



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (cwf)
FOLDER: K000795 - 358 pages
COMPANY: POLYMER TECHNOLOGY (POLYTECHG)
PRODUCT: LENS, CONTACT (OTHER MATERIAL) - DAILY (HQD)
SUMMARY: Product: RIGID GAS PERMEABLE CONTACT LENS

DATE REQUESTED: Aug 25, 2016

DATE PRINTED: Aug 25, 2016

Note: Printed



MAY 26 2000

510(k) Premarket Notification
BOSTON XO Contact Lens Material

K000795

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
BOSTON XO**

1. SUBMITTER INFORMATION:

Polymer Technology
Global Vision Care
1400 N. Goodman Street
Rochester, New York 14603-0450

2. CONTACT PERSON:

	Debra Ketchum Manager, Regulatory Affairs
Address:	1400 North Goodman Street P.O. Box 450 Rochester, New York 14603-0450
Telephone No.:	(716) 338-8638
Fax No.:	(716) 338-0702
E-mail Address:	dketchum@bausch.com

3. DEVICE IDENTIFICATION:

Classification Name:	Rigid Gas Permeable (hydrophobic) Contact Lens Material
Proprietary Name:	BOSTON XO (hexafocon A) Contact Lens Material
Common Name:	fluoro silicone acrylate rigid gas permeable contact lens material

4. PREDICATE DEVICE:

BOSTON ES (enflucocon A) has been selected as the predicate device for BOSTON XO (hexafocon A).

5. DESCRIPTION OF THE DEVICE:

The BOSTON XO Contact Lens Material, hexafocon A, is composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer.

The color additives conform to 21 CFR part 74.3206. The hexafocon A material has an oxygen permeability, DK of 100, a specific gravity of 1.26, and the lens visible light transmittance of at least 70%. The hexafocon A name has been adopted by the United States Adopted Names Council (USAN).

510(k) Premarket Notification
BOSTON XO Contact Lens Material

6. **INDICATIONS FOR USE:**

The *BOSTON XO* contact lens material is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfection system only.

7. **DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:**

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the *BOSTON XO* contact lens material. The results of all testing demonstrated that the safety and effectiveness of the *BOSTON XO* is equivalent to the currently marketed BOSTON ES contact lens material. A summary of these results from the preclinical studies is presented below.

Toxicology:

In-Vitro Cytotoxicity:

USP Agar Diffusion Cytotoxicity was completed in accordance with USP XXII. The test article meets the requirements of the Agar Diffusion Test.

Acute Ocular Irritation:

Acute Ocular Irritation test was performed and produced no ocular irritation.

Systemic Injection

The lens material meets the requirements of the Systemic Injection Test and is considered non-toxic.

Shelf Life:

The *BOSTON XO* (hexafocon A) is a hydrophobic rigid gas permeable contact lens material with <1% water content. This material will be shipped dry. The data presented supports substantial equivalence of this *BOSTON XO* (hexafocon A) contact lens material to the already marketed BOSTON ES (enflucocon A) contact lens material. Based on the Premarket Notification Guidance Document for Daily Wear Contact Lenses, May 12, 1994, shelf-life studies are not required for clearance of this material.

510(k) Premarket Notification
BOSTON XO Contact Lens Material

Solution Compatibility:

Studies were conducted on blue tinted lens material with the ultraviolet light absorber. Lenses were run through 30 cycles of cleaning and conditioning to establish the compatibility of the lens material with the recommended care regimen. The parameters of ultraviolet and visible light (UV/vis) spectra, base curve, lens diameter, power and surface quality were recorded prior to and upon completion of 30 cycles. Initial and final data were compared. There were no significant changes to lens parameters after 30 complete cycles.

Clinical Testing

Below is a summary of the clinical study carried out to evaluate the safety and efficacy of the *BOSTON XO* (hexafocon A) contact lens material when used as a daily wear contact lens for the correction of visual acuity.

A total of 128 eyes (64 patients) were entered into the study by 3 Investigators. Prior to entry into this study each patient was required to read and sign a Statement of Informed Consent. All patients who signed a Statement of Informed Consent are accounted for in this report. Of the 128 eyes (64 patients enrolled), 102 eyes (51 patients) completed the study.

The safety and efficacy measures for this study were:

Safety: Adverse Events, Positive Slit Lamp Findings,
Symptoms/Complaints and Keratometry Changes

Efficacy: Refractive Changes, Lens Visual Acuity, Lens VA Line
Changes, Lens Deposits, and Lens Wettability.

The sponsor concludes that *BOSTON XO* (hexafocon A) contact lens material is equivalent in safety and efficacy to the predicate device, Boston ES (enfluocon A).

8. SUBSTANTIAL EQUIVALENCE

The *BOSTON XO* contact lens material is substantially equivalent to the currently marketed *BOSTON ES* contact lens material, which was cleared in 510(k) Premarket Notification No. K943177 on August 25, 1994. The difference between the two devices is a change in the components.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 26 2000Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Debra L.B. Ketchum
Manager, Regulatory Affairs
Polymer Technology
Global Vision Care
1400 N Goodman Street
P.O. Box 450
Rochester, NY 14603-0450

Re: K000795
Trade Name: BOSTON XO Contact Lens
Regulatory Class: II
Product Code: 86 HQD
Dated: March 10, 2000
Received: March 13, 2000

Dear Ms. Ketchum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

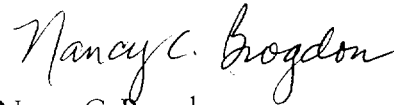
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Ms. Debra L.B. Ketchum

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) PREMARKET NOTIFICATION
BOSTON EO Contact Lens Material

Polymer Technology
1400 North Goodman Street
P.O. Box 450
Rochester, NY 14603-0450

Indications for Use Statement

510(k) Number (if known): K 000 795

Device Name: BOSTON XO

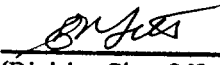
Indications for Use:

BOSTON XO (hexafocon A) Contact Lens Material is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfecting system only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter-Use


(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 000 795



**MAY 26 2000**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Debra L.B. Ketchum
Manager, Regulatory Affairs
Polymer Technology
Global Vision Care
1400 N Goodman Street
P.O. Box 450
Rochester, NY 14603-0450

Re: K000795
Trade Name: BOSTON XO Contact Lens
Regulatory Class: II
Product Code: 86 HQD
Dated: March 10, 2000
Received: March 13, 2000

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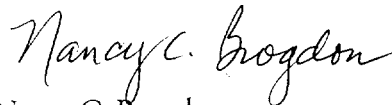
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Sincerely yours,



Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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510(K) PREMARKET NOTIFICATION
BOSTON EO Contact Lens Material

Polymer Technology
1400 North Goodman Street
P.O. Box 450
Rochester, NY 14603-0450

Indications for Use Statement

510(k) Number (if known): K 000 795

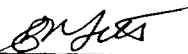
Device Name: BOSTON XO

Indications for Use:

BOSTON XO (hexafocon A) Contact Lens Material is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfecting system only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter-Use


(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 000 795



SE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Eleanor M. Felton

Subject: 510(k) Number K000795

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed (required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

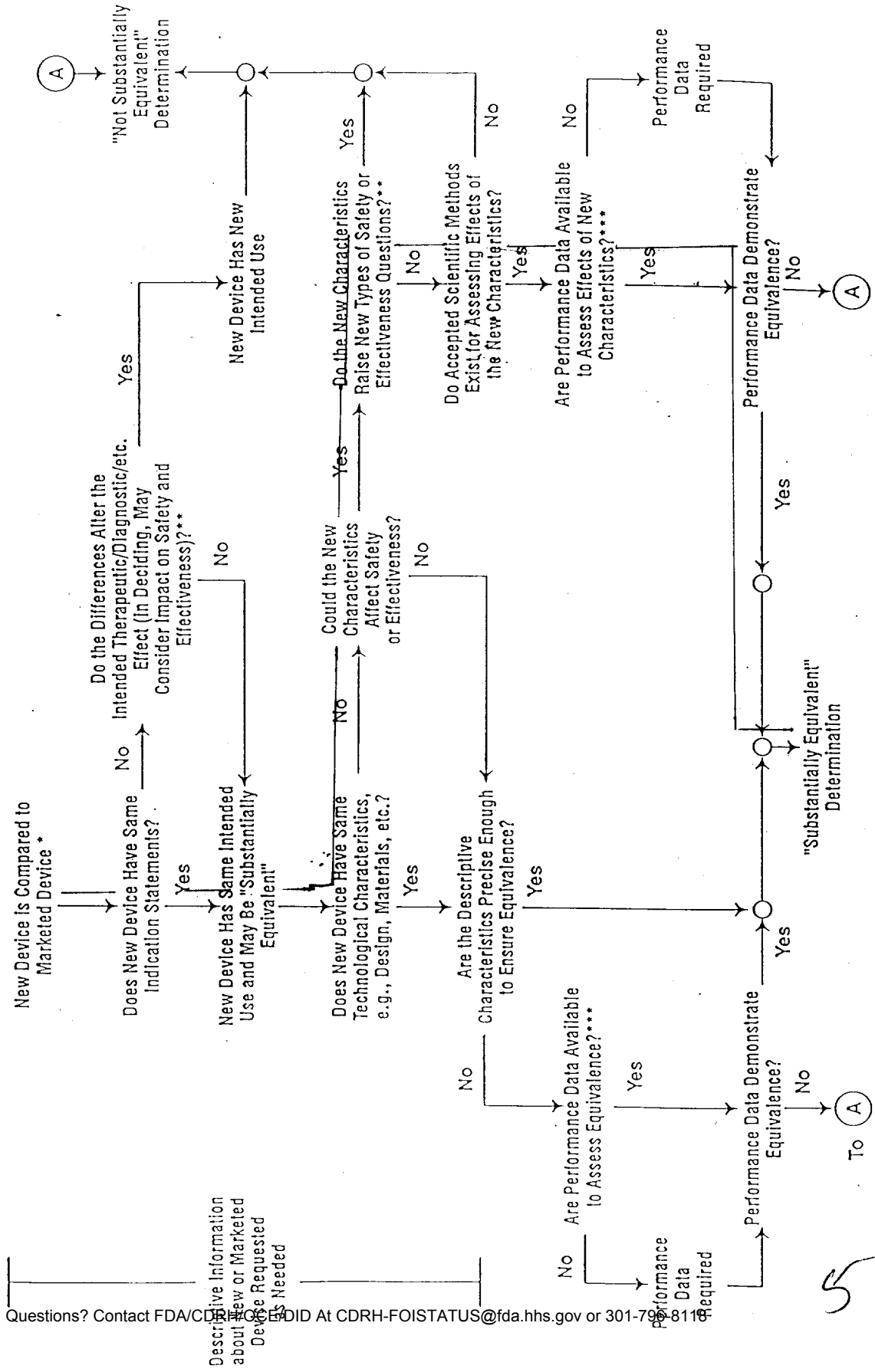
86 HQD class II

Review: Savoca VES 5/25/00
(Branch Chief) (Branch Code) (Date)

Final Review: Nancy C Brogdon 5-25-00
(Division Director) (Date)

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510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Questions? Contact FDA/CDRH at FOIA@fda.hhs.gov or 301-795-8111

* 510(k) Submissions/Additional Information (Pre-Amendments) (Classified Post-Amendments) Devices Is Unclear.
 ** This Decision is Primarily Based on Descriptive Information Alone, But Limited Technical Information Is Sometimes Required.
 *** Data May Be in 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K000795

Reviewer: Eleanor M. Felton

Division/Branch: DOD / VEDB

Device Name: Boston DXD (hexaflexin A) RGP contact lens

Product To Which Compared (510(K) Number If Known): K980741

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?		✓	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	✓		If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		✓	If YES = Stop NE
9. Accepted Scientific Methods Exist?	✓		If NO = Stop NE
10. Performance Data Available?	✓		If NO = Request Data
11. Data Demonstrate Equivalence?	✓		Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. **Intended Use:** The BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes. These lenses may be disinfected using a chemical disinfecting system only.
2. **Device Description:** The device has the same designs and indications for use as the predicate device. The device is manufactured from a new lens material, hexafocon A. The device is not life-supporting or life sustaining; is not implanted (short-term or long-term); does not use software; is shipped non-sterile; is supplied for multiple use; is for home use as a prescription device; does not contain drug or biological product as a component; and is not a kit. The application contains the appropriate draft proposed labeling for the device. Additionally, the application contains the necessary chemistry/manufacturing information, clinical study of 102 eyes completing 3 months, and toxicology testing which included Cytotoxicity, Acute Systemic Toxicity and Primary Ocular Irritation tests. The results of these tests demonstrated that the device is safe and effective for use and is substantially equivalent to the predicate device.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED


1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics: The device is manufactured from a new lens material, hexafocon A.
6. Explain how new characteristics could or could not affect safety or effectiveness: The new material underwent toxicology testing and the applicant provided chemistry/manufacturing information, and clinical testing which demonstrated that the device is safe and effective for its intended use.
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new: Based upon the information in the application, there are no new safety or effectiveness questions because the toxicology, clinical and chemistry/manufacturing information addressed the potential concerns.
9. Explain why existing scientific methods can not be used:

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10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: The toxicology data demonstrated that the device is safe and non-toxic and non-cytotoxic, the clinical data demonstrated that the lenses are effective in correcting visual acuity in the proposed patient population. The special controls, i.e., labeling is appropriate for the device. This device is substantially equivalent to the predicate device.

ATTACH ADDITIONAL SUPPORTING INFORMATION

8

Date: May 18, 2000
From: Eleanor M. Felton, HFZ-460 
To: Record
Subject: BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lens for Daily Wear
Review of Amendment and Decision Memo
K000795

On May 17, 2000 I received a fax from Polymer Technology which contained revised labeling for the subject device. The changes requested were provided. The changed included deleting all reference to the lens material being the #1 doctor recommended, inclusion of the bifocal/multifocal lens into the Professional Fitting Guide with the other lens designs, and including the bifocal/multifocal in all other parts of the labeling. The subject device is substantially equivalent to the predicate device.

Date: May 11, 2000
From: Eleanor M. Felton, HFZ-460 *EMF*
To: Record
Subject: BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lens for Daily Wear
Review of Amendment and Decision Memo
K000795

On May 1, 2000 Polymer Technology provided a response to the concerns sent to them on April 17, 2000. This information was reviewed and determined to be deficient in the area of labeling, with all other areas responded to appropriately. A chemistry review May 9, 2000 determined the device to be substantially equivalent to the predicate device. The applicant provided responses to the clinical concerns regarding decreases in visual acuity and identifying "other" symptoms. The applicant has provided a Disclosure Statement for the clinical investigators, and provided revised labeling. The labeling remains deficient because the applicant promotes the lenses as "The #1 Doctor Recommended RGP Material". This is a new lens material and therefore cannot be the #1 doctor recommended material unless the device was marketed prior to notification to FDA. Additionally, the labeling now makes reference to a multifocal lens (not previously mentioned). The applicant can keep it in the labeling but it should be noted that this was not reflected in the previously provided labeling. The labeling for the bifocal/multifocal should either be included in the Professional Fitting Guide or, if the applicant desires to keep it separate, provide a complete Fitting Guide for the bifocal/multifocal. Additionally, multifocal should be included in other parts of the labeling.

In a telephone call to Debra Ketchum on May 16, 2000 I informed her of the above mentioned deficiencies. Ms. Ketchum stated that she would send revisions.

10

Records processed under FOIA Request #2016-1776 Released ON 8/31/16

*** TX REPORT ***

TRANSMISSION OK

TX/RX NO 0805
CONNECTION TEL 917163380702
SUBADDRESS
CONNECTION ID
ST. TIME 04/18 13:26
USAGE T 02'59
PGS. 2
RESULT OK



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CDRH Division of Ophthalmic Devices

9200 Corporate Boulevard
Rockville, MD 20850
FAX NO. 301 480-4201
or 301 827-4601

Date: 4-18-00 Time: _____
To: Debra Katcham FAX #: _____
Organization: Polymer Technology
From: Eleanor Felton
Department: FOA
Subject: Boston XO
No. of Pages: 2
(Including Cover Sheet)
Comments:

As Requested FYI Read and Destroy

Response Needed Signature Circulate
Questions? Contact FDA CDRH/DOE/DISA/CDRH/FOI/STATUS@fda.hhs.gov or 301-796-8118

11



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CDRH Division of Ophthalmic Devices

9200 Corporate Boulevard
Rockville, MD 20850
FAX NO. 301 480-4201
or 301 827-4601

Date: 4-18-00 Time: _____

To: Debra Katchum FAX #: _____

Organization: Polymer Technology

From: Eleanor Felton

Department: FDA

Subject: Boston XU

No. of Pages: 2
(Including Cover Sheet)

Comments:

- As Requested FYI Read and Destroy
- Response Needed Signature Circulate
- For Correction Investigate File

Division Director's Office	301 594-2205
Diagnostic and Surgical Devices Branch	301 594-2018
Vitreoretinal and Extraocular Devices Branch	301 594-1744
Intraocular and Corneal Implants Branch	301 594-2053
Mail Code: HFZ 460	

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12

Date: April 17, 2000
From: Eleanor M. Felton, HFZ-460 *EMF*
To: Record
Subject: Boston XO Rigid Gas Permeable Contact Lens for Daily Wear
K000795
Memo of Telephone Conversation

On April 17, 2000 I called and spoke with Debra Ketchum of Polymer Technology and provided her with the following deficiencies, concerns, and/or issues for clarification:

The applicant has not provided Disclosure Statements for the clinical investigators.

The labeling, as proposed, is deficient because of the following:

1. The applicant has not provided shipping labels for the device.
2. The lens description in the package insert and the fitting guide does not show add powers for presbyopia.
3. The fitting guide does not have cylinder powers
4. The labeling (overall) does not show the amount of light transmission
5. The fitting guide does not provide guidance for fitting the presbyopic patient
6. The fitting guide contains a precaution regarding reduction in visibility. This precaution is not provided in any labeling for the patient (the one that really needs to know).

(b)(4)



Identify "Other" symptoms, problems and complaints and reasons for lens replacement.

Correct the typo on page 198.

Provide an engineering drawing of each lens configuration for which clearance is requested.

Provide the manufacturing information regarding thermal polymerization conditions and alternate designs (e.g. aspheric, bifocal, and toric).

FROM: Daniel W. C. Brown, Ph.D., Ophthalmic Toxicologist

DWB
4/10/2008

K000795 Boston XO Contact Lens Material

TOXICOLOGICAL REVIEW and RECOMMENDATION

CYTOTOXICITY

(b)(4)



Result: As tested, the extract (lenses) was non-cytotoxic.

ACUTE SYSTEMIC TOXICITY

(b)(4)



Result: Non-toxic.

PRIMARY OCULAR IRRITATION

(b)(4)



14

Result: As tested, the extracts were non-irritating to ocular tissues.

CONCLUSION: The toxicological data submitted in this document is appropriate and adheres to the toxicology guidance as suggested in the guidance document, **PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES, 1994**. The data supports the sponsor's contention that the device is biocompatible and is safe for its intended use. Therefore, the referenced device is recommended for **APPROVAL** from a toxicological aspect.

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Addendum to a Chemistry Review Dated April 3, 2000

This amendment (K000795/A1) is in response to deficiencies listed in the chemistry review dated April 3, 2000.


(b)(4)



Comment: Satisfactory

Recommendation

The sponsor has submitted responses for the deficiencies satisfactorily. Approval is recommended from a chemistry perspective.


Tzeng M. Chen, Ph.D. 5/9/2000

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From: Chemist (HFZ-460)

To: The Record

Subject: Manufacturing/Chemistry Review for Boston (hexafocon A) XO RGP Contact Lens, submitted by Polymer Technology (K000795)

Introduction:

The Boston (hexafocon A) XO RGP Contact Lens, a fluorosilicone contact lens, is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfection system only. The sponsor claims that the referenced device is substantially equivalent to Boston ES RGP Contact Lens (K943177).

Manufacturing/Chemistry Review

- 1. Chemical composition, (b)(4)

Component	Weight %	Mole %	Function
(b)(4)			

Comment: Satisfactory

- 2. Manufacturing information, (b)(4) and Appendix 4

(b)(4)

Comment: The manufacturing information about thermal polymerization conditions and alternate designs (e.g., aspheric, bifocal and toric) was not submitted.

- 3. Lens-solution compatibility, (b)(4)

Care regimen tested: (b)(4) on (b)(4) g (b)(4)
: (b)(4), (b)(4)
\$

19

Results: P61-124

The parameters were not significantly changed after 30 cycles.

Comment: Satisfactory

4. Physicochemical properties comparison, (b)(4)

Physicochemical properties	Boston XO	Boston ES
(b)(4)		

Comment: Satisfactory

Recommendation

Boston (hexafocon A) XO RGP Contact lenses are a flurosilicone acrylate contact lenses, same as the predicate device (Boston ES). The sponsor has not submitted the manufacturing information about thermal polymerizations and alternate designs (e.g., aspheric, bifocal and toric). Upon submitting this information satisfactorily from the sponsor, approval is recommended from a manufacturing/chemistry perspective.


Zeng M. Chen, Ph.D.

4/3/00



Date: April 3, 2000
From: Eleanor M. Felton, HFZ-460
To: Record
Subject: BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lens for Daily Wear
K000795
Decision Memo

On March 13, 2000 FDA received a premarket notification (510(k)) application from Polymer Technology Corporation which requested clearance for the BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lens for Daily Wear. The developmental names used for are Quantum II, RD-171, and B7-100. These names also appear at various points within the document. Based upon the limited information submitted, it appears that the applicant intends to market the lenses in spherical, aspherical, toric, and bifocal configurations.

The applicant states that the lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

The applicant claims the subject device to be substantially equivalent to the BOSTON ES (enflucocon A) RGP contact lens material, which was determined to be SE on August 25, 1994 in 510(k) K943177 and K980741. Additionally, the applicant states that Quantum II (hexafocon A) and the BOSTON XO (hexafocon A) are the same with the exception of the BOSTON XO containing 0.5% of a polymerizable ultraviolet blocker.

The applicant provided data and information on the chemistry of the device, toxicological studies of the device, a clinical study of the spherical configuration of the lens, and proposed labeling.

*The applicant has not provided Disclosure Statements for the clinical investigators.

The application contains a copy of a letter from USAN, which shows the nonproprietary name for the device. Proposed labeling for the device consists of a professional fitting guide, package insert, and a patient care guide. The labeling, as proposed, is deficient because of the following:

1. The applicant has not provided shipping labels for the device.
2. The lens description in the package insert and the fitting guide does not show add powers for presbyopia.
3. The fitting guide does not have cylinder powers
4. The labeling (overall) does not show the amount of light transmission
5. The fitting guide does not provide guidance for fitting the presbyopic patient

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6. The fitting guide contains a precaution regarding reduction in visibility. This precaution is not provided in any labeling for the patient (the one that really needs to know).

The applicant conducted a clinical study of the subject device and the following was noted:

BOSTON XO

(b)(4)



*Other is not explained or specified.

Discontinued Patients

(b)(4)



RECOMMENDATION: I recommend that the applicant be called and asked to provide a respond to the following:

The applicant has not provided Disclosure Statements for the clinical investigators.

The labeling, as proposed, is deficient because of the following:

1. The applicant has not provided shipping labels for the device.
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5. The fitting guide does not provide guidance for fitting the presbyopic patient
6. The fitting guide contains a precaution regarding reduction in visibility. This precaution is not provided in any labeling for the patient (the one that really needs to know).

(b)(4)



Identify "Other" symptoms, problems and complaints and reasons for lens replacement.

Correct the typo on page 198.

Provide an engineering drawing of each lens configuration for which clearance is requested.

Provide the manufacturing information regarding thermal polymerization conditions and alternate designs (e.g. aspheric, bifocal, and toric).

Concur: *Bernard P. Lepore* Date: 4/10/00

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Screening Checklist For all Premarket Notification 510(k) Submissions

Device Name: Boston XO (hereafter A) RGP Lens						K060795						
Submitter (Company):												
Items which should be included (circle missing & needed information)						S P E C I A L	A B B R E V I A T E D		T R A D I T I O N A L		✓ IF ITEM IS NEEDED AND IS MISSING	
						YES	NO	YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as:												
a) "Special 510(k): Device Modification"										✓		
b) "Abbreviated 510(k)"												
c) Traditional 510(k)						GO TO # 2,3		GO TO # 2,4,5		GO TO #2 4,5		
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS												✓ IF ITEM IS NEEDED
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)						NA		YES		NO		✓
						SPECIALS		ABBREVIATED		TRADITIONAL		AND IS
						YES	NO	YES	NO	YES	NO	MISSING
a) trade name, classification name, establishment registration number, device class												
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA						
d) compliance with Section 514 - performance standards						NA						
e) address of manufacturer												
f) Truthful and Accurate Statement												
g) Indications for Use enclosure												
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)												
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)												
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals												
k) Proposed Labeling:												
i) package labeling (user info)												
ii) statement of intended use												
iii) advertisements or promotional materials												
i) MRI compatibility (if claimed)												
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:												
i) Labeling												
ii) intended use												
iii) physical characteristics												
iv) anatomical sites of use												
v) performance (bench, animal, clinical) testing						NA						
vi) safety characteristics						NA						
m) If kit, kit certification												
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE												
a) Name & 510(k) number of legally marketed (unmodified) predicate device												25
b) STATEMENT - INTENDED USE AND INDICATIONS FOR												
												* If no - STOP not a special

USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							26

inapplicable requirements or deviations noted below			
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No
 Date: 3/16/02

Reviewer: [Signature]
 Concurrence by Review Branch: [Signature]
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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	✓	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

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TELEFAX**POLYMER TECHNOLOGY**

Vision Care Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

Tel: 001-716-338-8638
Fax: 001-716-338-0702

To: Eleanor Felton
Fax: 301 480 4201
From: Debra Ketchum
Date: 5/17/00

**Pages including this
cover page:** 31

Dear Eleanor,

Attached is the revised labeling discussed yesterday. The revisions reflect the following:

1. The Bifocal/Multifocal Fitting Procedure has been included in the Professional Fitting and Information Guide.
2. In the Introduction section of the Patient Care Guide, "Bifocal/Multifocal" has been added.
3. The front pages of the Professional Fitting Information Guide, Package Insert and Patient Care Guide include "Bifocal/Multifocal".
4. The parameter sections of the Professional Fitting Information Guide and Package Insert reflect "Bifocal/Multifocal" parameters.
5. In the Wearing Restrictions and Indications Section of the Patient Care Guide, "daily" has been added.
6. "#1 Doctor Recommended RGP Material" has been removed from the flat pack card.

Should you have any questions, please contact me.

Sincerely,



Debra Ketchum
Manager, Regulatory Affairs

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PROFESSIONAL FITTING AND INFORMATION GUIDE

BOSTON[®] XO
(hexafocon A)

*Spherical & Aspherical Contact
Lenses for Myopia & Hyperopia,
Bifocal/Multifocal Contact Lenses for
Presbyopia and Toric Lenses
to Correct Astigmatism in
Not aphakic and Aphakic Persons*

CAUTION:
*Federal Law Prohibits Dispensing
Without a Prescription*

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- Introduction
- Product Description - BOSTON® XO
- Lens Parameters Available - BOSTON® XO
- Actions
- Indications
- Contraindications, Warnings, Precautions, and Adverse Reactions
- Selection of Patients
- Fitting Procedure Outline
 - Pre-Fitting Examination
 - Initial Lens Diameter Selection
 - Initial Lens Base Curve Selection
 - Initial Lens Evaluation
 - Initial Lens Power Selection
 - Initial Lens Center Thickness Selection
 - Remaining Lens Parameter Selection
 - Follow-up Care
- In-Office Care of Trial Lenses
- Recommended Initial Wearing Schedule
- Clinical Assessment
 - Criteria of a Well-fitted Lens
 - Optimizing Fitting Characteristics
 - Problem Solving
- Bifocal/Multifocal Fitting Procedure
- Monovision Fitting Guidelines
- Patient Lens Care Directions
- Care for a Sticking (Non-Moving) Lens
- Laboratory Lens Cleaner
- In-Office Lens Modifications
- Removal of Surface Deposits
- Reporting of Adverse Reactions
- How Supplied

PRODUCT DESCRIPTION - BOSTON XO

The BOSTON XO Contact Lens material, hexafocon A, is composed of aliphatic siloxanyl fluoromethacrylate copolymer with an ultraviolet absorber. The tinted lenses contain the following color additives:

Color	Color Additive
Ice Blue	D & C Green No. 6
Violet	D & C Violet No. 2

The BOSTON XO Contact Lenses are a hemispherical shell of the following dimensions:

Spherical Lens Design	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	5.00 mm to 9.00 mm in .01 mm increments
Aspherical Lens Designs	
<i>(Some of these designs are patented; manufacture of these lenses in Boston XO (hexafocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.00 mm to 9.20 mm in 0.01 mm increments
Bifocal/Multifocal Lens Designs	
<i>(Some of these designs are patented; manufacture of these lenses in Boston XO (hexafocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	8.5 mm to 11.5 mm
Base Curve Range	6.30 mm to 9.50 mm in 0.01 mm increments
Segment Heights	-2.00 mm to +1.00 mm in 0.5 mm increments
Add Powers	+1.00D to +3.75D in 0.5D increments
Prism Ballast	0.5 to 3.5 prism diopters in 0.5D increments
Toric Lens Designs	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.80 mm to 9.50 mm in 0.01 mm increments
Toricity	Up to 9.00 Diopters

The lenses described above can have a center thickness of 0.07 to 0.65 mm that will vary with lens design, power and diameter.

The physical/optical properties of the lens are:

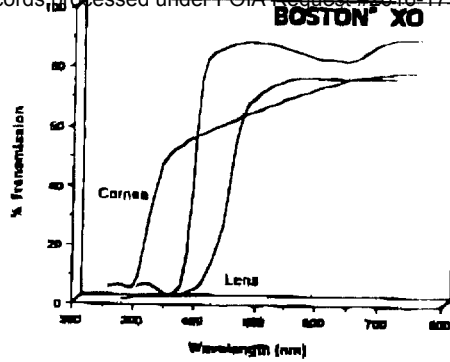
Specific Gravity	1.27
Refractive Index	1.415
Light Absorbance (640 nm)	4.6 Ice Blue
(Absorbance units/inch)	5.5 Violet
Light Transmittance*	92%
*Average %T (400-800nm)	
Surface Character	Hydrophobic
Wetting Angle	49°
Water Content	<1%
Oxygen Permeability	140* (100**)
(x 10 ⁻¹¹ (cm ³ O ₂ · cm)/(cm ² · sec · mmHg) @ 35° C)	

**polarographic method (ISO/Fatu)

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BOSTON XO - 0.07 mm thick BOSTON XO (Ice Blue)
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.
CRYSTALLINE 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, figure 5.

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.

WARNING

UV-absorbing contact lenses are **NOT** substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

ACTIONS

BOSTON XO Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina.

INDICATIONS

BOSTON XO Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. These lenses may be disinfected using a chemical disinfecting system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE BOSTON XO Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the BOSTON XO Contact Lenses
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

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 eyecare practitioner's directions 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 eyecare practitioner.

PRECAUTIONS

Practitioner Note: BOSTON XO Contact Lenses are not sterile when shipped from the Authorized BOSTON Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

- Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness:
- | Color | Center Thickness |
|----------|------------------|
| Ice Blue | >0.65 mm |
| Violet | >0.65 mm |

Special Precautions for Eyecare Practitioners:

- 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 eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.
- 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.
- Aphakic patients should not be fitted with BOSTON[®] XO Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eyecare practitioner's office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.

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- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the ultraviolet (UV) light absorber in the BOSTON XO Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the FITTING PROCEDURE for detailed instructions.)

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the conditioning/storage solution and lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp the BOSTON XO Contact Lenses.
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
 - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for BOSTON XO Contact Lenses and those instructions provided by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.

- Ask the eyecare practitioner about wearing lenses during water activities and other sports.
- Inform the patient to alert their health care practitioner (doctor) that they wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Always contact the eyecare practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- 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.

ADVERSE EFFECTS

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

- Comfort is less than when lens was first placed on the eye
- Feeling of something in the eye such as a foreign body, scratched area
- Excessive watering (tearing) of the eyes

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

Immediately remove lenses

If the discomfort or problem stops, then closely inspect 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 eyecare practitioner.

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 the eye care practitioner.

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

- Eyes stinging, burning, itching (irritation), or other eye pain
- 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 symptoms, he or she should be instructed to:

Immediately remove lenses

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

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SELECTION OF PATIENTS

BOSTON® XO Contact Lenses are rigid gas permeable lenses for the daily wear patient who may require the correction of visual acuity for myopia, hyperopia, astigmatism or presbyopia. BOSTON XO lenses are suitable for patients who have never worn contact lenses, for current PMMA wearers, for patients wanting to upgrade their current rigid gas permeable lenses, as well as for some patients who have been unsuccessful with soft contact lenses.

- Lens Diameter = 9.6 mm
- Initial Base Curve:
 - Flat K 42.75D 7.90 mm
 - + Corneal Astigmatism Factor 0.25D flatter than Flat K
 - = Initial Base Curve 42.50D
- Base Curve Radius 42.50D = 7.94 mm

FITTING PROCEDURE OUTLINE

1. Pre-Fitting Examination
2. Initial Lens Diameter Selection
3. Initial Lens Base Curve Selection
4. Initial Lens Evaluation
5. Initial Lens Power Selection
6. Initial Lens Center Thickness Selection
7. Remaining Lens Parameter Selection
8. Follow-Up Care

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 daily wear or extended wear contact lenses (consider patient hygiene and mental and physical state),
- make ocular measurements for initial contact lens parameter selection,
- collect and record baseline clinical information to which post-fitting examination results can be compared,

A pre-fitting examination should include distance and reading refraction, keratometry and slit lamp evaluation to rule out any contraindications to contact lens wear. Careful assessment of the cornea, lids, conjunctiva and precorneal tear film establishes a baseline against which the practitioner can compare any changes resulting from contact lens wear.

2. Initial Lens Diameter Selection

For minus lenses, an initial lens diameter of 9.6 mm is recommended. For plus lenses, an initial lens diameter of 9.2 mm is recommended. It is important that the optical zone of the lens covers the pupil adequately, even in dim illumination.

3. Initial Lens Base Curve Radius Selection

The initial base curve radius selection is primarily a function of the lens diameter selected and the amount of corneal astigmatism present:

Step One:

Measure central corneal curvature and identify the Flat K (lowest dioptric power).

Example:

K = 42.75/44.75 @ 90 Flat K = 42.75D (7.90mm)
The "flat K" is used as a reference point from which the Base Curve Radius is chosen.

Step Two:

Calculate the corneal astigmatism (difference between the flat and steep K).

In This Example:

K = 42.75/44.75 @ 90 Corneal Astigmatism = 2.00D

Step Three:

Calculate the Base Curve Radius by referring to the Corneal Astigmatism Factor Chart for a given lens diameter.

Example: K = 42.75/44.75 @ 90 Flat K = 7.90 mm
• Corneal Astigmatism = 2.00D

Select 9.2 mm or 9.6 mm initial diameter. Choose base curve according to chart.

Corneal Astigmatism Factors		
Corneal Astigmatism	9.2 mm Diameter	9.6 mm Diameter
0.00 to 0.50D	0.50D flatter	0.75D flatter
0.75 to 1.25D	0.25D flatter on flat "K"	0.50D flatter
1.50 to 2.00D	on flat "K"	0.25D flatter on flat "K"
2.25 to 2.75D	0.25D steeper	on flat "K"
3.00 to 3.50D	0.50D steeper	0.25D steeper

This chart assumes an optical zone that is 1.4 - 1.6 mm smaller than the lens diameter.

4. Initial Lens Evaluation

A. Lens Positioning

Patient comfort is largely determined by lens positioning on the cornea. A slightly superior, lid-attachment positioning is generally preferred to enhance comfort and encourage normal blinking patterns. Ideally, the upper edge of the lens should be located at or near the superior limbus and remain covered during each blink. A central lens positioning is acceptable but requires the lens periphery to be designed with minimal edge lift and edge contours that are rolled slightly inward to reduce blink-related sensation. Inferior lens positioning, which interferes with normal blinking and promotes lens binding and 3-9 staining, should be avoided.

Note for fitting the hyperopic eye:

Single-cut plus lenses tend to position low. If the inferior decentration is modest, this design may be preferable, especially for smaller corneas. In many cases, lenticular-designed plus lenses offer better centration and more predictable blink-induced lens movement. Special attention must be directed to the edge design of interpalpebral lenticular lenses to insure that they provide minimal lid sensation by being well-tapered and rolled slightly inward.

B. Fluorescein Pattern

Typically, the fluorescein pattern of the final lens should show some mild apical bearing ("feather touch") or alignment and the absence of peripheral bearing over more than 180° of its circumference. Excessive apical pooling or bearing should be avoided. A moderate edge lift is necessary to permit the edge of the lens to slide over the corneal surface with minimal resistance.

The presence of the UV-absorber in the BOSTON® XO (hexafocon A) Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. A simple, inexpensive approach is the use of an auxiliary yellow Kodak Wratten #12 filter in conjunction with the cobalt blue filter of the biomicroscope.

Slit Lamp Application (if desired):

1. All customary light intensities and filter settings (Cobalt Blue) are left in place.
2. The Kodak Wratten Filter #12* (yellow) is secured on the patient side of the slit lamp microscope with a small piece of adhesive tape.

Burton Lamp Application (necessary):

1. Replace blue bulbs with ordinary white bulbs.
2. Place Kodak Wratten Filter #47* (blue) over white bulb area.
3. Place Kodak Wratten Filter #12 (yellow) over patient side of viewing lens.

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4. Use system in usual manner.

Important Note: Use of the Wratten filters will also enhance the view of non-UV rigid lenses and corneal fluorescein evaluation.

*Wratten #12 and #47 filters are available from Authorized BOSTON Manufacturers in the following kits: #7503 Slit Lamp Filter Kit, #7502 Burton Lamp Modification Kit.

5. Initial Lens Power Selection

A. Empirical Fitting

Step One:

Follow the steps for INITIAL LENS DIAMETER and BASE CURVE RADIUS SELECTION.

Step Two:

Employ the rules of SAM (steeper add minus) or FAP (flatter add plus) to determine lens power.

Example:

Spectacle Rx: -3.00-1.50 @ 180
K Readings: 42.75/44.75 @ 90

Flat K = 42.75D (7.90mm)

Corneal Astigmatism: = 2.00D
Lens Diameter = 9.6mm

Initial Base Curve:

Flat K = 42.75D 7.90 mm
+ Corneal Astigmatism Factor 0.25D *rather than Flat K*
= Initial Base Curve 42.50D
Base Curve Radius 42.50D = 7.94 mm

Since the base curve is 0.25D flatter than K, employ the FAP principle to determine contact lens power.

Base Curve: 42.50D *0.25 flatter than Flat K*
Sph power of spec Rx: -3.00D

FAP adjustment $\leftarrow +0.25D$
Lens Power -2.75D

The lens in this example would be ordered as:

Base curve: 42.50D
Power: -2.75D
Diameter: 9.6mm

B. Trial Fitting

Step One:

Perform a spherical refraction over the best-fitting trial lens.

