Johnson & Johnson Vision Care, Inc.

Clinical Study Protocol

Evaluation of Two Marketed Multifocal Contact Lenses

Protocol CR-5860

Version: 3.0, Amendment 2.0

Date: 01-SEP-2017

Investigational Products: Dailies Total 1* Multifocal Contact Lens and Biotrue ONEday® for Presbyopia Contact Lens.

Key Words: Presbyopia, Daily Disposable, Dispensing, Multifocal, Nesofilcon A, Delefilcon A.

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

Confidentiality Statement:

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PROTOCOL TITLE, NUMBER, VERSION

Title: Evaluation of Two Marketed Multifocal Contact Lenses
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SPONSOR NAME AND ADDRESS

Johnson & Johnson Vision Care, Inc. (JJVC)
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MEDICAL MONITOR

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[redacted]

The Medical Monitor must be notified by the clinical institution/site by e-mail, fax, or telephone within 24 hours of learning of a Serious Adverse Event. The Medical Monitor may be contacted during business hours for adverse event questions. General study related questions should be directed towards your assigned clinical research associate.

The Medical Monitoring Plan is maintained as a separate document and included in the Trial Master File.

AUTHORIZED SIGNATURES

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

Author	Thomas R. Karkkainen, OD, MS, FAAO Title: Sr. Principal Research Optometrist	DATE
Clinical Operations Manager	[redacted] Clinical Operations Manager	DATE
Biostatistician	[redacted] Biostatistician IV	DATE
Data Management	[redacted] Clinical Project Manager-Data and Systems	DATE
Approver	[redacted] Presbyopia Platform Sr. Manager	DATE

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Date
1.0	Tom Karkkainen	Original Protocol	23-June-2017
2.0	[redacted]	Change Secondary Objective on page 17 to CLUE vision score.	30-June-2017
3.0	Tom Karkkainen	In section 2.3 updated hypotheses.	01-September-2017

SYNOPSIS

Protocol Title	Evaluation of Two Marketed Multifocal Contact Lenses
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Development phase, phase 0 (Research)
Trial Registration	This study will be registered on ClinicalTrials.gov by the Sponsor
Test Article(s)	Investigational Products: Biotrue ONEday and Oneday for Presbyopia and Dailies Total 1 Multifocal Contact Lenses. Control Products: None
Wear and Replacement Schedules	Wear Schedule: Daily Replacement Schedule: Daily Disposable
Objectives	Primary Objective: To evaluate the visual performance of a marketed multifocal contact lens in a population of presbyopes with myopia and hyperopia. Secondary Objective: CLUE vision score
Study Endpoints	Primary endpoints: The primary endpoints in this study are distance and near binocular high luminance, high contrast visual performance on logMAR scale. Secondary endpoint: The secondary endpoint is overall quality of vision assessed using the Contact Lens User Evaluation questionnaire (CLUE™). Other endpoint: Ease of fit as evaluated by the number of lenses used to optimize.

<table>
<tr><td>Study Design</td><td>This is a single-masked, randomized, cross-over, dispensing pilot study. There will be six study visits. Visit 1 will include baseline measurements and screening to ensure eligibility. Eligible subjects will be randomized and fit in one of the study lenses and dispensed for 2-4 days. At Visit 2 additional measurements will be performed and it will be determined if lens optimization is required and lenses dispensed for an additional 6-8 days. At Visit 3 the primary endpoint data used for analysis will be collected. There will be a 4-8-day washout before the subject will be fit with the 2nd lens at Visit 4 and dispensed for 2-4 days. At Visit 5 additional measurements will be performed and it will be determined if lens optimization is required and lenses dispensed for an additional 6-8 days. At Visit 6 the primary endpoint data used for analysis will be collected.

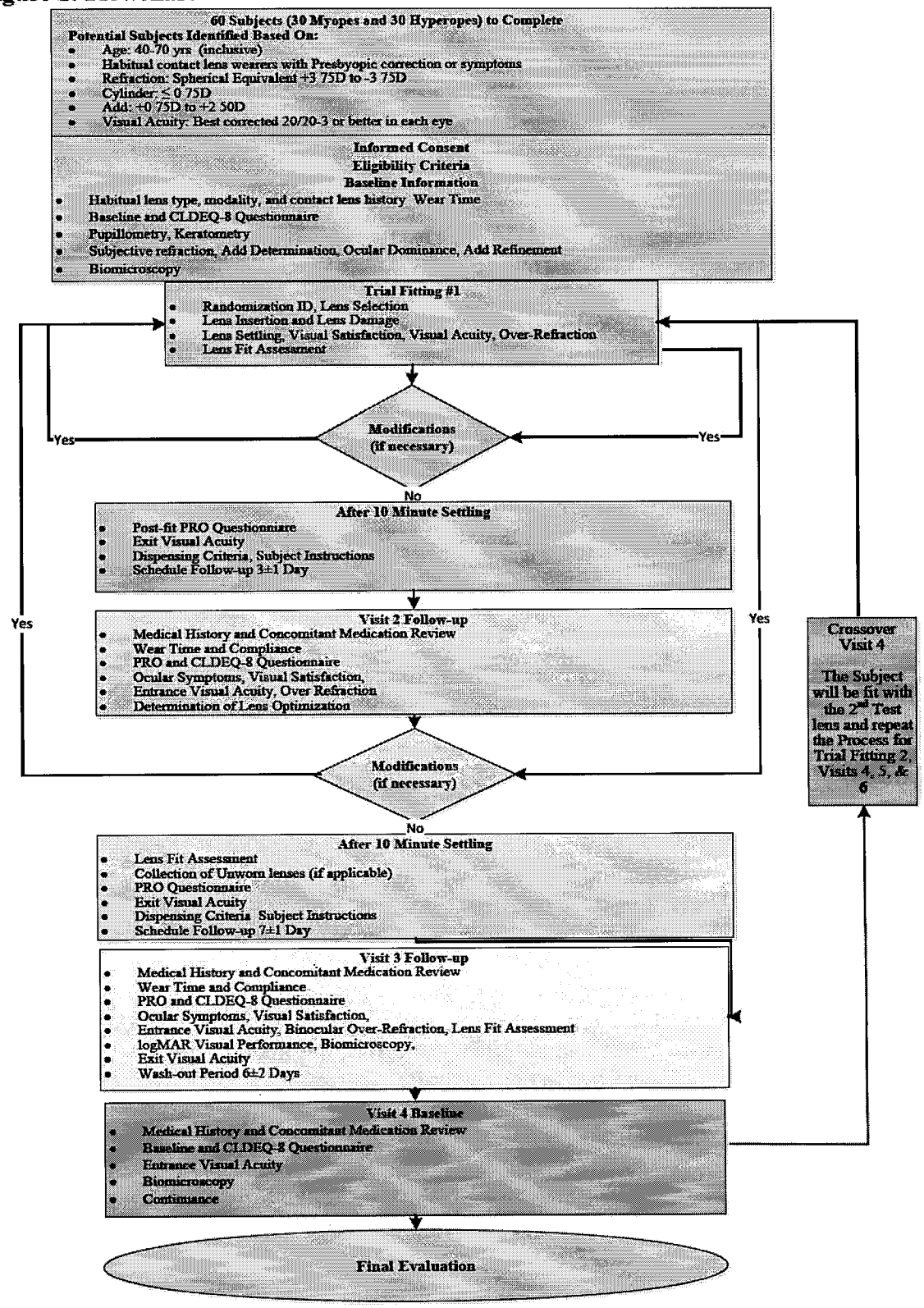
See the flow chart at the end of the synopsis table for the schematic of the study visits and procedures of main observations.</td></tr>
<tr><td>Sample Size</td><td>A total of approximately 80 eligible subjects will be enrolled into the study with 60 (30 myopes and 30 hyperopes) subjects targeted to complete the study. An attempt will be made to evenly distribute the subjects across the following ADD groups.

<table><tr><td>ADD 0.75 D to 1.50 D</td><td>ADD 1.75 D to 2.50 D</td></tr><tr><td>30 Subjects</td><td>30 Subjects</td></tr></table></td></tr>
<tr><td>Study Duration</td><td>The study recruitment is anticipated to be approximately 3 weeks and the data collection approximately and additional 3 weeks.</td></tr>
<tr><td>Anticipated Study Population</td><td>Habitual contact lens wearer who are myopic or hyperopic and have presbyopia.</td></tr>
<tr><td>Eligibility Criteria</td><td>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. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. The subject must be between at least 40 years of age and not greater than 70 years of age.
4. The subject's distance spherical equivalent refraction must be in the range of +3.75 D to -3.75 D.</td></tr>
</table>

	5. The subject's refractive cylinder must be ≤ -0.75 D in each eye. 6. The subject's ADD power must be in the range of +0.75 D to +2.50 D in each eye. 7. The subject must have best corrected visual acuity of $20/20^{-3}$ or better in each eye. 8. The subject must own a pair of wearable spectacles if required for their distance vision. 9. The subject must be an adapted soft contact lens wearer in both eyes (i.e. worn lenses a minimum of 2 days per week for at least 8 hours per wear day, for 1 month or more duration). 10. The subject must either be wearing a presbyopic contact lens correction (e.g., reading spectacles over contact lenses, multifocal or monovision contact lenses, etc.) or respond positively to at least one symptom on the "Presbyopic Symptoms Questionnaire". Potential subjects who meet any of the following criteria will be excluded from participating in the study: 1. Ocular or systemic allergies or disease, or use of medication which might interfere with contact lens wear. 2. Pregnancy or lactation. 3. Currently diagnosed with diabetes. 4. Infectious diseases (e.g. hepatitis, tuberculosis) or an immune-suppressive disease (e.g. HIV). 5. Clinically significant (Grade 3 or 4) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities or bulbar injection, or any other corneal or ocular abnormalities which would contraindicate contact lens wear. 6. Entropion, ectropion, extrusions, chalazia, recurrent styes, dry eye, glaucoma, history of recurrent corneal erosions. 7. Any previous, or planned, ocular or intraocular surgery (e.g., radial keratotomy, PRK, LASIK, lid procedures, cataract surgery, retinal surgery, etc.). 8. A history of amblyopia, strabismus or binocular vision abnormality. 9. Any ocular infection or inflammation. 10. Any ocular abnormality that may interfere with contact lens wear. 11. Use of any ocular medication, with the exception of rewetting drops. 12. History of herpetic keratitis. 13. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.

	14. Employee of clinical site (e.g., Investigator, Coordinator, Technician)
Disallowed Medications/Interventions	Any systemic medications that may affect contact lens wear and any ocular medications with the exception of rewetting drops. Previous ocular or intraocular surgery.
Measurements and Procedures	The key assessments for this study will be distance and near binocular high luminance, high contrast visual performance on logMAR scale and overall quality of vision assessed using the Contact Lens User Evaluation questionnaire (CLUE™).
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	ETDRS light box and logMAR High Contrast and Low Contrast 3M charts, Guillon-Poling Near Charts, Desk lamps, Chart holder, Sekonic light meter, Pupillometer, Contact lens cases, and Eye-Cept® rewetting drops.
Principal Investigator(s) and Study Institution(s)/Site(s)	A full list of Principal Investigators, clinical sites, and institutions is kept separately from the Study Protocol and is included in the study Trial Master File.

Figure 1: Flowchart



COMMONLY USED ABBREVIATIONS AND DEFINITIONS OF TERMS

ADD	Plus Power Required for Near Use
ADE	Adverse Device Effect
AE	Adverse Event/Adverse Experience
BCVA	Best Corrected Visual Acuity
BSCVA	Best Spectacle Corrected Visual Acuity
CFR	Code of Federal Regulations
CLUE	Contact Lens User Experience
CLDEQ-8	8-Item Contact Lens Dry Eye Questionnaire
COAS	Complete Ophthalmic Analysis System
COM	Clinical Operations Manager
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
CT	Center Thickness
CTP	Clinical Technical Procedure
D	Diopter
DMC	Data Monitoring Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
IRB	Institutional Review Board
IRT	Item Response Theory
ISO	International Organization for Standardization
ITT	Intent-to-Treat
JJVC	Johnson & Johnson Vision Care, Inc.
LC	Limbus Center
LogMAR	Logarithm of Minimal Angle of Resolution
MedDRA©	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NIH	National Institutes of Health
OD	Right Eye
OHRP	Office for Human Research Protections
OHSR	Office for Human Subjects Research
OS	Left Eye
OU	Both Eyes
PD	Protocol Deviation

PHI	Protected Health Information
PI	Principal Investigator
PIG	Patient Instruction Guide
PQC	Product Quality Complaint
PRO	Patient Reported Outcome
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
VA	Visual Acuity

1. INTRODUCTION AND BACKGROUND

Johnson & Johnson Vision recently launched a daily disposable multifocal contact lens, 1-Day ACUVUE® Brand MOIST® Multifocal. Since the launch of this lens additional daily disposable multifocal contact lenses have been approved and marketed. The purpose of this clinical study is to evaluate the performance of two of the newer competitor lenses that have been launched. The data will help to better understand the performance strengths and weaknesses of each product.

1.1. Name and Descriptions of Investigational Products

This study will test two (2) marketed multifocal contact lenses, Biotrue ONEday® for Presbyopia and Dailies Total 1® Multifocal Contact Lens. Further details about the test articles are found in Section 6 of this protocol.

1.2. Intended Use of Investigational Products

The intended use of the lenses is to correct distance spherical refractive error and presbyopia. Greater details on each of the marketed products can be found in the package insert in the appendices of this protocol.

1.3. Summary of Findings from Nonclinical Studies

Not Applicable – Marketed product only.

1.4. Summary of Known Risks and Benefits to Human Subjects

The contact lenses are currently marketed products that, like all multifocal contact lenses, act as a refractive media to correct for distance spherical refractive error and presbyopia. Beyond having their vision corrected by the contact lenses the subject will have no direct benefit from participating in the study.

The intent of these products is for use as a daily disposable contact lens that the subject wears while awake. The lenses are not intended for extended wear or reuse. This evaluation is for daily disposable modality only. Anticipated risks and adverse reactions with this lens are like other soft daily wear contact lenses used to correct presbyopia. A listing of examples of adverse reactions is found in the Section 13 of this protocol. The Investigator should follow normal clinical guidelines regarding examination and care of subjects who participate in this trial. For the most comprehensive clinical information regarding the marketed products refer to the package insert for the marketed product locate in the appendices of this clinical protocol.

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

A PubMed literature search using the term "Biotrue Oneday for Presbyopia" and "Dailies Total 1 Multifocal Contact Lens" revealed no results. Additional information regarding the marketed products can be found in the package inserts located in the appendices of this clinical protocol.

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

Primary Objective:
To evaluate the visual performance of a marketed multifocal contact lens in a population of presbyopes with myopia and hyperopia.

Secondary Objective:
CLUE vision score

Exploratory Objective: Not Applicable

2.2. Endpoints

Primary Endpoint
The primary endpoint in this study are distance and near binocular high luminance, high contrast visual performance on logMAR scale.

Secondary Endpoint
The secondary endpoint is overall quality of vision assessed using the Contact Lens User Evaluation questionnaire (CLUE™). CLUE is a validated Patient Reported Outcome (PRO) questionnaire developed to measure general and throughout the day comfort/vision, as well as symptoms of discomfort/poor vision, lens handling and packaging. Derived CLUE scores using Item Response Theory (IRT) follow a normal distribution with a population average score of 60 (SD 20), where higher scores indicate a more favorable/positive response. A 5-point increase in an average CLUE score translates into 10% shift in the distribution of scores for population of soft contact lens wearers. Both primary and secondary endpoints will be assessed after wearing each optimized study lens for 6-8 days.

Other Observations:
The other endpoints are the ease of fit as measured by the total number of lenses required to optimize vision each lens type and the ocular physiological response are measured by the average corneal staining grade using the FDA biomicroscopy scale for corneal staining. The data for the ease of fit and corneal staining will be summarized.

2.3. Hypotheses

Primary Hypotheses

1. After 8-12 days of lens wear, the distance, binocular, high luminance, high contrast visual performance of the two test lenses will be superior to +0.01 logMAR.
2. After 8-12 days of lens wear, the near, binocular, high luminance, high contrast visual performance of the two test lenses will be superior to +0.17 logMAR.

Secondary Hypothesis

1. After 8-12 days of lens wear, the overall quality of vision of the two test lenses will be superior to 32 CLUE points.

Other Hypotheses: Not applicable.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

Healthy male and female volunteers who are presbyopic will be recruited for the study. The subjects will all be adapted wearers of soft contact lenses in both eyes.

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. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. The subject must be between at least 40 years of age and not greater than 70 years of age.
4. The subject's distance spherical equivalent refraction must be in the range of +3.75 D to -3.75 D.
5. The subject's refractive cylinder must be $\leq$ -0.75 D in each eye.
6. The subject's ADD power must be in the range of +0.75 D to +2.50 D in each eye.
7. The subject must have best corrected visual acuity of $20/20^{-3}$ or better in each eye.
8. The subject must own a pair of wearable spectacles if required for their distance vision.
9. The subject must be an adapted soft contact lens wearer in both eyes (i.e. worn lenses a minimum of 2 days per week for at least 8 hours per wear day, for 1 month or more duration).
10. The subject must either be wearing a presbyopic contact lens correction (e.g., reading spectacles over contact lenses, multifocal or monovision contact lenses, etc.) or respond positively to at least one symptom on the "Presbyopic Symptoms Questionnaire".

3.3. Exclusion Criteria

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

1. Ocular or systemic allergies or disease, or use of medication which might interfere with contact lens wear.
2. Pregnancy or lactation.
3. Currently diagnosed with diabetes.
4. Infectious diseases (e.g. hepatitis, tuberculosis) or an immune-suppressive disease (e.g. HIV).
5. Clinically significant (Grade 3 or 4) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities or bulbar injection, or any other corneal or ocular abnormalities which would contraindicate contact lens wear.
6. Entropion, ectropion, extrusions, chalazia, recurrent styes, dry eye, glaucoma, history of recurrent corneal erosions.
7. Any previous, or planned, ocular or intraocular surgery (e.g., radial keratotomy, PRK, LASIK, lid procedures, cataract surgery, retinal surgery, etc.).
8. A history of amblyopia, strabismus or binocular vision abnormality.
9. Any ocular infection or inflammation.

10. Any ocular abnormality that may interfere with contact lens wear.
11. Use of any ocular medication, with the exception of rewetting drops.
12. History of herpetic keratitis.
13. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.
14. Employee of clinical site (e.g., Investigator, Coordinator, Technician)

3.4. Enrollment Strategy

Study subjects will be recruited from the clinical site's subject database.

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

This is a single-masked, crossover, randomized, dispensing clinical trial. A total of approximately 60 eligible subjects will be targeted to complete the study. The subjects will be randomized and fit in the study lens and wear each lens type for approximately three days then undergo optimization, if required, and wear the optimized pair for approximately 1 week. The primary endpoint is visual performance. The secondary endpoint is the CLUE vision score.

4.2. Study Design Rationale

The study is a prospective, bilateral, crossover evaluation. As we have no historical clinical data on the lenses being tested the study design includes a washout period to minimize any potential carry-over effect.

4.3. Enrollment Target and Study Duration

Approximately 80 subjects will be recruited (40 myopes and 40 hyperopes) with an aim of completing a total of 60 subjects in the final cohort.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

The study lenses will be worn in a bilateral and random fashion using a 2×2 crossover design with 2 lens types and 2 periods. Using a computer-generated randomization scheme provided by the study biostatistician, each subject will randomly be assigned to one of two unique sequences of the two lens types (Test1/Test2 or Test2/Test1). Randomization will be stratified by site.

Permuted block randomization will be used to avoid bias in the assignment of subjects to treatment, and to enhance the validity of statistical comparisons across treatment groups. Each block will contain two different lens trial sequences.

The order of lens wear will be based on the randomization scheme assigned to the study site. The study site will follow the randomization scheme provided and will complete enrollment according to the randomization list and will not pre-select or assign subjects.

This is a single masked study: subjects will be masked to the identities of the study lenses.

5.2. Masking

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

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

5.3. Procedures for Maintaining and Breaking Randomization 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 randomization codes:

1. Investigator or designee (documented on the Delegation Log) will consult the lens fitting schedule/randomization 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 randomization 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	Test 2	
Name	Dailies Total 1® Multifocal Contact Lens	Biotrue ONEday® for Presbyopia Contact Lens	Biotrue ONEday® Contact Lenses
Manufacturer	Alcon®	Bausch and Lomb	Bausch and Lomb
Compass Protocol(s) and/or Lot Number or Other Identifier	Over-labeled	Over-labeled	Over-labeled
Lens Material	delefilcon A	nesofilcon A	nesofilcon A
Nominal Base Curve @ 22°C	8.5	8.6	8.6
Nominal Diameter @ 22°C	14.1	14.2	14.2
Nominal Distance Powers (D)	+4.25 D to -4.00 D in 0.25D steps	+4.50 D to -4.00 D in 0.25 D steps	+4.00 D to -4.00 D in 0.25 D steps
Nominal ADD Powers (D)	LO MED HI	Low (+0.75 to +1.50 Spectacle Add) High (+1.75 to +2.50 Spectacle Add)	Not Applicable
Water Content	33% (Core Water Content)	78%	78%
Center Thickness	0.09 mm (-1.00 D)	0.1 mm (-3.00 D)	0.1 mm (-3.00 D)
Oxygen Permeability (Dk)	156 @ -3.00D	42 @center for -3.00 D	42 @center for -3.00D
Modality in Current Study	Daily Disposable	Daily Disposable	Daily Disposable
Replacement Frequency	Daily	Daily	Daily
Packaging Form (vial, blister, etc.)	Blister	Blister	Blister

Each subject what completes the study will wear approximately 22 lenses. As there are 60 subjects approximately 1320 lenses would be used for each lens type.

6.2. Ancillary Supplies/Products

The following solutions will be used in this study:

Table 2: Ancillary Supplies

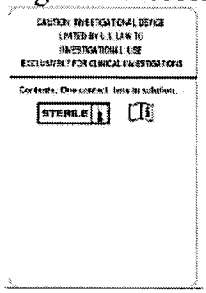
	Solution
Solution Name/Description	Eye-Cept® Rewetting drops
Manufacturer	Optics Laboratory
Preservative	Non-preserved

6.3. Administration of Test Articles

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

6.4. Packaging and Labeling

The test articles will be packaged in blisters, as the primary packaging. The test article will be over-labeled to mask the subject to the identity of the lens. The test articles will be in investigational cartons sealed with a tamper evident seal, commercial cartons, or in plastic bags as the secondary packaging form. 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

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 to JJVC.

6.7. Accountability of Test Articles

JJVC will provide the Investigator with sufficient quantities of study articles and supplies to complete the investigation. The Investigator is asked to retain all lens shipment documentation for the test article accountability records.

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

1. What was dispensed for the subject for trial fitting, to wear out of the office, or issued for the subject to replace appropriately between visits
2. What was returned to the Investigator unused
3. The number and reason for unplanned replacements.

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

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

Visit Information	Visit 1 Screening, Baseline, Treatment 1	Visit 2 Treatment 1 Follow-up 1	Visit 3 Treatment 1 Follow-up 2	Visit 4 Baseline 2 Treatment 2	Visit 5 Treatment 2 Follow-up 1	Visit 6 Treatment 2 Follow-up 2 Final Evaluation
Time Point	Day 1	Day 3±1 from V1	Day 7±1 from V2	Day 6±2 from V3	Day 3±1 from V4	Day 7±1 from V5
Estimated Visit Duration	2.5 hours	1.5 hours	1.5 hours	1.5 hours	1.5 hours	1.5 hours
Statement of Informed Consent	x					
Demographics	x					
Medical History/Concomitant Medications	x					
Adverse Event Medical History/Concomitant Medications Review		x	x	x	x	x
Habitual Contact Lens Information	x					
Contact Lens History	x					
Wear Time	x	x	x		x	x
Screening Inclusion/Exclusion	x					

Visit Information	Visit 1 Screening, Baseline, Treatment 1	Visit 2 Treatment 1 Follow-up 1	Visit 3 Treatment 1 Follow-up 2	Visit 4 Baseline 2 Treatment 2	Visit 5 Treatment 2 Follow-up 1	Visit 6 Treatment 2 Follow-up 2 Final Evaluation
Time Point	Day 1	Day 3±1 from V1	Day 7±1 from V2	Day 6±2 from V3	Day 3±1 from V4	Day 7±1 from V5
Estimated Visit Duration	2.5 hours	1.5 hours	1.5 hours	1.5 hours	1.5 hours	1.5 hours
Criteria						
Baseline PRO Questionnaire	x			x		
CLDEQ-8 Questionnaire	x	x	x	x	x	x
PRO Questionnaire		x	x	x	x	x
Compliance		x	x		x	x
Subject Reported Ocular Symptoms	x	x	x	x	x	x
Screening Eligibility	x					
Entrance Snellen Distance Visual Acuity	x	x	x	x	x	x
Subjective Sphero-Cylindrical Refraction	x					
Lens Removal	x	x	x	x	x	x
Pupillometry	x					
Keratometry	x					
Near Add Determination	x					
Ocular Dominance	x					
Add Refinement	x					

Visit Information	Visit 1 Screening, Baseline, Treatment 1	Visit 2 Treatment 1 Follow-up 1	Visit 3 Treatment 1 Follow-up 2	Visit 4 Baseline 2 Treatment 2	Visit 5 Treatment 2 Follow-up 1	Visit 6 Treatment 2 Follow-up 2 Final Evaluation
Time Point	Day 1	Day 3±1 from V1	Day 7±1 from V2	Day 6±2 from V3	Day 3±1 from V4	Day 7±1 from V5
Estimated Visit Duration	2.5 hours	1.5 hours	1.5 hours	1.5 hours	1.5 hours	1.5 hours
Near Visual Acuity	x					
Biomicroscopy	x	x	x	x	x	x
Baseline Inclusion/Exclusion Eligibility	x					
Continuance				x		
Randomization ID	x					
Lens Assignment	x	x (if lenses are modified)		x	x (if lenses are modified)	
Lens Insertion, Lens Damage & Settling	x	x (if lenses are modified)		x	x (if lenses are modified)	
Visual Satisfaction	x	x	x	x	x	x
Visual Acuity and Over Refraction	x	x	x	x	x	x
Binocular Over Refraction			x			x
Lens Fit Assessment	x	x	x	x	x	x
Visual Performance			x			x
Modification (if required)	x	x		x	x	
Exit Distance and Near Visual Acuity	x	x	x	x	x	
Collection of		x	x		x	x

Visit Information	Visit 1 Screening, Baseline, Treatment 1	Visit 2 Treatment 1 Follow-up 1	Visit 3 Treatment 1 Follow-up 2	Visit 4 Baseline 2 Treatment 2	Visit 5 Treatment 2 Follow-up 1	Visit 6 Treatment 2 Follow-up 2 Final Evaluation
Time Point	Day 1	Day 3±1 from V1	Day 7±1 from V2	Day 6±2 from V3	Day 3±1 from V4	Day 7±1 from V5
Estimated Visit Duration	2.5 hours	1.5 hours	1.5 hours	1.5 hours	1.5 hours	1.5 hours
Unworn Lens (if applicable)						
Dispensing Criteria	x	x		x	x	
Instructions	x	x	x	x	x	
Dispense Test Article	x	x		x	x	
Schedule Follow-up	x	x	x	x	x	
Final Evaluation						x

7.2. Detailed Study Procedures

VISIT 1

Subjects must report to the visit wearing their habitual contact lenses, to accurately assess baseline CLUE performance. If the subject is not wearing their lenses they must be rescheduled.

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	Record the brand of their current contact lens, lens parameters, modality (i.e. daily wear, extended wear, etc.) and cleaning regiment.	
1.5	Contact Lens History	Record the subject's correction type (i.e. monovision, multifocal, sphere with readers, etc.).	
1.6	Wear Time	Record the subjects wear time and comfortable wear time with their habitual contact lenses.	
1.7	Eligibility after Screening	All responses to Screening Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria must be answered "no" for the subject to be considered eligible.	

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.8	Baseline Questionnaire and CLDEQ-8 Questionnaire	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of their habitual lenses using the PRO questions and the Contact Lens Dry Eye Questionnaire	

1.9	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
1.10	Entrance Distance and Near Visual Acuity	Record the distance and near Snellen visual acuity (OD, OS, and OU) to the nearest letter with their habitual contact lens correction in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
1.11	Lens Removal	Have the subject remove their habitual lenses and store in an approved solution.	
1.12	Pupillometry	The pupil measurements will be performed OD and OS under bright illumination (7.3-7.9 EV) and dark illumination (≤0 EV) using a Neuroptic Pupillometer or similar instrument. The room illuminance will be measured for each condition using the Sekonic lightmeter or similar instrument.	[redacted]
1.13	Keratometry	Keratometry will be performed OD and OS recording the steep and flat dioptric power, corresponding meridians and clarity of mires.	[redacted]
1.14	Subjective Sphero-cylindrical Refraction	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. Record the refraction and distance visual acuity to the nearest letter. ***Note:*** *Best distance visual acuity with sphero-cylindrical refraction must be at least 20/20^{-3} in each eye for the subject to enroll in the study.*	[redacted]
1.15	Near ADD Determination	The near reading addition will be determined using the binocular crossed cylinder technique at 40 cm followed by optimization in a trial frame in step 1.17 below.	[redacted]
1.16	Ocular Dominance	Determine the distance ocular dominance with the best distance correction in place using a +1.00-blur test. If the results are equivocal use the sighting dominance test to determine the dominant eye used for the study	Appendix E
1.17	Add Refinement	Place the BCC result in the trial frame and refine the near prescription with trial lenses (or flippers) under binocular conditions.	[redacted]
1.18	Near Visual Acuity	Using the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm. Record the near visual acuity OD, OS and OU at 40 cm.	

1.19	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness ([redacted]) 0.5 unit increments will be used in the grading. Corneal Staining Assessment ([redacted] will be graded in 1.0 increments. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
1.20	Eligibility after Baseline	All responses to Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria questions must be answered "no" for the subject to be considered eligible. Determine whether the subject is eligible to participate in the study based on the examination findings. If so, proceed to lens fitting. If not, complete the final evaluation and discharge the subject.	

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
1.21	Randomization ID	Record the Randomization ID per the random scheme.	
1.22	Lens Selection	Select the lens pair and power based on the randomization table and appropriate fitting guide for each eye. Record the test lens parameters (power and lot number).	Appendix G or H Fitting Guides
1.23	Lens Insertion	The Investigator or the subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable. Worn, damaged lenses must be saved in saline and a product complaint form completed.	
1.24	Lens Settling	Allow the study lenses to settle for a minimum of 10 minutes.	
1.25	Visual Satisfaction	Determine if the subject's vision is acceptable with the lenses. Allow the subject to look	

		down a hallway or out of a window for distance vision assessments, and for them to read a book, magazine or similar for near vision.	
1.26	Distance and Near Visual Acuity	Measure the distance and near visual acuity OD, OS and OU. Record the results. **Note:** Use the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm to measure the Near visual acuity	[redacted]
1.27	Over-refraction	Perform a distance over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over-refraction may also be refined under binocular conditions. Record the results. The results of the distance over-refraction may also be checked for the impact on near vision under monocular and/or binocular conditions.	
1.28	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). The subject will not proceed to wear the lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in all three movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
1.29	Modifications	If the subjects vision is unacceptable for at least one distance or the Investigator determines that the visual acuity or over-refraction are not acceptable then a lens modification must be made. Up to two attempts at modification are	Appendix G or H Fitting Guides

		permitted if necessary, in order to achieve an acceptable distance and near binocular performance for the subject, and to enable them to wear that particular lens type. Follow the appropriate fitting guide allowing for at least 10 minutes of settling time between each lens modification attempted. If modifications are required steps 1.22-1.28 will be repeated for each modification.	
1.30	PRO Post-Fit Questionnaire	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire.	
1.31	Exit Distance and Near Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU. **Note**: The distance visual acuity must be at least 20/30 OU for the lenses to be dispensed.	[redacted]
1.32	Dispensing Criteria	The lenses will be dispensed for 2-4 days. • Distance Snellen acuity equal to or better than 20/30 OU • Subject must indicate that the vision is acceptable. • Subject must indicate that the comfort of the lenses is acceptable. • Lenses must have an acceptable general lens fit.	
1.33	Subject Instructions	Instruct the Subject the following: • The lenses will be worn on a daily wear basis. • Only enough lenses will be dispensed to the subject to wear for the required number of days until their follow-up visit. No additional lenses will be dispensed. • A new lens will be opened and worn each day. • Instruct the subject to bring back all Unworn study lenses • Instruct the subject no cleaning or	

		disinfecting solutions will be used. If determined necessary by the Investigator sterile non-preserved rewetting drops may be dispensed to be used as needed for dryness. • Subjects will be instructed to wear lenses for a minimum of 6 hours a day, every day during the study. • Subjects will be instructed to wear their glasses when not wearing the study lenses. • A patient instruction booklet will be provided. **Note**: In the event a lens is lost or damaged, the subject will return to the clinical site for replacement. As much as reasonably possible, a damaged lens and packaging should be returned to the clinical site (wet, if possible) and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.	
1.34	Schedule Follow-up Visit	The subject will be scheduled to return for their follow-up appointment in 3±1 days. **Note**: To count the follow-up visit as a day of wear the Subject must have worn the study lenses for 6 hours prior to the visit.	

VISIT 2

The subjects must present to Visit 2 wearing the study lenses.

Visit 2: Treatment 1 Follow-Up 1			
Step	Procedure	Details	[redacted]
2.1.	Adverse Events, Medical History and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit. Record any adverse events or medical history changes from the previous study visit.	
2.2.	Wearing Time	Record the average wearing time and comfortable wearing time.	
2.3.	Compliance	Confirm compliance with the prescribed wear schedule.	

		Note: Subjects must have worn lenses for at least 6 hours per day. To be counted as a day of wear at this visit the Subject must have worn the study lenses for 6 hours prior to the visit.	
2.4.	PRO and CLDEQ-8 Questionnaires	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire and the Contact Lens Dry Eye Questionnaire	
2.5.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
2.6.	Visual Satisfaction	Record whether the subjects distance and near vision with the lenses is acceptable.	
2.7.	Distance and Near Entrance Visual Acuity	Measure the distance and near visual acuity OD, OS and OU to the nearest letter. Record the results. **Note:** Use the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm to measure the Near visual acuity	[redacted]
2.8.	Distance Over-refraction and Distance Visual Acuity	Perform a distance over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over-refraction may also be refined under binocular conditions. Record the results and distance visual acuity OD and OS. The results of the distance over-refraction may also be checked for the impact on near vision under monocular and/or binocular conditions.	
2.9.	Determination of Lens Optimization	If the subjects vision is unacceptable for at least one distance or the Investigator determines that the visual acuity or over-refraction are not acceptable then a lens modification must be made. Up to two attempts at modification are permitted if necessary, to achieve an acceptable distance and near binocular performance for the subject, and to enable them to wear that lens type. Follow the appropriate fitting guide allowing for at least 10 minutes of settling time between each lens modification attempted.	Appendix G or H Fitting Guides

2.10.	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in all three movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
2.11.	Collection of unworn lenses	Collect unworn lenses returned by the subject when lens power has been optimized. **Note**: If lens power was not changed allow the subject to use the unworn lenses dispensed at Visit 1 and dispense enough lenses of the same power to last the subject until their next visit.	
2.12.	Lens Removal	The optimized study lenses will be removed and discarded.	
2.13.	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
2.14.	Insertion of Study Lenses	Dispense the subject new lenses that match the Distance and ADD power of the lenses that were removed in Step 2.12 above. Dispense enough lenses to last the subject	

		until their next visit.	
2.15.	PRO Questionnaire	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire.	
2.16.	Exit Distance and Near Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
2.17.	Dispensing Criteria	The lenses will be dispensed for 6-8 days. • Distance Snellen acuity equal to or better than 20/30 OU • Subject must indicate that the vision is acceptable. • Subject must indicate that the comfort of the lenses is acceptable. • Lenses must have an acceptable general lens fit.	
2.18.	Subject Instructions	Instruct the Subject the following: • The lenses will be worn on a daily wear basis. • Only enough lenses will be dispensed to the subject to wear for the required number of days until their follow-up visit. No additional lenses will be dispensed. • A new lens will be opened and worn each day. • Instruct the subject to bring back all Unworn study lenses • Instruct the subject no cleaning or disinfecting solutions will be used. If determined necessary by the Investigator sterile non-preserved rewetting drops may be dispensed to be used as needed for dryness. • Subjects will be instructed to wear lenses for a minimum of 6 hours a day, every day during the study. • Subjects will be instructed to wear their glasses when not wearing the study lenses.	

		Note: In the event a lens is lost or damaged, the subject will return to the clinical site for replacement. As much as reasonably possible, a damaged lens and packaging should be returned to the clinical site (wet, if possible) and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.	
2.19.	Schedule Follow-up Visit	The subject will be scheduled to return for their follow-up appointment in 7±1 days. Instruct the subject to bring their habitual contact lenses or glasses to Visit 3. No lenses will be dispensed at Visit 3.	

VISIT 3

The subjects must present to Visit 3 wearing the study lenses.

Visit 3: Treatment 1 Follow-Up 2			
Step	Procedure	Details	[redacted]
3.1	Adverse Events, Medical History and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit. Record any adverse events or medical history changes from the previous study visit.	
3.2	Wearing Time	Record the average wearing time and comfortable wearing time.	
3.3	Compliance	Confirm compliance with the prescribed wear schedule. **Note:** Subjects must have worn lenses for at least 6 hours per day. To be counted as a day of wear at this visit the Subject must have worn the study lenses for 6 hours prior to the visit.	
3.4	PRO and CLDEQ-8 Questionnaires	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire and the Contact Lens Dry Eye Questionnaire	
3.5	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]

3.6	Visual Satisfaction	Record whether the subjects distance and near vision with the lenses is acceptable.	
3.7	Distance and Near Entrance Visual Acuity	Measure the distance and near visual acuity OD, OS and OU to the nearest letter. Record the results. **Note:** Use the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm to measure the Near visual acuity	[redacted]
3.8	Binocular Over-refraction	Perform a binocular over-refraction and record the OD and OS results and distance visual acuity. **Note:** No lens changes are allowed based on the over-refraction.	Appendix F
3.9	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in all three movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
3.10	Visual Performance	Visual performance will be recorded OD, OS and OU for the following: **Distance, Bright** Illuminance ETDRS Charts **3M-HC#1, HC#2, HC#3** and **LC#1, LC#2 and LC#3** **Near, Bright** Illuminance Reduced Guillon-Poling charts High Contrast and Low Contrast Intermediate (64cm) and Near (40cm).	[redacted]

		Distance, Dim Illuminance (with **Distance goggles**) ETDRS Charts **3M-HC#4, HC#5, HC#6** **Near, Dim** Illuminance (with **Near goggles**) Reduced Guillon-Poling charts High Contrast Intermediate (64 cm) and Near (40 cm). **Note:** • The room illuminance must be between 7.3 and 7.9 EV. • Distance, HC-1 Chart luminance Acceptable EV Range 10.5-10.7. • Guillon-Poling, Near Chart luminance Acceptable EV Range 10.8-11.1. • Do not use the Mesopic filter for Dim luminance (Dim luminance will be simulated by using the goggles)	
3.11	Collection of unworn lenses	Collect unworn lenses returned by the subject.	
3.12	Lens Removal	The study lenses can be removed, and saved in sterile saline in labeled glass vials	
3.13	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
3.14	Exit Distance and Near Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the subject's habitual correction in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
3.15	Wash-out Period	Subject will complete a 6±2 days wash-out period during which they can wear their habitual contact lenses or glasses.	

		Note: *Instruct the Subject to report to Visit 4 wearing their habitual contact lenses.*	

Visit 4

Subjects must report to this visit wearing their habitual contact lenses, to accurately assess baseline CLUE performance. If the subject is not wearing their lenses they must be rescheduled.

Visit 4: Baseline			
Step	Procedure	Details	[redacted]
4.1	Adverse Events, Medical History and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit.	
4.2	Baseline Questionnaire and CLDEQ-8 Questionnaire	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of their habitual lenses using the PRO questions and the Contact Lens Dry Eye Questionnaire	
4.3	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
4.4	Entrance Distance and Near Visual Acuity	Record the distance and near Snellen visual acuity (OD, OS, and OU) to the nearest letter with their habitual contact lens correction in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
4.5	Lens Removal	Have the subject remove their habitual lenses and store in an approved solution.	
4.6	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness [redacted]) 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
4.7	Continuance	Determine whether the subject is eligible to continue in the study based on the examination findings.	

Visit 4: Treatment 2 Lens Fitting			
Step	Procedure	Details	[redacted]
4.8	Lens Selection	Select the lens pair and power based on the randomization table and appropriate fitting guide for each eye. Record the test lens parameters (power and lot number).	Appendix G or H Fitting Guides
4.9	Lens Insertion	The Investigator or the subject inserts the study lenses. Record the time of lens insertion. Check for lens damage under the slit lamp before proceeding with lens settling. Replace damaged lenses if applicable. Worn, damaged lenses must be saved in saline and a product complaint form completed.	
4.10	Lens Settling	Allow the study lenses to settle for a minimum of 10 minutes.	
4.11	Visual Satisfaction	Determine if the subject's vision is acceptable with the lenses. Allow the subject to look down a hallway or out of a window for distance vision assessments, and for them to read a book, magazine or similar for near vision.	
4.12	Distance and Near Visual Acuity	Measure the distance and near visual acuity OD, OS and OU. Record the results. **Note:** Use the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm to measure the Near visual acuity	[redacted]
4.13	Over-refraction	Perform a distance over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over-refraction may also be refined under binocular conditions. Record the results. The results of the distance over-refraction may also be checked for the impact on near vision under monocular and/or binocular conditions.	
4.14	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). The subject will not proceed to wear the lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze	[redacted]

		• presence of edge lift • presence of unacceptable movement (excessive or insufficient) in all three movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	
4.15	Modifications	If the subjects vision is unacceptable for at least one distance or the Investigator determines that the visual acuity or over-refraction are not acceptable then a lens modification must be made. Up to two attempts at modification are permitted if necessary, to achieve an acceptable distance and near binocular performance for the subject, and to enable them to wear that particular lens type. Follow the appropriate fitting guide allowing for at least 10 minutes of settling time between each lens modification attempted. If modifications are required steps 4.8 to 4.14 will be repeated for each modification.	Appendix G or H Fitting Guides
4.16	PRO Post-Fit Questionnaire	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of their study lenses using the PRO questionnaire.	
4.17	Exit Distance and Near Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU. **Note:** The distance visual acuity must be at least 20/30 OU for the lenses to be dispensed.	[redacted]
4.18	Dispensing Criteria	The lenses will be dispensed for 2-4 days. • Distance Snellen acuity equal to or better than 20/30 OU • Subject must indicate that the vision is acceptable.	

		• Subject must indicate that the comfort of the lenses is acceptable. • Lenses must have an acceptable general lens fit.	
4.19	Subject Instructions	Instruct the Subject the following: • The lenses will be worn on a daily wear basis. • Only enough lenses will be dispensed to the subject to wear for the required number of days until their follow-up visit. No additional lenses will be dispensed. • A new lens will be opened and worn each day. • Instruct the subject to bring back all Unworn study lenses • Instruct the subject no cleaning or disinfecting solutions will be used. If determined necessary by the Investigator sterile non-preserved rewetting drops may be dispensed to be used as needed for dryness. • Subjects will be instructed to wear lenses for a minimum of 6 hours a day, every day during the study. • Subjects will be instructed to wear their glasses when not wearing the study lenses. **Note**: In the event a lens is lost or damaged, the subject will return to the clinical site for replacement. As much as reasonably possible, a damaged lens and packaging should be returned to the clinical site (wet, if possible) and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.	
4.20	Schedule Follow-up Visit	The subject will be scheduled to return for their follow-up appointment in 3±1 days. **Note**: To count the follow-up visit as a day of	

		wear the Subject must have worn the study lenses for 6 hours prior to the visit.	

VISIT 5

The subjects must present to Visit 5 wearing the study lenses.

Visit 5: Treatment 2 Follow-Up 1			
Step	Procedure	Details	[redacted]
5.1	Adverse Events, Medical History and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit. Record any adverse events or medical history changes from the previous study visit.	
5.2	Wearing Time	Record the average wearing time and comfortable wearing time.	
5.3	Compliance	Confirm compliance with the prescribed wear schedule. **Note**: Subjects must have worn lenses for at least 6 hours per day. To be counted as a day of wear at this visit the Subject must have worn the study lenses for 6 hours prior to the visit.	
5.4	PRO and CLDEQ-8 Questionnaires	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire and the Contact Lens Dry Eye Questionnaire	
5.5	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
5.6	Visual Satisfaction	Record whether the subjects distance and near vision with the lenses is acceptable.	
5.7	Distance and Near Entrance Visual Acuity	Measure the distance and near visual acuity OD, OS and OU to the nearest letter with the study lenses in place. Record the results. **Note:** Use the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm to measure the Near visual acuity	[redacted]
5.8	Distance Over-refraction and Distance Visual Acuity	Perform a distance over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over-refraction may also be refined under binocular conditions. Record the results and distance visual acuity OD and OS.	

		The results of the distance over-refraction may also be checked for the impact on near vision under monocular and/or binocular conditions.	
5.9	Determination of Lens Optimization	If the subjects vision is unacceptable for at least one distance or the Investigator determines that the visual acuity or over-refraction are not acceptable then a lens modification must be made. Up to two attempts at modification are permitted if necessary, to achieve an acceptable distance and near binocular performance for the subject, and to enable them to wear that particular lens type. Follow the appropriate fitting guide allowing for at least 10 minutes of settling time between each lens modification attempted.	Appendix G or H Fitting Guides
5.10	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in all three movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.*	[redacted]
5.11	Collection of unworn lenses	Collect unworn lenses returned by the subject when lens power has been optimized. **Note**: If lens power was not changed allow the subject to use the unworn lenses dispensed at Visit 4 and dispense enough lenses of the same power to last the subject until their next visit.	
5.12	Lens Removal	The optimized study lenses will be removed and discarded.	

5.13	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
5.14	Insertion of Study Lenses	Dispense the subject new lenses that match the Distance and ADD power of the lenses that were removed in Step 5.12 above. Dispense enough lenses to last the subject until their next visit.	
5.15	PRO Questionnaire	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of their study lenses using the PRO questionnaire.	
5.16	Exit Distance and Near Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
5.17	Dispensing Criteria	The lenses will be dispensed for 6-8 days. • Distance Snellen acuity equal to or better than 20/30 OU • Subject must indicate that the vision is acceptable. • Subject must indicate that the comfort of the lenses is acceptable. • Lenses must have an acceptable general lens fit.	
5.18	Subject Instructions	Instruct the Subject the following: • The lenses will be worn on a daily wear basis. • Only enough lenses will be dispensed to the subject to wear for the required number of days until their follow-up visit. No additional lenses will be dispensed.	

		• A new lens will be opened and worn each day. • Instruct the subject to bring back all Unworn study lenses • Instruct the subject no cleaning or disinfecting solutions will be used. If determined necessary by the Investigator sterile non-preserved rewetting drops may be dispensed to be used as needed for dryness. • Subjects will be instructed to wear lenses for a minimum of 6 hours a day, every day during the study. • Subjects will be instructed to wear their glasses when not wearing the study lenses. **Note:** In the event a lens is lost or damaged, the subject will return to the clinical site for replacement. As much as reasonably possible, a damaged lens and packaging should be returned to the clinical site (wet, if possible) and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor.	
5.19	Schedule Follow-up Visit	The subject will be scheduled to return for their follow-up appointment in 7±1 days.	

VISIT 6

The subjects must present to Visit 6 wearing the study lenses.

Visit 6: Treatment 2 Follow-Up 2			
Step	Procedure	Details	[redacted]
6.1	Adverse Events, Medical History and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit. Record any adverse events or medical history changes from the previous study visit.	
6.2	Wearing Time	Record the average wearing time and comfortable wearing time.	
6.3	Compliance	Confirm compliance with the prescribed wear schedule.	

