Professional Fitting and Information Guide

Focus® Dailies®, Focus® Dailies® Toric and **Dailies® AquaComfort Plus®**
(nelfilcon A) ONE-DAY CONTACT LENSES

Rx only

Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed eye care professional

CIBA VISION™

Shared Passion for Healthy Vision and Better Life

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Introduction

Congratulations and thank you for choosing Focus® DAILIES®, Focus® DAILIES® Toric, and/or DAILIES® AquaComfort Plus® (nelfilcon A) One-Day Contact Lenses for your patients. CIBA VISION has combined the benefits of a biocompatible lens material with a patented, state of the art manufacturing process to make DAILIES® One-Day Contact Lenses the most desirable daily wear option for your spherical and astigmatic soft lens patients.

Daily Disposability: The New Standard in Daily Wear Contact Lenses

By eliminating the need for lens care, daily disposable lenses offer your patients a major advancement in wearing convenience. The next time you prescribe lenses, consider the health and comfort benefits of beginning each wearing period with a new pair of fresh, sterile lenses that are worn once and then discarded. DAILIES® One-Day Contact Lenses offer you the opportunity to provide all these benefits to your spherical and astigmatic soft lens patients.

LightStream® Technology: What it Means to You and Your Patients

All DAILIES® One-Day Contact Lenses are made from the proprietary patented material nelfilcon A with a water content of 69% by weight. The unique properties of this material have made it possible to produce a thin design for optimum comfort while maintaining excellent handling and visual acuity. The use of process automation, precision glass and quartz molds, and photolithographic edge forming help ensure every lens has the same crisp optics, smooth surface finish and consistent edge quality. DAILIES® lenses are produced under strictly controlled process conditions and inspected to exacting quality tolerances. As a result, you can be confident your patients will experience consistent vision, comfort, and ease of handling every day.

Fitting DAILIES® One-Day Contact Lenses is easy and predictable. This guide contains important information regarding fitting procedures and aftercare of the DAILIES® patient.

Product Description

Focus® DAILIES® (nelfilcon A) Soft (hydrophilic) One-Day Contact Lenses are available in spherical and toric lens designs. DAILIES® AquaComfort Plus® (nelfilcon A) Soft (hydrophilic) One-Day Contact Lenses are available in spherical lens design. The lenses are to be prescribed for single use Daily Disposable Wear. The lens material is 69% water and 31% nelfilcon A polymer (poly vinyl alcohol partially acetalized with N-formylmethyl acrylamide).

Currently Available Lens Parameters[1]

Spherical **Focus® DAILIES® One-Day Contact Lenses** are available in the following dimensions:

• Base Curve:	8.6 mm
• Diameter:	13.8 mm
• Power Range:	-0.50D to -6.00D (0.25 steps) -6.50D to -10.00D (0.50 steps) +0.50D to +6.00D (0.25 steps)
• Center Thickness	0.10 mm at -3.00 D (varies with power)

[1] Check for actual product availability as additional parameters may be introduced over time.

• Optic Zone Diameter:	7.0 to 8.0 mm (varies with power; 7.8 mm at -3.00D)

FOCUS® DAILIES® TORIC lenses are available in the following dimensions:

• Base Curve:	8.6 mm
• Diameter:	14.2 mm
• Power Range:	+4.00D to -6.00D (0.25D steps) -6.50D to -8.00D (0.50D steps) includes plano Cylinder: -0.75D, -1.50D Axis: 20º, 70°, 90°, 110°, 160°, 180º
• Center Thickness	0.10 mm at -3.00 D (varies with power)
• Optic Zone Diameter:	7.5 to 8.5 mm (varies with power)

Spherical **DAILIES® AquaComfort Plus® ONE-DAY CONTACT LENSES** are available in the following dimensions:

• Base Curve:	8.7 mm
• Diameter:	14.0 mm
• Power Range:	-0.50D to -6.00D (0.25D steps) -6.50D to -10.00D (0.50D steps) +0.50D to +6.00D (0.25D steps)
• Center Thickness	0.10 mm at -3.00 D (varies with power)
• Optic Zone Diameter:	7.1 to 8.1 mm (varies with power)

Hereafter, FOCUS® DAILIES®, FOCUS® DAILIES® TORIC, and DAILIES® AquaComfort Plus® (nelfilcon A) ONE-DAY CONTACT LENSES will be referred to as DAILIES® unless product distinction is necessary.

LENS PROPERTIES

• Specific gravity:	1.06
• Refractive index (hydrated):	1.38
• Light transmittance:	clear ≥ 97%, Visitint 96% (approx.)
• Oxygen permeability (Dk):	26×10^{-11} (cm^2/sec)(ml O_2/ml x mm Hg) measured at 35° C (Fatt corrected)
• Water content:	69% by weight in normal saline

HOW SUPPLIED

DAILIES® ONE-DAY CONTACT LENSES are supplied sterile in strips of foil sealed blister packs containing isotonic phosphate-acetate buffered saline solution. The package storage saline may also contain up to 0.05% Poloxamer. In addition, the package storage saline for DAILIES® AquaComfort Plus® ONE-DAY CONTACT LENSES contains polyethylene glycol (PEG) and hydroxypropyl methylcellulose (HPMC). These blister pack containers are attached to form a single strip. The base curve, lens power, lot number and expiration date are marked on the foil seal of each individual container. The diameter is marked on the rightmost container of each blister pack strip.

Replacement and Wear Schedule

DAILIES® One-Day Contact Lenses are intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to begin the next wearing period with a fresh new lens.
The maximum daily wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that DAILIES® One-Day Contact Lenses are safe to wear during sleep.

INDICATIONS

DAILIES® One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes.

