

FITTING & PATIENT MANAGEMENT GUIDE

ACUVUE® ADVANCE™ Brand Contact Lenses *for ASTIGMATISM* (galyfilcon A)

Visibility Tinted with UV Blocker for Daily Wear



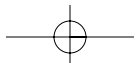
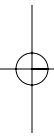
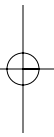


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INTRODUCTION AND PRODUCT DESCRIPTION

CAUTION: Federal Law Restricts This Device To Sale By Or On The Order Of A Licensed Practitioner.

See Package Insert for Actions, Contraindications, Warnings, Precautions, Adverse Reactions and Patient Lens Care Directions.

Introduction

The ACUVUE® ADVANCE™ Brand Contact Lenses *for ASTIGMATISM* have a water content of 47% by weight. For a complete listing of available lens parameters, please refer to “Available Lens Parameters.”

Product Description

The ACUVUE® ADVANCE™ Brand Contact Lenses *for ASTIGMATISM* are available as an astigmatic (toric) lens. The lens material (galyfilcon A) is a copolymer of 2-hydroxyethyl methacrylate and (3-methacryloxy-2-hydroxypropyloxy) propylbis(trimethylsiloxy)methylsilane and N,N-dimethylacryl amide, and polyvinylpyrrolidone and mPDMS-monomethacrylate(n=11), and 2-propenoic acid, 2-methyl-, 1,2-ethandiyl ester. The ACUVUE® ADVANCE™ *for ASTIGMATISM* Contact Lens Visibility Tinted with UV Blocker is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling. A benzotriazole UV-absorbing monomer is used to block UV radiation. 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.

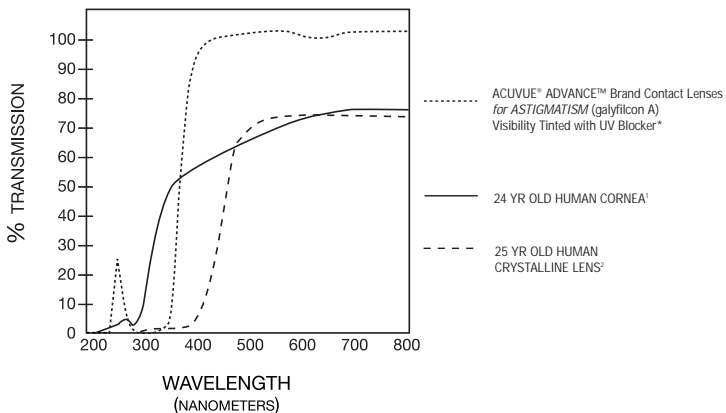
WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear, such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed.

AVAILABLE LENS PARAMETERS

Diameter:	14.5mm		
Center Thickness:	Low minus lens – varies with power (e.g., -3.00D: 0.070mm)		
	Plus lens – varies with power (e.g., +3.00D: 0.131mm)		
Base Curve:	8.6mm		
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)	

TRANSMITTANCE CURVES

ACUVUE® ADVANCE™ Brand Contact Lenses *for ASTIGMATISM* (galyfilcon A) Visibility Tinted with UV Blocker, 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 (-3.00D lens, 0.070mm center thickness)

1. Lerman, S., *Radiant Energy and the Eye*, MacMillan, New York, 1980, p. 58, figure 2-21
2. Waxler, M., Hitchins, V.M., *Optical Radiation and Visual Health*, CRC Press, Boca Raton, Florida, 1986, p. 10, figure 5

WEARING RESTRICTIONS AND INDICATIONS

ACTIONS

See Package Insert for "Actions".

INDICATIONS (USES)

The ACUVUE® ADVANCE™ Brand Contact Lens *for ASTIGMATISM* (galyfilcon A) is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes who are hyperopic or myopic and may have 0.50D to 3.00D of astigmatism.

Eye Care Professionals may prescribe the lens for frequent replacement wear with cleaning, disinfection and scheduled replacement (see Package Insert). When prescribed for frequent replacement wear, the lens may be disinfected using a chemical disinfection system only.

