Johnson & Johnson Vision Care, Inc.

Clinical Study Protocol

Short-Term Clinical Comparison of Two Silicone Hydrogel Daily Disposable Contact Lenses

Protocol CR-5932

Version: 2.0, Amendment 1.0

Date: 14-March-2017

Investigational Products: ACUVUE OASYS® 1·Day and 1·DAY ACUVUE® TruEye®, in flat and steep base curves

Key Words: Senofilcon A, narafilcon A, ACUVUE OASYS® 1·Day and 1·DAY ACUVUE® TruEye®, base curve, daily wear, non-dispensing

Statement of Compliance to protocol, GCP and applicable regulatory guidelines:
This trial will be conducted in compliance with the protocol, the International Conference on Harmonisation Good Clinical Practice E6 (ICH-GCP), ISO 14155, the Declaration of Helsinki, and all applicable regulatory requirements.

Confidentiality Statement:

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PROTOCOL TITLE, NUMBER, VERSION

Title: Short-Term Clinical Comparison of Two Silicone Hydrogel Daily Disposable Contact Lenses

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Date: 14-March-2017

SPONSOR NAME AND ADDRESS

Johnson & Johnson Vision Care, Inc. (JJVC)
7500 Centurion Parkway,
Jacksonville, FL 32256

MEDICAL MONITOR

Name: [redacted]
Title: Associate Director, Global Strategic Medical Affairs for EMA and Regional GMA Team Lead
Address: Johnson & Johnson Medical Ltd., Pinewood Campus, Nine Mile Ride, Wokingham RG40 3EW.
[redacted]
Email: asulley1@its.jnj.com

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.

[redacted]

AUTHORISED SIGNATURES

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations, ICH guidelines, ISO 14155 and the Declaration of Helsinki.

Author	 Name: [redacted] Title: Statistician	15-03-17 DATE
Study Responsible Clinician	See electronic signature report Name: [redacted] FAAO Title: Associate Director, Global Strategic Medical Affairs for EMA and Regional GMA Team Lead	DATE
Clinical Operations Manager	See electronic signature report [redacted] Clinical Operations Manager	DATE
Biostatistician	See electronic signature report [redacted] Biostatistician II Johnson & Johnson	DATE
Data Management	See electronic signature report [redacted] Data Manager	DATE
Reviewer	Not Applicable	DATE
Approver	See electronic signature report [redacted] Director, Global Strategic Medical Affairs	DATE

[redacted]

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Date
1.0	[redacted]	Original Protocol	04-March-2017
2.0	[redacted]	Changed the protocol title on the Protocol Compliance investigator(s) signature page to match with the protocol title on cover page.	14-March-2017

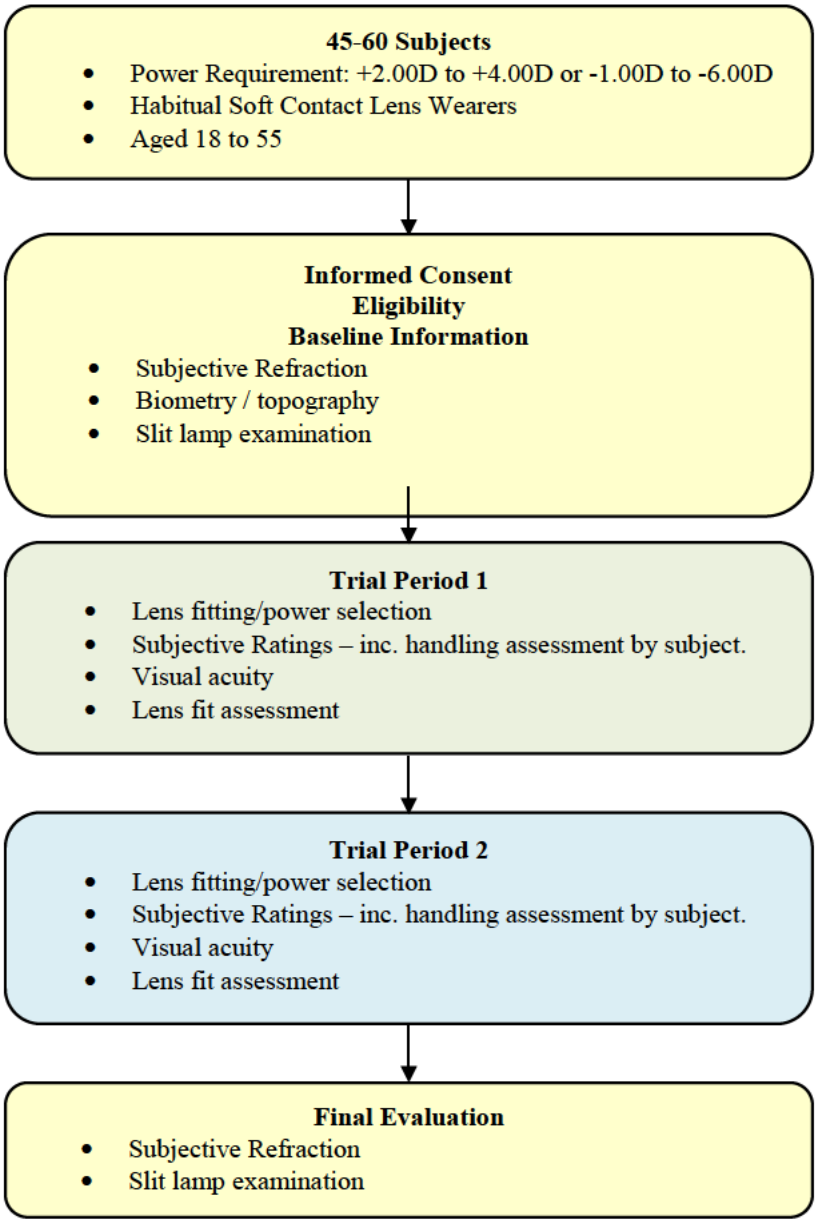
SYNOPSIS

Protocol Title	Short-Term Clinical Comparison of Two Silicone Hydrogel Daily Disposable Contact Lenses
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Post Marketing (Marketing claims), Phase 4
Trial Registration	This study will be registered on ClinicalTrials.gov by the Sponsor
Test Article(s)	Investigational Products: Senofilcon A contact lens in flat and steep base curves. Control Products: Narafilcon A contact lens in flat and steep base curves.
Wear and Replacement Schedules	Wear Schedule: Daily wear Replacement Schedule: Not applicable
Objectives	When introducing an updated version of an existing contact lens, it is helpful to compare it against the existing product in order to ensure it provides comparable, if not better, comfort, vision, and lens fit. It also gives insights into the ease of transition from one lens to the other. The main purpose of this study is to compare the performance of a new daily disposable silicone hydrogel lens (ACUVUE OASYS® 1·Day) with that of an existing similar lens: 1·DAY ACUVUE® TruEye®
Study Endpoints	**Primary Endpoints**: The primary endpoints are overall lens fit acceptability and lens power requirement. **Secondary Endpoints**: The secondary endpoints are subjective ratings of comfort, vision, quality and handling as well as high contrast visual acuity.
Study Design	This will be a 2 period one-day, double-masked, randomised, repeated measures, non-dispensing, cross-over study. Each subject will wear the steeper base curve of each design in one eye while the flatter base curve of each will be worn in the other. The two base curves of a given lens type will be worn simultaneously (i.e. contralaterally). A total of four lenses will therefore be worn by each subject (2 per eye). Lenses will be evaluated after 30-45 minutes settling. See the flow chart at the end of the synopsis table for the schematic of the study assessments and procedures of main observations.

Sample Size	45 to 60 eligible subjects will be enrolled and randomised into the study. A replacement subject may be enrolled if a subject discontinues from the study prematurely; the decision whether to enrol replacement subjects will be made by the joint agreement of the Investigator and Sponsor.
Study Duration	Approximately 8 weeks
Anticipated Study Population	Habitual soft contact lens users, myopes and hyperopes with astigmatism less than or equal to 1.00 D. Age range: 18-55 years.
Eligibility Criteria	Potential subjects must satisfy all of the following criteria to be enrolled in the study: 1. The subject must read and sign the Informed Consent form. 2. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol. 3. Healthy adult males or females aged 18-55 years. 4. The subject's spherical contact lens requirement in the range +2.00 D to +4.00 D or -1.00 D to -6.00 D. 5. The subject's refractive cylinder must be ≤1.00 D in each eye. 6. The subject must have visual acuity best correctable to 6/9 (20/30) or better for each eye. 7. The subject is a current soft contact lens wearer (defined as a minimum of 6 hours of DW per day, at least 5 days per week, for a minimum of 1 month prior to the study). 8. The subject must have normal eyes (i.e., no ocular medications or infections of any type). Potential subjects who meet any of the following criteria will be excluded from participating in the study: 1. Currently pregnant or lactating 2. Any systemic disease (e.g., Sjögren's Syndrome), allergies, infectious disease (e.g., hepatitis, tuberculosis), contagious immunosuppressive diseases (e.g., HIV), autoimmune disease (e.g. rheumatoid arthritis), or other diseases, by self-report, which are known to interfere with contact lens wear and/or participation in the study. 3. Use of systemic medications (e.g., chronic steroid use) that are known to interfere with contact lens wear. 4. 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

	5. Extended wear contact lens correction. 6. Any current use of ocular medication. 7. Any previous, or planned (during the course of the study) ocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.) 8. Any greater than Grade 2 slit lamp findings (e.g., oedema, corneal neovascularisation, corneal staining, tarsal abnormalities, conjunctival injection) on the FDA classification scale or any other ocular abnormality that may contraindicate contact lens wear. 9. Any contact lens-related history or signs of a corneal inflammatory event, or any other ocular abnormality that would contraindicate contact lens wear. 10. Participation in any contact lens or lens care product clinical trial within 14 days prior to study enrolment. 11. Employee, relative or friends of employees of any ophthalmic company, or investigational clinic (e.g., Investigator, Coordinator, Technician).
Disallowed Medications/Interventions	See above
Measurements and Procedures	Vision: High and low contrast visual acuity with CLs and spherical over-refraction (logMAR), vision quality (0-100). Comfort: On insertion and on settling (0-10, 11-point scale). Handling – subject graded (0-10) Lens fit: Horizontal & vertical centration, post-blink movement in primary gaze and up-gaze, version lag, edge tightness, tightness (push-up), diameter acceptance.
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	Saline for rinsing
Principal Investigator(s) and Study Institution(s)/Site(s)	[redacted] Visioncare Research [redacted], Aston University

Figure 1: Study Flowchart



COMMONLY USED ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse Event/Adverse Experience
BSCVA	Best Spectacle Corrected Visual Acuity
BVS	Best Vision Sphere
CFR	Code of Federal Regulations
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organisation
CT	Center Thickness
CTP	Clinical Technical Procedure
D	Diopter
DMC	Data Monitoring Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
FDA	Food and Drug Administration
GCP	Good Clinical Practice
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ISO	International Organisation for Standardisation
ITT	Intent-to-Treat
JJVC	Johnson & Johnson Vision Care, Inc.
LogMAR	Logarithm of Minimal Angle of Resolution
OD	Right Eye
OS	Left Eye
OU	Both Eyes
PD	Protocol Deviation
PI	Principal Investigator
PIG	Patient Instruction Guide
PQC	Product Quality Complaint
QA	Quality Assurance
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

When introducing an updated version of an existing contact lens, it is helpful to compare it against the existing product in order to ensure it provides comparable, if not better, comfort, vision, and lens fit.[3] It also gives insights into the ease of transition from one lens to the other. The main purpose of this study is to compare the performance of a new daily disposable silicone hydrogel lens (ACUVUE OASYS® 1·Day) with that of an existing similar lens: 1·DAY ACUVUE® TruEye®. This will provide useful information regarding the ease of refitting existing wearers of the existing lens into the new lens.

1.1. Name and Descriptions of Investigational Products

This study will compare two daily disposable lens designs in two different materials: ACUVUE OASYS® 1·Day (senofilcon A), 1·Day ACUVUE® TruEye® (narafilcon A).

1.2. Intended Use of Investigational Products

The study products are indicated for the correction of myopia and hyperopia. During the study, each test article will be worn for 30-45 minutes.

