

# Professional Fitting and Information Guide

**AIR OPTIX\* AQUA, AIR OPTIX\* plus HydraGlyde\*,  
AIR OPTIX\* for Astigmatism and  
AIR OPTIX\* AQUA Multifocal (Iotrafilcon B)  
Soft Contact Lenses**

**For Daily Wear and Extended Wear up to 6 Nights**

**Rx only**

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

**Alcon®**

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## Table of Contents

INTRODUCTION.....	5
PRODUCT DESCRIPTION.....	5
Lens Properties.....	5
Available Lens Parameters.....	5
Actions.....	6
INDICATIONS (Uses).....	6
CONTRAINDICATIONS, WARNINGS, PRECAUTIONS & ADVERSE EFFECTS...	7
ADVERSE EFFECT REPORTING.....	7
LENS CARE DIRECTIONS.....	7
FITTING GUIDELINES (Spherical Lenses).....	8
Patient Selection.....	8
Pre-fitting Examination.....	8
Trial Lens Evaluation.....	8
Lens Base Curve Selection.....	8
Initial Lens Power Selection.....	8
Lens Fit Assessment.....	9
Final Lens Power Determination.....	10
FITTING GUIDELINES (Toric Lenses).....	11
FITTING GUIDELINES (Multifocal Lenses).....	18
FITTING GUIDELINES (Monovision).....	26
DISPENSING VISIT.....	30
FOLLOW-UP EXAMINATIONS.....	31
Follow-Up Examination Procedures.....	31
LENS HANDLING HINTS.....	31
Lens Insertion.....	31
Lens Removal.....	32
Care for a Sticking Lens.....	32
IN OFFICE CARE OF TRIAL LENSES.....	33
ADDITIONAL INFORMATION.....	33
VERTEX DISTANCE CONVERSION CHART.....	35
PRODUCT PACKAGE INSERT.....	36
LENS CARE PRODUCT CHART FOR SOFT CONTACT LENSES...	38

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## INTRODUCTION

Thank you for prescribing **ALCON® AIR OPTIX® AQUA, AIR OPTIX® plus HydraGlyde®, AIR OPTIX® for Astigmatism, and AIR OPTIX® AQUA Multifocal** (lotrafilcon B) soft contact lenses. The lenses may be worn for daily wear and extended wear for up to six continuous nights 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 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 **AIR OPTIX® AQUA, AIR OPTIX® plus HydraGlyde®, AIR OPTIX® for Astigmatism, and AIR OPTIX® AQUA Multifocal** (lotrafilcon B) contact lens patient.

## PRODUCT DESCRIPTION

**ALCON® AIR OPTIX® AQUA, AIR OPTIX® plus HydraGlyde®, AIR OPTIX® for Astigmatism, and AIR OPTIX® AQUA Multifocal** (lotrafilcon B) soft contact lenses are available in spherical, toric, and multifocal 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

- Refractive Index (hydrated): 1.42
- Light Transmittance:  $\geq 96\%$
- Oxygen Permeability (Dk):  $110 \times 10^{-11} \text{ (cm}^2\text{/sec)(ml O}_2\text{/ml x mm Hg)}$ , measured at 35° C (intrinsic Dk - Coulometric method)
- Water Content 33% by weight in normal saline

### Available Lens Parameters<sup>1</sup>

#### AIR OPTIX® AQUA contact lenses

- Chord Diameter: 14.2 mm
- Center Thickness: 0.08 mm @ -3.00D (varies with power)
- Base Curve: 8.6mm
- Powers: Minus Powers: -0.25 to -8.00D (0.25D steps);  
-8.50 to -10.00D (0.50D steps)  
Plus Powers: +0.25 to +6.00D (0.25D steps)

#### AIR OPTIX® plus HydraGlyde® contact lenses

- Chord Diameter: 14.2 mm
- Center Thickness: Varies with power (0.08 mm @ -3.00D)
- Base Curve: 8.6mm
- Powers: Minus Powers: -0.25 to -8.00D (0.25D steps);  
-8.50 to -12.00D (0.50D steps)  
Plus Powers: +0.25 to +6.00D (0.25D steps);  
+6.50 to +8.00D (0.50D steps)

<sup>1</sup> Check for actual product availability as additional parameters may be introduced over time.

## <sup>2</sup> **AIR OPTIX\* for Astigmatism<sup>2</sup> contact lenses**

- Chord Diameter: 14.5 mm
- Center Thickness: 0.102 mm @ -3.00D (varies with power)
- Base Curve: 8.7 mm
- Powers: Minus Powers: plano to -6.00D (0.25D steps);  
-6.50 to -10.00D (0.50D steps)  
Plus Powers: +0.25 to +6.00D (0.25D steps)  
Cylinder power: -0.75, -1.25, -1.75, -2.25  
Axis: full circle (10° steps)

## **AIR OPTIX\* AQUA Multifocal contact lenses**

- Chord Diameter: 14.2 mm
- Center Thickness: 0.08 mm @ -3.00D (varies with power)
- Base Curve: 8.6 mm
- Powers: Minus Powers: plano to -10.00D (0.25D steps)  
Plus Powers: +0.25 to +6.00D (0.25D steps)  
ADD: LO, MED, HI

NOTE: Hereafter, lotrafilcon B spherical, toric, and multifocal lenses may be referred to as lotrafilcon B contact lenses unless product distinction is necessary.

## **Actions**

When hydrated and placed on the cornea, lotrafilcon B contact lenses act as a refracting medium to focus light rays on the retina.

## **INDICATIONS (Uses)**

**AIR OPTIX\* AQUA** and **AIR OPTIX\* plus HydraGlyde\* (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 and up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

**AIR OPTIX\* for Astigmatism (lotrafilcon B)** toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and up to 6.00 diopters (D) or less of astigmatism.

**AIR OPTIX\* AQUA Multifocal (lotrafilcon B)** multifocal soft contact lenses are indicated for the optical correction of presbyopia, with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters 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 and frequent replacement, as recommended by the eye care professional.

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

<sup>2</sup> May also be labeled as O<sub>2</sub>OPTIX for Astigmatism

## **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 ALCON® (lotrafilcon B) contact lenses, please notify Alcon Medical Safety in the USA at 1-800-757-9780.

