CIBA Vision®

Professional Fitting and Information Guide

Focus® Night & Day™ (lotrafilcon A) Soft Contact Lenses

Up to 6 Night Extended Wear

[Rx ONLY] [CAUTION: Federal Law (USA) Prohibits Dispensing Without a Prescription]

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INTRODUCTION

Thank you for prescribing Focus® NIGHT & DAY™ (lotrafilcon A) soft contact lenses. The superior material characteristics of NIGHT & DAY™ LENSES ALLOW them to be worn safely for up to 6 nights and 7 days before removal and replacement. NIGHT & DAY™ lenses are designed to provide the ultimate in contact lens convenience.

Fitting *Night & Day™* contact lenses is easy and predictable. This guide contains important information regarding fitting procedures and aftercare of the Night & Day™ patient.

Night & Day™ (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 which is surface treated.

- ***Lens Properties***
  - Specific Gravity: 1.08
  - Refractive Index (hydrated): 1.43
  - Light Transmittance: ≥ 99%
  - Oxygen Permeability (Dk): 140 x 10^{-11} (cm^2/sec)(ml O_2/ml x mm Hg), measured at 35° C Coulometric method)
  - Water Content 24% by weight in normal saline
- ***Available Lens Parameters***
  - Chord Diameter: [13.8 mm]
  - Center Thickness: 0.050 to 0.35mm (varies with power)
  - Base Curve: [8.6 mm]
  - Powers: [-0.25D 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, Night & Day™ (lotrafilcon A) contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

Vision Correction:

- Night & Day™ (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 and with up to approximately 1.50 diopters of astigmatism.

Wearing Schedule:

- Night & Day™ (lotrafilcon A) contact lenses may be prescribed for either daily wear or extended wear for 1 to 7 days between removals for cleaning and disinfection or disposal, as recommended by the eye care professional. Lenses should be replaced every month and when removed between replacement times must be cleaned and disinfected with a chemical, not heat, disinfection system before reinsertion.
- **See WARNINGS for information about the relationship between wearing schedule and corneal complications.**

CONTRAINDICATIONS (Reasons not to use)

DO NOT use Focus® Night & Day™ (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 that may be exaggerated by contact lens wear.
- 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 or ocular irritation of the 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.

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 an eye care professional 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 which is resistant to treatment and cure.
- **Smoking increases the risk of corneal ulcers for contact lens users[1,2] especially when lenses are worn overnight or while sleeping.**
- **The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses[2].** The risk increases with the number of consecutive days that the lenses are worn between removals, even with the first overnight use.

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:

- **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).**
- The following patients may not be suitable contact lens candidates and/or may experience a higher rate of adverse effects associated with contact lens wear:
  - ◊ 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.

[1] the CLAO Journal, January 1996, Volume 22, Number 1, pp. 30 - 37

[2] New England Journal of Medicine, September 21, 1989; 321 (12), pp 773 - 783

- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.
- 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.
- Periodic eye examinations are extremely important for contact lens wearers. Conduct appropriate follow-up examinations to determine ocular response, especially for extended wear patients.
- Clinical studies have shown that contact lenses made from the lotrafilcon A material are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material. Consequently, when selecting an appropriate lens design and parameters, the eye care professional should consider all factors that can affect the 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 health of the patient and lens performance on eye should be carefully evaluated on initial dispensing and monitored on an ongoing basis by the prescribing eye care professional.

- Fluorescein should not be used while the lenses are on the patient's eyes. The lenses absorb this dye and become discolored. Fluorescein in the eye should be thoroughly flushed with a sterile saline solution before the lens is reinserted.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have some one 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.

Eye Care Professionals should carefully instruct patients about the following care regimen and safety precautions:

- 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.
- Environmental fumes, smoke and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Discard any lens which has become dehydrated or damaged. Replace with a fresh new lens.
- 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.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, or aerosol products or foreign particles come in contact with lenses. If sprays are used, eyes should be kept closed until the spray has settled.
- Patients should inform their employer of being a contact lens wearer. Some jobs may require 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 the eye care professional before using any medication in the eye.
- Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. Patients should be informed of these potential conditions and proper remedial treatment should be prescribed if any of these conditions occur. Depending on the severity of the condition appropriate treatment may include the use of rewetting drops intended for use with soft contact lenses or temporary cessation of contact lens wear until the condition subsides.
- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so increases 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 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.
- 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.
- Carefully follow the handling, insertion, removal and wearing instructions in the *Focus® Night & Day™ 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.
- Good hygiene habits help promote safe and comfortable lens wear. Always wash and rinse hands before handling lenses.
- Always keep a supply of replacement lenses on hand.
- Never use tweezers or other sharp objects such as fingernails to remove the lens from the container to avoid damaging the lens.
- Do not use lenses beyond the expiration date.

It is strongly recommended that patients be provided with a copy of the *Focus® Night & Day™ Patient Instruction Booklet* available from CIBA Vision and understand its contents prior to dispensing the lenses.

ADVERSE EFFECTS

Potentially serious complications are usually accompanied by one or more of the following signs and symptoms:

- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging, itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on the eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

If any of the above signs or symptoms occur, the patient should be instructed to IMMEDIATELY REMOVE the lens(es). Identification of the problem and prompt treatment by the eye care professional may help avoid serious eye damage. Patients should be instructed not to insert a lens onto an eye this is red, irritated, or painful.

- **IMMEDIATELY** remove the lens(es).

1) If the discomfort stops, then look closely at the lens(es).
   - Planned Replacement Wear:
     - If the lens(es) are damaged in any way, DO NOT put the lens(es) back on the eye. Damaged lenses should be placed in the storage case, and the patient should contact the eye care professional.
     - If the lens has dirt, an eyelash or other foreign body on it, the patient should thoroughly clean, rinse and disinfect the lenses, prior to reinsertion.
   - Disposable Wear:
     - Lenses worn for disposable wear should be discarded upon removal from the eye, and replaced with a fresh, new lens.
2) If the problem continues after lens(es) have been removed, the patient should IMMEDIATELY contact their eye care professional.

- Patients should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, infiltrates and bacterial conjunctivitis must be managed and treated early to avoid more serious complications. Additionally, contact lens wear may be associated with ocular changes which require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE EFFECT REPORTING

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

Fitting Guidelines

1. *Patient Selection*

The patient characteristics necessary to achieve success with *Night & Day™* 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 *Night & Day™* 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 provided good movement, centration and comfort. This can be achieved for the majority of patients with the 8.6 mm 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 with the patient's tears, replacing the buffered, isotonic, saline which was in the vial or foil pack.

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 Night & Day™ (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. **Excessive lens movement** during the blink in primary or upgaze.
2. **Unsatisfactory Push-Up Test.**
   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.
3. **Poor centration** with limbal exposure on exaggerated eye movement.
4. **Reduced comfort.**
5. **Lens edge standoff.**
6. **Vision may be blurred** after the blink.

General Fitting Tips

- While helpful for monitoring corneal stability over time, keratometry is not a reliable predictor of base curve/fit relationship. Trial fitting of the individual eye is strongly recommended.
- A well fitting lens will show movement of 0.1 to 0.5 mm. A flat base curve/corneal relationship may actually show limited movement. Decentration and excessive lid sensation accompanied by limited movement often indicates the lens is too flat for that given eye.
- When prescribing *Night & Day™* 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 which 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**

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.

Night & Day™ 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.

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

A. Verification 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. Wearing and Replacement Schedule

Prescribe and explain the patient's wearing schedule and lens replacement schedule. The maximum suggested wearing time each day should be determined by the eye car professional based upon the patient's physiological eye condition because individual responses to contact lenses vary.

Daily Wear (less than one day, while awake)

- There may be a tendency for the daily wear patient to overwear the 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 gradually increases wearing time over a period of days or weeks. This allows more gradual adaptation of the ocular tissues to contact lens wear.

- Replace lenses every one month

Extended Wear (greater than one day including while sleeping)

- *Night & Day™* lenses are indicated for extended wear for 1 to 7 days between removal for cleaning, rinsing, and disinfection or disposal, if prescribed for disposable wear. Once the lens is removed, the patient's eyes should have a rest period with no lens wear of overnight or longer.

