PATIENT INFORMATION BOOKLET

Boston XO₂®
(hexafocus B)

Boston XO₂® with Tangible® Hydra-PEG®
(hexafocus B)

Spherical & Aspherical Contact Lenses for Myopia, Hyperopia, and Irregular Corneal Conditions

Bifocal Contact Lenses for Presbyopia

Toric Lenses to Correct Astigmatism in Non-Aphakic and Aphakic Persons

Spherical & Aspherical Scleral Contact Lenses for Myopia, Hyperopia, and Irregular Corneal Conditions

Gas Permeable Contact Lenses for Daily Wear

BAUSCH+LOMB

Boston®
Lenses & Materials

CAUTION: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
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INTRODUCTION
Boston XO2® (hexafocon B) and Boston XO® (hexafocon B) with Tangible® Hydra-PEG® Contact Lenses are manufactured from a gas permeable plastic material with and without an ultraviolet-absorber. They are intended for daily wear use only.

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.

Boston XO® with Tangible® Hydra-PEG® Contact Lenses are treated to incorporate Hydra-PEG® Technology (HTP), which is a thin polyethylene glycol (PEG)-based polymer that is covalently (permanently) bonded to the surface of the contact lens and designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with HTP, the underlying material, hexafocon B, is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (dynamic contact reading angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30 nm in thickness.

WEARING RESTRICTIONS AND INDICATIONS
Boston XO® (hexafocon B) and Boston XO® (hexafocon B) with Tangible® Hydra-PEG® Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism, and presbyopia) in aphoric and non-aphoric patients with non-dis eased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive surgery (e.g., LASIK).

Boston XO® and Boston XO® with Tangible® Hydra-PEG® Contact Lenses are also indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 500 diopters in non-diseased eyes.

Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment, and the saline bath provided by scleral lens designs. Boston XO® and Boston XO® with Tangible® Hydra-PEG® Scleral Contact Lens designs for daily wear are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

1. Cannot be adequately corrected with spectacle lenses.
2. Requires a rigid gas permeable contact lens surface to improve vision.
3. Is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities.

Common causes of corneal distortion include, but are not limited to, corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g., LASIK or radial keratotomy), or corneal transplantation. Causes may also include corneal degeneration (e.g., keratoconus, keratoglobus, lenticul marginal degeneration, Salzmann’s nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan’s dystrophy).

The Boston XO® and Boston XO® with Tangible® Hydra-PEG® Scleral Contact Lens designs for daily wear are also indicated for therapeutic use in eyes with ocular surface disease (e.g., ocular Graft-versus-Host disease, Sjögren’s syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g., Stevens-Johnson syndrome, chemical and thermal burns), disorders of the skin (e.g., atopy, eczematoid dysplasia), neurotrophic keratitis (e.g., Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g., anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the Boston® Scleral Lenses may concurrently provide correction of refractive error.

The lenses may be disinfected using a chemical disinfection (not heat) system only.

Do not store your lenses or rinse your lens case with water or OR

WARNING:

If these methods for removing your lenses are difficult for you, your eye care practitioner will

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WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. You should continue to use your protective UV-absorbing eyewear as directed.

PRECAUTIONS

Never reuse the solution. You may store the lenses in the unopened container until ready to dispense, up to a maximum of thirty days from the date of filling (see lens shipping carton label). If the lenses are stored for longer periods of time, they should be cleaned and disinfected with Boston SIMPLUS® Multi-Action Solution.

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

<table>
<thead>
<tr>
<th>Lens Type/Color</th>
<th>Center Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston XO2® and Boston XO2®</td>
<td>Blue 0.65 mm</td>
</tr>
<tr>
<td>with Tangible® Hydraglycol®</td>
<td></td>
</tr>
<tr>
<td>Boston XO2® and Boston XO2®</td>
<td>Ice Blue 0.65 mm</td>
</tr>
<tr>
<td>with Tangible® Hydraglycol®</td>
<td></td>
</tr>
<tr>
<td>Boston XO2® and Boston XO2®</td>
<td>Green 0.55 mm</td>
</tr>
<tr>
<td>with Tangible® Hydraglycol®</td>
<td></td>
</tr>
<tr>
<td>Boston XO2® and Boston XO2®</td>
<td>Violet 0.65 mm</td>
</tr>
<tr>
<td>with Tangible® Hydraglycol®</td>
<td></td>
</tr>
</tbody>
</table>

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 properly remove lenses or should have someone else available who can remove the lenses for you.
- You should remove your lenses immediately if your eyes become red or irritated.
- Different solutions often cannot be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Do not heat the conditioning/storage solution and/or lenses. Keep them away from extreme heat.
- Always use fresh, unexpired lens care solutions.
- Always follow directions in the Package Insert for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp Boston XO2® and Boston XO2® with Tangible® Hydraglycol® Contact Lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.

ADVERSE REACTIONS

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 or 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:

1. 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.

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 thorougly 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 any cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
• Handle the lenses with your fingertips and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.
• Start off correctly by getting into the habit of always using proper hygiene procedures so that they become automatic.

2. Handling the Lenses

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

3. Placing the Lens on the Eye

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

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

Note: 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 Lenses

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

1) A lens storage case.
2) Appropriate Lens Care System for your Boston XO 2® and Boston XO 5® with Tangible® Hydra-PEG® from the below Lens Care Chart.
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, re-center 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.

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

b. Remove the other lens by following the same procedure.
c. Follow the required lens care procedures described under the heading, LENS CARE DIRECTIONS.
LENS CARE DIRECTIONS

Eye care practitioners should review lens care directions with the patient, 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)

1. Rub and Rinse Time
   Instruction for Use:
   Follow the complete recommended lens rubbing and rinsing times in the labeling of your solution used for cleaning, disinfecting, and soaking your lenses to adequately disinfect your lenses and reduce the risk of contact lens infection.

   WARNING:
   • Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
   • Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

2. Soaking and Storing Your Lenses
   Instruction for Use:
   Use only fresh contact lens disinfecting solution each time you soak (store) your lenses.

   WARNING:
   Do not reuse or “top-off” old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. “Topping-off” is the addition of fresh solution to solution that has been sitting in your case.

3. Lens Case Care
   Instruction for Use:
   • Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/ contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with a fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry.
   • Replace your lens case according to the directions given to you by your eye care practitioner or the labeling that came with your case.
   • Contact lens cases can be a source of bacterial growth.

   WARNING:
   Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

4. Water Activity
   Instruction for Use:
   Do not expose your contact lenses to water while you are wearing them.

   WARNING:
   Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including, but not limited to, Acanthamoeba keratitis. If your lenses have been submerged in water, you should thoroughly clean and disinfect them before insertion. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

5. Discard Date on Solution Bottle
   Instruction for Use:
   Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking your contact lenses.

   WARNING:
   Using your solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

6. Basic Instructions
   Always wash, rinse, and dry hands before handling contact lenses.
   • Always use fresh, unexpired lens care solutions.
   • Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling, or if advised by the 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. The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lenses.
   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.
   The lens care products listed below are recommended by Bausch & Lomb for use with Boston XO2®, and Boston XO2® with Tangible® Hydra-PEG® Contact Lenses. Eye care practitioners may recommend alternate products that are appropriate for the patient’s use with his or her lens(es).

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**LENS CARE TABLE: For Boston XO2® Contact Lenses (Without Tangible® Hydra-PEG® Treatment)**

<table>
<thead>
<tr>
<th>Product Purpose</th>
<th>Lens Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>Boston ADVANCE® Cleaner</td>
</tr>
<tr>
<td></td>
<td>Boston® Cleaner</td>
</tr>
<tr>
<td></td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Disinfect</td>
<td>Boston ADVANCE® Conditioning Solution</td>
</tr>
<tr>
<td></td>
<td>Boston® Conditioning Solution</td>
</tr>
<tr>
<td></td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Store</td>
<td>Boston ADVANCE® Conditioning Solution</td>
</tr>
<tr>
<td></td>
<td>Boston® Conditioning Solution</td>
</tr>
<tr>
<td></td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Rinse</td>
<td>ScleraFil® Preservative Free Saline Solution</td>
</tr>
<tr>
<td>Lubricate/Retew</td>
<td>Boston® Rewetting Drops</td>
</tr>
<tr>
<td>Weekly Enzymatic Cleaner</td>
<td>Boston® ONE STEP Liquid Enzymatic Cleaner</td>
</tr>
</tbody>
</table>

**LENS CARE TABLE: For Boston XO2® Contact Lenses with Tangible® Hydra-PEG® Treatment**

<table>
<thead>
<tr>
<th>Product Purpose</th>
<th>Lens Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Disinfect</td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Store</td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Rinse</td>
<td>ScleraFil® Preservative Free Saline Solution</td>
</tr>
<tr>
<td>Lubricate/Retew</td>
<td>Boston® Rewetting Drops</td>
</tr>
</tbody>
</table>
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. Enzymatic cleaner not recommended for use with lenses coated with Tangible® Hydra-PEG®.

- 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 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 XO® and Boston XO® with Tangible® Hydra-PEG® 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. Lenses cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

- Your eye care practitioner may recommend a lubricating/rewetting solution for 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 XO® and Boston XO® with Tangible® Hydra-PEG® Contact Lenses. Enzymatic cleaner not recommended for use with lenses coated with Tangible® Hydra-PEG®.

7. Care for a Sticking (Non-Moving) Lens

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

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

- Some monovision lens wearers will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, discuss with your eye care practitioner whether you should have additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance vision is required.

- If you require very sharp near vision during prolonged close work, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for near when sharp near vision is required.

- Some monovision lens wearers require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your 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.

CONSIDERATIONS FOR BIFOCAL LENSES

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

Your eye care practitioner may discuss the following with you:

A. Adaptation

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

B. Driving at Night

Bifocal/multifocal contact lens wearers should experience night vision before actually driving while wearing their lenses.

C. Fiare at Night

Bifocal/multifocal contact lenses wearers may experience flare at night. This may occur with certain lens designs. With time, bifocal/multifocal contact lens wearers adapt to this situation.