Step Two:

If the spherical power of the over-refraction is greater than 4.75D, correct for the vertex distance.

Example: -5.00D at 12 mm = -4.75D at the cornea
-5.00D at 12 mm = -5.37D at the cornea

Step Three:

Combine the spherical over-refraction (corrected for vertex distance if appropriate) with the power of the trial lens to obtain the final contact lens power ordered.

Example: Trial lens -3.00D
Over-refraction (+)+1.00D
Power to order -2.00D

Spherical over-refraction (D)	4.00	5.50	7.00	8.50
to	5.25	6.75	8.25	10.00
Corresponding Power Compensation (D)	0.25	0.50	0.75	1.00

6. Initial Lens Center Thickness Selection

For best clinical results, the eyecare practitioner should always specify center thickness as part of the complete prescription. The stability and flexural resistance of BOSTON® XO (hexafacon A) permit the use of a wide range of center thicknesses and designs.

For eyes with less than 1.25 diopters of corneal toricity consider the following standard thickness table:

Lens Power	Recommended Thickness
Plano	0.18
-1.00	0.17
-2.00	0.16
-3.00	0.15
-4.00	0.14
-5.00	0.13
-6.00	0.12
-7.00	0.11
-8.00	0.10

In cases where corneal toricity is 1.50 diopter or greater, consider adding 0.01 mm of thickness per diopter of cylinder to the center thickness table to control blink-induced flexure.

7. Remaining Lens Parameter Selection

The final prescription should be provided to the Authorized BOSTON Manufacturer in a format which includes:

- base curve
- center thickness
- diameter
- optic zone
- power
- peripheral curves

By specifying the complete design, practitioner success and patient satisfaction are increased. The following suggested designs have proven successful in clinical testing. **Your Authorized BOSTON Manufacturer may also offer suggestions regarding lens design.**

Select remaining lens parameters: optical zone & peripheral (edge) design.

Specify 8.0 - 8.2 mm optic zone

instruct manufacturer to blend to finished size

Specify peripheral curve design as follows:

for 9.2 mm diameter		for 9.4 - 9.6 mm diameter	
Peripheral Curves		Peripheral Curves	
1st	2nd	1st	2nd
width	0.3 mm	0.3 mm	0.3 mm
radius	0.8 mm	2.3 mm	1.2 mm
*flatter than B.C.		*fatter than B.C.	

8. Follow-up Care

- a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, a conventional follow-up schedule for daily wear should be maintained.
- b. Prior to a follow-up examination, the contact lenses should be worn for at least 2 continuous hours and the patient should be asked to

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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, conduct a thorough biomicroscopy examination.
 - 1) The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is 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 refitted with a more appropriate lens.

IN-OFFICE CARE OF TRIAL LENSES

Eyecare practitioners should educate contact lens technicians concerning proper care of trial lenses.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected.

Practitioner Note: The BOSTON® XO Contact Lenses are not sterile when shipped from the Authorized BOSTON Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

RECOMMENDED INITIAL WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

BOSTON XO Contact Lenses are indicated for **daily wear**. The **maximum** suggested wearing time for these lenses is:

DAY	WEARING TIME (HOURS)*
1	4 to 8 hours
2	6 to 10 hours
3	8 to 14 hours
4	10 to 15 hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*if the lenses continue to be well-tolerated

CLINICAL ASSESSMENT

WARNING: BOSTON XO Contact Lenses are **NOT** intended for overnight (extended) wear.

1. Criteria of a Well-Fitted Lens

Patient comfort is largely determined by lens positioning on the cornea. A slightly superior, lid-attachment positioning is generally preferred to enhance comfort and encourage normal blinking patterns. Ideally, the upper edge of the lens should be located at or near the superior limbus and remain covered during each blink. A

central lens positioning is acceptable but requires the lens periphery to be designed with minimal edge lift and edge contours that are rolled slightly inward to reduce blink-related sensation. Inferior lens positioning, which interferes with normal blinking and promotes lens binding and 3-9 staining, should be avoided. Typically, the fluorescein pattern of the lens should show some mild apical bearing ("feather touch) or alignment and the absence of peripheral bearing over more than 180° of its circumference. Excessive apical pooling or bearing should be avoided. A moderate edge lift is necessary to permit the edge of the lens to slide over the corneal surface with minimal resistance.

2. Optimizing Fitting Characteristics

In order to achieve optimal performance, it is often necessary to modify the initial lens parameters. Practitioner observations and interpretation of lens positioning, fluorescein patterns, and lens movement are essential to this process. The following chart summarizes common fitting relationships.

INITIAL LENS ASSESSMENT			
	Optimum	Too Steep	Too Flat
Fluorescein Pattern	Parallel to Slight Apical Bearing Moderate Edge Lift	Excessive Apical Pooling Minimum Edge Lift	Excessive Apical Bearing Excessive Edge Lift
Position	Centered to Slightly Superior	Inferior	Superior Unstable
Movement	1-2 mm	Less Than 1 mm	More Than 2 mm
Comfort	Slight Initial Sensation	Initially Comfortable	Uncomfortable
Disposition	Prescribe	Select Flatter Base Curve or smaller diameter	Select Steeper Base Curve or larger diameter

3. Problem Solving

Persistent excessive lens awareness: This problem may be due to: the use of incompatible care products; improper use of care products (i.e., lens cleaning just prior to insertion); three and nine o'clock staining; deposits on the concave lens surface; accumulation of mucus under the lens; poor edge design, incomplete blinking or steeply fitted lenses.

Three and nine o'clock staining: If the lens positions low, it should be redesigned to achieve a higher position so as to avoid a false blink pattern. The lens periphery should be well tapered and its edge rolled slightly inward to minimize upper lid sensation and avoid incomplete reflex blinks. If the lens positions centrally, the diameter should be reduced, the periphery well tapered and the edge rolled slightly inward. Complete blinking should be encouraged. *Above all, be certain that the lens has not been fitted too steeply.*

Generalized corneal staining: In cases of diffuse staining not apparently related to back surface deposits on the lens, solution or preservative incompatibility should be ruled out.

Ocular redness without staining: This problem may be caused by some component of the care solutions such as preservatives or the presence of pingueculae, infectious or allergic conjunctivitis, or inadequate lens lubrication, including excessive mucus accumulation as occurs in dry eyes.

Excessive development of lens deposits: This unusual problem may be related to: increased mucus production, i.e., GPC, keratitis sicca, chronic allergies, etc. The more frequent use of the BOSTON® Rewetting Drops may be

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Example: 3 x - (2.00) -6.00 3 x add power
(+) -1.50 Near Zone
-7.50 Distance Zone

8) Specify the near and distance zone curves and powers.

Example: 43.00 / 47.00 -1.50 / -7.50
43.00/-1.50
47.00/-7.50

c. The third alternating vision design is an alternating vision bifocal lens with a spherical anterior surface and aspherical posterior surface. For distance vision, the majority of the pupil is covered by the near zone as the lens translates (moves upward) in downgaze. Prism ballasting and a small inferior truncation are incorporated to enhance orientational stability and translation in downgaze.

Fitting Principles

1) Trial fitting is always recommended

2) Initial Base Curve Selection

The initial base curve selection is primarily a function of the amount of corneal cylinder present. This bifocal lens with aspheric posterior surface will generally be fitted steeper (approximately 0.10 mm) than a similar diameter spherical lens.

a) For Minus Lenses -

Select a base curve radius equal to the radius of the flattest keratometer reading for corneas with less than 1.00D of corneal toricity. For corneas with 1.00D or greater corneal toricity, select a base curve radius equal to the mean of the two keratometer readings.

Example: K = 44.00 / 46.00 D
Mean K = 45.00D = 7.50 mm (see conversion chart)
Select 7.50 mm base curve trial lens

(If conversion of diopters to millimeters results in a base curve parameter not available, select the next available steeper base curve.)

b) For Plus Lenses -

Select a base curve radius equal to the corneal radius for spherical corneas. For toric corneas, select a base curve radius equal to the mean of the two keratometer readings.

3) Place the lens on the eye and allow it to settle (approximately 5 - 10 minutes).

3. Simultaneous Vision Multifocal Designs

a. The first simultaneous vision multifocal lens design has an aspheric back surface, which progressively adds plus power from center to edge. This power change is gradual. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During distance viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

1) Trial fitting is always recommended.

2) The base curve radius is chosen using conventional techniques. Due to the aspheric flattening of the lens back surface, the base curve chosen will be considerably steeper than standard spherical single vision rigid lenses. It is not unusual to select a base curve 2-4 D steeper than the flattest K.

The following formula can be used as a starting point:

Fit K + add power = 1.00 D + 1/2 corneal astigmatism.
Example: 42.00/44.00 + 2.00 add
42.00 + 2.00 + 1 + 1 = 46.00

3) Centration is critical for this design. If proper exact centration can not be obtained, do not fit this lens.

4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.

b. The second simultaneous vision multifocal lens design has an aspheric front surface, which progressively adds plus power from center to edge. This power change is gradual. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During distance viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

1) Trial fitting is always recommended.

2) The base curve radius is chosen using conventional techniques.

3) Centration is critical for this design. If proper exact centration can not be obtained, do not fit this lens.

4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.

c. The third simultaneous vision multifocal lens design lens employs a back surface annular design with a distinct distance and near zone. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During distance viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

1) Trial fitting is always recommended.

2) The base curve radius is chosen using conventional techniques.

3) Centration is critical for this design. If proper exact centration can not be obtained, do not fit this lens.

4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.

d. The fourth simultaneous vision multifocal lens design employs a front surface annular design with a distinct distance and near zone. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During distance viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

1) Trial fitting is always recommended.

2) The base curve radius is chosen using conventional techniques.

3) Centration is critical for this design. If proper exact centration can not be obtained, do not fit this lens.

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distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power

and store the lens wet in an approved wetting and soaking solution for at least four hours to ensure maximum patient comfort. Upon dispensing, evaluate the patient's lens using the same criteria previously described to evaluate the trial lens fitting.

4. Initial Lens Evaluation

A. Lens Positioning

Patient comfort is largely determined by lens position on the cornea. Generally, a well-fitted lens exhibits a central or slightly inferior/central position.

Generally, an optimal aspherical fit will show a thin, even layer of tears centrally which extend to near the edge where a moderate amount of edge lift will be observed. This fluorescein pattern is characterized by the absence of a discernible intermediate bearing area which is commonly observed with conventional spherical designs.

B. Fluorescein Pattern

Excessive apical pooling or bearing should be avoided. A moderate edge lift is necessary to permit the edge of the lens to slide over the corneal surface with minimal resistance.

The presence of the UV-absorber in the BOSTON lens may require equipment enhancement to visualize fluorescein patterns adequately. A simple, inexpensive approach is the use of an auxiliary yellow Kodak Wratten #12 filter in conjunction with the cobalt blue filter of the biomicroscope

Slit Lamp Application (if desired):

1. All customary light intensities and filter settings (Cobalt Blue) are left in place.
2. The Kodak Wratten Filter #12* (yellow) is secured on the patient side of the slit lamp microscope with a small piece of adhesive tape.

Burton Lamp Application (necessary):

1. Replace blue bulbs with ordinary white bulbs.
2. Place Kodak Wratten Filter #47* (blue) over white bulb area.
3. Place Kodak Wratten Filter #12 (yellow) over patient side of viewing lens.
4. Use system in usual manner.

Important Note:

Use of the Wratten filters will also enhance the view of non-UV rigid lenses and corneal fluorescein evaluation.

* Wratten #47 and #12 filters are available from Authorized BOSTON Manufacturers in the following kits: #7503 Slit Lamp Filter Kit, #7502 Burton Lamp Modification Kit

5. Determining Power and Dispensing the Lens

Once the appropriate base curve has been selected, over-refract to determine the appropriate distance dioptric power for the final lens order. Over-refractions of 4.00D or more should be corrected for vertex distance (see conversion table). The over-refraction should be added to the power of the trial lens to arrive at the final prescription.

Example: Over-refraction +0.50D
Trial Lens -3.00D
Lens Power Ordered -2.50D

Add power should be based on the spectacle add power required. Prior to dispensing the lens, clean the lens with an approved cleaner

6. Near Segment Positioning

A. Generally, in alternating vision designs the near segment line should be positioned slightly below the inferior margin of the pupil. This is achieved by varying the lens base curve/corneal fitting relationship and/or the segment height. Segment height is specified as either 0.5 mm or 1.0 mm below the geometric center of the lens, or as a segment height in mm from the bottom of the lens.

B. To bias toward better distance vision (decrease instability and improve acuity), less movement, lower post-blink segment positioning, and faster return times from post to pre-blink positions are helpful. The following may be helpful:

- Steepen Fit
- Lower Seg

C. To bias toward better near vision (increase acuity), more movement and higher post-blink segment positioning are useful. The following may be helpful:

- Flatten Fit
- Raise Seg

D. Lower segment positioning in conjunction with flatter fitting may represent the best compromise between distance and near visual performance.

E. Visual performance will improve with time as the patient learns to control the movement and positioning of the lens. The following patient instructions may be useful:

- Advise the patient that fluctuating vision at distance and near is possible, especially at first. Generally, blinking gently will improve distance vision.
- Strong blinking will improve near vision. When reading, the eyes, not the head, should turn downward.

DIOPTER TO MILLIMETER CONVERSION*

Posterior Apical Radius

Keratometric Reading	Radius Convex	Keratometric Reading	Radius Convex
47.75D = 7.07 mm		43.75D = 7.72 mm	
47.50D = 7.11 mm		43.50D = 7.76 mm	
47.25D = 7.14 mm		43.25D = 7.80 mm	
47.00D = 7.18 mm		43.00D = 7.85 mm	
46.75D = 7.22 mm		42.75D = 7.90 mm	
46.50D = 7.26 mm		42.50D = 7.95 mm	
46.25D = 7.30 mm		42.25D = 8.00 mm	
46.00D = 7.34 mm		42.00D = 8.04 mm	
45.75D = 7.38 mm		41.75D = 8.08 mm	
45.50D = 7.42 mm		41.50D = 8.13 mm	
45.25D = 7.46 mm		41.25D = 8.18 mm	
45.00D = 7.50 mm		41.00D = 8.23 mm	
44.75D = 7.55 mm		40.75D = 8.28 mm	
44.50D = 7.59 mm		40.50D = 8.33 mm	
44.25D = 7.63 mm		40.25D = 8.39 mm	
44.00D = 7.67 mm		40.00D = 8.44 mm	

* Calculated

VERTEX DISTANCE CONVERSION

Spectacle Lens Correction	Vertex Distance at 12 mm	
	Plus Lenses	Minus Lenses
4.00	4.25	3.87
4.50	4.75	4.25
5.00	5.25	4.75
5.50	5.87	5.12

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6.00	6.50	5.62
6.50	7.00	6.00
7.00	7.62	6.50
7.50	8.25	6.87
8.00	8.87	7.25
8.50	9.50	7.75
9.00	10.12	8.12
9.50	10.75	8.50
10.00	11.37	8.87
10.50	12.00	9.37
11.00	12.75	9.72
11.50	13.37	10.12
12.00	14.00	10.50
12.50	14.75	10.87
13.00	15.50	11.25
13.50	16.12	11.62
14.00	16.75	12.00
14.50	17.50	12.37
15.00	18.25	12.75
15.50	19.00	13.00
16.00	19.75	13.50
16.50	20.50	13.75
17.00	21.50	14.12
17.50	22.25	14.50
18.00	23.00	14.75
18.50	23.75	15.12
19.00	24.75	15.50
19.50	25.50	15.81
20.00	26.12	16.11

Practitioner Note: The BOSTON RGP Contact Lenses are not sterile when shipped from the authorized manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

RECOMMENDED INITIAL WEARING SCHEDULE:

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

The BOSTON RGP Contact Lenses are indicated for daily wear. The maximum suggested wearing time for these lenses is:

Day	Wearing Time (Hours)*
1	4 to 8 Hours
2	6 to 10 Hours
3	8 to 14 Hours
4	10 to 15 Hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*If the lenses continue to be well tolerated.

WARNING: BOSTON RGP Bifocal/Multifocal Contact Lenses are not intended for overnight (extended) wear.

CLINICAL ASSESSMENT:

1. Optimizing Fitting Characteristics

In order to achieve optimal performance, it is often necessary to modify the initial trial lens parameters. Practitioner observation and interpretation of lens positioning, fluorescein patterns, and lens movement are essential to this process. The following chart summarizes common fitting relationships.

INITIAL TRIAL LENS ASSESSMENT

	OPTIMUM	TOO STEEP	TOO FLAT
Fluorescein Pattern	Parallel to Slight Apical Bearing Moderate Edge Lift	Excessive Apical Pooling Minimum Edge Lift	Apical Touch Excessive Edge Lift
Position	Centered to Slightly Inferior	Inferior	Superior Unstable
Movement	1-2 mm	Less Than 1mm	More Than 2mm
Comfort	Slight Initial Sensation	Initially Comfortable	Uncomfortable
Disposition	Prescribe	Select Flatter Base Curve or smaller diameter	Select Steeper Base Curve or larger diameter

2. Problem Solving

Persistent excessive lens awareness: This problem may be due to: the use of incompatible care products; improper use of care products (i.e., lens cleaning just prior to insertion); inadequately blended peripheral curves; three and nine o'clock staining; deposits on the concave lens surface; accumulation of mucus under the lens; poor edge design, incomplete blinking or steeply fitted lenses.

Three and nine o'clock staining: If the lens positions low, it should be redesigned to achieve a higher position so as to avoid a false blink pattern. The lens periphery should be well tapered and its edge rolled slightly inward to minimize upper lid sensation and avoid incomplete reflex blinks. If the lens positions centrally, the diameter should be reduced, the periphery well tapered and the edge rolled slightly inward. Complete blinking should be encouraged. Above all, be certain that the lens has not been fitted too steeply.

Generalized corneal staining: In cases of diffuse staining not apparently related to rear surface deposits on the lens, solution or preservative incompatibility should be ruled out.

7. Follow-up Care

- Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, a conventional follow-up schedule for daily wear should be maintained.
- Prior to a follow-up examination, the contact lenses should be worn for at least 2 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
- 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.
- After the lens removal, instill sodium fluorescein into the eyes and conduct a thorough biomicroscopy examination.
 - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
 - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
 - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

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.

IN OFFICE CARE OF TRIAL LENSES:

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected.

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Ocular redness without staining: This problem may be caused by some component of the care solutions such as preservatives or the presence of pingueculae, infectious or allergic conjunctivitis, or inadequate lens lubrication, including excessive mucus accumulation as occurs in dry eyes.

Excessive development of lens deposits: This unusual problem may be related to: Increased mucus production, i.e. GPC, keratitis sicca, chronic allergies, etc. The more frequent use of the BOSTON Rewetting Drops may be helpful in these cases. However, excessive deposition has been found to be most often related to inappropriately polished lens surfaces which simulate an orange peel appearance visible only with magnification of 20X or greater. In most cases, deposits are easily removed by cleaning with the BOSTON Cleaner or BOSTON Advance Cleaner, however, in extreme cases, it may be necessary for the practitioner to lightly polish the lenses with the BOSTON Cleaning Polish. In the event that deposits cannot be removed by cleaning or polishing, the lens should be replaced.

Lens surface dry spots: The presence of discrete non-wetting areas on a new or recently modified or polished lens, may be due to the persistence of hydrophobic products used during lens fabrication.

Other causes of loss of surface wettability include: surface contamination with cosmetics, hair spray, skin preparations; inadequate tear lubrication; incomplete blinking; the use of incompatible preserved care solutions; and dry lens storage.

Reduced contact lens-corrected vision: Reduced vision correction unrelated to changes in refractive error may be due to lens warpage, front surface deposits, or switched lenses.

Reported lens breakage: Lens breakage problems may be due to careless handling or storage procedures (see Patient Instructions booklet) or the use of lenses having less-than-recommended center, edge or junction thickness, especially for patients having poor manual dexterity.

CONSIDERATIONS FOR BIFOCAL/MULTIFOCAL LENSES:

Presbyopic patients who are considering bifocal/multifocal contact lenses should be informed of the benefits as well as the problems they may encounter while adapting to bifocal/multifocal lens wear.

The following areas should be discussed with the patients:

1. **Adaptation**

Both bifocal spectacle and bifocal/multifocal contact lens wearers need to learn to adapt to proper head positioning. The patient must position the head upright while rotating the eyes downward to read. Once the patient has adapted, proper positioning becomes effortless.

2. **Driving at Night**

Patients wearing bifocal/multifocal contact lenses should experience night vision before actually driving while wearing their lenses.

3. **Flare at Night**

Patients wearing bifocal/multifocal contact lenses may experience flare at night. This may occur with certain lens designs (high seg positions or small distance fields). With time, patients adapt to this situation.

4. **Visual Expectation**

Patients wearing bifocal/multifocal contact lenses may experience visual acuities less than what could be achieved with bifocal spectacles.

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 may not be a good candidate for monovision with the BOSTON XO 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 not to 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, 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.

2. **Eye Selection**

Generally, the nondominant 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 "dominate 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 the appropriate plus power trial spectacle 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 plus power trial 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, consider correcting the eye on that side for near.

Example:

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

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3. Contact Lens Considerations

Unilateral Lens Correction

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

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and no lens on the other eye.

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 eye 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 can be 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 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 distance objects, observe the reactions. Only after these visual 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 the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

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

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mildly blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for only minutes 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 use the lenses first 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 dri-

ving 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 drive only 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 eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the Patient Instructions.

PATIENT LENS CARE DIRECTIONS

Eyecare practitioners should review with the patient all lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

General Lens Care (First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

Always wash, rinse, and dry hands before handling contact lenses.

- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling or instructed by the eyecare practitioner.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in the mouth.
- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.

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Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or a cleaning solution **does not substitute for disinfection.**

The lens care products listed below are recommended by Polymer Technology for use with BOSTON® XO Contact Lenses. Eyecare practitioners may recommend alternate products that are appropriate for the patient's use with his or her lenses).

LENS CARE TABLE

Product Purpose	Lens Care System Chemical (Not Heat)
Clean	BOSTON Advance® Cleaner or BOSTON® Cleaner
Disinfect	BOSTON Advance® Comfort Formula Conditioning Solution or BOSTON® Conditioning Solution
Store	BOSTON Advance® Comfort Formula Conditioning Solution or BOSTON® Conditioning Solution
Multi-Action (Clean, Condition, Disinfect, Rinse and Cushion)	BOSTON Simplicity® Multi Action Solution
Lubricate/Rewet	BOSTON® Rewetting Drops
Weekly Enzymatic Cleaner	BOSTON® ONE STEP Liquid Enzymatic Cleaner

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as recommended by the eyecare practitioner to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eyecare practitioner. Follow the instructions provided in the Disinfection Solution Packaging.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the Package Insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer or the eyecare practitioner; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable

- Eyecare practitioners may recommend a Weekly Enzymatic Cleaner which can be used to effectively remove protein deposits from BOSTON XO Contact Lenses.
- BOSTON XO Contact Lenses **cannot** be heat (thermally) disinfected.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving/cannot be removed), the patient should be instructed to apply one to three drops of a recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 5 minutes, the patient should immediately consult the eyecare practitioner.

LABORATORY LENS CLEANER

Residue left by body oils, household solvents, and personal care products may be removed with an enhanced cleaning agent such as BOSTON Laboratory Lens Cleaner. This clear, colorless surfactant is for **laboratory and in-office use only**. When lenses are received from the Authorized BOSTON Manufacturer, they should be cleaned with BOSTON Laboratory Lens Cleaner prior to use of the BOSTON Care System and an overnight soak. Lenses exhibiting a nonwetting surface should be cleaned with BOSTON Laboratory Lens Cleaner as a method of first choice. **The BOSTON Laboratory Lens Cleaner is intended for PROFESSIONAL USE ONLY. It is not available for resale or distribution to patients.**

IN-OFFICE LENS MODIFICATIONS

Edge reshaping and surface repolishing can be performed by conventional techniques if the following precautions are observed: 1) avoid polishing compounds or cleaners that contain ammonia, alcohol or organic solvents; 2) completely remove all traces of adhesive (if double-backed tape is used) with the special authorized solvent; (The use of any other solvent may cause surface breakdown.) Minimize exposure to the solvent and immediately remove all traces with BOSTON® Cleaner or BOSTON Advance® Cleaner followed by a thorough water rinse. 3) perform the initial lens modifications cautiously because the response of this polymer to these procedures is more rapid than that of silicone acrylate materials; 4) more extensive modifications should not be attempted. Best results will be obtained by using the BOSTON® Cleaning Polish which is available from Authorized BOSTON Manufacturers. 5) The Original BOSTON® Care System, BOSTON Advance® Comfort Formula Care System or BOSTON Simplicity Multi-Action Care System including the overnight soak should be used prior to lens dispensing.

Caution: Damage may result from improper modification techniques. Please Note: BOSTON® Envision® and BOSTON® MultiVision due to their preformed back surface should not be modified. Consult your Authorized BOSTON Manufacturer or contact Polymer Technology for more detailed information.

Warning: Do not use solvents such as alcohols, esters, ketones or chlorinated hydrocarbons (including naphtha, lighter fluid, etc.) since they may damage the lens surfaces and increase the brittleness of the lens.

**Use only the solvent supplied by your lens labo-

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rubbing a solvent-saturated cloth over the lens surfaces and quickly removing the solvent with a surfactant. Do not soak the lenses in the solvent.

REMOVAL OF SURFACE DEPOSITS

Deposits are easily removed from the surfaces of BOSTON® XO (hexafocan A) Contact Lenses. These deposits are best identified by inspecting the cleaned and dried lens with a slit lamp in a dark room using a medium-width illuminating beam. Surface deposits should be gently removed with BOSTON® Cleaning Polish, which is available in a kit form with a polishing pad that permits practitioners to manually clean and polish their patient's rigid gas permeable lenses. THE BOSTON LENS® Cleaning Polish and Manual Polishing Machine are available from Authorized BOSTON Manufacturers.

Caution: Applying excessive and prolonged pressure to the lens during the polishing procedure may alter its surface optics.

REPORTING OF ADVERSE REACTIONS

All serious adverse reactions observed in patients wearing BOSTON® XO Contact Lenses or adverse experiences with the lenses should be reported to:

Consumer Affairs
Polymer Technology
1400 North Goodman Street
Rochester, NY 14603-0450
1-800-333-4730

HOW SUPPLIED

Each lens is supplied (non-sterile) in a plastic lens storage case. The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber (if present) and lot number. Additional parameters of add power, segment height, prism ballast and truncation may be included for bifocal/multifocal lenses.

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1400 North Goodman Street
Rochester, New York 14603-0450
1-800-333-4730

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PACKAGE INSERT

BOSTON[®] XO (hexafocon A)

*Spherical & Aspherical Contact
Lenses for Myopia & Hyperopia.
Bifocal/Multifocal Contact Lenses for
Presbyopia and Toric Lenses
to Correct Astigmatism in
Not aphakic and Aphakic Persons*

*Fluoro Silicone Acrylate
Rigid Gas Permeable
Contact Lenses
For
Daily Wear*

IMPORTANT:
*Please read carefully and keep
this information for future use.
This package insert is intended
for the eyecare practitioner,
but should be made available
to patients upon request. The
eyecare practitioner should
provide the patient with the
patient instructions that
pertain to the patient's
prescribed lens.*

CAUTION:
*Federal Law Prohibits Dispensing
Without a Prescription*

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DESCRIPTION

BOSTON® XO (hexafocon A) material is used for the manufacturing of daily wear rigid gas permeable contact lenses. BOSTON XO are wettable, non-hydrophilic rigid gas permeable contact lenses that are not surface treated and are made from siloxanyl fluoromethacrylate copolymer containing an ultraviolet absorber. BOSTON XO Contact Lenses are available in ice blue and violet.

Color	Color Additive
Ice Blue	D & C Green No. 6
Violet	D & C Violet No. 2

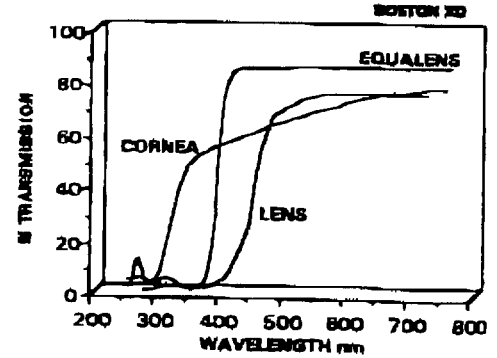
The physical characteristics of the BOSTON XO material was designed to facilitate the fabrication of high-quality rigid gas permeable contact lenses in a wide range of lens designs.

Spherical Lens Design	
Power Range	-20.00D to +20.00D In 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	5.00 mm to 9.00 mm in .01 mm increments
Aspherical Lens Designs	
<i>Some of these designs are patented; manufacture of these lenses in Boston XO (hexafocon A) materials are authorized to licensed labs only</i>	
Power Range	-20.00D to +20.00D In 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.00 mm to 9.20 mm In 0.01 mm increments
Bifocal/Multifocal Lens Designs	
<i>Some of these designs are patented; manufacture of these lenses in Boston XO (hexafocon A) materials are authorized to licensed labs only</i>	
Power Range	-20.00D to +20.00D In 0.25D increments
Diameter	8.5 mm to 11.5 mm
Base Curve Range	6.30 mm to 9.50 mm In 0.01 mm increments
Segment Heights	-2.00 mm to +1.00 mm in 0.5 mm increments
Add Powers	+1.00D to +3.75D in 0.5D increments
Prism Ballast	0.5 to 3.5 prism diopters in 0.5D increments
Toric Lens Designs	
Power Range	-20.00D to +20.00D In 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.80 mm to 9.50 mm In 0.01 mm increments
Toricity	Up to 9.00 Diopters

Physical/Optical Properties of BOSTON XO:

Specific Gravity	1.27
Refractive Index	1.415
Light Absorbance <small>(Absorbance Units/nch)</small>	
Ice Blue <small>(with UV absorber)</small>	4.6
Violet <small>(with UV absorber)</small>	5.5
Light Transmittance*	92%
*Average %T (400-800nm)	
Surface Character	Hydrophobic
Wetting Angle	49°
Water Content	<1%
Oxygen Permeability	140* (100**)
(x 10 ⁻¹¹ (cm ³ O ₂ · cm)/(cm ² · sec · mmHg) @ 35° C)	

**polarographic method (ISO/Fatt)



BOSTON XO - 0.07 mm thick BOSTON XO (Ice Blue)

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.

CRYSTALLINE 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, figure 5.

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.

WARNING

UV-absorbing contact lenses are **NOT** substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

ACTIONS

BOSTON XO Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS (USES)

BOSTON XO Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. These contact lenses may be disinfected using a chemical disinfecting system only.

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CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE BOSTON XO Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation 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), if not aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the BOSTON XO contact lens materials.
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

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 eyecare practitioner's directions 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 these 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 eyecare practitioner.

PRECAUTIONS

Practitioner Note: BOSTON XO contact lenses are not sterile when shipped from the Authorized BOSTON® Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

- Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness
- | Color | Center Thickness |
|----------|------------------|
| Ice Blue | >0.65 mm |
| Violet | >0.65 mm |

Special Precautions for Eyecare Practitioners:

- 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 eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

- 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.
- Aphakic patients should not be fitted with the BOSTON XO Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eyecare practitioner's office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the ultraviolet (UV) light absorber in the BOSTON XO Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the conditioning/storage solution and/or lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp the BOSTON XO Contact Lenses.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.

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- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the BOSTON XO Contact Lenses and in those prescribed by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eyecare practitioner about wearing lenses during water activities and other sports.
- Inform your health care practitioner (doctor) that you wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the lens case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Always contact your eyecare practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

- 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.

ADVERSE EFFECTS

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 the eye
- Feeling of something in the eye such as a 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 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 eyecare practitioner. 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, **immediately remove the lenses and consult the eyecare practitioner.**

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

FITTING

Conventional methods of fitting contact lenses apply to BOSTON XO Contact Lenses. For a detailed description of the fitting techniques, refer to the BOSTON XO Professional Fitting and Information Guide, copies of which are available from:

Practitioner Marketing Representative
 Polymer Technology
 1400 North Goodman Street
 Rochester, NY 14603-0450
 1-800-225-1241

Professional Fitting Guides are also available through your Authorized BOSTON® Manufacturer.

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WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eyecare practitioner.

Patients tend to overwear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

BOSTON® XO Contact Lenses are indicated for daily wear. The suggested wearing time for these lenses is:

DAY	WEARING TIME (Hours)*
1	4 to 8 hours
2	6 to 10 hours
3	8 to 14 hours
4	10 to 15 hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*if the lenses continue to be well-tolerated.

WARNING: BOSTON XO Contact Lenses are **NOT** intended for overnight (extended) wear.

LENS CARE DIRECTIONS

Eyecare practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

General Lens Care (First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

Always wash, rinse, and dry hands before handling contact lenses.

- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling, or if advised by the eyecare practitioner.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or a cleaning solution **does not substitute for disinfection.**

The lens care products listed below are recommended by Polymer Technology for use with the BOSTON XO Contact Lenses. Eyecare practitioners may recommend alternate products that are appropriate for the patient's use with his or her lenses).

LENS CARE TABLE

Product Purpose	Lens Care System Chemical (Not Heat)
Clean	Boston ADVANCE® Cleaner or Boston® Cleaner
Disinfect	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution
Store	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston Conditioning Solution
Multi-Action (Clean, Condition, Disinfect, Rinse and Cushion)	Boston SIMPLICITY® Multi-Action Solution
Lubricate/Rewet	Boston® Rewetting Drops
Weekly Enzymatic Cleaner	Boston® ONE STEP Liquid Enzymatic Cleaner

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as directed by your eyecare practitioner to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eyecare practitioner. Follow the instructions provided in the disinfecting solution packaging.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Eyecare practitioners may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from BOSTON® XO Contact Lenses.
- BOSTON XO Contact Lenses **cannot** be heat (thermally) disinfected.

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LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer or the eyecare practitioner, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving/cannot be removed), the patient should be instructed to apply one to three drops of a recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 5 minutes, the patient should immediately consult the eyecare practitioner.

EMERGENCIES

The patients 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, THEN REMOVE LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied (nonsterile) in a plastic lens storage case. The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber (if present) and lot number. Additional parameters of add power, segment height, prism ballast and truncation may be included for bifocal/multifocal lenses.

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REPORTING OF ADVERSE REACTIONS

All serious adverse reactions observed in patients wearing the BOSTON® XO Contact Lenses or adverse experiences with the lenses should be reported to:

Consumer Affairs
Polymer Technology
1400 North Goodman Street
Rochester, NY 14603-0450
1-800-333-4730

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1400 North Goodman Street
Rochester, NY 14603-0450
1-800-333-4730

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Print Date: 04/00

LB6273/01

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PATIENT CARE GUIDE

BOSTON[®] XO (hexafocon A)

*Spherical & Aspherical Contact
Lenses for Myopia & Hyperopia,
Bifocal/Multifocal Contact Lenses for
Presbyopia and Toric Lenses
to Correct Astigmatism in
Not aphakic and Aphakic Persons*

*Fluoro Silicone Acrylate
Rigid Gas Permeable
Contact Lenses
For
Daily Wear*

CAUTION:
*Federal Law Prohibits
Dispensing Without a Prescription*

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 - (Cleaning, Rinsing, Disinfecting, Storage and Rewetting/Lubricating)
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 - Care for a Sticking (Nonmoving) Lens
 - Lens Case Cleaning and Maintenance
 - Emergencies
- Instructions for Monovision Wearer
- Prescribed Wearing Schedule
- Appointment Schedule

INTRODUCTION

Your eyecare practitioner has fit you with contact lenses known as BOSTON® XO. BOSTON XO spherical, toric and bifocal/multifocal lenses are manufactured from BOSTON XO contact lens material. It is essential that you strictly follow the recommended handling, cleaning and storage procedures. Failure to do so may eventually impair the performance of your lenses.

WEARING RESTRICTIONS AND INDICATIONS

BOSTON XO Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfection (not heat) system only.

BOSTON XO Contact Lenses described in this booklet should be removed daily from your eyes for routine cleaning and disinfecting as prescribed by your eyecare practitioner. **DO NOT WEAR YOUR BOSTON XO CONTACT LENSES WHILE SLEEPING.**

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE BOSTON XO Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the BOSTON XO contact lens material
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential to follow your eyecare practitioner's directions 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 should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, **immediately remove lenses** and promptly contact your eyecare practitioner.

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PRECAUTIONS

You should carefully adhere to the following care regimen and safety precautions:

- Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness

Color	Center Thickness
Ice Blue	>0.65 mm
Violet	>0.65 mm

- Before leaving the eyecare practitioner's office, you should be able to properly remove lenses or should have someone else available who can remove the lenses for you.
- You should remove your lenses immediately if your eyes become red or irritated.
- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the wetting/soaking solution and lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package insert for the use of contact lens solutions.
 - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp BOSTON® XO Contact Lenses.
 - Sterile unopened solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
 - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected overnight prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, immediately consult your eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions that follow for the BOSTON XO Contact Lenses and those provided by your eyecare practitioner.

- Never wear lenses beyond the period recommended by your eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eyecare practitioner about wearing lenses during water activities and other sports.
- Inform your health care practitioner (doctor) that you wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Always contact your eyecare practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Follow your eyecare practitioner's instruction as to a recommended follow-up schedule.

ADVERSE EFFECTS

The following problems may occur:

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

If you notice any of the above:

Immediately remove 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 your eyecare practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, **immediately remove the lenses and consult your eyecare practitioner.**

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

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PERSONAL CLEANLINESS FOR LENS HANDLING**1. Preparing the Lens for Wearing**

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

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

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

2. Handling the Lenses

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or cracks.

3. Placing the Lens on the Eye

After thoroughly washing and rinsing your hands, and after proper cleaning and conditioning of the lens, follow these steps to insert the lens:

- Remove the lens from its storage compartment.
- Rinse the lens with fresh conditioning solution, if desired.
- Inspect the lens to be sure that it is clean, uniformly wet and free of debris.
- Rub several drops of conditioning solution over the lens surfaces.
- Place the lens on the top of the index finger of your dominant hand. Place the middle finger of the same hand close to the lower lash and hold down the lower lid.
- Use the forefinger or middle finger of your other hand to lift the upper lid and then place the lens on the eye. It is not necessary to press the lens against the eye.
- Gently release the lids and blink. The lens will center automatically. Always verify its proper position by checking your vision immediately after insertion.
- Use the same technique or reverse the hand when inserting the other lens.

There are other methods of lens placement. If the above method is difficult for you, your eye-care practitioner will provide you with an alternate method.

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

- The lens is not centered on the eye (see "Centering the Lens," next in this booklet).

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

- a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
- b. The lens is on the wrong eye.

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

4. Centering the Lens

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

- Close your eyelids and gently massage the lens into place through the closed lids.

