PROFESSIONAL FITTING AND INFORMATION GUIDE

Boston® Equalens®
(itafluorofocon A)

Extended Wear
Spherical & Aspherical Rigid Gas Permeable
Contact Lenses for Myopia & Hyperopia
in Not-Aphakic Persons

Daily Wear
Spherical, Aspherical, Toric & Bifocal/Multifocal
Rigid Gas Permeable Contact Lenses for
Myopia, Hyperopia, Astigmatism & Presbyopia
in Aphakic and Not-Aphakic Persons

BAUSCH+LOMB
Boston®
Lenses & Materials

℞ ONLY CAUTION:
Federal (USA) Law restricts this device to sale by or on the order of a licensed practitioner.

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INTRODUCTION

Boston® Equalens® (itafluorofocon A) Spherical Rigid Gas Permeable (RGP) 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

The Boston® Equalens® Rigid Gas Permeable contact lens material, itafluorofocon A, for daily wear or extended wear is composed of methyl-methacrylate-fluoroitaconate-siloxanyl copolymer with an ultraviolet absorber (Uvinul D-49). The lenses are available in clear (untinted), blue, or electric blue. The tinted lenses contain the color additive D & C Green No. 6.

LENS PARAMETERS AVAILABLE

The Boston® Equalens® contact lens is a hemispherical shell of the following dimensions:

Spherical Lens Design	
Power Range	-20.00D to +20.00D (daily wear) -20.00D to +12.00D (extended wear) in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	5.00 mm to 9.00 mm in 0.01 mm increments
Aspherical Lens Designs	
(Some of these designs are patented; manufacture of these lenses in Boston® Equalens® (itafluorofocon A) materials are authorized to licensed labs only)	
Power Range	-20.00D to +20.00D (daily wear) -20.00D to +12.00D (extended wear) 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
Toric Lens Designs (Daily Wear)	
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
Bifocal/Multifocal Lens Designs (Daily Wear)	
(Some of these designs are patented; manufacture of these lenses in Boston® Equalens® (itafluorofocon A) materials are authorized to licensed labs only)	
Power Range	-20.00D to +12.00D 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

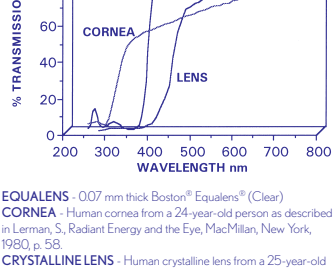
The lenses described above can have a center thickness of 0.07 to 0.65 mm that will vary with lens design, power, and diameter.

The physical/optical properties of the lens are:

Specific Gravity	1.19	
Refractive Index	1.439	
Light Absorption (640 nm)	10.0	Blue
Light Absorption (640 nm) (Absorbance Units/Inch)	23.6	Electric Blue
Surface Character	Hydrophobic	
Wetting Angle	30°	
Water Content	<1%	
Oxygen Permeability	64* (47**)	

* Gas to Gas Method
($\times 10^{-11}$ (cm^2/sec) (mL O_2 x mmHg)) @ 35° C)

**Polarographic Method (ISO/Fatt)



EQUALENS - 0.07 mm thick Boston® Equalens® (Clear)
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

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

WARNING

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

ACTIONS

The Boston® Equalens® contact lens, when placed on the human cornea, acts as a refracting medium to focus light rays on the retina to improve visual acuity.

INDICATIONS (USES)

Boston® Equalens® (itafluorofocon A) RGP contact lenses are indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. The lens is indicated for extended wear for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes in powers from -20.00D to +12.00D.

The 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.

The lens may be disinfected using a chemical disinfection system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Boston® Equalens® 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 non-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® Equalens® contact lens material
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes
- Patient inability or unwillingness, because of age, infirmity, or other mental or physical conditions, or an adverse working or living environment, to understand or comply with any warnings, precautions, restrictions, or directions.

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.**
- 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.
- Daily wear lenses are **not** indicated for overnight wear, and daily wear patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens users.
- Clinical studies indicate that the majority of patients who wish to wear Boston® Equalens® contact lenses for extended wear do so with favorable results. However, suitability as an extended wear patient should be discussed with the contact lens practitioner.
- All contact lens wearers must see their eye care practitioner as directed. If the lenses are for extended wear, the eye care practitioner may prescribe more frequent visits.

PRECAUTIONS

Practitioner Note: Boston® Equalens® 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 this lens in conditions of low illumination for the following colors and center thicknesses:

Color	Center Thickness
Blue	>0.65 mm
Electric Blue	>0.35 mm

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 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® Equalens® 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 promptly 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 UV light absorber in the Boston® Equalens® contact lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the FITTING GUIDE 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 wetting/soaking 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® Equalens® contact lenses.
  - 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 saline 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 rehydrated overnight prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking (Non-Moving) Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care 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® Equalens® contact lens and those prescribed 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.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eye care practitioner about wearing lenses during water activities and other sports.
- Inform your doctor (health care practitioner) that you 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 do not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to ensure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

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

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on 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 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, **immediately remove the lenses and consult the eye care 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.

