

Professional Fitting and Information Guide

FOCUS® DAILIES®
FOCUS® DAILIES® Toric
FOCUS® DAILIES® Progressives
DAILIES® AquaComfort Plus®
DAILIES® AquaComfort Plus® Toric
DAILIES® AquaComfort Plus® Multifocal
(nelfilcon A) One-Day Contact Lenses



CAUTION: United States of America
(USA) federal law restricts this
device to sale by or on the order of a
licensed eye care professional

Alcon®
a Novartis company

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INTRODUCTION

Thank you for choosing DAILIES® (nelfilcon A) One-Day Contact Lenses for your patients. This guide contains important information regarding fitting procedures for DAILIES® (nelfilcon A) One-Day Contact Lenses and aftercare for your contact lens patient.

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® (nelfilcon A) One-Day Contact Lenses offer you the opportunity to provide all these benefits to your spherical, astigmatic, and presbyopic soft lens patients.

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

DAILIES® (nelfilcon A) One-Day Contact Lenses are made from the proprietary patented material nelfilcon A with a water content of 69% by weight. 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.

PRODUCT DESCRIPTION

FOCUS® DAILIES® and DAILIES® AquaComfort Plus® (nelfilcon A) soft (hydrophilic) One-Day Contact Lenses are available in spherical, toric, and multifocal lens designs. The lenses are to be prescribed for single use, daily disposable wear. 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 tint to make them easier to see when handling.

FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® Toric (nelfilcon A) contact lenses feature printed scribe marks and an inversion mark on the front lens surface (refer to Section “Toric Fitting Guidelines” for further detail). These print marks contain the color additive phthalocyanine green.

CURRENTLY AVAILABLE LENS PARAMETERS¹

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: -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

- Tint: (varies with power)
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
- Power Range: +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)
- 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: +5.00D to -6.00D (0.25D steps)
Single Progressive Add
- Effective Range up to +3.00D
- Center thickness: 0.11 mm at -3.00D
(varies with power)
- Tint: Light blue handling tint

DAILIES® AquaComfort Plus® (nelfilcon A) 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 -3.00D
(varies with power)
- Tint: Light blue handling tint

DAILIES® AquaComfort Plus® Toric (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base Curve: 8.8 mm
- Diameter: 14.4 mm
- Power Range: +4.00D to -6.00D (0.25D steps)
-6.50D to -8.00D (0.50D steps)
Cylinder: -0.75D, -1.25D, -1.75D
Axis: 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°
- Center Thickness: 0.10 mm at -3.00D
(varies with power)
- Tint: Light blue handling tint

DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.7 mm
- Diameter: 14.0 mm
- Powers available: +6.00D to -10.00D (0.25D steps);
ADD: LO, MED, HI
- Center thickness: 0.10 mm at -3.00D
(varies with power)
- Tint: Light blue handling tint

Hereafter, FOCUS® DAILIES®, FOCUS® DAILIES® Toric, FOCUS® DAILIES® Progressives, DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric, and DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) One-Day Contact Lenses will be referred to as DAILIES® (nelfilcon A) One-Day Contact Lenses unless product distinction is necessary.

LENS PROPERTIES

- Refractive Index (hydrated): 1.38 (hydrated)
 - Light transmittance: VISITINT® lens ≥ 92% (@ 610 nm)
 - Oxygen permeability (Dk): $26 \times 10^{-11}(\text{cm}^2/\text{sec})$
(mL O₂/mL x mm Hg) measured at 35°C
(Fatt, edge effect corrected)
 - Water content: 69% by weight in normal saline
- Approved Power Range: -20.00D to +20.00D

HOW SUPPLIED

DAILIES® (nelfilcon A) One-Day Contact Lenses are packaged in strips of five foil sealed blister packs containing phosphate-acetate buffered saline solution and are steam sterilized. The package storage saline may contain up to 0.05% Poloxamer. In addition, the package storage saline for DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric and DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) One-Day Contact Lenses contains polyethylene glycol (PEG) and hydroxypropyl methylcellulose (HPMC). The package is marked with the base curve, diameter, lens power, lot number and expiration date

REPLACEMENT AND WEAR SCHEDULE

DAILIES® (nelfilcon A) 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. Studies have not been conducted to show that DAILIES® (nelfilcon A) 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.

INDICATIONS (USES)

FOCUS® DAILIES® and DAILIES® AquaComfort Plus® (nelfilcon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® Toric (nelfilcon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes with 6.00 diopters (D) or less of astigmatism.

FOCUS® DAILIES® Progressives and DAILIES® AquaComfort Plus® Multifocal (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 1.50 diopters (D) or less of astigmatism that does not interfere with visual acuity.

DAILIES® (nelfilcon A) 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, AND ADVERSE REACTIONS

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

ADVERSE REACTION REPORTING

If a patient experiences any serious adverse effects associated with the use of DAILIES® (nelfilcon A) contact lenses, in the USA please notify Alcon Medical Safety at 1 800-241-7468.

FITTING GUIDELINES

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

FITTING GUIDELINES (Spherical Lenses)

1. Patient Selection

The patient characteristics necessary to achieve success with DAILIES® (nelfilcon A) 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
- biomicroscopy

3. Trial Lens Evaluation

DAILIES® (nelfilcon A) One-Day Contact Lenses are available in a single base curve/diameter combination of 8.6/13.8 mm for FOCUS® DAILIES® contact lenses and 8.7/14.0 mm for DAILIES® AquaComfort Plus® contact lenses. 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® (nelfilcon A) 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.**

Allow the lenses to settle on the eyes for approximately **5 to 10 minutes**. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

Criteria of a Well-Fitted Lens

A well-fitted DAILIES® (nelfilcon A) One-Day Contact Lens has the following characteristics:

1. **Good centration with full corneal coverage** in all fields of gaze
2. **Sufficient movement to allow tear exchange** under the lens during the blink; 0.1 to 0.5 mm is generally considered optimal.
3. **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.
4. **Good comfort and stable visual response** (with over-refraction)

Characteristics of a Tight (Steep) Lens Fit

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

1. **Insufficient or no lens movement** during the blink in primary or upgaze
2. **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.
3. **Good centration**
4. **Good comfort**
5. **Fluctuating vision** between blinks

Characteristics of a Loose (Flat) Lens Fit

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

1. **Reduced comfort**, usually accompanied by lower lid sensation
2. **Poor centration** with limbal exposure on exaggerated eye movement
3. **Lens edge standoff**
4. **Excessive lens movement** during the blink in primary or upgaze
5. **Unsatisfactory Push-Up Test**
 - A loose fitting lens will move easily but may remain decentered or slip under the upper lid.
6. **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 the given eye.

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

C. Final Lens Power Determination

After the characteristics of a well-fitted lens have been satisfied, conduct a spherical over-refraction to determine the proper lens power to be dispensed.

