# *ALTIUS*™

# PROFESSIONAL FITTING GUIDE

For the

## Performance Vision Technologies, Inc.

**ALTIUS™ (ocufilcon D) Performance-Tinted**
**Soft (Hydrophilic) Daily Wear Contact Lenses**

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

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## DESCRIPTION OF LENS

The **ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses** are hemispherical shells with molded spherical base curves and molded front surfaces. The hydrophilic characteristics allow aqueous solutions to enter the lens. The lenses are fabricated from ocufilcon D, which is a hydrophilic co-polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and methacrylic acid (MAA), cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 45% ocufiocon D and 55% water by weight when immersed in saline solution. The (ocufiocon D) name has been adopted by the United States Adopted Names Council (USAN).

The **ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses** are subsequently tinted to achieve different colors using permanently listed color additives that conform to 21 CFR Part 73. The lenses are processed to incorporate the 'listed' color additives and contain only the amount of the additive needed to accomplish the intended coloring effect. The lenses contain one or a combination of one or more of the following 'listed' color additives: Reactive Black 5, Reactive Yellow 15, Reactive Orange 78, and Reactive Red 180

The **ALTIUS™ (ocufilcon D) Performance-Tinted Contact Lenses** are designed to aid visual performance in athletic settings. ALTIUS™ (ocufilcon D) Performance Tinted Contact Lenses enhance contrast in a wide range of outdoor light conditions. This enables the wearer to see a ball or selected objects with greater clarity than with the naked eye.

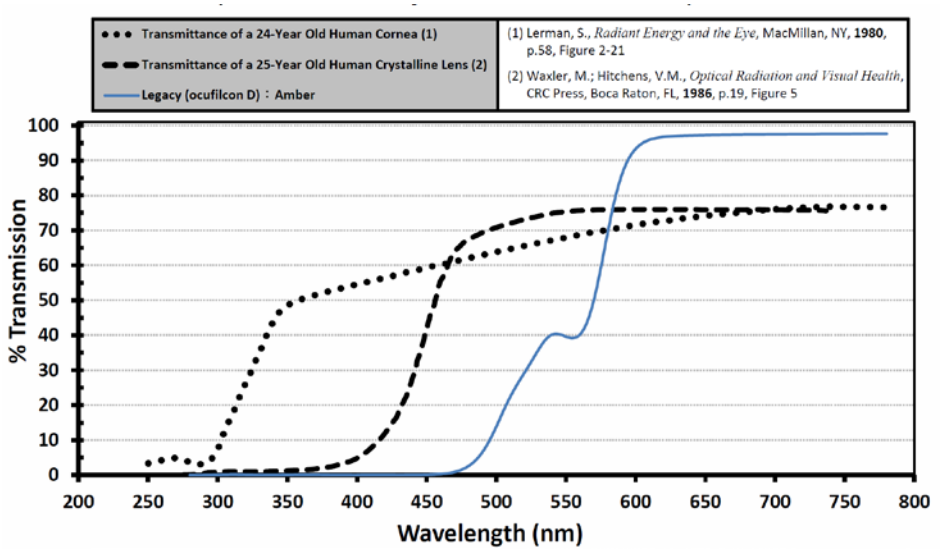
The **ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses** incorporate a UV absorbing monomer. The lenses block >95% in the UVB range (280nm - 315nm), and >50% in the UVA range (316nm - 380nm).

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

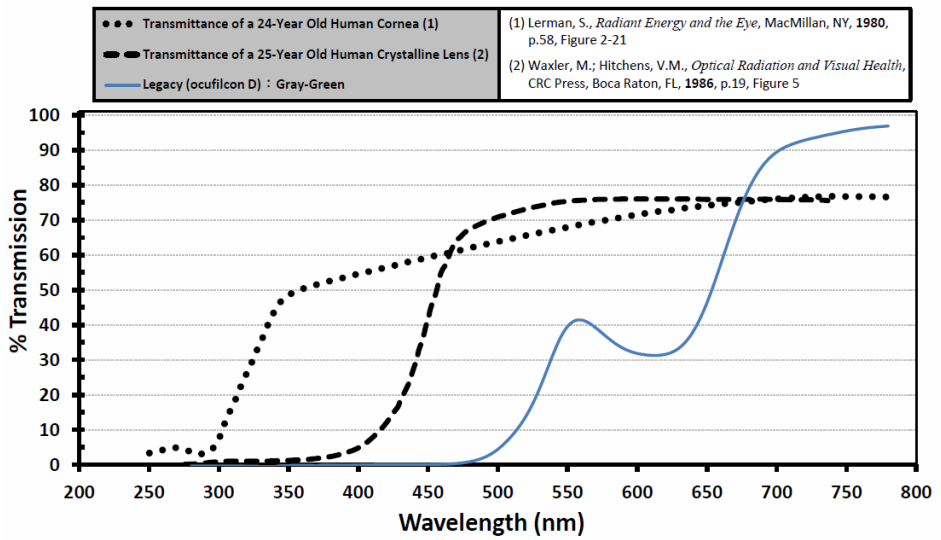
Note: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye-care practitioner for more information.

