

Example 1:		
Diagnostic lens:		-2.00D
	Spherical over-refraction	-0.25D
	Final lens power:	-2.25D

Example 2:		
Diagnostic lens:		-2.00D
	Spherical over-refraction	+0.25D
	Final lens power:	-1.75D

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

III. TORIC FITTING GUIDELINES

Although most aspects of the fitting procedure are identical for all types of soft contact lenses, including torics, there are some additional steps and/or rules to follow to assure the proper fit of toric lenses.

The only new steps you must follow in prescribing the ACUVUE® OASYS™ Brand Contact Lenses *for ASTIGMATISM* are that you must determine the stability, repeatability and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

A. How to Determine Lens Cylinder and Axis Orientation for ACUVUE® OASYS™ Brand Contact Lenses *for ASTIGMATISM*

1. Locate the Orientation Marks

To help determine the proper orientation of the toric lens, you'll find two primary marks about 1mm from the lens edge representing the vertical position on opposite ends of the lens at 6 and 12 o'clock (Fig. 1). Because of the lens' ballasting system, either mark can represent the vertical position – there is no “top” and “bottom” as in a prism-ballasted lens. You don't need to view both marks to assess orientation; simply look for the 6 o'clock mark as you would with a prism-ballasted lens.

Figure 1

You'll need a biomicroscope and a 1mm or 2mm parallelepiped to highlight the marks when the lens is fitted to the eye. There are a number of techniques you can use to improve the visibility of the 6 o'clock mark. With your parallelepiped and medium magnification (10x or 15x), slowly pan down the lens, looking just below the direct illumination at the retroilluminated area. Backlighting the mark this way should make them more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark.

dizziness, headaches and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to 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 may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during 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.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Monovision fitting 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 clear near vision and 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.

2. Observe Lens Rotation and Stability

Observe the position and stability of the “bottom” mark. It usually stabilizes at the 6 o'clock position. If it does, calculation of the lens power will be straightforward. The 6 o'clock position is not a “must”, however; the absolute requirement is that the axis position be stable and repeatable.

The mark may stabilize somewhat left or right (drift) of the vertical meridian and still enable you to fit a toric lens for that eye, as long as the lens always returns to the same “drift axis” position after settling. The deviation can be compensated for in the final prescription. Your objective is to ensure that whatever position the initial lens assumes near 6 o'clock, this position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they must return quickly to the original stable position. If the lens does not return quickly, you may need to select a different lens.

Assessing Rotation

Imagine the eye as a clock dial and every hour represents a 30° interval. If the orientation mark of the initial lens stabilizes somewhat left or right of the vertical position, the final lens will orient on the eye with the same deviation. You can use an axis reticule in the slit lamp or use a line-scribed lens in a spectacle trial frame to measure or estimate the “drift angle” of the cylinder axis.

To compensate for this “drift”, measure or estimate the “drift”, then add or subtract it from the refractive axis to determine the correct cylinder axis. Use the LARS (Left Add, Right Subtract) method to determine which direction to compensate.

B. How to determine the Final Lens Power for ACUVUE® OASYS™ Brand Contact Lenses *for ASTIGMATISM*

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the patient's refractive axis, it is not advisable to over-refract because of the difficulty in computing the resultant power.

In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible. So, here is how to determine the final lens power.

For the Sphere:

If sphere alone or combined sphere and cylinder Rx \geq +4.00D, compen-

— sate for vertex distance. If sphere alone or combined sphere and cylinder Rx \leq ± 4.00D, vertex compensation is not necessary.

For the Cylinder:
Adjust the axis by the drift angle using LARS. Choose a cylinder that is \geq 0.25D from the refractive cylinder.

PATIENT MANAGEMENT

Dispensing Visit

• **PROVIDE THE PATIENT WITH A COPY OF THE ACUVUE® OASYS™ Brand Contact Lenses and the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM PATIENT INSTRUCTION GUIDE. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE (DISPOSABLE OR FREQUENT REPLACEMENT).**

- Recommend an appropriate cleaning and disinfecting system and provide the patient with instructions regarding proper lens care. Chemical or hydrogen peroxide disinfection is recommended.
- Schedule a follow-up examination.

Follow-up Examinations

- Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule, lens replacement schedule and proper lens care and handling procedures.
- Recommended Follow-up Examination Schedule for ACUVUE® OASYS™ Brand Contact Lenses and ACUVUE® OASYS™ Brand Contact Lenses *for ASTIGMATISM* (complications and specific problems should be managed on an individual patient basis):
 - One week from the initial lens dispensing to patient
 - One month post-dispensing
 - Every three to six months thereafter

NOTE: More frequent or additional follow-up visits may be recommended for patients on an extended wear schedule.

