PROFESSIONAL FITTING AND INFORMATION GUIDE FOR DAILY WEAR CORNEAL, SEMI-SCLERAL AND SCLERAL LENSES

Acuity 100™ (hexafocon A)
Rigid Gas Permeable Contact Lenses

CAUTION: Federal (U.S.A) law restricts this device to sale by or on the order of a licensed eye care professional.

Acuity | 100

TABLE OF CONTENTS

	Page
Introduction	2
Description	2
Lens Parameters Available	2
Actions	3
Indications (Uses)	3
Contraindications	3
Warnings	4
Precautions	5
Adverse Reactions	7
Selection of Patients	7
Preparing an RGP Lens for Fitting	8
Pre-fitting Examination	8
Fitting Procedure	9
1. Spherical and Aspheric Designs	9
2. Acuity Polymers Toric Designs	10
3. Multifocal Lenses	12
4. Irregular Cornea Fitting Procedures	15
Follow-up Care for All Lenses	17
In-Office Care of Trial Lenses	17
Recommended Initial Wearing Schedule	17
Clinical Assessment	17
Monovision Fitting Guidelines	17
Semi-scleral and Scleral Lens Fitting Guidelines	19
Handling of Acuity 100™ (hexafocon A) Contact Lenses	21
Patient Lens Care Directions	21
Care for a Sticking (Non-Moving) Lens	22
How Supplied	22
Reporting of Adverse Reactions	22

INTRODUCTION

The Acuity 100™ (hexafocon A) Contact Lens is composed of aliphatic siloxanyl fluoromethac - rylate copolymer with a UV light absorber. The lens is available in clear, blue, ice blue, violet, and green tints. The tinted lenses contain the following color additives:

Color	Color Additive
Blue	D & C Green No. 6
Ice Blue	D & C Green No. 6
Violet	D & C Violet No. 2
Green	D & C Green No. 6 Solvent Yellow 18

For a complete list of available lens parame - ters, please refer below.

DESCRIPTION

The Acuity 100™ (hexafocon A) Rigid Gas Per - meable Contact Lens is available as a spherical, aspheric, prism ballast toric or prism ballast multifocal design, for daily wear only.

Semi-scleral and scleral lenses are available for daily wear only.

Lenses for the management of irregular cor - neas are available for daily wear only.

LENS PARAMETERS AVAILABLE

(Note: not all parameter combinations are available in all designs)

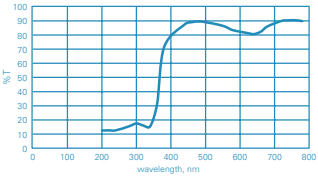
Spherical and Aspheric Lens:	
Diameter	7.0 to 21.0mm
Base Curve Range	4.00 to 11.50mm
Power Range	-20.00 to +20.00D (in 0.25D steps)
Toric Lens:	
Diameter	7.0 to 21.0mm
Base Curve Range	4.00 to 11.50mm
Power Range	-20.00 to +20.00D (in 0.25D steps)
Toricity	Up to 9.00 Diopters
Multifocal Lens (Centered, Decentered, Crescent):	
Diameter	7.0 to 21.0mm
Base Curve Range	4.00 to 11.50mm
Power Range	-20.00 to +20.00D
Add Power	+1.00 to +3.75D
Segment Heights	-2.00mm to +1.00mm
Prism Ballast	0.5 to 3.5 prism diopters

The lenses above can have a center thickness (CT) of 0.07 to 0.65mm, depending on the design, power and diameter of the lens.

The physical/optical properties of the lens are:

Hardness, Shore D:	80
Specific Gravity:	1.27
Refractive Index:	1.415
Light Absorbance (640nm)	8.5 Blue Tint
Light Absorbance (640nm)	5.3 Ice Blue Tint
Light Absorbance (585nm)	5.3 Violet Tint
Light Absorbance (640nm)	4.9 Green
Surface Character:	Hydrophobic
Wetting Angle (advancing/receding):	79/23° degrees
Light Transmittance:	89% [average %T (380-780nm)]
Water Content:	Less than 1.0% by weight
Oxygen Permeability: Edge Corrected	111 *

*ISO/Fatt Method: DKUnits=x10^{-11}(cm^3 O$_2$X(cm)/(sec)(cm^2)(mmHg)]@35°C



ACUITY 100™ (hexafocon A) Contact Lens - Spectral transmittance curve for Acuity 100™ (hexafocon A) Contact Lens - Ice Blue Tint and UV absorbing agent (sample thickness Acuity 100™ (hexafocon A) lens thickness = 0.12mm.

NOTE

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

ACTIONS

The Acuity 100™ (hexafocon A) Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina. The Acuity 100 semi-scleral and scleral contact lens when placed on the conjunctiva, vaults over the cornea and acts as a refracting medium to focus light rays on the retina.

The Acuity 100™ (hexafocon A) Contact Lens is a lathe cut firm contact lens with spherical or aspheric back surfaces. The posterior curve is selected to properly fit an individual eye, and the anterior curve is selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

The Acuity 100™ (hexafocon A) Toric Contact Lens provides a more even surface over the different curvatures of the astigmatic cornea and thus helps to focus light rays on the retina.

The Acuity 100™ (hexafocon A) Multifocal Contact Lens provides the necessary optical powers to correct different refractive errors for distance and near requirements.

INDICATIONS (Use)

The Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens is available as a spherical, aspheric, prism ballast toric or multifocal design and prism ballast multifocal lenses are indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

The lenses may be prescribed for daily wear in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery.

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

CONTRAINDICATIONS (Reasons not to use)

DO NOT USE the Acuity 100™ (hexafocon A) Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior segment of the eye
- Any eye disease, injury, or abnormality (other than irregular corneal conditions as described in the "Indications" Section) that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes), except when using a semi-scleral or scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and the contact lens
- Corneal hypoesthesia (reduced corneal sensitivity), except when using a semi-scleral or scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and the contact lens and acts as a protective barrier for the cornea
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the Acuity 100™

(hexafocon A) Contact Lens

- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated
- Incomplete healing following eye surgery

WARNINGS

Problems with contact lenses and lens care products could result in serious injury to the eye.

It is essential that the patient follows the direc - tions of the eye care practitioner and all labeling instructions for proper use of contact lenses and lens care products, including the lens case.

Patients should be advised of the following instructions for use and warnings pertaining to contact lens wear:

1. Soaking and Storing Your Lenses

   Instruction for Use:
   Use only fresh multi-purpose (contact lens disinfecting) solution each time you soak (store) your lenses.

   WARNING:

   Do not reuse or "top off" old solution left in your lens case since solution reuse 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 your case.

2. Rub and Rinse Time

   Instruction for Use:
   Rub and rinse your lenses according to the recommended lens rubbing and rinsing times in the labeling of your multi-purpose solution to adequately disinfect your lenses.

   WARNING:
   Rub and rinse your lenses for the recom - mended amount of time to help prevent serious eye infections.

   Never use water, saline solution, or rewetting drops to disinfect your lenses. These solu - tions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

3. Lens Case Care

   Instruction for Use:
   Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfect - ing solutions/contact lens cleaner. Never use water. Cleaning should be followed by rins - ing 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 your lens case according to the directions given you by your eye care professional or the labeling that came with your case.

   Contact lens cases can be a source of bacterial growth.

   WARNING:

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

4. Water Activity

   Instruction for Use:

   Do not expose your contact lenses to water while you are wearing them.