- It is suggested that the new contact lens wearer first be evaluated on a daily wear schedule. If the patient is judged to be an acceptable extended wear candidate, they eye care professional may determine an extended wear scheduled based upon the response of the patient. If the patient is not an adapted contact lens wearer, it is important to build wearing time gradually until the patient's physiological response to the prescribed regiment is found to be clinically acceptable.

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- Replace lenses every one (1) month if worn for monthly replacement, or upon removal from the eye is prescribed for disposable wear, after extended wear of up to 7 days.

D. Lens Care Directions

Recommend an appropriate cleaning, rinsing, and disinfecting system, and provide the patient with instructions for proper lens care, including the case. Hydrogen peroxide or chemical disinfection is recommended; heat disinfection is not recommended.

Disposable Wear:

- No lens care is indicated, as lenses are discarded upon removal from the eye.
- Lenses should be cleaned, rinsed and disinfected only on an emergency basis when replacement lenses are not available. (See **Basic Instructions for Lens Cleaning, Rinsing and Disinfection** below.)

Planned Replacement:

- Patients must adhere to a recommended care regimen. Lenses must be cleaned, rinsed, and disinfected after each removal and prior to reinsertion on the eye according to the package inserts and instructions provided with the lens care products recommended by the eye care professional. Failure to follow the complete regimen in accordance with manufacturer's package inserts and instructions may contribute to problems (see **Adverse Effects**) and/or result in the development of serious ocular complications as discussed in **Warnings**.

Basic Instructions for Lens Cleaning and Disinfection:

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

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 discarded or stored 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.
- Use of an enzyme cleaner is not recommended. Deposited lenses should be discarded and replaced with a new lens.
- A chemical method of disinfection using AOSEPT® or Quick CARE®, or SOLO care™ is recommended.
- Heat disinfection should not be used.

- Lens compatibility with an abrasive type cleaner such as Opticlean I or II 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 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.
  - Always empty and rinse the lens case with fresh sterile rinsing or disinfecting solution and allow to air dry. At the next use of the lens case, fill with fresh sterile solution.
  - Replace the lens case at regular intervals to help prevent case contamination by microorganisms which 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 to avoid lens dehydration when the lenses are not being worn.
- 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.

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 and Day Lenses.

Give the patient a copy of CIBA Vision's **Patient Instruction Booklet** for *Focus® Night & Day™* 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 (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.
- 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 or the characteristics 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

Lens Placement

- 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.

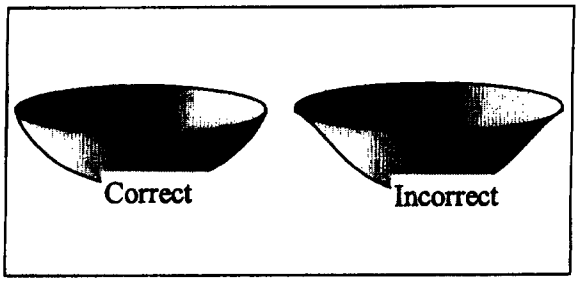
One way to do this is to place the lens between your thumb and index finger and squeeze the edges together gently.

- 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 your fingers.

Photographs or line drawings of Method 1 (right side vs wrong side out)

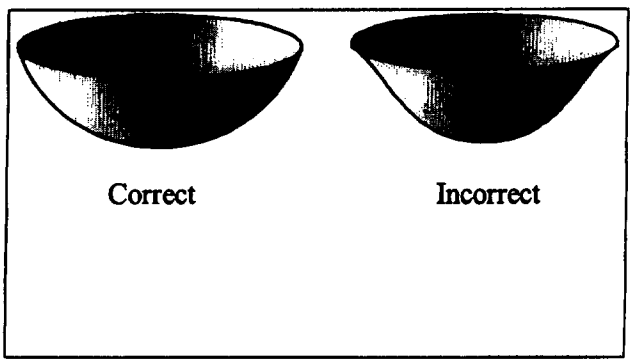
Another way is to place the lens on the tip of your index finger and check its shape.

- If the edge appear 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 your index finger and hold it up against a light source.
- If the lens is right side out, you should be able to read "CIBA" 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 your 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 your contact lenses if you use rewetting drops (approved for use with soft lenses) recommended by your 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 carbonate 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.

GENERAL 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.

ADDITIONAL INFORMATION

CIBA Vision is pleased to assist with fitting or clinical questions regarding *Night & Day™* contact lenses. Eye care professionals having questions or problems should contact the CIBA Vision Technical Consultation department, in the USA at (800) -241-7468. To order *Night & Day™* contact lenses contact your CIBA Vision sales representative or call Customer Service, in the USA at (800) 241-5999.

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HOW SUPPLIED

Each lens is supplied sterile in a foil sealed plastic container containing isotonic buffered saline solution. The package is marked with the base curve, diameter, dioptric power, tint color (if applicable), manufacturing lot number, and expiration date.

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 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 left without a lens.
  - **Bilateral myope**: A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.
  - **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 Night & Day™ 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.	

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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 **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 **(800) 241- 5999.**

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, AVAILABLE IN THE U.S.A

AOSEPT® Lens Care System	
AOSEPT® Disinfectant	Disinfecting solution
AOSEPT® Lens Cup	Lens case for AOSEPT Disinfectant and AODISC Neutralizer
AODISC® Neutralizer	Neutralizes AOSEPT into a gentle buffered saline solution
Softwear® Saline	Rinsing and storage
Miraflow® Extra Strength Daily Cleaner	Cleaner
Pure Eyes® Disinfection System	
Pure Eyes® Disinfectant/Soaking Solution	Disinfecting solution
Pure Eyes® Cleaner/Rinse	Cleaning and rinsing solution
Pure Eyes® Lens Case/built-in neutralizer	Neutralizes Pure Eyes Disinfectant into a gentle buffered saline solution
Quick CARE® Care System	The Quick CARE System cleans, disinfects, rinses, and soaks in about 5 minutes
Quick CARE® Starting Solution	
Quick CARE® Finishing Solution	
SOLO-care™ brand Multi-purpose Solution	Multipurpose solution for cleaning, rinsing, disinfecting, storing, & protein removal
Other CIBA Vision® Lens Care Products	
CIBA Vision® Cleaner	Cleaning
CIBA Vision® Saline	Rinsing
CIBA Vision® Lens Drops	Lubricating
Focus® Lens Drops	Lubricating
Unizyme® Enzymatic Cleaner	Protein removal

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia USA 30097

Part #: [*insert part number*] Date: [*insert month,year*]

CIBA Vision.
A Novartis Company

Printed In [Insert USA or Canada]

CIBA Vision®

Patient Instruction Booklet

Focus® Night & Day™ (lotrafilcon A) Soft Contact Lenses

For Up to 6 Nights Extended Wear
With Planned Replacement

℞ only CAUTION: Federal Law (USA) Prohibits Dispensing Without a Prescription

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Commonly Used Terms

Cornea The clear "window" of the eye, permitting light to enter, located in front of the iris and pupil

- Iris - The colored part of the eye which controls the size of the pupil
- Pupil - The black round opening surrounded by the iris

Disinfect A process which kills harmful microorganisms (germs) which can cause serious eye infections

Lens Deposits Particles such as cosmetics, lotions, protein from the tear film, environmental pollutants, etc., which collects on the lens surface

INTRODUCTION

Welcome!

Focus® Night & Day™ soft contact lenses worn for **planned replacement** represents a convenient and healthy way to wear soft contact lenses. By replacing your lenses with new lenses on a regular basis, lens deposits are less likely to build up over time. Lens deposits can affect vision and may eventually cause irritation or discomfort to the eye.

About Your Contact Lenses

Night & Day™ lenses are available in a spherical lens design, and are intended for either daily wear or extended wear for 1 to 7 days, as recommended by your eye care professional. Lenses should be replaced every month and when removed between replacement times must be cleaned and disinfected with a chemical, not heat, disinfection system before reinsertion. For your eye health, **it is important that you follow the wearing and replacement schedule as prescribed by your eye care professional.** If you wear your lenses too long, you can harm your eyes.