D. Visual Expectation

Bifocal contact lens wearers may experience visual acuities less than could be achieved with bifocal spectacles.

WARNING: Bausch + Lomb Boston XO® and Boston XO® with Tangible® Hydra-PEG® Contact Lenses are NOT intended for overnight (extended) wear.
Gas Permeable Contact Lenses for Daily Wear

Spherical & Aspherical Contact Lenses for Boston XO2® and Boston XO2® (hexafocon B) and Boston XO2® heat) system only.

LENS CARE DIRECTIONS

PRECAUTIONS

To maintain the orthokeratology effect of myopia reduction, Contact Lenses are also indicated for daily wear in an orthokeratology setting, with careful attention being given to lens care and disinfection (e.g., Stevens-Johnson syndrome, chemical damage, and thermal damage). The lens case should be cleaned at the end of each day and not left filled for more than three days. The lens case should be stored upside down with the lens outside of it. The lens case must be emptied and refilled (never use water) prior to disinfecting the lenses.

W ARNINGS

Do not expose your contact lenses to water while you are wearing them. Exposure to water while wearing contact lenses may increase the risk of ocular infection, including, but not limited to, bacterial, fungal, and viral infections. Do not reuse or “top-off” old solution left in your lens case since this may increase the risk of ocular infection, including, but not limited to, bacterial, fungal, and viral infections. Do not use any non-sterile solution. Only use fresh solution so you do not destroy harmful germs. The lens case must be emptied and refilled (never use water) prior to disinfecting the lenses.

• Unusual eye secretions
• Redness of the eye
• Change in vision
• Sensation of a foreign object in the eye
• Acute pain
• Analyze the lens
• Itching
• Watery eyes
• Electronic devices (e.g., cell phones, computers, televisions)
• Dryness
• Foreign body sensation
• Tearing
• Unusual sensitivity to light

Do not wear your lenses if any of the above symptoms occur, as this could indicate a serious condition such as developing cataracts or other eye disorders. Consult your eye care practitioner immediately.

When any of the above problems occur, a serious condition such as developing cataracts or other eye disorders may not only cause vision loss or blindness. Exposure to water while wearing contact lenses may increase the risk of ocular infection, including, but not limited to, bacterial, fungal, and viral infections. Do not expose your contact lenses to water while you are wearing them. Exposure to water while wearing contact lenses may increase the risk of ocular infection, including, but not limited to, bacterial, fungal, and viral infections. Do not reuse or “top-off” old solution left in your lens case since this may increase the risk of ocular infection, including, but not limited to, bacterial, fungal, and viral infections. Do not use any non-sterile solution. Only use fresh solution so you do not destroy harmful germs. The lens case must be emptied and refilled (never use water) prior to disinfecting the lenses.

Do not use any non-sterile solution. Only use fresh solution so you do not destroy harmful germs. The lens case must be emptied and refilled (never use water) prior to disinfecting the lenses.

Note:

• Use the forefinger or middle finger of your other hand to separate the upper and lower lids, stretch the skin outward and slightly downward to read. Once the bifocal patient has adapted, the bifocal patient can read with their right eye to read. Once the bifocal patient has adapted, the bifocal patient can read with their right eye to read.

• After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens practitioner or visit a hospital emergency department. Then remove your lenses promptly, if possible, and urgently consult your eye care practitioner.
PACKAGE INSERT

Boston XO₂®
(hexafocon B)

Boston XO₂® with Tangible® Hydra-PEG®
(hexafocon B)

Spherical & Aspherical Contact Lenses for Myopia, Hyperopia, and Irregular Corneal Conditions

Bifocal Contact Lenses for Presbyopia

Toric Lenses to Correct Astigmatism in Non-Aphakic and Aphakic Persons

Spherical & Aspherical Scleral Contact Lenses for Myopia, Hyperopia, and Irregular Corneal Conditions

Gas Permeable Contact Lenses for Daily Wear

BAUSCH + LOMB

Boston®
Lenses & 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 Law restricts this device to sale by or on the order of a licensed practitioner.
DESCRIPTION

Boston XO₂® (hexafocon B) and Boston XO₂® (hexafocon B) with Tangible® Hydra-PEG® are manufactured from a gas permeable contact lens material composed of siloxanyl fluoromethacrylate copolymer. Boston XO₂® and Boston XO₂® with Tangible® Hydra-PEG® is available with or without an ultraviolet absorber (Uvinul D-49 or MHB).

Boston XO₂® with Tangible® Hydra-PEG® Contact Lenses are treated to incorporate Hydra-PEG® Technology (HPT), which is a thin polyethylene glycol (PEG)-based polymer that is covalently (permanently) bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with HPT, the underlying material, hexafocon B, is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (dynamic contact receding angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30 nm in thickness.

The lenses described in the first column can have a center thickness of 0.07 mm to 0.25 mm that will vary with lens design, power and diameter.

### Power Range

<table>
<thead>
<tr>
<th>Spherical Lens Design</th>
<th>Power Range</th>
<th>Diameter</th>
<th>Base Curve Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-20.00D to +20.00D</td>
<td>7.0 mm to 21.0 mm</td>
<td>5.00 mm to 9.00 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aspherical Lens Designs</th>
<th>Power Range</th>
<th>Diameter</th>
<th>Base Curve Range</th>
</tr>
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<tbody>
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<td></td>
<td>-20.00D to +20.00D</td>
<td>7.0 mm to 21.0 mm</td>
<td>6.00 mm to 9.20 mm</td>
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<table>
<thead>
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<th>Bifocal Lens Designs</th>
<th>Power Range</th>
<th>Diameter</th>
<th>Base Curve Range</th>
</tr>
</thead>
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<td></td>
<td>-20.00D to +20.00D</td>
<td>7.0 mm to 21.0 mm</td>
<td>6.80 mm to 9.50 mm</td>
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<table>
<thead>
<tr>
<th>Toric Lens Designs</th>
<th>Power Range</th>
<th>Diameter</th>
<th>Base Curve Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-20.00D to +20.00D</td>
<td>7.0 mm to 21.0 mm</td>
<td>4.00 mm to 9.00 mm</td>
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</table>

<table>
<thead>
<tr>
<th>Irregular Corneal Lens Designs</th>
<th>Power Range</th>
<th>Diameter</th>
<th>Base Optic Zone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-20.00D to +20.00D</td>
<td>7.0 mm to 21.0 mm</td>
<td>5.00 mm to 9.00 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scleral Contact Lens Designs</th>
<th>Power Range</th>
<th>Diameter</th>
<th>Normalized Vaults</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+35.00D to -25.00D</td>
<td>16.00 mm to 21.00 mm</td>
<td>2.50 mm to 6.00 mm</td>
</tr>
</tbody>
</table>
Material: copolymer. Boston XO2® (hexafocon B) and Boston XO2® with Tangible® Hydra-PEG® Contact Lens/Material:

- Color: Blue, D & C Green No. 6
- Ice Blue: D & C Green No. 6
- Violet: D & C Violet No. 2
- Green: D & C Green No. 6

C.I. Solvent Yellow No. 18

Specific Gravity: 1.19
Refractive Index: 1.424
Light Transmittance: *

**ISO/Fatt Method:

<table>
<thead>
<tr>
<th>Color</th>
<th>Transmittance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue</td>
<td>83%</td>
</tr>
<tr>
<td>Ice Blue</td>
<td>90%</td>
</tr>
<tr>
<td>Violet</td>
<td>90%</td>
</tr>
<tr>
<td>Green</td>
<td>90%</td>
</tr>
</tbody>
</table>

Surface Character: Hydrophobic
Wetting Angle: 38°
Wetting Angle w/Hydra-PEG: 10°
Water Content: <1%
Oxygen Permeability:
Edge Corrected: 141**
Non-Edge Corrected: 161**

*Average CIE Luminous Y Transmittance (381 nm – 780 nm) (lens center thickness = 0.65 mm)
**ISO/Fatt Method

DK Units = x 10⁻⁹ (cm²·O₂/cm)/(sec·cm²·mmHg) \( @ \) 35°C

<table>
<thead>
<tr>
<th>Wavelength (nm)</th>
<th>Transmission (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>200</td>
<td>100</td>
</tr>
<tr>
<td>300</td>
<td>80</td>
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<tr>
<td>400</td>
<td>60</td>
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<td>500</td>
<td>40</td>
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<tr>
<td>600</td>
<td>20</td>
</tr>
<tr>
<td>700</td>
<td>0</td>
</tr>
<tr>
<td>800</td>
<td>0</td>
</tr>
</tbody>
</table>

Boston XO2® and Boston XO2® with Tangible® Hydra-PEG®,
0.07 mm thick Boston XO2®, and Boston XO2® with Tangible® Hydra-PEG® Contact Lens/Material (Ice Blue)


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. Persons should continue to use their protective UV-absorbing eyewear as directed.

**Actions**

Boston XO2® and Boston XO2® with Tangible® Hydra-PEG® Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina.

**Indications (Uses)**

Boston XO2® (hexafocon B) and Boston XO2® with Tangible® Hydra-PEG® Contact Lenses are 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. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive surgery (e.g., LASIK).

Boston XO2® and Boston XO2® with Tangible® Hydra-PEG® Contact Lenses are also indicated for daily wear in an anterior keratoplasty fitting program for the temporary reduction of myopia of up to 5.00 dipters in non-diseased eyes.

Note: To maintain the anterior keratoplasty effect of myopia reduction, lenses wear must be continued on a prescribed wearing schedule.

Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment, and the saline bath provided by scleral lens designs.

Boston XO2® and Boston XO2® with Tangible® Hydra-PEG® Scleral Contact Lens designs for daily wear are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

1. Cannot be adequately corrected with spectacle lenses.
2. Requires a rigid gas permeable contact lens surface to improve vision.
3. Is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities.

Common causes of corneal distortion include but are not limited to corneal infections, trauma, traumas as a result of scar formation secondary to refractive surgery (e.g., LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g., keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann’s nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan’s dystrophy).

