PACKAGE INSERT / FITTING GUIDE

BAUSCH + LOMB
ULTRA® contact lenses
with MoistureSeal® TECHNOLOGY

BAUSCH + LOMB
ULTRA® contact lenses
For Presbyopia
with MoistureSeal® TECHNOLOGY

BAUSCH + LOMB
ULTRA® contact lenses
For Astigmatism
with MoistureSeal® TECHNOLOGY

BAUSCH + LOMB
ULTRA® contact lenses
Multifocal for Astigmatism
with MoistureSeal® TECHNOLOGY

℞ ONLY **CAUTION:** Federal law restricts this device to sale by or on the order of a licensed practitioner.

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SYMBOL REFERENCE GUIDE

For labels and cartons:

CE 0050	Quality System Certification Symbol
	Meets EU Packaging Directive
STERILE	Sterilized Using Steam
⚠	Caution
DIA $\varnothing_T$	Diameter
EXP	Use-By Date
LOT	Batch Code
EC REP	Authorized Representative in the European Community
℞ ONLY	Prescription Only (USA)
PWR F'_V	Power
BC	Base Curve
SVS	Single Vision Spherical
ADD	Add Power
AX	Cylinder Axis
CYL	Cylinder Power
SPH	Sphere Power
	Temperature Limit
YYYY-MM-DD	Effective Date
	Manufacturer

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TABLE OF CONTENTS

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IMPORTANT

This package insert and fitting guide has been developed to provide practitioners with information covering characteristics of the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens and to illustrate fitting procedures. It is effective as of revision date on cover and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.

This package insert and fitting guide is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens and the recommended wearing schedule.

DESCRIPTION

The Bausch + Lomb ULTRA® (samfilcon A) Contact Lens material, samfilcon A, is a hydrophilic copolymer of a siloxane methacrylate and N-vinyl pyrrolidone, and is 46% water by weight when immersed in a sterile borate buffered saline with poloxamine solution. This lens is tinted with up to 200 ppm of Reactive Dye 246. The Bausch + Lomb ULTRA® (samfilcon A) Contact Lenses utilizes MoistureSeal® Technology which creates a unique material and a hydrophilic surface.

The physical/optical properties of the lens are:

Specific Gravity:	1.048
Refractive Index:	1.411
Light Transmittance:	C.I.E. value—at least 95%
Water Content:	46%
Oxygen Permeability:	114 x 10^{-11} [cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg) @ 35°C Polarographic Method (Boundary and Edge Corrected)

The Bausch + Lomb ULTRA® (samfilcon A) Contact Lenses may be prescribed for Frequent/Planned Replacement or Disposable Wear.

The Bausch + Lomb ULTRA® (samfilcon A) Contact Lens for Presbyopia features 3-Zone Progressive™ Design.

The Bausch + Lomb ULTRA® (samfilcon A) Contact Lens for Astigmatism features the OpticAlign® Design for stability.

The Bausch + Lomb ULTRA® (samfilcon A) Multifocal for Astigmatism Contact Lens features both a 3-Zone Progressive™ Design and an OpticAlign® Design.

LENS PARAMETERS AVAILABLE

The Bausch + Lomb ULTRA® (samfilcon A) Contact Lens is a hemispherical shell of the following dimensions:

Diameter:	14.2mm
Center Thickness:	0.05mm to 0.50mm
Base Curve:	8.5mm
Powers:	+6.00D to -6.00D* in 0.25D steps -6.00D to -12.00D* in 0.50D steps

The Bausch + Lomb ULTRA® (samfilcon A) Contact Lens for Presbyopia is a hemispherical shell of the following dimensions:

Diameter:	14.2mm
Center Thickness:	0.05mm to 0.50mm
Base Curve:	8.5mm
Powers:	+6.00D to -10.00D* in 0.25D steps
Add Powers:	Low (+0.75D to +1.50D) and High (+1.75D to +2.50D)

The Bausch + Lomb ULTRA® (samfilcon A) Contact Lens for Astigmatism is a hemispherical shell of the following dimensions:

Diameter:	14.5mm
Center Thickness:	0.05mm to 0.50mm
Base Curve:	8.6mm
Powers:	+6.00D to -6.00D in 0.25D steps -6.00D to -9.00D in 0.50D steps
Cylinder Powers:	-0.75D, -1.25D, -1.75D, -2.25D and -2.75D
Axis:	10° to 180° in 10° increments

The Bausch + Lomb ULTRA® (samfilcon A) Contact Lens Multifocal for Astigmatism is a hemispherical shell of the following dimensions:

Diameter:	14.5mm
Center Thickness:	0.05mm to 0.50mm
Base Curve:	8.6mm
Powers:	+4.00D to -6.00D in 0.25D steps
Add Powers:	Low (+0.75D to +1.50D) and High (+1.75D to +2.50D)
Cylinder Powers:	-0.75D, -1.25D, -1.75D, -2.25D and -2.75D
Axis:	10° to 180° in 10° increments for -0.75D, -1.25D and -1.75D 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, and 180° for -2.25D and -2.75D

*Additional powers may be introduced over time, check periodically for product availability.