		Note: Subjects must have worn lenses for at least 6 hours per day. To be counted as a day of wear at this visit the Subject must have worn the study lenses for 6 hours prior to the visit.	
6.4	PRO and CLDEQ-8 Questionnaires	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire and the Contact Lens Dry Eye Questionnaire	
6.5	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
6.6	Visual Satisfaction	Record whether the subjects distance and near vision with the lenses is acceptable.	
6.7	Distance and Near Entrance Visual Acuity	Measure the distance and near visual acuity OD, OS and OU to the nearest letter. Record the results. **Note:** Use the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm to measure the Near visual acuity	[redacted]
6.8	Binocular Over-refraction	Perform a binocular over-refraction and record the OD and OS results and distance visual acuity. **Note:** No lens changes are allowed based on the over-refraction.	Appendix F
6.9	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). • The subject should not proceed to wear the lenses if any of the following is observed: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • presence of unacceptable movement (excessive or insufficient) in all three movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study.*	[redacted]

		Remove the lenses, perform a slit-lamp evaluation, and complete the Final Evaluation form.	
6.10	Visual Performance	Visual performance will be recorded OD, OS and OU for the following: **Distance, Bright** Illuminance ETDRS Charts **3M-HC#1, HC#2, HC#3** and **LC#1, LC#2 and LC#3** **Near, Bright** Illuminance Reduced Guillon-Poling charts High Contrast and Low Contrast Intermediate (64cm) and Near (40cm). **Distance, Dim** Illuminance (with **Distance goggles**) ETDRS Charts **3M-HC#4, HC#5, HC#6** **Near, Dim** Illuminance (with **Near goggles**) Reduced Guillon-Poling charts High Contrast Intermediate (64 cm) and Near (40 cm). **Note:** • The room illuminance must be between 7.3 and 7.9 EV. • Distance, HC-1 Chart luminance Acceptable EV Range 10.5-10.7. • Guillon-Poling, Near Chart luminance Acceptable EV Range 10.8-11.1. • Do not use the Mesopic filter for Dim luminance (Dim luminance will be simulated by using the goggles)	[redacted]
6.11	Collection of unworn lenses	Collect unworn lenses returned by the subject.	
6.12	Lens Removal	The study lenses can be removed, and saved in sterile saline in labeled glass vials	
6.13	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments.	[redacted]

		If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	

FINAL EVALUATION

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

Note: If the subject is a screen-failure and a refraction and/or biomicroscopy procedure has just been performed, you may intentionally blank out these forms at the Final Evaluation in EDC.

Final Evaluation			
Step	Procedure	Details	[redacted]
F.1	Subjective spherocylindrical Refraction	Perform subjective spherocylindrical refraction with a phoropter and record the best corrected distance visual acuity to the nearest letter (OD, OS, OU).	
F.2	Final Exam Form	Indicate if the subject completed the study successfully. If subject discontinued from the study indicate the reason.	

7.3. Unscheduled Visits

If, during the investigation, a subject requires an unscheduled visit to the clinical site, the following information will be collected at a minimum:

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

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

Any ocular and non-ocular Adverse Events that are ongoing at the time of the study visit will be followed by the Investigator, within licensure, until they have resolved, returned to pre-treatment status, stabilized, or been satisfactorily explained. If further treatment i.e., beyond licensure is required, the subject will be referred to the appropriate health care provider.

The following information will be collected during an unscheduled visit.

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	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
U.4	Entrance VA	Record the entrance distance and near visual acuity (OD, OS and OU) to the nearest letter.	[redacted]
U.5	Subjective Sphero-cylindrical Refraction	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. Record the refraction and distance visual acuity to the nearest letter.	[redacted]
U.6	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading. Corneal Staining Assessment ([redacted] will be graded in 1.0 increments. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
U.7	Lens Dispensing	Additional lenses may be dispensed if the subject loses, tears, or runs out of lenses.	
U.8	Exit Visual Acuity	Record the subject's exit distance and near visual acuity (OD, OS and OU) to the nearest letter.	[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;
- have not withdrawn/discontinued for any reason described in Section 8.2;
- Complete all study visits

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)
- Subject not compliant with study lens wear schedule
- Subject not successfully dispensed due to lack of efficacy and safety including poor vision, poor comfort or unacceptable fit

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: Any ocular medications except for rewetting drops.
Concomitant therapies that are disallowed include: Any therapies that may contraindicate lens wear.

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

If more than 2 subjects in the investigational soft contact lens group develop serious expected (e.g., definite or probable MK) or unexpected device related adverse events, the study will be suspended. Upon review and consultation with IRB, and JJVC safety review committee, the study may be terminated.

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 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 hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity (e.g., a sight threatening event, a significant persistent or permanent change, impairment, damage, or disruption to the subject's body)
- Is a congenital anomaly/birth defect, or

- Requires intervention to prevent permanent damage (the use of the test article resulting in a condition which requires medical or surgical intervention to preclude permanent impairment of the body structure or a body function). Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in the above definition.

Diagnoses and conditions that are considered Ocular Serious Adverse Events include, but not limited to:

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

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

Diagnoses and conditions that are considered Ocular Significant Adverse Events include, but not limited to the following:

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

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

Diagnoses and conditions that are considered Ocular Non-Significant Adverse Events include, but not limited to the following:

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

Adverse Device Effect (ADE) – 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 categorized correctly. Elements of categorization will include:

- Seriousness/Classifications (see definition in Section 13.1)
- Causality or Relatedness – i.e. the relationship between the test article, study treatment or study procedures and the adverse event (not related; 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.

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

Changes in the severity of an AE shall be documented to allow an assessment of the duration of the event at each level of intensity to be performed. Adverse events characterized as intermittent require documentation of the onset and duration of each episode. Changes in the assessment of relationship to the Test Article shall also be clearly documented.

Subjects who present with an adverse event shall be followed by the Investigator, within licensure, until all signs and symptoms have returned to pre-treatment status, stabilized, or been satisfactorily resolved. If further treatment beyond licensure is required, the patient will be referred to the appropriate health care provider. The Investigator will use his/her clinical judgment as to whether 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 randomization code to determine the identity of the treatment that the subject received. The Sponsor and study monitor should be notified prior to unmasking the test articles.

In the event of a serious/significant adverse event, the Investigator must:

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

Unanticipated (Serious) Adverse Device Effect (UADE)

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

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

Non-Serious Adverse Events

All non-serious adverse events, including non-serious adverse device effects, will be reported to the sponsor by the Investigator no later than 2 days from discovery.

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

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

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

The Sponsor will report applicable Adverse Events to the local health authorities according 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 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

All data summaries and statistical analyses will be performed using the SAS software Version 9.4 (SAS Institute, Cary, NC). Throughout the analysis of data, the results for each subject/eye will be used when available for summarization and statistical analysis. Unscheduled visits will be summarized 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 summarized with descriptive statistics (n, mean, standard deviation (SD), median, minimum and maximum). Frequency count and percentage of subjects or eyes within each category will be provided for categorical data.

Summaries will be presented by study lens type and will be performed separately by completion status. All analyses will be conducted on per-protocol population (see section 14.3).

14.2. Sample Size Justification

A total of approximately 80 eligible subjects will be enrolled into the study at this site and at least 60 subjects will complete this study. This is a pilot study for assessing the test articles. As such, the sample size calculation was not based on any power analysis with regard to the primary endpoint. The collected data will be used to design future trials.

14.3. Analysis Populations

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

Per-Protocol Population:
All subjects who have successfully completed all visits and did not substantially deviate from the protocol as determined by the trial cohort review committee prior to database hard lock (Per-Protocol Population). Justification of excluding subjects with protocol deviations in the per-protocol population set will be documented in a memo to file.

Intent-to-Treat (ITT) Population:
All randomized subjects regardless of actual treatment and subsequent withdrawal from study or deviation from protocol. At least one observation should be recorded.

14.4. Level of Statistical Significance

All planned analysis for this study will be conducted with an overall type I error rate of 5%. No adjustment for multiple comparisons will be conducted unless specified otherwise. This is a pilot study and all the hypotheses are exploratory in nature.

14.5. Primary Analysis

Primary efficacy analysis:

Visual Performance:
Near and distance binocular, high luminance, high contrast visual performance on logMAR scale will be analyzed separately using a linear mixed model to test for the difference between the study lens systems. Each model will include the experimental design factors: sequence of lens wear, lens wearing period and lens type as fixed effects. Other baseline characteristics known of importance such as age, gender, and/or add power will be included as fixed covariates when appropriate. The covariance between residual errors from the same subject across lens wearing periods will be selected based on the finite-sample corrected Akaike's Information Criterion (Keselman et al. 1998). Covariance structures considered may include: Homogenous compound symmetry (CS) and Unstructured covariance structure (UN). The structure that returns the lowest Akaike Information Criteria Corrected (AICC) will be selected as the structure that best fit the data.

Comparisons will be carried out using 95% confidence intervals constructed of least squared means (LSM) from the linear mixed models. Statistical superiority will be concluded if the upper limit of the confidence intervals of the test lens is below +0.01 logMAR for distance and +0.17 for near.

14.6. Secondary Analysis

CLUE Vision Score:
Overall quality of vision scores will be analyzed using a linear mixed model adjusting for baseline values as fixed covariates. The model will include the experimental design factors: sequence of lens wear, period, lens type as fixed effects. The covariance between residual errors from the same subject across lens wearing periods will be selected based on the finite-sample corrected Akaike's Information Criterion (Keselman et al. 1998). Covariance structures considered may include: Homogenous compound symmetry (CS) and Unstructured covariance structure (UN). The structure that returns the lowest Akaike Information Criteria Corrected (AICC) will be selected as the structure that best fit the data.

Comparisons will be carried out using 95% confidence intervals constructed of least squared means (LSM) from the linear mixed models. Statistical superiority will be concluded if the lower limit of the confidence intervals of the test lens is above 32 points.

In all models, the Kenward and Roger method (Kenward and Roger, 1997) will be used for the calculation of the denominator of degrees of freedom.

14.7. Other Exploratory Analyses

Not applicable.

14.8. Interim Analysis

Not Applicable

14.9. Procedure for Handling Missing Data and Drop-Outs

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

Subject dropout is expected to be one of the main reasons of missing data in this clinical trial. Past clinical trials don't provide the evidence that subject dropout is systematic or not-at-random. To evaluate the impact of missing data, sensitivity analysis will be conducted using multiple imputation methods if the proportion of subject dropout is greater than the 15%. The SAS/STAT procedures PROC MI and PROC MIANALYZE will be utilized with a parametric regression method used to make at least 5 imputations.

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 Bioclinica Express version 5.5 EDC system. An authorized data originator will enter study data into the eCRFs using the EDC system. Data collected on equipment that is not captured in EDC will be formatted to the specification of the JJVC database manager and sent to JJVC for analysis.

External Date Sources for this study include: Not Applicable

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

Edit checks, electronic queries, and audit trails are built into the system to ensure accurate and complete data collection. Data will be transmitted from the clinical site to a secure central database as forms are completed or updated, ensuring information accuracy, security, and confidentiality. After the final database lock, the Investigator will be provided with Individual Patient Profiles (IPP) including the full audit trail on electronic media in PDF format for all 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 the source record.

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

16. DATA MANAGEMENT

16.1. Access to Source Data/Document

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

16.2. Confidentiality of Information

Information concerning the investigational product and patent application processes, scientific data or other pertinent information is confidential and remains the property of JJVC. The Investigator may use this information for the purposes of the study only. It is understood by the Investigator that JJVC will use information developed in this clinical study about 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 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 fulfill its obligation

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

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

- Protocol amendments
- Revision(s) to informed consent form and any other written materials to be provided to subjects
- If applicable, new or revised subject recruitment materials approved by the Sponsor
- Revisions to compensation for study-related injuries or payment to subjects for participation in the study
- Investigator's Brochure amendments or new edition(s)
- Summaries of the status of the study (at least annually or at intervals stipulated in guidelines of the IEC/IRB)
- Reports of adverse events that are serious, unanticipated, and associated with the test articles, according to the IRB's requirements
- New information that may adversely affect the safety of the subjects or the conduct of the study
- Major protocol deviations as required by the IEC/IRB
- Report of deaths of subjects under the Investigator's care
- Notification if a new Investigator is responsible for the study at the clinical site
- Any other requirements of the IEC/IRB

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

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

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

18.4. Informed Consent

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

Before entry into the study, the Investigator or an authorized member of the clinical site personnel must explain to potential subject the aims, methods, reasonably anticipated benefits, and potential hazards of the study, and any discomfort it may entail. Subjects will be informed that their participation is voluntary and that they may withdraw consent to participate at any time.

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

18.5. Privacy of Personal Data

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

All information obtained during the course of the investigation will be regarded as confidential. All personal data gathered in this trial will be treated in strictest confidence by Investigators, monitors, Sponsor's personnel and IEC/IRB. No data will be disclosed to any third party without the express permission of the subject concerned, with the exception of Sponsor personnel (monitor, auditor), IEC/IRB and regulatory organizations in the context of their investigation related activities that, as part of the investigation will have access to the CRFs and subject records.

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

These data must be collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data privacy protection laws and regulations. The Sponsor ensures that the personal data will be:

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

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

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

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

19. STUDY RECORD RETENTION

In compliance with the ICH/GCP guidelines, 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
- Scheduling a study visit outside the subject's acceptable visit range

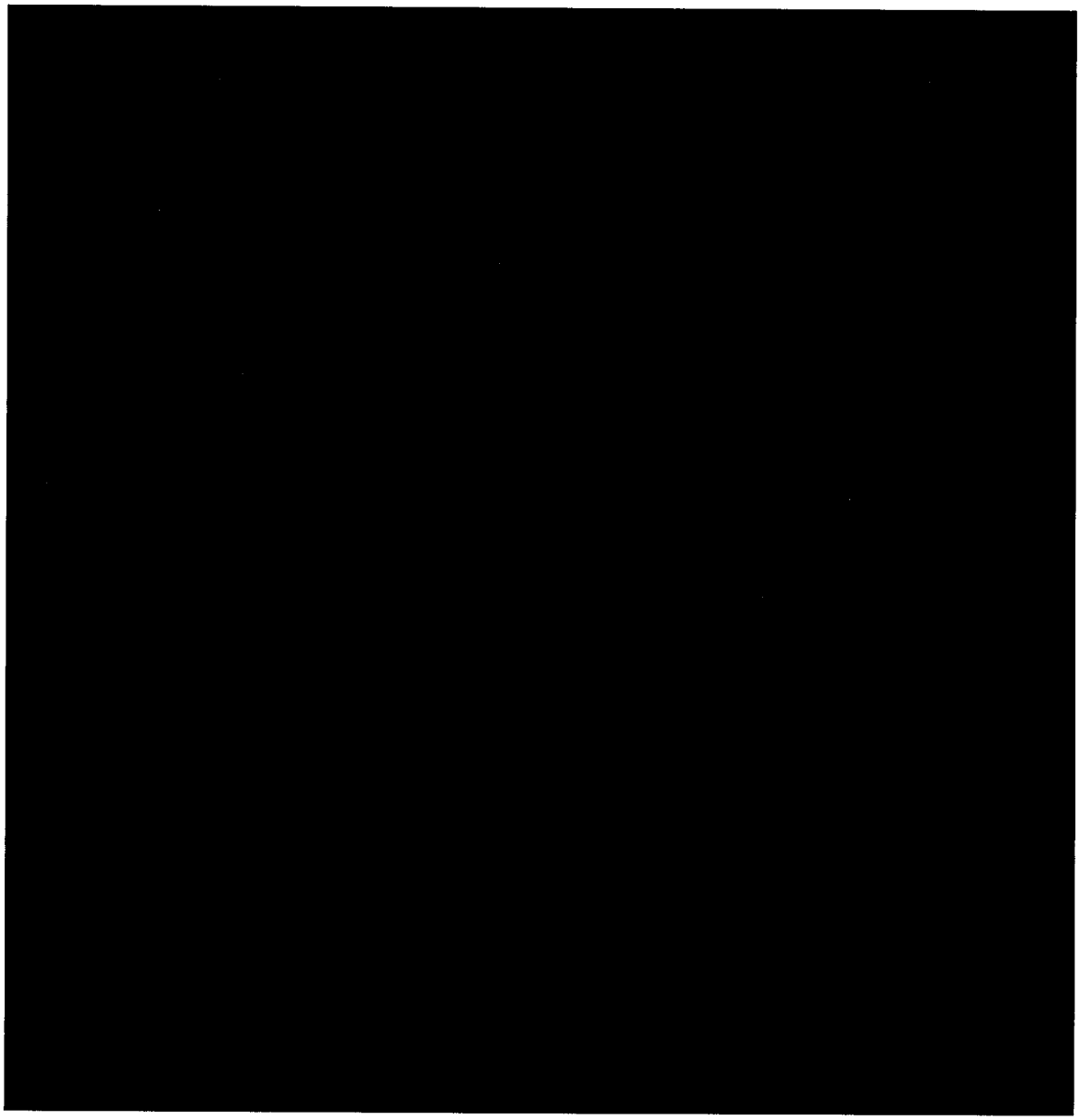
21. PUBLICATION

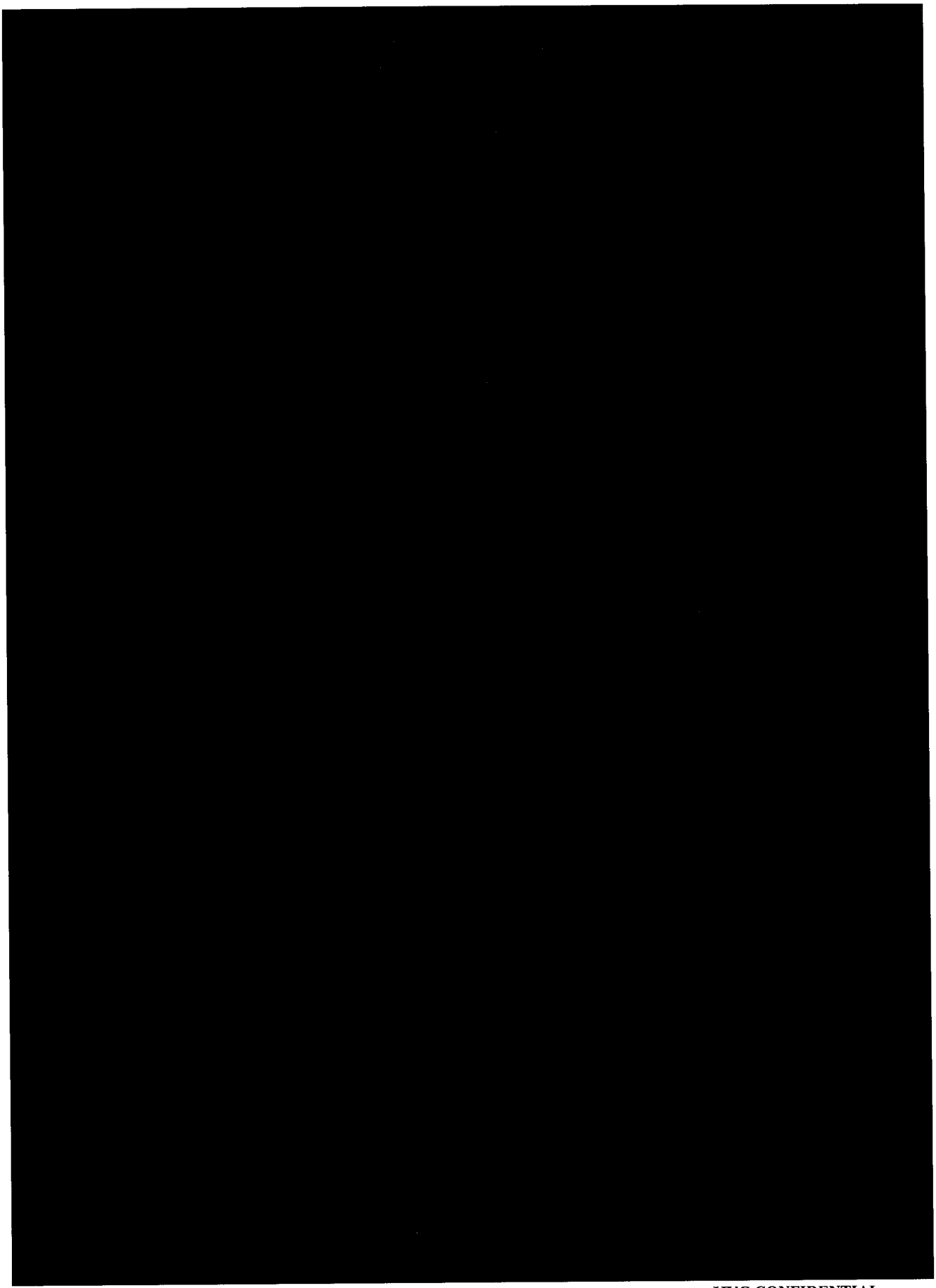
This study will be registered on ClinicalTrials.gov by the Sponsor

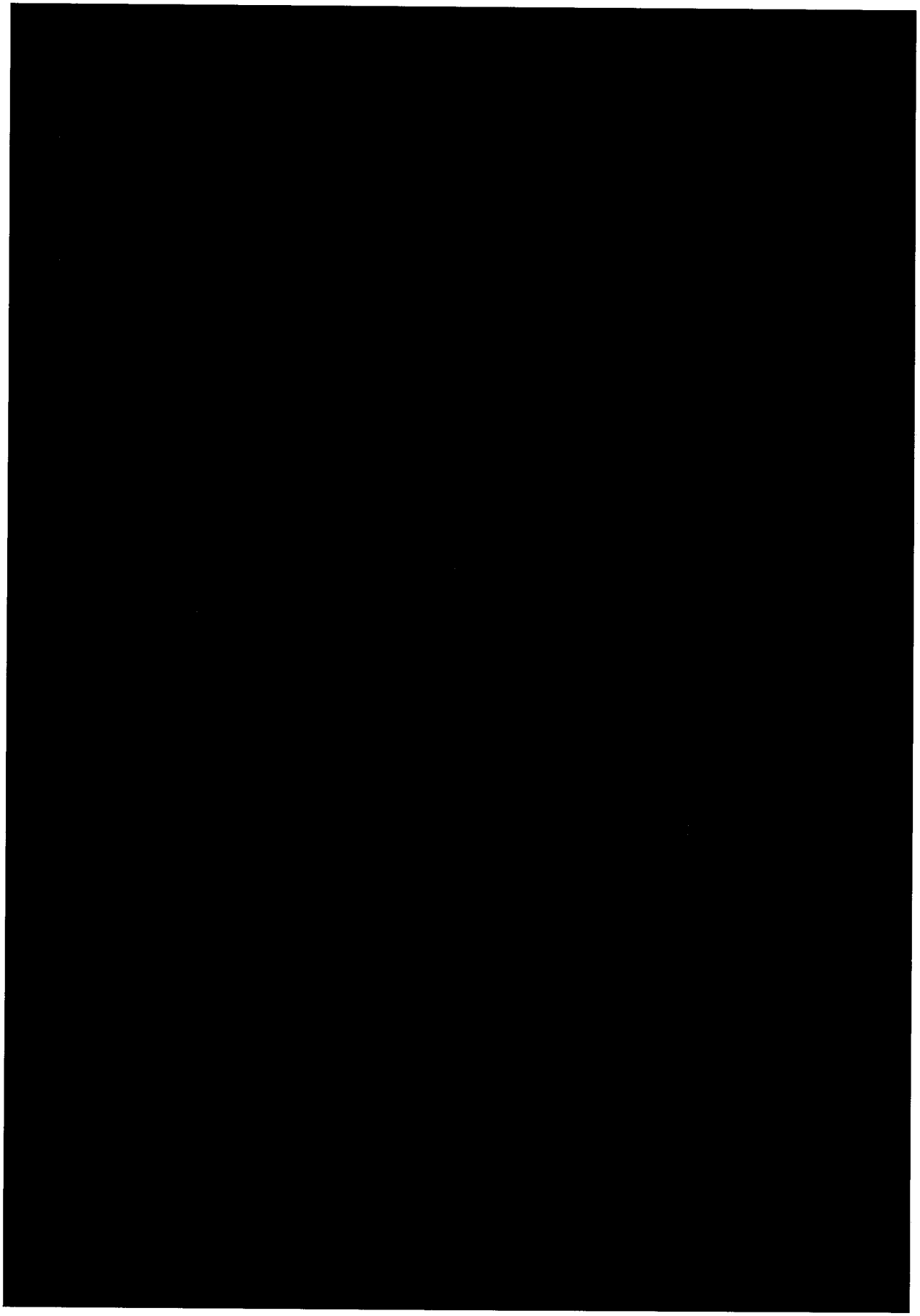
22. REFERENCES

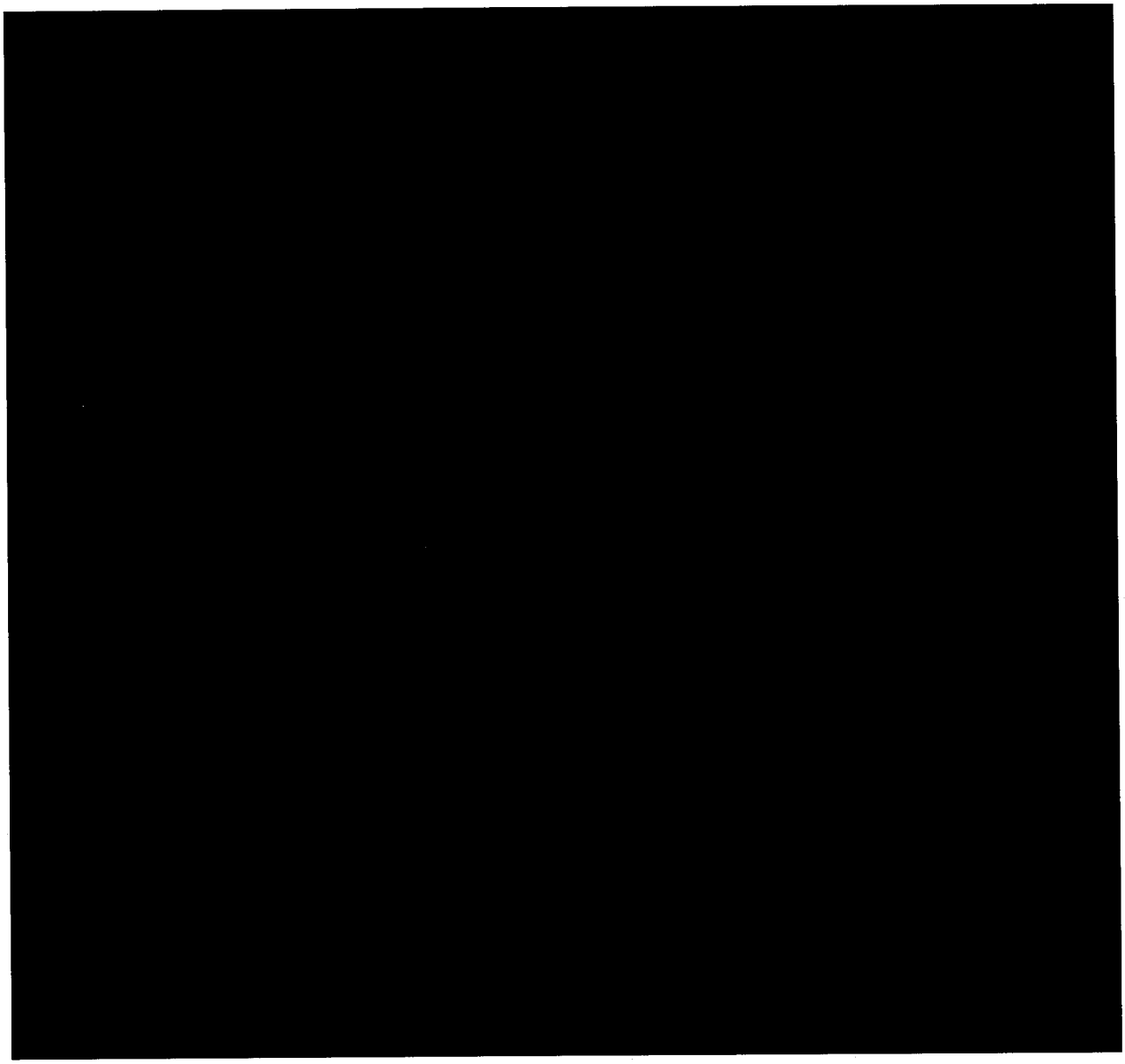
1. Keselman HJ, Algina J, Kowalchuk RK, Wolfinger RD. A Comparison of Two Approaches for Selecting Covariance Structures in the Analysis of Repeated Measures. *Communications in Statistics—Simulation and Computation.* 1998;(27):591–604.

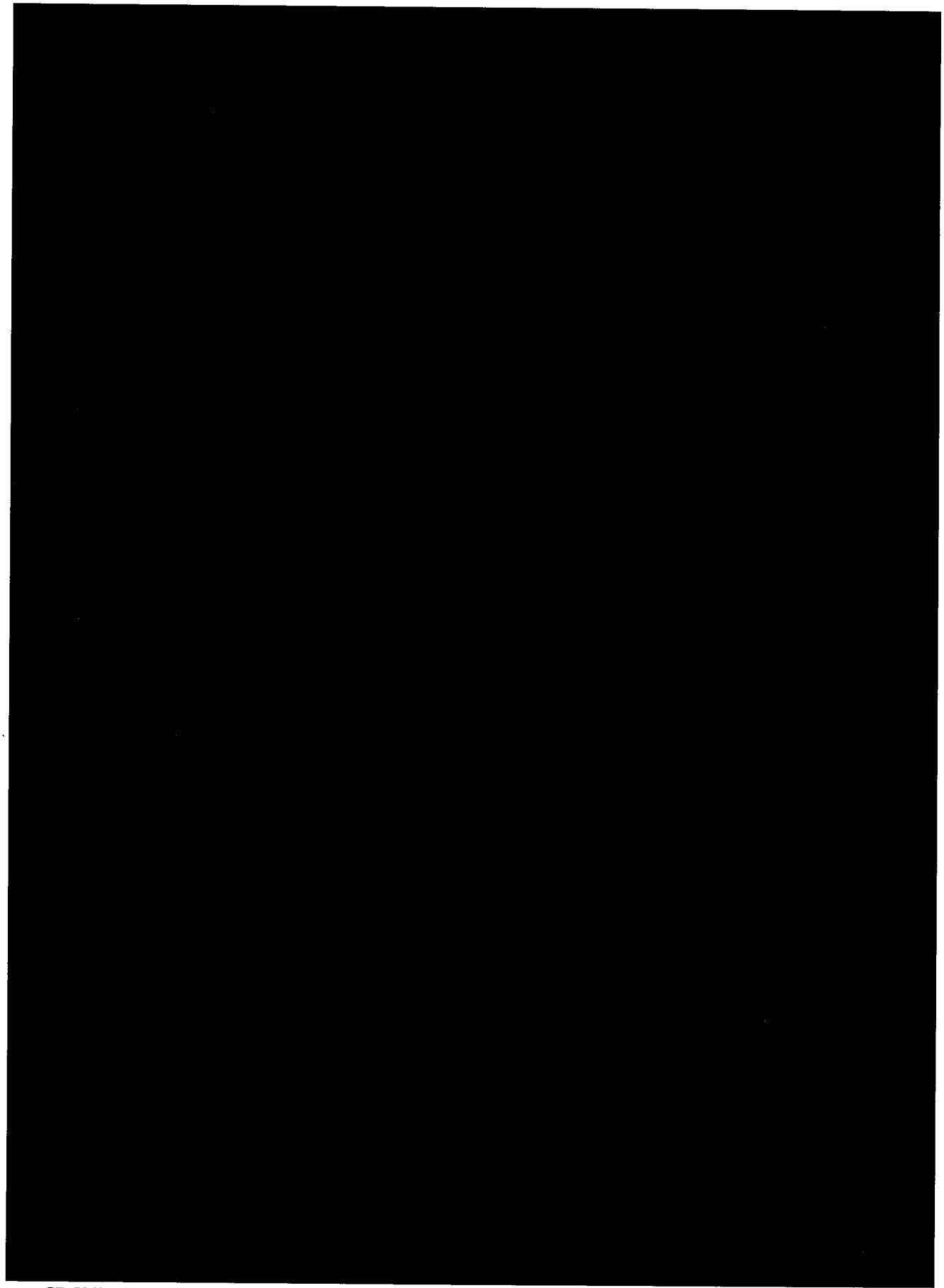
APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