## **LENS CARE DIRECTIONS**

For general information about contact lens care, refer to the ***Package Insert*** that is printed in the back of this guide.

## **FITTING GUIDELINES**

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

## **FITTING GUIDELINES (Spherical Lenses)**

### **1. Patient Selection**

The patient characteristics necessary to achieve success with **AIR OPTIX\* AQUA** and **AIR OPTIX\* plus HydraGlyde\*** (lotrafilcon B) soft contact 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 **AIR OPTIX\* AQUA** and **AIR OPTIX\* plus HydraGlyde\*** (lotrafilcon B) contact lenses. For additional tips on fitting the monovision patient refer to the section **FITTING GUIDELINES (MONOVISION)**.

### **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 +  $\frac{1}{2}$  (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.

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

### 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 **AIR OPTIX\* AQUA** and **AIR OPTIX\* plus HydraGlyde\*** (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 upward 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 upward gaze.
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 upward gaze.
  - 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-fitted lens will show movement of 0.1 to 0.5 mm.
- When prescribing lotrafilcon B contact 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:**

<b>Diagnostic lens:</b>	<b>-4.50D</b>
<b>Over-refraction:</b>	<b>-0.25</b>
<b>Final lens power:</b>	<b>-4.75D</b>

## FITTING GUIDELINES (Toric Lenses)

The geometry of an **AIR OPTIX\* for Astigmatism** (Iotrafalcon B) toric contact 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** contact lenses feature three 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 1.0 mm in from the lens edge, with the 6 o'clock scribe line being slightly wider than the others. 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** contact 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 **FITTING GUIDELINES (MONOVISION)**.

### 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 the **Package Insert**, **INDICATIONS** and **CONTRAINDICATIONS** sections)
- 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** soft contact 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 Rx
- 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 *FITTING GUIDELINES (MONOVISION)* section.**

### **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 Rx 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.

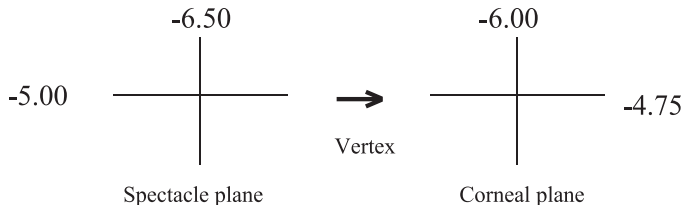
## Cylinder Lens Power:

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** contact lens cylinder power according to the chart below:

Refraction Vertexed	AIR OPTIX* for Astigmatism contact lens
Cylinder Power	Cylinder Power
-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:**  $-5.00D - 1.50 \times 180$  (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:

**Corneal plane cylinder – Selected cylinder = Spherical Compensation**

**Example:**

<b>Spectacle Rx:</b>	-4.50 -1.50 x 180
<b>Corneal Plane Rx:</b>	-4.25 -1.25 x 180
<b>Selected cylinder power:</b>	-0.75D
<b>Spherical adjustment needed</b>	$= -1.25 - (-0.75) / 2 = -0.25$
<b>Toric Rx:</b>	-4.50 -0.75 x 180 (assuming no rotation)

## 6. Lens Fit Evaluation

- 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.
- AIR OPTIX\* for Astigmatism** (lotrafilcon B) contact lenses achieve rotational stability on the eye in just **30 seconds**.
- 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** (lotrafilcon B) contact lens satisfies the following criteria:

- Full corneal coverage and good centration (no limbal exposure)
- Sufficient lens movement to allow tear exchange under the lens during blink in primary or upward gaze

### **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.**
- Good comfort
  - 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), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

- Good centration
- Insufficient or no lens movement during a blink in primary or upward gaze

**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), 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 upward gaze

**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:**

<b>Spectacle Rx:</b>	-2.50 -0.75 x 160
<b>Diagnostic Lens:</b>	-2.00 -0.75 x 170
<b>Over-refraction:</b>	-0.50 sphere
<b>Orientation:</b>	10 degrees clockwise (add) (160 + 10)
<b>Final power to order:</b>	-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.

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

<b>Spectacle Rx:</b>	-2.75 -0.75 x 180
<b>Diagnostic Lens:</b>	-2.00 -0.75 x 010
<b>Over-refraction:</b>	-0.75 sphere
<b>Orientation:</b>	10 degrees counterclockwise (subtract) (180-10)
<b>Final power to order:</b>	-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:**

<b>Spectacle Rx cylinder:</b>	<b>x 170</b>
<b>Orientation:</b>	<b>20 degrees clockwise</b>
<b>Axis calculation:</b>	<b>170 + 20 = 190</b>
(The 190 degrees is outside the traditional axis range)	
<b>Difference:</b>	<b>190 - 180 = 10</b>
<b>Axis to order:</b>	<b>x 010</b>

**Example 2:**

<b>Spectacle Rx cylinder:</b>	<b>x 010</b>
<b>Orientation:</b>	<b>20 degrees counterclockwise</b>
<b>Axis calculation:</b>	<b>10 - 20 = -10</b>
<b>Difference:</b>	<b>180 -  -10  = 170</b>
(The -10 degrees is outside the traditional axis range)	
<b>Axis to order:</b>	<b>x 170</b>

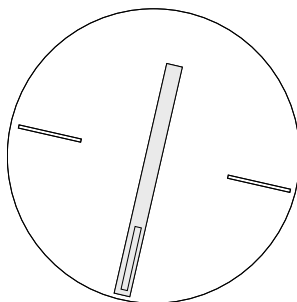
- **NOTE:** Scribe marks on dispensed lenses must be at the same orientation as the trial lenses. Record rotation compensation as part of the final Rx.



## 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 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:

<b>Diagnostic lens:</b>	-2.00 -1.25 x 180
<b>Over-refraction:</b>	-0.50 sphere
<b>Final power to order:</b>	-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 1-800-757-9780 or visit [www.virtualconsultant.alcon.com](http://www.virtualconsultant.alcon.com).**

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

## FITTING GUIDELINES (Multifocal Lenses)

The **ALCON® AIR OPTIX® AQUA Multifocal** (lotrafilcon B) soft contact lens is a progressive aspheric simultaneous vision soft contact lens available in three ADD powers [low (LO), medium (MED) and high (HI)]. For each lens the near and intermediate powers are concentrated primarily in the central portion of the optical zone while distance power is contained in the surrounding portion. The continuous changes in power across the surface of the lens allow patients requiring a reading addition of up to + 3.00 D to see clearly at far, intermediate, and near distances.