OR

- Gently push the off-centered lens onto the cornea while the eye is open using finger pressure on the upper or lower lid next to the edge of the lens.

5. Removing the Lens

Before removing your lenses, it is recommended that you have the following items available:

- 1) A lens storage case.
- 2) **Two Bottle Care System**
Boston ADVANCE® Cleaner or Boston® Cleaner, **AND**
Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution.

OR

- 1) **One Bottle Care System**
Boston SIMPLICITY® Multi-Action Solution (Clean, Condition, Disinfect, Rinse & Cushion)

- 3) A clean towel.

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. There are two suggested methods of lens removal:

TWO-FINGER METHOD

- 1) Place a towel under your eye to catch the lens.
- 2) Place the tip of the forefinger of one hand on the middle of the upper lid margin and the forefinger of the other hand on the middle of the lower lid margin.
- 3) Press the lid margin inward and then together. The lens should be wedged out of your eye onto your hand or towel.
- 4) The lens may come out but remain on your eyelid or hand or be decentered onto the white part of your eye. If the latter occurs, recenter the lens onto your cornea before repeating the removal procedure.

BLINK METHOD

Seat yourself at a table covered with a clean towel and lean over until you are looking down at the surface.

- 1) Place your index finger at the outer junction of your upper and lower lids, stretch the skin outward and slightly upward. (Do not allow your lid to slide over the lens.)

- 2) Blink briskly. The lens will be pinched by the pressure of your eyelids and the lens will pop out onto the clean surface of the towel, or you may catch the lens in the palm of your hand.
- c. Remove the other lens by following the same procedure.
- d. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, STORAGE AND REWETTING/LUBRICATING)

Note: If these methods for removing your lenses are difficult for you, your eyecare practitioner will provide you with an alternate method.

CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, STORAGE AND REWETTING/LUBRICATING)

1. Basic Instructions

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

You should adhere to the recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to place and remove lenses and do not have someone available to place and remove them for you, you should not attempt to wear contact lenses.

When you first get your lenses, be sure you can place the lenses on your eyes and remove them while you are in your eyecare practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfecting. Your eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Patient Instructions for the BOSTON® XO Contact Lenses.

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

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

- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- The lens care products listed below are recommended by Polymer Technology for use with your BOSTON XO Contact Lenses. Your eyecare practitioner may recommend alternate products that are appropriate for you to use with your BOSTON XO Contact Lenses.

LENS CARE TABLE

Product Purpose	Lens Care System
	Chemical (Not Heat)
Clean	Boston ADVANCE® Cleaner or Boston® Cleaner
Disinfect	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution
Store	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston Conditioning Solution
Multi-Action (Clean, Condition, Disinfect, Rinse and Cushion)	Boston SIMPLICITY® Multi-Action Solution
Lubricate/Rewet	Boston® Rewetting Drops
Weekly Enzymatic Cleaner	Boston® DINE STEP Liquid Enzymatic Cleaner

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups) and rinse the lens thoroughly as recommended by your eyecare practitioner to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the above recommended system by your eyecare practitioner and/or the manufacturer. Follow the instructions provided in the disinfection solution labeling.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the Package Insert or your eyecare practitioner for information on storage of your lenses.
- Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eyecare practitioner for a recommendation on how to store your lenses.
- BOSTON XO Contact Lenses **cannot** be heat (thermally) disinfected.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case

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manufacturer or the eyecare practitioner; then allow the lens case to air dry. When the case is used again, refill it with fresh storage solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.

- Your eyecare practitioner may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable
- Your eyecare practitioner may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from your BOSTON® XO Contact Lenses.

2. Care for a Sticking (Nonmoving) Lens

If the lens sticks (stops moving/cannot be removed), apply one to three drops of a recommended lubricating or rewetting solution directly to your eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 5 minutes, you should immediately consult your eyecare practitioner.

3. Lens Case Cleaning and Maintenance

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer or the eyecare practitioner, and allowed to air dry after each use. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.

4. Emergencies

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

INSTRUCTIONS FOR THE MONOVISION WEARER

- You should be aware that, as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in all gazes that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to monovision. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer is your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations which are not visually demanding. For example, be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers' license requirements with monovision correction.
- Some monovision lens wearers will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, discuss with your eyecare practitioner whether

you should have additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance vision is required.

- If you require very sharp near vision during prolonged close work, you may want to discuss with your eyecare practitioner having additional contact lenses prescribed so that both eyes are corrected for near when sharp near vision is required.
- Some monovision lens wearers require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.
- It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- **The decision to be fit with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering and discussing your needs.**

CONSIDERATIONS FOR BIFOCAL/MULTIFOCAL LENSES

Patients who are considering bifocal/multifocal contact lenses should be highly motivated and must be informed of the benefits as well as the problems that may be encountered while adapting to bifocal/multifocal contact lens wear.

Your eyecare practitioner may discuss the following with you:

- 1. Adaptation**
Both bifocal spectacle and bifocal/multifocal contact lens wearers need to learn to adapt to proper head positioning. The bifocal patient must position the head upright while rotating the eyes downward to read. Once the bifocal patient has adapted, proper positioning becomes effortless.
- 2. Driving at Night**
Bifocal/multifocal contact lens wearers should experience night vision before actually driving while wearing their lenses.
- 3. Flare at Night**
Bifocal/multifocal contact lenses wearers may experience flare at night. This may occur with certain lens designs. With time, bifocal contact lens wearers adapt to this situation.
- 4. Visual Expectation**
Bifocal/multifocal contact lens wearers may experience visual acuities less than could be achieved with bifocal spectacles.

SAMPLE OF WEARING AND APPOINTMENT SCHEDULES

Wearing Schedule

DAY	WEARING TIME (Hours)
1	4 to 8 Hours
2	6 to 10 Hours
3	8 to 14 Hours
4	10 to 15 Hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*if the lenses continue to be well-tolerated.

WARNING: BOSTON XO Contact Lenses are **NOT** intended for overnight (extended) wear.

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APPOINTMENT SCHEDULE

Minimum number of hours lenses to be worn at time of appointment: _____

Your appointments are on:

Month	Year	Time	Date

PATIENT/EYECARE PRACTITIONER INFORMATION:

Eyecare Practitioner Information

Practitioner Name: _____

Practice Name: _____

Practitioner Address: _____

Practitioner Phone Number: _____

Recommended Lens Care Regimen: _____

Cleaning Solution: _____

Conditioning Solution: _____

Rewetting Solution: _____

Weekly Enzymatic Cleaner: _____

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYECARE PRACTITIONER IMMEDIATELY.

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Rochester, NY 14603-0450
1-800-333-4730

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Print Date: 04/00

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Contains: One Two
 BOSTON® RGP Contact Lenses
 Patient: _____
 Material: _____
 UV Absorber: Yes No

Right		Left
	B.C.	
	POWER	
	C.T.	
	Diameter	
	Lot #	
	Tint	

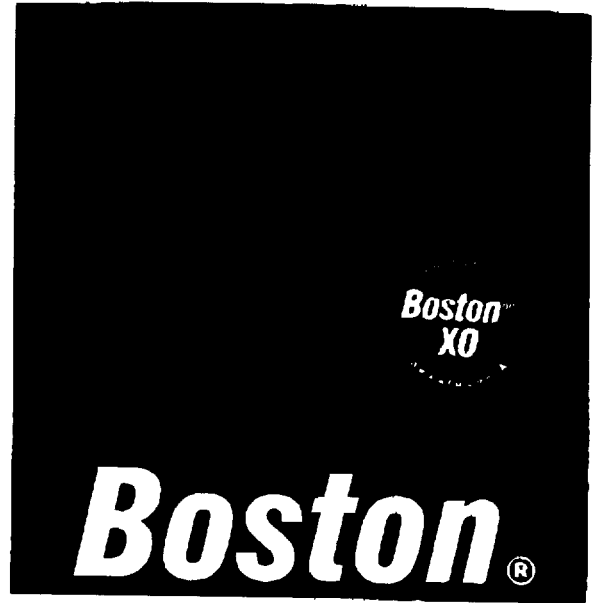
CAUTION: Federal Law prohibits dispensing without prescription

See package Insert for important safety information.

The BOSTON® Lens material manufactured by:
Polymer Technology, Wilmington, MA 01887

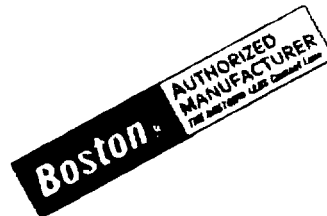
Do not accept this BOSTON Lens order if the Authorized
Manufacturer insignia is not intact.

©1997 THE BOSTON LENS BOSTON, EQUALENS, ENVISION,
BOSTON RXD, BOSTON ES, BOSTON 7 and BOSTON MULTIVISION are trademarks of
Polymer Technology, a Division of Wilmington Partners, L.P.



PRACTITIONER NOTE: The BOSTON Lenses are not sterile when shipped from the Authorized Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

Do not accept this BOSTON Lens order if the Authorized Manufacturer insignia is not intact.



IN CASE OF EMERGENCY

I am wearing BOSTON® Contact Lenses.
I use BOSTON® Solutions.

My Practitioner

Phone

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POLYMER TECHNOLOGY

1400 N. GOODMAN STREET • P.O. BOX 450 • ROCHESTER, NEW YORK 14603-0450



May 1, 2000

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices & Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) Premarket Notification
K000795
BOSTON XO Contact Lens

Attn: Eleanor Felton, HFZ-460

Dear Ms. Felton:

This is in response to your letter dated April 17, 2000.

Item #1:

The applicant has not provided Disclosure Statements for the clinical investigators.

Response #1:

Disclosure Statements for the clinical investigators can be found in Appendix A.

Item #2:

The labeling, as proposed, is deficient because of the following:

1. The applicant has not provided shipping labels for the device.
2. The lens description in the package insert and the fitting guide does not show add powers for presbyopia.
3. The fitting guide does not have cylinder powers.
4. The labeling (overall) does not show the amount of light transmission.
5. The fitting guide does not provide guidance for fitting the presbyopic patient.
6. The fitting guide contains a precaution regarding reduction in visibility. This precaution is not provided in any labeling for the patient (the one that really needs to know).

Response #2:

Revised labeling which addresses the above concerns can be found in Appendix B. Please note, a separate fitting guide has been developed for fitting the presbyopic patient. That document is also included in Appendix B. You will

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5/14



note that a reference to the availability of the Presbyopic Fitting Guide has been added to the Boston XO Professional Fitting Guide.

Item #3:

(b)(4)

Identify "Other" symptoms, problems and complaints and reasons for lens replacement.

Correct the typo on page 198.

Response #3:

A table has been provided which identifies the eyes with Snellen line decreases of 2 or more lines and reasons for the decreases. Decreases in sixteen eyes were due to monovision. Decreases for three eyes were due to heavy deposits, power change, and unexplained increase in over-refraction cylinder. The table can be found in Appendix C

The "Other" symptoms, problems and complaints and reasons for lens replacement can be found in Table 8.C (Details of Symptoms/Complaints Reported as Other) and Table 10.C (Details of Unscheduled Lens Replacements Reported as Other). These two tables are provided in Appendix D.

The corrected page 198 can be found in Appendix E

Item #4:

Provide an engineering drawing of each lens configuration for which clearance is requested.

Response #4:

Engineering drawings can be found in Appendix F.

Item #5:

Provide the manufacturing information regarding thermal polymerization conditions and alternate designs (e.g. aspheric, bifocal, and toric).

Response #5:

The thermal polymerization conditions can be found in Appendix G. The polymerization conditions do not change with design

Should you have any questions, please do not hesitate to telephone me at (716) 338-5477.

Sincerely,

Debra L.B. Ketchum
Manager, Regulatory Affairs

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Form Approved: OMB No. 0910-0396

Expiration Date: 3/31/02

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

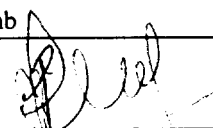
With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	See Attached List for Study #001	

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).
- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Brian Levy, O.D., M.Sc.	Vice President Global Biological and Clinical Research
FIRM / ORGANIZATION	
Bausch & Lomb	
SIGNATURE	DATE
	4/25/00

Paperwork Reduction Act Statement

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5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

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CLINICAL INVESTIGATOR LIST FOR CLINICAL STUDY #001

1. Paul Blaze, O.D.
2. Michael Goldsmid, O.D.
3. Frank Toscane. O.D.

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PROFESSIONAL FITTING AND INFORMATION GUIDE

**BOSTON® XO
(hexafocon A)**

*Spherical & Aspherical Contact
Lenses for Myopia & Hyperopia.
Bifocal Contact Lenses for
Presbyopia and Toric Lenses
to Correct Astigmatism in
Not aphakic and Aphakic Persons*

CAUTION:
*Federal Law Prohibits Dispensing
Without a Prescription*

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PRODUCT DESCRIPTION - BOSTON XO

The BOSTON XO Contact Lens material, hexafocon A, is composed of aliphatic siloxanyl fluoromethacrylate copolymer with an ultraviolet absorber. The tinted lenses contain the following color additives:

Color	Color Additive
Ice Blue	D & C Green No. 6
Violet	D & C Violet No. 2

The BOSTON XO Contact Lenses are a hemispherical shell of the following dimensions:

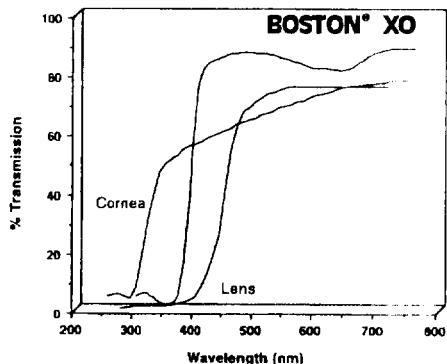
Spherical Lens Design	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	5.00 mm to 9.00 mm in .01 mm increments
Aspherical Lens Designs	
<i>(Some of these designs are patented; manufacture of these lenses in Boston XO (hexafocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.00 mm to 9.20 mm in 0.01 mm increments
Bifocal Lens Designs	
<i>(Some of these designs are patented; manufacture of these lenses in Boston XO (hexafocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	8.5 mm to 11.5 mm
Base Curve Range	6.30 mm to 9.50 mm in 0.01 mm increments
Segment Heights	-2.00 mm to +1.00 mm in 0.5 mm increments
Add Powers	+1.00D to +3.75D in 0.5D increments
Prism Ballast	0.5 to 3.5 prism diopters in 0.5D increments
Toric Lens Designs	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.80 mm to 9.50 mm in 0.01 mm increments
Toricity	Up to 9.00 Diopters

The lenses described above can have a center thickness of 0.07 to 0.65 mm that will vary with lens design, power and diameter.

The physical/optical properties of the lens are:

Specific Gravity	1.27
Refractive Index	1.415
Light Absorbance (640 nm)	4.6 Ice Blue
absorbance units/inch	5.5 Violet
Light Transmittance*	92%
*Average %T (400-800nm)	
Surface Character	Hydrophobic
Wetting Angle	49°
Water Content	<1%
Oxygen Permeability	140* (100**)
(x 10 ⁻¹¹ (cm ³ O ₂ · cm) / (cm ² · sec · mmHg) @ 35° C)	

**polarographic method (ISO/Fatt)



BOSTON XO - 0.07 mm thick BOSTON XO (Ice Blue)
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.
CRYSTALLINE 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 figure 5

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

WARNING

UV-absorbing contact lenses are **NOT** substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

ACTIONS

BOSTON XO Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina.

INDICATIONS

BOSTON XO Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. These lenses may be disinfected using a chemical disinfecting system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE BOSTON XO Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions

- Allergy to any ingredient in a solution which is to be used to care for the BOSTON XO Contact Lenses
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

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 eyecare practitioner's directions 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 eyecare practitioner.

PRECAUTIONS

Practitioner Note: BOSTON XO Contact Lenses are not sterile when shipped from the Authorized BOSTON Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

- Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness:

Color	Center Thickness
Ice Blue	>0.65 mm
Violet	>0.65 mm

Special Precautions for Eyecare Practitioners:

- 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 eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the practitioner.

- 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.
- Aphakic patients should not be fitted with BOSTON® XO Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eyecare practitioner's office the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the ultraviolet (UV) light absorber in the BOSTON XO Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the FITTING PROCEDURE for detailed instructions.)

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the conditioning/storage solution and lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp the BOSTON XO Contact Lenses.
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
 - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for BOSTON XO Contact Lenses and those instructions provided by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare practitioner about wearing lenses during water activities and other sports.
- Inform the patient to alert their health care practitioner (doctor) that they wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Always contact the eyecare practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- 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.

ADVERSE EFFECTS

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

- Comfort is less than when lens was first placed on the eye
- Feeling of something in the eye such as a foreign body, scratched area
- Excessive watering (tearing) of the eyes

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

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Immediately remove lenses

If the discomfort or problem stops, then closely inspect 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 eyecare practitioner.

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 the eye care practitioner.

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

- Eyes stinging, burning, itching (irritation), or other eye pain
- 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 symptoms, he or she should be instructed to:

Immediately remove lenses

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

SELECTION OF PATIENTS

BOSTON® XO Contact Lenses are rigid gas permeable lenses for the daily wear patient who may require the correction of visual acuity for myopia, hyperopia, astigmatism or presbyopia. BOSTON XO lenses are suitable for patients who have never worn contact lenses, for current PMMA wearers, for patients wanting to upgrade their current rigid gas permeable lenses, as well as for some patients who have been unsuccessful with soft contact lenses.

FITTING PROCEDURE OUTLINE

1. Pre-Fitting Examination
2. Initial Lens Diameter Selection
3. Initial Lens Base Curve Selection
4. Initial Lens Evaluation
5. Initial Lens Power Selection
6. Initial Lens Center Thickness Selection
7. Remaining Lens Parameter Selection
8. Follow-Up Care

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 daily wear or extended wear contact lenses (consider patient hygiene and mental and physical state),
- make ocular measurements for initial contact lens parameter selection,
- collect and record baseline clinical information to which post-fitting examination results can be compared,

A pre-fitting examination should include distance and reading refraction, keratometry and slit lamp evaluation to rule out any contraindications to contact lens wear. Careful assessment of the cornea, lids, conjunctiva and precorneal tear film establishes a baseline against which the practitioner can compare any changes resulting from contact lens wear.

2. Initial Lens Diameter Selection

For minus lenses, an initial lens diameter of 9.6 mm is recommended. For plus lenses, an initial lens diameter of 9.2 mm is recommended. It is important that the optical zone of the lens covers the pupil adequately, even in dim illumination.

3. Initial Lens Base Curve Radius Selection

The initial base curve radius selection is primarily a function of the lens diameter selected and the amount of corneal astigmatism present:

Step One:

Measure central corneal curvature and identify the Flat K (lowest dioptric power).

Example:

K = 42.75/44.75 @ 90 Flat K = 42.75D (7.90mm)

The "flat K" is used as a reference point from which the Base Curve Radius is chosen.

Step Two:

Calculate the corneal astigmatism (difference between the flat and steep K).

In This Example:

K = 42.75 / 44.75 @ 90 Corneal Astigmatism = 2.00D

Step Three:

Calculate the Base Curve Radius by referring to the Corneal Astigmatism Factor Chart for a given lens diameter.

Example: K = 42.75/44.75 @ 90 Flat K = 7.90 mm

- Corneal Astigmatism = 2.00D
- Lens Diameter = 9.6 mm
- Initial Base Curve:

Flat K	42.75D	7.90 mm
+ Corneal Astigmatism Factor	0.25D	flatter than Flat K
= Initial Base Curve	42.50D	
- Base Curve Radius = 42.50D = 7.94 mm

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Select 9.2 mm or 9.6 mm initial diameter.
Choose base curve according to chart.

Corneal Astigmatism Factors*		
Corneal Astigmatism	9.2 mm Diameter	9.6 mm Diameter
0.00 to 0.50D	0.50D flatter	0.75D flatter
0.75 to 1.25D	0.25D flatter	0.50D flatter
1.50 to 2.00D	on flat "K"	0.25D flatter
2.25 to 2.75D	0.25D steeper	on flat "K"
3.00 to 3.50D	0.50D steeper	0.25D steeper

*This chart assumes an optical zone that is 1.4 - 1.6 mm smaller than the lens diameter

4. Initial Lens Evaluation

A. Lens Positioning

Patient comfort is largely determined by lens positioning on the cornea. A slightly superior, lid-attachment positioning is generally preferred to enhance comfort and encourage normal blinking patterns. Ideally, the upper edge of the lens should be located at or near the superior limbus and remain covered during each blink. A central lens positioning is acceptable but requires the lens periphery to be designed with minimal edge lift and edge contours that are rolled slightly inward to reduce blink-related sensation. Inferior lens positioning, which interferes with normal blinking and promotes lens binding and 3-9 staining, should be avoided.

Note for fitting the hyperopic eye:

Single-cut plus lenses tend to position low. If the inferior decentration is modest, this design may be preferable, especially for smaller corneas. In many cases, lenticular-designed plus lenses offer better centration and more predictable blink-induced lens movement. Special attention must be directed to the edge design of interpalpebral lenticular lenses to insure that they provide minimal lid sensation by being well-tapered and rolled slightly inward.

B. Fluorescein Pattern

Typically, the fluorescein pattern of the final lens should show some mild apical bearing ("feather" touch) or alignment and the absence of peripheral bearing over more than 180° of its circumference. Excessive apical pooling or bearing should be avoided. A moderate edge lift is necessary to permit the edge of the lens to slide over the corneal surface with minimal resistance.

The presence of the UV-absorber in the BOSTON® XO (hexafocon A) Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. A simple, inexpensive approach is the use of an auxiliary yellow Kodak Wratten #12 filter in conjunction with the cobalt blue filter of the biomicroscope.

Slit Lamp Application (if desired):

1. All customary light intensities and filter settings (Cobalt Blue) are left in place
2. The Kodak Wratten Filter #12* (yellow) is secured on the patient side of the slit lamp microscope with a small piece of adhesive tape

Burton Lamp Application (necessary):

1. Replace blue bulbs with ordinary white bulbs.
2. Place Kodak Wratten Filter #47* (blue) over white bulb area.
3. Place Kodak Wratten Filter #12 (yellow) over patient side of viewing lens.
4. Use system in usual manner.

Important Note: Use of the Wratten filters will also enhance the view of non-UV rigid lenses and corneal fluorescein evaluation.

*Wratten #12 and #47 filters are available from Authorized BOSTON Manufacturers in the following kits: #7503 Slit Lamp Filter Kit, #7502 Burton Lamp Modification Kit.

5. Initial Lens Power Selection

A. Empirical Fitting

Step One:

Follow the steps for INITIAL LENS DIAMETER and BASE CURVE RADIUS SELECTION.

Step Two:

Employ the rules of SAM (steeper add minus) or FAP (flatter add plus) to determine lens power.

Example:

Spectacle Rx: -3.00-1.50 cx 180
K Readings: 42.75/44.75 @ 90

Flat K = 42.75D (7.90mm)

Corneal Astigmatism: = 2.00D
Lens Diameter = 9.6mm

Initial Base Curve:

Flat K = 42.75D 7.90 mm
+ Corneal Astigmatism Factor 0.25D flatter than Flat K
= Initial Base Curve 42.50D
Base Curve Radius 42.50D = 7.94 mm

Since the base curve is 0.25D flatter than K, employ the FAP principle to determine contact lens power.

Base Curve: 42.50D 0.25D flatter than Flat K
Sph power of spec Rx: -3.00D

FAP adjustment +(+0.25D)
Lens Power -2.75D

The lens in this example would be ordered as:

Base curve: 42.50D
Power: -2.75D
Diameter: 9.6mm

B. Trial Fitting

Step One:

Perform a spherical refraction over the best-fitting trial lens.

Step Two:

If the spherical power of the over-refraction is greater than 4.75D, correct for the vertex distance.

Example: -5.00D at 12 mm = -4.75D at the cornea
+5.00D at 12 mm = +5.37D at the cornea

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Step Three:

Combine the spherical over-refraction (corrected for vertex distance if appropriate) with the power of the trial lens to obtain the final contact lens power ordered.

Example: Trial lens 3.00D
 Over-refraction (+) +1.00D
 Power to order -2.00D

Vertex Conversion Chart (12 mm distance) <i>For minus powers reduce by amount shown. For plus powers increase by amount shown.</i>				
±Spherical over-refraction (D)	4.00 to 5.25	5.50 to 6.75	7.00 to 8.25	8.50 to 10.00
Corresponding Power				
Compensation (D)	0.25	0.50	0.75	1.00

6. Initial Lens Center Thickness Selection

For best clinical results, the eyecare practitioner should always specify center thickness as part of the complete prescription. The stability and flexural resistance of BOSTON® XO (hexafocon A) permit the use of a wide range of center thicknesses and designs.

For eyes with less than 1.25 diopters of corneal toricity consider the following standard thickness table

Minus Lens Center Thickness	
Lens Power	Recommended Thickness
Plano	0.18
-1.00	0.17
-2.00	0.16
-3.00	0.15
-4.00	0.14
-5.00	0.13
-6.00	0.12
-7.00	0.11
-8.00	0.10

In cases where corneal toricity is 1.50 diopter or greater, consider adding 0.01 mm of thickness per diopter of cylinder to the center thickness table to control blink-induced flexure.

7. Remaining Lens Parameter Selection

The final prescription should be provided to the Authorized BOSTON Manufacturer in a format which includes:

- base curve
- center thickness
- diameter
- optic zone
- power
- peripheral curves

By specifying the complete design, practitioner success and patient satisfaction are increased. The following suggested designs have proven successful in clinical testing. **Your Authorized BOSTON Manufacturer may also offer suggestions regarding lens design.**

<i>Select remaining lens parameters: optical zone & peripheral (edge) design.</i>			
Specify 8.0 – 8.2 mm optic zone			
<i>instruct manufacturer to blend to finished size</i>			
Specify peripheral curve design as follows:			
for 9.2 mm diameter		for 9.4 – 9.6 mm diameter	
Peripheral Curves		Peripheral Curves	
	1st	2nd	
Width	0.3 mm	0.3 mm	Width 0.3 mm 0.3 mm
Radius*	0.8 mm	2.3 mm	Radius* 1.2 mm 2.8 mm
*flatter than B.C.		*flatter than B.C.	

8. Follow-up Care

- a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, a conventional follow-up schedule for daily wear should be maintained.
- b. Prior to a follow-up examination, the contact lenses should be worn for at least 2 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, conduct a thorough biomicroscopy examination.
 - 1) The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is 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 refitted with a more appropriate lens.

IN-OFFICE CARE OF TRIAL LENSES

Eyecare practitioners should educate contact lens technicians concerning proper care of trial lenses.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected.

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Rochester, New York 14603-0450
1-800-333-4730

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Practitioner Note: The BOSTON® XO Contact Lenses are not sterile when shipped from the Authorized BOSTON Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

RECOMMENDED INITIAL WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

BOSTON XO Contact Lenses are indicated for **daily wear**. The **maximum** suggested wearing time for these lenses is:

DAY	WEARING TIME (Hours)*
1	4 to 8 hours
2	6 to 10 hours
3	8 to 14 hours
4	10 to 15 hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*if the lenses continue to be well-tolerated

CLINICAL ASSESSMENT

WARNING: BOSTON XO Contact Lenses are **NOT** intended for overnight (extended) wear

1. Criteria of a Well-Fitted Lens

Patient comfort is largely determined by lens positioning on the cornea. A slightly superior, lid-attachment positioning is generally preferred to enhance comfort and encourage normal blinking patterns. Ideally, the upper edge of the lens should be located at or near the superior limbus and remain covered during each blink. A central lens positioning is acceptable but requires the lens periphery to be designed with minimal edge lift and edge contours that are rolled slightly inward to reduce blink-related sensation. Inferior lens positioning, which interferes with normal blinking and promotes lens binding and 3-9 staining, should be avoided.

Typically, the fluorescein pattern of the lens should show some mild apical bearing ("feather touch) or alignment and the absence of peripheral bearing over more than 180° of its circumference. Excessive apical pooling or bearing should be avoided. A moderate edge lift is necessary to permit the edge of the lens to slide over the corneal surface with minimal resistance.

2. Optimizing Fitting Characteristics

In order to achieve optimal performance, it is often necessary to modify the initial lens parameters. Practitioner observations and interpretation of lens positioning, fluorescein patterns, and lens movement are essential to this process. The following chart summarizes common fitting relationships

INITIAL LENS ASSESSMENT			
	Optimum	Too Steep	Too Flat
Fluorescein Pattern	Parallel to Slight Apical Bearing Moderate Edge Lift	Excessive Apical Pooling Minimum Edge Lift	Excessive Apical Bearing Excessive Edge Lift
Position	Centered to Slightly Superior	Inferior	Superior Unstable
Movement	1-2 mm	Less Than 1 mm	More Than 2 mm
Comfort	Slight Initial Sensation	Initially Comfortable	Uncomfortable
Disposition	Prescribe	Select Flatter Base Curve or smaller diameter	Select Steeper Base Curve or larger diameter

3. Problem Solving

Persistent excessive lens awareness: This problem may be due to: the use of incompatible care products; improper use of care products (i.e., lens cleaning just prior to insertion); three and nine o'clock staining; deposits on the concave lens surface; accumulation of mucus under the lens; poor edge design, incomplete blinking or steeply fitted lenses.

Three and nine o'clock staining: If the lens positions low, it should be redesigned to achieve a higher position so as to avoid a false blink pattern. The lens periphery should be well tapered and its edge rolled slightly inward to minimize upper lid sensation and avoid incomplete reflex blinks. If the lens positions centrally, the diameter should be reduced, the periphery well tapered and the edge rolled slightly inward. Complete blinking should be encouraged. *Above all, be certain that the lens has not been fitted too steeply.*

Generalized corneal staining: In cases of diffuse staining not apparently related to back surface deposits on the lens, solution or preservative incompatibility should be ruled out.

Ocular redness without staining: This problem may be caused by some component of the care solutions such as preservatives or the presence of pingueculae, infectious or allergic conjunctivitis, or inadequate lens lubrication, including excessive mucus accumulation as occurs in dry eyes.

Excessive development of lens deposits:

This unusual problem may be related to: increased mucus production, i.e., GPC, keratitis sicca, chronic allergies, etc. The more frequent use of the BOSTON® Rewetting Drops may be helpful in these cases. However, excessive deposition has been found to be most often related to inappropriately polished lens surfaces which simulate an orange peel appearance visible only with magnification of 20X or greater. In many cases, deposits are easily removed by cleaning with original BOSTON Cleaner, BOSTON Advance Cleaner and/or BOSTON ONE STEP Liquid Enzymatic Cleaner. However, in extreme cases, it may be necessary to lightly polish the lenses with the BOSTON ONE STEP Liquid Enzymatic Polish. In the event that deposits cannot be removed by cleaning or polishing, the lens should be replaced.

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Lens surface dry spots: The presence of discrete non-wetting areas on a new or recently modified or polished lens are usually due to the persistence of hydrophobic products used during lens fabrication. These hydrophobic contaminants have a greater affinity for BOSTON® XO (hexaFocon A) polymers and if not removed with the BOSTON® Laboratory Lens Cleaner, the lenses should be returned to the Authorized BOSTON® Manufacturer for a special solvent cleaning.

Other causes of loss of surface wettability include: surface contamination with cosmetics, hair spray, skin preparations; inadequate tear lubrication; incomplete blinking; the use of incompatible preserved care solutions; and dry lens storage.

Unstable vision: This problem may be due to excessive blink-induced lens flexure resulting from a steep fit. Unstable vision may also result from excessive blink-induced lens movement, an excessively small optical zone diameter, or surface dry spots.

Reduced contact lens-corrected vision: Reduced vision correction unrelated to changes in refractive error may be due to lens warpage, front surface deposits, or switched lenses

Repeated lens breakage: Lens breakage problems may be due to careless handling or storage procedures (see Patient Instructions booklet)

BIFOCAL/MULTIFOCAL CONTACT LENS FITTING PROCEDURES FOR THE PRESBYOPIC PATIENT

A separate Fitting Guide is available through your Authorized Boston Manufacturer.

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 may not be a good candidate for monovision with the BOSTON XO 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 not to 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

tion as they have with bifocal reading glasses. Each patient should 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.

2. Eye Selection

Generally, the nondominant 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 "dominate 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 the appropriate plus power trial spectacle 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 plus power trial lens over the right or left eye.

B. Refractive Error Method

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

C. Visual Demands Method

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

Example:

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

3. Special Fitting Considerations

Unilateral Lens Correction

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

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and no lens on the other eye.

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 eye uncorrected for near.

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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 can be 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 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 distance objects, observe the reactions. Only after these visual 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 the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

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

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mildly blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for only minutes 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 use the lenses first 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 pas-

senger 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 drive only 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 eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the Patient Instructions.

PATIENT LENS CARE DIRECTIONS

Eyecare practitioners should review with the patient all lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

General Lens Care

(First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

Always wash, rinse, and dry hands before handling contact lenses.

- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. **Do not**

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alternate or mix lens care systems unless indicated on solution labeling or instructed by the eyecare practitioner.

- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in the mouth.
- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or a cleaning solution **does not substitute for disinfection.**

The lens care products listed below are recommended by Polymer Technology for use with BOSTON® XO Contact Lenses. Eyecare practitioners may recommend alternate products that are appropriate for the patient's use with his or her lenses).

LENS CARE TABLE

Product Purpose	Lens Care System
Clean	BOSTON Advance® Cleaner or BOSTON® Cleaner
Disinfect	BOSTON Advance® Comfort Formula Conditioning Solution or BOSTON® Conditioning Solution
Store	BOSTON Advance® Comfort Formula Conditioning Solution or BOSTON® Conditioning Solution
Multi-Action (Clean, Condition, Disinfect, Rinse and Cushion)	BOSTON Simplicity® Multi-Action Solution
Lubricate/Rewet	BOSTON® Rewetting Drops
Weekly Enzymatic Cleaner	BOSTON® ONE STEP Liquid Enzymatic Cleaner

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as recommended by the eyecare practitioner to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eyecare practitioner. Follow the instructions provided in the Disinfection Solution Packaging.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the Package Insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer or the eyecare practitioner; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Eyecare practitioners may recommend a Weekly Enzymatic Cleaner which can be used to effectively remove protein deposits from BOSTON XO Contact Lenses.
- BOSTON XO Contact Lenses **cannot** be heat (thermally) disinfected.

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CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving/cannot be removed), the patient should be instructed to apply one to three drops of a recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 5 minutes, the patient should immediately consult the eyecare practitioner

LABORATORY LENS CLEANER

Residue left by body oils, household solvents, and personal care products may be removed with an enhanced cleaning agent such as BOSTON Laboratory Lens Cleaner. This clear, colorless surfactant is for **laboratory and in-office use only**. When lenses are received from the Authorized BOSTON Manufacturer, they should be cleaned with BOSTON Laboratory Lens Cleaner prior to use of the BOSTON Care System and an overnight soak. Lenses exhibiting a nonwetting surface should be cleaned with BOSTON Laboratory Lens Cleaner as a method of first choice. **The BOSTON Laboratory Lens Cleaner is intended for PROFESSIONAL USE ONLY. It is not available for resale or distribution to patients.**

IN-OFFICE LENS MODIFICATIONS

Edge reshaping and surface repolishing can be performed by conventional techniques if the following precautions are observed: 1) avoid polishing compounds or cleaners that contain ammonia alcohol or organic solvents;* 2) completely remove all traces of adhesive (if double-backed tape is used) with the special authorized solvent** (the use of any other solvent may cause surface breakdown.) Minimize exposure to the solvent and immediately remove all traces with BOSTON* Cleaner or BOSTON Advance* Cleaner followed by a thorough water rinse. 3) perform the initial lens modifications cautiously because the response of this polymer to these procedures is more rapid than that of silicone acrylate materials; 4) more extensive modifications should not be attempted. Best results will be obtained by using the BOSTON* Cleaning Polish which is available from Authorized BOSTON Manufacturers. 5) The Original BOSTON* Care System, BOSTON Advance* Comfort Formula Care System or BOSTON Simplicity Multi-Action Care System including the overnight soak should be used prior to lens dispensing.

Caution: Damage may result from improper modification techniques. Please Note: BOSTON* Envision* and BOSTON* MultiVision due to their preformed back surface should not be modified. Consult your Authorized BOSTON Manufacturer or contact Polymer Technology for more detailed information.

***Warning:** Do **not** use solvents such as alcohols, esters, ketones or chlorinated hydrocarbons (including naphtha, lighter fluid, etc.) since they may damage the lens surfaces and increase the brittleness of the lens.

****Use only the solvent supplied by your lens laboratory, and minimize solvent exposure time by rubbing a solvent-saturated cloth over the lens surfaces and quickly removing the solvent with a surfactant. Do not soak the lenses in the solvent.**

REMOVAL OF SURFACE DEPOSITS

Deposits are easily removed from the surfaces of BOSTON* XO (hexafocon A) Contact Lenses. These deposits are best identified by inspecting the cleaned and dried lens with a slit lamp in a dark room using a medium-width illuminating beam. Surface deposits should be gently removed with BOSTON* Cleaning Polish, which is available in a kit form with a polishing pad that permits practitioners to manually clean and polish their patient's rigid gas permeable lenses. THE BOSTON LENS* Cleaning Polish and Manual Polishing Machine are available from Authorized BOSTON Manufacturers.

Caution: Applying excessive and prolonged pressure to the lens during the polishing procedure may alter its surface optics.

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REPORTING OF ADVERSE REACTIONS

All serious adverse reactions observed in patients wearing BOSTON® XO Contact Lenses or adverse experiences with the lenses should be reported to

Consumer Affairs
Polymer Technology
1400 North Goodman Street
Rochester, NY 14603-0450
1-800-333-4730

HOW SUPPLIED

Each lens is supplied (non-sterile) in a plastic lens storage case. The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber (if present) and lot number. Additional parameters of add power, segment height, prism ballast and truncation may be included for bifocal lenses.

**PACKAGE
INSERT**

**BOSTON® XO
(hexafocon A)**

*Spherical & Aspherical Contact
Lenses for Myopia & Hyperopia,
Bifocal Contact Lenses for
Presbyopia and Toric Lenses
to Correct Astigmatism in
Not aphakic and Aphakic Persons*

*Fluoro Silicone Acrylate
Rigid Gas Permeable
Contact Lenses
For
Daily Wear*

IMPORTANT:

*Please read carefully and keep
this information for future use.
This package insert is intended
for the eyecare practitioner,
but should be made available
to patients upon request. The
eyecare practitioner should
provide the patient with the
patient instructions that
pertain to the patient's
prescribed lens.*

CAUTION:

*Federal Law Prohibits Dispensing
Without a Prescription*

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DESCRIPTION

BOSTON® XO (hexafocon A) material is used for the manufacturing of daily wear rigid gas permeable contact lenses. BOSTON XO are wettable, non-hydrophilic rigid gas permeable contact lenses that are not surface treated and are made from siloxanyl fluoromethacrylate copolymer containing an ultraviolet absorber. BOSTON XO Contact Lenses are available in ice blue and violet.