About This Booklet

Read this booklet carefully and follow all of the instructions.

This booklet explains how to wear and care for your new lenses. The information applies to *Night & Day™* lenses when prescribed for planned replacement wear. If you have questions about the wear and care of your lenses after reading this booklet, call or visit your eye care professional. Also, you may call CIBA Vision Consumer Relations toll free in the USA at 1-800-875-3001.
Successful, safe contact lens wear depends on following the recommendations of your eye care professional and practicing good lens care habits. If you do not, you may:

- increase the chances of serious eye infection and injury
- cause damage to your contact lenses

WARNINGS AND PRECAUTIONS

What You Should Know About Contact Lens Wear

Warning

Serious injury to the eye, scarring of the cornea, and loss of vision may result from problems associated with wearing contact lenses and using lens care products.

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Immediately call or visit your eye care professional for persistent symptoms of any eye discomfort, watering, vision change, or redness.

Extended Wear

Overnight wear of contact lenses has been shown to increase the risk of certain serious contact lens related complications. The risk increases with the number of days in a row that the lenses are worn between removals, beginning with the first overnight use.[1]

Do not wear your Night & Day™ contact lenses for extended wear (24 hours a day including during sleep) unless directed by your eye care professional.

If your eye care professional has directed you to wear your lenses for extended wear, wearing your lenses for fewer nights per week of overnight wear can reduce this risk.

Smoking
Smoking increases the risk of serious problems with contact lens wear, especially when lenses are worn overnight[1, 2] If you smoke, be sure to inform your eye care professional.

Following Directions
Be sure to follow exactly the instructions of your eye care professional and manufacturers' labeled lens care instructions for the proper use and care of your contact lenses and lens care products, including lens cases. Failure to do so may put you at significant risk of developing a serious eye infection.

Use Proper Lens Care Solutions

Do not use saliva, tap water, distilled water, or homemade saline solution for any purpose in caring for your lenses. The use of these solutions has been associated with serious eye infections including Acanthamoeba keratitis, a corneal infection which is resistant to treatment and cure.

Adverse Effects (Possible Problems)

It is possible that problems can occur and may be accompanied by one or more of the following conditions:

- Feeling of something in the eye
- Unusual eye secretions
- Eye redness
- Sensitivity to light (photophobia)
- Eyes burn, sting or itch
- Eyes water
- Reduced sharpness of vision
- Rainbows or halos around objects
- Uncomfortable lens
- Feeling of dryness

A serious condition such as corneal ulcer or eye infection may be present and may progress rapidly. Even less serious reactions such as a scratched cornea must be treated promptly to avoid more serious complications.

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[1] the CLAO Journal, January 1996, Volume 22, Number 1, pp 30 - 37
[2] New England Journal of Medicine, September 21, 1989; 321 (12), pp 773 - 783

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What To Do if a Problem Occurs

If you experience any of the above signs or symptoms, immediately remove your lens(es). Identification of the problem and prompt treatment may help avoid serious eye damage. Do not insert a new or spare lens onto an eye that is red, irritated, or painful. A new lens may hide symptoms and delay treatment.

Discuss and follow your eye care professional's recommendations should you experience any eye discomfort with your lenses.

- **IMMEDIATELY remove the lens(es),**

1. **If the discomfort stops, then look closely at the lens(es).**
    - **If the lens(es) are damaged in any way, DO NOT put the lens(es) back on your eye. Place the lens(es) in the storage case, or discard and contact the eye care professional.**
    - **If the lenses have dirt, an eyelash or other foreign body on them, and the lens(es) appear undamaged, thoroughly clean, rinse and disinfect the lenses, then reinsert. After reinsertion, if the problem continues, remove the lens(es) immediately and contact the eye care professional.**
2. **If discomfort continues after you have removed your lenses,**

    IMMEDIATELY contact the eye care professional.

WHEN LENSES SHOULD NOT BE WORN

Contact lenses should not be worn under certain general health and eye conditions. Only your eye care professional can determine if continued contact lens wear is right for you. These include the following:

- Inflammation or infection in or around the eye or eyelids.
- Excessive dryness of the eyes that makes contact lens wear uncomfortable.
- Any condition which reduces corneal sensitivity.
- Systemic diseases that may be affected by or impact lens wear.
- Allergic conditions, reactions or ocular irritation caused or exaggerated by lens wear or certain preservatives in lens care products.
- The use of any medication, including some eye medications, that shouldn't be used with, or interferes with contact lens wear.
- If eyes become red or irritated.

GENERAL GUIDELINES FOR SAFE CONTACT LENS WEAR

Wearing Your Lenses

- Your lenses are provided to you in a foil sealed plastic container. Never use a lens if the container seal is broken, as damage or contamination may have occurred.
- Don't wear your lenses longer than recommended by your eye care professional, no matter how comfortable the lenses feel. Doing so increases the risk of adverse effects.
- Don't excessively rub your eyes while the lenses are in. You may harm your eyes or damage the lens.
- Don't get water, soap, or shampoo into your eyes during a bath or shower. These substances could get on your lenses and irritate your eyes.
- Be aware that hot and windy conditions may dry out your lenses. For example, air from a hair dryer, ceiling fan, or open car window may dry out your lenses and irritate your eyes.
- Always inform your eye care professional, physician and employer that you wear contact lenses. Contact lenses may not be used with certain medications or medical procedures, may not be suitable for certain occupations, or may require eye protection equipment.
- Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of:
    - eye infection, including but not limited to Acanthamoeba keratitis
    - damage to the lenses by chemicals in the water
    - loss of the lenses

Storing Your Lenses

- Store your lenses in the recommended solution when not being worn. Soft lenses are made of special materials that must be kept wet at all times to avoid damage from drying out.
- Always use fresh solution when storing your lenses. Previously used solutions can become contaminated and increase the risk of infection.
- Always follow the manufacturer's instructions for the lens care system your eye care professional has prescribed.

When to Remove Your Lenses

- Remove your lenses for sleeping unless your eye care professional has prescribed overnight wear for you. Not all people can wear lenses while sleeping. Sleeping with lenses on increases the risk of eye infection.
- Remove your lenses immediately if they become uncomfortable. Discomfort can be an early warning sign of a more serious problem. If the discomfort continues after lens removal, contact your eye care professional. Early treatment can help avoid more serious complications.
- Remove your lenses if you will be in the presence of irritating liquids, gases, chemicals, or smoke. Your lenses can become damaged by absorbing these substances and irritate or injure your eyes. If exposed to these substances while wearing your lenses, see the section titled "Emergencies" in the back of this booklet.
- ***Note: Lenses removed from your eye must be cleaned, rinsed, and disinfected after each wearing period if they are to be reused.***

Cosmetic Products and Your Lenses

- Lens damage, eye irritation or infection may result if cosmetics, lotion, soap, cream, hair spray, deodorant, perfume, or aerosol products come in contact with your lenses. If sprays are used, close your eyes until the spray has settled.
- Apply eye make-up only after you have inserted the lenses. Otherwise, make-up can become trapped under the lens and irritate or injure your eyes.
- Do not use nail polish remover while wearing your lenses. The fumes can damage the lenses.

Other Eye Care Products and Medications

- Do not use eye drops, solutions, or medications in your eyes unless directed by your eye care professional. These solutions may damage your lenses or irritate your eyes.
- Certain medications may cause blurred vision, lens dryness, or lens discomfort. These include antihistamines, decongestants, diuretics, muscle relaxants, oral contraceptives, tranquilizers, and motion sickness medications. Always inform your eye care professional if you experience any problems with your lenses while taking such medications.
- Do not use solutions made only for hard contact lenses. They can damage your soft lenses, which may result in serious eye complications.

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LENS PLACEMENT ON THE EYE

Introduction

Cleanliness is one of the most important aspects of handling and caring for your contact lenses. Starting with clean hands helps to reduce the chance of eye infections and irritation.

