Professional Fitting and Information Guide

NIGHT & DAY®

TM

AIR OPTIX™ breathable contact lenses®
NIGHT&DAY™ AQUA

NIGHT & DAY® and AIR OPTIX™ NIGHT & DAY® AQUA
(lotrafilcon A) Soft Contact Lenses
For Daily Wear and Up to 30 Nights Continuous Wear

Rx only

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

CIBA VISION™

Shared Passion for Healthy Vision and Better Life

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INTRODUCTION

Thank you for prescribing CIBA VISION® NIGHT & DAY® and AIR OPTIX™ NIGHT & DAY® AQUA (lotrafilcon A) soft contact lenses. NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA lenses allow you, the eye care professional, to offer your patients the comfort and convenience of extended wear lenses that can be worn for up to 30 nights of continuous wear.

Fitting NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA contact lenses is easy and predictable. This guide contains important information regarding fitting procedures and aftercare of the NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA patients.

NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA (lotrafilcon A) soft contact lenses are available in a spherical lens design. The lens material is approximately 24% water and 76% lotrafilcon A, a fluoro-silicone containing hydrogel that is surface treated. This breakthrough lens material provides a high level of oxygen to the eyes and has been surface treated to wet with the tears. Lenses may contain the color additive copper phthalocyanine, a light blue handling tint which makes them easier to see when handling.

Lotrafilcon A soft contact lenses are also available to eye care professionals for therapeutic use as a bandage, and can be worn after surgery, in the treatment of corneal complications of corneal erosions and edema, and after trauma. Patients can benefit from high oxygen levels (175 Dk/t) without hypoxic stress, maintaining sound corneal metabolism and physiology. Close professional supervision is necessary, and patient compliance is essential for successful therapeutic use.

PRODUCT DESCRIPTION

• Lens Properties

• Specific Gravity:	1.08
• Refractive Index (hydrated):	1.43
• Light Transmittance:	≥ 96%
• Oxygen Permeability (Dk):	140 x 10^{-11} (cm^2/sec) ($ml\ O_2$/ml x mm Hg), measured at 35˚C (intrinsic Dk - Coulometric method)
• Water Content:	24% by weight in normal saline

• Available Lens Parameters[1]

• Chord Diameter:	13.8 mm
• Center Thickness:	0.080 mm @ -3.00D (varies with power)
• Base Curve:	8.4 mm, 8.6 mm
• Powers:	plano to -8.00D (0.25D steps); -8.50D to -10.00D (0.50D steps); +0.25D to +6.00D (0.25D steps)

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

• Actions

When hydrated and placed on the cornea, lotrafilcon A contact lenses act as a refracting medium to focus light rays on the retina. When hydrated and placed on the cornea for therapeutic use, lotrafilcon A contact lenses act as a bandage to protect the cornea.

INDICATIONS (USES)

- NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA (lotrafilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters of astigmatism.

- The lenses may be prescribed for daily wear or extended wear for up to 30 nights of continuous wear, with removal for disposal, or cleaning and disinfection prior to reinsertion, as recommended by the eye care professional.

- Lotrafilcon A soft contact lenses are also indicated for therapeutic use. Use as a bandage to protect the cornea and to relieve corneal pain in the treatment of acute or chronic ocular pathologies such as bullous keratopathy, corneal erosions, entropion, corneal edema, and corneal dystrophies as well as post-surgical conditions resulting from cataract extraction and corneal surgery. Lotrafilcon A soft contact lenses for therapeutic use can also provide optical correction during healing if required.

See WARNINGS for information about the relationship between wearing schedule and corneal complications.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS

For additional important prescribing and safety information, refer to the Package Insert that is printed in the back of this guide. The package insert includes summaries of results of the pre-market and post-market extended wear studies and a retrospective report on therapeutic use.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of lotrafilcon A contact lenses, please notify CIBA VISION Corporation, **Technical Consultation in the USA at 1-800-241-7468.**

FITTING GUIDELINES

Please see the appropriate sections of this booklet that contain guidelines for spherical fitting techniques, monovision fitting techniques and for therapeutic use.

SPHERICAL FITTING GUIDELINES

1. Patient Selection

The patient characteristics necessary to achieve success with NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA 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.

While lotrafilcon A lenses are indicated for up to 30 nights of continuous wear, your patients should be told to follow some basic safety precautions. Patients should check their eyes every day to make sure they are comfortable and free of redness or irritation, and that their vision is clear. The Patient Instruction Booklet contains a list of problem symptoms and patients should be instructed to contact you if a problem persists.

The following procedures should be followed when fitting NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA 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
- 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 assessment
- biomicroscopy

3. Trial Lens Evaluation

A. Lens Base Curve Selection

A well-fitted lens provides good movement, centration, and comfort. If the steepest keratometry reading is less than 44.00 diopters the initial lens of choice should be the 8.6 base curve. If comfort is reduced, movement is excessive or fluctuation of vision occurs, then switch to the 8.4 base curve. If the steeper keratometry reading is 44.00 diopters or greater then select the 8.4 as the initial lens for evaluation. If this provides insufficient movement or fluctuation of vision occurs, then switch to the 8.6 base curve.

B. Initial Lens Power Selection

The initial power selection should be as close as possible to the patient's prescription after taking into account spherical equivalent and vertex calculations, if necessary.

