

Johnson & Johnson Vision Care, Inc.

Clinical Study Protocol

Protocol Title

Clinical Evaluation of 2-Week Reusable ACUVUE 2 Vivid Style

Protocol CR-6180

Version: 3.0

Date: 08 Jan 2018

Investigational Products: ACUVUE 2 Vivid Style Color contact Lenses

Key Words: ACUVUE 2 Vivid Style, reusable, Etafilcon A, dispensing, logMAR visual acuity, subjective vision

Statement of Compliance to protocol, GCP and applicable regulatory guidelines:

This trial will be conducted in compliance with the protocol, ISO 14155,¹ the International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP),² the Declaration of Helsinki,³ and all applicable regulatory requirements.

Confidentiality Statement:

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PROTOCOL TITLE, NUMBER, VERSION

Title: Clinical Evaluation of 2-week Reusable ACUVUE 2 Vivid Style

Protocol Number: CR-6180

Version: 3.0

Date: 08 Jan 2018

SPONSOR NAME AND ADDRESS

Johnson & Johnson Vision Care (JJVC)

7500 Centurion Parkway

Jacksonville, FL 32256

MEDICAL MONITOR

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Title: Principal Research Optometrist

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Email: mbishop4@its.jnj.com
[REDACTED]

The Medical Monitor must be notified by the clinical institution/site by e-mail, fax, or 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 Medical Monitoring Plan is maintained as a separate document and included in the Trial Master File.

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,⁴ ICH guidelines,² ISO 14155,¹ and the Declaration of Helsinki.³

Author/Study
Responsible
Clinician

See Electronic Signature Page
Meredith Bishop, OD, MS, FAAO
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DATE

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Date
1.0	Meredith Bishop	Original Protocol	21 Dec 2017
2.0	[REDACTED]	Addition of Over-label Protocol Number	02 Jan 2018
3.0	[REDACTED]	Following CRRC review, changed status of registration on CT.gov website, updated introduction, removed references to MRD questions, updated package insert for approved product.	08 Jan 2018

SYNOPSIS

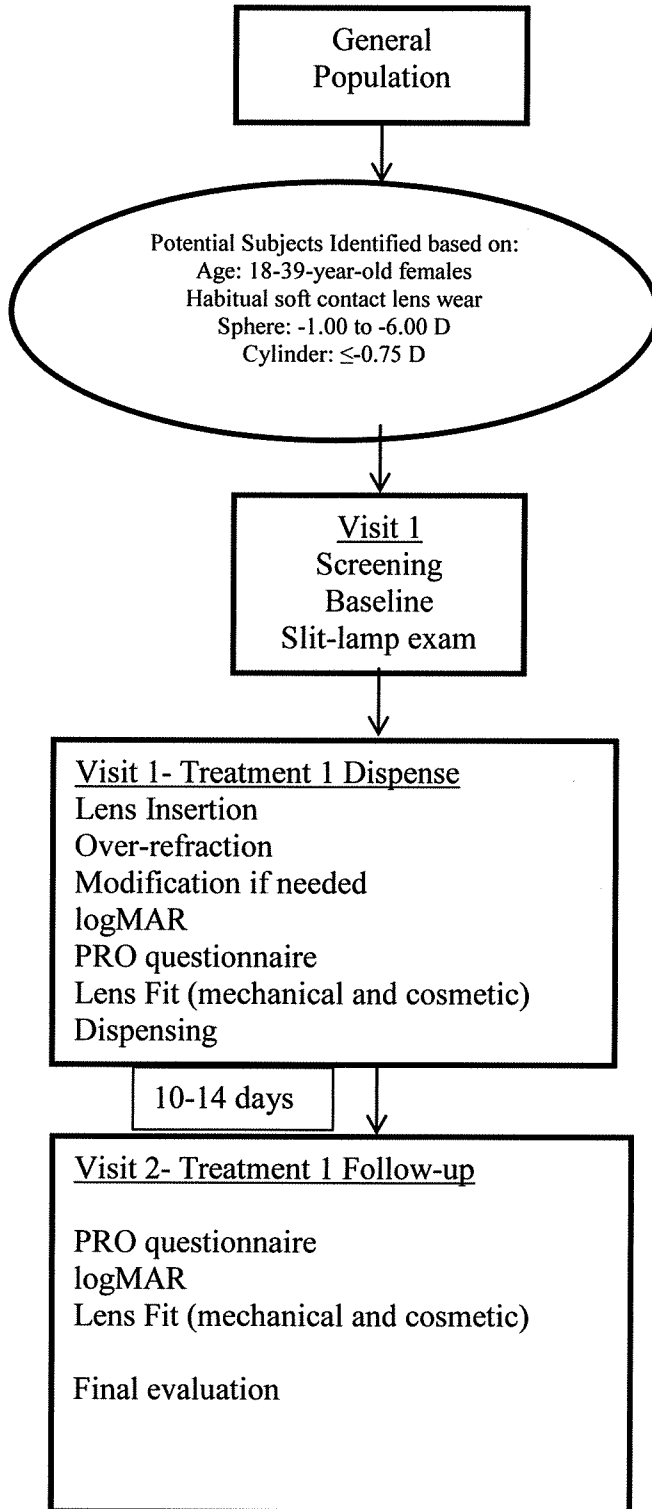
Protocol Title	Clinical Evaluation of 2-Week Reusable ACUVUE 2 Vivid Style
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Confirmatory phase, Phase 3
Trial Registration	This study will be registered on ClinicalTrials.gov by the Sponsor.
Test Article(s)	Investigational Products: Not applicable Marketed Products: ACUVUE 2 Vivid Style
Wear and Replacement Schedules	Wear Schedule: Daily Wear Replacement Schedule: Two weeks
Objectives	The purpose of this study is to evaluate the logMAR visual performance of one brand of cosmetic contact lenses.
Study Endpoints	Primary endpoint: logMAR visual performance Other observations: mechanical and cosmetic lens fit, and CLUE vision, comfort, and handling.
Study Design	<p>This will be a single site, non-randomized, brand-masked, bilateral, single treatment study. There will be 2 visits. There will be a 10 to 14-day wear period between visits.</p> <p>Visit 1: Baseline and eligibility, insert treatment #1, logMAR vision, post fit questionnaire, lens fit assessment. Dispense treatment #1 for 12 (\pm2) days</p> <p>Visit 2: Follow up on treatment #1: Subjective questionnaire, logMAR vision, lens fit, and physiology assessment. Final evaluation.</p> <p>See the flow chart (Figure 1) at the end of the synopsis table for the schematic of the study visits and procedures of main observations.</p>
Sample Size	Up to 25 subjects will be enrolled with the aim of approximately 20 subjects completing.
Study Duration	The study is expected to last up to 2 months. The enrollment period will also be up to 1 month.
Anticipated Study Population	We will aim to recruit up to 25 female subjects, ages 18 to 39 years (inclusive). Subject must be habitual contact lens wearers.

Eligibility Criteria	<p>Potential subjects must satisfy all of the following criteria to be enrolled in the study:</p> <ol style="list-style-type: none">1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form2. Appear able and willing to adhere to the instructions set forth in this clinical protocol (i.e., willing to wear only the study lenses and not use habitual lenses during the study)3. Females between 18 and 39 (inclusive) years of age at the time of screening4. The subject's vertex corrected spherical equivalent distance refraction must be in the range of -1.00 D to -6.00 D (inclusive) in each eye5. The subject's refractive cylinder must be less than or equal to 0.75 D (inclusive) in each eye6. Have spherical best corrected visual acuity of 20/30 or better in each eye7. Be a current soft contact lens wearer in both eyes with a minimum of 6 hours/day and 5 days/week over the last month by self-report8. The subject must be willing to be photographed and/or video-taped
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Eligibility Criteria	<p>Potential subjects who meet any of the following criteria will be excluded from participating in the study:</p> <ol style="list-style-type: none"> 1. Currently pregnant or lactating 2. Any systemic disease (eg, Sjögren’s Syndrome), allergies, infectious disease (eg, hepatitis, tuberculosis), contagious immunosuppressive diseases (eg, HIV), autoimmune disease (eg rheumatoid arthritis), or other diseases, by self-report, which are known to interfere with contact lens wear and/or participation in the study (at the investigators discretion) 3. Use of systemic medications (eg, chronic steroid use) that are known to interfere with contact lens wear (at the investigators discretion) 4. Any previous, or planned (during the study) ocular surgery (eg, radial keratotomy, PRK, LASIK, etc.) 5. Any previous history or signs of a contact lens-related corneal inflammatory event (eg, past peripheral ulcer or round peripheral scar), or any other ocular abnormality that would contraindicate contact lens wear 6. Participation in any contact lens or lens care product clinical trial within seven (7) days prior to study enrollment 7. Employee or family members of clinical site (eg, Investigator, Coordinator, Technician) <p>Exclusion Criteria after Baseline</p> <ol style="list-style-type: none"> 8. Any ocular allergies, infections or other ocular abnormalities that are known to interfere with contact lens wear and/or participation in the study. This may include, but not be limited to entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or corneal distortion (at the investigators discretion) 9. Clinically significant (Grade 3 or 4 on FDA scale) tarsal abnormalities, bulbar injection, corneal edema, corneal vascularization, corneal staining, or any other abnormalities of the cornea which would contraindicate contact lens wear.
Disallowed Medications/Interventions	None

Measurements and Procedures	logMAR visual acuity, PRO questionnaires (comfort, vision, and handling), lens fit assessment, cosmetic lens fit assessment/hula hoop assessment, and safety parameters (slit lamp findings, entrance/exit visual acuity).
Microbiology or Other Laboratory Testing	None
Study Termination	The occurrence of one or more Unanticipated Adverse Device Effect (UADE), or any SAE where relationship to study agent cannot be ruled out, will result in stopping further dispensing investigational product. In the event of a UADE or SAE, the Sponsor Medical Monitor may unmask the treatment regimen of subject(s) and may discuss this with the Principal Investigator before any further subjects are enrolled.
Ancillary Supplies/ Study-Specific Materials	EyeCept (Optics Laboratory, Inc.), LacriPure (Menicon), Blink Revitalens (Johnson & Johnson Vision), Fluorescein (Akorn, Inc.)
Principal Investigator(s) and Study Institution(s)/Site(s)	A full list of Principal Investigators, clinical sites, and institutions is kept separately from the Study Protocol and is included in the study Trial Master File.

Figure 1: Study Flowchart



COMMONLY USED ABBREVIATIONS AND DEFINITIONS OF TERMS

ADD	Plus Power Required For Near Use
ADE	Adverse Device Effect
AE	Adverse Event/Adverse Experience
BCVA	Best Corrected Visual Acuity
BSCVA	Best Spectacle Corrected Visual Acuity
CFR	Code of Federal Regulations
CLUE	Contact Lens User Experience
COAS	Complete Ophthalmic Analysis System
COM	Clinical Operations Manager
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
CT	Center Thickness
CTP	Clinical Technical Procedure
D	Diopter
DMC	Data Monitoring Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food and Drug Administration
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
ISO	International Organization for Standardization
ITT	Intent-to-Treat
JJVC	Johnson & Johnson Vision Care, Inc.
LC	Limbus Center
LogMAR	Logarithm of Minimal Angle of Resolution
MedDRA [®]	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NIH	National Institutes of Health
OD	Right Eye
OHRP	Office for Human Research Protections
OHSR	Office for Human Subjects Research
OS	Left Eye
OU	Both Eyes
PD	Protocol Deviation
PHI	Protected Health Information
PI	Principal Investigator
PIG	Patient Instruction Guide

PQC	Product Quality Complaint
PRO	Patient Reported Outcome
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
VA	Visual Acuity

1. INTRODUCTION AND BACKGROUND

Cosmetic contact lenses can have patterns of varying size and opacities. When designing new cosmetic patterns, it is important to test the performance in a clinical study.

In the current study, we will collect objective and subjective performance measures of a marketed cosmetic soft contact lens. This study will provide pilot information on this lens type and be used to calculate sample sizes for future investigational cosmetic contact lens studies.

1.1. Name and Descriptions of Investigational Products

This study will include one marketed contact lens. Further details about the test articles are found in Section 6 of this protocol.

1.2. Intended Use of Investigational Products

The intended use of the investigational product is to correct vision. The investigational product contains a cosmetic pattern, so it also affects the visual appearance of the eye. During this dispensing study, one lens type will be worn for approximately 2 weeks.

1.3. Summary of Findings from Nonclinical Studies

Not Applicable - Marketed Product Only

1.4. Summary of Known Risks and Benefits to Human Subjects

The following risks/adverse events can be associated with wearing soft contact lenses in general:

- The eyes may burn, sting and/or itch.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion.
- There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal

abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.

- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photo-phobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.
- Due to the reduction in light transmittance with cosmetically tinted lenses, some patients may experience visual symptoms while wearing the Study Contact Lenses. In addition, some patients may experience reduced peripheral awareness due to the opaque iris pattern.

There is no direct benefit to the subjects for participating in the study, although they will be able to try out marketed and investigational cosmetic contact lenses. The information from this study will aid if the further development and assessment of new potential cosmetic contact lenses.

For the most comprehensive clinical information regarding the marketed contact lenses refer to the package inserts (APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT))

1.5. Relevant Literature References and Prior Clinical Data Relevant to Proposed Clinical Study

For the most comprehensive clinical information regarding the marketed contact lenses refer to the package insert (APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)).

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

Primary Objective:

The primary objective of this study is to evaluate the Objective vision Logarithm of Minimal Angle of Resolution (logMAR) high illuminance/high contrast of one brand of marketed cosmetic contact lens.

2.2. Endpoints

Primary endpoint: LogMAR objective vision (high illumination/high contrast) at lens fit.

Other observations (descriptively summarized) will include:

Subjective Vision (CLUE)

Subjective Comfort (CLUE)

Subjective Handling (CLUE)

LogMAR objective vision (high illumination/low contrast, low illumination/high contrast)

Mechanical Lens fit

Cosmetic Lens fit/Hula Hoop

Ocular Physiology

2.3. Hypotheses

Due to the exploratory nature of this pilot study, there will be no planned hypotheses. Instead, descriptive summaries (ie, tables and figures) of study endpoints will be provided for each lens type.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

Females aged 18 to 39 years (inclusive) who are habitual soft contact lens wearers will be recruited for this clinical study. Subjects must meet all the inclusion and none of the exclusion criteria listed in Section 3.2.

3.2. Inclusion Criteria

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

1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form
2. Appear able and willing to adhere to the instructions set forth in this clinical protocol (i.e., willing to wear only the study lenses and not use habitual lenses during the study)
3. Females between 18 and 39 (inclusive) years of age at the time of screening
4. The subject's vertex corrected spherical equivalent distance refraction must be in the range of -1.00 D to -6.00 D (inclusive) in each eye
5. The subject's refractive cylinder must be less than or equal to 0.75 D (inclusive) in each eye
6. Have spherical best corrected visual acuity of 20/30 or better in each eye
7. Be a current soft contact lens wearer in both eyes with a minimum of 6 hours/day and 5 days/week over the last month by self-report
8. The subject must be willing to be photographed and/or video-taped.

