

PATIENT CARE GUIDE

Boston® EQUALENS® (itafluorofocan 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® Materials

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® (itafluorofocan A) Contact Lenses are manufactured from a rigid gas permeable plastic material. They are intended for daily wear or extended wear use. It is essential that you follow the recommended handling, cleaning and storage procedures. Failure to do so may eventually impair the performance of your lenses. You should always carry a spare pair of lenses with you.

WEARING RESTRICTIONS AND INDICATIONS

Boston EQUALENS (itafluorofocan A) RGP Contact Lens is 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 +2.00D.

The lens indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes.

The lens may be disinfected using a chemical disinfection system only. The Boston EQUALENS Contact Lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye care practitioner. IF YOU ARE ON A DAILY WEAR SCHEDULE, DO NOT WEAR YOUR Boston EQUALENS CONTACT LENSES WHILE SLEEPING.

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 nonaphakic
- 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

WARNINGS

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential to follow your 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 you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, **immediately remove lenses** and promptly contact your eye care practitioner.
- Daily wear lenses are **not** indicated for overnight wear, and should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- 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, your suitability as an extended wear patient should be discussed with your contact lens practitioner.
- All contact lens wearers must see their eye care practitioner as directed. If your lenses are for extended wear, your eye care practitioner may prescribe more frequent visits.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

PRECAUTIONS

Practitioner Note: 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.

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

- Before leaving the eye care practitioner's office, you should be able to promptly remove lenses or should have someone else available who can remove the lenses for you.
- You should remove your lens immediately if your eye becomes red or irritated.
- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the wetting/soaking solution and lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
- Always follow directions in the package insert for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp the Boston EQUALENS 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 rehydrated overnight prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, immediately consult your eye care practitioner.

ADVERSE EFFECTS

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

IF YOU NOTICE ANY OF THE ABOVE:

- **Immediately remove lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact your 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, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, **immediately remove the lenses and consult your eye care practitioner.**
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You should **keep the lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.
- 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, immediately consult your eye care practitioner.

PERSONAL CLEANLINESS FOR LENS HANDLING

1. Preparing the Lens for Wearing

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

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

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

2. Handling the Lenses

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

3. Placing the Lens on the Eye

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

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

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

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

- The lens is not centered on the eye (see "Centering the Lens," next in this booklet).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
 - a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
 - b. The lens is on the wrong eye.

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

4. Centering the Lens

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

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

OR

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

5. Removing the Lens

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

1. A lens storage case.
 2. **Two Bottle Care System** Boston Advance® Cleaner or Boston® Cleaner AND Boston Advance® Comfort Formula Conditioning Solution or Boston® Conditioning Solution.
- OR
1. **One Bottle Care System** Boston Simplus® Multi-Action Solution (Clean, Condition, Disinfect, Rinse & Cushion)
 3. A clean towel.

Always remove the same lens first.

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

TWO-FINGER METHOD

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

BLINK METHOD

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

1. Place your index finger at the outer junction of your upper and lower lids, stretch the skin outward and slightly upward. (Do not allow your lid to slide over the lens.)
2. Blink briskly. The lens will be pinched by the pressure of your eyelids and the lens will pop out onto the clean surface of the towel, or you may catch the lens in the palm of your hand.
- c. Remove the other lens by following the same procedure.
- d. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, STORAGE AND REWETTING/LUBRICATING).

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

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

1. Basic Instructions

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

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

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

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

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

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care (chemical not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**
- Always remove, clean, rinse and disinfect your lenses according to the schedule prescribed by your eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- The lens care products listed below are recommended by Bausch & Lomb Incorporated for use with your Boston EQUALENS Contact Lens. Your eye care practitioner may recommend alternate products that are appropriate for you to use with your Boston EQUALENS Contact Lens.

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

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

- Boston EQUALENS Contact Lenses **cannot** be heat (thermally) disinfected.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer or the eye care practitioner; then allow the lens case to air dry. When the case is used again, refill it with fresh storage solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eye care practitioner.
- Your eye care practitioner may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.
- Your eye care practitioner may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from your Boston EQUALENS Rigid Gas Permeable Contact Lenses.

2. Care for a Sticking (Nonmoving) Lens

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

3. Lens Case Cleaning and Maintenance

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

4. Emergencies

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

INSTRUCTIONS FOR THE MONOVISION WEARER

- You should be aware that, as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight-ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer is your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations which are not visually demanding. For example, it would be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers' license requirements with monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eye care practitioner.
- It is important that you follow your eye care practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- **The decision to be fit with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering and discussing your needs.**

WEARING AND APPOINTMENT SCHEDULES

DAILY WEAR (DURING WAKING HOURS)

Prescribed Wearing Schedule

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

*If the lenses continue to be well-tolerated. Lenses should be removed daily for cleaning and disinfecting for 4 hours (or overnight) before wearing.