Example:

Trial lens:	-4.50D
Over-refraction:	-0.25D
Final Lens Power:	-4.75D

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

FITTING GUIDELINES (Toric Lenses)

The geometry of a FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® 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 and DAILIES® AquaComfort Plus® 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 and DAILIES® AquaComfort Plus® 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.

1. Patient Selection

The patient characteristics necessary to achieve success with FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® 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 and DAILIES® AquaComfort Plus® Toric lenses. For additional tips on fitting the monovision patient refer to the section *Monovision Fitting Guidelines*.

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

- 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
- biomicroscopy

3. Fitting Methods

The following method is recommended for fitting FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® 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

- Determine the appropriate sphere and cylinder power (vertex corrected if necessary).
- Select cylinder axis based on spectacle prescription – assume no rotation.
- 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.
- Evaluate lens orientation, fit, and vision.
- Dispense lens if characteristics of a **Well-Fitted Lens** are satisfied.
- Reevaluate lens orientation, fit, and vision at the end of the trial period (typically one day to a week).**
- 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

- Select diagnostic lens with similar sphere, cylinder power and axis as vertex corrected spectacle Rx.
- Evaluate lens orientation, fit, vision and over-refraction.
- Order multipack if characteristics of a **Well-Fitted Lens** are satisfied.
- 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.

4. Trial Lens Evaluation

FOCUS® DAILIES® Toric lenses are available in a single base curve/diameter combination of 8.6/14.2 mm. DAILIES® AquaComfort Plus® Toric lenses are available in a single base curve/diameter combination of 8.8/14.4 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 $\pm 4.00D$, a vertex distance correction is necessary. This will determine the spherical lens power required at the corneal plane.

Cylinder Lens Power:

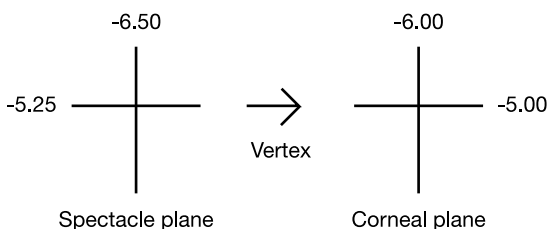
Two cylinder powers are available for FOCUS® DAILIES® Toric contact lenses. The -0.75D cylinder power will normally allow correction of -0.75 to -1.50 diopters of astigmatism. The -1.50D cylinder power will normally allow correction of -1.50 to -2.25 diopters of astigmatism.

Three cylinder powers are available for DAILIES® AquaComfort Plus® Toric contact lenses. These three powers will normally allow correction of -0.75 to -2.50 diopters of astigmatism.

Select DAILIES® AquaComfort Plus® Toric cylinder power according to the chart below:

Refraction Vertexed Cylinder Power	DAILIES® AquaComfort Plus® Toric Cylinder Power
-0.75	-0.75
-1.00	-0.75
-1.25	-1.25
-1.50	-1.25
-1.75	-1.75
-2.00	-1.75
-2.25	-1.75
-2.50	-1.75

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



Example:

Spectacle Rx: $-5.25D -1.25 \times 180$ (vertex distance = 12 mm)

Corneal Plane Rx: $-5.00 -1.00 \times 180$

DAILIES® Toric Rx: $-5.00 -0.75 \times 180$

- 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:

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

Example:

Spectacle Rx:	$-4.50 -1.50 \times 180$
Corneal Plane Rx:	$-4.25 -1.25 \times 180$
Selected cylinder power	$-0.75D$
Spherical equivalent =	$[-1.25 - (-0.75)] / 2 = -0.25$
DAILIES® Toric:	$-4.50 -0.75 \times 180$

B. Lens Fit Assessment

FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® 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.**

Allow the lenses to settle on the eyes for approximately **5 to 10 minutes**. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

Criteria of a Well-Fitted Lens

A well-fitted FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® Toric (nelfilcon A) 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.
 - A well-fitted lens will move freely when pushed upward with fingertip

pressure and return quickly to its original position.

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

Characteristics of a Tight (Steep) Lens Fit

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

1. **Insufficient or no lens movement** during the blink in primary or upgaze
2. **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.
3. **Good centration**
4. **Good comfort**
5. **Fluctuating vision** between blinks

Characteristics of a Loose (Flat) Lens Fit

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

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

Spectacle refractive axis + Trial lens rotation	=	Axis to order
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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
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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 for FOCUS® DAILIES® Toric, therefore either order 180 or 160, or switch to DAILIES® AquaComfort Plus® Toric)

- **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:	-0.75 sphere
(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

The visual result is evaluated by first performing a spherical over-refraction and then measuring visual acuity. If visual acuity is acceptable, the determination of lens power required after the over-refraction will be uncomplicated. In this case, the axis in accepted notation will be the difference between the absolute value determined and 180 degrees.

Example:

Diagnostic Lens: -2.00 -0.75 x 180

Over-refraction: -0.50 sphere

Final Power to Order: -2.50 -0.75 x ...*

***Determination of final cylinder axis to order will be made after compensation for lens orientation.**

If the spherical over-refraction does not yield acceptable vision proceed to perform a spherocylindrical over-refraction. For the resultant lens power to order from this over-refraction call Professional Consultation in the U.S.A. at 1-800-241-7468 or visit www.virtualconsultant.alcon.com.

FITTING GUIDELINES

(FOCUS® DAILIES® Progressives Contact Lenses)

The FOCUS® DAILIES® Progressives (nelfilcon A) lens is a progressive aspheric simultaneous vision soft contact lens. The lens design incorporates a constant near power profile into each lens across the full range of distance powers. This simplifies the fitting procedure by eliminating add powers as a separate variable. For each lens, the near and intermediate powers are concentrated primarily in the central portion of the optical zone while the surrounding portion is weighted towards distance. The continuous changes in power across the surface of the lens allow patients requiring a reading addition of up to +3.00D to see clearly at far, intermediate and near distances.

1. PATIENT SELECTION

The eye care professional should weigh several factors when considering patient selection for a FOCUS® DAILIES® Progressives (nelfilcon A) soft contact lens fitting. When fitting a lens intended to correct for presbyopia, it is especially important to evaluate the particular visual needs, objectives, lifestyle and expectations of the individual patient. Prospective candidates may include current contact lens wearers, former wearers, and persons with no previous wear history. For former wearers it is important to determine the cause for discontinuation. Good success has been achieved with FOCUS® DAILIES® Progressives lenses in all three wearing groups.

There are two general categories of candidates based on anticipated usage: those who seek to wear their lenses as their principal means of vision correction, and those who wish to integrate the use of their contact lenses

with spectacles. The integrative user often seeks to wear their lenses for sports or other occasional activities while reverting to spectacles under poor lighting or otherwise demanding vision conditions. In general, even the part-time user does not require more than a few moments re-adaptation time following an interval of no lens wear.