HOW THE LENS WORKS (ACTIONS)

In its hydrated state, the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

INDICATIONS

Single Vision Spherical (SVS) Vision Correction
The Bausch + Lomb ULTRA® (samfilcon A) Contact Lens is indicated for daily wear or extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

Presbyopia Vision Correction
The Bausch + Lomb ULTRA® (samfilcon A) Contact Lens for Presbyopia is indicated for daily wear or extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for add powers ranging from +0.75D to +5.00D.

Astigmatism Vision Correction
The Bausch + Lomb ULTRA® (samfilcon A) Contact Lens for Astigmatism is indicated for daily wear or extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism up to 5.00 diopters.

Multifocal for Astigmatism Vision Correction
The Bausch + Lomb ULTRA® (samfilcon A) Multifocal for Astigmatism Contact Lens is indicated for daily wear or extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters and require an add power ranging from +0.75D to +5.00D.

Frequent/Planned Replacement Wear
When prescribed for Frequent/Planned Replacement Wear, the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.

Disposable Wear
When prescribed for Disposable Wear, the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens is to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens, Bausch + Lomb ULTRA® (samfilcon A) Contact Lens for Presbyopia, Bausch + Lomb ULTRA® (samfilcon A) Contact Lens for Astigmatism, and Bausch + Lomb ULTRA® (samfilcon A) Multifocal for Astigmatism Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)

- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS

After a thorough eye examination, including appropriate medical background, patients should be fully apprised by the prescribing professional of all the risks with contact lens wear. **Patients should be advised of the following warnings pertaining to contact lens wear:**

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care practitioner's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear lenses are not indicated for overnight wear, and **patients should be instructed not to wear lenses while sleeping**. Clinical studies have shown that the risk of adverse reactions is increased when daily wear lenses are worn overnight.
- When prescribed for Frequent/Planned Replacement Wear, the need for strict compliance with the lens care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule should be emphasized to the patient.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove the lenses** and promptly contact his or her eye care practitioner.

Extended Wear

The risk of microbial keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfecting or disposal schedule has not been adhered to by the patient; improper lens disinfection or cleaning by the patient; contamination of lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants.

While the great majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates, and endothelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.

The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, practitioners' views of extended wearing times vary from not prescribing extended wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing extended wearing periods up to 7 days with specified intervals of no lens wear for certain patients, with follow-up visits, and with proper care regimen.

PRECAUTIONS

Special Precautions for Eye Care Practitioners

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers.

  Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the prescribing eye care practitioner should carefully monitor the continuing ocular health of the patient and lens performance on eye.
- Eye care practitioners should instruct the patient to REMOVE A LENS IMMEDIATELY if an eye becomes red or irritated.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with sterile saline solution that is recommended for in-eye use.
- The patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care practitioner.
- As with any contact lens, follow-up visits are necessary to ensure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Aphakic patients should not be fitted with Bausch + Lomb ULTRA® (samfilcon A) Contact Lenses until the determination is made that the eye has healed completely.
- Patients who wear aspheric contact lenses, such as the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens for Presbyopia, to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Eye care practitioners should carefully instruct patients about the following lens care and safety precautions. It is strongly recommended that patients be provided with a copy of the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens Patient Information Booklet available from Bausch + Lomb and understand its contents prior to dispensing the lenses.

Handling Precautions

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Be sure that before leaving the eye care practitioner's office, the patient is able to remove lenses promptly or have someone else available to remove them.
- Be certain that the fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle lenses carefully and avoid dropping them.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the Patient Information Booklet for the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens and those prescribed by the eye care practitioner.

- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Lens Wearing Precautions

- Never wear lenses beyond the period recommended by the eye care practitioner.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking (Non-Moving) Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Solution Precautions

Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer's labeled lens care instructions with the patient.