   WARNING:

   Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been sub- mersed in water when swimming in pools, lakes or oceans, you should discard them and replace them with a new pair. Ask your eye care practitioner (professional) for rec - ommendations about wearing your lenses during any activity involving water.

5. Discard Date on Multipurpose Solution Bottle

   Instruction for Use:

   Discard any remaining solution after the recommended time period indicated on the bottle of multipurpose solution used for dis - infecting and soaking your contact lenses.

   The Discard date refers to the time you can safely use contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

   WARNING:

   Using your multi-purpose solution beyond the discard date could result in contamina - tion of the solution and can lead to severe infection, vision loss or blindness.

   To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.

   To avoid contaminating your solution, DO NOT transfer to other bottles or containers.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF YOU EXPERIENCE:

- Eye Discomfort
- Excessive Tearing
- Vision Changes
- Loss of Vision
- Eye Redness
- Or Other Eye Problems

YOU SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

- 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 serious adverse reactions is increased when these lenses are worn overnight.

- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care professional's 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 serious adverse reactions is increased when daily wear lenses are worn overnight.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when lenses are worn overnight or while sleeping. [1,2]
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care professional.
- UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. Persons should continue to use their protective UV-absorbing eyewear as directed.
- Never use tap water.
- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water such as when swimming in pools, lakes or oceans, you should thoroughly clean and disinfect them before insertion. Ask your eye care professional for recommendations about wearing your lenses during any activity involving water.

[1]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

PRECAUTIONS:

CAUTION: non-sterile. Always clean and disinfect lenses prior to use.

Special Precautions for Eye care Professionals:

- 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 and wear schedule for a patient, the eye care professional should consider all lens characteristics that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care professional.
- The following patients may experience a higher rate of adverse effects associated with contact lens wear:
  - Patients with a history of acute inflammatory reactions to contact lens wear.
  - Patients with a history of giant papillary conjunctivitis associated with contact lens wear.
  - Patients with a history of ocular allergies may need to temporarily discontinue lens wear during certain times of the year.
  - Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule, or follow-up visit schedule.
  - Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.
  - Patients who are unwilling or unable to adhere to a recommended care regimen, or who are unable to insert and remove lenses, should not be provided with them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The use of fluorescein is contraindicated in those persons who have a known hypersensitivity to any component.
- The presence of the ultraviolet (UV) light absorber in the Acuity 100™ (hexafocon A) Contact Lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Aphakic and other post-surgical persons should not be fitted with Acuity 100™ (hexafocon A) Contact Lenses until the de - termination is made that the eye has healed completely.
- Upon receipt, lenses should be cleaned and conditioned prior to first insertion, following the manufacturer's instructions on the use of the contact lens solutions.
- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best-corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- It is advised that wound healing and corneal curvature are stable prior to fitting Acuity 100™ lenses for post-surgical or other compromised corneas.

Eye care professionals should carefully instruct patients about the following care regimen and safety precautions. It is strongly recommend - ed that patients be provided with a copy of the Patient Instructions for the Acuity 100 ™ (hexafocon A) Rigid Gas Permeable Contact Lens available from Acuity Polymers Inc. 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.
- Before leaving the eye care professional's of- fice, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the Acuity 100™ (hexafocon A) Contact Lens and those prescribed by the eye care professional.
- Never use tweezers or other tools to remove lenses from the lens container unless specifi - cally indicated for that use.

Solution Precautions:

- 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.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may reduce the ability of the lens surface to return to a wettable state.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Do not heat the cleaning, wetting, and/or soaking solution and lenses. Keep away from extreme heat.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the Acuity 100™ (hexafocon A) Contact Lenses.

Lens Wearing Precautions:

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

Lens Case Precautions:

- Contact lens cases can be a source of bacte- rial growth. Lens cases should be emptied, cleaned, rinsed with the sterile contact lens solution recommended by the lens case manufacturer (never use tap water), and allowed to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens manufacturer or your eye care professional.

Topics to Discuss with the Patient:

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

- Patients should be advised about wearing lenses during water activities and other sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- Always contact the eye care professional before using any medicine in the eyes.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, oral contraceptives and motion sickness medications. Caution patients using such medications accordingly and prescribe proper remedial measures.

Who Should Know That the Patient is Wearing Contact Lenses:

- Patients should inform the doctor (health care professional) about being a contact lens wearer.
- Patients should always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact 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 that something is in the eye such as a foreign body or 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 lenses.
- If the discomfort or problem stops, then 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 professional. 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 the eye care professional .

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 professional 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.

During use for the management of irregular corneal conditions, an adverse effect may be due to the original condition or may be due to the effects of wearing a contact lens. There is a possibility that the existing condition might become worse when a lens is used on an eye with an irregular corneal condition. The patient should be instructed to avoid serious eye damage by contacting the eye care professional IMMEDIATELY if there is an increase in symptoms while wearing the lens.

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, anterior chamber 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 combinations 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 Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens is available as a spherical, aspheric, prism ballast toric or multifocal design and prism ballast multifocal lenses are indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

The lenses may be prescribed for daily wear in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery.

Persons who require only vision correction and who would not or could not adhere to a recommended care regimen for the Acuity 100™ (hexafocon A) Contact Lens 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 ensuring patient compliance.

The patient characteristics necessary to achieve success with Acuity 100 ™ lenses are similar to those for other rigid gas permeable contact lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for rigid gas permeable contact lens wear. It is necessary to make an assessment of general health, patient hygiene, motivation and the willingness to comply with practitioner instructions.

PREPARING AN RGP LENS FOR FITTING

Acuity 100™ (hexafocon A) Contact Lenses should be thoroughly cleaned with the recommended cleaning solution and disinfected/hydrated in the recommended soaking/conditioning solution according to the labeled directions for use prior to placement on the eye to insure maximum surface wettability.

PRE-FITTING EXAMINATION

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

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

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 of the cornea, bulbar conjunctiva, and limbus, anterior chamber and tarsal abnormalities.

The following evaluations apply to all Corneal lens designs:

1. Characteristics of a Well-Fit Lens

   A good fit positions appropriately following the blink with minimal lag and the optical portion of the lens does not deviate from the pupil when the lens is drawn upwards. Ideally, the lens will ride up with the blink and then quickly return to a position of rest.

2. Characteristics of a Steep Lens

   A steep lens usually shows restricted movement. The fluorescein pattern will show central pooling, excessive intermediate bearing with inadequate edge lift.

3. Characteristics of a Flat Lens

   A flat lens will often position high under the upper lid or drop rapidly when released from the lid. This lens may be comfortable for the patient, but often provides poor vision. The fluorescein pattern will show central bearing or touch when the lens is centered on the eye. Horizontal decentration or movement may also indicate a flat lens.

4. Fluorescein Evaluation

   The fluorescein pattern should indicate good tear exchange with an alignment lens-to-cornea relationship. The presence of the ultraviolet (UV) light absorber in the Acuity 100™ (hexafocon A) Contact Lens material requires the addition of a yellow Wratten filter modification of the Slit Lamp and Burton lamp to visualize the fluorescein pattern adequately.

The following evaluations apply to all Semi-scleral and Scleral lens designs:

1. Characteristics of a Well-Fit Lens

   A good fit positions centered over the cornea or may lag slightly inferiorly. There is little or no movement of the lens with blinking. The lens completely vaults the cornea and the limbus. The fitting zone of the lens settles into the conjunctiva and aligns to the sclera.