- Preferably, at the follow-up visits, lenses should be worn for at least six hours. If the lenses are being worn for continuous wear, the examination should be performed as early as possible on the morning following overnight wear.
- Recommended Procedures for Follow-Up Visits:
 - Solicit and record patient's symptoms, if any.
 - Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.
 - Perform an over-refraction at distance and near to check for residual refractive error.
 - With the biomicroscope, judge the lens fitting characteristics (as described in the General Fitting Guidelines) and evaluate the lens

surface for deposits and damage.

5. Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein (*unless contraindicated*).

- The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
- The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
- Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

If any observations are abnormal, use professional judgment to alleviate the problem and restore the eye to optimal conditions. If the criteria for successful fit are not satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and refill the patient.

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the Eye Care Professional. Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

Daily Wear (less than 24 hours, while awake)

- For Daily Wear, VISTAKON® recommends that the ACUVUE® OASYS™ Brand Contact Lenses and the ACUVUE® OASYS™ Brand Contact Lenses *for ASTIGMATISM* prescribed for frequent replacement wear be discarded and replaced with a new lens every 2 weeks. However, the Eye Care Professional is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.
- When prescribed for disposable wear, the ACUVUE® OASYS™ Brand Contact Lenses and the ACUVUE® OASYS™ Brand Contact Lenses *for ASTIGMATISM* should be discarded upon removal.

The maximum suggested wearing time for these lenses is:

DAY	HOURS
1	6-8
2	8-10
3	10-12
4	12-14
5 and after	all waking hours

Since the manifest refraction called for a power of –4.75D, adjust for the vertex distance and reduce the sphere by 0.25D and prescribe the –1.75D cylinder. Compensate for the 10° axis drift by subtracting it from the manifest refraction. Here is the Rx prescribed:

O.S. –4.50 –1.75 x 80

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

IV. MONOVISION (SPHERICAL AND TORIC FITTING GUIDELINES)

A. Patient Selection

Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.00 D) in one eye may not be a good candidate for monovision correction with the ACUVUE® OASYS™ Brand Contact Lens and the ACUVUE® OASYS™ Brand Contact Lens *for ASTIGMATISM*.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision correction. Monovision contact lens wear may not be optimal for such activities as:

- (a) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- (b) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

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 spectacles (multifocal, bifocal, trifocal, readers, progressives). Each patient should understand that Monovision, as well as other presbyopic alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments (e.g., reading a menu in a dim restaurant,

driving at night in rainy/foggy conditions, etc.). During the fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision and straight ahead and upward gaze that monovision contact lenses provide.

B. Eye Selection
Generally, the non-dominant eye is corrected for near vision. The following two methods for eye dominance can be used.

- Ocular Preference Determination Methods**
Method 1: Determine which eye is the “sighting eye”. Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.
Method 2: Determine which eye will accept the added power with the least reduction in vision. Place a hand-held trial lens equal to the spectacle near ADD 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.

Other methods include the refractive error method and the visual demands method.

- Refractive Error Method**
For anisometropic correction, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.
- 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 secretary who places copy to the left side of the desk will function best with the near lens on the left eye.

C. Special Fitting Characteristics

- 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 only require a distance lens.
Example:
A presbyopic emmetropic patient who requires a +1.75D ADD would

Contact Lenses *for ASTIGMATISM prescribed for frequent replacement wear:* Eye Care Professional should review with the patient, lens care directions for cleaning, disinfecting and storing, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

Care for sticking (non-moving) lenses
If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should immediately consult the Eye Care Professional.

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

HOW SUPPLIED

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with 0.005% methyl ether cellulose. The plastic package is marked with base curve, diopter power, diameter, color (visibility tint noted on visibility tinted product only), lot number and expiration date. [ADD power, cylinder and axis will be included as appropriate].

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing ACUVUE® OASYS™ Brand Contact Lenses and ACUVUE® OASYS™ Brand Contact Lenses *for ASTIGMATISM* or experienced with the lenses should be reported to:

VISTAKON®, Division of Johnson & Johnson Vision Care, Inc.
P.O. Box 10157
Jacksonville, FL 32247-0157
Tel: 1-800-843-2020
www.acuvue.com

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have a +1.75D lens on the near eye and the other eye left without a lens. A presbyopic patient requiring a +1.50D ADD who is –2.50D myopic in the right eye and – 1.50D myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

2. 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.

3. Trial Lens Fitting
A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the General Fitting Instructions for base curve selection in this Package Insert.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine the distance correction and the near correction. Next determine the near ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Allow the lenses to settle for about 20 minutes with the correct power lenses 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 tests 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 newsprint and finally smaller type sizes.

After the patient's performance under the above conditions is completed, 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 guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

4. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision,

IMPORTANT: Please read carefully and keep this information for future use.

This Package Insert and Fitting Guide 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 the patient instructions that pertain to the patient's prescribed lens.

ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR® Plus

ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® Plus (senofilcon A)

Visibility Tinted with UV Blocker For Daily and Extended Wear