- Always use **fresh, unexpired** lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Fill the lens case with fresh solution every time the lenses are stored and never "top-off" or re-use solution. Discard the solution immediately after the lenses have been removed from the lens case.
- Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn (stored). Prolonged periods of drying will damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens in the Patient Information Booklet if lens surface does become dried out.
- Do not use saliva or anything other than the recommended solution for lubricating or wetting lenses.
- Tap water, distilled water or homemade saline should not be used as a substitute for any component in the lens care regimen since they have been associated with an *Acanthamoeba* keratitis infection.

- Never use conventional hard contact lens solutions that are not also recommended for use with prescribed lenses.
- Do not mix or alternate lens care systems or solutions unless indicated in the lens care system labeling.
- Do not heat the chemical disinfection solution or lenses.

Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air-dry.
- Lens cases should be replaced at least every three months or as recommended by the lens case manufacturer or eye care practitioner.

Topics to Discuss with the Patient

- As with any contact lens, follow-up visits are necessary to ensure the continuing health of the eyes. The patient should be instructed as to a recommended follow-up schedule.
- Patients should be advised 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.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.

Who Should Know That the Patient is Wearing Contact Lenses

- Patients should inform their doctor (health care professional) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you do not wear lenses.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to

- **Immediately remove the lenses.**
- If the discomfort or problem stops, the patient should look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult his or her eye care practitioner.**

  If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should **immediately remove the lenses and contact his or her eye care practitioner** or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial staining or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare, and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combination may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

SELECTION OF PATIENTS

The eye care practitioner should not fit patients who cannot or will not adhere to a recommended care or replacement regimen, or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and cleaning instructions could lead to serious eye infections which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also to ensure compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.

Patients selected to wear Bausch + Lomb ULTRA® (samfilcon A) Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part time), and desired lens usage (reading, recreation, or hobbies).

Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes), and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear.

If these symptoms persist, the patient should be instructed to contact his or her eye care practitioner.

PRACTITIONER FITTING SETS

Lenses must be discarded after a single-use and must not be used from patient to patient.

GENERAL FITTING PROCEDURE

1. Pre-Fitting Examination

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

- Determine whether a patient is a suitable candidate for contact lenses (consider patient hygiene and mental and physical state),
- Make ocular measurements for initial contact lens parameter selection, and
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include spherocylinder refraction and Visual Acuity (VA), keratometry, and biomicroscopic examination.

2. Initial Lens Power Selection

a. Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane. Select the appropriate lens and place on the eye.

b. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics. The time required will vary with the individual.

c. Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. Initial Lens Evaluation

a. To determine proper lens parameters, observe the lens relationship to the eye using a slit lamp.
   - Movement: The lens should provide discernible movement with:
     – Primary gaze blink
     – Upgaze blink
     – Upgaze lag
   - Centration: The lens should provide full corneal coverage

b. Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens. If after the lens has settled on the eye, the patient reports lens sensation, or if the lens is moving or decentering excessively, the lens should not be dispensed. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, the lens should not be dispensed.

4. Criteria of a Well-Fitted Lens

If the lens fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient, and provides satisfactory visual performance, it is a well-fitted lens and can be dispensed.

5. Characteristics of a Tight (Steep) Lens

A lens which is much too steep may subjectively and objectively cause distortion which will vary after a blink. However, if a lens is only marginally steep, the initial subjective and objective vision and comfort findings may be quite good. A marginally steep lens may be differentiated from a properly fitted lens by having the patient gaze upward. A properly fitted lens will tend to slide downward approximately 0.5mm while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

Toric Lens: With your finger, gently rotate the lens approximately 45° to the temporal side. It should reorient with 5 to 10 blinks back to the same stabilized position.

6. Characteristics of a Loose (Flat) Lens

A lens that is too flat will decenter, especially on post-blink, have a tendency to edge lift inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva. A flat fitted lens will have a tendency to be uncomfortable and irritating with fluctuating vision. A flat fitted lens has a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

7. Follow-Up Care

a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, the following schedule is a suggested guideline for follow-up.
   - 24 hours
   - 1 to 2 weeks
   - Every six months thereafter

   At the initial follow-up evaluations the eye care practitioner should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief. Depending on the patient's prior experience with contact lenses and/or continuous wear, the eye care practitioner may consider prescribing a one week period of daily wear adaptation prior to beginning continuous wear.

b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear. If the patient is wearing the lenses for continuous wear, the follow-up examination should be conducted as early as possible the morning after overnight wear.

c. With lenses in place on the eyes, evaluate fitting performance to ensure that Criteria of a Well-Fitted Lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

d. After the lens removal, instill sodium fluorescein [unless contraindicated] into the eyes and conduct a thorough biomicroscopy examination.
   1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.
   2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
   3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

   If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the Criteria of a Well-Fitted Lens are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

TORIC FITTING GUIDELINES

a. Determine contact lens power. The toric trial lens is used to optimize lens fitting characteristics and determine axis orientation. Lens power is determined by the spectacle refraction. It is preferable to use the spectacle Rx as the basis for the contact lens power. The sphere and cylinder power of the spectacle Rx becomes the closest sphere and cylinder power of the contact lens.