Color	Color Additive
Ice Blue	D & C Green No. 6
Violet	D & C Violet No. 2

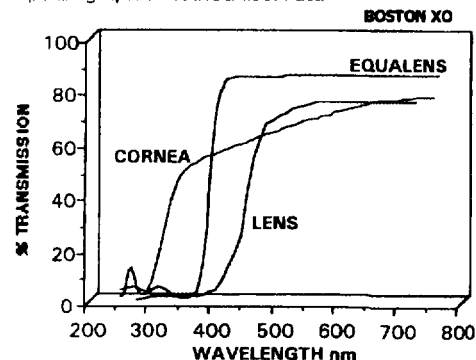
The physical characteristics of the BOSTON XO material was designed to facilitate the fabrication of high-quality rigid gas permeable contact lenses in a wide range of lens designs.

Spherical Lens Design	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	5.00 mm to 9.00 mm in .01 mm increments
Aspherical Lens Designs	
<i>(Some of these designs are patented; manufacture of these lenses in Boston XO (hexafocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.00 mm to 9.20 mm in 0.01 mm increments
Bifocal Lens Designs	
<i>(Some of these designs are patented; manufacture of these lenses in Boston XO (hexafocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	8.5 mm to 11.5 mm
Base Curve Range	6.30 mm to 9.50 mm in 0.01 mm increments
Segment Heights	-2.00 mm to +1.00 mm in 0.5 mm increments
Add Powers	+1.00D to +3.75D in 0.5D increments
Prism Ballast	0.5 to 3.5 prism diopters in 0.5D increments
Toric Lens Designs	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.80 mm to 9.50 mm in 0.01 mm increments
Toricity	Up to 9.00 Diopters

Physical/Optical Properties of BOSTON XO:

Specific Gravity	1.27
Refractive Index	1.415
Light Absorbance (absorbance units/inch)	
Ice Blue (with UV absorber)	4.6
Violet (with UV absorber)	5.5
Light Transmittance*	92%
*Average %T (400-800nm)	
Surface Character	Hydrophobic
Wetting Angle	49°
Water Content	<1%
Oxygen Permeability	140* (100**)
	(x 10 ¹¹ (cm ³ O ₂ · cm)/(cm ² · sec · mmHg) @ 35° C)

**polarographic method (ISO/Fatt)



BOSTON XO - 0.07 mm thick BOSTON XO (Ice Blue)
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.
CRYSTALLINE 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, figure 5.

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.

WARNING

UV-absorbing contact lenses are **NOT** substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

ACTIONS

BOSTON XO Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS (USES)

BOSTON XO Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. These contact lenses may be disinfected using a chemical disinfecting system only.

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CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE BOSTON XO Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation 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), if not aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the BOSTON XO contact lens materials.
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

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 eyecare practitioner's directions 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 these 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 eyecare practitioner.

PRECAUTIONS

Practitioner Note: BOSTON XO contact lenses are not sterile when shipped from the Authorized BOSTON® Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen

- Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness

<p>Color Ice Blue Violet</p>	<p>Center Thickness >0.65 mm >0.65 mm</p>
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Special Precautions for Eyecare Practitioners:

- 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 eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

- 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.
- Aphakic patients should not be fitted with the BOSTON XO Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eyecare practitioner's office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the ultraviolet (UV) light absorber in the BOSTON XO Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the conditioning/storage solution and/or lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp the BOSTON XO Contact Lenses.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.

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- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.
- 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 make-up. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the BOSTON XO Contact Lenses and in those prescribed by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eyecare practitioner about wearing lenses during water activities and other sports.
- Inform your health care practitioner (doctor) that you wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the lens case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Always contact your eyecare practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

- 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.

ADVERSE EFFECTS

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 the eye
- Feeling of something in the eye such as a 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 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 eyecare practitioner. 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, **immediately remove the lenses and consult the eyecare practitioner.**

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

FITTING

Conventional methods of fitting contact lenses apply to BOSTON XO Contact Lenses. For a detailed description of the fitting techniques, refer to the BOSTON XO Professional Fitting and Information Guide, copies of which are available from:

Practitioner Marketing Representative
Polymer Technology
1400 North Goodman Street
Rochester, NY 14603-0450
1-800-225-1241

Professional Fitting Guides are also available through your Authorized BOSTON® Manufacturer.

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WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eyecare practitioner.

Patients tend to overwear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

BOSTON® XO Contact Lenses are indicated for daily wear. The suggested wearing time for these lenses is:

DAY	WEARING TIME (Hours)*
1	4 to 8 hours
2	6 to 10 hours
3	8 to 14 hours
4	10 to 15 hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*if the lenses continue to be well-tolerated.

WARNING: BOSTON XO Contact Lenses are **NOT** intended for overnight (extended) wear

LENS CARE DIRECTIONS

Eyecare practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

General Lens Care (First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

Always wash, rinse, and dry hands before handling contact lenses.

- Always use **fresh unexpired** lens care solutions
- Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling, or if advised by the eyecare practitioner.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or a cleaning solution **does not substitute for disinfection.**

The lens care products listed below are recommended by Polymer Technology for use with the BOSTON XO Contact Lenses. Eyecare practitioners may recommend alternate products that are appropriate for the patient's use with his or her lenses).

LENS CARE TABLE

Product Purpose	Lens Care System Chemical (Not Heat)
Clean	Boston ADVANCE® Cleaner or Boston® Cleaner
Disinfect	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution
Store	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston Conditioning Solution
Multi-Action (Clean, Condition, Disinfect, Rinse and Cushion)	Boston SIMPLICITY® Multi-Action Solution
Lubricate/Rewet	Boston® Rewetting Drops
Weekly Enzymatic Cleaner	Boston® ONE STEP Liquid Enzymatic Cleaner

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as directed by your eyecare practitioner to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eyecare practitioner. Follow the instructions provided in the disinfecting solution packaging.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Eyecare practitioners may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from BOSTON® XO Contact Lenses.
- BOSTON XO Contact Lenses **cannot** be heat treated daily.

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LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer or the eyecare practitioner, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving/cannot be removed), the patient should be instructed to apply one to three drops of a recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 5 minutes, the patient should immediately consult the eyecare practitioner.

EMERGENCIES

The patients 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, THEN REMOVE LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied (nonsterile) in a plastic lens storage case. The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber (if present) and lot number. Additional parameters of add power, segment height, prism ballast and truncation may be included for bifocal lenses.

REPORTING OF ADVERSE REACTIONS

All serious adverse reactions observed in patients wearing the BOSTON® XO Contact Lenses or adverse experiences with the lenses should be reported to:

Consumer Affairs
Polymer Technology
1400 North Goodman Street
Rochester, NY 14603-0450
1-800-333-4730

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Rochester, NY 14603-0450
1-800-333-4730

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Print Date: 04/00

LB6273/01

**PATIENT
CARE
GUIDE**

**BOSTON® XO
(hexafocon A)**

*Spherical & Aspherical Contact
Lenses for Myopia & Hyperopia,
Bifocal Contact Lenses for
Presbyopia and Toric Lenses
to Correct Astigmatism in
Not aphakic and Aphakic Persons*

*Fluoro Silicone Acrylate
Rigid Gas Permeable
Contact Lenses
For
Daily Wear*

CAUTION:
*Federal Law Prohibits
Dispensing Without a Prescription*

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INTRODUCTION

Your eyecare practitioner has fit you with contact lenses known as BOSTON® XO. BOSTON XO spherical and toric lenses are manufactured from BOSTON XO contact lens material. It is essential that you strictly follow the recommended handling, cleaning and storage procedures. Failure to do so may eventually impair the performance of your lenses.

WEARING RESTRICTIONS AND INDICATIONS

BOSTON XO Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfection (not heat) system only.

BOSTON XO Contact Lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eyecare practitioner. **DO NOT WEAR YOUR BOSTON XO CONTACT LENSES WHILE SLEEPING.**

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE BOSTON XO Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the BOSTON XO contact lens material
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential to follow your eyecare practitioner's directions 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 should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, **immediately remove lenses** and promptly contact your eyecare practitioner.

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PRECAUTIONS

You should carefully adhere to the following care regimen and safety precautions:

- Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness:

Color	Center Thickness
Ice Blue	>0.65 mm
Violet	>0.65 mm

- Before leaving the eyecare practitioner's office, you should be able to properly remove lenses or should have someone else available who can remove the lenses for you.
- You should remove your lenses immediately if your eyes become red or irritated.
- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions
 - Do not heat the wetting/soaking solution and lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package insert for the use of contact lens solutions.
 - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp BOSTON® XO Contact Lenses.
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
 - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected overnight prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, immediately consult your eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions that follow for the BOSTON XO Contact Lenses and those provided by your eyecare practitioner.

- Never wear lenses beyond the period recommended by your eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eyecare practitioner about wearing lenses during water activities and other sports.
- Inform your health care practitioner (doctor) that you wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Always contact your eyecare practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Follow your eyecare practitioner's instruction as to a recommended follow-up schedule.

ADVERSE EFFECTS

The following problems may occur:

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

If you notice any of the above:

Immediately remove 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 your eyecare practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, **immediately remove the lenses and consult your eyecare practitioner.**

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

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PERSONAL CLEANLINESS FOR LENS HANDLING

1. Preparing the Lens for Wearing

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

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

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

2. Handling the Lenses

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or cracks.

3. Placing the Lens on the Eye

After thoroughly washing and rinsing your hands, and after proper cleaning and conditioning of the lens, follow these steps to insert the lens:

- Remove the lens from its storage compartment.
- Rinse the lens with fresh conditioning solution, if desired.
- Inspect the lens to be sure that it is clean, uniformly wet and free of debris.
- Rub several drops of conditioning solution over the lens surfaces.
- Place the lens on the top of the index finger of your dominant hand. Place the middle finger of the same hand close to the lower lash and hold down the lower lid.
- Use the forefinger or middle finger of your other hand to lift the upper lid and then place the lens on the eye. It is not necessary to press the lens against the eye.
- Gently release the lids and blink. The lens will center automatically. Always verify its proper position by checking your vision immediately after insertion.
- Use the same technique or reverse the hand when inserting the other lens.

There are other methods of lens placement. If the above method is difficult for you, your eye-care practitioner will provide you with an alternate method.

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

- The lens is not centered on the eye (see "Centering the Lens," next in this booklet)

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

- a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
- b. The lens is on the wrong eye.

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

4. Centering the Lens

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

- Close your eyelids and gently massage the lens into place through the closed lids.

OR

- Gently push the off-centered lens onto the cornea while the eye is open using finger pressure on the upper or lower lid next to the edge of the lens.

5. Removing the Lens

Before removing your lenses, it is recommended that you have the following items available:

- 1) A lens storage case.
- 2) **Two Bottle Care System**
Boston ADVANCE® Cleaner or Boston® Cleaner. **AND**
Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution.

OR

- 3) A clean towel.
- 4) **One Bottle Care System**
Boston SIMPLICITY® Multi-Action Solution (Clean, Condition, Disinfect, Rinse & Cushion)

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. There are two suggested methods of lens removal:

TWO-FINGER METHOD

- 1) Place a towel under your eye to catch the lens.
- 2) Place the tip of the forefinger of one hand on the middle of the upper lid margin and the forefinger of the other hand on the middle of the lower lid margin.
- 3) Press the lid margin inward and then together. The lens should be wedged out of your eye onto your hand or towel.
- 4) The lens may come out but remain on your eyelid or hand or be decentered onto the white part of your eye. If the latter occurs, recenter the lens onto your cornea before repeating the removal procedure.

BLINK METHOD

Seat yourself at a table covered with a clean towel and lean over until you are looking down at the surface.

- 1) Place your index finger at the outer junction of your upper and lower lids, stretch the skin outward and slightly upward. (Do not allow your lid to slide over the lens.)

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- 2) Blink briskly. The lens will be pinched by the pressure of your eyelids and the lens will pop out onto the clean surface of the towel, or you may catch the lens in the palm of your hand.
- c. Remove the other lens by following the same procedure.
- d. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, STORAGE AND REWETTING/LUBRICATING).

Note: If these methods for removing your lenses are difficult for you, your eyecare practitioner will provide you with an alternate method.

CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, STORAGE AND REWETTING/LUBRICATING)

1. Basic Instructions

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

You should adhere to the recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to place and remove lenses and do not have someone available to place and remove them for you, you should not attempt to wear contact lenses.

When you first get your lenses, be sure you can place the lenses on your eyes and remove them while you are in your eyecare practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfecting. Your eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Patient Instructions for the BOSTON® XO Contact Lenses.

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

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

- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- The lens care products listed below are recommended by Polymer Technology for use with your BOSTON XO Contact Lenses. Your eyecare practitioner may recommend alternate products that are appropriate for you to use with your BOSTON XO Contact Lenses.

LENS CARE TABLE

Product Purpose	Lens Care System Chemical (Not Heat)
Clean	Boston ADVANCE® Cleaner or Boston® Cleaner
Disinfect	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution
Store	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston Conditioning Solution
Multi-Action (Clean, Condition, Disinfect, Rinse and Cushion)	Boston SIMPLICITY® Multi-Action Solution
Lubricate/Rewet	Boston® Rewetting Drops
Weekly Enzymatic Cleaner	Boston® ONE STEP Liquid Enzymatic Cleaner

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups) and rinse the lens thoroughly as recommended by your eyecare practitioner to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the above recommended system by your eyecare practitioner and/or the manufacturer. Follow the instructions provided in the disinfection solution labeling.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the Package Insert or your eyecare practitioner for information on storage of your lenses.
- Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eyecare practitioner for a recommendation on how to store your lenses.
- BOSTON XO Contact Lenses **cannot** be heat (thermally) disinfected.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution recommended by the lens case

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manufacturer or the eyecare practitioner; then allow the lens case to air dry. When the case is used again, refill it with fresh storage solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.

- Your eyecare practitioner may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.
- Your eyecare practitioner may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from your BOSTON® XO Contact Lenses.

2. Care for a Sticking (Nonmoving) Lens

If the lens sticks (stops moving/cannot be removed), apply one to three drops of a recommended lubricating or rewetting solution directly to your eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 5 minutes, you should immediately consult your eyecare practitioner.

3. Lens Case Cleaning and Maintenance

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer or the eyecare practitioner, and allowed to air dry after each use. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.

4. Emergencies

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

INSTRUCTIONS FOR THE MONOVISION WEARER

- You should be aware that, as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in all gazes that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to monovision. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer is your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations which are not visually demanding. For example, be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers' license requirements with monovision correction.

- Some monovision lens wearers will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, discuss with your eyecare practitioner whether

you should have additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance vision is required.

- If you require very sharp near vision during prolonged close work, you may want to discuss with your eyecare practitioner having additional contact lenses prescribed so that both eyes are corrected for near when sharp near vision is required.
- Some monovision lens wearers require supplemental spectacles to wear over the monovision correction to provide the dearest vision for critical tasks. You should discuss this with your eyecare practitioner.
- It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- **The decision to be fit with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering and discussing your needs.**

CONSIDERATIONS FOR BIFOCAL LENSES

Patients who are considering bifocal contact lenses should be highly motivated and must be informed of the benefits as well as the problems that may be encountered while adapting to bifocal contact lens wear.

Your eyecare practitioner may discuss the following with you:

- 1. Adaptation**
Both bifocal spectacle and bifocal contact lens wearers need to learn to adapt to proper head positioning. The bifocal patient must position the head upright while rotating the eyes downward to read. Once the bifocal patient has adapted, proper positioning becomes effortless.
- 2. Driving at Night**
Bifocal contact lens wearers should experience night vision before actually driving while wearing their lenses.
- 3. Flare at Night**
Bifocal contact lenses wearers may experience flare at night. This may occur with certain lens designs. With time, bifocal contact lens wearers adapt to this situation.
- 4. Visual Expectation**
Bifocal contact lens wearers may experience visual acuities less than could be achieved with bifocal spectacles.

SAMPLE OF WEARING AND APPOINTMENT SCHEDULES

Wearing Schedule

DAY	WEARING TIME (Hours)*
1	4 to 8 Hours
2	6 to 10 Hours
3	8 to 14 Hours
4	10 to 15 Hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*if the lenses continue to be well-tolerated.

WARNING: BOSTON XO Contact Lenses are **NOT** intended for overnight (extended) wear.

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APPOINTMENT SCHEDULE

Minimum number of hours lenses to be worn at time of appointment: _____

Your appointments are on:

Month	Year	Time	Date

PATIENT/EYECARE PRACTITIONER INFORMATION:

Eyecare Practitioner Information

Practitioner Name: _____

Practice Name: _____

Practitioner Address: _____

Practitioner Phone Number: _____

Recommended Lens Care Regimen: _____

Cleaning Solution: _____

Conditioning Solution: _____

Rewetting Solution: _____

Weekly Enzymatic Cleaner: _____

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYECARE PRACTITIONER IMMEDIATELY.

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BIFOCAL/MULTIFOCAL CONTACT LENS FITTING PROCEDURE

FOR THE PRESBYOPIC PATIENT

There are two categories of presbyopic lens designs discussed in this fitting guide, bifocal alternating vision designs and multifocal simultaneous vision designs. Fitting information for each design is discussed in the following sections.

1. Pre-Fitting Examination

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

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

A prefitting examination should include distance and near refraction, keratometry and slit lamp evaluation to rule out any contraindications to contact lens wear. Careful assessment of the cornea, lids, conjunctiva and precorneal tear film establishes a baseline against which the practitioner can compare any changes resulting from contact lens wear.

2. Alternating Vision Bifocal Designs

- a. The first alternating vision design has a spherical base curve, a segment for distance correction and a segment for near correction. For distance vision, the majority of the pupil is covered by the distance zone. For near vision, the majority of the pupil is covered by the near zone as the lens translates (moves upward) in downgaze. This design is prism ballasted to enhance stabilization.

Fitting Principles

- 1) Trial fitting is always recommended.
- 2) The base curve radius and distance powers are chosen using conventional techniques.

- 3) The near add power is based on the patient's refraction.
 - 4) The diameter is chosen to place the segment line, which divides the distance, and near zones at or slightly below the inferior pupil margin.
 - 5) With blinking the lens should move 1-2 mm. The segment line will raise above the inferior pupil margin but should drop quickly. If not, distance vision will be adversely affected.
 - 6) Decreasing lens movement will generally improve distance vision. The following fitting adjustments will generally decrease movement:
 - Increase diameter
 - Steepen Base Curve
 - Increase Prism Ballasting
 - 7) Increasing lens movement will generally improve near vision. The following fitting adjustments may increase movement:
 - Decrease Diameter
 - Flatten Base Curve
 - Decrease Prism Ballasting
- b. The second alternating vision lens design has a spherical base curve corresponding to the near point power and a steeper spherical curve segment corresponding to the distance power. For distance vision, the majority of the pupil is covered by the distance zone segment. For near vision, the majority of the pupil is covered by the near zone as the lens translates (moves upward) in downgaze. This design is prism ballasted and may have a small inferior truncation to enhance stabilization.

Fitting Principles

- 1) Trial fitting is always recommended.
- 2) The base curve radius is chosen using conventional techniques.
- 3) Determine the distance spherical power to obtain optimum visual acuity.

Fitting Principles

- 1) Trial fitting is always recommended
- 2) Initial Base Curve Selection

The initial base curve selection is primarily a function of the amount of corneal cylinder present. This bifocal lens with aspheric posterior surface will generally be fitted steeper (approximately 0.10 mm) than a similar diameter spherical lens.

- a) For Minus Lenses -

Select a base curve radius equal to the radius of the flattest keratometer reading for corneas with less than 1.00D of corneal toricity. For corneas with 1.00D or greater corneal toricity, select a base curve radius equal to the mean of the two keratometer readings.

Example: K = 44.00 /46.00 D
Mean K = 45.00D = 7.50 mm (see conversion chart)
Select 7.50 mm base curve trial lens

(If conversion of diopters to millimeters results in a base curve parameter not available, select the next available steeper base curve.)

- b) For Plus Lenses -

Select a base curve radius equal to the corneal radius for spherical corneas. For toric corneas, select a base curve radius equal to the mean of the two keratometer readings.

- 3) Place the lens on the eye and allow it to settle (approximately 5 - 10 minutes).

3. Simultaneous Vision Multifocal Designs

- a. The first simultaneous vision multifocal lens design has an *aspheric back surface*, which progressively adds plus power from center to edge. This power change is gradual. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During distance viewing, the patient selectively attends to

the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

- 1) Trial fitting is always recommended.
- 2) The base curve radius is chosen using conventional techniques. Due to the aspheric flattening of the lens back surface, the base curve chosen will be considerably steeper than standard spherical single vision rigid lenses. It is not unusual to select a base curve 2-4 D steeper than the flattest K.

The following formula can be used as a starting point:

Flat K + add power + 1.00 D + 1/2 corneal astigmatism.

Example: 42.00/44.00 + 2.00 add

$$42.00 + 2.00 + 1 + 1 = 46.00$$

- 3) Centration is critical for this design. If proper exact centration can not be obtained, do not fit this lens.
 - 4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.
- b. The second simultaneous vision multifocal lens design has an *aspheric front surface*, which progressively adds plus power from center to edge. This power change is gradual. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During distance viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

- 1) Trial fitting is always recommended.
- 2) The base curve radius is chosen using conventional techniques.

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- 3) Centration is critical for this design. If proper exact centration can not be obtained, do not fit this lens.
 - 4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.
- c. The third simultaneous vision multifocal lens design lens employs a *back surface annular design with a distinct distance and near zone*. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During distance viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

- 1) Trial fitting is always recommended.
 - 2) The base curve radius is chosen using conventional techniques.
 - 3) Centration is critical for this design. If proper exact centration can not be obtained, do not fit this lens.
 - 4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.
- d. The fourth simultaneous vision multifocal lens design employs a *front surface annular design with a distinct distance and near zone*. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During distance viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

- 1) Trial fitting is always recommended.

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- 2) The base curve radius is chosen using conventional techniques.
- 3) Centration is critical for this design. If proper exact centration can not be obtained, do not fit this lens.
- 4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.

4. Initial Lens Evaluation

A. Lens Positioning

Patient comfort is largely determined by lens position on the cornea. Generally, a well-fitted lens exhibits a central or slightly inferior/central position.

Generally, an optimal aspherical fit will show a thin, even layer of tears centrally which extend to near the edge where a moderate amount of edge lift will be observed. This fluorescein pattern is characterized by the absence of a discernible intermediate bearing area which is commonly observed with conventional spherical designs.

B. Fluorescein Pattern

Excessive apical pooling or bearing should be avoided. A moderate edge lift is necessary to permit the edge of the lens to slide over the corneal surface with minimal resistance.

The presence of the UV-absorber in the BOSTON lens may require equipment enhancement to visualize fluorescein patterns adequately. A simple, inexpensive approach is the use of an auxiliary yellow Kodak Wratten #12 filter in conjunction with the cobalt blue filter of the biomicroscope.

Slit Lamp Application (if desired):

1. All customary light intensities and filter settings (Cobalt Blue) are left in place.

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2. The Kodak Wratten Filter #12* (yellow) is secured on the patient side of the slit lamp microscope with a small piece of adhesive tape.

Burton Lamp Application (necessary):

1. Replace blue bulbs with ordinary white bulbs.
2. Place Kodak Wratten Filter #47* (blue) over white bulb area.
3. Place Kodak Wratten Filter #12 (yellow) over patient side of viewing lens.
4. Use system in usual manner.

Important Note:

Use of the Wratten filters will also enhance the view of non-UV rigid lenses and corneal fluorescein evaluation.

- * Wratten #47 and #12 filters are available from Authorized BOSTON Manufacturers in the following kits: #7503 Slit Lamp Filter Kit, #7502 Burton Lamp Modification Kit

5. Determining Power and Dispensing the Lens

Once the appropriate base curve has been selected, over-refract to determine the appropriate distance dioptric power for the final lens order. Over-refractions of 4.00D or more should be corrected for vertex distance (see conversion table). The over-refraction should be added to the power of the trial lens to arrive at the final prescription.

Example:	Over-refraction	+0.50D
	<u>Trial Lens</u>	<u>-3.00D</u>
	Lens Power Ordered	-2.50D

Add power should be based on the spectacle add power required. Prior to dispensing the lens, clean the lens with an approved cleaner and store the lens wet in an approved wetting and soaking solution for at least four hours to ensure maximum patient comfort. Upon dispensing, evaluate the patient's lens using the same criteria previously described to evaluate the trial lens fitting.

6. Near Segment Positioning

- A. Generally, in alternating vision designs the near segment line should be positioned slightly below the inferior margin of the pupil. This is achieved by varying the lens base curve/corneal fitting relationship and/or the segment height. Segment height is

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specified as either 0.5 mm or 1.0 mm below the geometric center of the lens, or as a seg height in mm from the bottom of the lens.

- B. To bias toward better distance vision (decrease instability and improve acuity), less movement, lower post-blink segment positioning, and faster return times from post to pre-blink positions are helpful. The following may be helpful:
 - Steepen Fit
 - Lower Seg

- C. To bias toward better near vision (increase acuity), more movement and higher post-blink segment positioning are useful. The following may be helpful:
 - Flatten Fit
 - Raise Seg

- D. Lower segment positioning in conjunction with flatter fitting may represent the best compromise between distance and near visual performance.

- E. Visual performance will improve with time as the patient learns to control the movement and positioning of the lens. The following patient instructions may be useful:
 - Advise the patient that fluctuating vision at distance and near is possible, especially at first. Generally, blinking gently will improve distance vision.
 - Strong blinking will improve near vision. When reading, the eyes, not the head, should turn downward.

DIOPTER TO MILLIMETER
CONVERSION*

Posterior Apical Radius

<u>Keratometric</u> <u>Reading</u>	<u>Radius</u> <u>Convex</u>	<u>Keratometric</u> <u>Reading</u>	<u>Radius</u> <u>Convex</u>
47.75D	= 7.07 mm	43.75D	= 7.72 mm
47.50D	= 7.11 mm	43.50D	= 7.76 mm
47.25D	= 7.14 mm	43.25D	= 7.80 mm
47.00D	= 7.18 mm	43.00D	= 7.85 mm
46.75D	= 7.22 mm	42.75D	= 7.90 mm

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46.50D	=	7.26 mm	42.50D	=	7.95 mm
46.25D	=	7.30 mm	42.25D	=	8.00 mm
46.00D	=	7.34 mm	42.00D	=	8.04 mm
45.75D	=	7.38 mm	41.75D	=	8.08 mm
45.50D	=	7.42 mm	41.50D	=	8.13 mm
45.25D	=	7.46 mm	41.25D	=	8.18 mm
45.00D	=	7.50 mm	41.00D	=	8.23 mm
44.75D	=	7.55 mm	40.75D	=	8.28 mm
44.50D	=	7.59 mm	40.50D	=	8.33 mm
44.25D	=	7.63 mm	40.25D	=	8.39 mm
44.00D	=	7.67 mm	40.00D	=	8.44 mm

* Calculated

VERTEX DISTANCE
CONVERSION

<u>Spectacle Lens Correction</u>	<u>Vertex Distance at 12 mm</u>	
	<u>Plus Lenses</u>	<u>Minus Lenses</u>
4.00	4.25	3.87
4.50	4.75	4.25
5.00	5.25	4.75
5.50	5.87	5.12
6.00	6.50	5.62
6.50	7.00	6.00
7.00	7.62	6.50
7.50	8.25	6.87
8.00	8.87	7.25
8.50	9.50	7.75
9.00	10.12	8.12
9.50	10.75	8.50
10.00	11.37	8.87
10.50	12.00	9.37
11.00	12.75	9.72
11.50	13.37	10.12
12.00	14.00	10.50
12.50	14.75	10.87
13.00	15.50	11.25
13.50	16.12	11.62
14.00	16.75	12.00
14.50	17.50	12.37
15.00	18.25	12.75
15.50	19.00	13.00
16.00	19.75	13.50
16.50	20.50	13.75

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17.00	21.50	14.12
17.50	22.25	14.50
18.00	23.00	14.75
18.50	23.75	15.12
19.00	24.75	15.50
19.50	25.50	15.81
20.00	26.12	16.11

7. Follow-up Care

- a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, a conventional follow-up schedule for daily wear should be maintained.
- b. Prior to a follow-up examination, the contact lenses should be worn for at least 2 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 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 is 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.

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IN OFFICE CARE OF TRIAL LENSES:

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected.

Practitioner Note: The BOSTON RGP Contact Lenses are not sterile when shipped from the authorized manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

RECOMMENDED INITIAL WEARING SCHEDULE:

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

The BOSTON RGP Contact Lenses are indicated for daily wear. The maximum suggested wearing time for these lenses is:

<u>Day</u>	<u>Wearing Time (Hours)*</u>
1	4 to 8 Hours
2	6 to 10 Hours
3	8 to 14 Hours
4	10 to 15 Hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*If the lenses continue to be well tolerated.

WARNING: BOSTON RGP Bifocal Contact Lenses are not intended for overnight (extended) wear.

CLINICAL ASSESSMENT:

1. Optimizing Fitting Characteristics

In order to achieve optimal performance, it is often necessary to modify the initial trial lens parameters. Practitioner observation and interpretation of lens positioning, fluorescein patterns, and lens movement are essential to this process. The following chart summarizes common fitting relationships.

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INITIAL TRIAL LENS ASSESSMENT

	<u>OPTIMUM</u>	<u>TOO STEEP</u>	<u>TOO FLAT</u>
Fluorescein Pattern	Parallel to Slight Apical Bearing Moderate Edge Lift	Excessive Apical Pooling Minimum Edge Lift	Apical Touch Excessive Edge Lift
Position	Centered to Slightly Inferior	Inferior	Superior Unstable
Movement	1-2 mm	Less Than 1mm	More Than 2mm
Comfort	Slight Initial Sensation	Initially Comfortable	Uncomfortable
Disposition	Prescribe	Select Flatter Base Curve or smaller diameter	Select Steeper Base Curve or larger diameter

2. Problem Solving

Persistent excessive lens awareness: This problem may be due to: the use of incompatible care products; improper use of care products (i.e., lens cleaning just prior to insertion); inadequately blended peripheral curves; three and nine o'clock staining; deposits on the concave lens surface; accumulation of mucus under the lens; poor edge design, incomplete blinking or steeply fitted lenses.

Three and nine o'clock staining: If the lens positions low, it should be redesigned to achieve a higher position so as to avoid a false blink pattern. The lens periphery should be well tapered and its edge rolled slightly inward to minimize upper lid sensation and avoid incomplete reflex blinks. If the lens positions centrally, the diameter should be reduced, the periphery well tapered and the edge rolled slightly inward. Complete blinking should be encouraged. *Above all, be certain that the lens has not been fitted too steeply.*

Generalized corneal staining: In cases of diffuse staining not apparently related to rear surface deposits on the lens, solution or preservative incompatibility should be ruled out.

Ocular redness without staining: This problem may be caused by some component of the care solutions such as preservatives or the presence of pingueculae, infectious or allergic conjunctivitis, or inadequate lens

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lubrication, including excessive mucus accumulation as occurs in dry eyes.

Excessive development of lens deposits: This unusual problem may be related to: increased mucus production, i.e. GPC, keratitis sicca, chronic allergies, etc. The more frequent use of the BOSTON Rewetting Drops may be helpful in these cases. However, excessive deposition has been found to be most often related to inappropriately polished lens surfaces which simulate an orange peel appearance visible only with magnification of 20X or greater. In most cases, deposits are easily removed by cleaning with the BOSTON Cleaner or BOSTON Advance Cleaner, however, in extreme cases, it may be necessary for the practitioner to lightly polish the lenses with the BOSTON Cleaning Polish. In the event that deposits cannot be removed by cleaning or polishing, the lens should be replaced.

Lens surface dry spots: The presence of discrete non-wetting areas on a new or recently modified or polished lens, may be due to the persistence of hydrophobic products used during lens fabrication.

Other causes of loss of surface wettability include: surface contamination with cosmetics, hair spray, skin preparations; inadequate tear lubrication; incomplete blinking; the use of incompatible preserved care solutions; and dry lens storage.

Reduced contact lens-corrected vision: Reduced vision correction unrelated to changes in refractive error may be due to lens warpage, front surface deposits, or switched lenses.

Repeated lens breakage: Lens breakage problems may be due to careless handling or storage procedures (see Patient Instructions booklet) or the use of lenses having less-than-recommended center, edge or junction thickness, especially for patients having poor manual dexterity.

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CONSIDERATIONS FOR BIFOCAL/MULTIFOCAL LENSES:

Presbyopic patients who are considering bifocal/multifocal contact lenses should be informed of the benefits as well as the problems they may encounter while adapting to bifocal lens wear.

The following areas should be discussed with the patients.

1. Adaptation
Both bifocal spectacle and bifocal/multifocal contact lens wearers need to learn to adapt to proper head positioning. The patient must position the head upright while rotating the eyes downward to read. Once the patient has adapted, proper positioning becomes effortless.
2. Driving at Night
Patients wearing bifocal/multifocal contact lenses should experience night vision before actually driving while wearing their lenses.
3. Flare at Night
Patients wearing bifocal/multifocal contact lenses may experience flare at night. This may occur with certain lens designs (high seg positions or small distance fields). With time, patients adapt to this situation.
4. Visual Expectation
Patients wearing bifocal/multifocal contact lenses may experience visual acuities less than what could be achieved with bifocal spectacles.

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Contains: One Two
 BOSTON® RGP Contact Lens(es)
 Patient
 Material
 UV Absorber: Yes No
 Right Left
 B.C.
 Power
 C.T.
 Diameter
 Lot #
 Tint

CAUTION: Federal Law prohibits dispensing without prescription

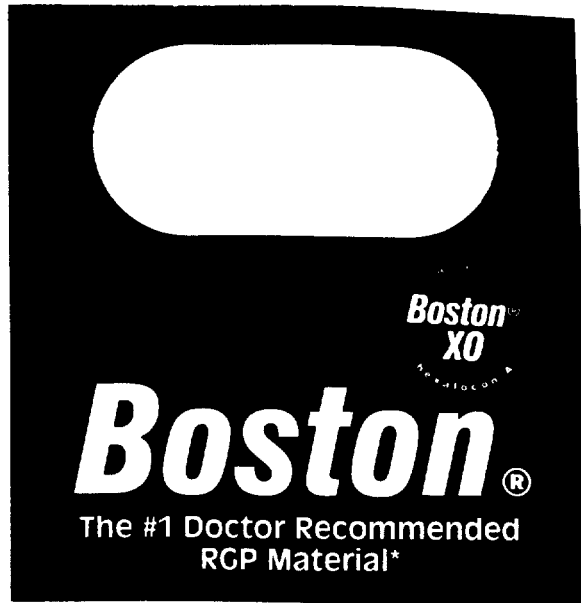
See package insert for important safety information.

The BOSTON® Lens material manufactured by:
Polymer Technology, Wilmington, MA 01887

Do not accept this BOSTON Lens order if the Authorized
Manufacturer insignia is not intact.

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BOSTON RXD, BOSTON ES, BOSTON 7 and BOSTON MultiVision
are trademarks of Polymer Technology.

*HPR Data



PRACTITIONER NOTE: The BOSTON Lenses are not sterile when shipped from the Authorized Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

Do not accept this BOSTON Lens order if the Authorized Manufacturer insignia is not intact.