2. Characteristics of a Tight Fitting Lens

   A tight lens usually shows blanching of the bulbar conjunctival blood vessels as they pass under the fitting zone of the lens. There may be impingement of the larger blood vessels resulting in localized conjunctival congestion and inflammation. There may be no fluorescein/tear flow under the lens.

3. Characteristics of a Flat Fitting Lens

   A flat fitting lens will have an area of corneal touch or bearing. This will usually result in localized epithelial staining in the area of lens bearing. This lens may initially be comfortable for the patient, but wear time is usually reduced due to increased discomfort with normal lens wear. The fluorescein pattern will show bearing or touch at the apex of the cornea, or where the elevation of the cornea is highest. Edge lift off may also indicate a flat fitting lens.

4. Fluorescein Evaluation

   The fluorescein tear flow test will demonstrate tear flow behind a semi-scleral or scleral lens. Fluorescein is applied to the front surface of a lens that has settled for the appropriate time (usually 20-30 minutes or longer). Fluorescein can be seen as it percolates behind the contact lens and colors the fluid in the chamber between the lens and the cornea. This is best seen and

evaluated using an optic section and white light at high intensity.

The fluorescein pattern can also be evaluated by adding fluorescein to the fluid in the bowl of the lens during lens application to the eye. The patient is instructed to position his/her head parallel to the floor and to look directly down.

The bowl of the lens is filled with non-preserved saline. A fluorescein strip is dipped into the saline, adding fluorescein to the solution. The lens is placed on the eye and allowed to settle for several minutes. The fluorescein pattern can be evaluated using cobalt blue light and a yellow Wratten filter. The lens is allowed to settle on the eye for 20-30 minutes or longer and the fluorescein pattern is again evaluated.

This method of lens evaluation will demonstrate areas of bearing, alignment and clearance. To estimate the amount of lens clearance, the practitioner must use an optic section and white light. Estimation of the fluid layer thickness can be made by referencing the thickness of the fluorescein colored green fluid in the optic section to the known thickness of the contact lens also seen in the optic section.

The presence of the ultraviolet (UV) light absorber in the Acuity 100™ (hexafocon A) Contact Lens material requires modification of the Burton lamp to visualize fluorescein patterns adequately.

5. Bubble Evaluation

Immediately upon lens insertion, inspection of the fit for bubbles trapped under the lens is made. If any are present, the lens is removed and reapplied. A properly placed lens will not have bubbles present in the fluid layer after insertion.

FITTING PROCEDURE

General Prescribing and Fitting Guidelines

Acuity Polymers provides the contact lens fitting professional with a choice of designs to accommodate most physical and optical requirements. Spherical lenses and aspheric designs are sufficient for the majority of single vision and monovision prescribing needs, and toric and multifocal lenses are available for patients with more specialized fitting and/or optical needs.

The use of Acuity 100™ (hexafocon A) Contact Lens material on irregular corneas may require ordering lenses outside of the standard parameters used for healthy eyes. The modifications of base curve to peripheral lens curve relationships, reverse geometry curves to control the sagittal height of the lens, lens diameters and thickness profiles will frequently be necessary to optimize the fitting relationship for each individual eye. Standard measuring and testing equipment and ordering by keratometric and refractive measurements is generally inadequate in designing lenses for these conditions. Whenever possible, it is recommended that trial lenses designed for keratoconus, pellucid marginal degeneration, penetrating keratoplasty or refractive (e.g., LASIK) surgery be used by the practitioner to evaluate fitting relationships and to be able to better predict the success of such lens designs In most cases, multiple lens orders and parameter adjustments will be necessary to achieve and optimum fit. Corneal topography may be required to gain insight into the peripheral corneal geometry. If topography reveals an oblate corneal surface (steeper in the periphery relative to the central cornea, commonly seen after LASIK or penetrating keratoplasty) a reverse geometry lens will often be required. If the topography reveals high regular astigmatism, a bitoric lens design will often be required. If topography reveals a very defined and localized area of steepening and ectasia as in keratoconus, a keratoconus design which may include a decentered optic zone may be indicated. Large diameter lenses may also be indicated in highly irregular corneas where lens stability is difficult to achieve with smaller corneal lens designs.

The general requirements and recommendations for fitting each type of lens are detailed below.

Please refer to the Semi-scleral and Scleral Lens Fitting Guidelines found later in this booklet for additional information regarding the fitting of these lens designs.

1. SPHERICAL AND ASPHERIC DESIGNS

A. Initial Design Selection

The table below lists the various spherical and aspheric designs available from Acuity Polymers, and recommendations for use.

Design	Description	Recommended uses
Aspheric	• Back surface low eccentricity aspheric design with junctionless periphery • Thin design • Designed for alignment fit, with diameters to provide under lid positioning • Low to moderate edge lift	• First time contact lens wearers • Soft toric candidates • Moderate with-the-rule astigmatism • Very helpful in cases where centration not ideal with spherical design • Easy to fit, design, order • Available for inventory fitting
Spherical	• Designed for interpalpebral or under lid alignment philosophy • Lenticulars standard to provide uniform edge profile across powers • Low to moderate edge lift • Standard thickness	• Current users or wearers of other standard thickness spherical designs • Moderate to high with-the-rule astigmatism or irregular corneas • Use when added mass or weight or thickness is desirable to minimize lid interaction

B. Initial Lens Diameter Selection

Lens centration and the interpalpebral distance are important factors in selecting a lens diameter. A diameter between 9.2mm and 9.6mm is recommended for lenses where a diameter choice is required. Ideally, the upper edge of the lens should be located at or near the superior lid and remain covered by the upper lid margin during the full cycle of each blink. It is important to verify that the optical zone of the lens covers the pupil adequately in dim light.

C. Initial Base Curve Selection

Acuity Polyners Spherical Design		
Corneal Astigmatism	**9.2mm Diameter**	**9.6mm Diameter**
0 to 0.75D	On K–0.25D FTK_{flat}	0.25D–0.50D FTK_{flat}
>1.00 to 1.75D	0.25D STK_{flat}–On K	On Kflat–0.25D FTK_{flat}
>2.00 to 2.50D	0.50D–0.25D STK_{flat}	0.25D STKflat–On K_{flat}
>2.50D	Recommend toric	Recommend toric

Acuity Polyners Aspheric Design	
Corneal Astigmatism	**Base Curve Selection**
0 to 0.75D	Fit on K_{flat} (round to next flatter BC)
1.00 to 1.75D	Fit on K_{flat} (round to next steeper BC)
2.00 to 2.50D	Fit 0.10mm steeper than K_{flat} (round to next steeper BC)
Greater than 2.50D	Consider bitoric design

D. Initial Lens Power Selection

1) Convert Rx to minus cylinder if necessary.
2) Correct for vertex distance if either meridian is greater than +/-4.00 using vertex distance chart.
3) Power will be equal to spherical component of the spectacle correction (corrected for vertex distance expressed in minus cylinder format) for an "On-K" fit.
4) SAMFAP (**S**teeper **A**dd **M**inus **F**latter **A**dd **P**lus) correction must be made if the lens is steeper or flatter than K (or than the trial lens used). Change the power by the dioptric equivalent of the change in base curve.

E. Characteristics of a Well-Fit Spherical/ Aspheric Lens

- The lens should center well over the pupillary zone on the cornea.
- The lens should move freely with the blink.
- The fluorescein pattern should show good tear exchange.

2. ACUITY POLYMERS TORIC DESIGNS

A. General Prescribing and Fitting Guidelines

The decision to move from a spherical to a toric lens design is based upon two factors, physical fit and optical requirements. Lenses can be designed with toric shapes and toric optics, toric shapes and spherical optics, or spherical back surfaces with toric optics. To help determine whether a toric lens is needed, the fitting professional should answer the following two questions.

