocol, all amendments, ICF(s), and advertisements
- IRB/EC annual study review
- IRB/EC correspondence and reports (e.g., AE reports, protocol deviations, and safety updates)
- regulatory documents (e.g., Financial Disclosure and Delegation of Authority forms)
- e-CRFs (will be provided by the sponsor after the completion of the trial)
- subject's signed ICF
- Device Investigator Agreement
- 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 Affairs.

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/EC, the Investigator must inform the Sponsor immediately that this request has been made.

8.7 Institutional Review Board

The Investigator should ensure their participation in the study, in addition to the protocol, subject recruitment materials (written information or materials including web pages, radio advertisements, television spots or written text developed to encourage subject enrollment) and the ICF to be used in this study are approved by their institution IRB/EC, or if not using their institution's IRB, approved by the reviewing central IRB/EC prior to entering any subjects in the study. Documentation of IRB/EC 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/EC 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/EC 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 the 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

N/A

[redacted]

APPENDIX B: METHODS OF CLINICAL EVALUATION

Any changes to the procedures described in this appendix will be provided under separate cover.

1.1 Visual Acuity/Refraction

It is essential that a standard procedure be used to obtain VA measurements. The VA and refraction measurements should be obtained by a physician, optometrist, or trained technician. All VA/Refraction must be measured using a phoropter in 0.25 D steps. One standard logMAR, chart high 90% contrast, with Sloan letters will be used to obtain the VA measurements in this study. The following VA equipment from Precision Vision, Inc. will be used in this study: 90% High Contrast 6.5 feet (2.0 meters) testing distance Translucent Chart (CAT. NO. 2103-2), and the Precision Vision Small Illuminator Cabinet (CAT. NO. 914).

1.2 Illumination of the logMAR Chart and Room Illumination

The internal illumination of the logMAR chart should be turned on. This will provide the nominal contrast for each of the charts. **Room illumination should be turned off**, to ensure that the illumination is consistent for each measurement. Ambient sources of light in the room, such as computer monitors, should be turned off or covered. A small source of illumination may be used to allow recording of data and to ensure that it is not difficult or dangerous for staff or subjects to move around the testing area, but these light sources should not be placed so that they are directed toward the subject during testing. The room lighting and any ambient sources should be consistent in their use and placement at each subject visit throughout the course of this study.

1.3 Determination of High Contrast Visual Acuity

The subject should be seated so that the distance from the subject's eyes to the logMAR chart is 6.5 feet (2.0 meters). The chart should be at eye level for the subject. The logMAR charts have two alternative letter sequences from 28 letters (0.3 logMAR) to 62 letters (-0.3 logMAR). It is recommended that one letter sequence is used for the right eye, and the second letter sequence is used for the left eye, to minimize learning effects at each visit. Care should be taken to completely occlude the eye not being measured.

Since the test distance of the chart is not at optical infinity, refractive power compensation is required to simulate optical infinity. The VA should be measured through the phoropter using the distance refractive correction with the addition of +0.50 D to compensate for the reduced test distance of 6.5 feet (2.0 meters).

If all letters are correctly identified on any given line, then the subject is encouraged to read the next smaller line. When the subject says they cannot read a letter, they should be required to guess. A maximum effort should be made to identify each letter. The subject continues reading down the chart to the last letter of a given line, **until the subject has missed 3 letters on a line with 5 letters**. The incorrect letters can occur at the beginning, middle, or end of this line and do not have to be consecutive.

The number of letters CORRECT will be recorded in the e-CRF. All correct letters will be entered into the system and the acuity score will be calculated during the analysis. To monitor the subjects' acuity during the trial, a Snellen – logMAR conversion table is provided below.

Snellen	logMAR
20/160	0.9
20/125	0.8
20/100	0.7
20/80	0.6
20/63	0.5
20/50	0.4
20/40	0.3
20/32	0.2
20/25	0.1
20/20	0
20/16	-0.1
20/12.5	-0.2
20/9.5	-0.3

2.0 Slit Lamp Examination

The following parameters will be assessed during the Slit Lamp Examination (without lenses):

Epithelial Edema

0 - None: No epithelial or sub-epithelial haziness. Normal transparency.
1 - Trace: Barely discernible localized epithelial or sub-epithelial haziness.
2 - Mild: Faint but definite localized or generalized epithelial haziness.
3 - Moderate: Significant localized or general epithelial haziness.
4 - Severe: Definite widespread, epithelial cloudiness giving dull glass appearance to cornea, or numerous coalescent buliae.