Spherical Equivalent Calculation

To determine initial lens power, convert the spherocylindrical spectacle Rx to its spherical equivalent as follows:

Spherical Equivalent = Sphere power + 1/2 (Cylinder Power)

Example:	**Spectacle Rx:**	**-4.50D -1.00 x 180**
	Spherical equivalent:	**-4.50D + (-0.50D) = -5.00D**

Vertex Distance Conversion

If the spherical equivalent is greater than ± 4.00D, a vertex distance correction is necessary (see *Vertex Distance Conversion Chart*) to determine the lens power required at the corneal plane.

Example:	**Spectacle Rx:**	**-4.50D -1.00 x 180**
	Spherical equivalent:	**-4.50D + (-0.50D) = -5.00D**
	Vertex compensation:	**-4.75 (initial lens power)**

C. Lens Fit Assessment

Allow the lenses to settle on the eyes for approximately **15 minutes.** This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

Evaluate the fit and movement of the lenses on the eye. The **Push-Up Test**, as described below, is an important part of the lens evaluation. The following guidelines will be helpful in fit evaluation:

Characteristics of a Well-Fitted Lens

A well-fitted lotrafilcon A contact lens satisfies the following criteria:

1. **Good centration and full corneal coverage** in all fields of gaze.
2. **Sufficient lens movement to allow tear exchange** under the lens during a blink in primary or up gaze.
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 nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.
   - A well fitted lens will move freely upward, stopping shortly after passing the limbus and then return freely 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 fit should not be dispensed. If a lens fit is judged to be too steep a flatter lens (larger base curve), if available, should be evaluated. 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 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

If a lens fit is judged to be too flat, a steeper lens (smaller base curve), if available, should be evaluated. A loose lens fit would display some or all of the following characteristics:

1. Lens edge standoff. Even minor lifting of the edge indicates a loose fitting lens.
2. Reduced comfort. This finding is often the only signal of a loose fitting lens. If initial comfort doesn't improve quickly, try a steeper base curve, if available.
3. Excessive lens movement during the blink in primary or upgaze. A loose fitting lens will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often times return lower than its original position.
4. Poor centration with limbal exposure on exaggerated eye movement.
5. Vision may be blurred after the blink.

General Fitting Tips

- Trial fitting of the individual eye is strongly recommended.
- A well fitting lens will show movement of 0.1 to 0.5 mm.
- When prescribing lotrafilcon A lenses for **extended wear**, it is important to **reevaluate** the lens fit for adequate movement at various times after the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens from sleeping, as well as at other times of the day. If the fit is judged to be too tight or steep, the patient must be refit into a lens that provides the criteria of a well-fitted lens.

D. 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: Diagnostic lens:	**-4.50**
Over-refraction:	**-0.25**
Final lens power:	**-4.75**

MONOVISION FITTING GUIDELINES

Patient Selection

A. Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. Patients with reduced visual acuity, such as the amblyopic patient, 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 potentially dangerous machinery or performing other potentially hazardous activities; and

2. driving automobiles (e.g., driving at night). Patients who cannot pass requirements for a driver's license with monovision correction should not drive with this correction. An additional over-correction can be prescribed to improve vision.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal or 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 disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide compared to spectacle bifocals.

Eye Selection

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

A) Ocular Preference Determination Methods

- Method 1 - Determine which eye is the "sight eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

- Method 2 - Determine which eye will accept the added power 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 person who places copy to the left side of the desk will usually function best with the near lens on the left eye.

Special Fitting Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

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

a) Emmetropic in one eye, astigmatic in the other

Spectacle Rx	Potential Monovision Rx
O.D. Plano	Uncorrected for distance
O.S. -1.00 -1.00 x 090	+0.50 -1.00 x 090 for near
Add: +1.50	

b) Myopic in one eye, astigmatic in the other

Spectacle Rx	Potential Monovision Rx
O.D. -1.50	Uncorrected for near
O.S. -2.00 -1.75 x 090	-2.00 -1.75 x 090 for distance

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

Astigmatism
Patients with less than 1.50 diopters of astigmatism might be successfully fit in lotrafilcon A spherical lenses.

- Determine which eye to use for the near prescription (see Eye Selection, A-C, above)
- Add the appropriate near add power to the spherical component of the astigmatic prescription for that eye.
- Example:

Spectacle Rx	Potential Monovision Rx
O.D.: -2.50 -1.00 x 180	-2.50 -1.00 x 180 for distance
O.S.: -3.00 -1.75 x 165	-2.00 -1.75 x 165 for near
Add: +1.00	
Dominant eye: O.D.	

Near Add Determination
Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

Trial Lens Fitting
A trial lens fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the General Fitting Guidelines and Base Curve Selection described earlier in the guide.

Case history and standard clinical evaluation procedures should be used to determine the suitability of monovision. 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 in place, observe the reaction to this mode of correction.

Immediately after 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. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision 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.

After evaluating 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 less favorable 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 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 patients 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 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 **NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA Patient Instruction Booklet**, which contains important instructions for the monovision wearer. You can obtain copies of the instruction book by contacting a customer service representative, in the USA at **1-800-241-5999**.

THERAPEUTIC USE

Patient Management
Close professional supervision is necessary for therapeutic use of lotrafilcon A lenses, and patient compliance will be critical to the success of this program. In some cases, application and removal of lenses will only be performed by the eye care practitioner. Please emphasize to your patient the importance of following the wear, disposal and follow-up care schedule you prescribe. Should you become aware through monitoring a patient is not adhering to the prescribed wear and replacement schedule it is recommended the patient be discontinued from the program. Patient files should be maintained to monitor routine patient follow-up schedules.

