

Professional Fitting and Information Guide



**O₂OPTIX[®], AIR OPTIX[™] AQUA and AIR
OPTIX[™] for Astigmatism (Iotrafilcon B) Soft
Contact Lenses For Daily Wear and up to 6
Nights Extended Wear**

Rx only

Caution: Federal law (USA) restricts this device to sale
by or on the order of a licensed eye care professional

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INTRODUCTION

Thank you for prescribing **O₂OPTIX[®], AIR OPTIX™ AQUA and AIR OPTIX™ for Astigmatism** (lotrafilcon B) soft contact lenses. The lenses may be worn for daily wear and up to 6 nights extended wear with removal for disposal, or cleaning and disinfection (chemical, not heat) prior to reinsertion, and frequent replacement with a fresh new lens.

However, you will determine the wear and replacement schedule as well as the length of time the patient's lenses are to be worn each day before removal for cleaning, rinsing, and disinfection. Based on these schedules, you will also determine the number of lenses each patient requires. This guide contains important information regarding fitting procedures and aftercare of the O₂OPTIX, AIR OPTIX AQUA and AIR OPTIX *for Astigmatism* patient.

Product Description

CIBA VISION[®] O₂OPTIX, AIR OPTIX AQUA and AIR OPTIX *for Astigmatism*¹ (lotrafilcon B) soft contact lenses are available in spherical and toric lens designs. The lens material is approximately 33% water and 67% lotrafilcon B, a fluoro-silicone containing hydrogel that is surface treated. Lenses contain the color additive copper phthalocyanine, a light blue handling tint which makes them easier to see when handling. This breakthrough lens material provides a high level of oxygen to the eyes and has been surface treated to wet with the tears.

• Lens Properties

- Specific Gravity: 1.08
- Refractive Index (hydrated): 1.42
- Light Transmittance: ≥ 96%
- Oxygen Permeability (Dk): 110 x 10⁻¹¹ (cm²/sec)
(ml O₂/ml x mm Hg),
measured at 35°C
(intrinsic Dk - Coulometric method)
- Water Content 33% by weight in normal saline

• Available Lens Parameters²

O₂OPTIX & AIR OPTIX AQUA (spherical)

- Chord Diameter: 14.2 mm
- Center Thickness: 0.080 mm @ -3.00D
(varies with power)
- Base Curve: 8.6 mm
- Powers: +6.00D to -10.00D
(0.25D steps to -8.00D;
0.50D steps from -8.50D to -10.00D)

AIR OPTIX *for Astigmatism*

- Chord Diameter: 14.5 mm
- Center Thickness: 0.102 mm @ -3.00D
(varies with power)
- Base Curve: 8.7 mm
- Powers: Plano to -6.00D (0.25D steps)
Cylinder: -0.75, -1.25, -1.75, -2.25
Axis: Full circle, 10° steps

¹May also be labeled as O₂OPTIX[®] *for Astigmatism*.

²Check for actual product availability as additional parameters may be introduced over time.

- **Actions**

When hydrated and placed on the cornea O₂OPTIX, AIR OPTIX AQUA and AIR OPTIX *for Astigmatism* (lotrafilcon B) contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

- O₂OPTIX and AIR OPTIX AQUA (lotrafilcon B) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.
- AIR OPTIX *for Astigmatism* (lotrafilcon B) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to 6.00 diopters (D) or less of astigmatism.

The lenses may be prescribed for daily wear or extended wear for up to 6 nights with removal for disposal, or cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.

See Warnings for information about the relationship between wearing schedule and corneal complications.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS & ADVERSE EFFECTS

For additional important prescribing and safety information, refer to the Package Insert that is printed in the back of this guide.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of lotrafilcon B contact lenses, please notify CIBA VISION Corporation, **Technical Consultation at 1-800-241-7468.**

FITTING GUIDELINES

Please see the appropriate sections of this booklet that contain guidelines for spherical, toric, and monovision fitting techniques.

FITTING GUIDELINES (Spherical Lenses)

1. Patient Selection

The patient characteristics necessary to achieve success with O₂OPTIX and AIR OPTIX AQUA lenses are similar to those for other spherical soft contact lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear.

The following procedures should be followed when fitting O₂OPTIX and AIR OPTIX AQUA lenses. For additional tips on fitting the monovision patient refer to the section *Monovision Fitting Guidelines*.

2. Pre-fitting Examination

A pre-fitting examination is necessary to:

- assess the patient's motivation, physical state and willingness to comply with instructions regarding hygiene and wear schedule
- make ocular measurements for initial contact lens parameter selection
- collect baseline clinical information to which post-fitting examination results can be compared

A pre-fitting examination should include:

- a thorough case history
- a spherocylindrical refraction
- keratometry
- tear assessment
- biomicroscopy

3. Trial Lens Evaluation

A. Lens Base Curve Selection:

A well-fitted lens provides good movement, centration, and comfort. This can be achieved for the majority of patients with the 8.6 mm base curve.

B. Initial Lens Power Selection

The initial power selection should be as close as possible to the patient's prescription after taking into account spherical equivalent and vertex calculations, if necessary.

Spherical Equivalent Calculation

To determine initial lens power, convert the spherocylindrical spectacle Rx to its spherical equivalent as follows:

Spherical Equivalent = Sphere power + 1/2 (Cylinder Power)

Example: **Spectacle Rx:** **-4.50D -1.00 x 180**
 Spherical equivalent : **-4.50D + (-0.50D) = -5.00D**

Vertex Distance Conversion

If the spherical equivalent is greater than $\pm 4.00D$, a vertex distance correction is necessary (see *Vertex Distance Conversion Chart*) to determine the lens power required at the corneal plane.