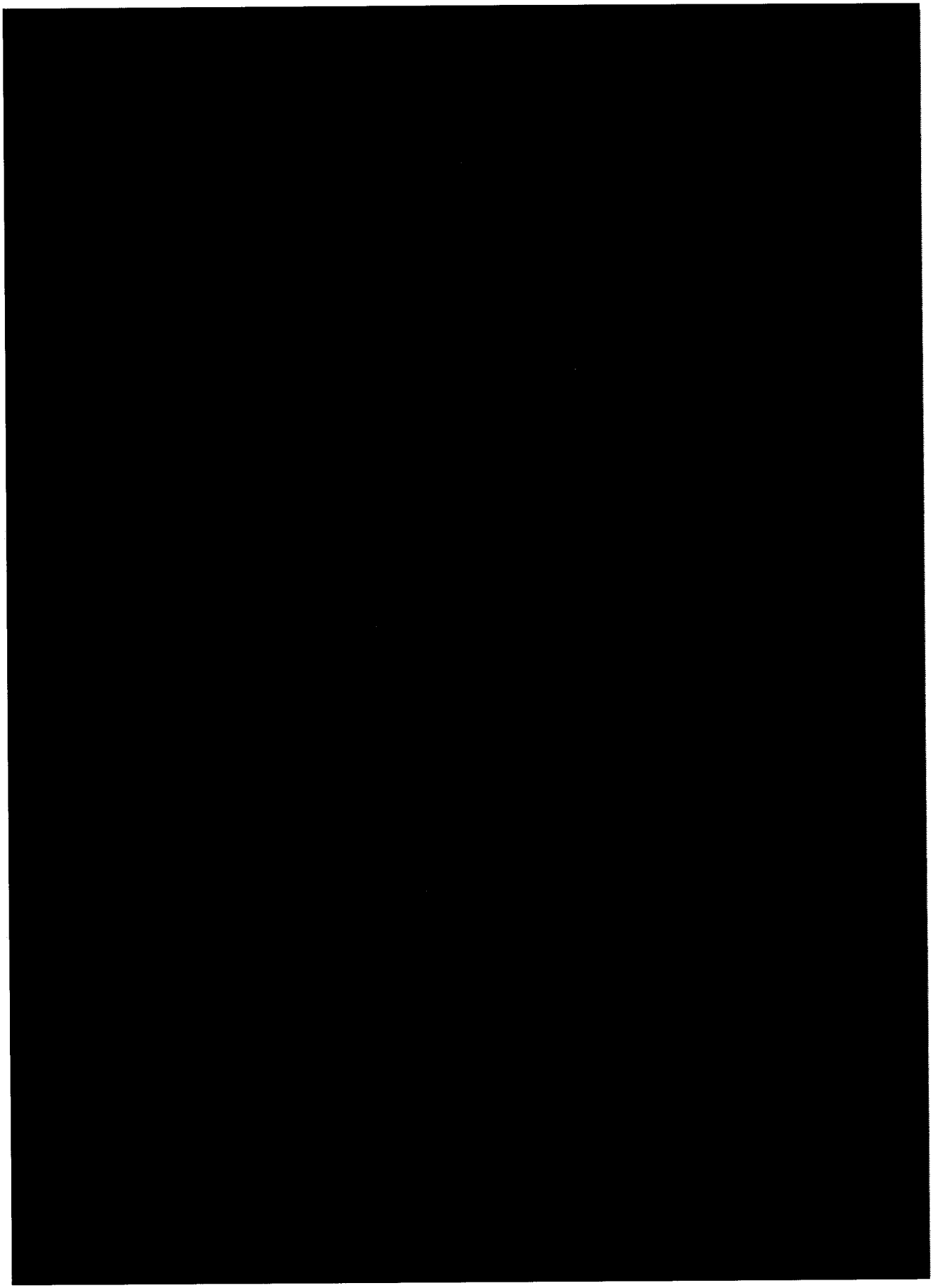


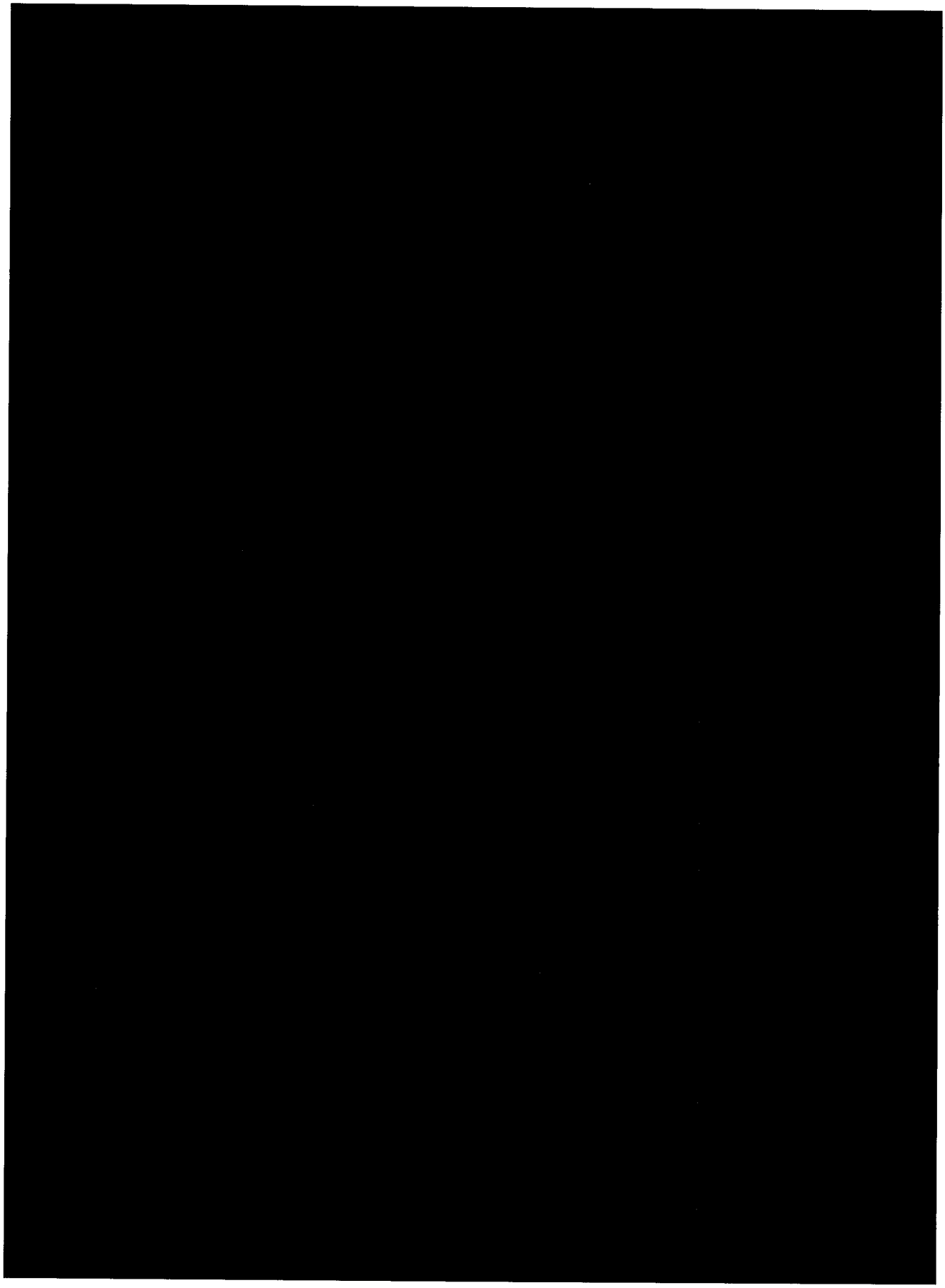


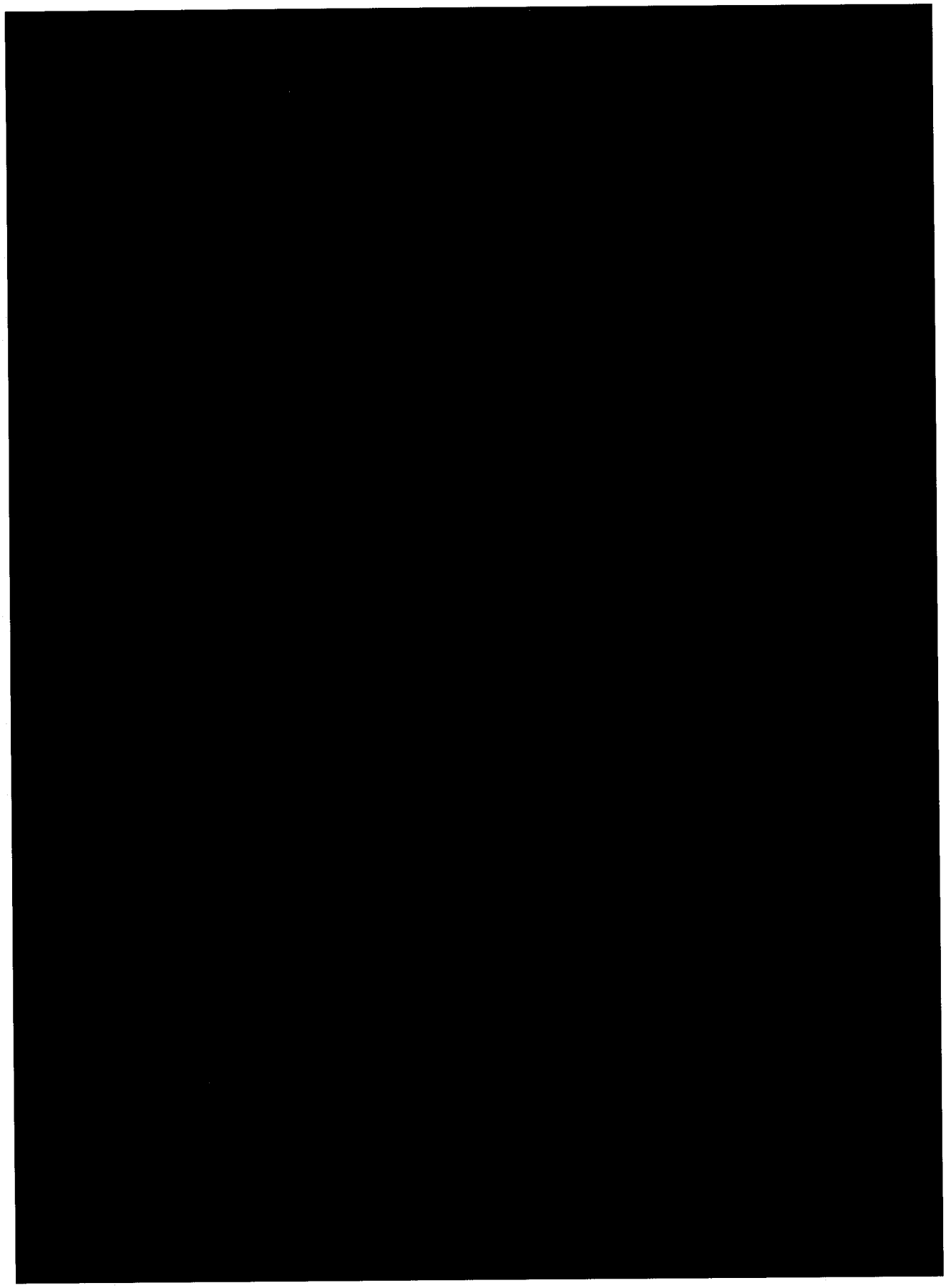


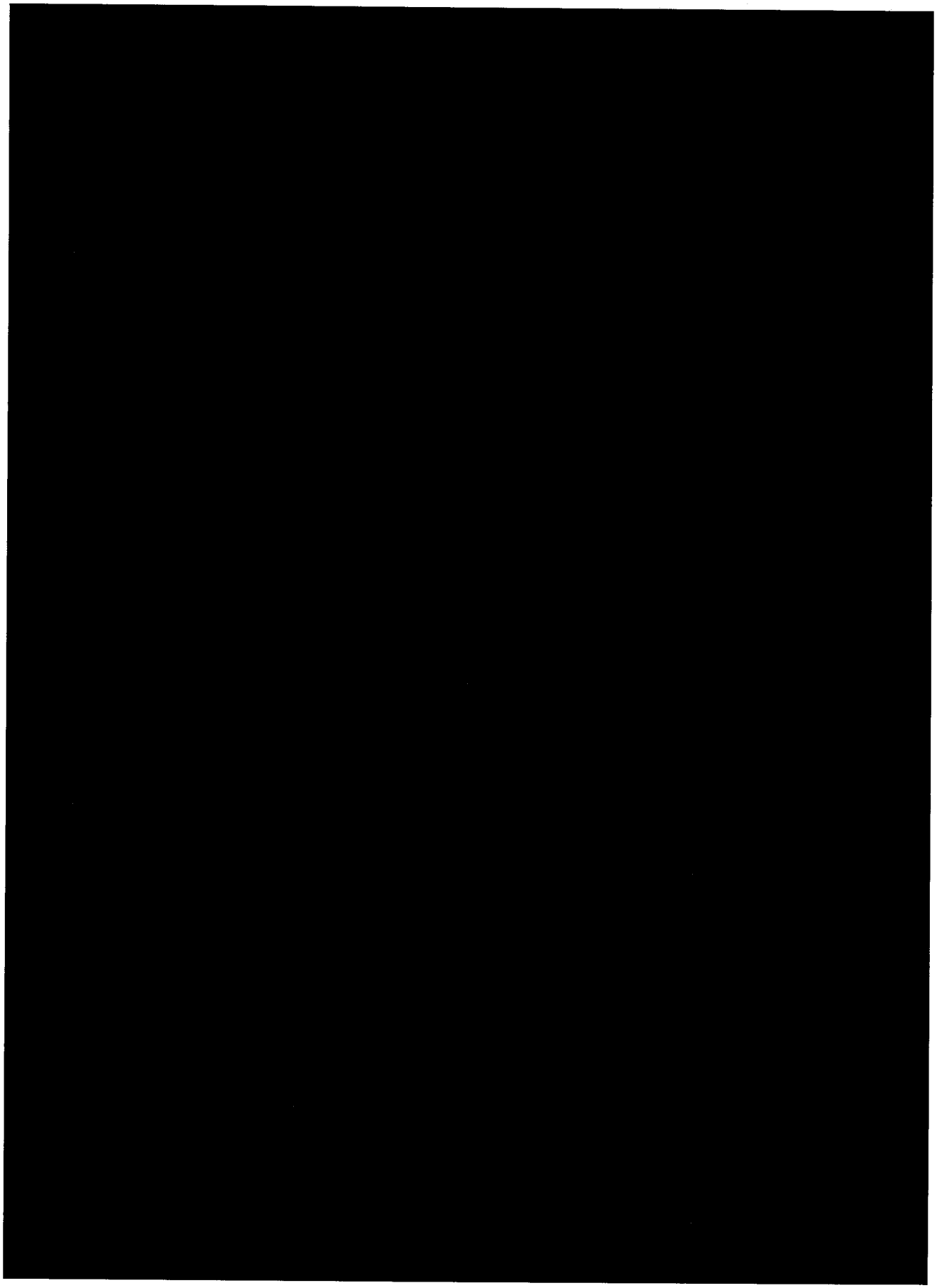


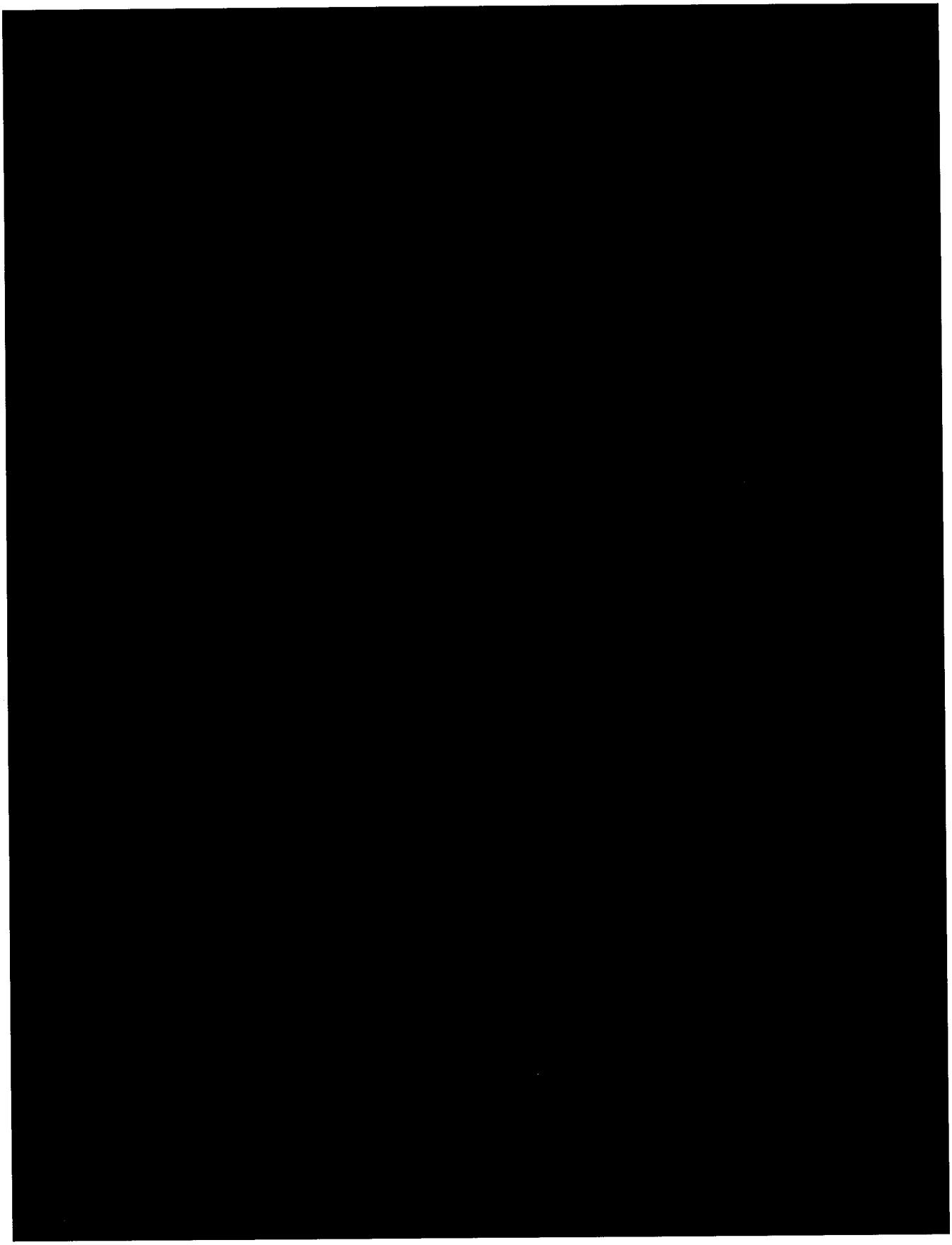


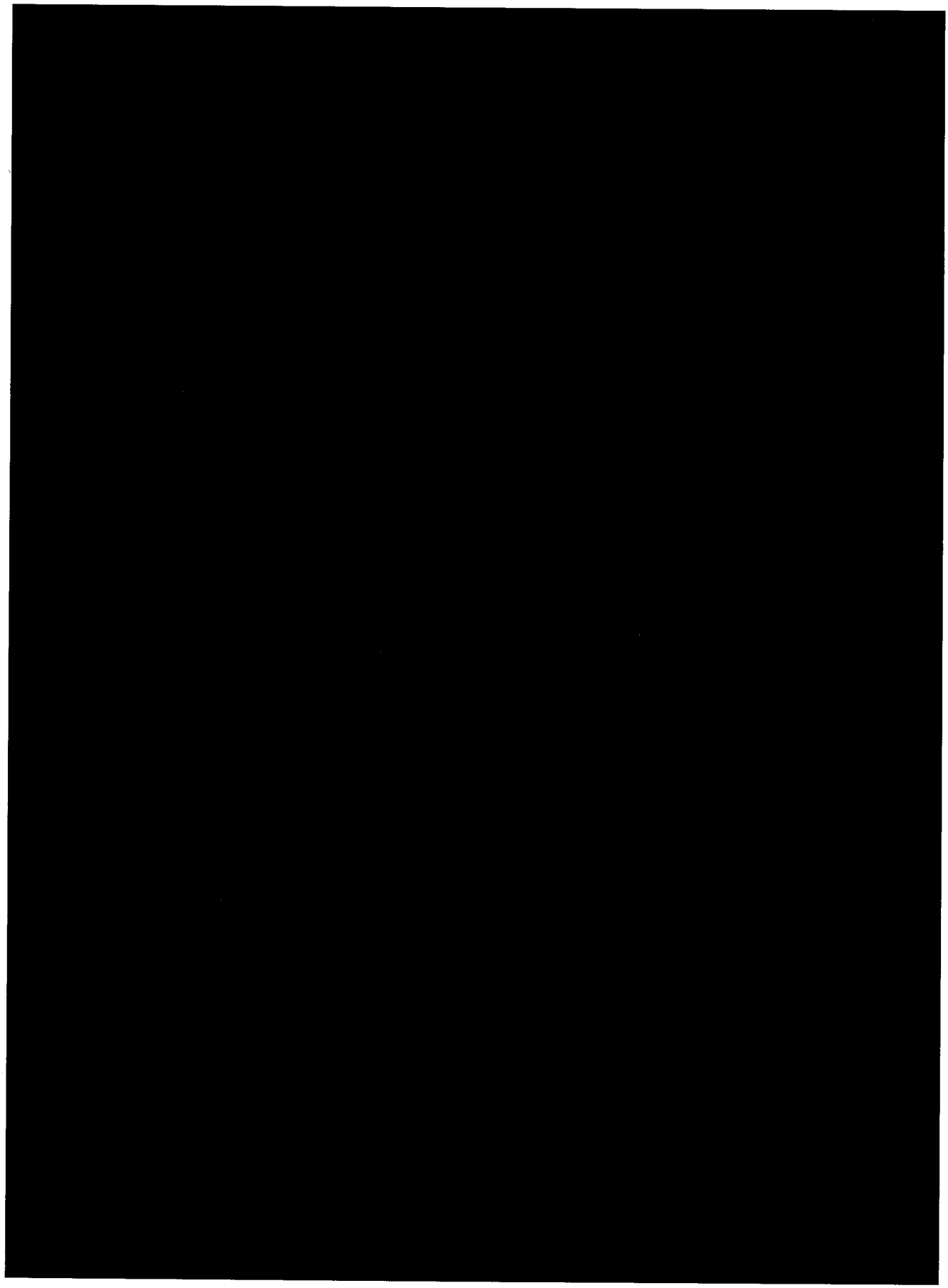


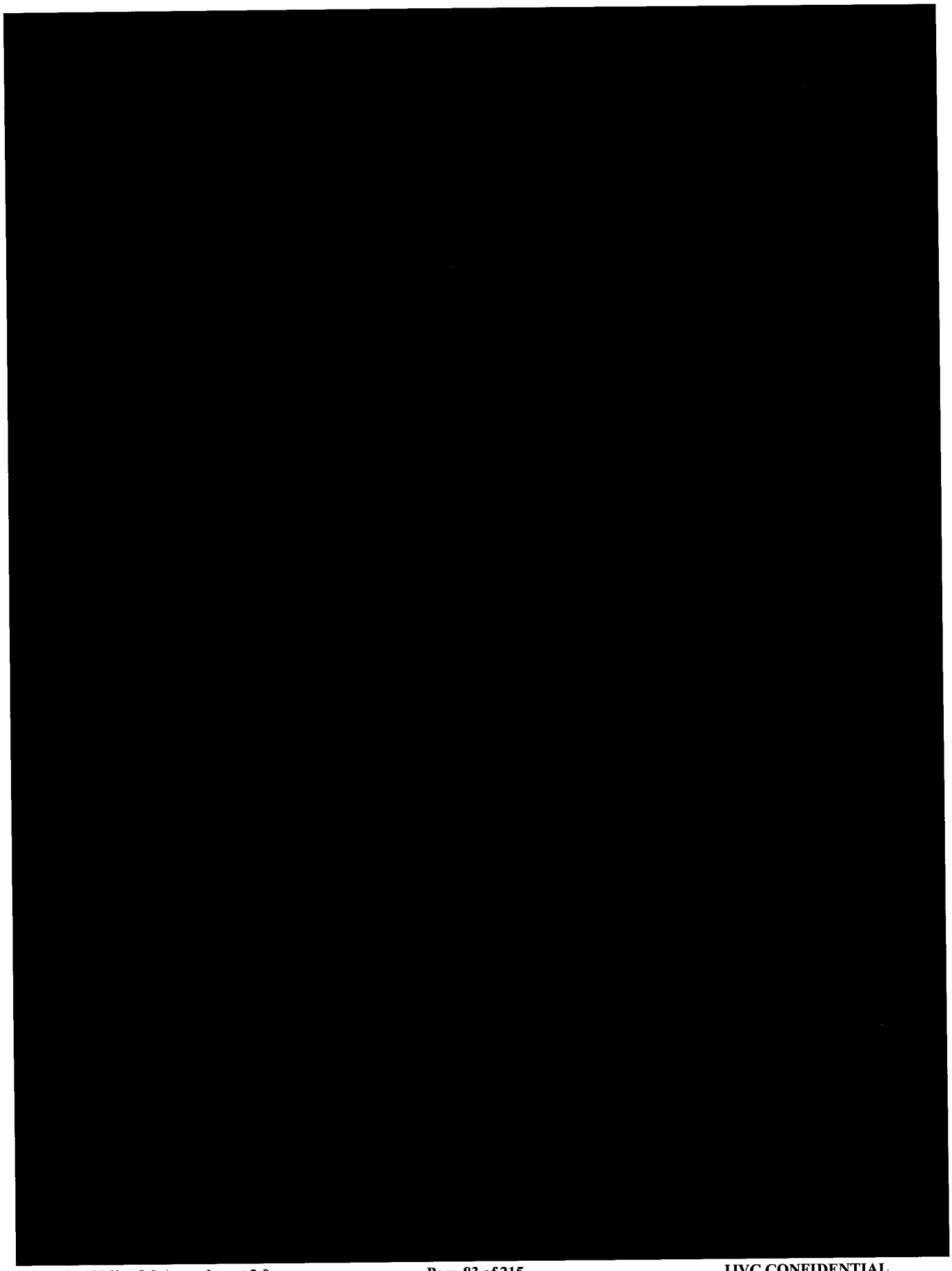


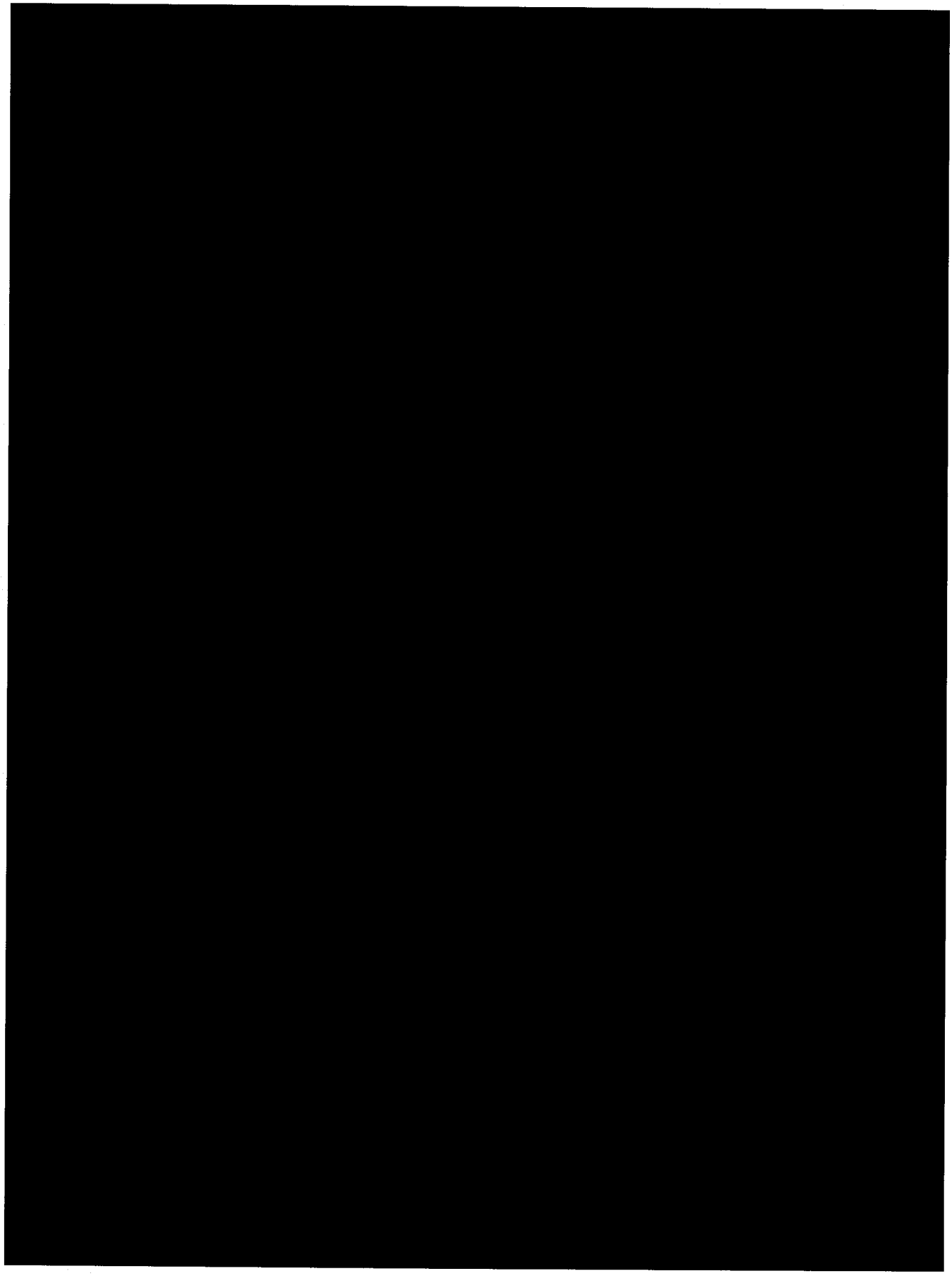


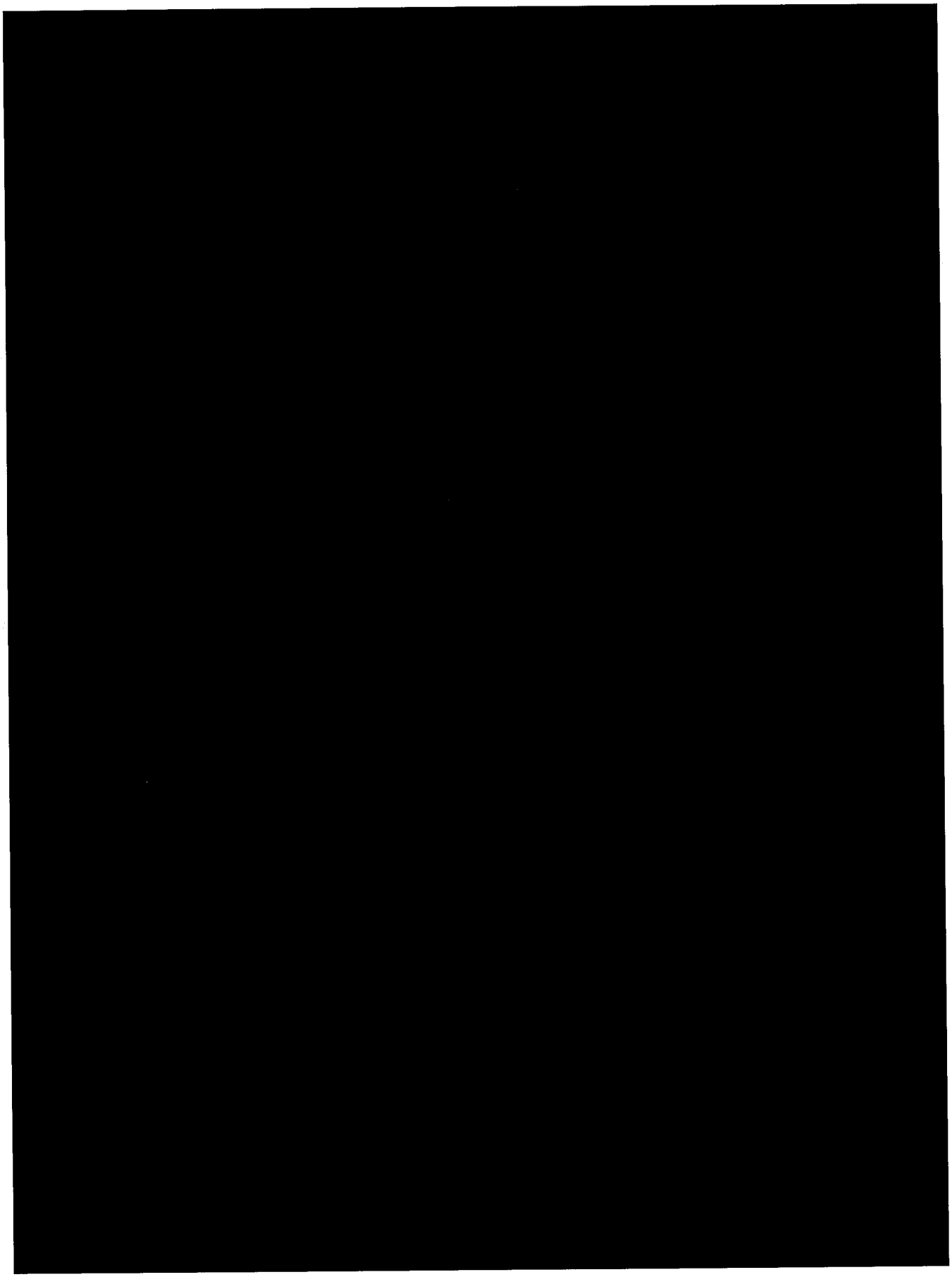


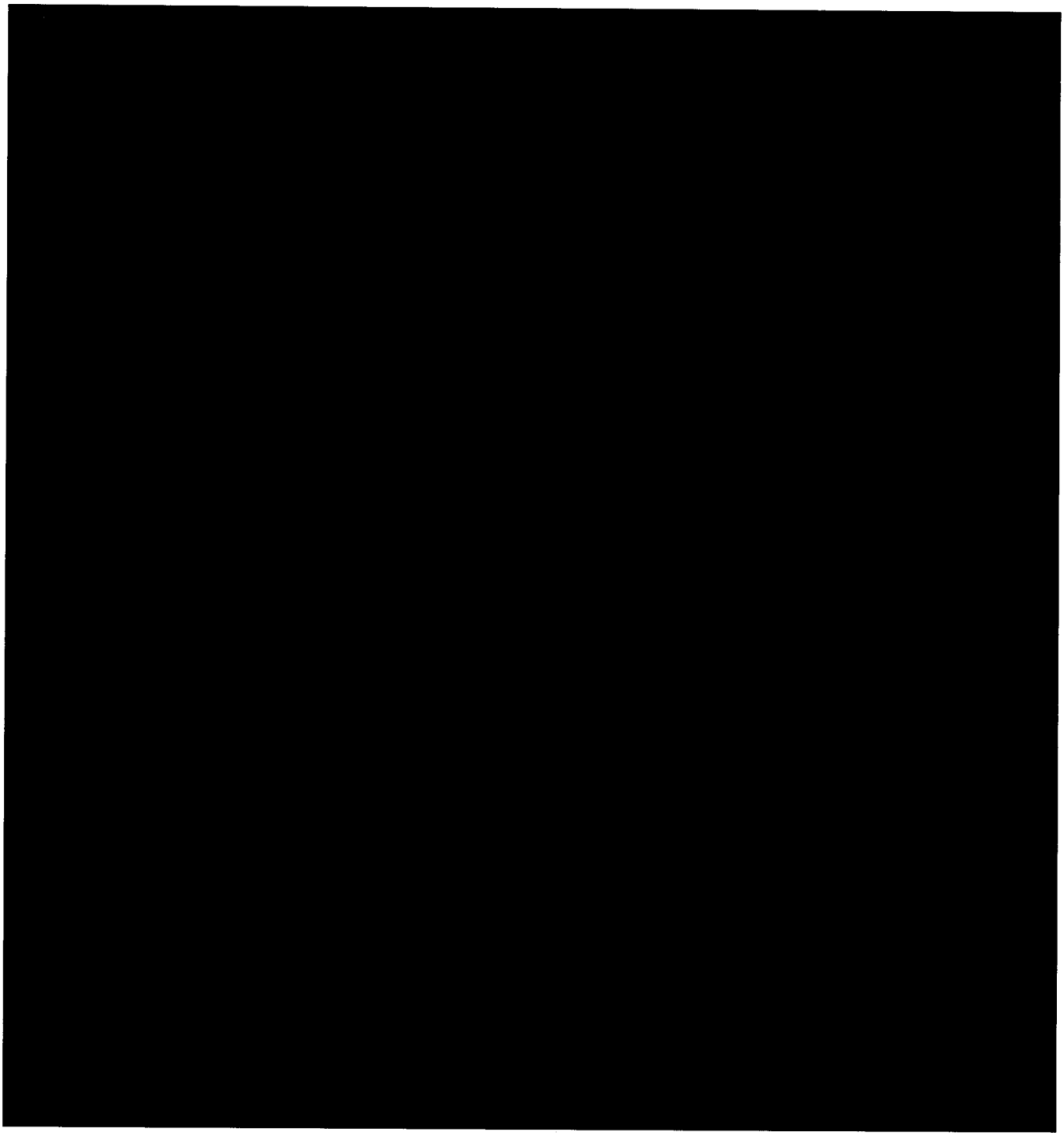


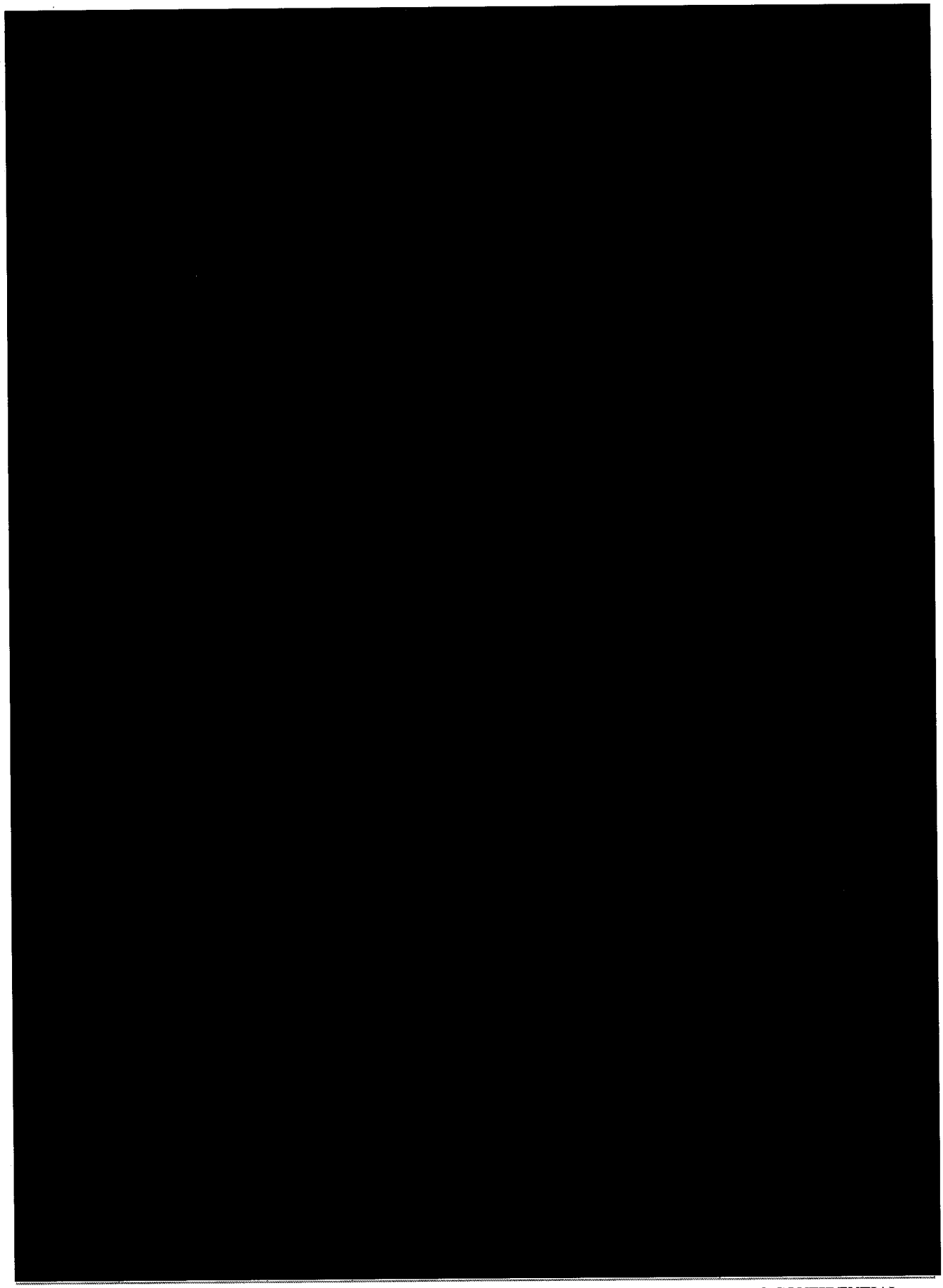


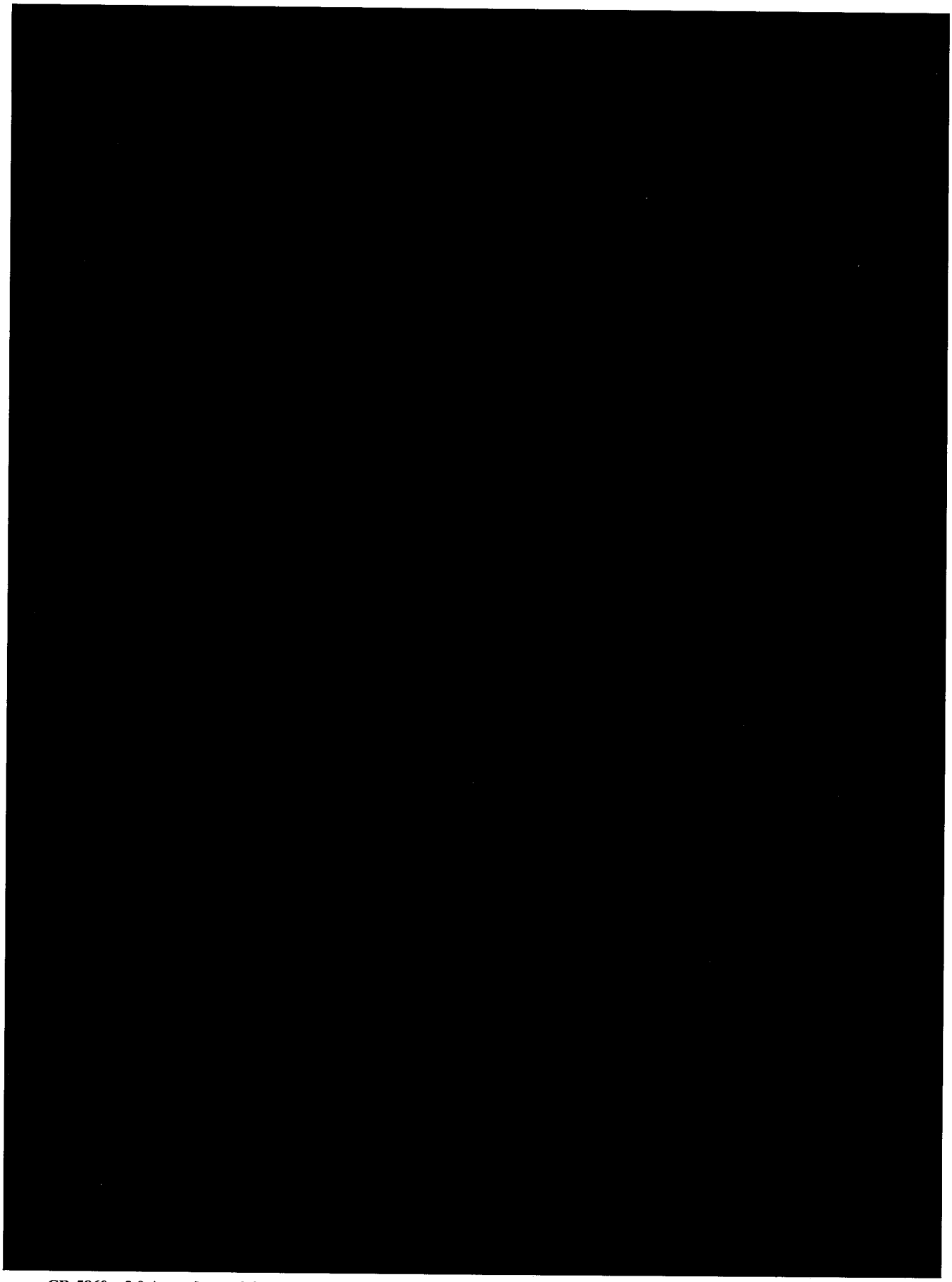


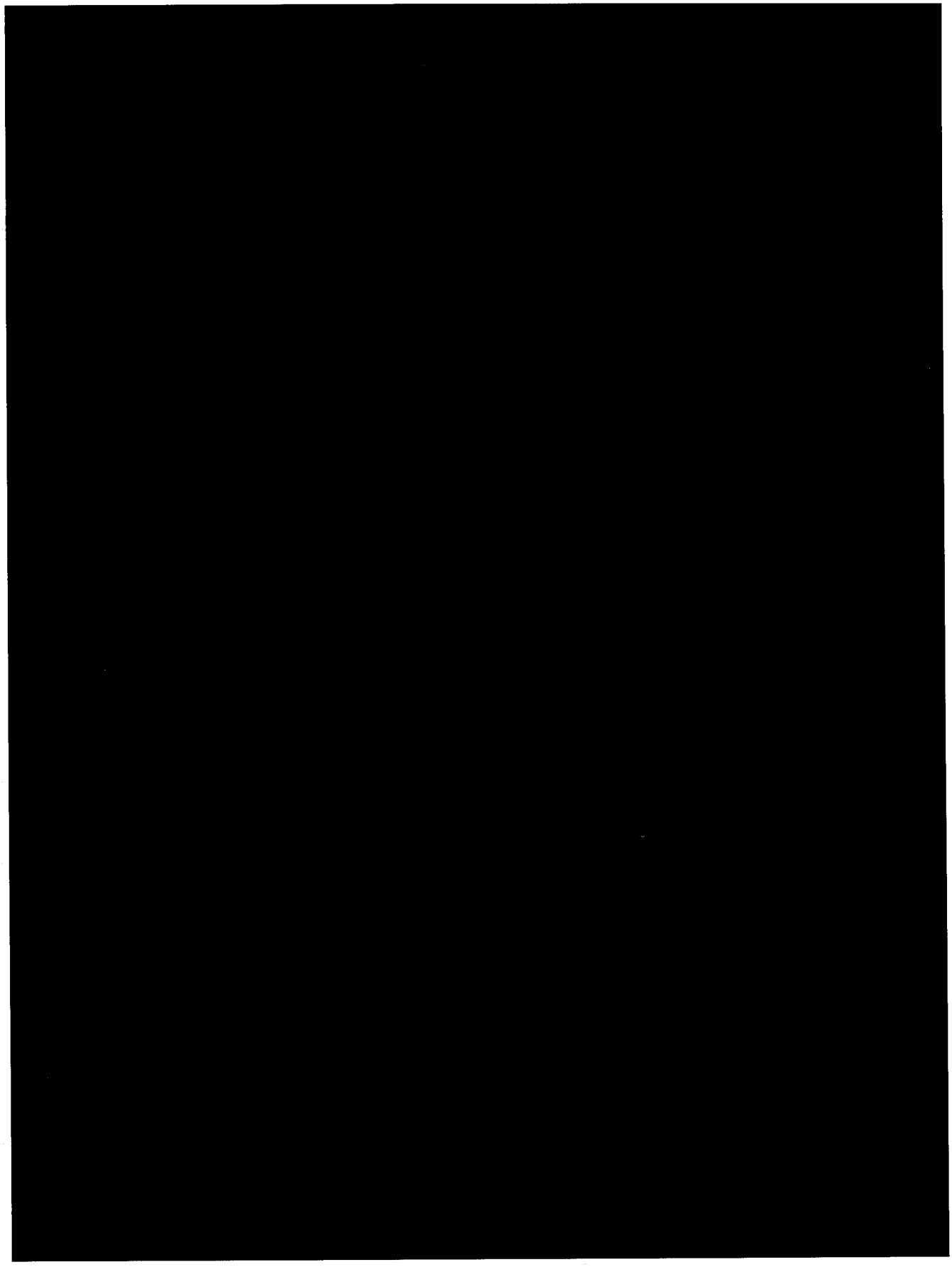


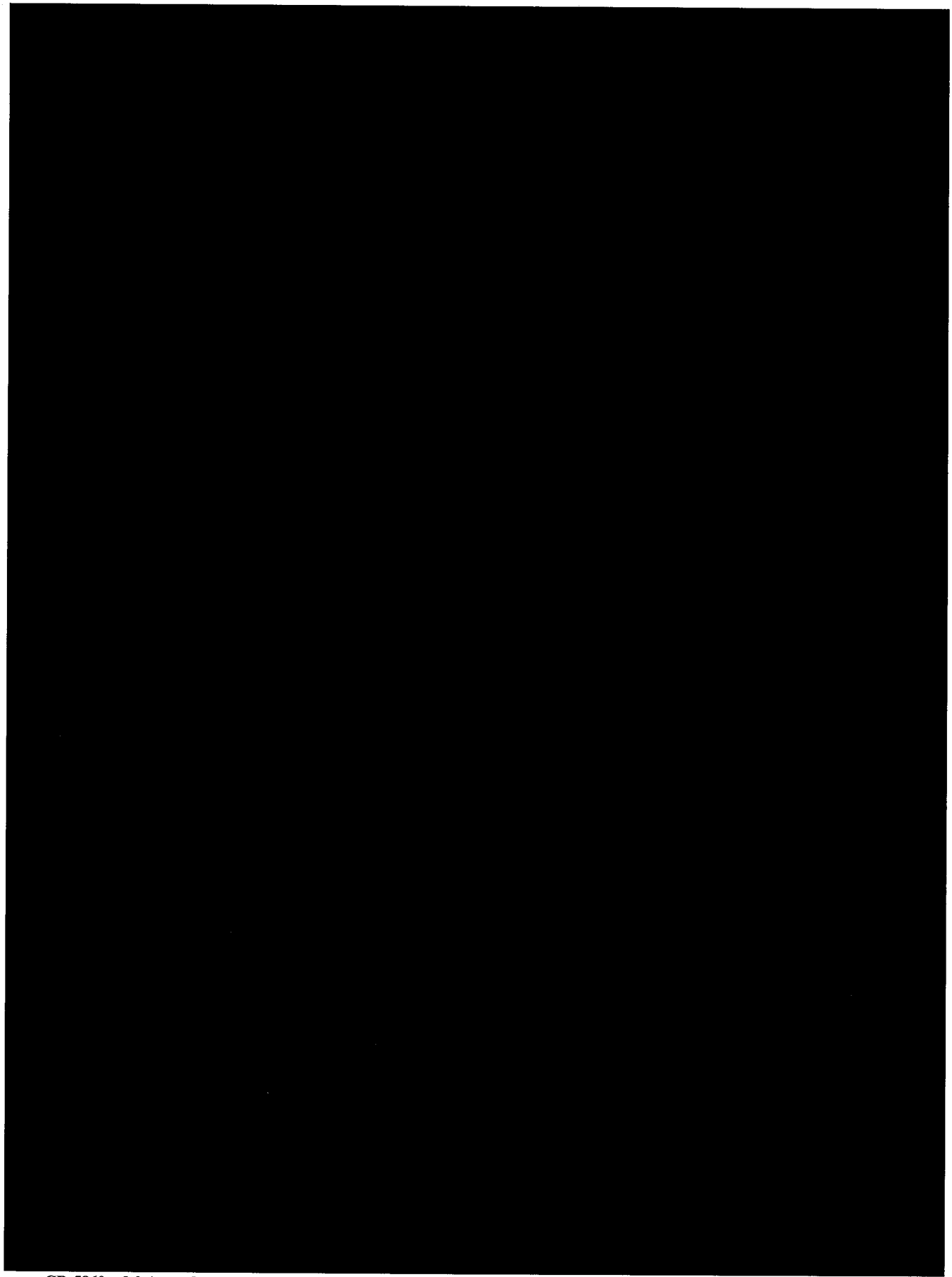


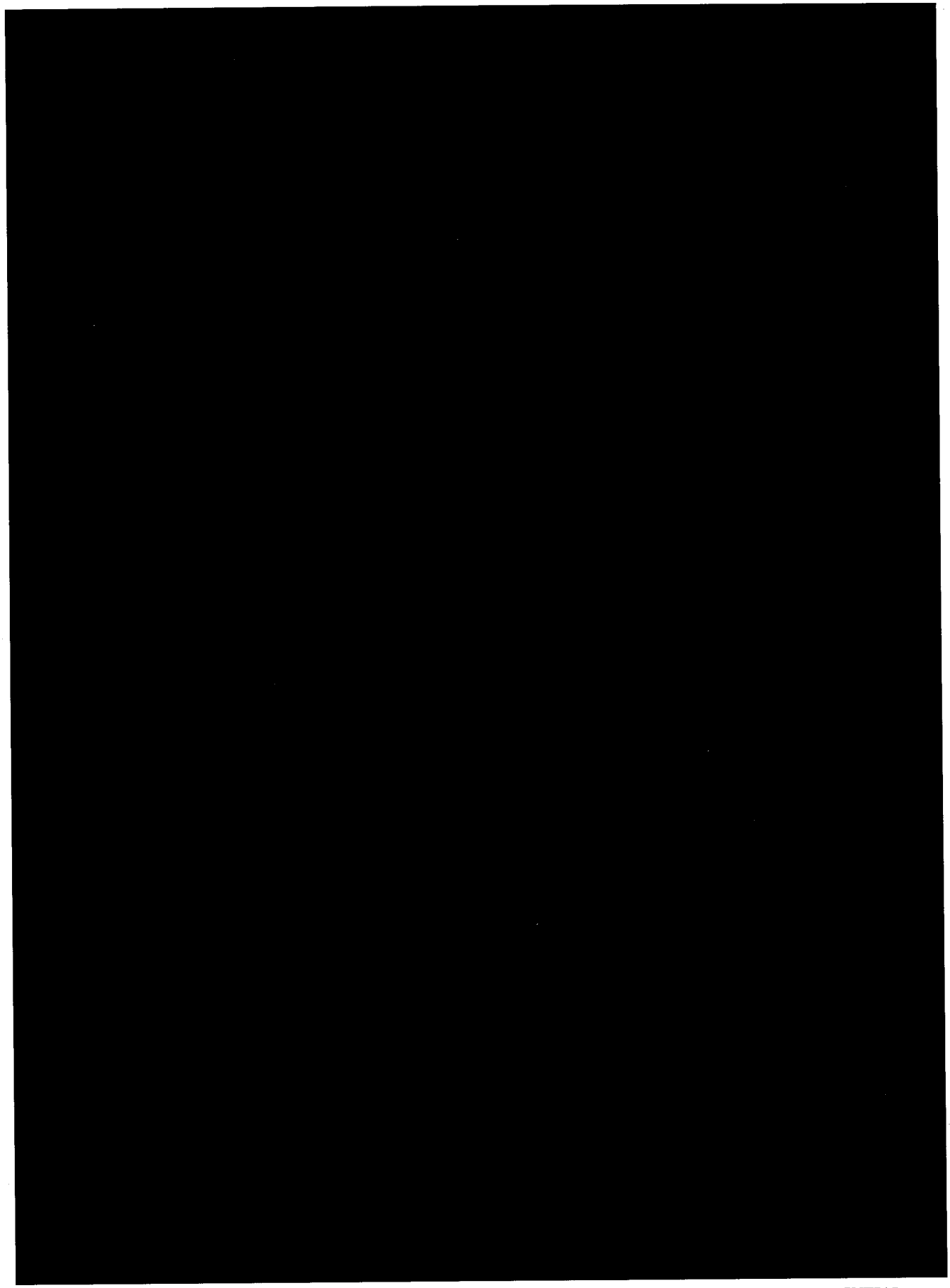


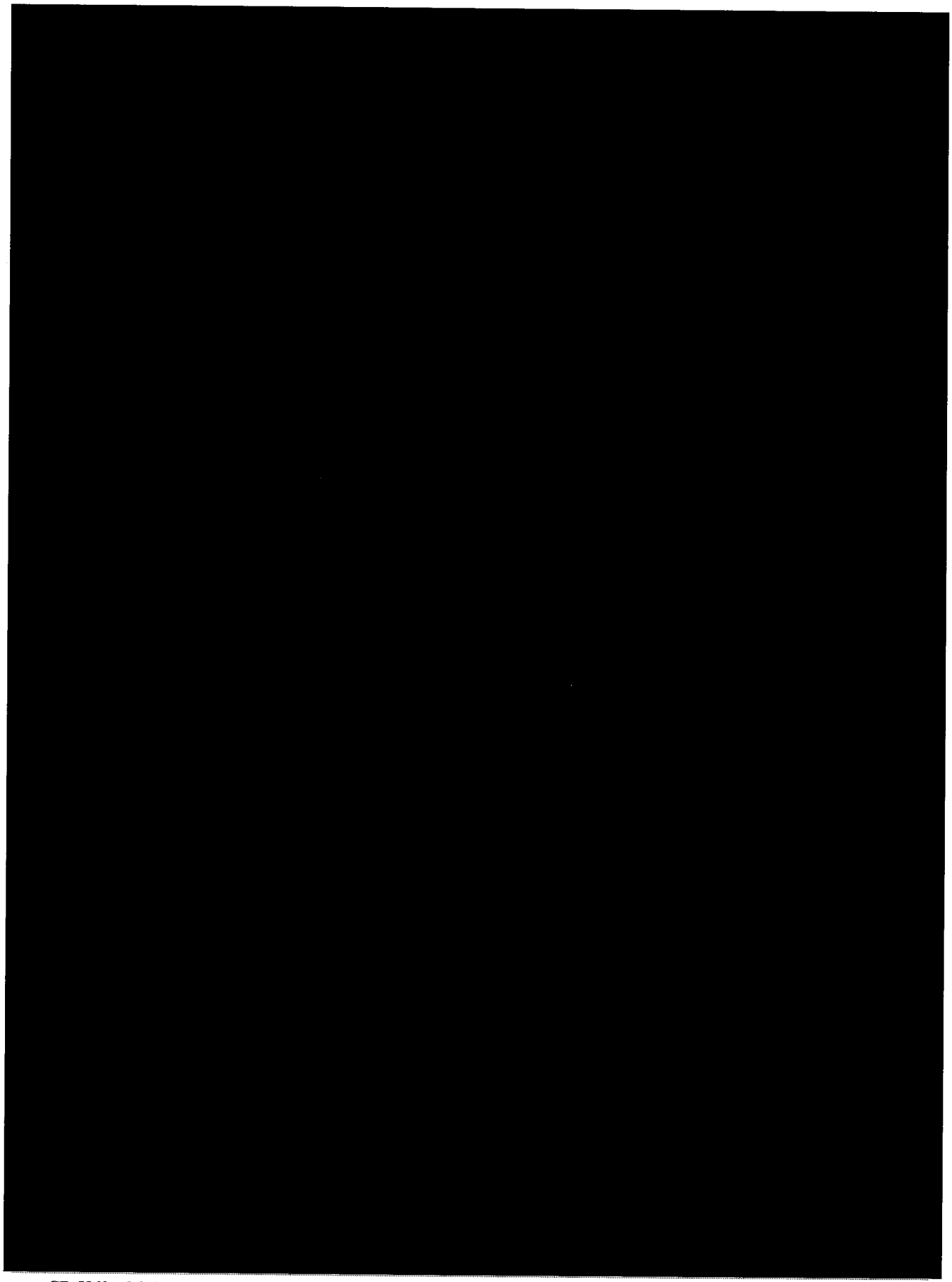