Patients fitted with lotrafilcon A lenses for therapeutic use must be monitored closely and instructed as to the risks, benefits and proper use of the lenses. The eye care practitioner should discuss with the patient the possibility the existing disease or condition might become worse when a soft contact lens for therapeutic use is used to treat an already diseased or damaged eye. Since in these cases the cornea may already be compromised, the cornea must be examined carefully and monitored continually to ensure that the lens is not interfering with the healing process.

Fitting
Follow the general guidelines for fitting spherical lenses and consider this additional important information:

- For therapeutic fitting objectives, fit is evaluated by patient comfort, the interface space, amount of lens movement and ability of the lens to center on the cornea.
- The therapeutic environment can be controlled by increasing or decreasing tear film, that is increasing or decreasing interface space between the lens and cornea. Considerable lens movement against the cornea may increase pain and further erode the already damaged epithelium. Depending on patient circumstance, a desired fit should permit only limited lens movement and provide an appropriate interface space.
- Good tear volume and quality are important aspects of soft lens wear and should be critically evaluated as part of the pre-fit diagnostic work-up.
- Patients fitted with contact lenses for therapeutic use should be followed closely during treatment. Patients should be examined frequently for proper fit of the lens. A healing cornea may change in geometric relationship between the eye and lens.
- Medications necessary for treatment should be used with caution and under close supervision by the eye care practitioner. Tonicity and pH of solutions can effect lens fit and movement and may require lens removal after applying a recommended lubricating solution.

DISPENSING VISIT

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.

Lotrafilcon A lenses are supplied in sterile in foil sealed blister pack containers. Open the foil pack by peeling back the foil lidding material and gently slide the lens out of the container with your finger or pour the lens onto the palm of your clean hand.

Conduct the following steps with each patient, even if they have previously worn contact lenses:

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 the patient on hygiene and handling of lenses. Patients who are unable to place and remove lenses should not be provided with them.

C. Lens Wear and Replacement Schedules (see Package Insert)

Prescribe and explain the patient's wearing and replacement schedules.

D. Lens Care Directions (see Package Insert)

Recommend an appropriate cleaning, rinsing, and disinfecting system, and provide the patient with instructions for proper lens care, including the case.

E. Additional Instructions

Review the Package Insert

Provide the patient with all relevant information and precautions on the proper use of the lenses that are prescribed.

Provide the Patient Instruction Booklet for NIGHT & DAY Lenses

Give the patient a copy of the CIBA VISION **Patient Instruction Booklet** for NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA soft contact lenses. Review the contents so the patient clearly understands the prescribed lens wear, care, and replacement schedule. You can obtain copies of the instruction book by contacting a customer service representative, in the USA at **1-800-241-5999**.

FOLLOW-UP EXAMINATIONS

Follow-up care is extremely important for continued successful contact lens wear and for monitoring the patient's ocular response to lens wear. Follow-up care 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 wearing schedule, replacement schedule, and proper lens care and handling procedures.

NOTE: If you have prescribed an **extended wear** schedule, more frequent or additional visits may be necessary to monitor corneal health and to see that the characteristics of a **Well-Fitted Lens** are maintained.

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 a biomicroscope, evaluate lens fitting characteristics and examine the lens surface for deposits.
- Remove the lenses and conduct a thorough biomicroscopic examination with fluorescein. Rinse eyes with saline before re-inserting lenses.
- Evert upper lids to determine condition of tarsal conjunctiva.
- Periodically perform keratometry and spectacle refractions. These results should be recorded to compare to 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 are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

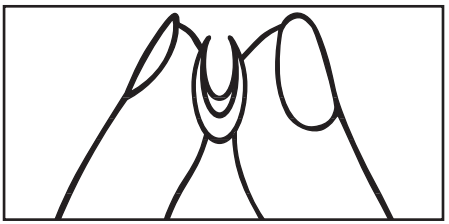
LENS HANDLING HINTS

Lens Insertion

- When about to place the lens on the eye, make sure the lens sits up on the placement finger. The finger should be dry so surface tension does not cause the lens to adhere to the finger.
- Check to see that the lens is right side out. A lens that is placed on the eye inside out may not feel comfortable or provide good vision.

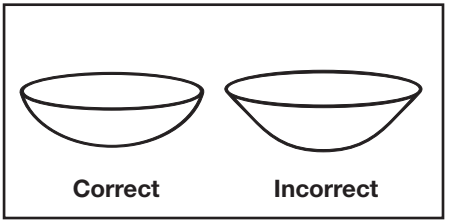
One way to do this is to place the lens between the thumb and index finger and squeeze the edges together gently.

- If the edges come together, the lens is right side out.
- If the edges turn outward, the lens is wrong side out. Carefully reverse it with the fingers.



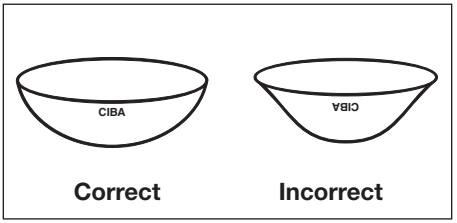
Another way is to place the lens on the tip of the index finger and check its shape.

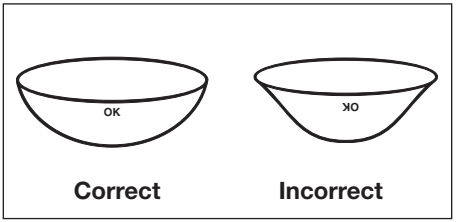
- If the edge appears bowl-shaped, it is right side out.
- If the edge has a lip or flares outward, it is wrong side out and must be reversed.