Example: **Spectacle Rx:** **-4.50D -1.00 x 180**
 Spherical equivalent: **-4.50D + (-0.50D) = -5.00D**
 Vertex compensation: **-4.75 (initial lens power)**

C. Lens Fit Assessment

Allow the lenses to settle on the eyes for approximately **5 to 10 minutes**. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

Evaluate the fit and movement of the lenses on the eye. The **Push-Up Test**, as described below, is an important part of the lens evaluation. The following guidelines will be helpful in fit evaluation:

Characteristics of a Well-Fitted Lens

A well-fitted O₂OPTIX and AIR OPTIX AQUA (lotrafilcon B) contact lens satisfies the following criteria:

1. **Good centration and full corneal coverage** in all fields of gaze.
2. **Sufficient lens movement to allow tear exchange** under the lens during a blink in primary or up gaze.
3. **Satisfactory Push-Up Test**
 - This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.
 - A well fitted lens will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.
4. **Good comfort and stable visual response** (with over refraction).

Characteristics of a Tight (Steep) Lens Fit

A tight or steep fit should not be dispensed. If a lens fit is judged to be too steep a flatter lens (larger base curve), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

1. Insufficient or no lens movement during a blink in primary or upgaze.
2. Unsatisfactory Push-Up Test
 - **A tight fitting lens will resist movement.** If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
3. Good centration.
4. Good comfort.
5. Fluctuating vision between blinks.

Characteristics of a Loose (Flat) Lens Fit

If a lens fit is judged to be too flat, a steeper lens (smaller base curve), if available, should be evaluated. A loose lens fit would display some or all of the following characteristics:

1. Lens edge standoff. Even minor lifting of the edge indicates a loose fitting lens.
2. Reduced comfort. This finding is often the only signal of a loose fitting lens. If initial comfort doesn't improve quickly, try a steeper base curve, if available.
3. Excessive lens movement during the blink in primary or upgaze.
 - A loose fitting lens will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often times return lower than its original position.
4. Poor centration with limbal exposure on exaggerated eye movement.
5. Vision may be blurred after the blink.

General Fitting Tips

- Trial fitting of the individual eye is strongly recommended.
- A well fitting lens will show movement of 0.1 to 0.5 mm.
- When prescribing lotrafilcon B lenses for **extended wear**, it is important to **reevaluate** the lens fit for adequate movement at various times after the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens from sleeping, as well as at other times of the day. If the fit is judged to be too tight or steep, the patient must be refit into a lens that provides the criteria of a well-fitted lens.

D. Final Lens Power Determination

After the characteristics of a well fitted lens have been satisfied, conduct a **spherical over-refraction** to determine the proper lens power to be dispensed.

Example:	Diagnostic lens:	-4.50
	Over-refraction:	-0.25
	Final lens power:	-4.75

FITTING GUIDELINES (Toric Lenses)

The geometry of an AIR OPTIX *for Astigmatism* lens is a prism ballast design. The prism ballast design uses a toric geometry on one surface of the lens and spherical on the opposite. Stabilization is achieved by the prism at the vertical meridian on the front surface (dynamic stabilization) and with cylinder power parameters on the back surface.

To aid the fitting process, AIR OPTIX *for Astigmatism* lenses feature scribe lines on the front lens surface to enable assessment of the lens orientation. These lines are at 3, 6 and 9 o'clock positions approximately 1.0mm in from the lens edge, with the 6 o'clock scribe line being slightly wider. The lens orientation findings are then used for calculation of axis compensations.

1. Patient Selection

The patient characteristics necessary to achieve success with AIR OPTIX *for Astigmatism* lenses are similar to those for spherical lenses.

A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear.

The following procedures should be followed when fitting AIR OPTIX *for Astigmatism* lenses. For additional tips on fitting the monovision patient refer to the section *Monovision Fitting Guidelines*.

2. Pre-fitting Examination

A pre-fitting examination is necessary to:

- determine whether a patient is a suitable candidate for contact lenses in general (see package insert, **Indications** and **Contraindications**).
- determine whether a patient is astigmatic to a degree requiring a toric visual correction
- make ocular measurements for initial contact lens parameter selection
- collect baseline clinical information to which post-fitting examination results can be compared

A pre-fitting examination should include:

- a thorough case history
- a spherocylindrical refraction
- keratometry
- tear assessment
- biomicroscopy

3. Fitting Methods

The following method is recommended for fitting AIR OPTIX *for Astigmatism* lenses to maximize success. This method allows for an extended trial period outside the office which will help the eye care professional to minimize chair time, reduce trial lens usage and inventories, as well as increase the accuracy of final lens orientation and the final multipack prescription.

Trial Period Method

- a) Make initial base curve selection if more than one available.
- b) Determine the appropriate sphere and cylinder power.
- c) Select cylinder axis based on spectacle prescription - assume no rotation.
- d) Place trial lens on the eye. Order trial lens if it is not in office inventory - having the correct lens allows the patient to experience good vision during the trial period.
- e) Evaluate fit, vision, and lens orientation.
- f) Dispense lens if characteristics of a **Well-Fitted Lens** are satisfied.
- g) **Reevaluate fit, vision, and lens orientation at the end of the trial period (typically a few days to a week).**
- h) Order multipack after fitting adjustments, if any, are made to satisfy the characteristics of a **Well-Fitted Lens**.

The following alternatives are offered to describe the more traditional methods of fitting lenses. While these methods are adequate to use, they can lead to an increase in chair time, trial lens usage, and multipack purchases as the fit and vision of the lens are refined.

Empirical Method

- a) Make initial base curve selection if more than one available.
- b) Determine the appropriate sphere and cylinder.
- c) Select the cylinder axis assuming zero rotation.
- d) Order multipack.
- e) Evaluate fit, vision, and lens orientation.
- f) Dispense lens if characteristics of a **Well-Fitted Lens** are satisfied.
- g) Reorder multipacks if adjustments are made.

In Office Trial Lens Fitting Method

- a) Make base curve selection if more than one available.
- b) Select diagnostic lens with similar sphere, cylinder power and axis as spectacle prescription.
- c) Evaluate fit, vision, over-refraction, and lens orientation.
- d) Order multipack if characteristics of a **Well-Fitted Lens** are satisfied.
- e) Reorder multipack if further adjustments are necessary.