Achieving high success with **AIR OPTIX® AQUA Multifocal** contact lenses is dependent on several factors, including the patient's motivation, expectations and visual wearing environment, as well as your skill in optimizing the lens powers to balance binocular performance at distance and near. The information in this guide is designed to provide you with the tools to manage your presbyopic patients through each stage of the process from the initial case history to post-fitting follow-up.

### 1. Pre-fitting Examination

**A pre-fitting examination is necessary to:**

- Determine whether a patient is a suitable candidate for **AIR OPTIX® AQUA Multifocal** soft contact lenses
- 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
- Detailed assessment of patient's individual visual demands
- Understanding of patient's objectives for lens wear and expectations
- A distance spherocylindrical refraction and near ADD determination
- Eye dominance determination and measurement of pupil diameter
- Keratometry
- Tear assessment
- Biomicroscopy

Note: The importance of a thorough case history should not be underestimated. The information gained through careful listening and probing will help greatly in satisfying each patient's unique needs.

### 2. Patient Selection

The eye care professional should weigh several factors when considering patient selection for an **AIR OPTIX® AQUA Multifocal** (lotrafilcon B) soft contact lens fitting. When fitting a lens intended to correct for presbyopia, it is especially important to evaluate the particular visual needs, objectives, lifestyle and expectations of the individual patient. Prospective candidates may include current contact lens wearers, former wearers, and persons with no previous wear history. For former wearers it is important to determine the cause for discontinuation.

Good success has been achieved with **AIR OPTIX\* AQUA Multifocal** soft contact lenses in all three wearing groups.

There are two general categories of candidates based on anticipated usage: those who seek to wear their lenses as their principal means of vision correction, and those who wish to integrate the use of their contact lenses with spectacles. The integrative user often seeks to wear their lenses for sports or other occasional activities while reverting to spectacles under poor lighting or otherwise demanding vision conditions. In general, even the part-time user does not require more than a few moments re-adaptation time following an interval of no lens wear.

While candidates with greater than 1.00 diopter of refractive error have often been thought of as better candidates than those with low error or emmetropia, this is a generalization that often does not hold true for a given individual. Success is influenced by many factors and the eye care professional is encouraged to offer **AIR OPTIX\* AQUA Multifocal** (lotrafilcon B) soft contact lenses to all interested presbyopic patients who satisfy the standard requirements for soft contact lens wear.

To summarize patient selection, the characteristics of “ideal candidates” and those that will be more difficult to fit are listed below:

#### **Ideal Candidates**

- Refractive cylinder  $\leq 1.00$  D
- Near add  $> +0.75$  D
- Attainable visual demands that do not depend upon resolving very fine (smaller than 20/20 letters) details at *both* distance and near for extended periods
- Emphasis on tasks where it is advantageous to have objects simultaneously in focus over a large range of viewing distances
- Expectations consistent with actual everyday visual demands
- Motivated to wear lenses and understands that vision may not *always* be as sharp as with spectacles for some distances or lighting conditions
- Unable to adapt to monovision correction

#### **Less than Ideal Candidates**

- Critical or very fine visual demands at both distance and near
- Emerging presbyope with plano or very low distance powers
- Refractive cylinder  $\geq 1.50$  D (any axis) in one or both eyes or against-the-rule refractive cylinder  $> 1.00$  D in one or both eyes
- Monocular distance acuities poorer than 20/20 with spherical equivalent refractive correction
- Myopic anisometropia where the refractive error for one of the two eyes is low ( $\leq 1.50$  D) and has not been habitually corrected
- Pupil size larger ( $> 4$  mm) or smaller ( $< 3$  mm) than norm for presbyopic population under natural illumination conditions
- Abnormal binocular sensory function (e.g., amblyopia or strabismus)
- Expectation to discard and never use spectacles again, even for special tasks or viewing conditions
- Highly satisfied monovision wearers
- Any other contraindications to successful contact lens wear such as tear abnormality or lid margin disease

### 3. Initial Lens Selection

#### A. Initial Base Curve Selection

**AIR OPTIX® AQUA Multifocal** contact lenses are available in a single 8.6 mm base curve.

#### B. Initial Lens Power Selection

**Note:** A careful maximum plus spherocylindrical refraction and nearpoint add determination should be conducted prior to selecting an **AIR OPTIX® AQUA Multifocal** trial lens. Autorefractometer findings should be refined manually to rule out effects of instrument myopia and ensure proper control of residual accommodation.

The **AIR OPTIX® AQUA Multifocal** soft contact lens design makes selecting the initial lens power easy. The optimum starting point is with a power that is *more plus or least minus*, vertex-corrected equivalent spectacle refraction.

#### C. Initial ADD Selection

The **AIR OPTIX® AQUA Multifocal** contact lens 3 ADD SYSTEM allows personalized fitting for presbyopic patients. The table below makes initial ADD selection easy.

**AIR OPTIX® AQUA Multifocal ADD Selection**

AIR OPTIX® AQUA Multifocal ADD selection	
SPECTACLE ADD	BOTH EYES
Up to +1.25	LO
+1.50 to +2.00	MED
+2.25 to +2.50	HI

#### Example 1:

	OD	OS
Spherical Rx:	-4.50 -0.75 x 90	-4.00D
Spherical equivalent (least minus):	-4.75D	-4.00D
Vertex corrected power:	-4.50D	-4.00D
Spectacle ADD:	+0.75D	
Eye Dominance:	OD	
Initial Trial lens:	4.50 LO	-4.00 LO

**Example 2:**

	OD	OS
Spherical Rx:	+4.25 -0.25 x 180	+4.00 -0.50 x 180
Spherical equivalent (least minus):	+4.25D	+3.75D
Vertex corrected power:	+4.50D	+3.75D
Spectacle ADD:		+2.00D
Eye Dominance:		OS
Initial Trial lens:	+4.50 MED	+3.75 MED

**4. Initial Lens Fitting Evaluation**

- Insert the lenses selected in Step 3 above. If the exact power is not available, choose the next closest lens power in your trial set.
- 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.
- 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 evaluating the physical fit of the lens:

**Characteristics of a Well-fitted Lens**

A well-fitted **AIR OPTIX\* AQUA Multifocal** (Iotraficon B) contact lens satisfies the following criteria:

- Full corneal coverage and good centration (no limbal exposure). A lens that is decentered >1 mm, regardless of the direction, is less likely to give adequate vision.
- Lens movement of 0.3 mm or less should be present to allow tear exchange under the lens during a blink in primary gaze or upward gaze.