A third way to tell if the lens is right side out is to look at the lens engravings at the edge of the lens.

- Place the lens on the tip of the index finger and hold it up against a light source.
- If the lens is right side out, the patient should be able to read "CIBA" or "OK" at the edge of the lens. If the lens is inside out, the engravings will be reversed. Carefully turn the lens right side out with the fingers.





- 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.
- Remember to remove the same lens first (right or left), then the other lens. This helps avoid getting the lenses mixed up.
- It may be easier to remove the contact lenses if the patient uses rewetting drops (approved for use with soft lenses) recommended by the eye care professional 10 to 15 minutes before lens removal. This will also help prevent lens tearing during the removal process.

Care for a Sticking 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 solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. If the lens continues to stick, the patient should **immediately** consult the eye care professional.

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 phosphate buffered saline with or without 1% Copolymer 845 additive. 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.

For fitting and diagnostic purposes, the **lenses should be disposed of after a single use and not be re-used from patient to patient.**

ADDITIONAL INFORMATION

CIBA VISION is pleased to assist with fitting or clinical questions regarding NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA contact lenses. Eye care professionals having questions or problems should contact the CIBA VISION Technical **Consultation department, in the USA at 1-800-241-7468**. To order NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA lenses contact your CIBA VISION sales representative or call **Customer Service, in the USA at 1-800-241-5999**.

Package Insert for NIGHT & DAY® and AIR OPTIX™ NIGHT & DAY® AQUA (lotrafilcon A) Soft Contact Lenses

D7348E/98541

IMPORTANT: This package insert is effective as of September, 2008 and applicable to the lotrafilcon A soft contact lens 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 CIBA VISION Corporation by calling CIBA VISION Customer Service at 1-800-241-5999 or download from our website at www.cibavision.com.
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  - Light Transmittance: ≥ 96%
  - Oxygen Permeability (Dk): 140 x 10^{-11} (cm^2/sec) (ml O_2 /ml x mm Hg), measured at 35°C (intrinsic Dk - Coulometric method)
  - Water Content 24% by weight in normal saline
- **Lens Parameters**
  - Diameter Range: 13.0 to 15.0 mm
  - Power Range: -20.00 to +20.00D
  - Base Curve Range: 8.0 to 9.2 mm
- **Lens Parameters Available[1]**
  - Chord Diameter Available: 13.8 mm
  - Center Thickness: 0.080 mm @ -3.00D (varies with power)
  - Base Curves Available: 8.4 mm, 8.6 mm
  - Powers Available: plano to -8.00D (0.25D steps); -8.50D to -10.00D (0.50D steps); +0.25D to +6.00D (0.25D steps)

ACTIONS
When hydrated and placed on the cornea, lotrafilcon A contact lenses act as a refracting medium to focus light rays on the retina. When hydrated and placed on the cornea for therapeutic use, lotrafilcon A contact lenses act as a bandage to protect the cornea.

INDICATIONS (USES)
- NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA (lotrafilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters of astigmatism.
- The lenses may be prescribed for daily wear or extended wear for up to 30 nights of continuous wear, with removal for disposal, or cleaning and disinfection prior to reinsertion, as recommended by the eye care professional.
- Lotrafilcon A soft contact lenses are also indicated for therapeutic use. Use as a bandage to protect the cornea and to relieve corneal pain in the treatment of acute or chronic ocular pathologies such as bullous keratopathy, corneal erosions, entropion, corneal edema, and corneal dystrophies as well as post-surgical conditions resulting from cataract extraction and corneal surgery. Lotrafilcon A soft contact lenses for therapeutic use can also provide optical correction during healing if required.

See WARNINGS for information about the relationship between wearing schedule and corneal complications.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT use lotrafilcon A contact lenses when any of the following exists:
- Inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease which may be exacerbated by or interferes with contact lens wear
- Allergic reactions of ocular surfaces or adnexa that may be caused by or exaggerated by wearing contact lenses
- Allergy to any ingredient in a solution which must be used to care for the contact lenses
- 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

For THERAPEUTIC USE, the eye care professional may prescribe lotrafilcon A lenses to aid in the healing process of certain corneal conditions.

WARNINGS
Advise patients of the following warnings pertaining to contact lens wear:

- **Serious eye injury, scarring of the cornea, and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products.** To reduce these risks, emphasize to the patient the need for strict compliance with the lens care regimen including hand washing, proper lens disinfection, cleaning of the lens case, wearing restrictions, wearing schedules, and follow-up visit schedules.
- **Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.** Instruct patients at the dispensing visit and subsequent visits to **immediately** remove their lenses and **promptly** contact their eye care practitioner if they should experience eye discomfort, foreign body sensation, excessive tearing, vision changes, redness of the eye or other problems with their eyes.
- **Non-compliance with the manufacturer's labeled lens care instructions may put the patient at significant risk of developing a serious eye infection.**
- **Tap water, distilled water, or homemade saline solution should NOT be used as a substitute for any component in the lens care process.** The use of tap and distilled water has been associated with Acanthamoeba keratitis, a corneal infection that is resistant to treatment and cure.
- **Smoking increases the risk of corneal ulcers for contact lens users,[2,3] especially when lenses are worn overnight or while sleeping.**
- **The risk of microbial keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses.[3] (See POST-MARKET EXTENDED WEAR STUDY SUMMARY)**