SELECTION OF PATIENTS

Boston® Equalens® Spherical contact lenses are rigid gas permeable lenses for the daily wear or extended wear patient who may require the correction of visual acuity for myopia, hyperopia, astigmatism, or presbyopia. The Boston® Equalens® spherical 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 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.

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 ensure that they provide minimal lid sensation by being well-tapered and rolled slightly inward.

Plus power lenses, especially those having lenticular designs, are still capable of peripheral flexure despite their greater center thickness. It is, therefore, equally important to avoid a steep fitting lens-cornea relationship. **Remember, it is better to err in the direction of a flat fit rather than a steep fit.**

2. Initial Lens Diameter Selection

For minus lenses, an initial trial lens diameter of 9.6 mm is recommended. For plus lenses, an initial trial 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. Diameters of 9.2 mm to 9.6 mm will generally provide stable, flare-free vision.

3. Initial Lens Base Curve Selection

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

Step 1:

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

Example:

K = 42.75/45.00 x 90 Flat K = 42.75D (7.90 mm)

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

Step 2:

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

Example:

K = 42.75/45.00 x 90 Corneal Astigmatism = 2.25D

Step 3:

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

Example: K = 42.75/45.00 x 90 Flat K = 7.90D

- Corneal Astigmatism = 2.25D
- Lens Diameter = 9.2 mm
- Initial Base Curve:

Flat K	42.75D
+ Corneal Astigmatism Factor	0.25D steeper than Flat K
= Initial Base Curve	43.00D

- Base Curve Radius 43.00D = 7.84 mm

4. Initial Lens Evaluation

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.

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 three and nine o'clock staining, should be avoided.

B. Fluorescein Pattern

Typically, the fluorescein pattern of the final trial 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® Equalens® (itafluorofocon A) 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. 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 4.75D, 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 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

Vertex Conversion Chart
(12 mm distance)
For minus powers reduce by amount shown.
For plus powers increase by amount shown.

±Spherical over-refraction (D)	4.50 to 5.50	5.75 to 6.75	7.00 to 8.50	8.75 to 10.50
Corresponding Power Compensation (D)*	0.25	0.50	0.75	1.00

6. Initial Lens Center Thickness Selection

For best clinical results, the eye care practitioner should always specify center thickness as part of the complete prescription. Below is our recommendation for the standard thicknesses to be utilized.

Select appropriate center thickness from the table.

Minus Lens Center Thickness

Lens Power	Center 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	0.13
-7.00	0.13
-8.00	0.13

(Add 0.02 to 0.04 CT if corneal toricity exceeds 1.5D)

Lens center thickness should also be considered when designing lenses for overnight wear since, during sleep, the oxygen available to the underlying cornea is essentially limited to that which diffuses through the lens. For this reason, extended wear lenses should be manufactured with minimum center thickness to maximize oxygen transmissibility. **For best clinical results, the fitter should always specify the desired center thickness as part of the complete prescription.**

7. Remaining Lens Parameter Selection

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

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

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 optical 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 ensure 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 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.

Practitioner Note: The Boston® Equalens® 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 eye care practitioner regardless of how comfortable the lenses feel.

The Boston® Equalens® contact lenses are indicated for **daily wear** or **extended wear**. The **maximum** suggested wearing time for these lenses is:

DAILY WEAR (DURING WAKING HOURS)

The suggested daily wear schedule for Boston® Equalens® contact lens 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.

Lenses should be removed daily for cleaning and disinfecting for 4 hours (or overnight) before wearing.

EXTENDED WEAR (OVERNIGHT)

The suggested wearing schedule for Boston® Equalens® contact lens for extended wear is to initially adapt to daily wear during the first week of wear as described above. During the second week the patient should comfortably wear the lenses during all waking hours. Then;

DAY	WEARING TIME (Hours)*
15-21	24 hours a day

*if the lenses continue to be well-tolerated.

The maximum suggested wearing time for Boston® Equalens® contact lens extended wear is 1 week (7 days). Lenses should be removed for cleaning and disinfecting for 8-10 hours (overnight) at the end of 1 week of extended wear, or more frequently depending on the overall patient tolerance.