DAILIES® One-Day Contact Lenses are to be prescribed for single use Daily Disposable Wear. DAILIES® lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

Contraindications, Warnings & Precautions

For additional important prescribing and safety information, refer to the Package Insert which is printed in the back of this guide.

Fitting Guidelines

Please see the appropriate sections of this booklet for spherical, toric and monovision fitting guidelines.

Spherical Fitting Guidelines

1. Patient Selection

The patient characteristics necessary to achieve success with DAILIES® One-Day Contact Lenses are similar to those for other spherical soft contact lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear.

The following procedures should be followed when fitting DAILIES® lenses. For additional tips on fitting the monovision patient refer to the section *Monovision Fitting Guidelines* at the end of this guide.

2. Pre-fitting Examination

A pre-fitting examination is necessary to:

- assess the patient's motivation, physical state and willingness to comply with instructions regarding hygiene and wear schedule
- make ocular measurements for initial contact lens parameter selection
- collect baseline clinical information to which post-fitting examination results can be compared

The pre-fitting examination should include:

- a thorough case history
- a spherocylindrical refraction
- keratometry

- tear film assessment
- biomicrosopy

3. Trial Lens Evaluation

DAILIES® ONE-DAY CONTACT LENSES are available in a single base curve/diameter combination of 8.6/13.8 mm for Focus® DAILIES® and 8.7/14.0 mm for DAILIES® AquaComfort Plus®. Following initial power selection, a trial lens should be placed on the eye for assessment of lens fit and comfort, and final power verification.

A. Initial Lens Power Selection

Select an initial lens power as close as possible to the patient's spherical equivalent refraction.

The spherical equivalent refraction is determined as follows:

Spherical Equivalent = Sphere power + Cylinder Power/2
Example: Spectacle Rx: -3.00D -1.00 x 180
Spherical Equivalent: -3.00D + -0.50D = -3.50D

Remember: If the spherical equivalent is greater than $\pm$ 4.00D, a vertex distance correction is necessary to determine the correct lens power at the corneal plane.

B. Lens Fit Assessment

DAILIES® One-Day Contact Lenses should be comfortable immediately upon placement on the eye. Care should be taken to ensure the lens is free of foreign particles such as lint, and is not inverted prior to placement on the eye. **Reflex tearing due to an uncomfortable lens may cause the lens to stop moving and give the appearance of a tight fit.**

Lens fit should be assessed within the first five minutes following insertion. Clinical studies[2] have shown lens movement at 5 minutes following insertion to be the best predictor of movement after 8 hours. Assessment of fit between 10 and 30 minutes following insertion may lead to an underestimate of the true movement characteristics.

Criteria of a Well-Fitted Lens

A properly fit DAILIES® ONE-DAY CONTACT LENS has the following characteristics:

- **Good centration with full corneal coverage** in all fields of gaze
- **Sufficient movement to allow tear exchange** under the lens during the blink; 0.1 to 0.5 mm is generally considered optimal.
- **Satisfactory Push-Up Test**

- This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid margin and gently nudge the edge of the lens upward.

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[2] Data on file.

- **A well-fitted lens will move freely when pushed upward with fingertip pressure and return quickly to its original position.**

• **Good comfort and stable visual response** (with over-refraction)

Characteristics of a Tight Lens

A tight lens fit would display some or all of the following characteristics:

• **Insufficient or no lens movement** during the blink in primary or upgaze

• **Unsatisfactory Push-Up Test**

- **A tight fitting lens will resist movement.** If successfully nudged upward, the lens may remain decentered or return slowly to its original position

• **Good centration**

• **Good comfort**

• **Fluctuating vision** between blinks

Characteristics of a Loose Lens

A loose lens fit would display some or all of the following characteristics:

• **Reduced comfort,** usually accompanied by lower lid sensation

• **Poor centration** with limbal exposure on exaggerated eye movement

• **Lens edge standoff**

• **Excessive lens movement** during the blink in primary or upgaze

• **Unsatisfactory Push-Up Test**

- **A loose fitting lens will move** easily but may remain decentered or slip under the upper lid

• **Vision may be blurred** after the blink

An inverted lens will mimic the characteristics of a loose lens. If any of the above signs occur remove the lens and check to make sure it is not inverted.

General Fitting Tips

• While helpful for monitoring corneal stability over time, keratometry is not a reliable predictor of base curve/fit relationship. Trial fitting of the individual eye is strongly recommended.

• A well fitting lens will show less movement than generally thought, 0.1 to 0.5 mm is considered optimal.

• A flat base curve/cornea relationship may actually show limited movement. Decentration and excessive lid sensation accompanied by limited movement often indicates the lens is too flat for that given eye.

If the criteria for a well fitted lens cannot be achieved do not dispense.

C. Final Lens Power Determination

When you are satisfied that the lens is well fitted, determine the final power by over-refraction through the trial lenses. This is done by adding the spherical equivalent of the over-refraction to the power of the trial lens on the eye.

Example:

Trial lens:	-2.00D
Over-refraction:	+0.50 -0.50 x 15
Spherical Equivalent:	+0.25D
Final Lens Power:	-1.75D

Use a fresh, new pair of lenses for each trial fitting. Do not attempt to disinfect and re-use trial lenses.

TORIC FITTING GUIDELINES

The geometry of a Focus® DAILIES® Toric lens is a double thin zone design. The back surface tri-curve toric design is available in one base curve and fits a wide variety of eyes, reducing fitting time and inventory requirements. The Focus® DAILIES® Toric lens design has a constant thickness difference between the vertical, thin zones and a horizontal thicker zone, resulting in consistent and excellent stabilization over the power range.

To aid the fitting process, Focus® DAILIES® Toric lenses feature scribe lines on the front lens surface to enable assessment of the lens orientation. These lines are at 3 and 9 o'clock positions approximately 1.0 mm in from the lens edge. The vertical line of the "K" on the "OK" inversion mark coincides with the 90 degree meridian of the lens and thus might also be used for the assessment of the lens orientation. The lens orientation findings are then used for calculation of axis compensations.