PRECAUTIONS
To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:

Special Precautions to the Eye Care Professional:
- When selecting an appropriate lens and wear schedule for a patient, the eye care professional should consider all lens characteristics that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. All refractive powers, design configurations, or lens parameters were not evaluated in clinical trials. At the extremes of the power range (above +10.00 or -15.00) oxygen transmissibility is slightly below the established threshold level required to prevent overnight corneal edema[4]. The prescribing eye care professional should carefully assess the potential impact of these factors and carefully monitor the continuing ocular health of the patient and lens performance on the eye.
- The following patients may not be suitable extended wear contact lens candidates, and/or may experience a higher rate of adverse effects associated with contact lens wear:
  - Patients with a history or acute inflammatory reactions to contact lens wear.
  - Patients with a history of giant papillary conjunctivitis associated with contact lens wear.
  - Patients with a history of ocular allergies may need to temporarily discontinue lens wear during certain times of the year.
  - Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule or follow-up visit schedule.

- Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.
- Patients who would not, or could not, adhere to a recommended care regimen, or who are unable to place and remove lenses, should not be provided with them.

- Patients should be monitored closely during the first month of continuous wear as this period of observation may predict the eventual success of the patient. Those with inflammatory reactions during this early phase may not be suitable candidates for continuous wear.
- Aphakic patients should not be fitted with Iotrafilcon A contact lenses until the determination is made that the eye has healed completely.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- In addition, for therapeutic use:
  - Close professional supervision is necessary for therapeutic use of Iotrafilcon A lenses.
  - Medications necessary for treatment should be used with caution under close supervision by the eye care professional.

Eye care professionals should carefully instruct patients about the following care regimen and safety precautions. For therapeutic use, in some circumstances only the eye care professional will insert and remove lenses and if so, patients should be instructed NOT to handle lenses themselves.

Handling Precautions:
- Be sure that before leaving the eye care professional's office the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear. **Always wash and rinse hands before handling lenses.**
- REMOVE A LENS IMMEDIATELY if an eye becomes red or irritated.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA contact lenses.
- Always handle lenses carefully. If a lens is dropped small particles or fibers may adhere to the lens surface which can irritate the eye. Lenses should be cleaned and disinfected prior to insertion or replaced with a sterile, fresh new lens.
- Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Lens Wearing Precautions:
- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- 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 Care for a Sticking Lens section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- The eye care professional should be consulted 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.
- Patients should be advised to always have a pair of spectacles that they are willing to wear if a problem occurs with their contact lenses. This is especially important for patients with high refractive errors, since they may be hesitant to discontinue lens wear if back-up spectacles are not readily available.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Lenses should be disposed of and replaced according to the eye care professional's recommendations.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always keep a supply of replacement lenses on hand.
- Do not use lenses beyond the expiration date.

Solution Precautions:
- Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer's labeled lens care instructions with the patient (see Lens Care Directions).
- Only use fresh, unexpired lens care solutions recommended for use with soft contact lenses and follow directions in the product package inserts.
- If a lens is exposed to air while off the eye it may become dry, brittle, and permanently damaged. If this should occur, the lens should be discarded and replaced with a new one to avoid possible irritation or injury to the eye. Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn.
- Do not use thermal (heat) disinfection and do not heat lens care products.
- Saliva or anything other than the recommended solution for lubricating or wetting lenses should not be used with the lenses.

Lens Case Precautions:
- Contact lens cases can be a source of bacterial growth and require proper use, cleaning and replacement at regular intervals as recommended by the lens case manufacturer or eye care professional.

Other Topics to Discuss with Patients:
- Periodic eye examinations are extremely important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response, especially for extended wear patients. CIBA VISION recommends that patients see their eye care professional twice each year or as recommended by the eye care professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such medications accordingly and prescribe proper remedial measures.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Who Should Know That the Patient is Wearing Contact Lenses:
- Patients should inform their health care practitioners that they are wearing contact lenses.
- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that lenses not be worn.

It is strongly recommended that patients be provided with a copy of the NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA *Patient Instruction Booklet* available from CIBA VISION and understand its contents prior to dispensing the lenses.

ADVERSE DEVICE EFFECTS
The most commonly observed adverse device effects in the clinical study of Iotrafilcon A lenses were conjunctivitis, infiltrative keratitis, and non-infectious peripheral ulcer (See CLINICAL STUDY RESULTS for details).

Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:
- Moderate to severe eye pain not relieved by removing the lens
- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging or 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

Patients should be instructed that if any of the above signs or symptoms are noticed, he or she should:

- **IMMEDIATELY REMOVE THE LENSES.**

- **If the discomfort or problem stops, then look closely at the lens(es):**
  - If the lens(es) is in any way damaged, DO NOT put the lens(es) back on the eye. Discard damaged lens(es), and contact the eye care professional.
  - If the lens(es) have dirt, an eye lash or other foreign body on it, thoroughly clean, rinse, and disinfect prior to reinsertion.
- **If the discomfort or problem continues after removing lens(es) or upon reinsertion, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**

- The patient should be instructed **NOT** to use a new lens as self-treatment for the problem.

- **The patient 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 carefully to avoid more serious complications.**

- Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegethism, tarsal papillary changes, conjunctival injection or iritis.