3.3. Exclusion Criteria

Exclusion Criteria after Screening:

1. Currently pregnant or lactating
2. Any systemic disease (eg, Sjögren's Syndrome), allergies, infectious disease (eg, hepatitis, tuberculosis), contagious immunosuppressive diseases (eg, HIV), autoimmune disease (eg rheumatoid arthritis), or other diseases, by self-report, which are known to interfere with contact lens wear and/or participation in the study (at the investigators discretion)
3. Use of systemic medications (eg, chronic steroid use) that are known to interfere with contact lens wear (at the investigators discretion)
4. Any previous, or planned (during the study) ocular surgery (eg, radial keratotomy, PRK, LASIK, etc.)

5. Any previous history or signs of a contact lens-related corneal inflammatory event (eg, past peripheral ulcer or round peripheral scar), or any other ocular abnormality that would contraindicate contact lens wear
6. Participation in any contact lens or lens care product clinical trial within seven (7) days prior to study enrollment
7. Employee or family members of clinical site (eg, Investigator, Coordinator, Technician)

Exclusion Criteria after Baseline

8. Any ocular allergies, infections or other ocular abnormalities that are known to interfere with contact lens wear and/or participation in the study. This may include, but not be limited to entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, or corneal distortion (at the investigators discretion)
9. Clinically significant (Grade 3 or 4 on FDA scale) tarsal abnormalities, bulbar injection, corneal edema, corneal vascularization, corneal staining, or any other abnormalities of the cornea which would contraindicate contact lens wear.

3.4. Enrollment Strategy

Study subjects will be recruited from the Institution/clinical site's subject database and/or utilizing Independent Ethics Committee (IEC) or Institutional Review Board (IRB) approved materials by a market research company.

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

This is a single site, bilateral, dispensing, brand-masked, 1 treatment dispensing study. There will be 2 visits.

4.2. Study Design Rationale

This study will provide exploratory information on the test article.

4.3. Enrollment Target and Study Duration

Approximately 25 subjects ages 18 to 39 years (inclusive) who are habitual soft contact lens wearers will be enrolled in this 2-visit, single-site clinical study. The study will last approximately 2 months with a 1 month enrollment period.

Enrollment is defined as execution of the informed consent and/or assent form.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

The study lenses will be worn in a bilateral fashion. Since there is only 1 treatment, there is no randomization.

5.2. Masking

Due to visible print differences, subjects and investigators will be aware of the patterns/variants of the investigational product. However, subjects will be masked to the lens brand to prevent bias during the lens discussions.

Under normal circumstances, the mask should not be broken until all subjects have completed the study and the database is finalized. Otherwise, the mask should be broken only if specific emergency treatment/course of action would be dictated by knowing the treatment status of the subject. In such cases, the Investigator may, in an emergency, contact the medical monitor. In the event the mask is broken the Sponsor must be informed as soon as possible. The date, time, and reason for the unmasking must be documented in the subject record. The Investigator is also advised not to reveal the study treatment assignment to the clinical site or Sponsor personnel.

Subjects who have had their treatment assignment unmasked are expected to return for all remaining scheduled evaluations. Subjects who are discontinued may be replaced.

5.3. Procedures for Maintaining and Breaking the Masking

The Clinical Supply Unit will generate a unique code for all study lenses. The test articles mask shall not be broken unless information concerning the lens type is necessary for the urgent medical treatment of a subject. The Sponsor must be notified before the mask is broken.

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 1: Test Articles

	Test
Name	ACUVUE 2 Vivid Style
Manufacturer	Johnson & Johnson
Nominal Base Curve @ 22°C	8.3 mm
Nominal Diameter @	14.0 mm

22°C	
Nominal Distance Powers (D)	-1.00 to -6.00 D
Modality in Current Study	Daily
Replacement Frequency	Two Week
Packaging Form (vial, blister, etc.)	Blister

Each subject will wear approximately 2 of the lenses.

6.2. Ancillary Supplies/Products

The following solutions will be used in this study:

Table 2: Ancillary Supplies

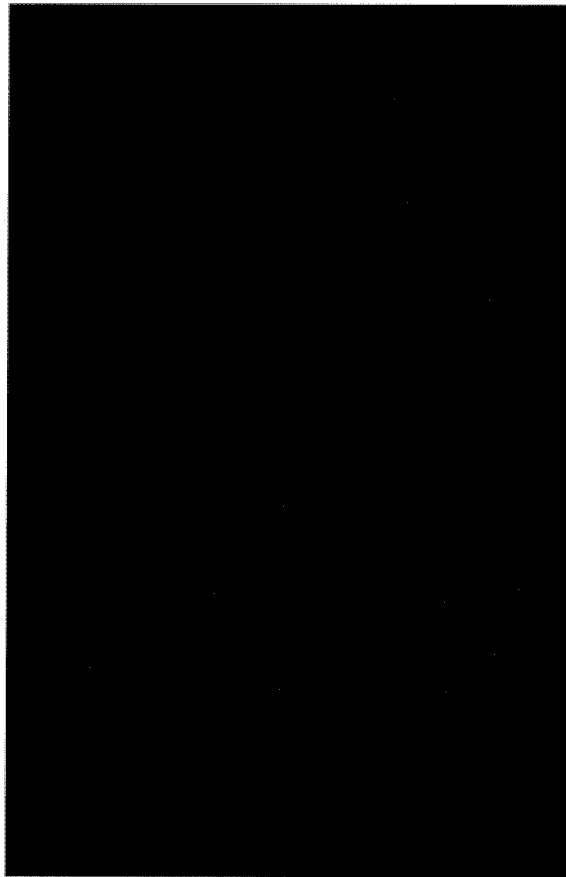
Solution Name/Description	Solution			
	EyeCept	LacriPure	Fluorescein	Blink Revitalens
Manufacturer	Optics Laboratory, Inc.	Menicon	Akorn, Inc.	Johnson & Johnson Vision
Preservative	None	None	None	None
Other distinguishing items (dye, packaging, approval status, etc.)	NA	NA	D&C Yellow No. 8, 0.6 mg	NA

6.3. Administration of Test Articles

Test articles will be dispensed to subject meeting all eligibility requirements, including any dispensing requirements set forth in this clinical protocol. Subjects will be dispensed an adequate supply of test articles to complete the study. Lost or damaged test articles may be replaced at the discretion of the Investigator and/or the Sponsor.

6.4. Packaging and Labeling

The test articles will be packaged in blisters as the primary packaging. The test article will be over-labeled to mask the subject/Investigators to the identity of the lens. The test articles will be in plastic bags as the secondary packaging form. [REDACTED]



6.5. Storage Conditions

Test articles will be maintained at ambient temperatures at the clinical site. Test articles must be kept under secure conditions.

6.6. Collection and Storage of Samples

No samples will be collected as part of the study procedures.

When possible, any lens or test article associated with an Adverse Events and/or a Product Quality Complaint must be retained and stored in a glass vial with moderate solution pending directions from the sponsor for potential return back to JJVC.

6.7. Accountability of Test Articles

JJVC 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.

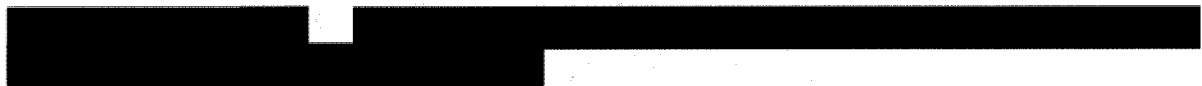
Test article must be kept in a locked storage cabinet, accessible only to those assigned by the Investigator for dispensing. The Investigator may delegate this activity to authorized study site personnel listed on the Site Delegation Log. All test articles must be accounted. This includes:

1. What was dispensed for the subject for trial fitting, to wear out of the office, or issued for the subject to replace appropriately between visits

2. What was returned to the Investigator unused
3. The number and reason for unplanned replacements

The Investigator will collect all unused test articles from the subjects at the end of the subject's participation. Subject returned unused test articles must be separated from the clinical study inventory of un-dispensed test articles, and must be labeled with the subject number and date of return. Following final reconciliation of test articles by the monitor, the Investigator or monitor will return all unused test articles to JJVC.

If there is a discrepancy between the shipment documents and the contents, contact the study monitor immediately.



7. STUDY EVALUATIONS

7.1. Time and Event Schedule

Table 3: Time and Events

Visit Information	Visit 1 Screening, Baseline, Dispense Treatment 1	Visit 2 Treatment 1 Follow-up, Final Evaluation
Time Point	Day 1	Day 12 + 2 days from V1
Estimated Visit Duration	2 hours	1 hour
Study Informed Consent	X	
Inclusion/Exclusion Screening Criteria	X	
Demographics	X	
Medical History & medication review	X	X
Habitual Lens Info	X	
PRO Baseline CLUE	X	
HVID	X	
Keratometry	X	
Subjective Refraction	X	
Biomicroscopy	X	X
Subject Reported Ocular Symptoms	X	X
Eligibility after baseline exam	X	
Randomization	X	
Lens Fitting #1	X	
PRO Post Fit (CLUE)	X	
PRO Follow Up (CLUE)		X
Distance VA & over refraction	X	X
LogMAR VA	X	

Visit Information	Visit 1 Screening, Baseline, Dispense Treatment 1	Visit 2 Treatment 1 Follow-up, Final Evaluation
Time Point	Day 1	Day 12 ± 2 days from V1
Estimated Visit Duration	2 hours	1 hour
Cosmetic Lens Fit Assessment	X	X
Hula Hoop Assessment	X	X
Lens Fit Assessment	X	X
Wettability Characteristics	X	X
Lens Surface Assessment	X	X
Lens Dispensing & instruction	X	
Adverse Event Review		X
Final Evaluation		X

7.2. Detailed Study Procedures

VISIT 1

The subjects must present to Visit 1 wearing their habitual contact lenses.

The subjects must present to Visit 1 wearing their habitual contact lenses.

Visit 1: Screening			
Step	Procedure	Details	
1.1	Statement of Informed Consent	Each subject must read, understand, and sign the Statement of Informed Consent before being enrolled into the study. The Principal Investigator or his/her designee conducting the informed consent discussion must also sign the consent form. Note: The subject must be provided a signed copy of this document.	
1.2	Demographics	Record the subject's date of birth, gender, race and ethnicity.	
1.3	Medical History and Concomitant Medications	Questions regarding the subjects' medical history and concomitant medications.	
1.4	Habitual Lenses	Questions regarding the subject's habitual lens type and parameters.	
1.5	Eligibility after Screening	All responses to Screening Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria must be answered "no" for the subject to be considered eligible.	

Visit 1: Baseline			
Step	Procedure	Details	
1.6	PRO Baseline Questionnaire	The subject will respond to the PRO Baseline (CLUE) Questionnaire	
1.7	Entrance Visual Acuity	Record the distance Snellen visual acuity (OD, OS, and OU) to the nearest letter with their habitual contact lens correction in place. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	
1.8	Remove Habitual Contact Lenses	The subject's habitual lenses will be removed and stored in their own lens case. If they forgot to bring their lens case, one will be provided to them.	
1.9	Iris Color	Record iris color in both eyes (self-reported)	
1.10	Horizontal visible iris diameter (HVID)	Measure the horizontal visible iris diameter for each eye separately using a pd stick in normal room illumination. Measure from the edge of the iris nasally to the edge of the iris temporally. Record in mm to one decimal place.	
1.11	Keratometry	Record the keratometry readings OD and OS.	
1.12	Subjective Spherocylindrical Refraction	Complete subjective spherocylindrical refraction and record the resultant distance visual acuity (OD, OS and OU) to the nearest letter. Note: The subjects contact lens powers based on the vertexed (12 mm), spherical equivalent must be between -1.00 and -6.00 D.	
1.13	Slit Lamp Findings	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. If any slit lamp findings are Grade 3 or higher, the subject is ineligible to continue. Continue to the Final Evaluation Form and dismiss the subject. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	
1.14	Eligibility after Baseline	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.	

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	
1.15	Lens Selection	Assign the study lens. Select the contact lens power based on the vertexed (12 mm), spherical equivalent subjective refraction.	
1.16	Lens Insertion	The Subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable. Note: Designated site staff should observe the insertion process. If it appears that the subject attempts to insert a lens that is “inside-out”, they should interfere to avoid incorrect insertion. Note 2: If the lens moves excessively on the eye after insertion, ask the subject to remove the lens, confirm lens is not inverted (correct if it is) and reinsert.	
1.17	Lens Settling	Allow the study lenses to settle for a minimum of 5 minutes.	
1.18	Subjective Best Sphere Over Refraction	Perform subjective best sphere refraction over the study lenses with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the best corrected distance visual acuity to the nearest letter (OD, OS, OU).	
1.19	Lens Power Modification (if applicable)	Adjust the lens power if the subject’s best sphere over-refraction is not plano. For each power modification, repeat steps (1.16 to 1.19). Two power modifications are allowed.	
1.20	Visual Acuity	Record the distance Snellen visual acuity (OD, OS, and OU) to the nearest letter with the study contact lens correction in place. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	
1.21	Distance ETDRS LogMAR Visual Acuity	[REDACTED] , please confirm room illuminance and chart luminance acceptable ranges for both high/low contrast visual acuity testing. 1. Under high illumination and high chart luminance, record the distance (4 meter)	

		<p>ETDRS high contrast visual acuity twice OD (HC1-HC2) and twice OS (HC3-HC4).</p> <p>2. Under high illumination and high chart luminance, record the distance (4 meter) ETDRS low contrast visual acuity twice OD (LC1-LC2) and twice OS (LC3-LC4).</p> <p>3. With the goggles on, under normal illumination and chart luminance, record the distance (4 meter) ETDRS high contrast visual acuity twice OD (HC5-HC26) and twice OS (HC7-HC8). Allow subject to adjust to dim condition for 3 minutes.</p> <p>Letter-by-letter results will be recorded into the electronic data capture form, which will calculate the visual performance score for each chart read.</p>	
1.22	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
1.23	Post-Fit Questionnaire	The subject will respond to the CLUE Post-Fit Questionnaire	
1.24	Cosmetic Lens Fit Assessment (without slit-lamp)	██████████ will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	
1.25	Hula Hoop Assessment (without slit-lamp)	██████████ will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	
1.26	Subjective Lens Fit Assessment	<p>Evaluate overall lens fit acceptance (acceptable/unacceptable) based on centration, movement and other fitting characteristics.</p> <p>An unacceptable fit will be any one or more of the following criteria:</p> <ul style="list-style-type: none"> • Presence of limbal exposure (appearance of clear cornea) in any gaze; 	

		<ul style="list-style-type: none"> • Presence of edge lift; • Presence of unacceptable movement (excessive or insufficient) in <u>all three</u> of the following conditions: primary gaze, up gaze, and Josephson push up. <p>Note: if lens fit is unacceptable subject will be discontinued from the study.</p>	
1.27	Wettability Characteristics	Record the white light lens wettability of both lenses.	████████
1.28	Surface Deposits	Record any front and back surface lens deposits.	████████
1.29	Continuance	<p>For the subject to continue in the study, they must meet all three of the following criteria:</p> <ul style="list-style-type: none"> • Visual acuity is 20/30 or better OD and OS • The lens fit is acceptable OD and OS • Investigator approval. If the Investigator does not approve the dispensing of the first study lens, then the study is terminated for that subject. 	
1.30	Dispense	<p>The lenses will be dispensed for a 12 ± 2 day wearing period.</p> <ul style="list-style-type: none"> • Subject is willing to wear the lenses for the dispensing period for 6 hours per day, and will not wear their habitual lenses during the dispensing period. • The lenses will be worn as daily wear only. • Subjects will be given Revitalens solution. • Rewetting drops are permitted if needed. • A patient instruction booklet will be provided. • Subjects will be scheduled for their 2-week follow-up visit, ensuring that they wear the study lens at least 6 hours on the day of the follow-up visit. <p>* Note: In the event a lens is lost or damaged, the subject will return to the clinical site for replacement. As much as reasonably possible, a damaged lens and packaging should be returned to the clinical site (wet, if possible) and then returned to the Sponsor. If lens damage is present, complete the Product</p>	

		Quality Complaint Form. The lens will be stored in labeled vial with saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.	
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VISIT 2

The subjects must present to Visit 2 wearing test article for at least six (6) hours on the day of the visit.