NOTE: For information on fitting the monovision wearer with toric lenses, please refer to the monovision fitting guidelines.

4. Initial Base Curve Selection

- A **Well-Fitted Lens** provides **good movement, centration, and comfort with the available 8.7 base curve.**

5. Initial Lens Power Selection

Spherical Lens Power:

- To determine the initial lens spherical power, use the spherical component of the spectacle prescription in minus cylinder form.
- If this spherical component is greater than $\pm 4.00D$, a vertex distance correction is necessary. This will determine the spherical lens power required at the corneal plane.

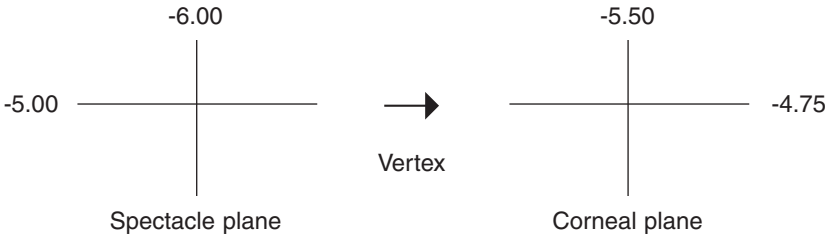
Cylinder Lens Power:

Up to four cylinder powers may be available for AIR OPTIX *for Astigmatism* contact lenses. When available, these four powers will normally allow correction of -0.75 to -3.00 diopters of astigmatism.

Select AIR OPTIX *for Astigmatism* cylinder power according to the chart below:

<u>Refraction Vertexed Cylinder Power</u>	<u>AIR OPTIX <i>for Astigmatism</i> Cylinder Power</u>
-0.75	-0.75
-1.00	-0.75
-1.25	-1.25
-1.50	-1.25
-1.75	-1.75
-2.00	-1.75
-2.25	-2.25
-2.50	-2.25
-2.75	-2.25
-3.00	-2.25

Note: If the combination of sphere power and cylinder power is greater than $\pm 4.00D$, vertex distance compensation must be performed for each power meridian.



Example:

Spectacle Rx: $-5.00 - 1.00 \times 180$ (vertex distance = 12 mm)

Corneal Plane Rx: $-4.75 - 0.75 \times 180$

Toric Rx: $-4.75 - 0.75 \times 180$ (assuming no rotation)

- When the difference between the cylinder correction at the corneal plane and the selected cylinder to fit the patient differs by 0.50D or more, it is necessary to make a compensation to the spherical component using the following formula:

$\frac{\text{Corneal plane cylinder} - \text{Selected cylinder}}{2}$	=	Spherical Power Compensation
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Example:

Spectacle Rx: $-4.50 - 1.50 \times 180$

Corneal Plane Rx: $-4.25 - 1.25 \times 180$

Selected cylinder power: $-0.75D$

Spherical adjustment needed = $[-1.25 - (-0.75)] / 2 = -0.25$

Toric: $-4.50 - 0.75 \times 180$ (assuming no rotation)

6. *Lens Fit Evaluation*

- a) Allow the lenses to settle on the eyes for approximately **5 to 10 minutes**. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate with the patient's tears, replacing the buffered, isotonic saline which was in the foil pack.
- b) AIR OPTIX *for Astigmatism* lenses achieve rotational stability on the eye in just **30 seconds**.
- c) Evaluate the fit of the lenses on the eye. The **Push-Up Test**, as described below is an important part of the lens evaluation. The following guidelines will be helpful in fit evaluation:

Characteristics of a Well-Fitted Lens

A well-fitted AIR OPTIX *for Astigmatism* (Iotrafilcon B) contact lens satisfies the following criteria:

1. Full corneal coverage and good centration (no limbal exposure).
2. Sufficient lens movement to allow tear exchange under the lens during blink in primary or upgaze

Push-Up Test:

- **This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.**
 - **A well fitted lens will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.**
3. Good comfort.
 4. Acceptable visual acuity with over-refraction.

Characteristics of a Tight (Steep) Lens Fit

A tight or steep fit should not be dispensed. If a lens fit is judged to be too steep a flatter lens (larger base curve radius), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

1. Good centration.
2. Insufficient or no lens movement during a blink in primary or upgaze.

Push-Up Test:

- **A tight fitting lens will resist movement. If successfully nudged upward, the lens may remain decentered or return slowly to its original position.**
3. Good comfort.
 4. Blurred vision between blinks.

Characteristics of a Loose (Flat) Lens Fit

If a lens fit is judged to be too flat a steeper lens (smaller base curve radius), if available, should be evaluated. A loose lens fit would display some or all of the following characteristics:

1. Decentration.
2. Excessive lens movement during a blink in primary or upgaze.

Push-Up Test:

- **A loose fitting lens will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often times return lower than its original position.**
3. Reduced comfort.
 4. Lens edge standoff.
 5. Blurred vision immediately after the blink.

7. Initial Lens Orientation Evaluation

A. No Rotation

When the scribe lines orient vertically, **the cylinder axis of the lens that is dispensed or ordered should be the same as the spectacle refractive axis** - not the trial lens axis.

Contact lens cylinder axis	=	Spectacle refractive axis
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B. Clockwise Rotation

When the scribe lines rotate clockwise as observed looking at the patient, (i.e., temporally for the right eye, nasally for the left eye), **add the degree of rotation to the spectacle refractive axis** - not the trial lens axis.

Spectacle refractive axis + Trial lens rotation	=	Axis to order
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Example:

Spectacle Rx: -2.50 -0.75 x 160

Diagnostic Lens: -2.00 -0.75 x 170

Over-refraction: -0.50 sphere

Orientation: 10 degrees clockwise (add) (160 + 10)

Final power to order: -2.50 -0.75 x 170

C. Counterclockwise Rotation

When the scribe lines rotate counterclockwise, **subtract the degree of rotation from the spectacle refractive axis - not the trial lens axis.**

$$\text{Spectacle refractive axis} - \text{Trial lens rotation} = \text{Axis to order}$$

Example:

Spectacle Rx: -2.75 -0.75 x 180

Diagnostic Lens: -2.00 -0.75 x 010

Over-refraction: -0.75 sphere

Orientation: 10 degrees counterclockwise (subtract) (180-10)

Final power to order: -2.75 -0.75 x 170

- **NOTE:** Occasionally when a cylinder axis compensation is made for orientation, the result may fall outside the traditional range of 0 to 180 degrees. In this case, the axis in accepted notation will be the difference between the **absolute value** determined and 180 degrees.

