
PATIENT INSTRUCTIONS

***Boston® IV
(itafocon B)***

***Boston® II
(itafocon A)***

***Silicone Acrylate
Rigid Gas Permeable
Contact Lenses
For
Daily Wear***



**Bausch & Lomb
Boston®
Materials**

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

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INTRODUCTION

Your eyecare practitioner has fit you with contact lenses known as Boston® IV or Boston® II. These lenses are manufactured from Boston IV and Boston II lens material. 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® IV (itafocon B) and Boston® II (itafocon A) are Rigid Gas Permeable Contact Lens materials, composed of methyl-methacrylate-dimethylitaconate-siloxanyl copolymer. Boston IV lens materials are available in clear and blue. The blue Boston IV lens materials contain the color additive D & C Green No. 6. Boston II lens materials are available in clear, blue and green. The blue Boston II lens material contain the color additive D & C Green No. 6; the green Boston II lens material contain the color additive D & C Green No. 6 and C.I. Solvent Yellow No. 18.

WEARING RESTRICTIONS AND INDICATIONS

Boston IV and Boston II Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism, presbyopia and keratoconus) in aphakic and not aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfection (not heat) system only.

Boston IV and Boston II contact lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eyecare practitioner. **DO NOT WEAR YOUR THE BOSTON IV OR BOSTON II CONTACT LENSES WHILE SLEEPING.**

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE BOSTON IV or BOSTON II Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for Boston IV or Boston II contact lenses
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

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

PRECAUTIONS

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

- Before leaving the eyecare 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 wetting/soaking solution and lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package insert for the use of contact lens solutions.
 - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp the Boston® IV and Boston® II Contact Lenses.
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
 - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected overnight prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, immediately consult your eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions that follow for Boston IV and Boston II Contact Lenses and those provided by your eyecare practitioner.
- Never wear lenses beyond the period recommended by your eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eyecare practitioner about wearing lenses during water activities and other sports.
- Inform your health care practitioner (doctor) that you wear 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 your eyecare practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Follow your eyecare practitioner's instruction as to a recommended follow-up schedule.

ADVERSE EFFECTS

The following problems may occur:

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

If you notice any of the above:

Immediately remove lenses.

- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact your eyecare 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 eyecare 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 thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.

- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.

- Handle the lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper 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.

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

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

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

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

4. Centering the Lens

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

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

OR

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

5. Removing the Lens

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

- 1) A lens storage case.
- 2) **Two Bottle Care System**
Boston ADVANCE® Cleaner or Boston® Cleaner. **AND**
Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution.

OR

- **One Bottle Care System**
Boston SIMPLUS® Multi-Action Solution (Removes Protein, Cleans, Disinfects, Conditions & Cushions)
- 3) A clean towel.

Always remove the same lens first.

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

TWO-FINGER METHOD

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

BLINK METHOD

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

- 1) Place your index finger at the outer junction of your upper and lower lids, stretch the skin outward and slightly upward. (Do not allow your lid to slide over the lens.)
 - 2) Blink briskly. The lens will be pinched by the pressure of your eyelids and the lens will pop out onto the clean surface of the towel, or you may catch the lens in the palm of your hand.
- c. Remove the other lens by following the same procedure.

d. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, STORAGE AND REWETTING/LUBRICATING).

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

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

1. Basic Instructions

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

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

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

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

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

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care (chemical not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling, or if advised by your eyecare practitioner.**
- Always remove, clean, rinse and disinfect your lenses according to the schedule prescribed by your eyecare practitioner. The use of an enzyme or any cleaning solution **does not substitute for disinfection.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

- The lens care products listed below are recommended by Bausch & Lomb for use with either your Boston IV or Boston II Contact Lenses. Your eyecare practitioner may recommend alternate products that are appropriate for you to use with your Boston IV or Boston II Contact Lenses.