Visit 2: Treatment 1 Follow-Up			
Step	Procedure	Details	
2.1.	Adverse Events and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit. Record any adverse events or medical history changes from the previous study visit.	
2.2.	Wearing Time	Record the average wearing time and comfortable wearing time.	
2.3.	Compliance	Confirm compliance with the prescribed wear schedule.	
2.4.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	
2.5.	Follow-Up Questionnaire	The subject will respond to the CLUE Follow-Up Questionnaire	
2.6.	Entrance Visual Acuity	Record the distance Snellen visual acuity (OD, OS, and OU) to the nearest letter with study contact lens in place. Subjects must read the smallest line until at least 50% of the letters are read incorrectly.	
2.7.	Cosmetic Lens Fit Assessment (without slit-lamp)	██████████ will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	
2.8.	Hula Hoop Assessment (without slit-lamp)	██████████ will be assessed by the investigator (without slit-lamp) in primary gaze and extreme gaze (right, left, and upgaze) at a normal conversation distance (approximately three (3) feet away from the subject).	
2.9.	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting	

		<p>characteristics.</p> <p>An unacceptable fit will be any one or more of the following criteria:</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 three</u> of the following conditions: primary gaze, up gaze, and Josephson push up. <p>Note: if lens fit is unacceptable subject will be discontinued from the study.</p>	
2.10.	Wettability Characteristics	Record the white light lens wettability of both lenses.	██████
2.11.	Surface Deposits	Record any front and back surface lens deposits.	██████
2.12.	Remove lenses	The lenses will be removed and discarded.	

FINAL EVALUATION

The final evaluation will ordinarily take place immediately following the last scheduled follow-up visit per the study protocol. It may also take place at any point the subject discontinues the study or is terminated from the study.

Final Evaluation			
Step	Procedure	Details	
F.1	Final Exam Form	Indicate if the subject completed the study successfully. If subject discontinued from the study, indicate the reason.	██████
F.2	Subjective spherocylindrical Refraction	Perform bare-eye subjective spherocylindrical refraction with a phoropter and record the best corrected <u>distance</u> visual acuity to the nearest letter (OD, OS, and OU).	██████
F.3	Exit Slit Lamp Biomicroscopy	<p>FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility.</p> <p>If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.</p>	██████

7.3. Unscheduled Visits

If, during the investigation, a subject requires an unscheduled visit to the clinical site, 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 must be completed and subject record 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 test article dispensed or collected from the subject, if applicable
- 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 record must be completed documenting the date and primary reason for withdrawal and the study CRA notified.

Any ocular and non-ocular Adverse Events that are ongoing at the time of the study visit will be followed by the Investigator, within licensure, until they have resolved, 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.

The following information will be collected during an unscheduled visit.

Unscheduled Visit			
Step	Procedure	Details	
U.1	Chief Complaints	Record the subject's chief complaints for reasons for the unscheduled visit.	
U.2	Adverse Events and Concomitant Medications Review	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	
U.3	Entrance VA	Record the entrance distance visual acuity (OD, OS and OU) to the nearest letter.	
U.4	Subjective Spherocylindrical Refraction	Perform bare-eye subjective spherocylindrical refraction with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the best corrected <u>distance</u> visual acuity to the nearest letter (OD, OS, and OU).	
U.5	Slit Lamp Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be	

Unscheduled Visit			
Step	Procedure	Details	
		instilled.	
U.6	Dispensing (if applicable)	Additional lenses may be dispensed.	
U.7	Exit Visual Acuity	Record the subject's exit distance visual acuity (OD, OS, and OU) to the nearest letter.	

7.4. Laboratory Procedures

Not applicable.

8. SUBJECTS COMPLETION/WITHDRAWAL

8.1. Completion Criteria

Subjects are considered to have completed the study if they:

- provided informed consent and/or assent;
- they are eligible;
- Completed all three phases of testing;
- Have not withdrawn/discontinued from the study for any reason described in Section 8.2.

8.2. Withdrawal/Discontinuation from the Study

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

- Subject death during the study period
- Subject withdrawal of consent and/or assent
- Subject not compliant to protocol
- Subject lost to follow-up
- Subject no longer meets eligibility criteria (eg the subject becomes pregnant)
- Subject develops significant or serious adverse events causing discontinuation of study lens wear
- Subjects who have experienced a Corneal Infiltrative Event (CIE)
- Investigator's clinical judgment regarding the subject safety reasons (that it is in the best interest of the subject to stop treatment)

For discontinued subjects, the Investigator will:

- Complete the current visit (scheduled or unscheduled)
- Complete the Final Evaluation, indicating the reason that the subject was discontinued from the study
- Record the spherocylindrical refraction with best corrected distance visual acuity
- Collect used test article(s) (worn or brought to the visit) from the subject and discard them, unless otherwise stated in Section 7.2
- Collect all unused test article(s) from the subject

An additional subject may be enrolled if a subject discontinues from the study prematurely.

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 (or equivalent) as the final attempt.

9. PRE-STUDY AND CONCOMITANT INTERVENTION/MEDICATION

Concomitant medications will be documented during screening and updated during the study. Disallowed medications for this study include: Not applicable.
Concomitant therapies that are disallowed include: Not applicable.

10. DEVIATIONS FROM THE PROTOCOL

Investigator will notify study sponsor upon identification of a protocol deviation. Major protocol deviations must be reported to the sponsor within 24 hours after discovery of the protocol deviation. The Investigator will report deviations per IRB/IEC requirements. All deviations will be tracked and corrective actions implemented as appropriate.

If it becomes necessary for the Investigator to implement a deviation in order to eliminate an immediate hazard to the trial subject, the Investigator may implement the deviation immediately without notification to the sponsor. Within 24 hours after the implemented deviation, the Investigator must notify and provide the rationale to the Sponsor and, as required, the IEC/IRB.

11. STUDY TERMINATION

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

The Sponsor will 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 are compromised.

JJVC reserves the right to terminate the study at any time for any reason. Additionally, the IEC/IRB reserves the right to terminate the study if an unreasonable risk is determined. The study can be terminated by the Principal Investigator at the individual clinical site due to specific clinical observations, if in their opinion, after a discussion with JJVC, it is determined that it would be unwise to continue at the clinical site.

JJVC (and the IEC/IRB and DMC, 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 IEC/IRB and Regulatory Authority as required by local regulatory requirements.

12. PROCEDURE FOR HANDLING 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.

Potential complaints may come from a variety of sources including but not limited to subjects, clinical research associates (CRA), clinical operations managers (COM), medical monitors, and site personnel, etc. The following are not considered product quality complaints:

- Subject satisfaction inquiries reported via “Subjective Questionnaires” and “Patient Reported Outcomes (PRO)”
- Clinical test articles that are stored improperly or damaged after receipt at the investigational site
- Lens replacements that occur due to drops/fall-outs
- Damage deemed by clinicians or clinical staff to be caused by handling by the user, and not indicative of a quality deficiency (i.e. tears, rips, etc.), only in situations where there is no deficiency alleged by the subject

Within 24 hours of site personnel becoming aware that a PQC has occurred, the PQC must be recorded in the EDC system, which will trigger 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 or when an EDC system is not used, 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 will contact the study site to collect additional information which will include:

- Date the complaint was received/recorded in the EDC System (Date of Sponsor Awareness)
- Who received the complaint
- Study number
- Clinical 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 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) findings if applicable

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

Once a complaint is received, it will be assessed by the COM, CRA, or trained site personnel to determine if it is an Adverse Event/Serious Adverse Event (AE/SAE). If the complaint results in an AE/SAE, the COM/CRA, or trained site personnel will follow Section 13 of this protocol. If the AE/SAE was potentially the result of a product quality related deficiency, these procedures also apply and will be executed in parallel.

In some cases, a PQC form may be generated in EDC by the site in error. In this event, the PQC forms will be marked “Intentionally Left Blank” or “ILB”. Justification for ILB must be documented.

13. ADVERSE EVENTS

13.1. Definitions and Classifications

Adverse Event (AE) – An AE is “any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device.

Note 1 to entry: This definition includes events related to the investigational medical device or the comparator.

Note 2 to entry: This definition includes events related to the procedures involved.

Note 3 to entry: For users or other persons, this definition is restricted to events related to investigational medical devices.”¹

An AE includes any condition (including a pre-existing condition) that:

1. Was not present prior to the study, but appeared or reappeared following initiation of the study
2. Was present prior to the study, but worsened during the study. This would include any condition resulting from concomitant illnesses, reactions to concomitant medications, or progression of disease states
3. Pregnancy must be documented as an adverse event and must 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 (e.g., a sight threatening event, 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 test article 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 Ocular Serious Adverse Events include, but not limited to:

- Microbial Keratitis (MK)
- Iritis (including cells in the anterior chamber)
- 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 Ocular Significant Adverse Events include, but not limited to 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
- Non-contact lens related corneal events - e.g. Epidemic Keratoconjunctivitis (EKC)
- Asymptomatic Corneal Scar
- Any corneal event which necessitates temporary lens discontinuation > 2 weeks

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 Ocular Non-Significant Adverse Events include, but not limited to the following:

- Non-significant Infiltrative Event (NSIE)
- Contact Lens Papillary Conjunctivitis (CLPC)

- Superficial Punctate Keratitis (SPK)
- 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) – An ADE is an “adverse event related to the use of an investigational medical device.

Note 1 to entry: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.

Note 2 to entry: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.”¹

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.

13.2. Assessing Adverse Events

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/Classifications (see definition in Section 13.1)
- Causality or Relatedness – i.e. the relationship between the test article, study treatment or study procedures and the adverse event (not related; unlikely related; possibly related; related - see definition in Section 13.2.1)
- Adverse Event Severity – Adverse event severity is used to assess the degree of intensity of the adverse event (mild; moderate; severe for all events - see definition in Section 0)
- Outcome – not recovered or not resolved; recovering or resolving; recovered or resolved with sequelae; recovered or resolved; death related to adverse event; unknown
- Actions Taken – none; temporarily discontinued; permanently discontinued; other

13.2.1. Causality Assessment

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, study treatment or study procedures

- Unlikely Related – 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
- Possibly Related – An adverse event that might be due to the use of the test article, or to the study treatment or study procedures. 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
- Related – 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 of concomitant disease(s). The relationship in time is very suggestive, e.g. it is confirmed by de-challenge and re-challenge

13.2.2. Severity Assessment

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, study treatment or study procedure 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

13.3. Documentation and Follow-Up of Adverse Events

The recording and documenting of adverse events (ocular and non-ocular) begins when the subjects are exposed to the test article, study treatment or study procedure. Adverse events reported before the use of test article, start of study treatment, or study procedures will be recorded as medical history. However, if the condition deteriorates at any time during the study it will be recorded and reported as an AE. Untoward medical events reported after the subject’s exit from the study will be recorded as adverse events at the discretion of the Investigator.

Upon finding an adverse event, the Principal Investigator will document the condition in the subject record and in the eCRFs. He/she will complete the Adverse Event /eCRF.

Complete descriptions of all adverse events must be available in the subject record. All Adverse Events including local and systemic reactions not meeting the criteria for “serious adverse events” shall be captured on the appropriate case report form or electronic data system. All adverse events occurring while the subject is enrolled in the study must be documented appropriately regardless of relationship.

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)
- Drawings or photographs (where appropriate) that detail the finding (e.g., size, location, and depth, etc.)
- Date the clinical site was notified
- Date and time of onset
- Date and time of resolution
- Adverse event classification, severity, and relationship to test articles, 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, he/she will complete the Corneal Infiltrate Assessment 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, the date of culture collection and laboratory utilized will be recorded.

Changes in the severity of an AE shall 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 Test Article shall also be clearly documented.

Subjects who present with an adverse event shall 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 beyond licensure is required, the patient will be referred to the appropriate health care provider. The Investigator will use his/her clinical judgment as to whether a subject reporting with an adverse event will 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 document the adverse event appropriately and complete the Adverse Event eCRF. Any subjects with ongoing adverse events related to the test article, study treatment or study procedures, 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. Non-ocular adverse events that are not related to the test article, study treatment, or study procedures may be recorded as "ongoing" without further follow-up.

13.4. Reporting Adverse Events

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 any serious

/significant adverse events, and 2 days from discovery for any non-significant adverse event. In addition, a written report will be submitted by the Principal Investigator to the IEC/IRB according to their requirements (Section 13.4.2). The report will comment whether the adverse event was considered to be related to the test article, study treatment or study procedures.

13.4.1. Reporting Adverse Events to Sponsor

Serious/Significant Adverse Events

The Investigator will inform the sponsor of all serious/significant 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 eCRF. All subjects experiencing a serious/significant 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/significant adverse event, the Investigator must:

- Notify the Sponsor immediately
- Obtain and maintain in the subject's records all pertinent medical 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 test article
- Notify the IEC/IRB as required by the IEC/IRB 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 IEC/IRB 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 IEC/IRB and participating Investigators within 10 working days after the Sponsor first receives notification of the effect.

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 2 days from discovery.

13.4.2. Reporting Adverse Events to the Responsible IEC/IRB and Health Authorities

Adverse events that meet the IEC/IRB requirements for reporting must be reported within the IEC/IRB's written guidelines. Each clinical site will refer to and follow any guidelines set

forth by their Approving IEC/IRB. Each clinical site will refer to and follow any guidelines set forth by their local governing Health Authorities.

The Sponsor will report applicable Adverse Events to the local health authorities according to the written guidelines, including reporting timelines.

13.4.3. Event of Special Interest

Not applicable.

13.5. Reporting of Pregnancy

Subjects reporting pregnancy (by self-report) during the study will be discontinued after the event is recorded as an Adverse Event. Once discontinued, pregnant participants and their fetuses will not be monitored for study related purposes. At the Investigator's discretion, the study participant may be followed by the Investigator through delivery. However, this data will not be collected as part of the clinical study database. Pregnant participants 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.

14. STATISTICAL METHODS

14.1. General Considerations

Statistical analysis will be undertaken by the study biostatistician. A general description of the statistical methods to be implemented in this clinical trial is outlined below.

All data summaries and statistical analyses will be performed using the SAS software Version 9.4 (SAS Institute, Cary, NC). Throughout the analysis of data, the results for each subject/eye will be used when available for summarization.

Summary tables (descriptive statistics and/or frequency tables) will be provided for all baseline variables, efficacy variables, and safety variables as appropriate. Continuous variables will be summarized with descriptive statistics (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.

Further exploratory analysis can be undertaken, if necessary, at the discretion of the clinical project leader.

14.2. Sample Size Justification

This pilot study is not powered to test for any planned hypotheses. Hence, the sample size was chosen based on availability of time and resources. Targeting 20 subjects to complete the study will be sufficient to evaluate descriptive summaries of study endpoints.

14.3. Analysis Populations

Safety Population:

All subjects who were administered any test article excluding subjects who drop out prior to administering any test article. At least one observation should be recorded.