Epithelial Microcysts

0 - None: No microcysts seen using retroillumination.
1 - Trace: Fewer than 50 microcysts over central or para-central cornea. No overlying staining or surface anomaly.
2 - Mild: More than 50 microcysts over central or paracentral cornea. No overlying staining or surface anomaly.
3 - Moderate: More than 50 microcysts, tending to be coalescent and accompanied by overlying faint staining or dry spots.
4 - Severe: Numerous, dense, coalescent microcysts accompanied by overlying significant staining or erosion.

Corneal Staining

Corneal staining must be assessed after the instillation of fluorescein. The Wratten Gel Filter must be used as a barrier filter in the observation pathway, in combination with the cobalt blue filter.

0 - None: No fluorescein staining.
1 - Trace: Minimal superficial staining or stippling, and non-coalescing. Includes superficial foreign body staining.
2 - Mild: Lightly coalescent or diffuse punctate staining, with no stain diffusion into stroma.
3 - Moderate: Significant or densely coalescent punctate staining, including slight diffusion of stain into stroma.
4 - Severe: Severe abrasion or erosion with loss of epithelial substance. Marked and rapid diffusion of stain into stroma.

Limbal Injection

0 - None: No hyperemia present. Normal appearance of limbal vessels including prominent limbal vascular arcades.
1 - Trace: Very slight hyperemia of limbal vessels in one quadrant.
2 - Mild: Mild hyperemia of limbal vessels in more than one quadrant.
3 - Moderate: Marked hyperemia of limbal vessels in any quadrant.
4 - Severe: Marked hyperemia of limbal vessels in all quadrants.

Bulbar Injection

0 - None: No hyperemia present. Normal appearance of conjunctival vessels.
1 - Trace: Slight hyperemia of conjunctival vessels in one quadrant.
2 - Mild: Mild hyperemia of conjunctival vessels in more than one quadrant.
3 - Moderate: Marked hyperemia of conjunctival vessels in any quadrant.
4 - Severe: Marked hyperemia of conjunctival vessels in all quadrants.

Upper Lid Tarsal Conjunctival Abnormalities

0 - None: Normal, velvet tarsal conjunctival appearance. No hyperemia or enlarged papillae.
1 - Trace: Slight tarsal conjunctival hyperemia with slight loss of smoothness.
2 - Mild: Slight tarsal conjunctival hyperemia with slight loss of smoothness. Noticeable enlargement of papillae, but less than 1.0 mm in diameter.
3 - Moderate: Definite loss of smoothness with enlarged papillae, but less than 1.0 mm in diameter with marked tarsal conjunctival hyperemia.
4 - Severe: Localized or generalized giant papillae, larger than 1.0 mm in diameter and/or severe tarsal conjunctival hyperemia.

Corneal Neovascularization

0 - None: Normal appearing limbus, including prominent limbal vascular arcades.
1 - Trace: Vascularization less than 1.5 mm of advancement into cornea in one quadrant.
2 - Mild: Vascularization less than 1.5 mm of advancement into cornea in more than one quadrant.
3 - Moderate: Vascularization 1.5 mm to less than 2.5 mm of advancement into cornea in any quadrant.
4 - Severe: Vascularization more than 2.5 mm of advancement into cornea in any quadrant.

Corneal Infiltrates

0 - No infiltrates.
1 - Single infiltrate; (focal and peripheral), asymptomatic.
2 - Single or multiple infiltrate(s); with injection and/or associated symptoms.
3 - Single or multiple infiltrate(s); injection with overlying corneal defect(s).
4 - Single or multiple infiltrate(s); injection with diffusion of stain into stroma.

Absent or Present

New Corneal Scar
Corneal Striae
Conjunctivitis
Other Anterior Segment Abnormalities
External Adnexa Abnormalities

3.1 Method for the Examination, Description and Classification of Lens Deposits and Lens Surface Wettability

Introduction:

The following procedure has been developed to assist in the examination, description, and classification of deposits found on contact lenses and lens surface wettability.

Materials needed:

Slit Lamp

Procedure:

Each lens should be examined on the eye using the slit lamp employing a 7X to 15X magnification.