To summarize patient selection, the characteristics of “ideal candidates” and those that may be more “difficult to fit” are listed below:

Ideal Candidates

- Refractive cylinder ≤ 1.00 D.
- Near add $> +0.75$ D.
- Attainable visual demands that do not depend upon resolving very fine (smaller than 20/20 letters) details at both distance and near for extended periods.
- Emphasis on tasks where it is advantageous to have objects simultaneously in focus over a large range of viewing distances.
- Expectations consistent with actual everyday visual demands.
- Motivated to wear lenses and understands that vision may not always be as sharp as with spectacles for some distances or lighting conditions.

Less Than Ideal Candidates

- Critical or very fine visual demands at both distance and near.
- Emerging presbyopia with plano or very low distance powers. We recommend DAILIES® AquaComfort Plus® Multifocal soft contact lenses for this patient group.
- Refractive cylinder 1.50 D (any axis) in one or both eyes or against-the-rule refractive cylinder > 1.00 D in one or both eyes.
- Monocular distance acuities poorer than 20/20 with spherical equivalent refractive correction.
- Myopic anisometropia where the refractive error for one of the two eyes is low (< -1.50 D) and has not been habitually corrected.
- Pupil size larger than norm for presbyopic population (> 4 mm) under natural illumination conditions.
- Abnormal binocular sensory function (e.g., amblyopia or strabismus).
- Expectation to discard and never use spectacles again, even for special tasks or viewing conditions.
- Highly satisfied monovision wearers.
- Any other contraindications to successful contact lens wear such as tear abnormality or lid margin disease.

The following procedures should be followed when fitting FOCUS® DAILIES® Progressives One-Day Contact 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:

- determine whether a patient is a suitable candidate for FOCUS® DAILIES® Progressives contact lenses
- 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
- detailed assessment of patient's individual visual demands
- understanding of patient's objectives for lens wear and expectations
- a distance spherocylindrical refraction, near add determination and measurement of pupil diameter
- keratometry
- tear film assessment
- biomicroscopy

3. TRIAL LENS EVALUATION

FOCUS® DAILIES® Progressives lenses are available in a single base curve/diameter combination of 8.6/13.8 mm.

Note: A careful spherocylindrical maximum plus to best visual acuity refraction (M+BVA) and nearpoint add determination should be conducted prior to selecting trial lenses. Autorefraction findings should be refined manually to rule out effects of instrument myopia and ensure proper control of residual accommodation.

A. Initial Lens Power Selection

The FOCUS® DAILIES® Progressives lens design makes selecting the initial lens power easy. You need only manipulate the distance power. The optimum starting point is with a power that is more plus or less minus than the vertex corrected spherical equivalent spectacle refraction. Using the Power Selection Table provided on the following pages will simplify the process of initial lens selection.

Step 1. Convert the spectacle Rx to a spherical equivalent.

Spherical Equivalent = Sphere power + $\frac{1}{2}$ (Cylinder Power)
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Step 2. In the Power Selection Table locate the spherical equivalent from step 1 on the vertical axis. There is no need to correct for vertex distance. The table compensates for a 13 mm vertex distance.

Step 3. Locate the spectacle add power on the horizontal axis.

Step 4. The intersection of these 2 boxes is the initial trial lens power.

Example: **Spectacle Rx:** **-6.00D -1.00 x 090 Add +1.75**
 Spherical Equivalent: **-6.50D**
 Initial trial lens: **-5.00D**

FOCUS® DAILIES® Progressives Contact Lenses **Power Selection Table**

Select the initial power from the table by matching the spherical equivalent spectacle refraction on the vertical scale with the add requirement on the horizontal scale.

***Table values compensated for vertex distance. No vertex conversion necessary.**

		ADD			
		1.00 to 1.25	1.50	1.75 to 2.25	2.50 to 3.00
Equivalent Sphere Spectacle Refraction *	0.00	+0.50	+0.75	+1.00	+1.25
	+0.25	+0.75	+1.00	+1.25	+1.50
	+0.50	+1.00	+1.25	+1.50	+1.75
	+0.75	+1.25	+1.50	+1.75	+2.00
	+1.00	+1.50	+1.75	+2.00	+2.25
	+1.25	+1.75	+2.00	+2.25	+2.50
	+1.50	+2.00	+2.25	+2.50	+2.75
	+1.75	+2.25	+2.50	+2.75	+3.00
	+2.00	+2.50	+2.75	+3.00	+3.25
	+2.25	+2.75	+3.00	+3.25	+3.50
	+2.50	+3.00	+3.25	+3.50	+3.75
	+2.75	+3.25	+3.50	+3.75	+4.00
	+3.00	+3.50	+3.75	+4.00	+4.25
	+3.25	+4.00	+4.25	+4.50	+4.75
	+3.50	+4.25	+4.50	+4.75	+5.00
	+3.75	+4.50	+4.75	+5.00	+5.00
	+4.00	+4.75	+5.00	+5.25	+5.50
	+4.25	+5.00	+5.25	+5.50	+5.75
	+4.50	+5.25	+5.50	+5.75	+6.00

*** Table values compensated for 13mm vertex distance. No vertex conversion necessary.**

Shaded boxes indicate powers not currently available in FOCUS® DAILIES® Progressives contact lenses.

ADD

Equivalent Sphere Spectacle Refraction *

	1.00 to 1.25	1.50	1.75 to 2.25	2.50 to 3.00
0.00	+0.50	+0.75	+1.00	+1.25
-0.25	+0.75	+1.00	+1.25	+1.50
+0.25	+0.50	+0.75	+1.00	+1.75
-0.50	0.00	+0.25	+0.50	+0.75
-0.75	-0.25	0.00	+0.25	+0.50
-1.00	-0.50	-0.25	0.00	+0.25
-1.25	-0.75	-0.50	-0.25	0.00
-1.50	-1.00	-0.75	-0.50	-0.25
-1.75	-1.25	-1.00	-0.75	-0.50
-2.00	-1.50	-1.25	-1.00	-0.75
-2.25	-1.75	-1.50	-1.25	-1.00
-2.50	-2.00	-1.75	-1.50	-1.25
-2.75	-2.25	-2.00	-1.75	-1.50
-3.00	-2.50	-2.25	-2.00	-1.75
-3.25	-2.75	-2.50	-2.25	-2.00
-3.50	-3.00	-2.75	-2.50	-2.25
-3.75	-3.25	-3.00	-2.75	-2.50
-4.00	-3.50	-3.25	-3.00	-2.75
-4.00	-3.50	-3.25	-3.00	-2.75
-4.25	-3.50	-3.25	-3.00	-2.75
-4.50	-3.75	-3.50	-3.25	-3.00
-4.75	-4.00	-3.75	-3.50	-3.25
-5.00	-4.25	-4.00	-3.75	-3.50
-5.25	-4.50	-4.25	-4.00	-3.75
-5.50	-4.50	-4.25	-4.00	-3.75
-5.75	-4.75	-4.50	-4.25	-4.00
-6.00	-5.00	-4.75	-4.50	-4.25
-6.25	-5.25	-5.00	-4.75	-4.50
-6.50	-5.50	-5.25	-5.00	-4.75
-6.75	-5.75	-5.50	-5.25	-5.00
-7.00	-6.00	-5.50	-5.50	-5.25
-7.25	-6.00	-5.75	-5.50	-5.25

-7.50	-6.50	-6.00	-5.75	-5.50
-7.75	-6.75	-6.50	-6.00	-5.75
-8.00	-7.00	-6.75	-6.50	-6.00
-8.25	-7.25	-7.00	-6.75	-6.50

*** Table values compensated for 13mm vertex distance. No vertex conversion necessary.**

Shaded boxes indicate powers not currently available in FOCUS® DAILIES® Progressives contact lenses.