1) Is there more than 2.50D with-the-rule (WTR) or 1.50D against-the-rule (ATR) corneal astigmatism (as measured by keratometry or topography)?

If yes, a toric back surface shape is recommended for an optimal lens-to-cornea relationship.

Calculation method:

- Subtract K reading closest to vertical or 90 degrees (K_V) from K reading closest horizontal or 180 degrees (K_H) using the dioptric values to get the corneal astigmatism value and orientation

  ➞ negative values indicate WTR astigmatism

  ➞ positive values indicate ATR astigmatism

EXAMPLE:

K's: 43.00@180/46.00@90

$K_H - K_V$ = 43.00 - 46.00 = -3.00D (WTR)

2) Is there a difference of more than 0.75D between the amount of corneal astigmatism (as measured by keratometry or topography) and the amount of refractive cylinder in the spectacle refraction (corrected for vertex distance to the corneal plane and expressed in minus cylinder format)?

If yes, toric optics may be required to provide optimal visual acuity.

Calculation method:

- Transpose spectacle Rx to minus cylinder format if necessary.
- Correct for vertex distance if either meridian exceeds ± 4.00 diopters
- Making sure signs are maintained, subtract the corneal cylinder (CylK) from refractive cylinder (Cyl Rx)

EXAMPLE:

K's: 43.00@180/46.00@90;
Rx_{Spec}:–6.75 + 3.75 x 90

Correct for vertex distance
–6.25 + 3.25 x 90

Transpose to minus cyl:
–3.00 – 3.25 x 180

Cyl_{Rx} - Cyl_K: –3.25 – (–3.00) = – 0.25
(spherical optics will be adequate)

The table below details the indications for the single vision designs offered by Acuity Polymers:

Design	Corneal cylinder	Refractive cylinder (at cornea)
Spherical or Aspheric	Low (under 2.50 WTR or 1.50 ATR)	CylRx–CylK
Back Toric	Moderate to high (over 2.50 WTR or 1.50 ATR)	CylRx–1.5X CylK
Front Toric	Low (under 2.50 WTR or 1.50 ATR)	CylRx-Cyl K > 0.75D
Bitoric (spherical power effect-SPE) Spherical optics	Moderate to high (over 2.50 WTR or 1.50 ATR)	CylRx–CylK
Bitoric (Cylindrical power equivalent-CPE) Toric optics	Moderate to high (over 2.50 WTR or 1.50 ATR)	CylRx-CylK > 0.75D

B. Diameter Selection

Acuity Polymers recommends beginning with a 9.6mm diameter. The horizontal diameter should provide coverage of approximately 80% of the horizontal visible iris diameter.

C. Base Curve Selection

The base curve for a front toric design should be selected according to the rules for a spherical lens.

For toric base curves (back torics and bitorics), the flat curve should be selected according to the rules for a spherical lens. The second curve should be steeper by an amount approximately 1 diopter less than the total corneal astigmatism for with-the-rule corneas to allow for movement and tear exchange. For against-the-rule corneas, up to 100% of the back surface astigmatism can be corrected to provide horizontal stability.

EXAMPLE:

K's: 43.00@180/46.00@90

K_H - K_V = 43.00 - 46.00 = -3.00 (WTR) or 3D total corneal astigmatism

Flat BC = on flat K = 43.00D (7.85mm)

Steep BC = 3 – 1 or 2 diopters steeper = 45.00D (7.50mm)

D. Power Selection

Front toric

Perform a sphero-cylindrical over-refraction of the best fitting spherical lens, and add the over-refraction to the power of the spherical lenses. Generally, 1.00 to 1.50 prism base down is added to stabilize the lens. The prism base can be moved in (base toward the patient's nose) or out (base toward patient's ear) to compensate for lens rotation if required.

EXAMPLE:

Spherical trial lens:
BC 7.80 DIA 9.2 POWER -3.00

Best spherical over-refraction
-1.00DS VA: 20/30

Sphero-cyl over-refraction:
-0.50 - 1.00 x 90 VA 20/15

Lens order:
7.80 9.2-3.50 -1.00 x 90 1 p.d. base down

Back toric

The use of a back toric only lens is rare, usually occurring in cases of significant against-the-rule corneal astigmatism. In these cases, the power determination is usually performed empirically. When the refractive astigmatism to corneal astigmatism ratio is between 1.3 and 1.5, a toric base lens is indicated.

EXAMPLE:

K's: 45.00/43.00@90 (pl - 2.00 x 90)

Rx: +2.00 - 3.00 x 90

Refractive/Corneal cyl ratio = 3/2 = 1.5
(back toric indicated)

Select base curves equal to corneal cylinder for ATR cornea
→ 43.00/45.00 for 9.2mm lens

Calculate the spherical power as for a spherical lens; the additional toric power needed will be created by the back surface. NOTE: This lens will have a cylindrical power when read in a lensometer.

Spherical Power Effect (SPE) Bitoric:

An SPE bitoric corrects only corneal astigmatism, just as a spherical lens does. The powers on an SPE are just as simple to calculate. The first power is calculated exactly as for a spherical lens, using the BC-cornea relationship and the SAMFAP rule, as outlined in the spherical fitting section. The second power is determined by the amount of toricity of the back surface of the lens. The second power will be more minus than the first by the dioptric value of the back surface cylinder.

EXAMPLE:

K's: 43.00@180/46.00@90;
$Rx_{\text{corneal plane}}$: – 1.00 – 2.75 x 180

BC selection (2D toricity, on K):
7.85/7.50mm (43.00/45.00D)

Power: –1.00/–3.00 (on K/2D more minus)

Cylindrical Power Equivalent (CPE) Bitoric:

A CPE bitoric corrects all refractive astigmatism, similar to a front toric. Its effectiveness will be affected by lens orientation and stability, as with front toric lenses. The powers on a CPE lens are best calculated as two separate lenses, one for the flat meridian and one for the steep meridian. Each meridian is calculated exactly as for a spherical lens, using the BC-cornea relationship and the SAMFAP rule, as outlined in the spherical fitting section.

EXAMPLE:

K's: 43.00@180/46.00@90;
Rx $_{\text{corneal plane}}$: – 1.00 – 3.75 x 180

Flat meridian: 43.00/–1.00; on K fit, 9.2mm diameter ➞ 7.85 mm (43.00D) / –1.00

Steep meridian: 46.00/–4.75; fit 1D flat, 9.2mm diameter ➞ 7.50mm (45.00D) / –3.75

Final lens order: 7.85/7.50 (43.00D/45.00D); 9.2mm diameter; –1.00/–3.75

3. MULTIFOCAL LENSES

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 bifocal reading glasses. Each patient should understand that multifocal lenses, 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 multifocal contact lenses provide.

Acuity Polymers Decentered Target Design Lens Fitting Procedure

The Acuity Polymers Decentered Target Design is a one-piece, back surface add bifocal which works primarily on the alternating or translating vision principle. It features a round distance zone decentered superiorly which allows a combination of simultaneous and translating vision options for optimal viewing at all distances. The back surface add eliminates image jump and associated blur or doubling at the distance-near junction.