Refer to the following transmittance profile for the ALTIUS™ (ocufilcon D) Performance-Tinted Contact Lenses, as well as a human cornea and a human lens:

Amber Tint




Gray-Green Tint




Note: the above % transmission data are based on measurements from -3.00 D lenses. The data was obtained from measurements with a spectrophotometer taken through the central 3-5 mm portion of the ALTIUS™ (ocufilcon D) contact lens.

| Parameter | Range | Tolerance* |
|---|---|---|
| **Chord Diameter** | 14.20 mm | ±0.20 mm |
| **Center Thickness** | 0.05 mm to 0.15 mm | When ≤ 0.10 mm → ±0.010 mm + 10%<br>When > 0.10 mm → ±0.015 mm + 5% |
| **Base Curve** | 8.70 mm | ±0.20 mm |
| **Back Vertex Power (F'v)** | +20.00D to -20.00D<br>(in 0.25D steps) | When 0.00 < \|F'v\| ≤ 10.00 D → ±0.25 D<br>When 10.00 < \|F'v\| ≤ 20.00 D → ±0.50 D |
| **Cylinder Power (F'c)** | -0.25D to -4.00D<br>(in 0.25D steps) | When 0.00 < \|F'c\| ≤ 2.00 D → ±0.25 D<br>When 2.00 < \|F'c\| ≤ 4.00 D → ±0.37 D |
| **Cylinder Axis** | 10° to 180°<br>(in 10° steps) | When 0.00 < \|F'c\| ≤ 1.50 D → ± 8°<br>When\|F'c\| > 1.50 D → ± 5° |
| **Surface Appearance** | - | Lenses should be clear with no surface defect |
| **Oxygen Permeability**<br>**(x $10^{-11}$($cm^2$/sec)(mlO2)/(ml x mmHg))** | 19.6 | ±20% |
| **Light Transmission - Tinted**<br>**(@ 380-780nm)** | >30% | ±5% |
| **Ultraviolet Radiation Transmittance** | < 5 % $T_{UVB}$<br>< 50 %$T_{UVA}$ | $T_{UVB\ (280\ to\ 315\ nm)} < 0.05T_V$<br>$T_{UVA\ (316\ to\ 380\ nm)} < 0.50T_V$ |
| **Water Content** | 55% | ±2% |
| **Refractive Index** | 1.410 (hydrated) | ±0.005 |

*ANSI Z80.20, Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties (2010)

## ACTIONS

In its hydrated state, the **ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses**, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

## INDICATIONS

The **ALTIUS™ (ocufilcon D) Performance-Tinted SPHERICAL** contact lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased that may exhibit astigmatism up to 2.0 diopters that does not interfere with visual acuity.

The **ALTIUS™ (ocufilcon D) Performance-Tinted TORIC** Soft Contact Lenses for daily wear are indicated for the correction of refractive error in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopters.

Eye care practitioners may prescribe any of the above lenses for single use daily disposable wear. When prescribed for daily disposable wear the lens is to be discarded after each removal.

**Special Precautions for Eyecare Practitioner:**

Due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, design configurations, or lens parameters available in the lens material were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors on the patient's ocular health must 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 eyecare practitioner.

## CONTRAINDICATIONS (REASONS NOT TO USE)

Please reference Contraindications (Reasons Not to Use) in the Package Insert.

## WARNINGS

Please reference Warnings in the Package Insert

## PRECAUTIONS

Please reference Precautions in the Package Insert

## ADVERSE REACTIONS

Please reference Adverse Reactions in the Package Insert

## PATIENT SELECTION

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended care of the **ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses** should not be provided with this lens. All necessary steps in lens care and all precautions and warnings should be discussed and understood by the patient (*Review Package Insert with patient*).