During therapeutic use, an adverse effect may be due to the original disease or injury or may be due to the effects of wearing a contact lens. There is a possibility that the existing disease or condition might become worse when a soft contact lens for therapeutic use is used to treat an already diseased or damaged eye. The patient should be instructed to avoid serious eye damage by contacting the eye care practitioner IMMEDIATELY if there is any increase in symptoms while wearing the lens.

ADVERSE EFFECT REPORTING
If a patient experiences any serious adverse effects associated with the use of Iotrafilcon A contact lenses, please notify:
CIBA VISION Corporation, Technical Consultation at **1-800-241-7468.**

CLINICAL STUDY RESULTS

PRE-MARKET EXTENDED WEAR STUDY SUMMARY

Study Description:

A total of 697 NIGHT & DAY subjects and 698 Control subjects from 59 investigative sites were enrolled in a prospective, randomized, controlled, open label clinical trial lasting one year.

NIGHT & DAY lenses were worn on an extended wear schedule for up to 30 nights of continuous wear. Control lenses were worn on an extended wear schedule for up to 6 nights of continuous wear. NIGHT & DAY subjects replaced lenses every month. Control subjects replaced lenses every week.

The groups were comparable with regard to age, lens power, gender and type of habitual correction. In each group the age ranged from 18 to 70 years with a mean age of 35 years. Lens power ranged from +6.00 D to -6.00 D for the NIGHT & DAY group and +4.50 to -6.50 for the Control group. 483 NIGHT & DAY subjects (966 eyes) and 579 Control subjects (1158 eyes) completed the study.

The primary safety endpoint analysis was the number of subjects in each group who developed one or more of corneal infiltrates ≥ Grade 3 or with overlying fluorescein staining.

The percentage reported was 5.0% in the NIGHT & DAY subjects and 3.1% in the Control subjects. These proportions are not statistically different (p = 0.073, chi-square). Life table analysis estimates the annualized rate for subjects experiencing one or more of these infiltrates was 6.1% per person-year for the NIGHT & DAY group (95% CI = 4.1% to 8.2%), and 3.3% per person-year for the Control group (95% CI = 1.9% to 4.7%).

The primary efficacy endpoint was the percentage of subjects able to successfully maintain the extended wearing schedule and the percentage of eyes maintaining Snellen contact lens visual acuity within 2 lines of dispensing were the efficacy endpoints analyzed. The NIGHT & DAY group had 175 subjects (350 eyes) discontinue whereas the Control group had 102 subjects (204 eyes) discontinue. Discomfort was most often reported as the reason for discontinuation in each group. The wearing schedules reported by the NIGHT & DAY subjects who completed the clinical study is presented below. Contact lens visual acuity within two lines of dispensing was maintained in 98.1% of the NIGHT & DAY eyes and 97.9% of the Control eyes. There was no loss of best corrected visual acuity in either group.

Average Achieved Wearing Schedule
(n = 966 eyes, one year)

Consecutive Nights	
0 – 2	1.5%
3 – 4	1.0%
5 – 7	2.0%
8 – 14	6.9%
15 – 21	14.0%
22 – 31	67.2%
Not Reported	7.3%

Adverse device effects were reported at the following annual rates during the clinical study. There were no reports of microbial keratitis in either group.

Eyes With At Least One Adverse Device Effect

Eyes Dispensed: Night & Day = 1316 Control = 1362	**Night & Day** %	**Control** %
Conjunctivitis / Hordeolum / Chalazion	3.87%	4.99%
Infiltrative Keratitis	3.11%	2.06%
Non-infectious corneal ulcer or scar	1.00%	0.44%
Asymptomatic Infiltrates	0.68%	0.37%
Severe staining, edema, microcysts, injection	0.23%	0.00%
Temporary Refractive change > 1.00 D	0.15%	0.00%
Other*	0.31%	0.44%
TOTAL EYES with at least one Adverse Device Effect	**9.4%**	**8.3%**

*Thygeson's keratitis, recurrent erosion in NIGHT & DAY and subconjunctival hemorrhage, blepharokeratoconjunctivitis, intraepithelial keratitis and optic neuritis in the Control group.

- Fewer NIGHT & DAY subjects (19.8%) reported symptoms of dryness compared to the Control (24.2%) This finding of less dryness was noted in the case history, study questionnaire and subject diary.

POST-MARKET EXTENDED WEAR STUDY SUMMARY

A total of 6,245 NIGHT & DAY wearers who had been prescribed NIGHT & DAY lenses for extended wear of up to 30 consecutive nights were registered in a year-long observational study from 131 clinical practices. Wearers were subsequently contacted at 3 and 12 months after enrollment to determine typical wearing schedules, discontinuation of lens wear, and the occurrence of any problems that might be indicative of corneal inflammation, ulceration or infection. Medical records were obtained from all such reports and reviewed to determine the presence of signs or symptoms of corneal inflammation or infection. All infiltrative conditions were reviewed and classified by an independent review committee of ophthalmologic specialists.