The Boston XO2® and Boston XO2® with Tangible® Hydra-PEG® Scleral Contact Lens designs for daily wear are also indicated for therapeutic use in eyes with ocular surface disease (e.g., ocular Graft-versus-Host disease, Sjögren’s syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g., Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g., atopy, eczdermal dysplasia), neurotrophic keratitis (e.g., Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g., anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the Boston XO2® Scleral Lenses may concurrently provide correction of refractive error.

The lenses may be disinfected using a chemical disinfection (not heat) system only.
CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Boston XO® and Boston XO® with Tangible® Hydra-PEG® Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation of the anterior chamber of the eye
- Any eye disease, injury, or abnormality, other than irregular corneal conditions as described in the INDICATIONS section, that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hyposthesia (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 adhesia that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the Boston XO® and Boston XO® with Tangible® Hydra-PEG® Contact Lens materials.
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

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

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner’s directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these daily wear lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care practitioner.

PRECAUTIONS

- Never reuse the solution. You may store the lenses in the unopened container until ready to dispense, up to a maximum of thirty days from the date of filling (see lens shipping carton label). If the lenses are stored for longer periods of time, they should be cleaned and disinfected with Boston SIMPLUS® Multi-Action Solution.
- Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness:

<table>
<thead>
<tr>
<th>Lens Type/Color</th>
<th>Center Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston XO® and Boston XO® with Tangible® Hydra-PEG®</td>
<td>Blue &gt;0.65 mm</td>
</tr>
<tr>
<td>Boston XO® and Boston XO® with Tangible® Hydra-PEG®</td>
<td>Ice Blue &gt;0.65 mm</td>
</tr>
<tr>
<td>Boston XO® and Boston XO® with Tangible® Hydra-PEG®</td>
<td>Green &gt;0.55 mm</td>
</tr>
<tr>
<td>Boston XO® and Boston XO® with Tangible® Hydra-PEG®</td>
<td>Violet &gt;0.65 mm</td>
</tr>
</tbody>
</table>

Special Precautions for Eye Care Practitioners:

- When wet shipped, Boston XO® and Boston XO® with Tangible® Hydra-PEG® Contact Lenses are packaged non-sterile in a preserved aqueous solution, either Boston SIMPLUS® Multi-Action Solution or Boston ADVANCE® Conditioning Solution. Boston SIMPLUS® Multi-Action Solution contains poloxamine, hydroyxalkyl phosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethylcellulose, glucam, and preserved with polyaminopropylbiguanide (00005%). chlorhexidine gluconate (0003%). Boston ADVANCE® Conditioning Solution contains polyaminopropylbiguanide (00005%), chlorhexidine gluconate (0003%), and edetate disodium (005%) as preservatives. If the patient has experienced a prior history of allergy to any of the ingredients inBoston SIMPLUS® Multi-Action Solution or Boston ADVANCE® Conditioning Solution, remove the lenses from the solution and soak for 24 hours in unpreserved saline solution prior to cleaning, disinfecting, and dispensing.
- Due to the small number of patients enrolled in clinical investigations 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 XO® and Boston XO® with Tangible® Hydra-PEG® Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eye care practitioner’s office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the UV-absorber in the Boston XO® and Boston XO® with Tangible® Hydra-PEG® Contact Lens materials may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Professional Fitting and Information 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 conditioning/storage solution and/or lenses. Keep them away from extreme heat.
- Always use fresh, unexpired lens care solutions.
- Always follow directions in the Package Insert for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a non-sterile solution. Only use fresh solution each time you soak your lenses.
- Use only fresh contact lens disinfecting solution each time you soak your lenses.
- Topping-off is the practice of placing old solution left in your lens case back into your lens case. Use only fresh contact lens disinfecting solution each time you soak your lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed...
with water, and carefully dried by blotting with a soft lint-free
tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfect prior
to insertion.

- Boston XO,® and Boston XO,® with Tangible® Hydra-PEG®
  Contact Lenses must be stored in the lens storage case with the
  recommended solutions. Dry storage is not recommended.
- If the lens sticks (stops moving) on the eye, the patient should be
  instructed to 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 lenses 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
  Information Booklet for the Boston XO,® and Boston XO,® with
  Tangible® Hydra-PEG® Contact Lenses and in 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.
- Patients should be advised about wearing lenses during sporting
  and water related activities. Exposure to water while wearing
  contact lenses in activities such as swimming, water skiing, and
  hot tubs may increase the risk of ocular infection including, but
  not limited to, Acanthamoeba keratitis.
- Instruct patient to inform his or her doctor (health care
  professional) that the patient wears contact lenses.
- Never use tweezers or other tools to remove lenses from the
  lens case unless specifically indicated for that use. To remove the
  lens from the case, pour the solution containing the lens into the
  palm of your hand.
- Do not touch the lens with fingernails.
- Instruct the patient to contact his or her eye care practitioner
  before using any medicine in the eyes.
- Instruct the patient to inform his or her employer that he or
  she wears 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 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 or
  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, the lens should not be placed
  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
For detailed descriptions of the conventional fitting techniques
and special fitting considerations for the Boston XO,® and
Boston XO,® with Tangible® Hydra-PEG® Contact Lenses, refer to
the Boston XO,® Professional Fitting and Information Guide, copies of which are available from:

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. Boston XO,® and Boston XO,®
with Tangible® Hydra-PEG® Contact Lenses are indicated for
daily wear.

WARNING: Bausch + Lomb Boston XO,® and Boston XO,®
with Tangible® Hydra-PEG® Contact Lenses are NOT
intended for overnight (extended) wear.

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)
1. Rub and Rinse Time
   Instruction for Use:
   Follow the complete recommended lens rubbing and rinsing times
   in the labeling of your solution used for cleaning, disinfecting, and
   soaking your lenses to adequately disinfect your lenses and reduce
   the risk of contact lens infection.

   WARNING:
   - Rub and rinse your lenses for the recommended amount of time
to help prevent serious eye infections.
   - Never use water, saline solution, or rewetting drops to disinfect
     your lenses. These solutions will not disinfect your lenses. Not
     using the recommended disinfectant can lead to severe infection,
     vision loss or blindness.
2. Soaking and Storing Your Lenses

**Instruction for Use:**
Use only fresh contact lens disinfecting solution each time you soak (store) your lenses.

**WARNING:**
Do not reuse or “top-off” old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. “Topping-off” is the addition of fresh solution to solution that has been sitting in your case.

3. Lens Case Care

**Instruction for Use:**
- Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. *Never use water.* Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with a fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry.
- Replace your lens case according to the directions given to you by your eye care practitioner or the labeling that came with your case.
- Contact lens cases can be a source of bacterial growth.

**WARNING:**
Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

4. Water Activity

**Instruction for Use:**
Do not expose your contact lenses to water while you are wearing them.

**WARNING:**
Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection including, but not limited to, Acanthamoeba keratitis. If your lenses have been submerged in water, you should thoroughly clean and disinfect them before inserting. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

5. Discard Date on Solution Bottle

**Instruction for Use:**
Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking your contact lenses.

**WARNING:**
Using your solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

6. Basic Instructions

Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh, unexpired lens care solutions.
- Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling or if advised by the 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. The lens case must be emptied and retipped with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lenses.

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.

The lens care products listed below are recommended by Bausch + Lomb for use with Boston XO2® and Boston XO2® with Tangible® Hydra-PEG® 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: For Boston XO2® Contact Lenses**

(Without Tangible® Hydra-PEG® Treatment)

<table>
<thead>
<tr>
<th>Product Purpose</th>
<th>Lens Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>Boston ADVANCE® Cleaner</td>
</tr>
<tr>
<td></td>
<td>Boston® Cleaner</td>
</tr>
<tr>
<td></td>
<td>Boston® SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Disinfect</td>
<td>Boston ADVANCE® Conditioning Solution</td>
</tr>
<tr>
<td></td>
<td>Boston® Conditioning Solution</td>
</tr>
<tr>
<td></td>
<td>Boston® SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Store</td>
<td>Boston ADVANCE® Conditioning Solution</td>
</tr>
<tr>
<td></td>
<td>Boston® Conditioning Solution</td>
</tr>
<tr>
<td></td>
<td>Boston® SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Rinse</td>
<td>ScleraFil® Preservative Free Saline Solution</td>
</tr>
<tr>
<td></td>
<td>Boston® SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Lubricate/Revet</td>
<td>Boston® Rewetting Drops</td>
</tr>
<tr>
<td>Weekly Enzymatic Cleaner</td>
<td>Boston® ONE STEP Liquid Enzymatic Cleaner</td>
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**LENS CARE TABLE: For Boston XO2® Contact Lenses with Tangible® Hydra-PEG® Treatment**

<table>
<thead>
<tr>
<th>Product Purpose</th>
<th>Lens Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>Boston® SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Disinfect</td>
<td>Boston® SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Store</td>
<td>Boston® SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Rinse</td>
<td>ScleraFil® Preservative Free Saline Solution</td>
</tr>
<tr>
<td></td>
<td>Boston® SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Lubricate/Revet</td>
<td>Boston® Rewetting Drops</td>
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</tbody>
</table>

**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. Enzymatic cleaner not recommended for use with lenses coated with Tangible® Hydra-PEG®.

- 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 solution as recommended by the lens case manufacturer; then allow the lens case to air-dry. When the case is used again, refill it with fresh storage solution. Replace the 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 XO2® and Boston XO2® with Tangible® Hydra-PEG® Contact Lenses. Enzymatic cleaner not recommended for use with lenses coated with Tangible® Hydra-PEG®.

• Boston XO2® and Boston XO2® with Tangible® Hydra-PEG® Contact Lenses cannot be heat (thermally) disinfected.

7. 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.

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

HOW SUPPLIED
Each lens is supplied (non-sterile) in a plastic lens storage case, dry or in solution (Boston ADVANCE® Conditioning Solution or Boston SIMPLUS® Multi-Action Solution). The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber (if present), and lot number. Additional parameters of add power, segment height, prism ballast, and truncation may be included for bifocal lenses.