The Decentered Target Design is excellent for patients who would do well in a spectacle lens with a progressive style of near add, who have the following characteristics:

Physical Features	Viewing Demands
Aperture size normal to large	Heavy near and intermediate requirements
Lower lid at or above lower limbus in primary gaze	Near and/or intermediate demands in all gazes
Upper lid in upper 1/3 of cornea or higher	Add requirements minimal to high
Pupil size average to large	
Spherical or low to moderate with-the-rule corneas	

A. Diameter Selection

Acuity Polymers recommends beginning with a moderate diameter with truncation for the initial lens (9.4/9.0mm). Lenses which are too large in the vertical diameter may interact excessively with the upper lid causing a lens which is held too high or too long after the blink, or which gets forced down behind the lower lid on down gaze.

The horizontal diameter should provide coverage of approximately 80% of the horizontal visible iris diameter. Vertically, the lower edge of the lens should rest on the lower lid or at the lower limbus, with the upper edge of the lens resting at or just under the upper lid margin. Generally, problems with lens translation should be addressed by altering the vertical (truncated) dimension of the lens. If the lower lid is too low to allow positioning of the optical zone over the pupil without excessive upper lid interaction, a centered target design should be used.

B. Base Curve Selection

The base curve should be selected to be approximately equal to or 0.50D steeper than the flattest keratometry reading. Steeper curves will limit the ability of the lens to translate up on down gaze, while flatter curves may result in lens instability. The Centered Target or Crescent Seg toric designs are indicated when corneal astigmatism exceeds 2.50D.

C. Power Selection

The distance power of the diagnostic lens should be as close to the patient's actual power as possible. The initial power should be calculated using the procedure outlined for spherical lenses. Distance power should be adjusted according to the over-refraction of the trial lenses using a trial frame and/or loose lenses whenever possible. The near add power should be approximately equal to the add power required in spectacle lenses. Add power should be assessed using the range of useable vision for the required text size rather than strictly by visual acuity.

D. Seg Height and Distance Zone Size Selection

Acuity Polymers recommends an initial seg height of 4.0mm with a 4.5mm distance zone. When viewed with fluorescein, the distance zone should be visible as a bright green round pool centered over the pupil in primary gaze. Seg height should be evaluated with the best distance over-refraction in place in trial lenses (do not use a phoropter for near testing). The patient should place normal reading material at their normal reading distance at a point just above eye level, and move it down in an arc to their normal reading position, keeping their chin up and moving only their eyes. Ask them to note when the print changes from blurry to clear. This transition zone should be located midway between their normal distance and near viewing zones. Small movements of the chin up and down can be used to reposition the transition zone temporarily for viewing objects in the intermediate area.

A change of 0.1mm in seg height will result in a 1-2" change in the position of the transition zone. *Example:* If the patient has to move the reading material down 3-4" more than is comfortable for reading, the seg height should be raised approximately 0.3mm.

The distance optic zone may be made up to approximately 5 mm depending on add power. If optimal distance viewing cannot be obtained with proper seg height adjustments and zone size manipulations, the Crescent Design should be used.

E. Characteristics of a Well-Fit Acuity Polymers Decentered Target Lens Design

- Lens rests on the lower lid margin or at the inferior limbus with the upper edge near the upper lid margin
- Lens moves up minimally with the blink and quickly returns to its resting position at the lower lid
- The lens should translate up freely on down gaze, with the truncation remaining on the lower lid during translation
- The distance-to-near transition zone should be intermediate between the patient's habitual reading position and primary gaze

Acuity Polymers Crescent Seg Design Lens Fitting Procedure

The Acuity Polymers Crescent Seg Design is a one-piece, front surface add bifocal which works on the alternating or translating vision principle. It offers a large distance viewing zone as well as a large near area for maximum visual performance in all gazes.

The Crescent seg design is excellent for patients who would do well in a spectacle lens with a Flat top or "D" segment, who have the following characteristics:

Physical Features	Viewing Demands
Aperture size normal to large	Mainly distance & near viewing requirements
Lower lid at or above lower limbus in primary gaze	Few intermediate demands
Upper lid in upper 1/3 of cornea or higher	Add requirements moderate to high
Pupil size average to small	
Nearly any corneal and/or refractive cylinder can be corrected	

A. Diameter Selection

Acuity Polymers recommends beginning with a moderate diameter with truncation for the initial lens (9.4/9.0mm). Lenses which are too large in the vertical diameter may interact excessively with the upper lid causing a lens which is held too high or too long after the blink, or which gets forced down behind the lower lid on down gaze.

The horizontal diameter should provide coverage of approximately 80% of the horizontal visible iris diameter. Vertically, the lower edge of the lens should rest on the lower lid or at the lower limbus, with the upper edge of the lens resting at or just under the upper lid margin. Generally, problems with lens translation should be addressed by altering the vertical (truncated) dimension of the lens. If the lower lid is too low to allow positioning of the optical zone over the pupil without excessive upper lid interaction, a centered target design should be used.

B. Base Curve Selection

The base curve should be selected to be approximately equal to or 0.50D flatter than the flattest keratometry reading. Steeper curves will limit the ability of the lens to translate up on down gaze. Bitoric designs are indicated when corneal astigmatism exceeds 2.50D.

C. Power Selection

The distance power of the diagnostic lens should be as close to the patient's actual power as possible. The initial power should be calculated using the procedure outlined for spherical lenses. Distance power should be adjusted according to the over-refraction of the trial lenses using a trial frame and/or loose lenses whenever possible. The near add power should be approximately equal to the add power required in spectacle lenses. Add power should be assessed using the range of useable vision for the required text size rather than strictly by visual acuity.

D. Seg Height Selection

Acuity Polymers recommends an initial seg height of 4.0mm. Seg height should be evaluated with the best distance over-refraction in place in trial lenses (do not use a phoropter for near testing). The patient should place normal reading material at their normal reading distance at a point just above eye level, and move it down in an arc to their normal reading position, keeping their chin up and moving only their eyes. Ask them to note when the print changes from blurry to clear. This transition zone should be located midway between their normal distance and near viewing zones. Small movements of the chin up and down can be used to reposition the transition zone temporarily for viewing objects in the intermediate area.

A change of 0.1mm in seg height will result in a 1-2" change in the position of the transition zone. *Example:* If the patient has to move the reading material down 3-4" more than is comfortable for reading, the seg height should be raised approximately 0.3mm.

If the patient does not adapt to the presence of the transition zone within 1 to 2 weeks of wear, a no-jump design (Target or Decentered Target) should be used.

E. Characteristics of a Well-Fit Acuity Polymers Crescent Seg Design Lens

- Lens rests on the lower lid margin or at the inferior limbus with the upper edge near the upper lid margin
- Lens moves up minimally with the blink and quickly returns to its resting position at the lower lid
- The lens should translate up freely on down gaze, with the truncation remaining on the lower lid during translation
- The distance-to-near transition zone should be intermediate between the patient's habitual reading position and primary gaze

Acuity Polymers Centered Target Design Lens Fitting Procedure

The Acuity Polymers Centered Target Design is a one-piece, back surface add bifocal which works primarily on the simultaneous vision principle and does not require lower lid interaction for optimal performance. It features a round centered distance zone with a surrounding near zone which allows many patients full intermediate viewing for computer and dashboard viewing. The back surface add eliminates image jump and associated blur or doubling at the distance-near junction.

The Centered Target Design is excellent for patients who have the following characteristics:

Physical Features	Viewing Demands
Ideal for small apertures	Heavy near and intermediate requirements
Works well with very large apertures or where lower lid is below lower limbus	Near and/or intermediate demands in all gazes
Pupil size average to large	Add requirements minimal to high
Spherical or with-the-rule corneas best	
Toric back and front surfaces available to accommodate most corrections	

A. Diameter Selection

Acuity Polymers recommends beginning with a moderate diameter for the initial lens (9.0 to 9.4mm). The horizontal diameter should provide coverage of approximately 75-80% of the horizontal visible iris diameter.