**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.
- Good comfort
  - 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), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

- Good centration
- Insufficient or no lens movement during a blink in primary gaze or upward gaze

3. Excessive conjunctival drag (visible movement of the conjunctival vessels when the lens moves during a blink or during the push-up test). Note: presbyopes often have loose conjunctiva, some conjunctival movement is occasionally seen and may not be a sign of a tight fit. See **Push-up Test** below.

**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.**

4. Good comfort
5. 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), 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 the blink in primary or upward gaze

**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

### **5. Initial Lens Visual Evaluation**

While lenses are settling, it is helpful to take the patient from the exam room to a “real-world” setting such as a room with an outside view. Once an acceptable fit has been achieved, the visual performance of the lenses may be evaluated. Visual acuity is tested at distance. If necessary, a spherical over-refraction should be performed using a trial frame or hand held lenses rather than a phoropter. This technique is essential when fitting multifocal lenses because it allows the patient to maintain the head posture and direction of gaze (relationship between eye and head) that he or she would naturally use during everyday tasks. This ensures that the visual performance of the lens is being assessed under conditions where the on-eye positioning matches that which will occur when the lens is being used, for example, for near work activities. In addition, pupil size will not be artificially increased by the reduction in light associated with looking through the aperture of the phoropter cells, or decreased by proximal cues associated with the nearness of the instrument.

### **6. Fitting Procedures**

- Step 1. After the trial lenses have settled for 15 minutes, measure distance acuity while the patient is viewing the chart binocularly (i.e., simultaneously with both eyes). Next, evaluate the patient’s subjective

impression of the near vision when trying to read typical everyday material (e.g., a newspaper, magazine, and cell phone). Lighting and reading distance should be what is normal for the patient.

Step 2. If distance or near vision is unsatisfactory, perform a **distance** over-refraction on eye as follows. Use hand-held trial lenses and encourage plus. For example, if a plano and a +0.25D over-refraction yields the same results, use the +0.25 endpoint. Re-check visual acuity and visual quality as described in step 1 above. If over-refraction is other than plano, go immediately to new trial lenses, keeping the ADD the same.

Step 3. If distance and near vision are satisfactory, dispense lenses and remind patient to use good light when reading fine print. It is helpful to let the patient experience the lenses in their natural environment before further procedures for enhancing vision are performed.

Step 4. **Enhanced Near Vision.** If near vision is unsatisfactory, determine the dominant eye by the following method. Determine the eye with **greatest plus acceptance** by placing +1.50 handheld trial lens over each eye alternately while patient views the distance with both eyes open. Consider the eye for which binocular vision blurs least with the +1.50 to be the non-dominant eye.

Step 4A: Check the patient's binocular acuity with +0.50 over the non-dominant eye to determine if near vision is improved and distance vision is still acceptable. If so, place a new trials lens with the same ADD on the non-dominant eye, **adjusting the distance power by +0.50.**

Enhanced near vision, Step A		
SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
Up to +1.25	LO	LO with additional +0.50
+1.50 to +2.00	MED	MED with additional +0.50
+2.25 to +2.50	HI	HI with additional +0.50

Next, re-check visual acuity and visual quality as described in Step 1 above. If satisfactory, dispense new distance lens power for the non-dominant eye. If near vision is still unsatisfactory, proceed to Step B:

**Step 4B:** If near vision is still unsatisfactory, adjust ADD as shown below.

Enhanced near vision, Step B		
SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
Up to +1.25	MED	MED
+1.50 to +2.00	MED	HI
+2.25 to +2.50	HI	MED

*Note: It is common to question the rather non-intuitive step we suggest for enhancing vision at near in the HI ADD range, where the suggestion is to “back-off” to a MED ADD for the non-dominant eye, the same suggestion we make for enhancing distance vision (below). The reason for this is that after establishing (in Step A) that increasing plus is not helpful, the next most common reason for blur at near (or distance) is unacceptable ghosting that degrades the image quality. Backing down to the MED ADD in one eye can often relieve that and actually improve vision at near.*

**Step 5: Enhanced Distance Vision.** If distance over-refraction did not improve visual acuity, adjust ADD according to the chart below.

SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
+1.50 to +2.00	LO	MED
+2.25 to +2.50	HI	MED

## Dispensing Visit (Multifocal lenses)

**AIR OPTIX® AQUA Multifocal** (Iotraficon B) soft contact lenses are supplied in multipack cartons with individual foil-sealed lens containers. Locate the opening flap on the multipack carton and pull up to break the seal.

The lenses are supplied in an easy-to-open foil container designed to maintain sterility of the lens and saline storage solution. To open an individual lens container peel back the lid and carefully remove the lens from its container. (Do not use tweezers or other tools to remove the lens from the package. This could damage the lens.)

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

### 1. Evaluation 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.



## 2. Lens Placement and Removal Directions

Instruct the patient on proper lens placement and removal procedures. Patients who are unable to place and remove lenses should not be provided with them.

## 3. Specific Instructions for Presbyopic Patients

Specific instructions, explanations and demonstrations are important for optimizing patient success with multifocal contact lenses. The following information and instructions have proven useful in advising patients who wear **AIR OPTIX\* AQUA Multifocal** soft contact lenses.