Example 1:

Spectacle Rx cylinder: x 170

Orientation: 20 degrees clockwise

Axis calculation: $170 + 20 = 190$

(The 190 degrees is outside the traditional axis range)

Difference: $190 - 180 = 10$

Axis to order: x 010

Example 2:

Spectacle Rx cylinder: x 010

Orientation: 20 degrees counterclockwise

Axis calculation: $10 - 20 = -10$

Difference: $180 - |-10| = 170$

(The -10 degrees is outside the traditional axis range)

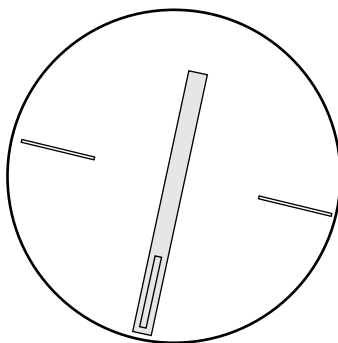
Axis to order: x 170

- **NOTE:** Scribe marks on dispensed lenses must be at the same orientation as the trial lenses. Record rotation compensation as part of the final Rx.

D. Scribe Lines

To view the scribe lines, the following tips may be helpful:

- The first step is to narrow the slit lamp beam to approximately 0.5 mm in a horizontal orientation. Focus the beam on the lens surface at the 6 o'clock position.
- Slowly move the beam in an up and down fashion. As the beam passes near and through the scribe marks it will be easy to see in retro illumination.
- Once the scribe line is located, rotate the light beam so it is parallel to the 6 o'clock scribe mark, ensure the light beam passes through the center of the pupil, and measure the amount of lens rotation. Scribe lines are also located at 3 and 9 o'clock.



8. Initial Visual Evaluation

The visual result is evaluated by first performing a spherical over-refraction and then measuring visual acuity. If visual acuity is acceptable, the determination of lens power required after the over-refraction will be uncomplicated.

Example:

Diagnostic lens: -2.00 -1.25 x 180

Over-refraction: -0.50 sphere

Final power to order: -2.50 -1.25 x _____ *

If the spherical over-refraction does not yield acceptable vision proceed to perform a spherocylindrical over-refraction. For the resultant lens power to order from this over-refraction call **Technical Consultation in the U.S.A. at 1-800-241-7468, or visit www.virtualconsultant.cibavision.com.**

*Determination of final cylinder axis to order will be made after compensation for lens orientation.

FITTING GUIDELINES (Monovision)

Patient Selection

A. Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. Patients with reduced visual acuity, such as the amblyopic patient, may not be a good candidate for monovision.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it must 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 requirements for a driver's license with monovision correction should not drive with this correction. An additional over-correction can be prescribed to improve vision.

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 must 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 compared to spectacle bifocals.

Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used:

A) Ocular Preference Determination Methods

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

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

B) Refractive Error Method

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

C) Visual Demands Method

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

Example:

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

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.

Examples:

- **Emmetrope:** A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye would be without a lens.
- **Bilateral myope:** A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.
- **Unilateral astigmat:**

a) Emmetropic in one eye, astigmatic in the other

<u>Spectacle Rx</u>	<u>Potential Monovision Rx</u>
O.D. Plano	Uncorrected for distance
O.S. -1.00 -1.00 x 090	+0.50 -1.00 x 090 for near
Add: +1.50	

b) Myopic in one eye, astigmatic in the other

<u>Spectacle Rx</u>	<u>Potential Monovision Rx</u>
O.D. -1.50	Uncorrected for near
O.S. -2.00 -1.75 x 090	-2.00 -1.75 x 090 for distance

Amblyopia

The amblyopic patient may not be a good candidate for monovision.

Astigmatism

Patients with less than 1.50 diopters of astigmatism might be successfully fit in O₂OPTIX and AIR OPTIX AQUA spherical lenses.

Patients with ≥ 0.75 diopters of astigmatism might be good candidates for monovision using AIR OPTIX *for Astigmatism* lenses (check available cylinder powers).

- Determine which eye to use for the near prescription (see Eye Selection, A-C, above)
- Add the appropriate near add power to the spherical component of the astigmatic prescription for that eye.

Example: <u>Spectacle Rx</u>	<u>Potential Monovision Rx</u>
O.D.: -2.50 - 1.00 x 180	-2.50 -0.75 x 180 for distance
O.S.: -3.00 - 1.75 x 165	-2.00 -1.75 x 165 for near
Add: +1.00	
Dominant eye: O.D.	

Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

Trial Lens Fitting

A trial lens fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the General Fitting Guidelines and Base Curve Selection described earlier in the guide.

Case history and standard clinical evaluation procedures should be used to determine the suitability of monovision. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed, should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After evaluating the patient's performance under the above conditions, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

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

Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a few minutes or for several weeks. The longer these symptoms persist, the poorer the chance for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses 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 is recommended that patients 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 only drive under optimal driving conditions. After adaptation, and success with these activities, the patient should be able to drive under other conditions with caution.

Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below:

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.
- Have supplemental spectacles to wear over the monovision contact lenses for specific visual tasks. This is particularly applicable for those patients who cannot meet driver's licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs. All patients should be supplied with a copy of the **Patient Instruction Booklet**, which contains important instructions for the monovision wearer. You can obtain copies of the instruction book by contacting **a customer service representative, in the USA at 1-800-241-5999**.

DISPENSING VISIT

To help ensure patient success the following steps should be conducted with each patient, even if they have previously worn contact lenses. Even experienced wearers are prone to develop bad habits over time.