Step 1 – Wash, Rinse, and Dry Hands

- **Wash your hands thoroughly** with soap that does not have any oils, lotions, or perfumes.
    - Thorough hand washing will remove dirt, germs, and oils that could get on the lenses and cause irritation or infection. Using the proper soap prevents chemical residues from getting on the lenses.
- **Rinse your hands thoroughly** after washing.
    - This removes all traces of soap and dirt.
- **Dry your hands** with a lint-free towel.
    - This helps keep lint and dust from getting on your lenses and irritating your eyes.
- Long fingernails can make lens placement, removal and cleaning more difficult. Sharp, rough fingernails can damage the lenses.

Always wash your hands before handling your lenses. This will remove dirt and oils that could get on the lenses. Proper hand washing also helps prevent eye infections.

Photograph of proper hand washing technique

Step 2 – Open the Multipack Carton and Lens Container

Night & Day™ contact lenses are supplied sterile in multipack cartons with individual foil sealed plastic containers. Locate the opening flap on the multipack carton and pull up to break the seal.

Each multipack carton and lens container is marked with the lens power (your vision prescription). Lens powers may not be the same for both eyes, so multipack cartons have a check box for your eye care professional to mark indicating which lens is for your left and right eye. Be sure to open and use the correct lens for each eye.

The Lens Package

- Each *Night & Day™* soft contact lens is supplied in a foil sealed plastic container designed to maintain sterility of the lens and saline solution. To open an individual container, follow these simple steps:

    1. Shake the lens package gently, and peel back lid.
    2. Carefully remove the lens from package.
        - With a clean finger, gently slide the lens out of the lens container or pour the lens onto the palm of your clean hand.
        - Do not use tweezers or other tools to remove the lens from container. This could damage the lens.

Step 3 – Inspect the Lens for Damage or Foreign Matter

- Thoroughly rinse the lens with the recommended sterile saline solution according to the manufacturer's instructions. This will remove any possible traces of dust, lint or other particles from the lens. Foreign material could get trapped under the lens and cause eye discomfort.
- Examine the lens to be sure it is clean and moist and does not have any nicks, tears, or particles sticking to it.
    - Place the lens on the tip of your index finger and hold it up against a bright light.
    - If the lens appears damaged or dried out, do not use it. Discard it and use the next lens in the multipack.

Never handle your lenses over a sink with an open drain. Shut the drain or place a clean paper towel over the opening to keep from losing your lenses.

Step 4 – Make Sure the Lens Is Right Side Out

Check to see that your lens is right side out. A lens that is placed on the eye inside out may not feel comfortable or provide good vision.

Method 1

One way to do this is to place the lens between your 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 your fingers.

Photographs or line drawings of Method 1 (right side vs wrong side out)

Method 2

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

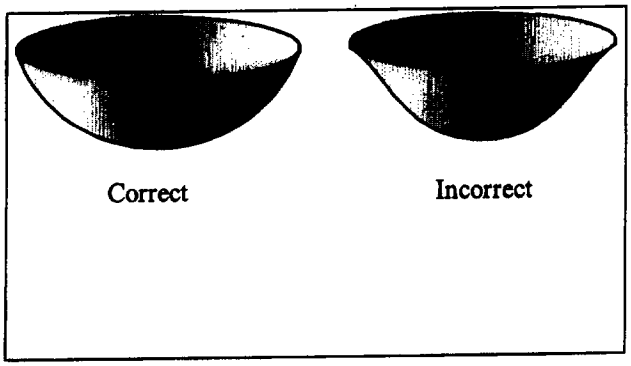
- If the edge appear bowl-shaped, it is right side out.
- If the edge has a lip or flares outward, it is wrong side out and must be reversed.

Correct Incorrect

Method 3

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 your index finger and hold it up against a light source.
- If the lens is right side out, you should be able to read "CIBA" 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 your fingers.



Step 5 - Place Lens on Eye

After you have thoroughly washed, rinsed, and dried your hands, rinsed and inspected the lens, and made sure it is right side out, you are ready to place the lens on your eye.

Remember to start with the same lens first (right or left), then the other lens. This helps avoid getting the lenses mixed up.

1. **Place the lens on the tip of your right index finger** (left index finger if you are left-handed and this is easier for you). Make sure your finger is completely dry, or the lens will stick to your finger and be difficult to transfer to your eye.

2. Place the middle finger of the same hand close to your lower eyelashes and pull down the lower eyelid.

3. Use the fingers of the other hand to lift the upper right eyelid.

4. Place the lens directly on the eye (cornea) by gently rolling it off the index finger.

Photograph of lens placement technique, depicting proper positioning of fingers, eyelids, and lens.

5. Look down and slowly remove your right hand, releasing the lower lid.

6. Look straight ahead and slowly remove your left hand, releasing the upper lid.

7. Blink gently. The lens should center automatically.

Photograph of lens placement technique, depicting proper positioning of fingers, eyelids, and lens.

8. Repeat steps 1-7 above for the other lens.

Your eye care professional may suggest alternate methods for insertion of the lens onto the eye.

If your vision is blurred or the lens is uncomfortable on your eye, check for the following:

- The lens is not centered on the eye (see ***Centering the Lens***, next section)
- The lens is centered. Remove the lens (see ***Lens Removal*** section) and check for the following:
    - Cosmetics, oils, or particles on the lens. Clean and rinse the lens and place on the eye again.
    - The lens is on the wrong eye.
    - The lens is wrong side out.
    - The lens may be torn or damaged. If so, do not place the lens back on your eye. Discard the lens and replace it with a new lens.

If your vision is still blurred or the lens is uncomfortable after checking the above, remove both lenses and contact your eye care professional.

After you have successfully inserted your lenses, you should ask yourself:

- Do the lenses ***feel good?*** (There should be no discomfort.)
- Do my eyes ***look good?*** (Your eyes should not be red or swollen or have any discharge.)
- Is my ***vision good?*** (You should be able to see clearly out of each eye individually and together.)

If the answer to any of these questions is no, immediately remove your lenses and contact your eye care professional.

Centering the Lens

Occasionally a lens will be displaced onto the white part of the eye during lens placement or during lens wear. To center a lens, follow one of the methods below:

Method 1. Look in the direction of the displaced lens. Blink gently. The lens should automatically move toward the center of the eye and into the correct position.

Method 2. Close your eyelids and gently massage the lens into place through the closed eyelid.

Photograph of lens centering technique, method 2.

Method 3. Gently push the off-centered lens onto the cornea with the eye open, using gentle finger pressure on the edge of the upper or lower eyelid.

LENS REMOVAL

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 your contact lenses if you use rewetting drops (approved for use with soft lenses) recommended by your eye care professional 10 to 15 minutes before lens removal. This will also help prevent lens tearing during the removal process.

Step 1 - Wash, Rinse, and Dry Hands

- **Wash your hands thoroughly** with soap that does not have any oils, lotions, or perfumes.

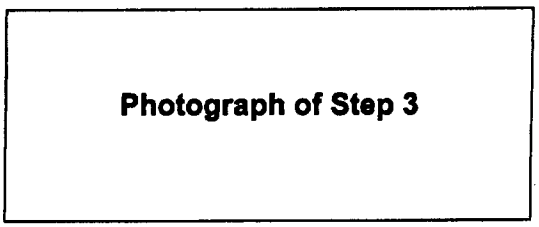
Refer to the section, "Lens Placement on the Eye" for important additional information.

Step 2 - Make Sure Lens is on the Eye

Make sure the lens is centered on your eye before trying to remove it. Cover the other eye; if your vision is blurred, the lens is either off center or not on the eye at all. Locate the lens with a mirror and re-center it using one of the methods described in the section, ***Centering the Lens.***

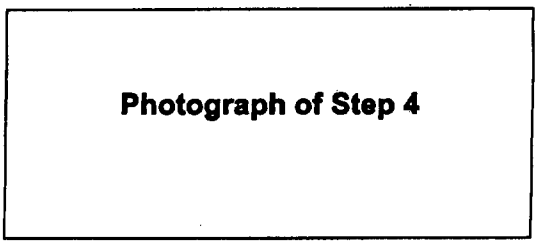
Step 3 - Pull Down Lower Eyelid

Look upward, keeping your head level. Pull down the lower lid of your eye with your middle finger.