PATIENT SELECTION

The patient characteristics necessary to achieve success with Focus® DAILIES® Toric lenses are similar to those for spherical lenses. A thorough pre-fitting examination should be conducted to ensure the astigmatic patient is a suitable candidate for soft contact lens wear.

The following procedures should be followed when fitting Focus® DAILIES® Toric lenses. For additional tips on fitting the monovision patient refer to the section *Monovision Fitting Guidelines*.

1. Pre-fitting Examination

A pre-fitting examination is necessary to:

- assess the patient's motivation, physical state and willingness to comply with instructions regarding hygiene and wear schedule
- determine whether a patient is astigmatic to a degree requiring a toric visual correction
- make ocular measurements for initial contact lens parameter selection
- collect baseline clinical information to which post-fitting examination results can be compared

A pre-fitting examination should include:

- a thorough case history
- a spherocylindrical refraction
- keratometry
- tear film assessment
- biomicrosopy

2. Fitting Methods

The following method is recommended for fitting Focus® DAILIES® Toric lenses to maximize success. This method allows for an extended trial period outside the office which will help the eye care professional to minimize chair time, reduce trial lens usage and inventories, as well as increase the accuracy of final lens orientation and the final multipack prescription.

Trial Period Method

a) Determine the appropriate sphere power.

b) Based on the patient's vertex corrected refraction, select a lens with -0.75 or -1.50 cylinder power.

c) Select cylinder axis (20°, 70°, 90°, 110°, 160° or 180º) based on spectacle prescription.

d) Place trial lens on the eye. Order trial lens if it is not in office inventory - having the correct lens allows the patient to experience good vision during the trial period.

e) Evaluate lens orientation, fit, and vision.

f) Dispense trial lens if characteristics of a **Well-Fitted Lens** are satisfied.

g) **Reevaluate lens orientation, fit, and vision at the end of the trial period (typically one day to a week).**

h) Order multipack after power and/or orientation adjustments, if any, are made to satisfy the characteristics of a **Well-Fitted Lens**.

The following alternatives are offered to describe the more traditional methods of fitting lenses. While these methods are adequate to use, they can lead to an increase in chair time, trial lens usage, and multipack purchases as the fit and vision of the lens are refined.

In Office Trial Lens Fitting Method

a) Select diagnostic lens with similar sphere, -0.75 or -1.50 cylinder power and axis (20°, 70°, 90°, 110°, 160°, 180°) based on vertex corrected spectacle Rx.

b) Evaluate lens orientation, fit, vision and over-refraction.

c) Order multipack if characteristics of a **Well-Fitted Lens** are satisfied.

d) Reorder multipack if further adjustments are necessary.

NOTE: For information on fitting the monovision wearer with toric lenses, please refer to the monovision fitting guidelines.

3. Trial Lens Evaluation

Focus® DAILIES® Toric lenses are available in a single base curve/ diameter combination of 8.6/14.2 mm. A **Well-Fitted Lens** provides **good movement, centration, and comfort**.

A. Initial Lens Power Selection

Spherical Lens Power:

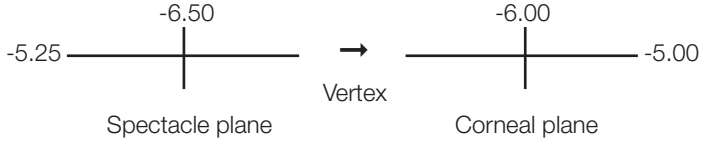
- To determine the initial lens spherical power, use the spherical component of the spectacle Rx in minus cylinder form.

- If this spherical component is greater than ± 4.00D, a vertex distance correction is necessary. This will determine the spherical lens power required at the corneal plane.

Cylinder Lens Power:

Two cylinder powers are available for Focus® DAILIES® Toric contact lenses. The -0.75 cylinder power will normally allow correction of -0.75 to -1.50 diopters of astigmatism. The -1.50 cylinder power will normally allow correction of -1.50 to -2.25 diopters of astigmatism.

- **Note:** If the combination of sphere power and cylinder power is greater than ±4.00D, vertex distance compensation must be performed for each power meridian.



Example: Spectacle Rx: -5.25D - 1.25 x 180 (vertex distance = 12 mm)
Corneal Plane Rx: -5.00 -1.00 x 180
DAILIES® Toric Rx: -5.00 -0.75 x 180

- When the difference between the cylinder correction at the corneal plane and the selected cylinder to fit the patient differs by 0.50D or more, it is necessary to make a compensation to the spherical component using the following formula:

$$\frac{\text{Corneal plane cylinder - Available lens cylinder}}{2} = \text{Spherical Compensation}$$

Example:	**Spectacle Rx:**	-4.50 -1.50 x 180
	Corneal Plane Rx:	-4.25 -1.25 x 180
	Selected cylinder power:	-0.75D
	Spherical equivalent =	(-1.25 - (-0.75)) / 2 = -0.25
	Focus DAILIES® Toric:	-4.50 -0.75 x 180

B. Lens Fit Assessment

Focus® DAILIES® Toric One-Day Contact Lenses should be comfortable immediately upon placement on the eye. Care should be taken to ensure the lens is free of foreign particles such as lint, and is not inverted prior to placement on the eye. **Reflex tearing due to an uncomfortable lens may cause the lens to stop moving and give the appearance of a tight fit.**

Lens fit should be assessed within the first five minutes following insertion. Clinical studies[2] have shown lens movement at 5 minutes following insertion to be the best predictor of movement after 8 hours. Assessment of fit between 10 and 30 minutes following insertion may lead to an underestimate of the true movement characteristics.