Lotrafilcon B lenses are supplied sterile in foil sealed blister pack containers. Open the foil pack by peeling back the foil lidding material and gently slide the lens out of the container with your finger or pour the lens onto the palm of your clean hand.

Conduct the following steps with each patient, even if they have previously worn contact lenses:

A. *Verification of Lens Fit*

Evaluate lens fit and visual response with the lens on the eye. The criteria of a well-fitted lens should be met and the patient's visual acuity should be acceptable. If not, the patient should be refitted with a more appropriate lens.

B. *Hygiene and Lens Handling Instructions*

Good hygiene and proper lens handling are important factors in achieving safe, comfortable lens wear. Instruct the patient on hygiene and handling of lenses. Patients who are unable to place and remove lenses should not be provided with them.

C. *Lens Wear and Replacement Schedules (see Package Insert)*

Prescribe and explain the patient's wearing and replacement schedules.

D. *Lens Care Directions (see Package Insert)*

Recommend an appropriate cleaning, rinsing, and disinfecting system, and provide the patient with instructions for proper lens care, including the case.

E. *Additional Instructions*

Review the Package Insert

Provide the patient with all relevant information and precautions on the proper use of the lenses that are prescribed.

Provide the Patient Instruction Booklet for O₂OPTIX, AIR OPTIX AQUA and AIR OPTIX for Astigmatism Lenses.

Give the patient a copy of CIBA VISION **Patient Instruction Booklet** for O₂OPTIX, AIR OPTIX AQUA and AIR OPTIX *for Astigmatism* soft contact lenses. Review the contents so the patient clearly understands the prescribed lens wear, care, and replacement schedule. You can obtain copies of the instruction book by contacting a **customer service representative, in the USA at 1-800-241-5999.**

FOLLOW-UP EXAMINATIONS

Follow-up care is extremely important for continued successful contact lens wear and for monitoring the patient's ocular response to lens wear. Follow-up care should include:

- Case history, including questions to identify any problems related to contact lens wear
- Management of specific problems, if any, and
- A review with the patient of the lens wearing schedule, replacement schedule, and proper lens care and handling procedures.

NOTE: If you have prescribed an **extended wear** schedule, more frequent or additional visits may be necessary to monitor corneal health and to see that the characteristics of a **Well-Fitted Lens** are maintained.

Follow-Up Examination Procedures

- Prior to a follow-up examination, the contact lenses should be worn for at least four continuous hours.
- Record patient's symptoms, if any.
- Measure visual acuity monocularly and binocularly with the contact lenses in place.
- Perform an over-refraction to check for residual refractive error.
- With a biomicroscope, evaluate lens fitting characteristics and examine the lens surface for deposits.
- Remove the lenses and conduct a thorough biomicroscopic examination with fluorescein. Rinse eyes with saline before re-inserting lenses.
- Evert upper lids to determine condition of tarsal conjunctiva.
- Periodically perform keratometry and spectacle refractions. These results should be recorded to compare to the initial measurements.
- If any observations are abnormal, use professional judgment to manage the problem and restore the eye to optimal conditions. If visual requirements are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

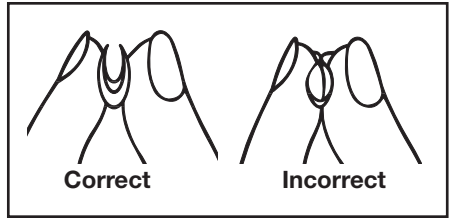
LENS HANDLING HINTS

Lens Insertion

- When about to place the lens on the eye, make sure the lens sits up on the placement finger. The finger should be dry so surface tension does not cause the lens to adhere to the finger.
- Check to see that the lens is right side out. A lens that is placed on the eye inside out may not feel comfortable or provide good vision.

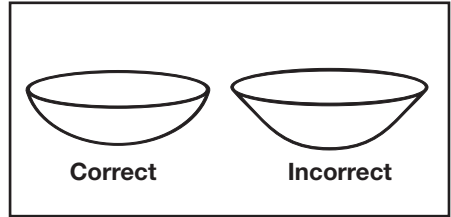
One way to do this is to place the lens between your thumb and index finger and squeeze the edges together gently.

- If the edges come together, the lens is right side out.
- If the edges turn outward, the lens is wrong side out. Carefully reverse it with your fingers.



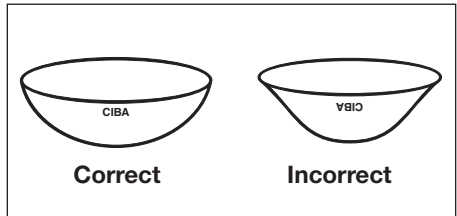
Another way is to place the lens on the tip of your index finger and check its shape.

- If the edge appears bowl-shaped, it is right side out.
- If the edge has a lip or flares outward, it is wrong side out and must be reversed.



A third way to tell if the lens is right side out is to look at the lens engravings at the edge of the lens.

- Place the lens on the tip of your index finger and hold it up against a light source.
- If the lens is right side out, you should be able to read "CIBA" at the edge of the lens. If the lens is inside out, the engravings will be reversed. Carefully turn the lens right side out with your fingers.



- Place the lens directly onto the cornea (placing it on the lower sclera can lead to the lens folding after a blink). While continuing to hold both lids in place, the patient should look down to seat the lens. The lids may then be released.

Lens Removal

- To remove the lens from the cornea, assure that the fingers are clean and dry.
- Slide the lens off the cornea (down or to the side) onto the sclera. This produces a fold in the lens, which assists in removal. With the index finger and thumb, gently pinch the lens off the eye.
- Remember to remove the same lens first (right or left), then the other lens. This helps avoid getting the lenses mixed up.
- It may be easier to remove contact lenses if you use rewetting drops (approved for use with soft lenses) recommended by the eye care professional 10 to 15 minutes before lens removal. This will also help prevent lens tearing during the removal process.

Care for a Sticking Lens

- If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. If the lens continues to stick, the patient should **immediately** consult the eye care professional.

