

**Johnson & Johnson Vision Care
7500 Centurion Parkway
Jacksonville, FL 32256**

Clinical Study Protocol

Investigation of ocular symptoms and signs in existing contact lens wearers following extensive digital device use: ACUVUE OASYS®, vs B+L Ultra™ (BASIL)

Protocol Number CR-5816

Version 7.0, Amendment 6.0

Date: 17 July 2017

Distribution

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Key Words

Contact Lenses

Digital Devices

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1.1 PROTOCOL TITLE, NUMBER, DATE

TITLE: Investigation of Ocular Symptoms and Signs in Existing Wearers Fitted with Contact Lenses Following Extensive Digital Device Use

PROTOCOL NUMBER: CR-5816

VERSION: VERSION 7.0, Amendment 6.0

DATE: 17 July 2017


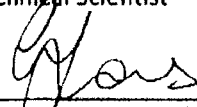
1.2 NAME AND ADDRESS OF SPONSOR

Johnson & Johnson Vision Care

7500 Centurion Parkway, Jacksonville, FL 32256

1.3 AUTHORIZED SIGNATURES

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations, ICH guidelines, and the Declaration of Helsinki.

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1.4 MEDICAL MONITOR

NAME: Chantal Coles-Brennan, BSc, OD

TITLE: Principal Research Optometrist

ADDRESS: 7500 Centurion Parkway, Suite 100, Jacksonville, FL 32256

24 HOUR CONTACT TELEPHONE #: [REDACTED]

The Medical Monitor should be notified by the clinical site in writing and by telephone within 24 hours of learning of a Serious Adverse Event. The Medical Monitor may be contacted during business hours for adverse event questions. General study related questions should be directed towards your assigned clinical research associate.

The clinical site may be supplied an Adverse Event form to complete regarding the adverse event evaluation.

1.5 INVESTIGATOR(S) SIGNATURE PAGE

The Principal Investigator is responsible for ensuring that all study site personnel, including sub-investigators and other staff members, adhere to all ICH regulations and GCP guidelines regarding clinical trials during and after study completion.

I have read and understand the protocol specified above and agree on its content. I agree to conduct this study according to this protocol and GCP and ICH guidelines, the Declaration of Helsinki, and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. I shall not disclose the information contained in this protocol or any results obtained from this study without written authorization.

Principal Investigator:

Signature

Date

Name (Printed)

Institution Name _____

1.6 ESTIMATED REPORT DATE

The clinical study report is expected within 60 days after hard data lock.

1.7 CHANGE HISTORY

Document Change History			
Revision	Originator	Description of Change(s)	Date
Version 1.0	Marc Schulze, Lyndon Jones, and Chantal Coles-Brennan	Original Protocol	19 February 2016
Version 2.0, Amendment 1.0	Chantal Coles-Brennan	Exclusion criteria: deleted 'by keratometry'; Visit 2 & 6, step 12, added 'MRD' questionnaire; Visit 4 & 8, step 17, added 'MRD' questionnaire	07 March 2016
Version 3.0, Amendment 2.0	Chantal Coles-Brennan	Updated contact lens cleaning solution from 'CLEAR CARE®' to 'OPTI-FREE® PUREMOIST®'; updated Visit 1 Subjective Sphero-Cylindrical Refraction from -1.25 to -1.00	23 March 2016
Version 4.0, Amendment 3.0	Chantal Coles-Brennan	Update enrollment to 'Approximately 115 subjects'; Changed a word from 'enrolled' to 'continued' in section 4.2 ; Updated reporting product quality complains procedure in section 4.11	20 June 2016
Version 5.0, Amendment 4.0	Chantal Coles-Brennan	Update enrollment to 'Approximately 135 subjects'	19 July 2016
Version 6.0, Amendment 5.0	Chantal Coles-Brennan	Update enrollment to 'Approximately 250 subjects' Additional verbiage to sample size in synopsis and section 2.6 and section 9.2	16 February 2017

Version 7.0, Amendment 6.0	Chantal Coles-Brennan	Update statistician Update study design to single (subject) masked study (from double masked study) (Sections 1.8; 2.4; 4.4; 4.5; 4.6; 4.7.1; 4.10)	17 July 2017

1.8 PROTOCOL SYNOPSIS

Protocol Number and Title: CR-5816 – Investigation of ocular symptoms and signs in current lens wearers following extensive digital device use: ACUVUE OASYS® vs Bausch & Lomb ULTRA™ (BASIL)
Sponsor: JJVCI, 7500 Centurion Parkway, Jacksonville, FL 32256
Investigational Product: Approved products, used as per package insert Contact Lens Types <ul style="list-style-type: none"> • ACUVUE OASYS® with HYDRACLEAR® PLUS (Johnson & Johnson Vision Care, Inc.) • ULTRA™ with MoistureSeal™ Technology (Bausch & Lomb, Inc.) Contact Lens cleaning solution <ul style="list-style-type: none"> • OPTI-FREE® PUREMOIST® (Alcon Laboratories, Inc.)
Ancillary Supplies: Saline
Randomization and Dispensing: Subjects will be randomized into one of two lens sequences: TEST/CONTROL or CONTROL/TEST to wear each of two contact lens types (ACUVUE OASYS® with HYDRACLEAR® PLUS, ULTRA™ contact lenses with MoistureSeal™ Technology) for a 4-week period with each lens type.
Principal Investigator: Name: Dr Lyndon Jones Title: PhD, FCOptom, FAAO
Study Sites: External: Centre for Contact Lens Research (CCLR), School of Optometry and Vision Science, University of Waterloo, Waterloo, Canada.
Microbiology or Other Testing Laboratory: None
Phase or Type of Study: Clinical Claims Study

Objectives:

The primary objectives of this study are:

- To assess subjective overall comfort in a group of existing contact lens wearers who are heavy digital device users (>8hrs in a typical day).
- To compare the subjective overall comfort ratings when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses.

The secondary objectives of this study include:

- To compare the time to haze (TTH) when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses.
- To compare the comfortable wear time (CWT) and overall wear time (WT) when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses.
- To compare the subjective assessments of lens handling, as assessed using the Contact Lens User Experience (CLUE™) questionnaire, when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses, using a cross-over group design.
- To compare the subjective assessments of Comfort at the end of the day, as assessed using the Contact Lens User Experience (CLUE™) questionnaire, when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses.
- To compare the difference between total time of device use and comfortable wear time on a typical day when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses.

Study Design: This study is a group sequential, adaptive, prospective, single (subject)-masked, randomized, 2x2 cross-over dispensing design. After eligibility for the study has been confirmed during the screening visit, eligible subjects will wear each of the study lenses (ACUVUE OASYS® with HYDRACLEAR® PLUS, ULTRA™ with MoistureSeal™ Technology) for four weeks, in accordance with manufacturers' guidelines, with the order of lens wear being randomized.

Sample Size: Approximately 135 subjects will be enrolled to target completion of 80 subjects. An interim analysis will dictate if additional subjects will be enrolled to reach a maximum of 250 subjects. A maximum of 250 enrolled subjects was considered to account for any discontinuations due to adverse events as seen in phase 1. The study enrolment will be stopped after 50 additional phase 2 subjects complete the final visit. At this time existing subjects will be allowed to complete the study.

Qualification, Dispensing and Follow-Up Procedures:

Screening (V1): Subjects will complete informed consent. Demographics and medical history will be reviewed. Subjects must meet all of the study eligibility criteria to continue in the study.

Lens Dispense visits (V2 & V6): Subjects will be randomized to wear each of the two lens types for a total of 4 weeks. Randomization will occur at V2, when subjects will be dispensed either 1 pair of ACUVUE OASYS® with HYDRACLEAR® PLUS or 1 pair of ULTRA™ contact lenses with MoistureSeal™ Technology, according to their randomization schedule. Subjects will be dispensed the other (second) lens type at the second dispense visit (V6).

Follow-up Visits: All volunteers will return to the clinic on Day 1, Day 14 (± 3 days) and Day 28 (± 3 days) during each of the two study periods (V3, V4, V5 & V7, V8, V9). Adverse event and concomitant medication will be reported, if applicable. Clinical assessments will be performed. Subjects will be asked to complete a questionnaire on their experience with the study lenses. At V4 or V8 (Day 14), depending on the randomization schedule, ACUVUE OASYS® CLs will be replaced with a new pair according to the manufacturer's guidelines after 14 days of wear, while the ULTRA™ CLs (4-week replacement) will not be exchanged.

Eligibility Criteria:**INCLUSION CRITERIA**

Potential subjects must satisfy all of the following criteria to be continued in the study:

- The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form.
- The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
- The subject must be between 18 and 40 years of age.
- The subject's vertex corrected spherical equivalent distance refraction must be in the range of -0.50D to -8.00D in each eye.
- The subject's refractive cylinder must be no more than -1.00 D cylindrical correction in each eye after vertexing to the corneal plane.
- The subject must have best corrected visual acuity of 0.20 or better in each eye.
- The subject must be a current wearer of daily, spherical, soft contact lenses (no bifocal or multifocal contact lenses, no extended wear or monovision) for at least 5 days/week and at least 8 hours/day during the month prior to enrollment.
- The subject must be using digital devices (any combination of computers, tablets, smart-phones etc.) for at least 8 hours over the course of a typical day.
- The subject should own a wearable pair of spectacles and wear them the day of the baseline visit.
- The subject must have normal eyes with no evidence of abnormality or disease that in the opinion of the investigator would contraindicate contact lens wear.
- The subject must meet normal eligibility conditions of binocular vision tests.
- The subject may not have any double vision at near with their habitual CL correction.

EXCLUSION CRITERIA

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

- Currently pregnant or lactating (subjects who become pregnant during the study will be discontinued).
- Any ocular or systemic allergies or diseases that may interfere with contact lens wear (at the investigator's discretion).
- Any systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear (at the investigator's discretion).
- Use of any medication that causes side effects similar to side effects experienced when using digital devices, such as a subject reporting headaches associated with birth control pills (at the investigator's discretion).

- Any infectious disease (e.g., hepatitis, tuberculosis) or a contagious immunosuppressive disease.
- Any active ocular infection.
- Entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or moderate or above corneal distortion.
- Any previous, or planned, ocular or interocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.).
- Clinically significant (grade 3 or 4) corneal edema, corneal vascularization, corneal staining, or any other abnormalities of the cornea which would contraindicate contact lens wear.
- Clinically significant (grade 3 or 4) tarsal abnormalities or bulbar injection which might interfere with contact lens wear.
- Any known hypersensitivity or allergic reaction to the study products.
- Participation in any contact lens or lens care product clinical trial within 7 days prior to study enrollment.
- History of binocular vision abnormality or strabismus.
- Employee of investigational clinic (e.g., Investigator, Coordinator, Technician).

Schedule of Events:

A detailed schedule of events can be found in section 4.4.1.

Disallowed Medications:

Use of any prescription or over-the-counter (OTC) medications that may affect contact lens wear from 24 hours prior to receiving the study product throughout the study period. This is at the investigator's discretion.

Stopping Rules: The occurrence of one or more Unanticipated Adverse Device Effect (UADE), or any SAE where relationship to study agent cannot be ruled out, may result in stopping further dispensing of investigational product. In the event of a UADE or SAE, the Sponsor Medical Monitor may discuss this with the Investigator before any further subjects are enrolled. See other stopping rules in the Statistical Analysis Plan for more information.

Clinical Safety: Assessments by the Investigator will occur at all post-screening study visits and will include review of Adverse Events and Concomitant Medications.

Laboratory Review: Not applicable

Safety Review Board:

A Safety Review Board (SRB) will be formed in association with this study. The SRB will include the medical monitor and clinical research manager (CRM). The medical monitor and CRM will review and evaluate all events and will determine if the remaining subjects assigned to that treatment group may proceed with treatment.

Study Endpoints:

- The primary endpoint in this study is overall subjective comfort using CLUE questionnaire
- The secondary endpoints of this study are: (1) time to haze (TTH) (2) Average wear time and comfortable wear time (3) CLUE lens handling (4) Comfort at the end of the day [REDACTED] (5) Difference between total time of device use and comfortable wear time on a typical day

Other Observations:

- Keeping your eyes from feeling dry at the end of the day [REDACTED]
- Clarity of vision at the end of the day [REDACTED]
- CLDEQ-8
- Contrast sensitivity
- CLUE™ Comfort and Comfort at the end of the day [REDACTED] of ACUVUE OASYS® throughout the 4-week wear period (dispense 1, 2-week follow-up, dispense 2, 2-week follow-up2).

Hypotheses**Primary Hypotheses:**

- The overall CLUE comfort of ACUVUE OASYS® test lens will be non-inferior to the ULTRA™ control lens over the 4 weeks wear period.

Secondary Hypotheses:

- ACUVUE OASYS® test lens will be statistically non-inferior to the control lens ULTRA™ with regards to time to haze (TTH) over the 4 weeks wear period using a non-inferiority margin of 2 seconds;
- ACUVUE OASYS® test lens will be non-inferior to the ULTRA™ control lens with regards to comfortable wear time and Average wear time over the 4 weeks lens period using a non-inferiority margin of 2 hours;
- In terms of Difference between total time of device use and comfortable wear time on a typical day, the test lens ACUVUE OASYS® will be non-inferior to the control lens ULTRA™ over the 4 weeks lens wear period using a non-inferiority margin of -2 hours;
- ACUVUE OASYS® test lens will be non-inferior to the ULTRA™ control lens with regards to lens handling over the 4 weeks lens wear period.
- ACUVUE OASYS® test lens will be non-inferior to the ULTRA™ control lens with regards to Comfort at the end of the day over the 4 weeks lens period using a non-inferiority margin of 0.67 odds ratio.

Tertiary Hypotheses:

- The overall comfort of the test lens will be non-inferior to the control lens for CLUE comfort in at least one of the study time points (2-week and 4-week).

Statistical Methods: All data summaries and statistical analyses will be performed using the SAS software Version 9.4 or higher (SAS Institute, Cary, NC), unless otherwise specified. Summary tables will be provided for all baseline and safety variables as appropriate.

Comfort CLUE scores, Time to haze and Average and Comfortable wear times and difference between total time of device use and comfortable wear time on a typical day will be analyzed using a Bayesian hierarchical model to compare between test and control lenses.

P3 questions will be analyzed independently using Bayesian Multinomial models for ordinal data.

2.1 NAME AND DESCRIPTION OF INVESTIGATIONAL PRODUCTS

The following contact lenses (CL) will be used in this study:

LENSES		
Test Article Form	ACUVUE OASYS® with HYDRACLEAR® PLUS	ULTRA™ with MoistureSeal™ Technology
Manufacturer	Johnson & Johnson Vision Care, Inc.	Bausch + Lomb, Inc.
Packaging Form	Blister Packs	Blister Packs
Distance Powers (D)	-0.50 to -6.00 (0.25) -6.50 to -8.00 (0.50)	-0.50 to -6.00 (0.25) -6.50 to -8.00 (0.50)
Base Curve	8.4	8.5
Material	senofilcon A	samfilcon A
Replacement schedule	2 weeks	4 weeks
Health Canada License No	67836	94501
Health Canada Medical Device Class	2	2

The following solutions will be used in this study:

SOLUTIONS	
Solution Name / Description	OPTI-FREE® PUREMOIST®
Manufacturer	Alcon Laboratories, Inc.
Packaging Form	Original

Saline will be used to rinse each eye after Physiology / Slit Lamp Biomicroscopy procedures.

2.2 SUMMARY OF FINDINGS FROM NONCLINICAL STUDIES

See package insert.

2.3 SUMMARY OF KNOWN RISKS AND BENEFITS TO HUMAN SUBJECTS

See package insert.

2.4 DESCRIPTION OF TRIAL TREATMENTS

This is a prospective, single (subject)-masked, dispensing, 2x2 cross-over adaptive design study with two CL wear periods. After eligibility for the study has been confirmed during the screening visit, eligible subjects will wear each of the study lenses (ACUVUE OASYS® with HYDRACLEAR® PLUS, ULTRA™ with MoistureSeal™ Technology) for four weeks, in accordance with manufacturers' guidelines, with the order of lens wear being randomized. All contact lenses and care solutions are Health Canada approved medical devices and are being used on-label. See Section 2.1 for the description of the test articles.

2.5 STATEMENT OF COMPLIANCE TO PROTOCOL, GCP, AND APPLICABLE REGULATORY GUIDELINES

This trial will be conducted in compliance with the protocol, the International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP), the Declaration of Helsinki, and all applicable regulatory requirements.

2.6 DESCRIPTION OF POPULATION TO BE STUDIED, ENROLLMENT TARGETS, AND STUDY DURATION

This is a group sequential, adaptive design where the enrollment will be performed in two phases. Approximately 135 subjects will be initially enrolled and approximately 80 subjects are targeted to complete the study. An interim analysis will be performed when all subjects have

completed both lens types. This interim will be used to estimate if more subjects are needed. Based on the interim analysis, it has been determined that an additional 50 participants to complete are required. Therefore, additional subjects will be added up to a maximum of 250 in total. The maximum enrollment after phase 2 was considered to account for any anticipated adverse events as experienced in phase 1. The study enrolment will be stopped after 50 additional phase 2 subjects complete the final visit. At this time existing subjects will be allowed to complete the study.

In order to be suitable for the study, volunteer subjects need to fulfill the following entry requirements:

- “Heavy” users of digital devices (i.e. using computers, tablets, smart-phones etc. for at least 8 hours (combined) over the course of a typical day);
- Existing soft contact lens wearers who wear their CLs for at least 5 days a week and 8 hours a day during digital device use;
- Contact Lens prescription in the range of -0.50D to -8.00D, with refractive astigmatism between 0 and -1.00D in both eyes.

A complete listing of eligibility criteria can be seen in Sections 4.2 (Inclusion Criteria) and 4.3 (Exclusion Criteria).

2.7 RELEVANT LITERATURE REFERENCES AND PRIOR DATA

See Package Insert.

3.1 DESCRIPTION OF OBJECTIVES AND PURPOSE

A large market research project has indicated that when wearers use digital devices (DigDev) (computers, tablets, smart-phones etc.), wearers of ACUVUE OASYS® do better than those wearing other lenses in terms of ocular comfort. This study will assess how various silicone hydrogel lenses perform when worn in contact-lens wearing subjects who work on computer devices.

The primary objectives of this study are:

- To assess subjective overall comfort in a group of existing contact lens wearers who are heavy digital device users (>8hrs in a typical day).
- To compare the subjective overall comfort ratings when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses, using a cross-over group design.

The secondary objectives of this study include:

- To compare the time to haze (TTH) when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses.
- To compare the comfortable wear time (CWT) and overall wear time (WT) when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses.

- To compare the subjective assessments of lens handling, as assessed using the Contact Lens User Experience (CLUE™) questionnaire, when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses.
- To compare the subjective assessments of Comfort at the end of the day, as assessed using the Contact Lens User Experience (CLUE™) questionnaire, when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses.
- To compare the difference between total time of device use and comfortable wear time on a typical day when these subjects are wearing ACUVUE OASYS® and ULTRA™ silicone hydrogel lenses.

4.1 PRIMARY AND SECONDARY ENDPOINTS

The primary endpoint of this study is the assessment of overall CLUE comfort in heavy digital device users at follow-up. All hypotheses are exploratory in nature.

The secondary endpoints of this study include (1) measurements of time to haze (TTH), (2) Average wear time and comfortable wear time, (3) CLUE lens handling in heavy digital device users at follow-up, (4) Comfort at the end of the day [REDACTED] and (5) Difference between total time of device use and comfortable wear time on a typical day.

TTH is a metric that has been developed at the CCLR in order to measure the maximum time a CL wearer can keep their eye open without their vision becoming hazy; it is a measure of how the drying of the CL surface with open eyes affects vision. [REDACTED]

Subjective assessments of comfort and handling will be performed using the Contact Lens User Experience™ (CLUE™) questionnaire. CLUE is a validated patient-reported outcomes (PRO) questionnaire to assess patient-experience attributes of soft contact lenses (comfort, vision, handling, and packaging) in a contact-lens wearing population in the US, ages 18-65. Derived CLUE scores using Item Response Theory (IRT) follow a normal distribution with a population average score of 60 (SD 20), where higher scores indicate a more favorable/positive response with a range of 0-120. A 5 point increase in an average CLUE score translates into 10% shift in the distribution of scores for population of soft disposable contact lens wearers.

Other Observations	
1	Keeping your eyes from feeling dry at the end of the day [REDACTED]
2	Clarity of vision at the end of the day (Item ID P3_0006_p07)
3	CLDEQ8
4	Near Contrast Sensitivity
5	CLUE™ Comfort and Comfort at the end of the day [REDACTED] of ACUVUE OASYS® throughout the 4-week wear period (dispense 1, 2-week follow-up 1, dispense 2, 2-week follow-up 2).

Primary Hypothesis:

The overall CLUE comfort score of the ACUVUE OASYS® test lens will be non-inferior to the ULTRA™ control lens in adapted SCL wearers (i.e. at least 5 days/week and 8 hours/day wear) who use digital devices for at least 8 hours a day over the 4 weeks wear period.

Secondary Hypotheses:

- ACUVUE OASYS® test lens will be statistically non-inferior to the control lens ULTRA™ with regards to time to haze (TTH) over the 4 weeks wear period using a non-inferiority margin of 2 seconds.
- ACUVUE OASYS® test lens will be non-inferior to the ULTRA™ control lens with regards to comfortable wear time and Average wear time over the 4 weeks lens period using a non-inferiority margin of 2 hours.
- In terms of Difference between total time of device use and comfortable wear time on a typical day, the test lens ACUVUE OASYS® will be non-inferior to the control lens ULTRA™ over the 4 weeks lens wear period using a non-inferiority margin of -2 hours.
- ACUVUE OASYS® test lens will be non-inferior to the ULTRA™ control lens with regards to lens handling over the 4 weeks lens wear period.
- ACUVUE OASYS® test lens will be non-inferior to the ULTRA™ control lens with regards to Comfort at the end of the day [REDACTED] over the 4 weeks lens period using a non-inferiority margin of 0.67 Odds ratio.

Tertiary Hypotheses:

- The overall comfort of the test lens will be non-inferior to the control lens for CLUE comfort in at least one of the study time points (2-week and 4-week).

4.2 INCLUSION CRITERIA

Potential subjects must satisfy all of the following criteria to be continued in the study:

- The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form.
- The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
- The subject must be between 18 and 40 years of age.
- The subject's vertex corrected spherical equivalent distance refraction must be in the range of -0.50D to -8.00D in each eye.
- The subject's refractive cylinder must be no more than -1.00 D cylindrical correction in each eye after vertexing to the corneal plane.
- The subject must have best corrected visual acuity of 0.20 or better in each eye.

- The subject must be a current wearer of daily, spherical, soft contact lenses (no bifocal or multifocal contact lenses, no extended wear or monovision) for at least 5 days/week and at least 8 hours/day during the month prior to enrollment.
- The subject must be using digital devices (any combination of computers, tablets, smart-phones etc.) for at least 8 hours over the course of a typical day.
- The subject should own a wearable pair of spectacles and wear them the day of the baseline visit.
- The subject must have normal eyes with no evidence of abnormality or disease that in the opinion of the investigator would contraindicate contact lens wear.
- The subject must meet normal eligibility conditions of binocular vision tests.
- The subject may not have any double vision at near with their habitual CL correction.

4.3 EXCLUSION CRITERIA

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

- Currently pregnant or lactating (subjects who become pregnant during the study will be discontinued).
- Any ocular or systemic allergies or diseases that may interfere with contact lens wear (at the investigator's discretion).
- Any systemic disease, autoimmune disease, or use of medication, which may interfere with contact lens wear (at the investigator's discretion).
- Use of any medication that causes side effects similar to side effects experienced when using digital devices, such as a subject reporting headaches associated with birth control pills (at the investigator's discretion).
- Any infectious disease (e.g., hepatitis, tuberculosis) or a contagious immunosuppressive disease.
- Any active ocular infection.
- Entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or moderate or above corneal distortion.
- Any previous, or planned, ocular or interocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.).
- Clinically significant (grade 3 or 4) corneal edema, corneal vascularization, corneal staining, or any other abnormalities of the cornea which would contraindicate contact lens wear.
- Clinically significant (grade 3 or 4) tarsal abnormalities or bulbar injection which might interfere with contact lens wear.
- Any known hypersensitivity or allergic reaction to the study products.
- Participation in any contact lens or lens care product clinical trial within 7 days prior to study enrollment.

- History of binocular vision abnormality or strabismus.
- Employee of investigational clinic (e.g., Investigator, Coordinator, Technician).

4.4 STUDY DESIGN, TIME AND EVENTS SCHEDULE, FLOWCHART

This is a group sequential, adaptive, prospective, single (subject)-masked, randomized, 2x2 cross-over, dispensing design study. After a screening visit to determine eligibility, subjects will return for the first study lens dispense visit after a required 24 hour no-lens wear washout period. If, for scheduling purposes, the washout duration needs to be longer than 24 hours, the subject will be allowed to wear their habitual contact lenses, except during the last 24 hours prior to the next study visit, when only habitual spectacle wear will be permitted. During the two study periods, subjects will wear each of two lens types (ACUVUE OASYS® with HYDRACLEAR® PLUS, ULTRA™ with MoistureSeal™ Technology) for 4 weeks bilaterally (randomized order). There will be a 7 day minimum wash out requirement prior to V6 (dispense Lens 2). Subjects will be allowed to wear their own lenses during the washout except for the last 24 hours prior to dispensing of lens type 2. Subjects will be masked to the lens type during the two treatment periods. Due to the different replacement schedules for ACUVUE OASYS® with HYDRACLEAR® PLUS (2 weeks) and ULTRA™ with MoistureSeal™ Technology (4 weeks) CLs, subjects wearing ACUVUE OASYS® will have their lenses replaced with a fresh pair at the Day 14 visit while subjects wearing Ultra® will be re-dispensed the same lenses at the Day 14 visit. Lens replacement will be handled by study personnel; subjects will not be aware if lenses will have been replaced at either the Day 14 visits in lens wearing phase 1 (V4) or phase 2 (V8).

