

III. MONOVISION (SPHERICAL 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 **1•DAY ACUVUE® TruEye™** Brand Contact Lenses.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision correction. Monovision contact lens wear may not be optimal for 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 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 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 adaptation symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the 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 "1•DAY ACUVUE® TruEye™ Brand Contact Lenses Patient Instruction Guide".

PATIENT MANAGEMENT

Dispensing Visit

- PROVIDE THE PATIENT WITH A COPY OF THE 1•DAY ACUVUE® TruEye™ Brand Contact Lenses PATIENT INSTRUCTION GUIDE. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING SCHEDULE.**

- Schedule a follow-up examination.

Follow-up Examinations

- Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific

problems, if any, and a review with the patient of the wear schedule and handling procedures.

- Recommended Follow-up Examination Schedule for **1•DAY ACUVUE® TruEye™** Brand Contact Lenses (complications and specific problems should be managed on an individual patient basis):
 - One week from the initial lens dispensing to patient
 - One month post-dispensing
 - Every three to six months thereafter

Preferably, at the follow-up visits, lenses should be worn for at least six hours.

- Recommended Procedures for Follow-Up Visits:

- Solicit and record patient's symptoms, if any.
- Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.
- Perform an over-refraction at distance and near to check for residual refractive error.
- With the biomicroscope, judge the lens fitting characteristics (as described in the General Fitting Guidelines) and evaluate the lens surface for deposits and damage.
- Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein (unless contraindicated).

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

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

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

WEARING SCHEDULE

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

DAILY DISPOSABLE WEAR (less than 24 hours, while awake)

- For daily disposable wear, VISTAKON® recommends that **1•DAY ACUVUE® TruEye™** Brand Contact Lenses be discarded upon removal.

The maximum suggested wearing time for these lenses is:

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

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.

For **1•DAY ACUVUE® TruEye™** Brand Contact Lenses prescribed for daily wear single use only: The Eye Care Professional should review with patients that no cleaning or disinfection is needed. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

CARE FOR A STICKING (NON-MOVING) LENS

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 Tinted), lot number and expiration date.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing **1•DAY ACUVUE® TruEye™** Brand Contact Lenses or experienced with the lenses should be reported to:

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

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



20400361

©Johnson & Johnson Vision Care, Inc. 2010
Printed in U.S.A.
Revision date 3/10
Revision number: AT-03-10-01

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.

1•DAY ACUVUE® TruEye™
Brand Contact Lenses with
HYDRACLEAR® 1
(narafilcon B)

Visibility Tinted with UV Blocker
For Single Use Daily Wear Only

1-DAY ACUVUE® TruEye™ Brand Contact Lenses with HYDRACLEAR® 1 (narafilecon B) Visibility Tinted with UV Blocker for Daily Wear Single Use only.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
	Diameter
	Base Curve
	Diopter (lens power)
	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
	Manufactured by or in
	Visibility Tinted Lens Orientation Correct
	Visibility Tinted Lens Inside Out

Spherical Lenses For:
Myopia, Hyperopia, Phakic or Aphakic

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

DESCRIPTION

The 1-DAY ACUVUE® TruEye™ Brand Contact Lenses with HYDRACLEAR® 1 (narafilecon B) is available as a Spherical Lens. The lens is made of a silicone hydrogel material containing an internal wetting agent with visibility tinted UV absorbing monomer. The 1-DAY ACUVUE® TruEye™ Brand Contact Lenses with HYDRACLEAR® 1 (narafilecon B) Visibility Tinted with UV Blocker is tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling. A benzotriazole UV-absorbing monomer is used to block UV radiation. 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.

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, and wearing instructions in the "Patient Instruction Guide" for the 1-DAY ACUVUE® TruEye™ Brand Contact Lenses and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.
- Do not touch the lens with fingernails.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for a Sticking Lens". The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the Eye Care Professional about wearing lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- Always discard lenses worn as prescribed by the Eye Care Professional.