- a. A contact lens that contains different powers for distance and near involves greater technological and optical complexity than does a bifocal or multifocal spectacle lens. This is because the contact lens moves *with the eye*, rather than having the eye move up and down while the lens remains suspended in a frame. While the contact lens therefore gives an unobstructed field of view and greater freedom regarding *where* to look, these advantages *may* mean that the sharpness of vision *may* not always be exactly the same as what would be experienced with spectacles.
- b. Although many individuals use **AIR OPTIX\* AQUA Multifocal** soft contact lenses for full-time wear, it is not unusual to find that there may be some activities where one prefers to wear spectacles, or where the disadvantages associated with spectacles are outweighed by other issues. This is an entirely normal and natural response to the challenges presented by presbyopia.
- c. Situations where vision with multifocal contact lenses may be less sharp or otherwise “different” than what is experienced with spectacles often involve low illumination (e.g., a semi-dark room), reduced visibility (e.g., outdoor conditions of fog or heavy rain), or isolated sources of very bright light (e.g., headlights of an oncoming vehicle on a narrow country road). ***Patients should be instructed to make use of good light when reading fine print.***
- d. Patients should be aware that it might be advisable to refrain from wearing their lenses while driving, flying an airplane or operating heavy machinery under these conditions until they gain some experience with the lenses in a similar visual environment.
- e. Small changes in lens power can often make an enormous difference in the quality of the vision experienced with multifocal contact lenses. Such changes can be best tailored to individual needs only after the lenses have been worn during the tasks and environmental conditions that the patient will personally encounter on a day-to-day basis. Confidence and assurance that such refinements, if needed, can be achieved is important for patient motivation during the initial period of lens wear.

## **FITTING GUIDELINES (Monovision)**

### **1. Patient Selection**

#### **A) Monovision Needs Assessment**

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. 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.

### **2. Eye Selection**

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

#### **A) Ocular Preference Determination Methods**

- Method 1 - Determine which eye is the "sight eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.
- Method 2 - Determine which eye will accept the added power 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.

## 3. Special Fitting Considerations

### Unilateral Lens Correction

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

#### • 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 left 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

Although patients with less than 1.50 diopters of astigmatism might be successfully fit in **AIR OPTIX\* AQUA** (Iotrafilcon B) spherical lenses, patients with  $\geq 0.75$  diopters of astigmatism might be better candidates for monovision using **AIR OPTIX\* for Astigmatism** (Iotrafilcon B) toric soft contact 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 – 0.75 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 ***Fitting Guidelines*** and ***Base Curve Selection*** sections 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 booklet by contacting an Alcon customer service representative in the USA at **(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.

**AIR OPTIX\* AQUA, AIR OPTIX\* plus HydraGlyde\*, AIR OPTIX\* for Astigmatism and AIR OPTIX\* AQUA Multifocal (lotrafilcon B)** soft contact 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 AIR OPTIX\* AQUA, AIR OPTIX\* plus HydraGlyde\*, AIR OPTIX\* for Astigmatism and AIR OPTIX\* AQUA Multifocal (lotrafilcon B) soft contact lenses***

Give the patient a copy of the ***Patient Instruction Booklet*** for the contact lenses you have prescribed. 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 Alcon customer service in the USA at (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.

### 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.

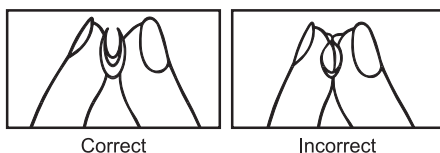
## LENS HANDLING HINTS

### 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.

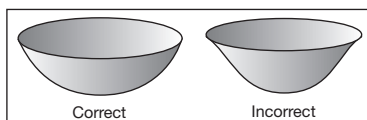
One way to do this is to place the lens between your thumb and index finger and squeeze the edges together gently.

- 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.



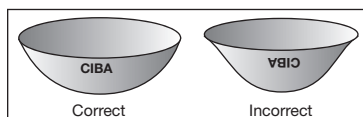
Another way is to place the lens on the tip of your index finger and check its shape.

- If the edge appear 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 solution with or without additives. 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

Alcon is pleased to assist with fitting or clinical questions regarding **AIR OPTIX\* AQUA, AIR OPTIX\* plus HydraGlyde\*, AIR OPTIX\* for Astigmatism and AIR OPTIX\* AQUA Multifocal (Iotrafalcon B)** soft contact lenses. Eye care professionals having questions or problems should contact the Alcon Technical Consultation department, in the USA at (800) -241-7468. To order **AIR OPTIX\* AQUA, AIR OPTIX\* plus HydraGlyde\*, AIR OPTIX\* for Astigmatism and AIR OPTIX\* AQUA Multifocal (Iotrafalcon B)** contact lenses contact your Alcon sales representative or call Customer Service, in the USA at (800) 241-5999.

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## 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

**IMPORTANT:** This package insert is effective as of July 2016 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 Alcon by calling Customer Service at +1-800-241-5989 or downloaded from our website at [www.alcon.com](http://www.alcon.com). Alcon also makes available a Patient Instruction Booklet, which is recommended to be given to patients.

### Only

**CAUTION:** Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.

### PRODUCT DESCRIPTION

**AIR OPTIX® AQUA, AIR OPTIX® plus HydraGlyde®, AIR OPTIX® for Astigmatism, AIR OPTIX® AQUA Multifocal and O<sub>2</sub>OPTIX® (lotrafilcon B)** soft contact lenses are made of a hydrophilic polymer that is approximately 33% water. AIR OPTIX® AQUA Multifocal, AIR OPTIX® plus HydraGlyde®, and 6% lotrafilcon B, a fluoro-silicone containing hydrogel which is surface treated with a hydrophilic coating to reduce surface friction, a light blue handling tint, to make them easier to see when handling.

- Lens Properties:**
  - Refractive Index (hydrated): 1.42
  - Light Transmittance: >90% @ 610 nm, >100%
  - Oxygen Permeability (Dk): 110 x 10<sup>-9</sup> (cm<sup>2</sup>/sec) (ml, ml x mm Hg, measured at 35 °C (intrinsic Dk-Coumotech method))
  - Water Content: 33% by weight in normal saline

### Lens Parameters:

- Lens Parameters:**
  - Diameter Range: 13.0 to 15.0 mm
  - Power Range: -20.00 to +20.00
  - Base Curve Range: 8.0 to 9.2 mm

### Lens Parameters Available:

- AIR OPTIX® AQUA and O<sub>2</sub>OPTIX®** contact lenses (spherical):
  - Chord Diameter: 14.2 mm
  - Center Thickness: 0.6 mm @ -3.00D (varies with power)
  - Base Curve: 8.6 mm
- Power:**
  - Minus Powers: -0.25 to -8.00 (-0.250 steps), -8.50 to -10.00 (-0.500 steps)
  - Plus Powers: +0.25 to +6.00 (+0.250 steps)

