

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, compensate 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.

Case Examples

Example 1

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

Choose a diagnostic lens for each eye with an axis as close to 180° as possible. 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.

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.

Here is the Rx Prescribed/Ordered:

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

Example 2

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

Choose diagnostic lenses of -3.00 -0.75 x 90 for the right eye and -4.50 -1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate. The orientation mark on the right lens rotates left from the 6 o'clock position by 10°.

The fitting indicates the following:

Right Eye

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

Here is the Rx prescribed:
O.D. -3.00 -0.75 x 100

Left Eye

The lens on the left eye shows good centration, movement and a consistent tendency for the mark to drift right by 10° from the 6 o'clock position following a forced blink.

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. 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 ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS. The ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS 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 drivers license requirements with the ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA are not recommended for patients who have -1.00 D or greater of refractive cylinder as this level

of uncorrected cylinder may lead to additional visual compromise.

The ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS come 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 "HIGH" = "high" near ADD lens (Max +2.50 ADD)

B. The ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA Contact Fitting Instructions

Step 1 Determine:
- Eye dominance (the methods described in MONOVISION SPHERE AND TORIC FITTING GUIDELINES may be used)
- Spherical equivalent distance prescription (vertex corrected if necessary and rounded to less minus if between powers)
- Near ADD

Step 2 Select the initial trial lens as follows:
- For each eye select the trial lens distance power that is closest to the patient's distance spherical equivalent.
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 "HIGH" near ADD lens on each eye

Step 3 Allow the lens to settle for a minimum 10 minutes.

Step 4 - 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 (see **Multifocal Troubleshooting** below). The use of hand-held trial lenses is recommended.

- 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 dispensing and follow up information in **PATIENT MANAGEMENT**).

C. Multifocal Troubleshooting

Unacceptable Near Vision:

Determine the amount of additional plus, or less minus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the non-dominant eye to the next highest ADD power.

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

Extended Wear (greater than 24 hours, including while asleep)

• The Eye Care Professional should determine the wearing and replacement schedule, based upon the patient's history and their ocular examination, as well as the practitioner's experience and clinical judgment.

• ACUVUE® OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS (senofilcon A), ACUVUE® OASYS® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS (senofilcon A) or ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS (senofilcon A) have been approved for extended wear for up to 6 nights/ 7 days of continuous wear. Not all patients can achieve the maximum wear time.

• It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Professional.

• Once removed, it is recommended that the lens remain out of the eye for a period of rest overnight or longer and discarded in accordance with the prescribed wearing schedule. The Eye Care Professional should examine the patient during the early stages of extended wear.

• For **Therapeutic** lens wear, close supervision by the Eye Care Professional is necessary. ACUVUE® OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS (senofilcon A), ACUVUE® OASYS® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS (senofilcon A) or ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS (senofilcon A) 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 with HYDRACLEAR® PLUS (senofilcon A), ACUVUE® OASYS® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS (senofilcon A) and ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS (senofilcon A) should be discarded upon removal.

LENS CARE DIRECTIONS

When lenses are dispensed, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions in accordance with the individual patient's lens type and wearing schedule. The Eye Care Professional should recommend an appropriate care system tailored to the patient's individual requirements.

For complete information concerning contact lens handling, care, cleaning, disinfecting and storage, refer to the ACUVUE® OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS (senofilcon A), the ACUVUE® OASYS® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS (senofilcon A) and the ACUVUE® OASYS® Brand Contact

Unacceptable Distance Vision:

Determine the amount of additional minus, or less plus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the dominant eye to the next lowest ADD power. If the patient is wearing two low ADD lenses change the dominant eye to a sphere lens with a power equal to the spherical equivalent distance prescription.

Unacceptable Distance and Near Vision:

Determine the amount of additional plus and/or minus over one or both eyes that is acceptable while checking the effect on distance and near vision. If additional plus and/or minus is not required change the lens power in the dominant eye to the next lowest ADD power and the lens power in the non-dominant eye to the next highest ADD power if applicable.