As an alternative to the Table, the following simple calculations can be made:

Initial Lens Power = Vertex corrected spherical equivalent + $\frac{1}{2}$ (Spectacle Add Power)

Note: If either plane of the spherocylindrical spectacle Rx is greater than $\pm 4.00D$, a vertex distance correction is necessary to determine the lens distance power required at the corneal plane (see Vertex Distance Conversion Chart in the back of this booklet).

Example 1: Spectacle Rx: +4.50 -0.50 x 090 Add +1.00
Spherical equivalent: +4.25 D
Vertex corrected Rx: +4.50 D
Initial trial lens: $+4.50 + (1.00/2) = +5.00$ D
DAILIES® Toric: -4.50 -0.75 x 180

Example 2: Spectacle Rx: -6.00 -1.00 x 090 Add +2.00
Spherical equivalent: -6.50 D
Vertex corrected Rx: -6.00 D
Initial trial lens: $-6.00 + (2.00/2) = -5.00$ D

B. Lens Fit Assessment

FOCUS® DAILIES® Progressives 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.**

Allow the lenses to settle on the eyes for approximately **5 to 10 minutes**. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

Criteria of a Well-Fitted Lens

A well-fitted FOCUS® DAILIES® Progressives lens has the following characteristics:

1. **Good centration with full corneal coverage in all fields of gaze**
2. **Sufficient movement to allow tear exchange** under the lens during the blink; 0.1 to 0.5 mm is generally considered optimal.
3. **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.

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

Characteristics of a Tight (Steep) Lens Fit

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

1. **Insufficient or no lens movement** during the blink in primary or upgaze
2. **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.
3. **Good centration**
4. **Good comfort**
5. **Fluctuating vision** between blinks

Characteristics of a Loose (Flat) Lens Fit

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

1. **Reduced comfort**, usually accompanied by lower lid sensation
2. **Poor centration** with limbal exposure on exaggerated eye movement
3. **Lens edge standoff**
4. **Excessive lens movement** during the blink in primary or upgaze
5. **Unsatisfactory Push-Up Test**
 - **A loose fitting lens will move easily but may remain decentered or slip under the upper lid.**
6. **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 the given eye.

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

C. Initial Lens Visual Evaluation

While lenses are settling, it is helpful to take the patient from the exam room to a “real-world” setting such as a room with an outside view. Once an acceptable fit has been achieved, the visual performance of the lenses may be evaluated. Visual acuity is tested at distance. If necessary, a spherical over-refraction should be performed using a trial frame or hand-held lenses rather than a phoropter. This technique is essential when fitting multifocal lenses because it allows the patient to maintain the head posture and direction of gaze (relationship between eye and head) that he or she would naturally use during everyday tasks. This ensures that the visual performance of the lens is being assessed under conditions where the on-eye positioning matches that which will occur when the lens is being used, for example, for near work activities. In addition, pupil size will not be artificially decreased by the reduction in light associated with looking through the apertures of the phoropter, or by proximal cues associated with the nearness of the instrument.

D. Fitting Procedure

Step 1: After the trial lenses have settled for 5 to 10 minutes, measure distance acuity while the patient is viewing the chart binocularly (i.e., simultaneously with both eyes). Using hand-held trial lenses, add +0.25 D simultaneously to each eye or alternatively one at a time to achieve best distance vision. Note whether or not this reduces the measured binocular distance acuity. If it does not, then there will be some extra tolerance for increasing the amount of plus for one or both eyes in the event that near vision is less than optimal.

Step 2: Evaluate the patient’s subjective impression of the near vision when trying to read typical everyday material (e.g., a newspaper, magazine, numbers on a watch). Lighting and reading distance should be what is normal for the patient.

Step 3: Allowing the patient to assume a natural reading position, measure binocular activity at 40 cm (16 in.) under good lighting conditions.

Step 4: The results of steps 2 and 3 will determine whether the patient requires an increment in plus power for near work activities. If the subjective quality of near vision is less than optimal, then use hand-held trial lenses to determine whether additional plus power will improve performance at near. Binocular viewing must be maintained throughout this assessment.

Improved vision at near may be achieved by adding plus to one or both eyes. If the testing performed in Step 1 indicated some tolerance for plus, determine whether the additional plus power for each eye will produce the necessary improvement in near vision.

If the patient cannot tolerate an additional plus power for each eye when viewing at distance or if this does not produce the

required improvement in near vision, then try adding plus power to just one eye. Determine which eye will accept the added power for near with the least reduction in distance vision.

Important note: +0.25 D may have a significant impact on visual acuity and/or subjective vision.

Place a plus power hand-held trial 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 at both distance and near with the extra plus power for the right eye or for the left eye. Although as much as +0.75 D may be added to one eye, visual performance and patient satisfaction with the lenses are more likely to be optimal if the amount of plus power added to one eye is +0.50 D or less. There are some patients for whom adding a small amount of plus power to improve vision at near will significantly disrupt distance vision. In such cases, success may be achieved with unocular (one eye only) FOCUS® DAILIES® Progressives lens (see Special Fitting Considerations in the next section).

Step 5: With the final over-refraction in place, evaluate the patient's subjective range of clear vision for tasks requiring near and intermediate viewing distances. Using a near vision acuity chart, ask the patient to find the lowest line he or she can read comfortably (i.e., without a great deal of extra effort). Then direct the patient's attention to letters in the row two lines up (i.e., larger) than the one previously selected. Have the patient slowly move the card closer until the first detectable but definite blur is experienced for these letters. Repeat, this time moving the card slowly further away.

This range of subjectively clear vision should be fairly well balanced about the specific patient's habitual near viewing distance that the patient uses for near work tasks in everyday life. If, for example, the patient's typical working distance falls near the extreme of the range of subjectively clear vision, try adding a small amount (i.e., 0.25 to 0.50 D) of plus or minus to one or both eyes.

E. Special Fitting Considerations

There are circumstances where optimal performance will be achieved by using only one FOCUS® DAILIES® Progressives contact lens. Some examples where a unocular FOCUS® DAILIES® Progressives lens might be recommended are indicated below. It is important to understand that in any case where a FOCUS® DAILIES® Progressives lens is worn on only one eye, best results will be obtained where careful assessment and optimization of the fit is carried out.