EXTENDED WEAR (OVERNIGHT)

The prescribed 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, you 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/Lenses 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 if recommended by your eye care practitioner.

APPOINTMENT SCHEDULE

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

Your appointments are on:

Month	Year	Time	Day

PATIENT/EYE CARE PRACTITIONER INFORMATION:

Eye Care Practitioner Information

Practitioner Name: _____

Practice Name: _____

Practitioner Address: _____

Practitioner Phone Number: _____

Recommended Lens Care Regimen: _____

Cleaning Solution: _____

Conditioning Solution: _____

Rewetting Solution: _____

Weekly Enzymatic Cleaner: _____

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

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PACKAGE INSERT

Boston® EQUALENS® (itafluorocon 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® Materials

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

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

DESCRIPTION

The Boston® EQUALENS® Rigid Gas Permeable Contact Lens material, itafluorocon A, for daily wear or extended wear is composed of methyl-methacrylate-fluoroacrylate-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.

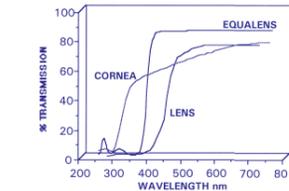
The Boston EQUALENS Contact Lens is a hemispherical shell of the following dimensions:

Spherical Lens Design	
Power Range	-20.000 to +20.000 (daily wear) -20.000 TO +12.000 (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	
<i>(Some of these designs are patented; manufacture of these lenses in Boston Equalens (itafluorocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.000 to +20.000 (daily wear) -20.000 TO +12.000 (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	-20.000 to +20.000 in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.80 mm to 9.50 mm in 0.05 mm increments
Toricity	Up to 9.00 Diopters
Bifocal/Multifocal Lens Designs (Daily Wear)	
<i>(Some of these designs are patented; manufacture of these lenses in Boston Equalens (itafluorocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.000 to +12.000 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	119	
Refractive Index	1.439	
Light Absorbance (640 nm)	100	Blue
Light Absorbance (640 nm) (Absorbance Units/Inch)	23.6	Electric Blue
Surface Character	Hydrophobic	
Wetting Angle	30°	
Water Content	<1%	
Oxygen Permeability	64* (47**)	
*Bausch & Lomb Incorporated, Gas to Gas Method ($\times 10^8$ (cm ² /sec) (mL O ₂ x mmHg)) @ 35° C)		
**Polarographic Method (ISO/Fat)		



EQUALENS - 0.07 mm thick Boston EQUALENS (Clear) Contact Lens/Material.

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, VM., *Optical Radiation and Visual Health*, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

NOTE

Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-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. Persons 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. The toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS (USES)

Boston EQUALENS (itafluorocon 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 non-aphakic persons with non-diseased eyes in powers from -20.000 to +2.000.

The lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non-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 nonaphakic
- 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

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear lenses are **not** indicated for overnight wear, and 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.
- 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.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- 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 eye care 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 Contact Lenses are not sterile when shipped from the Authorized Boston Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

- Patients may experience a reduction in visibility while wearing 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 ultraviolet (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 water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected prior to insertion.

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.

- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.

- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the Boston EQUALENS Contact Lenses 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 on hard surfaces.

- 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 your eye care practitioner before using any medicine in the eyes.

- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE EFFECTS

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

- 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.**

FITTING

Conventional methods of fitting contact lenses apply to Boston EQUALENS (itafluorocon A) Contact Lenses. For a detailed description of the fitting techniques, refer to the Boston EQUALENS Professional Fitting and Information Guide, copies of which are available from:

Practitioner Marketing Representative
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609
1-800-225-1241

Professional Fitting Guides are also available through your Authorized Boston Manufacturer.

WEARING SCHEDULE

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

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 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.

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 Lenses 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 Lenses 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.

LENS CARE DIRECTIONS

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

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

Basic Instructions:

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

- Always use **fresh unexpired** lens care solutions.

- Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solution are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling or if advised by the eye care practitioner.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.

- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of a cleaning solution **does not substitute for disinfection.**

The lens care products listed below are recommended by Bausch + Lomb for use with the Boston EQUALENS Contact Lenses. Eye care practitioners may recommend alternate products that are appropriate for the patient's use with his or her lens(es).

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

- Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as directed by your eye care practitioner to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eye care practitioner. Follow the instructions provided in the disinfecting solution packaging.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the 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 solutions 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 your 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.

LENS CASE CLEANING AND MAINTENANCE

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

CARE FOR A STICKING (NONMOVING) LENS

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

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **FLUSH EYES IMMEDIATELY WITH TAP WATER, THEN REMOVE LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

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Rochester, NY 14609
1-800-333-4730

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HOW SUPPLIED

Each lens is supplied (nonsterile) in a plastic lens storage case. The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber and lot number.

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
1-800-333-4730