

# PROFESSIONAL FITTING AND INFORMATION GUIDE

**BOSTON® MultiVision  
(enfluocon A) Contact Lens**

**Rigid Gas Permeable  
Contact Lenses for Daily Wear**

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LENS PARAMETERS AVAILABLE	
Power Range	-20.00D to +20.00D in 0.12D increments
Diameter	9.6 mm
Base Curve Range	7.30 mm to 8.30 mm in 0.1 mm increments
Add Powers	Nominal Add Power +1.50 D

## INTRODUCTION

Boston® MultiVision (enfluocon A) Contact Lenses are made from the Boston ES® (enfluocon A) fluoro silicon acrylate material with a water content of <1% by weight.

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

## PRODUCT DESCRIPTION

The Boston ES® (enfluocon A) is composed of aliphatic fluoritaconate siloxanyl methacrylate copolymer including a color additive (D & C Green No. 6) with an ultraviolet absorber (Uvinul D-49).

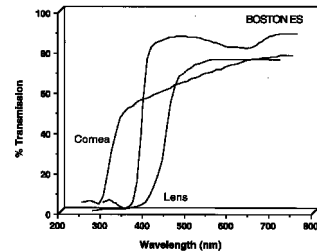
The lenses described above can have a center thickness of 0.10 to -0.69 mm that will vary with lens design and power.

The physical/optical properties of the lens are:

Specific Gravity	1.22
Refractive Index	1.443
Light Absorbance (640 nm)	10.2 (absorbance units/inch)
Surface Character	Hydrophobic
Wetting Angle	52°
Water Content	<1%
Oxygen Permeability	36* (18**)
	{x 10 <sup>-11</sup> (cm <sup>3</sup> O <sub>2</sub> · cm)/(cm <sup>2</sup> · sec · mmHg) @ 35° C}

\*gas to gas method

\*\*polarographic method (ISO/Fatt)



BOSTON® ES - 0.07 mm thick BOSTON ES (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.

## INDICATIONS

The BOSTON® MultiVision (enfluocon A) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in not aphakic persons with non-diseased eyes, who exhibit astigmatism of 4.00 diopters or less and can obtain satisfactory visual acuity. The lens provides a nominal functional add of +1.50 diopters. The lens may be disinfected using a chemical disinfecting system only.

## CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the BOSTON® MultiVision (enfluocon A) Contact Lens 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® MultiVision (enfluocon A) 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.

## Practitioner Note: BOSTON® MultiVision

(enfluocon A) 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.

- 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

• 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.
- 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.
- 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® MultiVision (enfluocon A) contact lens material 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® MultiVision (enfluocon A) 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 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® MultiVision (enfluocon A) Contact Lens and 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 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. Pour the lens into the 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.

#### SELECTION OF PATIENTS

BOSTON® MultiVision (enfluocon A) Contact Lens is a rigid gas permeable lens for the daily wear patient who may require the correction of visual acuity for myopia, hyperopia, astigmatism or presbyopia. BOSTON® MultiVision (enfluocon A) Contact 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.

#### PRE-FITTING EXAMINATION

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

- determine whether a patient is a suitable candidate for daily wear presbyopic 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 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.

#### FITTING GUIDE FOR THE BOSTON® MultiVision (enfluocon A) CONTACT LENS

**CAUTION:** Federal Law Prohibits Dispensing Without a Prescription

#### Background Information

The BOSTON MultiVision (enfluocon A) Contact Lens consists of a back surface aspheric design intended to provide distance and intermediate correction with a reading addition of +1.50D. The base curves range from 7.3 mm to 8.3 mm, in 0.1 mm steps, with an overall lens diameter of 9.6 mm. The lens parameters and lens design were chosen to maximize the ease of fit.

#### Fitting Principles

Although these lenses may be empirically fit, the best success has been found when they have been fit using diagnostic (trial) lenses. There are no conversion requirements or special techniques required for fitting this multifocal design. The following guidelines have been provided to maximize the fitting success of the lens.

#### Initial Base Curve Selection:

If the patient's corneal cylinder is less than or equal to 1.50D, then the initial base curve selected should correspond to the patient's flat K reading. If the patient's corneal cylinder is greater than 1.50D, the initial base curve selected should correspond to 0.1 to 0.2 mm steeper than the patient's flat K reading. In general, the goal of the fit of this multifocal design is to achieve good centration of the lens over the pupil, although superior central position may also be acceptable. The lens must translate well with the blink (1-2 mm) ensuring that the reading portion of the lens moves over the pupillary area upon down gaze. The patient should be instructed to keep their head erect while moving their gaze to an inferior position (much like progressive addition multifocal spectacle lenses) to maximally utilize the reading portion.