Per-Protocol Population:

All subjects who have successfully completed all visits 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 of excluding subjects with protocol deviations in the per-protocol population set will be documented in a memo to file.

Intent-to-Treat (ITT) Population:

All randomized subjects regardless of actual treatment and subsequent withdrawal from study or deviation from protocol. At least one observation should be recorded.

14.4. Level of Statistical Significance

All planned analysis for this study will be conducted with an overall type I error rate of 5%.

14.5. Primary Analysis

LogMAR objective vision (high illumination/high contrast) will be descriptively summarized.

14.6. Secondary Analysis

Not applicable.

14.7. Other Exploratory Analyses

Other observations will be descriptively summarized. These will include:

Subjective Vision (CLUE)

Subjective Comfort (CLUE)

Subjective Handling (CLUE)

LogMAR objective vision (high illumination/low contrast, low illumination/high contrast)

Mechanical Lens fit

Cosmetic Lens fit/Hula Hoop

Ocular Physiology

Further statistical exploratory analysis can be undertaken, if necessary, at the discretion of the clinical project leader.

14.8. Interim Analysis

Not applicable.

14.9. Procedure for Handling Missing Data and Drop-Outs

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

14.10. Procedure for Reporting Deviations from Statistical Plan

The analysis will be conducted according to that specified in above sections. 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.

15. DATA HANDLING AND RECORD KEEPING/ARCHIVING

15.1. Electronic Case Report Form/Data Collection

The data for this study will be captured on electronic case report forms (eCRFs) using an EDC system (Bioclinica Express 5.5). An authorized data originator will enter study data into the eCRFs using the EDC system. Data collected on equipment that is not captured in EDC will be formatted to the specification of the JJVC database manager and sent to JJVC for analysis.

External Data Sources for this study include: Not Applicable

The clinical data will be recorded on dedicated eCRFs specifically designed to match the study procedures for each visit. Once completed, the eCRFs will be reviewed for accuracy and completeness and signed by the Investigator. The sponsor or sponsor's representatives will be authorized to gain access to the subject recordation for the purposes of monitoring and auditing the study.

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 clinical site to a secure central database as forms are completed or updated, ensuring information accuracy, security, and confidentiality. After the final database lock, the Investigator will be provided with Individual Patient Profiles (IPP) including the full audit trail on electronic media in PDF format for all of the study data. The IPP must be retained in the study files as a certified copy of the source data for the study.

The content and structure of the eCRFs are compliant with ISO14155:2011.¹

15.2. Subject Record

At a minimum, subject record should be available for the following:

- subject identification
- eligibility
- 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

- medical history and concomitant medication
- test article receipt/dispensing/return records
- date of study completion
- reason for early discontinuation of test article or withdrawal from the study, if applicable

The subject record is the eCRF or an external record. The author of an entry in the subject record must be identifiable. The first point of entry is considered to be the source record.

Adverse event notes must be reviewed and initialed by the Investigator.

16. DATA MANAGEMENT

16.1. Access to Source Data/Document

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

16.2. 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 JJVC. The Investigator may use this information for the purposes of the study only. It is understood by the Investigator that JJVC 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.

16.3. Data Quality Assurance

Steps will be taken to ensure the accuracy and reliability of data, include the selection of qualified investigators and appropriate clinical sites and review of protocol procedures with the Principal Investigator. The Principal Investigator, in turn, must ensure that all Sub-Investigators and clinical site personnel are familiar with the protocol and all study-specific procedures and have appropriate knowledge of the study article.

Training on case report form completion will be provided to clinical site personnel before the start of the study. The Sponsor will review case report forms for accuracy and completeness remotely during the conduct of the study, 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 JJVC may visit clinical sites to review data produced during the study and to access compliance with applicable regulations pertaining to the

conduct of clinical trials. The clinical sites will provide direct access to study-related source data/documents and reports for the purpose of monitoring and auditing by JJVC and for inspection by local and regulatory authorities.

17. MONITORING

The study monitors will maintain close contact with the Principal Investigator and the Investigator's designated clinical site personnel. The monitor's responsibilities will include:

- Ensuring that the investigation is being conducted according to the protocol, any subsequent amendments, and regulatory requirements are maintained
- Ensuring the rights and wellbeing of subjects are protected
- Ensuring adequate resources, including facilities, laboratories, equipment, and qualified clinical site personnel
- Ensuring that protocol deviations are documented with corrective action plans, as applicable
- Ensuring that the clinical site has sufficient test article and supplies
- Clarifying questions regarding the study
- Resolving study issues or problems that may arise
- Reviewing of study records and source documentation verification in accordance with the monitoring plan

18. ETHICAL AND REGULATORY ASPECTS

18.1. 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. Subjects 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.

18.2. Investigator Responsibility

The Principal Investigator is responsible for ensuring that the clinical study is performed in accordance with the signed agreement, the investigational plan, Section 4 of the ICH E6 guidelines on Good Clinical Practice (GCP),² and applicable regulatory requirements. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation 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 64th WMA General Assembly 2013³ 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),² and applicable regulatory requirements.

18.3. 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
- 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 recruitment materials approved by the Sponsor
- Revisions to compensation for study-related injuries or payment to subjects for participation in the study
- 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 test articles, 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 clinical 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 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 retained at the clinical site and a copy provided to the CRO or Sponsor as applicable.

18.4. 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 is in accordance with principles that originated in the Declaration of Helsinki,³ current ICH² and ISO 14155¹ guidelines, applicable regulatory requirements, and Sponsor Policy.

Before entry into the study, the Investigator or an authorized member of the clinical site personnel must explain to potential subject 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.

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.

18.5. 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 clinical site personnel (e.g., name, clinic address and phone number, curriculum vitae) is subject to compliance with the Health Information Portability and Accountability Act (HIPAA) in the United States⁴ 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, Sponsor's personnel and IEC/IRB. 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), IEC/IRB and regulatory organizations in the context of their investigation related activities that, as part of the investigation will have access to the CRFs and subject records.

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.

19. STUDY RECORD RETENTION

In compliance with the ICH/GCP guidelines,² the Investigator/Institution will maintain all CRFs and all subject records that support the data collected from each subject, as well as all study documents as specified in ICH/GCP² and all study documents as specified by the applicable regulatory requirement(s). The Investigator/Institution will take measures to prevent accidental or premature destruction of these documents.

Essential documents must be retained until at least two (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 two (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 instructed by 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/she should contact JJVC.

20. FINANCIAL CONSIDERATIONS

Remuneration for study services and expenses will be set forth in detail in the Clinical Research Agreement. The Research Agreement will be signed by the Principal Investigator and a JJVC management representative prior to study initiation.

JJVC 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

JJVC reserves the right to withhold final remuneration until all study related activities have been completed, such as:

- Query resolution
- Case Report Form signature
- Completion of any follow-up action items

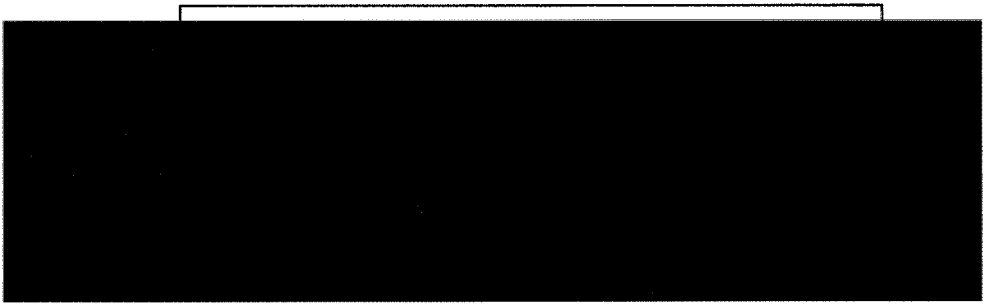
21. PUBLICATION

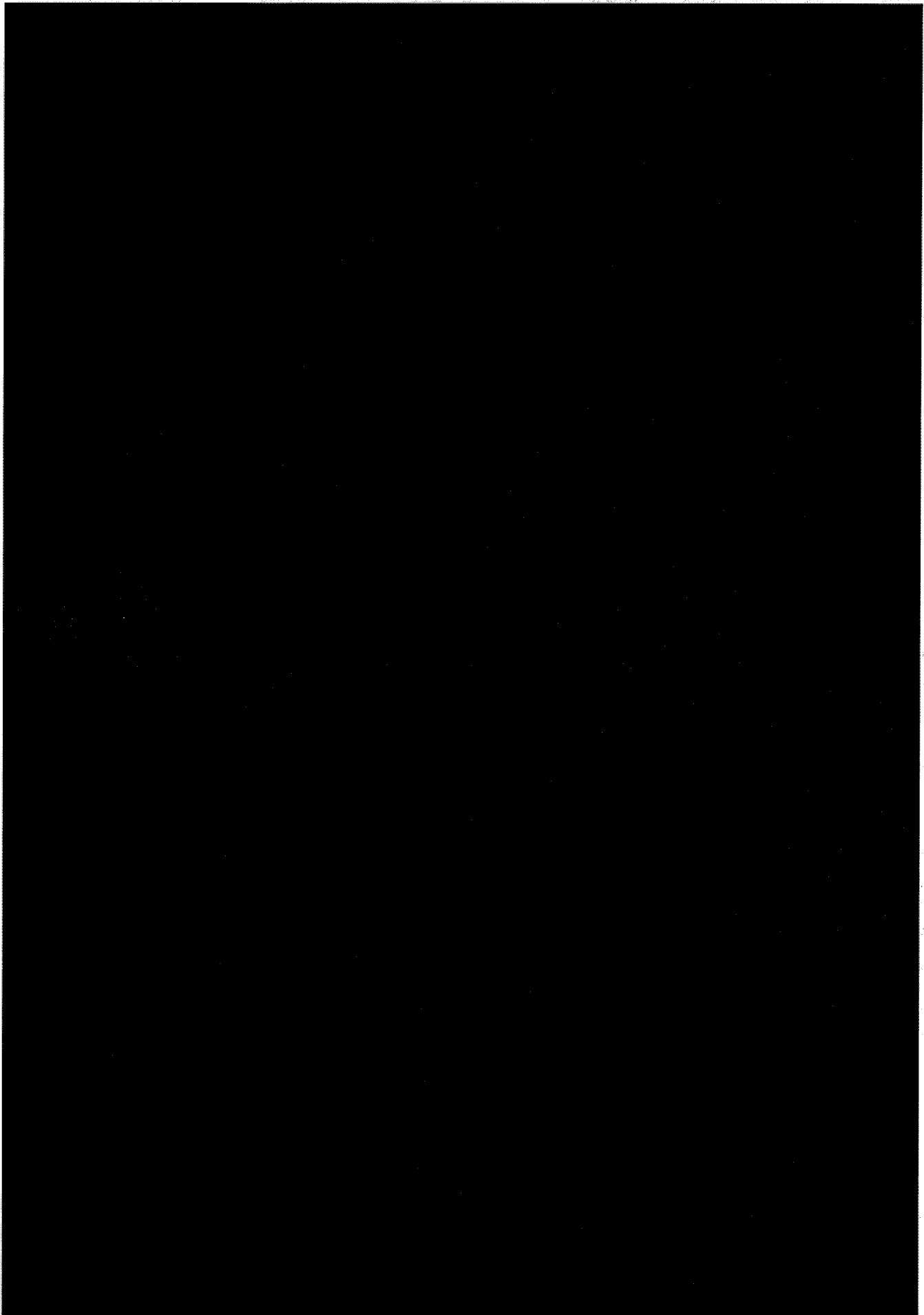
This study will be registered on ClinicalTrials.gov by the Sponsor.