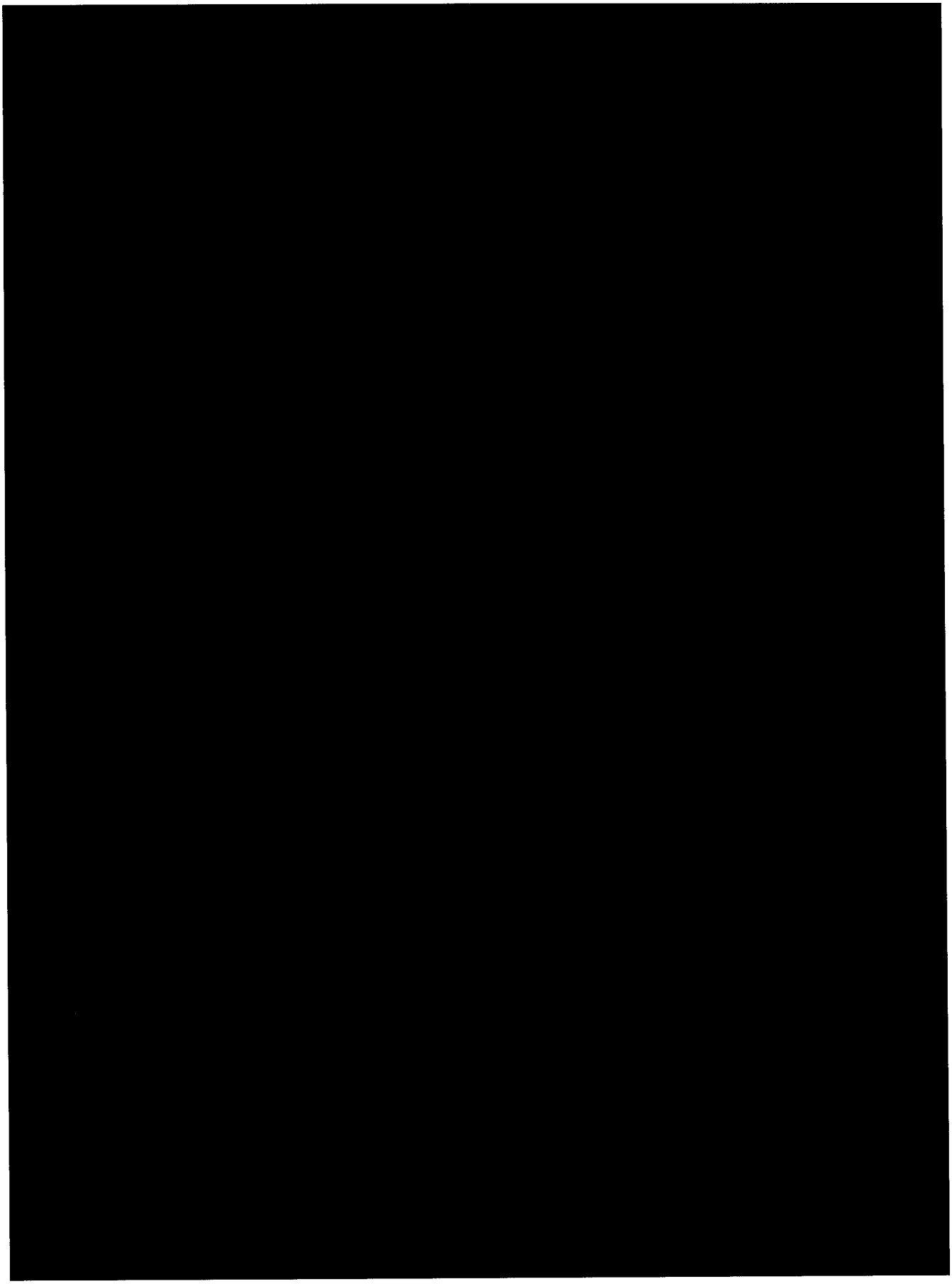


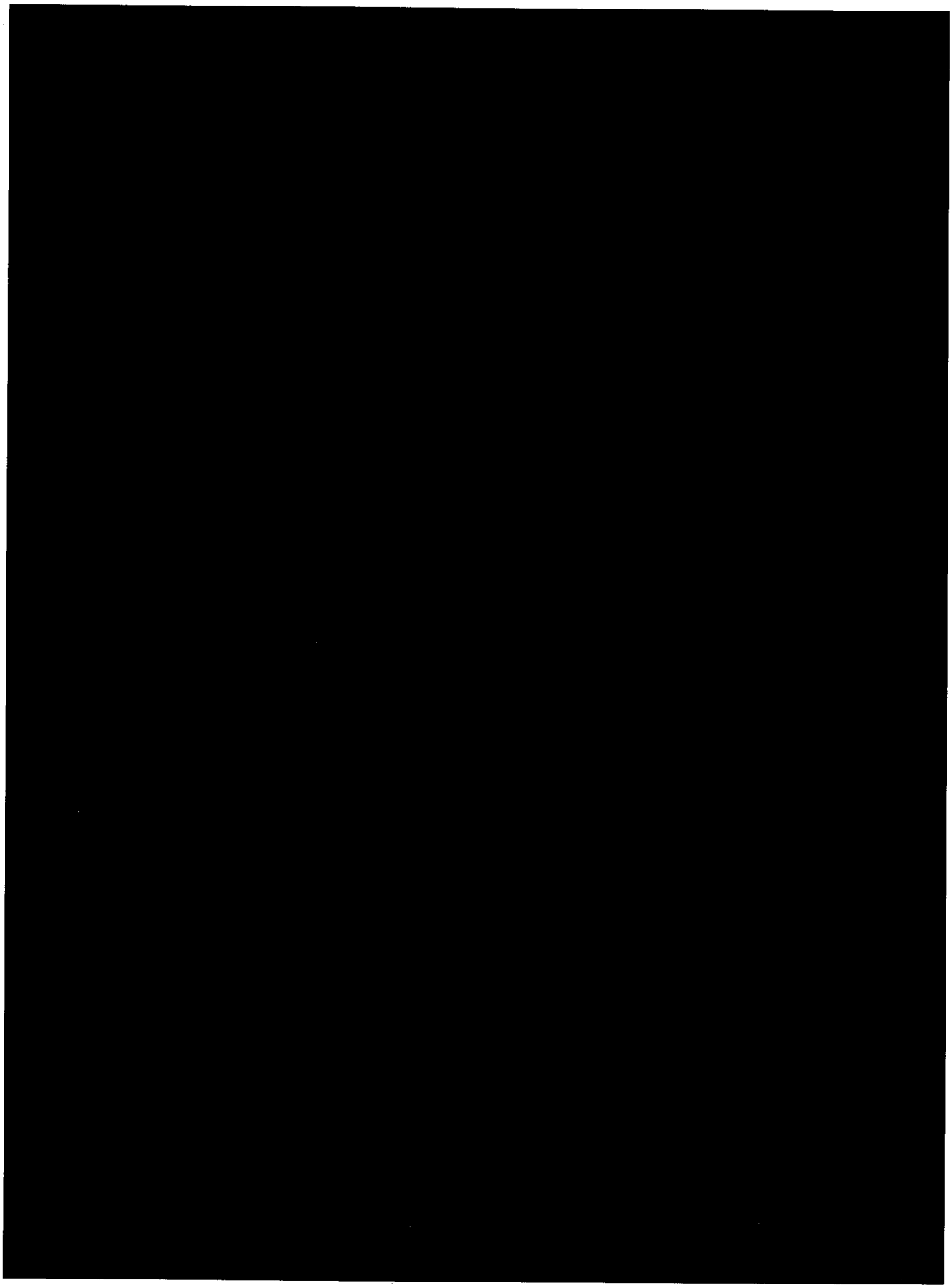


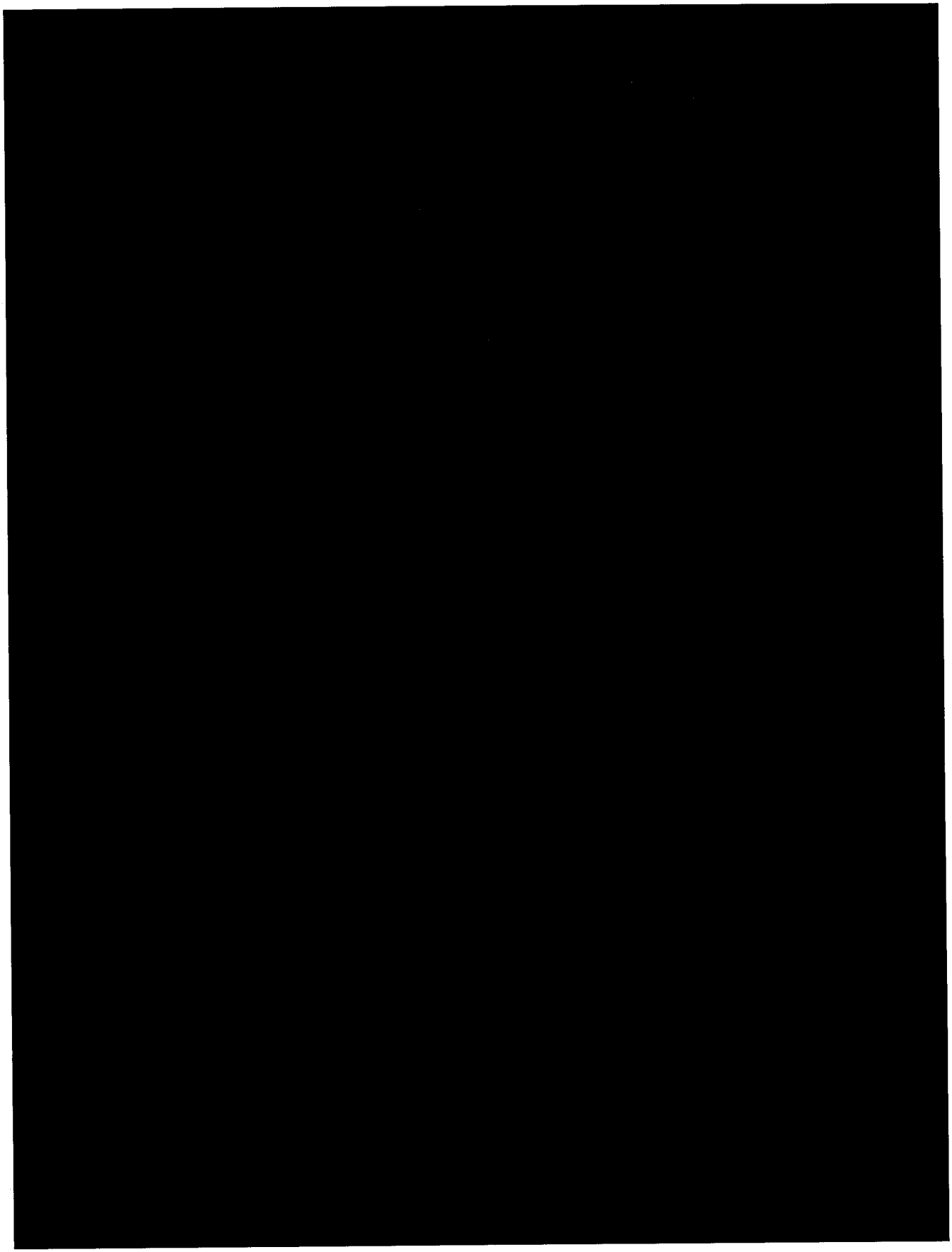


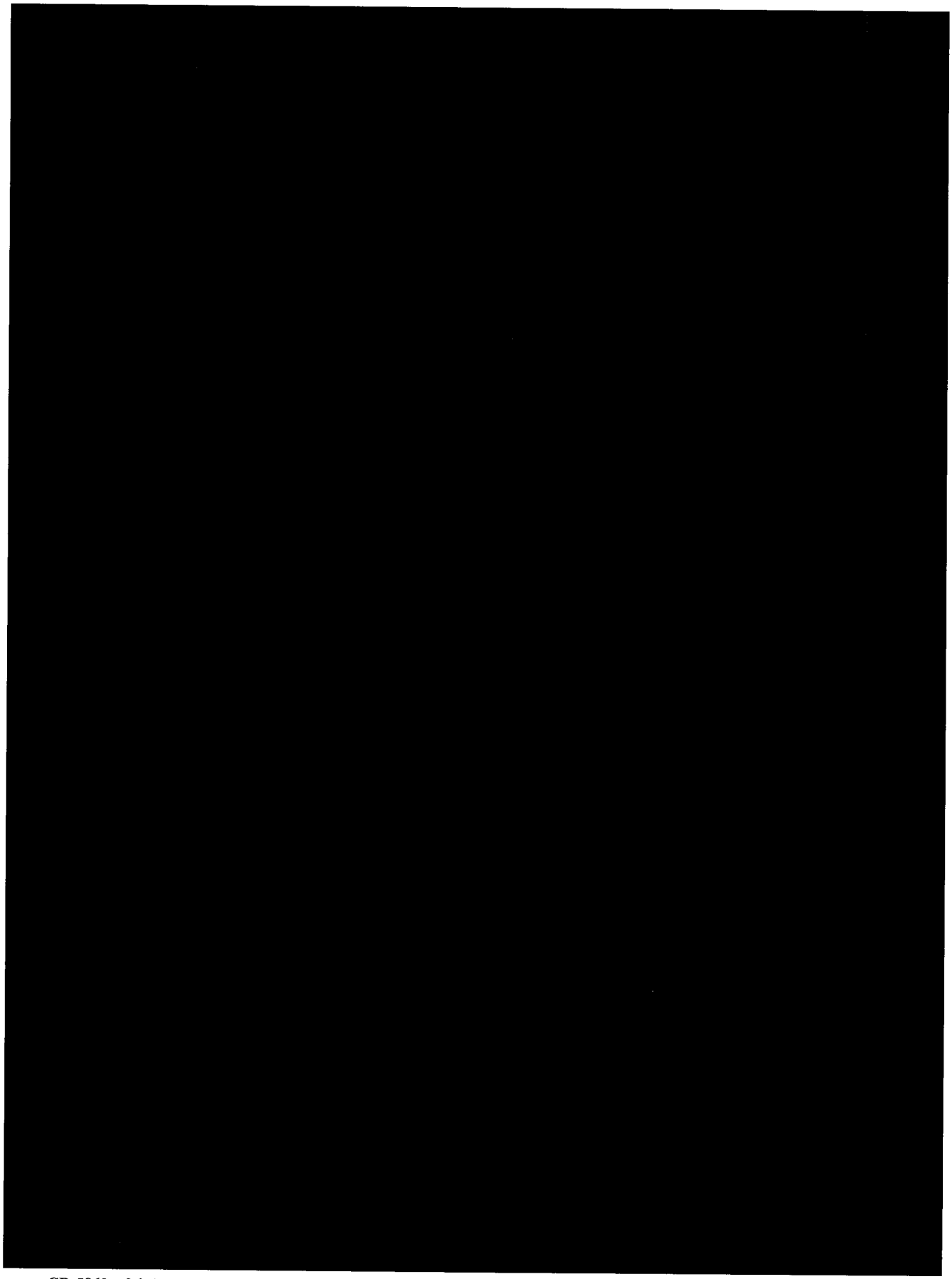


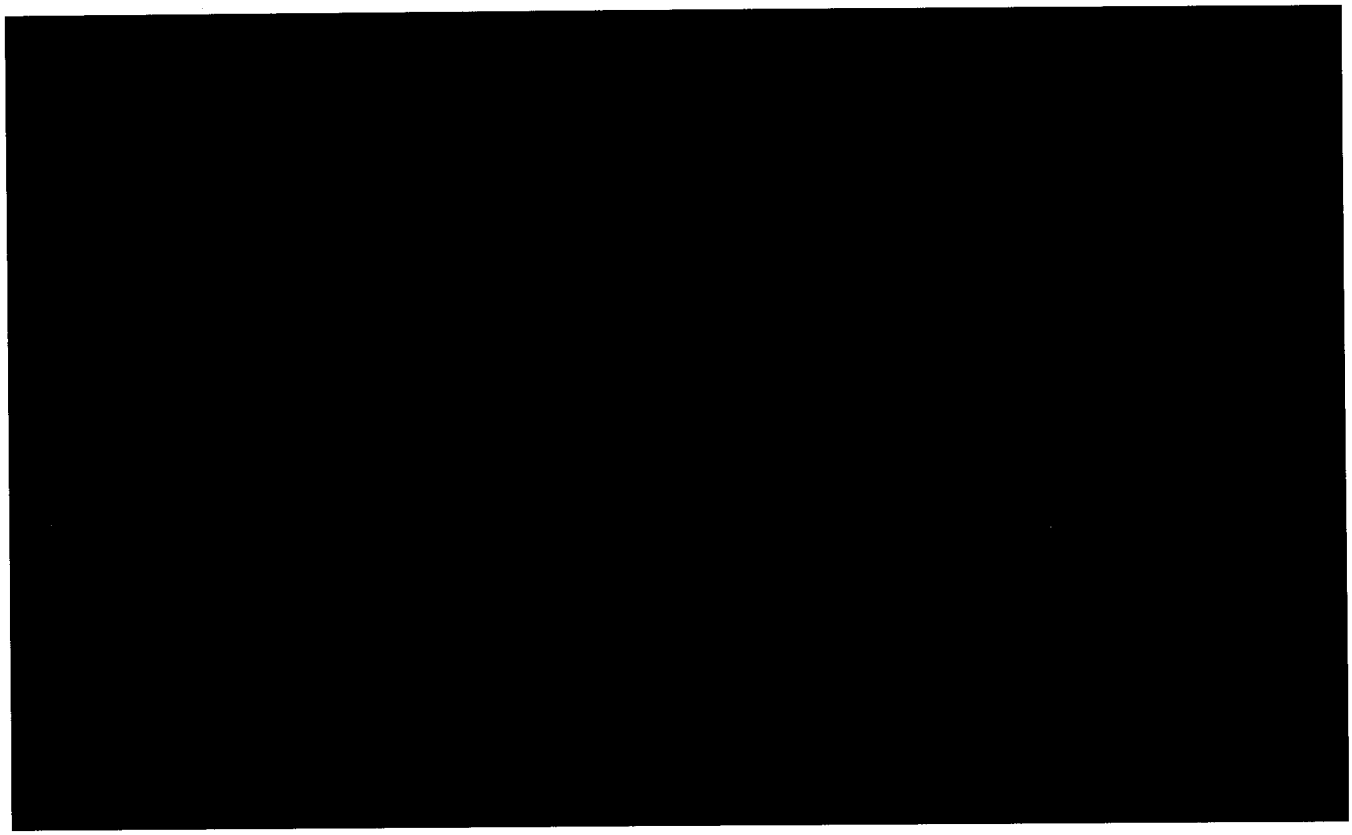


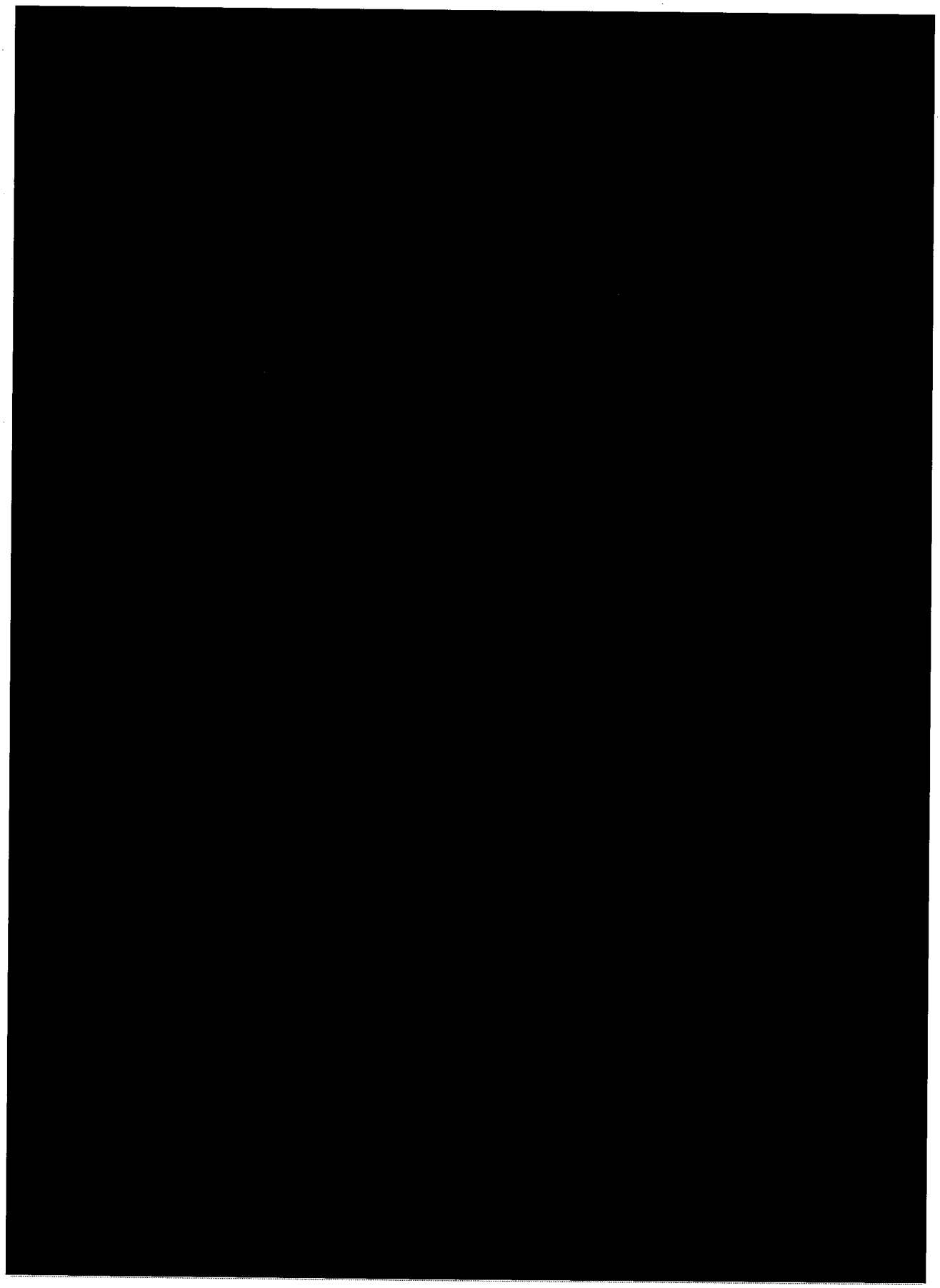


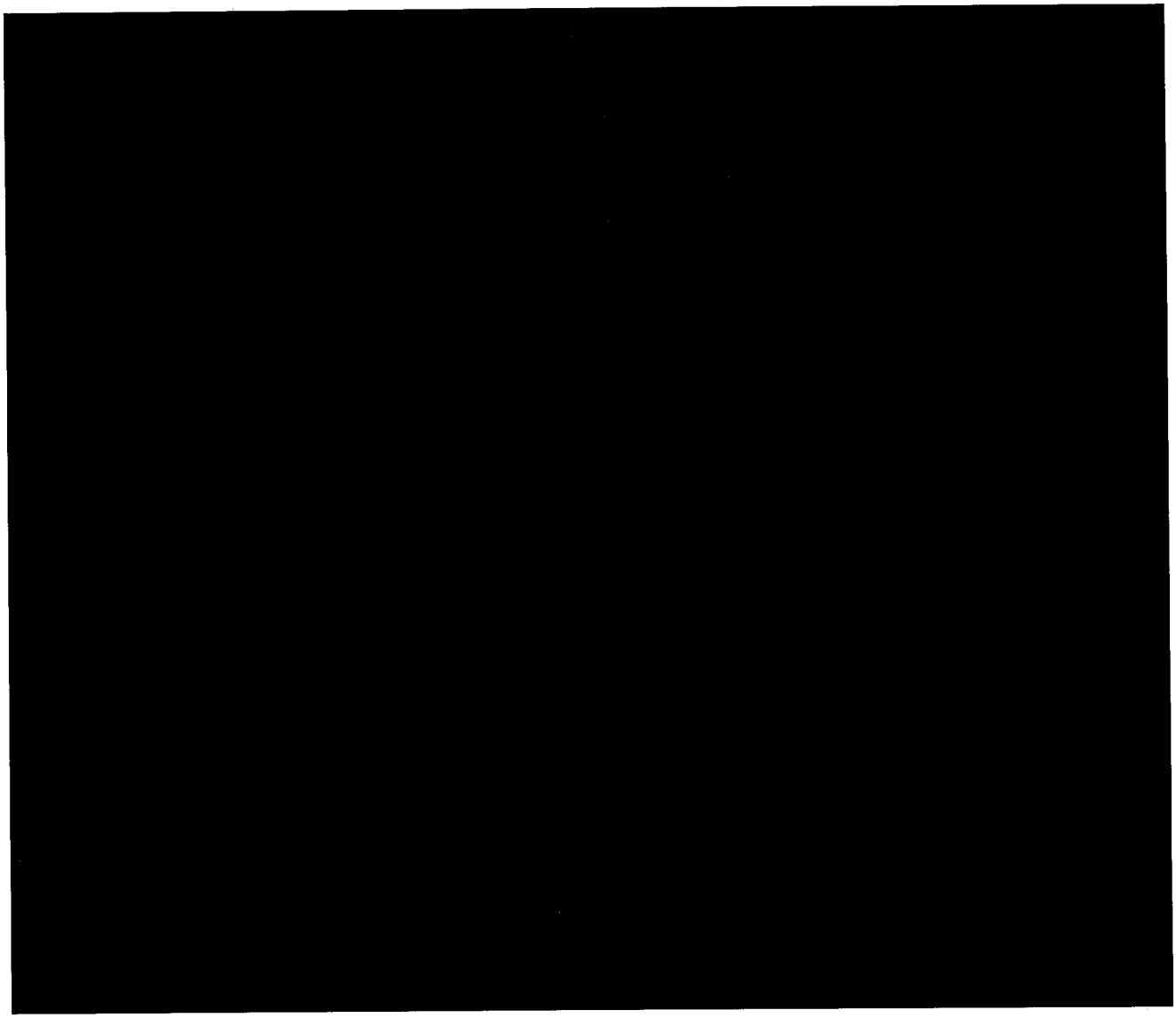


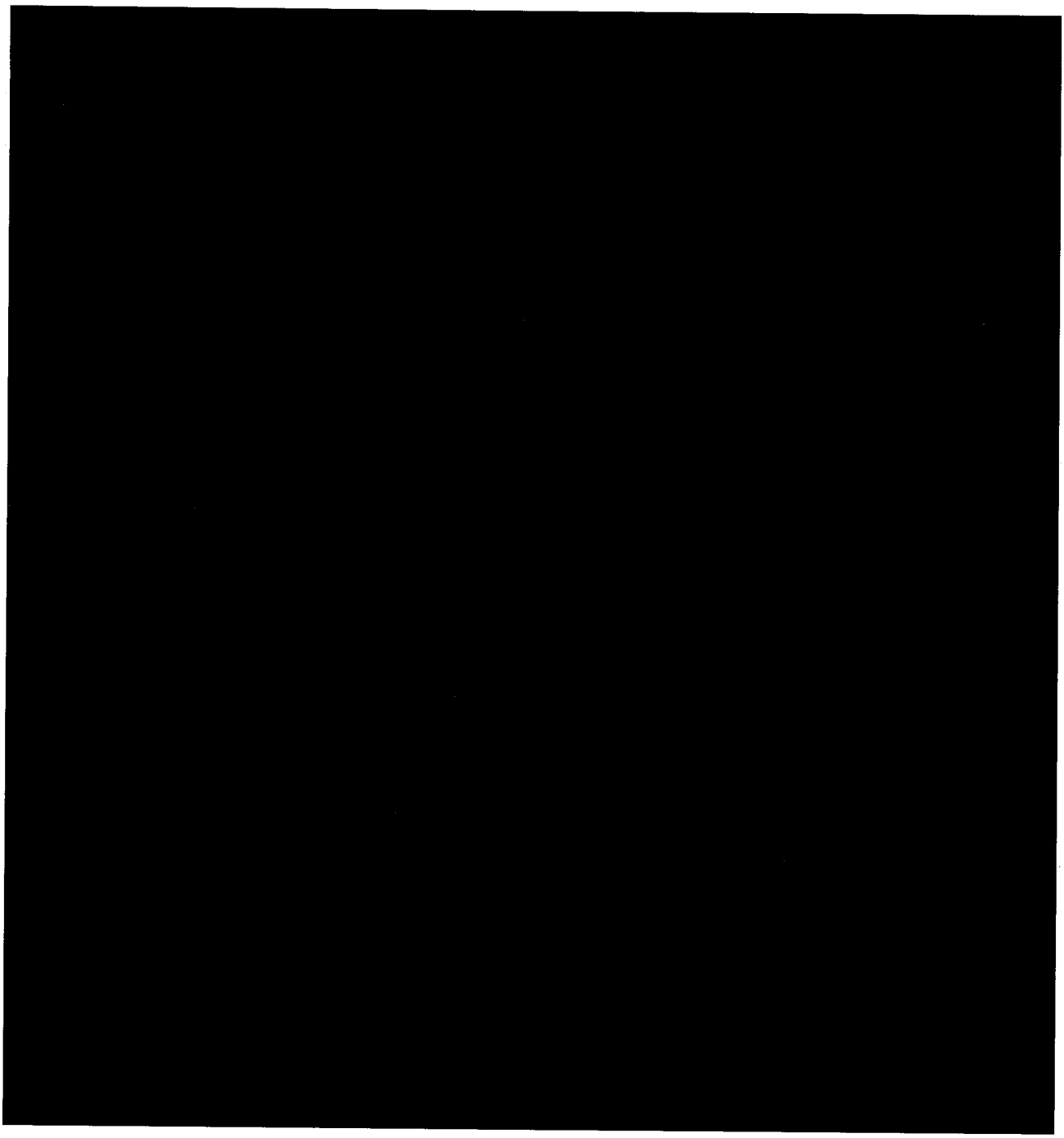


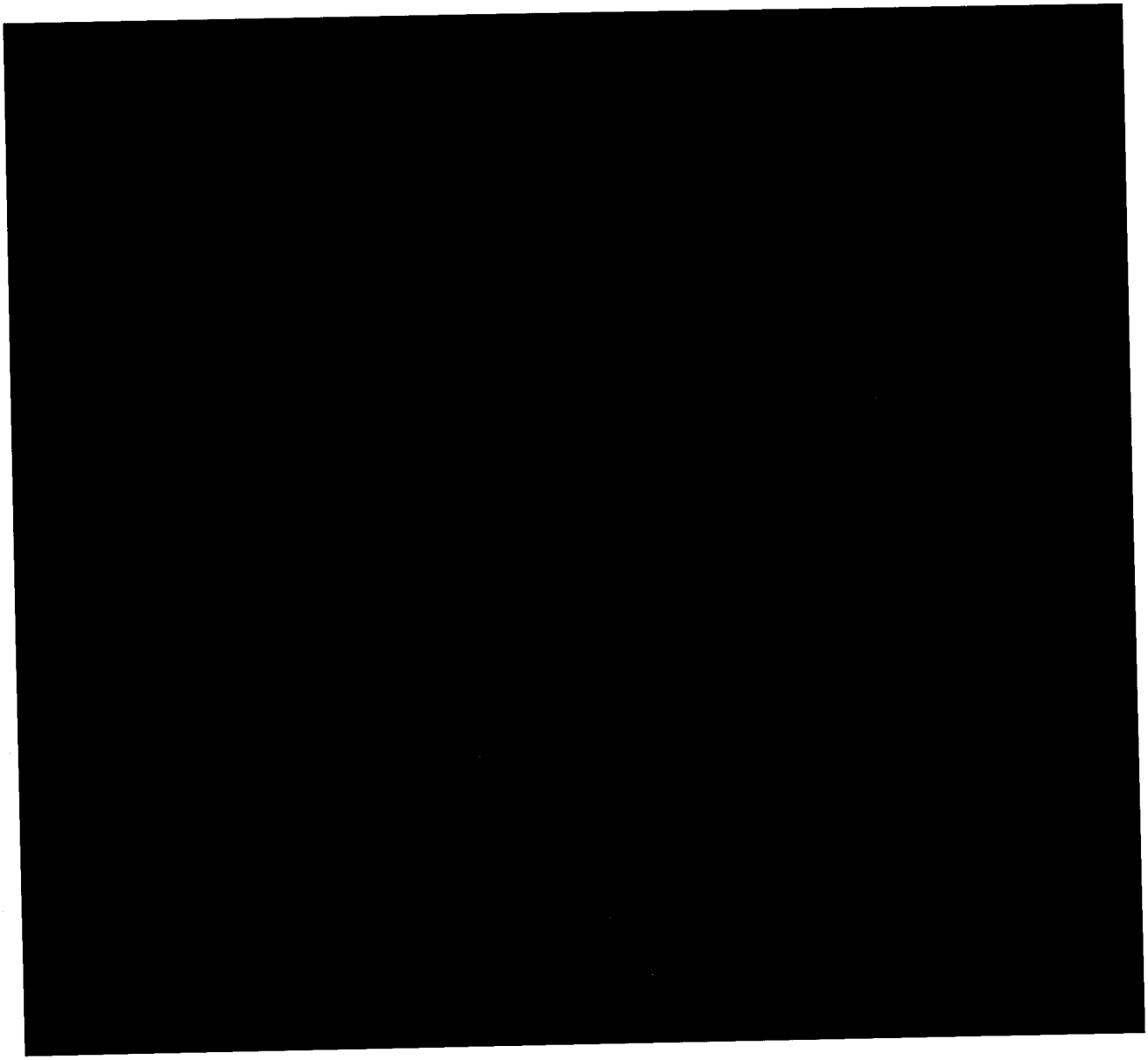


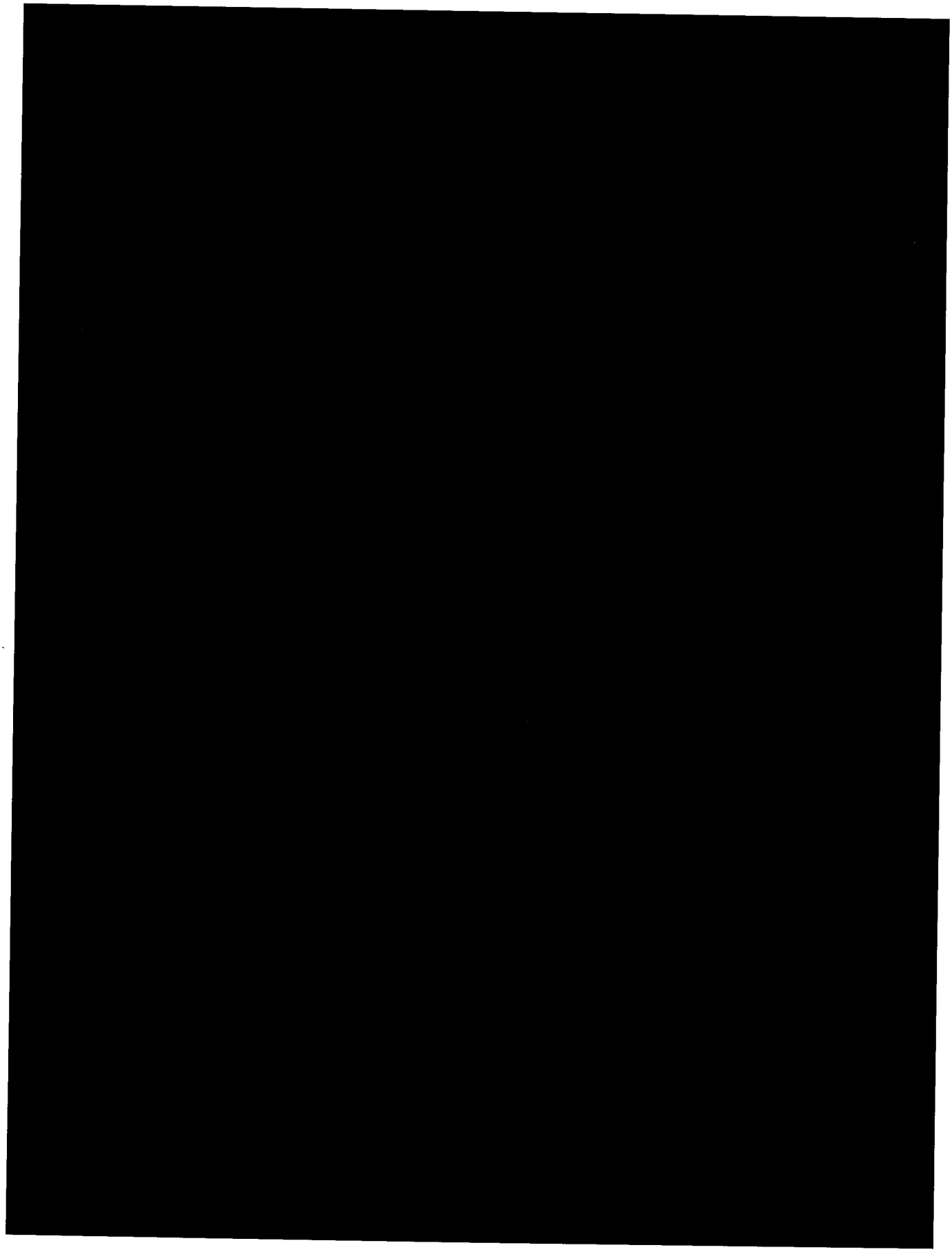


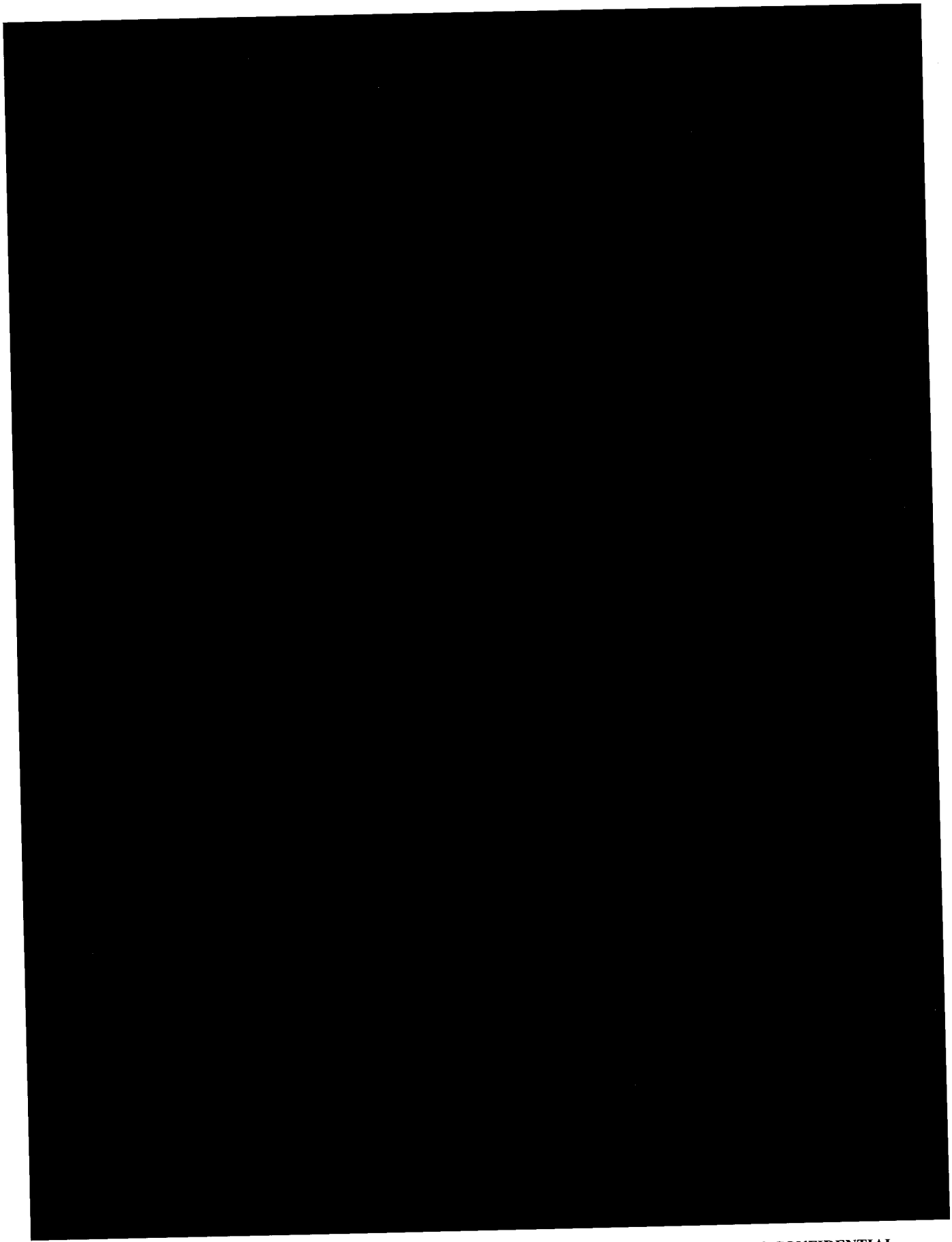


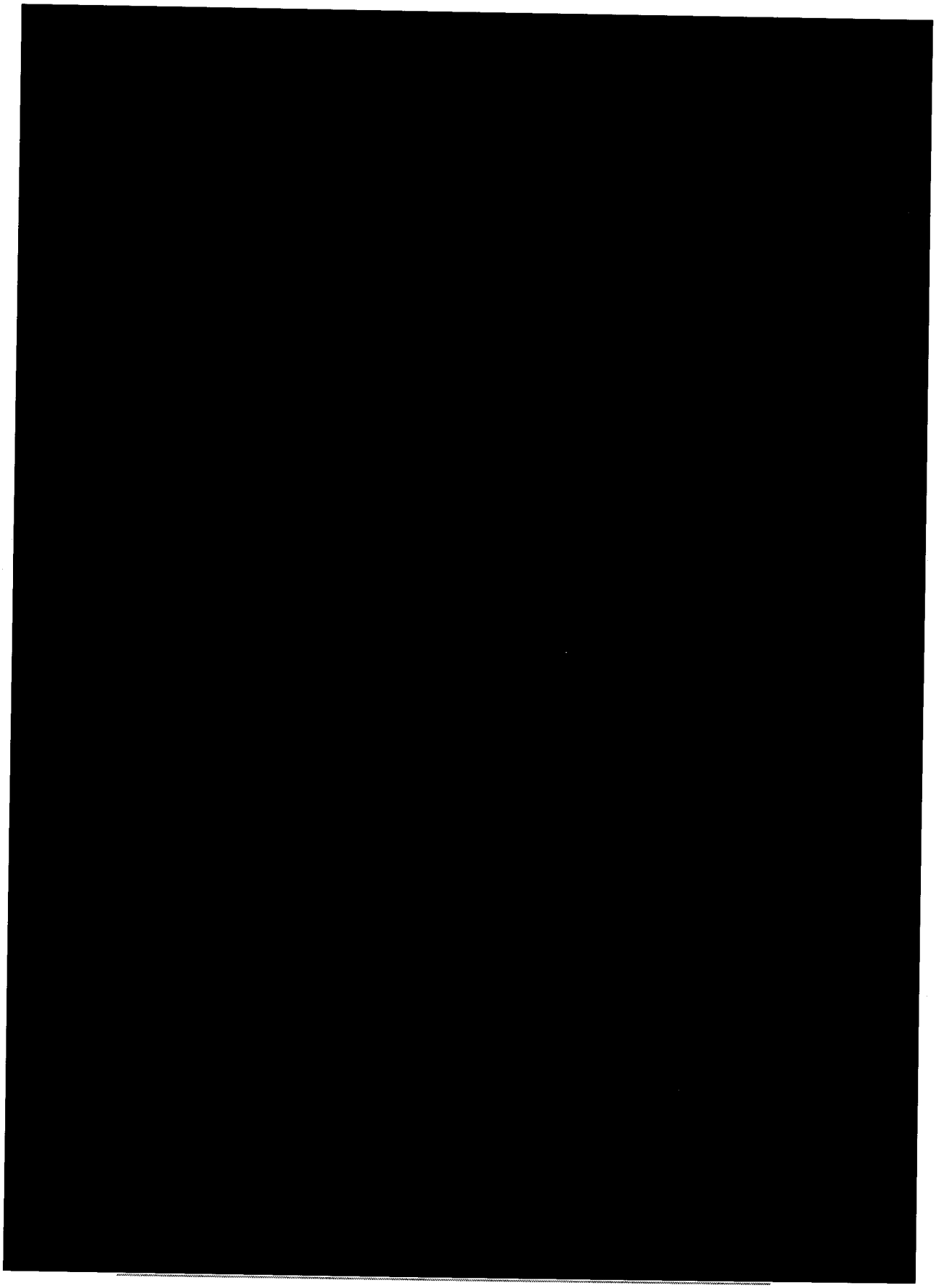


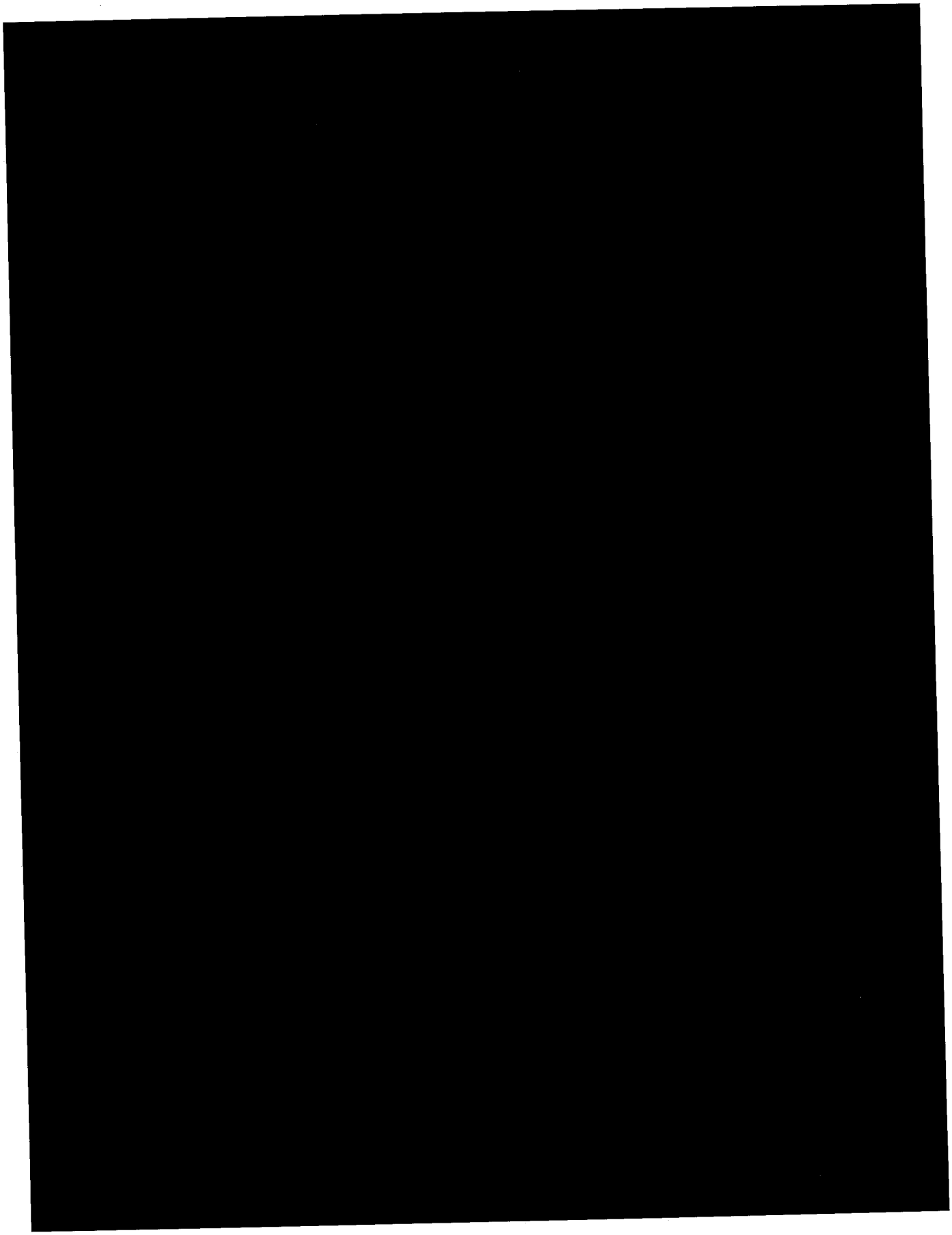


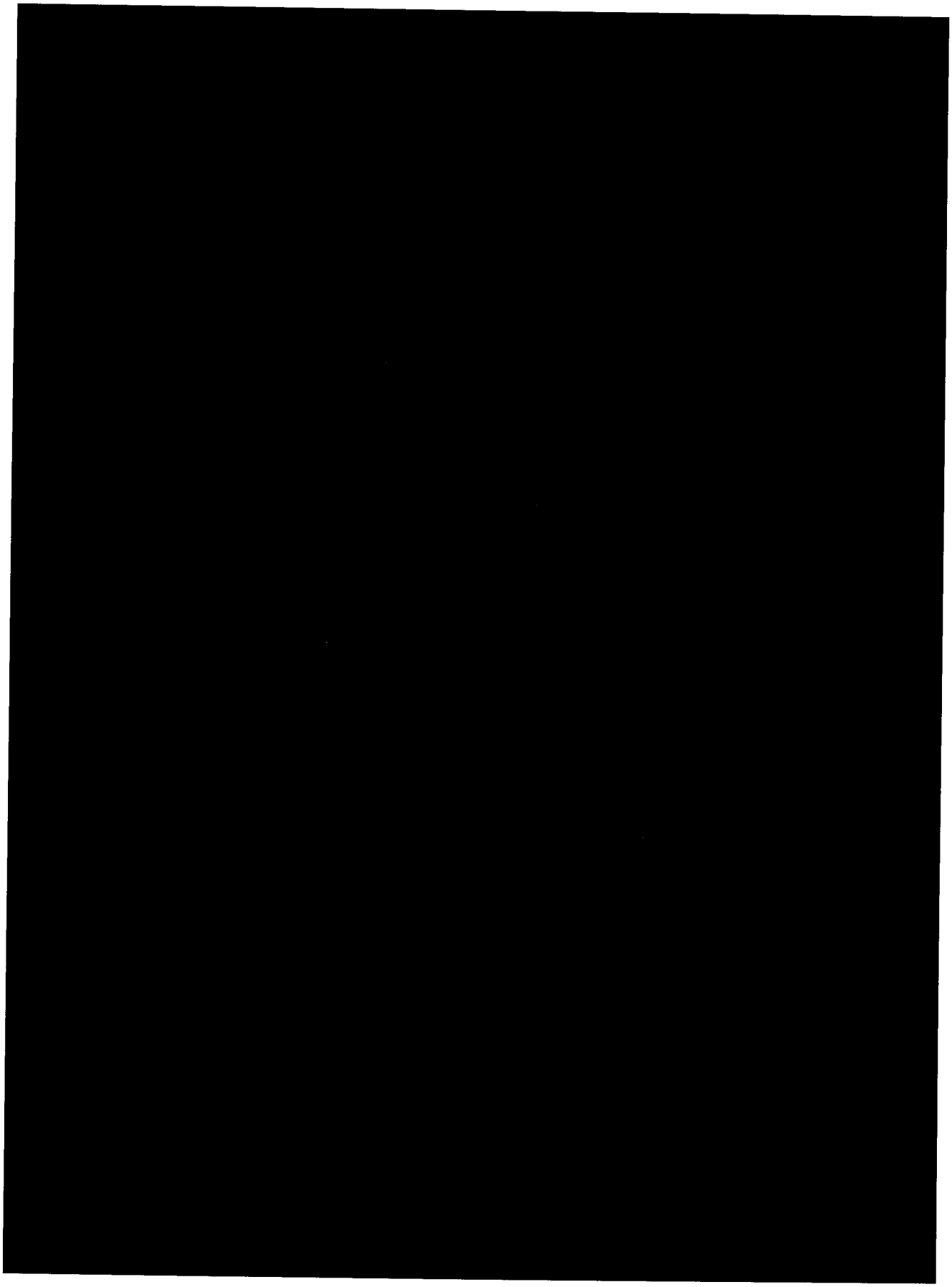


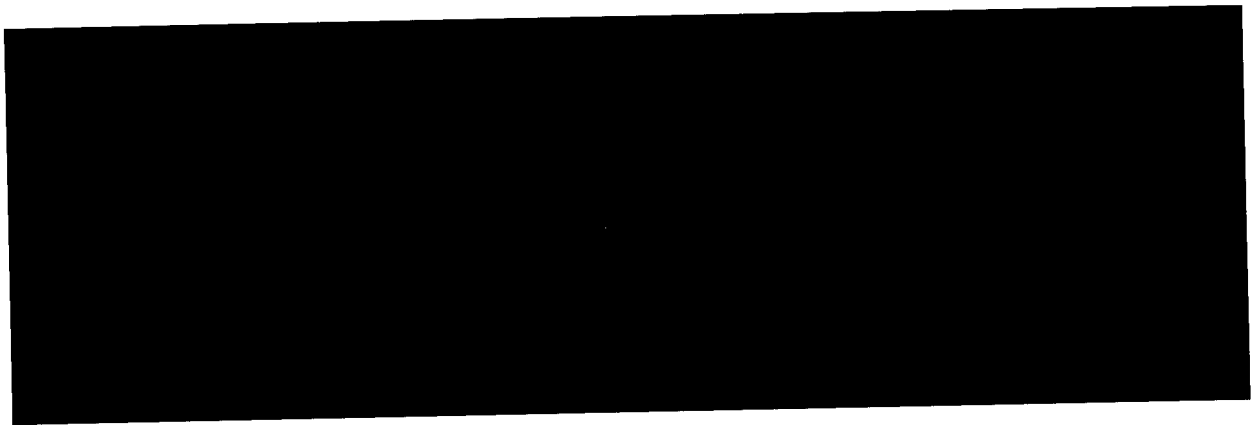












APPENDIX B: PATIENT INSTRUCTION GUIDE

Provided separately.