1.3. Summary of Findings from Nonclinical Studies

Not Applicable – Marketed product only.

1.4. Summary of Known Risks and Benefits to Human Subjects

For the most comprehensive clinical information, refer to the latest version of the relevant package inserts.

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

Refer to relevant package inserts.

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

The main purpose of this study is to compare the performance of a new daily disposable silicone hydrogel lens (ACUVUE OASYS® 1·Day) with that of an existing similar lens: 1·DAY ACUVUE® TruEye®.

Primary Objective(s)

The primary objective is to compare the performance of a new daily disposable silicone hydrogel lens (ACUVUE OASYS® 1·Day) with that of 1·DAY ACUVUE® TruEye®.

2.2. Endpoints

Primary Efficacy Endpoints

The primary endpoints are overall lens fit acceptability and lens power requirement.

Overall lens fit acceptability will be graded by the investigator on a 0-5 scale (VCR grading scale, where 5 indicates a perfect fit) and will be based on fitting characteristics such as centration and movement (not comfort or vision).

The proportion of subjects with similar (±0.00 D and ±0.25 D) lens power requirements for each lens type will be calculated. The lens requirements will be calculated from the lens power and spherical over-refraction by summing the lens power and the over-refraction.

Secondary Endpoints

The secondary endpoints are subjective ratings of comfort, vision quality and handling as well as high contrast visual acuity.

Comfort and handling will be scored by the subject on an 11-point scale (0-10).

Vision quality will be scored by the subject on a 0-100 scale.

High contrast visual acuity will be recorded with contact lenses only using logMAR charts.

2.3. Hypotheses

Both primary hypotheses must be met in order to satisfy the objectives of this study.

Primary Study Hypotheses	
1	The overall fit acceptance of ACUVUE® OASYS 1·Day will be non-inferior to that of 1·Day ACUVUE® TruEye® of similar base curve. A non-inferiority bound of 1.6 will be used for the odds ratio.
2	The lens power requirement for ACUVUE® OASYS 1·Day will be the same as that of 1·Day ACUVUE® TruEye® in at least 70% of cases and within ±0.25 D for at least 80% of cases.
Secondary Study Hypotheses	
1	The short-term comfort of ACUVUE® OASYS 1·Day will be non-inferior to that of 1·Day ACUVUE® TruEye® of similar base curve. A non-inferiority bound of 1.0 (0-10 scale) will be used.
2	The subjective vision quality of ACUVUE® OASYS 1·Day will be non-inferior to that of 1·Day ACUVUE® TruEye® of similar base curve. A non-inferiority bound of 10 (0-100 scale) will be used.
3	Monocular high contrast visual acuity with ACUVUE® OASYS 1·Day will be non-inferior to that of 1·Day ACUVUE® TruEye® of similar base curve. A non-inferiority bound of 0.1 logMAR will be used.
4	The handling performance of ACUVUE® OASYS 1·Day will be non-inferior to that of 1·Day ACUVUE® TruEye® of similar base curve. A non-inferiority bound of 1 (0-10 scale) will be used.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

Existing soft contact lens wearers, with a distance requirement in the range to +2.00 to +4.00 D or -1.00 to -6.00D and astigmatism <1.00 D in each eye. Age range: 18-55 years.

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

[redacted]

3. Healthy adult males or females aged 18-55 years
4. The subject's spherical contact lens requirement in the range +2.00 D to +4.00 D or -1.00 D to -6.00 D
5. The subject's refractive cylinder must be ≤1.00D in each eye
6. The subject must have visual acuity best correctable to 0.20 logMAR (6/9, 20/30) or better for each eye
7. The subject is a current soft contact lens wearer (defined as a minimum of 6 hours of DW per day, at least 5 days per week, for a minimum of 1 month prior to the study)
8. The subject must have normal eyes (ie, no ocular medications or infections of any type).

3.3. Exclusion Criteria

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

1. Currently pregnant or lactating
2. Any systemic disease (e.g., Sjögren's Syndrome), allergies, infectious disease (e.g., hepatitis, tuberculosis), contagious immunosuppressive diseases (e.g., HIV), autoimmune disease (e.g. rheumatoid arthritis), or other diseases, by self-report, which are known to interfere with contact lens wear and/or participation in the study
3. Use of systemic medications (e.g., chronic steroid use) that are known to interfere with contact lens wear.
4. 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
5. Extended wear contact lens correction.
6. Any current use of ocular medication.
7. Any previous, or planned (during the course of the study) ocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.)
8. Any greater than Grade 2 slit lamp findings (e.g., oedema, corneal neovascularisation, corneal staining, tarsal abnormalities, conjunctival injection) on the FDA classification scale or any other ocular abnormality that may contraindicate contact lens wear.
9. Any contact lens-related history or signs of a corneal inflammatory event, or any other ocular abnormality that would contraindicate contact lens wear.
10. Participation in any contact lens or lens care product clinical trial within 14 days prior to study enrolment.
11. Employee, relative or friends of employees of any ophthalmic company, or investigational clinic (e.g., Investigator, Coordinator, Technician).

3.4. Enrolment Strategy

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

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

This will be a one-day, double-masked, randomised, repeated measures, and non-dispensing cross-over study. Each subject will wear the steeper base curve of each design in one eye while the flatter base curve of each will be worn in the other. The two base curves of a given lens type will be worn simultaneously (i.e. contralaterally). A total of four lenses will therefore be worn by each subject (2 per eye).

Lenses will be evaluated after 30-45 minutes settling. There will be no washout period between study lenses.

4.2. Study Design Rationale

Since the main purpose of the study is to compare lens fit and lens power requirements, a one-day repeated measures study allows meaningful comparisons with relatively short periods between comparisons.

A limitation of this design is that the subjective endpoints (comfort, vision quality) are assessed after a relatively short wearing time. However, since these are secondary endpoints, this limitation is felt to be outweighed by the advantage of the close comparisons for the primary endpoints.

The main comparison between the relatively new daily disposable lens (ACUVUE OASYS® 1·Day) with that of the existing similar lens (1·DAY ACUVUE® TruEye®) will provide useful information regarding the ease of refitting existing wearers into the new lens.

4.3. Enrolment Target and Study Duration

Approximately 45-60 subjects will be enrolled across two sites (15-30 subjects per site) to ensure that at least 43 subjects will complete the study. Enrolled subjects will be habitual wearers of spherical contact lenses. All subjects will be between 18 and 55 years of age. Subjects will be considered enrolled after signing the informed consent. Subjects will wear the Test and Control contact lenses for approximately 45 minutes each for a total study duration of approximately 3 hours per subject.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

This will be a one-day, double-masked, randomised, repeated measures study. Each subject will wear three pairs of lenses each in two base curves. The order of the Test and Control lenses worn and the assignment of the steeper BC to right or left eyes will be randomised.

The randomisation scheme was created using a random number generating computer program (SAS version 9.4 or higher, SAS Institute, Cary, NC) with a blocking system of four subjects stratified by site. Each subject will be randomly assigned to wear one of two lens sequences with the steeper base curve randomly assigned to the left or right eye giving a total of four potential sequences:

i. T/C steeper lens in right eye
ii. T/C steeper lens in left eye
iii. C/T steeper lens in right eye
iv. C/T steeper lens in left eye

The study site must follow the randomisation scheme provided and complete enrolment according to the randomisation list and not pre-select or assign subjects. The randomised assignment of subjects will be performed prior to the first fitting. The following must have occurred prior to randomisation:

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

Randomly-permuted block randomisation will be used to avoid bias in the assignment of subjects to treatment, and to enhance the validity of statistical comparisons across treatment groups.

5.2. Masking

Both the investigator and the subjects are masked to the identity of the study lenses in order to reduce potential bias. To ensure lens masking, lenses will be over-labelled and coded to mask the lens foil. Over-labelling will be carried out by the study sponsor following specific SOPs (see ICH GCP guidelines Section 5.13).

Masking will be used to reduce potential bias. Subjects will be unaware of the identity of the investigational product. Investigators and clinical site personnel involved in the data collection will be masked as to the identity of the investigational product.

Under normal circumstances, the mask should not be broken until all subjects have completed the study and the database is finalised. 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 Randomisation Codes

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.

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

1. Investigator or designee (documented on the Delegation Log) will consult the lens fitting schedule/randomisation scheme to obtain the test article assignment for that subject prior to dispensing
2. Investigator or designee will record the subject's number on the appropriate line of the randomisation scheme
3. Investigator or designee will pull the appropriate test articles from the study supply. All test articles that are opened, whether dispensed (placed/fit on eye or dispensed outside the clinical site) or not, must be recorded on the Test Article Accountability Log in the "Dispensed" section

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 1: Test Articles

	Test 1	Control
Name	ACUVUE OASYS® 1·Day with HydraLuxe™	1·Day ACUVUE® TruEye®
Manufacturer	JJVCI	JJVCI
[redacted]	[redacted]	[redacted]
Lens Material	senofilcon A	narafilcon A
Nominal Base Curve @ 22 °C	8.50, 9.00	8.50, 9.00
Nominal Diameter @ 22 °C	14.3	14.2
Nominal Distance Powers (D)	-1.00 to -6.00,+2.00 to+4.00D in 0.25 steps, i.e. 30 x 6 SKUs)	
Nominal Cylinder Powers (D) and Axes	NA	NA
Nominal ADD Powers (D)	NA	NA
Water Content	38	46
Centre Thickness	0.085	0.085
Packaging Form (vial, blister, etc.)	Sterile blister pack	Sterile blister pack
Other	CE marked, Class 1 UV blocker, 1-2-3 marks	CE marked, Class 1 UV blocker, 1-2-3 marks

[redacted]

[redacted]

6.2. Ancillary Supplies/Products

The following solutions will be used in this study:

Table 2: Ancillary Supplies

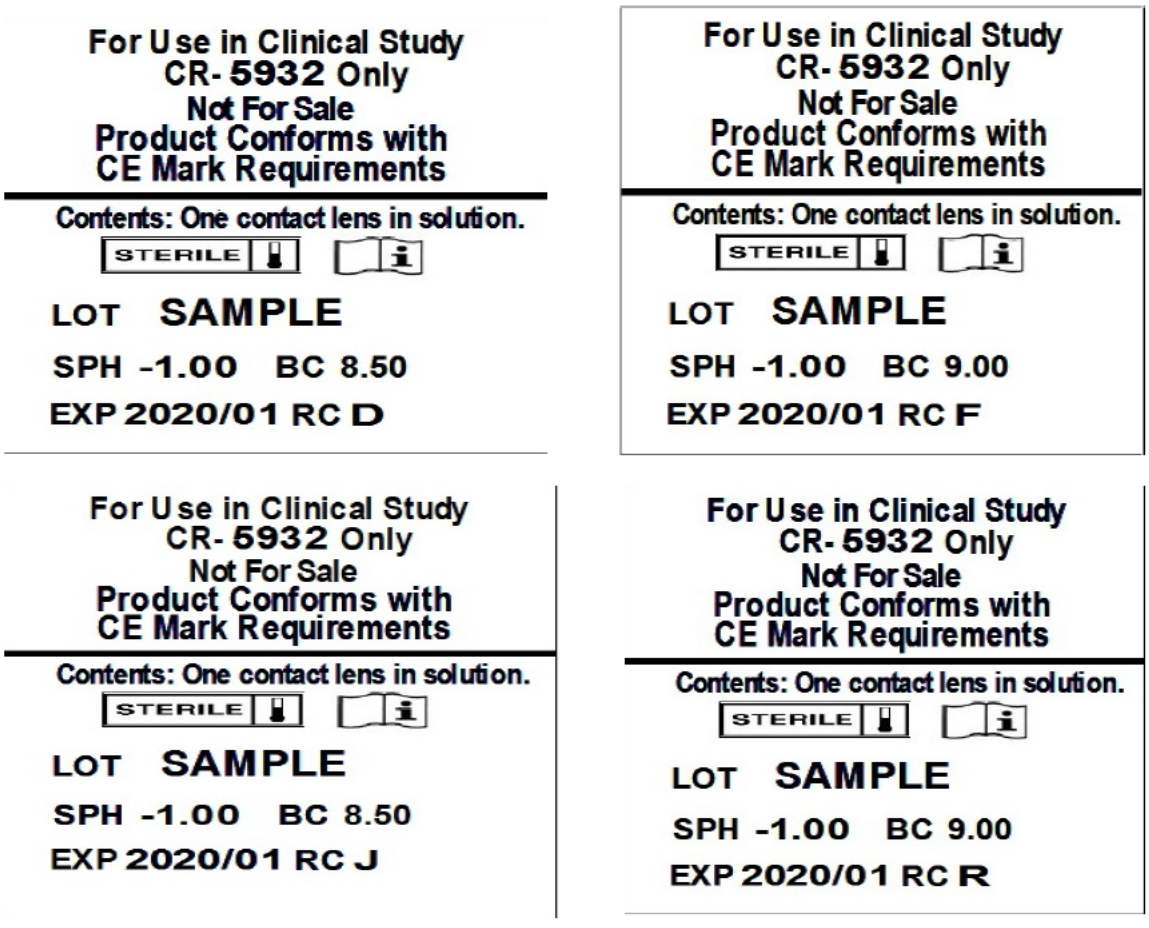
	Solution	
Solution Name/Description	Ami-dose Sterile Physiological Saline	Minims Saline
Manufacturer	Abatron	Bausch & Lomb
Preservative	Preservative free	Preservative free

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.