IN CASE OF EMERGENCY

I am wearing the BOSTON®

Contact Lens. I use The BOSTON® Solutions

My Practitioner

Phone

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Attachment A – Details of Eyes with VA Line Decreases of 2 or More Snellen Lines

(b)(4)



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Table 8.C
Details of Symptoms/Complaints
Reported as Other

(b)(4)



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Table 10 C

(b)(4)



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Attachment B – Corrected Page 198

Table 10.C
Details of Unscheduled Lens Replacements Reported as Other

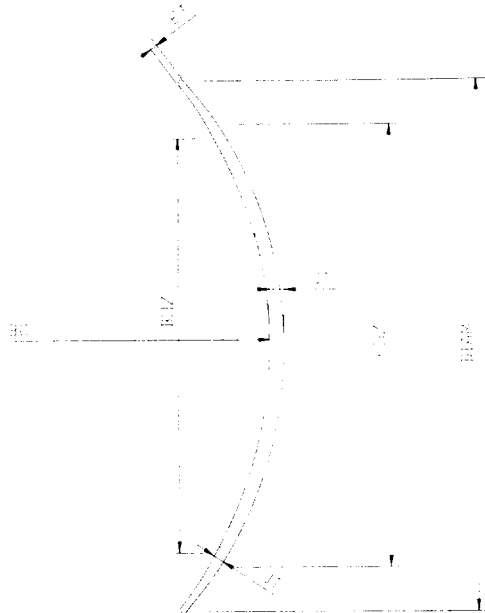
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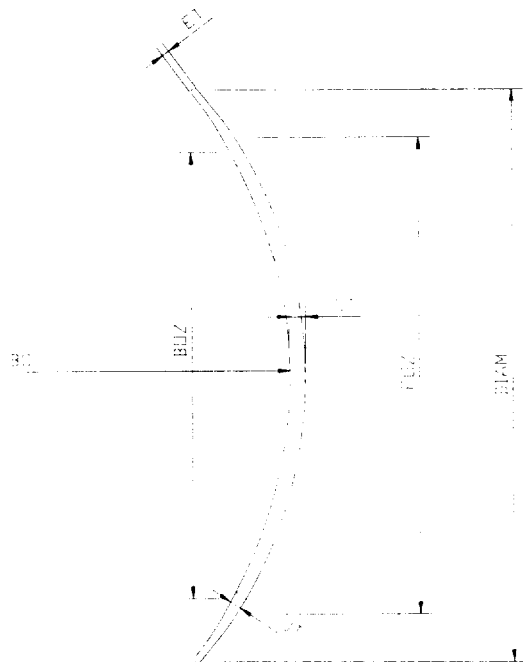
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Spherical Lens Designs



Parameter	Range
POWER	-20.00 to +20.00 D
DIAM = Overall Diameter	7.0 to 11.5 mm
BC = Base Curve Radius	5.00 to 9.00 mm
BOZ = Back Optical Zone	N/A
FOZ = Front Optical Zone	N/A
CT = Center Thickness	N/A
JT = Junction Thickness	N/A
ET = Edge Thickness	N/A

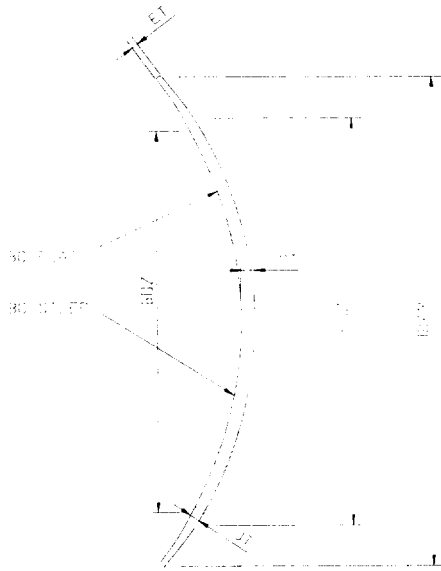
Aspherical Lens Designs



Parameter	Range
POWER	-20.00 to +20.00 D
DIAM = Overall Diameter	7.0 to 11.5 mm
BC = Base Curve Radius	6.00 to 9.20 mm
BOZ = Back Optical Zone	N/A
FOZ = Front Optical Zone	N/A
CT = Center Thickness	N/A
JT = Junction Thickness	N/A
ET = Edge Thickness	N/A

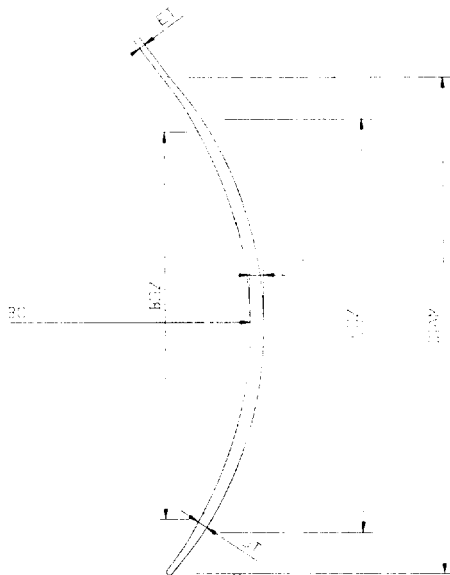
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Toric Lens Designs



Parameter	Range
POWER	-20.00 to +20.00 D
TORICITY	Up to 9.00 D
DIAM = Overall Diameter	7.0 to 11.5 mm
BC = Effective Base Curve Radius	6.80 to 9.50 mm
BC FLAT = Flat Base Curve Radius	N/A
BC STEEP = Steep Base Curve Radius	N/A
BOZ = Back Optical Zone	N/A
FOZ = Front Optical Zone	N/A
CT = Center Thickness	N/A
JT = Junction Thickness	N/A
ET = Edge Thickness	N/A

Bifocal Lens Designs

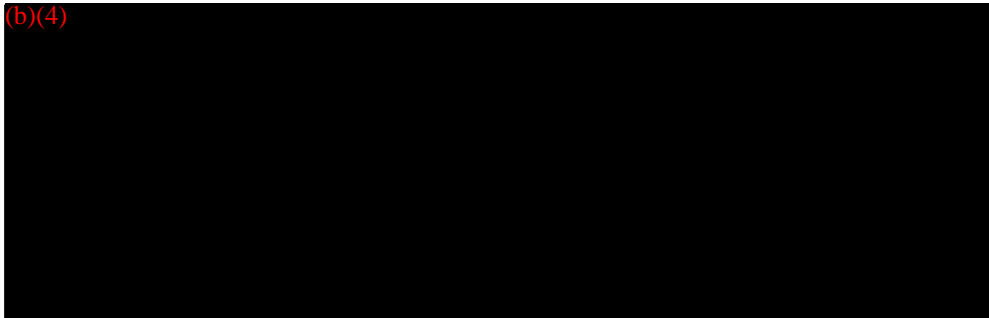


Parameter	Range
POWER	-20.00 to +20.00 D
ADD POWERS	+1.00 to +3.75 D
SEGMENT HEIGHTS	-2.00 to +1.00 mm
PRISM BALLAST	0.5 to 3.5 prism D
DIAM = Overall Diameter	8.5 to 11.5 mm
BC = Base Curve Radius	6.30 to 9.50 mm
BOZ = Back Optical Zone	N/A
FOZ = Front Optical Zone	N/A
CT = Center Thickness	N/A
JT = Junction Thickness	N/A
ET = Edge Thickness	N/A

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POLYMERIZATION CYCLE CONDITIONS FOR BOSTON XO



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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
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9200 Corporate Blvd.
Rockville, Maryland 20850

March 13, 2000

POLYMER TECHNOLOGY
GLOBAL VISION CARE
1400 N GOODMAN STREET
P.O. BOX 450
ROCHESTER, NY 14603
ATTN: DEBRA L.B. KETCHUM

510(k) Number: K000795
Received: 13-MAR-2000
Product: RIGID GAS PERMEABLE
CONTACT LENS

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

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K000795

POLYMER TECHNOLOGY CORPORATION

1400 N. GOODMAN STREET • ROCHESTER, NEW YORK 14692



March 10, 2000

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices & Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) Premarket Notification
BOSTON XO Contact Lens Material

Dear Sir or Madam:

Pursuant to 21 CFR Part 807, we are submitting the subject premarket notification for your review prior to market introduction.

The information marked as confidential and contained in the body of the submission is considered to be confidential within the meaning as set forth in 21 CFR Part 20.

Note: For the convenience of the Reviewer, an additional copy of the Indications Statement Form, and the 510(k) Summary were placed at the front of the attached submission.

Should you have any questions, please do not hesitate to telephone me at (716) 338-8638 or Douglas Fortunato at (716) 338-5477.

Sincerely,

Debra L.B. Ketchum

Debra L.B. Ketchum
Manager, Regulatory Affairs

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FDA/CDRH/OCE/DMC

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OP II

16

Center for Devices and Radiological Health
Records processed under FOIA Request #2016-1776 Released ON 8/31/16
Premarket Submission Cover Sheet

Date of Submission:

FDA Document Number:

Section A Type of Submission

- | | | | |
|---|---|--|---|
| <input checked="" type="checkbox"/> 510(k) | <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement - Regular |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special |
| | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> Report | <input type="checkbox"/> PMA Supplement - 30 day |
| | <input type="checkbox"/> IDE Report | | <input type="checkbox"/> PMA Supplement - Panel Track |

Section B1 Reason for Submission - 510(k)s Only

- | | | |
|---|---|---|
| <input type="checkbox"/> New device | <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in technology, design, materials or manufacturing process |
| <input type="checkbox"/> Other reason (specify):
Modified Device | | |

Section B2 Reason for Submission - PMAs Only

- | | | |
|---|---|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in design, component or specification: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Packager |
| <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Process change: | <input type="checkbox"/> Report submission: |
| <input type="checkbox"/> Indications | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Annual or periodic |
| <input type="checkbox"/> Instructions | <input type="checkbox"/> Sterilizer | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Packager | <input type="checkbox"/> Adverse reaction |
| <input type="checkbox"/> Shelf life | | <input type="checkbox"/> Device defect |
| <input type="checkbox"/> Trade name | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Request for applicant hold | |
| <input type="checkbox"/> Change in ownership | <input type="checkbox"/> Request for removal of applicant hold | |
| <input type="checkbox"/> Change in correspondent | <input type="checkbox"/> Request for extension | |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Request to move or add manufacturing site | |

Section B3 Reason for Submission - IDEs Only

- | | | |
|--|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion/extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approved |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Termination of study | <input type="checkbox"/> Protocol - feasibility | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol - other | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Unanticipated adverse effect | <input type="checkbox"/> Sponsor | <input type="checkbox"/> IOL submissions only: |
| <input type="checkbox"/> Emergency use: | <input type="checkbox"/> Report submission: | <input type="checkbox"/> Change in IOL style: |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Current investigator | <input type="checkbox"/> Request for protocol waiver |
| <input type="checkbox"/> Additional information | <input type="checkbox"/> Annual progress | |
| | <input type="checkbox"/> Site waiver limit reached | |
| <input type="checkbox"/> Other Reason (specify): | <input type="checkbox"/> Final | |

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Section C Product Classification

Product code: 86 HQD	C.F. R. Section 21 CFR 886.5916	Device Class
Classification Panel: Ophthalmic Devices		<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified

Section D Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and data. <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement
1 86 HQD	2	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K980741	1 BOSTON EO (enlufocon B) Lens Material	1 Polymer Technology
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section E Product Information - Applicable to All Applications

Common or usual name or classification name:

Trade or proprietary or model name	Model number
1 Rigid Gas Permeable Contact Lens	1 Not Applicable
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1 K943177	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: Laboratory Testing Animal trials Human trials

Indications (from labeling):

 BOSTON XO (hexafocon A) contact lens is indicated for daily wear for the correction of refractive ametropia (hyperopic and myopic, non-aphakic, presbyopic) patients with non-diseased eyes.

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Section F Manufacturing / Packaging / Sterilization Sites

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number: 1281950		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/Relabeler	
Company / Institution name: POLYMER TECHNOLOGY							
Division name (if applicable): n/a				Phone number (include area code): (716) 338-8638			
Street address: 100 Research Drive				FAX number (include area code): (716) 338-0702			
City: Wilmington		State / Province: MA		Country: United States		ZIP / Postal Code: 01887	
Contact name: Debra L.B. Ketchum							
Contact title: Manager, Regulatory Affairs							
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number:		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/Relabeler	
Company / Institution name:							
Division name (if applicable):				Phone number (include area code):			
Street address:				FAX number (include area code):			
City:		State / Province:		Country:		ZIP / Postal Code:	
Contact name:							
Contact title:							
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number:		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/Relabeler	
Company / Institution name:							
Division name (if applicable):				Phone number (include area code):			
Street address:				FAX number (include area code):			
Contact name:							
Contact title:							

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Section G Applicant or Sponsor

Company / Institution name: POLYMER TECHNOLOGY		FDA establishment registration number: 1313525	
Division name (if applicable): Global Vision Care		Phone number (include area code): (716) 338-8638	
Street address: 1400 N. Goodman Street, P.O. Box 450		FAX number (include area code): (716) 338-0702	
City: Rochester	State / Province: New York	Country: United States	ZIP / Postal Code: 14603-0450
Signature:			
Name: Debra L.B. Ketchum			
Title: Manager, Regulatory Affairs			

Section H Submission correspondent (if different from above)

Company / Institution name:			
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

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510(k) Elements	Authority (21 CFR)	Page Number
Device trade or proprietary name	807.87	4
Device common or usual name or classification	807.87	4
Establishment registration number (only applies if establishment is registered)	807.87	3
Class in which the device has been put under section 513 of the act and, if known, the appropriate panel; or if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.		4
Action taken by the party required to register to comply with the requirements of the act under Section 514 for special controls.	807.87	4
Proposed labels, labeling and advertisements sufficient to describe the device, its intended use, and the directions for its use. (Blue Book Memo #G91-1).	807.87	22 - 49
510(k) summary or a 510(k) statement.	807.87(h)	209 - 211
For class III only, a class III certification and class III summary.	807.87(l)	N/a
Photographs of the device.	807.87	N/a
Engineering drawings of the device.	807.87	N/a
Identification of the marketed device(s) to which equivalence is claimed during labeling and description of the device. Affiliated 510(k) numbers and product codes are voluntary in cover sheet.	807.87	8
Statement of similarities and/or differences with marketed devices.	807.87	8 - 9
Data to show consequences and effects of a modified device.	807.87	10
Submitter's name and address.	807.87	3
Contact person, telephone number and fax number	807.87	3
Representative/Consultant if applicable	807.87	n/a
Table of Contents	807.87	vi - viii
Name and address of manufacturing/packaging/sterilization facilities. Registration number of each facility when one exists.	807.87	3
Comparison table of the new device to the marketed device(s)	807.87	8 - 10
Action taken to comply with voluntary standards.	807.87	4
Performance data (bench, animal, clinical)	807.87	10 - 18
Sterilization information (Blue Book Memo #K90-1)	807.87	7
Software information (Blue Book Memo #K91-1)	807.87	n/a
Hardware information	807.87	n/a
Information requested in specific guidance documents (if applicable for this device)	807.87	*
Kit Certification Statement (for kit submission only)	807.87	n/a
Truthful and Accurate Statement	807.87	1

*Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997.

510(K) Premarket Notification

BOSTON XO Contact Lens Material

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Clinical Study Report	167 - 208
Appendix 9 510(k) Summary of Safety and Effectiveness	209 - 211

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Premarket Notification

Truthful and Accurate Statement

I certify that in my capacity as Manager, Regulatory Affairs, Polymer Technology, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.

Debra L.B. Ketchum

Debra L.B. Ketchum
Manager, Regulatory Affairs
Polymer Technology
1400 N. Goodman Street
P.O. Box 450
Rochester, New York 14603-0450

3-10-2000

Date

[Premarket Notification (510(k)) Number]

6. DEVICE IDENTIFICATION:

Classification

Name: Rigid Gas Permeable (hydrophobic) Contact Lens

Proprietary Name: Boston XO Contact Lens Material

Common Name: Fluoro silicone acrylate rigid gas permeable contact lens material

Development Name: Quantum II, RD-171 and B7-100

7. CLASSIFICATION NAME AND REFERENCE:

21 CFR 886.5916

Class II Ophthalmic Device

Daily wear contact lenses were reclassified from Class III to Class II medical devices under 59 FR 94 - 10397, March 4, 1994.

Class: These devices are Group III, Hydrophobic Material.

Device Panel and Product Code:

Ophthalmic: 86 HQD

8. PERFORMANCE STANDARDS:

No performance standards for this device have been promulgated under Section 514, Federal Food, Drug and Cosmetic Act (the Act).

Polymer Technology followed the CDRH guidelines Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, May 1994 and Testing Guidelines for Class III Contact Lenses, April, 1988.

9. INDICATIONS FOR USE:

The *Boston XO* is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfection system only.

The Statement of Indications for Use can be found in **Appendix 1**.

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10. DESCRIPTION OF THE DEVICE:

The *Boston XO* contact lens material, hexafocon A, is composed of aliphatic siloxanyl fluoro methacrylate copolymer.

The color additives conform to 21 CFR Part 74.3206. The hexafocon A material has an Oxygen Permeability of 100, a specific gravity of 1.27, and the lens visible light transmittance of at least 70%. The hexafocon A name has been adopted by the United States Adopted Names Council (USAN). A copy of the letter from USAN adopting the hexafocon A name can be found in **Appendix 2**.

11. PROPOSED LABELING AND PACKAGING

Proposed draft labeling or the *Boston XO* (hexafocon A) contact lens material can be found in **Appendix 3**. This includes the package insert, professional fitting and information guide, and patient instructions.

Advertising for the *Boston XO* (hexafocon A) contact lens material has not been developed at this time.

12. MANUFACTURING INFORMATION:

12.1 Chemical Composition

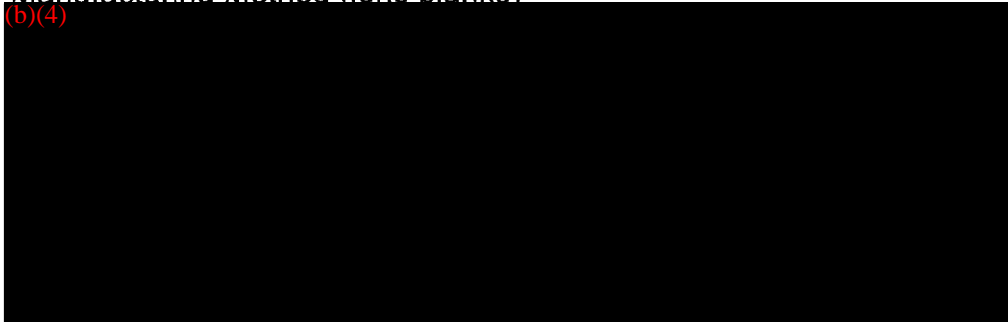
Component Name	Weight %	Mole%	Purpose
(b)(4)			

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12.2 Below is a description of the basic operations, procedures, and controls used in the routine manufacturing and packaging of the *Boston XO* (hexafocon A).

Manufacturing Method (lens blanks)

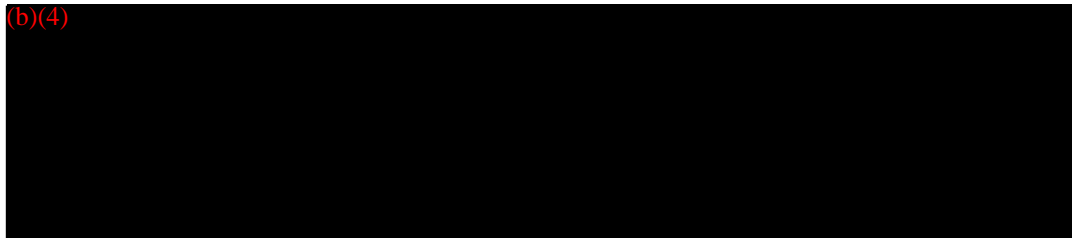
(b)(4)



(b)(4)

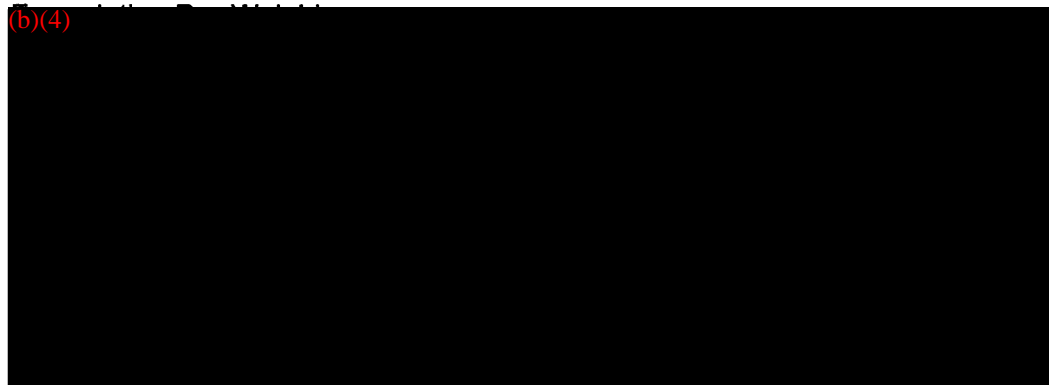


(b)(4)



The following list outlines the typical procedures followed to manufacture *Boston XO* (hexafocon A) contact lens material.

(b)(4)



A manufacturing flow chart can be found in **Appendix 4**.

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Packaging Materials and Methods

Printing, packaging, and labeling are performed in accordance with documented operating procedures, which are the same procedures utilized for previously approved BOSTON materials. All accepted contact lens blanks are packaged in polyethylene bags or plastic tubes or containers and corrugated cardboard boxes for shipment.

The packaging components for the *Boston XO* (hexafocon A) contact lens blanks and contact lenses are the same as those approved for other approved BOSTON materials such as BOSTON ES (enlufocon A). BOSTON ES (enlufocon A) was cleared on August 25, 1994 in 510(k) Premarket Notification No K943177. The packaging components includes the following:

- | | |
|----------------------------|-------------------------------------|
| polyethylene bags | standard plastic contact lens cases |
| plastic tubes and caps | package inserts |
| corrugated cardboard boxes | patient care guide |
| fitting guide | |

13. SHELF LIFE:

The *Boston XO* (hexafocon A) is a hydrophobic contact lens material with <1% water content. Based on the Premarket Notification Guidance Document for Daily Wear Contact Lenses, May 12, 1994, shelf-life studies are not required for clearance of this material.

14. STERILIZATION

Boston XO (hexafocon A) contact lens materials are shipped dry and labeled non-sterile, so therefore they are not required to be sterilized. Additionally, the proposed labeling includes the statement "Practitioner Note: The BOSTON lenses are not sterile when shipped from the authorized manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen."

Contact lens finishing laboratories that are authorized to manufacture the *BOSTON XO* (hexafocon A) contact lens materials are required to be in compliance with bioburden testing requirements. Guidance for this testing can be found in the Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, May 1994. Contact lens finishing laboratories must demonstrate an average bioburden level of <100 CFU/lens.

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15. MARKETED SUBSTANTIALLY EQUIVALENT DEVICES

15.1 Introduction:

The *BOSTON XO* (hexafocon A) contact lens material is substantially equivalent to the currently marketed *BOSTON ES* (enlufocon A) contact lens material cleared on August 25, 1994 in 510(k) Premarket Notification No K943177. The differences between the two devices are monomers and monomer ratios.

15.2 Basis of Equivalence:

The *BOSTON XO* contact lens material and the currently marketed *BOSTON ES* contact lens material are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia astigmatism and presbyopia) in aphakic and not-aphakic persons with nondiseased eyes. A copy of the proposed labeling can be found in **Appendix 3**.

Any other differences that do exist between the *BOSTON XO* and the predicate device, *BOSTON ES*, will not have any adverse effect on the safety and efficacy of the device. A substantial equivalence summary is presented below:

Substantial Equivalency Comparison Summary

Similarities

Feature	BOSTON XO	BOSTON ES
Daily Wear Indication	Same	Same
Indications for use	Same	Same
Contact Lens Material Type (Hydrophobic)	Same	Same
Water content	<1.0%	<1.0%
Manufacturing Process	Same	Same

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Differences

Feature	BOSTON XO	BOSTON ES
USAN polymer	hexafocon A	enflufocon A
*Oxygen Permeability	100	18

A comparison of the physicochemical properties of *BOSTON XO* (hexafocon A) contact lens material and the predicate device, *BOSTON ES* (enflufocon A) contact lens material is presented below:

Physicochemical Properties Comparison Summary

Physicochemical Properties	BOSTON XO	BOSTON ES
Refractive Index	1.415 ± .002	1.443 ± .003
*Light Absorbance	4.6 ± 0.4 (blue)	10.2 ± 0.06 (blue)
Water content	<1.0%	<1.0%
Specific Gravity	1.26 ± 0.01	1.22 ± 0.02
Wetting Angle (Captive Air Bubble)	49°	52°
Dry Hardness (Rockwell)	110 -115	117 - 120
**Oxygen Permeability	100	18

* ABS units per inch

** (x10⁻¹¹(cm³O₂ · cm)/(cm² · sec · mmHg) @ 35°C) (ISO/Fatt)

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Mechanical Properties	BOSTON XO		BOSTON ES	
	Average	Std.Dev.	Average	Std. Dev.
Modulus of elasticity (MPa)	1229	104	1888	41
Elongation at break (%) (reported as max. Strain)	5.48	1.26	4.46	0.41
Toughness (MPa x min.)	1.669	0.484	1.795	0.280
Flexural Strength (MPa) (reported as max. stress)	51.81	1.74	71.51	2.5

16. SAFETY AND EFFICACY INFORMATION

16.1 Introduction:

A series of preclinical and clinical testing was performed to demonstrate the safety and effectiveness of the *BOSTON XO* contact lens material. The clinical study was designed to demonstrate the safety and effectiveness of the device when used for daily wear.

Preservative Uptake/Release, Kligman Maximization Study, Three Week Ocular Safety in Rabbits, and the Clinical Study were conducted using *QUANTUM II*, (*hexafocon A*) contact lens material. *QUANTUM II* and *BOSTON XO* are the same product with the exception of *BOSTON XO* contains 0.5% of a polymerizable UV blocker, 4-methacryloxy-2-hydroxy benzophenone (MHB). The polymerizable UV monomer does not have the ability to disperse because it is tied into the matrix of the material, which is supported by Cytotoxicity, Systemic Injection, Acute Eye Irritation, Total Extractables, and Residual Monomer.

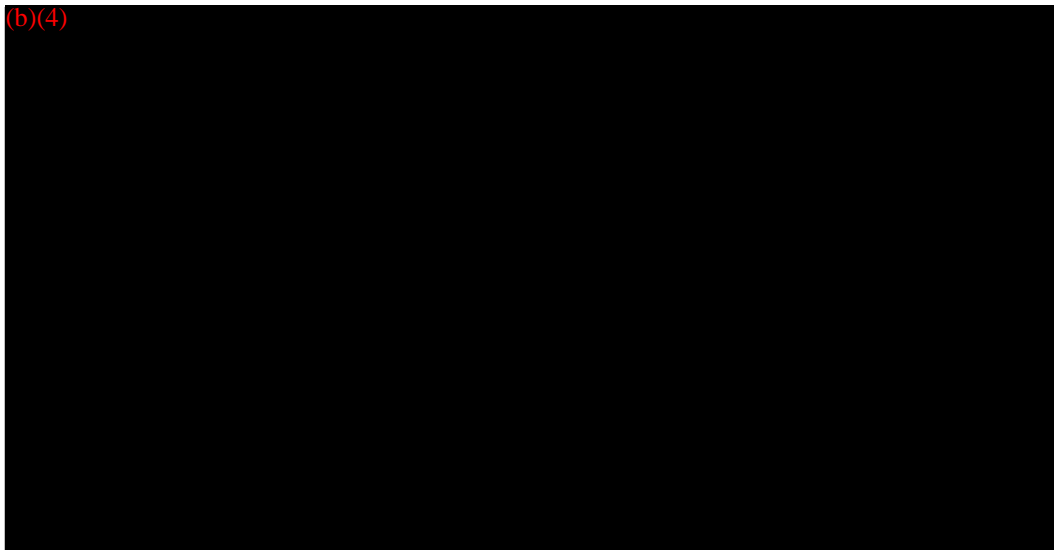
A summary of results from the preclinical and clinical tests is provided below. Full test reports for the preclinical tests described below can be found in **Appendix 5 - 7**. The clinical test report can be found in **Appendix 8**.

16.2 Leachability:

The final chemical composition of the *BOSTON XO* (hexafocon A) contact lens materials contains the polymers, additives, oligomers and residual monomer. The residual monomers and oligomers are not part of the lens material matrix, but are not water soluble and therefore, do not leach out into tears or contact lens care solutions.

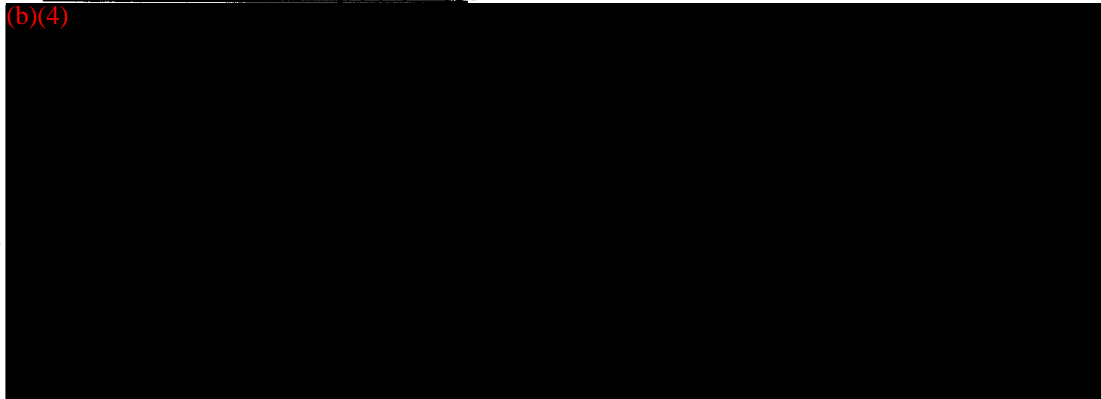
Additives:

(b)(4)



16.3 Lens/Solution Compatibility:

(b)(4)



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16.4 Residual Monomers

(b)(4)

A large black rectangular redaction box covers the content of section 16.4. The text "(b)(4)" is printed in red at the top left corner of the redacted area.

16.5 Total Extractables

(b)(4)

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16.6 Determination of Extractables Components

(b)(4)

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16.7 Preservative Uptake/Release

(b)(4)

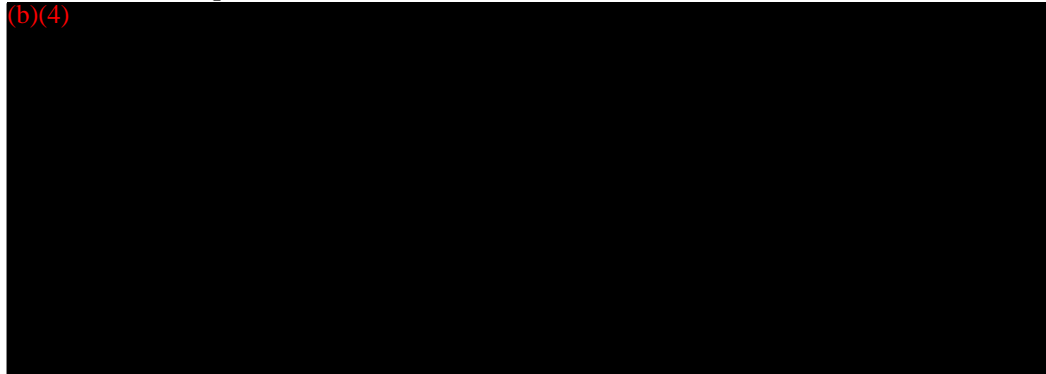


16.8 Physicochemical Properties

The data representing the properties of *BOSTON XO* (hexafocon A) contact lens material are based on three (3) lots of material. The procedures used to evaluate the *BOSTON XO* contact lens material are summarized below.

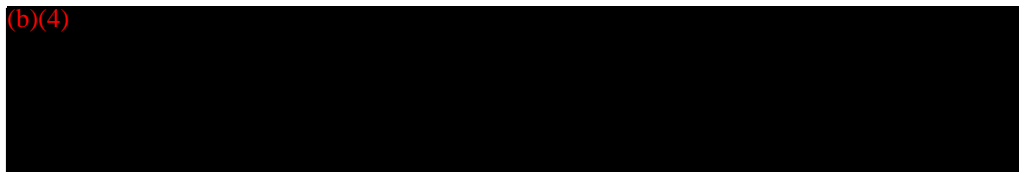
Color and Light Absorbance:

(b)(4)



Refractive Index:

(b)(4)



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Water Content:

The water content determination for the *BOSTON XO* (hexafocon A) contact lens material was done by a gravimetric method and found to be <1 %.

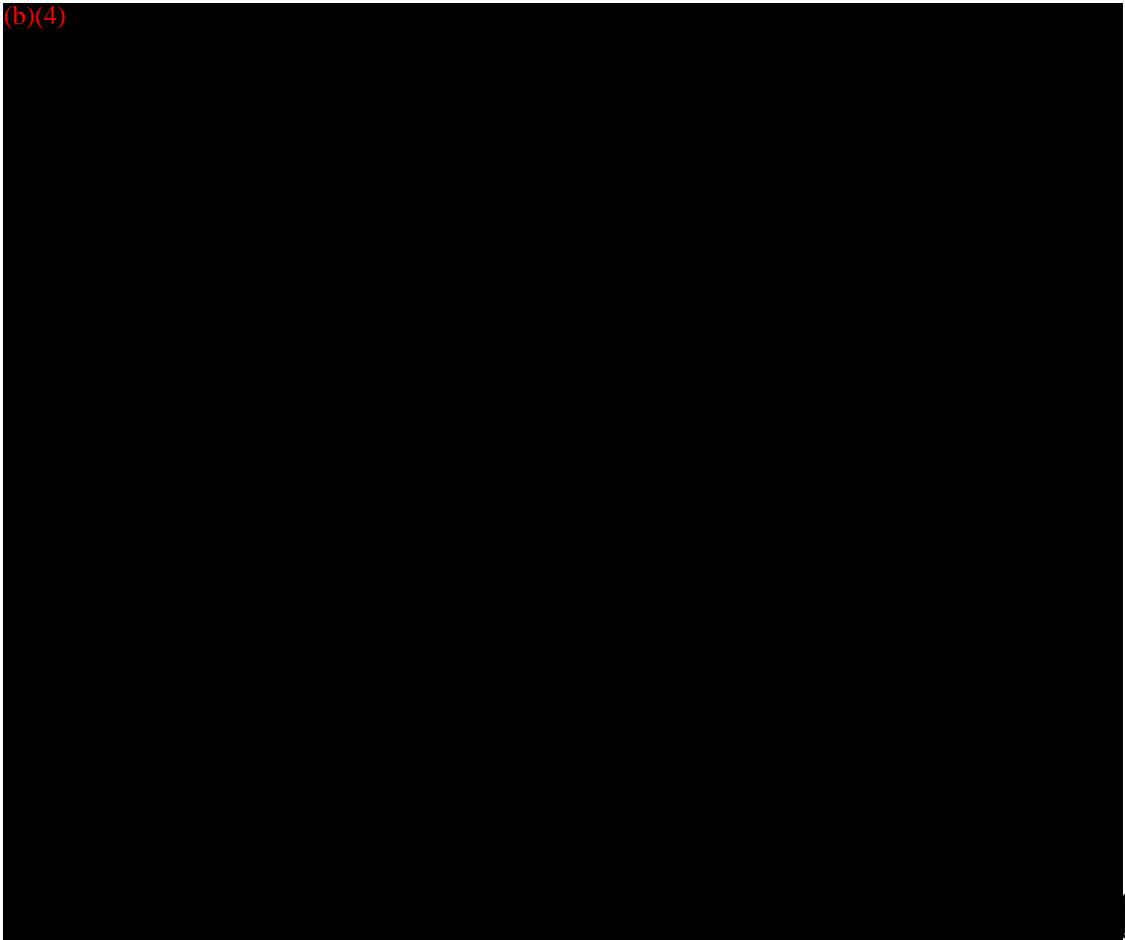
Wetting Angle:

The in vitro wetting angle of the *BOSTON XO* (hexafocon A) contact lens material was found to be $49^\circ \pm 3^\circ$ in accordance with the standard method published by the Contact Lens Manufacturers Association.

Oxygen-Permeability:

The oxygen permeability of the *BOSTON XO* (hexafocon A) contact lens material was measured using the ISO/Fatt method (ISO/DIS 9913-1.2). Four finely lapped disks of 12.8 mm diameter and thicknesses 0.2mm, 0.3mm, 0.4mm, and 0.5mm +/- 0.05 mm were measured twice. The resulting average Dk of the material was 100×10^{-11} (cm³O₂ · cm)/cm² · sec · mmHg @ 35° C (ISO/Fatt method).

Mechanical Properties:



(b)(4)



16.9 Toxicology Testing

In support of the claim of substantial equivalence to BOSTON ES (enfluocon A) contact lens material, the sponsor has conducted the toxicology testing on the *BOSTON XO* (hexafocon A) contact lens material according to the FDA Premarket Notification (510(k) Guidance document for Daily Wear Contact Lenses, May 12, 1994 and the FDA draft guideline, "Testing Guidelines for Class III Contact Lenses, April, 1988".

Cytotoxicity Test (USP)

BOSTON XO (hexafocon A) (b)(4)

. Therefore the test article is considered non-cytotoxic. A copy of the report can be found in **Appendix 7**.

Systemic Injection Test (USP)

(b)(4)

A large black rectangular redaction box covers the content of the Systemic Injection Test (USP) section.

Appendix 7.

Acute Eye Irritation Test (USP)

(b)(4)

A large black rectangular redaction box covers the content of the Acute Eye Irritation Test (USP) section.

Additional Recommended Testing

Preservative Uptake and Release testing was conducted, refer to section 16.7, because the *BOSTON XO*, (hexafocon A), contact lens material and the lens care regimen preservative systems do not carry the same electric charge.

Kligman Maximization Study

(b)(4)

A large black rectangular redaction box covers the content of the Kligman Maximization Study section.

Three Week Ocular Safety Study in Rabbits

(b)(4)



16.10 Clinical Testing

(b)(4)



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(b)(4)



A copy of the final report can be found in **Appendix 8**.

17. SUMMARY OF SAFETY AND EFFECTIVENESS

A Summary of Safety and Effectiveness is contained in **Appendix 9**.

18. REQUEST FOR CONFIDENTIALITY

Information marked as confidential and contained in the body of the submission is considered confidential by Polymer Technology within the meaning as set forth in 21 CFR Part 20.

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510(K) Premarket Notification
BOSTON XO Contact Lens Material

APPENDIX 1

INDICATIONS FOR USE STATEMENT

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Polymer Technology
1400 North Goodman Street
P.O. Box 450
Rochester, NY 14603-0450

Indications for Use Statement

510(k) Number (if known): _____

Device Name: BOSTON XO

Indications for Use:

BOSTON XO (hexafocon A) Contact Lens Material is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfecting system only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use _____

145

510(K) Premarket Notification
BOSTON XO Contact Lens Material

APPENDIX 2

UNITED STATES ADOPTED NAMES COUNCIL

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American Medical Association
515 North State Street
Chicago, Illinois 60610

UNITED STATES ADOPTED NAMES COUNCIL

June 25, 1997

Telefax: 312-464-4184
E-mail: Sophia_Fuerst@ama-assn.org

SOPHIA V. FUERST, Associate Secretary
(312) 464-5352

JJ-64

**Polymer Technology, a division of Wilmington Partners, L.P.
1400 North Goodman Street
Rochester, New York 14692**

**Attn: Debra Ketchum
Manager, Regulatory Affairs**

Dear Ms. Ketchum:

It is my pleasure to inform you that the USAN Council adopted **hexafocon A** as the United States Adopted Name for Quantum®II, Polymer Technology's hydrophobic contact lens material.

Enclosed is a copy of the Statement of Adoption on **hexafocon A**. I plan to schedule publication of this information in the journal of Clinical Pharmacology and Therapeutics unless you request a delay within the next thirty days. Please use the enclosed statement to provide comments or additions. If this information is accurate, and may be published, please initial the statement and return it to me.

Sincerely yours,

Sophia V. Fuerst
Associate Secretary
USAN Council

SF

Enclosure: N97;51

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SPONSORS: American Medical Association /American Pharmaceutical Association /U.S. Pharmacopeial Convention, Inc.

June 25, 1997

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL:

USAN (JJ-64)

HEXAFOCON A

PRONUNCIATION

hex a foe' kon

INGREDIENT FUNCTION

contact lens material (hydrophobic)

CHEMICAL NAMES

(1)

(2)



STRUCTURAL FORMULA

(See page 2)

MOLECULAR FORMULA

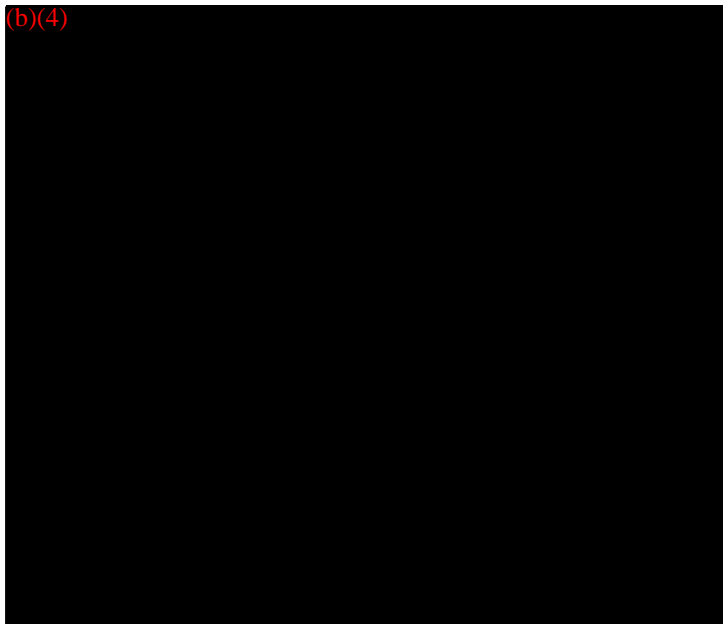
TRADEMARK

MANUFACTURER

WATER CONTENT
at ambient temperature (23±2°C)

OXYGEN PERMEABILITY
at 35°C (Dk Value)

CAS REGISTRY NUMBER



SF

148

510(K) Premarket Notification
BOSTON XO Contact Lens Material

APPENDIX 3

PROFESSIONAL FITTING AND INFORMATION GUIDE

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686372/61

**PROFESSIONAL
FITTING AND
INFORMATION
GUIDE**

**BOSTON® XO
(hexafocon A)**

*Spherical & Aspherical Contact
Lenses for Myopia & Hyperopia,
Bifocal Contact Lenses for
Presbyopia and Toric Lenses
to Correct Astigmatism in
Not aphakic and Aphakic Persons*

CAUTION:
*Federal Law Prohibits Dispensing
Without a Prescription*

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- Introduction
- Product Description - BOSTON® XO
- Lens Parameters Available - BOSTON® XO
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- Selection of Patients
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 - Pre-Fitting Examination
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- Removal of Surface Deposits
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INTRODUCTION

BOSTON® XO (hexafocon A) Contact Lenses are made from fluoro silicone acrylate with a water content of <1% by weight.