Criteria of a Well-Fitted Lens

A properly fit Focus® DAILIES® Toric (nelfilcon A) soft contact lens has the following characteristics:

- **Good centration with full corneal coverage** in all fields of gaze.

[2] Data on file.

- **Sufficient movement to allow tear exchange** under the lens during the blink: 0.1 to 0.5 mm is generally considered optimal.
- **Satisfactory Push-Up Test**
  - This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid margin and gently nudge the edge of the lens upward.
  - A well-fitted lens will move freely when pushed upward with fingertip pressure and return quickly to its original position.
- **Good comfort and stable visual response** (with over-refraction).

Characteristics of a Tight Lens

A tight lens fit would display some or all of the following characteristics:

- **Insufficient or no lens movement** during a blink in primary or upgaze
- **Unsatisfactory Push-Up Test:**
  - **A tight fitting lens will resist movement.** If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
- **Good centration**
- **Good comfort**
- **Fluctuating vision** between blinks

Characteristics of a Loose Lens

A loose lens would display some or all of the following characteristics:

- **Reduced comfort,** usually accompanied by lower lid sensation
- **Poor centration** with limbal exposure on exaggerated eye movement
- **Lens edge standoff**
- **Excessive lens movement** during a blink in primary or upgaze
- **Unsatisfactory Push-Up Test:**
  - **A loose fitting lens will move easily,** but may remain decentered or slip under the upper lid.
- **Vision may be blurred after the blink**

General Fitting Tips

- While helpful for monitoring corneal stability over time, keratometry is not a reliable predictor of base curve/fit relationship. Trial fitting of the individual eye is strongly recommended.
- A well fitting lens will show less movement than generally thought, 0.1 to 0.5 mm is considered optimal.
- A flat base curve/cornea relationship may actually show limited movement. Decentration and excessive lid sensation accompanied by limited movement often indicates the lens is too flat for that given eye.

If the criteria for a well fitted lens cannot be achieved do not dispense.

C. Initial Lens Orientation Evaluation

No Rotation

When the scribe lines orient horizontally, **the cylinder axis of the lens that is dispensed or ordered should be the same as the spectacle refractive axis** - not the trial lens axis.

Contact lens cylinder axis = Spectacle refractive axis

Clockwise Rotation

When the scribe lines rotate clockwise as observed looking at the patient, (i.e., temporally for the right eye, nasally for the left eye), **add the degree of rotation to the spectacle refractive axis** - not the trial lens axis.

Spectacle refractive axis + Trial lens rotation = Axis to order

Example:

Spectacle Rx:	-2.50 -0.75 x 150
Diagnostic Lens:	-2.00 -0.75 x 160
Over-refraction:	-0.50 sphere
Orientation:	10 degrees clockwise (add) (150 + 10)
Final power to order:	-2.50 -0.75 x 160

Counterclockwise Rotation

When the scribe lines rotate counterclockwise, **subtract the degree of rotation from the spectacle refractive axis - not the trial lens axis**.

Spectacle refractive axis - Trial lens rotation = Axis to order

Example:

Spectacle Rx:	-2.75 -0.75 x 180
Diagnostic Lens:	-2.00 -0.75 x 180
Over-refraction:	-0.75 sphere
Orientation:	10 degrees counterclockwise (subtract) (180 - 10)
Final power to order:	-2.75 -0.75 x 170 (not available, therefore either 180 or 160)

- **NOTE:** Occasionally when a cylinder axis compensation is made for orientation, the result may fall outside the traditional range of 0 to 180 degrees. In this case, the axis in accepted notation will be the difference between the absolute value determined and 180 degrees.

Example 1:

Spectacle Rx cylinder: x 180

Orientation: 20 degrees clockwise

Axis calculation: 180 + 20 = 200

(The 200 degrees is outside the traditional axis range)

Difference: 200 - 180 = 20

Axis to order: x 020

Example 2:

Spectacle Rx cylinder: x 010

Orientation: 10 degrees counterclockwise

Axis calculation: 10 - 10 = 0

Difference: 180 - 0 = 180

Axis to order: x 180

- **NOTE:** Scribe marks on dispensed lenses must be at the same orientation as the trial lenses. Record rotation compensation as part of the final Rx.

D. Initial Visual Evaluation

When you are satisfied that the lens fit is satisfactory, determine the final power by over-refraction through the trial lenses. This is done by adding the spherical over-refraction to the power of the trial lens on the eye.

Example:

Diagnostic Lens:	-2.00 -0.75 x 180
Over-refraction:	-0.50 sphere
Final Power to Order:	-2.50 -0.75 x 180

MONOVISION FITTING GUIDELINES

1. 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 in one eye, may not be a good candidate for monovision.

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

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

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 must understand that monovision, as well as other presbyopic contact lenses, or other 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 advantages as well as the disadvantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

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

A) Ocular Preference Determination Methods

- Method 1 - Determine which eye is the "sight 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 near with the least reduction in vision. Place a trial spectacle near add lens 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 corrections, 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 usually function best with the near lens on the left eye.

3. Special Fitting Considerations

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 require only a distance lens.

Examples:

- **Emmetrope:** A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.
- **Bilateral myope:** A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

Amblyopia

The amblyopic patient may not be a good candidate for monovision.

Near Add Determination

Prescribe the lens power for the near eye that provides optimal 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.

4. Trial Lens Fitting

A trial lens fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the *Fitting Guidelines* described earlier in the guide.

Case history and standard clinical evaluation procedures should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power, observe the patient's reaction at various distances and lighting conditions.

Once the correct power lenses are 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. Continue to observe the patient's reaction as he/she gazes around the room at objects of various sizes and distances. Only after these vision tasks 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.