6.4. Packaging and Labelling

The test articles will be packaged in blisters, as the primary packaging. The test article will be over-labelled to mask the subject/Investigators to the identity of the lens. The sample study label is shown below:



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 authorised study site personnel listed on the Site Delegation Log. All test articles must be accounted.

Following final reconciliation of test articles by the monitor, the Investigator will destroy both used and unused lenses per local guidelines and in accordance with sponsor policy.

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

[redacted]

7. STUDY EVALUATIONS

7.1. Time and Event Schedule

Table 3: Time and Events

Procedure	Screening	Baseline	Assessment 1	Assessment 2	Exit
Informed consent	✓	-	-	-	-
Eligibility screening	✓	-	-	-	-
Subject demographics	✓	-	-	-	-
General health and medication history and concomitant medications	✓	-	-	-	-
Subject's own contact lens information	✓	-	-	-	-
Habitual lenses	✓	-	-	-	-
Sphero-cylindrical refraction and visual acuity (VA)	-	✓	-	-	✓
Best vision sphere and monocular VA	-	✓	-	-	-
Ocular topography	-	✓	-	-	-
Slit lamp biomicroscopy	-	✓	-	-	✓
Lens information and any modification	-	-	✓	✓	-
Distance spherical over-refraction and monocular VA	-	-	✓	✓	-
Subjective ratings - comfort on insertion and settling and handling	-	-	✓	✓	-
Subjective Vision Quality	-	-	✓	✓	-
Lens fit assessments	-	-	✓	✓	-

7.2. Detailed Study Procedures

Subject should enter the study in habitual contact lenses or spectacles.

VISIT 1

Screening			
Step	Procedure	Details	[redacted]
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.	
Baseline			
Step	Procedure	Details	[redacted]
1.6	Subjective Refraction	The investigator will complete a subjective refraction (sphere and cylinder) and record the resultant high contrast distance monocular visual acuity to the nearest letter. Also, complete best vision sphere (BVS) and the resultant high and low contrast distance monocular visual acuity to the nearest letter. Best corrected high contrast distance visual acuity (BVA) must be 0.20 logMAR or better in each eye.	
1.7	Biometry measurements	Record the baseline Biometry measurements: – Corneal topography: Sim-K-readings and corneal shape factor, – Horizontal HVID – Horizontal & vertical corneal diameter, corneal sagittal height, corneo-scleral junction angle (Anterior OCT).	Topography Measurement using MEMONT E300 Corneal Topgrapher Measuring oculsr Topography by VISANTE OCT
1.8	Slit Lamp Findings	A slit lamp examination will be used to determine eligibility. The following findings will be graded:	Appendix D

		i. Limbal hyperaemia ii. Bulbar hyperaemia iii. Tarsal abnormalities iv. Corneal staining v. Conjunctival staining vi. Other significant findings If any of these slit lamp findings are higher than grade 2, the subject is ineligible to continue but may return at a later date to complete another Baseline. If after a total of two attempts the subject is deemed ineligible, then complete the Final Evaluation.	
1.9	Eye Rinse	The study coordinator, investigator, or technician will rinse the subject's eyes thoroughly with saline.	
1.10	Baseline Eligibility	All responses to Baseline Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria must be answered "no" for the subject to be considered eligible.	

Assessment 1: Lens Pair 1			
Step	Procedure	Details	[redacted]
1.11	Randomisation	Chose the study lens based on the Lens Fitting schedule	
1.12	Lens Fitting	The lens powers will be based on the vertex-corrected (12mm), best vision sphere subjective refraction. Record the parameters of the lenses on the (lens type / lot number, lens powers). The subject will insert the lenses. Check for any lens damage and replace if necessary.	
1.13	Subjective Ratings	Record handling and initial comfort.	Appendix D
1.14	Time Interval	Please wait for at least 30-45 minutes from final lens insertion to continue.	
1.15	Subjective Ratings	Ask subjects to grade comfort of the lenses.	Appendix D
1.16	Spherical Over-refraction	Perform a spherical over-refraction OD and OS.	
1.17	Visual Acuity	Record the high and low contrast distance monocular visual acuity with the contact lenses to the nearest letter. Smaller lines must be shown until the subject incorrectly	Appendix D

		identifies at least 50% of the letters.	
1.18	Vision Quality	Record subjective vision quality.	Appendix D
1.19	Lens Fit Assessment	Record the following lens fit characteristics using VCR assessment system: * i. Horizontal & vertical centration ii. Corneal coverage iii. Post-blink movement in primary gaze and up-gaze iv. Version lag v. Edge tightness vi. Tightness (push-up) vii. Diameter acceptance viii. Overall fit acceptability * This provides more precise fit assessments of fit than those used in routing studies	Appendix D
1.20	Lenses	Remove and discard lenses	

Assessment 2: Lens Pair 2			
Step	Procedure	Details	[redacted]
As per Lens Pair 1			

FINAL EVALUATION

The final evaluation will ordinarily take place immediately following Lens Pair 2. It may also take place at any point the subject discontinues the study or is terminated from the study.

Final Evaluation			
Step	Procedure	Details	[redacted]
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 sphero-cylindrical Refraction	Complete a subjective refraction (sphere and cylinder) and record the resultant high contrast distance monocular visual acuity to the nearest letter.	[redacted]

F.3	Exit Slit Lamp Biomicroscopy	The following findings will be graded: i. Limbal hyperaemia ii. Bulbar hyperaemia iii. Tarsal abnormalities iv. Corneal staining v. Conjunctival staining vi. Other significant findings	[redacted]

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, stabilised, 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.

Step	Procedure	Details	[redacted]
U.1	Chief Complaints	Record the subject's chief complaints for reasons for the unscheduled visit	
U.2	Change of Medical History and Concomitant Medications	Questions regarding the change of subjects' medical history and concomitant medications.	
U.3	Entrance VA	Record the entrance distance visual acuity (OD, OS and OU) to the nearest letter.	[redacted]
U.4	Subjective Sphero-cylindrical Refraction	Perform bare-eye subjective sphero-cylindrical 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	[redacted]

[redacted]

Step	Procedure	Details	[redacted]
		distance visual acuity to the nearest letter (OD, OS, OU).	[redacted]
U.5	Slit Lamp Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings. If no slit lamp finding is noted on the EDC form it is considered as a zero "0" grade for all observations listed. After the slit lamp examination, at the discretion of the Investigator, rinse the subject's eyes thoroughly with preservative-free saline.	[redacted]
U.6	Exit Visual Acuity	Record the subject's exit distance visual acuity (OD, OS and OU) to the nearest letter with the subjects wearing the study provided spectacle glasses.	[redacted]

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;
- They are eligible;
- Clinical assessments were completed with all three study contact lenses.

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
- Subject not compliant to protocol
- Subject lost to follow-up
- Subject no longer meets eligibility criteria (e.g. 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: use of medications that contraindicate contact lens wear.

Concomitant therapies that are disallowed include: therapies in which contact lens wear is contraindicated.

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 or not the lens was inserted
- Any related AE number if applicable
- Detailed complaint description (scheduled/unscheduled visit, wear time, symptoms, resolution of symptoms, etc.)
- Eye Care Provider objective (slit lamp) 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 applies 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 (unwanted) medical occurrence in a patient or clinical investigation subject administered a test article, study treatment or study procedure whether or not caused by the test article, study treatment or procedure. An AE can therefore be any unfavorable or unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of the test article, study treatment, or study procedure whether or not related to the test article, study treatment, or study procedure.

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 hospitalisation or prolongation of existing hospitalisation

- 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 hospitalisation may be considered an SAE when, based upon appropriate medical judgment, they may jeopardise 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 Neovascularisation
- Uveitis
- Endophthalmitis
- Hypopyon
- Hyphema
- Penetration of Bowman's Membrane
- Persistent Epithelial Defect
- Limbal cell Damage leading to Conjunctivalisation

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
- Localised Allergic Reactions
- Any corneal event not explicitly defined as serious or significant adverse event, which necessitates temporary lens discontinuation < 2 weeks

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

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 categorised correctly. Elements of categorisation 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; doubtful; possible; probable; very likely - 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 13.2.2).
- 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 action taken

13.2.1 Causality Assessment

Causality Assessment – A determination of the relationship between an adverse event and the test article, study treatment, or study procedure. The test article, study treatment or study procedure relationship for each adverse event shall 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, possible 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 utilised 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 characterised 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, stabilised, 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 or not 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.

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 or not 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 randomisation 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 the written guidelines, including reporting timelines.

13.5. Event of Special Interest

None.

13.6. Reporting of Pregnancy

Subjects reporting pregnancy (by self-report) during the course of 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 sponsor or under the authority of the sponsor. 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 or higher (SAS Institute, Cary, NC). Throughout the analysis of data, the results for each subject/eye will be used when available for summarisation and statistical analysis. Unscheduled visits will be summarised separately and will be excluded from the statistical analysis.

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 summarised 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. Unscheduled visits will be summarised separately if applicable.

14.2. Sample Size Justification

[redacted]

The sample size was estimated from the formula given by Diggle et al. (2002) for clustered binary data. The common correlation across measurements within subject eyes across period was assumed to be 0.5.

Assuming difference in proportion of 10%, 15%, 20%, the sample size calculation was as shown below:

[redacted]

Difference in Proportion	Number of Subjects needed by study arms
10%	88
12%	70
14%	53
15%	47

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 assessments 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.

14.4. Level of Statistical Significance

All planned analysis for this study will be conducted with an overall type I error rate of 5%. No adjustment for multiple comparisons will be conducted unless specified otherwise.

14.5. Primary Analysis

All analyses will be conducted on the analysis population (defined above). If the difference between the analysis and safety populations is higher than 15% then a sensitivity analysis will be conducted on all available data.

Primary Endpoints – Overall Fit Acceptance: Overall lens fit acceptability will be analysed using a generalised linear mixed model with a multinomial distribution and a cumulative logit link function. Sequence of lens wear, base curve, period, lens type, site, and the two-way interactions between lens type and base curve and between lens type and period will be included in each model as fixed effects. An appropriate covariance structure will be used to model the residual errors between measurements within same subject across study periods. The covariance structure will be selected based on the finite-sample corrected Akaike's Information Criterion. Covariance structures considered include:

- Unstructured Covariance Structure (UN)
- Homogenous Compound symmetry (CS)

The Kenward and Roger method[4] will be used for the denominator degree of freedom. If convergence is problematic, then reduced versions of the above model may be considered.

Comparisons between the Test lens and the control lens will be carried out using two-sided 95% confidence intervals constructed for odds ratio (Test/Control) by base curve. The lower limits of the 95% confidence intervals will be compared to 1.6 and 1 to Test for non-inferiority and superiority, respectively. Non-inferiority of the Test lens relative to the control will be concluded if the upper limit is below 1.6. The superiority will be established if the upper limit is below 1.