There will be a total of 9 study visits. Subjects will spend a total of 13 hours at the CCLR, with visit-specific durations as outlined below:

- Visit 1 – screening (2 hrs)
- Visit 2 – dispense lens type 1 (1 hr)
- Visit 3 – Day 1 follow-up with lens type 1 (1.5 hrs)
- Visit 4 – Day 14 follow-up with lens type 1 (1.5 hrs)
- Visit 5 – Day 28 follow-up with lens type 1 (1.5 hrs)
- Visit 6 – dispense lens type 2 (1 hr)
- Visit 7 – Day 1 follow-up with lens type 2 (1.5 hrs)
- Visit 8 – Day 14 follow-up with lens type 2 (1.5 hrs)
- Visit 9 – Day 28 follow-up with lens type 2 (1.5 hrs)

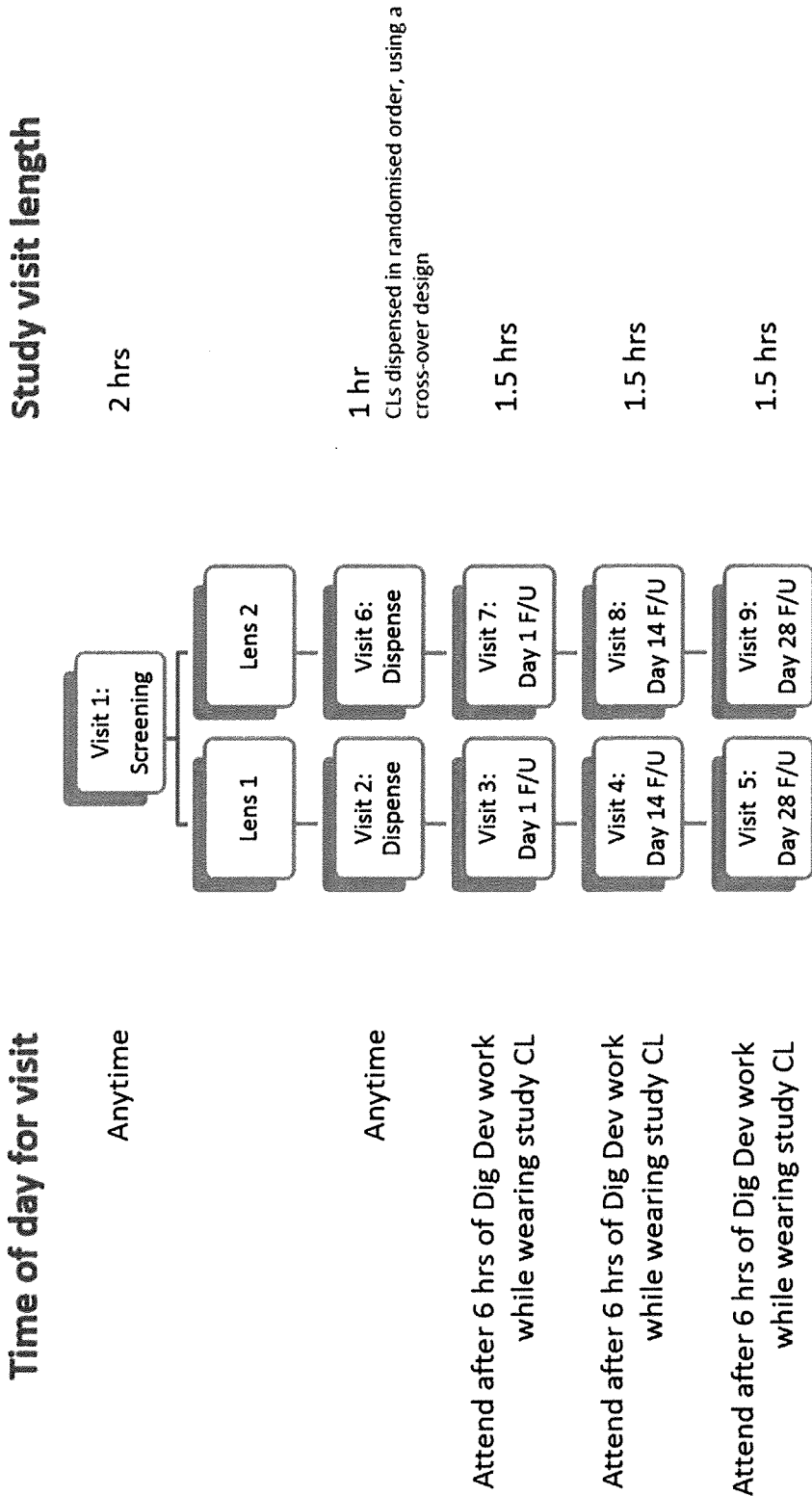
4.4.1 TIME AND EVENT SCHEDULE

Event	Visit 1 Screen <i>Day 0</i>	Visit 2 Lens 1 Fit & Dispense ≥1 day after V1 (last 24h no CL wear)	Visit 3 Lens 1 F/U Day 1 1 day after V2	Visit 4 Lens 1 F/U Day 14 14±2 days after V2	Visit 5 Lens 1 F/U Day 28 28±3 days after V2	Visit 6 Lens 2 Fit & Dispense ≥7 days after V5 (last 24h no CL wear)	Visit 7 Lens 2 F/U Day 1 1 day after V6	Visit 8 Lens 2 F/U Day 14 14±2 days after V6	Visit 9 Lens 2 F/U Day 28 28±3 days after V6
Statement of Informed Consent	X								
Demographics	X								
Medical History	X								
Medical History Changes		X	X	X	X	X	X	X	X
Conmeds	X								
Conmeds changes		X	X	X	X	X	X	X	X
Habitual Contact Lens Information	X								
Subject Total and Comfortable Wear Time	X		X	X	X		X	X	X
PRO Dig Dev use	X		X	X	X		X	X	X
Inclusion/Exclusion Criteria	X								
CLDEQ8 Questionnaire	X			X	X			X	X
CLUE Questionnaire	X	X	X	X	X	X	X	X	X
MRD	X	X	X	X	X	X	X	X	X
LogMAR Distance Visual Acuity	X	X	X	X	X	X	X	X	X
Subjective Sphero-Cylindrical Refraction	X								
Subjective Best Sphere Refraction	X								
Stereopsis	X								

Event	Visit 1 Screen Day 0	Visit 2 Lens 1 Fit & Dispense ≥1 day after V1 (last 24h no CL wear)	Visit 3 Lens 1 F/U Day 1 1 day after V2	Visit 4 Lens 1 F/U Day 14 14±2 days after V2	Visit 5 Lens 1 F/U Day 28 28±3 days after V2	Visit 6 Lens 2 Fit & Dispense ≥7 days after V5 (last 24h no CL wear)	Visit 7 Lens 2 F/U Day 1 1 day after V6	Visit 8 Lens 2 F/U Day 14 14±2 days after V6	Visit 9 Lens 2 F/U Day 28 28±3 days after V6
Binocular Vision Testing	X								
Biomicroscopy	X	X	X	X	X	X	X	X	X
Randomization (Study CL)		X							
Record Lens Information (fitting and dispensing)		X		X (only if randomized to ACUVUE OASYS®)		X		X (only if randomized to ACUVUE OASYS®)	
Compliance		X	X	X	X	X	X	X	X
Unscheduled Lens Replacements			X	X	X		X	X	X
Fitting of Study CL		X (Lens 1)				X (Lens 2)			
Distance Over Refraction over study CL		X (Lens 1)				X (Lens 2)			
Lens Modification (if applicable)		X (Lens 1)				X (Lens 2)			
Lens Fit Assessment		X (Lens 1)	X	X	X	X (Lens 2)	X	X	X
Dispense Patient Instruction Guide (CL & Solution, if applicable)		X (Lens 1)				X (Lens 2)			
Study Solution Dispense		X				X			
Tear Break-up Time (TBUT)			X	X	X		X	X	X

Event	Visit 1 Screen Day 0	Visit 2 Lens 1 Fit & Dispense ≥1 day after V1 (last 24h no CL wear)	Visit 3 Lens 1 F/U Day 1 1 day after V2	Visit 4 Lens 1 F/U Day 14 14±2 days after V2	Visit 5 Lens 1 F/U Day 28 28±3 days after V2	Visit 6 Lens 2 Fit & Dispense ≥7 days after V5 (last 24h no CL wear)	Visit 7 Lens 2 F/U Day 1 1 day after V6	Visit 8 Lens 2 F/U Day 14 14±2 days after V6	Visit 9 Lens 2 F/U Day 28 28±3 days after V6
CL surface wettability assessment			X	X	X		X	X	X
CL surface deposits			X	X	X		X	X	X
Distance and Near logMAR HCVA & LCVA			X	X	X		X	X	X
Near Contrast Sensitivity			X	X	X		X	X	X
Time to Haze			X	X	X		X	X	X
Subject Instructions	X	X	X	X	X	X	X	X	X
Study Completion (Exit Form)									X

4.4.2 OPTIONAL FLOWCHART



4.5 RANDOMIZATION AND MASKING

The study lenses will be dispensed and applied in a bilateral and random fashion using a 2 x 2 crossover design. Permuted block randomization will be used to minimize the potential for treatment imbalance and to enhance the validity of statistical comparisons across treatment groups. A block size of two sequences will be utilized. Using a computer-generated randomization scheme, each subject will randomly be assigned to one of the two possible lens wear sequences (TEST/CONTROL or CONTROL/TEST). Since there is only one site there is no need for stratification by site. The randomized assignment of subjects will be performed at the first dispense visit (V2). The following must have occurred prior to randomization:

- ⑩ Informed consent has been obtained
- ⑩ Subject meets all the inclusion / exclusion criteria
- ⑩ Subject history and baseline information has been collected

The identity of the study lenses will be masked to subjects. The study site will follow the randomization scheme provided and will complete enrollment according to the randomization list and will not pre-select or assign subjects. Every effort will be made to maintain masking throughout the study; however, due to the visibility of identifier markings on certain lens types, this may not always be possible.

To maintain masking of subjects during lens dispense at V2 and V6, a research assistant will transfer the study lenses and the original blister pack solution into paper cups designated to right and left eyes. The research assistant will take the paper cups to the exam room, where they will dispense the study lenses from the paper cups to the subject using disinfected tweezers. The subject is required to wash their hands prior to receiving the lenses for insertion.

To maintain masking of subjects at the two Day 14 visits (V4 and V8), a research assistant will consult the randomization schedule to determine if lenses need to be replaced (ACUVUE OASYS® with HYDRACLEAR® PLUS) or remain the same (ULTRA™ with MoistureSeal™). In case of ACUVUE OASYS® with HYDRACLEAR® PLUS, the research assistant will prepare two paper cups with a new pair of study lenses to be dispensed to the subject after the biomicroscopy exam (ocular health permitting), in the same way as described above for the initial lens dispense at V2 or V6. In case of ULTRA™ with MoistureSeal™ lenses, the subject will receive the same pair of lenses (ocular health permitting, dispensed from a paper cup with saline solution) prior to leaving the CCLR. The subject is required to wash their hands prior to receiving the lenses for insertion.

4.6 WEAR AND REPLACEMENT SCHEDULES, INCLUDING FORM, PACKAGING AND LABELING

Wear Schedule: This study has a requirement for the subjects to wear their lenses on a full-time (minimum 8 hours per day, 5 days per week) daily wear schedule.

Replacement Schedule: The replacement schedule depends on the CL type being used during each period of the study. All study lens types will be dispensed and replaced according to manufacturers' guidelines. There will be a total of two pairs of ACUVUE OASYS® with HYDRACLEAR® PLUS lenses and one pair of ULTRA™ with MoistureSeal™ lenses. One pair of ACUVUE OASYS® with HYDRACLEAR® PLUS CLs will be dispensed at the respective dispense visit (V2 or V6, depending on the randomization schedule determined at Visit 2), to be worn on a daily wear basis. The subject will remove the lenses at the Day 14 visit (either V4 or V8, depending on the randomization schedule) prior to the biomicroscopy examination, and will receive a new pair (ocular health permitting, dispensed from a paper cup with blister pack solution) prior to leaving the CCLR at this visit. In case of the ULTRA™ with MoistureSeal™ lens type, each subject will be

dispensed a single pair of this CL type at the respective dispense visit (V2 or V6, depending on the randomization schedule determined at Visit 2); this pair is to be worn on a daily wear basis for the full study period of 4 weeks, with no planned replacement of the lenses. At the Day 14 visit (either V4 or V8, depending on the randomization schedule), the subject will remove the lenses prior to the biomicroscopy examination, and will receive the same pair of lenses (ocular health permitting, dispensed from a paper cup with saline solution) prior to leaving the CCLR. Subjects will be masked to the lens type and thus to the potential lens replacement at this visit. Unscheduled replacements, for example in case of lost or damaged contact lenses, are permitted for both lens types, and will be recorded in the lens accountability log as required; in cases of an unscheduled replacement, lens(es) will also be dispensed from paper cup(s).

Test Article Packaging Description: Blister packaging in sterile packing solution

Labeling: Approved Labeling

4.7 DETAILED STUDY PROCEDURES

4.7.1 SEQUENCE OF EVENTS

Visit 1: Screening

VISIT 1 – SCREENING (History)			
Step	Descriptor	Details	CRF
The subject attends the visit wearing their habitual contact lenses.			
1	Statement of Informed Consent	Each subject must read, understand, and sign the Statement of Informed Consent before being enrolled in the study. <i>Note: The subject must be provided with a signed copy of this document.</i>	
2	Demographics	Age, date of birth, Global ID, gender, race, and ethnicity.	Demographics
3	Case History	<i>Questions regarding the subject's contact lens and medical history.</i> Please Note: <i>The subject must be a current wearer of daily, spherical, soft contact lenses (no bifocal or multifocal contact lenses, no extended wear or monovision) for at least 5 days/week and at least 8 hours/day during the month prior to enrollment.</i>	Subject's Own Lens Information Medical History Prior and Concomitant Medications
4	Subject Wear Time	Average wear time and comfortable wear time with subject's habitual soft contact lenses will be recorded.	Wear Time
5	Baseline Subject Reported Digital Device Use (Habitual CL)	Subjects answer questions about their digital device use (duration while using digital devices, purpose etc.).	Subject Reported Digital Device Use

6	Eligibility (Screening)	All responses to Inclusion Criteria questions must be answered “yes”, and all responses to Exclusion Criteria questions must be answered “no” for the subject to be considered eligible.	Eligibility Criteria
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VISIT 1 – SCREENING (Baseline)			
Step	Descriptor	Details	CRF
1	Entrance logMAR Distance Visual Acuity	Record the logMAR entrance distance visual acuity with the subject’s habitual soft contact lens correction in place OD, OS, OU. See Section 16.2	Visual Acuity
2	CLDEQ8 & CLUE Questionnaires (Habitual CL)	The subject will evaluate the vision and comfort characteristics of their habitual lenses using the CLUE and CLDEQ8 questionnaires.	Baseline Questionnaire
3	CL Removal	The subject removes their habitual CL prior to baseline assessments.	CL Removal
4	Subjective Sphero-Cylindrical Refraction	A monocular distance sphero-cylindrical refraction will be performed. Record the refraction and distance logMAR visual acuity to the nearest letter for OD, OS, and OU. <i>Note: The sphero-cylindrical refraction must show the astigmatism of both eyes to be $\leq -1.00D$. If not, the subject is not eligible to participate in the study.</i>	Refraction
5	Subjective Best Sphere Refraction	Optimal distance best sphere refraction (OD, OS) will be performed and the resultant visual acuity will be documented to the nearest letter. <i>Note 1: The subject must have best corrected visual acuity of 0.20 or better in each eye to be considered eligible for the study.</i> <i>Note 2: Confirm the subject’s vertex-corrected spherical equivalent of the sphero-cylindrical refraction (non-vertexed) is between -0.50DS and -8.00DS for each eye to be eligible for the study.</i>	Best sphere refraction
6	Stereo Acuity	Perform the stereopsis test and record stereo acuity in seconds of arc, with the subject’s best sphero-cylindrical refraction in the trial frame.	Stereo Acuity

7	Binocular Vision Testing	<p>The subject's binocular vision (BV) is assessed. BV tests are performed with the lenses from subjective refraction in place. BV tests to be performed include:</p> <ul style="list-style-type: none"> • Near Phoria (Unilateral & Bilateral Cover Test) • Near Point of Convergence • Amplitude of Accommodation • Near fusional reserves <p>Note: The subject must have normal binocular vision to be found eligible for the study. See Section 16.2 for CTPs detailing the BV testing procedures and acceptable ranges for normal BV.</p>	<p>Near Phoria</p> <p>Near Point of Convergence</p> <p>Amplitude of Accommodation</p> <p>Near fusional reserves</p>
8	Biomicroscopy	<p>The Efron slit lamp classification scale will be used to grade the findings. Subjects will be considered screen failures if they have slit lamp findings of grade 3 or higher. This includes corneal and conjunctival staining measurements with fluorescein (Section 16.2).</p>	<p>Biomicroscopy</p>
9	Eye Rinse	<p>The study investigator or technician will rinse the subject's eyes thoroughly with saline.</p>	<p>Eye Rinse</p>
10	Eligibility (Baseline)	<p>All responses to Inclusion Criteria questions must be answered "yes," and all responses to Exclusion Criteria questions must be answered "no" for the subject to be considered eligible.</p> <p>Note: If a subject presents with a clinical finding that, in the opinion of the investigator, is temporary but precludes him/her from being eligible at this point in time, the subject may be invited to attend a re-screen visit. A prompt will be answered whether another baseline visit is required.</p>	<p>Eligibility Criteria</p> <p>Re-Screen (Baseline) prompt</p>
11	Exit logMAR Visual Acuity	<p>Distance HC visual acuity will be measured for each eye with the spectacle correction in place. The acuity will be recorded to the nearest letter OD, OS, and OU (Section 16.2).</p>	<p>Exit Visual Acuity</p>
12	Subject Instructions	<p>Subjects will be instructed to do the following:</p> <ul style="list-style-type: none"> • Subjects are allowed to wear their habitual lenses during the first portion of the washout phase (i.e. if >24 hours), but are asked to only wear spectacles but no contact lenses during the <u>last 24 hours</u> of the washout period prior to V2. <p>Attend V2 (dispense lens type 1) wearing their habitual spectacles.</p>	<p>Instructions</p>

Visit 2: Baseline and Treatment 1 Dispense

VISIT 2 – Baseline			
Step	Descriptor	Details	CRF
		The subject attends the visit wearing their habitual spectacles.	

1	Changes in Concomitant Medications, Medical History and Adverse Events	Record any changes in concomitant medications and any adverse events that may have occurred since the last scheduled study visit.	Concomitant Medications Medical History Adverse Events (if applicable)
2	Compliance	Subject compliance with wearing the spectacles will be recorded.	Compliance
3	Entering Distance logMAR Visual Acuity	Distance visual acuity will be measured for each eye with the subject's habitual spectacle correction in place. The acuity will be recorded to the nearest letter OD, OS, and OU (Section 16.2).	Visual Acuity
4	Efron Biomicroscopy	The Efron slit lamp classification scale will be used to grade the findings. This includes corneal and conjunctival staining measurements with fluorescein (Section 16.2).	Biomicroscopy
5	Lens Fitting Prompt	If a subject presents with a clinical finding that, in the opinion of the investigator, is temporary but precludes him/her from being fit during this screening visit, the subject may be invited to attend a second dispense visit for lens type 1.	Lens Fitting Prompt
6	Eye Rinse	The study investigator or technician will rinse the subject's eyes thoroughly with saline.	Eye Rinse
VISIT 2 – Treatment 1			
7	Study Lens Selection	A research assistant will select the lens pair based on the randomization scheme (lens 1). The study lens parameters (power and lot number) will be recorded. <i>Note: The lens brand is masked to subject, and will be dispensed by a research assistant. Please see section 4.5 for details on lens dispense and maintaining masking.</i>	Randomization (Study CL) Lens information
8	Lens Damage	The investigator shall inspect the study lenses immediately after insertion for any damage with the biomicroscope under low to medium magnification. If there is any lens damage, replace with a new lens.	Lens Damage
9	logMAR Visual Acuity	Distance visual acuity will be measured for each eye with the subject's study lenses in place. The acuity will be recorded to the nearest letter OD, OS, and OU (Section 16.2). <i>Note: The distance visual acuity must be at least 0.20 OD and OS for the lenses to be dispensed. If the subject does not obtain an acceptable visual acuity up to two lens modifications can be made. If an acceptable visual acuity is not obtained, complete the biomicroscopy exam and Final Evaluation.</i>	Visual Acuity

10	Distance Over-refraction	Perform a monocular over-refraction and record the OD and OS results with the corresponding distance visual acuity. Record OU visual acuity. <i>Note: Up to two lens modifications can be made if necessary.</i>	Over-Refraction Lens Modification (if applicable)
11	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). An unacceptable lens fit will be any one or more of the following: <ul style="list-style-type: none"> • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all</u> three movement categories (primary gaze, upgaze, and push-up). <i>Note: If either lens is deemed unacceptable, the subject will not be able continue participation in the study (Section 16.2).</i>	Lens Fit Assessment
12	CLUE and MRD questionnaire	The subject will complete the CLUE and MRD questionnaire using the BioClinica kiosk to evaluate the study lenses (Section 16.1).	CLUE and MRD questionnaire
13	Solution Dispense	A research assistant will dispense the study solution. Subjects will be provided with one bottle of the lens care system and a new case. Subjects must only use the supplied contact lens solution for lens care. If they experience problems with the lens care system, they should discontinue use and contact the CCLR for instruction.	Solution Dispense
14	Subject Instructions Patient instruction guide	Subjects will be instructed: <ul style="list-style-type: none"> • to wear their study lenses for a minimum of 5 days/week for 8 hours/day. • to only use the provided study lenses and study solution (habitual spectacle use is permitted, but no other lens brand/kind). • to attend the Day 1 follow-up visit with their study lenses, having worn them for at least 6 hours while using digital devices. Each subject will receive a Patient Instruction Guide before leaving the office for the study contact lenses and solution they are provided with.	Instructions

Visit 3: Treatment 1 - Day 1 Follow-up

VISIT 3: Treatment 1 - Day 1 Follow-Up			
Step	Descriptor	Details	CRF
		The subject attends the visit wearing the study CLs, after having worn them for at least 6 hours while using digital devices.	

1	Changes in Concomitant Medications, Medical History and Adverse Events	Record any changes in concomitant medications and any adverse events that may have occurred since the last scheduled study visit.	Concomitant Medications Medical History Adverse Events (if applicable)
2	Subject Wear Time	Average wear time and comfortable wear time with the study lenses will be recorded.	Wear Time
3	Compliance	Subject compliance with wearing the study lenses will be recorded.	Compliance
4	Subject Reported Digital Device Use (Study Lens 1)	Subjects answer questions about their digital device use (duration while using digital devices, purpose etc.).	Subject Reported Digital Device Use
5	CLUE and MRD questionnaires	The subject will complete the CLUE and MRD questionnaire using the BioClinica kiosk to evaluate the study lenses (Section 16.1).	CLUE questionnaire
6	Unscheduled Lens Replacements	Any unscheduled lens replacements will be recorded (e.g. if subject tears lens while inserting and more than two lenses are used/day as a result).	Unscheduled Lens Replacement
7	Non-invasive tear break-up time (NITBUT)	The subject's non-invasive tear break-up time (NITBUT) will be assessed. Three measurements for each eye will be performed while the subject is wearing the study lenses (pre-lens NITBUT). See section 16.2	NITBUT
8	Contact Lens Wettability	The front surface wettability of the study lens will be graded at the slit lamp biomicroscope. The wettability will be graded from 0 (excellent) to 4 (severely reduced), in 0.25 steps. See Section 16.2.	CL Wettability
9	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). An unacceptable lens fit will be any one or more of the following: <ul style="list-style-type: none"> • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all</u> three movement categories (primary gaze, upgaze, and push-up). <i>Note: If either lens is deemed unacceptable, the subject will not be able continue participation in the study (Section 16.2).</i>	Lens Fit Assessment
10	Lens Surface Evaluation	Grading Scale (Section 16.2) will be used to grade the front and back surface deposits.	Debris and Deposits

11	Distance and Near logMAR HCVA and LCVA	The subject's distance and near logMAR visual acuity will be determined with high (HCVA) and low contrast (LCVA) letter charts with the study lenses. The acuity will be recorded to the nearest letter for OD, OS and OU. See section 16.2.	Distance and Near logMAR HCVA and LCVA
12	Near Contrast Sensitivity	The subject's contrast sensitivity will be tested at near using Mars Letter Contrast Sensitivity Test Cards with the study lenses. The subject's contrast sensitivity will be recorded to the nearest letter for OU, in 0.04 log unit incremental steps. See Section 16.2.	Near Contrast Sensitivity
13	Time to haze	The subject's "time to haze" will be determined at 1m distance with the study lenses. First, the subject's psychophysical contrast threshold will be determined using a computerized chart. "Time to haze" will then be measured at 1 level above threshold. Directly after, the subject's required "time to clear" will be determined by counting blinks until the subject has cleared the haze. See Section 16.2.	Time to haze
14	Efron Biomicroscopy	The Efron slit lamp classification scale will be used to grade the findings. This includes corneal and conjunctival staining measurements with fluorescein (Section 16.2).	Biomicroscopy
15	Eye Rinse (if applicable)	The study investigator or technician will rinse the subject's eyes thoroughly with saline if the subject would like to wear their study CL before leaving the CCLR.	Eye Rinse
16	Exit logMAR Visual Acuity	Distance visual acuity will be measured for each eye with the subject's spectacle correction or study lenses in place. The acuity will be recorded to the nearest letter OD, OS, and OU (Section 16.2).	Exit Visual Acuity
17	Subject Instructions	Subjects will be instructed: <ul style="list-style-type: none"> to wear their study lenses for a minimum of 5 days/week for 8 hours/day, while using digital devices. to only use the provided study lenses and study solution (habitual spectacle use is permitted, but no other lens brand/kind). to attend the Day 14 follow-up visit with their study lenses, having worn them for at least 6 hours while using digital devices. 	Instructions

Visit 4: Treatment 1 – Day 14 Follow-Up

VISIT 4: Treatment 1 – Day 14 Follow-Up			
Step	Descriptor	Details	CRF
		The subject attends the visit wearing the study CLs, after having worn them for at least 6 hours while using digital devices.	