   There are two exceptions:

   1. If spectacle cylinder power falls between available contact lens cylinder powers, prescribe the lesser contact lens cylinder power. The sphere power can be increased -0.25D to compensate if desired. Of course, this can vary depending on your interpretation of the patient's subjective responses.

      Example: Spectacle Rx: -2.00-1.00 X 180
      Contact Lens Power Ordered: -2.25-0.75 X 180

   2. When the spectacle lens power in any principal meridian is greater than 4.00D, the spectacle refraction should be vertexed to the corneal plane. This can affect both the sphere and cylinder powers ordered.

      Example: Spectacle Rx: -5.00-2.75 X 180
      Contact Lens Power Ordered: -4.75-2.25 X 180

b. Determine contact lens axis, the center guide mark should locate at the Inferior limbus. Once oriented, rotational rocking should be limited to less than 5°.

c. Allow the lens to settle for at least 3 minutes to achieve a state of equilibrium. Note the orientation of the guide mark relative to the vertical meridian. Regardless of which eye the lens is on, if the rotation is clockwise but stable, note the amount of rotation, add it to the refractive cylinder axis and order the resulting axis. If the rotation has stabilized counterclockwise, again note the rotation, subtract it from the refractive axis and order the resulting axis. The guide mark can be used to help you calculate the axis of the desired Rx lens.

   Example: Spectacle Rx: -2.50-1.25 X 80
   Rotation: 20° clockwise
   Final Lens Prescription: -2.50-1.25 X 100

d. Select patient's lenses.

e. Evaluate orientation of final Rx lenses. The orientation of the prescription should be the same as that observed for the trial lenses. For example, if the trial lens rotated clockwise 15° then the final prescription lens should also rotate clockwise 15°.

MULTIFOCAL FITTING GUIDELINES

1. Lens Selection

a. Update spectacle refraction and Add power.

b. Determine ocular dominance for distance vision.

c. Select lens distance prescription based upon spherical equivalent from spectacle prescription, adjusted for vertex distance if necessary.

d. Choose trial lenses based upon the above calculation and select Add power.
   - Bausch + Lomb ULTRA® for Presbyopia Low Add: +0.75D to +1.50D
   - Bausch + Lomb ULTRA® for Presbyopia High Add: +1.75D to +2.50D

2. Lens Fitting

a. Allow lens to equilibrate for at least 10 minutes before assessing fit and vision.

b. Evaluate distance and near vision binocularly in normal room illumination.

c. If vision at distance and near are satisfactory, dispense lenses and schedule follow-up exam within 1 to 2 weeks.

3. To Refine Near Vision

If patient is wearing two Low Add lenses:

- Refinement 1:
  Place Bausch + Lomb ULTRA® for Presbyopia High Add in non-dominant eye while keeping Bausch + Lomb ULTRA® for Presbyopia Low Add in dominant-eye.
- Refinement 2:
  If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1:
  Add +0.25D to the non-dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using handheld lenses.

4. To Refine Distance Vision

If patient is wearing two Low Add lenses:

- Refinement 1:
  Fit Bausch + Lomb ULTRA® SVS in dominant eye while keeping Bausch + Lomb ULTRA® for Presbyopia Low Add in non-dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, add -0.25D at a time to dominant eye using hand held lenses. Adjust contact lens power when vision is satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1:
  Fit with Bausch + Lomb ULTRA® for Presbyopia Low Add in dominant eye while keeping Bausch + Lomb ULTRA® for Presbyopia High Add in non-dominant eye.
- Refinement 2:
  If vision is still unsatisfactory, add -0.25D at a time to dominant eye using hand held lenses. Adjust contact lens power when vision is satisfactory.

5. Patient Education

All patients do not function equally well with multifocal correction. Patients may not perform as well for certain tasks with this correction as they have with multifocal reading glasses. Each patient should understand that multifocal correction 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 multifocal contact lenses provide.

MULTIFOCAL FOR ASTIGMATISM FITTING GUIDELINES

Adapt the fitting principles described in the GENERAL FITTING PROCEDURE, TORIC FITTING GUIDELINES followed by those in the MULTIFOCAL FITTING GUIDELINES.

