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FITTING & PATIENT MANAGEMENT GUIDE

ACUVUE® 2 *COLOURS*™ Brand (etafilcon A) Contact Lens



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Fitting and Patient Management Guide For ACUVUE® 2 COLOURS™ Brand (etafilcon A) Contact Lenses With UV Blocker For Daily and Extended Wear

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Package Insert attached to inside back cover.

INTRODUCTION AND PRODUCT DESCRIPTION

ACUVUE® 2 COLOURS™ Brand (etafilcon A) Soft (hydrophilic) Contact Lenses are made from etafilcon A with a water content of 58% by weight.

For a complete listing of available lens parameters, please refer to "AVAILABLE PARAMETERS".

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

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

Product Description

The ACUVUE® 2 COLOURS™ Brand (etafilcon A) Soft (hydrophilic) Contact Lens is available as a spherical lens. 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 ACUVUE® 2 COLOURS™ Brand Contact Lens contains a pigmented area that will mask or enhance the color of the natural iris. The lens is colored with one or more of the following color additives: iron oxides, titanium dioxide, phthalocyaninato (2-) copper, phthalocyanine green, vat orange 1 and reactive blue dye #4. The ACUVUE® 2 COLOURS™ Brand Contact Lens is available in the following opaque colors: Blue, Gray, Green and Honey. They are also available in the following enhancer colors: Blue, Green and Aqua.

In the ACUVUE® 2 COLOURS™ Brand Contact Lens with UV Blocker, a benzotriazole UV-absorbing monomer is used to block UV radiation. The UV-Blocking for ACUVUE® 2 COLOURS™ averages 97% in the UVB range of 280 nm to 315 nm and 81% in the UVA range of 316 nm to 380 nm.

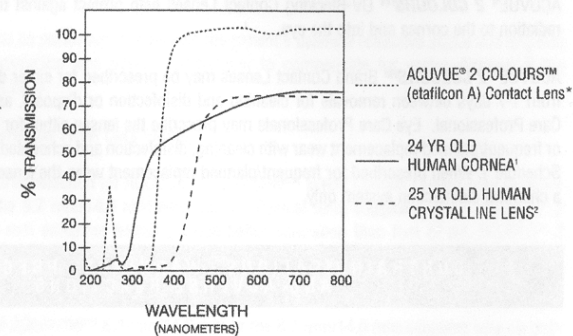
WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed.

AVAILABLE LENS PARAMETERS

Diameter:	14.0mm
Center Thickness:	Low minus lens – varies with power (e.g., -3.00D: 0.084mm)
Base Curve:	8.3mm and 8.7mm (enhancers); 8.3mm (opaques)
Powers:	0.00D -0.25D 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)

TRANSMITTANCE CURVES

ACUVUE® 2 COLOURS™ Brand (etafilcon A) Contact Lens with UV blocker (Opaque), 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 ACUVUE® 2 COLOURS™ Contact lens, 0.084mm center thickness).

1. Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21
2. Waxler, M. Hitchens, 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® 2 COLOURS™ Brand Contact Lenses are indicated for daily and extended wear to enhance or alter the apparent color of the eye and/or for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

Eye Care Professionals may prescribe the lens for either single-use disposable wear or for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system only.

ACUVUE® 2 COLOURS™ UV-Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

ACUVUE® 2 COLOURS™ Brand Contact Lenses may be prescribed for either daily wear or extended wear from 1-7 days between removals for cleaning and disinfection or disposal, as recommended by the Eye Care Professional. 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 disinfected using a chemical disinfection system only.

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® 2 COLOURS™ Brand (etafilcon A) Contact Lens. The ACUVUE® 2 COLOURS™ Brand Contact Lenses, 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.

1. Pre-fitting Examination

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

- Determine whether a patient is a suitable candidate for ACUVUE® 2 COLOURS™ Brand Contact Lenses (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. The near correction should be determined at the midpoint of the patient's habitual reading distance. When more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers that meet the patient's requirements.

LENS SELECTION

A. 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.

B. Enhancer Base Curve Selection (Trial Lens Fitting)

The initial enhancer base curve selection for ACUVUE® 2 COLOURS™ Brand Contact Lenses may be either the 8.3 mm/14.0 mm or the 8.7 mm/14.0 mm base curve. Clinical tests suggest that the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm enhancer lenses provide better centration than that of the ACUVUE® 2 COLOURS™ 8.7 mm/14.0 mm enhancer lenses. Both provide similar movement characteristics on eyes with a wide range of corneal curvatures.