1	Changes in Concomitant Medications, Medical History and Adverse Events	Record any changes in concomitant medications and any adverse events that may have occurred since the last scheduled study visit.	Concomitant Medications Medical History Adverse Events (if applicable)
2	Subject Wear Time	Average wear time and comfortable wear time with the study lenses will be recorded.	Wear Time
3	Compliance	Subject compliance with wearing the study lenses will be recorded.	Compliance
4	Subject Reported Digital Device Use (Study Lens 1)	Subjects answer questions about their digital device use (duration while using digital devices, purpose etc.).	Subject Reported Digital Device Use
5	CLDEQ 8, MRD & CLUE questionnaires	The subject will complete the CLDEQ8, MRD and CLUE questionnaire using the BioClinica kiosk to evaluate the study lenses while using digital devices (Section 16.1).	Questionnaire
6	Unscheduled Lens Replacements	Any unscheduled lens replacements will be recorded (e.g. if subject tears lens while insert and more than two lenses are used/day as a result).	Unscheduled Lens Replacement
7	Non-invasive tear break-up time (NITBUT)	The subject's non-invasive tear break-up time (NITBUT) will be assessed. Three measurements for each eye will be performed while the subject is wearing the study lenses (pre-lens NITBUT). See section 16.2	NITBUT
8	Contact Lens Wettability	The front surface wettability of the study lens will be graded at the slit lamp biomicroscope. The wettability will be graded from 0 (excellent) to 4 (severely reduced), in 0.25 steps. See Section 16.2.	CL Wettability
9	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). An unacceptable lens fit will be any one or more of the following: <ul style="list-style-type: none"> • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all</u> three movement categories (primary gaze, upgaze, and push-up). <i>Note: If either lens is deemed unacceptable, the subject will not be able continue participation in the study (Section 16.2).</i>	Lens Fit Assessment
10	Lens Surface Evaluation	Grading Scale (Section 16.2) will be used to grade the front and back surface deposits.	Debris and Deposits

11	Distance and Near logMAR HCVA and LCVA	The subject's distance and near logMAR visual acuity will be determined with high (HCVA) and low contrast (LCVA) letter charts with the study lenses. The acuity will be recorded to the nearest letter for OD, OS and OU. See section 16.2.	Distance and Near logMAR HCVA and LCVA
12	Near Contrast Sensitivity	The subject's contrast sensitivity will be tested at near using Mars Letter Contrast Sensitivity Test Cards with the study lenses. The subject's contrast sensitivity will be recorded to the nearest letter for OU, in 0.04 log unit incremental steps. See Section 16.2.	Near Contrast Sensitivity
13	Time to haze	The subject's "time to haze" will be determined at 1m distance with the study lenses. First, the subject's psychophysical contrast threshold will be determined using a computerized chart. "Time to haze" will then be measured at 1 level above threshold. Directly after, the subject's required "time to clear" will be determined by counting blinks until the subject has cleared the haze. See Section 16.2.	Time to haze
14	Lens Removal	Study lenses are removed from the eyes and placed into paper cups filled with saline. The sub-investigator will take the paper cups to a research assistant, who will determine if the lenses need replacement (in case of ACUVUE OASYS® with HYDRACLEAR® PLUS) or remain the same (in case of ULTRA™ with MoistureSeal™), depending on the randomization schedule. After the biomicroscopy exam (see next item) has been completed, the study lenses will be dispensed by a research assistant. Please see section 4.5 for details on lens dispense and maintaining masking. In case of a product defect (e.g. lens edge tear), study lens(es) will be retained and returned to the sponsor, and a product complaint form will be completed in BioClinica. In case of a corneal adverse event, study lens(es) will be retained and analyzed at the CCLR.	Lens Removal Lens information (If applicable)
15	Efron Biomicroscopy	The Efron slit lamp classification scale will be used to grade the findings. This includes corneal and conjunctival staining measurements with fluorescein (Section 16.2).	Biomicroscopy
16	Eye Rinse (if applicable)	The study investigator or technician will rinse the subject's eyes thoroughly with saline. The subject is asked to insert the study lenses.	Eye Rinse
17	CLUE and MRD questionnaire	The subject will complete the CLUE and MRD questionnaire using the BioClinica kiosk to evaluate the study lenses (Section 16.1).	CLUE and MRD questionnaire
18	Exit logMAR Visual Acuity	Distance visual acuity will be measured for each eye with the subject's spectacle correction or study lenses in place. The acuity will be recorded to the nearest letter OD, OS, and OU (Section 16.2).	Exit Visual Acuity

19	Subject Instructions	<p>Subjects will be instructed:</p> <ul style="list-style-type: none"> • <i>to wear their study lenses for a minimum of 5 days/week for 8 hours/day, while using digital devices.</i> • <i>to only use the provided study lenses and study solution (habitual spectacle use is permitted, but no other lens brand/kind).</i> • <i>to attend the Day 28 follow-up with their study lenses, having worn them for at least 6 hours while using digital devices.</i> • <i>to return their study solution bottle and lens case at the Day 28 visit.</i> • <i>to bring their habitual spectacles to the Day 28 visit.</i> 	Instructions
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Visit 5: Treatment 1 – Day 28 Follow-Up

VISIT 5: Treatment 1 – Day 28 Follow-Up			
Step	Descriptor	Details	CRF
The subject attends the visit wearing the study CLs, after having worn them for at least 6 hours while using digital devices.			
1	Changes in Concomitant Medications, Medical History and Adverse Events	Record any changes in concomitant medications and any adverse events that may have occurred since the last scheduled study visit.	Concomitant Medications Medical History Adverse Events (if applicable)
2	Collection of Study Solutions	The site staff will collect the solution bottle and case used to clean the study lenses.	Solution Collection
3	Subject Wear Time	Average wear time and comfortable wear time with the study lenses will be recorded.	Wear Time
4	Compliance	Subject compliance with wearing the study lenses will be recorded.	Compliance
5	Subject Reported Digital Device Use (Study Lens 1)	Subjects answer questions about their digital device use (duration while using digital devices, purpose etc.).	Subject Reported Digital Device Use
6	CLDEQ 8, MRD & CLUE questionnaires	The subject will complete the CLDEQ8, MRD and CLUE questionnaire using the BioClinica kiosk to evaluate the study lenses while using digital devices (Section 16.1).	Questionnaire
7	Unscheduled Lens Replacements	Any unscheduled lens replacements will be recorded (e.g. if subject tears lens while insert and more than two lenses are used/day as a result).	Unscheduled Lens Replacement
8	Non-invasive tear break-up time (NITBUT)	The subject's non-invasive tear break-up time (NITBUT) will be assessed. Three measurements for each eye will be performed while the subject is wearing the study lenses (pre-lens NITBUT). See section 16.2	NITBUT
9	Contact Lens Wettability	The front surface wettability of the study lens will be graded at the slit lamp biomicroscope. The wettability will be graded from 0 (excellent) to 4 (severely reduced), in 0.25 steps. See Section 16.2.	CL Wettability

10	Lens Fit Assessment	<p>Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test).</p> <p>An unacceptable lens fit will be any one or more of the following:</p> <ul style="list-style-type: none"> • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all</u> three movement categories (primary gaze, upgaze, and push-up). <p><i>Note: If either lens is deemed unacceptable, the subject will not be able continue participation in the study (Section 16.2).</i></p>	Lens Fit Assessment
11	Lens Surface Evaluation	Grading Scale (Section 16.2) will be used to grade the front and back surface deposits.	Debris and Deposits
12	Distance and Near logMAR HCVA and LCVA	The subject's distance and near logMAR visual acuity will be determined with high (HCVA) and low contrast (LCVA) letter charts with the study lenses. The acuity will be recorded to the nearest letter for OD, OS and OU. See section 16.2.	Distance and Near logMAR HCVA and LCVA
13	Near Contrast Sensitivity	The subject's contrast sensitivity will be tested at near using Mars Letter Contrast Sensitivity Test Cards with the study lenses. The subject's contrast sensitivity will be recorded to the nearest letter for OU, in 0.04 log unit incremental steps. See Section 16.2.	Near Contrast Sensitivity
14	Time to haze	The subject's "time to haze" will be determined at 1m distance with the study lenses. First, the subject's psychophysical contrast threshold will be determined using a computerized chart. "Time to haze" will then be measured at 1 level above threshold. Directly after, the subject's required "time to clear" will be determined by counting blinks until the subject has cleared the haze. See Section 16.2.	Time to haze
15	Lens Removal	<p>Study lenses are removed from the eyes and are disposed of at the CCLR.</p> <p>In case of a product defect (e.g. lens edge tear), study lens (es) will be retained and returned to the sponsor, and a product complaint form will be completed in BioClinica. In case of a corneal adverse event, study lens(es) will be retained and analyzed at the CCLR.</p>	Lens Removal
16	Efron Biomicroscopy	The Efron slit lamp classification scale will be used to grade the findings. This includes corneal and conjunctival staining measurements with fluorescein (Section 16.2).	Biomicroscopy
17	Eye Rinse (if applicable)	The study investigator or technician will rinse the subject's eyes thoroughly with saline.	Eye Rinse
18	Exit logMAR Visual Acuity	Distance visual acuity will be measured for each eye with habitual spectacles or the subject's own lenses in place. The acuity will be recorded to the nearest letter OD, OS, and OU (Section 16.2).	Exit Visual Acuity

19	Subject Instructions	<p>Subjects will be instructed to do the following:</p> <ul style="list-style-type: none"> • <i>Subjects are allowed to wear their habitual lenses during the first portion of the washout phase (i.e. if >24 hours), but are asked to only wear spectacles but no contact lenses during the <u>last 24 hours</u> of the washout period prior to Visit 6.</i> <p><i>Attend the next study visit wearing their habitual spectacles, during which they will receive their study lenses.</i></p>	Instructions
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Visit 6: Baseline and Treatment 2 Dispense

VISIT 6 – Baseline			
Step	Descriptor	Details	CRF
The subject attends the visit wearing their habitual spectacles.			
1	Changes in Concomitant Medications, Medical History and Adverse Events	Record any changes in concomitant medications and any adverse events that may have occurred since the last scheduled study visit.	Concomitant Medications Medical History Adverse Events (if applicable)
2	Compliance	Subject compliance with wearing the spectacles will be recorded.	Compliance
3	Entering Distance logMAR Visual Acuity	Distance visual acuity will be measured for each eye with the subject’s habitual spectacle correction in place. The acuity will be recorded to the nearest letter OD, OS, and OU (Section 16.2).	Visual Acuity
4	Efron Biomicroscopy	The Efron slit lamp classification scale will be used to grade the findings. This includes corneal and conjunctival staining measurements with fluorescein (Section 16.2).	Biomicroscopy
5	Lens Fitting Prompt	If a subject presents with a clinical finding that, in the opinion of the investigator, is temporary but precludes him/her from being fit during this screening visit, the subject may be invited to attend a second dispense visit for lens type 2.	Lens Fitting Prompt
6	Eye Rinse	The study investigator or technician will rinse the subject’s eyes thoroughly with saline.	Eye Rinse

VISIT 6 – Treatment 2

7	Study Lens Selection	<p>A research assistant will select the lens pair based on the randomization scheme (lens 2). The study lens parameters (power and lot number) will be recorded.</p> <p><i>Note: The lens brand is masked to subject, and will be dispensed by a research assistant. Please see section 4.5 for details on lens dispense and maintaining masking.</i></p>	<p>Randomization (Study CL)</p> <p>Lens information</p>
8	Lens Damage	<p>The investigator shall inspect the study lenses immediately after insertion for any damage with the biomicroscope under low to medium magnification. If there is any lens damage, replace with a new lens.</p>	Lens Damage
9	logMAR Visual Acuity	<p>Distance visual acuity will be measured for each eye with the subject's study lenses in place. The acuity will be recorded to the nearest letter OD, OS, and OU (Section 16.2).</p> <p><i>Note: The distance visual acuity must be at least 0.20 OD and OS for the lenses to be dispensed. If the subject does not obtain an acceptable visual acuity up to two lens modifications can be made. If an acceptable visual acuity is not obtained, complete the biomicroscopy exam and Final Evaluation.</i></p>	Visual Acuity
10	Distance Over-refraction	<p>Perform a monocular over-refraction and record the OD and OS results with the corresponding distance visual acuity. Record OU visual acuity.</p> <p><i>Note: Up to two lens modifications can be made if necessary.</i></p>	<p>Over-Refraction</p> <p>Lens Modification (if applicable)</p>
11	Lens Fit Assessment	<p>Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test).</p> <p>An unacceptable lens fit will be any one or more of the following:</p> <ul style="list-style-type: none"> • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all</u> three movement categories (primary gaze, upgaze, and push-up). <p><i>Note: If either lens is deemed unacceptable, the subject will not be able continue participation in the study (Section 16.2).</i></p>	Lens Fit Assessment
12	CLUE and MRD questionnaire	<p>The subject will complete the CLUE and MRD questionnaire using the BioClinica kiosk to evaluate the study lenses (Section 16.1).</p>	CLUE and MRD questionnaire
13	Solution Dispense	<p>A research assistant will dispense the study solution. Subjects will be provided with one bottle of the lens care system and a new case. Subjects must only use the supplied contact lens solution for lens care. If they experience problems with the lens care system, they should discontinue use and contact the CCLR for instruction.</p>	Solution Dispense

14	Subject Instructions Patient instruction guide	<p>Subjects will be instructed:</p> <ul style="list-style-type: none"> • <i>to wear their study lenses for a minimum of 5 days/week for 8 hours/day.</i> • <i>to only use the provided study lenses and study solution (habitual spectacle use is permitted, but no other lens brand/kind).</i> • <i>to attend the Day 1 follow-up visit with their study lenses, having worn them for at least 6 hours while using digital devices.</i> <p>Each subject will receive a Patient Instruction Guide before leaving the office for the study contact lenses and solution they are provided with.</p>	Instructions
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Visit 7: Treatment 2 - Day 1 Follow-up

VISIT 7: Treatment 2 - Day 1 Follow-Up			
Step	Descriptor	Details	CRF
The subject attends the visit wearing the study CLs, after having worn them for at least 6 hours while using digital devices.			
1	Changes in Concomitant Medications, Medical History and Adverse Events	Record any changes in concomitant medications and any adverse events that may have occurred since the last scheduled study visit.	Concomitant Medications Medical History Adverse Events (if applicable)
2	Subject Wear Time	Average wear time and comfortable wear time with the study lenses will be recorded.	Wear Time
3	Compliance	Subject compliance with wearing the study lenses will be recorded.	Compliance
4	Subject Reported Digital Device Use (Study Lens 2)	Subjects answer questions about their digital device use (duration while using digital devices, purpose etc.).	Subject Reported Digital Device Use
5	CLUE and MRD questionnaires	The subject will complete the CLUE and MRD questionnaire using the BioClinica kiosk to evaluate the study lenses (Section 16.1).	CLUE questionnaire
6	Unscheduled Lens Replacements	Any unscheduled lens replacements will be recorded (e.g. if subject tears lens while inserting and more than two lenses are used/day as a result).	Unscheduled Lens Replacement
7	Non-invasive tear break-up time (NITBUT)	The subject's non-invasive tear break-up time (NITBUT) will be assessed. Three measurements for each eye will be performed while the subject is wearing the study lenses (pre-lens NITBUT). See section 16.2	NITBUT

8	Contact Lens Wettability	The front surface wettability of the study lens will be graded at the slit lamp biomicroscope. The wettability will be graded from 0 (excellent) to 4 (severely reduced), in 0.25 steps. See Section 16.2.	CL Wettability
9	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). An unacceptable lens fit will be any one or more of the following: <ul style="list-style-type: none"> • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all</u> three movement categories (primary gaze, upgaze, and push-up). <i>Note: If either lens is deemed unacceptable, the subject will not be able continue participation in the study (Section 16.2).</i>	Lens Fit Assessment
10	Lens Surface Evaluation	Grading Scale (Section 16.2) will be used to grade the front and back surface deposits.	Debris and Deposits
11	Distance and Near logMAR HCVA and LCVA	The subject's distance and near logMAR visual acuity will be determined with high (HCVA) and low contrast (LCVA) letter charts with the study lenses. The acuity will be recorded to the nearest letter for OD, OS and OU. See section 16.2.	Distance and Near logMAR HCVA and LCVA
12	Near Contrast Sensitivity	The subject's contrast sensitivity will be tested at near using Mars Letter Contrast Sensitivity Test Cards with the study lenses. The subject's contrast sensitivity will be recorded to the nearest letter for OU, in 0.04 log unit incremental steps. See Section 16.2.	Near Contrast Sensitivity
13	Time to haze	The subject's "time to haze" will be determined at 1m distance with the study lenses. First, the subject's psychophysical contrast threshold will be determined using a computerized chart. "Time to haze" will then be measured at 1 level above threshold. Directly after, the subject's required "time to clear" will be determined by counting blinks until the subject has cleared the haze. See Section 16.2.	Time to haze
14	Efron Biomicroscopy	The Efron slit lamp classification scale will be used to grade the findings. This includes corneal and conjunctival staining measurements with fluorescein (Section 16.2).	Biomicroscopy
15	Eye Rinse (if applicable)	The study investigator or technician will rinse the subject's eyes thoroughly with saline if the subject would like to wear their study CL before leaving the CCLR.	Eye Rinse
16	Exit logMAR Visual Acuity	Distance visual acuity will be measured for each eye with the subject's spectacle correction or study lenses in place. The acuity will be recorded to the nearest letter OD, OS, and OU (Section 16.2).	Exit Visual Acuity

17	Subject Instructions	<p>Subjects will be instructed:</p> <ul style="list-style-type: none"> to wear their study lenses for a minimum of 5 days/week for 8 hours/day, while using digital devices. to only use the provided study lenses and study solution (habitual spectacle use is permitted, but no other lens brand/kind). to attend the Day 14 follow-up visit with their study lenses, having worn them for at least 6 hours while using digital devices. 	Instructions
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Visit 8: Treatment 2 – Day 14 Follow-Up

VISIT 8: Treatment 2 – Day 14 Follow-Up			
Step	Descriptor	Details	CRF
The subject attends the visit wearing the study CLs, after having worn them for at least 6 hours while using digital devices.			
1	Changes in Concomitant Medications, Medical History and Adverse Events	Record any changes in concomitant medications and any adverse events that may have occurred since the last scheduled study visit.	Concomitant Medications Medical History Adverse Events (if applicable)
2	Subject Wear Time	Average wear time and comfortable wear time with the study lenses will be recorded.	Wear Time
3	Compliance	Subject compliance with wearing the study lenses will be recorded.	Compliance
4	Subject Reported Digital Device Use (Study Lens 2)	Subjects answer questions about their digital device use (duration while using digital devices, purpose etc.).	Subject Reported Digital Device Use
5	CLDEQ 8, MRD & CLUE questionnaires	The subject will complete the CLDEQ8, MRD and CLUE questionnaire using the BioClinica kiosk to evaluate the study lenses while using digital devices (Section 16.1).	Questionnaire
6	Unscheduled Lens Replacements	Any unscheduled lens replacements will be recorded (e.g. if subject tears lens while insert and more than two lenses are used/day as a result).	Unscheduled Lens Replacement
7	Non-invasive tear break-up time (NITBUT)	The subject's non-invasive tear break-up time (NITBUT) will be assessed. Three measurements for each eye will be performed while the subject is wearing the study lenses (pre-lens NITBUT). See section 16.2	NITBUT

8	Contact Lens Wettability	The front surface wettability of the study lens will be graded at the slit lamp biomicroscope. The wettability will be graded from 0 (excellent) to 4 (severely reduced), in 0.25 steps. See Section 16.2.	CL Wettability
9	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). An unacceptable lens fit will be any one or more of the following: <ul style="list-style-type: none"> • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all</u> three movement categories (primary gaze, upgaze, and push-up). <i>Note: If either lens is deemed unacceptable, the subject will not be able continue participation in the study (Section 16.2).</i>	Lens Fit Assessment
10	Lens Surface Evaluation	Grading Scale (Section 16.2) will be used to grade the front and back surface deposits.	Debris and Deposits
11	Distance and Near logMAR HCVA and LCVA	The subject's distance and near logMAR visual acuity will be determined with high (HCVA) and low contrast (LCVA) letter charts with the study lenses. The acuity will be recorded to the nearest letter for OD, OS and OU. See section 16.2.	Distance and Near logMAR HCVA and LCVA
12	Near Contrast Sensitivity	The subject's contrast sensitivity will be tested at near using Mars Letter Contrast Sensitivity Test Cards with the study lenses. The subject's contrast sensitivity will be recorded to the nearest letter for OU, in 0.04 log unit incremental steps. See Section 16.2.	Near Contrast Sensitivity
13	Time to haze	The subject's "time to haze" will be determined at 1m distance with the study lenses. First, the subject's psychophysical contrast threshold will be determined using a computerized chart. "Time to haze" will then be measured at 1 level above threshold. Directly after, the subject's required "time to clear" will be determined by counting blinks until the subject has cleared the haze. See Section 16.2.	Time to haze

14	Lens Removal	<p>Study lenses are removed from the eyes and placed into paper cups filled with saline. The sub-investigator will take the paper cups to a research assistant, who will determine if the lenses need replacement (in case of ACUVUE OASYS® with HYDRACLEAR® PLUS) or remain the same (in case of ULTRA™ with MoistureSeal™), depending on the randomization schedule. After the biomicroscopy exam (see next item) has been completed, the study lenses will be dispensed by a research assistant. Please see section 4.5 for details on lens dispense and maintaining masking.</p> <p>In case of a product defect (e.g. lens edge tear), study lens(es) will be retained and returned to the sponsor, and a product complaint form will be completed in BioClinica. In case of a corneal adverse event, study lens(es) will be retained and analyzed at the CCLR.</p>	Lens Removal Lens information (If applicable)
15	Efron Biomicroscopy	The Efron slit lamp classification scale will be used to grade the findings. This includes corneal and conjunctival staining measurements with fluorescein (Section 16.2).	Biomicroscopy
16	Eye Rinse (if applicable)	The study investigator or technician will rinse the subject's eyes thoroughly with saline. The subject is asked to insert the study lenses.	Eye Rinse
17	CLUE and MRD questionnaire	The subject will complete the CLUE and MRD questionnaire using the BioClinica kiosk to evaluate the study lenses (Section 16.1).	CLUE and MRD questionnaire
18	Exit logMAR Visual Acuity	Distance visual acuity will be measured for each eye with the subject's spectacle correction or study lenses in place. The acuity will be recorded to the nearest letter OD, OS, and OU (Section 16.2).	Exit Visual Acuity
19	Subject Instructions	<p>Subjects will be instructed:</p> <ul style="list-style-type: none"> • <i>to wear their study lenses for a minimum of 5 days/week for 8 hours/day, while using digital devices.</i> • <i>to only use the provided study lenses and study solution (habitual spectacle use is permitted, but no other lens brand/kind).</i> • <i>to attend the Day 28 follow-up with their study lenses, having worn them for at least 6 hours while using digital devices.</i> • <i>to return their study solution bottle and lens case at the Day 28 visit.</i> • <i>to bring their habitual spectacles to the Day 28 visit.</i> 	Instructions

Visit 9: Treatment 2 – Day 28 Follow-Up

VISIT 9: Treatment 2 – Day 28 Follow-Up			
Step	Descriptor	Details	CRF
The subject attends the visit wearing the study CLs, after having worn them for at least 6 hours while using digital devices.			
1	Changes in Concomitant Medications, Medical History and Adverse Events	Record any changes in concomitant medications and any adverse events that may have occurred since the last scheduled study visit.	Concomitant Medications Medical History Adverse Events (if applicable)
2	Collection of Study Solutions	The site staff will collect the solution bottle and case used to clean the study lenses.	Solution Collection
3	Subject Wear Time	Average wear time and comfortable wear time with the study lenses will be recorded.	Wear Time
4	Compliance	Subject compliance with wearing the study lenses will be recorded.	Compliance
5	Subject Reported Digital Device Use (Study Lens 2)	Subjects answer questions about their digital device use (duration while using digital devices, purpose etc.).	Subject Reported Digital Device Use
6	CLDEQ 8, MRD & CLUE questionnaires	The subject will complete the CLDEQ8, MRD and CLUE questionnaire using the BioClinica kiosk to evaluate the study lenses while using digital devices (Section 16.1).	Questionnaire
7	Unscheduled Lens Replacements	Any unscheduled lens replacements will be recorded (e.g. if subject tears lens while insert and more than two lenses are used/day as a result).	Unscheduled Lens Replacement
8	Non-invasive tear break-up time (NITBUT)	The subject's non-invasive tear break-up time (NITBUT) will be assessed. Three measurements for each eye will be performed while the subject is wearing the study lenses (pre-lens NITBUT). See section 16.2	NITBUT
9	Contact Lens Wettability	The front surface wettability of the study lens will be graded at the slit lamp biomicroscope. The wettability will be graded from 0 (excellent) to 4 (severely reduced), in 0.25 steps. See Section 16.2.	CL Wettability

10	Lens Fit Assessment	<p>Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test).</p> <p>An unacceptable lens fit will be any one or more of the following:</p> <ul style="list-style-type: none"> • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in <u>all</u> three movement categories (primary gaze, upgaze, and push-up). <p><i>Note: If either lens is deemed unacceptable, the subject will not be able continue participation in the study (Section 16.2).</i></p>	Lens Fit Assessment
11	Lens Surface Evaluation	Grading Scale (Section 16.2) will be used to grade the front and back surface deposits.	Debris and Deposits
12	Distance and Near logMAR HCVA and LCVA	The subject's distance and near logMAR visual acuity will be determined with high (HCVA) and low contrast (LCVA) letter charts with the study lenses. The acuity will be recorded to the nearest letter for OD, OS and OU. See section 16.2.	Distance and Near logMAR HCVA and LCVA
13	Near Contrast Sensitivity	The subject's contrast sensitivity will be tested at near using Mars Letter Contrast Sensitivity Test Cards with the study lenses. The subject's contrast sensitivity will be recorded to the nearest letter for OU, in 0.04 log unit incremental steps. See Section 16.2.	Near Contrast Sensitivity
14	Time to haze	The subject's "time to haze" will be determined at 1m distance with the study lenses. First, the subject's psychophysical contrast threshold will be determined using a computerized chart. "Time to haze" will then be measured at 1 level above threshold. Directly after, the subject's required "time to clear" will be determined by counting blinks until the subject has cleared the haze. See Section 16.2.	Time to haze
15	Lens Removal	<p>Study lenses are removed from the eyes and are disposed of at the CCLR.</p> <p>In case of a product defect (e.g. lens edge tear), study lens (es) will be retained and returned to the sponsor, and a product complaint form will be completed in BioClinica. In case of a corneal adverse event, study lens(es) will be retained and analyzed at the CCLR.</p>	Lens Removal
16	Efron Biomicroscopy	The Efron slit lamp classification scale will be used to grade the findings. This includes corneal and conjunctival staining measurements with fluorescein (Section 16.2).	Biomicroscopy
17	Eye Rinse (if applicable)	The study investigator or technician will rinse the subject's eyes thoroughly with saline.	Eye Rinse

FINAL EVALUATION			
Step	Descriptor	Details	CRF
1	Exit logMAR Visual Acuity	Distance visual acuity will be measured for each eye with the subject's spectacle correction in place. The acuity will be recorded to the nearest letter OD, OS, and OU (Section 16.2).	Exit Visual Acuity
2	Final Evaluation Form	Indicate if the subject completed the study successfully or not. If the subject discontinued, indicate the reason.	Subject Disposition
3	Protocol Deviations	Ensure any deviations that have been reported to the Sponsor have been recorded in the appropriate form.	Protocol Deviations Prompt Protocol Deviations

4.8 DISCONTINUATION CRITERIA

Johnson & Johnson Vision Care, Inc. reserves the right to terminate the study at any time for any reason. Additionally, the IRB/IEC reserves the right to terminate the study if an unreasonable risk is determined. The study may be terminated by the Principal Investigator or Medical Monitor due to specific clinical observations, if in their opinion it would be unwise to continue.