IN OFFICE CARE OF TRIAL LENSES:

Eye care professionals should understand and educate contact lens technicians concerning proper use of trial lenses.

- Each contact lens is shipped sterile in a sealed blister pack containing phosphate buffered saline with or without 1% Copolymer 845 additive. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use.
- For fitting and diagnostic purposes, the **lenses should be disposed of after a single use and not be re-used from patient to patient.**

ADDITIONAL INFORMATION

CIBA VISION is pleased to assist with fitting or clinical questions regarding O₂OPTIX, AIR OPTIX AQUA and AIR OPTIX *for Astigmatism* contact lenses. Eye care professionals having questions or problems should contact the CIBA VISION Technical Consultation department, in the USA at 1-800-241-7468. To order O₂OPTIX, AIR OPTIX AQUA or AIR OPTIX *for Astigmatism* lenses contact your CIBA VISION sales representative or call Customer Service, in the USA at 1-800-241-5999.

IMPORTANT: This package insert is effective as of February, 2008 and applicable to the (lotrafilcon B) contact lenses described below. Please read carefully and keep this information for future use.

This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from CIBA VISION Corporation by calling CIBA VISION Customer Service at 1-800-241-5999 or download from our website at www.cibavision.com. CIBA VISION makes available a *Patient Instruction Booklet*, which is recommended to be given to patients.

Rx only

CAUTION: FEDERAL (UNITED STATES) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL.

PRODUCT DESCRIPTION

O₂OPTIX[®], AIR OPTIX[™] AQUA and AIR OPTIX[™] *for Astigmatism* (lotrafilcon B) soft contact lenses are made from a lens material that is approximately 33% water and 67% lotrafilcon B, a silicone containing hydrogel which is surface treated. Lenses contain the color additive copper phthalocyanine, a light blue handling tint, which makes them easier to see when handling.

• Lens Properties

- Specific Gravity: 1.08
- Refractive Index (hydrated): 1.42
- Light Transmittance: ≥ 96%
- Oxygen Permeability (Dk): 110 x 10⁻¹¹ (cm²/sec) (ml O₂/ml x mm Hg), measured at 35°C (intrinsic Dk - Coulometric method)
- Water Content: 33% by weight in normal saline

• Lens Parameters

- Diameter Range: 13.0 to 15.0 mm
- Power Range: -20.00 to +20.00D
- Base Curve Range: 8.0 to 9.2 mm

• Lens Parameters Available:

- O₂OPTIX & AIR OPTIX AQUA (spherical)**
- Chord Diameter: 14.2 mm
 - Center Thickness: 0.080 mm @ -3.00D (varies with power)
 - Base Curve: 8.6mm
 - Powers: +6.00D to -10.00D (0.25D steps to -8.00D; 0.50D steps from -8.50D to -10.00D)

AIR OPTIX *for Astigmatism*

- Chord Diameter: 14.5 mm
- Center Thickness: 0.102 mm @ -3.00D (varies with power)
- Base Curve: 8.7mm
- Powers: Plano to -6.00D (0.25D steps)
Cylinder: -0.75, -1.25, -1.75, -2.25
Axis: Full circle, 10° steps

ACTIONS

When hydrated and placed on the cornea, O₂OPTIX, AIR OPTIX AQUA and AIR OPTIX *for Astigmatism* (lotrafilcon B) contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

- O₂OPTIX and AIR OPTIX AQUA (lotrafilcon B) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.
- AIR OPTIX *for Astigmatism* (lotrafilcon B) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to 6.00 (D) or less of astigmatism.

The lenses may be prescribed for daily wear or extended wear for up to 6 nights of continuous wear with removal for disposal, or cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE lotrafilcon B contact lenses when any of the following exists:

- Inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease which may be exacerbated by or interferes with contact lens wear
- Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exaggerated by the wearing of contact lenses
- Allergy to an ingredient in a solution which must be used to care for the contact lenses
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear
- If eyes become red or irritated

WARNINGS

Advise patients of the following warnings pertaining to contact lens wear:

- **Serious eye injury, scarring of the cornea, and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. To reduce these risks, emphasize to the patient the need for strict compliance with the lens care regimen including hand washing, proper lens disinfection, cleaning of the lens case, wearing restrictions, wearing schedules, and follow-up visit schedules.**
- **Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Instruct patients at the dispensing visit and subsequent visits to immediately remove their lenses and promptly contact their eye care practitioner if they should experience eye discomfort, foreign body sensation, excessive tearing, vision changes, redness of the eye or other problems with their eyes.**
- **Non-compliance with the manufacturer's labeled lens care instructions may put the patient at significant risk of developing a serious eye infection.**
- **Tap water, distilled water, or homemade saline solution should NOT be used as a substitute for any component in the lens care process.**
The use of tap and distilled water has been associated with Acanthamoeba keratitis, a corneal infection that is resistant to treatment and cure.

- **Smoking increases the risk of corneal ulcers for contact lens users,^{3,4} especially when lenses are worn overnight or while sleeping.**
- **The risk of microbial keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses.³ The risk increases with the number of consecutive days that the lenses are worn between removals, even with the first overnight use.**

PRECAUTIONS

To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:

Special Precautions to the Eye Care Professional:

Due to the small number of patients enrolled in the clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently when selecting an appropriate lens design and parameters, the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, 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 evaluated on initial dispensing and monitored on an ongoing basis by the prescribing eye care professional.