The group of registered wearers consisted of 63.7% female and 36.7% male with a mean age of 34.8 years and mean refractive error of -3.22 D. Responses to both questionnaires were received from 94.4% of the registered wearers and a further 3.9% responded to the 3-month questionnaire only. The total period of observation for the registered cohort was 5,561 person-years. A total of 4,999 (80.0%) of wearers completed 12 months of wear. The wearing schedule of these participants at one year is summarized below:

Continuous Wearing Schedule

Daily wear only	3.3%
1 to 6 nights	7.6%
1 to < 3 weeks	9.3%
3 to 4 weeks	53.0%
> 4 weeks	26.8%
Not Reported	67.2%

The key endpoints were the occurrence of microbial keratitis and sustained loss of best corrected visual acuity of 2 lines or greater after complete resolution of an incident microbial keratitis or other contact lens-related corneal condition. Infiltrative events occurred in 163 wearers, of which 154 received medication as part of their treatment. The following table summarizes the annualized incidence rates for infectious and infiltrative events for all registered wearers:

Annualized Incidence of Infiltrative and Infectious Adverse Events

Total Patient-Years of Observation = 5,561	**Number of Cases**	**Annualized Incidence** (events per 10,000 patient-years)	**1-sided upper 95%** Confidence Limit (events per 10,000 patient-years)
Infiltrative Adverse Events receiving medication	154	277 per 10,000	313.1 per 10,000
Total Infiltrative Adverse Events	163	293 per 10,000	330.1 per 10,000
Microbial keratitis (with or without vision loss)	10	18 per 10,000	30.5 per 10,000
With visual acuity loss (≥ 2 lines Snellen)	*2*	*4 per 10,000*	*11.3 per 10,000*
Other infiltrative keratitis of indeterminate etiology*	52	94 per 10,000	115.2 per 10,000
"Sterile" (non-infectious) infiltrates	97	174 per 10,000	202.8 per 10,000
Other or not contact lens-related infiltrates	4	7.2 per 10,000	16.5 per 10,000

*Cases of "indeterminate etiology" were considered unlikely to be infectious

The annualized rate of infiltrative events was higher amongst those reporting shorter wearing schedules suggesting that wearers showing difficulty of adapting to a 30 night schedule may not be suitable candidates for continuous wear. The incidence rate of infiltrates trended higher in refractive errors greater than ±5.00D, although these wearers also reported a higher rate of previous contact lens problems at baseline.

THERAPEUTIC USE STUDY SUMMARY

This clinical trial was a retrospective, consecutive case series evaluation. Three medical practices in Europe provided 41 consecutive case reports on 39 patients for whom NIGHT & DAY lenses were used in therapeutic applications for erosion or recurrent erosion, bullous keratopathy, corneal edema, corneal dystrophy, neurotrophic corneal ulcer, entropion, and after corneal surgeries. Twenty (49%) of the cases were for acute treatment of an ocular condition and 21 (51%) were for treatment of chronic conditions. The average age of the patients treated was 55.1 years of age. Twenty-four (59%) of the cases were reported in females and 17 (41%) were reported in males.

The primary variables of this trial were investigator assessments of pain relief, corneal changes by slit lamp evaluation, additional complications, and overall treatment success.

Pain relief was one of the treatment goals in 37 of the cases. Pain relief was considered fully effective in 78% of these cases, partially effective in 17% of the cases and ineffective in 6% of the cases. Improvement in corneal signs was one of the treatment goals in 19 of the cases. The outcome was fully effective in 74% of the cases and partially effective in the remaining 26%.

No additional complications were reported in 83% of the cases. Complications of corneal infection in 2 cases were considered as related to the lens use. Four cases of complications considered as unrelated to the lens included infiltrates, ulcer and irritation. Investigators considered the treatment to be fully successful for 71% of the cases and partially successful in a further 22% of the cases.

FITTING GUIDE AND PATIENT INFORMATION

- The lens must move adequately on the eye for a proper fit and continued health of the eye. When prescribing lotrafilcon A lenses for extended wear, it is important to reevaluate the lens fit for adequate movement at various times after the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens, as well as at other times of the day. If the fit is judged to be too tight or steep, the patient must be refit into a lens that provides the criteria of a well-fitted lens.
- Refer to the *Patient Instruction Booklet or Professional Fitting Guide* for more information. Both the professional fitting guide and a patient instruction booklet are available free of charge from:

CIBA VISION Corporation
11460 Johns Creek Parkway
Duluth, GA 30097 USA
1-800-241-5999

LENS WEARING SCHEDULES

The wearing schedule should be determined by the eye care professional. Not all patients can achieve the maximum wear time of up to 30 nights of continuous wear. Patients should be monitored closely during the first month of 30-night continuous wear. **If problems occur during this first month, the patient may not be suitable for the full 30-night wearing schedule.** The maximum suggested 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.

- **DAILY WEAR** (less than 24 hours, while awake):
  - To avoid any tendency for the daily wear patient to over wear the lenses initially, stress the importance of adhering to a proper, initial daily wearing schedule. Normal daily wear of lenses assumes a minimum of 6 hours of non lens wear per 24 hour period.
  - It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.

- **EXTENDED WEAR** (greater than 24 hours, including while asleep):
  - The eye care professional should establish an extended wear period up to 30 continuous nights that is appropriate for each patient. Once the lens is removed, the patient's eyes should have a rest period with no lens wear of overnight or longer, as recommended by the eye care professional.
  - **It is suggested that new contact lens wearers first be evaluated on a daily wear schedule. If the patient is judged to be an acceptable extended wear candidate, the eye care professional may determine an extended wear schedule based upon the response of the patient.**
  - See **WARNINGS** for information about the relationship between wearing schedule and corneal complications and **CLINICAL STUDY RESULTS** for important information about average wear times and other study findings.

- For **THERAPEUTIC USE**, close professional supervision is necessary. Lotrafilcon A lenses can be worn on a continuous wear basis for up to 30 nights and days or for shorter periods as directed by the eye care professional. The eye care professional should provide specific instructions regarding lens care, removal, insertion.