B. Base Curve Selection

The base curve should be selected to be approximately equal to or 0.50D steeper than the flattest keratometry reading. Toric designs are indicated when corneal astigmatism exceeds 2.50D.

C. Power Selection

The distance power of the diagnostic lens should be as close to the patient's actual power as possible. The initial power should be calculated using the procedure outlined for spherical lenses. Distance power should be adjusted according to the over-refraction of the trial lenses using a trial frame and/or loose lenses whenever possible. The near add power should be approximately equal to the add power required in spectacle lenses. Add power should be assessed using the range of useable vision for the required text size rather than strictly by visual acuity.

D. Distance Zone Size Selection

Acuity Polymers recommends an initial distance zone size of 3.5 to 4.0mm. When viewed with fluorescein, the distance zone should be visible as a bright green round pool centered over the pupil in primary gaze. Near vision performance should be evaluated with the best distance over-refraction in place in trial lenses (do not use a phoropter for near testing). The patient should place normal reading material at their normal reading position, keeping their chin up and moving only their eyes to view near objects. Small movements of the chin up and down can be used to optimize near viewing.

It is sometimes helpful to place a larger distance zone over the dominant eye to optimize distance viewing, with a smaller zone on the other eye to optimize near viewing.

E. Characteristics of a Well-Fit Acuity Polymers Centered Target Design Lens

- Lens is well centered throughout the blink cycle.
- Lens moves up minimally with the blink and quickly returns to a centered position.
- Lens should translate up slightly on down gaze.
- The round green circle of fluorescein should cover the pupil and be centered or displaced slightly high but still covering the pupil when viewed with a Burton lamp or slit lamp.
- The transition zone, if noticed, should be intermediate between the patient's habitual reading position and primary gaze.

4. IRREGULAR CORNEA FITTING PROCEDURES

Acuity 100 contact lenses are indicated for patients that have irregular corneal conditions (such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery) and desire a refractive correction with rigid gas permeable contact lenses, and who are not contra-indicated for wearing gas permeable contact lenses. Refer to CONTRAINDICATIONS (REASONS NOT TO USE).

Keratoconus is a non-inflammatory ocular condition in which the cornea progressively thins causing a cone-like bulge to develop. As the cornea steepens the anterior corneal surface (epithelium) becomes irregular resulting in visual impairment. This irregularity cannot be completely corrected with spectacles—instead, a rigid gas permeable contact lens is used to become the new anterior refracting surface. Pellucid marginal degeneration is characterized by non-inflammatory and progressive crescent-shaped corneal thinning inferiorly, often with against-the-rule astigmatism and a steepening topography pattern.

Special Fitting Considerations

Acuity 100 contact lenses for keratoconus, pellucid marginal degeneration, or after penetrating keratoplasty, radial keratotomy, or LASIK surgery are designed to be fitted so as to optically correct irregular astigmatism and thereby improve visual acuity. The lens designs and the manner in which the lens is fitted are intended to work together to accomplish this goal.

The keratoconus design utilizes smaller optic zone diameters, steeper base curves, spherical and/or aspherical periphery curves to closely approximate the unusual topography typical in patients with keratoconus. For example, keratoconus lens designs utilize small posterior optic zones and a series of peripheral curves to achieve this fitting relationship. These zone sizes may vary in lens diameters over 11.5 mm.

The pellucid marginal degeneration design utilizes larger lens diameters, larger optic zone diameters, flatter base curves, and spherical and/or aspherical periphery curves to closely approximate the unusual topography typical in patients with the condition.

Acuity 100 contact lenses for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery, may be fitted using a modification of the standard techniques for rigid gas permeable contact lenses.

Extended wear lenses should not be used to correct keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, LASIK or radial keratotomy surgery.

A. Pre-fitting Examination

A complete refraction and visual health examination should be performed.

Pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for Acuity 100 contact lenses for pellucid marginal degeneration, or following penetrating keratoplasty post-refractive (e.g., LASIK) surgery.
- Collect and record baseline clinical information to which fitting examination results can be compared.

B. Initial Lens Power Selection

Standard procedures for determining power of rigid gas permeable contact lenses may be used, including compensation for vertex distance.

C. Initial Lens Diameter Selection

For keratoconus conditions, lens diameters between 7.0 and 21.0 mm Acuity 100 are chosen to maximize positioning on the cornea and to minimize lens movement.

For pellucid marginal degeneration, lens diameters are typically between 9.5 mm and 21.0 mm.

For post-surgical indications, a larger lens diameter between 9.0 mm and 21.0 mm Acuity 100 is chosen to avoid fitting on or near the graft (suture) line. Lens diameters outside of this range are occasionally used for some eyes.

This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's judgment.

Lens diameter is primarily a function of the base curve but may be influenced by power (plus lenses require a larger diameter to compensate for weight) and anatomical considerations (small palpebral opening, excessively large pupil, etc.) and the patient's corneal topography.

NOTE: If the diameter chosen is larger than 16 mm, the practitioner should also refer to the section on large diameter lenses.

D. Initial Lens Base Curve Selection

For keratoconus, the base curve of the first lens fitted is generally equal to or slightly steeper than the flattest keratometry reading to achieve an apical clearance or apical alignment fitting relationship.

For pellucid marginal degeneration, the base curve chosen is generally flatter than the flattest "K" reading. It may be equal to the radius of curvature as measured 4 mm from the corneal apex by topography (which is usually flatter). If using "K" readings, the base curve chosen will be approximately 1.00 D flatter than the median "K" reading.

For post penetrating keratoplasty (corneal graft) fitting, initial base curve selection will depend on the shape and position of the graft.

The post-surgical cornea may be "prolate" where the graft is steeper than the surrounding peripheral "host" cornea. Typically, a slightly steeper-than-"K" or a reverse geometry lens may be required.

For post refractive surgical fitting (LASIK), the central cornea is much flatter than a "normal" (non- operated) cornea. Base curve choices are usually 0.50 to 1.00 D flatter than the pre-op flat "K" reading.

E. Initial Lens Evaluation

1. Movement:

Blink induced lens movement should show downward lens movement with the lid motion (average 1 mm) and then upward with the lid motion (average 1 mm) as with a standard gas permeable contact lens. During the interblink period the lens should have little or no motion (average less than 1 mm). Lens designs over 11.5 mm diameter may exhibit little or no movement.

2. Positioning:

The lens should position centrally or slightly inferiorly as it will tend to migrate to the steepest cornea area. Lens designs over 11.5 mm diameter will most always position centrally.

3. Characteristics of a Tight (too steep) Lens:

A lens that is too tight will show reduced movement upon blinking. Bubbles may be detected behind the lens. For lens designs over 11.5 mm diameter the presence of bubbles may not indicate a poor fitting lens.

4. Characteristics of a Loose (too flat) Lens:

A lens that is too loose will move excessively on the cornea following each blink. The lens may ride in either a position that is too high or too low, or in an eccentric position. A loose lens is usually uncomfortable for the patient.

6. Trial Lens Fitting

Trial lens fitting is recommended whenever possible. Trial lens fitting allows a more accurate determination of lens specifications for the lens fit and power. Choose the first lens according to the base curve selection criteria for the specific lens design. Trial lenses are essential in fitting patients whose corneal topography is distorted.