The following patients may not be suitable candidates and/or may experience a higher rate of adverse effects associated with contact lens wear:

- **Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule or follow-up visit schedule.**
- **Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.**
- Fluorescein, a yellow dye, should not be used while the lenses are on the patient's eyes. The lenses may absorb this dye and become discolored. Whenever fluorescein is used, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Eye Care Professionals should carefully instruct patients about the following care regimen and safety precautions:

Handling Precautions:

- Be sure that before leaving the eye care professional's office the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear.
- **Always wash and rinse hands before handling lenses.**
- **REMOVE A LENS IMMEDIATELY** if an eye becomes red or irritated.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for O:OPTIX, AIR OPTIX AQUA and AIR OPTIX *for Astigmatism* Contact Lenses.
- Always handle lenses carefully. If a lens is dropped small particles or fibers may adhere to the lens surface which can irritate the eye. Lenses should be cleaned and disinfected prior to insertion or replaced with a sterile, fresh new lens.
- Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Lens Wearing Precautions:

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the *Care for a Sticking Lens* section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- The eye care professional should be consulted about wearing lenses during water sports 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.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Lenses should be disposed of and replaced according to the eye care professional's recommendations.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always keep a supply of replacement lenses on hand.
- Do not use lenses beyond the expiration date.

Solution Precautions:

- Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer's labeled lens care instructions with the patient (see Lens Care Directions).
- Only use fresh, unexpired lens care solutions recommended for use with soft contact lenses and follow directions in the product package inserts.
- If a lens is exposed to air while off the eye it may become dry, brittle, and permanently damaged. If this should occur, the lens should be discarded and replaced with a new one to avoid possible irritation or injury to the eye. Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn.
- Do not use thermal (heat) disinfection and do not heat lens care products.
- Saliva or anything other than the recommended solution for lubricating or wetting lenses should not be used with the lenses.

Lens Case Precautions:

- Contact lens cases can be a source of bacterial growth and require proper use, cleaning and replacement at regular intervals as recommended by the lens case manufacturer or eye care professional.

Other Topics to Discuss with Patients:

- Periodic eye examinations are extremely important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response. CIBA VISION recommends that patients see their eye care professional twice each year or as recommended by the eye care professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, and blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such medications accordingly and prescribe proper remedial measures.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Who Should Know That the Patient is Wearing Contact Lenses:

- Patients should inform their health care practitioners that they are wearing contact lenses.
- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that lenses not be worn.

It is strongly recommended that patients be provided with a copy of the O-PTIX, AIR OPTIX AQUA and AIR OPTIX for *Astigmatism Patient Instruction Booklet* available from CIBA VISION and understand its contents prior to dispensing the lenses.

ADVERSE EFFECTS

Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:

- Moderate to severe eye pain not relieved by removing the lens
- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging or itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

Patients should be instructed that if any of the above signs or symptoms are noticed, he or she should:

- **IMMEDIATELY REMOVE THE LENSES.**
- **If the discomfort or problem stops, then look closely at the lens(es):**
 - If the lens(es) in any way damaged, DO NOT put the lens(es) back on the eye. Discard damaged lens(es), and contact the eye care professional.
 - If the lens(es) have dirt, an eye lash or other foreign body on it, thoroughly clean, rinse, and disinfect prior to reinsertion.
- **If the discomfort or problem continues after removing lens(es) or upon reinsertion, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**
- The patient should be instructed **NOT** to use a new lens as self-treatment for the problem.
- **The patient should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.**

- Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegethism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of lotrafilcon B contact lenses, please notify: CIBA VISION Corporation, Technical Consultation in the USA at **1-800-241-7468**.

FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to lotrafilcon B contact lenses. For a detailed description of the fitting techniques, refer to the O-PTIX, AIR OPTIX AQUA and AIR OPTIX for *Astigmatism Professional Fitting and Information Guide*. Both the professional fitting guide and a patient instruction booklet are available free of charge from:

CIBA VISION Corporation
11460 Johns Creek Parkway
Duluth, GA, USA 30097
1-800-241-5999

LENS WEAR & REPLACEMENT SCHEDULES

The wearing and replacement schedule should be determined by the eye care professional.

- **Daily Wear** (less than 24 hours, while awake):
 - To avoid tendency of the daily wear patient: to overwear the lenses initially, stress the importance of adhering to a proper, initial wearing schedule. Normal daily wear of lenses assumes a minimum of 6 hours of non lens wear per 24 hour period.
 - It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.
- **Extended Wear** (greater than 24 hours, including while asleep):
 - The eye care professional should establish an extended wear period up to 6 continuous nights that is appropriate for each patient. Once the lens is removed, the patient's eyes should have a rest period with no lens wear of overnight or longer, as recommended by the eye care professional.
 - **It is suggested that new contact lens wearers first be evaluated on a daily wear schedule. If the patient is judged to be an acceptable extended wear candidate, the eye care professional may determine an extended wear schedule based upon the response of the patient.**
 - See **Warnings** for information about the relationship between wearing schedule and corneal complications.
- **Lens Replacement**
The replacement schedule is determined by the eye care professional based upon the patient's individual needs and physiological conditions. CIBA VISION recommends up to four week replacement for lotrafilcon B lenses or as recommended by the eye care professional.

LENS CARE DIRECTIONS

Patients must adhere to a recommended care regimen. Lenses must be cleaned, rinsed, and disinfected after removal and prior to reinsertion on the eye according to the instructions in the package inserts provided with the lens care products recommended by the eye care professional. Failure to follow the complete regimen in accordance with manufacturer's instructions in the package inserts may contribute to problems (see ADVERSE EFFECTS) and/or result in the development of serious ocular complications as discussed in WARNINGS.

Disposable Wear:

- No lens care is indicated, as lenses are discarded upon removal from the eye.
- Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

Replacement Wear:

- When removed between replacement periods lenses must be cleaned and disinfected prior to reinsertion or be discarded and replaced with a fresh lens.

Basic Instructions for Lens Cleaning and Disinfection:

When lenses are dispensed, the eye care professional should recommend an appropriate system of lens care and provide the patient with instructions according to the package labeling.