Johnson & Johnson Vision Care, Inc. [and the IRB/IEC, if applicable] will evaluate all adverse events. If it is determined that an adverse event presents an unreasonable risk, the investigation, or that part of the investigation presenting the risk, will be terminated, as soon as possible.

Should the study be terminated (either prematurely or as scheduled), the Investigator will notify the Institutional Review Board (IRB), and Regulatory Authority as required by local regulatory requirements.

4.9 ACCOUNTABILITY PROCEDURES FOR STUDY ARTICLES

Johnson & Johnson Vision Care, Inc. will provide the Investigator with sufficient quantities of study articles and supplies to complete the investigation. The Investigator is asked to retain all lens shipment documentation for the test article accountability records. The Investigator may provide the subject additional lenses in the event a lens is damaged or lost between visits. Lens dispensation will be recorded on lens accountability logs, as well as, in the EDC system.

Test articles must be kept in a lockable room, accessible only to those assigned by the Investigator for dispensing. All investigational products must be accounted. This includes 1) what was dispensed for the subject to wear out of the office or issued for the subject to replace appropriately between visits and 2) the number and reason for unplanned replacements. The Investigator may delegate this activity to an authorized study site staff member on the Delegation Log.

Worn study lenses will be collected at the Day 14 (ACUVUE OASYS®) and Day 28 visit (both lens types) and disposed of at the site as per local guidelines. Following final reconciliation of test articles, the Investigator will **destroy on site the unused lenses per local guidelines.**

4.10 PROCEDURES FOR MAINTAINING AND BREAKING RANDOMIZATION CODES

Each type of test article except for the subject's habitual spectacles is assigned and labeled with a unique lens ID code (also serves as the randomization code). The identity of the contact lens test article type (ACUVUE OASYS® with HYDRACLEAR® PLUS, ULTRA™ with MoistureSeal™ Technology) will be masked to subjects.

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

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

1. The designee (documented on the delegation log) will consult the randomization scheme to obtain the study test article assignment for that subject prior to dispensing.
2. The designee will record the subject's number on the appropriate line of the randomization scheme.
3. The designee will pull the appropriate test articles from the study supply. All test articles that were opened, whether dispensed or not, must be recorded on the Test Article Accountability Log in the "Dispensed" section.

4.11 REPORTING PRODUCT QUALITY COMPLAINTS

A Product Quality Complaint (PQC) refers to any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of test articles after they have been released for clinical trial use. A PQC is associated with any investigational product (i.e. product manufactured or supplied specifically for a clinical trial).

Complaint Handling

Once site personnel have become aware that a PQC has occurred, it shall then be recorded in the EDC system, which triggers an automatic email notification to the appropriate COM/CRA and Clinical QA representative. In cases where the EDC system in use is not configured to send automatic notifications, then the COM/CRA is responsible for notifying Clinical QA upon discovery that a PQC has occurred.

Upon receipt of the EDC notification the COM/CRA shall complete the applicable sections of the Product Quality Complaint Form [REDACTED]

For each complaint, the following minimum information shall be recorded by the CRA/COM on the Product Quality Complaint Form [REDACTED]

- Date the complaint was received/recorded in the EDC System (Date of Sponsor Awareness)
- Who received the complaint
- Study number
- Investigational site information (contact name, site ID, telephone number)
- Lot number(s)
- Unique Subject Identifier(s)
- Indication of who first observed complaint (site personnel or subject)
- OD/OS indication, along with whether or not the lens was inserted
- Any related AE number if applicable
- Detailed complaint description (scheduled/unscheduled visit, wear time, symptoms, resolution of symptoms, etc.)

• Eye Care Provider objective (slit lamp) [REDACTED] applicable

- Confirmation of product availability for return (and tracking information, if available), or rationale if product is not available for return (Refer [REDACTED])

Clinical QA will assign a unique number to the PQC. Complaint numbering is assigned as follows:

RDTC-XX-001, where RDTC = R&D Technical Complaint, XX = last two digits of the current year, 001 = sequential numbering starting with 001.

5.1 WITHDRAWAL CRITERIA

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

- Lost to follow-up
- Withdrawal of consent
- Death
- Discontinuation of study treatment as a result of the investigator's belief that for safety reasons (e.g., adverse event) it is in the best interest of the subject to stop treatment.
- The subject becomes pregnant.
- Non-compliance to the protocol.

For discontinued subjects, the Investigator will:

- Complete the "last" Follow-up Visit form (scheduled or unscheduled)
- Complete the Final Evaluation form, indicating the reason that the subject was discontinued from the study
- Record the spherocylindrical refraction with best corrected distance visual acuity
- Collect used study lenses and test articles (worn or brought to the visit) from the subject and discard them
- Collect all unused study lenses and test articles from the subject

Subjects becoming pregnant during the study will be discontinued. Once discontinued, pregnant subjects and their fetuses will not be monitored for study related purposes. However, these data will not be collected as part of the clinical study database. Pregnant subjects are not discontinued from contact lens or solution related studies for safety concerns, but due to general concerns relating to pregnancy and contact lens use. Specifically, pregnant women are discontinued due to fluctuations in refractive error and/or visual acuity that occur secondary to systemic hormonal changes, and not due to unforeseen health risks to the mother or fetus.

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

6.1 PRESTUDY AND CONCOMITANT THERAPY

Concomitant medications will be documented during screening and during the study. If subjects are reporting concomitant medication use, they will be asked if they experience any associated side effects.

Subjects experiencing medication side effects such as headaches that may be confused with side effects caused by digital device use will be excluded from the study.

6.2 MONITORING TREATMENT COMPLIANCE

Johnson & Johnson Vision Care, Inc. representatives or designees will monitor the study in a manner consistent with ICH GCP E6. The study monitors will maintain close contact with the Principal Investigator and the Investigator's designated staff. The monitor's responsibilities will include:

- Ensuring that the investigation is being conducted according to the protocol
- Ensuring the rights and well-being of subjects are protected
- Ensuring that protocol deviations are documented with corrective action plans, as applicable
- Ensuring that the site has sufficient test article and supplies
- Clarifying questions regarding the study
- Resolving study issues or problems that may arise
- Reviewing the study records to ensure completeness and accuracy
- Study and subject source document records reviewed will include:
 - The Information and Consent Form per 21CFR Parts 50 and 56 and the HIPAA documents
 - Source documentation including consenting and HIPAA process, medical history, concomitant medications, and adverse event information as applicable. The source document should be initialed and dated by the study investigator/s.
 - Investigational product shipping, dispensing, accountability, and return/destruction records
 - Study related Regulatory documents as per ICH E3 section 8

Monitoring for this study will be specified in the monitoring plan which will be provided separately.

6.3 UNSCHEDULED VISITS

If, during the investigation, a subject experiences any investigational device-related difficulties and/or problems requiring an unscheduled visit to the clinic, the following information will be collected at a minimum:

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

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

Any investigational device-related difficulties and/or problems that are ongoing at the time of the final study visit will be followed by the Investigator, within licensure, until they have returned to pre-treatment status, stabilized, or been satisfactorily explained. If further treatment (i.e., beyond licensure) is required, the subject will be referred to the appropriate health care provider.

7.1 EFFICACY PARAMETERS

The primary efficacy parameter of this study is overall comfort using the CLUE questionnaire (at Spectacle Baseline and Follow-up Visits).

7.2 METHODS FOR ASSESSING, RECORDING, AND ANALYZING EFFICACY

See detailed study procedures in section 4.7 regarding methods for assessing and recording efficacy.

8.1 SAFETY PARAMETERS

All subjects randomized and treated will be in the safety analysis. All reported AEs will be summarized by treatment group. All safety data will be listed by group, subject, and time point.

The following safety parameters will be monitored and evaluated:

- Adverse events
- Slit Lamp Findings using Efron scale
- Lens Deposits
- Reasons for discontinuation

8.2 ADVERSE EVENTS

Non-Serious Adverse Events:

All non-serious adverse events, including non-serious adverse device effects, will be reported to the sponsor by the Investigator no later than 24 hours from discovery for review by the Medical Monitor.

Serious Adverse Events:

The Investigator will inform the sponsor of all serious adverse events occurring during the study period as soon as possible by e-mail, fax, or telephone, but no later than 24 hours following discovery of the event. The investigator is obligated to pursue and obtain information requested by the Sponsor in addition to that information reported on the CRF. All subjects experiencing a serious adverse event must be followed up and all outcomes must be reported.

When medically necessary, the investigator may break the randomization code to determine the identity of the treatment that the subject received. The Sponsor and study monitor should be notified prior to unmasking the test articles.

In the event of a serious adverse event, the investigator must:

- Notify the Sponsor immediately
- Obtain and maintain in the subject's file all pertinent medical records, information and medical judgment for colleagues who assisted in the treatment and follow-up of the subject
- Provide the Sponsor with a complete case history which includes a statement as to whether the event was or was not related to the use of the investigational test article
- Notify the IRB/IEC as required by the IRB/IEC reporting procedure according to national regulations

Unanticipated (Serious) Adverse Device Effect (UADE):

In the event of an Unanticipated (Serious) Adverse Device Effect (UADE), the Investigator will submit a report of the UADE to the Sponsor and IRB/IEC as soon as possible, but no later than 24 hours after the Investigator first learns of the effect. This report is in addition to the immediate notification mentioned above.

The Sponsor must conduct an evaluation of the UADE and must report the results of the evaluation to FDA, the IRB/IEC and participating investigators within 10 working days after the Sponsor first receives notification of the effect.

8.3 ADVERSE EVENT DEFINITIONS

Adverse Event (AE) – An AE is any untoward (unwanted) medical occurrence in a patient or clinical investigation subject administered a test article whether or not caused by the test article or treatment. An AE can therefore be any unfavorable or unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of the test article whether or not related to the test article.

An AE includes any condition (including a pre-existing condition) that: 1) was not present prior to study treatment, but appeared or reappeared following initiation of study treatment; or 2) was present prior to study treatment, but worsened during study treatment. This would include any condition resulting from concomitant illnesses, reactions to concomitant medications, or progression of disease states. Pregnancy should be documented as an adverse event and should be reported to the clinical monitor and to the Sponsor immediately upon learning of the event.

Serious Adverse Event (SAE) – An SAE is any untoward medical occurrence that:

- Results in death
- Is life threatening
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity (i.e., a significant persistent or permanent change, impairment, damage, or disruption to the subject's body)
- Is a congenital anomaly/birth defect, or
- Requires intervention to prevent permanent damage (the use of the investigational product resulting in a condition which requires medical or surgical intervention to preclude permanent impairment of the body structure or a body function). Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in the above definition.

Diagnoses and conditions that are considered Serious Adverse Events include:

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

Significant Adverse Events – Those events that are usually symptomatic and warrant discontinuation (temporary or permanent) of the test article (excluding Serious Adverse Events). Diagnoses and conditions that are considered Significant Adverse Events include the following:

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

Non-Significant Adverse Events – Those conditions that are usually asymptomatic and usually do not warrant discontinuation (temporary or permanent) of the test article. However, the Investigator may choose to treat as a precautionary measure. Diagnoses and conditions that are considered Non-Significant Adverse Events include the following:

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

Adverse Device Effect (ADE) – A sub-set of AEs, and include only those adverse events that are cause by or related to the investigational device or study procedure.

Unanticipated Adverse Device Effect (UADE) – Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, the test article, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan,

investigator's brochure or protocol, or any other unanticipated serious problem associated with the test article that relates to the rights, safety and welfare of subjects.

Causality Assessment – A determination of the relationship between an adverse event and the test article. The test article relationship for each adverse event should be determined by the investigator using these explanations:

- Not Related- An adverse event that is not related to the use of the test article.
- Doubtful – An adverse event for which an alternative explanation is more likely, e.g. concomitant treatment, concomitant disease(s), or the relationship of time suggests that a causal relationship is not likely.
- Possible – An adverse event that might be due to the use of the test article. An alternative explanation, e.g. concomitant treatment, concomitant disease(s), is inconclusive. The relationship in time is reasonable. Therefore, the causal relationship cannot be excluded.
- Probable – An adverse event that might be due to the use of the test article. The relationship in time is suggestive (e.g. confirmed by de-challenge). An alternative explanation is less likely, e.g. concomitant treatment or concomitant disease(s).
- Very Likely – An adverse event that is listed as a possible adverse effect (device) or adverse reaction (drug) and cannot be reasonably explained by an alternative explanation, e.g. concomitant treatment or concomitant disease(s). The relationship in time is very suggestive, e.g. it is confirmed by de-challenge and re-challenge.

Severity Assessment – A qualitative assessment of the degree of intensity of an adverse event as determined by the investigator or reported to him/her by the subject. The assessment of severity is made irrespective of test article relationship or seriousness of the event and should be evaluated according to the following scale:

- Mild – Event is noticeable to the subject, but is easily tolerated and does not interfere with the subject's daily activities.
- Moderate – Event is bothersome, possibly requiring additional therapy, and may interfere with the subject's daily activities.
- Severe – Event is intolerable, necessitates additional therapy or alteration of therapy and interferes with the subject's daily activities.

8.4 METHODS FOR ASSESSING, RECORDING AND ANALYZING SAFETY

The recording and documenting of adverse events (ocular and non-ocular) begin when the subjects are exposed to the test article or study treatment. Adverse events reported before the use of test article or start of study treatment should be recorded as medical history. Untoward medical events reported after the subject's exit from the study will be recorded as adverse events at the discretion of the Investigator.

All adverse events observed by the Investigator; reported by the subject spontaneously; or in response to direct questioning; will be recorded in the source document. Such documentation will include a description of the adverse event, time of onset, duration of event, treatment regimen instituted, any referral to another health care provider (if needed), any new concomitant medications, outcome, ocular damage (if any), and likely etiology. Best Corrected Visual Acuity (BCVA) should be recorded prior to the report of an adverse event (as part of the baseline evaluation), upon report of the subject's report of the adverse event, and after the adverse event has resolved. All adverse events will be followed in accordance with licensing requirements.

All adverse events will be documented in the appropriate section of the subject's Case Report Form (CRF).

In conjunction with the medical monitor, the Investigator will evaluate adverse events to ensure the events are categorized correctly. Elements of categorization will include:

Seriousness (see definition in Section 8.3)

Expectedness – i.e. if the event was unexpected or unanticipated in that it was not previously identified in nature, severity, or degree of incidence (see definition in Section 8.3)

Causality or Relatedness – i.e. the relationship between the test article and the adverse event (not related; doubtful; possible; probable; very likely - see definition in Section 8.3)

Adverse Event Intensity or Classification – Adverse event intensity is used to assess the degree of intensity of the adverse event (mild, moderate, severe for all events). In addition Adverse Event Classification is used to assess the severity of ocular adverse events (AE not requiring treatment, non-significant or significant see definition in Section 7.4).

Outcome – Fatal, not resolved, resolved, resolved with sequelae, resolving and unknown.

Actions Taken – None, temporarily discontinued, permanently discontinued, other action taken

Upon finding an adverse event, the Principal Investigator will document the condition on the follow-up visit worksheet source document and in the CRF's using photos or drawings (where appropriate) that detail size, location, and depth. He will also complete the Adverse Event Classification (AEC) Discovery form / eCRF. In addition, if an infiltrate(s) is present, he will complete the Corneal Infiltrate Assessment Form / eCRF. Where necessary, a culture of the corneal lesion will be collected to determine if the infection is microbial in nature. If cultures are collected, a source document note should be completed specifying the date of culture collection and laboratory utilized. An eCRF documenting this should be completed in a comment or unscheduled visit.

Complete description of all adverse events must be available in the source documents. All Adverse Events including local and systemic reactions not meeting the criteria for "serious adverse events" should be captured on the appropriate case report form or electronic data system. Information to be recorded, based on above assessment criteria, includes date site notified, event description, date and time of onset, investigator assessment of severity, relationship to Study Agent(s)/Intervention(s), and time of resolution/stabilization of the event. All adverse events occurring while on study must be documented appropriately regardless of relationship. Define a timeframe for CRF completion and entry of the adverse event information into the database, as applicable.

Any medical condition that is present at the time that the patient is screened should be considered as baseline and not recorded as an AE. However, if the condition deteriorates at any time during the study it should be recorded and reported as an AE.

Changes in the severity of an AE should be documented to allow an assessment of the duration of the event at each level of intensity to be performed. Adverse events characterized as intermittent require documentation of the onset and duration of each episode. Changes in the assessment of relationship to the Study Agent(s)/Interventions should also be clearly documented.

The investigator will notify the Sponsor of an adverse event by e-mail, facsimile, or telephone as soon as possible and no later than 24 hours from discovery for a serious / significant adverse event, and 2 days from discovery for a non-significant adverse event. In addition, a written report will be submitted by the

Principal Investigator to the IRB/IEC according to their requirements (Section 1212.3). Such a report should comment whether or not the adverse event was considered to be related to the test article.

8.5 ADVERSE EVENTS FOLLOW-UP

It is the Investigator's responsibility to maintain documentation of each reported adverse event. All adverse events will be followed in accordance with applicable licensing requirements. Such documentation will include the following:

- Adverse Event (Diagnosis not symptom)
- Detailed drawings or photographs, when appropriate
- Date and time of onset
- Date and time of resolution
- Adverse event intensity and classification, as applicable
- Treatment regimen instituted, including concomitant medications prescribed, in accordance with applicable licensing requirements
- Any referral to another health care provider if needed
- Outcome, ocular damage (if any)
- Likely etiology.
- Best corrected visual acuity at the discovery of the event and upon conclusion of the event

In addition, if an infiltrate(s) is present, the Investigator will complete the Corneal Infiltrate Assessment Form / eCRF.

Photographs or video recordings may be collected at the Investigator's discretion for purposes of documenting adverse event findings.

Visual acuity (best corrected) should be recorded prior to the report of an adverse event (as part of the Baseline Evaluation), upon the subject's report of the adverse event, and after the adverse event has resolved.

Subjects who present with an adverse event should be followed by the Investigator, within licensure, until all signs and symptoms have returned to pre-treatment status, stabilized, or been satisfactorily resolved. If further treatment (i.e. beyond licensure) is required, the patient will be referred to the appropriate health care provider. The Investigator should use his/her clinical judgment as to whether or not a subject (eye) reporting with an adverse event should continue in the study. If a subject is discontinued from the study, it will be the responsibility of the Investigator to record the reason for discontinuation. The investigator will also complete the Adverse Event Classification (AEC) Outcome form / eCRF. Any subjects with ongoing adverse events related to the test article as of the final study visit date should be followed to resolution of the adverse event or until referral to an appropriate health care provider, as recommended by the Investigator.

9.1 STATISTICAL METHODS TO BE EMPLOYED

This method is a general outline of the statistical methods that will be implemented in this clinical trial. For more details, refer to the stand-alone Statistical Analysis Plan (SAP) of this clinical study.

Cohort Populations:

CR-5816 Protocol v7.0, Amendment 6.0

- The analysis population will include subjects who have successfully completed all study visits without a protocol deviation documented as impacting the unbiased assessment of the hypotheses
- The safety population will include all randomized subjects who have successfully tried at least one study lens

Statistical Considerations:

Statistical programming and analyses will be performed using SAS (SAS Institute, Cary, NC) version 9.4 or higher. Throughout the analysis of the data, the results of each eye will be used when available for summarization and statistical analysis.

Summary tables (Descriptive statistics and/or frequency tables) will be reported at baseline and each post fit time period for all efficacy and safety variables for each subject/eye by study lens type (as appropriate) for both the completed and discontinued subjects. Continuous variables will be summarized with descriptive statistics (number non-missing (n), mean, standard deviation (SD), median, minimum and maximum). Frequency count and percentage of subjects or eyes within each category will be provided for categorical data. Unscheduled visits will be summarized separately if applicable.

Summaries will be presented by study article type (Test OR Control). The denominator for percentages of counts will be the same for each visit on the summary tables and will equal the final number of subjects or eyes in the group under consideration. Unscheduled visits will be summarized separately and excluded from the analysis.

Analysis Population Sets:

Primary and secondary analyses will be performed on all randomized subjects who completed the study and did not substantially deviate from the protocol as determined by the trial cohort review committee prior to database hard lock (Per-protocol population). Justification for excluding subjects with protocol deviations will be documented in a memo to file.

Primary Analysis:

CLUE Comfort scores will be analyzed using a Bayesian hierarchical model to compare between test and control lenses. The regression model will include baseline values, lens type, lens wearing sequence, lens wearing period. Subject will be included in the regression model as random effects factors. Non-informative prior distributions will be used for coefficients in the models as well as for the error terms. The Metropolis sampler algorithm as implemented in the SAS MCMC Procedure will be used to carry out parameter estimation. Results will be reported as regression coefficient mean estimates with credible intervals over all time points and within each timepoint. The null and alternative hypotheses for non-inferiority are as follows: $H_0: \mu_t - \mu_c \leq -5$, $H_a: \mu_t - \mu_c > -5$ where μ_t and μ_c are the comfort score mean of Test and Control lenses respectively. Non-inferiority will be declared if the lower bound of the credible interval of the mean difference between Test and Control is greater than -5. If non-inferiority is demonstrated, superiority will then be tested and can be used for any claim substantiation. Superiority will be concluded if the lower credible interval limit is above zero (0).

Secondary Analysis

Comfort at the end of the day [REDACTED] will be analyzed independently using Bayesian Multinomial models for ordinal data. Lens type, lens wearing sequence, lens wearing period will be included in each regression model as fixed effects; and subject as random factors. Independent vague prior distributions will be used for the coefficients in the models as well as for the error terms. The Metropolis sampler algorithm as implemented in the SAS MCMC Procedure will be used to carry out parameter estimation. Results will be reported as regression coefficient mean estimates and odds ratios with credible intervals. For each item, the null and alternative hypotheses for non-inferiority are as follows: $H_0: OR \leq 0.67$ $H_a: OR > 0.67$; where OR represents the odds ratio of having positive experience wearing the Test lens compared to the Control lens. For each endpoint, non-inferiority will be declared if the lower bound of the credible interval of OR is greater than 0.67. If non-inferiority is demonstrated, superiority will then be tested and can be used for any claim substantiation. Superiority will be concluded if the lower credible interval limit is above one (1). For further details and analyses of other endpoints please see the statistical analysis plan.

A post-hoc statistical analysis plan may be considered if necessary but only at the discretion of the Study Responsible Clinician and Study Biostatistician.

9.2 NUMBER OF SUBJECTS BY SITE AND JUSTIFICATION FOR SAMPLE SIZE

This is a group sequential adaptive design where enrollment of subjects will be conducted in two phases. The sample size calculation is based on the primary endpoint CLUE comfort using historical data from CR-5751, a double masked randomized parallel study.

Approximately 135 subjects will be initially enrolled and approximately 80 are targeted to complete the study. An interim analysis will be performed after all subjects have completed both lens types. This interim analysis will be used to estimate if more subjects are needed based on the predictive probability. If additional subjects are needed, up to a maximum of 250 subjects will be enrolled for this study. For details on the sample size calculation, please see CR-5816 Statistical Analysis Plan document v2.0.

9.3 LEVEL OF STATISTICAL SIGNIFICANCE

Unless otherwise specified, all planned analysis for this study will be conducted with a two-sided type 1 error rate of 5%. See CR-5816 Statistical Analysis Plan document for more details on the operating characteristics of this adaptive trial.

9.4 CRITERIA FOR STUDY TERMINATION

This is a group sequential adaptive trial with one stopping rule for superiority. The study will be conducted by initially enrolling approximately 135 subjects with a target completion of 80. The data from these participants has been analyzed to see if superiority can be concluded. After review of the predictive probability (PP) of trial success, it has been determined that an additional 50 participants are required to complete, so that more subjects up to a maximum of 250 subjects in total will be enrolled.