- AIR OPTIX® plus HydraGlyde®** contact lenses (spherical):
  - Chord Diameter: 14.2 mm
  - Center Thickness: 0.68 mm @ -3.00D (varies with power)
  - Base Curve: 8.6 mm
- Power:**
  - Minus Powers: -0.25 to -8.00 (-0.250 steps), -8.50 to -12.00 in 0.50D steps
  - Plus Powers: -0.25 to +6.00 (+0.250 steps), +6.50 to +8.00 (+0.500 steps)

- AIR OPTIX® for Astigmatism** contact lenses (toric):
  - Chord Diameter: 14.5 mm
  - Center Thickness: 0.12mm @ -3.00D (varies with power)
  - Base Curve: 8.7 mm
- Power:**
  - Minus Powers: plano to -4.00 (-0.250 steps), -4.50 to -10.00 (-0.500 steps)
  - Plus Powers: -0.25 to +6.00 (+0.250 steps)
  - Cylinder: -0.75, -1.25, -1.75 to -2.25
  - Axis: Full Circle, 10° steps

- AIR OPTIX® AQUA Multifocal** contact lenses:
  - Chord Diameter: 14.2 mm
  - Center Thickness: 0.68 mm @ -3.00D (varies with power)
  - Base Curve: 8.6 mm
- Power:**
  - Minus Powers: plano to -10.00 (-0.250 steps)
  - Plus Powers: +0.25 to +6.00 (+0.250 steps)
  - LO, MED, HAD

### ACTIONS

When hydrated and placed on the cornea, ALCON® (lotrafilcon B) soft contact lenses act as a refracting medium to focus light rays on the retina.

### INDICATIONS (Uses)

**AIR OPTIX® AQUA, AIR OPTIX® plus HydraGlyde®, and O<sub>2</sub>OPTIX® (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-degraded eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

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

**AIR OPTIX® AQUA Multifocal** (lotrafilcon B) soft contact lenses are indicated for the optical correction of presbyopia, with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-degraded eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

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
- Any active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids that may be aggravated by contact lens wear
- Microbial infection of the eye
- Inadequate tear film (dry eyes) that interferes with contact lens wear
- Corneal hypoxia-induced corneal sensitivity
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease that is exacerbated by or interferes with safe contact lens wear, handling, and/or care
- Allergic reactions or ocular irritation of the ocular surfaces or adhesion that may be caused by or exacerbated 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 recurrent eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal corneal response to contact lens wear
- Eye become red or irritated

### WARNINGS

Advancements 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 and contact lens storage, wearing schedules, and wearing contact lenses only as directed.
- 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 professional 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.**
- Non-sterile liquids (i.e., tap water, distilled water, homemade saline solution, or saliva) 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, especially when lenses are worn overnight and while sleeping.**
- The risk of microbial keratitis (a serious eye infection) has been shown to be greater among users of extended wear lenses than among users of daily wear lenses.** The risk increases with the number of consecutive days that the lenses are worn between cleanings, 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 for the Eye Care Professional:** Due to the small number of patients enrolled in the clinical investigation of lenses, of refractive powers, designs, configurations, or lens materials 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 overall health, including oxygen permeability, central and peripheral thickness and optic zone designs.
- 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 contact lens 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 wear and disinfection regimens, wearing schedules, wearing schedules.**
- 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 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, patients 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.
- Dietetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly as completely an on-diabetics.**
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives.** Caution patients accordingly.
- Patients who wear contact lenses to correct presbyopia may not achieve the best visual acuity for contact lens wear for near or near vision.** Vision requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

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

- Handing 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 Instruction Booklet** for the lotrafilcon B soft contact lenses prescriptive.
  - 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 lens.
  - Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container. Pour the lens into the hand.

### Lens Disinfection

- 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 to the eye, do not remove it. Follow the recommendations 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 while water

may increase the risk of corneal infection, including but not limited to *Acanthamoeba* keratitis.

- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hairspray, deodorant, aerosol products or foreign particles come in contact with lenses.
- Never allow contact lenses to come into contact with non-sterile liquids (including tap water) or contact with water.** Contamination can occur, which may lead to permanent eye damage.
- Do not share lenses with anyone** as this may spread micro-organisms which could result in serious eye health problems.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chances 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 or have back-up spectacles available.
- Do not use lenses beyond the expiration date, or exp

### 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 the **LENS CARE DIRECTIONS** section).
- Only use fresh, unopened 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 and 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 normal (tap) 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 Care 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 care 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 responses. Alcon 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, blurred vision, or vision changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness. Caution patients using 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 professional that they are wearing contact lenses.
- Patient should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn.

It is strongly recommended that patients be provided with a copy of the **AIR OPTIX® AQUA, AIR OPTIX® plus HydraGlyde®, AIR OPTIX® for Astigmatism and AIR OPTIX® AQUA Multifocal** soft contact lens **Patient Instruction Booklet** available from Alcon and understand its contents prior to dispensing the lenses.

### ADVERSE EFFECTS (Possible Problems)

Patients should be instructed to check eyes regularly to make sure they look well, feel comfortable and vision is clear. Potentially serious complications are usually accompanied by one or more of the following signs and symptoms:

- Moderate to severe eye pain not relieved by removing the lens
- Feeling of something in the eye (foreign body sensation)
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Sensitivity to light (photophobia)
- 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

These symptoms, if ignored, may lead to more serious complications.

### WHAT TO DO IF A PROBLEM OCCURS

Patients should be instructed that if any of the above signs or symptoms occur,

- IMMEDIATELY REMOVE LENSES.**
- If the discomfort or problem stops, then look closely at the lenses.**
  - If a lens is in any way damaged, **DO NOT** put it back on. If damaged lenses and consult the eye care professional.
  - If a lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lenses before reinsertion.
- If the above symptoms continue after removal or upon reinsertion of the lens, remove the lens immediately, then promptly contact an eye care professional.
- The patient should be informed that a serious condition such as corneal ulcer (ulcerative keratitis), infection, corneal exfoliation or ulcers may be present. These conditions may progress rapidly and may lead to permanent loss of vision. Lens insertion and removal should be performed with strict aseptic techniques. Bacterial conjunctivitis may be managed and treated properly to avoid more serious complications.
- Additional 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, increased tearing, generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, larval papillary changes, conjunctival injection or iritis.

