

## TORIC FITTING GUIDELINES

Although most aspects of the fitting procedure are identical for all types of soft contact lenses, including toric lenses, 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 1-DAY ACUVUE® MOIST 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 the patient.

### A. How to Determine Lens Cylinder and Axis Orientation

#### 1. Locate the Orientation Marks

To help determine the proper orientation of the toric lens, you'll find two primary marks approximately 1 mm 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' symmetrical stabilization design, 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 slit lamp biomicroscope with a 1 to 2 mm parallelepiped beam 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. Using a parallelepiped beam 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 it more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark.

#### 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

- 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."

### 2. 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.

### 3. 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

#### 1. Unilateral Vision Correction Requirement

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens whereas a bilateral myope would require corrective lenses on both eyes.

Example:

A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without correction.

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.

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. Final Lens Power

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 spectacle cylinder axis, it is not advisable to perform a full spherocylindrical over-refraction because of the difficulty in computing the resultant power. A spherical over-refraction without cylinder refraction may be performed. If the required cylinder correction falls between two available cylinder powers, it is recommended to prescribe the lower cylinder power lens. See below for instructions on how to determine the final lens power.

#### For the Sphere:

If sphere alone or combined sphere and cylinder Rx  $\geq$  +4.00D, compensate for vertex distance. If sphere alone or combined sphere and cylinder Rx  $<$  +4.00D, vertex compensation is generally not necessary, however may be required for larger vertex distances.

#### For the Cylinder:

Adjust the axis by the drift angle using the LARS method. Choose a cylinder power that is  $\leq$  0.50D from the vertex-corrected refractive cylinder.

Case Examples:

Example 1
Manifest (spectacle) refraction: O.D. -2.50D / -1.25D x 180° 20/20 O.S. -2.00D / -1.00D x 180° 20/20

### 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 Guidelines" for base curve selection described in this guide.

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 news print 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, dizziness, headaches and a feeling of slight imbalance. You should explain the adaptation 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

Choose a diagnostic lens for each eye with axis 180°. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens. If the lens has not yet stabilized, recheck until stable.

Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously. If the lens has not yet stabilized, recheck until stable.

Here is the Rx prescribed:

O.D. -2.50D / -1.25D x 180°  
O.S. -2.00D / -0.75D x 180°

Example 2

Manifest (spectacle) refraction:  
O.D. -3.00D / -1.00D x 90° 20/20  
O.S. -4.75D / -2.00D x 90° 20/20

Choose diagnostic lenses of -3.00D / -0.75D x 90° for the right eye and -4.50D / -1.75D x 90° for the left eye, the nearest lenses available to the spherical power, cylinder power, and axis needed. For the left eye, since the manifest refraction called for -4.75D, compensating for vertex distance the sphere is reduced by 0.25D to -4.50D. The cylinder power will be -1.75D. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens. If the lens has not yet stabilized, recheck until stable.

### Right Eye:

The orientation mark on the right lens rotates left from the 6 o'clock position by 10° and remains stable in this position. Compensation for this rotation should be done as follows:

Compensate the 10° axis drift by adding it to the manifest refraction axis.

Here is the Rx prescribed:

O.D. -3.00D / -0.75D x 100°

### Left Eye:

The orientation mark on the left lens rotates right from the 6 o'clock position by 10° and remains stable in this position.

Compensate for the 10° axis drift by subtracting it from the manifest refraction axis.

Here is the Rx prescribed:

O.S. -4.50D / -1.75D x 80°

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.

### 5. 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 their state driver's license requirements with a monovision correction.

- Make use of proper illumination when carrying out visual tasks.

Monovision fitting success can be improved with 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 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 GUIDE for these lenses. Copies are available for download from [www.acuvue.com](http://www.acuvue.com).**

## PATIENT MANAGEMENT

- Follow the accepted standard of care in fitting and following up with your patient.**
- Schedule the appropriate follow-up examination.**
- Preferably, at the follow-up visits, lenses should have been worn for at least six hours.**

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).