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

PRODUCT DESCRIPTION - BOSTON XO

The BOSTON XO Contact Lens material, hexafocon A, is composed of aliphatic siloxanyl fluoromethacrylate copolymer with an ultraviolet absorber. The tinted lenses contain the following color additives:

Color	Color Additive
Ice Blue	D & C Green No. 6
Violet	D & C Violet No. 2

The BOSTON XO Spherical Contact Lens is a hemispherical shell of the following dimensions:

LENS PARAMETERS AVAILABLE	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5mm
Base Curve Range	5.00 mm to 9.00 mm in 0.1 mm increments

The lenses described above can have a center thickness of 0.07 to 0.65 mm that will vary with lens design, power and diameter.

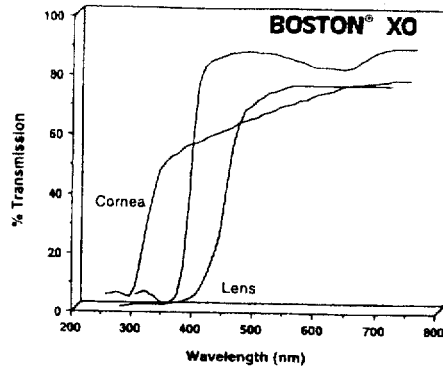
The physical/optical properties of the lens are:

Specific Gravity	1.27
Refractive Index	1.415
Light Absorbance (640 nm) (absorbance units/inch)	4.6 Ice Blue 5.5 Violet
Surface Character	Hydrophobic
Wetting Angle	49°
Water Content	<1%
Oxygen Permeability (x 10 ⁻¹¹ (cm ³ O ₂ · cm)/(cm ² · sec · mmHg) @ 35° C)	140* (100**)

**polarographic method (ISO/Fatt)

Light Trans

LSI



BOSTON XO - 0.07 mm thick BOSTON XO (Ice Blue)

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.

CRYSTALLINE LENS - Human crystalline lens from a 25-year-old person as described in Waxler, M., Hitchens, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

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.

WARNING

UV-absorbing contact lenses are **NOT** substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

ACTIONS

BOSTON XO Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina.

INDICATIONS

BOSTON XO Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. These lenses may be disinfected using a chemical disinfecting system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE BOSTON XO Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions

- Allergy to any ingredient in a solution which is to be used to care for the BOSTON XO Contact Lenses
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

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 eyecare practitioner's directions 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 eyecare practitioner.

PRECAUTIONS

Practitioner Note: BOSTON XO Contact Lenses are not sterile when shipped from the Authorized BOSTON Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

- Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness:
- | Color | Center Thickness |
|----------|------------------|
| Ice Blue | >0.65 mm |
| Violet | >0.65 mm |

Special Precautions for Eyecare Practitioners:

- 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 eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

- 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.
- Aphakic patients should not be fitted with BOSTON® XO Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eyecare practitioner's office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the ultraviolet (UV) light absorber in the BOSTON XO Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the FITTING PROCEDURE for detailed instructions.)

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the conditioning/storage solution and lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp the BOSTON XO Contact Lenses.
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
 - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for BOSTON XO Contact Lenses and those instructions provided by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare practitioner about wearing lenses during water activities and other sports.
- Inform the patient to alert their health care practitioner (doctor) that they wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Always contact the eyecare practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- 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.

ADVERSE EFFECTS

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

- Comfort is less than when lens was first placed on the eye
- Feeling of something in the eye such as a foreign body, scratched area
- Excessive watering (tearing) of the eyes

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

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025

Immediately remove lenses

If the discomfort or problem stops, then closely inspect 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 eyecare practitioner.

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 the eye care practitioner.

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

- Eyes stinging, burning, itching (irritation), or other eye pain
- 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 symptoms, he or she should be instructed to:

Immediately remove lenses

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

SELECTION OF PATIENTS

BOSTON® XO Contact Lenses are rigid gas permeable lenses for the daily wear patient who may require the correction of visual acuity for myopia, hyperopia, astigmatism or presbyopia. BOSTON XO lenses are suitable for patients who have never worn contact lenses, for current PMMA wearers, for patients wanting to upgrade their current rigid gas permeable lenses, as well as for some patients who have been unsuccessful with soft contact lenses.

FITTING PROCEDURE OUTLINE

1. Pre-Fitting Examination
2. Initial Lens Diameter Selection
3. Initial Lens Base Curve Selection
4. Initial Lens Evaluation
5. Initial Lens Power Selection
6. Initial Lens Center Thickness Selection
7. Remaining Lens Parameter Selection
8. Follow-Up Care

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 daily wear or extended wear contact lenses (consider patient hygiene and mental and physical state),
- make ocular measurements for initial contact lens parameter selection,
- collect and record baseline clinical information to which post-fitting examination results can be compared,

A pre-fitting examination should include distance and reading refraction, keratometry and slit lamp evaluation to rule out any contraindications to contact lens wear. Careful assessment of the cornea, lids, conjunctiva and precorneal tear film establishes a baseline against which the practitioner can compare any changes resulting from contact lens wear.

2. Initial Lens Diameter Selection

For minus lenses, an initial lens diameter of 9.6 mm is recommended. For plus lenses, an initial lens diameter of 9.2 mm is recommended. It is important that the optical zone of the lens covers the pupil adequately, even in dim illumination.

3. Initial Lens Base Curve Radius Selection

The initial base curve radius selection is primarily a function of the lens diameter selected and the amount of corneal astigmatism present:

Step One:

Measure central corneal curvature and identify the Flat K (lowest dioptric power).

Example:

K = 42.75/44.75 @ 90 Flat K = 42.75D (7.90mm)
The "flat K" is used as a reference point from which the Base Curve Radius is chosen.

Step Two:

Calculate the corneal astigmatism (difference between the flat and steep K).

In This Example:

K = 42.75/44.75 @ 90 Corneal Astigmatism = 2.00D

Step Three:

Calculate the Base Curve Radius by referring to the Corneal Astigmatism Factor Chart for a given lens diameter.

Example: K = 42.75/44.75 @ 90 Flat K = 7.90 mm

- Corneal Astigmatism = 2.00D
- Lens Diameter = 9.6 mm
- Initial Base Curve:

Flat K	42.75D	7.90 mm
+ Corneal Astigmatism Factor	0.25D	flatter than Flat K
= Initial Base Curve	42.50D	
- Base Curve Radius = 42.50D = 7.94 mm

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Select 9.2 mm or 9.6 mm initial diameter.
Choose base curve according to chart.

Corneal Astigmatism Factors*		
Corneal Astigmatism	9.2 mm Diameter	9.6 mm Diameter
0.00 to 0.50D	0.50D flatter	0.75D flatter
0.75 to 1.25D	0.25D flatter on flat "K"	0.50D flatter
1.50 to 2.00D	0.25D steeper	0.25D flatter on flat "K"
2.25 to 2.75D	0.25D steeper	0.25D steeper
3.00 to 3.50D	0.50D steeper	0.25D steeper

*This chart assumes an optical zone that is 1.4 - 1.6 mm smaller than the lens diameter.

4. Initial Lens Evaluation

A. Lens Positioning

Patient comfort is largely determined by lens positioning on the cornea. A slightly superior, lid-attachment positioning is generally preferred to enhance comfort and encourage normal blinking patterns. Ideally, the upper edge of the lens should be located at or near the superior limbus and remain covered during each blink. A central lens positioning is acceptable but requires the lens periphery to be designed with minimal edge lift and edge contours that are rolled slightly inward to reduce blink-related sensation. Inferior lens positioning, which interferes with normal blinking and promotes lens binding and 3-9 staining, should be avoided.

Note for fitting the hyperopic eye:

Single-cut plus lenses tend to position low. If the inferior decentration is modest, this design may be preferable, especially for smaller corneas. In many cases, lenticular-designed plus lenses offer better centration and more predictable blink-induced lens movement. Special attention must be directed to the edge design of interpalpebral lenticular lenses to insure that they provide minimal lid sensation by being well-tapered and rolled slightly inward.

B. Fluorescein Pattern

Typically, the fluorescein pattern of the final lens should show some mild apical bearing ("feather" touch) or alignment and the absence of peripheral bearing over more than 180° of its circumference. Excessive apical pooling or bearing should be avoided. A moderate edge lift is necessary to permit the edge of the lens to slide over the corneal surface with minimal resistance.

The presence of the UV-absorber in the BOSTON® XO (hexafocon A) Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. A simple, inexpensive approach is the use of an auxiliary yellow Kodak Wratten #12 filter in conjunction with the cobalt blue filter of the biomicroscope.

Slit Lamp Application (if desired):

1. All customary light intensities and filter settings (Cobalt Blue) are left in place.
2. The Kodak Wratten Filter #12* (yellow) is secured on the patient side of the slit lamp microscope with a small piece of adhesive tape.

Burton Lamp Application (necessary):

1. Replace blue bulbs with ordinary white bulbs.
2. Place Kodak Wratten Filter #47* (blue) over white bulb area.
3. Place Kodak Wratten Filter #12 (yellow) over patient side of viewing lens.
4. Use system in usual manner.

Important Note: Use of the Wratten filters will also enhance the view of non-UV rigid lenses and corneal fluorescein evaluation.

*Wratten #12 and #47 filters are available from Authorized BOSTON Manufacturers in the following kits: #7503 Slit Lamp Filter Kit, #7502 Burton Lamp Modification Kit.

5. Initial Lens Power Selection

A. Empirical Fitting

Step One:

Follow the steps for INITIAL LENS DIAMETER and BASE CURVE RADIUS SELECTION.

Step Two:

Employ the rules of SAM (steeper add minus) or FAP (flatter add plus) to determine lens power.

Example:

Spectacle Rx: -3.00-1.50 cx 180
K Readings: 42.75/44.75 @ 90

Flat K = 42.75D (7.90mm)

Corneal Astigmatism: = 2.00D
Lens Diameter = 9.6mm

Initial Base Curve:
Flat K = 42.75D 7.90 mm
+ Corneal Astigmatism Factor 0.25D flatter than Flat K
= Initial Base Curve 42.50D
Base Curve Radius 42.50D = 7.94 mm

Since the base curve is 0.25D flatter than K, employ the FAP principle to determine contact lens power.

Base Curve: 42.50D 0.25D flatter than Flat K
Sph power of spec Rx: -3.00D

FAP adjustment +(+0.25D)
Lens Power -2.75D

The lens in this example would be ordered as:

Base curve: 42.50D
Power: -2.75D
Diameter: 9.6mm

B. Trial Fitting

Step One:

Perform a spherical refraction over the best-fitting trial lens.

Step Two:

If the spherical power of the over-refraction is greater than 4.75D, correct for the vertex distance.

Example: -5.00D at 12 mm = -4.75D at the cornea
+5.00D at 12 mm = +5.37D at the cornea

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Step Three:

Combine the spherical over-refraction (corrected for vertex distance if appropriate) with the power of the trial lens to obtain the final contact lens power ordered.

Example: Trial lens -3.00D
 Over-refraction (+)+1.00D
 Power to order -2.00D

Vertex Conversion Chart (12 mm distance)				
For minus powers reduce by amount shown. For plus powers increase by amount shown.				
±Spherical over-refraction (D)	4.00 to 5.25	5.50 to 6.75	7.00 to 8.25	8.50 to 10.00
Corresponding Power Compensation (D)	0.25	0.50	0.75	1.00

6. Initial Lens Center Thickness Selection

For best clinical results, the eyecare practitioner should always specify center thickness as part of the complete prescription. The stability and flexural resistance of BOSTON® XO (hexafocon A) permit the use of a wide range of center thicknesses and designs.

For eyes with less than 1.25 diopters of corneal toricity consider the following standard thickness table:

Minus Lens Center Thickness	
Lens Power	Recommended Thickness
Plano	0.18
-1.00	0.17
-2.00	0.16
-3.00	0.15
-4.00	0.14
-5.00	0.13
-6.00	0.12
-7.00	0.11
-8.00	0.10

In cases where corneal toricity is 1.50 diopter or greater, consider adding 0.01 mm of thickness per diopter of cylinder to the center thickness table to control blink-induced flexure.

7. Remaining Lens Parameter Selection

The final prescription should be provided to the Authorized BOSTON Manufacturer in a format which includes:

- base curve
- center thickness
- diameter
- optic zone
- power
- peripheral curves

By specifying the complete design, practitioner success and patient satisfaction are increased. The following suggested designs have proven successful in clinical testing. **Your Authorized BOSTON Manufacturer may also offer suggestions regarding lens design.**

Select remaining lens parameters: optical zone & peripheral (edge) design.	
Specify 8.0 – 8.2 mm optic zone instruct manufacturer to blend to finished size	
Specify peripheral curve design as follows:	
for 9.2 mm diameter	for 9.4 – 9.6 mm diameter
Peripheral Curves 1st 2nd	Peripheral Curves 1st 2nd
Width 0.3 mm 0.3 mm	Width 0.3 mm 0.3 mm
Radius* 0.8 mm 2.3 mm	Radius* 1.2 mm 2.8 mm
*flatter than B.C.	*flatter than B.C.

8. Follow-up Care

- a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, a conventional follow-up schedule for daily wear should be maintained.
- b. Prior to a follow-up examination, the contact lenses should be worn for at least 2 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, conduct a thorough biomicroscopy examination.
 - 1) The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is 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 refitted with a more appropriate lens.

IN-OFFICE CARE OF TRIAL LENSES

Eyecare practitioners should educate contact lens technicians concerning proper care of trial lenses.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected.

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Rochester, New York 14603-0450
1-800-333-4730

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Practitioner Note: The BOSTON® XO Contact Lenses are not sterile when shipped from the Authorized BOSTON Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

RECOMMENDED INITIAL WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

BOSTON XO Contact Lenses are indicated for **daily wear**. The **maximum** suggested wearing time for these lenses is:

DAY	WEARING TIME (Hours)*
1	4 to 8 hours
2	6 to 10 hours
3	8 to 14 hours
4	10 to 15 hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*if the lenses continue to be well-tolerated.

CLINICAL ASSESSMENT

WARNING: BOSTON XO Contact Lenses are **NOT** intended for overnight (extended) wear.

1. Criteria of a Well-Fitted Lens

Patient comfort is largely determined by lens positioning on the cornea. A slightly superior, lid-attachment positioning is generally preferred to enhance comfort and encourage normal blinking patterns. Ideally, the upper edge of the lens should be located at or near the superior limbus and remain covered during each blink. A central lens positioning is acceptable but requires the lens periphery to be designed with minimal edge lift and edge contours that are rolled slightly inward to reduce blink-related sensation. Inferior lens positioning, which interferes with normal blinking and promotes lens binding and 3-9 staining, should be avoided.

Typically, the fluorescein pattern of the lens should show some mild apical bearing ("feather touch) or alignment and the absence of peripheral bearing over more than 180° of its circumference. Excessive apical pooling or bearing should be avoided. A moderate edge lift is necessary to permit the edge of the lens to slide over the corneal surface with minimal resistance.

2. Optimizing Fitting Characteristics

In order to achieve optimal performance, it is often necessary to modify the initial lens parameters. Practitioner observations and interpretation of lens positioning, fluorescein patterns, and lens movement are essential to this process. The following chart summarizes common fitting relationships.

INITIAL LENS ASSESSMENT			
	Optimum	Too Steep	Too Flat
Fluorescein Pattern	Parallel to Slight Apical Bearing Moderate Edge Lift	Excessive Apical Pooling Minimum Edge Lift	Excessive Apical Bearing Excessive Edge Lift
Position	Centered to Slightly Superior	Inferior	Superior Unstable
Movement	1-2 mm	Less Than 1 mm	More Than 2 mm
Comfort	Slight Initial Sensation	Initially Comfortable	Uncomfortable
Disposition	Prescribe	Select Flatter Base Curve or smaller diameter	Select Steeper Base Curve or larger diameter

3. Problem Solving

Persistent excessive lens awareness: This problem may be due to: the use of incompatible care products; improper use of care products (i.e., lens cleaning just prior to insertion); three and nine o'clock staining; deposits on the concave lens surface; accumulation of mucus under the lens; poor edge design, incomplete blinking or steeply fitted lenses.

Three and nine o'clock staining: If the lens positions low, it should be redesigned to achieve a higher position so as to avoid a false blink pattern. The lens periphery should be well tapered and its edge rolled slightly inward to minimize upper lid sensation and avoid incomplete reflex blinks. If the lens positions centrally, the diameter should be reduced, the periphery well tapered and the edge rolled slightly inward. Complete blinking should be encouraged. *Above all, be certain that the lens has not been fitted too steeply.*

Generalized corneal staining: In cases of diffuse staining not apparently related to back surface deposits on the lens, solution or preservative incompatibility should be ruled out.

Ocular redness without staining: This problem may be caused by some component of the care solutions such as preservatives or the presence of pingueculae, infectious or allergic conjunctivitis, or inadequate lens lubrication, including excessive mucus accumulation as occurs in dry eyes.

Excessive development of lens deposits: This unusual problem may be related to: increased mucus production, i.e., GPC, keratitis sicca, chronic allergies, etc. The more frequent use of the BOSTON® Rewetting Drops may be helpful in these cases. However, excessive deposition has been found to be most often related to inappropriately polished lens surfaces which simulate an orange peel appearance visible only with magnification of 20X or greater. In many cases, deposits are easily removed by cleaning with original BOSTON Cleaner, BOSTON Advance Cleaner and/or BOSTON ONE STEP Liquid Enzymatic Cleaner. However, in extreme cases, it may be necessary to lightly polish the lenses with the BOSTON Cleaning Polish. In the event that deposits cannot be removed by cleaning or polishing, the lens should be replaced.

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Lens surface dry spots: The presence of discrete non-wetting areas on a new or recently modified or polished lens are usually due to the persistence of hydrophobic products used during lens fabrication. These hydrophobic contaminants have a greater affinity for BOSTON® XO (hexafocon A) polymers and if not removed with the BOSTON® Laboratory Lens Cleaner, the lenses should be returned to the Authorized BOSTON® Manufacturer for a special solvent cleaning.

Other causes of loss of surface wettability include: surface contamination with cosmetics, hair spray, skin preparations; inadequate tear lubrication; incomplete blinking; the use of incompatible preserved care solutions; and dry lens storage.

Unstable vision: This problem may be due to excessive blink-induced lens flexure resulting from a steep fit. Unstable vision may also result from excessive blink-induced lens movement, an excessively small optical zone diameter, or surface dry spots.

Reduced contact lens-corrected vision: Reduced vision correction unrelated to changes in refractive error may be due to lens warpage, front surface deposits, or switched lenses.

Repeated lens breakage: Lens breakage problems may be due to careless handling or storage procedures (see Patient Instructions booklet).

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 may not be a good candidate for monovision with the BOSTON XO 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 not to 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, 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.

2. Eye Selection

Generally, the nondominant 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 "dominate 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 the appropriate plus power trial spectacle 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 plus power trial 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, consider correcting the eye on that side for near.

Example:

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

3. Special Fitting Considerations

Unilateral Lens Correction

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

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and no lens on the other eye.

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 eye uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the mid-point 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.

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5. Trial Lens Fitting

A trial fitting can be 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 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 distance objects, observe the reactions. Only after these visual 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 the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

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

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mildly blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for only minutes 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 use the lenses first 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 drive only 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 eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.**

***All patients should be supplied with a copy of the Patient Instructions.**

PATIENT LENS CARE DIRECTIONS

Eyecare practitioners should review with the patient all lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

General Lens Care (First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

Always wash, rinse, and dry hands before handling contact lenses.

- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling or instructed by the eyecare practitioner.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in the mouth.

- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or a cleaning solution **does not substitute for disinfection.**

The lens care products listed below are recommended by Polymer Technology for use with BOSTON® XO Contact Lenses. Eyecare practitioners may recommend alternate products that are appropriate for the patient's use with his or her lens(es).

LENS CARE TABLE

Product Purpose	Lens Care System Chemical (Not Heat)
Clean	BOSTON Advance® Cleaner or BOSTON® Cleaner
Disinfect	BOSTON Advance® Comfort Formula Conditioning Solution or BOSTON® Conditioning Solution
Store	BOSTON Advance® Comfort Formula Conditioning Solution or BOSTON® Conditioning Solution
Multi-Action (Clean, Condition, Disinfect, Rinse and Cushion)	BOSTON Simplicity® Multi-Action Solution
Lubricate/Rewet	BOSTON® Rewetting Drops
Weekly Enzymatic Cleaner	BOSTON® ONE STEP Liquid Enzymatic Cleaner

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as recommended by the eyecare practitioner to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eyecare practitioner. Follow the instructions provided in the Disinfection Solution Packaging.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the Package Insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer or the eyecare practitioner; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Eyecare practitioners may recommend a Weekly Enzymatic Cleaner which can be used to effectively remove protein deposits from BOSTON XO Contact Lenses.
- BOSTON XO Contact Lenses **cannot** be heat (thermally) disinfected.

CARE FOR A STICKING (NONMOVING) LENS

if the lens sticks (stops moving/cannot be removed), the patient should be instructed to apply one to three drops of a recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 5 minutes, the patient should immediately consult the eyecare practitioner.

LABORATORY LENS CLEANER

Residue left by body oils, household solvents, and personal care products may be removed with an enhanced cleaning agent such as BOSTON Laboratory Lens Cleaner. This clear, colorless surfactant is for **laboratory and in-office use only**. When lenses are received from the Authorized BOSTON Manufacturer, they should be cleaned with BOSTON Laboratory Lens Cleaner prior to use of the BOSTON Care System and an overnight soak. Lenses exhibiting a nonwetting surface should be cleaned with BOSTON Laboratory Lens Cleaner as a method of first choice. **The BOSTON Laboratory Lens Cleaner is intended for PROFESSIONAL USE ONLY. It is not available for resale or distribution to patients.**

IN-OFFICE LENS MODIFICATIONS

Edge reshaping and surface repolishing can be performed by conventional techniques if the following precautions are observed: 1) avoid polishing compounds or cleaners that contain ammonia, alcohol or organic solvents;* 2) completely remove all traces of adhesive (if double-backed tape is used) with the special authorized solvent.** (The use of any other solvent may cause surface breakdown.) Minimize exposure to the solvent and immediately remove all traces with BOSTON* Cleaner or BOSTON Advance* Cleaner followed by a thorough water rinse. 3) perform the initial lens modifications cautiously because the response of this polymer to these procedures is more rapid than that of silicone acrylate materials; 4) more extensive modifications should not be attempted. Best results will be obtained by using the BOSTON* Cleaning Polish which is available from Authorized BOSTON Manufacturers. 5) The Original BOSTON* Care System, BOSTON Advance* Comfort Formula Care System or BOSTON Simplicity Multi-Action Care System including the overnight soak should be used prior to lens dispensing.

Caution: Damage may result from improper modification techniques. Please Note: BOSTON* Envision* and BOSTON* MultiVision due to their preformed back surface should not be modified. Consult your Authorized BOSTON Manufacturer or contact Polymer Technology for more detailed information.

***Warning:** Do **not** use solvents such as alcohols, esters, ketones or chlorinated hydrocarbons (including naphtha, lighter fluid, etc.) since they may damage the lens surfaces and increase the brittleness of the lens.

**Use only the solvent supplied by your lens laboratory, and minimize solvent exposure time by rubbing a solvent-saturated cloth over the lens surfaces and quickly removing the solvent with a surfactant. Do not soak the lenses in the solvent.

REMOVAL OF SURFACE DEPOSITS

Deposits are easily removed from the surfaces of BOSTON* XO (hexafocon A) Contact Lenses. These deposits are best identified by inspecting the cleaned and dried lens with a slit lamp in a dark room using a medium-width illuminating beam. Surface deposits should be gently removed with BOSTON* Cleaning Polish, which is available in a kit form with a polishing pad that permits practitioners to manually clean and polish their patient's rigid gas permeable lenses. THE BOSTON LENS* Cleaning Polish and Manual Polishing Machine are available from Authorized BOSTON Manufacturers.

Caution: Applying excessive and prolonged pressure to the lens during the polishing procedure may alter its surface optics.

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REPORTING OF ADVERSE REACTIONS

All serious adverse reactions observed in patients wearing BOSTON® XO Contact Lenses or adverse experiences with the lenses should be reported to:

Consumer Affairs
Polymer Technology
1400 North Goodman Street
Rochester, NY 14603-0450
1-800-333-4730

HOW SUPPLIED

Each lens is supplied (non-sterile) in a plastic lens storage case. The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber (if present) and lot number. Additional parameters of add power, segment height, prism ballast and truncation may be included for bifocal lenses.

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510(K) Premarket Notification
BOSTON XO Contact Lens Material

APPENDIX 3

PACKAGE INSERT

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X B6273/01

360 UNDER 501A REQUEST # 2016 3776 Released ON 8/21/16

PACKAGE INSERT

BOSTON® XO (hexafocon A)

*Spherical & Aspherical Contact
Lenses for Myopia & Hyperopia,
Bifocal Contact Lenses for
Presbyopia and Toric Lenses
to Correct Astigmatism in
Not aphakic and Aphakic Persons*

*Fluoro Silicone Acrylate
Rigid Gas Permeable
Contact Lenses
For
Daily Wear*

IMPORTANT:

*Please read carefully and keep
this information for future use.
This package insert is intended
for the eyecare practitioner,
but should be made available
to patients upon request. The
eyecare practitioner should
provide the patient with the
patient instructions that
pertain to the patient's
prescribed lens.*

CAUTION:

*Federal Law Prohibits Dispensing
Without a Prescription*

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DESCRIPTION

BOSTON® XO (hexafocon A) material is used for the manufacturing of daily wear rigid gas permeable contact lenses. BOSTON XO are wettable, non-hydrophilic rigid gas permeable contact lenses that are not surface treated and are made from silox-anyl fluoromethacrylate copolymer containing an ultraviolet absorber. BOSTON XO Contact Lenses are available in ice blue and violet.

Color	Color Additive
Ice Blue	D & C Green No. 6
Violet	D & C Violet No. 2

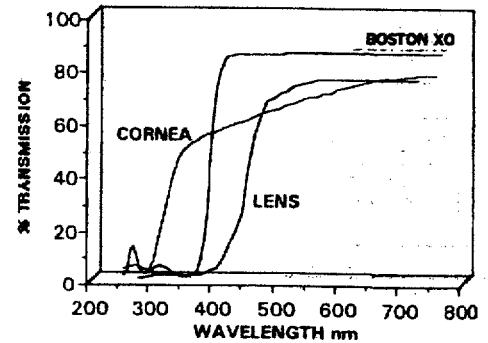
The physical characteristics of the BOSTON XO material was designed to facilitate the fabrication of high-quality rigid gas permeable contact lenses in a wide range of lens designs.

Spherical Lens Design	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	5.00 mm to 9.00 mm in .01 mm increments
Toric Lens Designs	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	8.25 mm to 11.5 mm
Base Curve Range	6.80 mm to 9.50 mm in 0.05 mm increments
Toricity	Up to 9.00 Diopters

Physical/Optical Properties of BOSTON XO:

Specific Gravity	1.27
Refractive Index	1.415
Light Absorbance (absorbance units/inch)	
Ice Blue (with UV absorber)	4.6
Violet (with UV absorber)	5.5
Surface Character	Hydrophobic
Wetting Angle	49°
Water Content	<1%
Oxygen Permeability	140* (100**)
	(x 10 ⁻¹¹ (cm ³ O ₂ · cm)/(cm ² · sec · mmHg) @ 35° C)

**polarographic method (ISO/Fatt)



BOSTON XO - 0.07 mm thick BOSTON XO (Ice Blue)

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.

CRYSTALLINE LENS - Human crystalline lens from a 25-year-old person as described in Waxier, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

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.

WARNING

UV-absorbing contact lenses are **NOT** substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

ACTIONS

BOSTON XO Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS (USES)

BOSTON XO Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. These contact lenses may be disinfected using a chemical disinfecting system only.

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CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE BOSTON XO Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation 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), if not aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the BOSTON XO contact lens materials.
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

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 eyecare practitioner's directions 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 these 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 eyecare practitioner.

PRECAUTIONS

Practitioner Note: BOSTON XO contact lenses are not sterile when shipped from the Authorized BOSTON® Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

Special Precautions for Eyecare Practitioners:

- 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 eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

- 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.
- Aphakic patients should not be fitted with the BOSTON XO Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eyecare practitioner's office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the ultraviolet (UV) light absorber in the BOSTON XO Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the conditioning/storage solution and/or lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp the BOSTON XO Contact Lenses.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.

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- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the BOSTON XO Contact Lenses and in those prescribed by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eyecare practitioner about wearing lenses during water activities and other sports.
- Inform your health care practitioner (doctor) that you wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the lens case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Always contact your eyecare practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

- 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.

ADVERSE EFFECTS

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 the eye
- Feeling of something in the eye such as a 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 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 eyecare practitioner. 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, **immediately remove the lenses and consult the eyecare practitioner.**

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

FITTING

Conventional methods of fitting contact lenses apply to BOSTON XO Contact Lenses. For a detailed description of the fitting techniques, refer to the BOSTON XO Professional Fitting and Information Guide, copies of which are available from:

Practitioner Marketing Representative
Polymer Technology
1400 North Goodman Street
Rochester, NY 14603-0450
1-800-225-1241

Professional Fitting Guides are also available through your Authorized BOSTON® Manufacturer.

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eyecare practitioner.

Patients tend to overwear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

BOSTON® XO Contact Lenses are indicated for daily wear. The suggested wearing time for these lenses is:

DAY	WEARING TIME (Hours)*
1	4 to 8 hours
2	6 to 10 hours
3	8 to 14 hours
4	10 to 15 hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*if the lenses continue to be well-tolerated.

WARNING: BOSTON XO Contact Lenses are **NOT** intended for overnight (extended) wear.

LENS CARE DIRECTIONS

Eyecare practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

General Lens Care (First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

Always wash, rinse, and dry hands before handling contact lenses.

- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling, or if advised by the eyecare practitioner.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or a cleaning solution **does not substitute for disinfection.**

The lens care products listed below are recommended by Polymer Technology for use with the BOSTON XO Contact Lenses. Eyecare practitioners may recommend alternate products that are appropriate for the patient's use with his or her lenses).

LENS CARE TABLE

Product Purpose	Lens Care System
	Chemical (Not Heat)
Clean	Boston ADVANCE® Cleaner or Boston® Cleaner
Disinfect	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution
Store	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston Conditioning Solution
Multi-Action (Clean, Condition, Disinfect, Rinse and Cushion)	Boston SIMPLICITY® Multi-Action Solution
Lubricate/Rewet	Boston® Rewetting Drops
Weekly Enzymatic Cleaner	Boston® ONE STEP Liquid Enzymatic Cleaner

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as directed by your eyecare practitioner to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eyecare practitioner. Follow the instructions provided in the disinfecting solution packaging.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Eyecare practitioners may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from BOSTON® XO Contact Lenses.
- BOSTON XO Contact Lenses **cannot** be heat (thermally) disinfected.

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LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer or the eyecare practitioner, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving/cannot be removed), the patient should be instructed to apply one to three drops of a recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 5 minutes, the patient should immediately consult the eyecare practitioner.

EMERGENCIES

The patients 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, THEN REMOVE LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied (nonsterile) in a plastic lens storage case. The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber (if present) and lot number. Additional parameters of add power, segment height, prism ballast and truncation may be included for bifocal lenses.

~~add~~
color

REPORTING OF ADVERSE REACTIONS

All serious adverse reactions observed in patients wearing the BOSTON® XO Contact Lenses or adverse experiences with the lenses should be reported to:

Consumer Affairs
Polymer Technology
1400 North Goodman Street
Rochester, NY 14603-0450
1-800-333-4730

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Print Date: 02/00

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APPENDIX 3

PATIENT INSTRUCTIONS

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- Wearing Restrictions and Indications
- Contraindications
- Warnings
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- Adverse Effects
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 - Preparing the Lens for Wearing
 - Handling the Lenses
 - Placing the Lens on the Eye
 - Centering the Lens
 - Removing the Lens
- Caring for Your Lenses
 - (Cleaning, Rinsing, Disinfecting, Storage and Rewetting/Lubricating)
 - Basic Instructions
 - Care for a Sticking (Nonmoving) Lens
 - Lens Case Cleaning and Maintenance
 - Emergencies
- Instructions for Monovision Wearer
- Prescribed Wearing Schedule
- Appointment Schedule

INTRODUCTION

Your eyecare practitioner has fit you with contact lenses known as BOSTON® XO. BOSTON XO spherical and toric lenses are manufactured from BOSTON XO contact lens material. It is essential that you strictly follow the recommended handling, cleaning and storage procedures. Failure to do so may eventually impair the performance of your lenses.

WEARING RESTRICTIONS AND INDICATIONS

BOSTON XO Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfection (not heat) system only.

BOSTON XO Contact Lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eyecare practitioner. **DO NOT WEAR YOUR BOSTON XO CONTACT LENSES WHILE SLEEPING.**

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE BOSTON XO Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the BOSTON XO contact lens material
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential to follow your eyecare practitioner's directions 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 should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, **immediately remove lenses** and promptly contact your eyecare practitioner.

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PRECAUTIONS

You should carefully adhere to the following care regimen and safety precautions:

- Before leaving the eyecare practitioner's office, you should be able to properly remove lenses or should have someone else available who can remove the lenses for you.
- You should remove your lenses immediately if your eyes become red or irritated.
- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the wetting/soaking solution and lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package insert for the use of contact lens solutions.
 - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp BOSTON® XO Contact Lenses.
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
 - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected overnight prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, immediately consult your eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions that follow for the BOSTON XO Contact Lenses and those provided by your eyecare practitioner.
- Never wear lenses beyond the period recommended by your eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.

- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eyecare practitioner about wearing lenses during water activities and other sports.
- Inform your health care practitioner (doctor) that you wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Always contact your eyecare practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Follow your eyecare practitioner's instruction as to a recommended follow-up schedule.

ADVERSE EFFECTS

The following problems may occur:

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

If you notice any of the above:

Immediately remove 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 your eyecare practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, **immediately remove the lenses and consult your eyecare practitioner.**

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

PERSONAL CLEANLINESS FOR LENS HANDLING

1. Preparing the Lens for Wearing

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

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045

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

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

2. Handling the Lenses

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or cracks.

3. Placing the Lens on the Eye

After thoroughly washing and rinsing your hands, and after proper cleaning and conditioning of the lens, follow these steps to insert the lens:

- Remove the lens from its storage compartment.
- Rinse the lens with fresh conditioning solution, if desired.
- Inspect the lens to be sure that it is clean, uniformly wet and free of debris.
- Rub several drops of conditioning solution over the lens surfaces.
- Place the lens on the top of the index finger of your dominant hand. Place the middle finger of the same hand close to the lower lash and hold down the lower lid.
- Use the forefinger or middle finger of your other hand to lift the upper lid and then place the lens on the eye. It is not necessary to press the lens against the eye.
- Gently release the lids and blink. The lens will center automatically. Always verify its proper position by checking your vision immediately after insertion.
- Use the same technique or reverse the hand when inserting the other lens.

There are other methods of lens placement. If the above method is difficult for you, your eye-care practitioner will provide you with an alternate method.

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

- The lens is not centered on the eye (see "Centering the Lens," next in this booklet).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
 - a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
 - b. The lens is on the wrong eye.

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

4. Centering the Lens

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

- Close your eyelids and gently massage the lens into place through the closed lids.

OR

- Gently push the off-centered lens onto the cornea while the eye is open using finger pressure on the upper or lower lid next to the edge of the lens.

5. Removing the Lens

Before removing your lenses, it is recommended that you have the following items available:

- 1) A lens storage case.
- 2) **Two Bottle Care System**
Boston ADVANCE® Cleaner or Boston® Cleaner. **AND**
Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution.

OR

- 3) **One Bottle Care System**
Boston SIMPLICITY® Multi-Action Solution (Clean, Condition, Disinfect, Rinse & Cushion)
- 3) A clean towel.

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. There are two suggested methods of lens removal:

TWO-FINGER METHOD

- 1) Place a towel under your eye to catch the lens.
- 2) Place the tip of the forefinger of one hand on the middle of the upper lid margin and the forefinger of the other hand on the middle of the lower lid margin.
- 3) Press the lid margin inward and then together. The lens should be wedged out of your eye onto your hand or towel.
- 4) The lens may come out but remain on your eyelid or hand or be decentered onto the white part of your eye. If the latter occurs, recenter the lens onto your cornea before repeating the removal procedure.

BLINK METHOD

Seat yourself at a table covered with a clean towel and lean over until you are looking down at the surface.

- 1) Place your index finger at the outer junction of your upper and lower lids, stretch the skin outward and slightly upward. (Do not allow your lid to slide over the lens.)
 - 2) Blink briskly. The lens will be pinched by the pressure of your eyelids and the lens will pop out onto the clean surface of the towel, or you may catch the lens in the palm of your hand.
- c. Remove the other lens by following the same procedure.
 - d. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, STORAGE AND REWETTING/LUBRICATING).

Note: If these methods for removing your lenses are difficult for you, your eyecare practitioner will provide you with an alternate method.

CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, STORAGE AND REWETTING/LUBRICATING)

1. Basic Instructions

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

You should adhere to the recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to place and remove lenses and do not have someone available to place and remove them for you, you should not attempt to wear contact lenses.

When you first get your lenses, be sure you can place the lenses on your eyes and remove them while you are in your eyecare practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfecting. Your eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Patient Instructions for the BOSTON® XO Contact Lenses.

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

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care (chemical not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling, or if advised by your eyecare practitioner.**
- Always remove, clean, rinse and disinfect your lenses according to the schedule prescribed by your eyecare practitioner. The use of an enzyme or any cleaning solution **does not substitute for disinfection.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- The lens care products listed below are recommended by Polymer Technology for use with your BOSTON XO Contact Lenses. Your eyecare practitioner may recommend alternate products that are appropriate for you to use with your BOSTON XO Contact Lenses.