V. 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 Lenses, the ACUVUE® OASYS® Brand Contact Lenses for ASTIGMATISM or the ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA.

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.

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.

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 anisometric 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 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 have a +1.75D lens on the near eye and the other eye left

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing ACUVUE® OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS (senofilcon A), ACUVUE® OASYS® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS (senofilcon A) and ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS (senofilcon A) **prescribed for disposable 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 replacement lenses or spectacles available. Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses or spectacles are not available.

For ACUVUE® OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS (senofilcon A), ACUVUE® OASYS® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS (senofilcon A) and ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS (senofilcon A) **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.

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.

HOW SUPPLIED

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with 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].

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, 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.

All patients should be supplied with a copy of the "ACUVUE® OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS (senofilcon A), the ACUVUE® OASYS® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS (senofilcon A) or the ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS (senofilcon A) Patient Instruction Guide".

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

ACUVUE® OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS

(senofilcon A)

Visibility Tinted with UV Blocker For Daily and Extended Wear

Johnson & Johnson Vision Care, Inc.

7500 Centurion Parkway
Jacksonville, FL 32256

USA

Tel: 1-800-843-2020

www.acuvue.com



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ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR® PLUS (senofilcon A); ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS (senofilcon A); ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS (senofilcon A) Visibility Tinted with UV Blocker for Daily and Extended Wear.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
	Batch Code
	Sterilizing Steam or Dry Heat
	Diameter
	Base Curve
	Diopter (lens power)
	Quality System Certification Symbol
	UV-Blocking
	Fee Paid for Waste Management
	Peel Back Foil
	CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Center Thickness
	Lens Orientation Correct
	Lens Inside Out
	Cylinder Power
	Axis
	“Low” near ADD
	“Medium” near ADD
	“High” near ADD
	Consult Instructions for Use
	Manufactured by or in

Spherical Lenses For:
Myopia, Hyperopia, Phakic or Aphakic

Multifocal Lenses For:
Presbyopia, Phakic or Aphakic

Toric Lenses For:
Myopic Astigmatism, Hyperopic Astigmatism, Mixed Astigmatism, Phakic or Aphakic

Lenses for Therapeutic Use as a Bandage Lens

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

radiation. The transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

Lens Properties:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.42
- Light Transmittance: 85% minimum
- Surface Character: Hydrophilic
- Water Content: 38%
- Oxygen Permeability:

VALUE
103 x 10⁻¹¹ (cm²/sec)
(ml O₂/ml x mm Hg) at 35°C
122 x 10⁻¹¹ (cm²/sec)
(ml O₂/ml x mm Hg) at 35°C

METHOD
Fatt (boundary corrected, edge corrected)
Fatt (boundary corrected, non-edge corrected)

Lens Parameters:

The ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR® PLUS (senofilcon A), ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS (senofilcon A) and the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS (senofilcon A) are a hemispherical and/or hemitric shell available within the following dimensions:

Diameter Range: 12.0mm to 15.0mm
Center Thickness: Low minus lens – varies with power
Plus lens – varies with power
Base Curve Range: 7.85mm to 10.00mm
Power Range: Spherical Powers: Daily Wear -20.00D to +20.00D
Extended Wear Powers: -20.00D to +14.00D
Multifocal ADD Powers: +0.25D to +4.00D
Cylinder Powers: -0.25D to -10.00D
Axis: 2.5° to 180°

AVAILABLE LENS PARAMETERS

ACUVUE® OASYS™ Brand Contact Lenses

Diameter: 14.0mm
Center Thickness: Low minus lens – varies with power (e.g., -4.00D: 0.070mm)
Plus lens – varies with power (e.g., +4.00D: 0.168mm)
Base Curve: 8.4mm, 8.8mm **Power Range:** -12.00D to +8.00D

ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM

Diameter: 14.5mm
Center Thickness: Low minus lens – varies with power (e.g., -4.00D: 0.080mm)
Plus lens – varies with power (e.g., +4.00D: 0.172mm)
Base Curve: 8.6mm

ACTIONS

In their hydrated state, the ACUVUE® OASYS™ Brand Contact Lenses, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM and the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA, when placed on the cornea, act as a refracting medium to focus light rays on the retina. When hydrated and placed on the cornea for therapeutic use, the ACUVUE® OASYS™ Brand Contact Lenses, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM and the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA act as a bandage to protect the cornea.