The occurrence of one or more Serious Unanticipated Adverse Device Effect (USADE), or any SAE where the relationship to study agent cannot be ruled out, may result in stopping further dispensing of investigational product. In the event of a USADE or SAE, the Sponsor may unmask the treatment regimen for the subject(s) and may discuss this with the Investigator before any further subjects are enrolled.

The sponsor may determine when a study will be stopped. The principal investigator always has the discretion to initiate stopping the study based on patient safety or if information indicates the study's results may be compromised.

9.5 PROCEDURE FOR ACCOUNTING FOR MISSING, UNUSED, AND SPURIOUS DATA

Missing or spurious values will not be imputed. The count of missing values will be included in the summary tables and listings.

When data are missing, the nature by which it is missing should be carefully understood. It should be carefully determined if, given the observed data, the missingness mechanism does not depend on the unobserved data. If missing data are dependent upon the reason it is missing, the analysis can be compromised and should be carefully considered.

If it is reasonable to consider that data are missing at random then analytical procedures can adequately provide valid inference in the presence of missing data. Although valid, the analysis will be less efficient than planned and the sample should be carefully considered in light of the study sample size assumptions.

9.6 PROCEDURE FOR REPORTING DEVIATIONS FROM STATISTICAL PLAN

The analysis will be conducted according to section 9.1. There are no known reasons for which it is planned to deviate from these analysis methods. If for any reason a change is made, the change will be documented in the study report along with a justification for the change.

9.7 EVALUABLE SUBJECTS

Subjects will be allocated to one of the three mutually exclusive groups:

1. Enrolled, Not Randomized: Subjects were considered to be Enrolled Not Randomized if they are (i) enrolled to the study (i.e. provided informed consent) but failed to satisfy the eligibility criteria (i.e. inclusion/exclusion criteria) or (ii) are not randomized to treatment for any reason.
2. Randomized, Not Completed: Subject are considered to have not completed the study if they (i) were discontinued because of one the reasons described in section 5.3 or(ii) have successfully completed all required visits with a protocol deviation that the study responsible clinician documents as impacting the assessment of the hypotheses.
3. Randomized, Completed: Subject are considered to have completed the study if (i) they are eligible, (ii) not discontinued (iii) have successfully completed all required visits without a protocol deviation that the study responsible clinician documents as impacting the assessment of the hypotheses.

The monitor will provide a list of the cohort and the non-cohort populations that will be given to the department Biostatistician, the Investigator, and the Clinical Database Administrator.

10.1 ELECTRONIC CASE REPORT FORMS/DATA COLLECTION

The data for this study will be captured on electronic case report forms (eCRFs) using an EDC system (BioClinica), when possible. Designated study site personnel will enter study data into the electronic CRFs (eCRFs) using the EDC system (BioClinica). Data collected on equipment that is not possible to be captured in EDC will be formatted to the specification of the JIVCI database manager and sent to JIVCI for analysis.

Data generated from post hoc measurements (e.g. Compositional characteristics of contact lens lipid uptake, CR-5816 Protocol v7.0, Amendment 6.0

Confidential

Measured tear film protective capability, Measured contact lens surface dehydration rate) will be collected on specific Microsoft Office Excel format worksheets at the clinical site and at the completion of the analysis transferred to Vistakon biostatistician for data analysis in such format.

The clinical data will be recorded on dedicated electronic case report forms (eCRFs) specifically designed to match the testing routine for each visit. Once completed, the eCRFs will be reviewed for accuracy and completeness and signed by the investigator. Unless otherwise stated, the eCRFs will be considered the source document. The sponsor or sponsor's representatives will be authorized to gain access to the source documentation for the purposes of monitoring and auditing the study.

BioClinica is compliant with all relevant aspects of ICH/Good Clinical Practices, and 21 CFR Part 11 (Electronic Records & Electronic Signatures) regulations. In addition, the Sponsor and BioClinica are Safe Harbor Certified.

Edit checks, electronic queries, and audit trails are built into the system to ensure accurate and complete data collection. Data will be transmitted from the investigational site to a secure central database as forms are completed or updated, ensuring information accuracy, security, and confidentiality. After the final database lock, the sponsor will provide the Investigator with a copy of the full data collected at the site, including the full audit trail on electronic media, for all of the study data in a format which facilitates easy manipulation and analysis. The exact format and process of sending these data will be mutually agreed.

The content and structure of the CRFs are compliant with ISO14155:2011 [3].

10.2 SOURCE DOCUMENTATION

At a minimum, source documentation should be available for the following to confirm data collected in the CRF: subject global identification, eligibility, and study identification; study discussion, provision of and date of informed consent; visit dates; results of safety and efficacy parameters as required by the protocol; a record of all adverse events; follow-up of adverse events; concomitant medication; investigational product receipt / dispensing / return records; study investigational product administration information; date of study completion; reason for early discontinuation of investigational product or withdrawal from the study, if applicable.

It is recommended that the author of an entry in the source documents be identifiable. Adverse event notes should be reviewed and initialed by the Investigator.

At a minimum, the type and level of detail of source data available for a study subject should be consistent with that commonly recorded at the site as a basis for standard medical care. Specific details required as source data for the study will be reviewed with the investigator before the study and will be described in the monitoring guidelines (or other equivalent documents).

10.3 ACCESS TO SOURCE DATA/DOCUMENTS

The Investigator(s) / Institution(s) will permit trial-related monitoring, audits, IRB/IEC review and regulatory inspection(s) by providing direct access to source data / documents. Should the clinical site be contacted for an audit by an IRB/IEC or regulatory authority, JJVCI should be contacted and notified in writing within 24 hours.

10.4 CONFIDENTIALITY OF INFORMATION

Information concerning the investigational product and patent application processes, scientific data or other pertinent information is confidential and remains the property of JJVCI. The Investigator may use this information for the purposes of the study only. It is understood by the Investigator that JJVCI will use information developed in this clinical study in connection with the development of the investigational product and therefore may disclose it as required to other clinical investigators and to regulatory agencies. In order to allow the use of the information derived from this clinical study, the Investigator understands that he/she has an obligation to provide complete test results and all data developed during this study to the Sponsor.

The Investigator may not submit for publication or presentation the results of this study without first receiving written authorization from JJVCI. JJVCI agrees that, before it publishes any results of the study, it shall provide the Investigator with at least 30 days for review of the pre-publication manuscript prior to the submission of the manuscript to the publisher.

11.1 DATA QUALITY ASSURANCE

Steps to be taken to ensure the accuracy and reliability of data include the selection of qualified investigators and appropriate study sites and review of protocol procedures with the principal investigator. The principle investigator, in turn, must ensure that all sub-investigators and study staff are familiar with the protocol and all study-specific procedures and have appropriate knowledge of the study article.

Guidelines for case report form completion will be provided and reviewed with study personnel before the start of the study. The sponsor, Johnson & Johnson Vision Care, Inc. will review case report forms for accuracy and completeness during monitoring visits and after transmission to data management. Any data discrepancies will be resolved with the investigator or designee, as appropriate.

Quality Assurance representatives from Johnson & Johnson Vision Care, Inc. may visit study sites to review data produced during the study and to access compliance with applicable regulations pertaining to the conduct of clinical trials. The study sites will provide direct access to study-related source data/documents and reports for the purpose of monitoring and auditing by Johnson & Johnson Vision Care, Inc. and for inspection by local and regulatory authorities.

12.1 STUDY-SPECIFIC DESIGN CONSIDERATIONS

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

12.2 INVESTIGATOR RESPONSIBILITY

The Investigator is responsible for ensuring that the clinical study is performed in accordance with the protocol, Section 4 of the ICH E6 guidelines on Good Clinical Practice (GCP), and applicable regulatory requirements. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the [REDACTED] on of human subjects. Compliance with this

standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles of the Declaration of Helsinki 59th WMA General Assembly 2008 and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with Section 8 of the ICH E6 guidelines on Good Clinical Practice (GCP), and applicable regulatory requirements.

12.3 INDEPENDENT ETHICS COMMITTEE OR INSTITUTIONAL REVIEW BOARD (IEC/IRB)

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

- final protocol and, if applicable, amendments
- Sponsor-approved informed consent form (and any other written materials to be provided to the subjects)
- Investigator's Brochure (or equivalent information) and amendments
- Sponsor-approved subject recruitment materials
- information on compensation for study-related injuries or payment to subjects for participation in the study, if applicable
- Investigator's curriculum vitae, clinical licenses, or equivalent information (unless not required, as documented by IEC/IRB)
- information regarding funding, name of the Sponsor, institutional affiliations, other potential conflicts of interest, and incentives for subjects
- any other documents that the IEC/IRB requests to fulfill its obligation

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

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

- protocol amendments
- revision(s) to informed consent form and any other written materials to be provided to subjects
- if applicable, new or revised subject recruiting materials approved by the Sponsor
- revisions to compensation for study-related injuries or payment to subjects for participation in the study, if applicable
- Investigator's Brochure amendments or new edition(s)
- summaries of the status of the study (at least annually or at intervals stipulated in guidelines of the IEC/IRB)
- reports of adverse events that are serious, unanticipated, and associated with the investigational product, according to the IRB's requirements
- new information that may adversely affect the safety of the subjects or the conduct of the study

- major protocol deviations as required by the IEC/IRB
- report of deaths of subjects under the Investigator's care
- notification if a new investigator is responsible for the study at the site
- any other requirements of the IEC/IRB

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

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

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

12.4 INFORMED CONSENT

Each subject must give written consent according to local requirements after the nature of the study has been fully explained. The consent form must be signed before performance of any study-related activity. The consent form that is used must be approved by both the Sponsor and by the reviewing IEC/IRB. The informed consent should be in accordance with principles that originated in the Declaration of Helsinki, current ICH and GCP guidelines, applicable regulatory requirements, and sponsor policy.

Before entry into the study, the Investigator or an authorized member of the investigational staff must explain to potential subjects the aims, methods, reasonably anticipated benefits, and potential hazards of the study, and any discomfort it may entail. Subjects will be informed that their participation is voluntary and that they may withdraw consent to participate at any time. They will be informed that choosing not to participate will not affect the care they will receive. Finally, they will be told that the Investigator will maintain a subject identification register for the purposes of long-term follow-up if needed and that their records may be accessed by health authorities and authorized sponsor staff without violating the confidentiality of the subject, to the extent permitted by the applicable law(s) or regulations. By signing the informed consent form the subject is authorizing such access, and agrees to be contacted after study completion, by health authorities and authorized sponsor staff, for the purpose of obtaining consent for additional safety evaluations if needed.

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

In the event of personnel changes related to principal or lead investigator /, the informed consent will be modified to update the Investigator's name, address, phone number and 24-hour emergency number.

12.5 PRIVACY OF PERSONAL DATA

The collection, processing and disclosure of personal data and medical information related to the Study Subject, and personal data related to Principal Investigator and any investigational staff (e.g., name, clinic address and phone number, curriculum vitae) is subject to compliance with the Data Protection Act of 1998 and other applicable personal data protection and security laws and regulations. Appropriate measures will be employed to safeguard these data, to maintain the confidentiality of the person's related health and medical information, to properly inform the concerned persons about the collection and processing of their personal data, to grant them reasonable access to their personal data and to prevent access by unauthorized persons.

All information obtained during the course of the investigation will be regarded as confidential. All personal data gathered in this trial will be treated in strictest confidence by investigators, monitors, Sponsors personnel and independent ethics committee. No data will be disclosed to any third party without the express permission of the subject concerned, with the exception of sponsor personnel (monitor, auditor), independent ethics committee and regulatory organizations in the context of their investigation related activities that, as part of the investigation will have access to the CRFs and source documents.

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

These data must be collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data privacy protection laws and regulations.

The Sponsor ensures that the personal data will be:

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

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

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

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

13.1 DATA HANDLING AND RECORD KEEPING

In compliance with the ICH/GCP guidelines, the Investigator / Institution will maintain all CRFs and all source documents that support the data collected from each subject, as well as all study documents as specified in ICH/GCP Section 8, Essential Documents for the Conduct of a Clinical Trial, and all study documents as specified by the applicable regulatory requirement(s), for a duration of 25 years. The Investigator / Institution will take measures to prevent accidental or premature destruction of these documents.

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

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

If it becomes necessary for the Sponsor or the appropriate regulatory authority to review any documentation relating to this study, the Investigator must permit access to such reports.

If the Investigator has a question regarding retention of study records, he should contact JJVCI Research and Development.

14.1 FINANCIAL CONSIDERATIONS

Remuneration for study services and expenses will be set forth in detail in the Investigator's Research Agreement. The Research Agreement will be signed by the Principal Investigator and a Johnson & Johnson Vision Care management representative prior to study initiation.

Case Report Forms will be completed in real time according to the study procedures specified in the study protocol. Case Report Forms should be completed and reviewed and signed as applicable by the Investigator within 3 days of visit completion. Data queries must be addressed with complete responses within 3 days of generation. Johnson & Johnson Vision Care reserves the right to withhold remuneration until these activities are addressed.

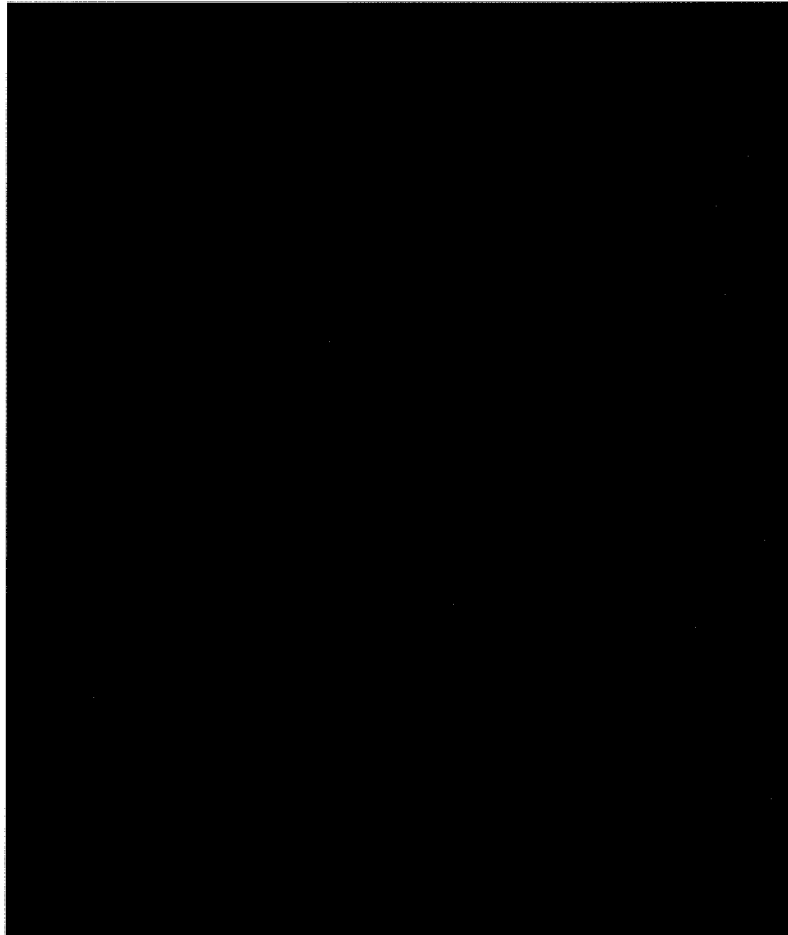
Johnson & Johnson Vision Care reserves the right to withhold remuneration for costs associated with protocol violations such as:

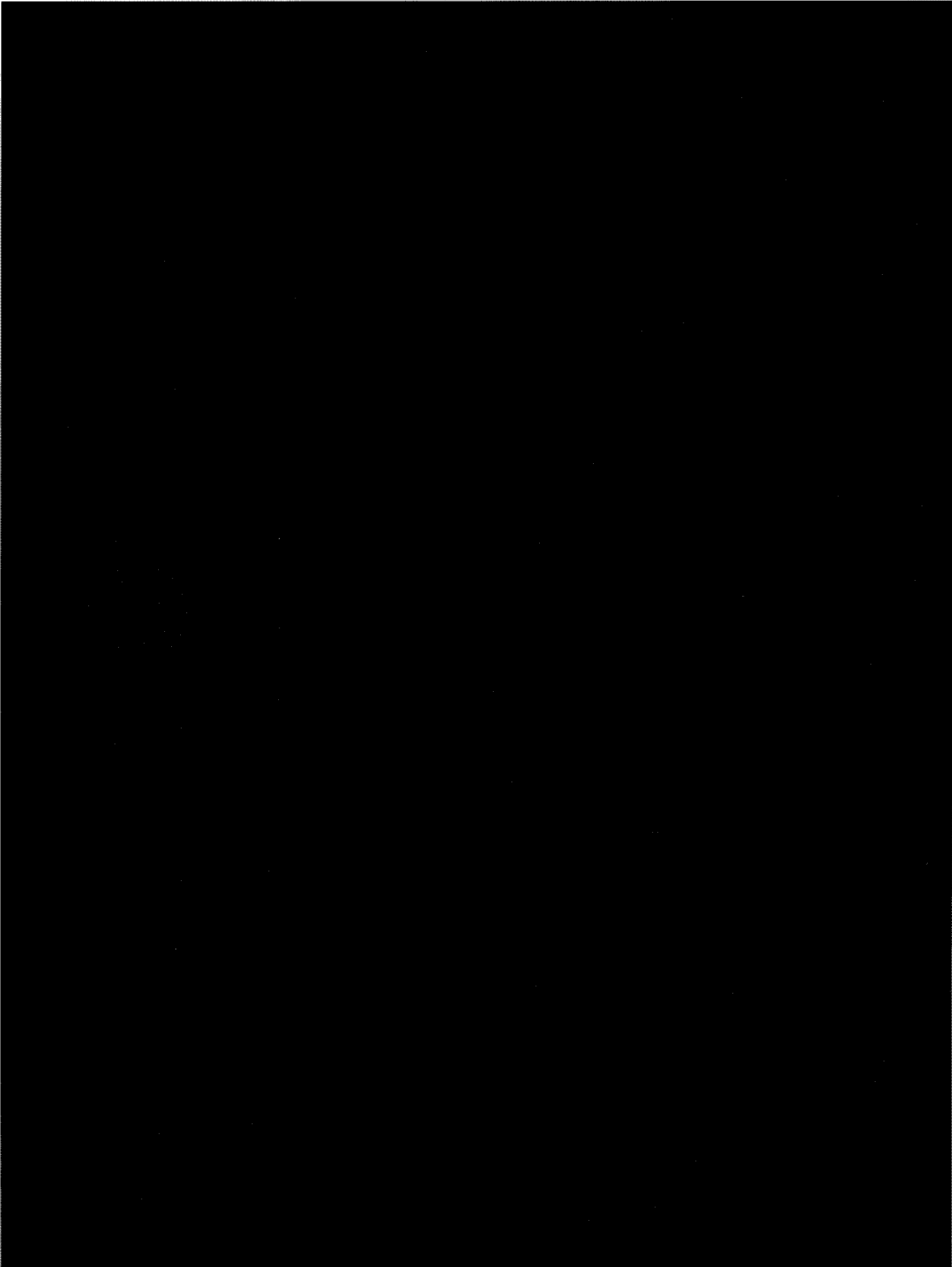
- Continuing an ineligible subject in the study
- Scheduling a study visit outside the subject's acceptable visit range

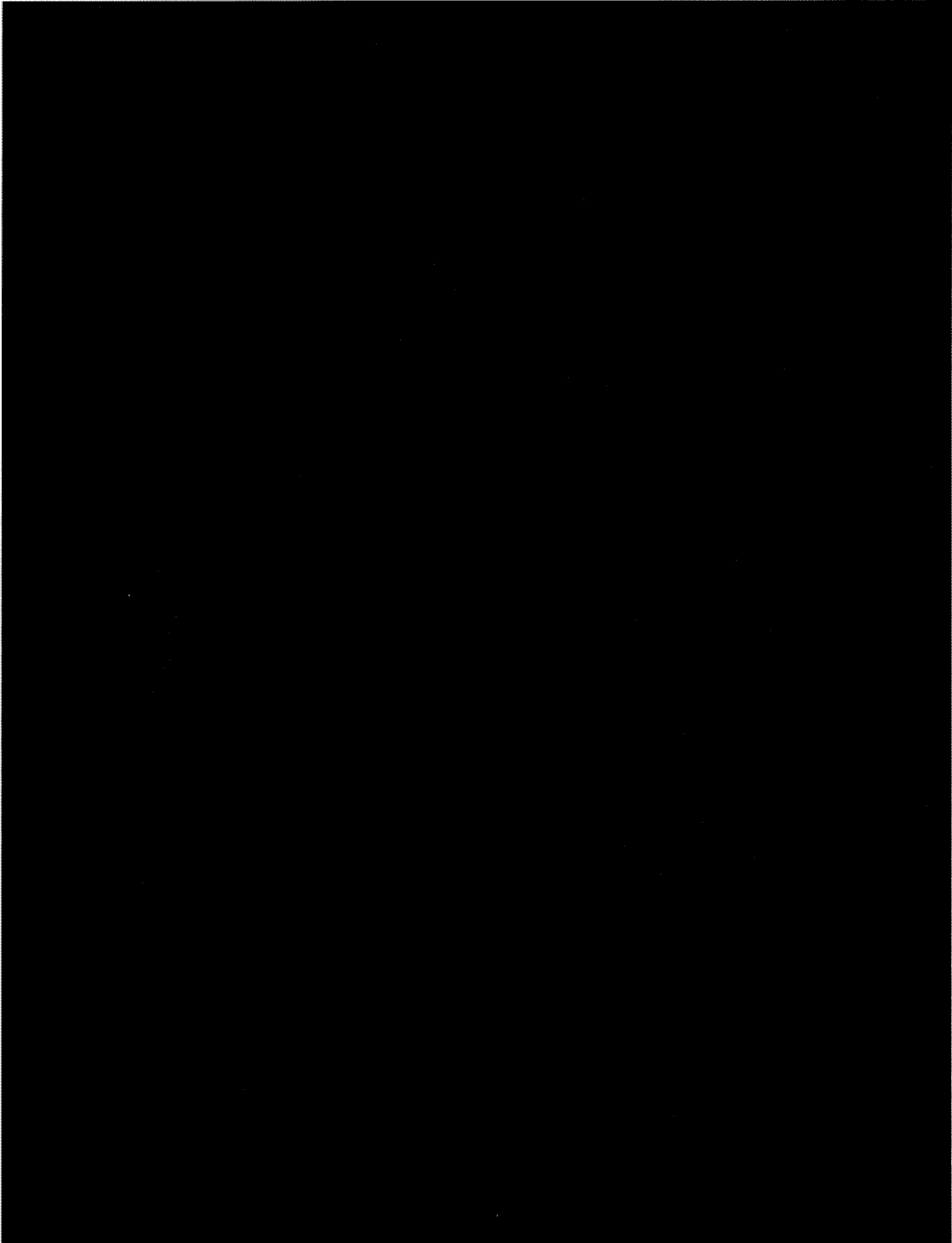
15.1 PUBLICATION

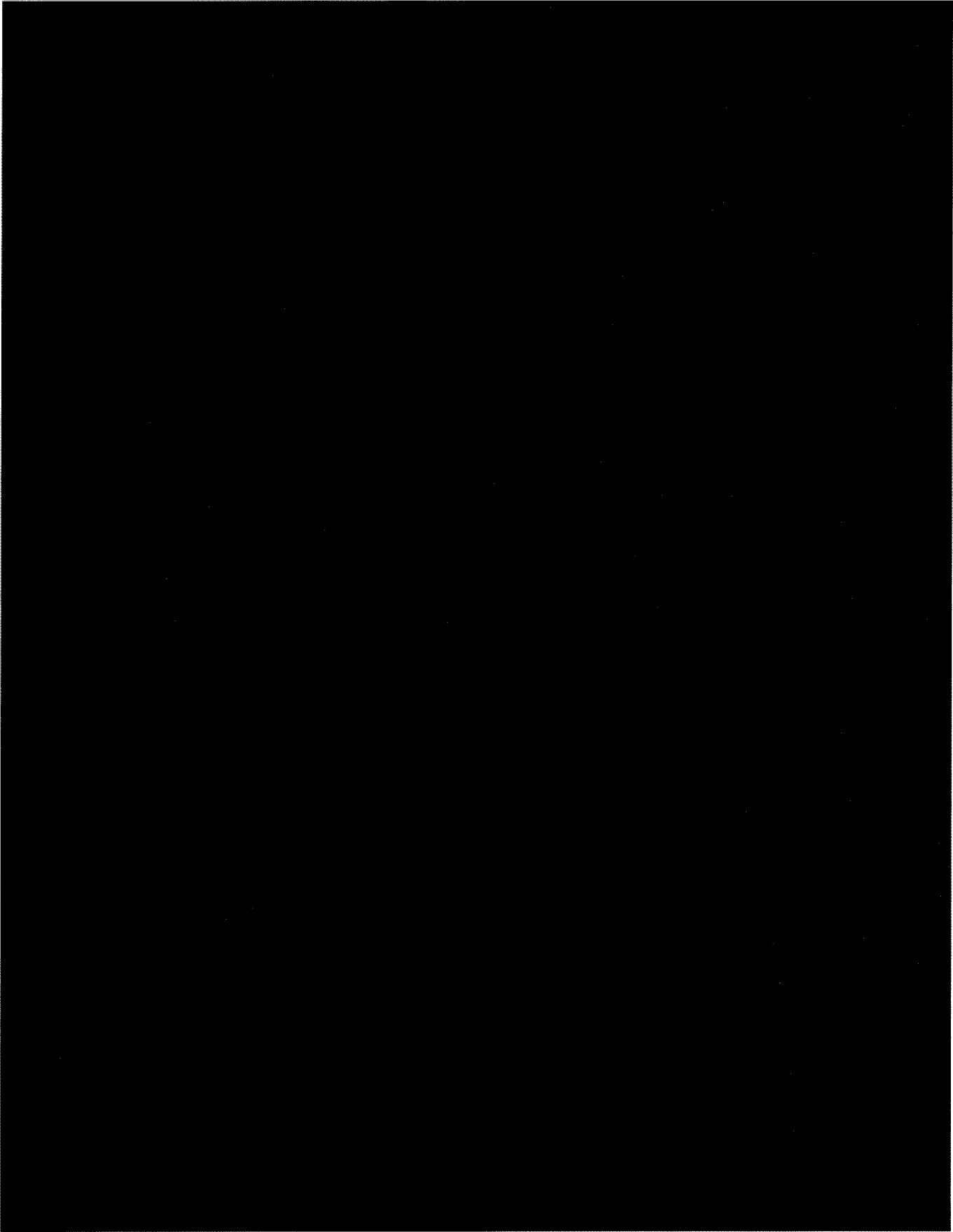
This study will be registered on ClinicalTrials.gov based on the following: this study is a comparison of two marketed products with regards to a health related outcome.