- If a lens dislocates on the eye, it may be possible to recenter it by:
  - Closing your eyelids and gently massaging the lens into place, or
  - Looking in the direction of the lens and blinking gently, or
  - Gently pulling the oil-coated lens onto the cornea with light finger pressure on the edge of the upper or lower eyelid.
- If a lens tears in your eye, remove the pieces carefully by pinching them as you would for normal lens removal. If the lens pieces do not seem to remove easily, do not pinch the eye tissue. Rinse with saline. If this does not help, contact the eye care professional for assistance.

#### ADVERSE EFFECTS REPORTING

If a patient experiences any serious adverse effects associated with the use of Iatrolin® B contact lenses, please notify **Alcon Medical Science, Inc. in the USA** at 1-800-757-4700.

#### FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to Iatrolin® B contact lenses. For a detailed description of the fitting techniques, refer to the **AR OPTIX™ AQUA, AR OPTIX™ AQUA Multifocal** (Iatrolin® B) contact lens **Professional Fitting and Insertion** and **AR OPTIX™ AQUA Multifocal** (Iatrolin® B) contact lens **Patient Insertion** fitting guide and a **Patient Instruction Booklet** are available free of charge from:

Alcon Laboratories, Inc.  
6201 South Freeway  
Fort Worth, TX 76134-2099 USA

or by calling Alcon Customer Service in the USA at 1-800-241-5999.

#### LENS WEAR AND REPLACEMENT SCHEDULES

The wearing and replacement schedule should be determined by an eye care professional based on the patient's individual needs and physiological conditions. The eye care professional may recommend daily wear only or extended wear periods up to 6 nights. Not everyone can reach the maximum wear time of 6 continuous nights.

##### Daily Wear (less than 24 hours, awake)

To avoid tendency of the daily wear patient to over wear 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-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** section for information about the relationship between wearing schedule and corneal complications.

#### Lens Replacement

The replacement schedule is determined by the eye care professional based on the patient's individual needs and physiological conditions. Alcon recommends up to 4 week replacement for Iatrolin® B lenses, or as recommended by the eye care professional.

#### LENS HANDLING INSTRUCTIONS

- Always wash and rinse hands thoroughly and dry completely with a clean, lint-free towel before handling contact lenses.
- Do not use if blister package is damaged or not sealed completely. This may result in product contamination which can lead to a serious eye infection.
- Shake the blister pack containing a fresh new lens gently prior to opening.
- Remove the lens from the blister pack (or lens storage case for previously worn lenses) by carefully pulling up on the palm of the hand.
- Ensure the lens is right side out and that you have the correct lens for each eye.
- Inspect the lenses prior to insertion.
- Do not insert damaged or unclear lenses.

#### Lens Insertion Instructions

- Wash and rinse hands thoroughly and dry completely with a clean, lint-free towel.
- Place a lens on the tip of your clean and dry right or left index finger. Place the middle finger of the same hand down to lower eyelids and pull down the lower eyelid.
- Use the fingers of the other hand to lift the upper eyelid.
- Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
- Look down and slowly release the lower lid.
- Look straight ahead and slowly release the upper lid.
- Blink gently.

#### Lens Removal Instructions

- Wash and rinse hands thoroughly, and dry completely with a clean, lint-free towel.
- Blink fully several times.
- While looking up, use the tip of the finger to slide the lens down onto the white part of the eye.
- Remove the lens by pinching gently between thumb and forefinger. Do not pinch the eye tissue.
- Never use tweezers, suction cups, sharp objects or finger nails to remove lenses from the lens container or eyes.

#### WATER ACTIVITIES

Do not expose contact lenses to water while wearing them.

**Warning:**  
Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If lenses have been submerged in water when showering or swimming, discard them and replace with a new pair. Ask the eye care professional for recommendations about wearing lenses during any activity involving water.

#### LENS CARE INSTRUCTIONS

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

#### 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 lens care regimen to provide the patient with instructions according to the package labeling.

The eye care professional should follow the following instructions with the patient:

- Each time lenses are removed from the eye they must be properly cleaned, rinsed, and disinfected before reuse. If removed while the patient is away from the eye care professional, the lenses must be properly cleaned, rinsed, and disinfected 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, and disinfected in accordance with the package labeling of the lens care products recommended by the eye care professional. Typical instructions for lens care products include the steps presented below. **IMPORTANT:** Hydrogen Peroxide disinfecting solutions, such as CLEAR CARE® PLUS Cleaning & Disinfecting Solution, are not multi-purpose solutions. For hydrogen peroxide disinfecting solutions follow the manufacturer's instructions.
- Soaking and Storing Your Lenses:
  - Use only fresh contact lens care solution each time you soak (store) your lenses.

- Warning:**
  - Each time lenses are "top up" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. To "top-up" means to add fresh solution to solution that has been sitting in your lens case.
- Rub and Rinse Time:
  - Some lens care products require a rub and rinse cycle. If so, follow the lens care manufacturer's instructions for solution quantity and rub and rinse time to reduce the risk of serious eye infections.
  - The amount of time you can store lenses before cleaning, rinsing, and disinfecting must not be repeated with very varying depending on the lens care product used.

- Warning:**
  - Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections.
  - Contact lenses (sometimes referred to as a lens flat pack or lens storage case). While others are specially designed to contain a neutralizing disc for use with hydrogen peroxide cleaning and disinfecting systems. If not being worn on a daily disposable basis, lenses that have been cleaned and disinfected can be stored in the unopened case for a period of time that varies depending on the contact lens solution and lens care used. Always follow the instructions provided by the manufacturer for the lens care products used.

#### Basic Instructions for the Lens Case

- Discard Date for Lens Cleaning and Disinfecting Solutions
  - After opening, discard any remaining solution after the period recommended by the lens care manufacturer. If using the lens care products listed below, discard remaining solution as follows:
    - CLEAR CARE® PLUS Cleaning & Disinfecting Solution - 3 months after opening.
    - OPTI-FREE® PureMoist® Multi-Purpose Disinfecting Solution - 6 months after opening.