Power Range: Sphere: plano to -6.00D (in 0.25D increments)
-6.50D to -9.00D (in 0.50D increments)
+0.25D to +6.00D (in 0.25D increments)
Cylinder: -0.75D, -1.25D, -1.75D, -2.25D
Axis: 10° to 180° (in 10° increments)

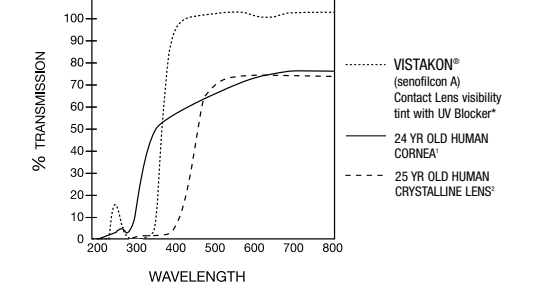
ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS
Diameter: 14.3mm
Center Thickness: Low minus lens – varies with power (e.g., -4.00D: 0.070mm)
Plus lens – varies with power (e.g., +4.00D: 0.170mm)

The transmittance characteristics are less than 1% in the UVB range of 280nm to 315nm and less than 10% in the UVA range of 316nm to 380nm for the entire power range.

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. Consult your Eye Care Professional for more information.

TRANSMITTANCE CURVES

ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR® PLUS (senofilcon A), ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS (senofilcon A) and the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS (senofilcon A) Contact Lens Visibility Tinted with UV Blocker vs.24 yr. old human cornea and 25 yr. old human crystalline lens.



*The data was obtained from measurements taken through the central 3-5mm portion for the thinnest marketed lens (-1.00D lens, 0.070mm center thickness).

- Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, figure 2-21
- Waxler, M., Hitchings, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 13, figures 5

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.

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).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and 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, photo-phobia, 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 discomfort or problem stops, the patient should then look closely at the lens.

If the lens is in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and apply a new fresh lens on the eye.

If the lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, he or she should be instructed to dispose of the lens and apply a new fresh lens.

If the problem continues, the patient SHOULD NOT put the lens back on the eye but IMMEDIATELY CONSULT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be instructed NOT to use a new lens as self-treatment for the problem.

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.

INDICATIONS (USES)

All ACUVUE® OASYS™ Brand Contact Lenses, ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM and ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The ACUVUE® OASYS™ Brand Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism.

The ACUVUE® OASYS™ Brand Contact Lens for PRESBYOPIA is indicated for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D or less of astigmatism.

The ACUVUE® OASYS™ Brand Contact Lens for ASTIGMATISM is indicated for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism.

Eye Care Professionals may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement (see "Wearing Schedule"). When prescribed for frequent/planned replacement wear, the lenses may be cleaned and disinfected using a chemical disinfection system only.

ACUVUE® OASYS™ Brand Contact Lenses, ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM and ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA

FITTING GUIDELINES

I. GENERAL FITTING INSTRUCTIONS

ACUVUE® OASYS™ Brand Contact Lenses
ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM
ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA

A. Patient Selection:

Patients selected to wear ACUVUE® OASYS™ Brand Contact Lenses, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM and the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA 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.

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 the ACUVUE® OASYS™ Brand Contact Lenses, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM or the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

have been approved for daily and extended wear for up to 6 nights/7 days of continuous wear. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Professional.