- A patient for whom the standard fitting procedures described above do not result in acceptable vision at both distance and near. This

might occur with an individual who has very critical (very fine) visual demands at both distance and near, or with an emmetropic patient who is entering presbyopia but has never worn any form of visual correction at either distance or near. Fitting one eye with a FOCUS® DAILIES® Progressives lens and the other eye with a single vision lens (or possibly, no lens) maintains a greater degree of binocular function than would be the case when using two single vision lenses in a monovision format (one eye biased for distance and one eye biased for near).

- Unilateral astigmat:

- a) Emmetropic in one eye, astigmatic in the other

Spectacle Rx

Potential Contact Lens Rx

O.D. Plano

+0.75 FOCUS® DAILIES® Progressives lens

O.S. -1.00

-1.00 -0.75 x 090 FOCUS® DAILIES® Toric lens

-1.00 x 090

Add: +1.50 D

- b) Myopic in one eye, astigmatic in the other

Spectacle Rx

Potential Contact Lens Rx

O.D. -1.50

-0.50 FOCUS® DAILIES® Progressives lens

O.S. -2.00

-2.00 -1.50 x 090 FOCUS® DAILIES® Toric lens

-1.75 x 090

Add: +2.00 D

- If a patient is a *bilateral* astigmat:

A choice must be made regarding on which of the two eyes the FOCUS® DAILIES® Progressives lens will be worn. The best way to determine this is to allow the patient to walk around for several minutes while wearing the multifocal lens, for example, on the right eye, and wearing the single vision lens (if any) normally predicted from the distance spectacle Rx on the left eye. Print and various objects should be observed at a variety of distances. After a few minutes, reverse the assignment of lenses to eyes so that the left eye receives the multifocal while the right eye receives the single vision lens (if any) that would be normally predicted from the spectacle Rx. If the patient indicates that one of the two trials seemed to result in vision being acceptable over a greater range, or vision that seemed “more natural”, then lenses should be assigned to eyes accordingly.

- When the particular eye that will wear the FOCUS® DAILIES® Progressives lens has been determined (either from the patient's spectacle Rx if a unilateral astigmat, or from the trials described in the bullet point above, then additional testing to optimize the power of the lens (if any) selected for each eye should still be performed. Follow procedures detailed previously for optimizing the FOCUS® DAILIES® Progressives lens. It is common that the final lens powers selected may be slightly different (more plus or less minus) for the eye wearing the multifocal lens and/or for the eye wearing the spherical or toric lens than

would be predicted from the patient's spectacle Rx.

SUMMARY OF FITTING PROCEDURE

1. Carefully assess patient's needs and expectations
2. Assess ocular health including adequacy of the lacrimal system
3. Perform a maximum plus spherocylindrical spectacle refraction and determine the spectacle add
4. Assess the fit of the 8.6 mm base curve
5. Select trial lens power from the Power Selection Table or the vertex corrected **"Spherical Equivalent Plus ½ the Add"** rule
6. Over-refract to full plus that allows good distance acuity using hand held lenses and trial frame
7. Assess near vision binocularly
8. Fine tune power as necessary
9. Verify physical fit and dispense lenses
10. Explain lens handling and care procedures
11. Perform first follow-up at 3-5 days following dispensing; modify power if necessary based on patient's real-world experience

FITTING GUIDELINES (DAILIES® AquaComfort Plus® Multifocal Contact Lenses)

The DAILIES® AquaComfort Plus® Multifocal soft contact lens is an aspheric simultaneous vision soft contact lens, available in three ADDs; low (LO), medium (MED) and high (HI). For each lens, the near and intermediate powers are concentrated primarily in the central portion of the optical zone while the distance power is contained in the surrounding portion. The continuous changes in power across the surface of the lens allow patients requiring a reading addition of up to + 3.00D to see clearly at far, intermediate, and near distances.

Achieving high success with DAILIES® AquaComfort Plus® Multifocal lenses is dependent on several factors, including the patient's motivation, expectations and visual wearing environment, as well as optimizing the lens powers to balance binocular performance at distance and near. The information in this guide is designed to provide you with the tools to manage your presbyopic patients through each stage of the process from the initial case history to post-fitting follow-up.

1. Patient Selection

The eye care professional should weigh several factors when considering patient selection for a DAILIES® AquaComfort Plus® Multifocal soft contact lens fitting. When fitting a lens intended to correct for presbyopia, it is especially important to evaluate the particular visual needs, objectives, lifestyle and expectations of the individual patient. Prospective candidates may include current contact lens wearers, former wearers, and persons with no previous wear history. For former wearers, it is important to determine the cause for discontinuation.

There are two general categories of candidates based on anticipated

usage: those who seek to wear their lenses as their principal means of vision correction, and those who wish to integrate the use of their contact lenses with spectacles. The integrative user often seeks to wear their lenses for sports or other occasional activities while reverting to spectacles under poor lighting or otherwise demanding vision conditions. In general, even the part-time user does not require more than a few moments re-adaptation time following an interval of no lens wear.

While candidates with greater than 1.00 diopter of refractive error have often been thought of as better candidates than those with low error or emmetropia, this is a generalization that often does not hold true for a given individual. Success is influenced by many factors and the eye care professional is encouraged to offer DAILIES® AquaComfort Plus® Multifocal contact lenses to all interested presbyopic patients who satisfy the standard requirements for soft contact lens wear.

To summarize patient selection, the characteristics of “ideal candidates” and those that will be more “difficult to fit” are listed below:

Ideal Candidates

- Refractive cylinder $\leq 1.00\text{D}$.
- Attainable visual demands that do not depend upon resolving very fine (smaller than 20/20 letters) details at both distance and near for extended periods.
- Emphasis on tasks where it is advantageous to have objects simultaneously a large range of viewing distances.
- Expectations consistent with actual everyday visual demands.
- Motivated to wear lenses and understands that vision may not always be as sharp as with spectacles for some distances or lighting conditions.
- Unable to adapt to monovision correction.

Less than Ideal Candidates

- Critical or very fine visual demands at both distance and near.
- Refractive cylinder $> 1.50\text{D}$ (any axis) in one or both eyes or against-the-rule refractive cylinder $> 1.00\text{D}$ in one or both eyes.
- Monocular distance acuities poorer than 20/20 with spherical equivalent refractive correction.
- Myopic anisometropia where the refractive error for one of the two eyes is low ($\leq 1.50\text{D}$) and has not been habitually corrected.
- Pupil size larger ($> 4\text{ mm}$) or smaller ($< 3\text{ mm}$) than norm for presbyopic population under natural illumination conditions.
- Abnormal binocular sensory function (e.g., amblyopia or strabismus).
- Expectation to discard and never use spectacles again, even for special tasks or viewing conditions.
- Any other contraindications to successful contact lens wear such as tear abnormality or lid margin disease.

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 and assessments 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
- detailed assessment of patient's individual visual demands
- understanding of patient's objectives for lens wear and expectations
- a distance spherocylindrical refraction, near add determination and measurement of pupil diameter
- keratometry
- tear film assessment
- biomicroscopy

Note: The importance of a thorough case history should not be underestimated. The information gained through careful listening and probing will help greatly in satisfying each patient's unique needs.