Primary Endpoints – Lens Power Requirement: The difference in lens power requirement between the Test and Control lenses will be calculated by base curve for the purpose of the analyses. The proportions, and the corresponding 95% confidence intervals, of eyes with no difference in lens power requirement and with a difference within ±0.25 D will be calculated. The 95% two-sided confidence intervals of the proportions will be calculated using the method of Wilson.[3] The lower limits of the confidence intervals will be compared to 70% and 80%. Equivalence will be established if the lower limit of the proportion with no differences is above 70% and if the lower limit of the proportion within ±0.25 D is above 80%.

14.6. Secondary Analysis

Secondary Endpoints – Comfort and Handling: The subjective ratings of comfort and handle ability will be analysed using a linear mixed model. Sequence of lens wear, base curve, period, lens type, site, and the two-way interactions between lens type and base curve and between lens type and period will be included in each model as fixed effects. An appropriate covariance structure will be used to model the residual errors between measurements within same subject across study periods. The covariance structure will be selected based on the finite-sample corrected Akaike's Information Criterion. Covariance structures considered include:

- Unstructured Covariance Structure (UN)
- Homogenous Compound symmetry (CS)

The Kenward and Roger method[4] will be used for the denominator degree of freedom. If convergence is problematic, then reduced versions of the above model may be considered.

Comparisons between the Test lens and the Control lens will be carried out using two-sided 95% confidence intervals constructed for least-square mean differences (Test minus Control) separately for each base curve. The lower limits of the 95% confidence intervals will be compared to -1 and 0 to Test for non-inferiority and superiority, respectively. Non-inferiority of the Test lens relative to the Control will be concluded if the lower limit is above -1. The superiority will be established if the lower limit is above 0.

Secondary Endpoints – Vision Quality: The subjective rating of vision quality will be analysed using a linear mixed model. Sequence of lens wear, base curve, period, lens type, site, and the two-way interactions between lens type and base curve and between lens type and period will be included in each model as fixed effects. An appropriate covariance structure will be used to model the residual errors between measurements within same subject across study periods. The covariance structure will be selected based on the finite-sample corrected Akaike's Information Criterion. Covariance structures considered include:

- Unstructured Covariance Structure (UN)

- Homogenous Compound symmetry (CS)

The Kenward and Roger method[4] will be used for the denominator degree of freedom. If convergence is problematic, then reduced versions of the above model may be considered.

Comparisons between the Test lens and the Control lens will be carried out using two-sided 95% confidence intervals constructed for least-square mean differences (Test minus Control) separately for each base curve. The lower limits of the 95% confidence intervals will be compared to -10 and 0 to Test for non-inferiority and superiority, respectively. Non-inferiority of the Test lens relative to the Control will be concluded if the lower limit is above -10. The superiority will be established if the lower limit is above 0.

Secondary Endpoints – High Contrast Visual Acuity: Monocular high contrast VA scores will be analysed using a linear mixed model. Sequence of lens wear, base curve, period, lens type, site, and the two-way interactions between lens type and base curve and between lens type and period will be included in each model as fixed effects. An appropriate covariance structure will be used to model the residual errors between measurements within same subject eye across study periods. The covariance structure will be selected based on the finite-sample corrected Akaike's Information Criterion. Covariance structures considered include:

- Unstructured Covariance Structure (UN)
- Homogenous Compound symmetry (CS)

The Kenward and Roger method[4] will be used for the denominator degree of freedom. If convergence is problematic, then reduced versions of the above model may be considered.

Comparisons between the Test lens and the Control lens will be carried out using two-sided 95% confidence intervals constructed for least-square mean differences (Test minus Control) separately for each base curve. The upper limits of the 95% confidence intervals will be compared to 0.1 and 0 logMAR to Test for non-inferiority and superiority, respectively. Non-inferiority of the Test lens relative to the Control will be concluded if the upper limit is below 0.10 logMAR. The superiority will be established if the upper limit is below 0.00 logMAR.

14.7. Other Exploratory Analyses

Further exploratory analysis can be undertaken if necessary at the discretion of the Study Responsible Clinician.

14.8. Interim Analysis

There will be no interim analysis.

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). An authorised 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.

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 authorised 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.

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 initialled 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), 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 2013 and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with Section 8 of the ICH E6 guidelines on Good Clinical Practice (GCP), and applicable regulatory requirements.

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 fulfil 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, current ICH and GCP guidelines, applicable regulatory requirements, and Sponsor policy.

Before entry into the study, the Investigator or an authorised 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 Data Protection Act of 1998 and other applicable personal data protection and security laws and regulations. Appropriate measures will be employed to safeguard these data, to maintain the confidentiality of the person’s related health and medical information, to properly inform the concerned persons about the collection and processing of their personal data, to grant them reasonable access to their personal data and to prevent access by unauthorised 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 organisations 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 organisational measures to protect the personal data against unauthorised 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, 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/GCP Section 8, Essential Documents for the Conduct of a Clinical Trial, 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 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents will be retained for a longer period if required by the applicable regulatory requirements or 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 Investigator's Research Agreement. The Research Agreement will be signed by the Principal Investigator and a JJVC management representative prior to study initiation.

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

JJVC reserves the right to withhold remuneration for costs associated with protocol violations such as:

- Continuing an ineligible subject in the study

21. PUBLICATION

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

22. REFERENCES

1. Young G, Schnider C, Hunt C, Efron S. Corneal topography and soft contact lens fit. *Optom Vis Sci.* 2010; 87:358-366.
2. Stroup, W.W. *Generalized Linear Mixed Models, Modern Concepts, Methods and Applications* 2013.467-497
3. Wilson EB. Probable inference, the law of succession, and statistical inference. *J Am Stat Assoc.* 1927;22:309-312.
4. Kenward MG, Roger JH, Small sample inference for fixed effects from restricted maximum likelihood. Biometrics 1997; 53: 983-997
5. International Conference on Harmonization Guideline for Good Clinical Practice E6(R1) (ICH-GCP). Available at: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf
6. ISO 14155:2011: Clinical investigation of medical devices for human subjects – Good clinical practice.
7. Declaration of Helsinki – Ethical principles for Medical Research Involving Human Subjects. Available at:http://www.wma.net/en/30publications/10policies/b3/index.html

APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

APPENDIX B: PATIENT INSTRUCTION GUIDE

A patient instruction guide will be provided separately

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

- Investigational Products: Senofilcon A contact lens in flat and steep base curves.
- Control Products: Narafilcon A contact lens in flat and steep base curves

released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

E. Final Lens Power (Spherical)
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:	-2.00D
Spherical over-refraction:	-0.25D
Final lens power:	-2.25D

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

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If the fit is acceptable, dispense the lenses and instruct the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.

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, daily disposable modality, and proper lens handling procedures.

Recommended Follow-up Examination Schedule (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 (unless contraindicated).
   - 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, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
   - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

MONOVISION FITTING GUIDELINES

A. Patient Selection

Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient with significant astigmatism (greater than 1.00D) in one eye may not be a good candidate for monovision correction with these lenses.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision 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 driver's license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

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 spectacles (multifocal, bifocal, trifocal, readers, or progressives). 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. Therefore, caution should be exercised. 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.

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

1. 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."

2. 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.

3. 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.

C. Special Fitting Characteristics

1. Unilateral Vision Correction Requirement

There are circumstances where only one contact lens is required. As an example, an emmetripoc patient would only require a near lens, whereas a bilateral myope would require corrective lenses on both eyes.

Examples: A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without correction.

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 eye uncorrected for near.

2. Near ADD Determination

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

3. 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 is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

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

4. 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 adaptation symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be 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.

5. 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 their meet state driver's licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Monovision fitting success 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 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 PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.

PATIENT MANAGEMENT

Dispensing Visit
Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with methyl ether cellulose. To remove 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 apply and remove his or her lenses.
- Explain daily disposable lens wear and schedule a follow-up examination.
- **Provide the patient with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.**
  REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULES.

IMPORTANT: Please read carefully and keep this information for future use.

This Package Insert is intended for the Eye Care Professional, but should be made available to patients upon request.

The Eye Care Professional should provide the patient with the appropriate instructions that pertain to the patient's prescribed lenses. Copies are available for download at www.acuvue.com.

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 satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and refit the patient.

WEARING SCHEDULE

The wearing schedule should be determined by the Eye Care Professional. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Maximum wearing time should be determined by the Eye Care Professional based upon the patient's physiological eye condition, because individual response to contact lenses varies.

The maximum suggested wearing time for these lenses is:

Day	Hours
1	6-8
2	8-10
3	10-12
4	12-14
5 and after	all waking hours

REPLACEMENT SCHEDULE

These lenses are indicated for daily disposable wear and should be discarded upon removal.

LENS CARE DIRECTIONS

When lenses are prescribed for daily disposable wear, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions for daily disposable lens wear at the time they are dispensed.

The Eye Care Professional should review with patients that no cleaning or disinfection is needed with daily disposable lenses. Patients should always dispose of lenses when they are removed and have spare lenses or spectacles available.

Basic Instructions

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Eye Care Professionals may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

Care for a Sticking (Non-Moving) Lens

If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should immediately consult the Eye Care Professional.

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

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

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: 1-800-843-2020
www.acuvue.com

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
Tel: 1-800-843-2020
www.acuvue.com

20400995

In Canada: Johnson & Johnson Vision Care, division of Johnson & Johnson, Inc.
In USA: Johnson & Johnson Vision Care, Inc.
Printed in USA.
Revision date 05/15
Revision number: AO-03-15-01

ACUVUE® OASYS WITH HydraLuxe™
BRAND CONTACT LENSES

senofilcon A Soft (hydrophilic) Contact Lenses
Visibility Tinted with UV Blocker
for Daily Disposable Wear

℞ Only

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

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	Consult Instructions for Use
	Manufactured by or in
	Date of Manufacture
	Use By Date (expiration date)
LOT	Batch Code
STERILE	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CE 0086	Quality System Certification Symbol
UV Blocking	UV-Blocking
	Fee Paid for Waste Management
Rx Only	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)

DESCRIPTION

ACUVUE OASYS® Brand Contact Lenses made with HydraLuxe™ Technology are soft (hydrophilic) contact lenses available as spherical lenses.

These lenses are made of a silicone hydrogel material containing an internal wetting agent, visibility tint, and UV absorbing monomer and are tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling.

A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics for these lenses are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

Lens Properties:

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 - 1.12
- Refractive Index: 1.42
- Light Transmission: 85% minimum
- Surface Character: Hydrophilic
- Water Content: 38%
- Oxygen Permeability:

VALUE	METHOD
122 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) at 35°C	Fatt (boundary corrected, non-edge corrected)
103 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) at 35°C	Fatt (boundary corrected, edge corrected)

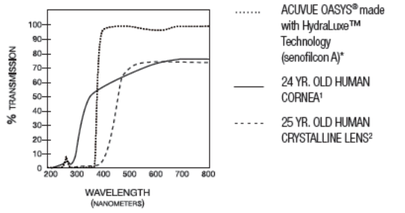
AVAILABLE LENS PARAMETERS

ACUVUE OASYS® Brand Contact Lenses made with HydraLuxe™ Technology are hemispherical shells of the following dimensions:

Diameter:	14.3 mm
Center Thickness:	0.085 mm to 0.221 mm (varies with power)
Base Curve:	8.5 mm, 9.0 mm
Powers:	-0.50D to -6.00D (in 0.25D increments) -6.50D to -10.00D (in 0.50D increments) -10.50D to -12.00D (in 0.50D increments) +0.50D to +6.00D (in 0.25D increments) +6.50D to +8.00D (in 0.50D increments)

TRANSMITTANCE CURVES

ACUVUE OASYS® made with HydraLuxe™ Technology (senofilcon A) Visibility Tinted with UV Blocker vs. 24 yr. old human cornea and 25 yr. old human crystalline lens.



* The data was obtained from measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-3.00D lens, 0.085 mm center thickness).
¹Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21
²Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5

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. The patient should continue to use UV absorbing eyewear as directed.

ACTIONS

In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays onto the retina.

The transmittance characteristics for these lenses are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-Blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-Blocking contact lenses reduces the risk of developing cataracts or other eye disorders. The Eye Care Professional should be consulted for more information.