REPORTING OF ADVERSE REACTIONS
All serious adverse reactions observed in patients wearing Boston XO2® and Boston XO2® with Tangible® Hydra-PEG® 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

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8185200
Rev. 2019-06
PROFESSIONAL FITTING AND INFORMATION GUIDE

Boston XO$_2$®
(hexafocon B)

Boston XO$_2$® with Tangible® Hydra-PEG®
(hexafocon B)

Spherical & Aspherical Contact Lenses for Myopia,
Hyperopia, and Irregular Corneal Conditions

Bifocal Contact Lenses for Presbyopia

Toric Lenses to Correct Astigmatism in Non-Aphakic
and Aphakic Persons

Spherical & Aspherical Scleral Contact Lenses for
Myopia, Hyperopia, and Irregular Corneal Conditions

Gas Permeable Contact Lenses for Daily Wear

CAUTION: Federal Law restricts this device to
sale by or on the order of a licensed practitioner.
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REMOVAL OF SURFACE DEPOSITS

REPORTING OF ADVERSE REACTIONS

HOW SUPPLIED

DESCRIPTION

Boston XO® (hexafocon B) and Boston XO® (hexafocon B) with Tangible® Hydra-PEG® are manufactured from a gas permeable contact lens material composed of siloxanyl fluoromethacrylate copolymer. Boston XO® and Boston XO® with Tangible® Hydra-PEG® is available with or without an ultraviolet absorber (UVuvi D-49 or M4B).

Boston XO® with Tangible® Hydra-PEG® Contact Lenses are treated to incorporate Hydra-PEG® Technology (HPT), which is a thin polyethylene glycol (PEG)-based polymer that is covalently (permanently) bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material.

When treated with HPT, the underlying material, hexafocon B, is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (dynamic contact receding angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30 mm in thickness.

Boston XO® and Boston XO® with Tangible® Hydra-PEG® Contact Lenses are hemispherical shells of the following dimensions:

<table>
<thead>
<tr>
<th>Spherical Lens Design</th>
<th>Aspherical Lens Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Range</td>
<td>Power Range</td>
</tr>
<tr>
<td>-20.00D to +20.00D</td>
<td>-20.00D to +20.00D</td>
</tr>
<tr>
<td>in 0.25D increments</td>
<td>in 0.25D increments</td>
</tr>
<tr>
<td>Diameter</td>
<td>Diameter</td>
</tr>
<tr>
<td>70 mm to 210 mm</td>
<td>70 mm to 210 mm</td>
</tr>
<tr>
<td>Base Curve Range</td>
<td>Base Curve Range</td>
</tr>
<tr>
<td>5.00 mm to 9.00 mm</td>
<td>6.00 mm to 9.20 mm</td>
</tr>
<tr>
<td>in 0.01 mm increments</td>
<td>in 0.01 mm increments</td>
</tr>
</tbody>
</table>

Boston XO® and Boston XO® with Tangible® Hydra-PEG® materials are authorized to licensed labs only.

<table>
<thead>
<tr>
<th>Bifocal Lens Designs</th>
<th>Toric Lens Designs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Range</td>
<td>Power Range</td>
</tr>
<tr>
<td>-20.00D to +20.00D</td>
<td>-20.00D to +20.00D</td>
</tr>
<tr>
<td>in 0.25D increments</td>
<td>in 0.25D increments</td>
</tr>
<tr>
<td>Diameter</td>
<td>Diameter</td>
</tr>
<tr>
<td>70 mm to 210 mm</td>
<td>70 mm to 210 mm</td>
</tr>
<tr>
<td>Base Curve Range</td>
<td>Base Curve Range</td>
</tr>
<tr>
<td>6.80 mm to 9.50 mm</td>
<td>6.80 mm to 9.50 mm</td>
</tr>
<tr>
<td>in 0.01 mm increments</td>
<td>in 0.01 mm increments</td>
</tr>
<tr>
<td>Prism Ballast</td>
<td>Toricity</td>
</tr>
<tr>
<td>0.5 to 3.5 prism dipters</td>
<td>Up to 90 Dipters</td>
</tr>
</tbody>
</table>

Boston XO® and Boston XO® with Tangible® Hydra-PEG® materials are authorized to licensed labs only.

Irregular Cornea Lens Designs (keratoconus, pellucid marginal degeneration, post-penetrating keratoplasty, or post-refractive surgery (e.g., LASIK))

<table>
<thead>
<tr>
<th>Sceral Contact Lens Designs</th>
<th>Power Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Power Range</td>
</tr>
<tr>
<td></td>
<td>-35.00D to -25.00D</td>
</tr>
<tr>
<td></td>
<td>in 0.25D increments</td>
</tr>
<tr>
<td></td>
<td>Diameter</td>
</tr>
<tr>
<td></td>
<td>70 mm to 210 mm</td>
</tr>
<tr>
<td></td>
<td>Base Curve Range</td>
</tr>
<tr>
<td></td>
<td>4.00 mm to 9.00 mm</td>
</tr>
<tr>
<td></td>
<td>in 0.01 mm increments</td>
</tr>
<tr>
<td></td>
<td>Base Optic Zone</td>
</tr>
<tr>
<td></td>
<td>5.00 mm to 9.00 mm</td>
</tr>
<tr>
<td></td>
<td>in 0.01 mm increments</td>
</tr>
</tbody>
</table>

The lenses described in the table above can have a center thickness of 0.07 mm to 0.65 mm that will vary with lens design, power, and diameter.
Physical/Optical Properties of Boston XO® and Boston XO® with Tangible® Hydra-PEG® Contact Lens/Material:

The tinted lenses contain the following color additives:

<table>
<thead>
<tr>
<th>Color</th>
<th>Color Additive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue</td>
<td>D &amp; C Green No. 6</td>
</tr>
<tr>
<td>Ice Blue</td>
<td>D &amp; C Green No. 6</td>
</tr>
<tr>
<td>Violet</td>
<td>D &amp; C Violet No. 2</td>
</tr>
<tr>
<td>Green</td>
<td>D &amp; C Green No. 6</td>
</tr>
<tr>
<td></td>
<td>C.I. Solvent Yellow No. 1B</td>
</tr>
</tbody>
</table>

Specific Gravity: 1.19
Refractive Index: 1.424

Light Transmittance:

- Tint Transmittance
  - Blue: 83%
  - Ice Blue: 90%
  - Violet: 90%
  - Green: 90%

Average CIE Luminous Y Transmittance: (381 nm - 780 nm) (lens center thickness = 0.65 mm)

Surface Character: Hydrophobic

Wetting Angle: 38°
Wetting Angle w/ Hydra-PEG: 10°
Water Content: <1%
Oxygen Permeability:
  - Edge Corrected: 141**
  - Non-Edge Corrected: 161**

**ISO/Fatt Method

DK Units = \(4 \times 10^{-11} \text{ cm}^2 \text{O}_{2} \text{cm}/(\text{sec} \cdot \text{cm}^2 \cdot \text{mmHg})\) @ 35°C

![Graph: Transmission vs Wavelength](image)

Corneal Transmission: 50%
Lens Transmission: 40%

Boston XO®, and Boston XO® with Tangible® Hydra-PEG®:

**0.07 mm thick Boston XO® Contact Lens/Material (Ice Blue)


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. Patients should be instructed to consult their 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.

ACCTIONS

Boston XO®, and Boston XO® with Tangible® Hydra-PEG® Contact Lenses, when placed on the cornea, act as a retarding medium to focus light rays on the retina.

INDICATIONS

Boston XO®, (hexafocon B) and Boston XO®, (hexafocon B) with Tangible® Hydra-PEG® Contact Lenses are 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. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK surgery).

Boston XO®, and Boston XO®, with Tangible® Hydra-PEG® Contact Lenses are also indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes.

Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs.

Boston XO®, and Boston XO®, with Tangible® Hydra-PEG® Scleral Contact Lens designs for daily wear are also indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

1. Cannot be adequately corrected with spectacle lenses.
2. Requires a rigid gas permeable contact lens surface to improve vision.
3. Is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities.

Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g., LASIK) or corneal transplantation. Causes may also include corneal degeneration (e.g., keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann’s nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Buckler’s dystrophy, Cogan’s dystrophy).

The Boston XO®, and Boston XO®, with Tangible® Hydra-PEG® Scleral Contact Lens designs for daily wear are also indicated for therapeutic use in eyes with ocular surface disease (e.g., ocular Grafil- versus Host disease, Sjögren’s syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g., Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g., atopic, eczematous dermatitis), neurotrophic keratitis (e.g., Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g., anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the Boston XO® Scleral Lenses may concurrently provide correction of refractive error.

The lenses may be disinfected using a chemical disinfection (not heat) system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Boston XO®, and Boston XO®, with Tangible® Hydra-PEG® Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation, or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality, other than irregular corneal conditions as described in the INDICATIONS section, that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoplasia (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 XO®, and Boston XO®, with Tangible®- Hydra-PEG® Contact Lenses materials.
• Any active corneal infection (bacterial, fungal, or viral)
• Red or irritated eyes

WARNINGS
Patients should be advised of the following warnings pertaining to contact lens wear:
• Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner’s directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
• Daily wear lenses are not indicated for overnight wear and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when daily wear lenses are worn overnight.
• Studies have shown that contact lenses wearers who are smokers have a higher incidence of adverse reactions than non-smokers.
• If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove the lenses and promptly contact his or her eye care practitioner.

PRECAUTIONS

Practitioner Note: Bausch + Lomb Boston XO®, and Boston XO®, with Tangible®-Hydra-PEG® 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.