# ***Fitting Procedure for the ALTIUS™ (ocufilcon D) Sphere Lens***

**FITTING PROCEDURE**

1. Pre-fitting Examination
2. Initial lens power selection
3. Initial lens diameter and base curve selection
4. Initial lens evaluation
5. Follow-up care

**1. Pre-fitting Examination**

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

- determine whether a patient is a suitable candidate for daily wear contact lenses (refer to contraindications)
- collect and record baseline clinical information to which post-fitting examination results can be compared
- make ocular measurements for initial contact lens parameter selection

**2. Initial Lens Power Selection**

a) Convert the spectacle Rx to minus cylinder forms
b) Compensate the spectacle Rx for vertex distance if the power is greater then + or – 4.00 diopters
c) Drop the cylinder
d) Add + 0.25 diopter to compensate for minus tear lens
e) If refractive astigmatism exceeds 0.75 diopter, determine equivalent sphere and then compensate for power by adding +0.25 diopter for minus tear lens

**1. Initial Lens Diameter and Base Curve Selection**

The lens is currently offered in one diameter (14.20 mm) and one base curve (8.7)

**2. Initial Lens Evaluation**

a) Check Lens Centration, Movement, and Size

The criteria for a well fit lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.5 millimeters, lags downward about 1 to 2 millimeters on upward gaze, and does not move excessively as a result of blinking or exaggerated eye movements.

After the trial lens settled on the eye (5 – 10 minutes), manipulate the lens using

lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with the slightest pressure and return to the centered position when released. Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1 – 2 millimeters.

b) Refract Over the Lens and Determine Visual Acuity

Allow approximately 10 minutes for fluid equilibration and patient adaptation prior to over refracting. Determine best visual acuity when final over refraction has been achieved. If good visual acuity cannot be obtained through the lens with spherocylindrical over refraction, re-evaluation of the physical fit should be considered. Trial lens procedure should be repeated with lenses of different base curves.

c) Determine the Optical Power for the Lens Selected

When the proper physical fit has been determined, convert the over refraction through the diagnostic lens to equivalent sphere and add this to the power of the trail lens. This will provide the final power of the lens.

**3. Follow-up Care**

a) Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear.

b) Prior to a follow-up examination, the contact lenses should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

c) With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continues to be satisfied. Examine the lenses closely for surface deposition and/or damage.

d) After the lens removal, conduct a thorough biomicroscopy examination.

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

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examinations, the patient should be re-fitted with a more appropriate lens.

# ***Fitting procedure for the ALTIUS™ (ocufilcon D) Toric***

**FITTING PROCEDURE**

1. Pre-fitting Examination
2. Initial lens power selection
6. Initial lens diameter and base curve selection
7. Initial lens evaluation
8. Follow-up care

## 1. Pre-fitting Examination

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

- Determine whether a patient is a suitable candidate for daily wear contact lens (refer to contraindications)
- Collect and record baseline clinical information to which post-fitting examination results can be compared
- Make ocular measurements for initial contact lens parameter selection

## 2. Initial Lens Power Selection

a) Convert the spectacle Rx to minus cylinder forms
b) Determine the cylinder axis
   Available any axis (10˚ steps)
c) Determine the cylinder power
   Available powers -0.25D/-0.50D/-0.75D/-1.00D/-1.25D/-1.50D/-1.75D/-2.00D/-2.25D
d) Determine the sphere power
   1. Compensate the spherical Rx for vertex distance of the power is greater than plus or minus 2.25 diopters
   2. Add + 0.25 to sphere to compensate for the minus tear lens

## 3. Initial Lens Diameter and Base Curve Selection

The lens is currently offered in one diameter (14.20mm) and one base curve (8.7)

## 4. Initial Lens Evaluation

A. Check Lens Centration, Movement, and Size

The criteria for a well fit lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.5 millimeters, lags downward about 1 to 2 millimeters on upward gaze, and does not move excessively as a result of blinking or exaggerated eye movements.

After the trial lens settled on the eye (5 – 10 minutes), manipulate the lens using lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with the slightest pressure and return to the centered position when released.

Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1 – 2 millimeters.

B. Refract Over the Lens and Determine Visual Acuity

Allow approximately 10 minutes for fluid equilibration and patient adaptation prior to over refracting. Determine best visual acuity when final over refraction has been achieved. If good visual acuity cannot be obtained through the lens with spherocylindrical over refraction, re-evaluation of the physical fit should be considered. Trial lens procedure should be repeated with lenses of different base curves.

C. Lens Orientation Evaluation and Determination of Lens Axis

**ALTIUS™ (ocufilcon D) toric contact lenses** are marked at 6 o'clock for ease in properly orienting the lens and observing rotation.