Following assessment of the patient's performance under the above conditions, 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 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 drive only under 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.
- Have supplemental spectacles to wear over the monovision contact lenses for specific visual tasks. 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 the clear near vision in 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 appropriate DAILIES® Patient Instruction Booklet.

LENS DISPENSING EXAMINATION

To help ensure patient success the following steps should be conducted with each patient, even if they have previously worn contact lenses. Even experienced wearers are prone to develop bad habits over time.

A. Verification of Lens Fit

Evaluate lens fit and visual response with the lens on the eye. The criteria of a well-fitted lens should be met and the patient's visual acuity should be acceptable. If not, the patient should be refitted with a more appropriate lens.

B. Hygiene and Lens Handling Instructions

Good hygiene and proper lens handling are important factors in achieving safe, comfortable lens wear. Instruct each patient about proper hygiene and handling of the lenses. Patients who are unable to place and remove lenses should not be provided with them. See *Lens Handling Hints* below.

C. Recommended Wearing and Replacement Schedule

Prescribe and explain the recommended daily wear schedule. Also explain that the lenses are to be discarded after each wearing period. Determine the maximum suggested daily wearing period based upon the patient's physiological eye condition. There may be a tendency for the patient to overwear their lenses initially. Therefore, the importance of adhering to a proper initial daily wearing schedule should be stressed to these patients. It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that allows for a gradual increase in wearing time.

D. Additional Instructions

- Provide the patient with a copy of the Patient Instruction Booklet for Focus® DAILIES®, Focus® DAILIES® Toric, and DAILIES® AquaComfort Plus® ONE-DAY CONTACT LENSES. Review the contents with the patient so that he or she has a clear understanding of the prescribed Wearing and Replacement schedule.

- Review the Package Insert for DAILIES® ONE-DAY CONTACT LENSES and provide the patient with all relevant information and precautions on proper use of their lenses.
- Discuss the importance of periodic, routine eye examinations to assure the continuing health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. CIBA VISION recommends that patients see their eye care professional once each year or as recommended by the eye care professional.

FOLLOW-UP EXAMINATIONS

Follow-up care is necessary to ensure continued successful contact lens wear. Follow-up examinations should include:

- Case history, including questions to identify any problems related to contact lens wear
- Management of specific problems, if any, and
- A review with the patient of the lens wear and replacement schedule, proper lens handling procedures, and ensure sufficient supply of spare lenses.

Follow-Up Examination Procedures

- Prior to a follow-up examination, the contact lenses should be worn for at least four continuous hours.
- Record patient's symptoms, if any.
- Measure visual acuity monocularly and binocularly with the contact lenses in place.
- Perform an over-refraction to check for residual refractive error.

- With lenses in place, evaluate the fitting performance of the lenses to assure the criteria of a well fitted lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- Remove the lenses and conduct a thorough biomicroscopy examination.
- Periodically perform keratometry and spectacle refractions and compare the results with the initial measurements.
- If any observations are abnormal, use professional judgment to manage the problem and restore the eye to optimal conditions. If visual requirements or the criteria of a well-fitted lens are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

Lens Handling Hints

Removal of Lenses From Package

DAILIES® One-Day Contact Lenses are supplied in strips of easy-to-open blister pack containers designed to maintain sterility of the lens and saline solution. Separate a single blister pack for each eye by tearing along the perforation in the foil label. To open, shake the blister pack gently, then grasp the tapered end of the plastic base between thumb and forefinger and peel back the foil. Carefully remove the lens from its container by pouring the lens into the palm of your clean hand.
Do not use tweezers or other tools to remove the lens from the package, as this could damage the lens.

Lens Placement

- When about to place the lens on the eye, make sure the lens sits up on the placement finger. Make sure the finger is dry so surface tension does not cause the lens to adhere to the finger.
- Be sure the lens is right side out. With the spherical lenses, this is best done with the “taco test” by placing the lens in a skin crease in the palm of the hand and gently closing the hand. When correct side out the lens edges will fold in like a taco, when inverted the lens edges will flare out. Due to the thin design of DAILIES® One-Day Contact Lenses, examination of the lens profile may be misleading since edge flare may not occur when the lens is inverted. With the toric lenses, the “OK” inversion mark should be legible from the outside of the lens when the lens is right side out.
- Place the lens directly onto the cornea (placing it on the lower sclera can lead to the lens folding after a blink). While continuing to hold both lids in place, the patient should look down to seat the lens. The lids may then be released.

Lens Removal

- To remove the lens from the cornea, assure that the fingers are clean and dry.
- Slide the lens off the cornea (down or to the side) onto the sclera. This produces a fold in the lens which assists in removal. With the index finger and thumb, gently pinch the lens off the eye.

Care for a Sticking or Torn Lens

- If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating or rewetting solution in accordance with package labeling. The patient should blink forcefully several times, then while looking up slide the lens down onto the white part of the eye and remove the lens by pinching it between the thumb and forefinger. If the lens continues to stick, the patient should immediately consult the eye care professional.
- If a lens tears in the eye it will feel uncomfortable. Advise patients it is not possible to lose a contact lens or part of a contact lens behind the eye and that they should calmly remove the pieces by carefully pinching them as they would for normal lens removal. If lens pieces do not seem to remove easily the eye may be rinsed with sterile saline. Excessive pinching should be avoided. If rinsing with saline does not help, instruct patients to contact the eye care professional for assistance. Lenses can be easily located by the eye care professional using fluorescein.

In Office Care of Trial Lenses

Eye care professionals should understand and educate contact lens technicians concerning proper use of trial lenses.

- Each contact lens is shipped sterile in a sealed blister pack containing isotonic phosphate-acetate buffered saline. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use.
- DAILIES® lenses are for disposable wear only and should be discarded after a single use.

General Emergencies / Emergency Lens Care

See ***Package Insert*** for information regarding general emergencies and advice on emergency lens care.