**All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download from [www.acuvue.com](http://www.acuvue.com)**

## MULTIFOCAL FITTING GUIDELINES

### A. Presbyopic Needs Assessment & Patient Education

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). 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. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the 1-DAY ACUVUE® MOIST MULTIFOCAL Contact Lenses. Wear may not be optimal for such activities as:

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

These lenses are not recommended for patients who have -1.00D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise.

These lenses are available in the following ADD powers:

- Lens "LOW" = "low" near ADD lens (Max +1.25 ADD)
- Lens "MID" = "medium" near ADD lens (Max +1.75 ADD)
- Lens "HGH" = "high" near ADD lens (Max +2.50 ADD)

### B. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Vertex distance compensation is generally only necessary

- Provide the patient with a copy of the PATIENT INSTRUCTION GUIDE for these lenses, which can be found at [www.acuvue.com](http://www.acuvue.com). REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE (DAILY DISPOSABLE).**

## WEARING SCHEDULE

The wearing schedule should be determined by the Eye Care Professional. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Maximum wearing time should be determined by the Eye Care Professional based upon the patient's physiological eye condition, because individual response to contact lenses varies.

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

## REPLACEMENT SCHEDULE

These lenses are indicated for daily disposable wear and should be discarded upon removal.

When disposed of after a single daily use, these lenses may reduce the risk of developing giant papillary conjunctivitis.<sup>4</sup>

When worn as a daily disposable lens, these lenses may provide improved comfort for many patients who experience mild discomfort and itching associated with allergies during contact lens wear, compared to lenses replaced at intervals of greater than 2 weeks.

Clinical research has shown that when worn on a daily disposable basis, these lenses may provide improved comfort for 2 out of 3 patients who reported suffering from discomfort associated with allergies during contact lens wear.

<sup>4</sup> The CLAO Journal, July 1999, Volume 25, Number 3

for refractions  $\geq$  ± 4.00D, but may sometimes also be required for lower refractions in the case of large vertex distances. Determine the spherical equivalent distance prescription for a multifocal patient. Determine the eye dominance using one of the methods below:

**Method 1 (preferred):** Determine which eye will accept the added power with the least reduction in vision while both eyes are open. Place a hand-held trial lens equal to +1.50D 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 +1.50D lens over the right or left eye, which is the non-dominant eye.

**Method 2:** 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.

### C. Select the Initial Trial Lens

- For each eye, select the trial lens distance power that is closest to the patient's distance spherical equivalent. Vertex distance compensation is generally only necessary for refractions  $\pm$  4.00D, but may sometimes also be required for lower refractions in the case of large vertex distances.
- Select the near power of the lens based on the patients ADD range as follows:
  - ADD: +0.75 to +1.25 use a "LOW" near ADD lens on each eye
  - ADD: +1.50 to +1.75 use a "MID" near ADD lens on each eye
  - ADD: +2.00 to +2.50 use a "MID" near ADD on the dominant eye and a "HGH" near ADD lens on the non-dominant eye
- Allow the lenses to settle for a minimum 10 minutes.
- Assess distance and near vision binocularly and monocularly.
- Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near.
- Make adjustments in power as necessary based on the distance over-refraction. The use of hand held trial lenses is recommended. Check the impact on distance and near vision.
- If vision is still unacceptable, make adjustments in power as necessary (see "Multifocal Troubleshooting" below). If distance and near vision are 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 PATIENT MANAGEMENT section).

## LENS CARE DIRECTIONS

When lenses are dispensed, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions for daily disposable lens wear.

The Eye Care Professional should review with patients that no cleaning or disinfection is needed with disposable lenses. Patients should always dispose of lenses when they are removed and have spare lenses or spectacles available.

### Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Eye Care Professionals may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

For complete information concerning contact lens handling and care, refer to the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at [www.acuvue.com](http://www.acuvue.com).