INDICATIONS (USES)

ACUVUE OASYS® Brand Contact Lenses made with HydraLuxe™ Technology are indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism.

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

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 hypoesthesia (reduced corneal sensitivity).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa 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., rewetting drops) that contain chemicals or preservatives (such as mercury, Thimerosal, etc.) to which some people may develop an allergic response.
- Any active corneal infection (bacterial, fungal, protozoal or viral).
- If eyes become red or irritated.

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 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.

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

Specific Instructions for Use and Warnings:

- **Water Activity**

Instructions for Use

Do not expose contact lenses to water while wearing them.

WARNING:
Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If lenses have been submersed in water when participating in water sports or swimming in pools, hot tubs, lakes or oceans, the patient should be instructed to discard them and replace them with a new pair. The Eye Care Professional should be consulted for recommendations regarding wearing lenses during any activity involving water.

PRECAUTIONS

Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.
- Patients who wear these lenses to correct presbyopia using monovision may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eye Care Professionals should carefully instruct patients about the following care regimen and safety precautions.

Handling Precautions:

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her.
- **DO NOT** use if the sterile blister package is opened or damaged.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- **DO NOT** touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the "Patient Instruction Guide" for the prescribed wearing schedule and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Slide the lens up the side of the bowl until it is free of the container.
- Do not touch the lens with fingernails.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for a Sticking (Non-Moving) Lens." The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- The patient should be advised to never allow anyone else to wear their lenses. They have been prescribed to fit their eyes and to correct their vision to the degree necessary. Sharing lenses greatly increases the chance of eye infections.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Always discard lenses worn as prescribed by the Eye Care Professional.

Lens Care Precautions:

- The patient should be informed that no cleaning or disinfection is needed when lenses are worn for daily disposable wear. Patients should always dispose of lenses when removed and have spare lenses or spectacles available.

Other Topics to Discuss with Patients:

- Always contact the Eye Care Professional before using any medicine in the eyes.
- 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 being a contact lens wearer.
- 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.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur when wearing contact lenses:

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- 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, or 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, photophobia, 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 self-examination 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 stops, the patient should discard the lens and place a new fresh lens on the eye. If after inserting the new lens, the problem continues, the patient should be directed to IMMEDIATELY REMOVE THE LENS AND CONTACT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be instructed NOT to use a new lens as self-treatment for the problem.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING GUIDELINES

A. Patient Selection
Patients selected to wear these lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear

Patients who do not meet the above criteria should not be provided with contact lenses.

B. Pre-fitting Examination
Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription (including determining the preferred reading distance for presbyopes), keratometry, and biomicroscopic evaluation.

Based on this evaluation, if it is determined that the patient is eligible to wear these lenses, the Eye Care Professional should proceed to the lens fitting instructions as outlined below.

C. 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 ±4.00D.

D. Base Curve Selection (Trial Lens Fitting)
An 8.5 mm/14.3 mm trial contact lens should be selected for patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

The trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. Criteria of a Properly Fit Lens

   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.

2. Criteria of a Flat Fitting Lens

   A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If the lens is judged to be flat fitting, it should not be dispensed to the patient.

3. Criteria of a Steep Fitting Lens

   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 lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial trial base curve is judged to be flat or steep fitting, the alternate base curve, if available, should be trial fit and evaluated after the patient has adjusted to the lens. The lens should move freely when manipulated digitally with lower lid, and then return to a properly centered position when

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

III. MONOVISION (SPHERICAL) FITTING GUIDELINES

A. Patient Selection

Monovision Needs Assessment
For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient with significant astigmatism (greater than 1.00D) in one eye may not be a good candidate for monovision correction with the 1-DAY ACUVUE® TruEye® Brand Contact Lenses.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision correction. Monovision contact lens wear may not be optimal for such activities as:

(a) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(b) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

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 spectacles (multifocal, bifocal, trifocal, readers, progressives). 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. Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments (e.g., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). 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.

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 satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and refit the patient.

WEARING SCHEDULE

The wearing schedule should be determined by the Eye Care Professional. Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

Daily Wear (less than 24 hours, while awake)
For Daily Disposable Wear, JJVCI recommends that the 1-DAY ACUVUE® TruEye® Brand Contact Lenses be discarded upon removal.

Maximum wearing time should be determined by the Eye Care Professional based on the patient's physiological eye condition, because individual response to contact lenses varies. However, JJCVI recommended maximum wearing time for these lenses is:

DAYS	HOURS
1	6-8
2	8-10
3	10-12
4	12-14
5 and after	all waking hours

Studies have not been completed to show that the lens is safe to wear during sleeping.

LENS CARE DIRECTIONS:
When lenses are dispensed, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions in accordance with the individual patient's lens type and wearing schedule.

For 1-DAY ACUVUE® TruEye® Brand Contact Lenses: The Eye Care Professional should review with patients that no cleaning or disinfection is needed. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

B. Eye Selection

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

1. 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.

2. 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.

3. 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.

C. Special Fitting Characteristics

1. 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 the other eye left without a lens.

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.

Care for sticking (non-moving) lenses
If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should immediately consult the Eye Care Professional.

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

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

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

3. 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 Instructions for base curve selection in this Package Insert.

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 newsprint and finally smaller type sizes.

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

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

4. 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 adaptation symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation. To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be 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.

Monovision fitting success 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 "1-DAY ACUVUE® TruEye® Brand Contact Lenses Patient Instruction Guide".

REPORTING OF ADVERSE REACTIONS

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

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
Tel: 1-800-843-2020
www.acuvue.com

PATIENT MANAGEMENT

Dispensing Visit

- **PROVIDE THE PATIENT WITH A COPY OF THE 1-DAY ACUVUE® TruEye® Brand Contact Lenses PATIENT INSTRUCTION GUIDE. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING SCHEDULE**.
- Schedule a follow-up examination.

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 and handling procedures.
- Recommended Follow-up Examination Schedule for 1-DAY ACUVUE® TruEye® Brand Contact Lenses (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
- 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 (unless contraindicated).
     - 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, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
     - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
  6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
Tel: 1-800-843-2020
www.acuvue.com

20400875

Printed in U.S.A.
Revision date: 1/11/13
Revision number: AS011303

IMPORTANT: Please read carefully and keep this information for future use.

This Package Insert and Fitting Guide is intended for the Eye Care Professional, but should be made available to patients upon request. The Eye Care Professional should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

1-DAY ACUVUE® TruEye® Brand Contact Lenses with HYDRACLEAR® 1 Technology

(narafilcon A)

Visibility Tinted with UV Blocker for Daily Wear Single Use Only

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
⚠	See Instruction Leaflet
⌛	Use By Date (expiration date)
LOT	Batch Code
STERILE	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CE 0086	Quality System Certification Symbol
	UV-Blocking
	Fee Paid for Waste Management
	Peel Back Foil
Rx Only	CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner
C.T.	Center Thickness
	Lens Orientation Correct
	Lens Inside Out
	Consult Instructions for Use
	Manufactured by or in

Spherical Lenses For: Myopia, Hyperopia, Phakic or Aphakic 1-DAY ACUVUE® TruEye® Brand Contact Lenses with HYDRACLEAR® 1 (narafilcon A)

CAUTION: Federal U.S.A. law restricts this device to sale by or on the order of a licensed practitioner.

DESCRIPTION

The 1-DAY ACUVUE® TruEye® Brand Contact Lenses with HYDRACLEAR® 1 Technology (narafilcon A) are available as Spherical lenses. The lens is made of a silicone hydrogel material containing an internal wetting agent with visibility tinted UV absorbing monomer. 1-DAY ACUVUE® TruEye® Brand Contact Lenses with HYDRACLEAR® 1 (narafilcon A) Visibility Tinted with UV Blocker are tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling.

A benzotriazole UV-absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

Lens Properties:

- Specific Gravity (calculated): 1.06
- Refractive Index: 1.41
- Light Transmittance: 85% minimum
- Surface Character: Hydrophilic
- Water Content: 46%
- Oxygen Permeability:

VALUE	METHOD
100 x 10^{-11} (cm²/sec) (ml O_2/ml x mm Hg) at 35°C	Fatt (boundary corrected, edge corrected).

Lens Parameters:

The 1-DAY ACUVUE® TruEye® Brand Contact Lenses with HYDRACLEAR® 1 (narafilcon A) are a hemispherical shell available within the following dimensions:

Diameter Range:	12.0mm to 15.0mm
Center Thickness:	Low minus lens – (0.085mm) Plus Lens - varies with power (e.g., +3.00D, 0.171mm)
Base Curve:	7.80mm to 10.00mm
Powers:	-20.00D to +20.00D

Available Lens Parameters:

Minus

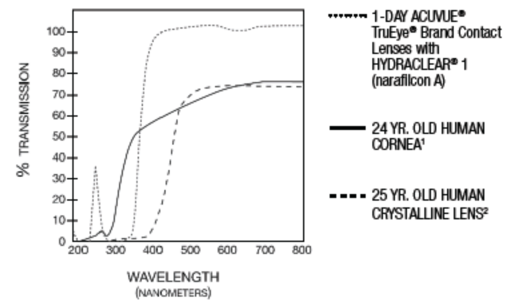
Diameter:	14.2mm
Base Curve:	8.5mm and 9.0mm
Center Thickness:	Minus lens - varies with power (e.g., -3.00D, 0.085mm)
Power Range:	-0.50D to -10.00D (in 0.25D increments) -10.50D to -12.00D (in 0.50D increments)

Plus

Diameter:	14.2mm
Base Curve:	8.5mm and 9.0mm
Center Thickness:	Plus lens - varies with power (e.g., +3.00D, 0.171mm)
Power Range:	+0.50D to +6.00D (in 0.25D increments)

Transmittance Curves:

1-DAY ACUVUE® TruEye® Brand Contact Lenses Visibility Tinted With UV Blocker vs., 24-Yr.-Old Human Cornea And 25-Yr.-Old Human Crystalline Lens.



*The data was obtained from measurements taken through the central 3-5mm portion for the thinnest marketed lens (-1.00D lens, 0.085mm center thickness).

1. Lerman, S., Radient Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21
2. Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5

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.

ACTIONS

In its hydrated state the 1-DAY ACUVUE® TruEye® Brand Contact Lenses, when placed on the cornea, act as a refracting medium to focus light rays onto the retina.

The transmittance characteristics are less than 1% in the UVB range of 280nm to 315nm and less than 10% in the UVA range of 316nm to 380nm for the entire power range.

Note: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

INDICATIONS (USES)

All 1-DAY ACUVUE® TruEye® Brand Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The 1-DAY ACUVUE® TruEye® Brand Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism.

Eye Care Professionals should prescribe the lenses for daily wear single use only (see "Wearing Schedule"). The lenses are to be discarded upon removal. Therefore, no cleaning or disinfection is required.

CONTRAINDICATION (REASONS NOT TO USE)

DO NOT USE the 1-DAY ACUVUE® TruEye® Brand Contact Lens when any of the following conditions exist:

- Inflammation or infection in or around the eye or eyelids
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Any previously diagnosed condition that makes contact lens wear uncomfortable
- Severe dry eye
- Reduced corneal sensitivity (corneal hypoesthesia)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues (adnexa) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS

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

- 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.
- Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Studies have shown that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users[1].
- When daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is greater than among those who do not wear them overnight.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- Studies have shown that the risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.

If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Professional. It is recommended that contact lens wearers see their Eye Care Professional routinely as directed.

¹New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

PRECAUTIONS

Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness and optic zone diameter.

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.
- Patients who wear the 1-DAY ACUVUE® TruEye® Brand Contact Lenses to correct presbyopia using Monovision may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eye Care Professionals should carefully instruct lens wear patients about the following care regimen and safety precautions:

Handling Precautions:

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- **DO NOT** use if the sterile blister package is opened or damaged.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- **DO NOT** touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the "Patient Instruction Guide" for the 1-DAY ACUVUE® TruEye® Brand Contact Lenses and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.
- Do not touch the lens with fingernails.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for a Sticking Lens". The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the Eye Care Professional about wearing lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- Always discard lenses worn as prescribed by the Eye Care Professional.

Lens Care Precautions:

- The patient should be informed that no cleaning or disinfection is needed with daily wear single use only lenses. Patients should always dispose of lenses when removed and have replacement lenses or spectacles available.