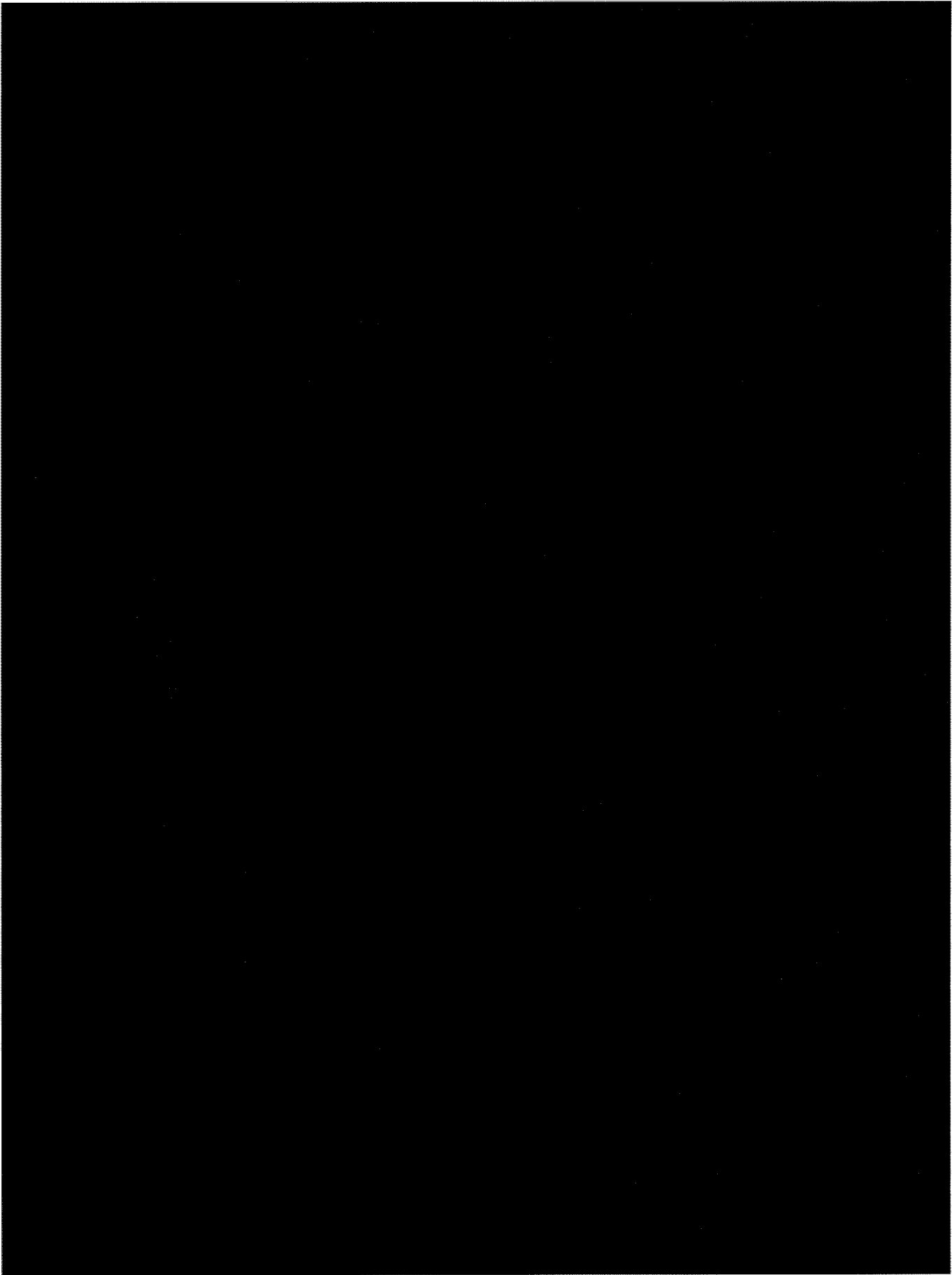
16.1 PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