ACUVUE® ADVANCE™ *for ASTIGMATISM* (galyfilcon A) UV-Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS

See Package Insert for "Contraindications", "Warnings", "Precautions" and "Adverse Reactions".

GENERAL FITTING GUIDELINES

PATIENT SELECTION

You should first assess the patient's needs and ensure that the patient is an appropriate candidate for the ACUVUE® ADVANCE™ *for ASTIGMATISM* (galyfilcon A) Contact Lens. The ACUVUE® ADVANCE™ *for ASTIGMATISM* (galyfilcon A) Contact Lens, like other soft contact lenses, will require the appropriate and usual physiological and diagnostic assessments necessary to ensure proper patient selection. Refer to the Package Insert for additional information on patient selection.

Pre-fitting Examination

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for ACUVUE® ADVANCE™ Brand Contact Lenses *for ASTIGMATISM* (galyfilcon A) (consider patient hygiene and mental and physical state), and
- Take ocular measurements for the initial contact lens parameter selection, and

- Collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination may include a determination of optimal distance and near spectacle correction and corneal curvature measurements.

LENS SELECTION

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 proper fit of toric lenses. In prescribing the ACUVUE® ADVANCE™ *for ASTIGMATISM* (galyfilcon A) Contact Lens, 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. Base Curve Fitting

In clinical tests, the ACUVUE® ADVANCE™ *for ASTIGMATISM* (galyfilcon A) 8.6mm/14.5mm Contact Lens have performed successfully on eyes with a range of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

An ACUVUE® ADVANCE™ *for ASTIGMATISM* (galyfilcon A) 8.6mm/14.5mm trial lens should be placed on each of the patient's astigmatic eyes and evaluated after the patient has adjusted to the lenses. 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.

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® ADVANCE™ *for ASTIGMATISM* (galyfilcon A) 8.6mm/14.5mm Contact Lens is judged to be flat fitting, it should not be dispensed to the patient.

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® ADVANCE™ *for ASTIGMATISM* (galyfilcon A) 8.6mm/14.5mm Contact Lens is judged to be steep fitting, it should not be dispensed to the patient.

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 trial lens power. Remember to compensate for vertex distance if the sphere or the combined sphere and cylinder refraction is greater than $\pm 4.00D$. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate.

C. Cylinder Power and Axis Determination

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 (90°) 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 90° 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.



You'll need a biomicroscope and a 1mm or 2mm parallel piped 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 parallel piped and medium magnification (10X or 15X), slowly pan down the lens, looking just below the direct illumination at the retroilluminated area. Backlighting the mark this way should make them more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark.

2. Observe Lens Rotation and Stability

Observe the position and stability of the “bottom” mark. It usually stabilizes at the 90° position – at 6 o'clock. 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 of the vertical meridian (drift) 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. A horizontal line running through the 9 o'clock and 3 o'clock position would be 0° and a vertical line running through the 6 o'clock and 12 o'clock position would be 90°. Thus, 7 o'clock would be 60° and 5 o'clock would be 120° on the phoropter.

If the orientation mark of the initial lens stabilizes somewhat left or right of the 90° 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” and round it off into 5° increments, 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.

D. Final Lens Determination

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 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 $> \pm 4.00D$, compensate for vertex distance. If sphere alone or combined sphere and cylinder Rx $\leq \pm 4.00D$, vertex compensation is not necessary.

For the Cylinder:

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

Case Examples

Example 1

Manifest (spectacle) refraction:

O.D. $-2.50 -1.25 \times 180$ 20/20

O.S. $-2.00 -1.00 \times 180$ 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. $-2.50 -1.25 \times 180$

O.S. $-2.00 -0.75 \times 180$

Example 2

Manifest (spectacle) refraction:

O.D. $-3.00 -1.00 \times 90$ 20/20

O.S. $-4.75 -2.00 \times 90$ 20/20

Choose diagnostic lenses of $-3.00 -0.75 \times 90$ for the right eye and $-4.50 -1.75 \times 90$ 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

MONOVISION FITTING GUIDELINES

PATIENT SELECTION

A. Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient may not be a good candidate for monovision correction with the ACUVUE® ADVANCE™ Brand Contact Lenses for ASTIGMATISM (galyfilcon A).