Other Topics to Discuss with Patients:

- Always contact the Eye Care Professional before using any medicine in the eyes.
- 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?

- Inform the doctor (Health Care Professional) about being a contact lens wearer.
- Always inform the 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.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur when wearing contact lenses:

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- 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, photophobia or dry eyes may occur if the lenses are worn continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part self-examination 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 discomfort or problem stops, the patient should then look closely at the lens.

If the lens is in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and place a new fresh lens on the eye.

If the lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, he or she should be instructed to dispose of the lens and apply a new fresh lens.

If the problem continues, the patient SHOULD NOT put the lens back on the eye but IMMEDIATELY CONSULT HIS OR HER Eye Care Professional.

The patient should be instructed NOT to use a new lens as self-treatment for the problem.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING GUIDELINES

I. GENERAL FITTING INSTRUCTIONS

1-DAY ACUVUE® TruEye® Brand Contact Lenses

A. Patient Selection

Patients selected to wear 1-DAY ACUVUE® TruEye® Brand Contact Lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear

Patients who do not meet the above criteria should not be provided with contact lenses.

B. Pre-fitting Examination

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription (including determining the preferred reading distance for presbyopes), keratometry and biomicroscopic evaluation.

Based on this evaluation, if it is determined that the patient is eligible to wear the 1-DAY ACUVUE® TruEye® Brand Contact Lenses, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

C. 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 ±4.00D.

D. Base Curve Selection (Trial Lens Fitting)

For the 1-DAY ACUVUE® TruEye® Brand Contact Lenses, the 8.5mm/14.2mm contact lens should be selected for myopic patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

A 1-DAY ACUVUE® TruEye® Brand Contact Lens trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. Criteria of a Properly Fit Lens

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.

2. Criteria of a Flat Fitting Lens

A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If the 1-DAY ACUVUE® TruEye® Brand Contact Lens is judged to be flat fitting, it should not be dispensed to the patient.

3. Criteria of a Steep Fitting Lens

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 1-DAY ACUVUE® TruEye® Brand Contact Lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial 1-DAY ACUVUE® TruEye® Brand Contact Lens base curve is judged to be flat or steep fitting, the alternate base curve, if available, should be trial fit and evaluated after the patient has adjusted to the lens. The lens should move freely when manipulated digitally with lower lid and then return to a 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.

II. Spherical Lens Fitting Guidlines

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:	-2.00D
Spherical over-refraction	-0.25D
Final lens power:	-2.25D

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

APPENDIX D: GRADING & MEASUREMENT SYSTEM

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APPENDIX E: [redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS

[redacted] **Determination of Distance Spherocylindrical Refractions**

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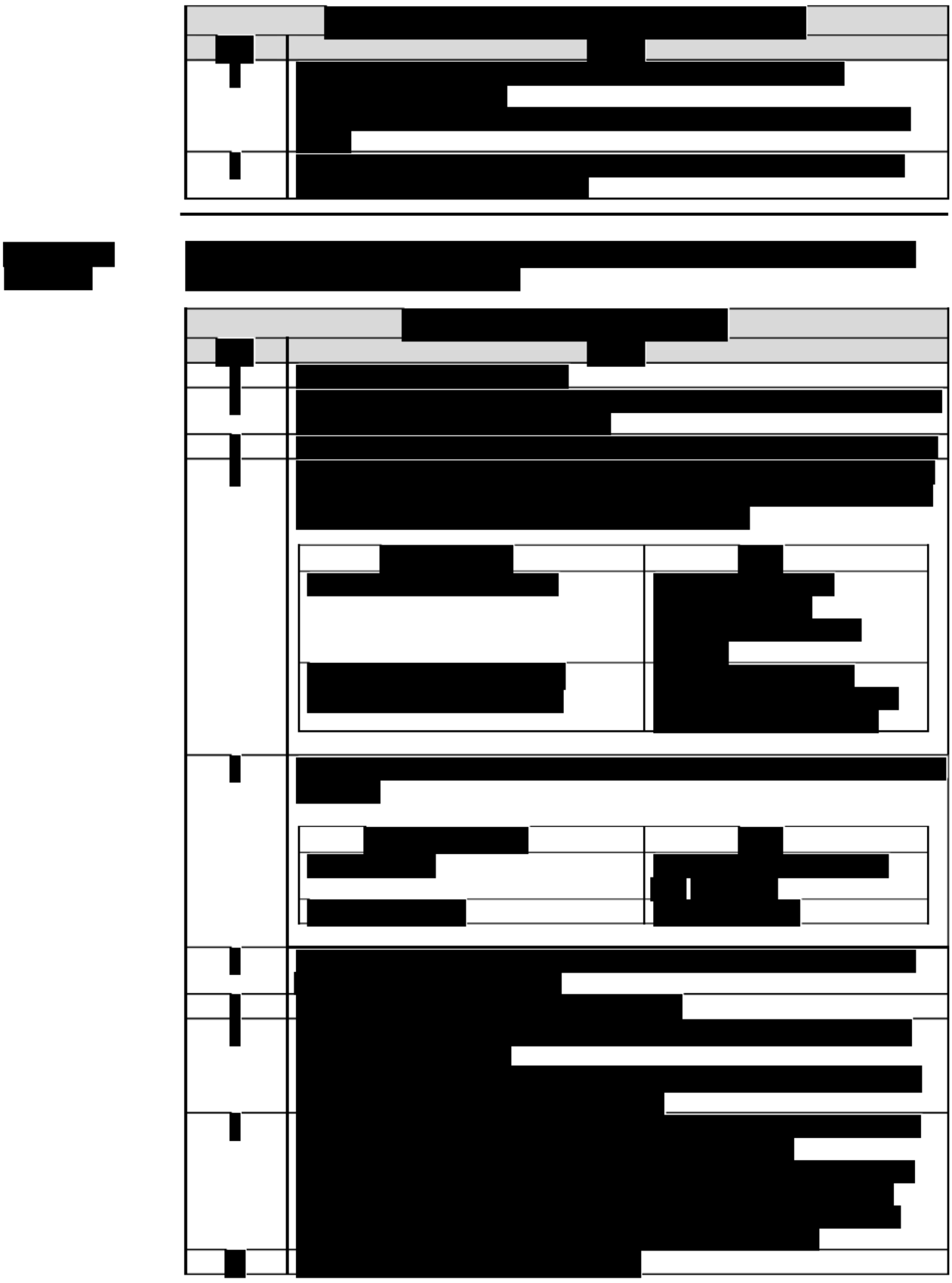

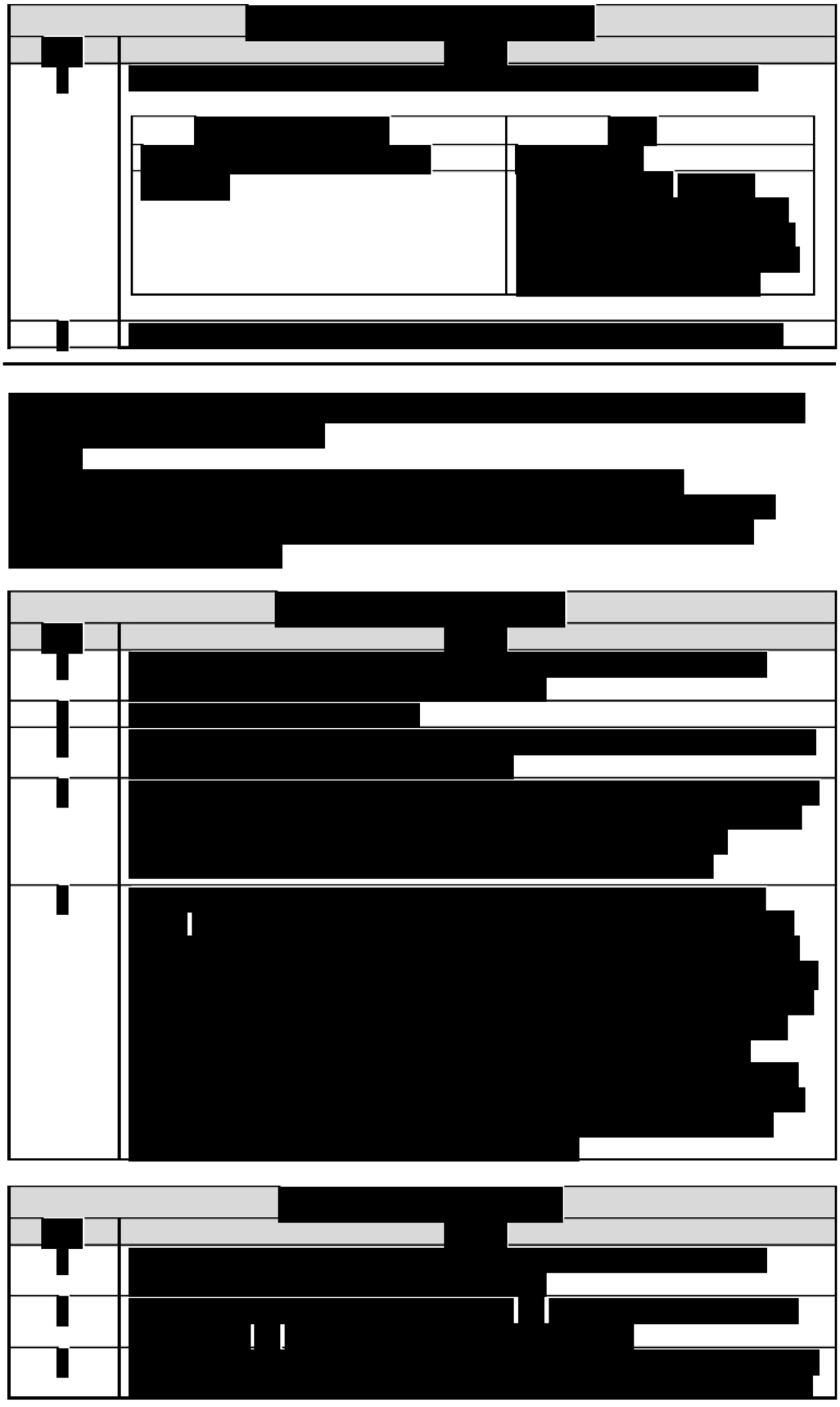

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APPENDIX F: [redacted] BIOMICROSCOPY SCALE

[redacted] **Biomicroscopy Scale**

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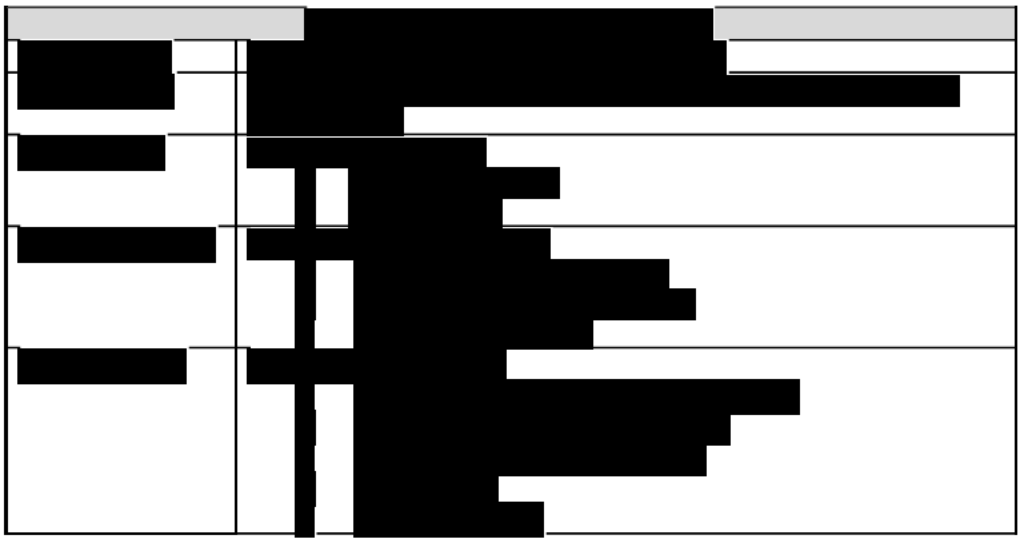