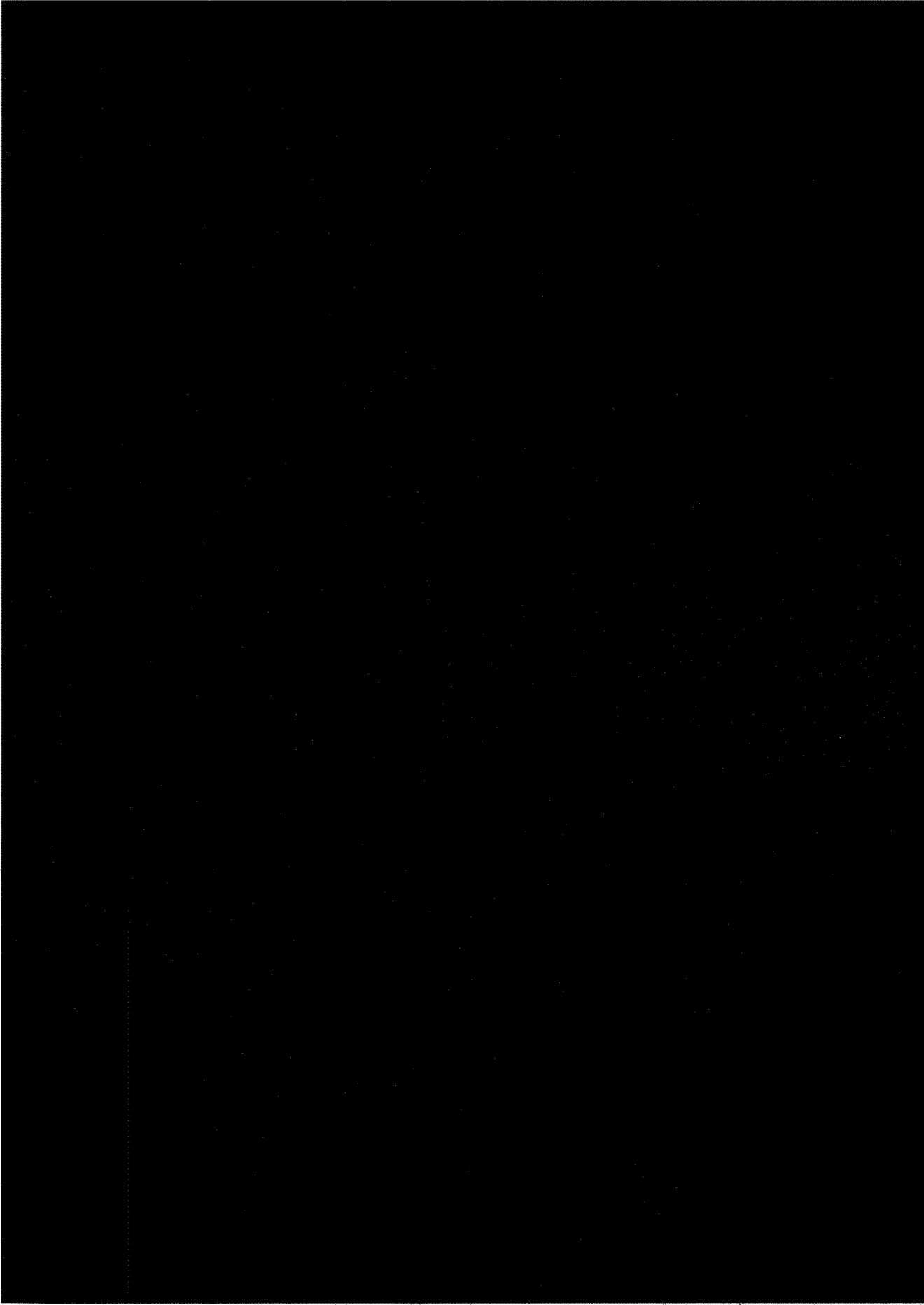
22. REFERENCES

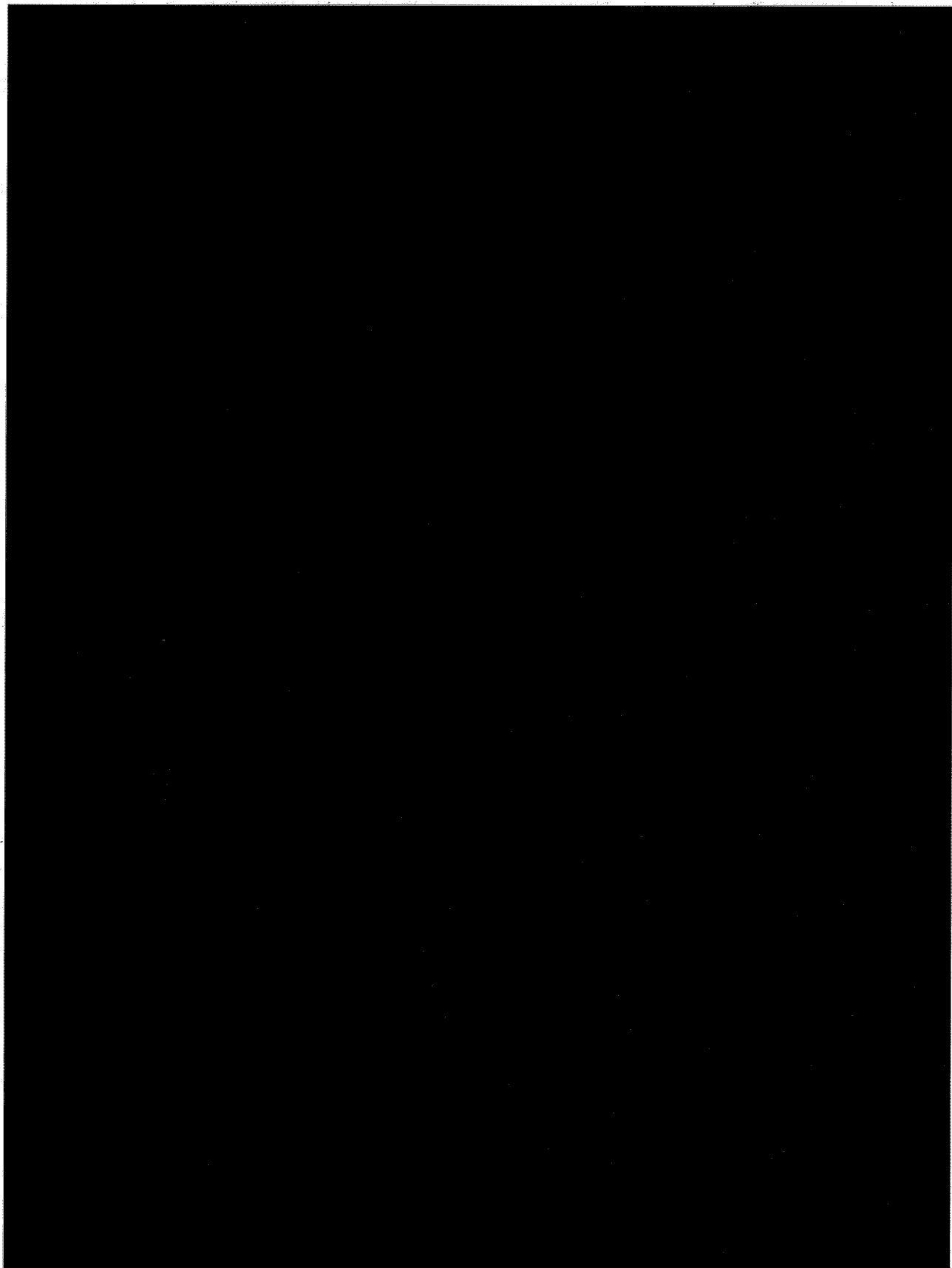
1. ISO 14155:2011: Clinical Investigation of Medical Devices for Human Subjects — Good Clinical Practice. Available at: <https://www.iso.org/standard/45557.html>
2. International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP). Available at: <http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html>
3. Declaration of Helsinki - Ethical principles for Medical Research Involving Human Subjects. Available at: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
4. United States (US) Code of Federal Regulations (CFR). Available at: <https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>
5. Health Information Portability and Accountability Act (HIPAA). Available at: <https://www.hhs.gov/hipaa/for-professionals/privacy/index.html>

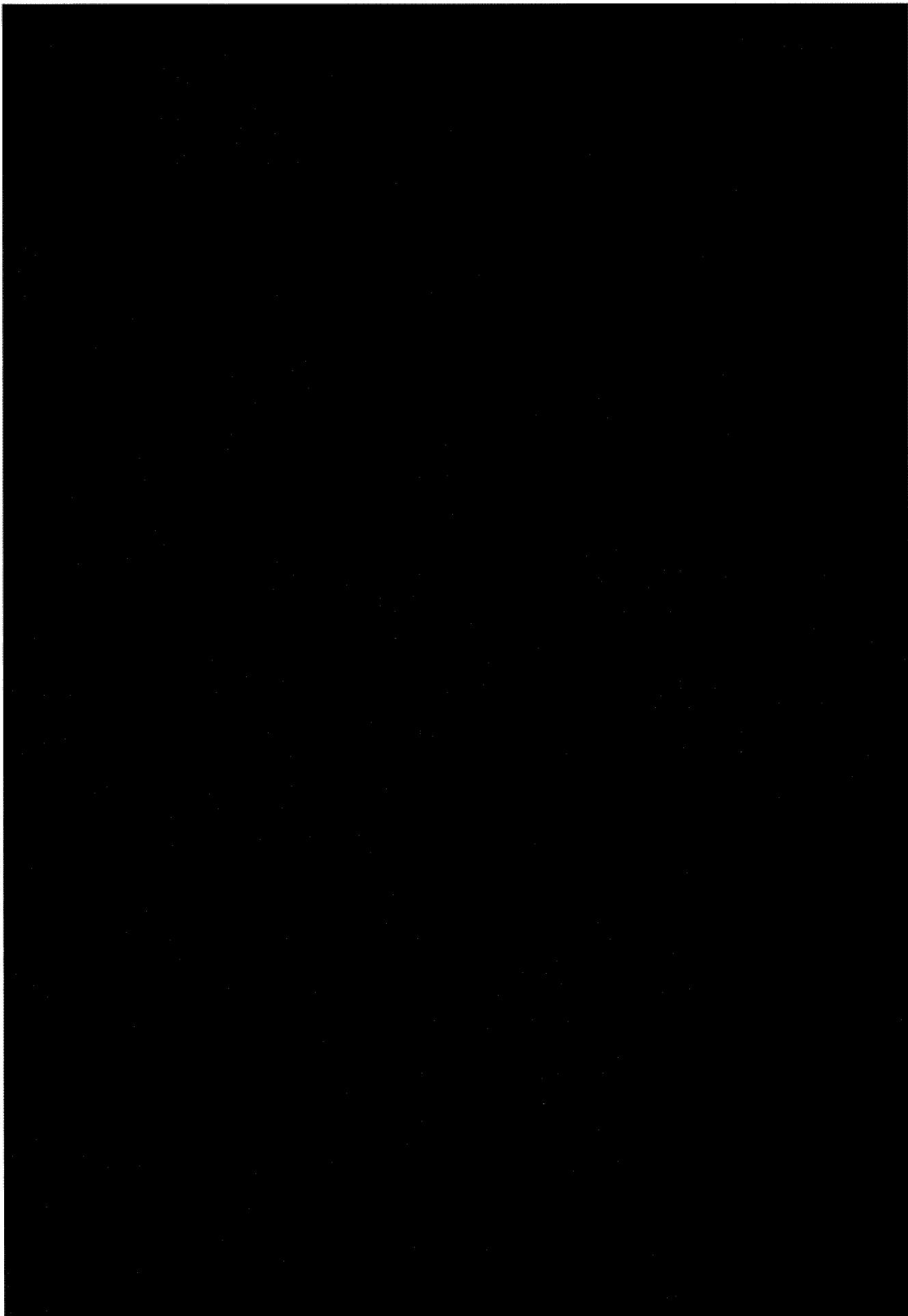


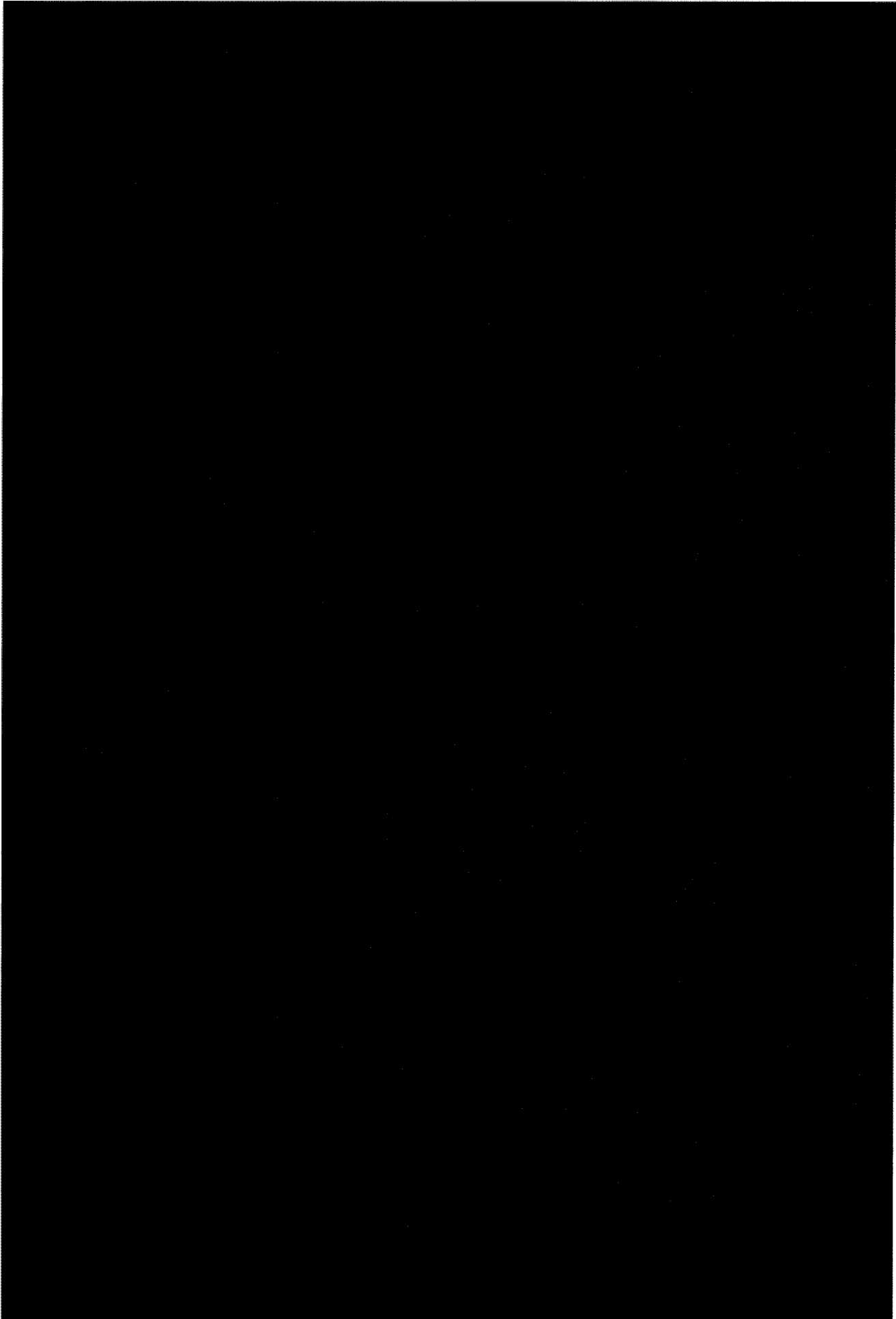


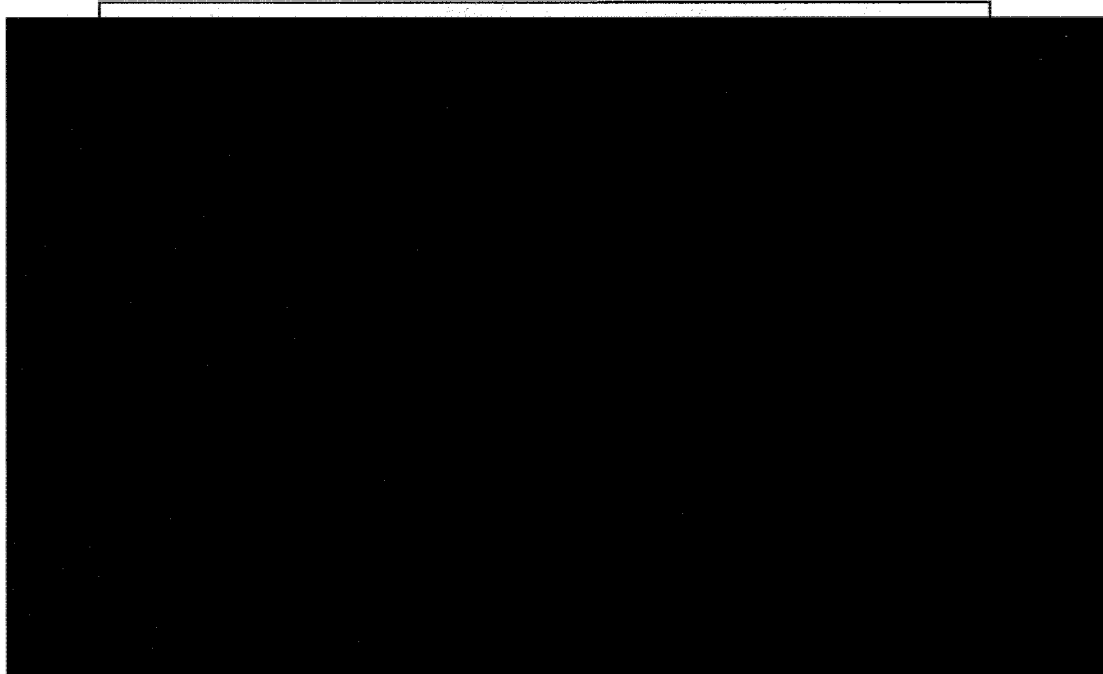












APPENDIX B: PATIENT INSTRUCTION GUIDE

To be provided separately.

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

Acuvue 2 Vivid Style

the Eye Care Professional's office, the patient should be instructed to remove the lenses or should have someone else available to remove the lenses for him or her.

If the sterile blister package is opened or damaged, and the hands are not washed before handling lenses, do not get lenses, ointments, creams, deodorants, or sprays in the eyes. It is best to put on lenses before putting on makeup. Cosmetics are less likely to damage lenses than oil-based cosmetics.

When contact lenses with the fingers or hands if the hands are clean and dry, use the lens materials, as microscopic scratches of the lenses may cause distorted vision and/or injury to the eye.

When handling, insertion, removal, cleaning, disinfecting, or wearing instructions in the "Patient Instruction Guide" for the lens care regimen and those prescribed by the Eye Care Professional should be followed.

When lenses are removed, do not drop them. Lenses should be removed carefully and avoid dropping them.

When using other tools to remove lenses from the lens container, use the specific instructions for that use. Slide the lens up the side of the lens container. If it is free of the container.