- Lens Properties:**
- **Specific Gravity:** 1.07
 - **Refractive Index:** 1.41
 - **Light Transmittance:** 85% minimum
 - **Surface Character:** Hydrophilic
 - **Water Content:** 48%
 - **Oxygen Permeability:**

VALUE	METHOD
55 x 10-11 (cm ² /sec)	Polarographic edge and boundary corrected (ml O ₂ /ml x mm Hg) at 35°C

Lens Parameters:

The 1-DAY ACUVUE® TruEye™ Brand Contact Lenses with HYDRACLEAR® 1 (narafilecon B) is a hemispherical shell available within the following dimensions:

- Diameter Range:** 12.0mm to 15.0mm
Center Thickness: Low minus lens – (e.g., -1.00D: 0.085mm)
 Plus lens – varies with power (e.g., +3.00D: 0.170mm)
Base Curve Range: 7.80mm to 10.00mm
Power Range:
Spherical Powers: -20.00D to +20.00D

AVAILABLE LENS PARAMETERS

Base Curve	Diameter	Power Range
Minus		
8.5mm, 9.0mm	14.2mm	-0.50D to -6.00D (in 0.25D increments) -6.50D to -12.00D (in 0.50D increments)
Plus		
8.5mm, 9.0mm	14.2mm	+0.50D to +6.00D (in 0.25D increments)
Center Thickness		
minus - varies with power (e.g., -3.00D, 0.085mm)		
plus - varies with power (e.g., +3.00D, 0.171mm)		

Lens Care Precautions:

The patient should be informed that no cleaning or disinfection is needed with daily wear single use only lenses. Patients should always dispose of lenses when removed and have replacement lenses or spectacles available.

Other Topics to Discuss with Patients:

- Always contact the Eye Care Professional before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness, may cause dryness of the eye, increased lens awareness or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Who Should Know That the Patient is Wearing Contact Lenses?

- Inform the doctor (Health Care Professional) about being a contact lens wearer.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

ADVERSE REACTIONS

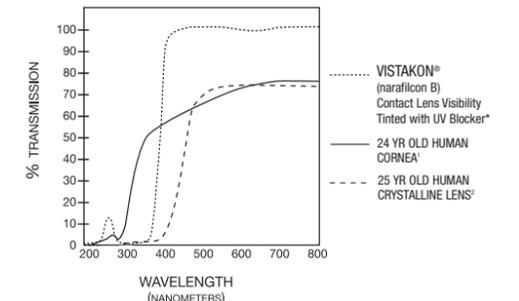
The patient should be informed that the following problems may occur when wearing contact lenses:

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



TRANSMITTANCE CURVES

The 1-DAY ACUVUE® TruEye™ Brand Contact Lenses 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 (-1.00D lens, 0.085mm 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

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.

ACTIONS

In its hydrated state, the 1-DAY ACUVUE® TruEye™ Brand Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

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.

abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.

- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

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

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

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS.

If the 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.

FITTING GUIDELINES

I. GENERAL FITTING INSTRUCTIONS

1-DAY ACUVUE® TruEye™ Brand Contact Lenses

A. Patient Selection:

- Patients selected to wear 1-DAY ACUVUE® TruEye™ Brand Contact Lenses should be chosen based on:
- Motivation to wear lenses

INDICATIONS (USES)

All 1-DAY ACUVUE® TruEye™ Brand Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The 1-DAY ACUVUE® TruEye™ 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.

Eye Care Professionals should prescribe the lenses for daily wear single use only (see "Wearing Schedule"). The lenses are to be discarded upon removal. Therefore, no cleaning or disinfection is required.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the 1-DAY ACUVUE® TruEye™ Brand Contact Lens when any of the following conditions exist:

- Inflammation or infection in or around the eye or eyelids
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Any previously diagnosed condition that makes contact lens wear uncomfortable
- Severe dry eye
- Reduced corneal sensitivity (corneal hypoesthesia)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues (adnexa) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

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 users*

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

- 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 1-DAY ACUVUE® TruEye™ Brand Contact Lenses, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

C. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00 D.

D. Base Curve Selection (Trial Lens Fitting)

For the 1-DAY ACUVUE® TruEye™ Brand Contact Lenses, the 8.5mm/14.2mm 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.

A 1-DAY ACUVUE® TruEye™ Brand Contact Lens trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. Criteria of a Properly Fit Lens

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

- 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 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 1-DAY ACUVUE® TruEye™ Brand Contact Lenses 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 lens wear patients about the following care regimen and safety precautions:

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 1-DAY ACUVUE® TruEye™ Brand Contact Lens is judged to be flat fitting, it should not be dispensed to the patient.

3. Criteria of a Steep Fitting Lens

A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation and resistance when pushing the lens up digitally with the lower lid. If the 1-DAY ACUVUE® TruEye™ Brand Contact Lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial 1-DAY ACUVUE® TruEye™ Brand Contact Lens 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:	-2.00 D
Spherical over-refraction	-0.25 D
Final lens power:	-2.25 D

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

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**).