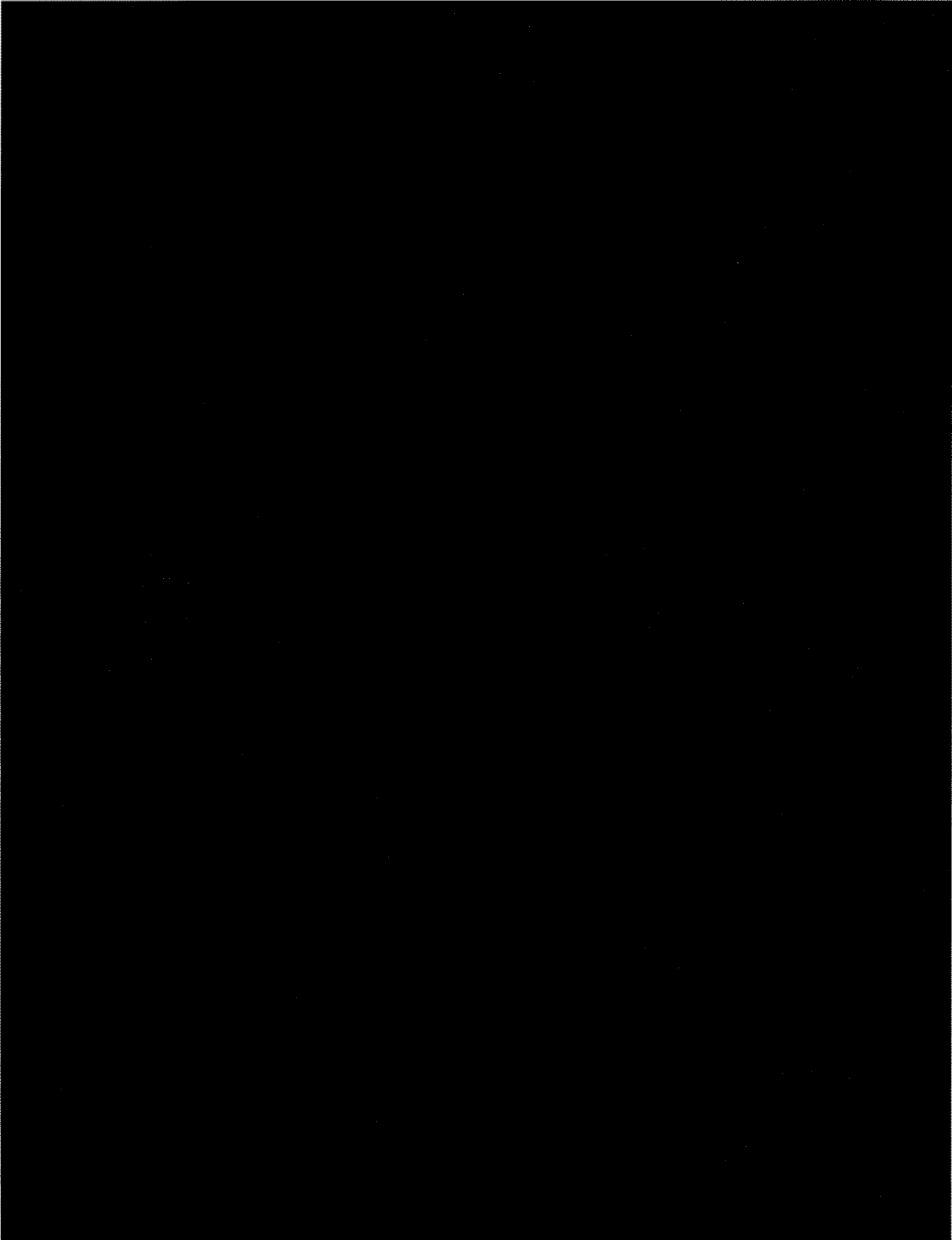


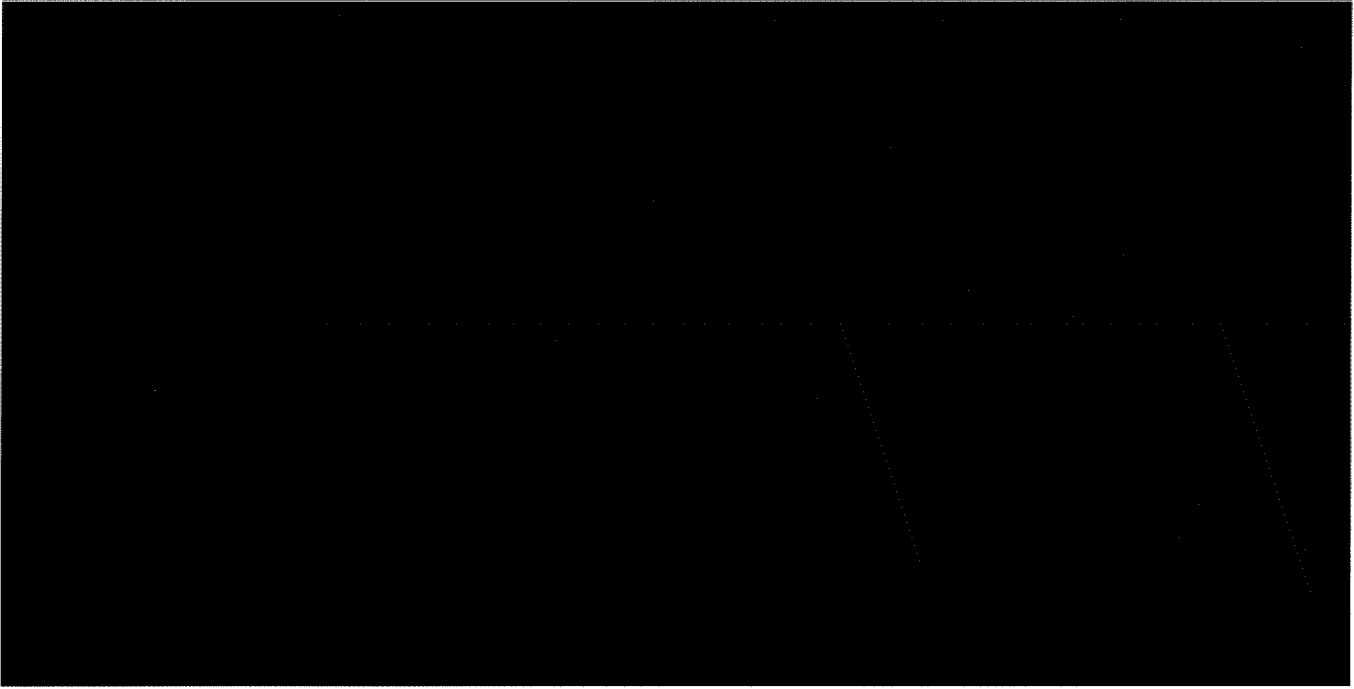


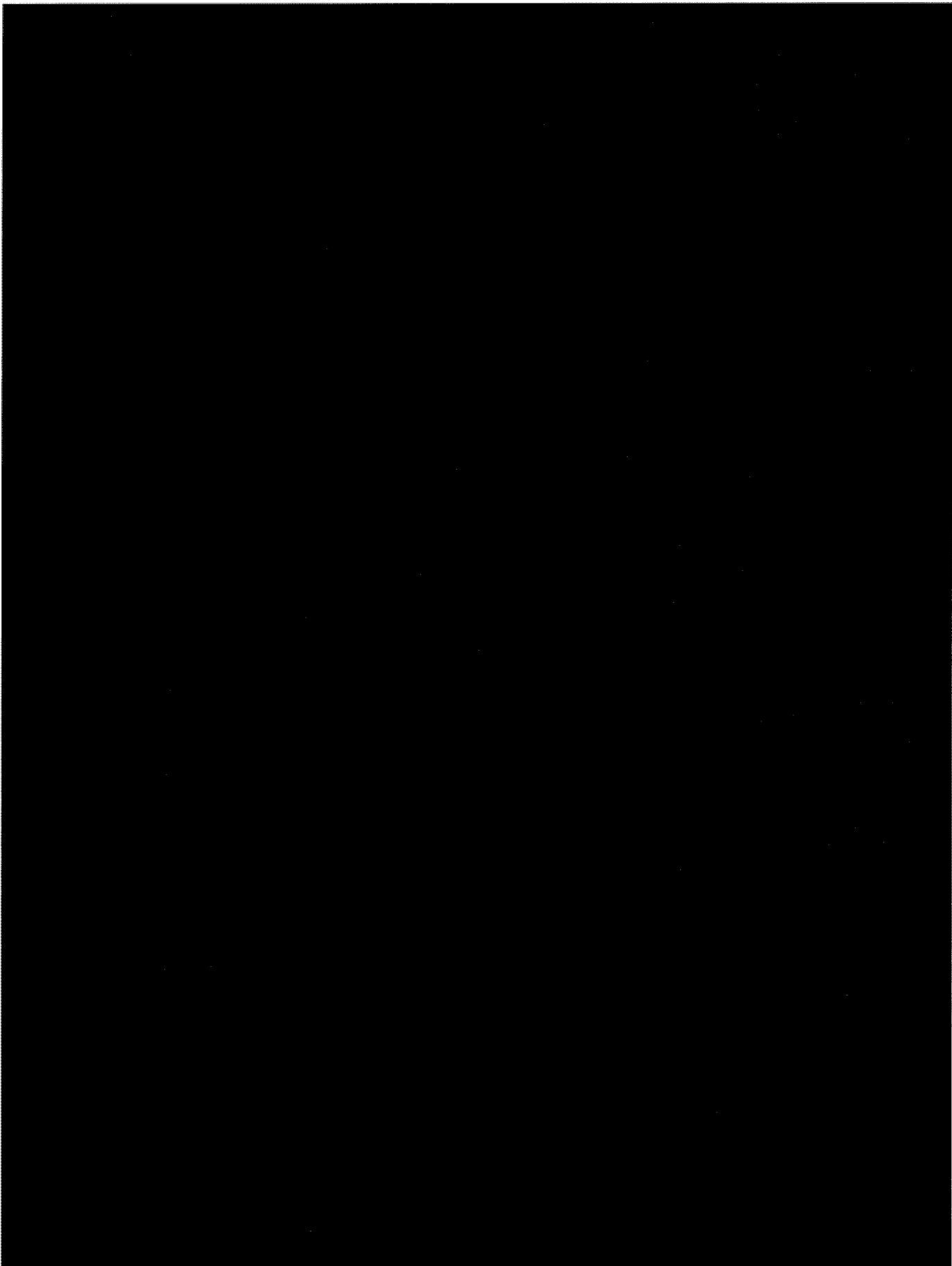


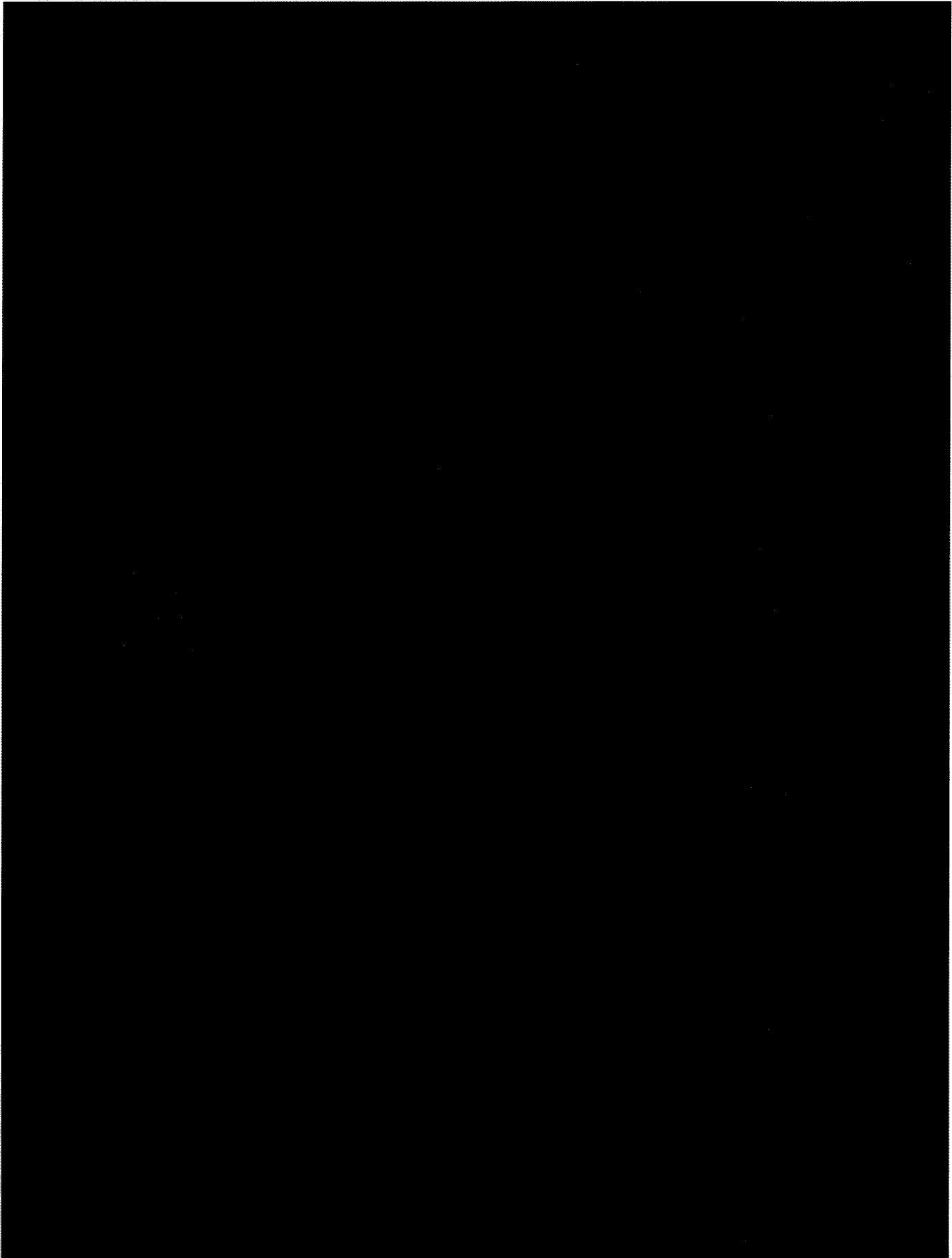


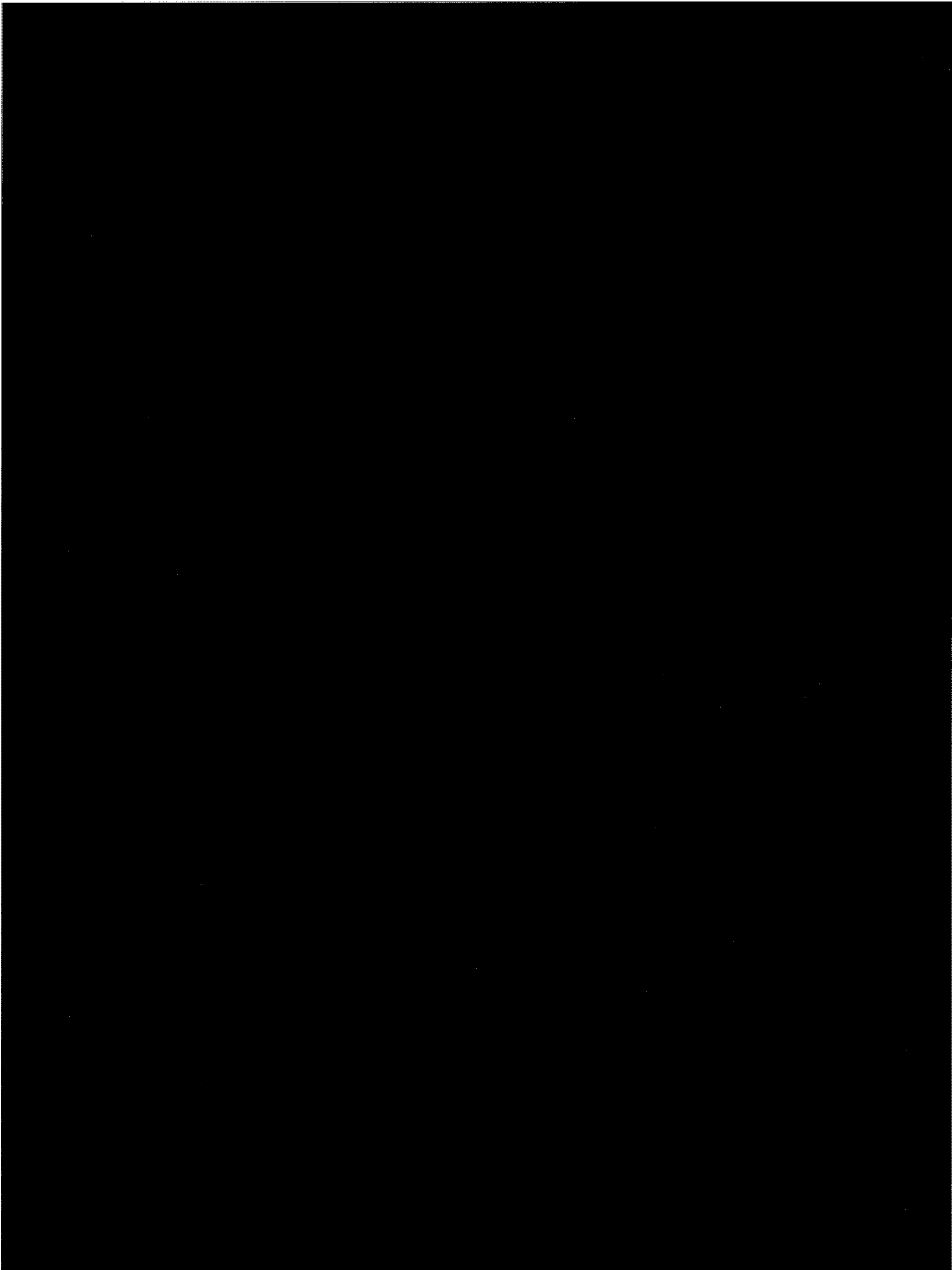


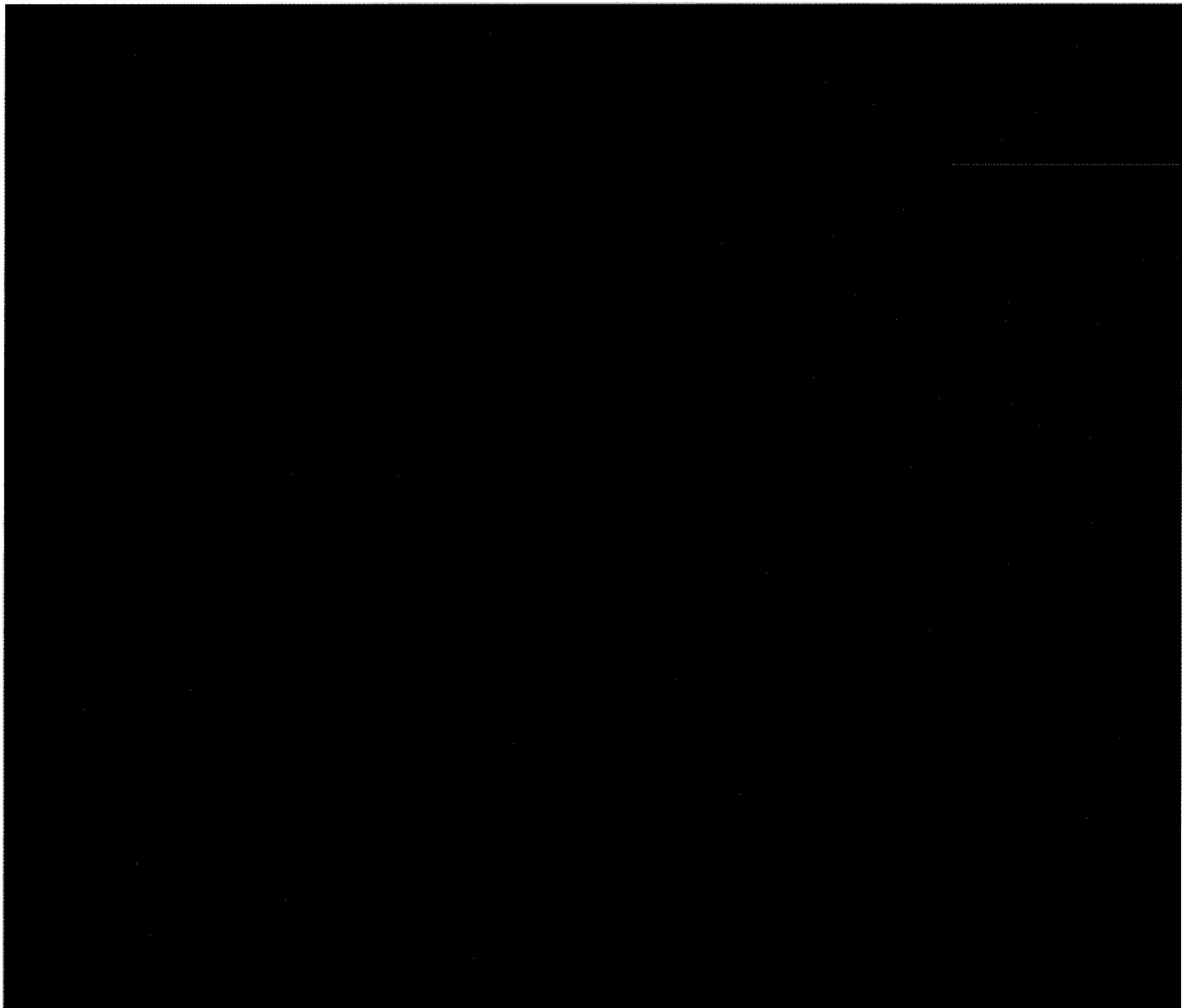


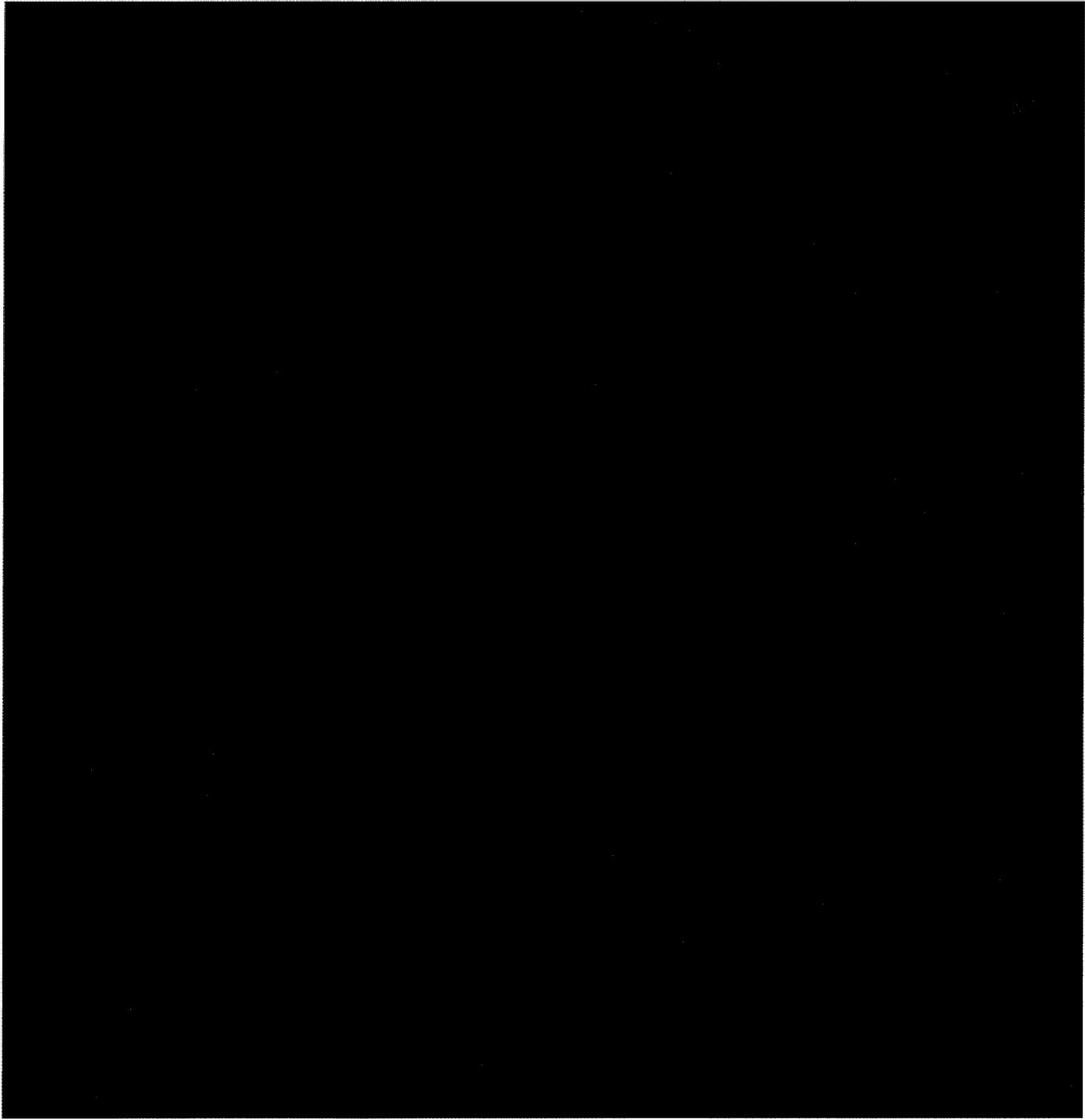


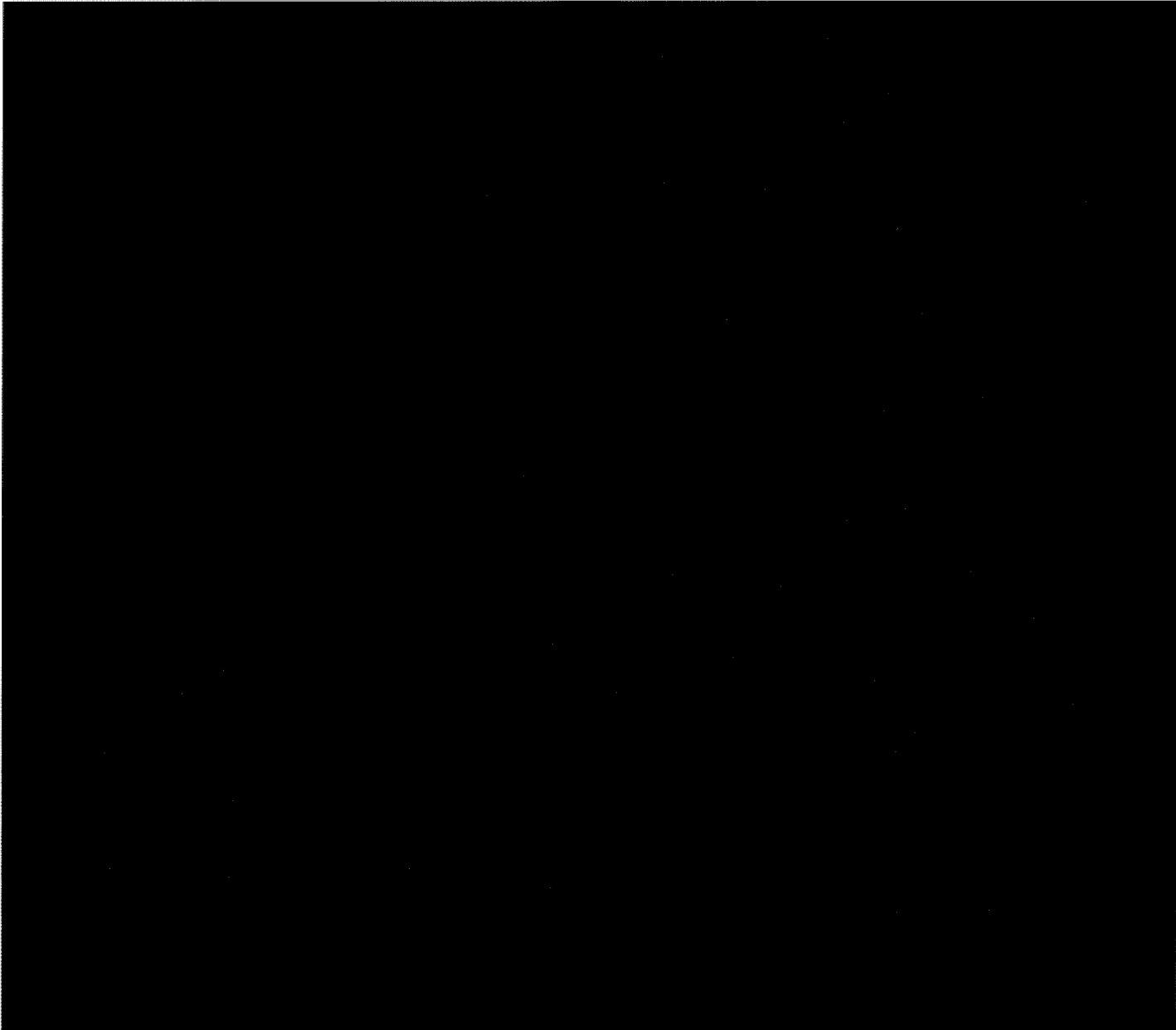


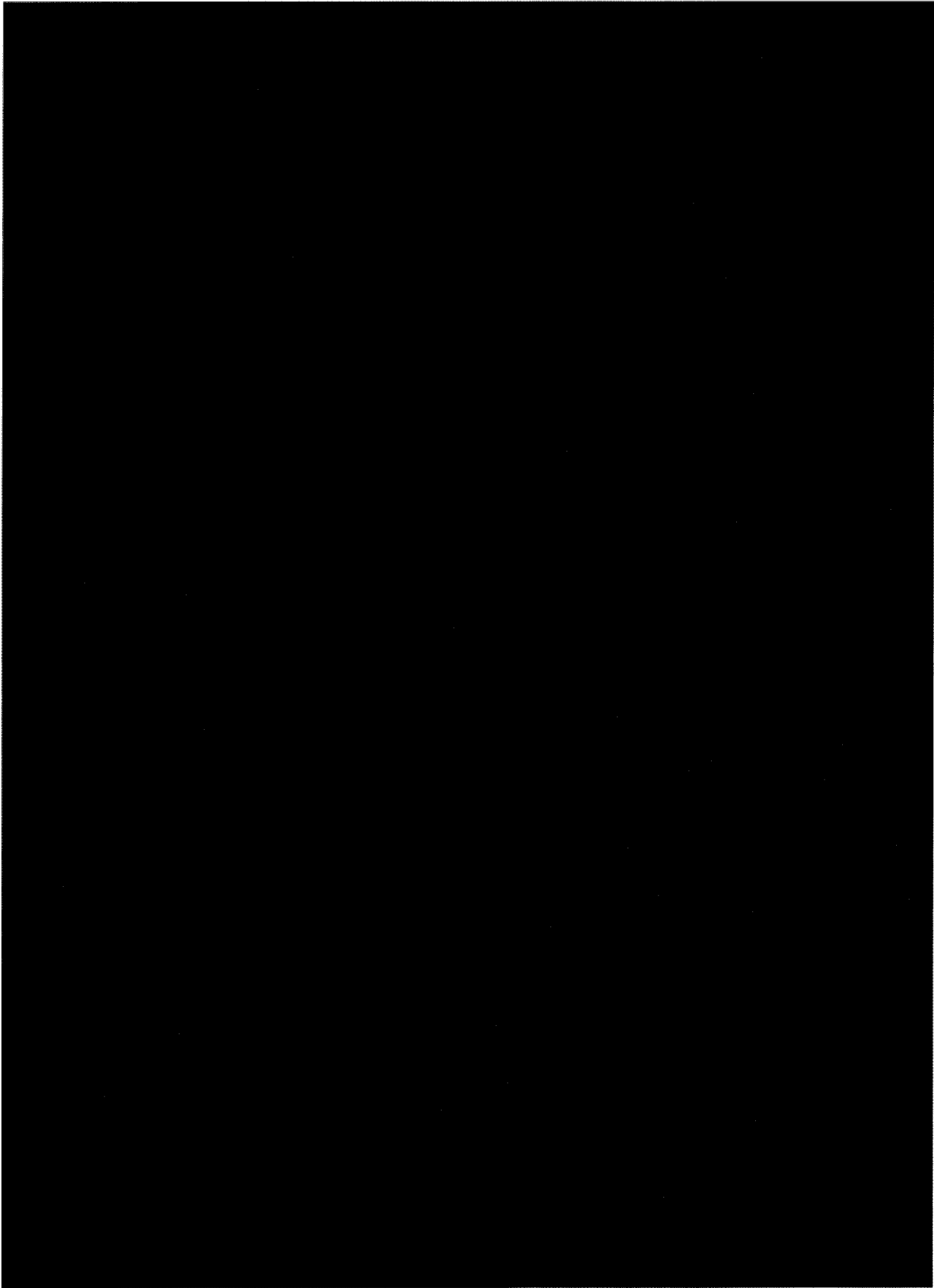


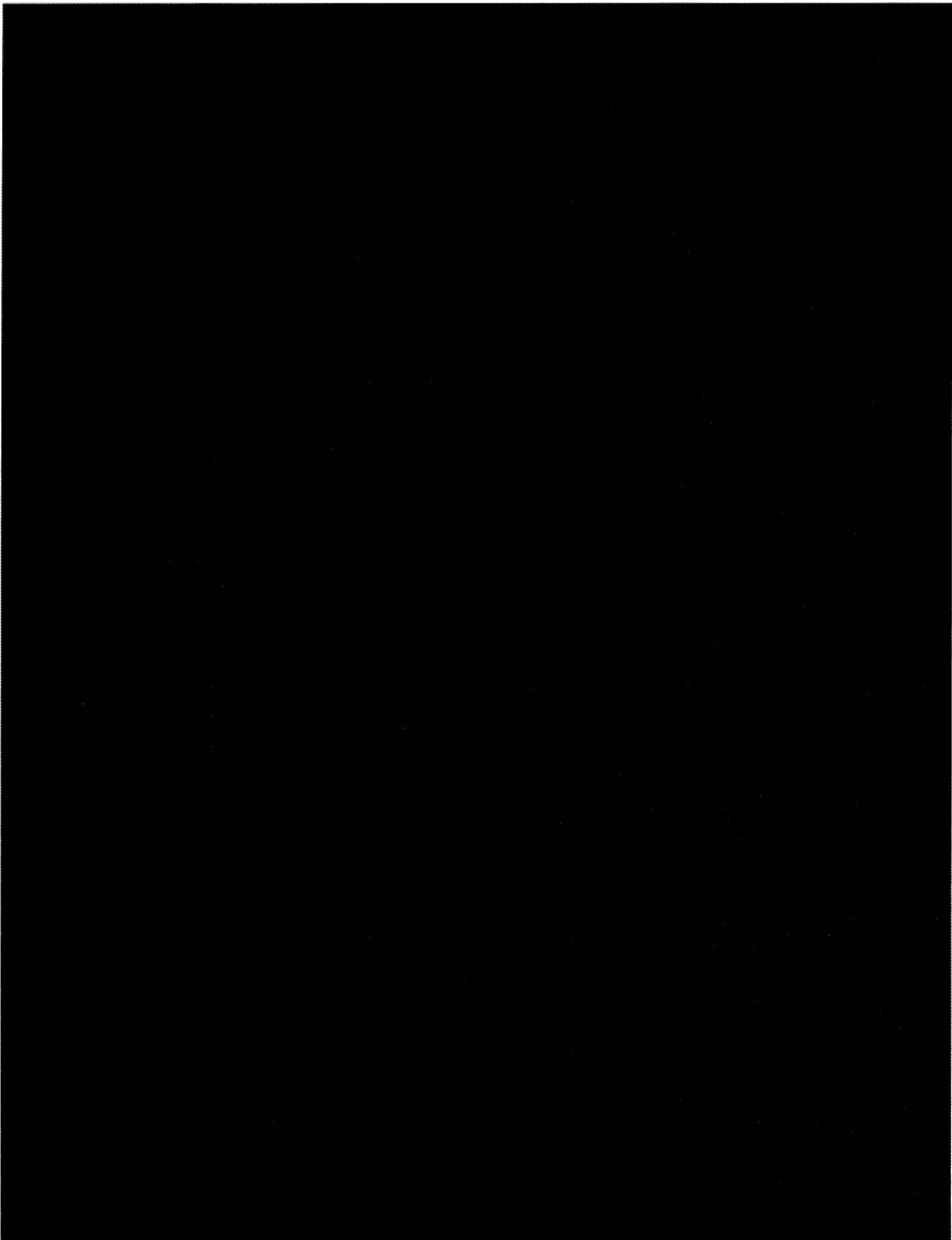


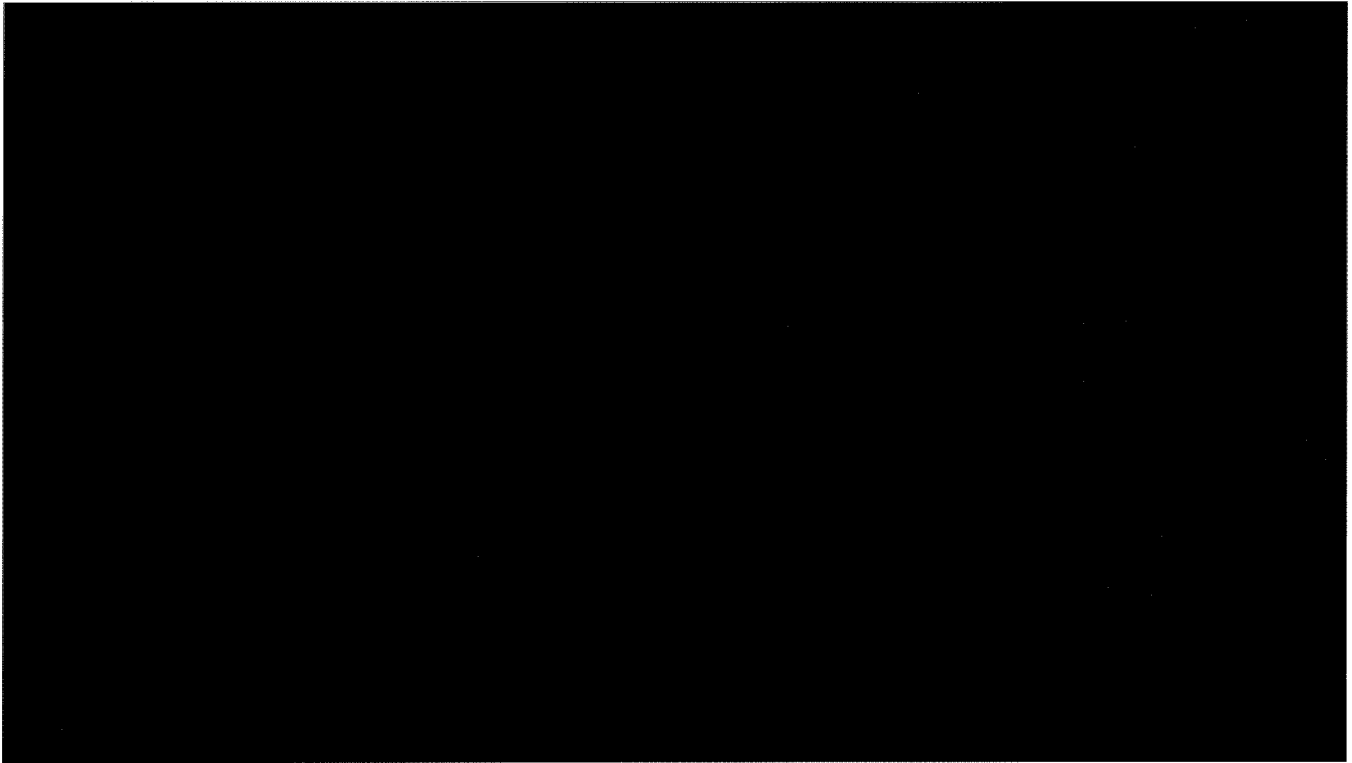












16.2 CLINICAL TECHNICAL PROCEDURES [REDACTED]

- Examination of the Anterior Segment using Slit Lamp Biomicroscopy (Efron Scale)
- Lens Fitting Characteristics [REDACTED]
- Front and Back Surface Lens Deposit Grading Procedure [REDACTED]
- In vivo CL Surface Wettability
- Non-invasive Tear Break-up Time (NITBUT)
- LogMAR Visual Acuity
- Randot Stereopsis
- Fusional Reserves (at near) and Near & Distance Phoria (unilateral & bilateral cover test)
- Amplitude of Accommodation
- NPC (Near Point of Convergence)
- Time to Haze
- Mars Near Contrast Sensitivity

16.3 PATIENT INSTRUCTION GUIDE (INVESTIGATIONAL PRODUCT)

Provided separately

16.4 PACKAGE INSERT (APPROVED PRODUCT)

PACKAGE INSERT / FITTING GUIDE

BAUSCH + LOMB
 ULTRA™ contact
 lenses
 with MoistureSeal™ technology
 (semifluor A)

Visibility Tinted Soft (hydrophilic)
 Contact Lenses

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

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 ®/TM are trademarks of Bausch + Lomb Incorporated or its affiliates.
 Other product brand names are trademarks of their respective owners.
 Name and Address of Manufacturer:
 Bausch + Lomb Incorporated
 1400 North Goodman Street
 Rochester, New York, USA 14609
 Printed in the USA.

SL7956
 819500

SYMBOL REFERENCE GUIDE
 For labels and cartons:

- CE 0050 Quality System Certification Symbol
- Recycling symbol Free Paid for Waste Management
- STERILE!! Sterile Using Steam or Dry Heat
- Warning triangle See Instruction Leaflet
- DIA Ø Diameter
- EXP (E) Use by Date (Expiration Date)
- LOT Batch Code
- EC REP Authorized Representative in European Community
- Rx ONLY Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
- PWR (Fv) Diopter (Lens Power)
- BC Base Curve
- Thermometer icon Storage Temperature

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

IMPORTANT
 This package insert and fitting guide has been developed to provide practitioners with information covering characteristics of the Bausch + Lomb Ultra (semifluor A) Visibility Tinted Soft (hydrophilic) Contact Lens and to illustrate fitting procedures. It is effective as of September 2013 and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use. This package insert and fitting guide is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with the patient instructions that pertain to the patient's prescribed lens and the recommended wearing schedule.

LENS PARAMETERS AVAILABLE
 The Bausch + Lomb Ultra (semifluor A) Visibility Tinted Soft (hydrophilic) Contact Lens is a hemispherical shell of the following dimensions:

Diameter: 14.2mm
 Center Thickness: 0.05mm to 0.50mm
 Base Curve: 8.5mm
 Powers (Spherical): +6.00D to -12.00D*

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

HOW THE LENS WORKS (ACTIONS)
 In its hydrated state, the Bausch + Lomb Ultra (semifluor A) Visibility Tinted Soft (hydrophilic) Contact Lens when placed on the cornea acts as a refracting medium to focus light rays on the retina.

DESCRIPTION
 The Bausch + Lomb Ultra (semifluor A) Visibility Tinted Soft (hydrophilic) Contact Lens is a soft hydrophilic contact lens which is available as a spherical lens. The lens material, semifluor A, is a hydrophilic copolymer of a silicone methacrylate and N-vinyl pyrrolidone, and is 46% water by weight when immersed in a sterile borate buffered saline with polyoxamine solution. This lens is tinted blue with up to 200 ppm of Reactive Blue Dye 246.

The physical / optical properties of the lens are:

Specific Gravity: 1.048
 Refractive Index: 1.411
 Light Transmittance: C.I.E. value—at least 95%
 Water Content: 46%
 Oxygen Permeability: 114x 10⁻¹⁰ (cm² STP) / (sec x cm² x mmHg) @ 35° C (Polarographic Method) (Boundary and Edge-Corrected)

The Bausch + Lomb Ultra (semifluor A) Visibility Tinted Soft (hydrophilic) Contact Lenses, with semifluor A lens material, are manufactured by the MoistureSeal™ manufacturing process, which combines lens molding through packaging in a continuous fashion by a cast molding process which creates a hydrophilic surface.

The Bausch + Lomb Ultra (semifluor A) Visibility Tinted Soft (hydrophilic) Contact Lenses may be prescribed for Frequent/Planned Replacement or Disposable Wear.

INDICATIONS
Vision Correction
 The Bausch + Lomb Ultra (semifluor A) Visibility Tinted Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2000 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +20.00D to -20.00D for daily wear.

Frequent/Planned Replacement Wear
 When prescribed for Frequent/Planned Replacement Wear, the Bausch + Lomb Ultra (semifluor A) Visibility Tinted Soft (hydrophilic) Contact Lens is to be discarded, rinsed and disinfected each time it is removed from the patient's eye and before the recommended wearing period prescribed by the eye care professional. The lens may be disinfected using a chemical disinfection system.

Disposable Wear
 When prescribed for Disposable Wear, the Bausch + Lomb Ultra (semifluor A) Visibility Tinted Soft (hydrophilic) Contact Lens is to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)
DO NOT USE the Bausch + Lomb Ultra (semifluor A) Visibility Tinted Soft (hydrophilic) Contact Lens when any of the following conditions exist:

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

WARNINGS

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

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow the eye care professional's directions for all lens care instructions. For proper use of lenses and lens care products, including the use of contact lens solutions, including contact lenses, can develop rapidly and lead to loss of vision.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of adverse reactions is increased when daily wear lenses are worn overnight.
- When prescribed for Frequent/Planned Replacement Wear, the need for strict compliance with the care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule should be emphasized to the patient.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non-smokers.

PRECAUTIONS

Special Precautions for Eye Care Professionals

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers.
- Consequently, when selecting an appropriate lens design and parameters, the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the prescribing eye care professional should carefully monitor the continuing ocular health of the patient and lens performance on eye.
- Eye care professionals should instruct the patient to REMOVE A LENS IMMEDIATELY if an eye becomes red or irritated.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with sterile saline solution that is recommended for in-eye use.
- The patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care professional.
- As with any contact lenses, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Aphakic patients should not be fitted with Bausch + Lomb Ultra (samfilcon A) Viability Limited Soft (hydrophilic) Contact Lenses until the determination is made that the eye has healed completely.

Handling Precautions

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

Solution Precautions

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

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Lens Wearing Precautions

- Never wear lenses beyond the period recommended by the eye care professional.
- 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 eyes. If nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eye care professional.
- Avoid, if possible, all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Care 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 Patient

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the eyes. The patient should be instructed as to a recommended follow-up schedule.
- Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of ocular infection including but not limited to Acanthamoeba keratitis.
- Always contact the eye care professional before using any medicine in the eyes.
- Who Should Know That the Patient is Wearing Contact Lenses
 - Patients should inform their doctor (health care professional) about being a contact lens wearer.
 - Patients should always inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you do not wear lenses.

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ADVERSE REACTIONS

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

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

If the patient notices any of the above, he or she should be instructed to immediately remove the lenses.

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

If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should immediately remove the lenses and contact his or her eye care professional or optician, 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 stroke may be present and may progress rapidly. Lens-induced reactions such as allergic conjunctivitis and dry eye and contact lens related problems 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 discharges, 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 ocular defects, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combination may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

SELECTION OF PATIENTS

The eye care professional should not fit patients who cannot or will not adhere to a recommended care or replacement regimen, or are unable to place and remove the lenses should be provided with them. Failure to follow handling and cleaning instructions could lead to serious eye infections which might result in corneal ulcers. Patient communication is vital because it relates not only to patient selection but also to ensure compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.