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

PACKAGE INSERT / FITTING GUIDE

BAUSCH + LOMB

Bio true®

ONEday
(nesofilcon A)
Soft (Hydrophilic)
Contact Lenses

BAUSCH + LOMB

Bio true®

ONEday
for Presbyopia
(nesofilcon A)
Soft (Hydrophilic)
Contact Lenses

BAUSCH + LOMB

Bio true®

ONEday
for Astigmatism
(nesofilcon A)
Soft (Hydrophilic)
Contact Lenses

℞ ONLY

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

Name and Address of Manufacturer:
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, New York, USA 14609

Printed in the U.S.A. 8101903

SYMBOL REFERENCE GUIDE

For label and cartons:

Do Not Reuse	
Temperature Limitation	
STERILE — Sterile Using Steam or Dry Heat	
See Instruction Leaflet	
CE 0050 — Indicates the CE Conformity Marking and the Notified Body Number	
EC REP — Authorized Representative in European Community	
℞ ONLY — Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner	
	Fee Paid for Waste Management
EXP (⌛)	Use by Date (Expiration Date)
LOT	Batch Code
DIA $Ø_T$	Diameter
PWR (F'_V)	Diopter (Lens Power)
BC	Base Curve
ADD	Low or High Add Power
SPH	Sphere Power (Diopters)
AX	Cylinder Axis (Degrees)
CYL	Cylinder Power (Diopters)
YYYY-MM-DD	Effective Date

8101903

TABLE OF CONTENTS

IMPORTANT

This package insert and fitting guide has been developed to provide practitioners with information covering characteristics of the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens and Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens and to illustrate fitting procedures. It is effective as of May 2016 (2016-05-01) and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.

This package insert and fitting guide is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with the patient instructions that pertain to the patient's prescribed lens and the recommended wearing schedule.

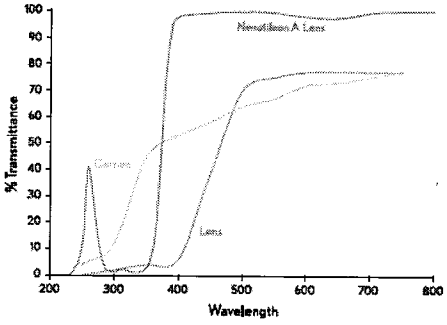
DESCRIPTION

The Bausch + Lomb Biotrue® ONEday lens material, Hypergel™ (nesofilcon A), is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone and is 78% water by weight when immersed in a sterile saline solution. A benzotriazole UV-absorbing monomer is incorporated into the manufacturing process to block UV radiation. The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm. This lens is tinted blue with Reactive Blue Dye 246.

The physical / optical properties of the lens are:

Specific Gravity:	1.039
Refractive Index:	1.374
Light Transmittance:	C.I.E. Y value - approximately 99%
Water Content:	78%
Oxygen Permeability (Dk):	42 x 10 $^{-9}$[$cm^3 O_2$(STP) x cm]/(sec x cm^2 x mmHg) @ 35° C (Polarographic Method)

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.



The typical transmittance profile of nesofilcon A lenses vs a Human Cornea and Human Lens:

Nesofilcon A Lens –Nominal Center Thickness 0.1 mm (-1.25D).

Cornea–Human Cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig. 2-21.

Lens–Human crystalline lens from a 25-year-old person as described in Waxler M., Hitchins V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, fig. 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.

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.

Note

The effectiveness of wearing UV absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduce the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

LENS PARAMETERS AVAILABLE

The Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens is a hemispherical shell of the following dimensions:

Diameter:	14.2mm 14.5mm (Astigmatism)
Center Thickness:	0.05mm to 0.75mm (varies with power)
Base Curve:	8.6mm 8.4mm (Astigmatism)
Powers (Spherical):	+6.00D to -6.00D in 0.25D steps -6.50D to -9.00D in 0.50D steps
Powers (Presbyopia) Add Powers:	+6.00D to -9.00D in 0.25D steps Low (+0.75D to +1.50D) and High (+1.75D to +2.50D)
Powers (Astigmatism):	+4.00D to -6.00D in 0.25D steps
Cylinder Powers:	-0.75D, -1.25D, -1.75D and -2.25D
Axis	0° to 180°

Additional parameters may be introduced over time, check for product availability.

HOW THE LENS WORKS (ACTIONS)

In its hydrated state, the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens and Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm.

INDICATIONS

SVS

The Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

Presbyopia

The Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in powers ranging from +20.00D to -20.00D with add power ranging from +0.75D to +5.00D.

Astigmatism

The Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters, that does not interfere with visual acuity. The lens may be prescribed in powers ranging from +20.00D to -20.00D for daily wear.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS

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

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care professional's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision.**
- Daily wear lenses are not indicated for overnight wear, and **patients should be instructed not to wear lenses while sleeping.** Clinical studies have shown that the risk of serious adverse reactions is increased when daily wear lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promptly contact his or her eye care professional.
- Patients should be instructed not to expose their contact lenses to water while wearing them.

  Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If their contact lenses have been submersed in water when swimming in pools, lakes or oceans, the contact lenses should be discarded and replaced with a new pair. Recommendations for wearing lenses during any water activity should be discussed with the patient.

PRECAUTIONS

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 eye should be carefully monitored by the prescribing eye care professional.
- Patients who wear contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Eye care professionals should instruct the patient to REMOVE A LENS IMMEDIATELY if an eye becomes red or irritated.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with sterile saline solution that is recommended for in-eye use.
- The patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care professional.
- As with any contact 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.

- Aphakic patients should not be fitted with Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lenses until the determination is made that the eye has healed completely.
- The lenses are prescribed for disposable wear, and are to be disposed of once they are removed from the patient's eye. It is important that patients be instructed to always have available a pair of replacement lenses. In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.
- Eyecare professionals should carefully instruct patients about the following safety precautions. It is strongly recommended that patients be provided with a copy of the Patient Information Booklet for Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens / Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens / Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens, available from Bausch + Lomb, and understand its contents prior to dispensing the lenses.

Handling Precautions:

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be sure that before leaving the eye care professional's office, the patient is able to remove lenses promptly or have someone else available to remove them.
- Be certain that the fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle lenses carefully and avoid dropping them.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning disinfecting, storing and wearing instructions in the Patient Information Booklet for the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses / Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses / Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lenses and those prescribed by the eye care professional.

- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Topics to Discuss with the Patient:

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the eyes. The patient should be instructed as to a recommended follow-up schedule.
- Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of ocular infection including but not limited to *Acanthamoeba* keratitis.
- Always contact the eye care professional before using any medicine in the eyes.

Who Should Know That the Patient is Wearing Contact Lenses:

- Patients should inform their doctor (health care professional) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you do not wear lenses.

ADVERSE REACTIONS

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

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

If the patient notices any of the above, he or she should be instructed to:

- **Immediately remove the lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. Place the lens in the storage case and contact the eye care professional. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult his or her eye care professional.**
- If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should **immediately remove the lenses and contact his or her eye care professional** or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial staining or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare, and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

SELECTION OF PATIENTS

The eye care professional should not fit patients who cannot or will not adhere to a recommended care or replacement regimen, or are unable to place and remove the lenses. Failure to follow handling and cleaning instructions could lead to serious eye infections which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also to ensure compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.

Patients selected to wear Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care professional must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

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

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

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

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

FITTING PROCEDURE

1. Pre-Fitting Examination

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

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

A pre-fitting examination should include spherocylinder refraction and VA, keratometry, and biomicroscopic examination.

2. Initial Lens Power Selection

a. Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.

b. Select the appropriate lens and place on the eye. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics.

c. Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. Initial Lens Evaluation

a. To determine proper lens parameters observe the lens relationship to the eye using a slit lamp.
   - Movement: The lens should provide discernible movement with:
     - Primary gaze blink
     - Upgaze blink
     - Upgaze lag
   - Centration: The lens should provide full corneal coverage.

b. Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens.

4. Criteria of a Well-Fitted Lens

If the initial lens selection fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient and provides satisfactory visual performance, it is a well fitted lens and can be dispensed.

5. Characteristics of a Tight (Steep) Lens

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

6. Characteristics of a Loose (Flat) Lens

If the lens is too flat, it will:

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

7. Follow-up Care

a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, the following schedule is a suggested guideline for follow up.
   - 3–4 days post-dispensing
   - 10 days
   - 1 month
   - 3 months
   - Every six months thereafter

   At the initial follow-up evaluations the eye care professional should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief.

b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

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

d. After the lens removal, instill sodium fluorescein [unless contraindicated] into the eyes and conduct a thorough biomicroscopy examination.
   1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.
   2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
   3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

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

PRACTITIONER FITTING SETS

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

WEARING SCHEDULE

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

Daily Wear

There may be a tendency for the daily wear patient to over-wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care professional. The wearing schedule chosen by the eye care professional should be provided to the patient. The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

MONOVISION FITTING GUIDELINES

1. Patient Selection

a. Monovision Needs Assessment
For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than one [1] diopter) in one eye may not be a good candidate for monovision with the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lenses.

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

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

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

2. Eye Selection

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

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

b. Refractive Error Method
For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

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

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

3. Special Fitting Considerations

Unilateral Lens Correction

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

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

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

4. Near Add Determination

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

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines.

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

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

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

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

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

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

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

7. Other Suggestions

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

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

- **The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs.**
- **All patients should be supplied with a copy of the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens / Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens / Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens Patient Information Booklet.**

MULTI-FOCAL FITTING GUIDELINES

1. Patient Selection

a. Good motivation

b. Realistic expectations

2. Lens Selection

a. Update spectacle refraction and Add power.

b. Determine ocular dominance for distance vision.

c. Select lens distance prescription based upon spherical equivalent from spectacle prescription, adjusted for vertex distance if necessary.

d. Choose trial lenses based upon the above calculation and select Add power.
   - Low Add: +0.75D to +1.50D
   - High Add: +1.75D to +2.50D

3. Lens Fitting

a. Equilibrate for 10 minutes.

b. Evaluate distance and near vision binocularly in normal room illumination.

c. If vision at distance and near are satisfactory, dispense lenses and schedule follow-up exam within 1-2 weeks.

4. To refine Near Vision

If patient is wearing two Low Add lenses:

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

If patient is wearing two High Add lenses:

- Refinement 1:
  Add +0.25D to the non-dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using handheld lenses.

5. To refine Distance Vision:

If patient is wearing two Low Add lenses:

- Refinement 1:
  Place SVS lens in dominant eye while keeping Low Add lens in non-dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, add -0.25D at a time to dominant eye using hand held lenses. Adjust contact lens power when vision in satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1:
  Place Low Add lens in dominant eye while keeping High Add lens in non-dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, add -0.25D at a time to dominant eye using hand held lenses. Adjust contact lens power when vision in satisfactory.

6. Patient Education

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

HANDLING OF LENSES

Patient Lens Care Direction

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

CARE FOR A STICKING (NONMOVING) LENS

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

EMERGENCIES

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

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens, or experienced with the lenses, should be reported to:

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

HOW SUPPLIED

Each sterile lens is supplied in a plastic package containing borate buffered saline solution with poloxamine. Each container is marked with the manufacturing lot number of the lens, diopter power, and expiration date.

Alcon a Novartis company	DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (delefilcon A) Soft Contact Lenses for Daily Disposable Wear	W900038292

IMPORTANT: This package insert is effective as of March 2016 and applicable to the delefilcon A contact lenses described below. 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 appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from Alcon by calling Customer Service at 1-800-241-5999 or download from our website at www.alcon.com. In addition, a Patient Instruction Booklet is available which is recommended to be given to patients.

℞ only

CAUTION: Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.

PRODUCT DESCRIPTION

DAILIES TOTAL1* and **DAILIES TOTAL1* Multifocal** (delefilcon A) soft contact lenses are made from a lens material that is 33% water and 67% (delefilcon A) polymer, a silicone containing hydrogel with added phosphatidylcholine. The core lens material containing 33% water transitions through a water gradient to a hydrogel surface layer that exceeds 80% water. Lenses contain the color additive copper phthalocyanine, a light blue tint, which makes them easier to see when handling.

Lens Properties

• Refractive Index hydrated:	1.42
• Light Transmittance:	93% (@ 610 nm, -1.00D)
• Oxygen Permeability (Dk):	140 x 10^{-11} (cm^2/sec)(ml O_2/ml x mm Hg), measured at 35° C (intrinsic Dk-Coulometric method)
• Water Content:	33% by weight in normal saline
• Surface Water Content:	≥ 80%

Lens Parameters

• Diameter Range	13.0 to 15.0 mm
• Spherical Power Range	-20.00 to +20.00D
• Base Curve Range	8.0 to 9.2 mm

Lens Parameters Available[1]

DAILIES TOTAL1* (delefilcon A) spherical

• Chord Diameter:	14.1 mm
• Center Thickness:	0.09 mm @ -3.00D (varies with power)
• Base Curve:	8.5 mm
• Powers:	-0.50 to -6.00D (0.25D steps); -6.50 to -12.00D (0.50D steps) +0.50 to +6.00D (0.25D steps)

DAILIES TOTAL1* Multifocal (delefilcon A)

• Chord Diameter:	14.1 mm
• Center Thickness:	0.09 mm @ -3.00D (varies with power)
• Base Curve:	8.5 mm
• Powers:	+6.00D to -10.00D (0.25D steps) ADD: LO, MED, HI

NOTE: Hereafter, **DAILIES TOTAL1*** spherical lenses and **DAILIES TOTAL1* Multifocal** contact lenses will simply be referred to as delefilcon A contact lenses unless product distinction is necessary.

ACTIONS

When hydrated and placed on the cornea, delefilcon A contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

DAILIES TOTAL1* (delefilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 (D) or less and who may have up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT use delefilcon A contact lenses when any of the following exists:

- Inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease which may be exacerbated by or interferes with contact lens wear
- Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exaggerated by the wearing of contact lenses
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear
- If eyes become red or irritated

WARNINGS

Advise patients of the following warnings pertaining to contact lens wear:

- **Problems** with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care professional's directions and all labeling instructions for proper use of lenses and lens care products. **Serious eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.**
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical study results have shown that the risk of serious adverse reactions is increased when contact lenses are worn overnight[2].
- Studies[2] have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, foreign body sensation, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care professional. It is recommended that contact lens wearers see their eye care professional regularly as directed.

PRECAUTIONS

To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:

Special Precautions for the Eye Care Professional:

Due to the small number of patients enrolled in the 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, 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 evaluated on initial dispensing and monitored on an ongoing basis by the prescribing eye care professional.

- Fluorescein, a yellow dye, should not be used while the lenses are on the patient's eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- Patients who wear contact lenses to correct presbyopia may not achieve the best possible 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.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. Alcon recommends that patients see their eye care professional once each year, or more often, as recommended by the eye care professional.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Eye Care Professionals should carefully instruct patients about the following safety precautions:

Handling Precautions:

- Be sure that before leaving the eye care professional's office the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear. **Always wash, rinse and thoroughly dry hands with a lint-free towel before handling lenses.**
- **REMOVE A LENS IMMEDIATELY** if an eye becomes red or irritated.
- Always handle lenses carefully. Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use.
- Do not use if blister package is damaged or not sealed completely. This may result in product contamination which can lead to a serious eye infection.
- Ensure that the correct lens for each eye is available. Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pouring the lens onto the palm of your clean hand. Ensure the lens is right side out. Inspect lenses prior to insertion. Do not insert damaged lenses.
- To insert lenses:
  - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses.
  - Place a lens on the tip of your clean and dry right or left index finger, place the middle finger of the same hand close to lower eyelashes and pull down the lower eyelid.
  - Use the fingers of the other hand to lift the upper eyelid.
  - Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
  - Look down and slowly remove the hand, releasing the lower lid.
  - Look straight ahead and slowly remove the other hand, releasing the upper lid.
  - Blink gently.
- To remove lenses:
  - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses. **Make sure hands are clean and completely dry.**
  - Blink fully several times.
  - While looking up, slide the lens down onto the white part of the eye.
  - Remove the lens by pinching gently between the thumb and forefinger. Do not pinch the eye tissue.
  - If the lens is difficult to grasp, dry fingers once more and try again. Do not use rewetting drops in this instance.
- If a lens decenters on the eye, it may be possible to recenter it by:
  - Closing the eye and massaging the lens into place, or
  - Looking in the direction of the lens and blinking gently, or
  - Gently pushing the off-centered lens onto the cornea with light finger pressure on the edge of the upper or lower eyelid.
- If a lens tears in the eye it will feel uncomfortable. Advise wearers it is impossible to lose a contact lens or part of a contact lens behind the eye and to remain calm. Lens pieces may be removed by pinching them as for normal lens removal, carefully avoiding pinching the eye tissue. If the lens pieces do not seem to remove easily, rinsing with saline is recommended. If this does not help, the wearer should contact an eye care professional for assistance.

Lens Wearing Precautions:

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the ***Care for a Sticking Lens*** section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.

- The eye care professional should be consulted about wearing lenses during water sports and water related activities. Exposure to water or other non-sterile liquids while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to *Acanthamoeba* keratitis.
- Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Lenses should be disposed of each day upon removal from the eye.
- Discard any lens which has become dehydrated or damaged. Replace with a sterile, fresh, new lens.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always carry spare lenses with you or have back-up spectacles available.
- Do not share lenses with anyone as this may spread micro-organisms which could result in serious eye health problems.
- Do not use lenses beyond their expiration date.

Other Topics to Discuss with Patients:
- Periodic eye examinations are extremely important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response. Alcon recommends that patients see their eye care professional once each year or as recommended by the eye care professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, and blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such medications accordingly and prescribe proper remedial measures.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Who Should Know that the Patient is Wearing Contact Lenses:
- Patients should inform their health care practitioners that they are wearing contact lenses.
- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn.

It is strongly recommended that patients be provided with a copy of the **DAILIES TOTAL1*** and **DAILIES TOTAL1* Multifocal Contact Lenses** (delefilcon A) Patient Instruction Booklet available from Alcon and understand its contents prior to dispensing the lenses.

ADVERSE EFFECTS

Patients should be instructed to check eyes regularly to make sure they look well, feel comfortable and vision is clear. Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:
- Moderate to severe eye pain not relieved by removing the lens
- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging or itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

WHAT TO DO IF A PROBLEM OCCURS

Patients should be instructed that if any of the above signs or symptoms are noticed, he or she should:
- **IMMEDIATELY REMOVE THE LENSES.**
- **If the discomfort or problem stops, discard the lens and replace it with a new one.**
- **If the discomfort or problem continues after removing lens(es) or upon insertion of a new lens, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**
- **The patient should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.**
- Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of **DAILIES TOTAL1*** brand (delefilcon A) contact lenses, please notify: Alcon Medical Safety in the USA at 1-800-757-9780.

FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to delefilcon A contact lenses. For a detailed description of the fitting techniques, refer to the **DAILIES TOTAL1*** and **DAILIES TOTAL1* Multifocal Contact Lenses** (delefilcon A) Professional Fitting and Information Guide. Both the professional fitting guide and a patient instruction booklet are available free of charge from:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134-2099
1-800-241-5999

LENS WEAR & REPLACEMENT SCHEDULES

DAILY WEAR (less than 24 hours, while awake):
- To avoid tendency of the daily wear patient to overwear the lenses initially, stress the importance of adhering to a proper, initial wearing schedule. Normal daily wear of lenses assumes a minimum of 6 hours of non lens wear per 24 hour period.
- It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.
    - The maximum daily wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. There may be a tendency for patients to overwear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that delefilcon A contact lenses are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period. Optimum individual wearing schedule will vary.
- Delefilcon A contact lenses are intended to be worn once (daily disposable wear) and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a fresh new lens.

EMERGENCY LENS CARE

Cleaning and disinfection of daily disposable lenses is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. It is important that the patient wash and dry their hands thoroughly before removing the lens. If the lens continues to stick, the patient should IMMEDIATELY consult the eye care professional.

IN OFFICE USE OF TRIAL LENSES

Eye care professionals should educate contact lens technicians concerning proper use of trial lenses.
Each contact lens is shipped sterile in a blister pack containing phosphate buffered saline solution. Hands should be thoroughly washed and rinsed and dried with a lint-free towel prior to handling a lens. In order to ensure sterility, the blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes lenses should be disposed of after a single use and not be re-used from patient to patient.

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 or fresh saline solution and immediately contact the eye care professional or visit a hospital emergency room without delay.

HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic container containing phosphate buffered saline solution with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly(acrylamide-acrylic) acid and is steam sterilized STERILE . The package is marked with the base curve, diameter, dioptric power and ADD power (multifocal lenses), manufacturing lot number and expiration date.

The following may appear on the labels or cartons:

Symbols/Signs/ Abbreviations	Description
Rx only	CAUTION: Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.
STERILE	Steam sterilized
EXP	Use by date (Expiry date)
LOT	Batch code
	Do not reuse
	Do not use if blister package is damaged
en	Example of two letter language code (English)
DIA	Diameter
BC	Base curve
PWR	Power
D	Diopter (lens power)
ADD	Addition power
CE 0086	European conformity sign
	Caution
	See product instructions
EC REP	Authorized Representative European Community
	Manufacturer
	Packaging waste license sign

Manufacturer:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134-2099
www.alcon.com
1-800-241-5999

March 2016 W900038292-0316

[1] Check for actual product availability as additional parameters may be introduced over time
[2] Schein, OD, Glynn RJ, Poggio EC, Seddon JM, Kenyon KR. The Relative Risk of Ulcerative Keratitis Among Users of Daily Wear and Extended Wear Soft Contact lenses. N Eng J Med. 1989; 32321 (12):773-783

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APPENDIX D: PRESBYOPIC SYMPTOMS QUESTIONNAIRE

Presbyopic Symptoms Questionnaire

1. [redacted]

[redacted]

[redacted]

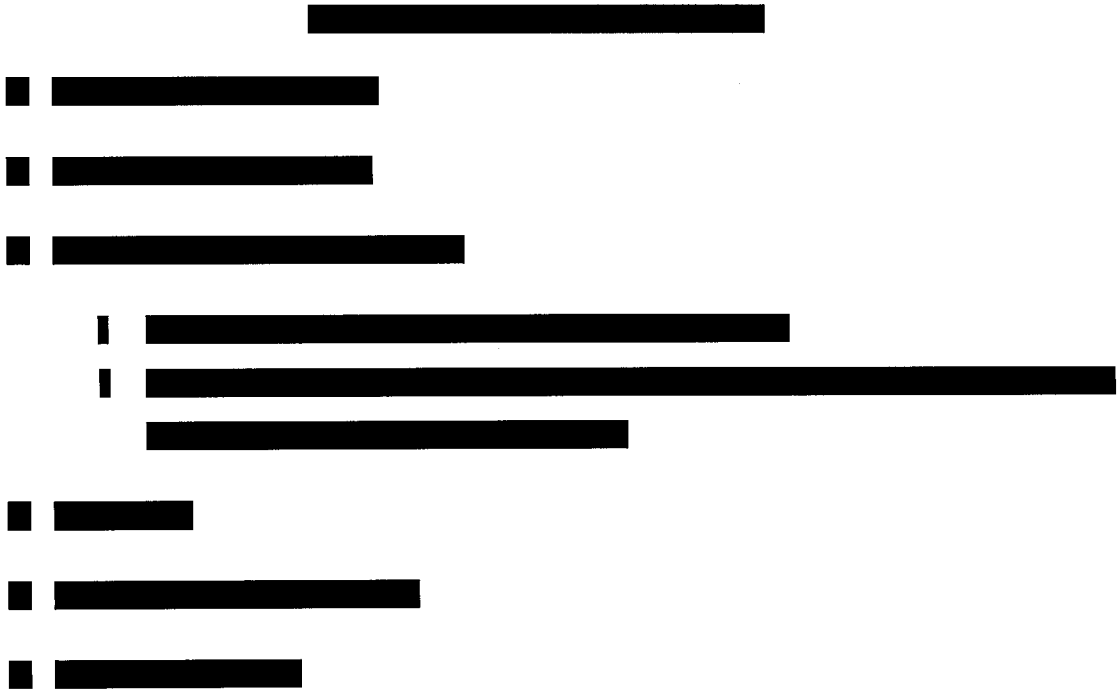
[redacted]

[redacted]

APPENDIX E: OCULAR DOMINANCE

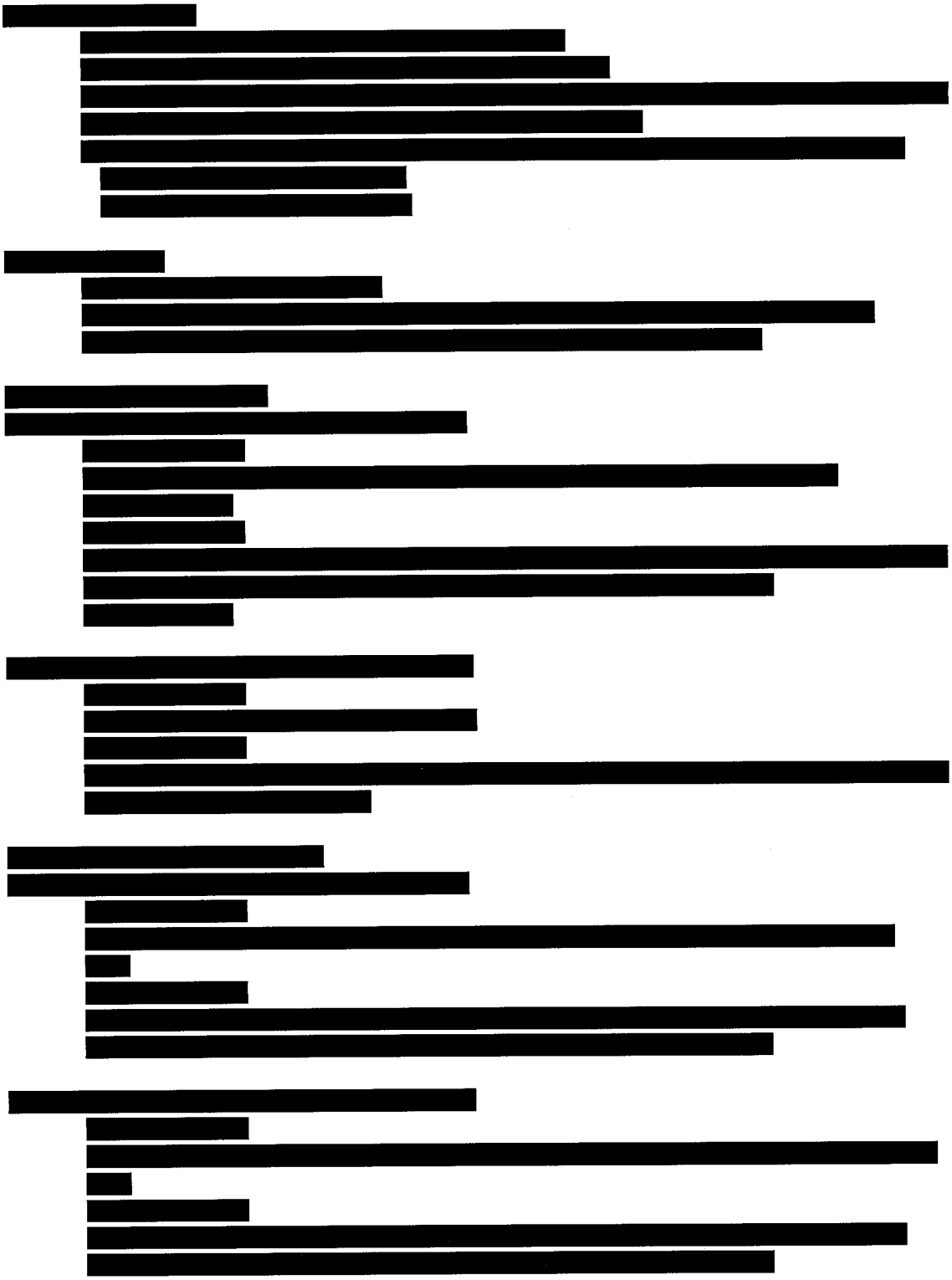
OCULAR DOMINANCE TEST

APPENDIX F: BINOCULAR OVER-REFRACTION



APPENDIX G: BIOTRUE ONEDAY® FOR PRESBYOPIA FITTING GUIDE

BIOTRUE MULTI-FOCAL FITTING GUIDELINES



APPENDIX H: DAILIES TOTAL 1® MULTIFOCAL FITTING GUIDE

Professional Fitting and Information Guide

DAILIES TOTAL1*
and
DAILIES TOTAL1* Multifocal
(delefilcon A) Soft Contact Lenses
For Single-Use, Daily Disposable Wear

Water Gradient One-Day Contact Lenses

℞ only

CAUTION: Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.

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a Novartis company

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Introduction
Thank you for prescribing DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (delefilcon A) daily disposable soft contact lenses. The benefits of a high oxygen transmissible and wettable lens material with a state of the art manufacturing process are combined to make DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (delefilcon A) lenses. This guide contains important information regarding fitting procedures and aftercare of the DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (delefilcon A) contact lens patient.

Daily Disposability:
By eliminating the need for lens care, daily disposable lenses offer your patients a major advancement in wearing convenience. The next time you prescribe lenses consider the health and comfort benefits of beginning each wearing period with a new pair of fresh, sterile lenses that are worn once and then discarded.

LightStream* Lens Technology:
DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses are made from a proprietary silicone hydrogel material with a water content of approximately 33% water. The use of process automation, precision glass and quartz molds and photolithographic edge forming help ensure every lens has the same crisp optics, smooth surface finish and consistent edge quality from lens to lens. Delefilcon A contact lenses are produced under strictly controlled process conditions and inspected to exacting quality tolerances. As a result, you can be confident your patients will experience consistent vision, comfort, and ease of handling every day.

PRODUCT DESCRIPTION
DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal soft contact lenses are made a silicone containing hydrogel that is approximately 33% water and 67% delefilcon A polymer with added phosphatidylcholine. The core lens material containing 33% water transitions through a water gradient to a hydrogel surface layer that exceeds 80% water. This structure enables a silicone hydrogel lens with a water gradient that has:

- Over 80% water at the surface of the lens to mimic the water content of the cornea.
- High level of oxygen transmissibility through the lens.
- Excellent overall comfort.

The lenses contain and release phosphatidylcholine (DMPC), a phospholipid found naturally in the tears. In addition, lenses contain the color additive copper phthalocyanine, a light blue tint which makes them easier to see when handling. The lenses are packaged in strips of 5 individual blisters containing buffered saline with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly(acrylamide-acrylic acid).

Lens Properties

• Refractive Index (hydrated):	1.42
• Light Transmittance:	≥ 93% (@610 nm, -1.00D)
• Oxygen Permeability (Dk):	140 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg), measured at 35°C, (intrinsic Dk - Coulometric method)
• Water Content	33% by weight in normal saline
• Surface Water Content	≥ 80%

Available Lens Parameters[1]

DAILIES TOTAL1* (delefilcon A)	Spherical contact lenses
• Chord Diameter Available:	14.1 mm
• Center Thickness:	0.09 mm @ -3.00D (varies with power)
• Base Curve:	8.5 mm
• Powers Available:	-0.50 to -6.00D (0.25D steps); -6.50 to -12.00D (0.50D steps) +0.50 to +6.00D (0.25D steps)

DAILIES TOTAL1* Multifocal (delefilcon A)

• Chord Diameter:	14.1 mm
• Center Thickness:	0.09 mm @ -3.00D (varies with power)
• Base Curve:	8.5 mm
• Powers:	-0.25 to -10.00D (0.25D steps); plano to +6.00D (0.25D steps) ADD: LO, MED, HI

[1]Check for actual product availability as additional parameters may be introduced over time.

Actions

When hydrated and placed on the cornea delefilcon A soft contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

DAILIES TOTAL1* (delefilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 (D) or less and who may have up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

See WARNINGS for information about the relationship between wearing schedule and corneal complications.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS

For additional important prescribing and safety information, refer to the Package Insert that is printed in the back of this guide.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of DAILIES TOTAL1* or DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses, in the USA please **contact Alcon Medical Safety at 1-800-757-9780.**

FITTING GUIDELINES

Please see the appropriate sections of this booklet that contain guidelines for spherical, multifocal and monovision fitting techniques.

FITTING GUIDELINES (Spherical Lenses)

1. **Patient Selection**

   The patient characteristics necessary to achieve success with DAILIES TOTAL1* (delefilcon A) spherical lenses are similar to those for other spherical soft contact lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear.

   The following procedures should be followed when fitting DAILIES TOTAL1* (delefilcon A) spherical lenses. For additional tips on fitting the monovision patient refer to the section *Monovision Fitting Guidelines.*

2. **Pre-fitting Examination**

   A pre-fitting examination is necessary to:

   - assess the patient's motivation, physical state and willingness to comply with instructions regarding hygiene and wear schedule
   - make ocular measurements for initial contact lens parameter selection
   - collect baseline clinical information to which post-fitting examination results can be compared

   A pre-fitting examination should include:

   - a thorough case history
   - a spherocylindrical refraction
   - keratometry
   - tear film assessment
   - biomicroscopy

3. **Trial Lens Evaluation**

   A. Lens Base Curve Selection

   A well-fitted lens provides good movement, centration and comfort. An optimal fit can be achieved for the vast majority of patients with the single 8.5 mm base curve.

   B. Initial Lens Power Selection

   The initial power selection should be as close as possible to the patient's prescription after taking into account spherical equivalent and vertex calculations, if necessary.

   Spherical Equivalent Calculation

   To determine initial lens power, convert the spherocylindrical spectacle Rx to its spherical equivalent as follows:

   Spherical Equivalent = Sphere power + 1/2 (Cylinder Power)

   Example: **Spectacle Rx:** **-4.50D -1.00 x 180**
   Spherical equivalent: **-4.50D + (-0.50D) = -5.00D**

   Vertex Distance Conversion

   If the spherical equivalent is greater than ± 4.00D, a vertex distance correction is necessary (see *Vertex Distance Conversion Chart*) to determine the lens power required at the corneal plane.

   Example: **Spectacle Rx:** **-4.50D -1.00 x 180**
   Spherical equivalent: **-4.50D + (-0.50D) = -5.00D**
   Vertex compensation: **-4.75 (initial lens power)**

C. Lens Fit Assessment

Allow the lenses to settle on the eyes for approximately 10 minutes. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

Evaluate the fit and movement of the lenses on the eye in primary and up gaze positions. The **Push-up Test,** as described below, is an additional test of the lens evaluation. The following guidelines will be helpful in fit evaluation:

Characteristics of a Well-fitted Lens

A well-fitted DAILIES TOTAL1® (delefilcon A) spherical contact lens satisfies the following criteria:

1. **Good centration and full corneal coverage** in all fields of gaze.
2. **Sufficient lens movement to allow tear exchange** under the lens during a blink in primary or upward gaze.
3. **Satisfactory Push-up Test**
   - This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.
   - A well fitted lens will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.
4. **Good comfort and stable visual response** (with over refraction).

Characteristics of a Tight (Steep) Lens Fit

A tight or steep lens fit would display some or all of the following characteristics:

1. Insufficient or no lens movement during a blink in primary or upward gaze.
2. **Unsatisfactory Push-up Test**
   - **A tight fitting lens will resist movement.** If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
3. Good centration.
4. Good comfort.
5. Fluctuating vision between blinks.

Characteristics of a Loose (Flat) Lens Fit

A loose lens fit would display some or all of the following characteristics:

1. **Reduced comfort,** usually accompanied by lower lid sensation.
2. **Poor centration** with limbal exposure on exaggerated eye movement.
3. **Lens edge standoff.**
4. **Excessive lens movement** during the blink in primary or upward gaze.
5. **Unsatisfactory Push-up Test**
   - A loose fitting lens will move easily but may remain decentered or slip under the upper lid.
6. **Vision may be blurred** after the blink.

An inverted lens may mimic the characteristics of a loose lens. If any of

the above signs occur remove the lens and check to make sure it is not inverted.

General Fitting Tips

- Trial fitting of the individual eye is recommended.
- A well fitting lens will show movement of 0.1 to 0.5 mm.

D. Final Lens Power Determination

After the characteristics of a well fitted lens have been satisfied, conduct a spherical over-refraction to determine the proper lens power to be dispensed.

Example:	**Diagnostic lens:**	**-4.50**
	Over-refraction:	**-0.25**
	Final lens power:	**-4.75**

FITTING GUIDELINES (Multifocal)

The **DAILIES TOTAL1* Multifocal** (delefilcon A) soft contact lens is a progressive aspheric simultaneous vision soft contact lens, intended to correct presbyopia with or without additional ammetropia, available in three ADD powers; low (LO), medium (MED) and high (HI). For each lens the near and intermediate powers are concentrated primarily in the central portion of the optical zone while the distance power is contained in the surrounding portion. The continuous changes in power across the surface of the lens allow patients requiring a reading addition of up to + 3.00D to see clearly at far, intermediate, and near distances.

Achieving high success with DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses is dependent on several factors, including the patient's motivation, expectations and visual wearing environment, as well as your skill in optimizing the lens powers to balance binocular performance at distance and near. The information in this guide is designed to provide you with the tools to manage your presbyopic patients through each stage of the process from the initial case history to post-fitting follow-up.

1. ***Pre-fitting Examination***

   A pre-fitting examination is necessary to:

   - determine whether a patient is a suitable candidate for DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses
   - make ocular measurements and assessments for initial contact lens parameter selection
   - collect baseline clinical information to which post-fitting examination results can be compared

   A pre-fitting examination should include:

   - a thorough case history
   - detailed assessment of patient's individual visual demands
   - understanding of patient's objectives for lens wear and expectations
   - a distance spherocylindrical refraction, near add determination and measurement of pupil diameter
   - keratometry
   - tear assessment
   - biomicroscopy

   Note: The importance of a thorough case history should not be underestimated. The information gained through careful listening and probing will help greatly in satisfying each patient's unique needs.

2. ***Patient Selection***

   The eye care professional should weigh several factors when considering patient selection for a DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lens fitting. When fitting a lens intended to correct for presbyopia, it is especially important to evaluate the particular visual needs, objectives, lifestyle and expectations of the individual patient. Prospective candidates may include current contact lens wearers, former wearers, and persons with no previous wear history. For former wearers it is important to determine the cause for discontinuation.

   There are two general categories of candidates based on anticipated usage: those who seek to wear their lenses as their principal means

of vision correction, and those who wish to integrate the use of their contact lenses with spectacles. The integrative user often seeks to wear their lenses for sports or other occasional activities while reverting to spectacles under poor lighting or otherwise demanding vision conditions. In general, even the part-time user does not require more than a few moments re-adaptation time following an interval of no lens wear.
While candidates with greater than 1.00 diopter of refractive error have often been thought of as better candidates than those with low error or emmetropia, this is a generalization that often does not hold true for a given individual. Success is influenced by many factors and the eye care professional is encouraged to offer DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses to all interested presbyopic patients who satisfy the standard requirements for soft contact lens wear.
To summarize patient selection, the characteristics of "ideal candidates" and those that will be more difficult to fit" are listed below:

Ideal Candidates

- Refractive cylinder < 1.00D.
- Attainable visual demands that do not depend upon resolving very fine (smaller than 20/20 letters) details at *both* distance and near for extended periods while wearing DAILIES TOTAL1* Multifocal contact lenses.
- Emphasis on tasks where it is advantageous to have objects simultaneously in focus over a large range of viewing distances.
- Expectations consistent with actual everyday visual demands.
- Motivated to wear lenses and understands that vision may not *always* be as sharp as with spectacles for some distances or lighting conditions.
- Unable to adapt to monovision correction.

Less than Ideal Candidates

- Critical or very fine visual demands at both distance and near.
- Refractive cylinder ≥ 1.00D (any axis) in one or both eyes or against-the-rule refractive cylinder > 1.00D in one or both eyes.
- Monocular distance acuities poorer than 20/20 with spherical equivalent refractive correction.
- Myopic anisometropia where the refractive error for one of the two eyes is low (≤1.50D) and has not been habitually corrected.
- Pupil size larger *(> 4 mm) or smaller (<3 mm)* than norm for presbyopic population under natural illumination conditions.
- Abnormal binocular sensory function (e.g., amblyopia or strabismus).
- Expectation to discard and never use spectacles again, including reading glasses, even for special tasks or viewing conditions.
- Highly satisfied monovision wearers.
- Any other contraindications to successful contact lens wear such as tear abnormality or lid margin disease.

3. ***Initial Lens Selection***

A. Initial Base Curve Selection

DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses are available in a single 8.5 mm base curve.

B. Initial Lens Power Selection

Note: A careful maximum plus spherocylindrical refraction and nearpoint add determination should be conducted prior to selecting a DAILIES TOTAL1* Multifocal (delefilcon A) trial lens. Autorefraction findings should be refined manually to rule out effects of instrument myopia and ensure proper control of residual accommodation.

The DAILIES TOTAL1* Multifocal lens design makes selecting the initial lens power easy. You need only manipulate the distance power. **The optimum starting point is with a power that is equal to or *more plus or less minus* than the vertex corrected spherical equivalent spectacle refraction.**

C. Initial ADD Selection

Note: A careful nearpoint ADD determination should be conducted prior to selecting a DAILIES TOTAL1* Multifocal (delefilcon A) trial lens

The DAILIES TOTAL1* Multifocal (delefilcon A) 3 ADD SYSTEM allows personalized fitting for presbyopic patients. The table below makes initial ADD selection easy.

DAILIES TOTAL1* MULTIFOCAL ADD SELECTION

SPECTACLE ADD	BOTH EYES
Up to +1.25	
+1.50 to +2.00	
+2.25 to +2.50	

Example 1:	OD		OS
Spherical Rx:	-4.50 -0.75 x 90		-4.00D
Spherical equivalent (least minus);	-4.75D		-4.00D
Vertex corrected power:	-4.50D		-4.00D
Spectacle Add:		+0.75D	
Eye Dominance:		OD	
Initial Trial Lens:	-4.50 LO		-4.00 LO

Example 2:	OD		OS
Spherical Rx:	+4.25 -0.25 x 180		+4.00 D -0.50 x 180
Spherical equivalent (least minus):	+4.25D		+3.75D
Vertex corrected power:	+4.50D		+3.75D
Spectacle Add:		+2.00D	
Eye Dominance:		OS	
Initial Trial Lens:	+4.50 MED		+3.75 MED

4. ***Initial Lens Fitting Evaluation***
   a) Insert the lenses selected in Section 3 (above). If the exact power is not available, choose the next closest least minus/most plus lens power in your trial set.
   b) Allow the lenses to settle on the eyes for approximately **10 minutes.** This allows time for the patient to adapt to the lenses and time for the lens to equilibrate with the patient's tears.
   c) Evaluate the fit of the lenses on the eye. The **Push-up Test** as described below is an important part of the lens evaluation. The following guidelines will be helpful in evaluating the physical fit of the lens:

Characteristics of a Well-fitted Lens

A well-fitted DAILIES TOTAL1* Multifocal (delefilcon A) contact lens satisfies the following criteria:

1. Full corneal coverage and good centration (no limbal exposure). A lens that is decentered > 1 mm, particularly temporal, is less likely to give adequate vision.
2. Lens movement of 0.1 to 0.5 mm should be present to allow tear exchange under the lens during a blink in primary gaze or upward gaze and to avoid variable vision.

   Push-up Test:
   - **This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.**
   - **A well fitted lens will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.**
3. Good comfort.
4. Acceptable visual acuity with over-refraction.

Characteristics of a Tight (Steep) Lens Fit

A tight or steep fit should not be dispensed. If a lens fit is judged to be too steep a flatter lens (larger base curve), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

1. Good centration.
2. Insufficient or no lens movement during a blink in primary gaze or upward gaze.
3. Excessive conjunctival drag (visible movement of the conjunctival vessels when the lens moves during a blink or during the push-up test). Note: presbyopes often have loose conjunctiva, some conjunctival movement is occasionally seen and may not be a sign of a tight fit. See Push-up Test below.

   Push-up Test:

   - **A tight fitting lens will resist movement. If successfully nudged upward, the lens may remain decentered or return slowly to its original position.**
4. Good comfort.
5. Blurred vision between blinks.

Characteristics of a Loose (Flat) Lens Fit

If a lens fit is judged to be too flat a steeper lens (smaller base curve), if available, should be evaluated. A loose lens fit would display some or all of the following characteristics:

1. Decentration.
2. Excessive lens movement during the blink in primary or upward gaze.

   Push-up Test:

   - **A loose fitting lens will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often times return lower than its original position.**
3. Reduced comfort.
4. Lens edge standoff.
5. Blurred vision immediately after the blink.

5. Initial Lens Visual Evaluation

While lenses are settling, it is helpful to take the patient from the exam room to a "real-world" setting such as a room with an outside view. Once an acceptable fit has been achieved, the visual performance of the lenses may be evaluated. Visual acuity is tested at distance. If necessary, a spherical over-refraction should be performed using a trial frame or hand held lenses rather than a phoropter. This technique is essential when fitting multifocal lenses because it allows the patient to maintain the head posture and direction of gaze (relationship between eye and head) that he or she would naturally use during everyday tasks. This ensures that the visual performance of the lens is being assessed under conditions where the on-eye positioning matches that which will occur when the lens is being used, for example, for near work activities. In addition, pupil size will not be artificially increased

by the reduction in light associated with looking through the aperture of the phoropter cells, or decreased by proximal cues associated with the nearness of the instrument.

6. ***Fitting Procedures***

Step 1. After the trial lenses have settled for approximately 10 minutes, measure distance acuity while the patient is viewing the chart binocularly (i.e., simultaneously with both eyes). Next, evaluate the patient's subjective impression of the near vision when trying to read typical everyday material (e.g., a newspaper, magazine, and cell phone). Lighting and reading distance should be what is normal for the patient.

Step 2. If distance or near vision is unsatisfactory, perform a ***binocular distance*** over-refraction, as follows. Use hand-held trial lenses and encourage plus. For example, if a Plano and +0.25D over-refraction yields the same results, use the +0.25D endpoint. Re-check visual acuity and visual quality as described in Step 1 above. If over-refraction is other than plano, go immediately to new trial lenses, keeping ADD the same.

Step 3. If distance and near vision are satisfactory, dispense lenses and remind patient to use good light when reading fine print or use additional reading glasses if needed. It is helpful to let the patient experience the lenses in their natural environment before further procedures for enhancing vision are performed.

Step 4. **Enhanced Near Vision.** If near vision is unsatisfactory, determine the dominant eye by the following method. Determine the eye with **greatest plus acceptance** by placing +1.50 handheld trial lens over each eye alternately while patient views in the distance with both eyes open. Consider the eye for which binocular vision blurs ***least*** with the +1.50 to be the non-dominant eye. Other methods to determine the dominant eye are appropriate.

Step 4A: Check the patient's binocular acuity with +0.50 over the non-dominant eye to determine if near vision is improved and distance vision is still acceptable. If so, place a new trial lens with the same ADD on the non-dominant eye, **adjusting the distance power by +0.50.**

Enhanced near vision, Step A		
SPECTACLE ADD	**DOMINANT EYE**	**NON-DOMINANT EYE (PLUS ACCEPTED)**
Up to +1.25		 with additional +0.50
+1.50 to +2.00		 with additional +0.50
+2.25 to +2.50		 with additional +0.50

Next, re-check visual acuity and visual quality as described in Step 1 above. If satisfactory, dispense new distance lens power for the non-dominant eye. If near vision is still unsatisfactory, proceed to Step B:

Step 4B: If near vision is still unsatisfactory, adjust ADD as shown below.