• Never reuse the solution. You may store the lenses in the unopened container only until ready to dispense, up to a maximum of thirty days from the date of filling (see lens shipping carton label). If the lenses are stored for longer periods of time, they should be cleaned and disinfected with Boston SIMPLUS® Multi-Action Solution.
• Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness:

<table>
<thead>
<tr>
<th>Lens Type/Color</th>
<th>Center Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston XO®, and Boston XO®, with Tangible®-Hydra-PEG® - Blue</td>
<td>&gt;0.65 mm</td>
</tr>
<tr>
<td>Boston XO®, and Boston XO®, with Tangible®-Hydra-PEG® - Ice Blue</td>
<td>&gt;0.65 mm</td>
</tr>
<tr>
<td>Boston XO®, and Boston XO®, with Tangible®-Hydra-PEG® - Green</td>
<td>&gt;0.55 mm</td>
</tr>
<tr>
<td>Boston XO®, and Boston XO®, with Tangible®-Hydra-PEG® - Violet</td>
<td>&gt;0.65 mm</td>
</tr>
</tbody>
</table>

Special Precautions for Eye Care Practitioners:
• When wet shipped, Boston XO®, and Boston XO®, with Tangible®-Hydra-PEG® Contact Lenses are packaged non-sterile in a preserved aqueous solution, either Boston SIMPLUS®, Multi-Action Solution or Boston ADVANCE® Conditioning Solution. Boston SIMPLUS® Multi-Action Solution contains polyoxime, hydroxyethyl phosphoryl, boric acid, sodium barate, sodium chloride, hydroxypropyl methyl cellulose, glucam, and preserved with polyaminopropyl biguanide (0.00005%); chlorhexidine gluconate (0.0033%). Boston ADVANCE® Conditioning Solution contains polyaminopropyl biguanide (0.00005%), chlorhexidine gluconate (0.0033%), and edetate disodium (0.05%) as preservatives. If the patient has experienced a prior history of allergy to any of the ingredients in Boston SIMPLUS® Multi-Action Solution or Boston ADVANCE® Conditioning Solution, remove the lens from the solution and soak for 24 hours in unpreserved saline solution prior to cleaning, disinfecting, and dispensing.
• Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design considerations, 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 XO®, and Boston XO®, with Tangible®-Hydra-PEG® Contact Lenses until the determination is made that the eye has healed completely.
• Before leaving the eye care practitioner’s office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.
• Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
• The presence of the UV-absorber in the Boston XO®, and Boston XO®, with Tangible®-Hydra-PEG® Contact Lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the FITTING-PROCEDURE for detailed instructions.)

Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:
• Different solutions often cannot be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
• Do not heat the conditioning/storage solution and/or lenses. Keep them away from extreme heat.
• Always use fresh, unexpired lens care solutions.
• Always follow directions in the Package Inserts for the use of contact lens solutions.
• Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp the Boston XO®, and Boston XO®, with Tangible®-Hydra-PEG® Contact Lenses.
• Sterile unreserved 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. These lenses should be cleaned and disinfected prior to insertion.
• Boston XO®, and Boston XO®, with Tangible®-Hydra-PEG® Contact Lenses must be stored in the lens storage case with the recommended solutions. Dry storage is not recommended.
• If the lens sticks (stops moving) on the eye, follow the refitting guidelines 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 Information Booklet for Boston XO®,® and Boston XO®,® with Tangible® Hydra-PEG® Contact Lenses and those instructions provided by the eye care practitioner.

Never wear lenses beyond the period recommended by the eye care practitioner.

If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Always handle lenses gently and avoid dropping them on hard surfaces.

Avoid all harmful or irritating vapors and fumes while wearing lenses.

Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to, Acanthamoeba keratitis.

The patient should be instructed to alert his or her doctor (health care professional) that the patient wears contact lenses.

Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the case, pour the solution containing the lens into the palm of your hand.

Do not touch the lens with fingernails.

Always contact the eye care practitioner before using any medicine in the eyes.

The patient should be instructed to inform his or her employer that the patient wears 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 continued 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 the lens was first placed on the eye
- Feeling of something in the eye, such as a foreign body or 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, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinset them. After reininsertion, 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. The Patient should keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

SELECTION OF PATIENTS

Boston XO®,® and Boston XO®,® with Tangible® Hydra-PEG® Contact Lenses are rigid gas permeable lenses for the daily wear patient who may require the correction of visual acuity for myopia, hyperopia, astigmatism, and presbyopia. Boston XO®,® and Boston XO®,® with Tangible® Hydra-PEG® Contact Lenses are suitable for patients who have never worn contact lenses, for current PMMA (poly methyl methacrylate) 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 (ALL STEPS ALSO APPLY TO LENSES COATED WITH TANGIBLE® HYDRA-PEG®)

1. Pre-Fitting Examination

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

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

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

2. Initial Lens Diameter Selection

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

3. Initial Lens Base Curve Radius Selection

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

- **Step One:** Measure central corneal curvature and identify the Flat K (lowest dioptic power).
  - Example: K = 42.75/44.75 @ 90° Flat K = 42.75D (700 mm)
  - The “Flat K” is used as a reference point from which the Base Curve Radius is chosen.

- **Step Two:** Calculate the corneal astigmatism (difference between the Flat and Steep K).
  - In this Example: K = 42.75/44.75 @ 90° Corneal Astigmatism = 2000

- **Step Three:** Calculate the Base Curve Radius by referring to the Corneal Astigmatism Factor Chart for a given lens diameter.
  - Example: K = 42.75/44.75 @ 90° Flat K = 790 mm
  - Corneal Astigmatism = 2000
  - Lens Diameter = 9.6 mm
  - Initial Base Curve:
    - Flat K = 42.75D 790 mm
    - + Corneal Astigmatism Factor = 0.025D flatter than Flat K
    - = Initial Base Curve
    - = Base Curve Radius
    - = 42500 = 794 mm
4. Initial Lens Evaluation

A. Lens Positioning

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

Note for fitting the hyperopic eye:

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

B. Fluorescein Pattern

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

The presence of the UV-absorber in the Boston XO2® (hexafocon B) Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. A simple, inexpensive approach is the use of an auxiliary yellow Kodak Wratten Filter #12 in conjunction with the cobalt blue filter of the biomicroscope.

Slt Lamp Application:

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

Burton Lamp Application:

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

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

*The Wratten Filter #12 is available from Authorized Boston® Manufacturers in the following kit: #7503 Boston® Sit Lamp Filter Kit.

5. Initial Lens Power Selection

A. Empirical Fitting

Step One:

Follow the steps for Initial Lens Diameter Selection and Initial Lens Base Curve Radius Selection.

Step Two:

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

Example:

Spectacle Rx: -3.00/-1.50 x 180
K Readings: 42.75/44.75 @ 90
Flat K = 42.50D (790 mm)

Corneal Astigmatism = 2.00D

Lense Diameter = 96 mm

Initial Base Curve:

Flat K = 42.75D

+ Corneal Astigmatism Factor 0.25D flatter than Flat K

= Initial Base Curve 42.50D

Base Curve Radius 42.50D = 794 mm

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

Base Curve: 42.50D 0.25 flatter than Flat K

Spherical Power of Spec Rx: -3.00D

FAP Adjustment: (+0.25D)

Lens Power: -2.75D

The lens in this example would be ordered as:

Base Curve: 42.50D

Power: -2.75D

Diameter: 96 mm

B. Trial Fitting

Step One:

Perform a spherical refraction over the best fitting trial lens.

Step Two:

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

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

+5.00D at 12 mm = +5.37D at the cornea

Step Three:

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

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

6. Initial Lens Center Thickness Selection

The eye care practitioner should always specify center thickness as part of the complete prescription. The stability and flexural resistance of Boston XO2® (hexafocon B) Contact Lenses Material permit the use of a wide range of center thicknesses and designs.

### Corneal Astigmatism Factors

<table>
<thead>
<tr>
<th>Corneal Astigmatism</th>
<th>9.2 mm Diameter</th>
<th>9.6 mm Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00 to 0.50D</td>
<td>0.50D flatter</td>
<td>0.75D flatter</td>
</tr>
<tr>
<td>0.75 to 1.25D</td>
<td>0.25D flatter</td>
<td>0.50D flatter</td>
</tr>
<tr>
<td>1.50 to 2.00D</td>
<td>on Flat K</td>
<td>0.25D flatter</td>
</tr>
<tr>
<td>2.25 to 2.75D</td>
<td>0.25D steeper</td>
<td>on Flat K</td>
</tr>
<tr>
<td>3.00 to 3.50D</td>
<td>0.50D steeper</td>
<td>0.25D steeper</td>
</tr>
</tbody>
</table>

*This chart assumes an optical zone that is 14 mm to 16 mm smaller than the lens diameter.
For eyes with less than 125 diopeters of corneal toxicity consider the following standard thickness table:

<table>
<thead>
<tr>
<th>Lens Power</th>
<th>Recommended Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>plano</td>
<td>018</td>
</tr>
<tr>
<td>-100</td>
<td>017</td>
</tr>
<tr>
<td>-200</td>
<td>016</td>
</tr>
<tr>
<td>-300</td>
<td>015</td>
</tr>
<tr>
<td>-400</td>
<td>014</td>
</tr>
<tr>
<td>-500</td>
<td>013</td>
</tr>
<tr>
<td>-600</td>
<td>013</td>
</tr>
<tr>
<td>-700</td>
<td>013</td>
</tr>
<tr>
<td>-800</td>
<td>013</td>
</tr>
</tbody>
</table>

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

7. Remaining Lens Parameter Selection
The final prescription should be provided to the Authorized Boston® Manufacturer in a format which includes:
- base curve
- diameter
- power
- peripheral curves

By specifying the complete design, practitioner success and patient satisfaction are increased. Your Authorized Boston® Manufacturer may also offer suggestions regarding lens design.

<table>
<thead>
<tr>
<th>Select remaining lens parameters:</th>
<th>optical zone &amp; peripheral (edge) design</th>
</tr>
</thead>
</table>

Specify 8.0 mm to 8.2 mm optic zone
Instruct manufacturer to blend to finished size

Specify peripheral curve design as follows:

<table>
<thead>
<tr>
<th>for 9.2 mm diameter</th>
<th>for 9.4 mm to 9.6 mm diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral Curves</td>
<td>Peripheral Curves</td>
</tr>
</tbody>
</table>

1st
Width 0.3 mm
Radius 0.8 mm

2nd
Width 0.3 mm
Radius 2.3 mm

*smaller than B.C.*

1. Pre-Fitting Examination
2.  The Kodak Wratten Filter #12* (yellow) is secured on the Slit Lamp Application:
3.  Use system in usual manner.
4. Use system in usual manner.