When cleaning the lens with fingernails.

Precautions:

- Do not use (stops moving) on the eye, follow the recommended instructions for a Stopping (Non-Moving) Lens. The lens should be used for the eye for the continued health of the eye. If non-movement continues, the patient should be instructed to immediately see the Eye Care Professional.

When using the lens care regimen recommended by the Eye Care Professional, the patient should be instructed to wear the lenses beyond the period recommended by the Eye Care Professional.

When the patient is advised to never allow anyone else to wear their lenses.

LENS CARE DIRECTIONS

The Eye Care Professional should provide appropriate and adequate warnings and instructions in the individual patient's lens type and wearing schedule. The professional should recommend an appropriate care system that meets the individual requirements.

When handling contact lens, care, cleaning, and storage, refer to the "Patient Instruction Guide" for the lens care regimen. Copies are available for download at www.acuvue.com.

When Prescribed for Frequent Replacement Wear:

The professional should review with the patient, the lens care regimen, disinfecting, and storing, including both basic lens care and specific instructions on the lens care regimen recommended by the Eye Care Professional.

When Prescribed for Disposable Wear:

The professional should review with the patient that no cleaning is needed with disposable lenses. Patients should always use the lenses as when they are removed and have spare lenses or spectacles when they are cleaned, rinsed, and disinfected. Lenses should only be cleaned, rinsed, and disinfected on a daily basis when replacement lenses or spectacles are not worn.

Out (Dehydrated) Lenses

When the lens is off the eye and exposed to air from the lens care regimen, its surface will become dry and gradually stiffen. If this should occur, discard the lens and use a new lens.

(Non-Moving) Lenses

When the lens is off the eye and exposed to air from the lens care regimen, the patient should be instructed to apply the lens to the eye.

When the patient is wearing contact lenses, exercise caution and keep eyes closed until the spray has settled.

When the patient is wearing contact lenses, avoid all harmful or irritating vapors and fumes while wearing lenses.

When the patient is wearing contact lenses, always discard lenses worn as prescribed by the Eye Care Professional.

When the patient is wearing contact lenses, use the following instructions:

When the patient is wearing contact lenses, different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.

When the patient is wearing contact lenses, never use solutions recommended for conventional hard contact lenses.

When the patient is wearing contact lenses, chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.

When the patient is wearing contact lenses, always use fresh, unexpired lens care solutions and lenses.

When the patient is wearing contact lenses, do not change solution without consulting with the Eye Care Professional.

When the patient is wearing contact lenses, always follow directions in the package insert for the use of contact lens solutions.

When the patient is wearing contact lenses, use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the contact lenses.

When the patient is wearing contact lenses, sterile unpreserved solutions, when used, should be discarded after the time specified in the directions.

When the patient is wearing contact lenses, do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.

When the patient is wearing contact lenses, always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will reduce the ability of the lens surface to return to a wearable state. Follow the lens care directions in "Care for A Dehydrated (Dried Out) Lens" if lens surface does become dried out.

EMERGENCIES

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

HOW SUPPLIED

ACUVUE[®] 2, ACUVUE[®] BIFOCAL, 1-DAY ACUVUE[®], and SUREVUE[™] Contact Lenses:

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. The plastic package is marked with base curve, diopter power, diameter, lot number, and expiration date.

1-DAY ACUVUE[®] for ASTIGMATISM Contact Lenses:

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. The plastic package is marked with base curve, diopter power, axis, cylinder, diameter, lot number, and expiration date.

ACUVUE[®] 2 COLOURS Contact Lenses:

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. The plastic package is marked with base curve, diopter power, diameter, lens color, lot number, and expiration date.

Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.

Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.

As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Who Should Know That the Patient is Wearing Contact Lenses?

Patients should inform all doctors (Health Care Professionals) about wearing a contact lens.

Patients should always inform their employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

occur when wearing contact lenses:

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first inserted.
- There may be a feeling of something in the eye (foreign body or scratch).

- There may be the potential for some temporary impairment of vision, peripheral corneal edema, or corneal infiltrates, peripheral corneal ulcers, or corneal abrasions. There may be the potential for other physiological changes such as local or generalized edema, corneal neovasculation, corneal staining, injection, tarsal abnormalities, iris, and pupil; some of which are clinically acceptable in low air humidity.
- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around lights, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

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

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

If the patient reports any problems, he or she should be instructed to **IMMEDIATELY REMOVE THE LENS**. If the problem or discomfort continues, the patient should discard the lens and place a new fresh lens. If after inserting the new lens, the problem continues, the patient should be instructed to **IMMEDIATELY REMOVE THE LENS AND CONTACT THE EYE CARE PROFESSIONAL**.

REPORTING OF ADVERSE REACTIONS

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

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
Tel: 1-800-943-2020
www.acuvue.com

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
Tel: 1-800-943-2020
www.acuvue.com



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Revised
Revision number

JE[®] Brand, and SUREVUE[™] Brand soft (hydrophilic) contact lenses available as spherical lenses. The ACUVUE[®] Brand BIFOCAL (bifocal) contact lenses are available as spherical bifocal lenses. The ACUVUE[®] Brand for ASTIGMATISM soft (hydrophilic) contact lenses are available as toric lenses.

ACUVUE[®] Brand (laticon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1,1,1-trimethylololpropanetriacrylate and ethylene glycol dimethacrylate.

ACUVUE[®] Brand lenses are tinted blue using Reactive Blue Dye #4 to make the lenses more comfortable to wear. The ACUVUE[®] 2 COLOURS Brand Contact Lenses are available in a pigmented area that will mask or enhance the color of the lens. The lens is colored with one or more of the following pigments: iron oxides, titanium dioxide, phthalocyanine (Zn), phthalocyanine green, vat orange 1, and Reactive Blue Dye #4. The ACUVUE[®] 2 COLOURS Brand Contact Lenses are available in the following colors: Blue, Gray, Green, Honey, Chestnut, Hazel, and Amber. They are also available in the following enhancer colors: Blue, Green, and Amber.

ACUVUE[®] Brand UV absorbing monomer is used to block UV radiation. The following table shows the UV absorption characteristics of the lenses.

Wavelength (nm)	UVB in the range of 316 nm to 380 nm	UVA in the range of 280 nm to 315 nm
316	82%	97%
320	86%	98%
330	88%	99%
340	81%	97%
350	82%	97%
360	82%	97%
380	87%	99%

INDICATIONS (USES)

ACUVUE[®] Brand contact lenses are described by brand name below. The definitions of the terms used are extended wear within these indications follow:

- WEAR: 1 to 7 days/6 nights of continuous wear while asleep.**
- R: Periods of less than 1 day while awake.**
- ACUVUE[®] Brand and SUREVUE[™] Brand Contact Lenses are indicated for use for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in phakic or aphakic persons with non-diseased eyes who do not have any of the following conditions:**
 - Brand Contact Lens BIFOCAL is indicated for daily and extended wear for the correction of distance and near vision in presbyopic persons with non-diseased eyes who may have 0.75D of astigmatism.
 - Brand Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in phakic and aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.
 - Brand Contact Lens is indicated for daily disposable wear for the correction of refractive ametropia (myopia and hyperopia) in phakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.
 - Brand Contact Lens for ASTIGMATISM is indicated for daily wear for the correction of visual acuity in phakic or aphakic persons with non-diseased eyes who are hyperopic or myopic with 0.50D to 2.50D of astigmatism.
 - Brand Contact Lens is indicated for daily and extended wear to enhance or alter the apparent color of the eye and/or for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in phakic or aphakic persons with non-diseased eyes who do not have any of the following conditions:

- Specific Gravity (calculated): 0.98 – 1.12
- ACUVUE[®] BIFOCAL: 0.98 – 1.13
- ACUVUE[®] 2 COLOURS: 1.40
- Refractive Index: 1.40
- Visible Light Transmission: 85% minimum, visibility tint 95% minimum, clear greater than 70%, color Hydrophilic
- Surface Character: 58%
- Water Content: 58%
- Oxygen Permeability: 58%

METHOD

VALUE
28.0 x 10⁻¹¹ (cm²/sec) (ml O₂/ml x mm Hg) at 35°C
21.4 x 10⁻¹¹ (cm²/sec) (ml O₂/ml x mm Hg) at 35°C

Lens Parameters:
These lenses are hemispherical or hemitoric shells of the following dimensions:
• Diameter Range: 12.0 mm to 15.0 mm
• Center Thickness: varies with power
• Base Curve Range: 7.85 mm to 10.00 mm
• Spherical Power Range: Daily Wear: -20.00D to +20.00D
Extended Wear: -20.00D to +14.00D

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

Frequent Wear Replacement:

When prescribed for frequent/planned replacement wear (see "Replacement Schedule"), the contact lenses are to be cleaned, rinsed, and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the contact lens may be disinfected using a chemical disinfection system only.

Disposable Wear:

When prescribed for disposable wear (see "Replacement Schedule"), the contact lenses are to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

- DO NOT USE these contact lenses when any of the following conditions exist:**
- Acute or subacute inflammation or infection of the anterior chamber of the eye.
 - Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids.
 - Severe insufficiency of lacrimal secretion (dry eye).
 - Corneal hypoaesthesia (reduced corneal sensitivity).
 - Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
 - Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
 - Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e., cleaning and disinfecting solutions, rewetting drops, etc.) that contain chemicals or preservatives (such as mercury, Thimerosal, etc.) to which some people may develop an allergic response.

- Cylinder Power Range: -0.25D to -10.00D
- Axis Range: 2.5° to 180°
- ACUVUE[®] BIFOCAL: -0.25D to +4.00D
- Bifocal ADD Power Range: 1.8 mm to 13.0 mm Diameter Range:

AVAILABLE LENS PARAMETERS

Base Curve	Diameter	Power Range
8.4 mm, 8.8 mm	14.0 mm	-0.50D to -6.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments)
8.8 mm	14.0 mm	-9.50D to -11.00D (in 0.50D increments)
9.1 mm	14.4 mm	+0.50D to +6.00D (in 0.25D increments) +6.50D to +8.00D (in 0.50D increments)

ACUVUE[®] Contact Lenses BIFOCAL

8.5 mm	14.2 mm	+6.00D to -9.00D (in 0.25D increments)
		(Labelled Power = Measured Distance Power +0.25D)
		ADD Powers: +1.00D to +2.50D (in 0.50D increments)
		(Labelled Power = Measured ADD Power -0.50D)

WARNINGS

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

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

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

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

- When prescribed for daily wear, patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when lenses are worn overnight, and that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users.³
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.

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

- 8.3 mm, 8.7 mm 14.0 mm
- 0.50D to -12.00D (in 0.25D increments)
-6.50D to -10.00D (in 0.50D increments)
+0.50D to +6.00D (in 0.25D increments)
+6.50D to +8.00D (in 0.50D increments)

ACUVUE[®] 2 COLOURS Contact Lenses

- 8.3 mm, 8.7 mm* 14.0 mm
- Plano to -6.00D (in 0.25D increments)
-6.50D to -9.00D (in 0.50D increments)
+0.25D to +6.00D (in 0.25D increments)

1-DAY ACUVUE[®] Contact Lenses

- 8.5 mm, 9.0 mm 14.2 mm
- 0.50D to -6.00D (in 0.25D increments)
-6.50D to -12.00D (in 0.50D increments)
+0.50D to +6.00D (in 0.25D increments)

1-DAY ACUVUE[®] Contact Lenses for ASTIGMATISM

- 8.5 mm 14.5 mm
- Plano to -6.00D (in 0.25D increments)
Cylinders: -0.75D, -1.25D, -1.75D, -2.25D, -2.75D, -3.25D, -3.75D, -4.25D, -4.75D, -5.25D, -5.75D, -6.25D, -6.75D, -7.25D, -7.75D, -8.25D, -8.75D, -9.25D, -9.75D, -10.25D, -10.75D, -11.25D, -11.75D, -12.25D, -12.75D, -13.25D, -13.75D, -14.25D, -14.75D, -15.25D, -15.75D, -16.25D, -16.75D, -17.25D, -17.75D, -18.25D, -18.75D, -19.25D, -19.75D, -20.25D, -20.75D, -21.25D, -21.75D, -22.25D, -22.75D, -23.25D, -23.75D, -24.25D, -24.75D, -25.25D, -25.75D, -26.25D, -26.75D, -27.25D, -27.75D, -28.25D, -28.75D, -29.25D, -29.75D, -30.25D, -30.75D, -31.25D, -31.75D, -32.25D, -32.75D, -33.25D, -33.75D, -34.25D, -34.75D, -35.25D, -35.75D, -36.25D, -36.75D, -37.25D, -37.75D, -38.25D, -38.75D, -39.25D, -39.75D, -40.25D, -40.75D, -41.25D, -41.75D, -42.25D, -42.75D, -43.25D, -43.75D, -44.25D, -44.75D, -45.25D, -45.75D, -46.25D, -46.75D, -47.25D, -47.75D, -48.25D, -48.75D, -49.25D, -49.75D, -50.25D, -50.75D, -51.25D, -51.75D, -52.25D, -52.75D, -53.25D, -53.75D, -54.25D, -54.75D, -55.25D, -55.75D, -56.25D, 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FITTING & PATIENT
MANAGEMENT GUIDE

ACUVUE® 2 COLOURS™ Brand (etafilcon A)
Contact Lens



TABLE OF CONTENTS

Fitting and Patient Management Guide
For ACUVUE® 2 COLOURS™ Brand (etafilcon A) Contact Lenses
With UV Blocker For Daily and Extended Wear

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Package Insert attached to inside back cover.

INTRODUCTION AND PRODUCT DESCRIPTION

ACUVUE® 2 COLOURS™ Brand (silflcon A) Soft (hydrophilic) Contact Lenses are made from silflcon A with a water content of 50% by weight.

For a complete listing of available lens parameters, please refer to "AVAILABLE PARAMETERS".

See Package Insert for "Actions", "Contraindications", "Warnings", "Precautions", "Adverse Reactions" and "Patient Lens Care Directions".

CAUTION: Federal Law Restricts This Device To Sale By Or On The Order Of A Licensed Practitioner.

Product Description

The ACUVUE® 2 COLOURS™ Brand (silflcon A) Soft (hydrophilic) Contact Lens is available as a spherical lens. The lens material (silflcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1, 1, 1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate. The ACUVUE® 2 COLOURS™ Brand Contact Lens contains a pigmented area that will mask or enhance the color of the natural iris. The lens is colored with one or more of the following color additives: iron oxides, titanium dioxide, phthalocyanine (2-) copper, 6-thiopyranone green, vat orange 1 and reactive blue dye #4. The ACUVUE® 2 COLOURS™ Brand Contact Lens is available in the following opaque colors: Blue, Gray, Green and Honey. They are also available in the following enhancer colors: Blue, Green and Aqua.

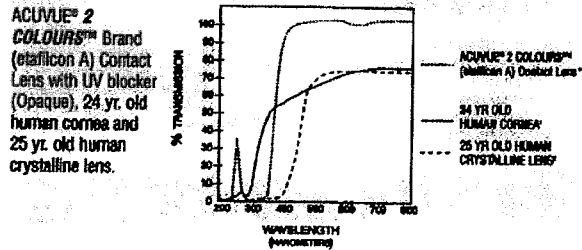
In the ACUVUE® 2 COLOURS™ Brand Contact Lens with UV Blocker, a benzotriazole UV-absorbing monomer is used to block UV radiation. The UV-blocking for ACUVUE® 2 COLOURS™ averages 97% in the UVB range of 280 nm to 315 nm and 81% in the UVA range of 316 nm to 380 nm.