Enhanced near vision, Step B		
SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
Up to +1.25		
+1.50 to +2.00		
+2.25 to +2.50		

Note: It is common to question the rather non-intuitive step we suggest for enhancing vision at near in the HI ADD range, where the suggestion is to "back off" to a MED ADD for the non-dominant eye, the same suggestion we make for enhancing distance vision (below). The reason for this is that after establishing (in Step A) that increasing plus is not helpful, the next most common reason for blur at near (or distance) is unacceptable ghosting that degrades the image quality. Backing down to the MED ADD in one eye can often relieve that and actually improve vision at near.

Step 5: **Enhanced Distance Vision.** If distance over-refraction did not improve visual acuity, adjust ADD according to the chart below.

SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
+1.50 to +2.00		
+2.25 to +2.50		

FITTING GUIDELINES (Monovision)

Patient Selection

A. Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. Patients with reduced visual acuity, such as the amblyopic patient, may not be a good candidate for monovision.

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

1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass requirements for a driver's license with monovision correction should not drive with this correction. An additional over-correction can be prescribed to improve vision.

B. Patient Education

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

Eye Selection

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

A). Ocular Preference Determination Methods

- Method 1 - Determine which eye is the "sight 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 for near with the least reduction in distance vision. Place a trial spectacle near ADD lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near ADD lens over the right or left eye.

B). Refractive Error Method

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

C). **Visual Demands Method**

- Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction, correct the eye on that side for near.
  Example:
  A person who places copy to the left side of the desk will usually function best with the near lens on the left eye.

Special Fitting Considerations

Unilateral Lens Correction

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

- **Examples:**
- **Emmetrope:** A presbyopic emmetropic patient who requires a +1.75 diopter ADD would have a +1.75 lens on the near eye and the other eye left without a lens.
- **Bilateral myope:** A presbyopic patient requiring a +1.50 diopter ADD who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.
- **Unilateral astigmat:**

a) Emmetropic in one eye, astigmatic in the other

Spectacle Rx	Potential Monovision Rx
O.D. Plano	Uncorrected for distance
O.S. -1.00 -1.00 x 090	+0.50 -1.00 x 090 for near
Add: +1.50	

b) Myopic in one eye, astigmatic in the other

Spectacle Rx	Potential Monovision Rx
O.D. -1.50	Uncorrected for near
O.S. -2.00 -1.75 x 090	-2.00 -1.75 x 090 for distance

Amblyopia

The amblyopic patient may not be a good candidate for monovision.

Astigmatism

Patients with less than 1.50 diopters of astigmatism might be successfully fit in DAILIES TOTAL1® (delefilcon A) spherical lenses.

- Determine which eye to use for the near prescription (see Eye Selection, A-C, above)
- Add the appropriate near add power to the spherical component of the astigmatic prescription for that eye.

Example:	Spectacle Rx	Potential Monovision Rx
	O.D.: -2.50 -0.75 x 180	-2.50 -0.75 x 180 for distance
	O.S.: -3.00 -1.75 x 165	-2.00 -1.75 x 165 for near
	Add: +1.00	
	Dominant eye: O.D.	

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.

Trial Lens Fitting

A trial lens fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the *General Fitting Guidelines and Base Curve Selection* described earlier in the guide.

Case history and standard clinical evaluation procedures should be used to determine the suitability of monovision. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

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

After evaluating the patient's performance under the above conditions, 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 less favorable prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a few minutes or for several weeks. The longer these symptoms persist, the poorer the chance 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 is recommended that patients 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 under 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.
- Have supplemental spectacles to wear over the monovision contact lenses for specific visual tasks. This is particularly applicable for those patients who cannot meet driver's licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs. All patients should be supplied with a copy of the **Patient Instruction Booklet**, which contains important instructions for the monovision wearer. You can obtain copies of the instruction book by calling customer service **in the USA at (800) 241- 5999.**

DISPENSING VISIT

To help ensure patient success the following steps should be conducted with each patient, even if they have previously worn contact lenses. Even experienced wearers are prone to develop bad habits over time.

DAILIES TOTAL1* brand (delefilcon A) lenses are supplied sterile in foil sealed blister pack containers. Open the foil pack by peeling back the foil lidding material and gently slide the lens out of the container with your finger, or pour the lens onto the palm of your clean hand.

Conduct the following steps with each patient, even if they have previously worn contact lenses:

A. Verification of Lens Fit

Evaluate lens fit and visual response with the lens on the eye. The criteria of a well-fitted lens should be met and the patient's visual acuity should be acceptable. If not, the patient should be refitted with a more appropriate lens.

B. Hygiene and Lens Handling Instructions

Good hygiene and proper lens handling are important factors in achieving safe, comfortable lens wear. Instruct the patient on hygiene and handling of lenses. Patients who are unable to place and remove lenses should not be provided with them.

C. Lens Wear and Replacement Schedules (see Package Insert)

Prescribe and explain the daily disposable wear schedule. Explain that lenses are to be discarded after each daily wearing period. Determine the maximum suggested daily wearing period based on the patient's physiological eye condition. There may be a tendency for the patient to overwear their lenses initially. For some patients who have never worn contact lenses consider a wearing schedule that allows for a gradual increase in wearing time.

D. Lens Care Directions (see Package Insert)

The lenses are not intended to be cleaned or disinfected and should be discarded after a single use. The eye care professional may recommend lens rewetting drops, as needed.

E. Specific Instructions for Presbyopic Patients

Specific instructions, explanations and demonstrations are important for optimizing patient success with multifocal contact lenses. The following information and instructions have proven useful in advising patients who wear DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lenses.

- A contact lens that contains different powers for distance and near involves greater technological and optical complexity than does a bifocal or multifocal spectacle lens. This is because the contact lens moves with the eye, rather than having the eye move up and down while the lens remains suspended in a frame. While the contact lens therefore gives an unobstructed field of view and greater freedom regarding where to look, these advantages may mean that the sharpness of vision may not always be exactly the same as what would be experienced with spectacles.
- Although many individuals use DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses for full-time wear, it is not unusual to find that there may be some activities where one prefers to wear spectacles, or where the disadvantages associated with spectacles are outweighed by other issues. This is an entirely normal and natural response to the challenges presented by presbyopia.
- Situations where vision with multifocal contact lenses may be less sharp or otherwise "different" than what is experienced with spectacles often involve low illumination (e.g., a semi-dark room), reduced visibility (e.g., outdoor conditions of fog or heavy rain), or isolated sources of very bright light (e.g., headlights of an oncoming vehicle on a narrow country road). **Patients should be instructed to make use of good light when reading fine print.**
- Patients should be aware that it might be advisable to refrain from wearing their lenses while driving, flying an airplane or operating heavy machinery while wearing their lenses until they gain some experience with the lenses in a similar visual environment.
- Small changes in lens power can often make a significant difference in the quality of the vision experienced with multifocal contact lenses. Such changes can be best tailored to

individual needs and environmental conditions that the patient will personally encounter on a day-to-day basis. Confidence and assurance that such refinements, if needed, can be achieved are important for patient motivation during the initial period of lens wear.

F. Additional Instructions

- ***Review the Package Insert***
  Provide the patient with all relevant information and precautions on the proper use of the lenses that are prescribed.
- ***Provide the Patient Instruction Booklet for DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (delefilcon A) Contact Lenses.***
  Give the patient a copy of the **Patient Instruction Booklet** for DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lenses. Review the contents so the patient clearly understands the prescribed lens wear, care, and replacement schedule. In the USA you can obtain copies of the instruction book by calling Alcon customer service **at (800) 241-5999.**

Follow-Up Examinations

Follow-up care is extremely important for continued successful contact lens wear. Follow-up care should include:

- Case history, including questions to identify any problems related to contact lens wear
- Management of specific problems, if any, and
- A review with the patient of the lens wearing schedule, replacement schedule and handling procedures.

Follow-up Examination Procedures

- Patients should be instructed to wear lenses prior to a follow-up examination.
- Record patient's symptoms, if any.
- Measure visual acuity monocularly and binocularly with the contact lenses in place.
- Perform an over-refraction to check for residual refractive error.
- With a biomicroscope, evaluate lens fitting.
- Remove the lenses and conduct a thorough biomicroscopic examination with fluorescein. Rinse eyes with saline before re-inserting lenses.
- Evert upper lids to determine condition of tarsal conjunctiva.
- Periodically perform keratometry and spectacle refractions. These results should be recorded to compare to the initial measurements.
- If any observations are abnormal, use professional judgment to manage the problem and restore the eye to optimal conditions. If visual requirements are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

LENS HANDLING HINTS

Lens Insertion

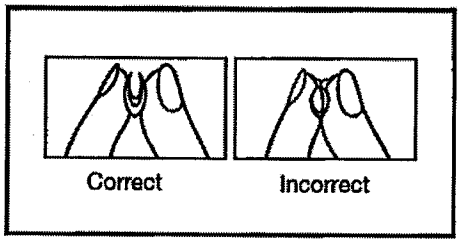
- When about to place the lens on the eye, make sure the lens sits up on the placement finger. The finger should be dry so surface tension does

not cause the lens to adhere to the finger.

- Check to see that the lens is right side out. A lens that is placed on the eye inside out may not feel comfortable or provide good vision.

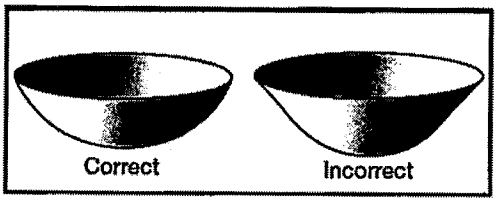
One way to do this is to perform the 'taco test' by placing the lens between your thumb and index finger and squeeze the edges together gently.

- If the edges come together, the lens is right side out.
- If the edges turn outward, the lens is wrong side out. Carefully reverse it with your fingers.



Another way is to place the lens on the tip of your index finger and check its shape.

- If the edge appears bowl-shaped, it is right side out.
- If the edge has a lip or flares outward, it is wrong side out and must be reversed.
- Place the lens directly onto the cornea (placing it on the lower sclera can lead to the lens folding after a blink). While continuing to hold both lids in place, the patient should look down to seat the lens. The lids may then be released.



Lens Removal

- **Wash hands thoroughly** with soap that does not have any oils, lotions or perfumes.
- **Carefully dry hands** with a clean, lint-free towel.

It is important to remind patients to **dry their hands thoroughly** prior to removing their lenses. The surface of DAILIES TOTAL1® brand lenses is designed to stay very wet and lubricious, or slippery while on the eye. If their fingertips are wet they are likely to slip across the surface of the lens making removal more difficult.

- Slide the lens off the cornea (down or to the side) onto the sclera. This produces a fold in the lens, which assists in removal. With the index finger and thumb, gently pinch the lens off the eye.
- Discard lenses.

Care for a Sticking Lens

- In the unlikely event that the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. If the lens continues to stick, the patient should **immediately** consult the eye care professional.

IN OFFICE CARE OF TRIAL LENSES

Eye care professionals should understand and educate contact lens technicians concerning proper use of trial lenses.

- Each contact lens is shipped sterile in a sealed blister pack containing phosphate buffered saline with additives. Hands should be thoroughly washed and rinsed and dried with a lint-free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use.
- Delefilcon A lenses are for daily disposable wear only and should be discarded after a single use. **The lenses should be disposed of after a single use and not be re-used from patient to patient.**

ADDITIONAL INFORMATION

For assistance with fitting or clinical questions regarding DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal contact lenses eye care professionals having questions or problems should contact Medical Information Systems in the USA at (800) 241-7468. To order DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal contact lenses contact your Alcon sales representative or call Customer Service, in the USA at (800) 241-5999.

VERTEX DISTANCE CONVERSION CHART
For minus lenses, read left to right; for plus lenses, read right to left.
(12 mm Vertex Distance)

-	+	-	+	-	+	-	+
4.00	3.87	7.50	6.87	12.00	10.37	19.00	15.50
4.25	4.00	7.62	7.00	12.50	10.75	19.25	15.62
4.50	4.25	7.75	7.12	12.75	11.00	19.25	15.75
4.75	4.50	7.87	7.25	13.00	11.25	19.75	16.00
5.00	4.75	8.00	7.37	13.50	11.50	20.00	16.12
5.12	4.87	8.12	7.50	13.75	11.75	20.25	16.25
5.37	5.00	8.25	7.62	14.00	12.00	20.50	16.50
5.50	5.12	8.50	7.75	14.25	12.25	20.75	16.62
5.62	5.25	8.75	8.00	14.75	12.50	21.00	16.75
5.75	5.37	9.00	8.25	15.00	12.75	21.25	17.00
5.87	5.50	9.25	8.37	15.50	12.75	21.75	17.25
6.00	5.62	9.50	8.62	15.75	13.25	22.25	17.50
6.12	5.75	9.75	8.75	16.25	13.50	22.50	17.75
6.37	5.87	10.00	9.00	16.75	13.75	23.00	18.00
6.50	6.00	10.25	9.12	17.00	14.00	23.50	18.25
6.62	6.12	10.50	9.25	17.25	14.25	23.75	18.50
6.75	6.25	10.75	9.37	17.62	14.37	24.25	18.75
6.87	6.37	11.00	9.62	18.00	14.50	24.75	19.00
7.00	6.50	11.25	9.75	18.12	14.75	25.00	19.25
7.12	6.62	11.50	10.00	18.50	15.00	25.50	19.50
7.37	6.75	11.75	10.25	18.75	15.25	26.00	19.75

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Alcon
a Novartis company

DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (delefilcon A) Soft Contact Lenses for Daily Disposable Wear

90003E292

IMPORTANT: This package insert is effective as of [illegible] and applicable to the delefilcon A contact lenses described below. 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 appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from Alcon by calling Customer Service at 1-800-[illegible] or download from our website at [illegible]. In addition, a Patient Instruction Booklet is available which is recommended to be given to patients.

Rx only

CAUTION: Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.

PRODUCT DESCRIPTION

DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lenses are made from a lens material that is 33% water and 67% (delefilcon A) polymer, a silicone containing hydrogel with added phosphatidylcholine. The core lens material containing 33% water transitions through a water gradient to a hydrogel surface layer that exceeds 80% water. Lenses contain the color additive copper phthalocyanine, a light blue tint, which makes them easier to see when handling.

Lens Properties

• Refractive Index hydrated:	1.42
• Light Transmittance:	93% (@ 610 nm, -3.00D)
• Oxygen Permeability (Dk):	140 x 10⁻¹¹ (cm²/sec)(ml O₂/ml x mm Hg), measured at 35° C (Intrinsic Dk-Coulometric method)
• Water Content:	33% by weight in normal saline
• Surface Water Content:	≥ 80%

Lens Parameters

• Diameter Range	13.0 to 15.0 mm
• Spherical Power Range	-20.00 to +20.00D
• Base Curve Range	8.0 to 9.2 mm

Lens Parameters Available¹

DAILIES TOTAL1* (delefilcon A) spherical

• Chord Diameter:	14.1 mm
• Center Thickness:	0.09 mm @ -3.00D (varies with power)
• Base Curve:	8.5 mm
• Powers:	-0.50 to -6.00D (0.25D steps); -6.50 to -10.00D (0.50D steps); +0.50 to +6.00D (0.25D steps)

DAILIES TOTAL1* Multifocal (delefilcon A)

• Chord Diameter:	14.1 mm
• Center Thickness:	0.09 mm @ -3.00D (varies with power)
• Base Curve:	8.5 mm
• Powers:	+6.00D to -10.00D (0.25D steps) ADD: LO, MED, HI

NOTE: Hereafter, DAILIES TOTAL1* spherical lenses and DAILIES TOTAL1* Multifocal contact lenses will simply be referred to as delefilcon A contact lenses unless product distinction is necessary.

ACTIONS

When hydrated and placed on the cornea, delefilcon A contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

DAILIES TOTAL1* (delefilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 (D) or less and who may have up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT use delefilcon A contact lenses when any of the following exists:

- Inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease which may be exacerbated by or interferes with contact lens wear
- Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exaggerated by the wearing of contact lenses
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear
- If eyes become red or irritated

WARNINGS

Advise patients of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care professional's directions and all labeling instructions for proper use of lenses and lens care products. Serious eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical study results have shown that the risk of serious adverse reactions is increased when contact lenses are worn overnight².
- Studies³ have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, foreign body sensation, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care professional. It is recommended that contact lens wearers see their eye care professional regularly as directed.

PRECAUTIONS

To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:

Special Precautions for the Eye Care Professional:

Due to the small number of patients enrolled in the 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, 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 evaluated on initial dispensing and monitored on an ongoing basis by the prescribing eye care professional.

- Fluorescein, a yellow dye, should not be used while the lenses are on the patient's eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- Patients who wear contact lenses to correct presbyopia may not achieve the best possible 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.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. Alcon recommends that patients see their eye care professional once each year, or more often, as recommended by the eye care professional.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Eye Care Professionals should carefully instruct patients about the following safety precautions:

Handling Precautions:

- Be sure that before leaving the eye care professional's office the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear. Always wash, rinse and thoroughly dry hands with a lint-free towel before handling lenses.
- REMOVE A LENS IMMEDIATELY if an eye becomes red or irritated.
- Always handle lenses carefully. Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use.
- Do not use if blister package is damaged or not sealed completely. This may result in product contamination which can lead to a serious eye infection.
- Ensure that the correct lens for each eye is available. Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pouring the lens onto the palm of your clean hand. Ensure the lens is right side out. Inspect lenses prior to insertion. Do not insert damaged lenses.
- To insert lenses:
  - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses.
  - Place a lens on the tip of your clean and dry right or left index finger, place the middle finger of the same hand close to lower eyelashes and pull down the lower eyelid.
  - Use the fingers of the other hand to lift the upper eyelid.
  - Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
  - Look down and slowly remove the hand, releasing the lower lid.
  - Look straight ahead and slowly remove the other hand, releasing the upper lid.
  - Blink gently.
- To remove lenses:
  - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses. Make sure hands are clean and completely dry.
  - Blink fully several times.
  - While looking up, slide the lens down onto the white part of the eye.
  - Remove the lens by pinching gently between the thumb and forefinger. Do not pinch the eye tissue.
  - If the lens is difficult to grasp, dry fingers once more and try again. Do not use rewetting drops in this instance.
- If a lens decenters on the eye, it may be possible to recenter it by:
  - Closing the eye and massaging the lens into place, or
  - Looking in the direction of the lens and blinking gently, or
  - Gently pushing the off-centered lens onto the cornea with light finger pressure on the edge of the upper or lower eyelid.
- If a lens tears in the eye it will feel uncomfortable. Advise wearers it is impossible to lose a contact lens or part of a contact lens behind the eye and to remain calm. Lens pieces may be removed by pinching them as for normal lens removal, carefully avoiding pinching the eye tissue. If the lens pieces do not seem to remove easily, flushing with saline is recommended. If this does not help, the wearer should contact an eye care professional for assistance.

Lens Wearing Precautions:

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the Care for a Sticking Lens section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.

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- The eye care professional should be consulted about wearing lenses during water sports and water related activities. Exposure to water or other non-sterile liquids while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to Acanthamoeba keratitis.
- Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Lenses should be disposed of each day upon removal from the eye.
- Discard any lens which has become dehydrated or damaged. Replace with a sterile, fresh, new lens.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always carry spare lenses with you or have back-up spectacles available.
- Do not share lenses with anyone as this may spread micro-organisms which could result in serious eye health problems.
- Do not use lenses beyond their expiration date.

Other Topics to Discuss with Patients:

- Periodic eye examinations are extremely important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response. Alcon recommends that patients see their eye care professional once each year or as recommended by the eye care professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, and blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such medications accordingly and prescribe proper remedial measures.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Who Should Know that the Patient is Wearing Contact Lenses:

- Patients should inform their health care practitioners that they are wearing contact lenses.
- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn.

It is strongly recommended that patients be provided with a copy of the DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal Contact Lenses (delefilcon A) Patient Instruction Booklet available from Alcon and understand its contents prior to dispensing the lenses.

ADVERSE EFFECTS

Patients should be instructed to check eyes regularly to make sure they look well, feel comfortable and vision is clear. Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:

- Moderate to severe eye pain not relieved by removing the lens
- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging or itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

WHAT TO DO IF A PROBLEM OCCURS

Patients should be instructed that if any of the above signs or symptoms are noticed, he or she should:

- IMMEDIATELY REMOVE THE LENSES.
- If the discomfort or problem stops, discard the lens and replace it with a new one.
- If the discomfort or problem continues after removing lens(es) or upon insertion of a new lens, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.
- The patient should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.
- Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of DAILIES TOTAL1* brand (delefilcon A) contact lenses, please notify Alcon Medical Safety in the USA at 1-800-757-9780.

FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to delefilcon A contact lenses. For a detailed description of the fitting techniques, refer to the DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal Contact Lenses (delefilcon A) Professional Fitting and Information Guide. Both the professional fitting guide and a patient instruction booklet are available free of charge from:

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134-2099
1-800-241-5999

LENS WEAR & REPLACEMENT SCHEDULES

DAILY WEAR (less than 24 hours, while awake):

- To avoid tendency of the daily wear patient to overwear the lenses initially, stress the importance of adhering to a proper, initial wearing schedule. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period.
- It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.
  - The maximum daily wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. There may be a tendency for patients to overwear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that delefilcon A contact lenses are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period. Optimum individual wearing schedule will vary.
- Delefilcon A contact lenses are intended to be worn once (daily disposable wear) and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a fresh new lens.

EMERGENCY LENS CARE

Cleaning and disinfection of daily disposable lenses is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. It is important that the patient wash and dry their hands thoroughly before removing the lens. If the lens continues to stick, the patient should IMMEDIATELY consult the eye care professional.

IN OFFICE USE OF TRIAL LENSES

Eye care professionals should educate contact lens technicians concerning proper use of trial lenses.
Each contact lens is shipped sterile in a blister pack containing phosphate buffered saline solution. Hands should be thoroughly washed and rinsed and dried with a lint-free towel prior to handling a lens. In order to ensure sterility, the blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes lenses should be disposed of after a single use and not be re-used from patient to patient.

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 or fresh saline solution and immediately contact the eye care professional or visit a hospital emergency room without delay.

HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic container containing phosphate buffered saline solution with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly(acrylamide-acrylic) acid and is steam sterilized [STERILE]. The package is marked with the base curve, diameter, dioptric power and ADD power (multifocal lenses), manufacturing lot number and expiration date.

The following may appear on the labels or cartons:

Symbols/Signs/Abbreviations	Description
[illegible]	[illegible]
STERILE	Steam sterilized
EXP	Use by date (Expiry date)
LOT	Batch code
	Do not reuse
	Do not use if the package is damaged
	Example of two letter language code (English)
DIA	Diameter
BC	Base curve
PWR	Power
D	Diopter (lens power)
ADD	Add lens power
CE	European conformity sign
	Caution
	See product instructions
EC REP	Authorized Representative in European Community
	Manufacturer
	Packaging waste / recycle sign

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Manufacturer:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134-2099
www.alcon.com
1-800-241-5999

March 2016 [illegible]

[1] Check for actual product availability as additional parameters may be introduced over time
[2] Schein, OD, Glynn RJ, Poggio EC, Seddon JM, Kenyon KR. The Relative Risk of Ulcerative Keratitis Among Users of Daily Wear and Extended Wear Soft Contact Lenses. N Eng J Med. 1989; 321 (12) 773-783

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Alcon®
a Novartis company
Manufacturer:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX
76134-2099, USA

March 2016

www.alcon.com
W900087400-0316

APPENDIX I: CLINICAL TECHNICAL PROCEDURES [redacted]

- [redacted] LIMBAL & CONJUNCTIVAL (BULBAR) REDNESS
- [redacted] EXPANDED SODIUM FLUORESCEIN CORNEAL STAINING
- [redacted] DETERMINATION OF NEAR ADD
- [redacted] NEAR LOGMAR VISUAL ACUITY MEASUREMENT PROCEDURE
- [redacted] LENS FITTING CHARACTERISTICS
- [redacted] SUBJECT REPORTED OCULAR SYMPTOMS
- [redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS
- [redacted] BIOMICROSCOPY SCALE
- [redacted] KERATOMETRY PROCEDURE
- [redacted] DISTANCE AND NEAR VISUAL ACUITY EVALUATION
- [redacted] ETDRS DISTANCE VISUAL ACUITY MEASURMENT PROCEDURE
- [redacted] MEASURING PUPIL DIAMETER WITH NEUROPTICS VIP-200 VARIABLE PUPILLOMETER

[redacted], LIMBAL & CONJUNCTIVAL (BULBAR) REDNESS

[redacted] Limbal & Conjunctival (Bulbar) Redness

[redacted]

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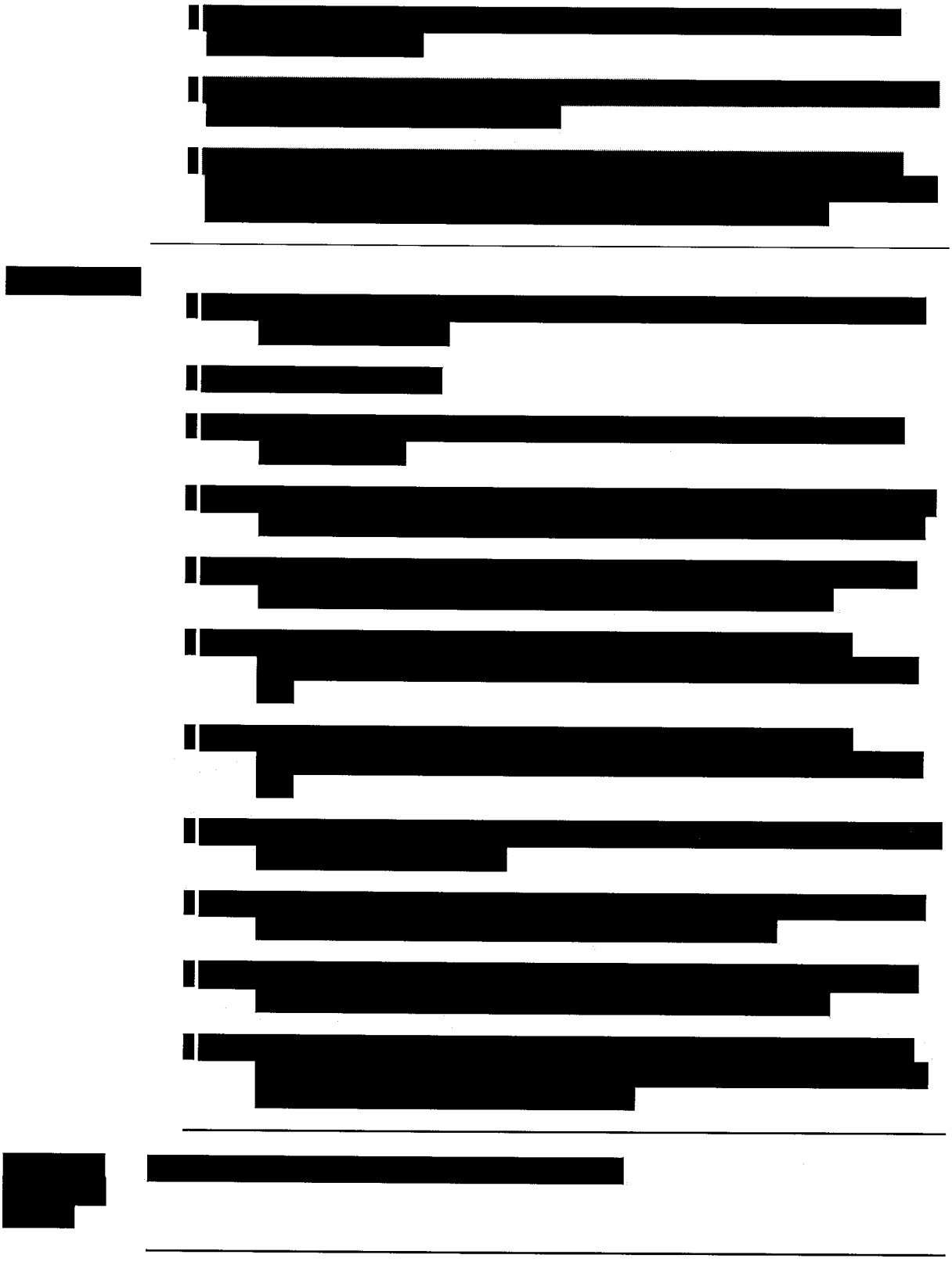

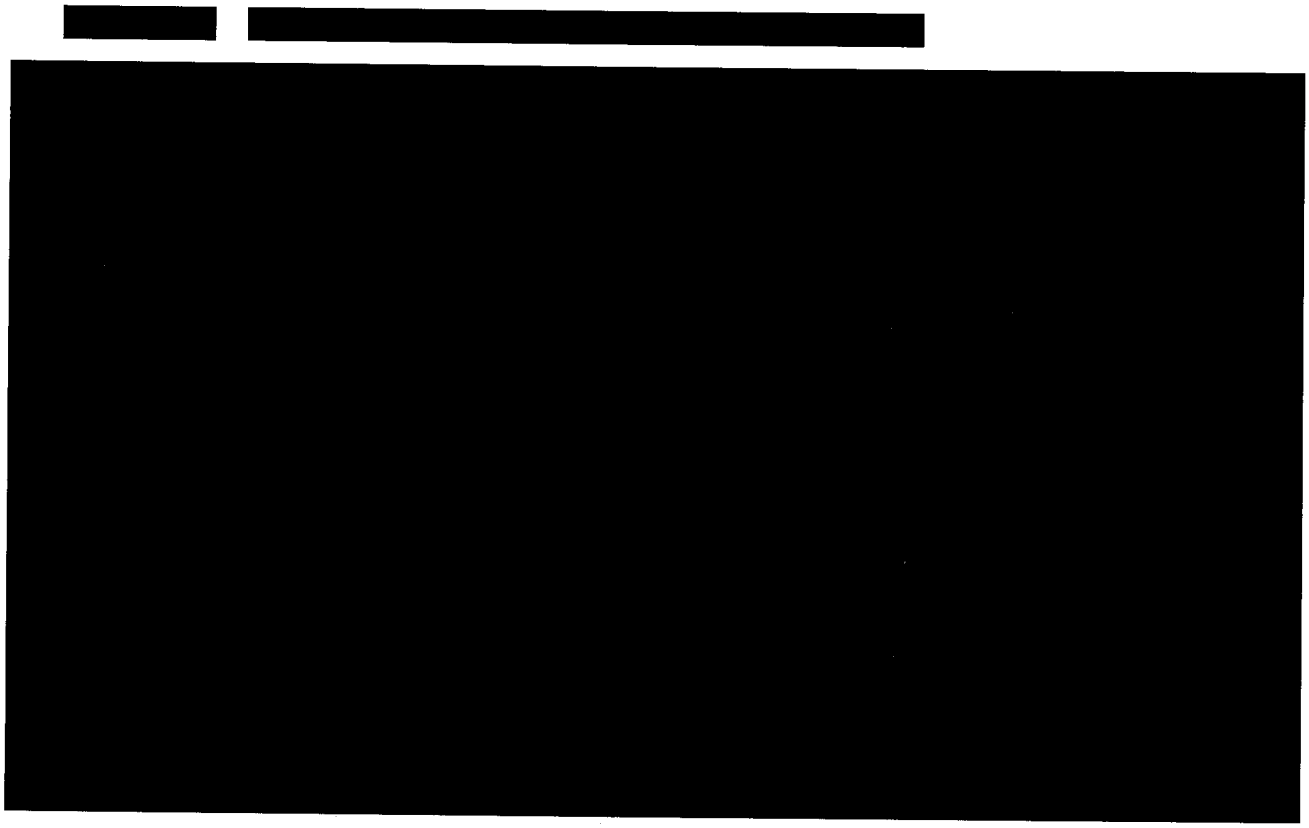

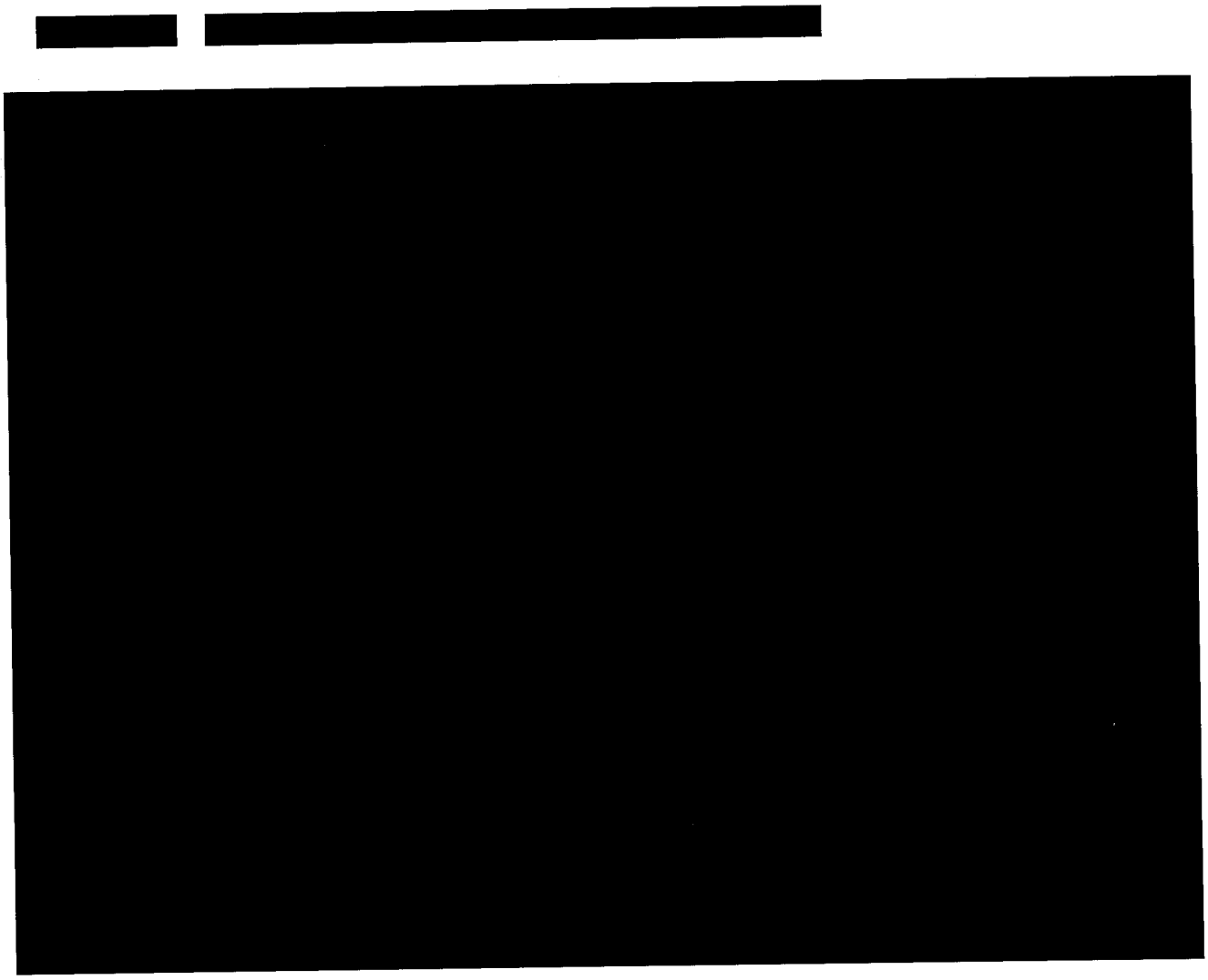

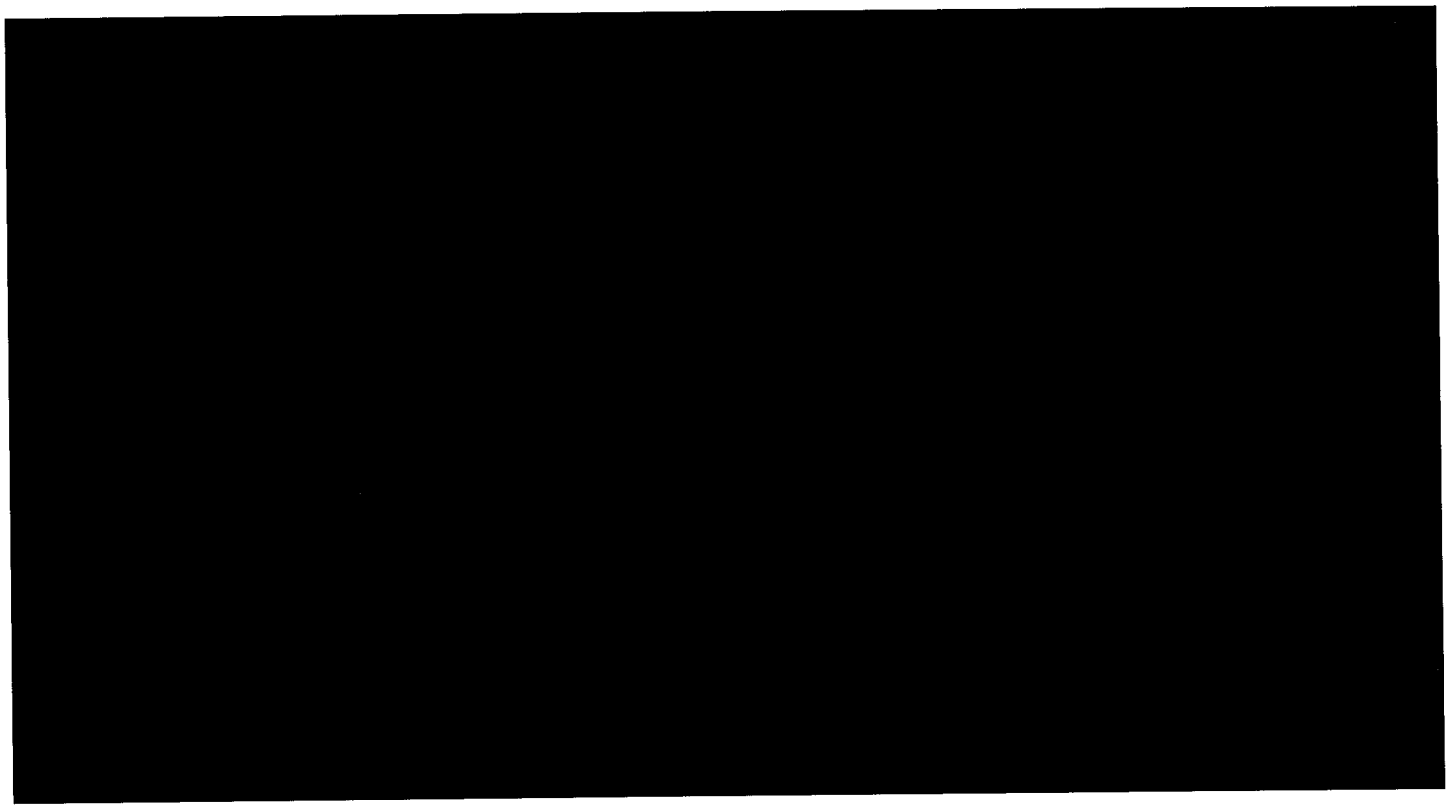

[redacted] EXPANDED SODIUM FLUORESCEIN CORNEAL STAINING

[redacted] Expanded Sodium Fluorescein Corneal Staining

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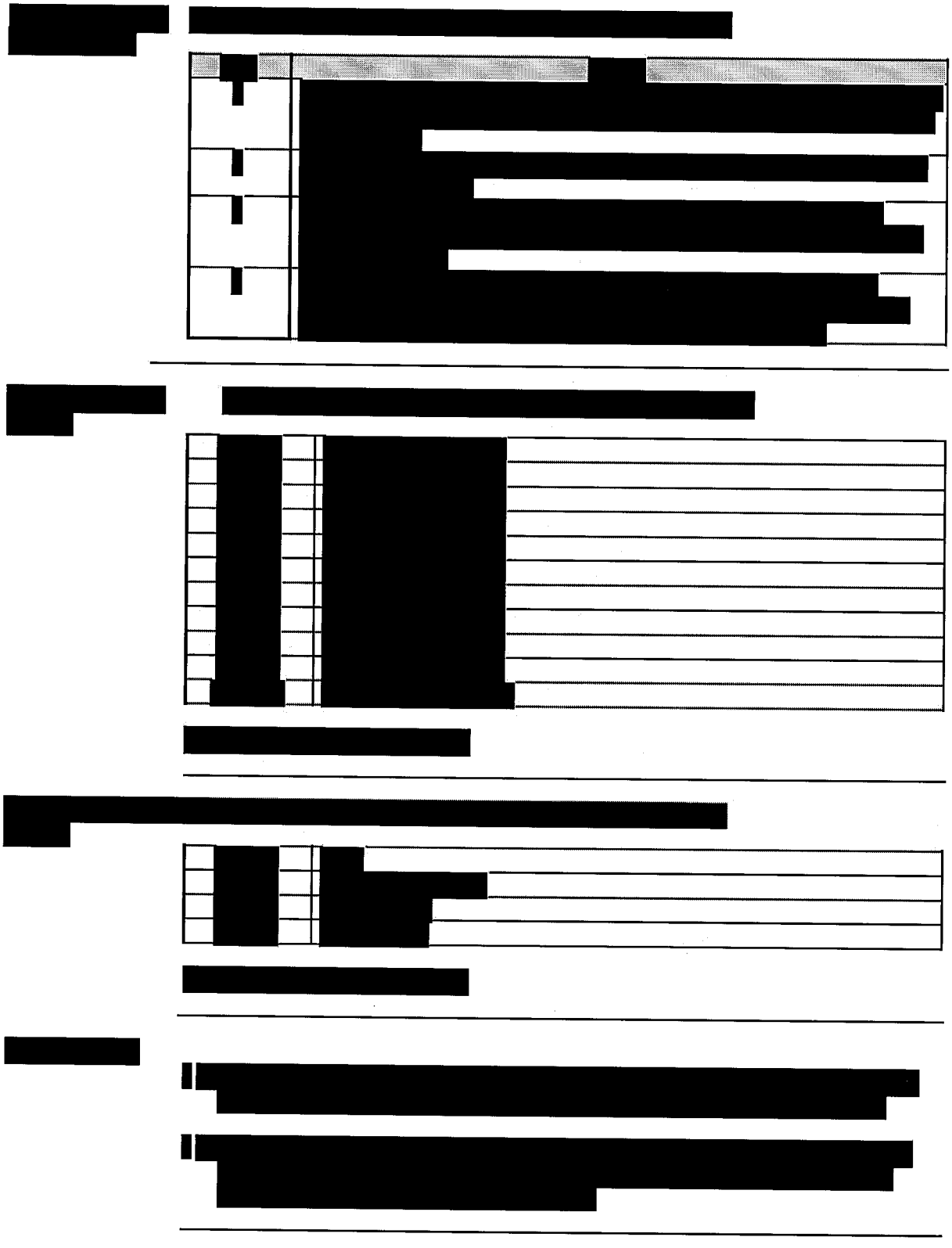

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[redacted] DETERMINATION OF NEAR ADD

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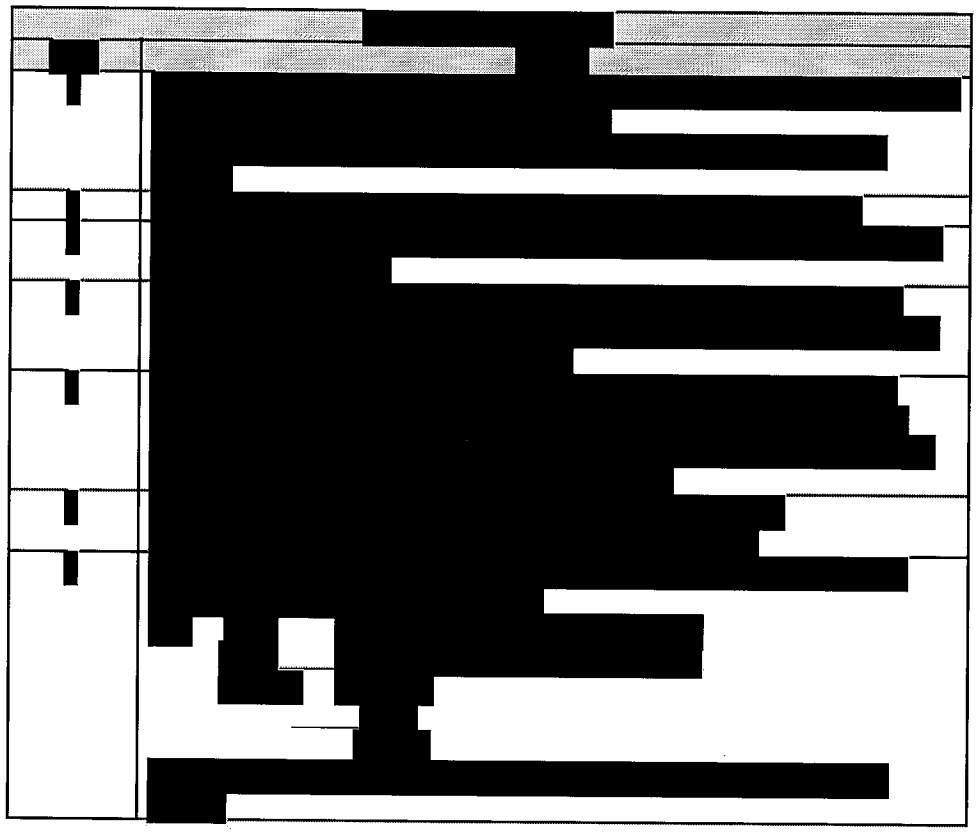