Adverse Reaction Reporting

If a patient experiences any serious adverse effects associated with the use of DAILIES® One-Day Contact Lenses, eye care professionals please notify:

CIBA VISION Corporation Technical Consultation at 1-800-241-7468.

Technical Consultation and Ordering Information

CIBA VISION is pleased to assist with fitting or clinical questions regarding DAILIES® One-Day Contact Lenses. Readers having questions or problems should contact the CIBA VISION Technical Consultation department at 1-800-241-7468.

To order DAILIES® One-Day Contact Lenses call CIBA VISION Customer Service toll-free at 1-800-241-5999.

IMPORTANT: This package insert is effective as of 10/2009 and supersedes all prior inserts for the product described below. Please read carefully and keep this information for future use. This package insert is intended for the eye care professional, but should be made available to patients upon request. Copies of this package insert are available without charge from CIBA VISION Corporation by calling CIBA VISION Customer Service in the US at 1-800-241-5999 or obtain a copy from our website at **www.cibavision.com.** The eye care professional should provide patients with appropriate instructions that pertain to the patient's prescribed lenses. CIBA VISION makes available a Patient Instruction Booklet which is recommended to be given to patients.

Rx only

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL.

DESCRIPTION

Focus® DAILIES® and DAILIES® AquaComfort Plus® (nelfilcon A) Soft (hydrophilic) ONE-DAY CONTACT LENSES are available in a spherical lens design, Focus® DAILIES® PROGRESSIVES (nelfilcon A) Soft (hydrophilic) ONE-DAY CONTACT LENSES are available in a multifocal lens design and Focus® DAILIES® Toric (nelfilcon A) Soft (hydrophilic) ONE-DAY CONTACT LENSES are available in a toric design. The lenses are to be prescribed for single use daily disposable wear.

LENS MATERIAL

The lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide).

- For VISITINT® lenses, the color additive copper phthalocyanine is added to the lens material to create a light blue edge to edge color to make them easier to see when handling.
- Print marks on Focus® DAILIES® Toric lenses contain the color additive phthalocyanine green.

LENS PROPERTIES

• Specific gravity:	1.06
• Refractive index:	1.38 (hydrated)
• Light transmittance:	Clear ≥ 97% VISITINT 96% (approx.)
• Oxygen permeability (Dk):	26×10^{-11} (cm^2/sec) (ml O_2 /ml x mm Hg) at 35°C (Fatt corrected)
• Water content:	69% by weight in normal saline
Approved Power Range:	-20.00D to +20.00D

LENS PARAMETERS[1]

Spherical Focus® DAILIES® (nelfilcon A) ONE-DAY CONTACT LENSES are available in the following dimensions:

• Base curve:	8.6 mm
• Diameter:	13.8 mm
• Powers available[1]:	-0.50D to -6.00D (0.25D steps); -6.50D to -10.00D (0.50D steps) +0.50D to +6.00D (0.25D steps)
• Center thickness:	0.10 mm at -3.00D (varies with power)
• Optic zone diameter:	7.0 to 8.0 mm (varies with power)
• Tint:	Light blue handling tint

Focus® DAILIES® PROGRESSIVES (nelfilcon A) ONE-DAY CONTACT LENSES are available in the following dimensions:

• Base curve:	8.6 mm
• Diameter:	13.8 mm
• Powers available:	-6.00D to +5.00D (0.25D steps) Single Progressive Add - Effective Range up to +3.00D
• Center thickness:	0.10 mm at -3.00D (varies with power)
• Optic zone diameter:	7.0 to 8.0 mm (varies with power)
• Tint:	Light blue handling tint

Focus® DAILIES® Toric (nelfilcon A) ONE-DAY CONTACT LENSES are available in the following dimensions:

• Base curve:	8.6 mm
• Diameter:	14.2 mm
• Powers available:	+4.00D to -6.00D (0.25D steps) -6.50D to -8.00D (0.50D steps) Cylinder: -0.75D, -1.50D
Axis: 20°, 70°, 90°,	110°, 160°, 180°
• Center thickness:	0.10 mm at -3.00D (varies with power)
• Optic zone diameter:	7.5 to 8.5 mm (varies with power)
• Tint:	Light blue handling tint

Spherical DAILIES® AquaComfort Plus® (nelfilcon A) ONE-DAY CONTACT LENSES are available in the following dimensions:

• Base curve:	8.7 mm
• Diameter:	14.0 mm
• Powers available[1]:	-0.50D to -6.00D (0.25D steps) -6.50D to -10.00D (0.50D steps) +0.50D to +6.00D (0.25D steps)
• Center thickness:	0.10 mm at -3.00D (varies with power)
• Optic zone diameter:	7.1 to 8.1 mm (varies with power)
• Tint:	Light blue handling tint

Hereafter, Focus® DAILIES®, Focus® DAILIES® PROGRESSIVES, Focus® DAILIES® Toric, and DAILIES® AquaComfort Plus® will be referred to as DAILIES® unless product distinction is necessary.

ACTIONS

- When hydrated and placed on the cornea DAILIES® ONE-DAY CONTACT LENSES act as a refracting medium to focus light rays on the retina.

INDICATIONS

- Focus® DAILIES®, Focus® DAILIES® Toric and DAILIES® AquaComfort Plus® (nelfilcon A) ONE-DAY CONTACT LENSES are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes.
- Focus® DAILIES® PROGRESSIVES (nelfilcon A) ONE-DAY CONTACT LENSES are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not-aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.
- Focus® DAILIES®, Focus® DAILIES® Toric, Focus® DAILIES® PROGRESSIVES and DAILIES® AquaComfort Plus® ONE-DAY CONTACT LENSES are to be prescribed for single use Daily Disposable Wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

CONTRAINDICATIONS
DO NOT USE DAILIES® ONE-DAY CONTACT LENSES when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids that may be exaggerated by contact lens wear.
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear.
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may be exacerbated by or interferes with contact lens wear.
- Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exaggerated by the wearing of contact lenses.
- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e., rewetting drops) that contain chemicals or preservatives (such as thimerosal) to which some people may develop an allergic response.
- Any active corneal infection (bacterial, fungal or viral).
- The use of any medication that is contraindicated or interferes with contact lens wear, including eye medications.
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear.
- If eyes become red or irritated.