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

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

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

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

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

FITTING PROCEDURE

1. Pre-Fitting Examination

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

2. Initial Lens Power Selection

- Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane. Select the appropriate lens and place on the eye.
- Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the toxicity, 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.

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- c. With lenses in place on the eyes, evaluate fitting performance to assure that **CRITERIA OF A WELL FITTED LENS** continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

- d. After the lens removal, instill sodium fluorescein [unless contraindicated] into the eyes and conduct a thorough biomicroscopy examination.

1. The presence of vertical corneal striae in the posterior central cornea and/or corneal edema.
2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the **CRITERIA OF A WELL FITTED LENS** are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

3. Initial Lens Evaluation

- a. To determine proper lens parameters, observe the lens relationship to the eye using a slit lamp.
- Movement: The lens should provide discernible movement with:
 - Primary gaze blink
 - Upgaze blink
 - Upgaze lag
 - Centration: The lens should provide full corneal coverage.
- b. Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens. If after the lens has settled on the eye, the patient reports lens sensation, or if the lens is moving or decentering excessively, the lens should not be dispensed. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, the lens should not be dispensed.
4. **Criteria of a Well-Fitted Lens**
- If the initial lens selection fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient and provides satisfactory visual performance, it is a well-fitted lens and can be dispensed.

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PRACTITIONER FITTING SETS

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

WEARING SCHEDULE

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

Daily Wear

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

Disposable Lens Wear

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

Frequent/Planned Replacement

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

5. Characteristics of a Tight (Steep) Lens

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

6. Characteristics of a Loose (Flat) Lens

If the lens is too flat, it will:

- Decenter, especially on post-blink.
- Have a tendency to edge lift inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva.
- Have a tendency to be uncomfortable and irritating with fluctuating vision.
- Have a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

7. Follow-up Care

- a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, the following schedule is a suggested guideline for follow-up.
- 24 hours
 - 10 days
 - 1 month
 - 3 months
 - Every six months thereafter
- At the initial follow-up evaluation the eye care professional should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief.
- b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

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MONOVISION FITTING GUIDELINES

1. Patient Selection

- a. **Monovision Needs Assessment**
- For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than one [1] diopter) in one eye may not be a good candidate for monovision with the Bausch + Lomb Ultra (lamiflucan A) Visuality (United Soft (hydrophilic) Contact Lenses).

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

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

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

2. Patient Education

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

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2. Eye Selection

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

a. Ocular Preference Determination Methods

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

b. Refractive Error Method

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

c. Visual Demands Method

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

Example:

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

3. Special Fitting Considerations

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

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

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

4. Near Add Determination

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

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines. Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

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

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

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

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation. To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

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

7. Other Suggestions

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

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
 - Having a third contact lens (near power) to use when critical near viewing is needed.
 - Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
 - Make use of proper illumination when carrying out visual tasks.
- Success in fitting monovision can be improved by the following suggestions:
- Reverse the distance and near eyes if a patient is having trouble adapting.
 - Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
 - Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.
 - The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs.
 - All patients should be supplied with a copy of the **Bausch + Lomb Ultra (samfilcon A) Visibility Limited Soft (hydrophilic) Contact Lens Patient Information Booklet**.

HANDLING OF LENS

Patient Lens Care Directions

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

Frequent / Planned Replacement Wear: For complete information concerning the care, cleaning and disinfection of contact lenses refer to the Bausch + Lomb Ultra (samfilcon A) Visibility Limited Soft (hydrophilic) Contact Lens Frequent/Planned Replacement Wear Patient Instruction Booklet.

Disposable Wear: For complete information concerning emergency lens care, refer to the Bausch + Lomb Ultra (samfilcon A) Visibility Limited Soft (hydrophilic) Contact Lens Patient Information Booklet.

CARE FOR A STICKING (NONMOVING) LENS

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

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb Ultra (samfilcon A) Visibility Limited Soft (hydrophilic) Contact Lenses or experienced with the lenses should be reported to:

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

HOW SUPPLIED

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

17.1 LIST OF ABBREVIATIONS

AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CIB	Clinical Investigator's Brochure
CRF	Case Report Form
CRO	Contract Research Organization
CS	Contrast Sensitivity
FDA	Food and Drug Administration
F/U	Follow-Up
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
IRB	Institutional Review Board
MedDRA ©	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NIH	National Institutes of Health
NFV	Negative Fusional Vergence
NPA	Near Point of Accommodation
NPC	Near Point of Convergence
OHRP	Office for Human Research Protections
OHSR	Office for Human Subjects Research
PFV	Positive Fusional Vergence
PHI	Protected Health Information
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect

VAS

Visual Analog Scale

APPENDIX A: Examination of the Anterior Segment Using Slit Lamp Biomicroscopy (Efron Scale)

APPENDIX B: [REDACTED]

[REDACTED] Lens Fitting Characteristics

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Lens Fitting Characteristics

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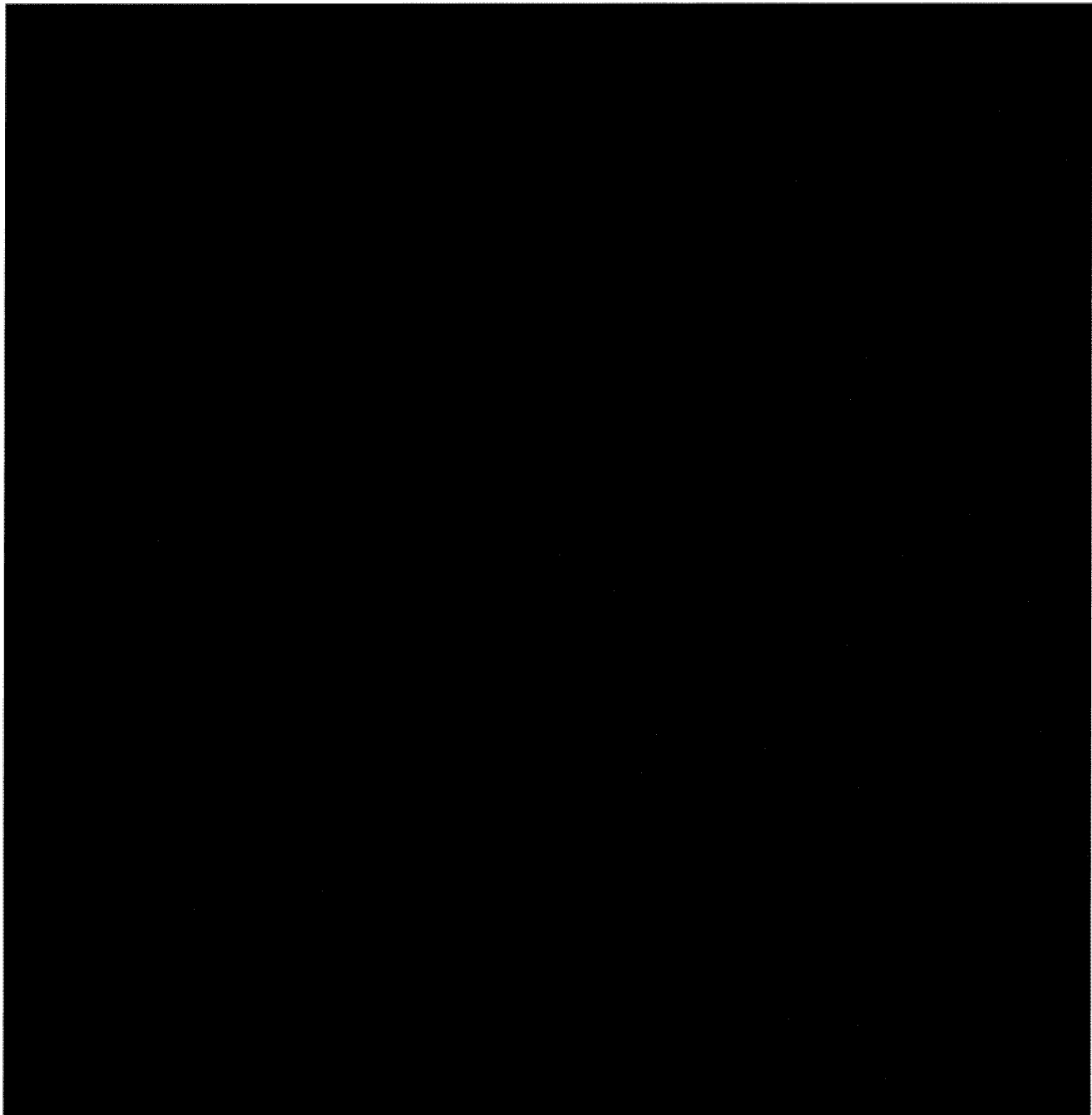
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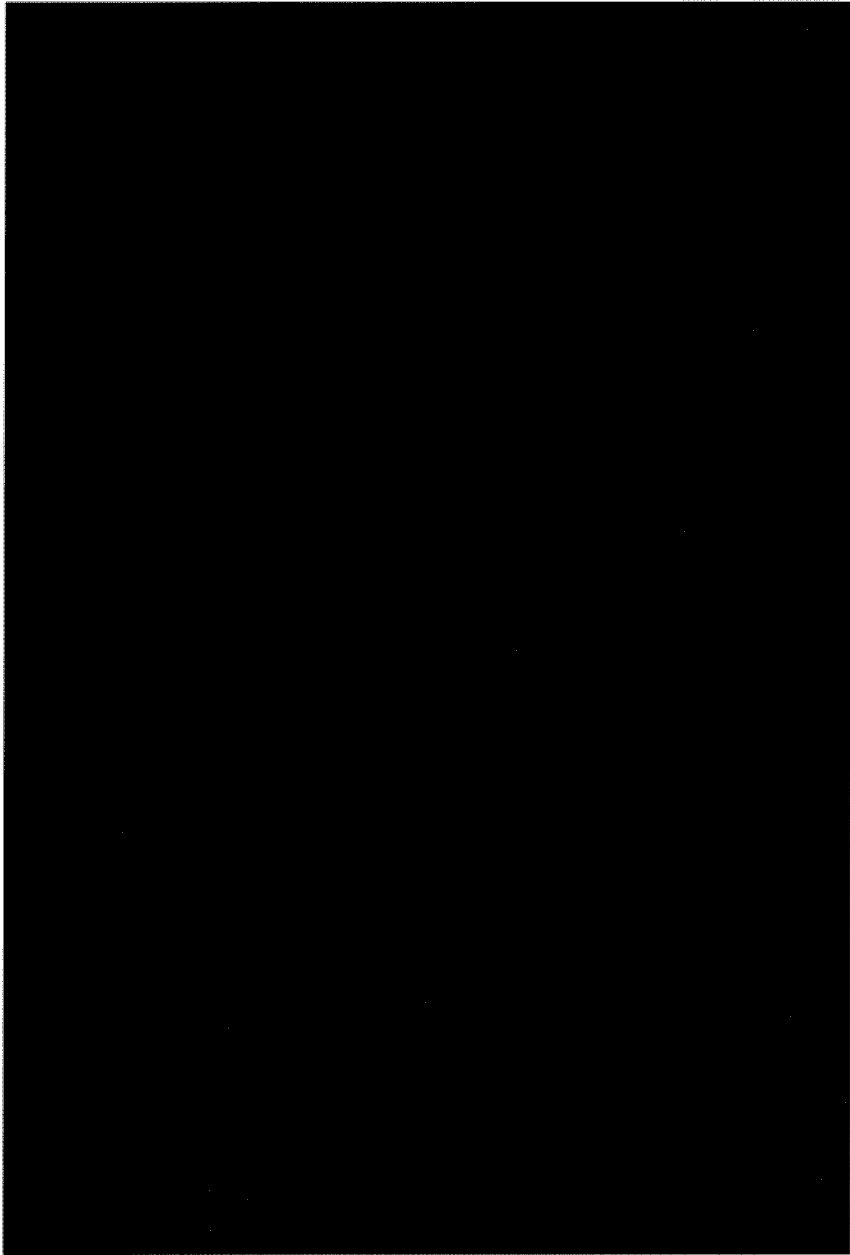
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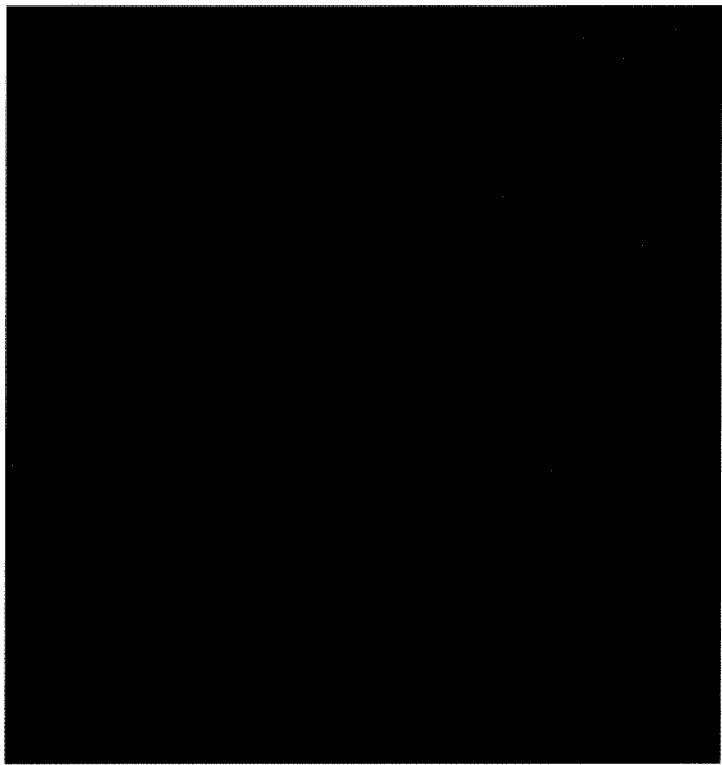
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APPENDIX C: [REDACTED]

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Front and Back Surface Lens Deposit Grading Procedure

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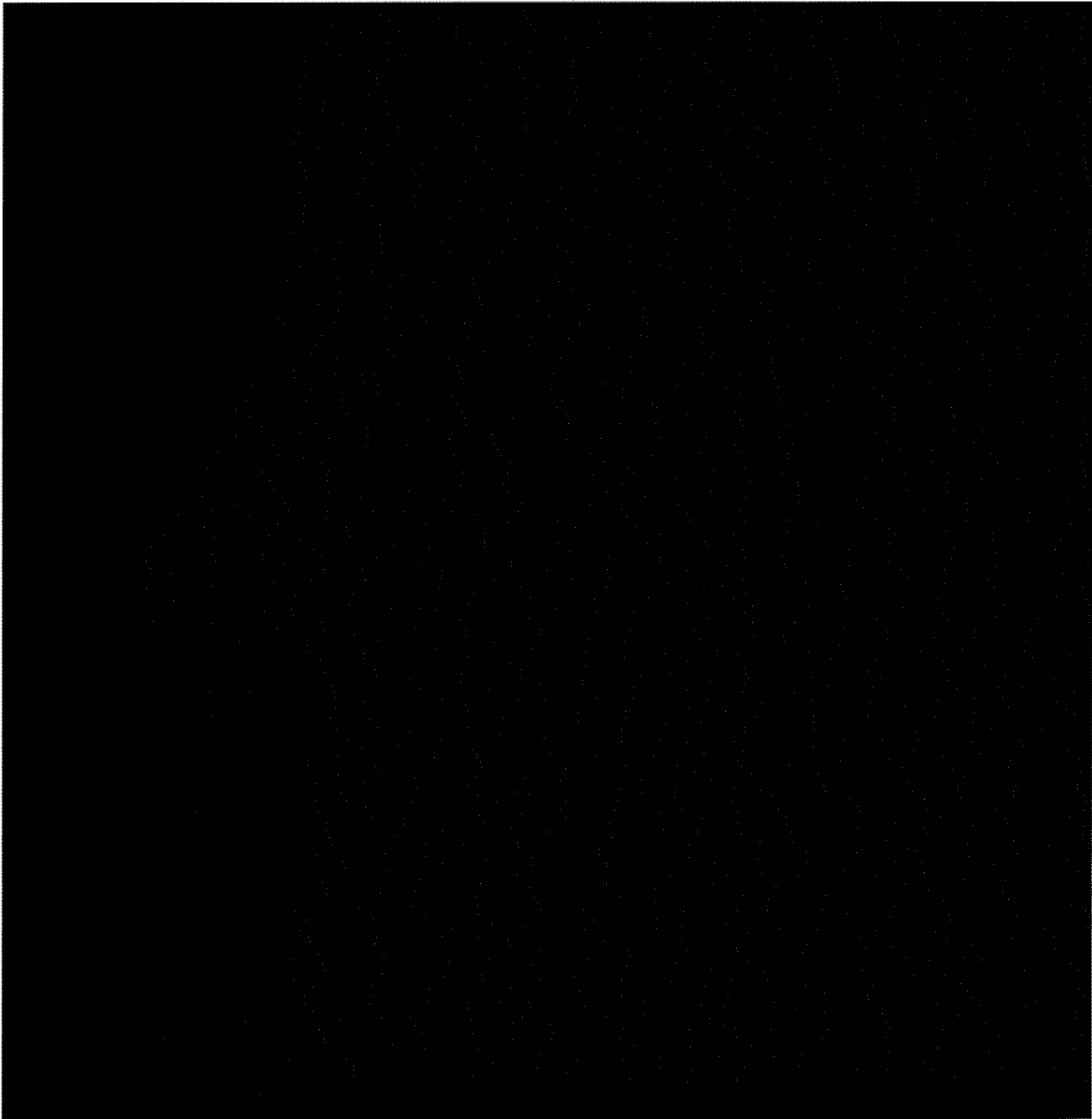
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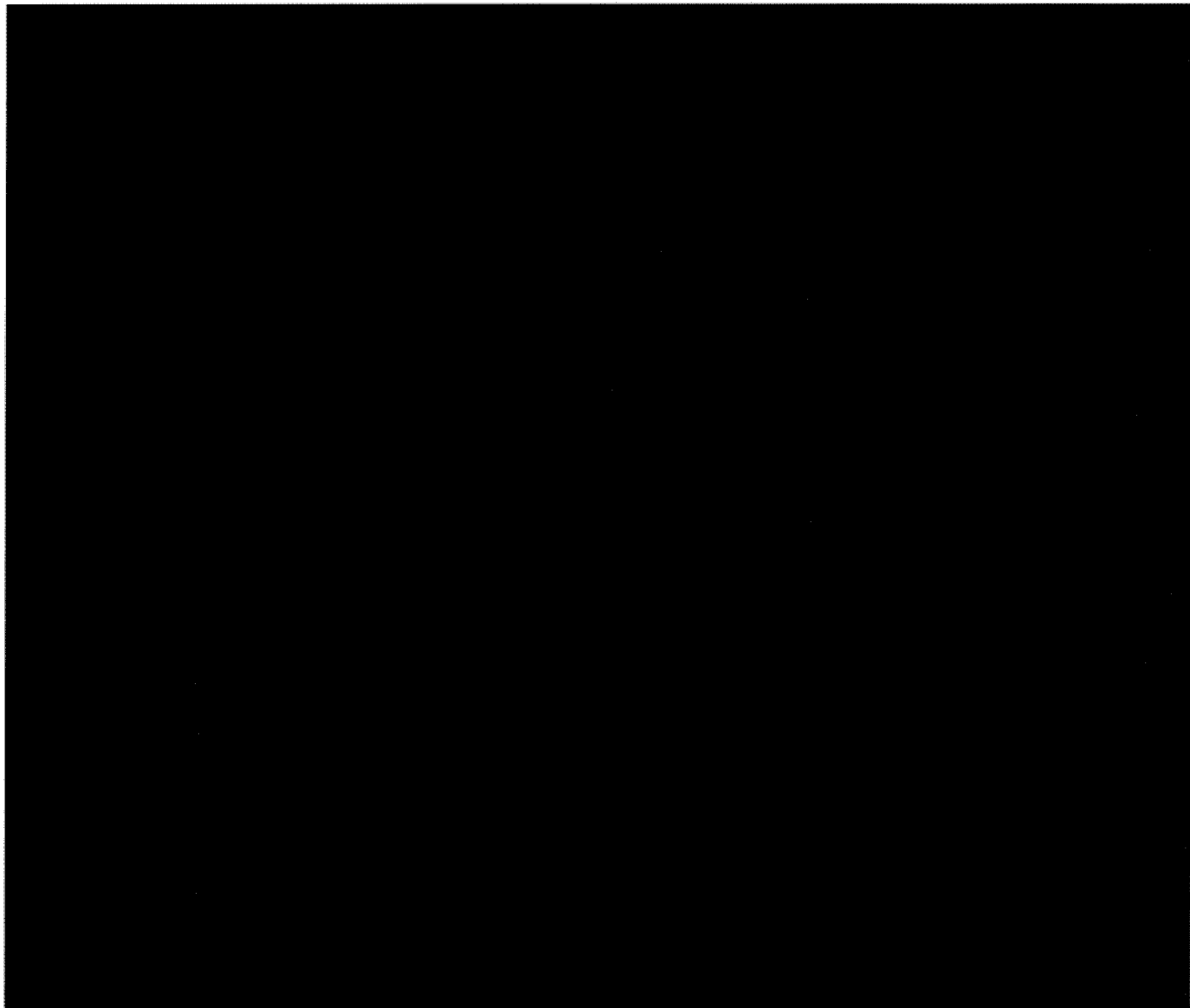
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APPENDIX D: In vivo CL Surface Wettability

In vivo CL Surface Wettability

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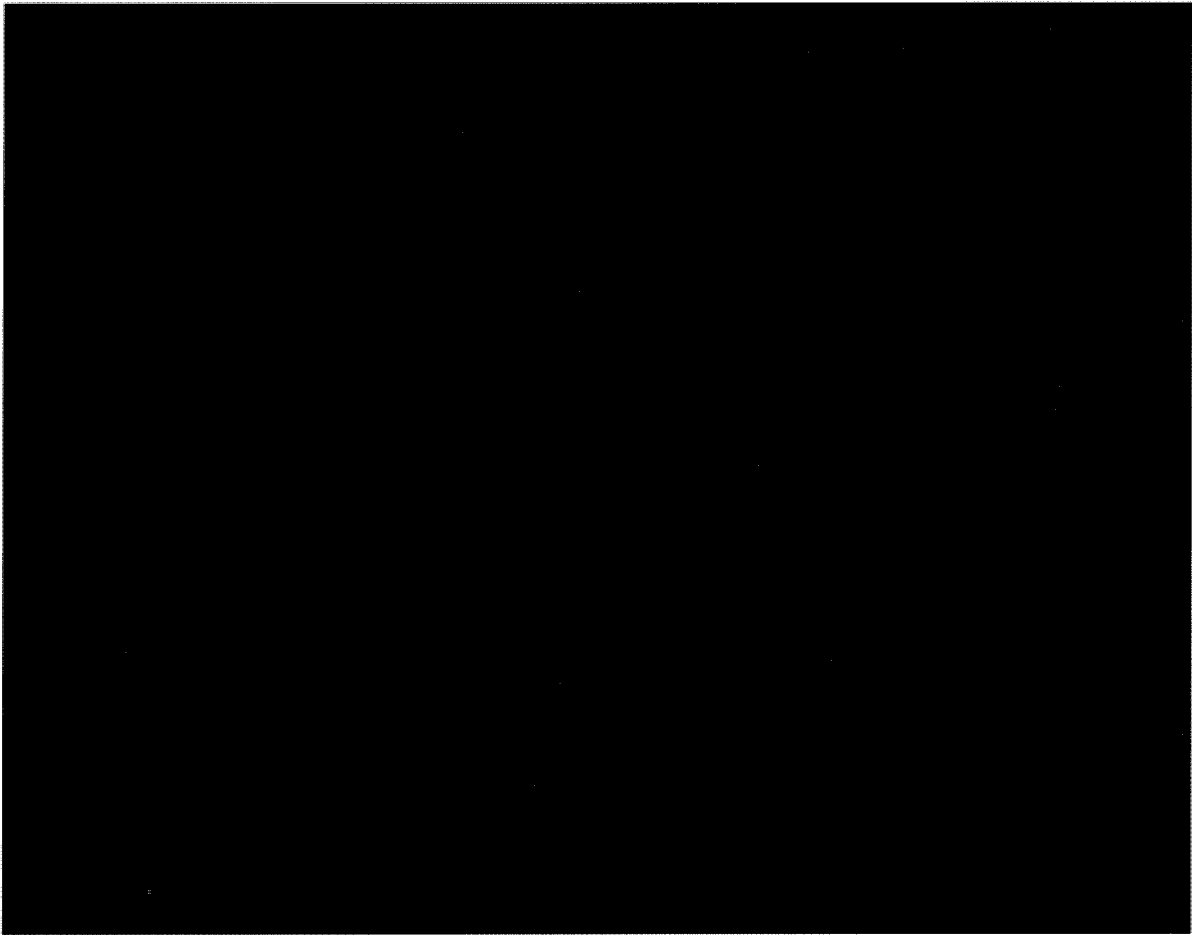
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APPENDIX E: Non- Invasive Tear Break-up Time (NITBUT)

Non-invasive Tear Break-up Time

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APPENDIX F: logMAR Visual Acuity

logMAR Visual Acuity

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APPENDIX G: Randot Stereopsis

Randot Stereopsis

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APPENDIX H: Near Fusional Reserves and Near & Distance Phoria (Unilateral & Bilateral Cover Test)

Near Phoria and Near Fusional Reserves

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[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

APPENDIX I: Amplitude of Accommodation

Amplitude of Accommodation

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

APPENDIX J: NPC (Near Point Convergence)

Near Point of Convergence (NPC)

[REDACTED]

[REDACTED]

[REDACTED]

APPENDIX K: Time to Haze

Time to Haze

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

APPENDIX L: Mars Near Contrast Sensitivity