7. Trial Lens Procedure

Select a trial lens and place the lens upon the eye. Evaluate the lens using white light for the following:

a. Centering

Lenses may not center well due to the unusual corneal topography in patients with keratoconus. Often the lens will position inferiorly over the steepest corneal area.

b. Movement

Lens movement should be equivalent to or slightly less than a standard RGP lens.

Evaluate the fluorescein pattern. The fluorescein pattern should show a lens with either mild apical clearance or "feather touch" (alignment) over the steepest conical area. In the periphery there should be another area of alignment and near the edge a thin band of pooling.

The fluorescein pattern provides the best method for monitoring the fit of the contact lens over time.

c. Special Follow-up Care

With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the lens demonstrates reduced movement consider exchanging for another of flatter base curve. Usually, a lens with a 0.50 diopters flatter base curve should be the next choice with variations from this based on the judgment of the eye care practitioner.

A lens with excessive movement should be replaced with another that is 0.50 diopters steeper base curve.

After lens removal, conduct a thorough biomicroscopy examination to detect the presence of unusual vertical corneal striae in the posterior central cornea and/or corneal neovascularization. Note: some vertical striae are typical in advanced stages of keratoconus. The presence of these conditions may be indicative of excessive corneal edema.

The recommended schedule for follow-up visits is the same as standard lenses.

NOTE: Practitioners should consult their finishing lab for available keratoconus, pellucid marginal degeneration, and

post-surgical lens designs. The design parameters must meet the parameters specified in the product labeling.

FOLLOW-UP CARE FOR ALL LENSES

- Follow-up examinations, as recommended by the eye care professional, are necessary to ensure continued successful contact lens wear. An unscheduled visit may be indicated whenever the wearer reports a change in vision, ocular discomfort, or redness of the eye.
- Prior to a follow-up examination, the contact lenses should be worn for at least four continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
- With lenses in place on the eyes, evaluate fitting performance to assure that characteristics of a well-fit lens continue to be satisfied for the appropriate lens design. Examine the lenses closely for surface deposition and/or damage.
- After the lens removal, instill sodium fluorescein into the eyes and conduct a thorough biomicroscopy examination.
- The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
- 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.
- 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 characteristics of a well-fit lens are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

IN-OFFICE CARE OF TRIAL LENSES

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

Each Acuity 100™ (hexafocon A) Contact Lens is shipped non-sterile. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens.

CAUTION: Non-sterile, clean and condition lenses prior to use.

RECOMMENDED INITIAL WEARING SCHEDULE

The wearing schedules should be determined by the eye care practitioner. Patients tend to over wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner. are also extremely important.

For the management of irregular corneal conditions, close supervision by the eye care professional is necessary. The eye care professional should determine the appropriate wearing time and provide specific instructions to the patient regarding lens care, insertion and removal.

Although many professionals have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eye care professional regardless of how comfortable the lenses feel.

Acuity 100™ (hexafocon A) Contact Lenses are indicated for daily wear. The maximum suggested wearing time for daily wear lenses is:

During Waking Hours*

Day	Hours
1	4-8
2	6-10
3	8-14
4	10-15
5	12-all waking hours
6 and after -	all waking hours

*If the lenses continue to be well tolerated.

Lenses should be removed daily for cleaning and disinfecting (according to lens care system instructions) before wearing.

CLINICAL ASSESSMENT

1. Vision should be crisp and clear after the blink.

2. The eye should be white and quiet.

Temporary discomfort may be caused by a foreign body under the lens surface. The lens should be removed, rinsed and reinserted. If the discomfort persists, the patient should consult the eye care professional before returning to lens wear.

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 may not be a good candidate for monovision with the Acuity 100™ (hexafocon A) Contact Lens. 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 overcorrection 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, 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.

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 "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 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 Demand Method

Consider the patients' 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

A. 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:

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.

A presbyopic patient requiring a +1.50 diopter add who is -2.25 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 and base curve selection described earlier in the guide.

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 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 the patient's performance under the above conditions are 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 other 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 professional in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the Patient Instructions for Acuity 100™ (hexafocon A) Contact Lenses.

SEMI-SCLERAL AND SCLERAL LENS FITTING GUIDELINES

1. Pre-Fitting Examination

The flatter keratometry reading (Flat K) and amount of corneal astigmatism should be determined. If corneal topography is done, note the steepest area on the map and the temporal quadrant. Using the Elevation map determine the highest point on the cornea. Measure the corneal limbal size. If accurate corneal measurements are not possible, choose a steep lens.

Looking from the side, estimate the sagittal height of the cornea and adjacent sclera.

2. Lens Diameter Selection

Select the appropriate lens diameter based on the condition of the eye and the available parameters. Select a lens diameter that will be able to vault the cornea and limbus and have an adequate diameter fitting zone beyond the limbus (probably 1-2 mm). Large HVID corneas may require 18 mm diameter lenses whereas normal and small HVID corneas probably will be well fit with a 16 mm diameter lens.

3. Base Curve Selection

Lenses designed to vault the cornea and limbus are most easily fit using the sagittal height of the cornea and the sagittal depth of the contact lens. Achieving clearance over the cornea and limbus is most easily determined using a trial lens set based on lenses with increasing amounts of sagittal depth.

A properly fit base curve will vault over the cornea avoiding all corneal touch. There should be no bubbles under the lens. Bubbles captured under the lens are most probably due to air capture during lens application to the eye. Remove the lens and reapply.

4. Lens Power Selection

Lens power can best be determined by adding the spherical value of the over-refraction to the trial lens power.

5. Fluorescein Examination

The fluorescein examination can best be conducted by placing the fluorescein into the cup of the lens prior to insertion. Evaluation of a trial lens that has apical touch is the best way to determine the proper sag. If central bearing is noted, the sag value should be increased by 0.1 mm for every 1.0 mm of touch. The optimal fit will be obtained with the minimum sag value that vaults the cornea with no apical bearing. The ideal pattern aligns the cornea with no bubbles at the limbus or under the optical cap.

The following evaluations apply to all Semi-scleral and Scleral lens designs:

A. Characteristics of a Well-Fit Lens

A good fit positions centered over the cornea or may lag slightly inferiorly. There is little or no movement of the lens with blinking. The lens completely vaults the cornea and the limbus. The fitting zone of the lens settles into the conjunctiva and aligns to the sclera. Bubbles should not be observed under the lens at any location (very small bubbles less than 0.10 mm can be ignored). There should not be any conjunctival impingement or excessive edge lift.

B. Characteristics of a Tight Fitting Lens

A tight lens usually shows blanching of the bulbar conjunctival blood vessels as they pass under the fitting zone of the lens. There may be impingement of the larger blood vessels resulting in localized conjunctival congestion and inflammation. There may be no fluorescein/tear flow under the lens.

C. Characteristics of a Flat Fitting Lens

A flat fitting lens will have an area of corneal touch or bearing. This lens may initially be comfortable for the patient, but wear time is usually reduced due to increased discomfort with normal lens wear. The fluorescein pattern will show bearing or touch at the apex of the cornea, or where the elevation of the cornea is highest. Edge lift off may also indicated a flat fitting lens. A lens fit with this appearance may result in localized epithelial staining in the area of lens bearing.