3. Initial Lens Selection

A. Initial Base Curve Selection

DAILIES® AquaComfort Plus® Multifocal lenses are available in a single 8.7 mm base curve.

B. Initial Lens Power Selection

Note: A careful maximum plus spherocylindrical refraction and nearpoint add determination should be conducted prior to selecting a DAILIES® AquaComfort Plus® Multifocal trial lens. Autorefraction findings should be refined manually to rule out effects of instrument myopia and ensure proper control of residual accommodation.

The DAILIES® AquaComfort Plus® Multifocal lens design makes selecting the initial lens power easy. **The optimum starting point is with a power that is the most plus or least minus vertex corrected spherical equivalent spectacle refraction.**

C. Initial ADD Selection

Note: A careful nearpoint ADD determination should be conducted prior to selecting an DAILIES® AquaComfort Plus® Multifocal trial lens

The DAILIES® AquaComfort Plus® Multifocal 3 ADD SYSTEM allows personalized fitting for presbyopic patients. The table below makes initial ADD selection easy.

DAILIES® AQUACOMFORT PLUS® MULTIFOCAL CONTACT LENSES ADD SELECTION

SPECTACLE ADD	BOTH EYES
Up to +1.25	LO
+1.50 to +2.00	MED
+2.25 to +2.50	HI

Example 1:	OD	OS
Spectacle Rx:	-4.50 -0.75 x 90	-4.00D
Spherical equivalent (least minus);	-4.75D	-4.00D
Vertex corrected power:	-4.50D	-4.00D
Spectacle Add:	+0.75D	
Eye Dominance:	OD	
Initial Trial Lens:	-4.50 LO	-4.00 LO

Example 2:	OD	OS
Spectacle Rx:	+4.25 -0.25 x 180	+4.00 D -0.50 x 180
Spherical equivalent (least minus);	+4.25D	-4.00D
Vertex corrected power:	+4.50D	-4.00D
Spectacle Add:	+2.00D	
Eye Dominance:	OS	
Initial Trial Lens:	+4.50 MED	-4.00 LO

4. Initial Lens Fitting Evaluation

DAILIES® AquaComfort Plus® Multifocal 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.**

Allow the lenses to settle on the eyes for approximately **5 to 10 minutes**. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

Characteristics of a Well-fitted Lens

A well-fitted DAILIES® AquaComfort Plus® Multifocal contact lens satisfies the following criteria:

- 1. **Full corneal coverage and good centration** (no limbal exposure). A lens that is decentered > 1 mm, particularly temporal, is less likely to give adequate vision.

2. **Sufficient movement to allow tear exchange** under the lens during the blink; 0.1 to 0.5 mm is generally considered optimal.
3. **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 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.
4. **Good comfort and stable visual response** (with over-refraction)

Characteristics of a Tight (Steep) Lens Fit

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

1. **Insufficient or no lens movement** during a blink in primary gaze or upward gaze
2. **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.
3. **Good centration**
4. **Good comfort**
5. **Fluctuating vision** between blinks

Characteristics of a Loose (Flat) Lens Fit

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

1. **Reduced comfort**, usually accompanied by lower lid sensation
2. **Poor centration** with limbal exposure on exaggerated eye movement
3. **Lens edge standoff**
4. **Excessive lens movement** during the blink in primary or upward gaze
5. **Unsatisfactory Push-up Test:**
 - A loose fitting lens will move easily but may remain decentered or slip under the upper lid.
6. **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 the given eye.

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

5. Initial Lens Visual Evaluation

While lenses are settling, it is helpful to take the patient from the exam room to a “real-world” setting such as a room with an outside view.

Once an acceptable fit has been achieved, the visual performance of the lenses may be evaluated. Visual acuity is tested at distance. If necessary, a spherical over-refraction should be performed using a trial frame or hand-held lenses rather than a phoropter. This technique is essential when fitting multifocal lenses because it allows the patient to maintain the head posture and direction of gaze (relationship between eye and head) that he or she would naturally use during everyday tasks. This ensures that the visual performance of the lens is being assessed under conditions where the on-eye positioning matches that which will occur when the lens is being used, for example, for near work activities. In addition, pupil size will not be artificially decreased by the reduction in light associated with looking through the aperture of the phoropter cells, or by proximal cues associated with the nearness of the instrument.

6. Fitting Procedures

Step 1. After the trial lenses have settled for 5 to 10 minutes measure distance acuity while the patient is viewing the chart binocularly (i.e., simultaneously with both eyes). Next, evaluate the patient’s subjective impression of the near vision when trying to read typical everyday material (e.g., a newspaper, magazine, and cell phone). Lighting and reading distance should be what is normal for the patient.

Step 2. If distance or near vision is unsatisfactory, perform a **distance** over-refraction on each eye as follows. Use hand-held trial lenses and encourage plus. For example, if a plano and +0.25D over-refraction yields the same results, use the +0.25D endpoint. Re-check visual acuity and visual quality as described in Step 1 above. If over-refraction is other than plano, go immediately to new trial lenses, keeping ADD the same.

Step 3. If distance and near vision are satisfactory, dispense lenses and remind patient to use good light when reading fine print. It is helpful to let the patient experience the lenses in their natural environment before further procedures for enhancing vision are performed.

Step 4. **Enhanced Near Vision.** If near vision is unsatisfactory, determine the dominant eye by the following method. Determine the eye with **greatest plus acceptance** by placing a +1.50 handheld trial lens over each eye alternately while patient

views in the distance with both eyes open. Consider the eye for which binocular vision blurs least with the +1.50 to be the non-dominant eye.

Step 4A: Check the patient's binocular acuity with +0.50 over the non-dominant eye to determine if near vision is improved and distance vision is still acceptable. If so, place a new trial lens with the same ADD on the non-dominant eye, **adjusting the distance power by +0.50.**

Enhanced near visions, Step A		
SPECTACLE ADD	DOMINATE EYE	NON-DOMINATE EYE (PLUS ACCEPTED)
Up to +1.25	LO	LO with additional +0.50
+1.50 to +2.00	MED	MED with additional +0.50
+2.25 to +2.50	HI	HI with additional +0.50

Next, re-check visual acuity and visual quality as described in Step 1 above. If satisfactory, dispense new distance lens power for the non-dominant eye.

If near vision is still unsatisfactory, proceed to Step B:

Step 4B: If near vision is still unsatisfactory, adjust ADD as shown below.

Enhanced near vision, Step B		
SPECTACLE ADD	DOMINATE EYE	NON-DOMINATE EYE (PLUS ACCEPTED)
Up to +1.25	MED	MED
+1.50 to +2.00	MED	HI
+2.25 to +2.50	HI	MED

Note: It is common to question the rather non-intuitive step we suggest for enhancing vision at near in the HI ADD range, where the suggestion is to "back off" to a MED ADD for the non-dominant eye, the same suggestion we make for enhancing distance vision (below). The reason for this is that after establishing (in Step A) that increasing plus is not helpful, the next most common reason for blur at near (or distance) is unacceptable ghosting that degrades the image quality. Backing down to the MED ADD in one eye can often relieve that and actually improve vision at near.