Step 4 - Slide Lens Down

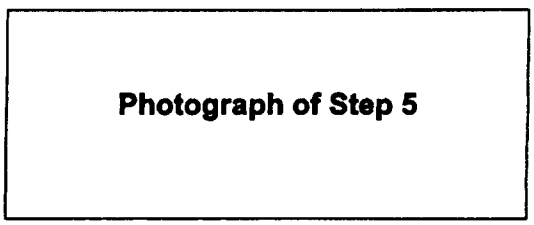
While looking up, place the tip of your index finger on the lower edge of the lens and slide it down onto the lower white part of your eye.



Step 5 - Pull Lens Off Eye

Still looking up, squeeze the lens gently between your thumb and index finger. Gently remove the lens from the eye.

Repeat Steps 2-5 for the other lens



REPLACING YOUR LENSES

Replace your lenses with a new pair as often as recommended by your eye care professional. Old lenses can cause discomfort, decreased vision and may adversely affect your eye health. CIBA Vision recommends lenses be replaced every one month, or sooner, as recommended by the eye care professional.

FOLLOW-UP CARE

Do not skip visits with your eye care professional just because your lenses feel comfortable. Routine follow-up visits help prevent problems. Only a thorough examination by your eye care professional can determine how your eyes are responding to contact lenses. Early signs of a problem can be detected and treated before they can be felt by you.

LENS CARE

In a planned replacement program *Night & Day™* lenses should be cleaned, rinsed, and disinfected each time they are removed from the eye and prior to re-insertion.

General Guidelines for Lens Care

- **Follow the complete lens care regimen exactly as directed in the specific labeling instructions which accompany the solutions recommended by your eye care professional. Failure to do so may contribute to problems listed in the Adverse Effects section or result in serious eye problems as discussed in the Warnings section.**
- Lenses removed from your eyes must be cleaned, rinsed, and disinfected after each wearing and before reuse.
    - **Cleaning** loosens and removes accumulations of film, deposits, and debris that can cause irritation, and prepares lenses for disinfection.
      Rinsing removes cleaning and disinfection solutions and helps make your lenses feel more comfortable.
      Disinfecting kills germs that can cause eye infections.
    - Failure to clean and rinse prior to disinfection may result in incomplete lens disinfection.
    - Saline solutions are used to rinse, **NOT** to clean or disinfect.
- A chemical method of disinfection, such as AOSEPT® , Quick CARE® or SOLO-care™, is recommended for use with *Night & Day™* contact lenses.
- *Night & Day™* contact lenses are not recommended for use with heat disinfection.
- Use of an enzymatic cleaner is not recommended. Worn lenses with protein deposits should be discarded and replaced with a new lens.

- Lens compatibility with an abrasive type cleaner such as Opticlean I or II has not been tested and is not recommended.
- Never use a hard (rigid) lens solution unless it is also indicated for use with soft contact lenses, as corneal injury could result.
- Do not alternate, change, or mix lens care systems or solutions for any one pair of lenses unless specifically indicated in the product labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. If in doubt, consult your eye care professional.
- If you remove your lenses and do not have access to your lens care products, do not reinsert the lenses. Store your lenses in the lens case until they can be cleaned, rinsed, and disinfected.
- Use only fresh, unexpired, sterile lens care solutions recommended for use with soft contact lenses according to the manufacturer's instructions provided with the specific products.
- **When opened, sterile, non-preserved, non-aerosol solutions must be discarded after the time specified in the label directions.**

Step 1 - Cleaning

Cleaning loosens and removes accumulations of film, deposits, and debris that can cause irritation, and prepares lenses for disinfection.

Wash, Rinse, and Dry Hands

Remove and Clean One Lens at a Time

Clean Lens

- **Place the lens in the palm of one hand and add cleaner according to the manufacturer's instructions for use.**
  - Rub the lens with firm but gentle pressure, in a back and forth (not circular) motion. A circular motion may cause the lens to split or tear.
  - The rubbing action of your finger against the lens removes mucus, dirt, and other material from the lens surface. These substances may not be visible even though they are present on your lenses.

Photograph or line drawing of correct lens cleaning technique

Step 2 - Rinsing

Rinsing removes cleaning and disinfecting solutions and helps make your lenses feel more comfortable.

- Thoroughly rinse the lens with fresh sterile saline solution according to the manufacturer's instructions for use.
- Make sure all of the cleaning solution has been rinsed off. Any remaining cleaner can irritate the eye and may interfere with the disinfection process.

Photograph or line drawing of proper lens rinsing technique

Step 3 - Disinfection

Disinfecting kills germs that can cause eye infection.

- Follow the manufacturer's instructions that come with the chemical disinfection system recommended by your eye care professional. In most cases, you will:

    1. Always fill the lens case with **fresh** disinfection solution.
    2. **Close tightly**. The lenses must be fully covered by the disinfection solution to ensure proper disinfection and to keep from drying out.
    3. **Allow lenses to remain in case for the length of time specified in the instructions**. This will help keep harmful germs from growing on your lenses.

Care of the Lens Case

Contact lens cases can be a source of growth for harmful organisms. These germs may be present even when the case looks clean. Putting clean lenses in a dirty or contaminated case makes the lenses unsafe to wear.

Rinse lens case
To prevent contamination and help avoid serious eye infection:

- Always empty the lens case after putting the lenses on your eyes
    - Rinse the case with either sterile saline solution or disinfecting solution recommended by your eye care professional
    - Allow the case to air dry.

Replace lens case regularly
Regular replacement will help prevent case contamination by germs which can be harmful to your eyes.

- Replace the lens case at regular intervals according to the manufacturer's instruction for use.
- If there are not instructions for how often to replace the case, follow the recommendations of your eye care professional.
- **Fresh solution should be used each time the lens is placed in the lens case. Never add fresh solution to old solution since this can increase the risk of lens and lens case contamination and eye infection.**

OTHER IMPORTANT INFORMATION

Using Wetting Drops (Lens Lubricant)

- If wetting drops are recommended by your eye care professional (such as CIBA Vision Lens Drops), follow the directions for use provided by the manufacturer. Not all lens lubricants can be used with soft contact lenses.

If a Lens Dries Out

- If a lens is exposed to air while off the eye it may become dry, brittle, and permanently damaged. If this should occur, discard the lens and use a new one to avoid possible irritation or injury to the eye.

Care for a Sticking Lens

- If a lens sticks (stops moving) or begins to dry on the eye, apply a lubricating solution recommended for soft lenses according to the manufacturer's instruction for use.
- Wait until the lens begins to move freely on the eye before trying to remove it. If the lens continues to stick, IMMEDIATELY consult your eye care professional.

Emergencies

- If chemicals of any kind (household cleaners, gardening solutions, laboratory chemicals, pesticides, etc.) are splashed into the eyes:
    - **Flush eyes immediately with tap water or fresh saline solution.**
    - **Remove the lenses and place them in the recommended storage solution.**
    - **Call or visit your eye care professional or a hospital emergency room immediately.**

INSTRUCTIONS FOR THE MONOVISION WEARER

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your distance visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger, rather than a driver of an automobile, during the first few days of lens wear. It is recommended that you drive with monovision correction only if you pass the driver's license requirements with your monovision correction.

- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

- If you require very sharp near vision during prolonged close work, you may want to have additional lenses prescribed so that both eyes are corrected for near when sharp near vision binocular vision is required.

- Some monovision patients require supplemental spectacles to wear over the monovision contact lens correction to provide the clearest vision for critical tasks. You should discuss this with your eye care professional.

- It is important that you follow your eye care professional's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.

- The decision to be fit with a monovision correction is most appropriately left to the eye care professional in conjunction with you, after carefully considering and discussing your needs.

LENS CARE PRODUCT CHART FOR SOFT CONTACT LENSES, AVAILABLE IN THE U.S.A.