Insert either the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm or the 8.7 mm/14.0 mm enhancer lens on both of the patient's eyes and evaluate the lens fit characteristics 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 enhancer lens may exhibit one or more of the following characteristics: decentration, tint visible on the sclera, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If either the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm or the 8.7 mm/14.0 mm enhancer lens is judged to be flat fitting, the lens should not be dispensed to the patient. If the ACUVUE® 2 COLOURS™ 8.7 mm/14.0 mm enhancer lens is selected as the first trial lens, and is judged to be flat fitting,

the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm enhancer lens should be trial fit and evaluated after the patient has adjusted to the lenses.

A steep fitting enhancer 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 either the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm or the 8.7 mm/14.0 mm enhancer lens is judged to be steep fitting, it should not be dispensed to the patient. If the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm enhancer lens is selected as the first trial lens, and is judged to be steep fitting, the ACUVUE® 2 COLOURS™ 8.7 mm/14.0 mm enhancer lens should be trial fit and evaluated after the patient has adjusted to the lenses.

C. Opaque Base Curve (Trial Lens Fitting)

The opaque base curve for ACUVUE® 2 COLOURS™ Brand Contact Lenses is 8.3 mm/14.0 mm. Clinical tests suggest that the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm opaque lenses provide optimal centration, while maintaining adequate movement characteristics on eyes with a wide range of corneal curvatures.

Insert the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm opaque lens on both of the patient's eyes and evaluate the lens fit characteristics after the patient has adjusted to the lenses. A properly fit opaque 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.

A flat fitting opaque lens may exhibit one or more of the following characteristics: decentration, opaque color overlapping the pupil area, tint visible on the sclera, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If the ACUVUE® 2 COLOURS™ 8.3 mm/14.0 mm opaque 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® 2 COLOURS™ 8.3mm/14.0mm contact lens is judged to be steep fitting, it should not be dispensed to the patient.

D. Final Lens Power

To assess vision for patients in need of vision correction for ACUVUE® 2 COLOURS™ Brand Contact Lenses, ACUVUE® 2 Brand trial lenses should be used in accordance with the fitting procedures for ACUVUE® 2 lenses.

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 (ACUVUE® 2):	-2.00 D
Spherical over-refraction	-0.25 D
Final lens power:	-2.25 D

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

In Summary:

- ACUVUE® 2 lenses may be used to determine the final lens power of the ACUVUE® 2 COLOURS™;
- ACUVUE® 2 COLOURS™ plano trial lenses may be used to assist patients in choosing a lens color;
- ACUVUE® 2 COLOURS™ plano trial lenses should be used to assess fit, cosmetic appearance, and vision/visual acceptance (for the patients who do not need vision correction).

MONOVISION FITTING GUIDELINES

PATIENT SELECTION

A. 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 1.00D) in one eye may not be a good candidate for monovision correction with the ACUVUE® 2 COLOURS™ Brand (etafilcon A) Contact Lens.

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.

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

B. 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.

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 a plano lens on the other eye.

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 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 are 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 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 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® 2 COLOURS™ Brand (etafilcon A) Contact Lenses Patient Instruction Guide".

PATIENT MANAGEMENT

Dispensing Visit

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. 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 the 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 insert and remove his or her lenses.
- Explain the daily and extended wear regimens and schedule a follow-up examination.
- PROVIDE THE PATIENT WITH A COPY OF THE APPROPRIATE ACUVUE® 2 COLOURS™ BRAND CONTACT LENSES PATIENT INSTRUCTIONS (DISPOSABLE OR FREQUENT REPLACEMENT). 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 and hydrogen peroxide disinfection is recommended. Heat disinfection is not advised.
- Review the Package Insert for the ACUVUE® 2 COLOURS™ Brand (etafilcon A) Contact Lens and provide the patient with all of the relevant information and precautions on the proper use of the ACUVUE® 2 COLOURS™ Brand Contact Lens.
- It is recommended that the new contact lens wearer first be evaluated on a daily wear schedule. If, in the opinion of the Eye Care Professional, the patient is determined to be an acceptable daily and extended wear candidate, the Eye Care Professional is encouraged to determine a wearing schedule based upon the response of the patient.

Follow-Up Examinations

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

Recommended Follow-up Examination Schedule for ACUVUE® 2 COLOURS™ Brand Contact Lenses for Daily and Extended Wear

(complications and specific problems should be managed on an individual patient basis):

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.

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, and reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
 - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

If any observations are abnormal, use professional judgment to alleviate the problem and restore the eye to optimal conditions. If the criteria for successful fit are not satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and 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® 2 COLOURS™ Brand Contact Lenses or experienced with the lenses should be reported to:



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

How Supplied

Each sterile lens is supplied in a foil-sealed package containing buffered saline solution. The plastic package is marked with base curve, diopter power, diameter, lens color, lot number and expiration date.

NOTES

A series of horizontal lines for taking notes, located on the right side of the page.

NOTES