2. Pre-Fitting Examination
3.  The Kodak Wratten Filter #12* (yellow) is secured on the Slit Lamp Application:
4.  Use system in usual manner.
5.  Use system in usual manner.

Note for fitting the hyperopic eye:

- 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.
- Piggyback conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the Criteria of a Well-Fitted Lens are not satisfied during any follow-up examination, the patient should be refitted with a more appropriate lens.

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 surface and increase the brittleness of the lens. Only use the solvent supplied by your lens laboratory and minimize solvent exposure time by rubbing a solvent-saturated cloth over the lens surfaces and quickly removing the solvent with a surfactant. Do not soak the lenses in the solvent.

REMOVAL OF SURFACE DEPOSITS

Deposits are easily removed from the surfaces of Boston XO2®, (hexafocon B) Contact Lenses. These deposits are best identified by inspecting the cleaned and dried lens with a slit lamp in a dark room using a medium-width illuminating beam. Surface deposits should be gently removed with Boston® Professional 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® Professional Cleaning Polish and Manual Polishing Machine are available from Authorized Boston® Manufacturers.

Caution: Applying excessive and prolonged pressure to the lens during the polishing procedure may alter its surface optics. Polishing not recommended for lenses coated with Tangible® Hydra-PEG®.

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 XO2® and Boston XO2® with Tangible® Hydra-PEG® 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

Patients should be instructed to carefully follow the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

Boston XO2® and Boston XO2® with Tangible® Hydra-PEG® Contact Lenses are intended for daily wear.

WARNING: Bausch + Lomb Boston XO2® and Boston XO2® with Tangible® Hydra-PEG® Contact Lenses are NOT intended for overnight (extended) wear.
Boston Spherical & Aspherical Scleral Contact Lenses for

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 a minimum edge lift and edge contours that are rolled slightly inward to reduce blink-related sensation. Interior lens positioning, which interferes with normal blinking, 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
Practitioner observations and interpretation of lens positioning, fluorescein patterns, and lens movement are essential to optimize the fitting process. The following chart summarizes common fitting relationships.

<table>
<thead>
<tr>
<th>INITIAL LENS ASSESSMENT</th>
<th>Optimum</th>
<th>Too Steep</th>
<th>Too Flat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluorescein Pattern</td>
<td>Parallel to slight apical bearing, Moderate edge lift</td>
<td>Excessive apical pooling, Minimum edge lift</td>
<td>Excessive apical bearing, Excessive edge lift</td>
</tr>
<tr>
<td>Position</td>
<td>Centered to slightly superior</td>
<td>Interior</td>
<td>Superior unstable</td>
</tr>
<tr>
<td>Movement</td>
<td>1 mm to 2 mm</td>
<td>Less than 1 mm</td>
<td>More than 2 mm</td>
</tr>
<tr>
<td>Comfort</td>
<td>Slight initial sensation</td>
<td>Initially comfortable</td>
<td>Uncomfortable</td>
</tr>
<tr>
<td>Disposition</td>
<td>Prescribe</td>
<td>Select flatter base curve or smaller diameter</td>
<td>Select steeper base curve or larger diameter</td>
</tr>
</tbody>
</table>

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

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

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

Ocular redness without staining: This problem may be caused by some component of the care solutions, such as preservatives or the presence of pungent, 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.). More frequent use of 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 only visible with magnification of 20X or greater. In many cases, for Boston XO® Contact Lenses without Tangible® Hydra-PEG®, deposits are easily removed by cleaning with original Boston® Cleaner, Boston ADVANCE® Cleaner, and/or Boston® ONE STEP Liquid Enzymatic Cleaner. For Boston XO® with Tangible® Hydra-PEG® Contact Lenses, DO NOT USE Boston® Cleaner, Boston ADVANCE® Cleaner, and/or Boston® ONE STEP Liquid Enzymatic Cleaner. However, in extreme cases, it may be necessary to lightly polish the lenses with Boston® Professional Cleaning Polish. In the event that deposits cannot be removed by cleaning or polishing, the lens should be replaced.

Polishing not recommended for lenses coated with Tangible® Hydra-PEG®.

Lens surface dry spots: The presence of discrete non-wetting areas on a new, recently modified, or polished lens is usually due to the persistence of hydrophobic products used during lens fabrication. These hydrophobic contaminants have a greater affinity for Boston XO® Contact Lenses and Boston XO® with Tangible® Hydra-PEG®.

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

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

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

Repeated lens breakage: Lens breakage problems may be due to careless handling or storage procedures (see Patient Information Booklet).

BIFOCAL/MULTIFOCAL CONTACT LENS FITTING PROCEDURE FOR THE PRESBYOPIC PATIENT

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

1. Pre-Fitting Examination
A pre-fitting patient history and examination are necessary to:

• Determine whether a patient is a suitable candidate for daily wear bifocal contact lenses (consider patient hygiene and mental and physical state);

• Make ocular measurements for initial contact lens parameter selection;

• Collect and record baseline clinical information to which post-fitting examination results can be compared.

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

2. Alternating Vision Bifocal Designs
A. The first alternating vision design has a spherical base curve, a segment for distance correction, and a segment for near correction. For distance vision, the majority of the pupil is covered by the distance zone. For near vision, the majority of the pupil is covered by the near zone as the lens translates (moves upward) in downgaze. This design is prism ballasted to enhance stabilization.
Fitting Principles
1) Trial fitting is always recommended.
2) The base curve radius and distance powers are chosen using conventional techniques.
3) The near add power is based on the patient’s refraction.
4) The diameter is chosen to place the segment line, which divides the distance, and near zones at or slightly below the inferior pupil margin.
5) With blinking the lens should move 1 mm to 2 mm. The segment line will raise above the inferior pupil margin but should drop quickly. If not, distance vision will be adversely affected.
6) Decreasing lens movement will generally improve distance vision. The following fitting adjustments will generally decrease movement:
   - Increase diameter
   - Steepen base curve
   - Increase prism ballasting

7) Increasing lens movement will generally improve near vision. The following fitting adjustments may increase movement:
   - Decrease diameter
   - Flatten base curve
   - Decrease prism ballasting

B. The second alternating vision lens design has a spherical base curve corresponding to the near point power and a steeper spherical curve segment corresponding to the distance power. For distance vision, the majority of the pupil is covered by the distance zone segment. For near vision, the majority of the pupil is covered by the near zone as the lens translates (moves upward) in downgaze. This design is prism ballasted and may have a small inferior truncation to enhance stabilization.

Fitting Principles
1) Trial fitting is always recommended.
2) The base curve radius is chosen using conventional techniques.
3) Determine the distance spherical power to obtain optimum visual acuity.
4) The diameter is chosen to correctly position the distance segment in front of the pupil in distance gaze. This can be visualized easily with fluorescein since the steeper distance segment pools with fluorescein.
5) The distance zone segment radius is calculated by multiplying the add requirement by two (2). This is added to the base curve (in dipters).
   Example: Base Curve = 43.00D
   Add +200 x 2 = 400D
   4700D (distance zone curvature)

6) Calculate the power of the near zone (which corresponds to the base curve) by adding the distance power determined in step 3 to the add requirement.
   Example: -3.50D (distance power)
   (+) +200D (add power)
   -1500D

7) Calculate the power of the distance zone segment by adding three (3) times the add power (as minus) to the near zone power.
   Example: 3 x - (200) = -600 (3 x add power)
   (+) -150 (near zone)
   -750 (distance zone)

8) Specify the near and distance zone curvatures and powers.
   Example: 43.00/4700 -150/-750
   43.00/-150
   4700/-750

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

Fitting Principles
1) Trial fitting is always recommended.
2) Initial Base Curve Selection
   The initial base curve selection is primarily a function of the amount of corneal cylinder present. This bifocal lens with aspheric posterior surface will generally be fitted steeper (approximately 0.10 mm) than a similar diameter spherical lens.
   a) For Minus Lenses
      Select a base curve radius equal to the radius of the flattest keratometer reading for corneas with less than 10.00D of corneal toricity. For corneas with 10.00D or greater corneal toricity, select a base curve radius equal to the mean of the two keratometer readings.
      Example: K = 44.00/46.00 D
      Mean K = 45.00D = 7.50 mm
      Select 750 mm base curve trial lens
      (If conversion of dioplers to millimeters results in a base curve parameter not available, select the next available steeper base curve.)
   b) For Plus Lenses
      Select a base curve radius equal to the corneal radius for spherical corneas. For toric corneas, select a base curve radius equal to the mean of the two keratometer readings.
   3) Place the lens on the eye and allow it to settle. (approximately 5 to 10 minutes).

3. Simultaneous Vision Multifocal Designs
A. The first simultaneous vision multifocal lens design has an aspheric back surface, which progressively adds plus power from center to edge. This power change is gradual. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During near viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.
   Fitting Principles
1) Trial fitting is always recommended.
2) The base curve radius is chosen using conventional techniques. Due to the aspheric flattening of the lens back surface, the base curve chosen will be considerably steeper than standard spherical single vision rigid lenses. It is not unusual to select a base curve 2D to 4D steeper than the flattest K.
   The following formula can be used as a starting point:
   Flat K + add power + 100 D + 1/2 corneal astigmatism.
   Example: 42.00/44.00 + 200 add $42.00 + 200 + 1/1 + 1 = 46.00$
   3) Centration is critical for this design. If proper exact centration cannot be obtained, do not fit this lens.
   4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.

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

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

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

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

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

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

**4. Initial Lens Evaluation**

**A. Lens Positioning**
Patient comfort is largely determined by lens position on the cornea. Generally, a well-fitted lens exhibits a central or slightly inferior/central position. Generally, an optimal aspherical fit will show a thin, even layer of tears centrally which extends to near the edge where a moderate amount of edge lift will be observed. This fluorescein pattern is characterized by the absence of a discernible intermediate bearing area which is commonly observed with conventional spherical designs.