AOSEPT® Lens Care System	
AOSEPT® Disinfectant	Disinfecting solution
AOSEPT® Lens Cup	Lens case for AOSEPT Disinfectant and AODISC Neutralizer
AODISC® Neutralizer	Neutralizes AOSEPT into a gentle buffered saline solution
Softwear® Saline	Rinsing and storage
Miraflow® Extra Strength Daily Cleaner	Cleaner
Pure Eyes® ***Disinfection System***	
Pure Eyes® Disinfectant/Soaking Solution	Disinfecting solution
Pure Eyes® Cleaner/Rinse	Cleaning and rinsing solution
Pure Eyes® Lens Case/built-in neutralizer	Neutralizes Pure Eyes Disinfectant into a gentle buffered saline solution
Quick CARE® Care System	The Quick CARE System cleans, disinfects, rinses, and soaks in about 5 minutes
Quick CARE® Starting Solution	
Quick CARE® Finishing Solution	
SOLO-CARE™ brand ***Multi-purpose Solution***	Multipurpose solution for cleaning, rinsing, disinfecting, storing, & protein removal
Other CIBA Vision® Lens Care Products	
CIBA Vision® Cleaner	Cleaning
CIBA Vision® Saline	Rinsing
CIBA Vision® Lens Drops	Lubricating
Focus® Lens Drops	Lubricating
Unizyme® Enzymatic Cleaner	Protein removal

WEARER INFORMATION

Eye Care Professional:		Contact Lens Information:	
Name:		Lens Brand/Type:	
Street:		Prescription/Date:	
City/State/Zip:			
Phone:			

Wear & Replacement Schedules:

The wearing and replacement schedules should be determined by your eye care professional. Patients tend to overwear the lenses initially. It is very important to adhere to the initial maximum wearing schedule. Regular checkups, as determined by your eye care professional, are also extremely important.

CIBA Vision Corporation recommends that the lens be discarded and replaced with a new lens every month. However, your eye care professional is encouraged to determine a lens replacement schedule based upon the response of the patient.

☐ ***Daily Wear Only (less than one day, while awake)***

☐ ***Extended Wear (Maximum 7 days)*** **: How many nights you can safely wear the lenses overnight will be established during the follow-up visits.**

Initial Wearing Schedule:

DAY	DATE (Month/Day)	Wearing Time (# Hours)	DAY	DATE (Month/Day)	Wearing Time (# Hours)
1	_____	_____	6	_____	_____
2	_____	_____	7	_____	_____
3	_____	_____	8	_____	_____
4	_____	_____	9	_____	_____
5	_____	_____	10	_____	_____

☐ ***REPLACEMENT SCHEDULE:***

Replace lenses every _____ days or every ___/___ weeks

LENS SUPPLIES (Product Name or Manufacturer):

Saline Solution:		***Enzymatic Cleaner:***	
Daily Cleaning Solution:		***Lens Wetting Drops:***	
Disinfecting Solution:			

Appointment Schedule:

Date:		**Time:**		**Date:**		**Time:**	
Date:		**Time:**		**Date:**		**Time:**	

Important: In the event that you experience difficulty wearing your lenses or do not understand the instructions given you, DO NOT WAIT for your next appointment. Phone your eye care professional immediately.

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, GA USA 30097
Part # [*insert part number*]

Printed in [*insert USA or Canada*]

CIBA Vision.
A Novartis Company
Print Date: [*insert month, year*]

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CIBA Vision®

Patient Instruction Booklet

Focus® Night & Day™ (lotrafilcon A) Soft Contact Lenses

When Prescribed for Disposable Wear

℞ only CAUTION: Federal Law (USA) Prohibits Dispensing Without a Prescription

Table of Contents

Commonly Used Terms

Cornea The clear "window" of the eye, permitting light to enter, located in front of the iris and pupil

- Iris - The colored part of the eye which controls the size of the pupil
- Pupil - The black round opening surrounded by the iris

Disinfect A process which kills harmful microorganisms (germs) which can cause serious eye infections

Lens Deposits Particles such as cosmetics, lotions, protein from the tear film, environmental pollutants, etc., which collects on the lens surface

INTRODUCTION

Welcome!

Focus® Night & Day™ soft contact lenses worn for disposable wear represent a convenient and healthy way to wear soft contact lenses. Disposable wear is designed for easy and simple contact lens wear in that each time the lens is removed you simply throw the used lens away and replace with a new sterile lens. Since lenses are not reused, it is important to always carry spare lenses or a pair of glasses with you.

By wearing and replacing lenses on a sing-use basis, lens deposits are less likely to build up over time. Lens deposits can affect vision and may eventually cause irritation or discomfort to the eye.

About Your Contact Lenses

Night & Day™ lenses are available in a spherical lens design, and are intended for either daily disposable wear or extended wear for 1 to 7 days, as recommended by your eye care professional. The lenses are intended for single-use and should be discarded upon removal from the eye. In an emergency when spare lenses or glasses are not available, the lenses must be cleaned, rinsed and disinfected with a chemical, not heat, disinfection system before reinsertion. For your eye health, **it is important that you follow the wearing and replacement schedule as prescribed by your eye care professional**. If you wear your lenses too long, you can harm your eyes.

About This Booklet

Read this booklet carefully and follow all of the instructions.

This booklet explains how to wear and care for your new lenses. The information applies to *Night & Day™* lenses when prescribed for disposable wear. If you have questions about the wear and care of your lenses after reading this booklet, call or visit your eye care professional. Also, you may call CIBA Vision Consumer Relations toll free in the USA at 1-800-875-3001.

Successful, safe contact lens wear depends on following the recommendations of your eye care professional and practicing good lens care habits. If you do not, you may:

- increase the chances of serious eye infection and injury
- cause damage to your contact lenses

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WARNINGS AND PRECAUTIONS

What You Should Know About Contact Lens Wear

Warning

Serious injury to the eye, scarring of the cornea, and loss of vision may result from problems associated with wearing contact lenses and using lens care products.

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Immediately call or visit your eye care professional for persistent symptoms of any eye discomfort, watering, vision change, or redness.

Extended Wear

Overnight wear of contact lenses has been shown to increase the risk of certain serious contact lens related complications. The risk increases with the number of days in a row that the lenses are worn between removals, beginning with the first overnight use.[1]

Do not wear your Night & Day™ contact lenses for extended wear (24 hours a day including during sleep) unless directed by your eye care professional.

If your eye care professional has directed you to wear your lenses for extended wear, wearing your lenses for fewer nights per week of overnight wear can reduce this risk.

Smoking

Smoking increases the risk of serious problems with contact lens wear, especially when lenses are worn overnight[1, 2] If you smoke, be sure to inform your eye care professional.

Following Directions

Be sure to follow exactly the instructions of your eye care professional regarding proper use of your contact lenses. Failure to do so may put you at significant risk of developing a serious eye infection.

Replacing your lenses

Begin each wearing period with a fresh new lens. At the end of the wearing period, remove and discard the lens.

Always keep spare lenses with you.

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[1] the CLAO Journal, January 1996, Volume 22, Number 1, pp 30 - 37
[2] New England Journal of Medicine, September 21, 1989; 321 (12), pp 773 - 783

Adverse Effects (Possible Problems)

It is possible that problems can occur and may be accompanied by one or more of the following conditions:

- Feeling of something in the eye
- Unusual eye secretions
- Eye redness
- Sensitivity to light (photophobia)
- Eyes burn, sting or itch
- Eyes water
- Reduced sharpness of vision
- Rainbows or halos around objects
- Uncomfortable lens
- Feeling of dryness

A serious condition such as corneal ulcer or eye infection may be present and may progress rapidly. Even less serious reactions such as a scratched cornea must be treated promptly to avoid more serious complications.

What To Do If a Problem Occurs

If you experience any of the above signs or symptoms, immediately remove your lens(es). Identification of the problem and prompt treatment may help avoid serious eye damage. Do not insert a new or spare lens onto an eye that is red, irritated, or painful. A new lens may hide symptoms and delay treatment.

Discuss and follow your eye care professional's recommendations should you experience any eye discomfort with your lenses.

- **IMMEDIATELY remove the lens(es),**

1. **If the discomfort stops, then look closely at the lens(es).**
    - **If the lens(es) are damaged in any way, DO NOT put the lens(es) back on your eye. Place the lens(es) in the storage case, or discard and contact the eye care professional.**
    - **If the lenses have dirt, an eyelash or other foreign body on them, and the lens(es) appear undamaged, thoroughly clean, rinse and disinfect the lenses, then reinsert. After reinsertion, if the problem continues, remove the lens(es) immediately and contact the eye care professional.**
2. **If discomfort continues after you have removed your lenses,**

    IMMEDIATELY contact the eye care professional.