The ACUVUE® OASYS™ Brand Contact Lenses, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM and the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA are also indicated for therapeutic use as a bandage lens for the following acute and chronic ocular conditions:

- For corneal protection in lid and corneal abnormalities such as entropion, trichiasis, tarsal scars and recurrent corneal erosion. In addition they are indicated for protection where sutures or ocular structure malformation, degeneration or paralysis may result in the need to protect the cornea from exposure or repeated irritation.
- For corneal pain relief in conditions such as bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, and post-keratoplasty.
- For use as a barrier during the healing process of epithelial defects such as chronic epithelial defects, corneal ulcer, neurotrophic and neuroparalytic keratitis, and chemical burns.
- For post surgical conditions where bandage lens use is indicated such as post refractive surgery, lamellar grafts, corneal flaps, and additional ocular surgical conditions.
- For structural stability and protection in piggy back lens fitting where the cornea and associated surfaces are too irregular to allow for corneal rigid gas permeable (RGP) lenses to be fit. In addition the use of the lens can prevent irritation and abrasions in conditions where there are elevation differences in the host/graph junction or scar tissue.

Lenses prescribed for therapeutic use may be worn for daily or extended wearing periods.

CONTRAINDICATIONS (REASONS NOT TO USE)

When prescribing contact lens wear for REFRACTIVE AMETROPIA USE, DO NOT USE the ACUVUE® OASYS™ Brand Contact Lenses, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM or the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA 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
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions

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. Remember to compensate for vertex distance if the refraction is greater than +4.00 D.

D. Base Curve Selection (Trial Lens Fitting)

For the ACUVUE® OASYS™ Brand Contact Lenses, the 8.4mm/14.0mm Contact Lens should be selected for myopic patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status. For ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM and ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA, the initial lens should be selected from the currently available base curves.

ACUVUE® OASYS™ Brand Contact Lenses or ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM or ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA 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. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

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 movement with the blink and/or edge standoff. If the ACUVUE® OASYS™ Brand Contact Lens, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM or the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA 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 ACUVUE® OASYS™ Brand Contact Lens, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM or the ACUVUE® OASYS™ Brand Contact Lens for PRESBYOPIA is judged to be steep fitting, it should not be dispensed to the patient.

If the initial ACUVUE® OASYS™ Brand Contact Lens, the ACUVUE® OASYS™ Brand Contact Lens for ASTIGMATISM or the ACUVUE® OASYS™ Brand Contact Lens for PRESBYOPIA is judged to be steep fitting, it should not be dispensed to the patient.

- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the ACUVUE® OASYS™ Brand Contact Lenses, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM and the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

For THERAPEUTIC USE, the Eye Care Professional may prescribe the ACUVUE® OASYS™ Brand Contact Lenses, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM and the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA to aid in the healing process of certain ocular conditions, which may include those cited above.

WARNINGS

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

- 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, including lens cases, are essential for the safe use of these products.
- Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Studies have shown that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users¹.
- When daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is greater than among those who do not wear them overnight.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- Studies have shown that the risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.

If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Professional. It is recommended that contact lens wearers see their Eye Care Professional routinely as directed.

PRECAUTIONS

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

¹New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

Contact Lens for PRESBYOPIA 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.

II. SPHERICAL LENS FITTING GUIDELINES

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**).

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 with HYDRACLEAR® PLUS

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

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 the ACUVUE® OASYS™ Brand Contact Lenses, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM and the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA to correct presbyopia using Monovision 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. 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 the lenses immediately if the eyes become red or irritated.

Eye Care Professionals should carefully instruct frequent replacement lens wear 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.
- DO NOT** use if the sterile blister package is opened or damaged.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the "Patient Instruction Guide" for the ACUVUE® OASYS™ Brand Contact Lenses, the ACUVUE® OASYS™ Brand Contact Lenses for ASTIGMATISM and the ACUVUE® OASYS™ Brand Contact Lenses for PRESBYOPIA and those prescribed by the Eye Care Professional.

the 6 o'clock mark as you would with a prism-ballasted lens.

Figure 1

You'll need a bi microscope 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 reticuloluminated area. Backgrounding the mark this way should make them 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 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 the ACUVUE®