LENS CARE TABLE

Product Purpose	Lens Care System Chemical (Not Heat)
Clean	Boston ADVANCE® Cleaner or Boston® Cleaner
Disinfect	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution
Store	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston Conditioning Solution
Multi-Action (Clean, Condition, Disinfect, Rinse and Cushion)	Boston SIMPLICITY® Multi-Action Solution
Lubricate/Rewet	Boston® Rewetting Drops
Weekly Enzymatic Cleaner	Boston® ONE STEP Liquid Enzymatic Cleaner

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups) and rinse the lens thoroughly as recommended by your eyecare practitioner to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the above recommended system by your eyecare practitioner and/or the manufacturer. Follow the instructions provided in the disinfection solution labeling.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the Package Insert or your eyecare practitioner for information on storage of your lenses.
- Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eyecare practitioner for a recommendation on how to store your lenses.
- BOSTON XO Contact Lenses **cannot** be heat (thermally) disinfected.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer or the eyecare practitioner; then allow the lens case to air dry. When the case is used again, refill it with fresh storage solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.
- Your eyecare practitioner may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

- Your eyecare practitioner may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from your BOSTON® XO Contact Lenses.

2. Care for a Sticking (Nonmoving) Lens

If the lens sticks (stops moving/cannot be removed), apply one to three drops of a recommended lubricating or rewetting solution directly to your eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 5 minutes, you should immediately consult your eyecare practitioner.

3. Lens Case Cleaning and Maintenance

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer or the eyecare practitioner, and allowed to air dry after each use. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.

4. Emergencies

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

INSTRUCTIONS FOR THE MONOVISION WEARER

- You should be aware that, as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in all gazes that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to monovision. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer is your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations which are not visually demanding. For example, be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers' license requirements with monovision correction.
- Some monovision lens wearers will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, discuss with your eyecare practitioner whether you should have additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance vision is required.
- If you require very sharp near vision during prolonged close work, you may want to discuss with your eyecare practitioner having additional contact lenses prescribed so that both eyes are corrected for near when sharp near vision is required.

- Some monovision lens wearers require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.
- It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- **The decision to be fit with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering and discussing your needs.**

CONSIDERATIONS FOR BIFOCAL LENSES

Patients who are considering bifocal contact lenses should be highly motivated and must be informed of the benefits as well as the problems that may be encountered while adapting to bifocal contact lens wear.

Your eyecare practitioner may discuss the following with you:

1. Adaptation

Both bifocal spectacle and bifocal contact lens wearers need to learn to adapt to proper head positioning. The bifocal patient must position the head upright while rotating the eyes downward to read. Once the bifocal patient has adapted, proper positioning becomes effortless.

2. Driving at Night

Bifocal contact lens wearers should experience night vision before actually driving while wearing their lenses.

3. Flare at Night

Bifocal contact lenses wearers may experience flare at night. This may occur with certain lens designs. With time, bifocal contact lens wearers adapt to this situation.

4. Visual Expectation

Bifocal contact lens wearers may experience visual acuities less than could be achieved with bifocal spectacles.

SAMPLE OF WEARING AND APPOINTMENT SCHEDULES

Wearing Schedule

DAY	WEARING TIME (Hours)*
1	4 to 8 Hours
2	6 to 10 Hours
3	8 to 14 Hours
4	10 to 15 Hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*if the lenses continue to be well-tolerated.

WARNING: BOSTON XO Contact Lenses are **NOT** intended for overnight (extended) wear.

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APPOINTMENT SCHEDULE

Minimum number of hours lenses to be worn at time of appointment: _____

Your appointments are on:

Month	Year	Time	Date

PATIENT/EYECARE PRACTITIONER INFORMATION:

Eyecare Practitioner Information

Practitioner Name: _____

Practice Name: _____

Practitioner Address: _____

Practitioner Phone Number: _____

Recommended Lens Care Regimen: _____

Cleaning Solution: _____

Conditioning Solution: _____

Rewetting Solution: _____

Weekly Enzymatic Cleaner: _____

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYECARE PRACTITIONER IMMEDIATELY.

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Rochester, NY 14603-0450
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510(K) Premarket Notification
BOSTON XO Contact Lens Material

APPENDIX 4

MANUFACTURING FLOW DIAGRAM

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Manufacturing Flow Chart for Boston XO

(b)(4)



APPENDIX 4

MANUFACTURING INFORMATION

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APPENDIX 4

MANUFACTURING INFORMATION

Below is a description of the basic operations, procedures, and controls used in the routine manufacturing and packaging of the *BOSTON XO* (hexafocon A).

Manufacturing Method (lens blanks)

(b)(4)



Packaging Materials and Methods

Printing, packaging, and labeling are performed in accordance with documented operating procedures, which are the same procedures utilized for previously approved BOSTON materials. All accepted contact lens blanks are packaged in polyethylene bags or plastic tubes or containers and corrugated cardboard boxes for shipment.

The packaging components for the *BOSTON ES* (enfluocon A) contact lens blanks and contact lenses are the same as those approved for other approved BOSTON materials such as *BOSTON ES* (enfluocon A). *BOSTON ES* (enfluocon A) was cleared on August 25, 1994 in 510(k) Premarket Notification No. K980741. The packaging components includes the following:

polyethylene bags	standard plastic contact lens cases
plastic tubes and caps	package inserts
corrugated cardboard boxes	patient care guide
fitting guide	

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510(K) Premarket Notification
BOSTON XO Contact Lens Material

APPENDIX 5
LEACHABILITY STUDY

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Polymer Technology

**DETERMINATION OF LEACHABLE D&C GREEN #6 DYE, D&C VIOLET #2
DYE, AND MHB UV BLOCKER FROM BOSTON XO**

Purpose:

This test is designed to detect the presence of leachable D&C Green #6 dye, D&C Violet #2 dye, and MHB UV blocker in lenses manufactured from Boston XO material.

Experimental:

(b)(4)



6

(b)(4)



Conclusions:

The summarized results are presented in Tables 1 and 2. No significant amounts of D&C Green #6 Dye, D&C Violet #2 Dye, or MHB UV blocker were found to be extracted into the saline over a two week period.

(b)(4)



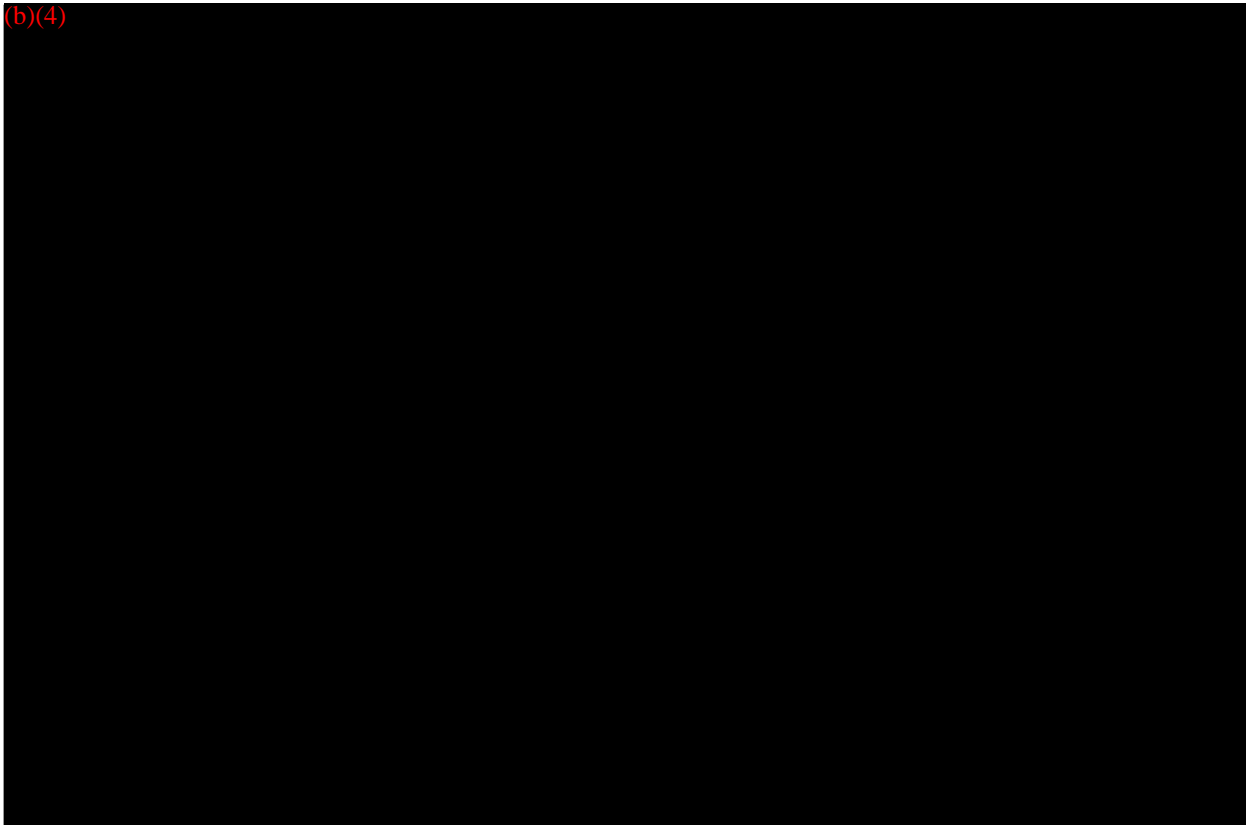
Figure 1: Calibration Curve for D&C Green #6 Dye

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D&C Green #6 Dye Calibration Curve

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Figure 2: Calibration Curve for D&C Violet #2 Dye



D&C Violet #2 Dye Calibration Curve

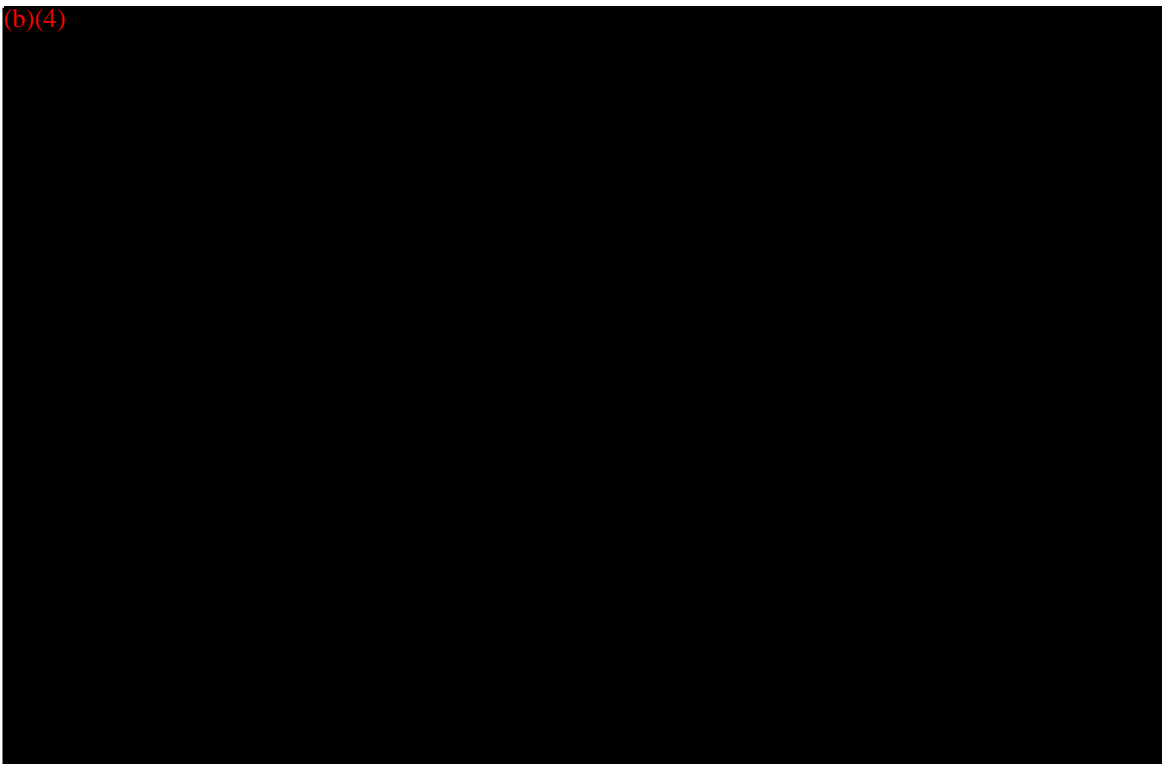
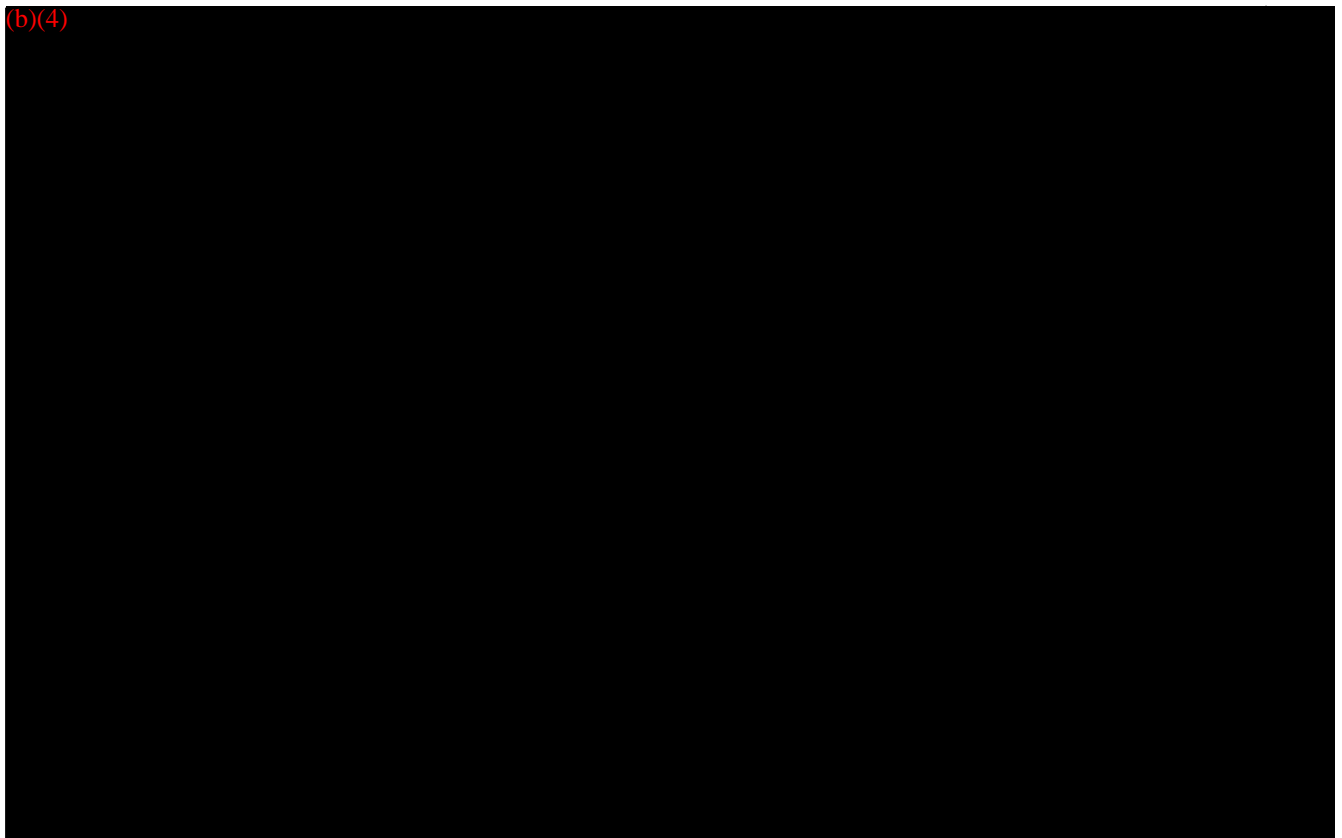


Figure 3: Calibration Curve for MHB UV Blocker



MHB UV Blocker Calibration Curve



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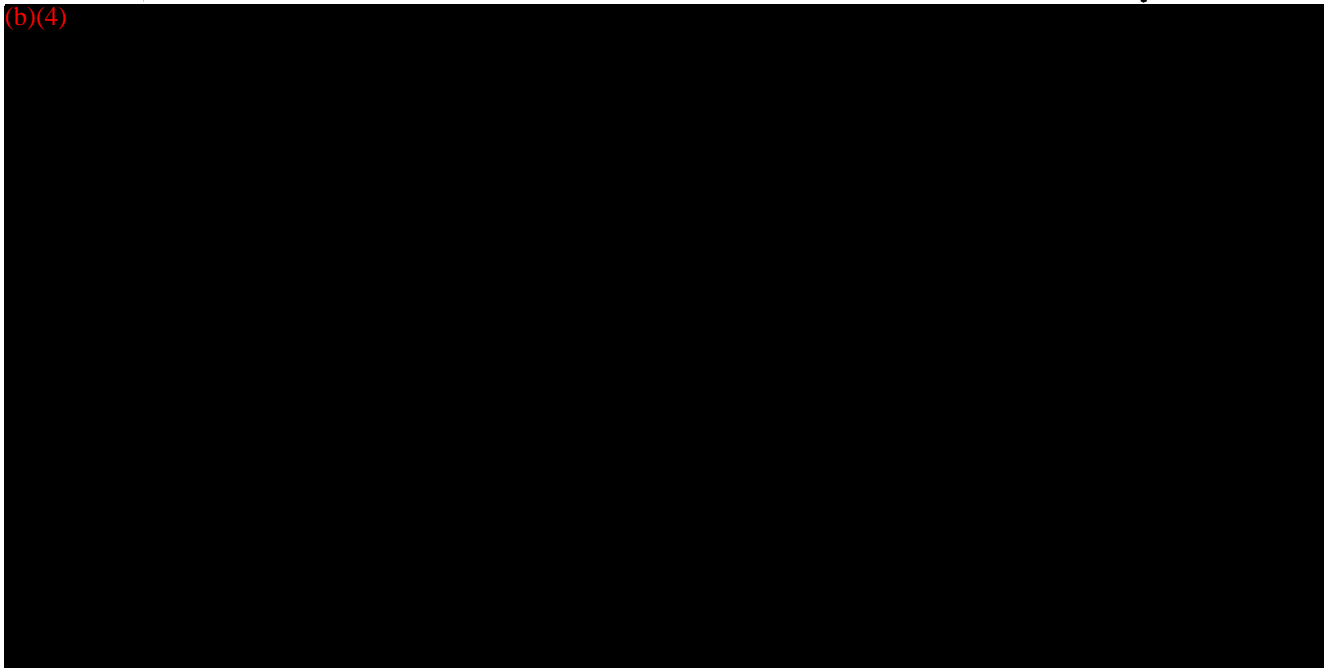
Table 1. Ice Blue Tinted Boston XO: D&C Green Dye #6 and MHB Leachability

(b)(4)

A large black rectangular redaction box covers the entire content of Table 1. The text "(b)(4)" is written in red at the top left corner of the redacted area.

Table 2. Violet Tinted Boston XO: D&C Violet Dye #2 and MHB Leachability

(b)(4)

A large black rectangular redaction box covers the entire content of Table 2. The text "(b)(4)" is written in red at the top left corner of the redacted area.

510(K) Premarket Notification
BOSTON XO Contact Lens Material

APPENDIX 6

LENS CYCLING STUDY

192

Polymer Technology

LENS CYCLING STUDY OF BOSTON XO

Purpose:

This test was designed to evaluate the dimensional and optical stability of BOSTON XO contact lenses after extended routine handling.

Experimental:

(b)(4)



(b)(4)



Boston XO Cycling 1/7/99

Boston XO Lens Cycling Study

Lot # 0036471
(b)(4)



* lens broke, unable to measure.

Table I

Boston XO Lens Cycling Study

Lot # 99070PTC006

(b)(4)



Table II

196
062

Boston XO Lens Cycling Study

Lot # 89063BTC007

(b)(4)



Table III

197
063

BXO 0036471-20

(b)(4)



064

198

(b)(4)



BXO 0036471-1

199

065

(b)(4)



BXO 0036471-2

207

066

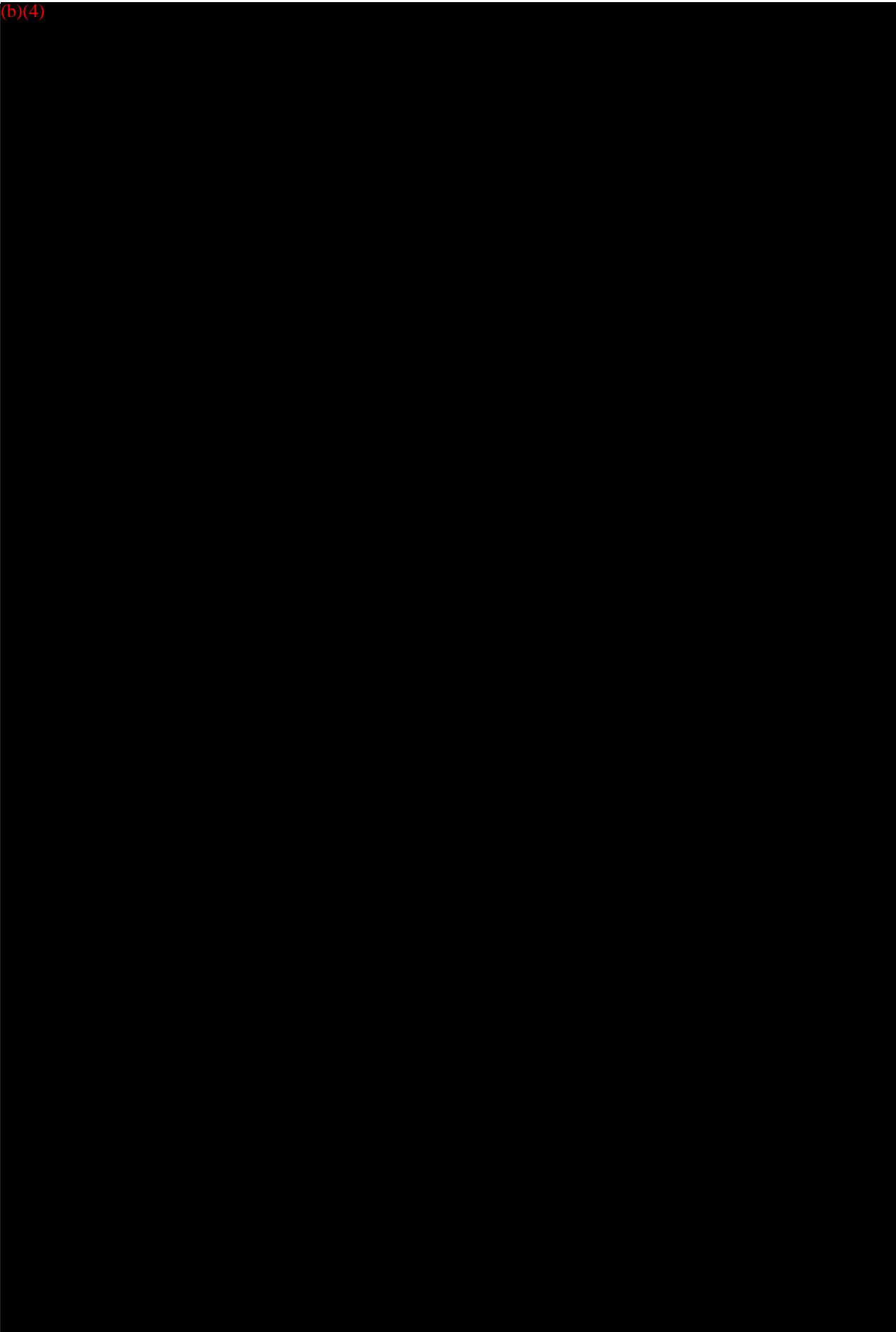
(b)(4)



BXO 0036471-3

201

(b)(4)



BXO 0036471-4

202

068

(b)(4)



BXO 0036471-5

203
069

(b)(4)



BXO 0036471-6

204
070

(b)(4)



BXO 0036471-7

205

071

(b)(4)



BXO 0036471-8

206

072

(b)(4)



BXO 0036471-9

207

073

(b)(4)



BXO 0036471-10

208

074

(b)(4)



BXO 0036471-11

209

075

(b)(4)



BXO 0036471-12

210

076

(b)(4)



BXO 0036471-13

211

077

(b)(4)



BXO 0036471-14

212

078

(b)(4)



BXO 0036471-15

213

079

(b)(4)



BXO 0036471-16

214

080

(b)(4)



215

081

(b)(4)



BXO 0036471-18

216

082

(b)(4)



BXO 0036471-19

217

083

(b)(4)



BXO 0036471-20

218

084

(b)(4)



BXO 99070PTC006-1

219

085

(b)(4)



BXO 99070PTC006-2

220

086

(b)(4)



BXO 99070PTC006-3

lee

087

(b)(4)



BXO 99070PTC006-4

eee

(b)(4)



BXO 99070PTC006-5

223

089

(b)(4)



BXO 99070PTC006-6

see

090

(b)(4)



BXO 99070PTC006-7

225

091

(b)(4)



BXO 99070PTC006-8

gpc

092

(b)(4)



BXO 99070PTC006-9

287

093

(b)(4)



BXO 99070PTC006-10

278

094

(b)(4)



BXO 99070PTC006-11

289
095

(b)(4)



BXO 99070PTC006-12

230

096

(b)(4)



BXO 99070PTC006-13

231
097

(b)(4)



BXO 99070PTC006-14

232

098

(b)(4)



BYD 00070PTC006 45

233
099

(b)(4)



BXO 99070PTC006-16

234
100

(b)(4)



BXO 99070PTC006-17

235

(b)(4)



BXO 99070PTC006-18

236

(b)(4)



BXO 99070PTC006-19

237

(b)(4)



BXO 99070PTC006-20

238
104

(b)(4)

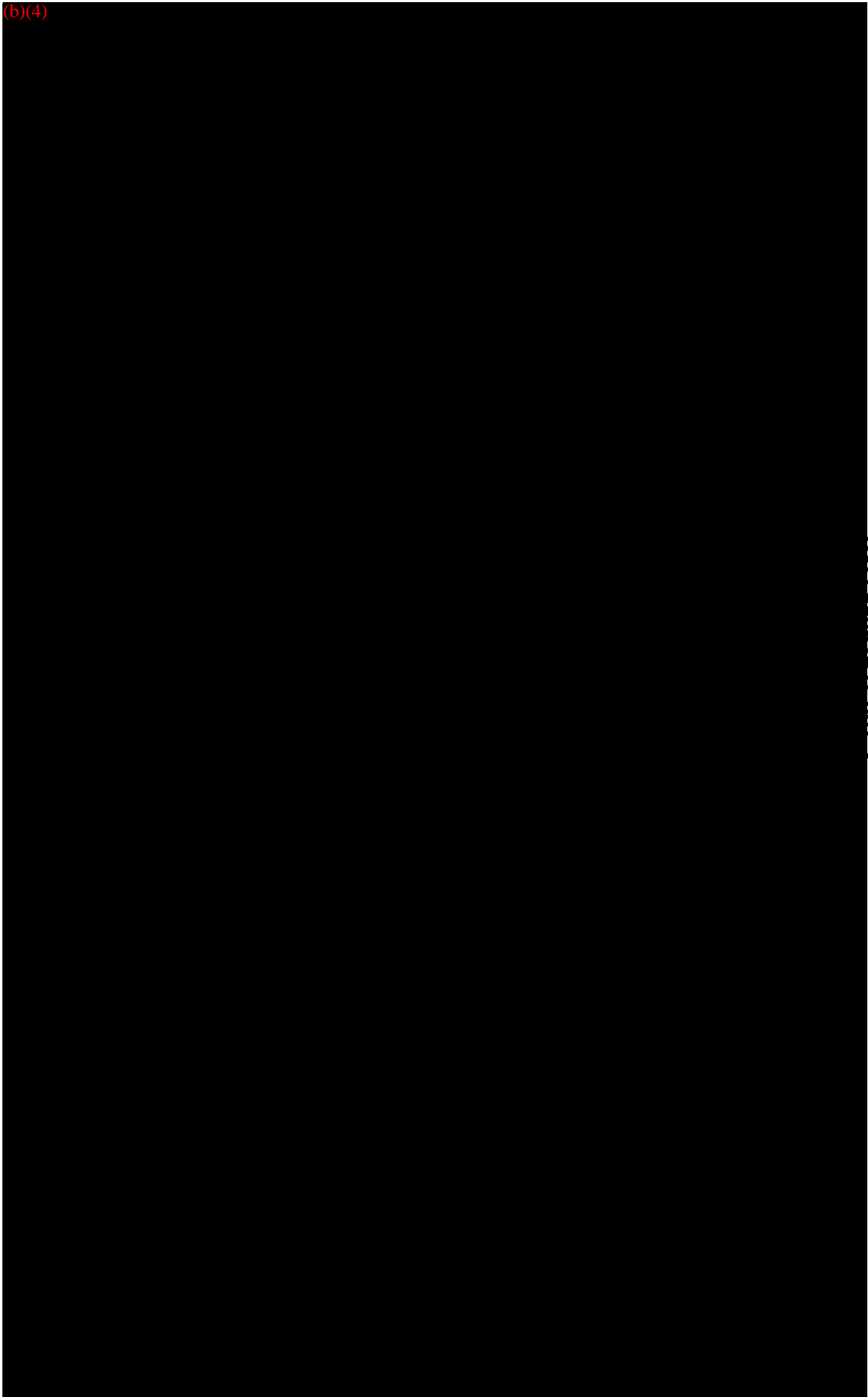


BXO 99063PTC007-1

239

105

(b)(4)



BYD 00063DTC007 2

240

(b)(4)



BXO 99063PTC007-3

201

(b)(4)



BXO 99063PTC007-4

242

(b)(4)



BXO 99063PTC007-5

24B

(b)(4)



BXO 99063PTC007-6

294

110

(b)(4)



BXO 99063PTC007-7

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(b)(4)



BXO 99063PTC007-8

246

(b)(4)



BXO 99063PTC007-9

247

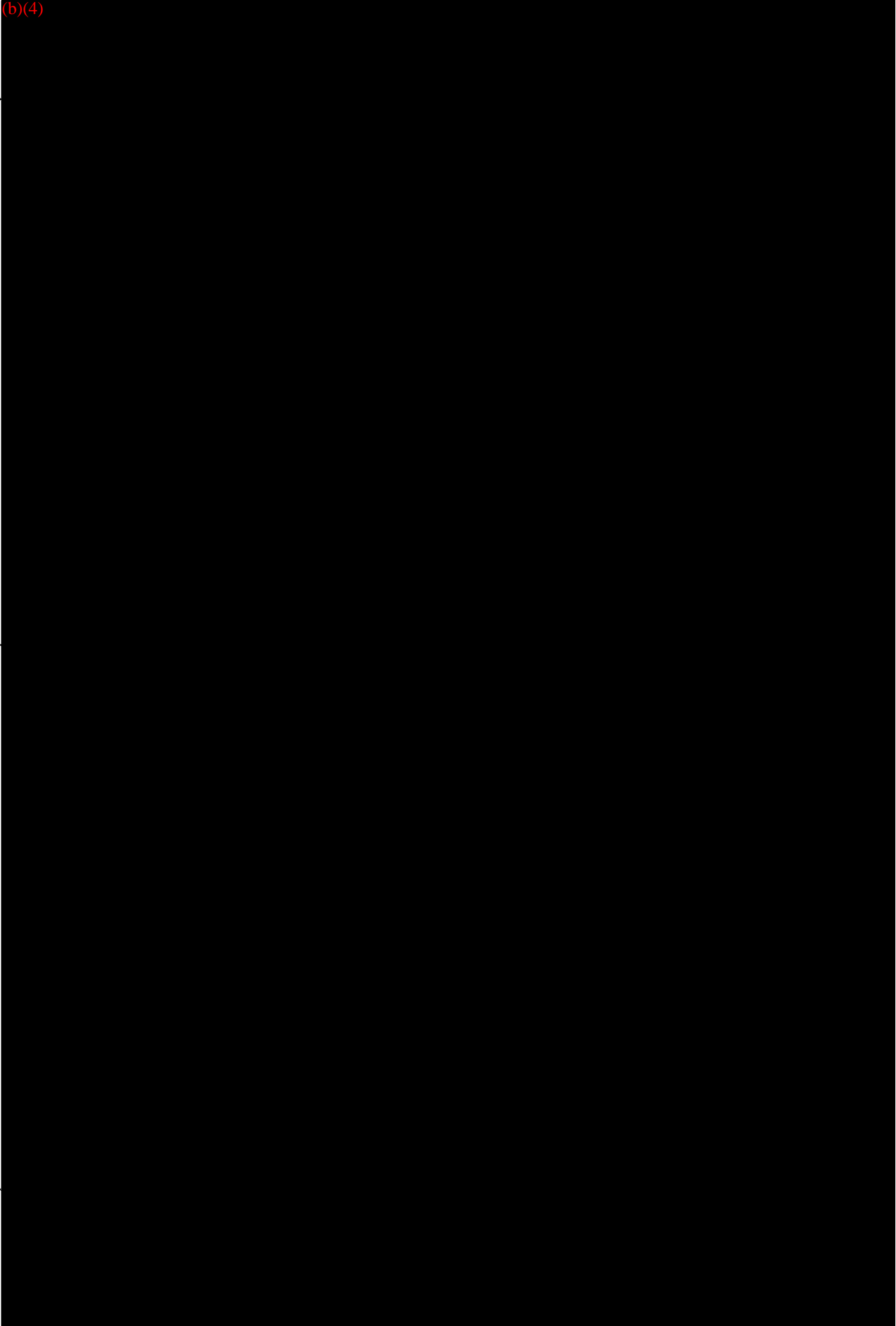
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BXO 99063PTC007-10

248

(b)(4)



BXO 99063PTC007-11

249

(b)(4)



BXO 99063PTC007-12

282

(b)(4)



BXO 99063PTC007-13

JST

(b)(4)



BXO 99063PTC007-14

252

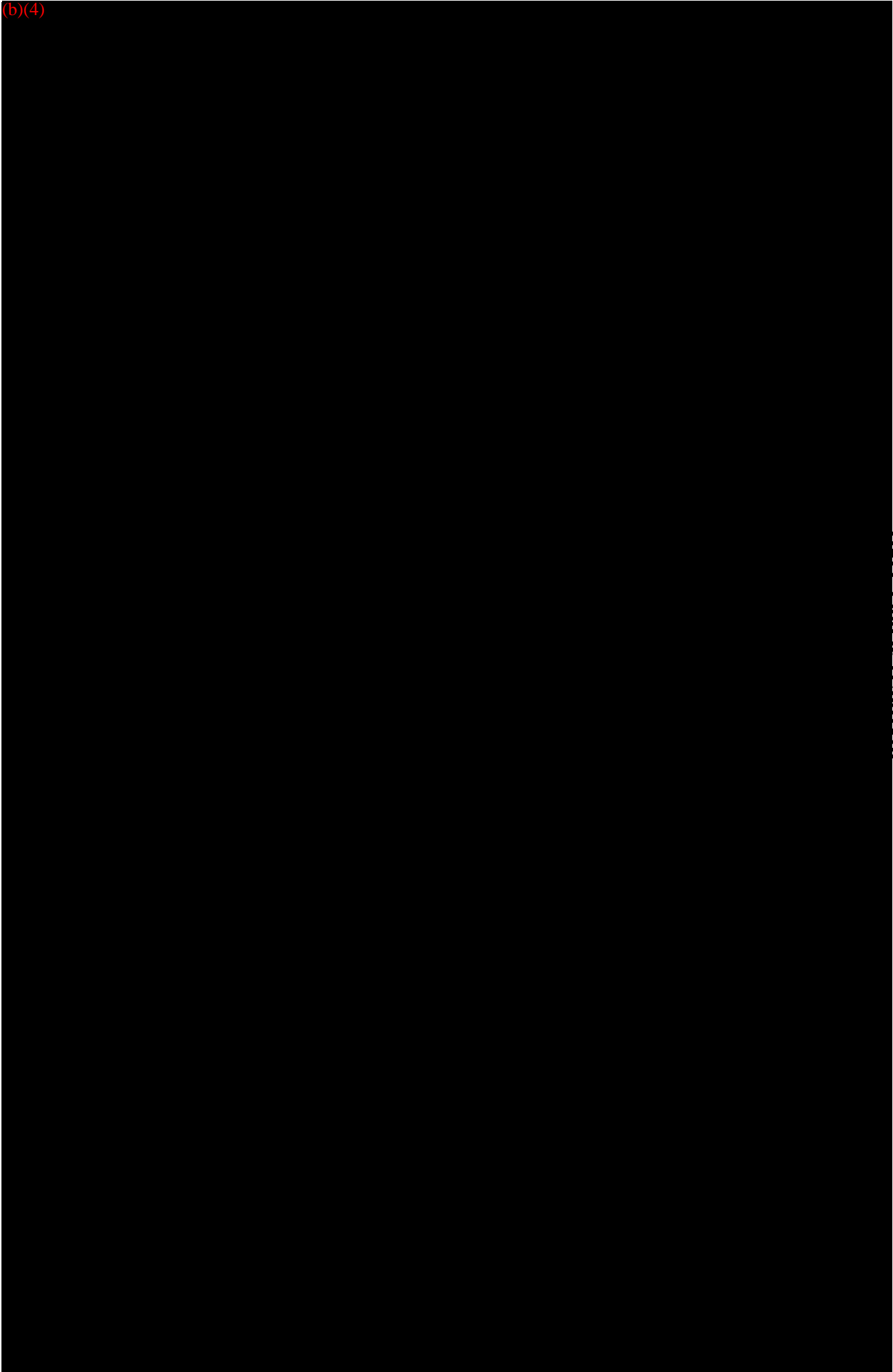
(b)(4)



BXO 99063PTC007-15

JSB

(b)(4)



BYO 99063PTC007 46

254

(b)(4)



BXO 99063PTC007-17

255

(b)(4)



BXO 99063PTC007-18

256

(b)(4)