Classify the deposit and record findings at each visit as follows:

I. Type of Deposit

Indicate the most prominent lens surface deposit found using the following classifications:

- crystalline deposits
- crust-like deposits
- film
- spots

II. Estimated Percentage of Lens Surface Covered By Deposits

Estimate the percentage of the lens surface that is covered by deposits using the following classifications:

0 - No deposits
1 - 1 - 25%
2 - 26 - 50%
3 - 51 - 75%
4 - 76 - 100%

III. Degree of Deposit

Indicate the degree of the deposit on the lens surface using the following classifications:

- light
- medium
- heavy

Classify the lens surface wettability and record findings at each visit as follows:

0 - Optimal (100% of anterior lens surface is wettable)
1 - Slight (Presence of small (<0.1 mm), individual, discrete non-wetting areas)
2 - Mild (Presence of single area of non-wetting between 0.1 mm and 0.5 mm in size)
3 - Moderate (Presence of several areas of non-wetting, each between 0.1 mm and 0.5 mm in size)
4 - Severe (Presence of one or more non-wetting areas greater than 0.5 mm in size)

APPENDIX C: SUBJECT INSTRUCTIONS

INTRODUCTION

You will participate in this study to evaluate the product performance of currently marketed Acuvue Vita contact lenses (Test) when compared to Bausch + Lomb Ultra contact lenses (Control). As a participant in this study, you will be randomly assigned to wear either the Test lenses for 1 month or the Control lenses for 1 month. You will wear the study lenses on a daily wear basis **and wear your lenses into the office for each of your follow-up visits**. All lenses, used and unused, must be returned to your eye care professional. Please keep all appointments and follow the instructions thoroughly, and do not depart from the care system your eye care professional has provided. If you have questions or problems, call your eye care professional. If you require a medical referral for any eye problems experienced during the study, please refer to your informed consent form.

Remember to bring your contact lens cases and worn lenses to all examinations.

Take Home Lens Performance Surveys

You will be asked to complete subjective assessments with the study lenses through a total of four take home surveys. Please complete the first two surveys after a minimum of 5 days of wear for each week and bring them with you to your 2-Week Follow-up Visit. Please complete one survey per week for the remaining two weeks of the study after a minimum of 5 days of wear for each remaining week. In addition, please remember to **sign and date all of the surveys on the last page.** Bring the 2 remaining completed surveys with you to your final 1-Month Follow-up Visit.

FOLLOW-UP VISITS

Regular follow-up examinations by your eye care professional are an important part of wearing contact lenses and this study. You must follow your eye care professional's directions for follow up examinations. Keep all appointments for your follow-up visits. Use the space below to record your appointments.
You must wear your contact lenses in to all visits.

Study Visit Schedule

1. 2-Week Follow-up _____ Date _____ Time

2. 1-Month Follow-up _____ Date _____ Time

These subject instructions apply to both Acuvue Vita contact lenses and the Bausch + Lomb Ultra contact lenses. It is essential to your safety that you read and understand the

information and instructions in these subject instructions, and have your eye care professional answer any questions, both before and after you receive contact lenses.

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

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

Adherence to your protocol-specified wearing schedule and visits to your eye care professional are also necessary for the proper and safe use of contact lenses.

It is important to not wear your lenses longer than recommended by your eye care professional since doing so increases the risk of adverse effects.

Spaces are provided in these subject instructions for you to record your schedule of follow-up visits. 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 for longer periods than your prescribed wearing schedule simply because they remain comfortable and you are not experiencing a problem. Only your eye care professional, through a professional examination, can determine how your eyes are reacting to the contact lenses and whether there are any early signs of possible problems.

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

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

WEARING RESTRICTIONS AND INDICATIONS:

For the purpose of this study, the lenses will be available in limited powers.

WARNINGS:

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

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

PRECAUTIONS:

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

Handling Precautions

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Before leaving your eye care professional's office be certain that you are able to remove your lenses promptly or have someone else available to remove them for you.
- Be certain that the fingers or hands are free of foreign materials before touching your lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle your lenses carefully and avoid dropping them.
- Do not touch the lens with your fingernails.
- Carefully follow the handling, insertion, removal, cleaning disinfecting, storing and wearing instructions in these subject instructions and those prescribed by your eye care professional.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Solution Precautions

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

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

Lens Wearing Precautions

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

Lens Case Precautions

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

Topics to Discuss with the Eye Care Professional:

- While you are in this study, your eye care professional will schedule you for specific follow-up visits to assure the continuing health of the eyes.
- Subjects should be advised about wearing lenses during sporting and water related

activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of ocular infection including but not limited to *Acanthamoeba* keratitis.

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

Who should know that you are wearing contact lenses?