D. Fluorescein Evaluation

The fluorescein pattern can be evaluated by adding fluorescein to the fluid in the bowl of the lens during lens application to the eye. The patient is instructed to position his/her head parallel to the floor and to look directly down. The bowl of the lens is filled with non-preserved saline. A fluorescein strip is dipped into the saline, adding fluorescein to the solution. The lens is placed on the eye and allowed to settle for several minutes. **(Note: The presence of the ultraviolet (UV) light absorber in the Acuity 100™ (hexafocon A) Contact Lens material requires the addition of a yellow written filter modification of the Slit Lamp and Burton lamp to visualize fluorescein pattern adequately.)** The fluorescein pattern can be evaluated using cobalt blue light with either instrument. The lens is allowed to settle on the eye for 20-30 minutes or longer and the fluorescein pattern is again evaluated. This method of lens evaluation will demonstrate areas of bearing, alignment and clearance. To estimate the amount of lens clearance, the practitioner must use an optic section and white light. Estimation of the fluid layer thickness can be made by referencing the thickness of the fluorescein colored green fluid in the optic section to the known thickness of the contact lens also seen in the optic section.

The fluorescein tear flow test will demonstrate tear flow behind a semi-scleral or scleral lens. Fluorescein is applied to the front surface of a lens that has settled for the appropriate time (usually 20-30 minutes or longer). Fluorescein can be seen as it percolates behind the contact lens and colors the fluid in the chamber between the lens and the cornea. This is best seen and evaluated using an optic section and white light at high intensity.

E. Bubble Evaluation

Immediately upon lens insertion, inspection of the fit for bubbles trapped under the lens is made. If any are present, the lens is removed and reapplied. A properly placed lens will not have bubbles present in the fluid layer after insertion.

The periphery should be evaluated once the ideal corneal clearance has been achieved. The edge should be adjusted if there is excessive edge lift or conjunctival impingement.

6. Troubleshooting

- Corneal edema: This can be caused by excessive corneal vaulting, poor tear flow or increased lens thickness or a combination of all these factors. The sag value should be re-evaluated to obtain the minimum sag that vaults with no apical bearing. Peripheral conjunctival impingement may be another possible cause for edema. The Peripheral curves (PCs) should be flattened with maintenance of the appropriate sag.
- Lens Awareness: This can be caused by excessive edge lift, due to the PCs being too flat or the sag being too low. The first step would be to determine whether the sag is appropriate. In many cases, the edge will improve when the sag is increased. If the sag is correct, steepening or flattening of the periphery may correct the problem.
- SPK: This may be caused by any apical bearing or a sensitivity to the solution used to fill the lens cup.
- Decreased visual acuity: If patients complain of decreased visual acuity after 8-10 hours of wear, have the patient clean, disinfect and reinsert the lens after a few hours of wear.
- Excessive redness: This may be a sign that the lens is fitting too tightly, the patient is using preserved solutions to apply the lens to the eye, or there is meridional tightness of the lens fit.

7. Patient Instructions

Patients should be instructed in the procedures for inserting and removing the lens. Patients may find it easiest to use the tripod insertion method. Place the lens between

the thumb, index and middle finger for insertion. The patient should be instructed to completely fill the cup of the lens with the recommended non-preserved solution, avoiding any bubbles. While facing downward toward a table top, the completely filled lens should be placed onto the eye as the patient looks directly at the center of the lens using the other hand and the a free finger on the hand with the lens to retract the eyelids away from the eye. Immerse the cornea into the bowl of fluid, gently applying the lens to the cornea. Do not push the lens onto the cornea - this will create negative pressure under the lens creating a tight fitting lens. Gently release eye lids. Check for bubbles. The lens should feel comfortable and the vision should clear as the excessive fluid is expelled from the eye.

Patients may be instructed to irrigate the lens with rewetting drops and massage the lens prior to blinking the lens out or to remove it with a contact lens suction cup.

Instructions for removal of the lens with a suction cup:

Place the suction cup near the edge of the lens in the 6 o'clock position. Gently rotate the lens nasally and temporally to insure the lens is movable. Lift the lens upward and outward, holding the eye lids away from the cornea. If the lens does not easily release from the eye, repeat lens rotation on the eye and rotate the suction cup superiorly and lift the lens out and down from the eye. Alternate as needed until the lens easily releases from the eye.

HANDLING OF ACUITY 100™ (hexafocon A) CONTACT LENSES

Conventional lens placement and removal applies to Acuity 100™ (hexafocon A) Contact Lenses. Please instruct the patient how to place and remove the lens. Make sure the patient is able to put on the lenses and remove them before the patient leaves your office.

PATIENT LENS CARE DIRECTIONS

Eye care professionals should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

GENERAL LENS CARE (To First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

- Always wash and rinse hands before handling contact lenses.
- Always use fresh unexpired lens care solutions.
- Use the recommended chemical (not heat) system of lens care. Carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs.
- Always remove, clean, rinse, enzyme (as recommended by the eye care professional) and disinfect lenses according to the schedule prescribed by the eye care professional. The use of an enzyme or any cleaning solution does not substitute for disinfection.

The lens care products listed below are recommended by Acuity Polymers for use with the Acuity 100™ (hexafocon A) Contact Lens. See Package Insert for other products that may be used with this lens. Eye care professionals may recommend alternate solutions that are appropriate for the patient's use with his or her lens. Care should be taken not to mix solutions from different companies and/or care systems unless specifically instructed to do so by the eye care professional.

Lens Care Table

Solution	Purpose
Lens Care System	Chemical (not heat) disinfection
Cleaning	Menicon Unique pH® Multi-Purpose Solution, Boston Advance® Cleaner, or Boston Simplus® Multi-Purpose Solution
Rinsing	Menicon Unique pH® Multi-Purpose Solution, Boston Advance® Conditioning Solution, Boston Simplus®, Sterile Saline Solution or other solution recommended by your eye care professional
Disinfection/Storage	Menicon Unique pH® Multi-Purpose Solution, Boston Advance® Conditioning Solution, Boston Simplus® or other solution recommended by your eye care professional
Lubrication/Rewetting	Boston Rewetting Drops
Periodic Protein Cleaning	Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses
Insertion of semi-scleral & scleral lenses	Sterile Non-preserved Solution or as recommended by your eye care professional

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

- **Clean** one lens first (always the same lens first to avoid mix-ups) with a recommended cleaning solution. **Rinse** the lens thoroughly with recommended solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- **After cleaning**, disinfect lenses using the system recommended by the manufacturer and/or the eye care professional.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care professional for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with sterile contact lens solution as recommended by the lens case manufacturer (never use tap water); then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care professional.
- Eye care professionals may recommend a **lubricating/rewetting** solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Acuity 100™ (hexafocon A) Contact Lenses cannot be heat (thermally) disinfected.

Chemical (Not Heat) Disinfection

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eye care professional.
- Thoroughly rinse lenses with a fresh saline solution or other solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution that may be irritating to the eyes. A thorough rinse in fresh sterile saline solution (or follow the instructions on the disinfection solution labeling) prior to placement on the eye should reduce the potential for irritation.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 10 minutes, the lens edge should be gently manipulated using the eyelid (do not touch the lens directly), and the patient should immediately consult the eye care professional.

HOW SUPPLIED

Each Acuity 100™ (hexafocon A) Contact Lens is shipped non-sterile in an individual plastic container. Follow the manufacturer's instructions on the disinfecting solution label.

The plastic container, packing slip or invoice is marked with the information for base curve, diopter power, diameter, center thickness, color, UV-absorber, lot number, hydration date and other required parameters specified by the design.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Acuity 100™ (hexafocon A) Contact Lenses should be reported to:

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1667 Lake Avenue
Building 59, Suite 303
Rochester, NY 14615
1-888-POLYMER (1-888-756-9637)
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