### Care for a Sticking (Non-Moving) Lens

During removal, if the lens sticks to the eye, 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

## EMERGENCIES

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

### D. Multifocal Troubleshooting

#### Unacceptable Near Vision:

If it has been determined that no change is required based on the over-refraction then add +0.25 D to the spherical power of the non-dominant eye.

#### Unacceptable Distance Vision:

If it has been determined that no change is required based on the over-refraction then make the changes as listed below:

- If the patient is wearing two "LOW" ADD lenses, change the dominant eye to an 1-DAY ACUVUE® MOIST MULTIFOCAL Contact Lens sphere lens with a power equal to the spherical equivalent distance prescription.
- If the patient is wearing two "MID" ADD lenses, change the ADD power in the dominant eye to the "LOW" ADD power.
- If the patient is wearing a "MID" ADD lens in the dominant eye and a "HGH" ADD lens in the non-dominant eye, change the non-dominant eye to a "MID" ADD lens and add +0.25D to the distance power. Once the changes have been made for the troubleshooting repeat steps 3-6 in section C above ("**Select the Initial Trial Lens**") to assess if the vision is acceptable.

### E. 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 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.

**All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download from [www.acuvue.com](http://www.acuvue.com).**

## HOW SUPPLIED

Each lens is supplied in a foil-sealed plastic package containing borate buffered saline solution with povidone. In the European Union, Borates (boric acid & sodium borate) are defined as CMR 1B substances in a concentration above 0.1% weight by weight and are safe when product is used according to label instructions. The plastic package is marked with the following:

- 1-DAY ACUVUE® MOIST: base curve, power, diameter, lot number, and expiration date
- 1-DAY ACUVUE® MOIST for ASTIGMATISM: base curve, power, diameter, cylinder, axis, lot number, and expiration date
- 1-DAY ACUVUE® MOIST MULTIFOCAL: base curve, power, diameter, ADD power, lot number, and expiration date

## REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing these lenses or experienced with the lenses should be reported to:

Johnson & Johnson Vision Care, Inc.  
7500 Centurion Parkway  
Jacksonville, FL 32256  
USA  
Tel: 1-800-843-2020  
[www.acuvue.com](http://www.acuvue.com)



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In Canada: Johnson & Johnson Vision Care, a Division of Johnson & Johnson (Canada) Inc.  
In USA: Johnson & Johnson Vision Care Inc.  
Printed in USA

SAP PN: 20602175  
Revision Date: March 2023  
Revision Number: M-03-23-00

## MONOVISION 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 with significant amounts of uncorrected astigmatism (greater than 1.00D) in one eye may not be a good candidate for monovision correction with these lenses.

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

- visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- driving automobiles (e.g., driving at night). Patients who cannot pass their state driver's 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. 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.

#### 1. 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.

## PACKAGE INSERT & FITTING INSTRUCTION GUIDE

**1-DAY ACUVUE® MOIST**  
**BRAND CONTACT LENSES**

**1-DAY ACUVUE® MOIST Brand Contact Lenses**  
**1-DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM**  
**1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses**

etafilcon A Soft (hydrophilic) Contact  
Lenses Visibility Tinted with UV Blocker  
for Daily Disposable Wear

**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 appropriate instructions that pertain to the patient's prescribed lenses. Copies are available for download at [www.acuvue.com](http://www.acuvue.com).**



CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner.