Step 5. Enhanced Distance Vision. If distance over-refraction did not improve visual acuity, adjust ADD according to the chart below.

SPECTACLE ADD	DOMINATE EYE	NON-DOMINATE EYE (PLUS ACCEPTED)
+1.50 to +2.00	LO	MED
+2.25 to +2.50	HI	MED

SUMMARY OF FITTING PROCEDURE

1. Carefully assess patient's needs and expectations
2. Assess ocular health including adequacy of the lacrimal system
3. Perform a maximum plus spherocylindrical spectacle refraction and determine the spectacle add
4. Assess the fit of the 8.7 mm base curve
5. Select trial lens power based on maximum plus vertex corrected sphere equivalent and using "Add Selection" table.
6. If necessary, over-refract to full plus that allows good distance acuity using hand held lenses and trial frame
7. Assess near vision binocularly
8. Fine tune power as necessary
9. Verify physical fit and dispense lenses
10. Explain lens handling and care procedures
11. Perform first follow-up at 3-5 days following dispensing; modify power if necessary based on patient's real-world experience

FITTING GUIDELINES (Monovision)

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

Not all patients will 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 "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 for near with the least reduction in distance 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 +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without a lens.
- **Bilateral myope:** 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.

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

few minutes or for several weeks. The longer these symptoms persist, the poorer the chance 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 is 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 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 driver's 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 Patient Instruction Booklet for DAILIES® (nelfilcon A) One-Day Contact Lenses.

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 over wear 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. Specific Instructions for Presbyopic Patients

Specific instructions, explanations and demonstrations are important for optimizing patient success with multifocal contact lenses. The following information and instructions have proven useful in advising patients who wear FOCUS® DAILIES® Progressives or DAILIES® AquaComfort Plus® Multifocal soft contact lenses.

1. A contact lens that contains different powers for distance and near involves greater technological and optical complexity than does a bifocal or multifocal spectacle lens. This is because the contact lens moves with the eye, rather than having the eye move up and down while the lens remains suspended in a frame. While the contact lens therefore gives an unobstructed field of view and greater freedom regarding where to look, these advantages may mean that the sharpness of vision may not always be exactly the same as what would be experienced with spectacles.
2. Although many individuals use FOCUS® DAILIES® Progressives or DAILIES® AquaComfort Plus® Multifocal contact lenses for full-time wear, it is not unusual to find that there may be some activities where one prefers to wear spectacles, or where the disadvantages associated with spectacles are outweighed by other issues. This is an entirely normal and natural response to the challenges presented by presbyopia.
3. Situations where vision with multifocal contact lenses may be less sharp or otherwise “different” than what is experienced with spectacles often involve low illumination (e.g., a semi-dark room),

reduced visibility (e.g., outdoor conditions of fog or heavy rain), or isolated sources of very bright light (e.g., headlights of an oncoming vehicle on a narrow country road).

4. Patients should be aware that it might be advisable to refrain from wearing their lenses while driving, flying an airplane or operating heavy machinery under these conditions until they gain some experience with the lenses in a similar visual environment.
5. Small changes in lens power can often make an enormous difference in the quality of the vision experienced with multifocal contact lenses. Such changes can be best tailored to individual needs only after the lenses have been worn during the tasks and environmental conditions that the patient will personally encounter on a day-to-day basis. Confidence and assurance that such refinements, if needed, can be achieved is important for patient motivation during the initial period of lens wear.

E. Additional Instructions

- All patients should be supplied with a copy of the Patient Instruction Booklet for DAILIES® (nelfilcon A) 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. You can obtain copies of the instruction book by calling Alcon Customer Service in the USA at 1-800-241-5999. Review the Package Insert for DAILIES® (nelfilcon A) 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. Alcon 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 to 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® (nelfilcon A) One-Day Contact Lenses are supplied in strips of five 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® (nelfilcon A) 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 packaging 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® One-Day Contact Lenses are for disposable wear only and should be discarded after a single use. **The lenses must not be re-used from patient to patient.**

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® (nelfilcon A) One-Day Contact Lenses, in the USA please contact Alcon Medical Safety at 1 800-241-7468.

TECHNICAL CONSULTATION AND ORDERING INFORMATION

Alcon is pleased to assist with fitting or clinical questions regarding DAILIES® (nelfilcon A) One-Day Contact Lenses. Eye care professionals having questions or problems should contact the Professional Consultation department, in the USA at (800) 241-7468. To **order** DAILIES® (nelfilcon A) One-Day Contact Lenses contact your Alcon sales representative or call Customer Service, in the USA at (800) 241-5999.

 <p>a Novartis company</p>	<p>FOCUS® DAILIES®, FOCUS® DAILIES® Toric, FOCUS® DAILIES® Progressives, DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric and DAILIES® AquaComfort Plus® Multifocal (nelficon A) One-Day Contact Lenses</p> <p>92024162</p>
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IMPORTANT: This package insert is effective as of October, 2013 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. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from Alcon by calling Customer Service at 1-800-241-5999 or download from our website at www.alcon.com. In addition a Patient Instruction Booklet is available which is recommended to be given to patients.



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® (nelficon A) Soft hydrophilic One-Day Contact Lenses are available in a spherical lens design. FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® Toric (nelficon A) Soft (hydrophilic) One-Day Contact Lenses are available in a toric design. FOCUS® DAILIES® Progressives and DAILIES® AquaComfort Plus® Multifocal (nelficon A) Soft (hydrophilic) One-Day Contact Lenses are available in a multifocal lens design. The lenses are to be prescribed for single use, daily disposable wear.

LENS MATERIAL

The lens material is 69% water and 31% Nelficon A Polymer (polyvinyl alcohol partially acetylated with 14-formylmethyl acrylamide).

- For VISINT® 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 and DAILIES® AquaComfort Plus® Toric (nelficon A) contact lenses contain the color additive phthalocyanine green.