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

AVAILABLE LENS PARAMETERS

Diameter: 14.0mm
 Center Thickness: Low minus lens - varies with power (e.g., -3.00D: 0.084mm)
 Base Curve: 8.3mm and 8.7mm (enhancers); 8.3mm (opaques)
 Powers: 0.00D
 -0.25D to -6.00D
 (in 0.25D increments)
 -6.50D to -9.00D
 (in 0.50D increments)
 +0.25D to +6.00D
 (in 0.25D increments)

TRANSMITTANCE CURVES



* The data was obtained from measurements taken through the central 3-6mm portion for the thinnest marketed lens (-3.00D ACUVUE® 2 COLOURS™ Contact lens, 0.064mm center thickness).

1. Lehman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21
2. Wuest, M. Hichins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1988, p. 10, figure 5

WEARING RESTRICTIONS AND INDICATORS

ACTIONS

See Package Insert for "Actions".

INDICATIONS (USES)

The ACUVUE® 2 COLOURS™ Brand Contact Lenses are indicated for daily and extended wear to enhance or alter the apparent color of the eye and/or for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

Eye Care Professionals may prescribe the lens for either single-use disposable wear or for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system only.

ACUVUE® 2 COLOURS™ UV-Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

ACUVUE® 2 COLOURS™ Brand Contact Lenses may be prescribed for either daily wear or extended wear from 1-7 days between removals for cleaning and disinfection or disposal, as recommended by the Eye Care Professional. Eye Care Professionals may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement (see "Wearing Schedule"). When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS

See Package Insert for "Contraindications", "Warnings", "Precautions" and "Adverse Reactions".

GENERAL FITTING GUIDELINES

PATIENT SELECTION

You should first assess the patient's needs and ensure that the patient is an appropriate candidate for the ACUVUE® 2 COLOURS™ Brand (standard A) Contact Lens. The ACUVUE® 2 COLOURS™ Brand Contact Lenses, like other soft contact lenses, will require the appropriate and usual physiological and diagnostic assessments necessary to ensure proper patient selection. Refer to the Package Insert for additional information on patient selection.

1. Pre-Fitting Examination

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

- Determine whether a patient is a suitable candidate for ACUVUE® 2 COLOURS™ Brand Contact Lenses (consider patient hygiene and mental and physical state), and
- Take ocular measurements for the initial contact lens parameter selection, and
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination may include a determination of optimal distance and near spectacle correction and corneal curvature measurements. The near correction should be determined at the midpoint of the patient's habitual reading distance. When more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers that meet the patient's requirements.

LENS SELECTION

A. Initial Power Determination

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

B. Enhancer Base Curve Selection (Total Lens Fitting)

The initial enhancer base curve selection for ACUVUE® 2 COLOURS™ Brand Contact Lenses may be either the 8.3 mm/14.0 mm or the 8.7 mm/14.0 mm base curve. Clinical tests suggest that the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm enhancer lenses provide better centration than that of the ACUVUE® 2 COLOURS™ 8.7 mm/14.0 mm enhancer lenses. Both provide similar movement characteristics on eyes with a wide range of corneal curvatures.

Insert either the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm or the 8.7 mm/14.0 mm enhancer lens on both of the patient's eyes and evaluate the lens fit characteristics after the patient has adjusted to the lenses. A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

A flat fitting enhancer lens may exhibit one or more of the following characteristics: decentration, not visible on the sclera, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If either the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm or the 8.7 mm/14.0 mm enhancer lens is judged to be flat fitting, the lens should not be dispensed to the patient. If the ACUVUE® 2 COLOURS™ 8.7 mm/14.0 mm enhancer lens is selected as the first trial lens, and is judged to be flat fitting,

the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm enhancer lens should be trial fit and evaluated after the patient has adjusted to the lenses.

A steep fitting enhancer lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation and resistance when pushing the lens up digitally with the lower lid. If either the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm or the 8.7 mm/14.0 mm enhancer lens is judged to be steep fitting, it should not be dispensed to the patient. If the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm enhancer lens is selected as the first trial lens, and is judged to be steep fitting, the ACUVUE® 2 COLOURS™ 8.7 mm/14.0 mm enhancer lens should be trial fit and evaluated after the patient has adjusted to the lenses.

C. Opaque Base Curve (Trial Lens Fitting)

The opaque base curve for ACUVUE® 2 COLOURS™ Brand Contact Lenses is 8.3 mm/14.0 mm. Clinical tests suggest that the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm opaque lenses provide optimal centration, while maintaining adequate movement characteristics on eyes with a wide range of corneal curvatures.

Insert the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm opaque lens on both of the patient's eyes and evaluate the lens fit characteristics after the patient has adjusted to the lenses. A properly fit opaque lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released.

A flat fitting opaque lens may exhibit one or more of the following characteristics: decentration, opaque color overlapping the pupil area, tint visible on the sclera, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm opaque lens is judged to be flat fitting, it should not be dispensed to the patient.

A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation and resistance when pushing the lens up digitally with the lower lid. If the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm contact lens is judged to be steep fitting, it should not be dispensed to the patient.

D. Final Lens Power

To assess vision for patients in need of vision correction for ACUVUE® 2 COLOURS™ Brand Contact Lenses, ACUVUE® 2 Brand trial lenses should be used in accordance with the fitting procedures for ACUVUE® 2 lenses.

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

Example 1:	
Diagnostic lens (ACUVUE® 2):	-2.00 D
Spherical over-refraction	-0.25 D
Final lens power:	-2.25 D

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

In Summary:

- ACUVUE® 2 lenses may be used to determine the final lens power of the ACUVUE® 2 COLOURS™.
- ACUVUE® 2 COLOURS™ plano trial lenses may be used to assist patients in choosing a lens color.
- ACUVUE® 2 COLOURS™ plano trial lenses should be used to assess fit, cosmetic appearance, and vision/visual acceptance (for the patients who do not need vision correction).

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 anisometropia (greater than 1.00D) in one eye may not be a good candidate for monovision correction with the ACUVUE® 2 COLOURS® Brand (multifocal A) Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision correction. Monovision contact lens wear may not be optimal for 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. Off may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic alternatives, 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 and straight ahead and upward gaze that monovision contact lenses provide.

EYE SELECTION

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

A. Ocular Preference Determination Methods

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

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

Other methods include the refractive error method and the visual demands method.

B. Refractive Error Method

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

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 function best with the near lens on the left eye.

SPECIAL FITTING CHARACTERISTICS

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 only require a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and a plano lens on the other eye.

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

Near ADD Determination

Always prescribe the less 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.

Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the General Fitting Guidelines for base curve selection described in this guide.

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

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

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

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

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

Other Suggestions

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

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.
- 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 clear near vision and 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 "ACUVUE® 2 COLOURS™ Brand (etafilcon A) Contact Lenses Patient Instruction Guide".

Dispensing Visit

Each sterile lens is supplied in a foil-wrapped plastic package containing buffered saline solution. In removing the lens from the container, peel back the foil seal, place a finger on the lens and slide the lens up the side of the bowl of the lens package until it is free of the container.

- Evaluate the physical fit and visual acuity of the lens on each eye.
- Teach the patient how to insert and remove his or her lenses.
- Explain the daily and extended wear regimens and schedule a follow-up examination.
- **PROVIDE THE PATIENT WITH A COPY OF THE APPROPRIATE ACUVUE® 2 COLOURS™ BRAND CONTACT LENSES PATIENT INSTRUCTIONS (DISPOSABLE OR FREQUENT REPLACEMENT). REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE.**
- Recommend an appropriate cleaning and disinfecting system and provide the patient with instructions regarding proper lens care (see Package Insert). Chemical and hydrogen peroxide disinfection is recommended. Heat disinfection is not advised.
- Review the Package Insert for the ACUVUE® 2 COLOURS™ Brand (Multifocal A) Contact Lens and provide the patient with all of the relevant information and precautions on the proper use of the ACUVUE® 2 COLOURS™ Brand Contact Lens.
- It is recommended that the new contact lens wearer first be evaluated on a daily wear schedule. If, in the opinion of the Eye Care Professional, the patient is determined to be an acceptable daily and extended wear candidate, the Eye Care Professional is encouraged to determine a wearing schedule based upon the response of the patient.

Follow-Up Examinations

Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule, lens replacement schedule, and proper lens care and handling procedures.

Recommended Follow-up Examination Schedule for ACUVUE® 2 COLOURS™ Brand Contact Lenses for Daily and Extended Wear

(complications and specific problems should be managed on an individual patient basis):

1. One week from the initial lens dispensing to patient
2. One month post-dispensing
3. Every three to six months thereafter

NOTE: Preferably, at the follow-up visits, lenses should be worn for at least six hours.

Recommended Procedures for Follow-Up Visits:

1. Solicit and record patient's symptoms, if any.
2. Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.
3. Perform an over-refraction at distance and near to check for residual refractive error.
4. With the biomicroscope, judge the lens fitting characteristics (as described in the "General Fitting Guidelines") and evaluate the lens surface for deposits and damage.
5. Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein.
 - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of ~~excessive~~ corneal edema.
 - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, and reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
 - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

If any observations are abnormal, use professional judgment to alleviate the problem and restore the eye to optimal conditions. If the criteria for successful fit are not fulfilled during any follow-up examinations, repeat the patient's trial fitting procedure and refit the patient.

Recommended Wearing Schedules

See Package Insert.

Patient Lens Care Directions

See Package Insert for "Lens Care Directions" for lenses worn on a frequent replacement schedule.

Chemical (Not Heat) Disinfection

See Package Insert for "Chemical Lens Disinfection" of lenses worn on a frequent replacement schedule.

Care For A Dried Out (Dehydrated) Lens

See Package Insert for "Care For A Dehydrated Lens" when lenses are worn on a frequent replacement schedule.

Care For A Sticking (Non-Wetting) Lens

See Package Insert for "Care For A Sticking Lens".

Reporting of Adverse Reactions

All serious adverse experiences and adverse reactions observed in patients wearing ACUVUE® 2 SOLOVUE™ Brand Contact Lenses or experienced with the lenses should be reported to:



VISTAKON, Division of Johnson & Johnson Vision Care, Inc.
P.O. Box 10157
Jacksonville, FL 32247-0157
1-800-843-2020

How Supplied

Each sterile lens is supplied in a foil-sealed package containing buffered saline solution. The plastic package is marked with base curve, diopter power, diameter, lens color, lot number and expiration date.