MONOVISION FITTING GUIDELINES

1. Patient Selection

a. Monovision Needs Assessment
   For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than one [1] diopter) in one eye may not be a good candidate for monovision with the Bausch + Lomb ULTRA® (samfilcon A) Contact Lenses.

   Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should 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 their state driver's license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

b. Patient Education
   All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision 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.

2. Eye Selection

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

a. Ocular Preference Determination Methods
   - Method 1–Determine which eye is the "sighting dominant 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 with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

b. Refractive Error Method
   For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

c. Visual Demands Method
   Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction, correct the eye on that side for near.

   Example:
   A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Considerations

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

Example:
A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 diopter lens on the near eye and the other eye left without a lens.

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.

4. 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.

5. Trial Lens Fitting

A trial 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.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power 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 distant 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 newsprint and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under conditions with caution.

7. Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below:

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.

- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.
- **The decision to fit a patient with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering the patient's needs.**
- **All patients should be supplied with a copy of the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens Patient Information Booklet.**

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Regular checkups, as determined by the eye care practitioner, are extremely important.

Daily Wear

There may be a tendency for the daily wear patient to over wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

Continuous Wear (greater than 24 hours or while asleep)

Bausch + Lomb recommends the contact lens wearer first be evaluated on a daily wear schedule. If successful, then gradual introduction of extended wear can be followed as determined by the prescribing eye care practitioner.

These lenses have been approved for extended wear for up to 7 days. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eye care practitioner. (See the factors discussed in WARNINGS section.) **Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the eye care practitioner.**

Disposable Lens Wear

No lens care is needed. The lenses are discarded every time they are removed from the eye. Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

Frequent/Planned Replacement Wear

When removed between replacement periods, lenses must be cleaned and disinfected before reinsertion, or be discarded and replaced with a new lens.

HANDLING OF LENS

Patient Lens Care Directions

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care practitioner should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system selected by the professional, the specific instructions for such products and the particular characteristics of the patient.

Frequent/Planned Replacement Wear

For complete information concerning the care, cleaning and disinfection of contact lenses refer to the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens Patient Information Booklet.

Disposable Wear

For complete information concerning emergency lens care, refer to the Bausch + Lomb ULTRA® (samfilcon A) Contact Lens Patient Information Booklet.

a. Soaking and Storing Lenses

Instructions for Use:

Use only fresh contact lens disinfecting solution each time you soak (store) your lenses.

WARNING:

Do not re-use or "top-off" old solution left in lens case since solution re-use reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-off" is the addition of fresh solution to solution that has been sitting in the case.

b. Rub and Rinse Time

Instructions for Use:

Follow the complete recommended lens rubbing and rinsing times in the labeling of the solution used for cleaning, disinfecting and soaking lenses to adequately disinfect lenses and reduce the risk of contact lens infection.

WARNING:

- Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections.
- **Never use water**, saline solution, or rewetting drops to disinfect lenses. These solutions will not disinfect lenses; not using the recommended disinfectant can lead to serious infection, vision loss or blindness.

c. Lens Case Care

Instructions for Use:

- Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solution/contact lens cleaner. **Never use water.** Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions **(never use water)** and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry.
- Replace lens case at least every three months, or as directed by your eye care practitioner.
- Contact lens cases can be a source of bacterial growth.

WARNING:

Do not store lenses or rinse lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

d. Water Activity

Instructions for Use:

Do not expose contact lenses to water while wearing them.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water when swimming in pools, lakes, or oceans, discard them and replace them with a new pair. Ask your eye care practitioner for recommendations about wearing lenses during any activity involving water.

e. Discard Date on Solution Bottle

Instructions for Use:

Discard any remaining solution after the recommended time period indicated on the bottle of the solution used for disinfecting and soaking contact lenses.

WARNING:

Using solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rewetting solution in their eye. The patient should be instructed to **not** use plain water, or anything other than the recommended solutions. The patient should be instructed to contact the eye care practitioner if the lens does not begin to move upon blinking after several applications of the solution, and to not attempt to remove the lens except on the advice of the eye care practitioner.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb ULTRA® (samfilcon A) Contact Lenses or experienced with the lenses should be reported to:

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, New York 14609 USA
Toll Free Telephone Number
In the Continental U.S., Alaska, Hawaii
1-800-553-5340
In Canada
1-888-459-5000 (Option 1 – English, Option 2 – French)

HOW SUPPLIED

Each sterile lens is supplied in a plastic blister package containing borate buffered saline with poloxamine solution. The container is marked with the manufacturing lot number of the lens, the base curve, sphere, diameter, and expiration date.