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:

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

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient 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. 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.

EYE SELECTION

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

A. 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.

B. 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.

C. Visual Demands Method

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

Example:

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

SPECIAL FITTING CHARACTERISTICS

Unilateral Lens Correction

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

Example:

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

A presbyopic patient requiring a +1.50D ADD who is -2.50D myopic in the right eye and -1.50D myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

Near ADD Determination

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

Trial Lens Fitting

A trial 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 a minimum of 3 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.

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 performances 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.

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

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of 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® ADVANCE™ Brand Contact Lenses *for ASTIGMATISM* (galyfilcon A) Patient Instruction Guide."

PATIENT MANAGEMENT

DISPENSING VISIT

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with up to 0.01% methyl ether cellulose. In removing the lens from the container, peel back the foil seal, place a finger on the lens and slide the lens up the side of bowl of the lens package until it is free of the container.

- Evaluate the physical fit and visual acuity of the lens on each eye.
- Teach the patient how to apply and remove his or her lenses.
- Explain the daily wear regimen and schedule a follow-up examination.
- PROVIDE THE PATIENT WITH A COPY OF THE ACUVUE® ADVANCE™ BRAND CONTACT LENSES *for ASTIGMATISM* (galyfilcon A) PATIENT INSTRUCTION GUIDE. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE.
- Recommend an appropriate cleaning and disinfecting system and provide the patient with instructions regarding proper lens care (see Package Insert). Chemical or hydrogen peroxide disinfection is recommended. Heat disinfection is not advised.
- Review the Package Insert for the ACUVUE® ADVANCE™ *for ASTIGMATISM* (galyfilcon A) Contact Lens and provide the patient with all of the relevant information and precautions on the proper use of ACUVUE® ADVANCE™ *for ASTIGMATISM* (galyfilcon A) Contact Lenses.

FOLLOW-UP EXAMINATIONS

Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule, lens replacement schedule and proper lens care and handling procedures.

A. Recommended Follow-up Examination Schedule for ACUVUE® ADVANCE™ for ASTIGMATISM (galyfilcon A) Contact Lenses for Daily Wear:

1. One week from the initial lens dispensing to patient
2. One month post-dispensing
3. Every three to six months thereafter

NOTE: Preferably, at the follow-up visits, lenses should be worn for at least six hours. (complications and specific problems should be managed on an individual patient basis)

B. Recommended Procedures for Follow-Up Visits:

1. Solicit and record patient's symptoms, if any.
2. Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.
3. Perform an over-refraction at distance and near to check for residual refractive error.
4. With the biomicroscope, judge the lens fitting characteristics (as described in the "General Fitting Guidelines") and evaluate the lens surface for deposits and damage.
5. Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein.
 - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
 - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
 - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

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

RECOMMENDED WEARING SCHEDULE

See Package Insert.

PATIENT LENS CARE DIRECTIONS

See Package Insert for "Lens Care Directions" for lenses worn on a frequent replacement schedule.

CHEMICAL (NOT HEAT) DISINFECTION

See Package Insert for "Chemical Lens Disinfection" of lenses worn on a frequent replacement schedule.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

See Package Insert for "Care For A Dehydrated Lens" when lenses are worn on a frequent replacement schedule.

CARE FOR A STICKING (NON-MOVING) LENS

See Package Insert for "Care For A Sticking Lens".

REPORTING OF ADVERSE REACTIONS

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

VISTAKON

DIVISION OF
Johnson & Johnson
Vision Care, Inc.

VISTAKON®, Division of Johnson & Johnson Vision Care, Inc.

P.O. Box 10157

Jacksonville, FL 32247-0157

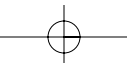
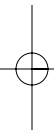
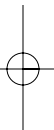
1-800-843-2020

HOW SUPPLIED

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with up to 0.01% methyl ether cellulose. The plastic package is marked with base curve, sphere power, cylinder power, axis, diameter, lot number and expiration date.



PASTE
PACKAGE INSERT
HERE





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

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