APPENDIX G: [redacted] DISTANCE AND NEAR VISUAL ACUITY EVALUATION

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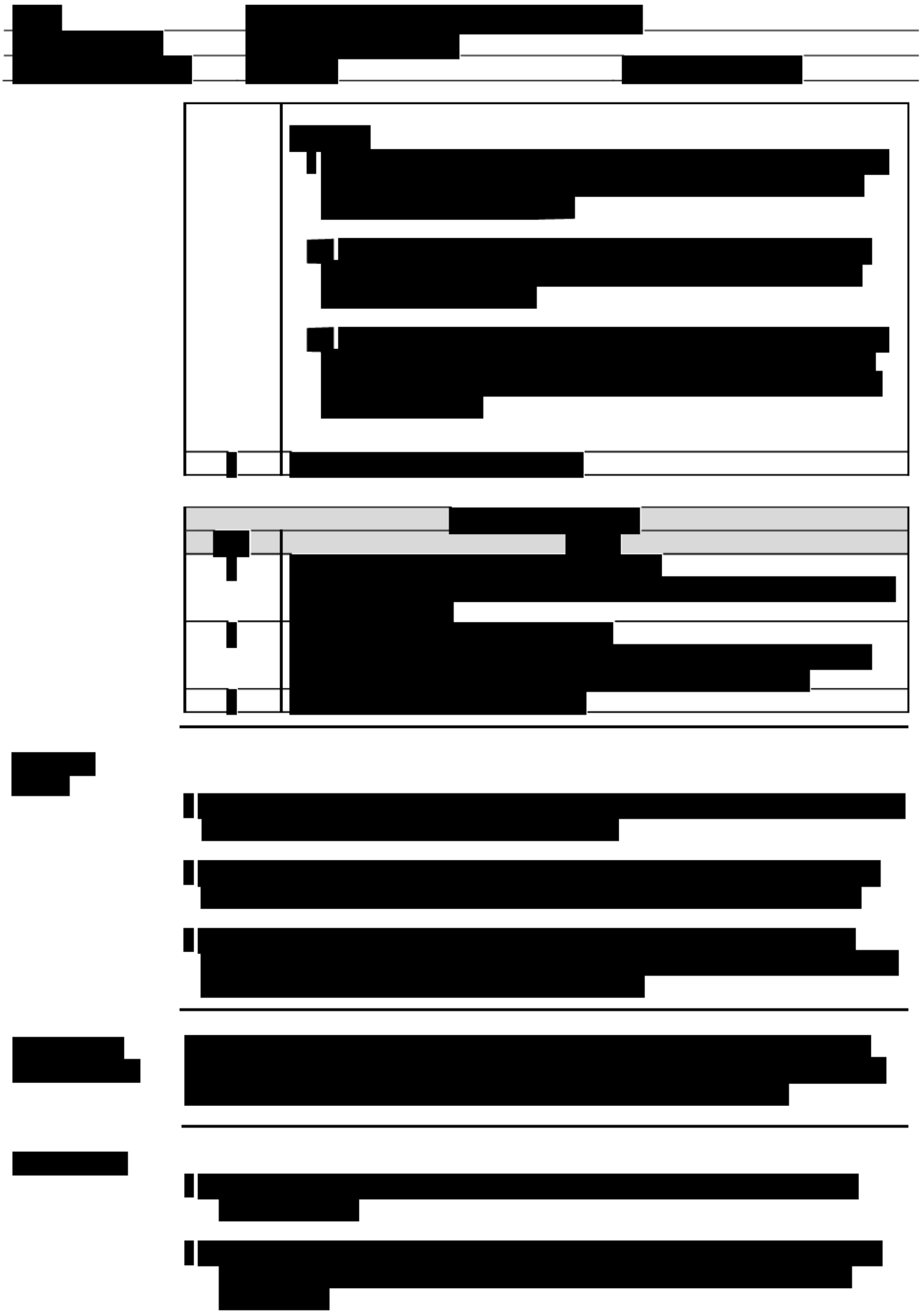

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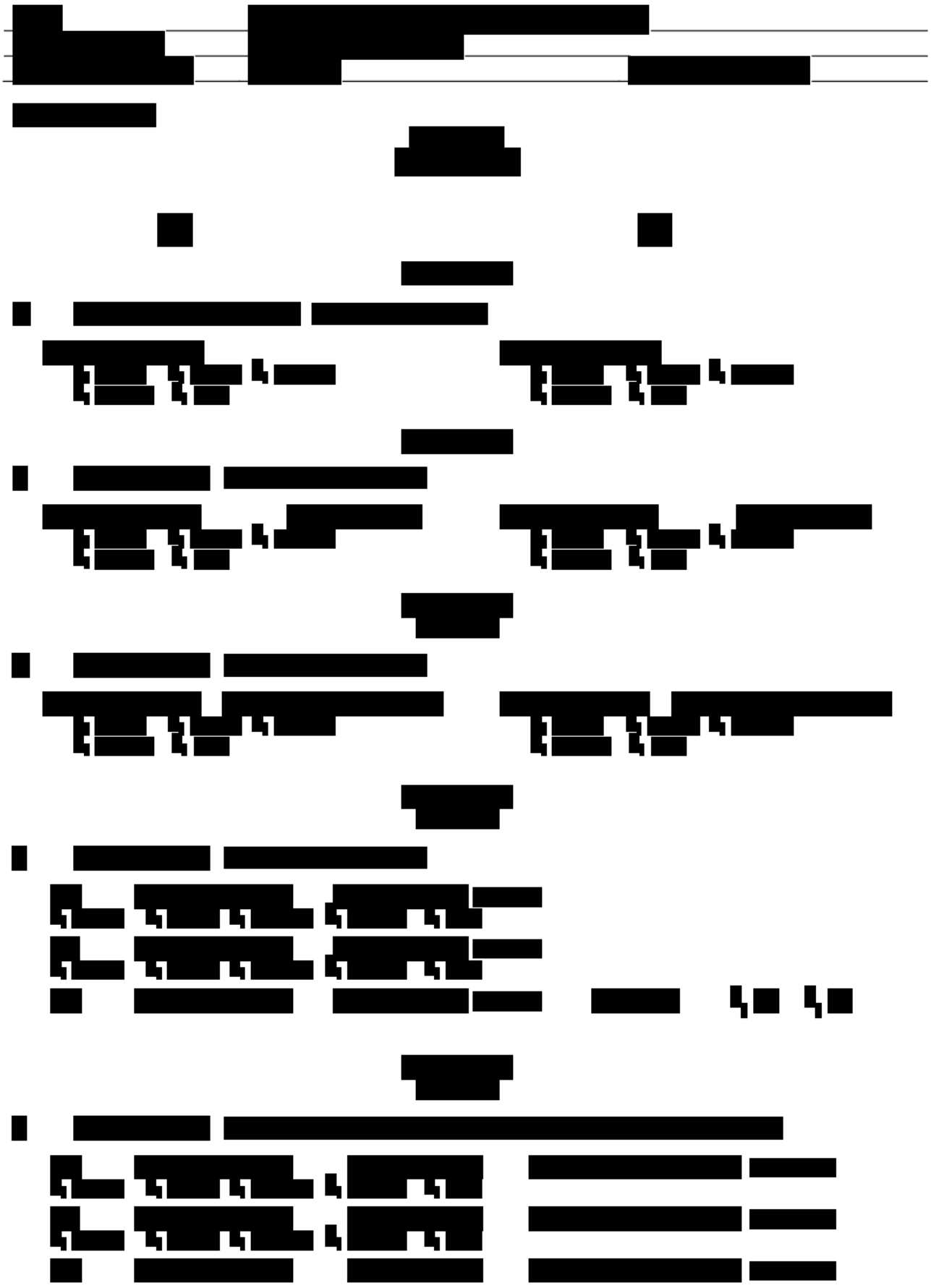


APPENDIX H: TOPOGRAPHY MEASUREMENT USING MEDMONT E300 CORNEAL TOPOGRAPHER

1.0 OBJECTIVES

Acquire and save corneal topography maps.

2.0 MATERIALS

The Medmont E300 Corneal Topographer is a computerized Videokeratometer using Placido-rings to map the surface of the human cornea.

SOFTWARE VERSION

The E300 Software is part of the Medmont Studio integrated software environment. The instructions in this Appendix apply to Medmont Studio 4 software *version 4.14.1.* Other versions of the software are unlikely to have substantial difference in basic function or data integrity.

3.0 DATA MANAGEMENT

The MEDMONT E300 software generates computer files which are considered source data. At a minimum, the Source Data must be saved in a secure location and a backup copy created.

Primary source data are the image files and the Medmont's internal database. Secondary source data are the output files for the selected map (.axl, .tgl, .dst, .hgt) and the pupil decentration vector (r, theta) which is recorded in the Case Report Form.

4.0 PROCEDURES

CALIBRATION

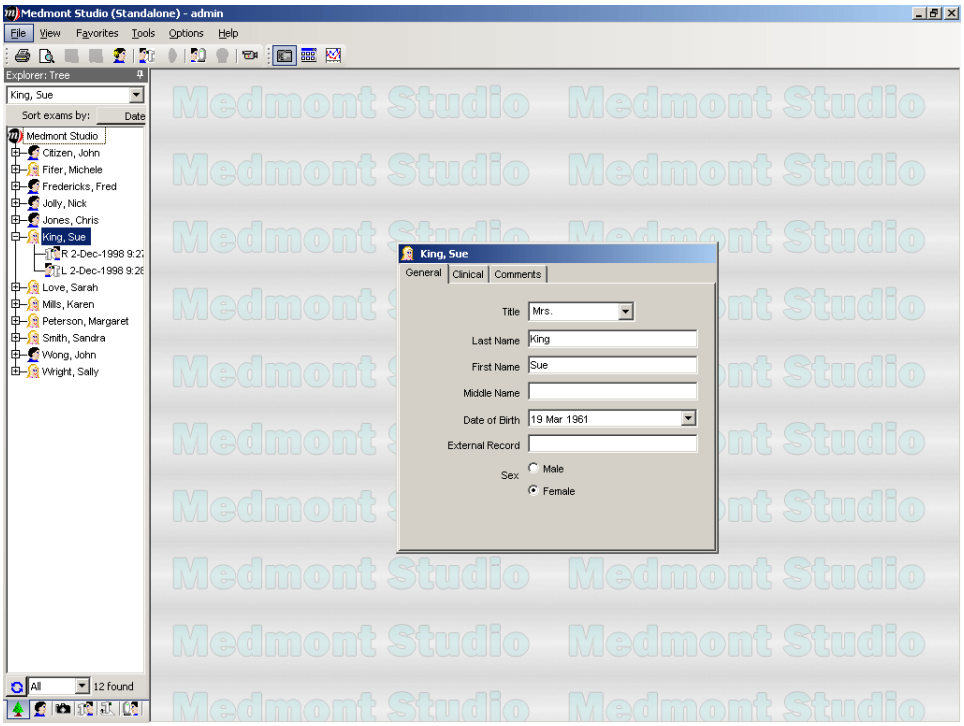
Medmont corneal topographer will be calibrated using the standard calibration object provided by the manufacturer following the steps described in the user manual.

CAPTURING AND SAVING TOPOGRAPHY

The following sections describe the steps to performing an examination with the Medmont E300 instrument.

PATIENT SELECTION

The recommended practise is to have a patient selected before starting to capture and analyse an exam. Figure 1 shows the Medmont Studio initial display with a patient selected in the explorer pane.



POSITIONING THE PATIENT

In order to capture good quality and accurate images some precautions should be followed in positioning the patient correctly.

The patient should sit comfortably in the chair. Ask the patient to put her chin onto the chinrest and put her forehead firmly against the forehead rest. She should then push her chin forward on the chinrest. If the patient has deep-set eyes instruct her to move her head back from the headrest. This rotates the eye away from the eyebrow and eyelashes and produces better coverage and fewer interruptions of rings on the upper cornea. Adjust the eye height to the level marks on the chinrest.

Ask the patient to look into the centre of the green fixation target and keep her gaze on this target. The target centre point together with the centre of the ring pattern on the eye defines the Video-Keratoscope axis (VK-axis), the reference axis to which the axial radius/power is calculated (the values for tangential radius/power are less affected by the fixation).