CLINICAL ASSESSMENT

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 three and nine o'clock 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 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	Excessive Apical Bearing Excessive Edge Lift
Position	Centered to Slightly Inferior	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); 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 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 Boston® Original Cleaner or Boston ADVANCE® 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. These hydrophobic contaminants have a greater affinity for Boston® Equalens® (itafluorofocon 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, an excessively small optical zone diameter, the use of low-minus thin lenses, 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) or the use of lenses having less than recommended center, edge or junction thickness, especially for patients having poor manual dexterity.

SPECIAL CONSIDERATIONS FOR EXTENDED (OVERNIGHT) WEAR

Individual corneal response to overnight lens wear can vary significantly. The persistence of central vertical striae in Descemet's membrane for more than four hours after awakening indicates that corneal deswelling is incomplete. Under these circumstances, the corneal oxygen supply should be further increased by reducing the lens thickness or redesigning the lens so as to enhance the efficiency of its tear pump.

Each patient should first demonstrate excellent subjective and objective tolerance to full time daily lens wear for at least one week before embarking on an extended wear schedule. After commencing an overnight wear program, the patient should be examined at 24 hours (preferably as early in the morning as possible), 48 hours, 1 week, 2 weeks, 4 weeks and monthly as needed.

Nominal changes in corneal contour while wearing Boston® Equalens® contact lenses for extended wear are expected and should approximate those found during daily wear of all rigid gas permeable materials. Since long term effects of significant degrees of corneal molding are not fully understood, it is recommended that the practitioner monitor keratometry at 6 month intervals. In addition, all patients should be completely examined at no more than one year intervals.

The intermittent adhesion of the lenses to the cornea during sleep is a phenomenon occasionally encountered during overnight wear of rigid lenses. Such lenses are found fixed to the underlying cornea, partially overlapping the limbus and are usually asymptomatic. In most instances the lens adhesion disappears spontaneously shortly after awakening leaving a compression ring that resolves after a few hours. This ring is identified by the collection of fluorescein in the circular groove. One should suspect that the lens has been fit too steeply or that the peripheral curves are not adequately blended if the base of the compression groove stains with fluorescein and causes discomfort. Some patients are more susceptible to experiencing this phenomenon than others, and they should be counselled to observe their lenses with a mirror on arising to confirm that they move freely on blinking.

Patients experiencing occasional adhesion should be instructed on a method of freeing the lens by compressing the lid margin just above or below the lens to release the suction. Additionally, the center thickness of the lens should be increased by at least 0.03 mm to reduce lens flexure and the base curve should be flattened by 0.75 diopters (0.15 mm) if the problem persists. Overnight wear should be discouraged if this problem resists all corrective measures.

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® Equalens® contact lens.

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 driver's 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 non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 - Determine which eye is the "sight eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 - Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

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

C. Visual Demands Method

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

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

3. Special Fitting Considerations

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

Example:
A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 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 is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

Case history and standard clinical evaluation 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 are completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

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

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some 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.

Note: 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.

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

PATIENT LENS CARE DIRECTIONS

The eye care practitioner 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, which is 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.**
- 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 a cleaning solution **does not substitute for disinfection.**

The lens care products listed in the following chart are recommended by Bausch + Lomb for use with the Boston® Equalens® contact lens. 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 Boston® Original Cleaner Boston SIMPLUS® Multi-Action Solution
Disinfect	Boston ADVANCE® Conditioning Solution Boston® Original Conditioning Solution Boston SIMPLUS® Multi-Action Solution
Store	Boston ADVANCE® Conditioning Solution Boston® Original Conditioning Solution Boston SIMPLUS® Multi-Action Solution
Rinse	ScleralFil® Preservative Free Saline Solution Boston SIMPLUS® Multi-Action Solution Bausch + Lomb Sensitive Eyes® Saline 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 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.
- 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.
- 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.
- 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® Equalens® contact lenses.
- Boston® Equalens® contact lenses **cannot** be heat (thermally) disinfected.

CARE FOR A STICKING (NON-MOVING) 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 non-movement of the lens continues after 5 minutes, the patient should **immediately** consult the eye care 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 compatible with silicone acrylate and fluoro silicone acrylate lenses 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 a Boston® Care System and an overnight soak. Lenses exhibiting a non-wetting surface should be cleaned with Boston® Laboratory Lens Cleaner as a method of first choice. **It 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® Original 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 Boston® Care System or Boston ADVANCE® Care System including the overnight soak in conditioning solution should be used prior to lens dispensing.

Caution: Damage may result from improper modification techniques. Consult your Authorized Boston® Manufacturer or contact Bausch + Lomb 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 the Boston® Equalens® (itafluorofocon A) 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 procedure may alter its surface optics.

REPORTING OF ADVERSE REACTIONS

All serious adverse reactions observed in patients wearing Boston® Equalens® contact lenses or adverse experiences with the lenses should be reported to:

Consumer Affairs
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA
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.

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA
www.bauschsvp.com
1-800-333-4730

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