SYMBOLS KEY	
The following symbols may appear on the label or carton:	
SYMBOL	DESCRIPTION
	Caution, Consult Instructions for Use
	Date of Manufacture
	Manufacturer
	Use-By Date (expiration date)
	Batch Code
	Sterilized Using Steam Heat
	Indicates a Single Sterile Barrier System
	CE Mark and Identification number of Notified Body
	UK Conformity Assessment Marking and Identification Number of Notified Body
	Fee Paid for Waste Management
	CAUTION: US Federal law restricts this device to sale by or on the order of a licensed practitioner
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)
	Authorized Representative in the European Community
	Authorized Representative in the United Kingdom

## WARNINGS

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

**EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. IF THE PATIENT EXPERIENCES:**

- Eye Discomfort,
- Excessive Tearing,
- Vision Changes,
- Loss of Vision,
- Eye Redness, or
- Other Eye Problems,

**THE PATIENT SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE EYE CARE PROFESSIONAL.**

- Patients should be instructed not to wear their lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when lenses are worn overnight, and that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users.<sup>3</sup>
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products are essential for the safe use of these products.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care.

<sup>3</sup>New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

### Specific Instructions for Use and Warnings:

- **Water Activity Instruction for Use**

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 submersed in water when

SYMBOL	DESCRIPTION
	Contains Hazardous Substances
	Do Not Re-Use (Single Use)
	Do Not Use if Package is Damaged
	Medical Device Symbol
<b>ASTIGMATISM</b>	Lenses for Astigmatism
<b>UV BLOCKING</b>	UV Blocking
	UV Blocking
<b>MULTIFOCAL</b>	Multifocal
	Package Opening Icon (Blister)
	Package Opening Icon (Carton)
<b>DIA</b>	Diameter
<b>BC</b>	Base Curve
<b>D</b>	Diopter (lens power)
<b>CYL</b>	Cylinder
<b>AXIS</b>	Axis
<b>MAX ADD</b>	Near ADD
<b>LOW</b>	"Low" near ADD
<b>MID</b>	"Medium" near ADD
<b>HGH</b>	"High" near ADD

Visit [www.acuvue.com/guides](http://www.acuvue.com/guides) for additional information about symbols.

## PRECAUTIONS

participating in water sports or swimming in pools, hot tubs, lakes, or oceans, the patient should be instructed to discard them and replace them with a new pair. The Eye Care Professional should be consulted for recommendations regarding wearing lenses during any activity involving water.

### Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.
- Patients who wear these lenses to correct presbyopia using monovision or multifocal correction may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes unless otherwise indicated. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.

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

#### Handling Precautions:

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

## DESCRIPTION

1-DAY ACUVUE® MOIST Brand Contact Lenses, 1-DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM, and 1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses are soft (hydrophilic) contact lenses available as spherical, toric, or multifocal lenses, and include LACREON® Technology.

The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1, 1, 1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate.

The lenses are tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling. A benzotriazole UV absorbing monomer is used to block UV radiation.

#### Lens Properties:

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 1.40
  - Refractive Index: 1.40
  - Light Transmittance: 85% minimum
  - Surface Character: Hydrophilic
  - Water Content: 58%
  - Oxygen Permeability (Dk):
- |  |   |
|--|---|
| <b>VALUE</b>   | <b>METHOD</b>                                 |
| 21.4 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /mL x mm Hg) @ 35°C | Fatt (boundary corrected, edge corrected)     |
| 28.0 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /mL x mm Hg) @ 35°C | Fatt (boundary corrected, NON-edge corrected) |

#### Lens Parameter Ranges:

- Diameter (DIA): 12.0 mm to 15.0 mm
- Center Thickness: varies with power
- Base Curve (BC): 7.85 mm to 10.00 mm
- Spherical Power (D): -20.00D to +20.00D
- Cylinder(CYL): -0.25D to +0.00D
- Axis(AXIS): 2.5° to 180°
- ADD Power: +0.25D to +4.00D

Each lens is supplied in a foil-sealed plastic package containing borate buffered saline solution with methyl ether cellulose.

- **DO NOT** use if the sterile blister package is opened or damaged.
- Always wash, rinse, and dry hands before handling lenses. It is best to put on lenses before putting on makeup.
- DO NOT touch contact lenses with fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the "Patient Instruction Guide" for Contact Lenses and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container. Slide the lens up the side of the bowl until it is free of the container.
- Do not touch the lens with fingernails.

#### Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "*Care for a Sticking (Non-Moving) Lens*". The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- The patient should be advised to never allow anyone else to wear their lenses. Sharing lenses greatly increases the chance of eye infections.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the Eye Care Professional about wearing lenses during sporting activities.
- The patient should be advised to never rinse the lenses in water from the tap. Tap water contains many impurities that can contaminate or damage the lenses and may lead to eye infection or injury.

#### Lens Care Precautions:

- The patient should be informed that no cleaning or disinfection is needed when lenses are worn for daily disposable wear. Patients should always dispose of lenses when removed and have spare lenses or spectacles available.

## AVAILABLE LENS PARAMETERS

1-DAY ACUVUE® MOIST Brand Contact Lenses are hemispherical shells of the following dimensions:

- Diameter (DIA):** 14.2 mm
- Center Thickness:** 0.084 mm to 0.230 mm (varies with power)
- Base Curve (BC):** 8.5 mm, 9.0 mm
- Powers (D):** -0.50D to -6.00D (in 0.25D increments)
- 6.50D to -12.00D (in 0.50D increments)
- +0.50D to +6.00D (in 0.25D increments)

1-DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM are hemitoric shells of the following dimensions:

- Diameter (DIA):** 14.5 mm
- Center Thickness:** 0.090 mm to 0.189 mm (varies with power)
- Base Curve (BC):** 8.5 mm
- Powers (D):** +0.00D to -6.00D (in 0.25D increments)
- Cylinder (CYL): -0.75D, -1.25D, -1.75D, -2.25D\*
- Axis(AXIS): 10°, 20°, 180° in 10° increments
- \*-2.25D cylinder is available in 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180° axes only
- 6.50D to -9.00D (in 0.50D increments)
- Cylinders(CYL): -0.75D, -1.25D, -1.75D, -2.25D\*
- Axis(AXIS): 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°
- \*-2.25D cylinder is available in 20°, 90°, 160°, 180° axes only
- +0.25D to +4.00D (in 0.25D increments)
- Cylinders (CYL): -0.75D, -1.25D, -1.75D
- Axis (AXIS): 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°

### Other Topics to Discuss with Patients:

- Always contact the Eye Care Professional before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- Do not change lens type (e.g. brand name, etc.) or parameters (e.g. diameter, base curve, lens power, etc.) without consulting the Eye Care Professional.
- Instruct patients to always confirm the lens parameters printed on the multi-pack and on the individual lens package match their prescription. If there is a mismatch the patient should not use the product.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

### Who Should Know That the Patient is Wearing Contact Lenses?

- Patients should inform all doctors (Health Care Professionals) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

## ADVERSE REACTIONS

**The patient should be informed that the following problems may occur when wearing contact lenses:**

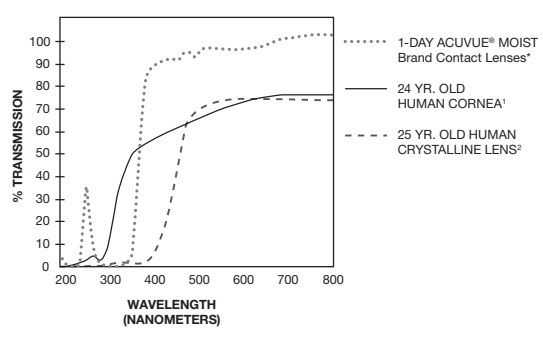
- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).

1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses (senofilcon A) are hemispherical shells of the following dimensions:

- Diameter (DIA):** 14.3 mm
- Center Thickness:** 0.084 mm to 0.207 mm (varies with power)
- Base Curve (BC):** 8.4 mm
- Powers (D):** -9.00D to +6.00D (in 0.25D increments)
- NearADD Powers (MAX ADD):** Medium Near ADD (MID): +1.75D
- High Near ADD (HGH): +2.50D

## TRANSMITTANCE CURVE

1-DAY ACUVUE® MOIST Brand Contact Lenses (senofilcon A) vs. 24 yr. old human cornea and 25 yr. old human crystalline lens.



