PROFESSIONAL FITTING AND INFORMATION GUIDE

BOSTON® ENVISION® with BOSTON® EO (enflufocon B) Aspherical Contact Lenses

Fluoro Silicone Acrylate Rigid Gas Permeable Contact Lenses for Daily Wear

CAUTION:
Federal Law Prohibits Dispensing Without a Prescription

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INTRODUCTION

The BOSTON® ENVISION® contact lens is made from the BOSTON® EO (enflufocon B) material and incorporates a patented back surface design for improved fitting ease and patient comfort. The BOSTON ENVISION lens with BOSTON EO is intended for daily wear.

PRODUCT DESCRIPTION - BOSTON EO ENVISION

The BOSTON EO ENVISION contact lens material, enflufocon B, is composed of an aliphatic fluoroitaconate siloxanyl methacrylate copolymer with an ultraviolet absorber (Uvinul D-49). The BOSTON EO ENVISION contact lens is available in blue. The blue tinted lenses contain D & C Green No. 6 as a color additive.

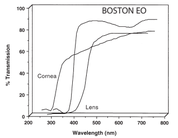
The BOSTON EO ENVISION design contact lens parameters are base curves 7.00 mm to 8.3 mm (in 0.1 mm steps) and a power range -20.00 to +20.00 D. Center thicknesses can be from 0.07 to 0.65 mm (varies with lens design, power and diameter). Note: No modification should be made to the back surface of BOSTON EO ENVISION contact lenses, as this will compromise clinical performance.

The physical/optical properties of the lens are:

Specific Gravity	1.23
Refractive Index	1.429
Light Absorbance (640 nm) (absorbance units/inch)	10.0 Blue
Surface Characteristic	Hydrophobic
Wetting Angle	49°
Water Content	<1%
Oxygen Permeability ($\times 10^{-11}$ (cm^2 O_2 · cm))/(cm^2 · sec · mmHg) @ 35° C)	82* (58**)

*gas to gas method

**polarographic method (ISO/Fatt)



BOSTON EO - 0.07 mm thick BOSTON EO (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

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

INDICATIONS

The BOSTON EO ENVISION Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia/monovision) 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 the BOSTON EO ENVISION 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 EO ENVISION 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 eye care 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 eye care practitioner.

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
Blue	>0.65 mm

Practitioner Note: BOSTON EO ENVISION 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 Eye Care 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 eye care 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 eye care practitioner.
- Patients who wear aspheric 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 EO ENVISION Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eye care 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.
- Eye care 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 EO ENVISION contact lens materials may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the FITTING PROCEDURE for detailed instructions.)

Eye care 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 BOSTON EO ENVISION 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 nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eye care 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 EO ENVISION Contact Lenses and those instructions provided by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care 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 eye care 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. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always contact the eye care 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
- 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

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 eye care 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.

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 EO ENVISION 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/monovision. BOSTON EO ENVISION 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 PHILOSOPHY OF THE BOSTON EO ENVISION DESIGN CONTACT LENS

The properties of the BOSTON EO (enflufocon B) polymer create fitting characteristics in which the base curve/cornea relationship becomes a most critical design parameter.

Although steeply fitted lenses made of earlier gas permeable materials may be well-tolerated, clinical studies of the BOSTON EO ENVISION design show that this practice will produce sub-optimal results. Choosing a base curve radius that is sufficiently flat so as to produce some contact between the lens and central cornea can minimize this effect.

The interpretation of diagnostic lens fluorescein patterns is the most accurate predictor of the final lens fit. This technique assures an accurate selection of the optimum base curve radius for a specific lens diameter. Ideally, the fluorescein pattern should demonstrate mild apical bearing ("feather" touch) or alignment and, most importantly, the absence of mid-peripheral bearing over more than 180° of its circumference.

DESCRIPTION OF THE BOSTON EO ENVISION DESIGN

The posterior surface of the BOSTON EO ENVISION contact lens consists of an ellipsoidal central posterior optical zone that merges into a peripheral hyperbolic curve. The aspheric surface avoids the characteristic mid-peripheral seal of spherical base curve contact lenses and provides a precisely defined peripheral back surface topography.

DIAGNOSTIC LENS SET

The more "forgiving" nature of the BOSTON EO ENVISION design allows the eye care practitioner to fit the majority of myopic patients with a lens trial set ranging in base curves from 7.00 mm (48.25 D) to 8.30 mm (40.75 D) in 0.10 mm steps. A diagnostic lens power of -3.00 D is suggested with an overall lens diameter of 9.6 mm.

The diagnostic lenses must be carefully cleaned after each use. They should be soaked in the appropriate disinfecting & conditioning solution in order to maintain their hydration and consistency of parameters.