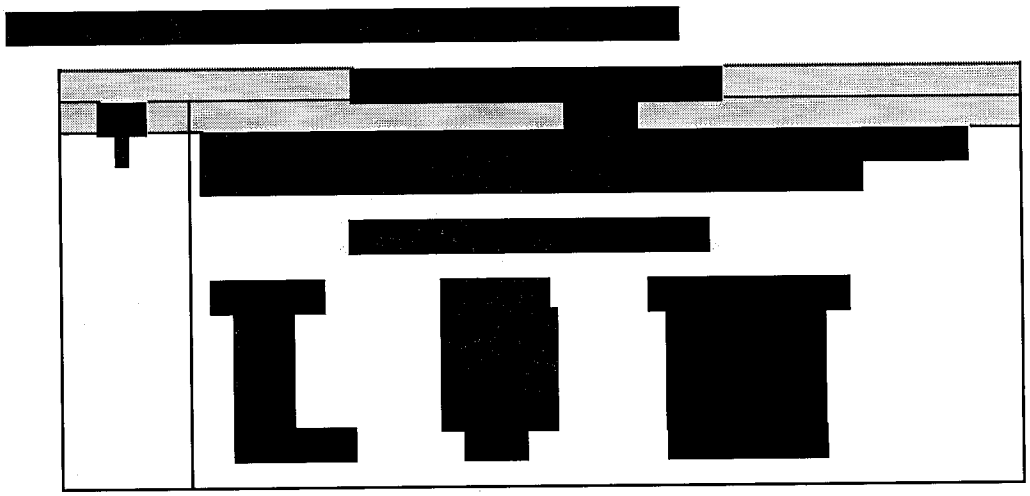

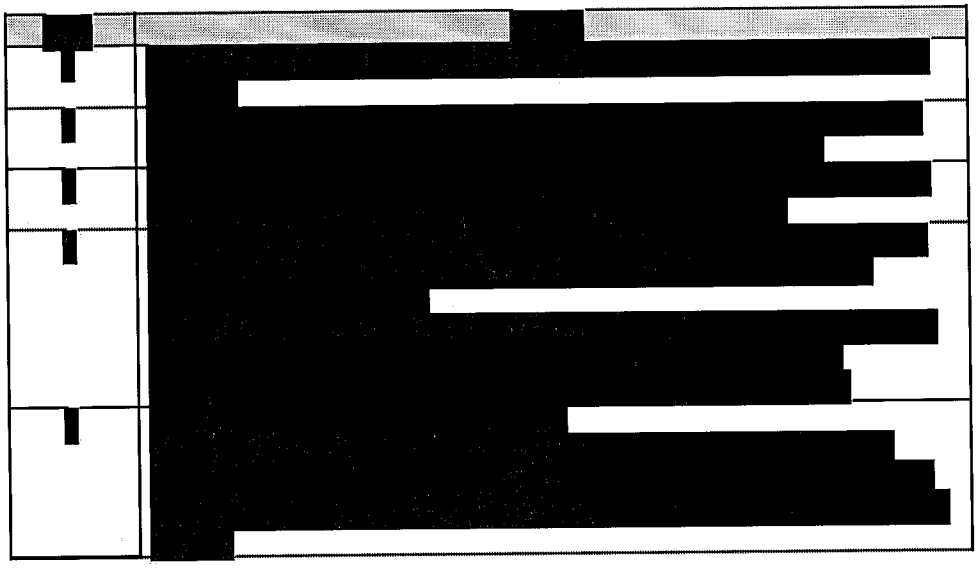

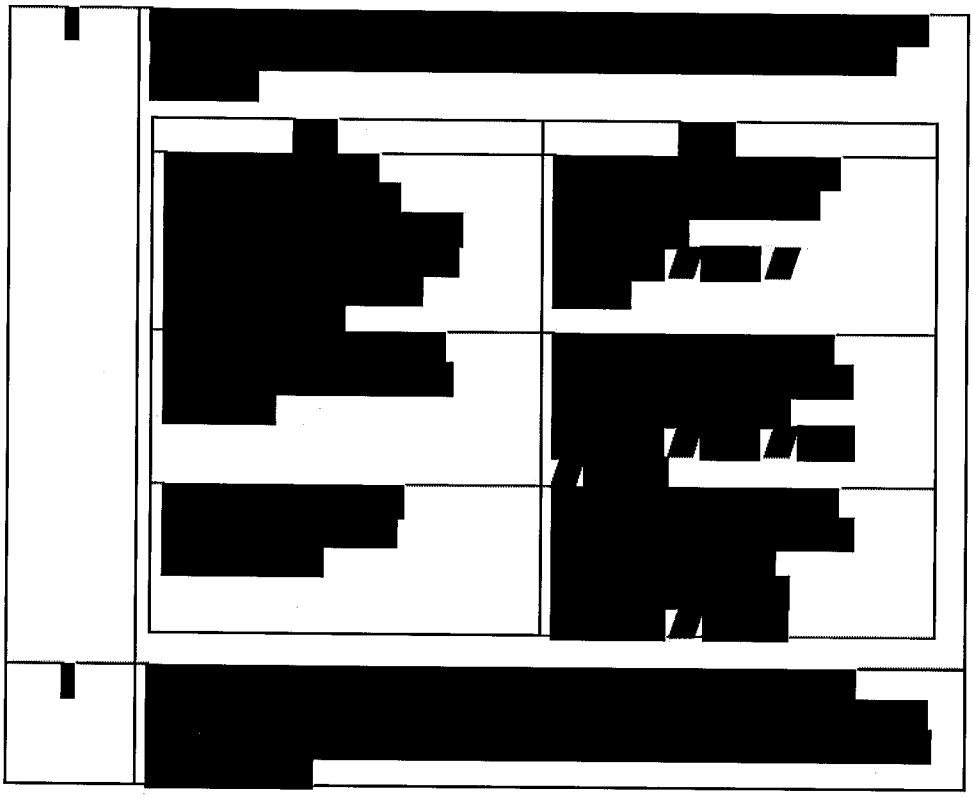

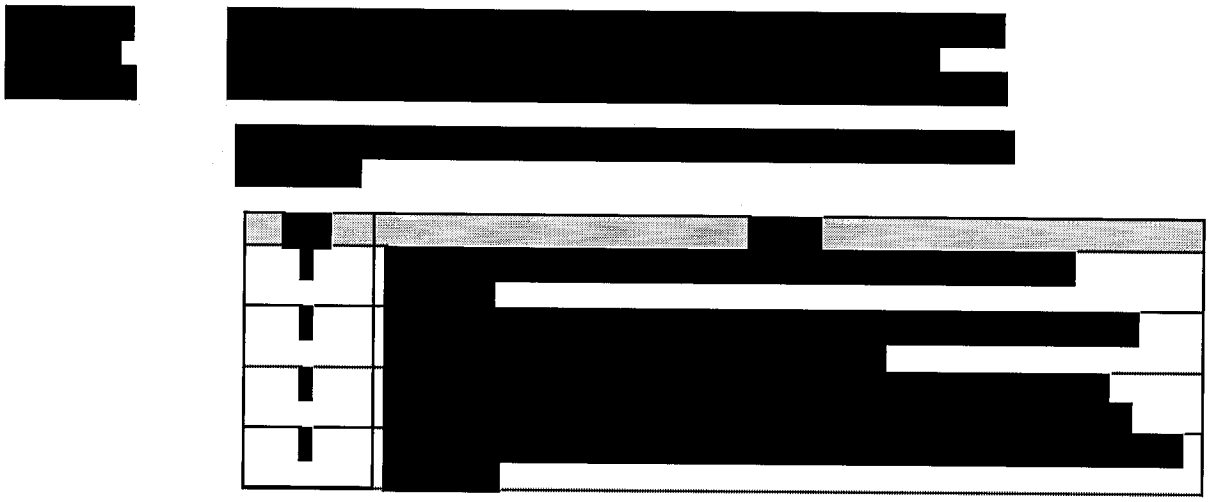

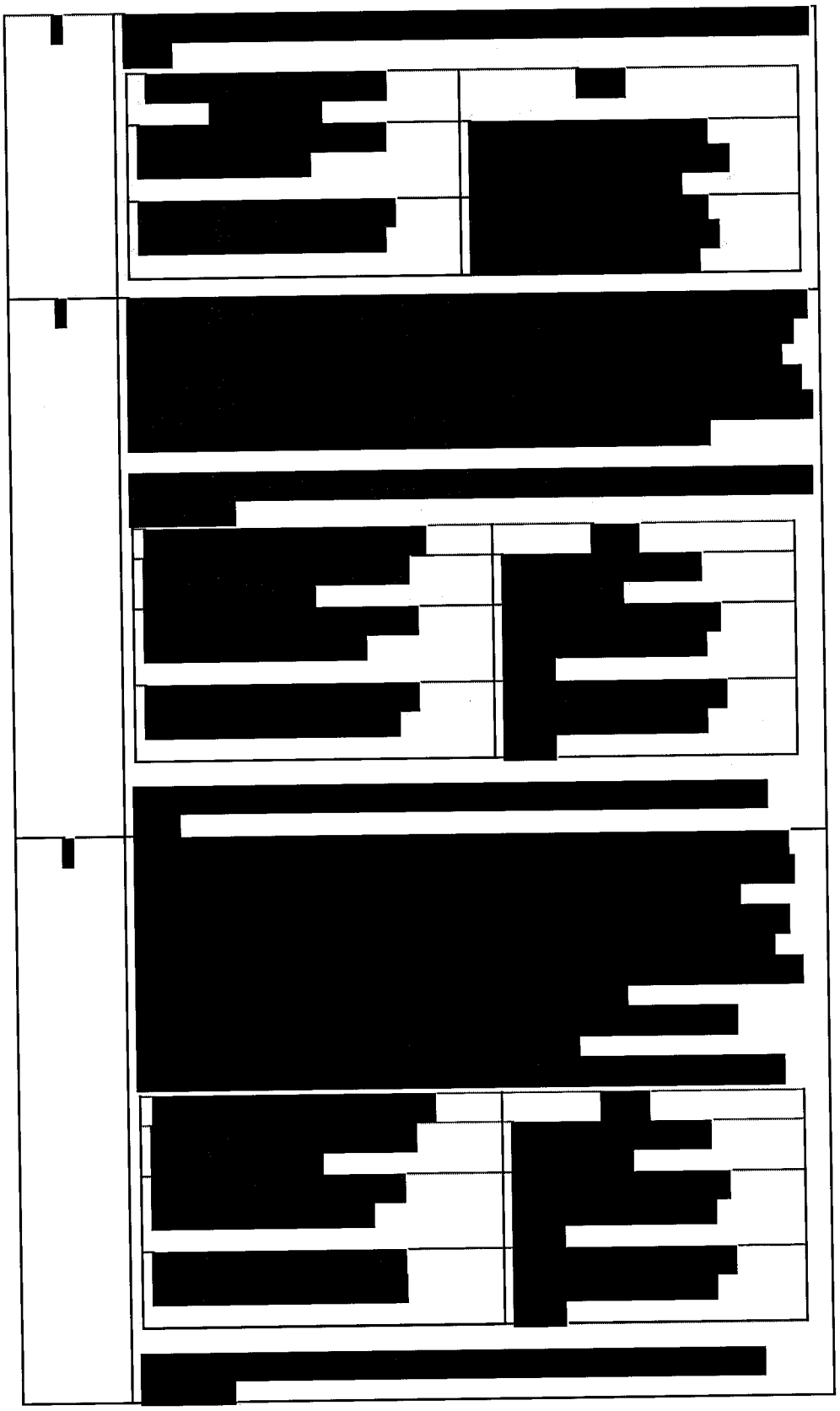

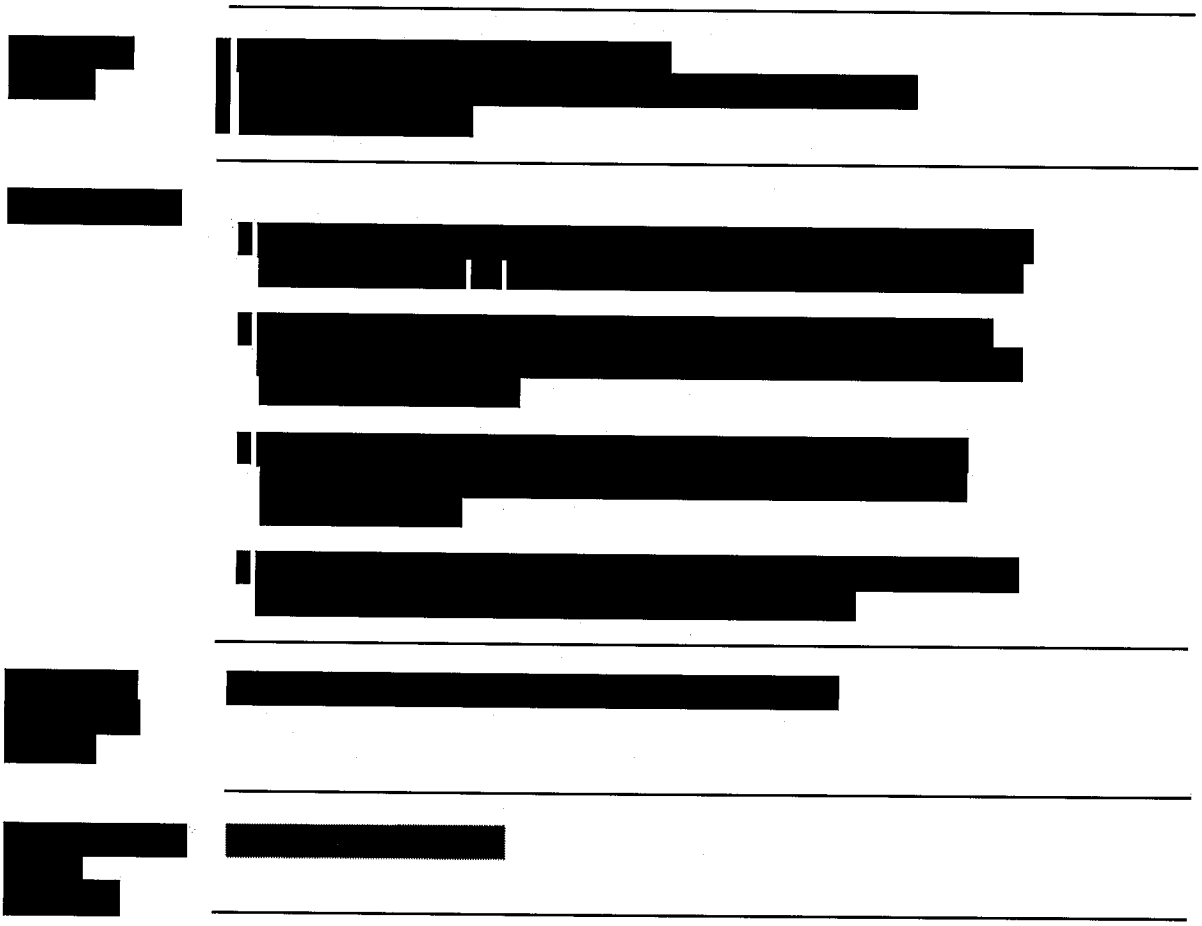

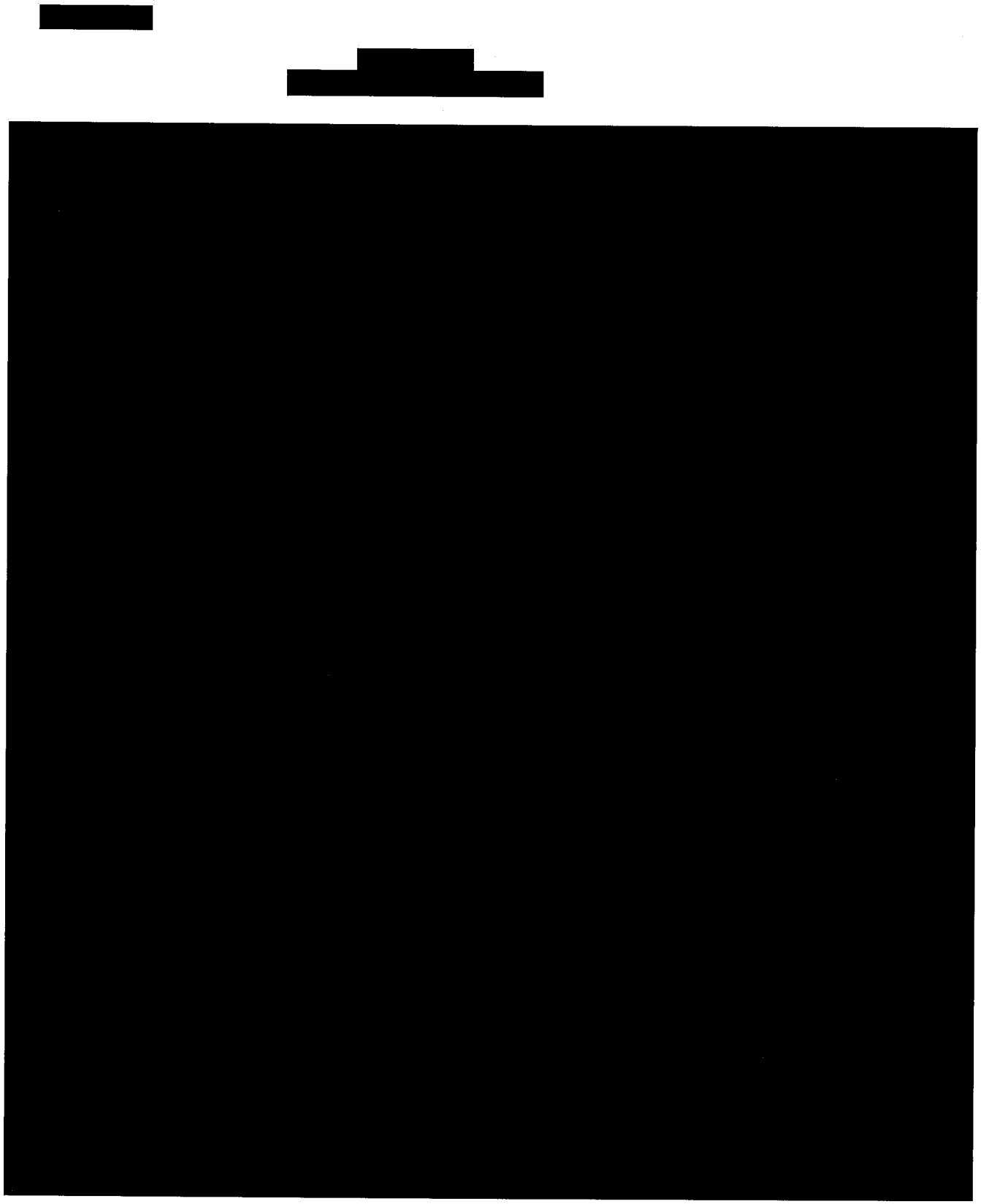

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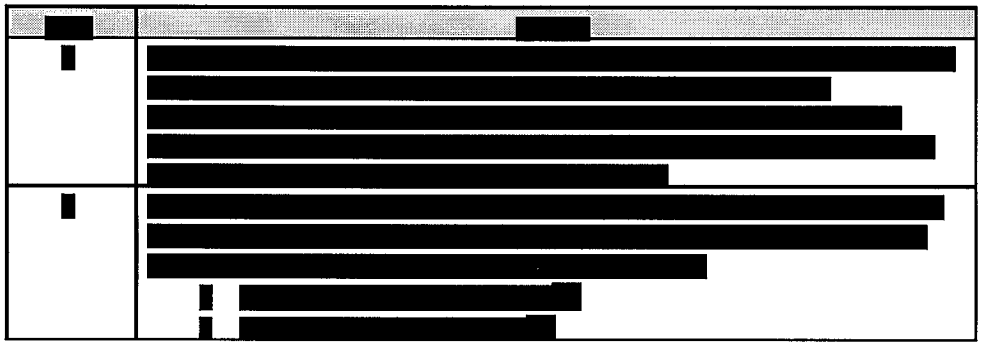

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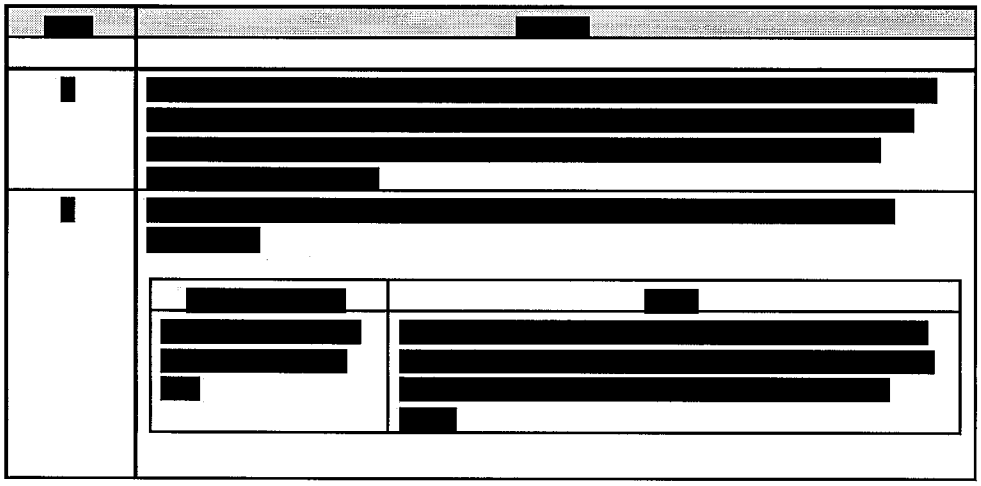

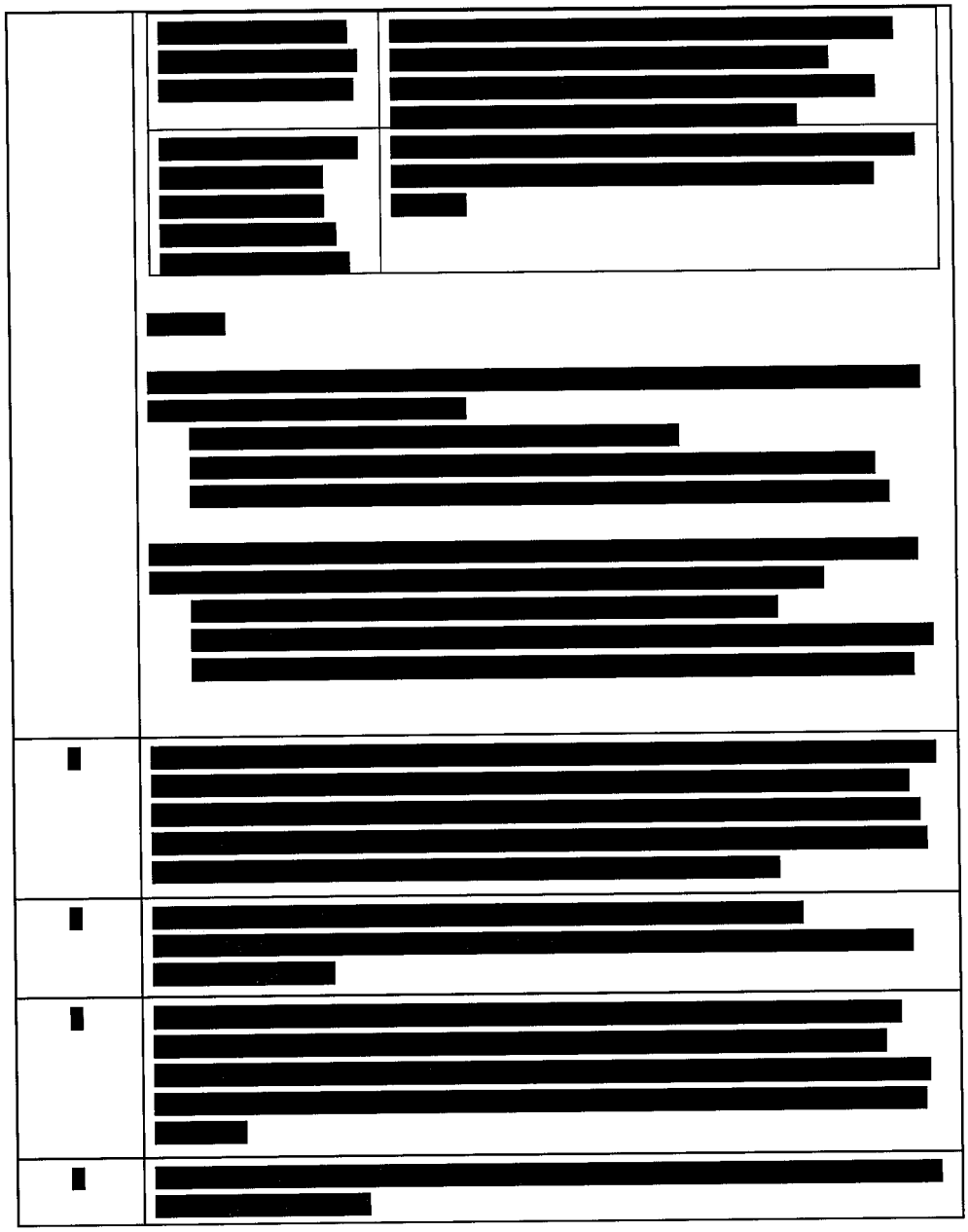

[redacted] LENS FITTING CHARACTERISTICS

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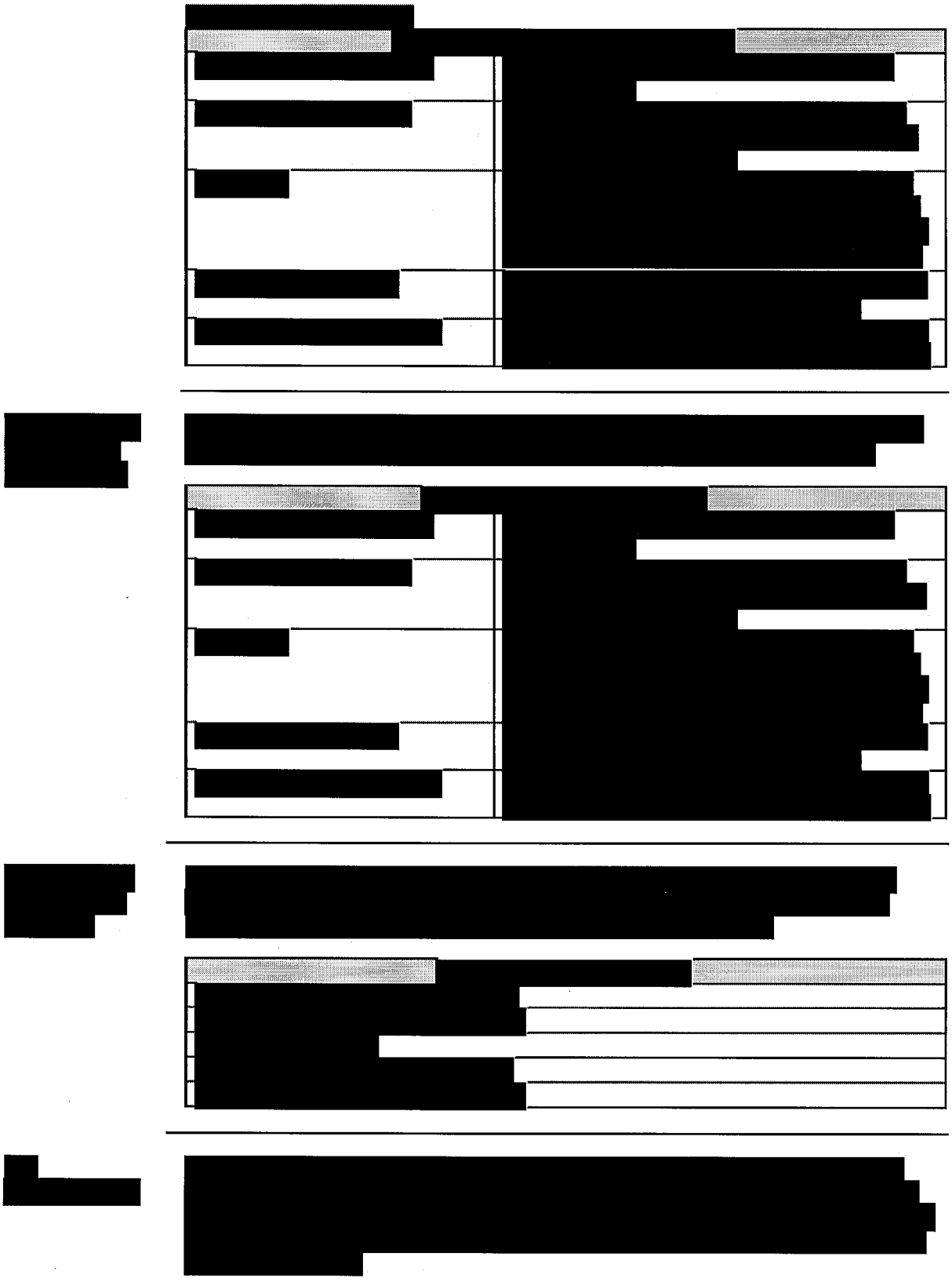

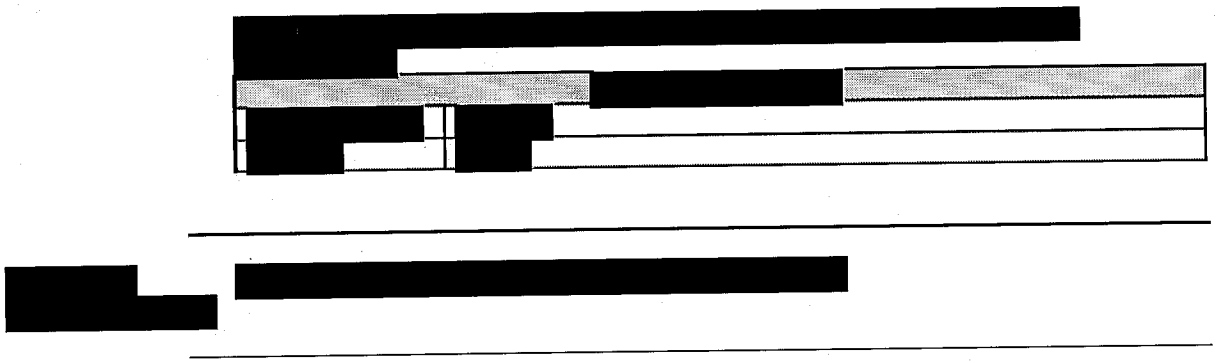

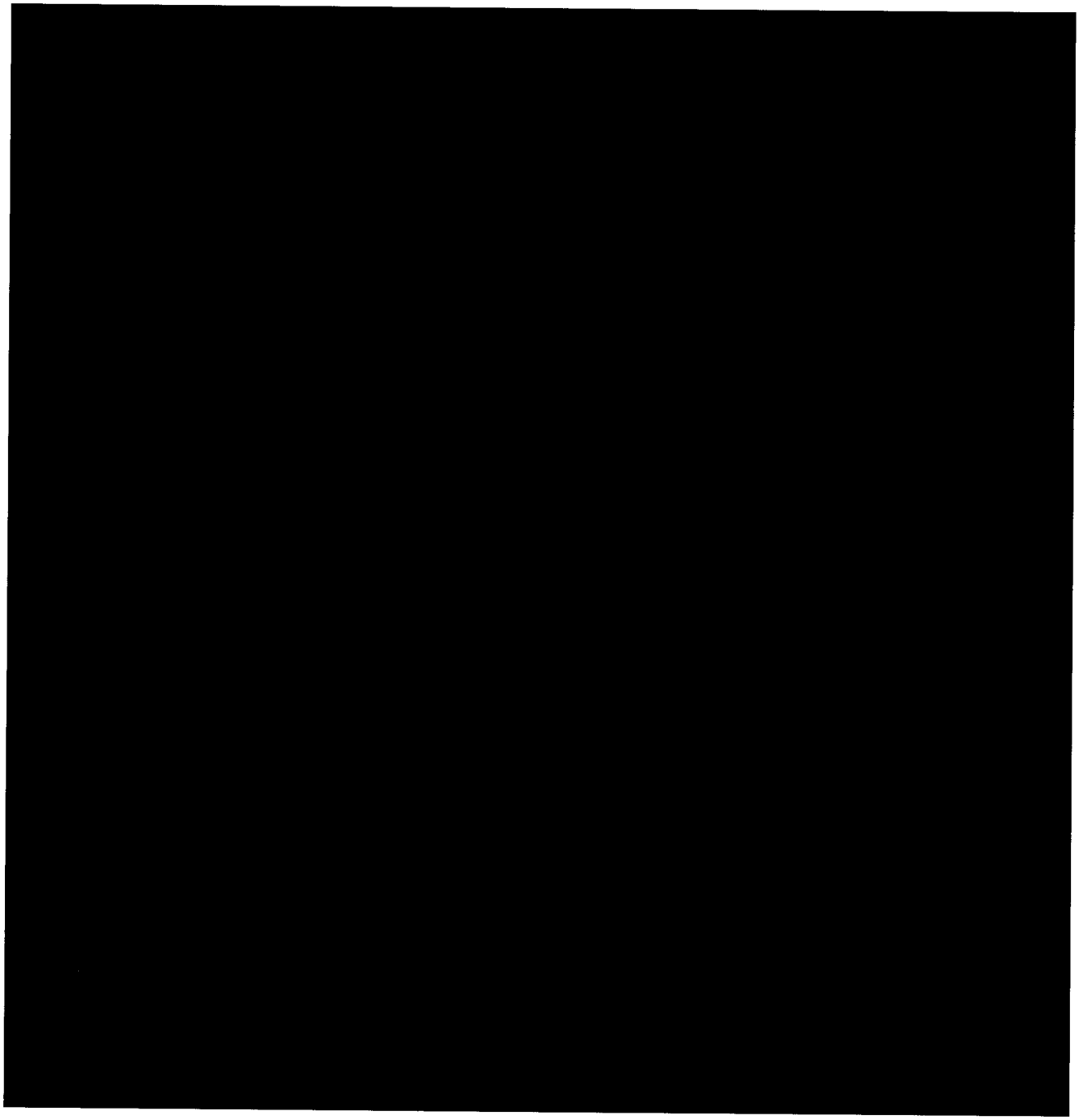

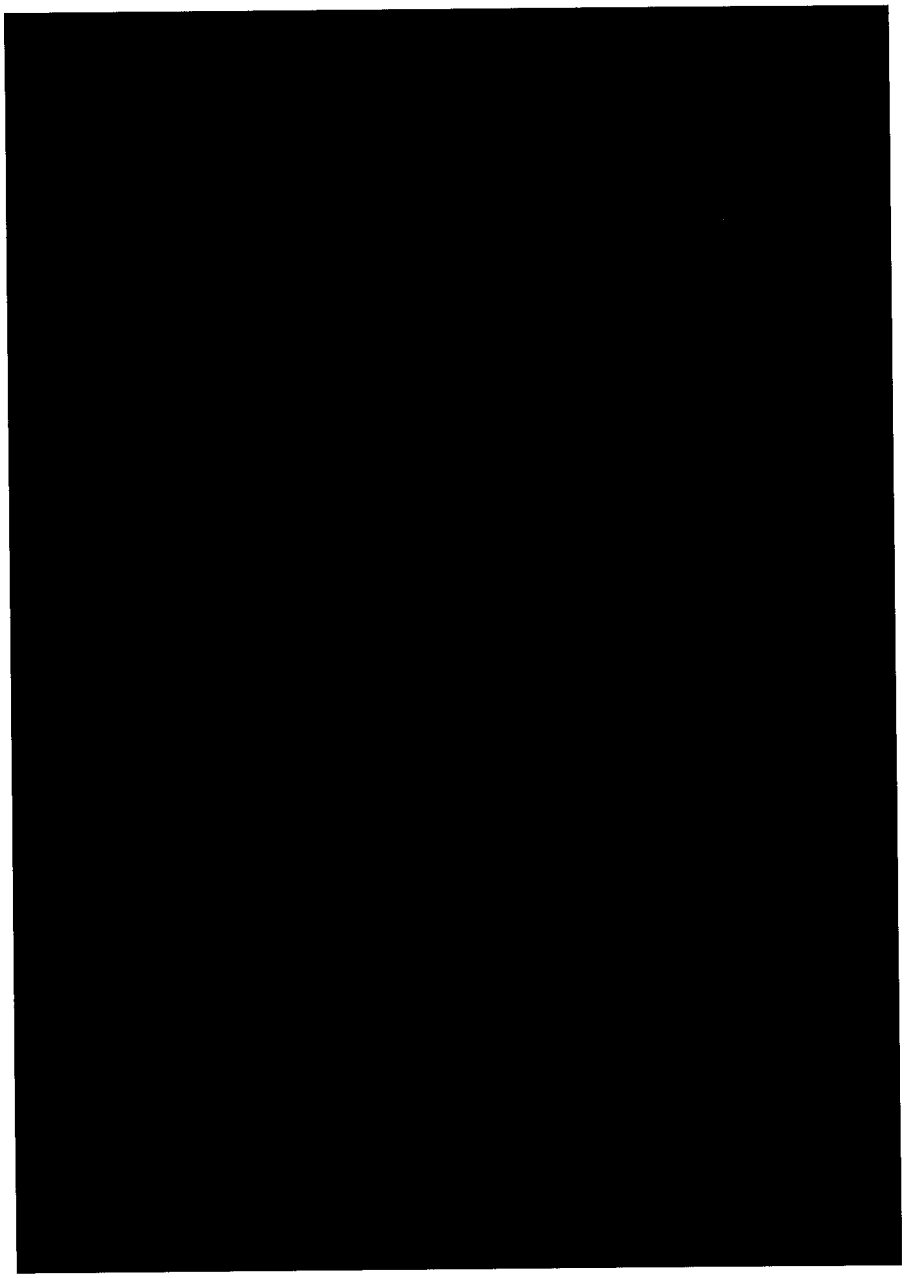

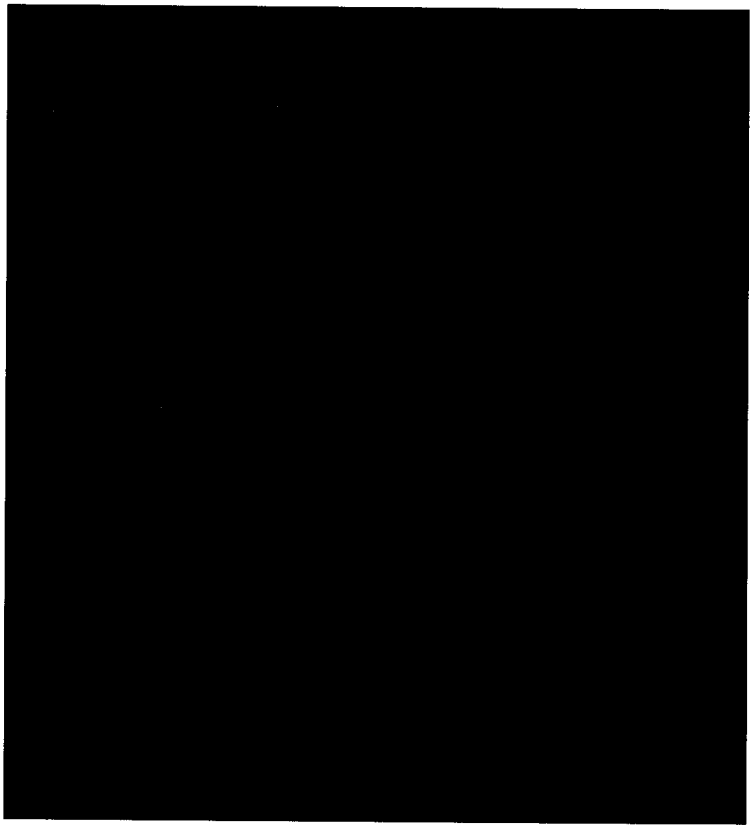

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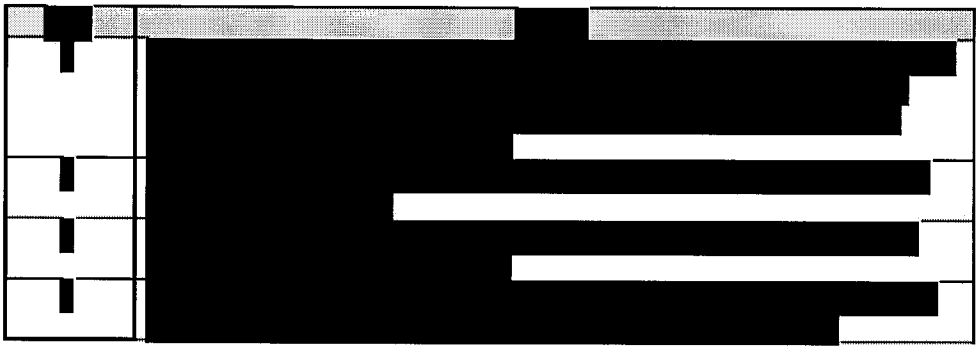

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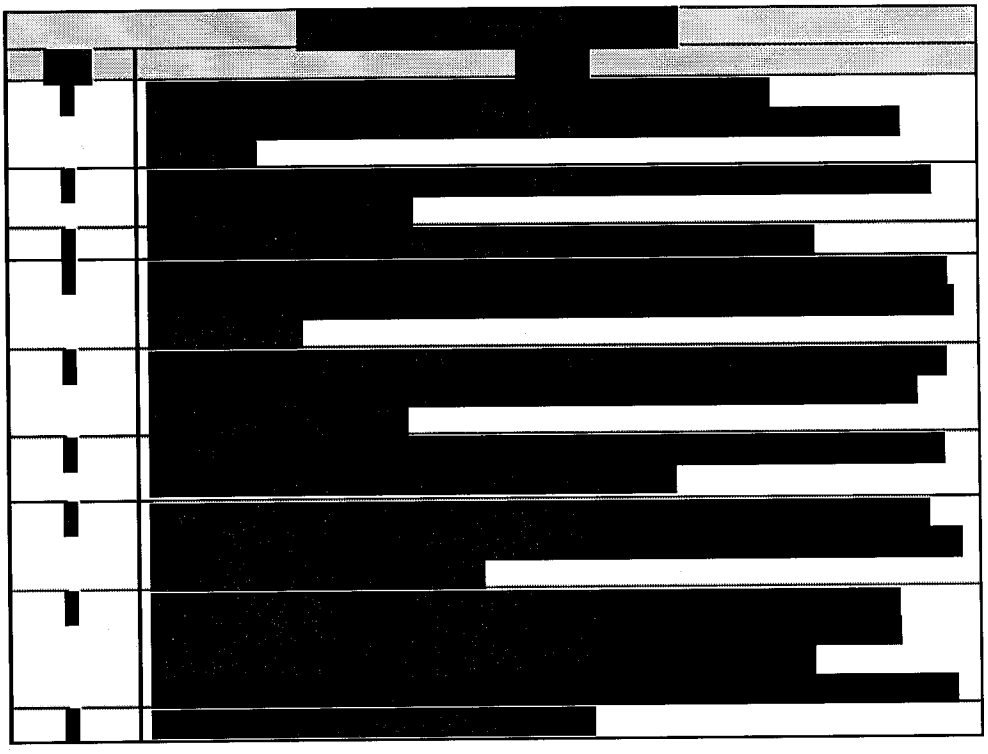