\*The data are representative measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-3.00D lens, 0.084 mm center thickness).

<sup>1</sup> Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21

<sup>2</sup> Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5

- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, or corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis, and conjunctivitis; some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Have I noticed a change in my vision?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS. If the problem or discomfort stops, the patient should discard the lens and place a new fresh lens on the eye.

If after inserting the new lens, the problem continues, the patient should be directed to IMMEDIATELY REMOVE THE LENS AND CONTACT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

## GENERAL FITTING GUIDELINES

### A. Patient Selection

Patients selected to wear these lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear

Patients who do not meet the above criteria should not be provided with contact lenses.

**WARNING: UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear, such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. The patient should continue to use UV absorbing eyewear as directed.**

## ACTIONS

In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The UV Blocking for these lenses averages 97% in the UVB range of 280 nm to 315 nm and 82% in the UVA range of 316 nm to 380 nm for the entire power range.

**WARNING: UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear, such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.**

**NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV Blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV Blocking contact lenses reduces the risk of developing cataracts or other eye disorders. The Eye Care Professional should be consulted for more information.**

## INDICATIONS (USES)

1-DAY ACUVUE® MOIST Brand Contact Lenses are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are nearsighted (myopic) or farsighted (hyperopic) and may have 1.00D or less of astigmatism that does not interfere with visual acuity.

1-DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM are indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 0.50D to 3.00D of astigmatism.

### B. Pre-fitting Examination

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription (including determining the preferred reading distance for presbyopes), keratometry, and biomicroscopic evaluation.

Based on this evaluation, if it is determined that the patient is eligible to wear these lenses, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

#### C. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Vertex distance compensation is generally only necessary for refractions  $\pm$  4.00D, but may sometimes also be required for lower refractions in the case of large vertex distances.

#### D. Base Curve Selection (Trial Lens Fitting)

The following trial lenses should be selected for patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

- 1-DAY ACUVUE® MOIST: 8.5 mm/14.2 mm
- 1-DAY ACUVUE® MOIST for ASTIGMATISM: 8.5 mm/14.5 mm
- 1-DAY ACUVUE® MOIST MULTIFOCAL: 8.4 mm/14.3 mm

The trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. **Criteria of a Properly Fit Lens**

A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink, and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released.

2. **Criteria of a Flat Fitting Lens**

A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive

1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses are indicated for daily disposable wear for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 0.75D or less of astigmatism.

The lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The lenses are to be prescribed for daily disposable wear. Therefore, no clearing or disinfection is required. Lenses should be discarded upon removal.

## CONTRAINDICATIONS (REASONS NOT TO USE)

**DO NOT USE these lenses when any of the following conditions exist:**

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eye)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e. rewetting drops) that contain chemicals or preservatives (such as mercury or Thimerosal, etc.) to which some people may develop an allergic response
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses
- Any active corneal infection (bacterial, fungal, protozoal, or viral)
- If eyes become red or irritated

movement with the blink, and/or edge standoff. If the lens is judged to be flat fitting, it should not be dispensed to the patient.

#### 3. Criteria of a Steep Fitting Lens

A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation, and resistance when pushing the lens up digitally with the lower lid. If the lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial base curve is judged to be flat or steep fitting, the alternate base curve, if available, should be trial fit and evaluated after the patient has adjusted to the lens. The lens should move freely when manipulated digitally with lower lid, and then return to a properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

#### E. Final Lens Power

A spherical over-refraction should be performed to determine the final lens power after the lens fit is judged acceptable. The spherical over-refraction should be combined with the trial lens power to determine the final lens prescription. The patient should experience good visual acuity with the correct lens power unless there is excessive residual astigmatism.

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**).

**All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download from [www.acuvue.com](http://www.acuvue.com).**