#### Example:

##### Step one:

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

In this 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.

In this example – K = 42.75/44.75 @ 90;

Flat K = 7.90D

Corneal Astigmatism = 2.00D

Lens Diameter = 9.6 mm

Initial Base Curve:

Flat K	42.75D	7.90mm
+ Corneal Astigmatism Factor	0.50D	steeper than Flat K
= Initial Base Curve	43.25D	
Base Curve Radius	43.25D	7.80 mm

You may use the above method to select your initial base curve or you may refer to the chart below:

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

Determine Flat K Range (diopters)	Select Base Curve Recommendation (mm)	
	Corneal Astigmatism < 1.50D	Corneal Astigmatism > 1.50D
40.00 - 40.25	-	8.3
40.50 - 40.75	8.3	8.2
41.00 - 41.25	8.2	8.1
41.50 - 41.75	8.1	8.0
42.00 - 42.25	8.0	7.9
42.50 - 42.75	7.9	7.8
43.00 - 43.50	7.8	7.7
43.75 - 44.00	7.7	7.6
44.25 - 44.50	7.6	7.5
44.75 - 45.25	7.5	7.4
45.50 - 45.75	7.4	7.3
46.00 - 46.50	7.3	-

With this initial base curve selection evaluate the following:

#### A. Lens Movement:

The lens MUST move freely with the blink. Poor translation will not place the reading portion of the lens in front of the pupillary zone upon down gaze. If the lens does not translate well, try a flatter base curve. The greatest effect of the add is achieved when the lens interacts with the lower lid in down gaze which will facilitate upward translation.

#### B. Lens Centration:

The lens should center over the pupil in primary gaze and translate upward in down gaze. The greatest effect of the add is achieved when the lens interacts with the lower lid in down gaze which will facilitate upward translation. If the lens is not well centered over the pupil in primary gaze (straight ahead) try a steeper base curve.

#### C. Fluorescein Pattern:

In evaluating the fluorescein pattern, divide the pattern into three zones: central, intermediate and peripheral. The ideal fluorescein pattern is one that demonstrates an aligned to slightly bearing central zone, an aligned intermediate zone and a peripheral zone that demonstrates a slightly high edge. This slightly high edge lift or fluorescein pooling, is normal as long as there is not an excessive amount of edge lift, i.e., creating bubble formation at the edge or causing the lens to be unstable.

The presence of the UV-absorber in the BOSTON® MultiVision (enfluocon A) contact 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:

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:**

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.

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 your Authorized BOSTON® Manufacturers in the following kits: #7503 Slit Lamp Filter kit, #7502 Burton Lamp Modification Kit.

**Optimizing Visual Performance:**

After an acceptable fluorescein pattern is achieved, further base curve adjustments may still be required to optimize visual performance.

Use the above fitting guidelines to achieve an optimum fit. Place the distance spherical over-refraction in a trial frame and measure the distance and near visual acuities. Use full room illumination at near, and record acuity to the single letter. If you have excellent distance visual acuity, and less than Jaeger 1 (J1) at near, continue the trial fitting to optimize near vision.

**Fit 0.1-0.2 mm Flatter If:**

- The lens does not have enough interaction with the lower lid in down gaze to move the lens upward.

- In down gaze, the lens binds to the superior cornea, preventing it from maximal translation. (Lift the upper lid while the patient moves from primary gaze to down gaze to make this assessment).

- The fluorescein pattern shows significant central pooling.

**Fit 0.1-0.2 mm Steeper If:**

- Lid attachment causes the lens to move to an excessively superior position.

- The lens decenters nasally or temporally

- The fluorescein pattern shows significant central bearing.

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	5.50	7.00	8.50
	to	to	to	to
Corresponding Power Compensation (D)	5.25	6.75	8.25	10.00
	0.25	0.50	0.75	1.00

The key to diagnostic fitting is primarily the patient's visual response. Order the base curve that provides the maximal distance and near vision with an acceptable overall fit based on fluorescein pattern interpretation.

**Initial Lens Power Selection**

**Step 1:**  
Perform a spherical refraction over the best-fitting trial lens.

**Step 2:**  
If the spherical power of the over-refraction is greater than 4.00D, 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 3:**  
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

**Initial Lens Center Thickness Selection**

For best clinical results, your Authorized BOSTON® Manufacturer will manufacture each BOSTON MultiVision contact lens with an optimal center thickness. If you choose to specify center thickness, we do not recommend center thicknesses for minus lenses below the following minimums:

Minus Lens Minimum Center Thickness	
Lens Power	Recommended Thickness
Plano	0.24
-0.50	0.20
-1.00	0.18
-1.50	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

**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 of 9.6mm
- distance power

**Follow-up Care**

Practitioner Note: The BOSTON® MultiVision (enfluoconA) 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.