- The eye care professional should review the following instructions with the patient:
 - **Lenses must be cleaned, rinsed, and disinfected each time they are removed, for any reason.** If removed while the patient is away from the lens care products, the lenses may not be reinserted, but should be stored until they can be cleaned, rinsed, and disinfected.
 - **Cleaning** is necessary to remove mucus, film, and contamination from the lens surface. **Rinsing** removes all traces of the cleaner and loosened debris. **Disinfecting** is necessary to destroy remaining microorganisms.
 - Lenses must be cleaned, rinsed, disinfected, and stored in accordance with the package labeling of the lens care products recommended by the eye care professional.
 - CIBA VISION recommends a chemical (not heat) method of disinfection such as Clear Care® or AQUIFY® Multi-Purpose Solution.
 - Use of Unizyme®, an enzymatic cleaner, is optional and may be recommended by the eye care professional if warranted.
 - Lens compatibility with an abrasive type cleaner such as OPTI-CLEAN®* II has not been tested and is not recommended.
 - Heat disinfection has not been tested and is not recommended.
- **To help avoid serious eye injury from contamination:**
 - Always wash, rinse and dry hands before handling the lenses.
 - Use only fresh sterile solutions recommended for use with soft (hydrophilic) contact lenses. When opened, sterile non-preserved solutions must be discarded after the time specified in the label directions.
 - Do not use saliva, tap water, homemade saline solution, distilled water, or anything other than a recommended sterile solution indicated for the care of soft lenses.
 - Do not reuse solutions.
 - Use only fresh solutions for each lens care step. Never add fresh solution to old solution in the lens case.
 - Follow the manufacturer's instructions for care of the lens case.
 - Replace the lens case at regular intervals to help prevent case contamination by microorganisms that can cause eye infection.
- Never use a hard (rigid) lens solution unless it is also indicated for use with soft contact lenses. Corneal injury may result if hard (rigid) lens solutions not indicated for use with soft lenses are used in the soft lens care regimen.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn to avoid lens dehydration.
- Unless specifically indicated in the labeling, do not alternate, change, or mix lens care systems or solutions for any one pair of lenses. If in doubt as to solution suitability, consult the eye care professional.

*OPTI-CLEAN® is a registered trademark of Alcon Laboratories, Inc.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. If the lens continues to stick, the patient should IMMEDIATELY consult the eye care professional.

IN OFFICE USE OF TRIAL LENSES

Eye care professionals should educate contact lens technicians concerning proper use of trial lenses.

Each contact lens is shipped sterile in a blister pack containing phosphate buffered saline solution. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes, the lenses should be disposed of after a single use and not be re-used from patient to patient.

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should:

flush eyes immediately with tap water or fresh saline solution, remove the lenses and place them in the recommended storage solution, and call or visit the eye care professional or a hospital emergency room immediately.

HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic container containing isotonic phosphate buffered saline with or without 1% Copolymer 845 and is steam sterilized. The package is marked with the base curve, diameter, dioptic power, manufacturing lot number and expiration date. The package may also contain the product code LFB 110.

CIBA VISION Corporation
11460 Johns Creek Parkway
Duluth, Georgia USA 30097

www.cibavision.com
Date: February, 2008
Printed In: USA



*May also be labeled as O-OPTIX® for Astigmatism

†Check for actual product availability as additional parameters may be introduced over time

‡CLAO Journal, January 1996; Volume 22, November 1, pp. 30-37

§New England Journal of Medicine, September 21, 1989;321 (12), pp.773-783

D7408H/98448

Vertex Distance Conversion Chart

For minus lenses, read left to right; for plus lenses, read right to left.
(12 mm Vertex Distance)

-	+	-	+	-	+	-	+
4.00	3.87	7.50	6.87	12.00	10.37	19.00	15.50
4.25	4.00	7.62	7.00	12.50	10.75	19.25	15.62
4.50	4.25	7.75	7.12	12.75	11.00	19.25	15.75
4.75	4.50	7.87	7.25	13.00	11.25	19.75	16.00
5.00	4.75	8.00	7.37	13.50	11.50	20.00	16.12
5.12	4.87	8.12	7.50	13.75	11.75	20.25	16.25
5.37	5.00	8.25	7.62	14.00	12.00	20.50	16.50
5.50	5.12	8.50	7.75	14.25	12.25	20.75	16.62
5.62	5.25	8.75	8.00	14.75	12.50	21.00	16.75
5.75	5.37	9.00	8.25	15.00	12.75	21.25	17.00
5.87	5.50	9.25	8.37	15.50	12.75	21.75	17.25
6.00	5.62	9.50	8.62	15.75	13.25	22.25	17.50
6.12	5.75	9.75	8.75	16.25	13.50	22.50	17.75
6.37	5.87	10.00	9.00	16.75	13.75	23.00	18.00
6.50	6.00	10.25	9.12	17.00	14.00	23.50	18.25
6.62	6.12	10.50	9.25	17.25	14.25	23.75	18.50
6.75	6.25	10.75	9.37	17.62	14.37	24.25	18.75
6.87	6.37	11.00	9.62	18.00	14.50	24.75	19.00
7.00	6.50	11.25	9.75	18.12	14.75	25.00	19.25
7.12	6.62	11.50	10.00	18.50	15.00	25.50	19.50
7.37	6.75	11.75	10.25	18.75	15.25	26.00	19.75

LENS CARE PRODUCT CHART FOR SOFT CONTACT LENSES,

AOSEPT®

AOSEPT® Disinfecting Solution
AOSEPT® Disposable Lens Cup and Disc

Disinfecting solution
Lens case with neutralizing disc
for AOSEPT Disinfecting
Solution

Clear Care®

Hydrogen Peroxide based
solution for cleaning disinfecting,
& protein removal

AQuify®

Multi-Purpose Solution

Includes the PRO-GUARD™ Lens Case

Multi-purpose solution for
cleaning, rinsing, disinfecting
and storing.
The PRO-GUARD™ lens case is
made of a special plastic infused
with silver ions, a known
antibacterial agent that kills
germs and helps prevent lens
case contamination. The
PRO-GUARD™ lens case should
not be used by persons who are
allergic to silver or other metals.

Other CIBA VISION® Lens Care Products

AQuify® Long-Lasting Comfort Drops
Unizyme® Enzymatic Cleaner

Softwear® Saline
Miraflo® Extra Strength Daily Cleaner

Lubricating and rewetting
Enzymatic cleaner for contact
lens protein removal
Rinsing and storage
Cleaner



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