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

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

**5. Slit Lamp Application**
1. All customary light intensities and filter settings (cobalt blue) are left in place.
2. The Kodak® Woven Filter #12* (yellow) is secured on the patient side of the slit lamp microscope with a small piece of adhesive tape.

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

**Note:** Use of the Woven Filter will also enhance the view of non-UV rigid lenses and corneal fluoroscein evaluation.

*A Woven Filter #12 is available from Authorized Boston® Manufacturers in the following kit: #7503 Boston Slit Lamp Filter Kit.

**5. Determining Power and Dispensing the Lens**
Once the appropriate base curve has been selected, over-refract to determine the appropriate distance dioptric power for the final lens order. Over-refractions of 4.00D or more should be corrected for vertex distance. The over-refraction should be added to the power of the trial lens to arrive at the final prescription.

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

Add power should be based on the spectacle add power required.

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

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

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

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

D. Lower segment positioning in conjunction with flatter fitting may represent the best compromise between distance and near visual performance.
E. Visual performance will improve with time as the patient learns to control the movement and positioning of the lens. The following patient instructions may be useful:

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

7. Follow-Up Care
A. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, a conventional follow-up schedule for daily wear should be maintained.
B. Prior to a follow-up examination, the contact lenses should be worn for at least 2 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
C. With lenses in place on the eyes, evaluate fitting performance to assure that Criteria of a Well-Fitted Lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
D. After the lens removal, instill sodium fluorescein into the eyes and conduct a thorough biomicroscopy examination:
   1. The presence of vertical corneal staining in the posterior central cornea and/or corneal neovascularization may indicate 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.
   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.

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

The following areas should be discussed with the patients.

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

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

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

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

MONOVISION FITTING GUIDELINES

1. Patient Selection
A. Monovision Needs Assessment
   For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient may not be a good candidate for monovision with the Boston XO2 Contact Lenses.

   Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:
   1) Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
   2) Driving automobiles (e.g., driving at night). Patients who cannot pass their state 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 “dominant eye.” Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

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

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

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

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

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

Refer to the Follow-Up Care section.
4. Initial Lens Evaluation

C. The third simultaneous vision multifocal lens design

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

Fitting Principles

4) The distance power is chosen using conventional spherical designs.

which extends to near the edge where a moderate edge lift is necessary to permit the edge of the slit lamp microscope with a small piece of adhesive to be placed on the side of the slit lamp microscope. The following may be helpful:

- Raise Segment
- Slit Lamp Application:

- A moderate edge lift is necessary to permit the edge of the slit lamp microscope with a small piece of adhesive to be placed on the side of the slit lamp microscope.

- The presence of corneal staining and/or limbal-conjunctival flare at night becomes irregular resulting in visual impairment. This irregularity can lead to severe infection, vision loss or blindness.

- For Pellucid Marginal Degeneration, the base curve chosen is flatter than K or a reverse geometry lens may be considered. If the patient requires critical vision (visual acuity and visual field), always prescribe the lens power for the near eye that provides best results.

- For keratoconus conditions, lens diameters between 7.0 mm and 8.0 mm are recommended. Pre-fitting patient history and examination are necessary to:

- Determine whether the patient functions best with the plus power trial lens over the right or left eye.
- Always prescribe the lens power for the near eye that provides the best compromise between distance and near vision.
- 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 (e.g., sunny and dry).

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 (e.g., sunny and dry).
- 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.

- Make use of proper illumination when performing 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 Information Booklet.

IRREGULAR CORNEA FITTING GUIDELINES

1. Patient Selection Criteria

Boston XO® Contact Lenses are indicated for patients who require a rigid contact lens who have a demonstrated need for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or LASIK surgery, who desire a refractive correction with rigid gas permeable contact lenses and who do not have any of the contraindications for gas permeable contact lenses. Refer to CONTRAINDICATIONS (REASONS NOT TO USE).

Keratoconus is a non-inflammatory ocular condition in which the cornea progressively thins causing a cone-like bulge to develop. As the cornea steepens the anterior corneal surface (epithelium) becomes irregular resulting in visual impairment. This irregularity cannot be completely corrected with spectacles, instead a rigid gas permeable contact lens is used to become the new anterior refracting surface.

Pellucid Marginal Degeneration is characterized by non-inflammatory and progressive crescent shaped corneal thinning inferiorly, often with against-the-rule astigmatism and a steepening topography pattern.

2. Special Fitting Considerations

Boston XO® Contact Lenses for keratoconus, pellucid marginal degeneration, or post-penetrating keratoplasty (PRK)/LASIK are designed to be fitted so as to optically correct irregular astigmatism and thereby improve visual acuity. The lens designs and the manner in which the lens is fitted are intended to work together to accomplish this goal.

The keratoconus design utilizes smaller optic zone diameters, steeper base curves, spherical and/or aspherical periphery curves to closely approximate the unusual topography typical in patients with keratoconus. For example, keratoconus lens designs utilize small posterior optic zones and a series of peripheral curves to achieve this fitting relationship. These zone sizes may vary in lens diameters over 11.5 mm.
The Pellucid Marginal Degeneration design utilizes larger lens diameters, larger optic zone diameters, flatter base curves, and spherical and/or aspherical periphery curves to closely approximate the unusual topography typical in patients with the condition. Boston XO® Contact Lenses for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery, may be fitted using a modification of the standard techniques for rigid gas permeable contact lenses.

A. Pre-Fitting Examination

Complete refraction and visual health examination should be performed.

Pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for Boston XO® Contact Lenses for keratoconus, pellucid marginal degeneration, irregular astigmatism, excessive dry eyes, or following penetrating keratoplasty or post-refractive (e.g., LASIK) surgery.
- Collect and record baseline clinical information to which fitting examination results can be compared.

B. Initial Lens Power Selection

Standard procedures for determining power of rigid gas permeable contact lenses such as over-refraction may be used, including compensation for vertex distance.

C. Initial Lens Diameter Selection

For keratoconus conditions, lens diameters between 7.0 mm and 21.0 mm are chosen to maximize positioning on the cornea and to minimize lens movement.

For pellucid marginal degeneration, lens diameters are typically between 9.5 mm and 21.0 mm.

For post-surgical indications, a larger lens diameter between 9.0 mm and 21.0 mm is chosen to avoid fitting on or near the graft (suture) line. Lens diameters outside of this range are occasionally used for some eyes.

This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner’s judgment.

Lens diameter is primarily a function of the base curve but may be influenced by power (plus lenses require a larger diameter to compensate for weight) and anatomical considerations (small palpebral opening, excessively large pupil, etc.) and the patient’s corneal topography.

Scleral Lens Fitting

In scleral lens designs (GP lens where some point of the lens rests on the sclera) lens diameter is a primarily a function of the lens design characteristics of base curve, sagittal depth, and fitting method.

D. Initial Lens Base Curve Selection

For keratoconus, the base curve of the first lens fitted is generally equal to or slightly steeper than the flattest keratometry reading to achieve an apical clearance or apical alignment fitting relationship.

For Pellucid Marginal Degeneration, the base curve chosen is generally flatter than the flattest K reading. It may be equal to the radius of curvature as measured 4 mm from the corneal apex by topography (which is usually flatter). If using K readings, the base curve chosen will be approximately 100D flatter than the median K reading.

For Post-Penetrating Keratoplasty (Corneal Graft) fitting, initial base curve selection will depend on the shape and position of the graft.

The post-operation cornea may be “Prolate” where the graft is steeper than the surrounding peripheral “flat” cornea. Typically, a slightly steeper than K base curve would be used.

The post-operation cornea may be “Oblate,” where the graft is flatter (sunken) than the surrounding host cornea. In this case, a base curve flatter than K or a reverse geometry lens may be required.

For post refractive surgical fitting (LASIK), the central cornea is much flatter than a “normal” (non-operated) cornea. Base curve choices are usually 0.50 to 1.00D flatter than the pre-op Flat K reading.

Scleral Lens Fitting

The base curve is selected to determine first trial lens. This base curve is generally between 1.50D flatter than the flattest keratometry reading to 2.00D steeper than the steepest keratometry reading to achieve a fit that aligns or provides a slight touch across the corneal surface.

E. Initial Lens Evaluation

Movement

Blink induced lens movement should show downward lens movement with the lid motion (average 1 mm) and then upward with the lid motion (average 1 mm) as with a standard gas permeable contact lens. During the interblink period the lens should have little or no motion (average less than 1 mm). For lens designs over 11.5 mm diameter may exhibit little or no movement.

Scleral Lens Fitting

Lens designs over 11.5 mm diameter exhibit little or no movement.

Positioning

The lens should position centrally or slightly inferiorly, as it will tend to migrate to the steepest corneal area. Lens designs over 11.5 mm diameter will most always position centrally.

Characteristics of a Tight (Too Steep) Lens

A lens that is too tight will show reduced movement upon blinking. Bubbles may be detected behind the lens. For lens designs over 11.5 mm diameter the presence of bubbles may not indicate a poor fitting lens.

Characteristics of a Loose (Too Flat) Lens

A lens that is too loose will move excessively on the cornea, following each blink. The lens may ride in either a position that is too high or too low in an eccentric position. A loose lens is usually uncomfortable for the patient.

Scleral Lens Fitting

Lens designs over 11.5 mm diameter will most always position centrally.

Characteristics of a Tight (Steep, Excessive Sagittal Depth) Lens Bubbles may be detected behind the lens but with lenses that are larger than 11.5 mm their presence may not indicate a poor fitting relationship.

Characteristics of a Loose (Too Flat, Insufficient Sagittal Depth) Lens Scleral lenses larger than 11.5 mm diameter generally will never have loose (excessive movement) fitting relationship although they may have a flat lens to cornea fitting relationship. Flat lenses are indicated by excessive bearing on the cornea usually best seen during fluorescein pattern evaluation.