LENS REPLACEMENT

Lenses should be replaced every month, as recommended by the eye care professional. Longer replacement periods have not been studied and are not recommended by CIBA VISION. When removed between replacements times lenses must be cleaned and disinfected prior to reinsertion or be discarded and replaced with a fresh new lens.

LENS CARE DIRECTIONS

Disposable Wear:

- No lens care is indicated, as lenses are discarded upon removal from the eye.
- Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

Replacement Wear:

- When removed between replacement periods lenses must be cleaned and disinfected prior to reinsertion or be discarded and replaced with a fresh lens.

Basic Instructions for Lens Cleaning and Disinfection:

When lenses are dispensed, the eye care professional should recommend an appropriate system of lens care and provide the patient with instructions according to the package labeling.

Failure to follow the complete regimen in accordance with manufacturer's package inserts may contribute to problems (see ADVERSE DEVICE EFFECTS) and/or result in the development of serious ocular complications as discussed in WARNINGS.

The eye care professional should review the following instructions with the patient:

- **Lenses must be cleaned, rinsed, and disinfected each time they are removed, for any reason.** If removed while the patient is away from the lens care products, the lenses may not be reinserted, but should be stored in a lens case filled with the recommended storage solution until they can be cleaned, rinsed, and disinfected.
- **Cleaning** is necessary to remove mucus, film, and contamination from the lens surface. **Rinsing** removes all traces of the cleaner and loosened debris. **Disinfecting** is necessary to destroy remaining microorganisms.
- Lenses must be cleaned, rinsed, disinfected and stored in accordance with the package labeling of the lens care products recommended by the eye care professional.
- CIBA VISION recommends a chemical method of disinfection, including AOSEPT®, Clear Care® or AQuify® Multi-Purpose Solution.
- Use of Unizyme®, an enzymatic cleaner, is optional and may be recommended by the eye care professional if warranted.
- Lens compatibility with an abrasive type cleaner such as OPTI-CLEAN®* II has not been tested and is not recommended.
- Heat disinfection has not been tested and is not recommended.
- **To help avoid serious eye injury from contamination:**
  - Always wash, rinse and dry hands before handling the lenses.
  - Use only fresh sterile solutions recommended for use with soft (hydrophilic) contact lenses. When opened, sterile non-preserved solutions must be discarded after the time specified in the label directions.
  - Do not use saliva, tap water, homemade saline solution, distilled water, or anything other than a recommended sterile solution indicated for the care of soft lenses.
  - Do not reuse solutions.
  - Use only fresh solutions for each lens care step. Never add fresh solution to old solution in the lens case.
  - Follow the manufacturer's instructions for care of the lens case.
  - Replace the lens case at regular intervals to help prevent case contamination by microorganisms that can cause eye infection.
- Never use a hard (rigid) lens solution unless it is also indicated for use with soft contact lenses. Corneal injury may result if hard (rigid) lens solutions not indicated for use with soft lenses are used in the soft lens care regimen.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn to avoid lens dehydration.
- Unless specifically indicated in the labeling, do not alternate, change, or mix lens care systems or solutions for any one pair of lenses. If in doubt as to solution suitability, consult the eye care professional.

*OPTI-CLEAN® is a registered trademark of Alcon Laboratories, Inc.

CARE FOR A STICKING 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 solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. If the lens continues to stick, the patient should IMMEDIATELY consult the eye care professional.

IN OFFICE USE OF TRIAL LENSES

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

Each contact lens is shipped sterile in a blister pack containing phosphate buffered saline solution. 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. For fitting and diagnostic purposes, the lenses should be disposed of after a single use and not be re-used from patient to patient.

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 or fresh saline solution, remove the lenses and place them in the recommended storage solution, and call or visit the eye care professional or a hospital emergency room immediately.**

HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic container containing isotonic phosphate buffered saline with or without 1% Copolymer 845 and is steam sterilized. The package is marked with the base curve, diameter, dioptric power, manufacturing lot number and expiration date.

CIBA VISION Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097 USA
www.cibavision.com

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Printed in: USA

[1]Check for actual product availability as additional parameters may be introduced over time.
[2]CLAO Journal, January 1996; Volume 22, Number 1, pp. 30-37
[3]New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783.
[4]Investigative Ophthalmology and Visual Science, October 1984; Vol. 25, pp. 1131-1167

D7348E/98541

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

LENS CARE PRODUCT CHART FOR SOFT CONTACT LENSES

AOSEPT®	
AOSEPT® Disinfecting Solution	Disinfecting solution
AOSEPT® Disposable Lens Cup and Disc	Lens case with neutralizing disc for AOSEPT Disinfecting Solution
Clear Care®	Hydrogen peroxide based solution for cleaning, disinfecting and protein removal
AQuify® Multi-Purpose Solution	Multipurpose solution for cleaning, rinsing, disinfecting and protein removal
Includes the PRO-GUARD™ Lens Case	The PRO-GUARD lens case is made of a special plastic infused with silver ions, a known antibacterial agent that kills germs and helps prevent lens case contamination. The PRO-GUARD lens case should not be used by persons who are allergic to silver or other metals.
Other CIBA VISION® Lens Care Products	
AQuify® Long-Lasting Comfort Drops	Lubricating and rewetting
Unizyme® Enzymatic Cleaner	Enzymatic Cleaner for contact lens protein removal
SoftWear® Saline	Rinsing and storage
Miraflow® Extra Strength Daily Cleaner	Cleaner

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