LENS PROPERTIES

- Refractive index: 1.38 (hydrated)
- Light transmittance: Visible: 92% (@ 610 nm)
- Oxygen permeability (Dk): 25 to 110 (cm2/aec) (O2 ml x mm Hg), measured at 35°C (first edge effect corrected) 69% by weight in normal saline
- Water content: 69% by weight in normal saline
- Approved Power Range: -0.50 to +2.00D

LENS PARAMETERS

FOCUS® DAILIES® (nelficon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.6 mm
- Diameter: 13.8 mm
- Powers available: -0.50D to -6.00D (0.25D steps); -6.50D to -10.00D (0.50D steps); +0.50D to +6.00D (0.50D steps) (varies with power)
- Center thickness: Light blue handling tint
- Tint: Light blue handling tint

FOCUS® DAILIES® Toric (nelficon 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: 70°, 75°, 90°, 110°, 160°, 180° 0.10 mm at -3.00D (varies with power)
- Center thickness: Light blue handling tint
- Tint: Light blue handling tint

FOCUS® DAILIES® Progressives (nelficon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.6 mm
- Diameter: 13.8 mm
- Powers available: +5.00D to -6.00D (0.25D steps) Single Progressive Add Effective Range up to +3.00D 0.1 mm at -3.00D (varies with power)
- Center thickness: Light blue handling tint
- Tint: Light blue handling tint

DAILIES® AquaComfort Plus® (nelficon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.7 mm
- Diameter: 14.0 mm
- Powers available: -0.50D to -6.00D (0.25D steps); -6.50D to -10.00D (0.50D steps); +0.50D to +6.00D (0.25D steps) 0.10 mm at -3.00D (varies with power)
- Center thickness: Light blue handling tint
- Tint: Light blue handling tint

DAILIES® AquaComfort Plus® Toric (nelficon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.8 mm
- Diameter: 14.4 mm
- Powers available: -4.00D to -6.00D (0.25D steps); -6.50D to -8.00D (0.50D steps); Cylinder: -0.75D, -1.25D, -1.75D Axis: 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180° 0.10 mm at -3.00D (varies with power)
- Center thickness: Light blue handling tint
- Tint: Light blue handling tint

DAILIES® AquaComfort Plus® Multifocal (nelficon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.7 mm
- Diameter: 14.0 mm
- Powers available: -0.50D to -6.00D (0.25D steps); -6.50D to -8.00D (0.50D steps); +0.50D to +6.00D (0.25D steps) 0.10 mm at -3.00D (varies with power)
- Center thickness: Light blue handling tint
- Tint: Light blue handling tint

- Base curve: 8.7 mm
- Diameter: 14.0 mm
- Powers available: +0.00D to -10.00D (0.25D steps); ADD: LO, MED, HI; 0.10 mm at -3.00D (varies with power)
- Center thickness: Light blue handling tint
- Tint: Light blue handling tint

Hereafter, FOCUS® DAILIES®, FOCUS® DAILIES® Toric, FOCUS® DAILIES® Progressives, DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric and DAILIES® AquaComfort Plus® Multifocal (nelficon A) One-Day Contact Lenses will be referred to as DAILIES® (nelficon A) One-Day Contact Lenses unless product distinction is necessary.

ACTIONS

- When hydrated and placed on the cornea DAILIES® (nelficon A) One-Day Contact Lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (Uses)

- FOCUS® DAILIES® and DAILIES® AquaComfort Plus® (nelficon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive anisometropia and hyperopia in not-astigmatic persons with non-diseased eyes with up to approximately 1.5D (diopters) (D) of astigmatism that does not interfere with visual acuity.
- FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® Toric (nelficon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive anisometropia (myopia and hyperopia) in not-astigmatic persons with non-diseased eyes with 6.00D (diopters) (D) or less of astigmatism.
- FOCUS® DAILIES® Progressives and DAILIES® AquaComfort Plus® Multifocal (nelficon A) One-Day Contact Lenses are indicated for the optical correction of refractive anisometropia (myopia or hyperopia) in not-astigmatic persons with non-diseased eyes who require a reading addition of +3.00 (diopters) (D) or less and who may have 1.50 (diopters) (D) or less of astigmatism that does not interfere with visual acuity.
- DAILIES® (nelficon A) 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 (Reasons not to use)

- Do not use DAILIES® (nelficon A) One-Day Contact Lenses when any of the following conditions exist:
 - Acute or subacute inflammation or infection of the anterior chamber of the eye.
 - Any eye disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids that may be exacerbated by contact lens wear.
 - Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear.
 - Corneal hyposthesia (induced corneal sensitivity).
 - Any systemic disease which may be exacerbated by or interferes with contact lens wear.
 - Allergic reactions or ocular irritation of the cornea or sclera that may be caused by or exacerbated 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 directions 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 lenses while sleeping. Clinical study results¹ 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.
 - Studies² have shown that contact lens wearers who smoke have an estimated 3 to 8 times greater risk of suffering ulcerative keratitis than 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 use their eye care professional regularly as directed.

PRECAUTIONS

Special Precautions for the Eye Care Professional:

Due to the small number 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 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. Alcon 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® (nelficon A) 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 your lenses in the case when removing 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 to remove 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, 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.
- Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.
- 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 conditions subside.

It is strongly recommended that patients be provided with a copy of the DAILIES® (nelficon A) One-Day Contact Lenses Patient Instruction Booklet available from Alcon Laboratories and understand its contents prior to dispensing the lenses.

ADVERSE REACTIONS

Potentially serious complications are usually accompanied by one or more of the following signs or 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 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 microcytes, 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® (neflicon A) One-Day Contact Lenses, licensed eye care professionals please notify: Alcon Medical Safety in the USA at 1-800-241-7468.

FITTING

For a detailed description of the fitting techniques, refer to the DAILIES® (neflicon A) One-Day Contact Lenses Professional Fitting and Information Guide, copies of which are available free of charge from:

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134
1-800-241-5999

REPLACEMENT AND WEAR SCHEDULE

DAILIES® (neflicon A) 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 hours, 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® (neflicon A) 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® contact lenses 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® contact lenses 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® contact lenses 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® lenses and was 9.5 at one-month with DAILIES® AquaComfort Plus® lenses. Additionally, average overall comfort

was 8.8 at baseline with FOCUS® DAILIES® and was 9.1 at one-month with DAILIES® AquaComfort Plus®, while the average comfort at the end of the day was 7.8 at baseline with FOCUS® DAILIES® lenses and was 8.5 at one-month with DAILIES® AquaComfort Plus® lenses (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 the lens sticks (stops moving) and 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 the manufacturer's instruction for use 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 the lens tears in your 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 do for normal lens removal. If the 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.

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® (neflicon A) One-Day Contact Lenses are packaged in strips of five foil sealed blister packs containing phosphate-acetate buffered saline solution and are steam sterilized **STERILE**. 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® DAILIES® AquaComfort Plus® Toric and DAILIES® AquaComfort Plus® Multifocal One-Day Contact Lenses contains polyethylene glycol (PEG) and hydroxypropyl methylcellulose (HPMC). The package is marked with the base curve, diameter, dioptric power, manufacturing lot number and expiration date.

The following may appear on the labels or cartons:

Symbols/Signs	Description
	CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.
	Steam sterilized
	Use by date (Expiry date)
	Batch code
	Example of two letter language code (English)
	Do Not Reuse
	Diameter
	Base curve
	Lens power
	"Low" near ADD
	"Medium" near ADD
	"High" near ADD
	European conformity sign
	See product instructions
	Authorized Representative European Community
	Manufacturer
	Packaging waste license sign

Alcon Laboratories, Inc.
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Fort Worth, TX
76134-2099, USA

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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.

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

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