FITTING PROCEDURE OUTLINE

1. Pre-Fitting Examination
2. Fitting Philosophy
3. Fitting Procedure
4. Initial Lens Evaluation
5. Initial Lens Power Selection - Trial Fitting
6. Lens Diameter
7. Initial Lens Center Thickness Selection
8. High Corneal Astigmatism
9. 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. Fitting Philosophy

The goal in creating the BOSTON EO ENVISION design was to enable the fitter to more closely approximate the corneal topography in order to distribute the pressure of the lens over the underlying corneal surface more uniformly and to avoid creating a seal at the mid-periphery of the lens.

3. Fitting Procedure

A. Measure the central corneal curvature and identify the flattest meridian.

Example: K's = 42.00/43.50 x 90°
Flat K = 42.00 D (8.04 mm)

B. Select the trial lens that is closest to the flat K.
Example: Flat K = 42.00 D (8.03 mm)
Initial Trial Lens = 8.00 mm

NOTE: Corneal astigmatism greater than 1.50 D should be evaluated with a 0.1 mm steeper lens. Greater than 2.50 D of corneal astigmatism may require a 0.2 mm steeper lens.

Determine Flat K Range (diopters)	Select Base Curve Recommendation (mm): Corneal Astigmatism < 1.50 D	Corneal Astigmatism > 1.50 D
39.75 - 40.25	8.3	8.2
40.50 - 41.00	8.2	8.1
41.25 - 41.75	8.1	8.0
42.00 - 42.50	8.0	7.9
42.75 - 43.25	7.9	7.8
43.50 - 44.00	7.8	7.7
44.25 - 44.75	7.7	7.6
45.00 - 45.50	7.6	7.5
45.75 - 46.25	7.5	7.4
46.50 - 47.00	7.4	7.3
47.25 - 47.75	7.3	7.2
48.00 - 48.50	7.2	7.1
48.75 - 49.25	7.1	7.0

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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. However, central lens positioning is acceptable.

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.

The presence of the UV-absorber in the BOSTON EO ENVISION contactlenses 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 slit lamp 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

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

6. Lens Diameter

An overall lens diameter of 9.6 mm is suggested for most myopic corneas. Small corneas may require a diameter of 9.3 mm while large corneas may require an overall lens diameter of 9.9 mm. The available range of diameters for the BOSTON EO ENVISION design is 9.3 - 10.3 mm.

7. Initial Lens Center Thickness Selection

The following table lists the suggested center thickness of BOSTON EO ENVISION lenses from Plano to -8.00D.

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

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				

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.

8. High Corneal Astigmatism

For patients with greater than 2.00 D of corneal astigmatism, it may be necessary to use trial lenses 0.10 to 0.20 mm steeper than the spherical equivalent. Utilize lens position. Additional thickness will reduce excessive edge lift along the steeper meridian, especially in with-the-rule astigmatism.

9. 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. 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

Eye care 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.

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 eye care practitioner regardless of how comfortable the lenses feel.

The BOSTON EO ENVISION 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

1. Criteria of a Well-Fitted BOSTON EO ENVISION 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.

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 pinguecullae, 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, the BOSTON Advance Cleaner and/or BOSTON one Step 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.

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.

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.

Practitioner Note: The BOSTON EO ENVISION 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.

WARNING: BOSTON EO ENVISION Contact Lenses are NOT intended for overnight (extended) wear.

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 upper eyelid/cornea 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	Usually Comfortable	Uncomfortable
Disposition	Prescribe	Select Flatter Base Curve	Select Steeper Base Curve

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; incomplete blinking or steeply fitted lenses.

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 EO ENVISION Contact Lenses.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (such as driving at night or 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 mono-vision, 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 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 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 eye care practitioner in conjunction with the patient after carefully considering the patient's needs.

*Available should be supplied with a copy of the Patient Instructions.

PATIENT LENS CARE DIRECTIONS

Eye care 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 eye care 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 eye care 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 EO ENVISION Contact Lenses. Eye care 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	BOSTON Simplicity® Multi-Action Solution
Lubricate/Rewet	BOSTON® Rewetting Drops
Weekly	BOSTON® ONE STEP Liquid Enzymatic Cleaner

BOSTON, BOSTON EO, ENVISION, BOSTON Advance and BOSTON Simplicity are registered trademarks of Polymer Technology.

- 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 eye care 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 eye care 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 eye care practitioner for information on storage of lenses.

(Chemical) Disinfecting and Storing 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 eye care 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 eye care practitioner.

Enzymatic Cleaner

- Eye care 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.
- Eye care practitioners may recommend a Weekly Enzymatic Cleaner which can be used to effectively remove protein deposits from BOSTON EO ENVISION Contact Lenses.
- BOSTON EO ENVISION 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 eye care practitioner.

IN-OFFICE LENS MODIFICATIONS

Caution: Damage may result from improper modification techniques. Please Note: BOSTON® EO ENVISION due to it's 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 EO ENVISION 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 EO ENVISION Contact Lenses or adverse experiences with the lenses should be reported to:

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.

Consumer Affairs
Polymer Technology
1400 North Goodman Street
P. O. Box 30450
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 and lot number.