- You may decide to inform your health care professional about being a contact lens wearer.
- Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear lenses.

Ask your eye care professional whether there are any other wearing restrictions that apply to you. Write those restrictions in the spaces provided below and follow them carefully:

_____

_____

_____

_____

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO):

You should be aware that the following problems may occur:

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

If you notice any of the above, you should:

- **Immediately remove your lenses**.
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on your eye. Place the lens in the storage case and contact your 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, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertions, if the problem continues, you should **immediately remove the lenses and consult your eye care professional**.

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

PERSONAL CLEANLINESS AND LENS HANDLING:

1. Preparing the Lens for Wearing:

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

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

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Handling the Lenses:

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Position the lens on your index finger, and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.
- Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly.

  a. Less than usual comfort,
  b. The lens may fold on the eye,
  c. Excessive lens movement on blink,
  d. Blurred vision.
- If the lens folds and sticks together: Place the lens in the palm of your hand and wet thoroughly with the recommended rinsing or storing solution. Then GENTLY rub the lens between your index finger and palm in a gentle back and forth motion.
- If the lens flattens or drapes across your finger, the lens or your finger may be too wet. To correct this, dry your finger by transferring the lens several times from one index finger to the other, drying the opposite finger each time.

3. Placing the Lens on the Eye:

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

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

The lens is not centered on the eye (see "Centering the Lens," next in these instructions).

If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:

- cosmetics or oils on the lens (replace the lens)
- the lens is on the wrong eye
- the lens is inside-out (it would also not be as comfortable as normal)

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

4. Centering the Lens

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

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

Or

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

5. Removing the Lens

Always remove the same lens first.

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

b) 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.

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

d) Follow the required lens care procedures described by your eye care professional.

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

6. Caring for Your Lenses (Cleaning, Rinsing, Disinfection, Storage)

For continued safe and comfortable wearing of your lenses, it is important that you **first clean and rinse, then disinfect** your lenses after each removal, using the lens care regimen recommended by your eye care professional. **Cleaning and rinsing** are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. **Disinfecting** is necessary to destroy harmful germs.

You should adhere to the lens care regimen recommended by your eye care professional. Failure to follow the lens care regimen may result in development of serious ocular complications as discussed in the "Warnings" section above.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh, unexpired lens care solutions.
- Use the recommended chemical (not heat) lens care system and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Always remove, clean, rinse, and disinfect your lenses according to the schedule prescribed by your eye care professional. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- Do not use saliva or anything other than the recommended solutions for

lubricating or rewetting your lenses. Do not put lenses in your mouth.

- Lenses prescribed in a frequent replacement program should be thrown away after the expiration of the wearing period prescribed by your eye care professional.
- Never rinse your lenses in water from the tap. There are two reasons for this:
  a) Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
  b) You might lose the lens down the drain.
- **Clean** one lens first (always the same lens first to avoid mix-ups), **rinse** the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, and rinsing, **disinfect** lenses using the system recommended by your eye care professional. Follow the instructions provided in the disinfection solution labeling.
- To store lenses, disinfect and leave them in the closed/ unopened case until ready to wear. If lenses are not to be used immediately after disinfection, you should consult the labeling of the storage solution for information on lens storage.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with **fresh** storage solution. Replace lens case at regular intervals.
- If necessary, you can use your habitual **Lubricating/Rewetting** drops while wearing your lenses following the instructions provided with your lens care product. If your lenses become dry while you are wearing them, directly apply the rewetting drops to restore moisture and maintain comfortable lens wear. If lens discomfort persists, discontinue use, remove your lenses and contact your eye care professional immediately.

7. Lens Case Cleaning and Maintenance

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry each time you remove the contact lenses from it. Lens cases should be replaced at regular intervals.

8. Care for a Sticking (Nonmoving) Lens:

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

9. Care for a Dried Out (Dehydrated) Lens

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, apply the recommended rinsing solution before handling.

To rehydrate the lens:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storing solution for at least 1 hour until it returns to a soft state.
- Clean the lens first, then disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft or if the surface remains dry, DO NOT USE THE LENS UNTIL IT HAS BEEN EXAMINED BY YOUR EYE CARE PROFESSIONAL.

10. Replacement and Return of Your Study Lenses

At each visit, you must return all used and unused lenses that were dispensed to you during the designated wear periods. At the 2-Week Follow-up Visit, and 1-Month Follow-up Visit, you will be required to wear your lenses to the visit.

11. Emergencies:

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