- 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.

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 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.

**WARNING:** BOSTON® MultiVision (enfluocon A) Contact Lenses are NOT intended for overnight (extended) wear.

**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.

**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® MultiVision (enfluocon A) 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 Lens**

Patient comfort is largely determined by lens positioning on the cornea. A central or slightly superior, lid-attachment positioning is generally preferred to enhance comfort and maximize lens performance. Inferior lens positioning, which interferes with normal blinking and promotes lens binding and 3-9 staining, as well as poor multifocal visual performance should be avoided.

Ideally, the fluorescein pattern of the lens should demonstrate alignment without excessive peripheral bearing. 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 trial 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 TRIAL LENS ASSESSMENT			
	Optimum	Too Steep	Too Flat
Fluorescein Pattern	Parallel to Slight Apical Bearing	Excessive Apical Pooling	Apical Touch
	Moderate Edge Lift	Minimum Edge Lift	Excessive Edge Lift
Position	Centered to Slightly Superior	Inferior	Superior Excessively Unstable
Movement	1-2 mm	Less Than 1 mm	More Than 2 mm
Comfort	Slight Initial Sensation	Initially Comfortable	Uncomfortable
Disposition	Evaluate vision, if optimal, then 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; poor edge design, incomplete blinking or steeply fitted lenses.

**Three and nine o'clock staining:** If the lens positions low, it should be refit to achieve a higher position so as to avoid a false blink pattern. Complete blinking should be encouraged.

**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. In most cases, deposits are easily removed by cleaning with original BOSTON® Cleaner or BOSTON Advance® Cleaner. In the event that deposits cannot be removed by cleaning 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. These hydrophobic contaminants have a greater affinity for BOSTON® ES (enflucocon 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.

Recurrent lens warpage: This may be due to repeated, excessive compression of lenses during handling (especially low-minus lenses having a less-than-recommended center thickness) or excessive flexing of minus lenses on astigmatic corneas. Carefully reviewing the proper technique for lens handling and increasing the center thickness by 0.02 to 0.04 mm to reduce lens flexure will minimize recurrent lens warpage.

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.

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.

#### MODIFIED MONOVISION FITTING TECHNIQUE\*

For BOSTON® MultiVision the definition of modified monovision is where one lens is corrected in the normal manner (full correction for distance) while the other lens is prescribed with a slight amount of plus power (+0.5D to +0.75D) over the normal distance correction. This additional plus power should increase near vision acuity in that eye and overall.

\*A mild over correction of +0.50 diopters will enhance the near nominal add without degrading the distance vision significantly.

NOTE: Modified Monovision correction should not be used when it is in conflict with the visual requirements for federal or state licensing.

#### 1. Patient Selection

##### A. Modified 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 modified monovision with the BOSTON® MultiVision (enflucocon A) 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 modified monovision. Modified 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 modified 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 modified 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 modified 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 modified 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 over-plus the more myopic (less hyperopic eye) to increase near correction.

##### C. Visual Demands Method

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

Example:

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

#### 3. 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.

#### 4. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience modified 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 appropriate amount of additional plus power for the near vision eye. 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.

#### 5. 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 adaptation 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.

#### 6. Other Suggestions

The success of the modified 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 supplemental spectacles to wear over the modified monovision contact lenses for specific visual tasks may improve the success of modified monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting modified 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 modified monovision

\*The decision to fit a patient with a modified 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 solution are safe for use with all lenses.

##### 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.

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 cleaning solution does not substitute for disinfection.

The lens care products listed below are recommended by Polymer Technology for use with the BOSTON® MultiVision Contact Lens. 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 Original BOSTON® Cleaner
Disinfect	BOSTON Advance® Comfort Formula Conditioning Solution or Original BOSTON® Conditioning Solution
Store	BOSTON Advance® Comfort Formula Conditioning Solution or Original BOSTON® Conditioning Solution
Multi-Action	BOSTON Simplicity® Multi-Action Solution
Lubricate/Rewet	BOSTON® Rewetting Drops
Weekly Enzymatic Cleaner	BOSTON® One Step Liquid Enzymatic Cleaner

BOSTON, BOSTON Advance and Boston Simplicity are registered trademarks of Polymer Technology, a Division of Wilmington Partners, L.P.

- 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.

- 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 rigid gas permeable contact lenses.
- BOSTON® MultiVision (enfluocon A) 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 re wetting 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.

#### REPORTING OF ADVERSE REACTIONS

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

Consumer Affairs  
Polymer Technology  
Division of Wilmington Partners L.P.  
1400 North Goodman Street  
Rochester, NY 14692  
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.