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

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care professional's direction and all labeling instructions for proper use of their lenses.
  Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear their lenses while sleeping. Clinical study results[2] have shown that the risk of ulcerative keratitis is nine times greater for daily wear users who wear their lenses overnight (outside the approved indication) compared to those who do not wear them overnight.
- Studies[2] have also shown that contact lens wearers who smoke have an estimated 3 to 8 times greater risk of suffering ulcerative keratitis than among those who are nonsmokers.
- If a patient experiences 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 regularly as directed.

PRECAUTIONS
Special Precautions to the Eye Care Professional:
Due to small numbers of patients enrolled in the 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, 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.

- 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, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- Patients who wear aspheric contact lenses to correct presbyopia 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.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continuing health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. CIBA VISION recommends that patients see their eye care professional once each year or as recommended by the eye care professional.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Eye care professionals should carefully instruct patients about the following safety precautions:

- Carefully follow the handling, insertion, removal, and wearing instructions in the DAILIES® ONE-DAY CONTACT LENSES Patient Instruction Booklet and any additional instructions provided by the eye care professional.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always keep spare lenses available to avoid reusing the lenses.
- Good hygiene habits help promote safe and comfortable lens wear. Always wash and rinse hands before handling lenses.
- Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pouring the lens onto the palm of your clean hand.
- Never use tweezers or other sharp objects such as fingernails to remove the lens from the container to avoid damaging the lens.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses. If sprays are used, eyes should be kept closed until the spray has settled.
- Always handle lenses carefully. If a lens is dropped, small particles or fibers may adhere to the lens surface which can irritate the eye. Replace with a sterile fresh, new lens.
- Consult the eye care professional about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to Acanthamoeba keratitis.
- Avoid all harmful or irritating vapors or fumes while wearing lenses.
- Promptly remove a lens to avoid serious injury in the event that dust, a foreign body or other contaminant gets between the lens and the eye.
- Discard any lens which has become dehydrated or damaged. Replace with a sterile fresh, new lens.
- Patients should be instructed to remove their lenses before sleeping.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the section Care for a Sticking Lens. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- Patients should inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or restrict the use of contact lenses in certain work environments.
- Patients should inform their physician that contact lenses are worn and should consult their eye care professional before using any medication in the eye.
- Do not use lenses beyond the expiration date.
- Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. Patients should be informed of these potential conditions and proper remedial treatment should be prescribed if any of these conditions occur. Depending on the severity of the condition appropriate treatment may include the use of rewetting drops intended for use with soft contact lenses or temporary cessation of contact lens wear until the condition subsides.

It is strongly recommended that patients be provided with a copy of the DAILIES® ONE-DAY CONTACT LENSES Patient Instruction Booklet available from CIBA VISION and understand its contents prior to dispensing the lenses.

ADVERSE REACTIONS
Potentially serious complications are usually accompanied by one or more of these signs and symptoms:

- Foreign body sensation
- Excessive watering or other unusual eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (sensitivity to light)
- Burning, stinging, itching or other pain associated with the eyes

- Comfort is less compared to when the lens was first placed on the eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

If any of the previous signs or symptoms occur:

- **The patient should IMMEDIATELY REMOVE THE LENS(ES). If the discomfort or problem stops, the patient should discard the lens and replace it with a new one. IF THE PROBLEM CONTINUES AFTER INSERTING A NEW LENS, THE PATIENT SHOULD IMMEDIATELY REMOVE THE LENS(ES) AND CONTACT AN EYE CARE PROFESSIONAL AT ONCE.**
- Patients should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, infiltrates and bacterial conjunctivitis must be managed and treated early to avoid more serious complications. Additionally, contact lens wear may be associated with ocular changes which require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE REACTION REPORTING

If a patient experiences any serious adverse effects associated with the use of DAILIES® ONE-DAY CONTACT LENSES, licensed eye care practitioners please notify: CIBA VISION Corporation Technical Consultation at 1-800-241-7468.

FITTING

For a detailed description of the fitting techniques, refer to the DAILIES® ONE-DAY CONTACT LENSES Professional Fitting and Information Guide, copies of which are available free of charge from:
CIBA VISION Corporation (1-800-241-5999)
11460 Johns Creek Parkway, Duluth, GA. 30097 U.S.A.

REPLACEMENT AND WEAR SCHEDULE

DAILIES® ONE-DAY CONTACT LENSES are intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a fresh new lens.

WEARING SCHEDULE

- **Daily Wear (Less than 24 hrs. while awake)**
  The maximum daily wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. There may be a tendency for patients to overwear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that DAILIES® ONE-DAY CONTACT LENSES are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period. Optimum individual wearing schedule will vary.

CLINICAL DETAILS

- **Seasonal Allergy Wearers**
  A one-month subjective trial of contact lens wearers with a history of seasonal allergic conjunctivitis was conducted during a month of expected high pollen count in various US cities. Information was collected about allergy-related symptoms, wear-time and comfort during lens wear. Study results found that these contact lens wearers experienced fewer days of burning and redness when wearing Focus® DAILIES® as compared to a new pair of their usual lenses. The effects of allergy medications that may have been used during the study were not assessed.