When an image is taken with the patient not fixated on the target, the videokeratoscope axis may not be reproducible in future exams. Axial power maps are identical for fixated eyes. The tangential power for both images should have their centre in the same position relative to the pupil centre. If there are differences between maps and you suspect fixation errors, re-instruct the subject where to fixate, then re-capture the image and compare the old maps with the new maps to decide which ones correspond to good fixation. Ask the patient to open her eyelid as much as possible and close the other eye if necessary.

CAPTURING PATIENT EXAMS

Click on the button or the File > New > E300 Patient Exam menu to display the E300 Capture View (see Figure 3). The red illumination rings inside the E300 cone should turn on. Ensure the Normal radio button is selected in Capture Control window (Figure 2).

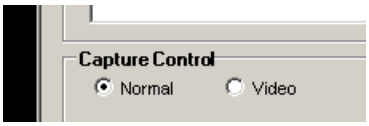


Figure 2. Selecting Normal (single frames) or Video capture control.

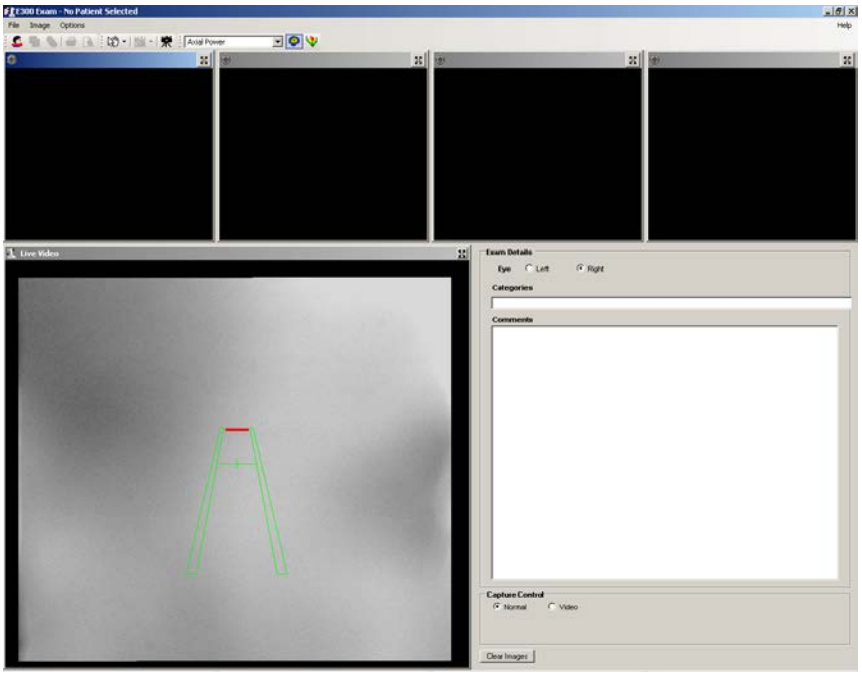


Figure 3. E300 Initial Capture Screen.

Select the eye to be examined in the Exam Details box (the right eye is the default).

The focussing window shows live video from the E300. The green and red target overlaid on the focussing window provides three-dimensional centring and focussing information. The green crosshair indicates the keratoscope axis. The red bar moving along a three-dimensional runway indicates the distance of the eye from the optimal focussing plane. The “view” is from the camera’s perspective, so if the red bar is at the top or narrowest part of the runway then the patient is still too far away.

The E300 joystick allows positioning in three dimensions. Move the joystick in the desired direction for movement left and right and for closer to or further away. Rotate the joystick knob for movement up and down, clockwise to raise, anti-clockwise to lower.

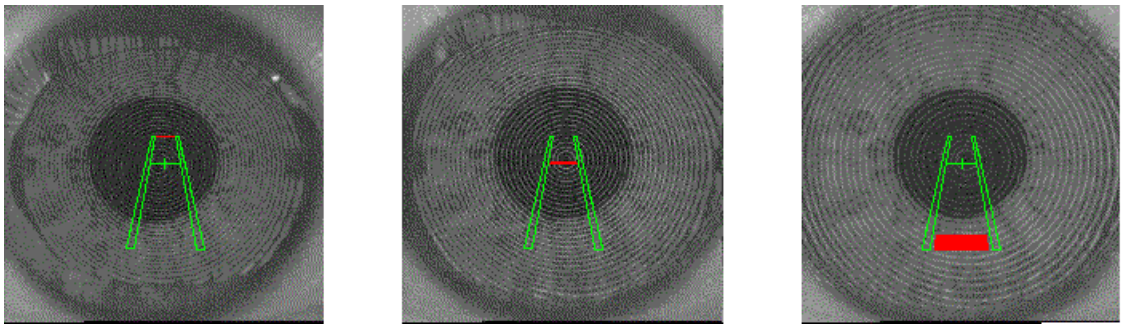


Figure 4. Focus examples showing Too Far, In Focus, and Too Near.

Using the joystick, position the E300 relative to the patient's eye so that the reflection of the Placido rings is centred on the green crosshair, and the red bar is over the horizontal green line. Once this is achieved, the software automatically captures the best set of images and displays them in the image windows along the top of the View pane, with the best images to the right. Images for automatic capturing are selected according to best centring, focussing and least eye movement. Figure 8 shows a typical capture screen display. It may not be possible to align the red focussing bar over the horizontal cross bar for patients with deep set eyes, because of contact between the bridge of the nose and the instrument. In this case, centre the Placido rings on the green crosshair and bring the red focussing bar as close to the horizontal green line as possible without causing patient discomfort. Provided that the red bar is somewhere within the focussing range (i.e. not at the very end) the software will automatically compensate for the focussing error.

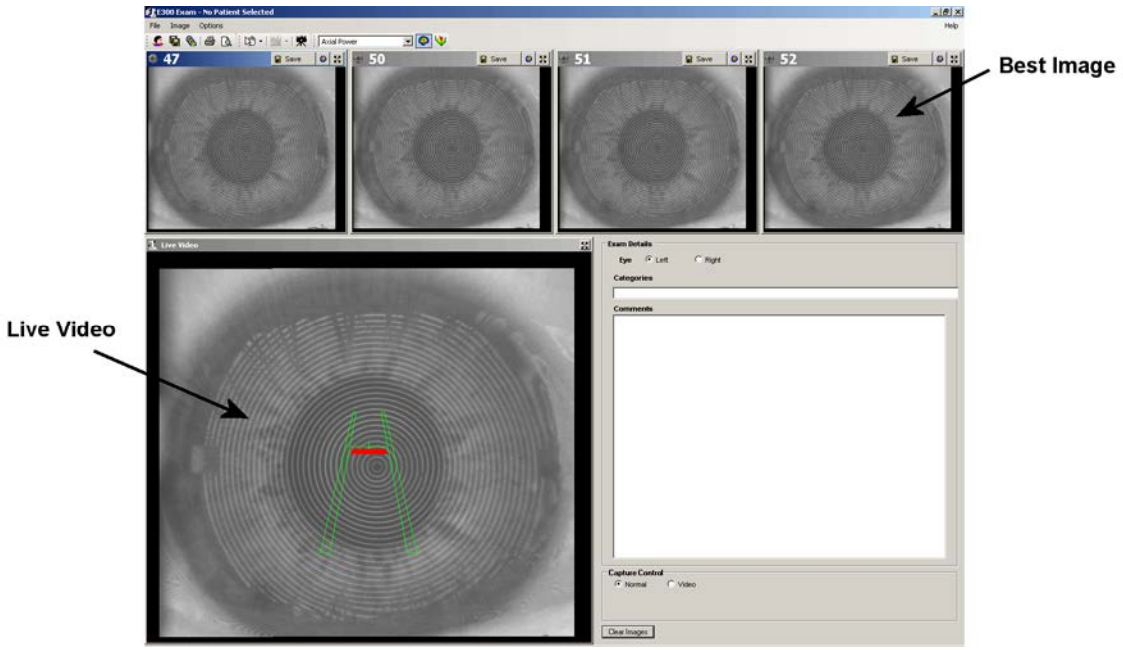


Figure 5. E300 Image Capture View.

SAVING THE BEST IMAGE

Each image captured is awarded a score out of 100 based on centring, focus and movement. The score is displayed as a large white number above each captured image. A good score for a normal eye will be over 75. Calibration balls can achieve scores of up to 100. Select the best image from those automatically captured. Typically this will be the right-most image. Click on an individual image's Expand/Collapse Testing a Patient button to expand the image to full-screen. You should consider the following factors when assessing images:

• Patient Fixation– choose images where the pupil is better centred with respect to the Placido rings.

• Eyelid Position – choose images where the patient's eyelid does not obscure large portions of the cornea or cause large eyelash shadows.

• Central Ring Clarity – choose images where the central Placido ring reflection is clearly visible. For some patients with extreme conditions, this may require shifting their fixation to get the central Placido ring area over an area with less surface irregularity. Click on an image's save button to save it. You can also save the set of images from the File > Save All Exams menu. Alternatively you may decide to analyse the image before saving. If this is the case then use File > Save from the analysis window. A Patient Exam item is added to the Explorer pane under the current patient. You can save more than one exam if you wish. To view the Exam Results, select the Exam in the Data pane and the View Mode (see Analyzing and Viewing Exam Results page 22 of the instruction manual).

EXPORTING THE ANALYSIS

For the selected map, record the pupil offset or decentration of the pupil center from the videokeratoscope axis as the pupil decentration vector (r, theta) from the screen.

The E300 software provides the facility to export raw topography data for the selected exam to a set of text files. This data can then be imported and manipulated by external software and tools. First select the exam analysis to export. Then select the button or the Analysis > Export menu and specify the "root" name and location of the files to create. Typically the file name is based on the study name, subject number, visit number, condition and eye (eg. 5032_001_V1bare_OD. The following files are created:

Filename.axl – axial curvature data (in mm)

Filename.tgl – tangential curvature data (in mm)

Filename.hgt – corneal height data (in mm)

Filename.dst – radial distance data (in mm)

5.0 PHOTODOCUMENTATION

Not applicable

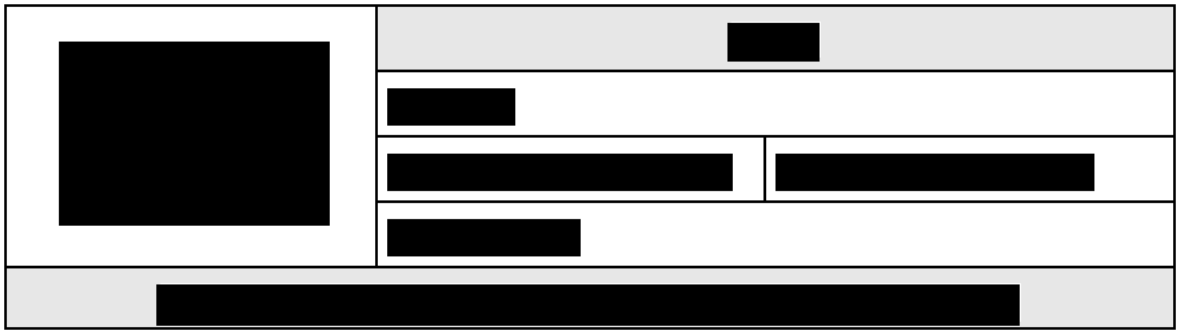
6.0 ADDITIONAL INFORMATION

Not applicable

7.0 TRAINING REQUIREMENTS

Read only

APPENDIX I: MEASURING THE OCULAR TOPOGRAPHY BY VISANTE OCT



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PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: CR-5932 Short-Term Clinical Comparison of Two Silicone Hydrogel Daily Disposable Contact Lenses

Version and Date: _V2.0 ,14-March-2017_____

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

I agree to conduct this study according to GCP and ICH guidelines, the Declaration of Helsinki, ISO 14155, United States (US) Code of Federal Regulations (CFR), 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 ICH 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 ICH 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 authorisation.

Principal Investigator:

_____ _____

Signature Date

_____

Name and Professional Position (Printed)

Institution/Site: _____

Institution/Site Name

_____

Institution/Site Address