WHEN LENSES SHOULD NOT BE WORN

Contact lenses should not be worn under certain general health and eye conditions. Only your eye care professional can determine if continued contact lens wear is right for you. These include the following:

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- Inflammation or infection in or around the eye or eyelids.
- Excessive dryness of the eyes that makes contact lens wear uncomfortable.

- Any condition which reduces corneal sensitivity.
- Systemic diseases that may be affected by or impact lens wear.
- Allergic conditions, reactions or ocular irritation caused or exaggerated by lens wear or certain preservatives in lens care products.
- The use of any medication, including some eye medications, that shouldn't be used with, or interferes with contact lens wear.
- If eyes become red or irritated.

GENERAL GUIDELINES FOR SAFE CONTACT LENS WEAR

Wearing Your Lenses

- Your lenses are provided to you in a foil sealed plastic container. Never use a lens if the container seal is broken, as damage or contamination may have occurred.
- Don't wear your lenses longer than recommended by your eye care professional, no matter how comfortable the lenses feel. Doing so increases the risk of adverse effects.
- Don't excessively rub your eyes while the lenses are in. You may harm your eyes or damage the lens.
- Don't get water, soap, or shampoo into your eyes during a bath or shower. These substances could get on your lenses and irritate your eyes.
- Be aware that hot and windy conditions may dry out your lenses. For example, air from a hair dryer, ceiling fan, or open car window may dry out your lenses and irritate your eyes.
- Always inform your eye care professional, physician and employer that you wear contact lenses. Contact lenses may not be used with certain medications or medical procedures, may not be suitable for certain occupations, or may require eye protection equipment.
- Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of:
    - eye infection, including but not limited to Acanthamoeba keratitis
    - damage to the lenses by chemicals in the water
    - loss of the lenses

When to Remove Your Lenses

- Remove your lenses for sleeping unless your eye care professional has prescribed overnight wear for you. Not all people can wear lenses while sleeping. Sleeping with lenses on increases the risk of eye infection.
- Remove your lenses immediately if they become uncomfortable. Discomfort can be an early warning sign of a more serious problem. If the discomfort continues after lens removal, contact your eye care professional. Early treatment can help avoid more serious complications.
- Remove your lenses if you will be in the presence of irritating liquids, gases, chemicals, or smoke. Your lenses can become damaged by absorbing these substances and irritate or injure your eyes. If exposed to these substances while wearing your lenses, see the section titled "General Emergencies" in the back of this booklet.
- ***Note: Lenses worn for disposable wear are disposed of upon removal from your eye. Start each wearing period with a fresh, new lens.***

Cosmetic Products and Your Lenses

- Lens damage, eye irritation or infection may result if cosmetics, lotion, soap, cream, hair spray, deodorant, perfume, or aerosol products come in contact with your lenses. If sprays are used, close your eyes until the spray has settled.
- Apply eye make-up only after you have inserted the lenses. Otherwise, make-up can become trapped under the lens and irritate or injure your eyes.
- Do not use nail polish remover while wearing your lenses. The fumes can damage the lenses.

Other Eye Care Products and Medications

- Do not use eye drops, solutions, or medications in your eyes unless directed by your eye care professional. These solutions may damage your lenses or irritate your eyes.
- Certain medications may cause blurred vision, lens dryness, or lens discomfort. These include antihistamines, decongestants, diuretics, muscle relaxants, oral contraceptives, tranquilizers, and motion sickness medications. Always inform your eye care professional if you experience any problems with your lenses while taking such medications.

LENS PLACEMENT ON THE EYE

Introduction

Cleanliness is one of the most important aspects of handling and caring for your contact lenses. Starting with clean hands helps to reduce the chance of eye infections and irritation.

Step 1 – Wash, Rinse, and Dry Hands

- **Wash your hands thoroughly** with soap that does not have any oils, lotions, or perfumes.
    - Thorough hand washing will remove dirt, germs, and oils that could get on the lenses and cause irritation or infection. Using the proper soap prevents chemical residues from getting on the lenses.

Always wash your hands before handling your lenses. This will remove dirt and oils that could get on the lenses. Proper hand washing also helps prevent eye infections.

- **Rinse your hands thoroughly** after washing.
    - This removes all traces of soap and dirt.
- **Dry your hands** with a lint-free towel.
    - This helps keep lint and dust from getting on your lenses and irritating your eyes.

Photograph of proper hand washing technique

- Long fingernails can make lens placement, removal and cleaning more difficult. Sharp, rough fingernails can damage the lenses.

Step 2 – Open the Multipack Carton and Lens Container

Focus® Night & Day™ contact lenses are supplied sterile in multipack cartons with individual foil sealed plastic containers. Locate the opening flap on the multipack carton and pull up to break the seal.

Each multipack carton and lens container is marked with the lens power (your vision prescription). Lens powers may not be the same for both eyes, so multipack cartons have a check box for your eye care professional to mark indicating which lens is for your left and right eye. Be sure to open and use the correct lens for each eye.

The Lens Package

- Each *Night & Day™* soft contact lens is supplied in a foil sealed plastic container designed to maintain sterility of the lens and saline solution. To open an individual container, follow these simple steps:

    1. Shake the lens package gently, and peel back lid.
    2. Carefully remove the lens from package.
        - With a clean finger, gently slide the lens out of the lens container or pour the lens onto the palm of your clean hand.
        - Do not use tweezers or other tools to remove the lens from container. This could damage the lens.

Step 3 – Inspect the Lens for Damage or Foreign Matter

- Thoroughly rinse the lens with the recommended sterile saline solution according to the manufacturer's instructions. This will remove any possible traces of dust, lint or other particles from the lens. Foreign material could get trapped under the lens and cause eye discomfort.
- Examine the lens to be sure it is clean and moist and does not have any nicks, tears, or particles sticking to it.
    - Place the lens on the tip of your index finger and hold it up against a bright light.
    - If the lens appears damaged or dried out, do not use it. Discard it and use the next lens in the multipack.

Never handle your lenses over a sink with an open drain. Shut the drain or place a clean paper towel over the opening to keep from losing your lenses.

Step 4 – Make Sure the Lens Is Right Side Out

Check to see that your lens is right side out. A lens that is placed on the eye inside out may not feel comfortable or provide good vision.

Method 1

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

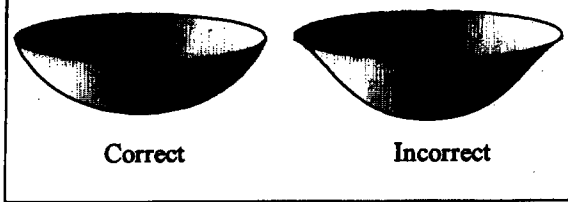
- If the edges come together, the lens is right side out.
- If the edges turn outward, the lens is wrong side out. Carefully reverse it with your fingers.

Photographs or line drawings of Method 1 (right side vs wrong side out)

Method 2

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

- If the edge appear 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.



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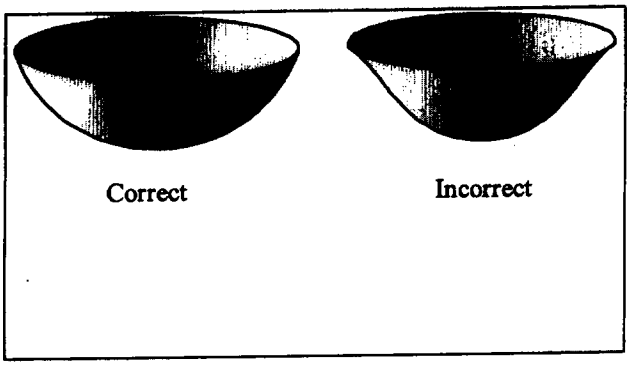
Method 3

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 your index finger and hold it up against a light source.
- If the lens is right side out, you should be able to read "CIBA" 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 your fingers.



Step 5 - Place Lens on Eye

After you have thoroughly washed, rinsed, and dried your hands, rinsed and inspected the lens, and made sure it is right side out, you are ready to place the lens on your eye.