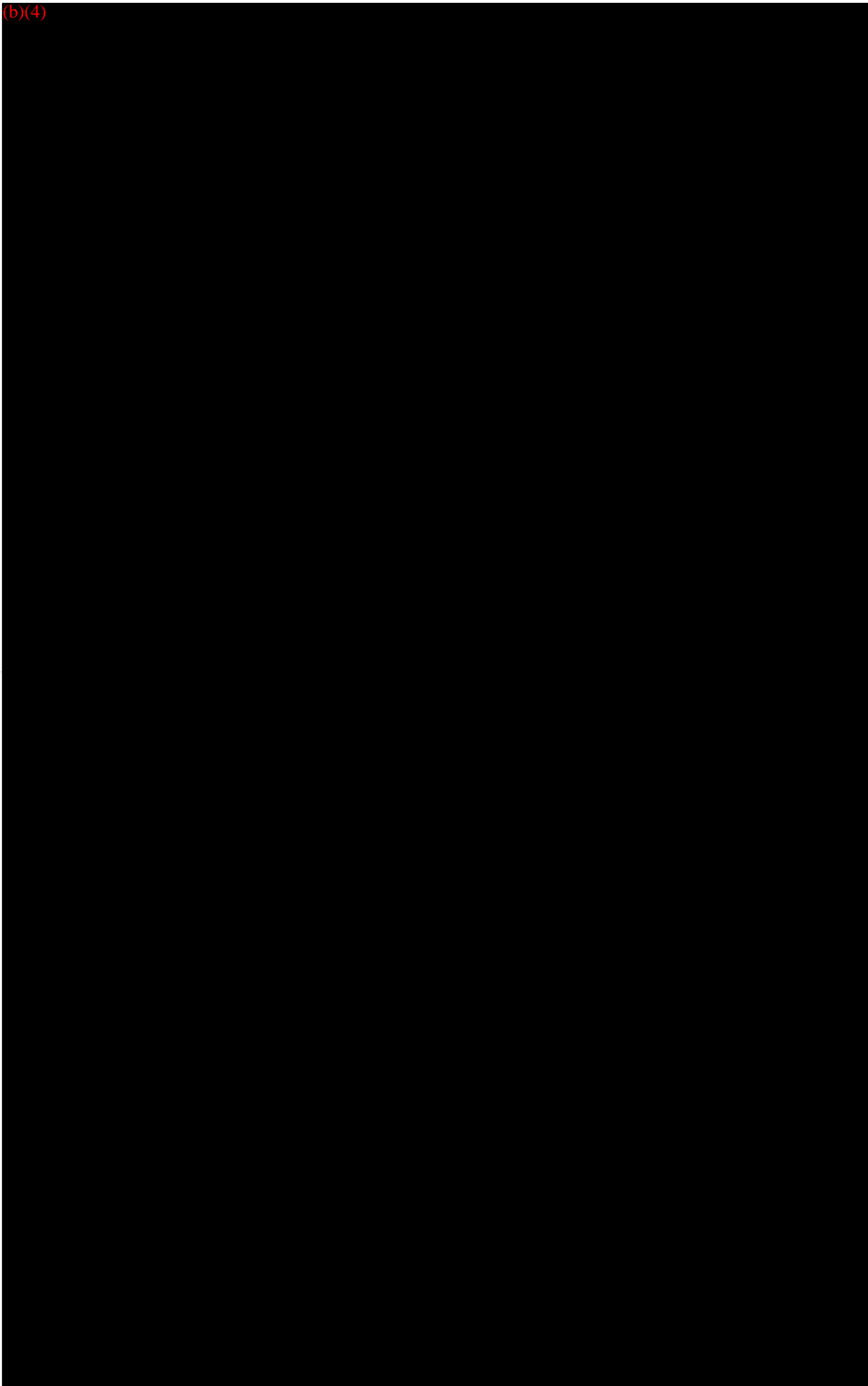


BXO 99063PTC007-19

LSR

123

(b)(4)



BYO 00062PTC007 20

258

510(K) Premarket Notification
BOSTON XO Contact Lens Material

APPENDIX 7

TOXICOLOGY

IN-VITRO CYTOTOXICITY REPORT

ACUTE OCULAR IRRITATION REPORT

SYSTEMIC INJECTION REPORT

289

510(K) Premarket Notification
BOSTON XO Contact Lens Material

APPENDIX 7
IN-VITRO CYTOTOXICITY REPORT

HeO

Lab No. 99T 11639 00

MG065-110

P.O. No. 8512424
GLP

STUDY TITLE:

CYTOTOXICITY STUDY USING THE ISO AGAROSE OVERLAY METHOD

(Extracts)

TEST ARTICLE:

Boston XO Contact Lenses

IDENTIFICATION NO.:

Lots: 99070PTC004, 99053PTC005, 99070PTC005

(b)(4)



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METHODS	5
RESULTS	6
CONCLUSION	6
RECORD STORAGE	6
CERTIFICATE OF QUALITY ASSURANCE INSPECTIONS	7

SUMMARY

(b)(4)



APPENDIX 7

ACUTE OCULAR IRRITATION REPORT

282

Confidential

Lab No. 99T 11639 00

TA008-800

P.O. No. 8512424
GLP

STUDY TITLE:

OCULAR IRRITATION STUDY OF EXTRACTS IN THE RABBIT

TEST ARTICLE:

Boston XO Contact Lenses

IDENTIFICATION NO.:

Lots: 99070PTC004, 99053PTC005, 99070PTC005

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SUMMARY

(b)(4) Study Protocol



(b)(4) Study Protocol



APPENDIX 7

SYSTEMIC INJECTION REPORT

292

Confidential

Lab No. 99T 11639 00

TU012-500

P.O. No. 8512424
GLP

STUDY TITLE:

USP SYSTEMIC TOXICITY STUDY IN THE MOUSE

(Extracts)

TEST ARTICLE:

Boston XO Contact Lenses

IDENTIFICATION NO.:

Lots: 99070PTC004, 99053PTC005, 99070PTC005

(b)(4) Study Protocol

B
Page 1 of

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(b)(4) Study Protocol

TU012-500

Lab No. 99T 11639 00

SUMMARY

(b)(4) Study Protocol



(b)(4) Study Protocol

510(K) Premarket Notification
BOSTON XO Contact Lens Material

APPENDIX 8

**COMPARISON OF BOSTON XO AND BOSTON ES
CLINICAL INVESTIGATION**

301

Comparison of BOSTON XO and BOSTON ES

Clinical Investigation

Population

(b)(4) Study Protocol



Visual Acuity at 3 months (Final Visit)

(b)(4) Study Protocol



Comparison of BOSTON XO and BOSTON ES

Clinical Investigation

Slit Lamp Findings

(b)(4) Study Protocol



303

Comparison of BOSTON XO and BOSTON ES

Clinical Investigation

Symptoms, Problems & Complaints

(b)(4) Study Protocol



Discontinuation

(b)(4) Study Protocol



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APPENDIX 8

CLINICAL STUDY REPORT

NOTE: Financial Disclosure by Clinical Investigators, 21 CFR Part 54, does not apply to this Clinical Study because it was completed in 1994.

306

**A CLINICAL EVALUATION OF THE
SAFETY AND EFFICACY OF THE
QUANTUM II RIGID GAS PERMEABLE CONTACT LENS
WHEN WORN ON A DAILY WEAR BASIS**

(STUDY #001)

FINAL REPORT

Prepared by
Global Field Clinical Services

February 2000

A CLINICAL EVALUATION OF QUANTUM II CONTACT LENS**TABLE OF CONTENTS**

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SUMMARY

(b)(4) Study Protocol



Conclusion

Based on the data presented, the sponsor concludes that the Quantum II RGP Contact Lens is safe and efficacious when used on a daily wear basis.

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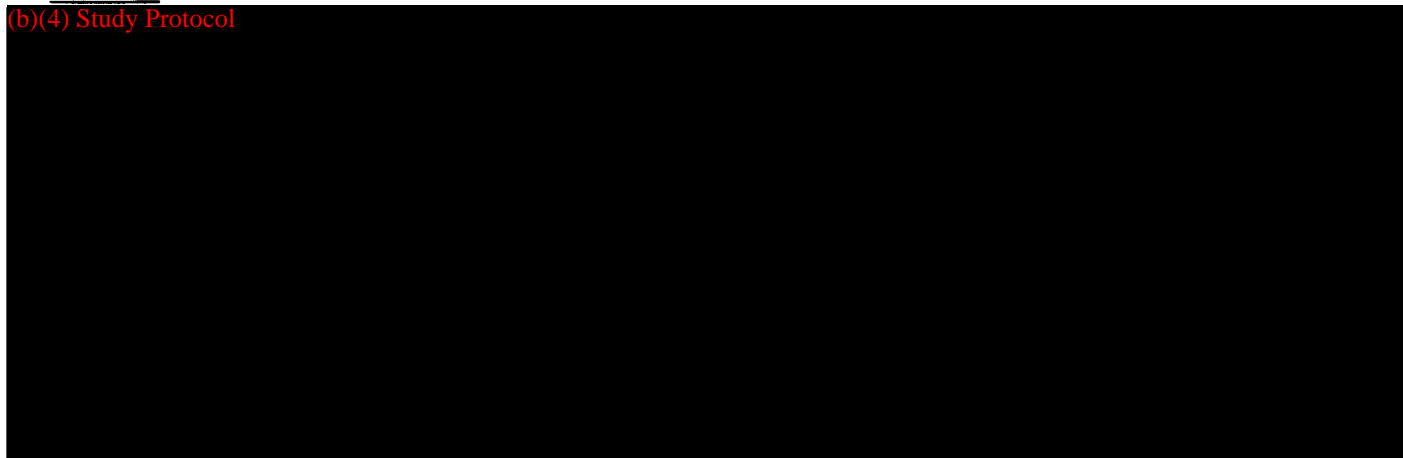
I. INTRODUCTION

A. Purpose

The purpose of this 3-month study was to evaluate the safety and efficacy of the Quantum II Rigid Gas Permeable (RGP) contact lens when worn by myopic and hyperopic phakic contact lens wearers on a daily wear basis. The study started in March, 1993 and concluded in May, 1994.

B. Methods

(b)(4) Study Protocol



C. Safety and Efficacy Measures

Safety:

Adverse Events
Positive Slit Lamp Findings

Symptoms/Complaints
Keratometry Changes

Efficacy

Refractive Changes
Lens Visual Acuity
Lens VA Line Changes

Lens Deposits
Lens Wettability

II. MAJOR STUDY CHARACTERISTICS

Device

Quantum II Rigid Gas Permeable (RGP) Contact Lens (Test)

FDA
Cleared

No

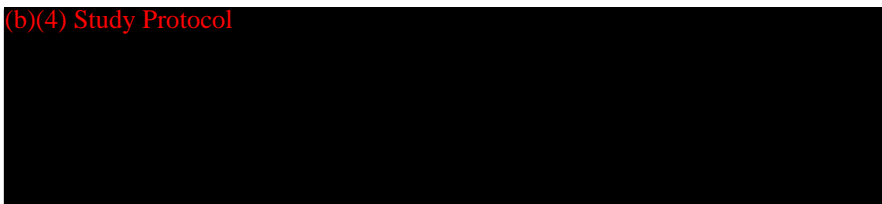
Lens Characteristics:

This study allowed for the use of Quantum II RGP contact lenses with the following parameters:

- (b)(4) Study Protocol
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Study Characteristics:

1. Duration:
2. Number of Investigators:
3. Number Enrolled:
4. Number Completed:



13

(b)(4) Study Protocol



III. PATIENT GROUPS

A. (b)(4) Study Protocol



B. Reasons for Discontinuation

(b)(4) Study Protocol



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IV. FOLLOW-UP VISIT SCHEDULE

Follow-up visits were required at 1 week, 2 weeks, 1 month, 2 months and 3 months after the Dispensing Visit. If a patient missed two scheduled follow-up visits, they were discontinued from the study.

A. Scheduled Follow-Up Visits

Table IV-1, which follows, indicates the number of potential eye visits, paperwork not received, missed visits, actual visits and the missed visit rate for all Completed Eyes. Refer to Tables 4.A and 4.B, in Appendix A, for detailed analysis of initial and scheduled follow-up visits for Completed and Discontinued Eyes, respectively.

 Table IV-1
 Visit Analysis – Scheduled Follow-Up Visits
 for Completed Eyes

	<u>Completed Eyes</u>
Potential Eye Visits	612
Paperwork Not Received	8
Missed Visits	16
Actual Visits	588
Missed Visit Rate	2.60%

B. Unscheduled Follow-up Visits

There were 10 unscheduled follow-up visits reported during the study. However, no data was collected concerning the reasons for the visits.

V. STUDY POPULATION AND DESCRIPTIVE DATA

Patient recruitment was open to myopic and hyperopic phakic eyes requiring lens powers from +10.00D to -20.00D. Table 5, in Appendix A, indicates that the ages of the 57 Enrolled Dispensed Patients ranged from 19 to 55, with a mean age of 36.4. There were 34 females and 23 males, with a ratio of 1.48 females to every male.

VI. SAFETY DATA

A. Adverse Events

There were no adverse events reported during the study.

B. Slit Lamp Findings

Table VI-1, which follows, presents a summary of slit lamp findings for Completed Eyes. Refer to Tables 6.A and 6.B, in Appendix A, for detailed slit lamp findings by visit for Completed and Discontinued Eyes (respectively) at scheduled and unscheduled follow-up visits.

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(b)(4) Study Protocol



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6

C. Study Related Symptoms/Complaints

(b)(4) Study Protocol



D. Keratometry Changes

(b)(4) Study Protocol



E. Unscheduled Lens Replacements

(b)(4) Study Protocol



VII. EFFICACY DATA

A. Refractive Changes

Tables 11.A and 11.B, in Appendix A, provide summaries of refractive changes, comparing baseline refraction to final visit refraction, for Completed and Discontinued Eyes, respectively. All refractive changes for Completed Eyes were 1 Diopter or less.

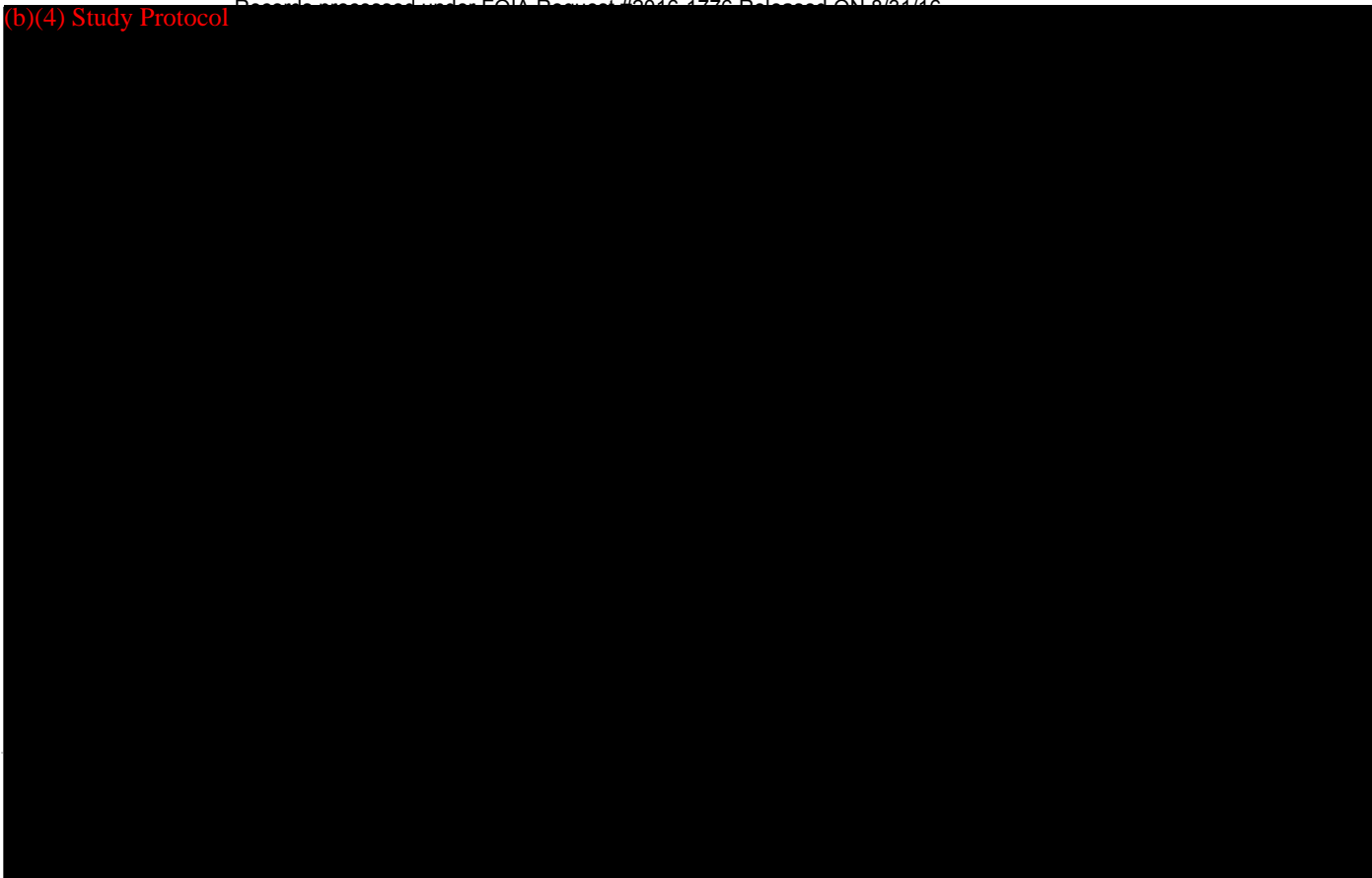
B. Visual Acuity Results

1. Distribution of Visual Acuities

(b)(4) Study Protocol



(b)(4) Study Protocol



C. Daily Wearing Time

Table VII-3, which follows, presents a summary of the average reported daily wear times. Refer to Tables 14.A and 14.B, in Appendix A, for detailed average daily wear times by visit for Completed and Discontinued Patients (respectively) at scheduled and unscheduled visits. The average daily wearing time across all visits ranged from 13.3 to 14.0 hours per day for Completed Patients.

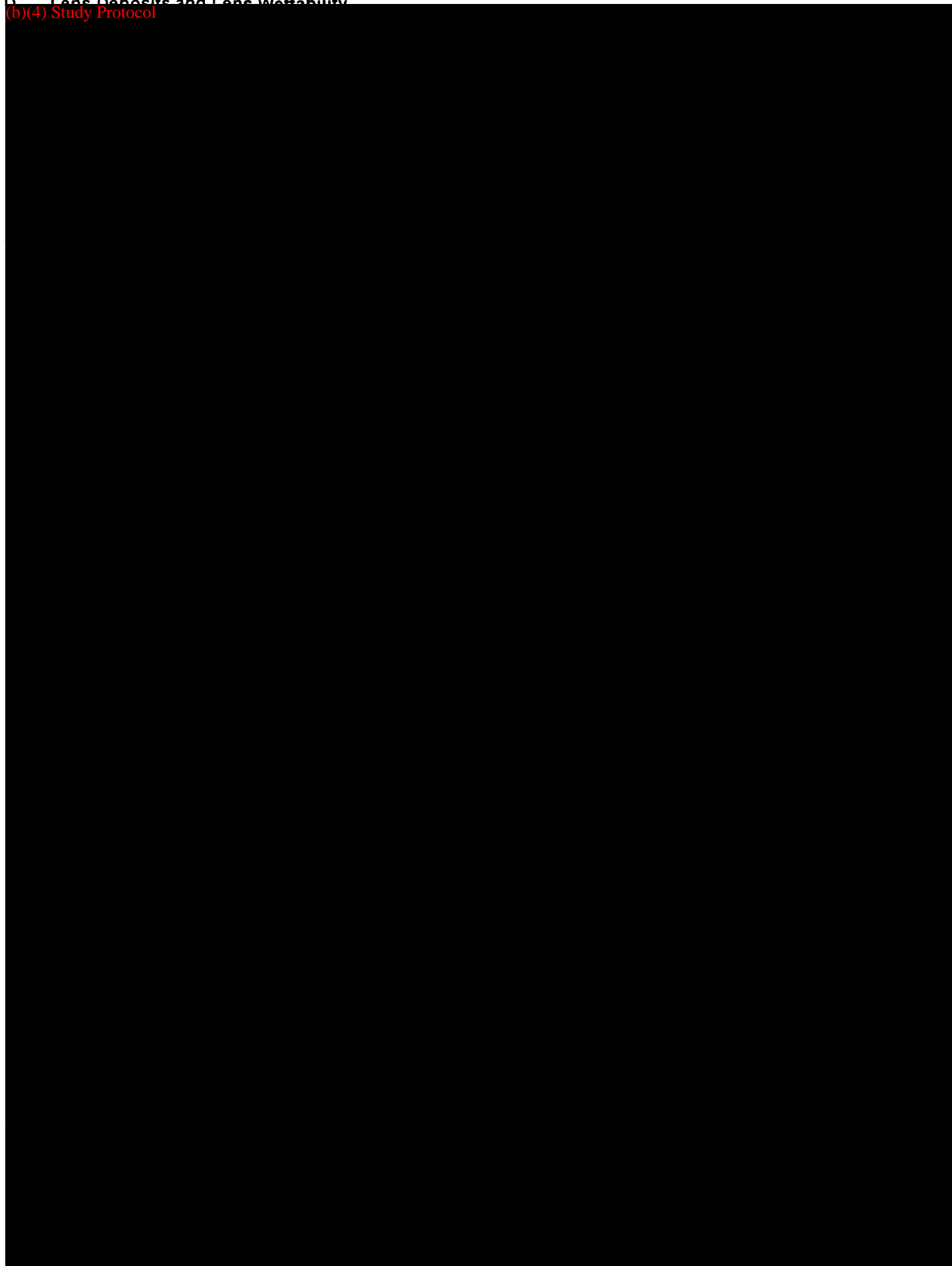
Table VII-3
Average Daily Wear Times for Completed Patients
at Scheduled and Unscheduled Follow-Up Visits (Pooled)

<u>Avg. Daily Wear</u> <u>Time (Hr.)</u>	<u>#</u>	<u>%</u>
1.0 to 4.0	6	2.4
4.1 to 6.0	0	0.0
6.1 to 8.0	12	4.8
8.1 to 10.0	19	7.6
10.1 to 12.0	33	13.1
12.1 to 14.0	50	19.9
14.1 to 16.0	118	47.0
16.1 to 18.0	13	5.2

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D. Lens Deposits and Lens Wettability

(b)(4) Study Protocol



(b)(4) Study Protocol



2

VIII. DISCUSSION

(b)(4) Study Protocol



IX. CONCLUSION

Based on the data presented, the sponsor concludes that the Quantum II RGP Contact Lens is safe and efficacious when used on a daily wear basis.

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APPENDIX A

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Table 1
Patient Study Status by
Investigator and Eye

(b)(4) Study Protocol



Table 2
Patient Accountability and Status by Eye

(b)(4) Study Protocol



Table 3
Reasons for Discontinuation by Visit
(Patients)

(b)(4) Study Protocol



Table 4.A
Analysis of Initial and Scheduled Follow-Up Visits
for Completed Eyes

(b)(4) Study Protocol



Table 4.B
Analysis of Initial and Scheduled Follow-Up Visits
for Discontinued Eyes

(b)(4) Study Protocol



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Table 5
Patient Demographics

(b)(4) Study Protocol



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Table 6.A
Slit Lamp Findings by Visit
for Completed Eyes

(b)(4) Study Protocol



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Table 6.A Cont'd
Slit Lamp Findings by Visit
for Completed Eyes

(b)(4) Study Protocol



Table 6.B
Slit Lamp Findings by Visit
for Discontinued Eyes

(b)(4) Study Protocol



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188

Table 6.8 Cont'd
Slit Lamp Findings by Visit
for Discontinued Eyes

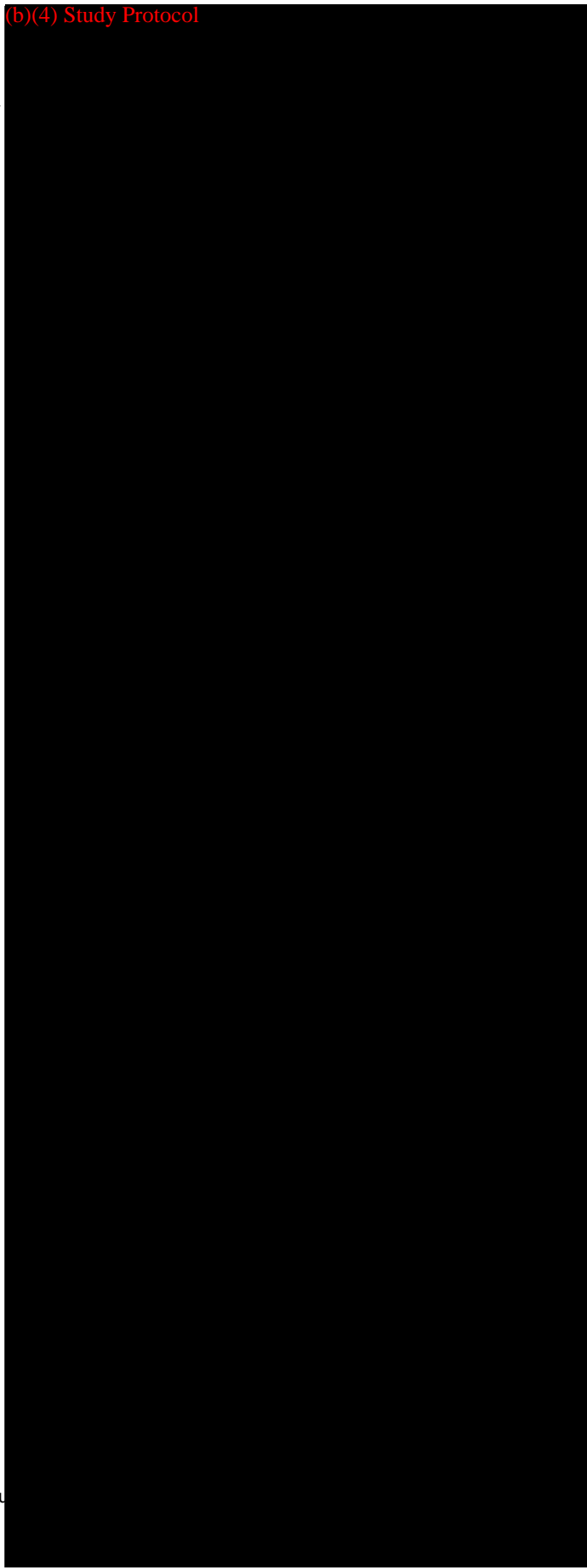
(b)(4) Study Protocol



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(b)(4) Study Protocol

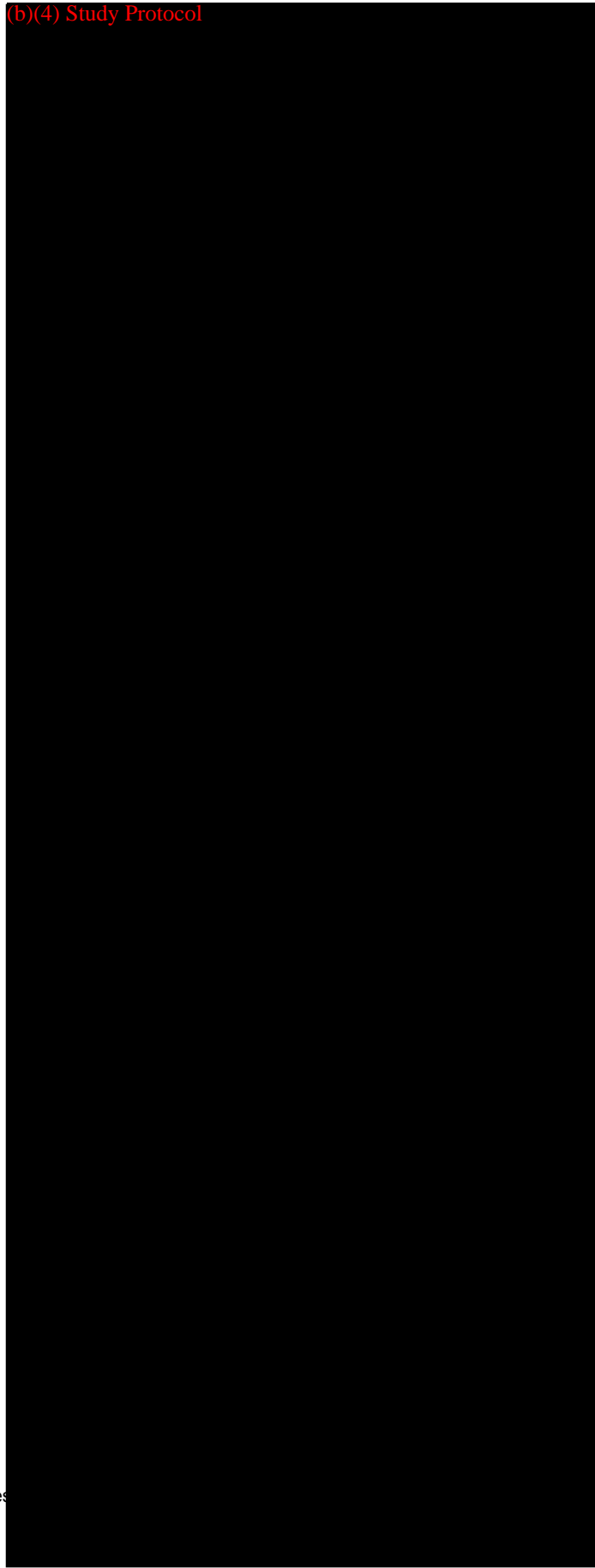
Table 7.A
Lens Comfort by Visit
for Completed Eyes



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(b)(4) Study Protocol

Table 7.B
Lens Comfort by Visit
for Discontinued Eyes



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Table 8.A
Symptoms/Complaints by Visit
for Completed Eyes

(b)(4) Study Protocol



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Table 8.B
Symptoms/Complaints by Visit
for Discontinued Eyes

(b)(4) Study Protocol



Table 8.C
Details of Symptoms/Complaints
Reported as Other

(b)(4) Study Protocol



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Table 9.A
Keratometry Change (Absolute Value) from Baseline
to Final Visit by Meridian
for Completed eyes

(b)(4) Study Protocol



Table 10.A
Reasons for Unscheduled Lens Replacements by Visit
for Completed Eyes

(b)(4) Study Protocol



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Table 10.B
Reasons for Unscheduled Lens Replacements by Visit
for Discontinued Eyes

(b)(4) Study Protocol



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Table 10.C
Details of Unscheduled Lens Replacements Reported as Other

(b)(4) Study Protocol



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Table 11.A
Refractive Changes (Absolute Value) from Baseline
to Final Visit
for Completed Eyes

(b)(4) Study Protocol



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Table 12.A
Visual Acuity: Initial Spherocylindrical Refractive VA
and Lens VA at Initial and All Follow-Up Visits
for Completed Eyes

(b)(4) Study Protocol



Table 12.B
Visual Acuity: Initial Spherocylindrical Refractive VA
and Lens VA at Initial and All Follow-Up Visits
for Discontinued Eyes

(b)(4) Study Protocol



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Table 13.A
Visual Acuity Line Changes: Comparison of Initial and Follow-Up Lens VA
to Initial Spherocylindrical Refractive VA
for Completed Eyes

(b)(4) Study Protocol



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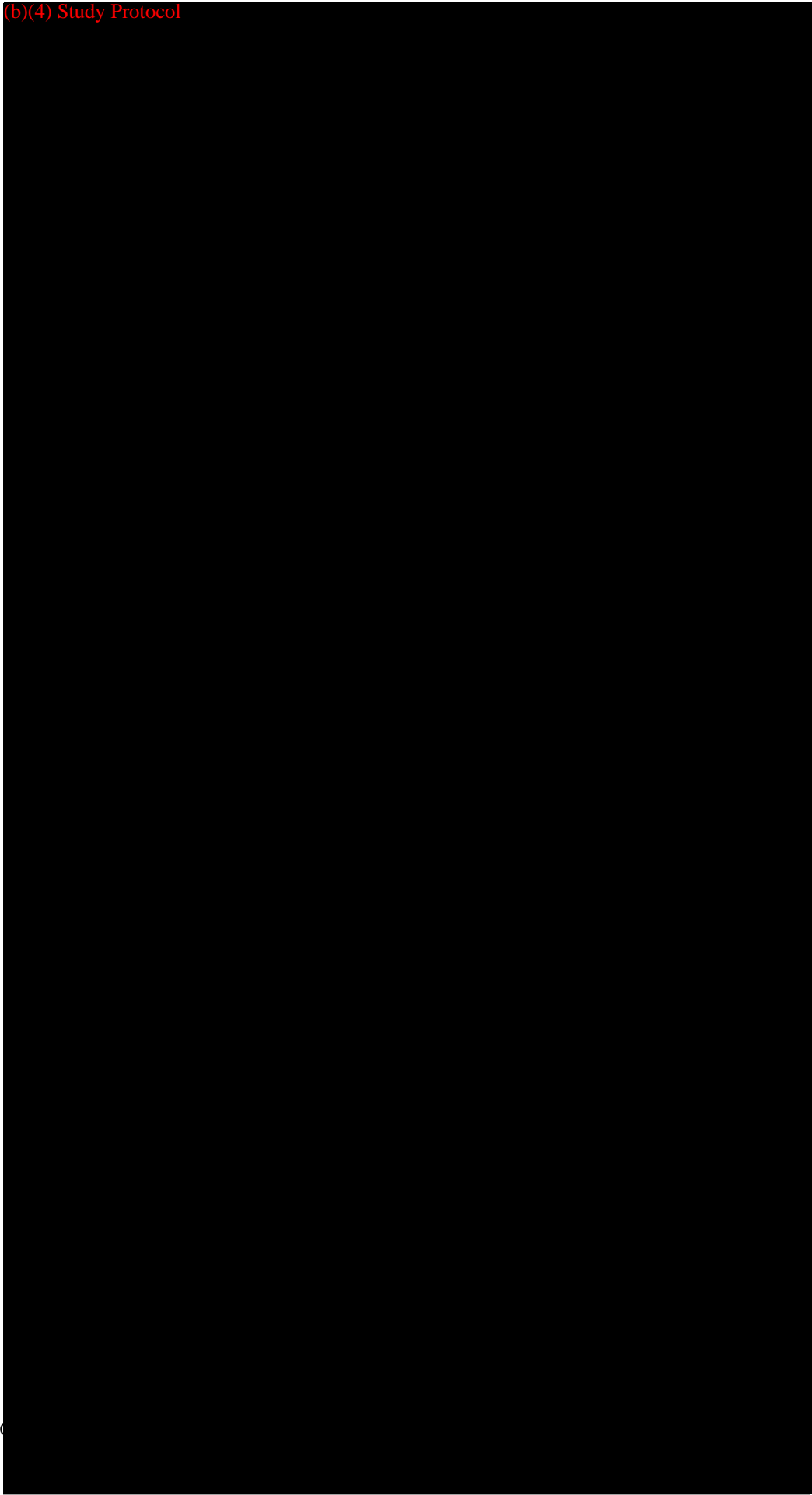
Table 13.B
Visual Acuity Line Changes: Comparison of Initial and Follow-Up Lens VA
to Initial Spherocylindrical Refractive VA
for Discontinued Eyes

(b)(4) Study Protocol



(b)(4) Study Protocol

Table 14.A
Average Daily Wear Time by Visit
for Completed Patients



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Table 15.A
Type and Percent Coverage of Lens Deposits
for Completed Eyes

(b)(4) Study Protocol



5
05

Table 15.B
Type and Percent Coverage of Lens Deposits
for Discontinued Eyes

(b)(4) Study Protocol



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Table 16.A
Degree of Lens Deposits by Visit
for Completed Eyes

(b)(4) Study Protocol



07
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Table 17
Descriptive Statistics for Lens Wettability Reports

(b)(4) Study Protocol



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510(K) Premarket Notification
BOSTON XO Contact Lens Material

APPENDIX 9

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BOSTON XO

1. **SUBMITTER INFORMATION:**

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Global Vision Care
1400 N. Goodman Street
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2. **CONTACT PERSON:**

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	Manager, Regulatory Affairs
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3. **DEVICE IDENTIFICATION:**

Classification Name:	Rigid Gas Permeable (hydrophobic) Contact Lens Material
Proprietary Name:	BOSTON XO (hexafocon A) Contact Lens Material
Common Name:	fluoro silicone acrylate rigid gas permeable contact lens material

4. **PREDICATE DEVICE:**

BOSTON ES (enflucocon A) has been selected as the predicate device for BOSTON XO (hexafocon A).

5. **DESCRIPTION OF THE DEVICE:**

The BOSTON XO Contact Lens Material, hexafocon A, is composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer.

The color additives conform to 21 CFR part 74.3206. The hexafocon A material has an oxygen permeability, DK of 100, a specific gravity of 1.26, and the lens visible light transmittance of at least 70%. The hexafocon A name has been adopted by the United States Adopted Names Council (USAN).

510(k) Premarket Notification
BOSTON XO Contact Lens Material

6. INDICATIONS FOR USE:

The *BOSTON XO* contact lens material is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfection system only.

7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the *BOSTON XO* contact lens material. The results of all testing demonstrated that the safety and effectiveness of the *BOSTON XO* is equivalent to the currently marketed BOSTON ES contact lens material. A summary of these results from the preclinical studies is presented below.

Toxicology:

In-Vitro Cytotoxicity:

USP Agar Diffusion Cytotoxicity was completed in accordance with USP XXII. The test article meets the requirements of the Agar Diffusion Test.

Acute Ocular Irritation:

Acute Ocular Irritation test was performed and produced no ocular irritation.

Systemic Injection

The lens material meets the requirements of the Systemic Injection Test and is considered non-toxic.

Shelf Life:

The *BOSTON XO* (hexafocon A) is a hydrophobic rigid gas permeable contact lens material with <1% water content. This material will be shipped dry. The data presented supports substantial equivalence of this *BOSTON XO* (hexafocon A) contact lens material to the already marketed BOSTON ES (enfluocon A) contact lens material. Based on the Premarket Notification Guidance Document for Daily Wear Contact Lenses, May 12, 1994, shelf-life studies are not required for clearance of this material.

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Solution Compatibility:

Studies were conducted on blue tinted lens material with the ultraviolet light absorber. Lenses were run through 30 cycles of cleaning and conditioning to establish the compatibility of the lens material with the recommended care regimen. The parameters of ultraviolet and visible light (UV/vis) spectra, base curve, lens diameter, power and surface quality were recorded prior to and upon completion of 30 cycles. Initial and final data were compared. There were no significant changes to lens parameters after 30 complete cycles.

Clinical Testing

Below is a summary of the clinical study carried out to evaluate the safety and efficacy of the *BOSTON XO* (hexafocon A) contact lens material when used as a daily wear contact lens for the correction of visual acuity.

A total of 128 eyes (64 patients) were entered into the study by 3 Investigators. Prior to entry into this study each patient was required to read and sign a Statement of Informed Consent. All patients who signed a Statement of Informed Consent are accounted for in this report. Of the 128 eyes (64 patients enrolled), 102 eyes (51 patients) completed the study.

The safety and efficacy measures for this study were:

Safety: Adverse Events, Positive Slit Lamp Findings,
Symptoms/Complaints and Keratometry Changes

Efficacy: Refractive Changes, Lens Visual Acuity, Lens VA Line
Changes, Lens Deposits, and Lens Wettability.

The sponsor concludes that *BOSTON XO* (hexafocon A) contact lens material is equivalent in safety and efficacy to the predicate device, Boston ES (enflucocon A).

8. SUBSTANTIAL EQUIVALENCE

The *BOSTON XO* contact lens material is substantially equivalent to the currently marketed BOSTON ES contact lens material, which was cleared in 510(k) Premarket Notification No. K943177 on August 25, 1994. The difference between the two devices is a change in the components.

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