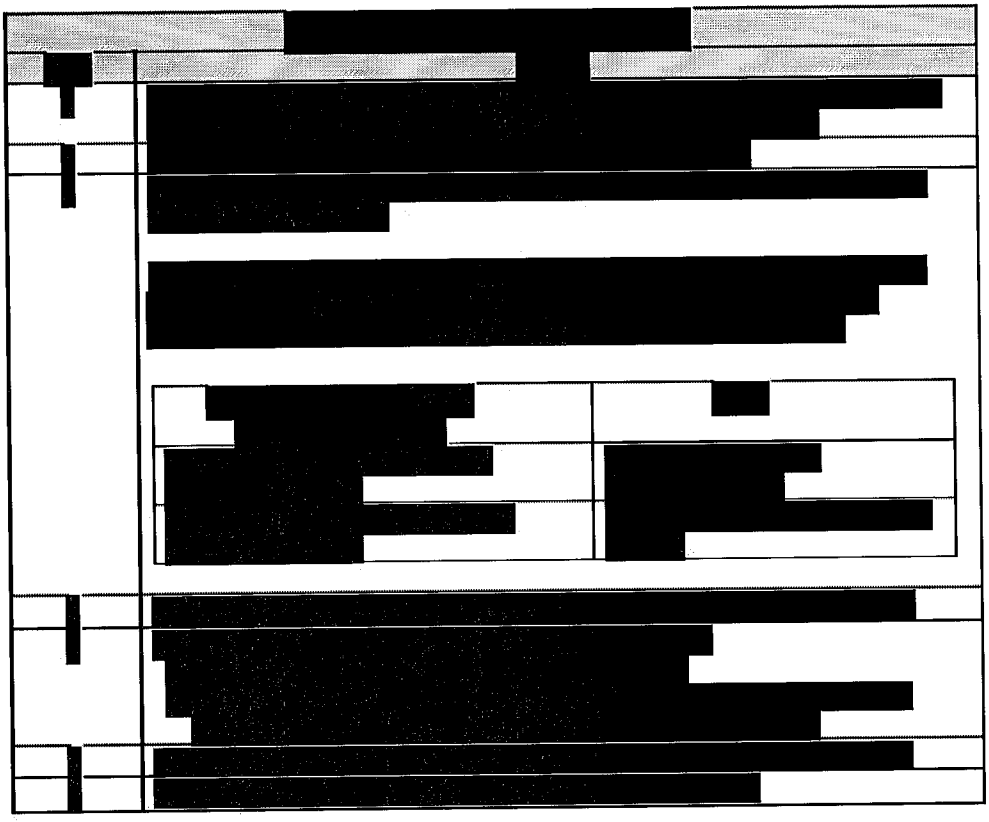

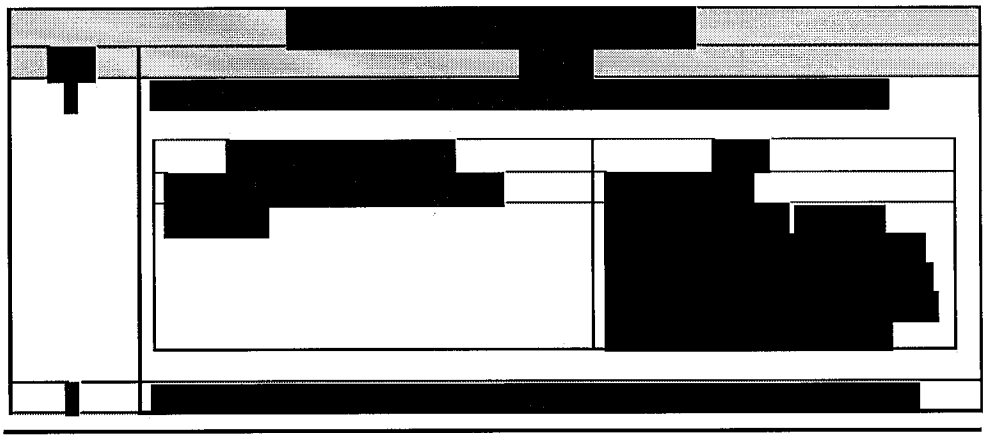

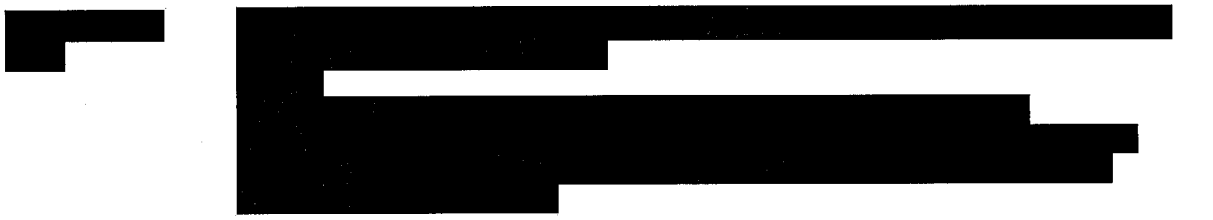

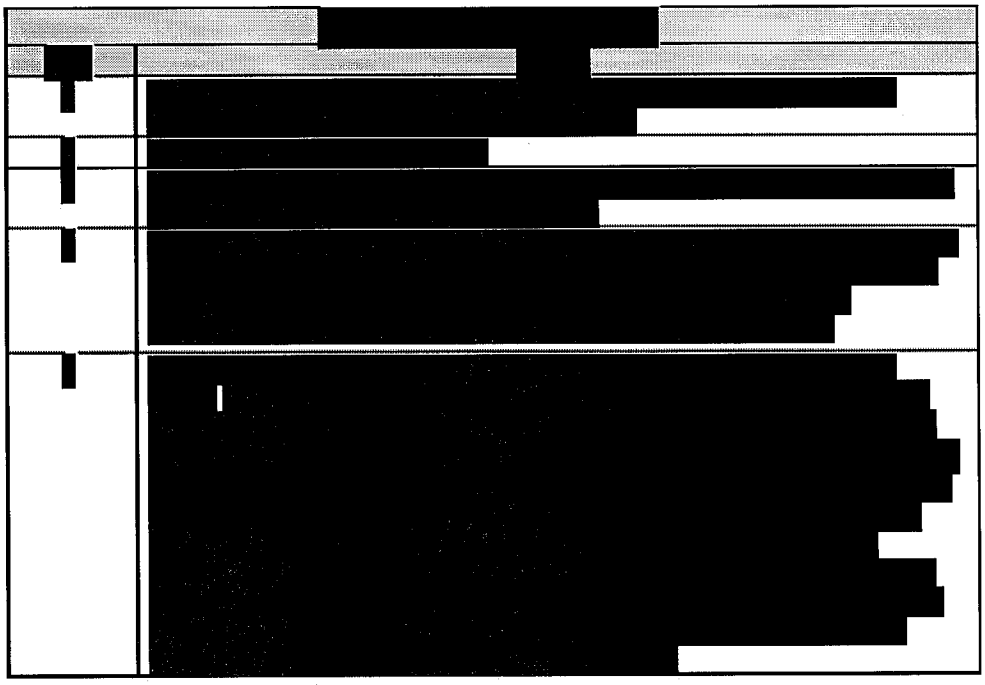

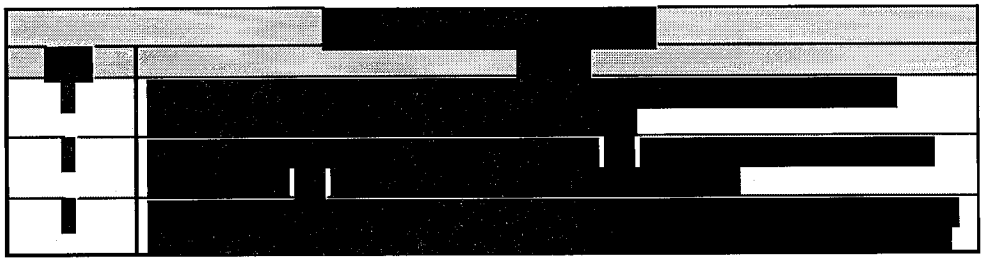

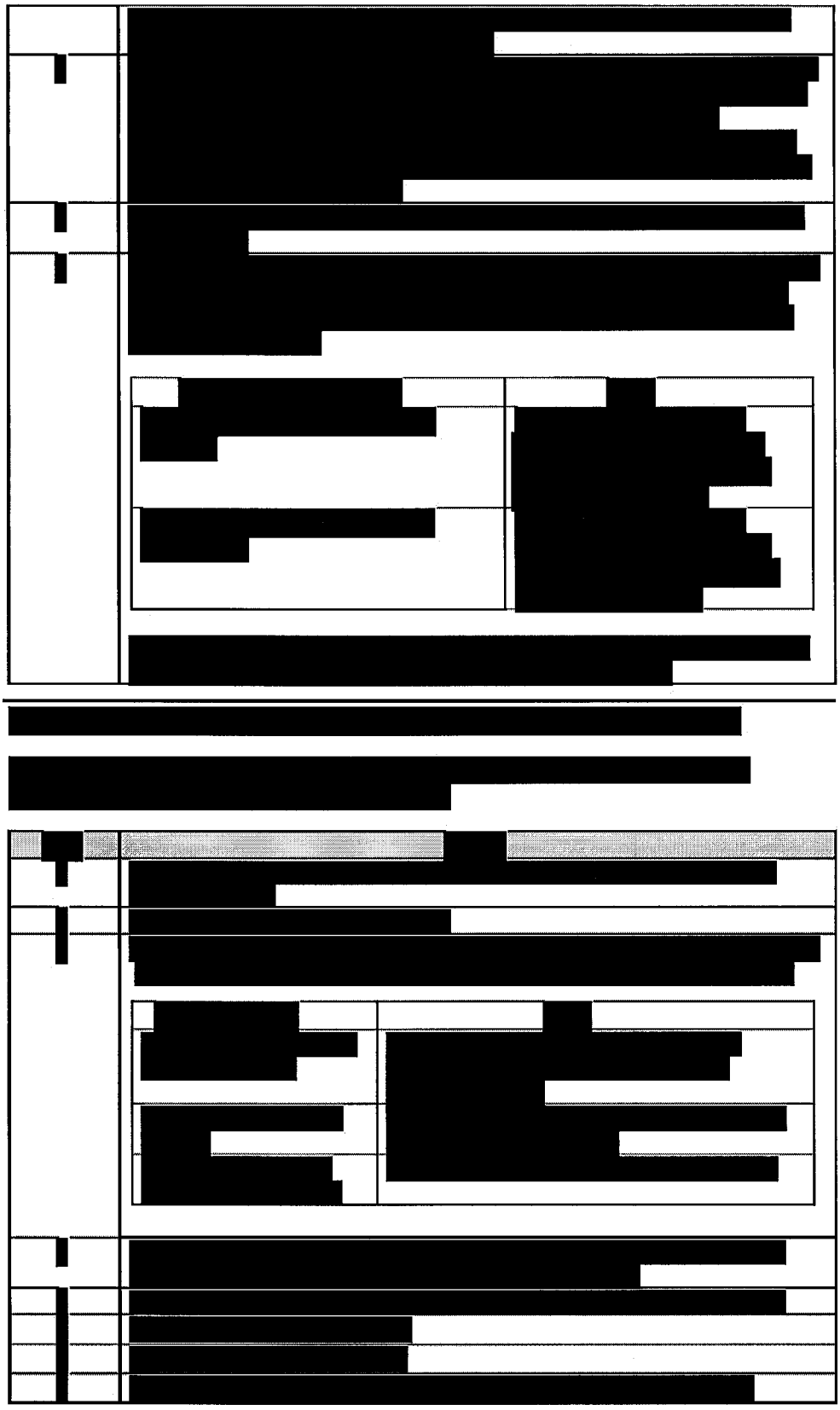

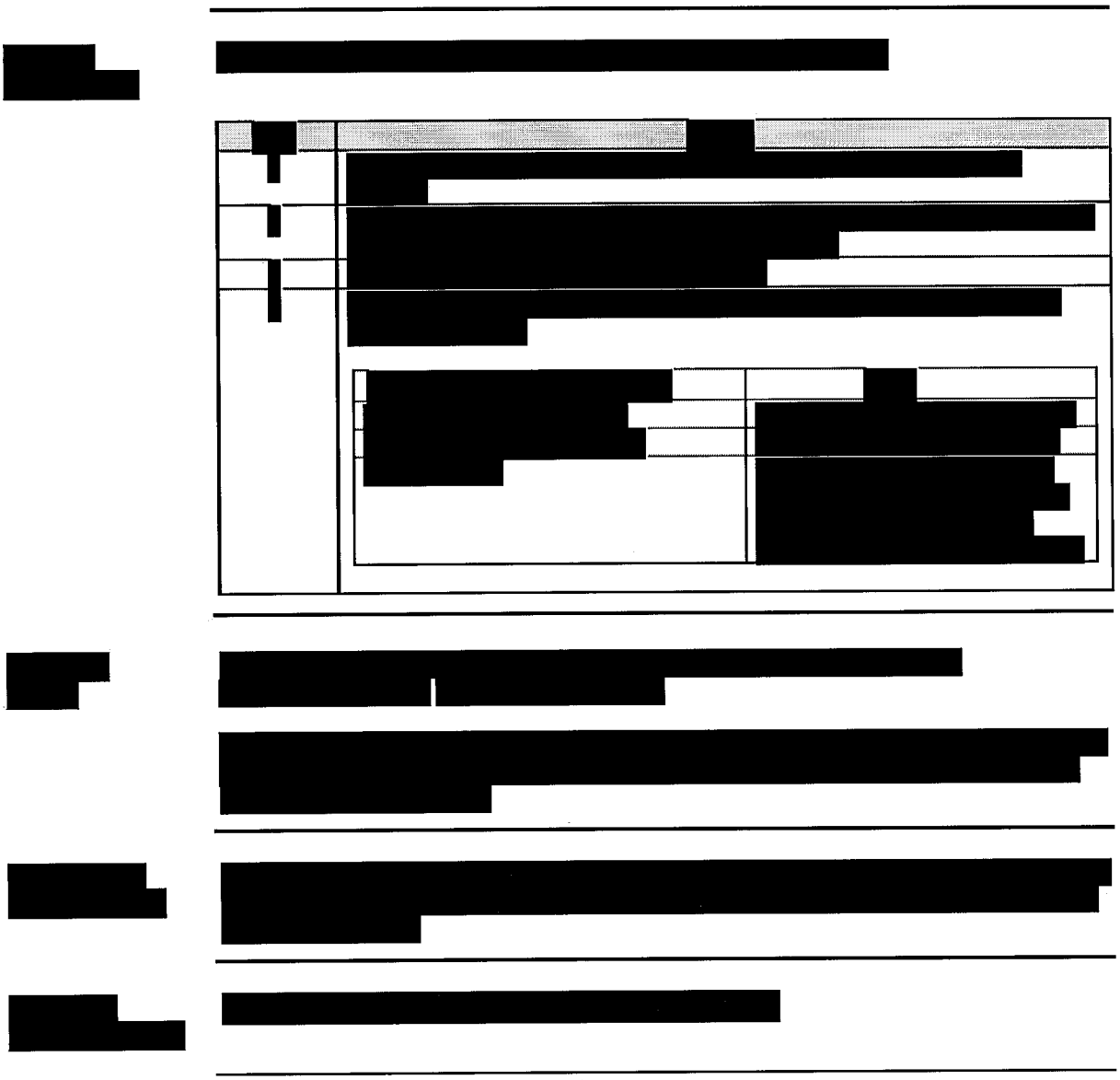

[redacted]BIOMICROSCOPY SCALE

[redacted] Biomicroscopy Scale

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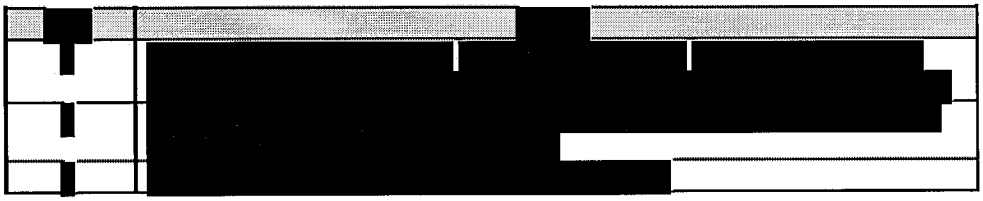

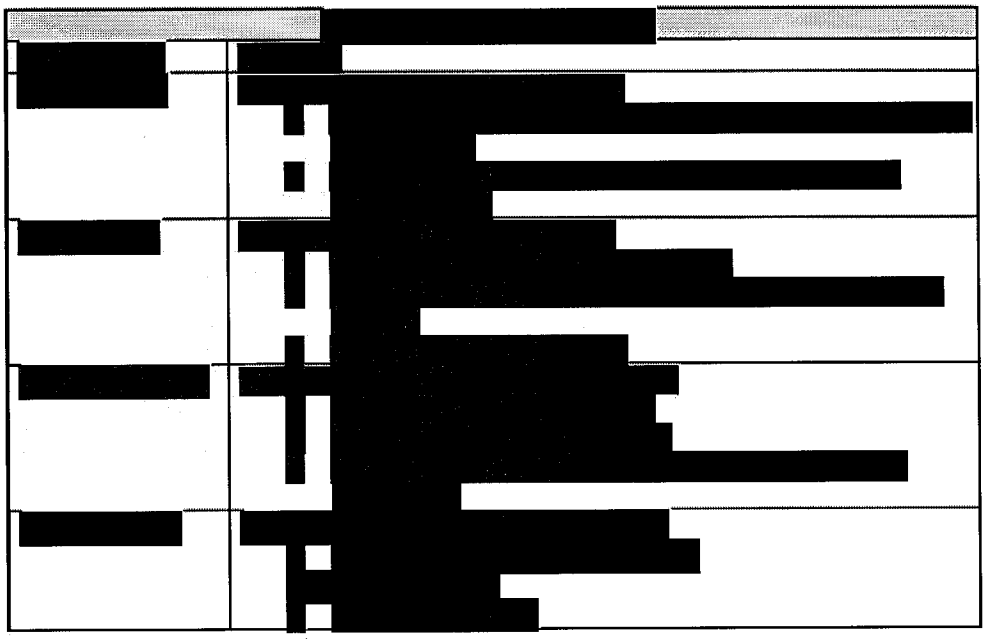

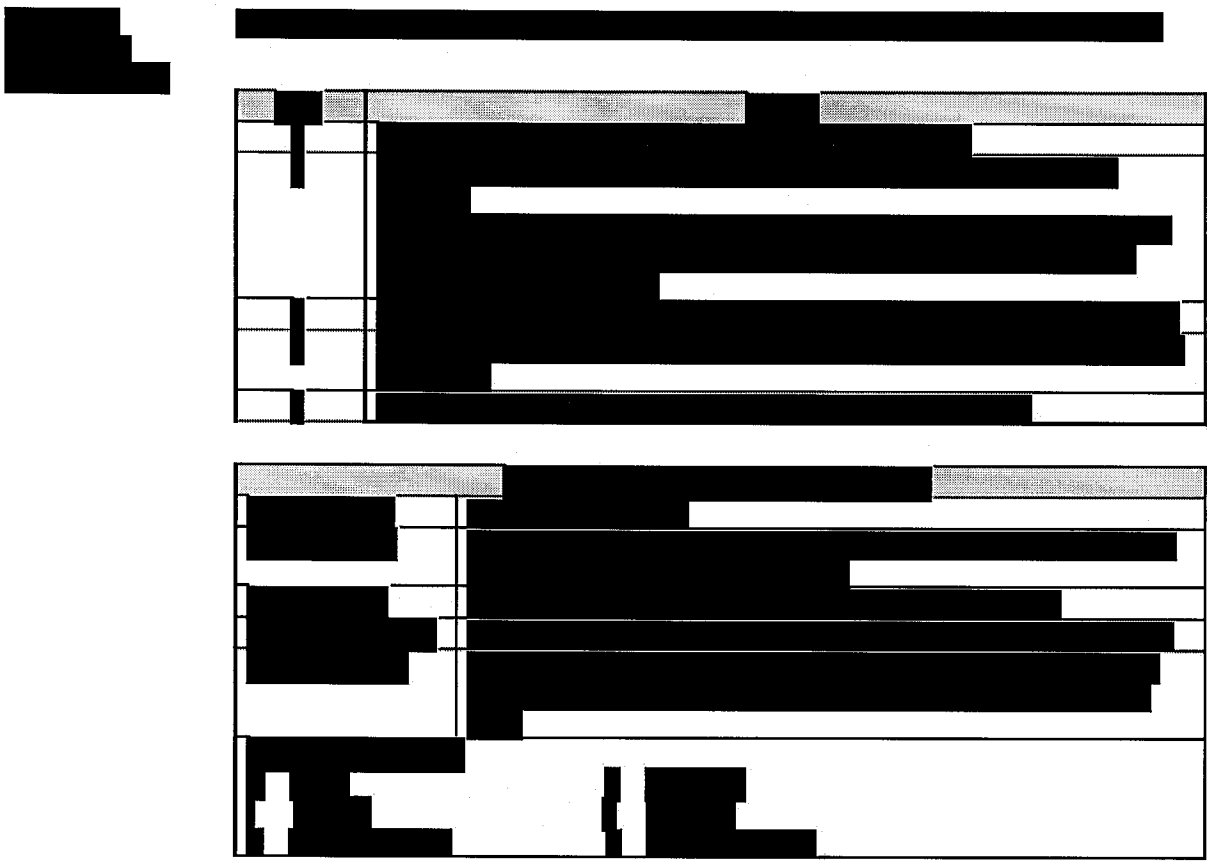

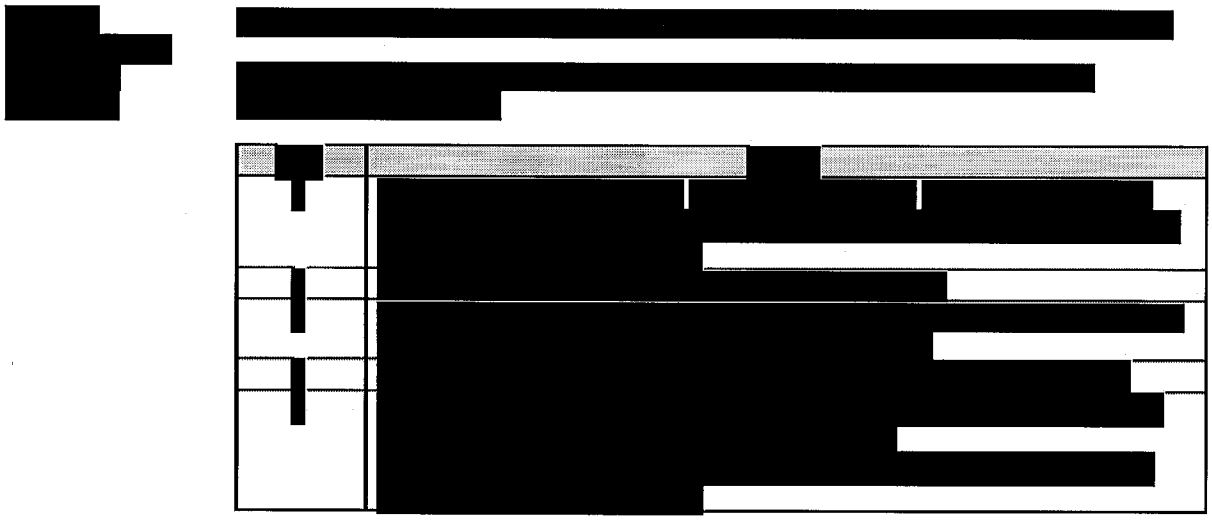

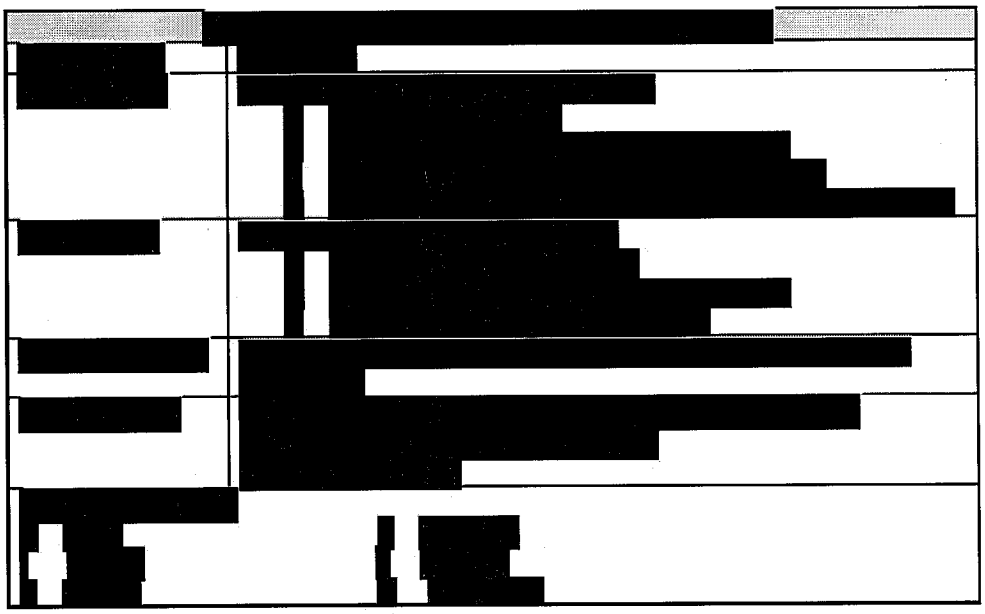

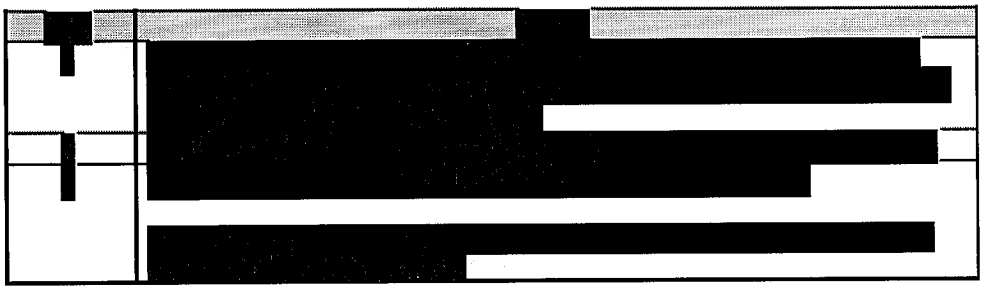

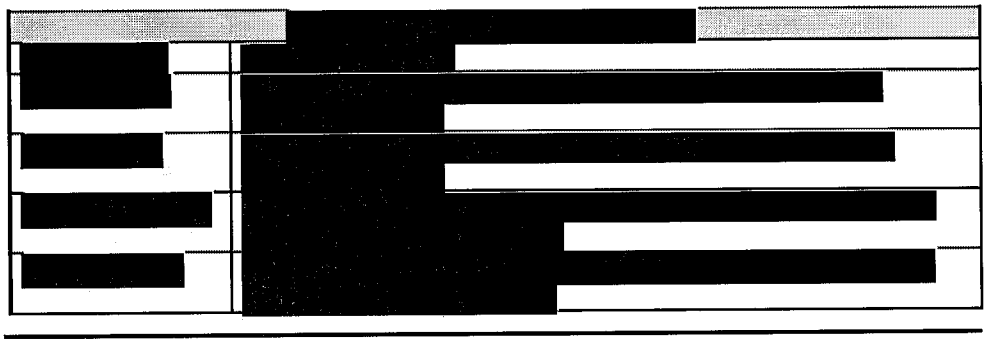

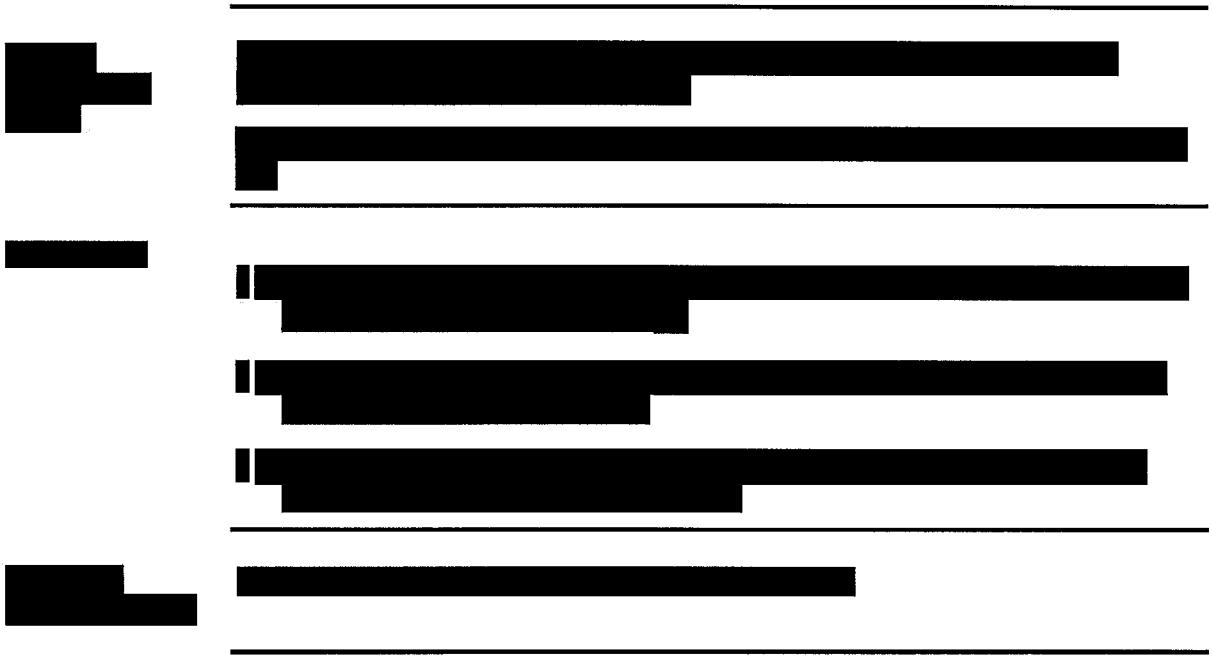

[redacted], KERATOMETRY PROCEDURE

[redacted] **Keratometry Procedure**

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[redacted] REQUIREMENTS

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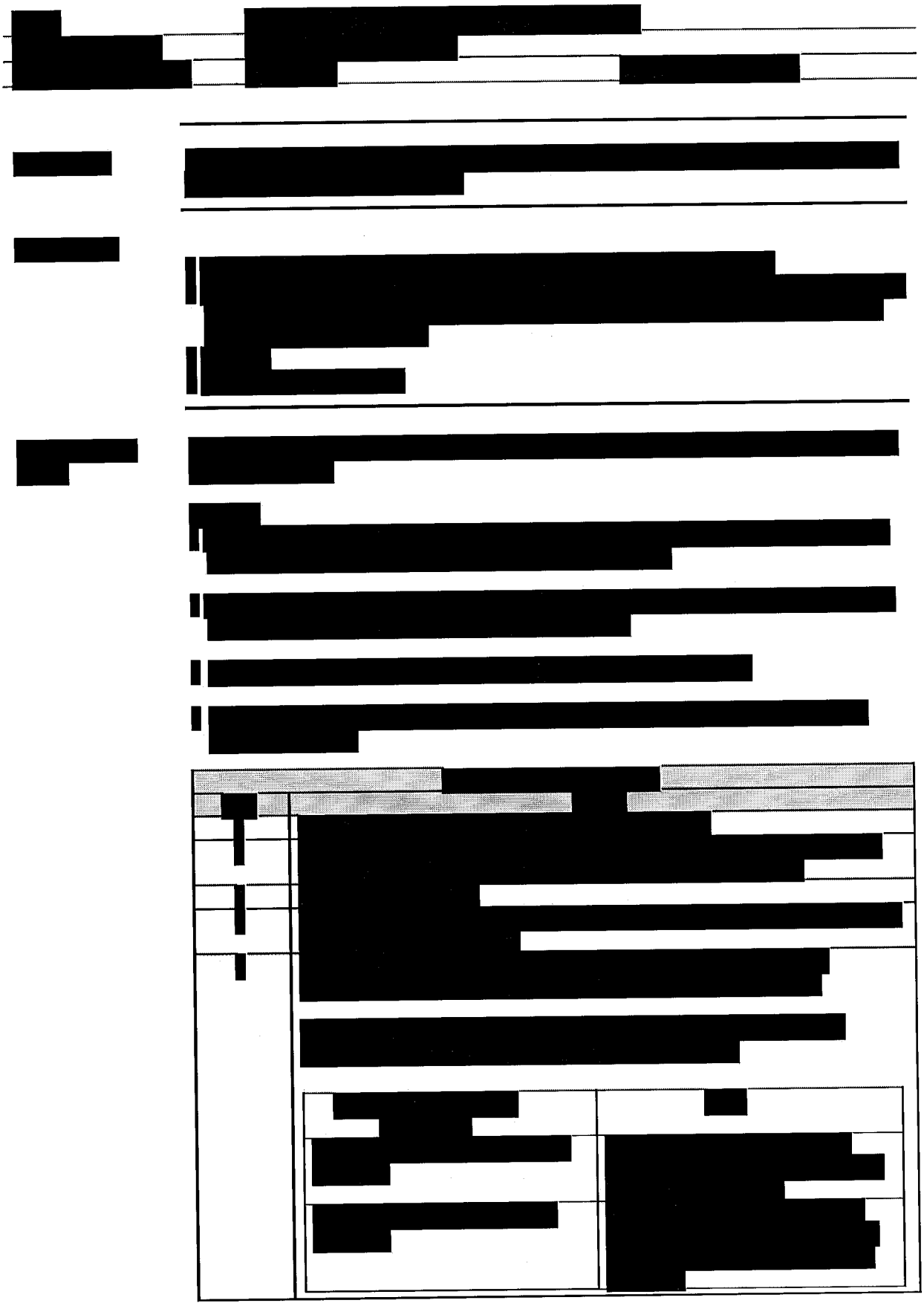

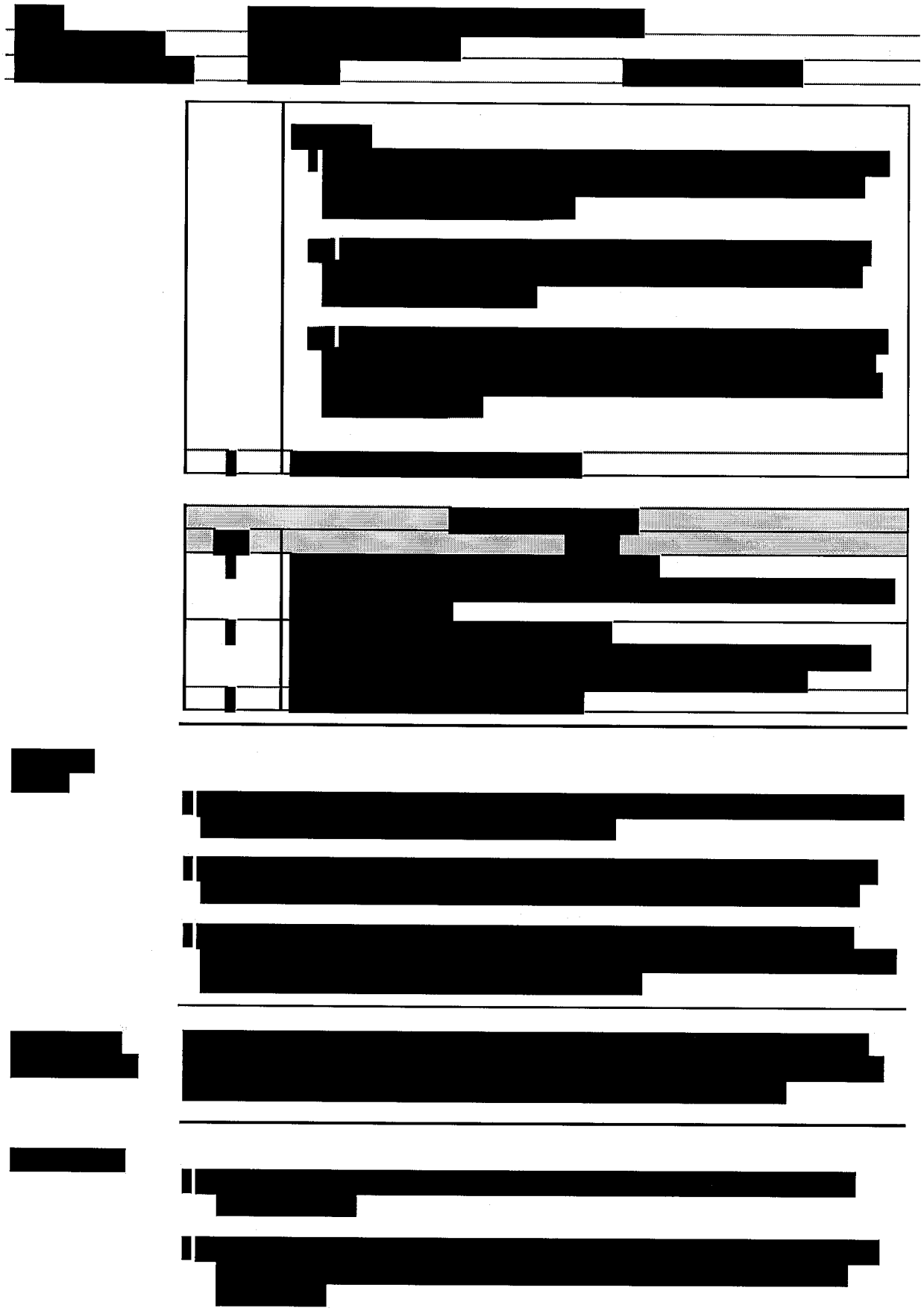

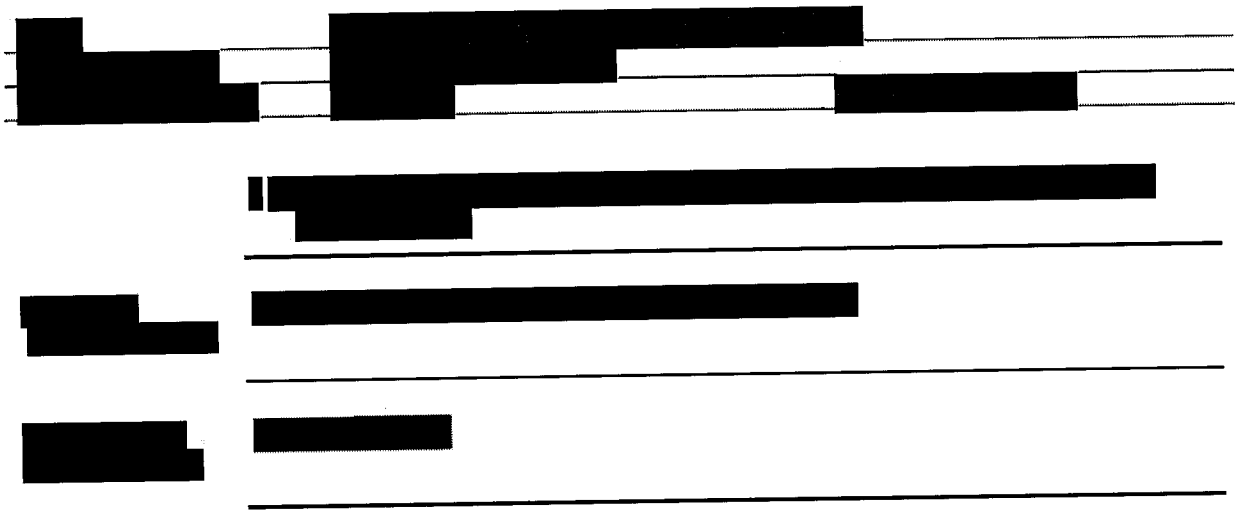

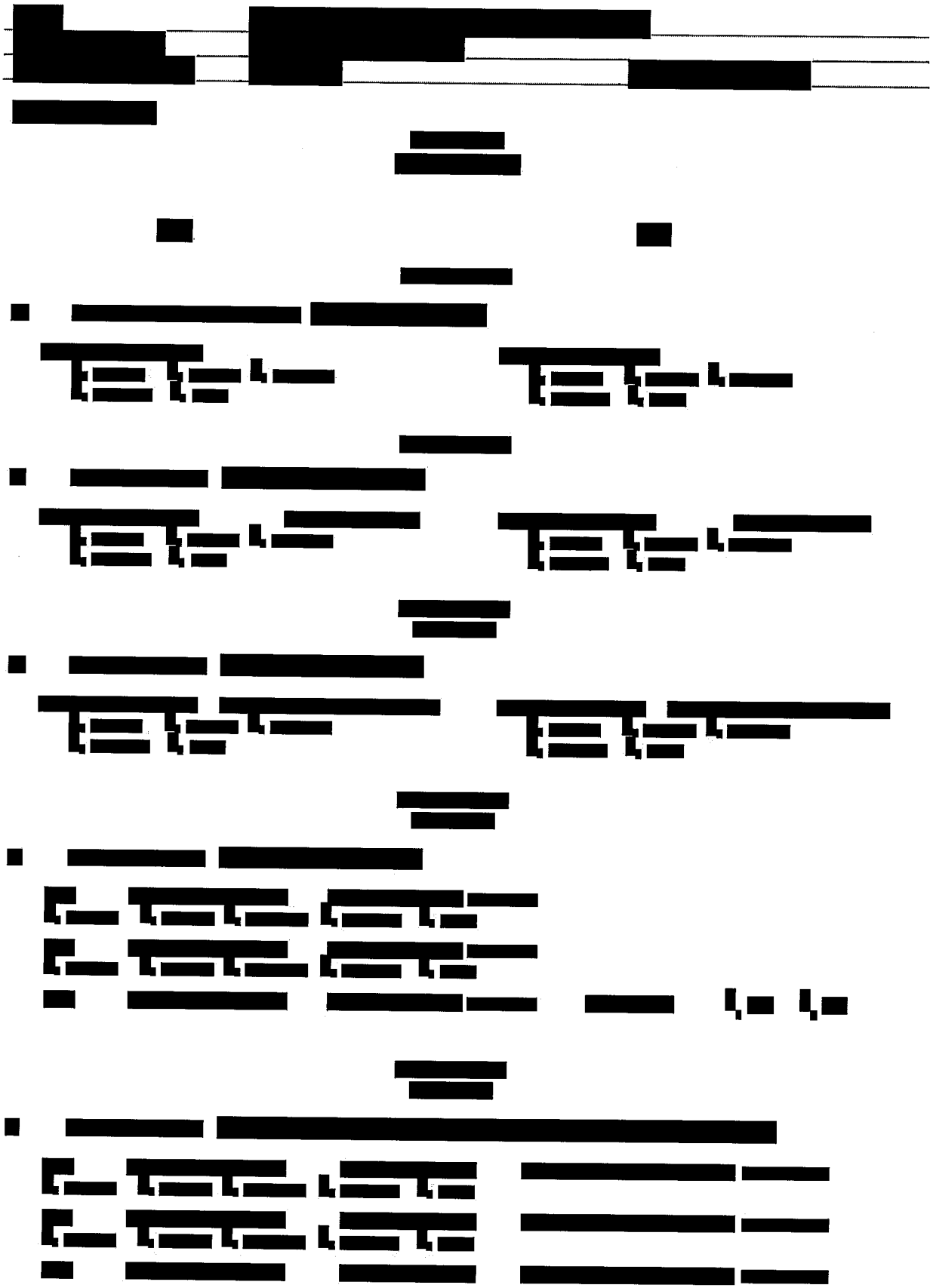

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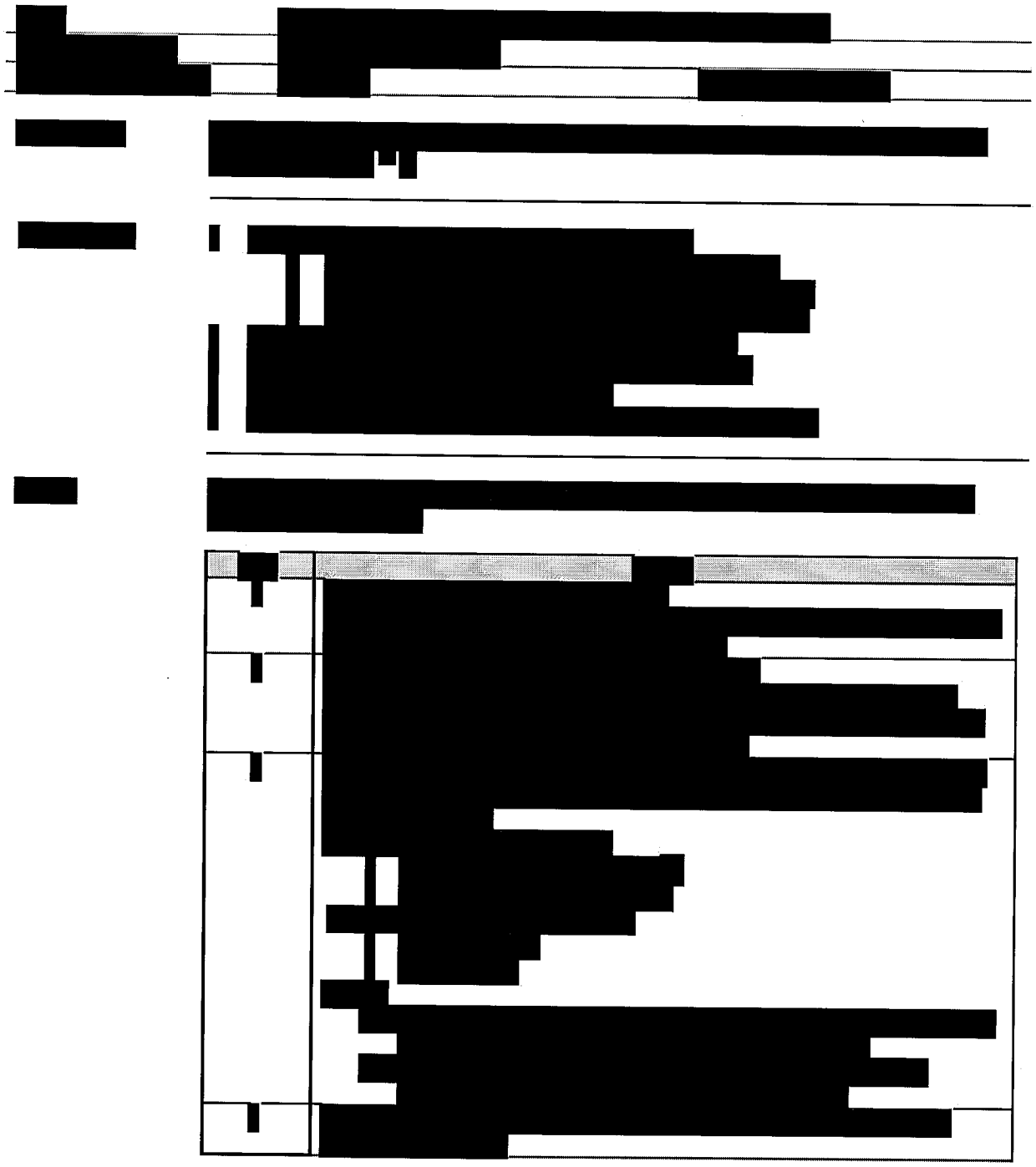

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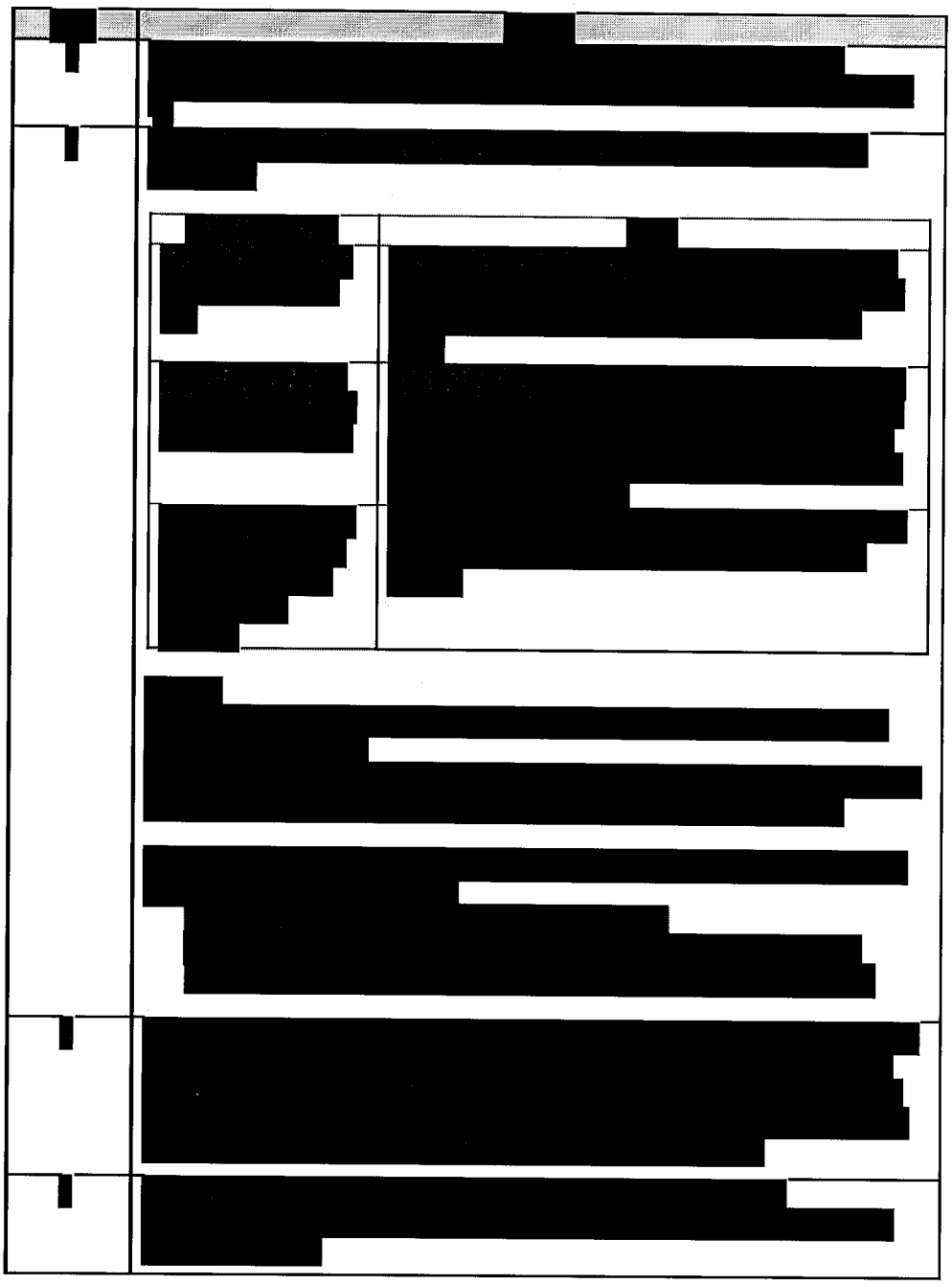

[redacted] MEASURING PUPIL DIAMETER WITH NEUROPTICS VIP-200 VARIABLE PUPILLOMETER

[redacted] Pupil Diameter with NeurOptics VIP-200 Variable Pupillometer

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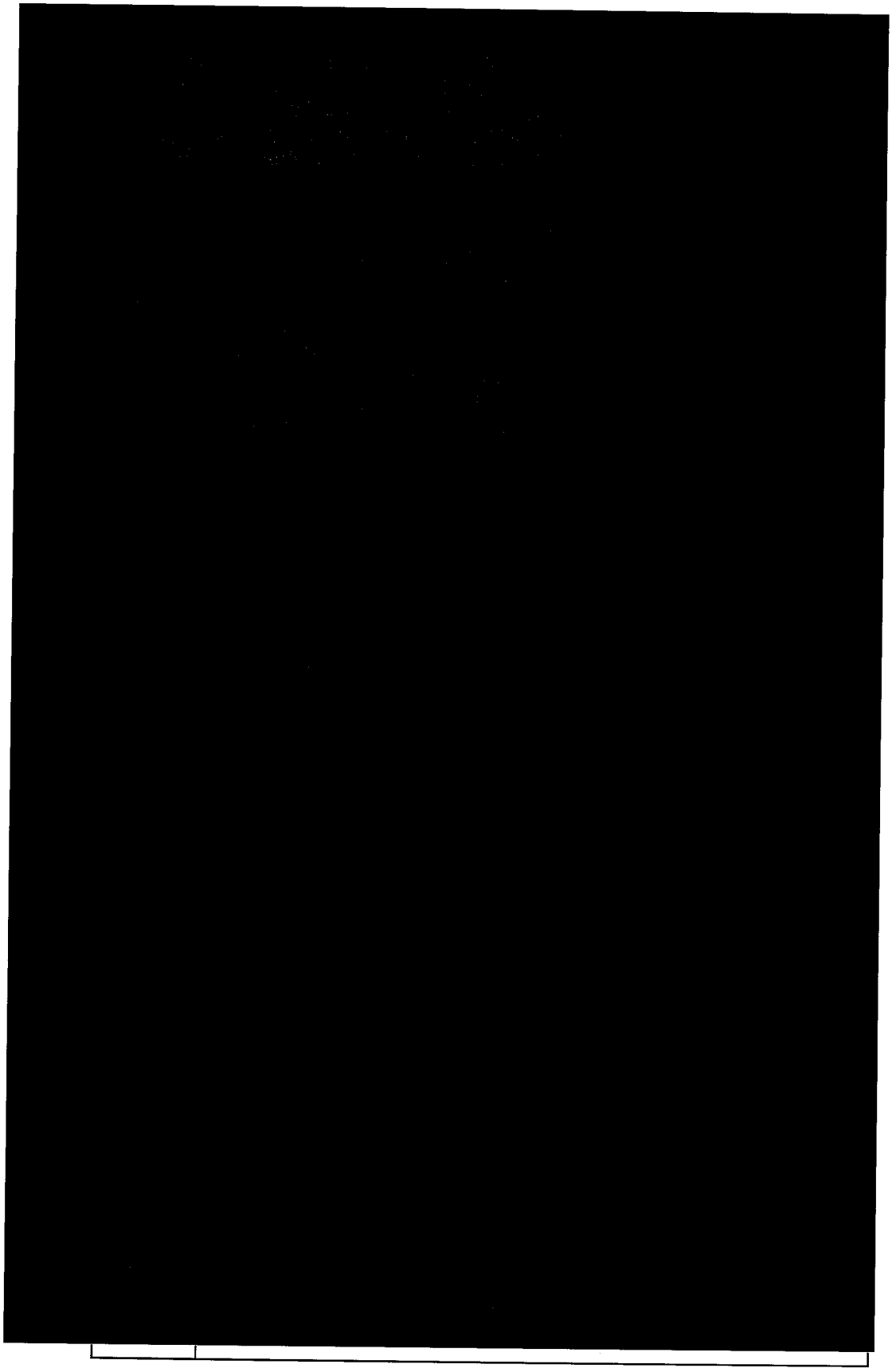

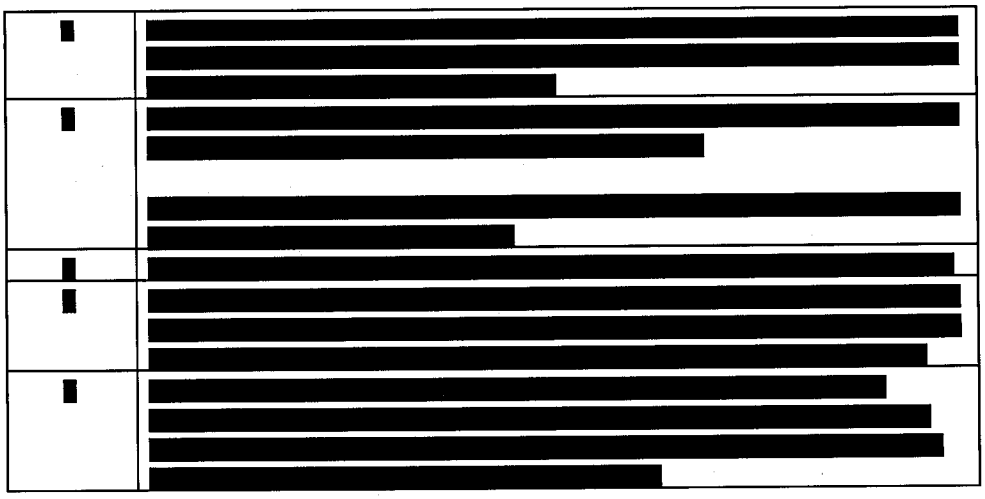

PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: CR-5860 Evaluation of Two Marketed Multifocal Contact Lenses
Version and Date: v3.0 Amendment 2.0, 01-SEPT-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 authorization.

Principal Investigator:

_____ _____
Signature Date

_____
Name and Professional Position (Printed)

Institution/Site:

_____
Institution/Site Name

_____
Institution/Site Address