Remember to start with the same lens first (right or left), then the other lens. This helps avoid getting the lenses mixed up.

1. **Place the lens on the tip of your right index finger** (left index finger if you are left-handed and this is easier for you). Make sure your finger is completely dry, or the lens will stick to your finger and be difficult to transfer to your eye.

2. Place the middle finger of the same hand close to your lower eyelashes and pull down the lower eyelid.

3. Use the fingers of the other hand to lift the upper right eyelid.

4. Place the lens directly on the eye (cornea) by gently rolling it off the index finger.

Photograph of lens placement technique, depicting proper positioning of fingers, eyelids, and lens.

5. Look down and slowly remove your right hand, releasing the lower lid.

6. Look straight ahead and slowly remove your left hand, releasing the upper lid.

7. Blink gently. The lens should center automatically.

Photograph of lens placement technique, depicting proper positioning of fingers, eyelids, and lens.

8. Repeat steps 1-7 above for the other lens.

Your eye care professional may suggest alternate methods for insertion of the lens onto the eye.

If your vision is blurred or the lens is uncomfortable on your eye, check for the following:

- The lens is not centered on the eye (see ***Centering the Lens***, next section)
- The lens is centered. Remove the lens (see ***Lens Removal*** section) and check for the following:
    - Cosmetics, oils, or particles on the lens. Clean and rinse the lens and place on the eye again.
    - The lens is on the wrong eye.
    - The lens is wrong side out.
    - The lens may be torn or damaged. If so, do not place the lens back on your eye. Discard the lens and replace it with a new lens.

If your vision is still blurred or the lens is uncomfortable after checking the above, remove both lenses and contact your eye care professional.

After you have successfully inserted your lenses, you should ask yourself:

- Do the lenses ***feel good?*** (There should be no discomfort.).
- Do my eyes ***look good?*** (Your eyes should not be red or swollen or have any discharge.)
- Is my ***vision good?*** (You should be able to see clearly out of each eye individually and together.)

If the answer to any of these questions is no, immediately remove your lenses and contact your eye care professional.

Centering the Lens

Occasionally a lens will be displaced onto the white part of the eye during lens placement or during lens wear. To center a lens, follow one of the methods below:

Method 1. Look in the direction of the displaced lens. Blink gently. The lens should automatically move toward the center of the eye and into the correct position.

Method 2. Close your eyelids and gently massage the lens into place through the closed eyelid.

Photograph of lens centering technique, method 2.

Method 3. Gently push the off-centered lens onto the cornea with the eye open, using gentle finger pressure on the edge of the upper or lower eyelid.

LENS REMOVAL

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 your contact lenses if you use rewetting drops (approved for use with soft lenses) recommended by your eye care professional 10 to 15 minutes before lens removal. This will also help prevent lens tearing during the removal process.

Step 1 - Wash, Rinse, and Dry Hands

- **Wash your hands thoroughly** with soap that does not have any oils, lotions, or perfumes.

Refer to the section, "Lens Placement on the Eye" for important additional information.

Step 2 - Make Sure Lens is on the Eye

Make sure the lens is centered on your eye before trying to remove it. Cover the other eye; if your vision is blurred, the lens is either off center or not on the eye at all. Locate the lens with a mirror and re-center it using one of the methods described in the section, ***Centering the Lens.***

Step 3 - Pull Down Lower Eyelid

Look upward, keeping your head level. Pull down the lower lid of your eye with your middle finger.

Photograph of Step 3

Step 4 - Slide Lens Down

While looking up, place the tip of your index finger on the lower edge of the lens and slide it down onto the lower white part of your eye.

Photograph of Step 4

Step 5 - Pull Lens Off Eye

Still looking up, squeeze the lens gently between your thumb and index finger. Gently remove the lens from the eye.

Repeat Steps 2-5 for the other lens

Photograph of Step 5

REPLACING YOUR LENSES

Replace your lenses with a new pair as often as recommended by your eye care professional. Old lenses can cause discomfort, decreased vision and may adversely affect your eye health.

FOLLOW-UP CARE

Do not skip visits with your eye care professional just because your lenses feel comfortable. Routine follow-up visits help prevent problems. Only a thorough examination by your eye care professional can determine how your eyes are responding to contact lenses. Early signs of a problem can be detected and treated before they can be felt by you.

EMERGENCY LENS CARE

Always carry a spare pair of lenses. If for some reason replacement lenses or glasses are not available, ad it becomes necessary to clean and disinfect the lenses prior to the prescribed removal and disposal interval, carefully follow the directions for use as outlined in the package inserts of the lens care products recommended by your eye care professional.

When *Focus® Night & Day™* lenses are prescribed for 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 for reuse when replacement lenses are not available.

OTHER IMPORTANT INFORMATION

Using Wetting Drops (Lens Lubricant)

- If wetting drops are recommended by your eye care professional (such as Focus® Lens Drops), follow the directions for use provided by the manufacturer. Not all lens lubricants can be used with soft contact lenses.

If a Lens Dries Out

- If a lens is exposed to air while off the eye it may become dry, brittle, and permanently damaged. If this should occur, discard the lens and use a new one to avoid possible irritation or injury to the eye.

Care for a Sticking Lens

- If a lens sticks (stops moving) or begins to dry on the eye, apply a lubricating solution recommended for soft lenses according to the manufacturer's instruction for use.
- Wait until the lens begins to move freely on the eye before trying to remove it. If the lens continues to stick, IMMEDIATELY consult your eye care professional.

General Emergencies

- If chemicals of any kind (household cleaners, gardening solutions, laboratory chemicals, pesticides, etc.) are splashed into the eyes:
  - Flush eyes immediately with tap water or fresh saline solution.
  - Remove the lenses and place them in the recommended storage solution.
  - Call or visit your eye care professional or a hospital emergency room immediately.

INSTRUCTIONS FOR THE MONOVISION WEARER

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your distance visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger, rather than a driver of an automobile, during the first few days of lens wear. It is recommended that you drive with monovision correction only if you pass the driver's license requirements with your monovision correction.

- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

- If you require very sharp near vision during prolonged close work, you may want to have additional lenses prescribed so that both eyes are corrected for near when sharp near vision binocular vision is required.

- Some monovision patients require supplemental spectacles to wear over the monovision contact lens correction to provide the clearest vision for critical tasks. You should discuss this with your eye care professional.

- It is important that you follow your eye care professional's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.

- The decision to be fit with a monovision correction is most appropriately left to the eye care professional in conjunction with you, after carefully considering and discussing your needs.

WEARER INFORMATION

Eye Care Professional:		**Contact Lens Information:**	
Name:		Lens Brand/Type:	
Street:		Prescription/Date:	
City/State/Zip:			
Phone:			

Wear & Replacement Schedules:

The wearing and replacement schedules should be determined by your eye care professional. Patients tend to overwear the lenses initially. It is very important to adhere to the initial maximum wearing schedule. Regular checkups, as determined by your eye care professional, are also extremely important.

CIBA Vision Corporation recommends that the lens be discarded and replaced with a new lens every month. However, your eye care professional is encouraged to determine a lens replacement schedule based upon the response of the patient.

☐ ***Daily Wear Only (less than one day, while awake)***

☐ ***Extended Wear (Maximum 7 days)*** **: How many nights you can safely wear the lenses overnight will be established during the follow-up visits.**

Initial Wearing Schedule

DAY	DATE (Month/Day)	Wearing Time (# Hours)	DAY	DATE (Month/Day)	Wearing Time (# Hours)
1			6		
2			7		
3			8		
4			9		
5			10		

☐ ***REPLACEMENT SCHEDULE***

Replace lenses every _____ days or every ___/___ weeks

LENS SUPPLIES (Product Name or Manufacturer):

Saline Solution:		***Enzymatic Cleaner:***	
Daily Cleaning Solution:		***Lens Wetting Drops:***	
Disinfecting Solution:			

Appointment Schedule:

Date:		**Time:**		**Date:**		**Time:**	
Date:		**Time:**		**Date:**		**Time:**	

Important: In the event that you experience difficulty wearing your lenses or do not understand the instructions given you, DO NOT WAIT for your next appointment. Phone your eye care professional immediately.

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