3. Trial Lens Fitting

Trial Lens Fitting

Trial lens fitting is recommended whenever possible. Trial lens fitting allows a more accurate determination of lens specifications for the lens fit and power. Choose the first lens according to the base curve selection criteria for the specific lens design. Trial lenses are essential in fitting patients whose corneal topography is distorted.

Trial Lens Procedure

Select a trial lens and place the lens upon the eye. Evaluate the lens using white light for the following:

Centering

Lenses may not center well due to the unusual corneal topography in patients with keratoconus. Often the lens will position inferiorly over the steepest corneal area.

Scleral Lens Fitting

The scleral lens design will almost always center well due to its large ocular surface coverage area.

Movement

Lens movement should be equivalent to or slightly less than a standard RGP lens.
4. Initial Lens Evaluation

- The base curve radius is chosen using conventional base curve selection will depend on the shape and position of the cornea's keratoconus. The presence of excess sagittal depth. Try trial lenses with different base curves until a good fit is achieved.

**Scleral Lens Fitting**

- The fluorescein pattern should show an area with a 0.5 diopters flatter base curve should be the next choice with variations from this based on the judgment of the eye care practitioner. A lens with excessive movement should be replaced with another that is 0.5 diopters steeper base curve.

**Scleral Lens Fitting**

- With lenses in place, evaluate the fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the lens demonstrates reduced movement, consider exchanging for another of flatter base curve. Usually, a lens with a 0.5 diopters flatter base curve should be the next choice with variations from this based on the judgment of the eye care practitioner. A lens with excessive movement should be replaced with another that is 0.5 diopters steeper base curve.

**4. Special Follow-Up Care**

A. With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the lens demonstrates reduced movement, consider exchanging for another of flatter base curve. Usually, a lens with a 0.5 diopters flatter base curve should be the next choice with variations from this based on the judgment of the eye care practitioner. A lens with excessive movement should be replaced with another that is 0.5 diopters steeper base curve.

**Scleral Lens Fitting**

- With lenses in place, evaluate the fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. If there is an exceptionally flat lens to cornea fitting relationship, choose the next steeper (increased sagittal depth) trial lens and evaluate. If there is an excessively steep lens to cornea fitting relationship, choose the next flatter (decreased sagittal depth) diagnostic lens from the manufacturer’s trial set. Repeat the trial lens evaluation procedures for centering, movement, and fluorescein pattern. Continue with this process until the optimum fit is achieved.

B. After the lens removal, conduct a thorough biomicroscopy examination to detect the presence of unusual vertical corneal striae in the posterior central cornea and/or corneal neovascularization. Note: Some vertical striae are typical in advanced stages of keratoconus. The presence of these conditions may be indicative of excessive corneal edema.

- The recommended schedule for follow-up visits are the same as standard lenses. Refer to the Follow-Up Care section.

**Note: Practitioners should consult their finishing lab for available keratoconus, pellucid marginal degeneration, and post-surgical lens designs. The design parameters must meet the parameters specified in the product labeling.**

**LENS CARE DIRECTIONS**

Eye care practitioners should review lens care directions with the patient, 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)**

1. **Rub and Rinse Time**

**Instruction for Use:**

- Follow the complete recommended lens rubbing and rinsing times in the labeling of your solution used for cleaning, disinfecting, and soaking your lenses to adequately disinfect your lenses and reduce the risk of contact lens infection.

**WARNING:**

- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water. saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

2. **Soaking and Storing Your Lenses**

**Instruction for Use:**

- Use only fresh contact lens disinfecting solution each time you soak (store) your lenses.

**WARNING:**

- Do not reuse or “top-off” old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. “Topping-off” is the addition of fresh solution to solution that has been sitting in your case.

3. **Lens Case Care**

**Instruction for Use:**

- Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with a fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry.
- Replace your lens case according to the directions given to you by your eye care practitioner or the labeling that came with your case.
- Contact lens cases can be a source of bacterial growth.

**WARNING:**

- Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

4. **Water Activity**

**Instruction for Use:**

- Do not expose your contact lenses to water while you are wearing them.

**WARNING:**

- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection including, but not limited to, Acanthamoeba keratitis. If your lenses have been submersed in water, you should thoroughly clean and disinfect them before insertion. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

5. **Discard Date on Solution Bottle**

**Instruction for Use:**

- Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking your contact lenses.

**WARNING:**

- Using your solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

6. **Basic Instructions**

- Always wash, rinse, and dry hands before handling contact lenses.
  - Always use fresh, unexpired lens care solutions.
  - Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling, or if advised by the 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. The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lenses.

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.

The lens care products listed below are recommended by Bausch & Lomb for use with Boston XO2 and Boston XO3 with Tangible® Hydro-PEG® 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: For Boston XO2, XO3 Contact Lenses (Without Tangible® Hydro-PEG® Treatment)

<table>
<thead>
<tr>
<th>Product Purpose</th>
<th>Lens Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>Boston ADVANCE® Cleaner</td>
</tr>
<tr>
<td></td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Disinfect</td>
<td>Boston ADVANCE® Conditioning Solution</td>
</tr>
<tr>
<td></td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Store</td>
<td>Boston ADVANCE® Conditioning Solution</td>
</tr>
<tr>
<td></td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Rinse</td>
<td>ScienFan® Preservative Free Saline Solution</td>
</tr>
<tr>
<td></td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Lubricate/Rewet</td>
<td>Boston® Rewetting Drops</td>
</tr>
<tr>
<td>Weekly Enzymatic</td>
<td>Boston® ONE STEP Liquid Enzymatic Cleaner</td>
</tr>
</tbody>
</table>

### LENS CARE TABLE: For Boston XO2, XO3 Contact Lenses with Tangible® Hydro-PEG® Treatment

<table>
<thead>
<tr>
<th>Product Purpose</th>
<th>Lens Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Disinfect</td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Store</td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Rinse</td>
<td>ScienFan® Preservative Free Saline Solution</td>
</tr>
<tr>
<td></td>
<td>Boston SIMPLUS® Multi-Action Solution</td>
</tr>
<tr>
<td>Lubricate/Rewet</td>
<td>Boston® Rewetting Drops</td>
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</tbody>
</table>

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. Enzymatic cleaner not recommended for use with lenses coated with Tangible® Hydro-PEG®.

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as recommended by the eye care practitioner to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eye care practitioner. Follow the instructions provided in the disinfection solution packaging.

- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the Package Insert or the eye care practitioner for information on storage of lenses.
- 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 fresh storage solution. Lenses should be replaced 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 XO2 and Boston XO3 with Tangible® Hydro-PEG® Contact Lenses. Enzymatic cleaner not recommended for use with lenses coated with Tangible® Hydro-PEG®.
- Boston XO2 and Boston XO3 with Tangible® Hydro-PEG® 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 LENSL CLEANER: NOT FOR USE WITH BOSTON XO2, XO3 TANGIBLE® HYDRA-PEG® CONTACT LENSES

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

### IN-OFFICE LENS MODIFICATIONS - NOT FOR USE WITH BOSTON XO2, XO3 TANGIBLE® HYDRA-PEG® CONTACT LENSES

Edge reshaping and surface repolishing can be performed by conventional techniques if the following precautions are observed:

1. Avoid polishing compounds or cleaners that contain ammonia, alcohol, or organic solvents.
2. Completely remove all traces of adhesive (if double-backed tape is used) with the special authorized solvent.** (The use of any other solvent may cause surface breakdown.) Minimize exposure to the solvent and immediately remove all traces with Boston® Cleaner or Boston ADVANCE® Cleaner followed by a thorough water rinse.
3. Perform the initial lens modifications cautiously because the response of this polymer to these procedures is more rapid than that of silicone acrylate materials.
4. More extensive modifications should not be attempted. Best results will be obtained by using Boston® Professional Cleaning Polish, which is available from Authorized Boston® Manufacturers.
5. The Original Boston® Care System, Boston ADVANCE® Comfort Formula Care System or Boston SIMPLUS® Multi-Action Care System, including the overnight soak, should be used prior to lens dispensing.

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* CAUTION:

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** Bausch & Lomb Incorporated
4. Initial Lens Evaluation

A. Lens Positioning

2) The base curve radius is chosen using conventional selective gaze. During distance viewing, the patient selectively attends the near correction. If the power zone cannot be obtained, do not fit this lens.

C. Flare at Night

Both bifocal spectacle and bifocal/multifocal contact lens designs (high segment positions or small distance fields). With the presence of the UV-absorber in the Boston® lens, the patient must position the head upright while rotating upward gaze that monovision contact lenses provide. It is necessary for the patient to realize the disadvantages as it is considered. If the patient requires critical vision (visual acuity and reaction to distance vision under these circumstances. Then have the following test for eye dominance can be used.

B. Driving at Night

2)  Driving automobiles (e.g., driving at night). Patients who use the lenses first in a comfortable familiar environment, such as use the lenses first in a comfortable familiar environment, such as use the lenses first in a comfortable familiar environment, such as.

D. Lower segment positioning in conjunction with flatter fitting may be used prior to lens dispensing.

- Lower Segment

Excessive apical pooling or bearing should be avoided. The success of the monovision technique may be further improved by the lens case manufacturer or the eye care practitioner; frequently used for some eyes.

2. Special Fitting Considerations

Characteristics of a Tight (Steep, Excessive Sagittal Depth) Lens

A lens that is too loose will move excessively on the cornea, should have little or no motion (average less than 1 mm). For keratoconus conditions, lens diameters outside of this range are generally flatter than the flattest K reading. It may be equal to the desired power or may deviate from it, but it should be within one diopter of the desired value. The following test for eye dominance can be used.

Characteristics of a Loose (Too Flat) Lens

Scleral Lens Fitting

A lens that is too loose will move excessively on the cornea, should have little or no motion (average less than 1 mm). For keratoconus conditions, lens diameters outside of this range are generally flatter than the flattest K reading. It may be equal to the desired power or may deviate from it, but it should be within one diopter of the desired value. The following test for eye dominance can be used.