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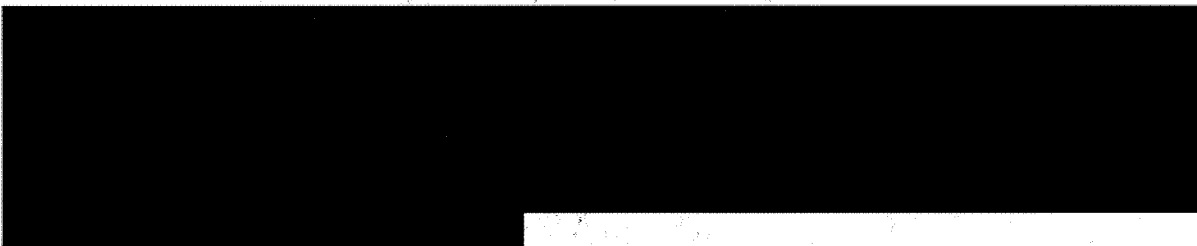
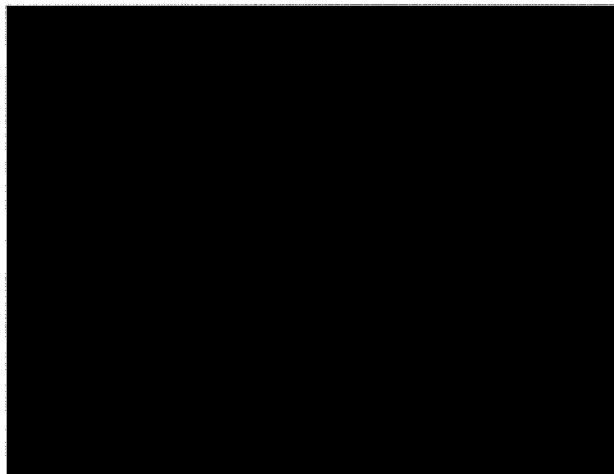
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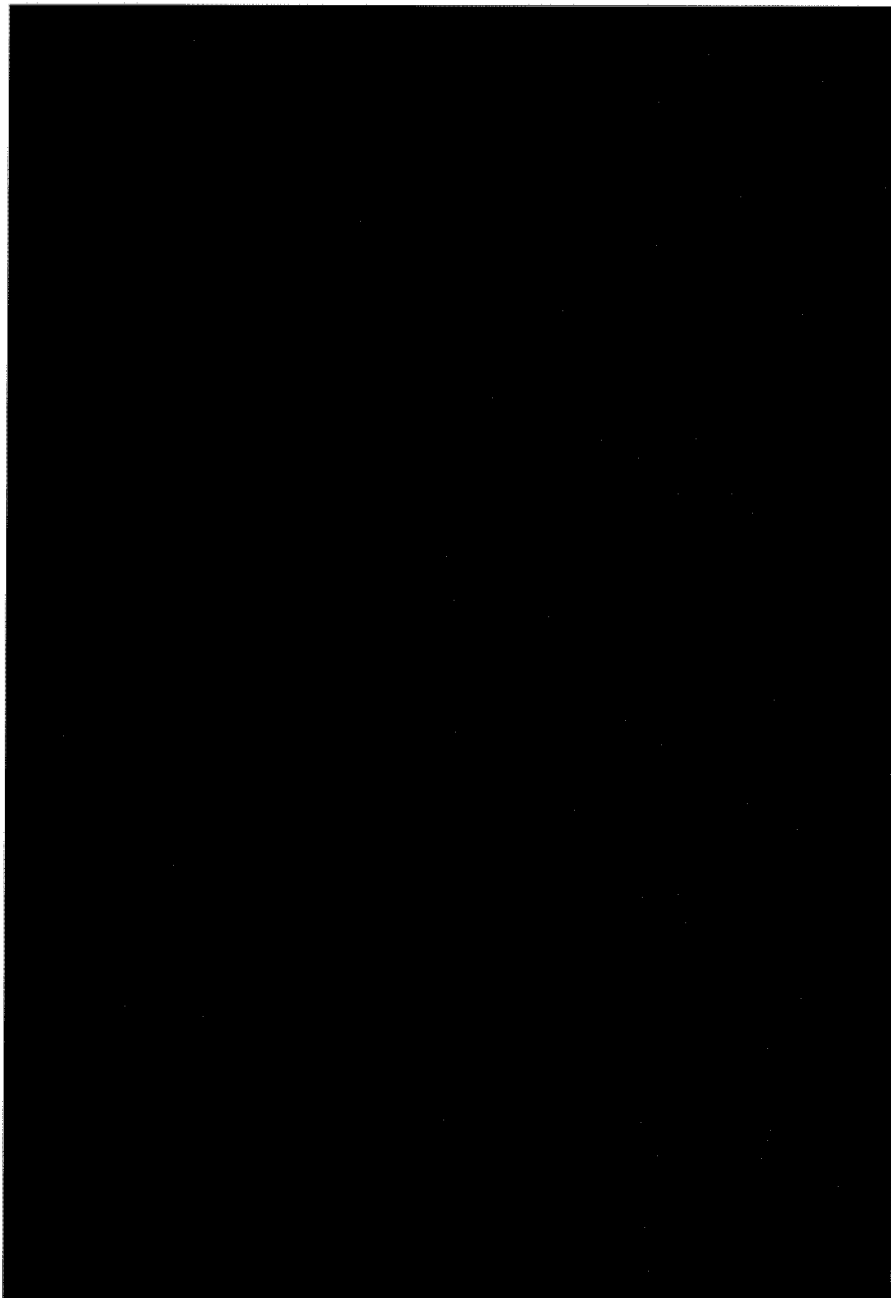
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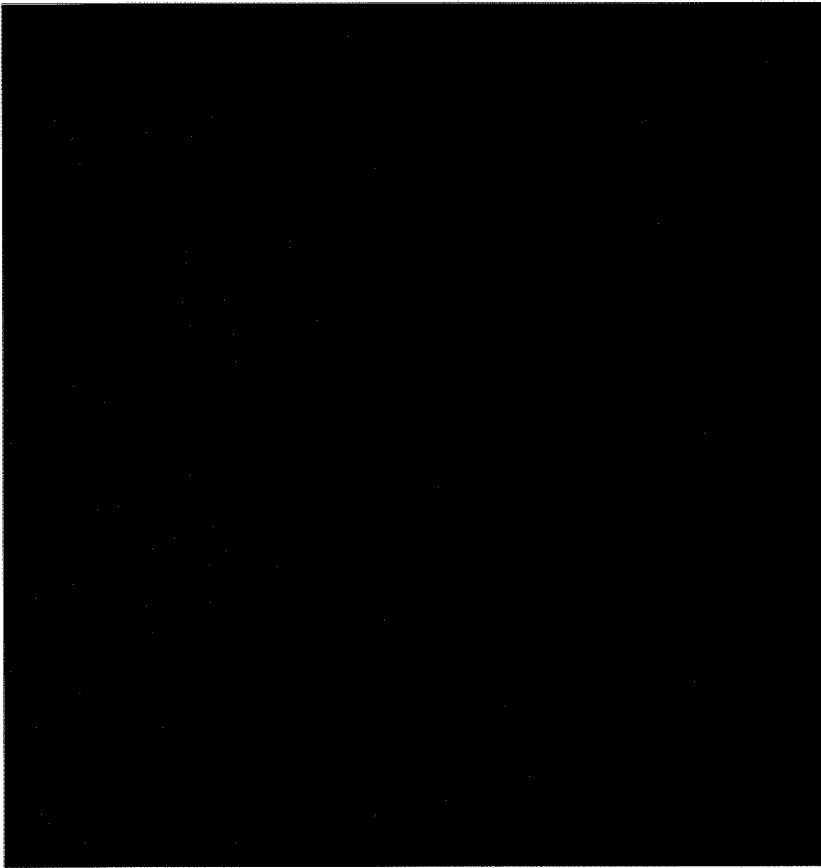
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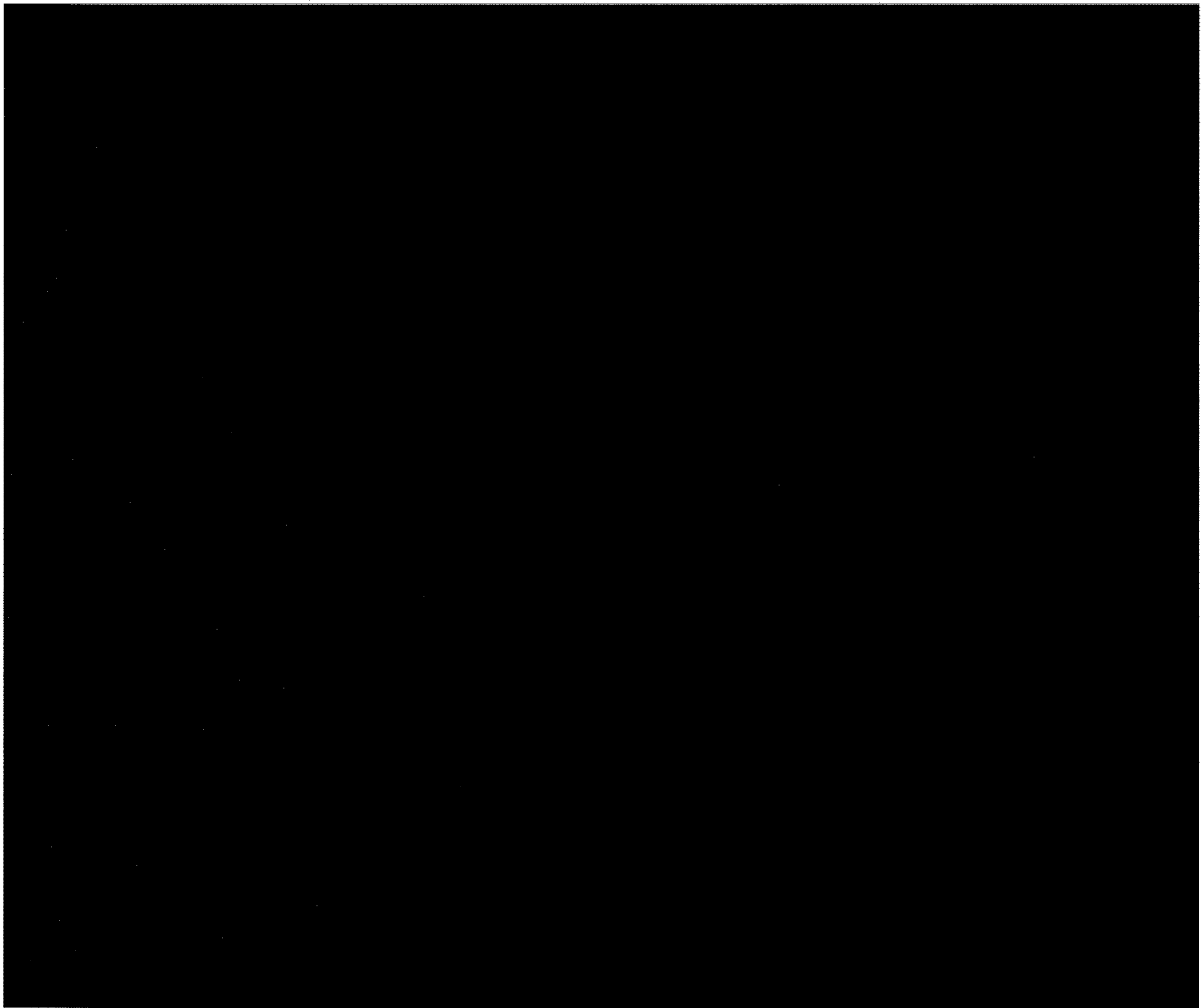
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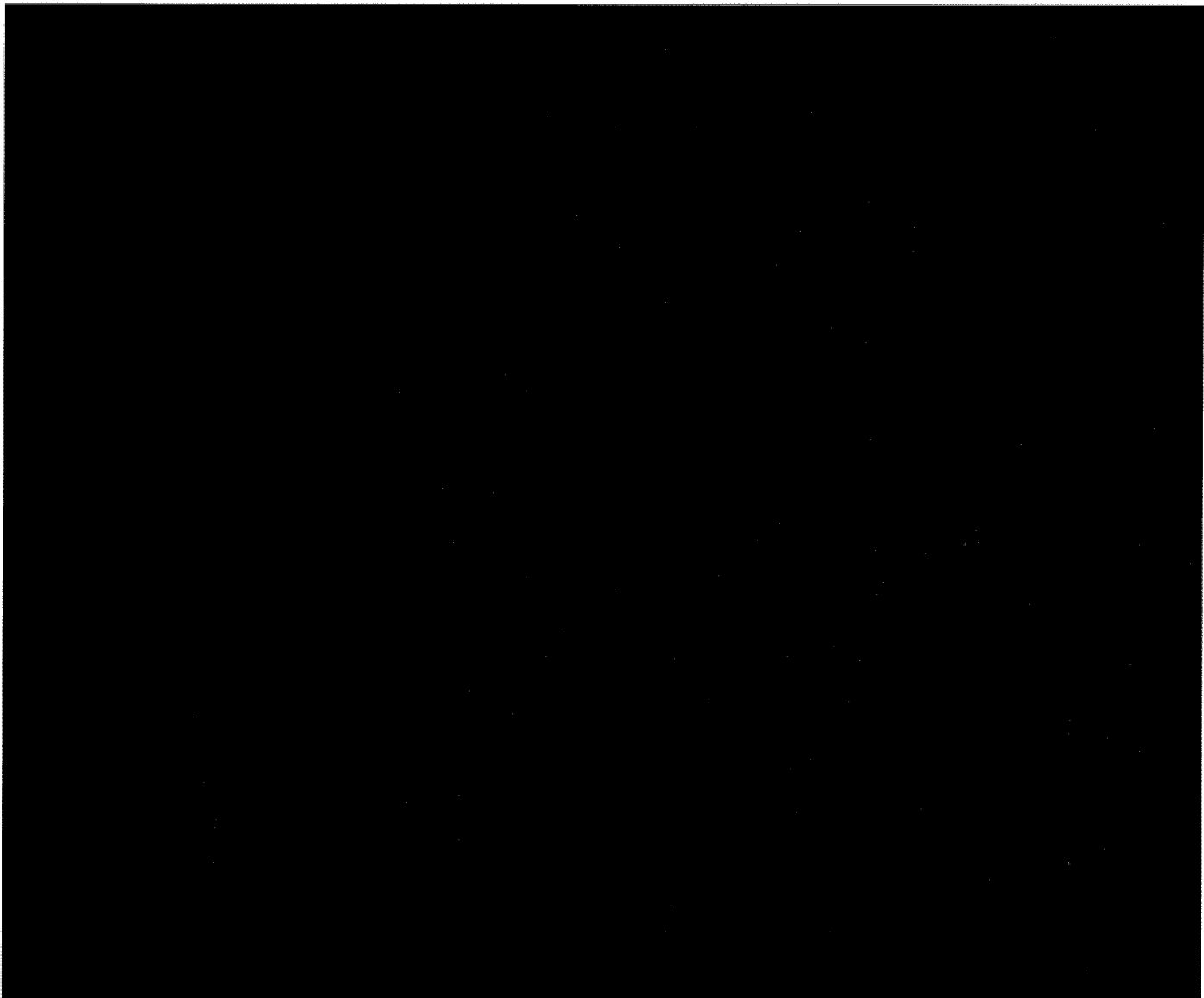
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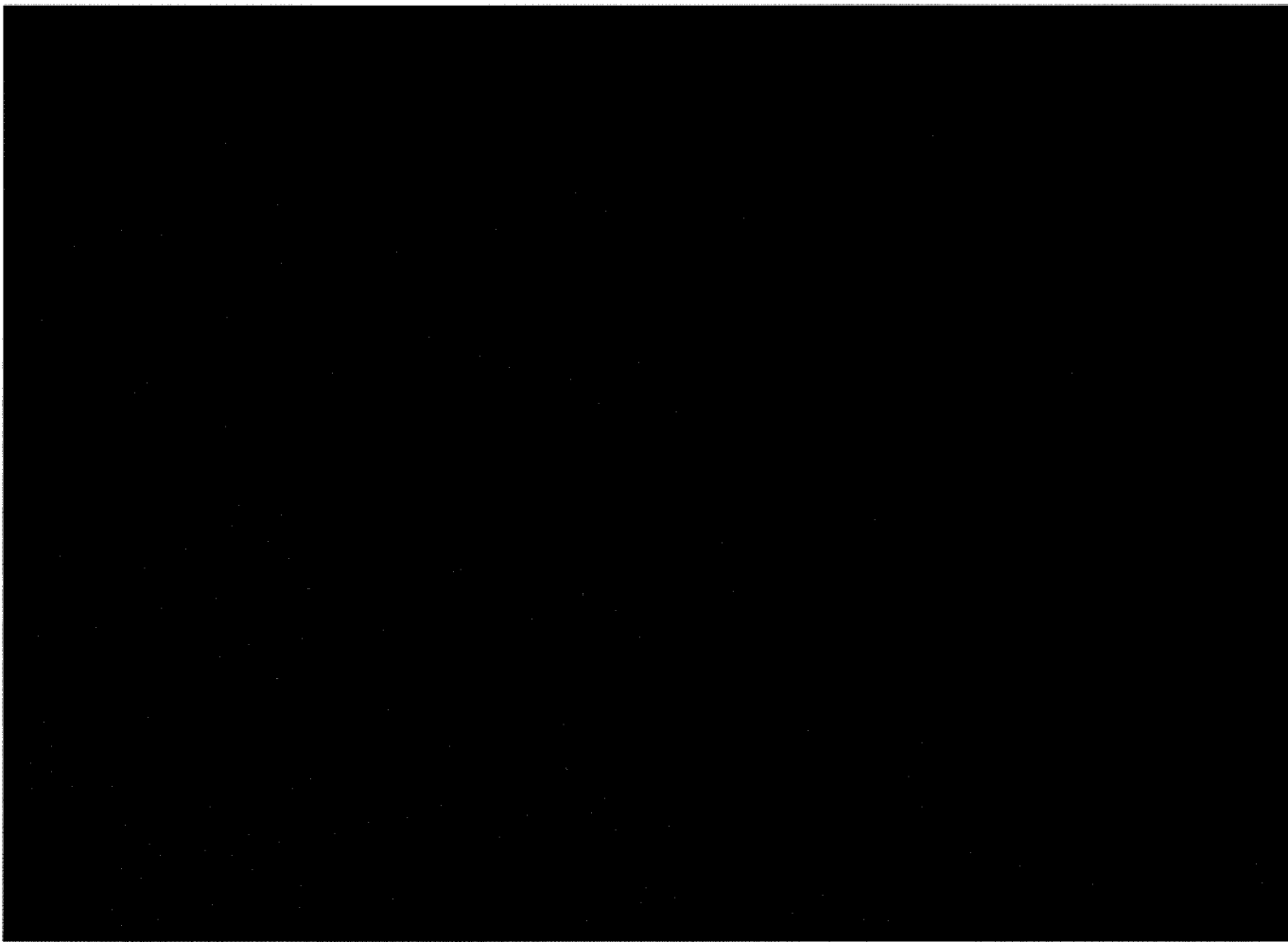
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PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number/Title: CR-6180 Clinical Evaluation of 2-Week Reusable ACUVUE 2 Vivid Style

Version and Date: 3.0 04 Jan 2018

I have read and understand the protocol specified above and agree on its content.

I agree to conduct this study according to ISO 14155,¹ GCP and ICH guidelines,² the Declaration of Helsinki,³ United States (US) Code of Federal Regulations (CFR),⁴ and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. The Principal Investigator is responsible for ensuring that all clinical site personnel, including Sub-Investigators adhere to all ICH² regulations and GCP guidelines regarding clinical trials during and after study completion.

I will assure that no deviation from, or changes to the protocol will take place without prior agreement from the Sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants.

I am responsible for ensuring that all clinical site personnel including Sub-Investigators adhere to all ICH² regulations and GCP guidelines regarding clinical trials during and after study completion.

All clinical site personnel involved in the conduct of this study have completed Human Subjects Protection Training.

I agree to ensure that all clinical site personnel involved in the conduct of this study are informed about their obligations in meeting the above commitments.

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 and Professional Position (Printed)

Institution/Site:

Institution/Site Name

Institution/Site Address