LENS CARE TABLE

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

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups) and rinse the lens thoroughly as recommended by your eyecare 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 eyecare 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 eyecare 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 eyecare practitioner for a recommendation on how to store your lenses.
- Boston IV and Boston II 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 eyecare practitioner; then allow the lens case to air dry. When the case is used again, refill it with fresh storage solution.

Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.

- Your eyecare practitioner may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.
- Your eyecare practitioner may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from your Boston® IV or Boston® II Rigid Gas Permeable Contact Lenses.

2. Care for a Sticking (Nonmoving) 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 nonmovement of the lens continues after 5 minutes, you should immediately consult your eyecare practitioner.

3. Lens Case Cleaning and Maintenance

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

4. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: **FLUSH YOUR EYES IMMEDIATELY WITH TAP WATER, THEN REMOVE YOUR LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT YOUR EYECARE 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 gazes 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 drivers' 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 eyecare practitioner whether you should have additional contact lenses pre-

scribed 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 eyecare 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 eyecare practitioner.
- It is important that you follow your eyecare 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 eyecare 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 that may be encountered while adapting to bifocal contact lens wear.

Your eyecare practitioner may discuss the following with you:

1. *Adaptation*

Both bifocal spectacle and bifocal 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.

2. *Driving at Night*

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

3. *Flare at Night*

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

4. *Visual Expectation*

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

SAMPLE OF WEARING AND APPOINTMENT SCHEDULES

Wearing Schedule

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

*if the lenses continue to be well-tolerated.

WARNING: Boston IV and Boston II Contact Lenses are **NOT** intended for overnight (extended) wear.

APPOINTMENT SCHEDULE

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

Your appointments are on:

Month	Year	Time	Date
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

PATIENT/EYECARE PRACTITIONER INFORMATION:

Eyecare Practitioner Information

Practitioner Name: _____

Practice Name: _____

Practitioner Address: _____

Practitioner Phone Number: _____

Recommended Lens Care Regimen: _____

Cleaning Solution: _____

Conditioning Solution: _____

Rewetting Solution: _____

Weekly Enzymatic Cleaner: _____

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

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PACKAGE INSERT

**Boston® IV
(itafocon B)**

**Boston® II
(itafocon A)**

*Spherical & Aspherical Contact
Lenses for Myopia & Hyperopia,
Keratoconus Contact Lenses,
Bifocal Contact Lenses for
Presbyopia and Toric Lenses
to Correct Astigmatism in
Not aphakic and Aphakic Persons*

*Silicone Acrylate
Rigid Gas Permeable
Contact Lenses
For
Daily Wear*

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

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

DESCRIPTION

Boston® IV (itafocon B) and Boston® II (itafocon A) are Rigid Gas Permeable Contact Lens materials, composed of methyl-methacrylate-dimethylitaconate-siloxanyl copolymer. Boston IV lens materials are available in clear and blue. The blue Boston IV lens materials contain the color additive D & C Green No. 6. Boston II lens materials are available in clear, blue and green. The blue Boston II lens material contain the color additive D & C Green No. 6; the green Boston II lens material contain the color additive D & C Green No. 6 and C.I. Solvent Yellow No. 18.

Boston IV & Boston II Contact Lenses are hemispherical shell of the following dimensions:

Spherical Lens Design	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	5.00 mm to 9.00 mm in .01 mm increments
Aspherical Lens Designs <i>(Some of these designs are patented; manufacture of these lenses in Boston IV (itafocon B) and/or Boston II (itafocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.00 mm to 9.20 mm in 0.01 mm increments
Bifocal Lens Designs <i>(Some of these designs are patented; manufacture of these lenses in Boston IV (itafocon B) and/or Boston II (itafocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	8.5 mm to 11.5 mm
Base Curve Range	6.30 mm to 9.50 mm in 0.01 mm increments
Segment Heights	-2.00 mm to +1.00 mm in 0.5 mm increments
Add Powers	+1.00D to +3.75D in 0.5D increments
Prism Ballast	0.5 to 3.5 prism diopters in 0.5D increments
Toric Lens Designs	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.80 mm to 9.50 mm in 0.01 mm increments
Toricity	Up to 9.00 Diopters
Keratoconus Lens Designs	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	4.00 mm to 9.00 mm in 0.01 mm increments
Base Optic Zone	5.00 mm to 9.00 mm in 0.01 mm increments