- Warning:**
    - Using your lens case solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.
- The above instructions are typical for a lens cleaning product, however you must always consult the instructions for the specific lens care product used.
- Alcon recommends a chemical (not heat) method of disinfection such as CLEAR CARE® PLUS Cleaning & Disinfecting Solution or OPTI-FREE® PureMoist® Multi-purpose Disinfecting Solution.
  - Use of 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 Daily Cleaner has not been tested and is not recommended.
  - Heat disinfection has not been tested and is not recommended.

Contact lens care solutions and contact lens cases vary and have different purposes and instructions for use. Some cases are intended exclusively for storing contact lenses (sometimes referred to as a lens flat pack or lens storage case), while others are specially designed to contain a neutralizing disc for use with hydrogen peroxide cleaning and disinfecting systems. If not being worn on a daily disposable basis, lenses that have been cleaned and disinfected can be stored in the unopened case for a period of time that varies depending on the contact lens solution and lens care used. Always follow the instructions provided by the manufacturer for the lens care products used.

- The eye care professional should instruct the patient on how to use the recommended lens care solution(s) and lens case.
- Contact lens cases can be a source of bacterial growth and require proper cleaning, drying and replacement to avoid contamination or damage to lenses.
- Clean contact lens cases with an appropriate contact lens solution and dry according to lens case instructions. Drying instructions, such as air-drying or wiping with lint-free towel, may vary depending on the lens case used.
- Replace contact lens cases at least once every 3 months, or as recommended by the lens care manufacturer.
- Replace specially designed lens cases containing a neutralizing disc according to manufacturer directions, or sooner if cleaned and disinfected lenses cause burning and stinging.

**Warning:**

- Do not store lenses or rinse your eyes with water or any non-sterile solution. Only use fresh disinfecting solution in order to avoid contamination of your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

#### To help avoid serious eye injury from contamination, the eye care professional should recommend the following instructions:

- Always wash, rinse and dry hands before handling the lenses.
- Use only fresh sterile solutions recommended for use with soft, reusable contact lenses. When opened, sterile non-preserved solutions must be discarded after the time specified in the label.
- Do not use salves, 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 are used with soft lenses or 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.

#### CARE FOR A STROKE/LENS

If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a sterile eye 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 with or without additives. Hands should be thoroughly washed, rinsed and dried with a lint-free towel prior to handling a lens. In order to ensure sterility, the blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes, the lenses should be discarded 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 applied to the eyes:

- **Rush eyes immediately with fresh saline solution or tap water.**
- **Remove and discard lens and immediately contact the eye care professional or visit a hospital emergency room without delay.**

#### HOW SUPPLIED












- Each lens is provided in a foil-wrapped plastic container containing buffered saline solution and is steam sterilized . The packaging saline may contain preservatives, as follows:
  - **AR OPTIX™ for Astigmatism, OPTIX™ contact lenses:** Phosphate Buffered Saline (PBS)
  - **AR OPTIX™ AQUA, AR OPTIX™ AQUA Multifocal contact lenses:** PBS with 1% CosmoPrep 845 wetting agent.
  - **AR OPTIX™ also Hydrogel contact lenses:** PBS with 0.2% VPDMAEMA and 0.04% Polyvinylpyrrolidone-polyoxyethylene wetting agents.

The blister package is marked with the base curve, diameter, diopter power, cylinder and axis (where applicable), ADD power (where applicable), manufacturing lot number, and expiration date.

The package labeling may also contain a product code (LF3 110 (spherical Iatrolin® B in PBS saline), LFB 110x (spherical Iatrolin® B in PBS-CosmoPrep 845 saline), LFB110x (spherical Iatrolin® B in PBS-CosmoPrep 845 saline), VPFDMAEMA (VPFDMAEMA in PBS), LFB 110-T (toric Iatrolin® B in PBS saline), LFB 110-MF (multifocal Iatrolin® B in PBS-CosmoPrep saline)).

Lenses are supplied in containers containing up to 6 individually sealed contact lenses.

The following may appear on the labels or cartons.

Symbol/Signs	Description
	Caution: Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.
	EXP (Expiry) Date: Use by (Expiry date)
	LOT: Batch code
	LSP: Example of two letter language code (English)
	USE: Do not use if blister package is damaged
	CE: European conformity sign
	I: Consult instructions for use
	E: Caution
	M: Authorized Representative European Community
	Manufacturer
	Packaging waste license sign
DIA	Diameter
BC	Base curve
PWR	Power
D	Diopter (lens power)
ADD	Addition power

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Check for actual product availability, which may change over time. Contamination of OPTIX™ lenses in the USA discontinued 2014  
May also be labeled as OPTIX™ for Astigmatism  
Cutter GR, Chalmers RL, Rosen M. The Clinical Presentation, Prevalence, and Risk Factors of Focal Corneal Infiltrates in Soft Contact Lens Wearers. The *Journal of Refractive Medicine and Corneal Surgery*. Jan 1996; 22(1):30-37.  
Schoen DO, Oyama RJ, Poggio EC, Seddon JM, Kanyon KR. The Relative Risk of Ulcerative Keratitis Among Users of Daily-Wear and Extended-Wear Soft Contact Lenses. *Am J Opht*. 1989; 32(1):773-83.

## LENS CARE PRODUCT CHART FOR SOFT CONTACT LENSES

### ***CLEAR CARE\* Cleaning & Disinfecting Solution***

3% Hydrogen peroxide based solution for cleaning, disinfecting & protein removal

### ***CLEAR CARE\* PLUS Cleaning & Disinfecting Solution***

3% Hydrogen peroxide based solution for cleaning, disinfecting & protein removal. Contains HydraGlyde\* Moisture Matrix multi-functional block copolymer that is primarily designed for wetting and lubricating silicone hydrogel lenses.

### ***OPTI-FREE\* PureMoist \* Multi-Purpose Disinfecting Solution***

Multi-purpose solution for cleaning, rinsing, disinfecting, and protein removal. Contains HydraGlyde\* Moisture Matrix multi-functional block copolymer that is primarily designed for wetting and lubricating silicone hydrogel lenses.

### ***Other ALCON® Lens Care Products***

OPTI-FREE\* Rewetting Drops

Lubricating and rewetting

CLEAR CARE\* RINSE & GO\*  
Rinsing Solution

Rinsing and storage

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