- **All Day Comfort**
  A one month study of 188 subjects was conducted for the purpose of evaluating comfort and wearing time for Focus® DAILIES® soft contact lenses. End of day comfort was measured using a 0 to 10 scale where 0 was unacceptable and 10 was excellent. Wearing time was also recorded in hours of wear per day.

  Baseline values for end of day comfort and average wearing time with the subject's pre-study lenses were 6.9 out of 10 and 13.5 hours, respectively. Study results found that the average end of day comfort for Focus® DAILIES® was 7.8 out of 10 with an average wearing time of 14.3 hours. The values for Focus® DAILIES® were statistically different compared to the baseline values collected from the pre-study lenses. As in this study, individual results may vary.

  Reference: Bauman, E. (1997). Daily Disposables Versus Other Soft Lens Modalities. Optician 214: 33-35, 37

- **DAILIES® AquaComfort Plus®**
  A one-month study was conducted for the purpose of evaluating the performance for DAILIES® AquaComfort Plus® lenses. Subjective performance measures were evaluated by having the subjects rate these attributes on a scale from 1 to 10, where 1 was "poor/not at all satisfied" and 10 was "excellent/completely satisfied," for both their previous Focus® DAILIES® lenses as well as DAILIES® AquaComfort Plus® lenses.

  Subjects rated DAILIES® AquaComfort Plus® statistically better for comfort at insertion compared to their own Focus® DAILIES® / All Day Comfort lenses. Specifically, average comfort at insertion was 9.0 at baseline with Focus® DAILIES® and was 9.5 at one-month with DAILIES® AquaComfort Plus®. Additionally, average overall comfort was 8.8 at baseline with Focus® DAILIES® and was 9.1 at one-month with DAILIES® AquaComfort Plus®, while average comfort at the end of day was 7.8 at baseline with Focus® DAILIES® and was 8.5 at one-month with DAILIES® AquaComfort Plus® (changes not statistically significant).

EMERGENCY LENS CARE

Cleaning and disinfection of the lens is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times.

CARE FOR A STICKING OR TORN LENS

If a lens sticks (stops moving) or cannot be removed from the eye, instruct the patient to apply 1 to 2 drops of a recommended lubricating or rewetting solution in accordance with package labeling. The patient should blink forcefully several times, then while looking up slide the lens down onto the white part of the eye and remove the lens by pinching it between the thumb and forefinger. If the lens continues to stick, the patient should immediately consult the eye care professional.

If a lens tears in the eye it will feel uncomfortable. Advise patients it is not possible to lose a contact lens or part of a contact lens behind the eye and that they should calmly remove the pieces by carefully pinching them as they would for normal lens removal. If lens pieces do not seem to remove easily the eye may be rinsed with sterile saline. Excessive pinching should be avoided. If rinsing with saline does not help, instruct patients to contact the eye care professional for assistance. Lenses can be easily located by the eye care professional using fluorescein.

GENERAL EMERGENCIES

Patients 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 OR FRESH SALINE SOLUTION, REMOVE AND DISCARD THE LENS, AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.** Additional information regarding emergency treatment may be provided on the product container label.

HOW SUPPLIED

DAILIES® ONE-DAY CONTACT LENSES are packaged in strips of five foil sealed blister packs containing isotonic phosphate-acetate buffered saline solution and are steam sterilized. Five blister pack containers are attached to form a single strip. The package storage saline may contain up to 0.05% Poloxamer. In addition, the package storage saline for DAILIES® AquaComfort Plus® ONE-DAY CONTACT LENSES contains polyethylene glycol (PEG) and hydroxypropyl methylcellulose (HPMC). The base curve, lens power, lot number and expiration date are marked on the foil seal of each individual container. The diameter is marked on the rightmost container of each strip of five blister packs.

CIBA VISION Corporation
11460 Johns Creek Parkway
Duluth, GA USA 30097

CIBA VISION

[1]Check for actual product availability as additional powers may be introduced over time.
[2]New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783.

100247/D7285G

Vertex Distance Conversion Chart

For minus lenses, read left to right; for plus lenses, read right to left.
(12 mm Vertex Distance)

-	+	-	+	-	+	-	+
4.00	3.87	7.50	6.87	12.00	10.37	19.00	15.50
4.25	4.00	7.62	7.00	12.50	10.75	19.25	15.62
4.50	4.25	7.75	7.12	12.75	11.00	19.25	15.75
4.75	4.50	7.87	7.25	13.00	11.25	19.75	16.00
5.00	4.75	8.00	7.37	13.50	11.50	20.00	16.12
5.12	4.87	8.12	7.50	13.75	11.75	20.25	16.25
5.37	5.00	8.25	7.62	14.00	12.00	20.50	16.50
5.50	5.12	8.50	7.75	14.25	12.25	20.75	16.62
5.62	5.25	8.75	8.00	14.75	12.50	21.00	16.75
5.75	5.37	9.00	8.25	15.00	12.75	21.25	17.00
5.87	5.50	9.25	8.37	15.50	12.75	21.75	17.25
6.00	5.62	9.50	8.62	15.75	13.25	22.25	17.50
6.12	5.75	9.75	8.75	16.25	13.50	22.50	17.75
6.37	5.87	10.00	9.00	16.75	13.75	23.00	18.00
6.50	6.00	10.25	9.12	17.00	14.00	23.50	18.25
6.62	6.12	10.50	9.25	17.25	14.25	23.75	18.50
6.75	6.25	10.75	9.37	17.62	14.37	24.25	18.75
6.87	6.37	11.00	9.62	18.00	14.50	24.75	19.00
7.00	6.50	11.25	9.75	18.12	14.75	25.00	19.25
7.12	6.62	11.50	10.00	18.50	15.00	25.50	19.50
7.37	6.75	11.75	10.25	18.75	15.25	26.00	19.75

CIBA VISION Corporation
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