Boston IV

PHYSICAL PROPERTIES

Hardness (Rockwell R)	117
Specific Gravity	1.10
Refractive Index	1.469
Light Transmittance (Above 500 nm)	>90%
Water Content	<1%
Oxygen Permeability	26* (18**)
Wetting Angle	17°

Boston II

PHYSICAL PROPERTIES

Hardness (Rockwell R)	119
Specific Gravity	1.13
Refractive Index	1.471
Light Transmittance (Above 500 nm)	>90%
Water Content	<1%
Oxygen Permeability	18* (11**)
Wetting Angle	20°

*gas to gas method

**polarographic method (ISO/Fatt)

ACTIONS

Boston IV and Boston II Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS (USES)

These lenses are indicated for daily wear. These lenses are intended to correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic, hyperopic or presbyopic, or have keratoconus and may exhibit up to 4.00D of corneal astigmatism that does not interfere with visual acuity. The lenses may be disinfected using a chemical disinfection system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE either Boston IV or Boston II 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 Keratoconus, that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for Boston IV or Boston II 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 eyecare practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear lenses are **not** indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when 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 eyecare practitioner.

PRECAUTIONS

Practitioner Note: Boston® IV and Boston® II contact lenses are not sterile when shipped from the Authorized Boston® Manufacturer. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

Special Precautions for Eyecare Practitioners:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, 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 eyecare 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 either Boston IV or Boston II Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eyecare practitioner's office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.

- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the conditioning/storage solution and/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 either the Boston IV or Boston II Contact Lenses.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on make-up. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for Boston IV and Boston II Contact Lenses and in those prescribed by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.

- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eyecare practitioner about wearing lenses during water activities and other sports.
- Instruct patient to inform his or her health care practitioner (doctor) 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. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Instruct the patient to contact his or her eyecare 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 EFFECTS

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

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

If the patient notices any of the above, he or she should be instructed to:

Immediately remove lenses.

- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the eyecare practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, **immediately remove the lenses and consult the eyecare practitioner.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **keep the lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING

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

Practitioner Marketing Representative
Boston Products Group of Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
1-800-225-1241

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

WEARING SCHEDULE

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

Boston IV and Boston II Contact Lenses are indicated for daily wear. The suggested wearing time for these lenses is:

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

*if the lenses continue to be well-tolerated.

WARNING: Boston IV and Boston II Contact Lenses are **NOT** intended for overnight (extended) wear.

LENS CARE DIRECTIONS

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

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

Basic Instructions:

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

- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all 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 eyecare practitioner.**

- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or a cleaning solution **does not substitute for disinfection**.

The lens care products listed below are recommended by Bausch & Lomb for use with either Boston IV or Boston II Contact Lenses. Eyecare practitioners may recommend alternate products that are appropriate for the patient's use with his or her lenses).

LENS CARE TABLE

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

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

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as directed by your eyecare practitioner to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eyecare practitioner. 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 eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Eyecare practitioners may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from Boston® IV or Boston® II Contact Lenses.
- Boston IV and Boston II Contact Lenses **cannot** be heat (thermally) disinfected.

LENS CASE CLEANING AND MAINTENANCE

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

CARE FOR A STICKING (NONMOVING) LENS

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

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 EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied (nonsterile) in a plastic lens storage case. The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber (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 either Boston® IV or Boston® II Contact Lenses or adverse experiences with the lenses should be reported to:

Consumer Affairs
Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
1-800-333-4730

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Rochester, NY 14609
1-800-333-4730

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