With the trial lens settled on the eye (5-10 minutes), note the orientation of the toric lens marking relative to the vertical meridian. If the toric lens marking is not oriented at 6 o'clock, a common method of axis compensation is called "LARS" (Left Add, Right Subtract). On either eye, if the rotation is left to the examiner, note the amount of rotation in degrees, ADD it to the refractive cylinder axis and order the resulting axis. If the rotation is to the right of the examiner, note the amount of rotation in degrees, SUBTRACT it from the refractive cylinder axis and order the resulting axis.

Example:

| | |
|---|---|
| Spectacle $R_x$: | -3.00 -1.00 X 080 |
| Rotation ~18° to the left of the examiner | |
| Adjusted Lens Prescription | -3.00 -1.00 X 098 |
| Round to the nearest axis increment | 10°-180° in 10° steps |
| Final Lens Selection | -3.00 -1.00 X 100 |

## 5. Follow-up Care

A. Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear.
B. Prior to a follow-up examination, the contact lenses should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
C. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continues to be satisfied. Examine the lenses closely for surface deposition and/or damage. Evaluate the orientation of the lens (note: the orientation of the prescribed lens should be the same as the orientation observed for the fitting. For example: if the lens marking rotated about 18° to the left during the fitting, the prescribed lens marking should also rotate about 18° to the left.
D. After the lens removal, conduct a thorough biomicroscopy examination.
    1. The presence of vertical corneal striae in the posterior central cornea and/or cornea neovascularization is indicative of excessive corneal edema.
    2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
    3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

    If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examinations, the patient should be re-fitted with a more appropriate lens.

## CLINICAL ASSESSMENT

### 1. Criteria of a Well-Fitted Lens

The criteria of a well fitted lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.5 millimeters, lags downward about 1 to 2 millimeters on upward gaze, and does not move excessively as a result of blinking or exaggerated eye movements.

After the trial lens settled on the eye (5 – 10 minutes), manipulate the lens using lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with the slightest pressure and return to the centered position when released.

Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1 – 2 millimeters.

2. **Characteristics of a Tight (Steep) Lens**

   A tight (steep) lens does not move easily on the cornea with slight pressure

3. **Characteristics of a Loose (Flat) Lens**

   A loose (flat) lens sags more than 2.0 millimeters on upward gaze

**FOLLOW-UP EXAMINATIONS**

* Within one week of lens dispensing
* After three weeks of lens wear
* After seven weeks of lens wear
* After each six month period of lens wear.

At the follow-up examinations, the patient should report good subjective quality of vision. Adaptation to vision with **ALTIUS™ (ocufilcon D) Soft Contact Lenses** should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the practitioner should:

1. Check distance and near acuity with lens in place.
2. Over-refract to verify lens prescription.
3. Observe the position of the lens on the cornea. The lens should be centered and move on upward gaze and with a blink.
4. Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.

5. Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
6. Perform a slit-lamp examination with and without Fluorescein. Check for corneal edema, corneal abrasion, vascularization, corneal infiltrates, and perilimbal injection. Reinsert the lens only after all residual Fluorescein has dissipated from the eye.

**RECOMMENDED WEARING SCHEDULE**

Close professional supervision is recommended to ensure safe and successful contact lens wear. If the patient complains of discomfort, decreased vision, ocular injection or corneal edema, the lens should be removed, and the patient scheduled for examination. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting the lens.

Patients tend to overwear the lens initially. It is important not to exceed the initial wearing schedule. Regular check-ups, as determined by the eyecare practitioner, are also extremely important.

**STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE ALTIUS™ (OCUFILCON D) SOFT CONTACT LENS IS SAFE TO WEAR DURING SLEEP.**

## EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

## REPORTING OF ADVERSE REACTIONS

Practitioners should report any adverse reactions to **ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses** within 5 days to Performance Vision Technologies, Inc. Additional Fitting Guides, Package Inserts and Patient Guides are available from:

**Performance Vision Technologies, Inc.**
2211 Fernwood Circle
Lake Oswego, OR 97034
United States
www.altiusvision.com
Email: info@altiusvision.com

## HOW SUPPLIED

The **ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses** are sterile in sealed blister packages containing a buffered saline solution with HPMC and poloxamer. The base of the package is made from polypropylene, which is covered with an aluminum foil seal on top. The blister packages are marked with the base curve, diameter, dioptric power, toric cylinder power, toric cylinder axis, lens color, manufacturing lot number, and expiration date of the lens.

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