IMPORTANT: Please read carefully and keep this information for future use.
This fitting guide is intended for the eyecare practitioner but should be made available to the patient upon request.

clear1-day (HIOXIFILCON A) DAILY DISPOSABLE SOFT CONTACT LENS (VISIBILITY TINT)

clear 1-day

clear1-day spherical

clear1-day toric

clear1-day multifocal

Symbols key

The table shows the symbols that may appear on label or carton

Symbol	Description
℞ Only	**CAUTION**: Federal Law (USA) restricts this device to sale by or on the order of a **Licensed Eye Care Practitioner**.
STERILE	Sterilized using steam or dry heat
	Caution
	Do not use if package is damaged and consult instructions for use
	Manufacturer
	Date of manufacture

Symbol	Description
D	Diopter (Lens Power)
	Temperature limits
	Do not resterilize
MD	Medical Device
REF	Catalogue number
#	Model number

EC REP	Authorized Representative in European Community
LOT	Batch code (Lot number)
	Use by date (Expiry date)
	Consult instructions for use or consult electronic instructions for use
CE	European conformity sign
BC	Base Curve
DIA	Diameter
	Importer

UDI	Unique Device Identifier
	Single sterile barrier system
	Keep dry
	Keep away from sunlight
	Fragile, Handle with care
	Do not reuse
	Recyclable material

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

clearlab®

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DESCRIPTION OF LENS:

The **clear1-day (Hioxifilcon** A) **Daily Disposable soft contact lenses** are available in spherical, toric, and multifocal lens designs. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

MATERIAL CHARACTERISTICS:

The non-ionic lens material, (Hioxifilcon A) is a random co-polymer of 2-hydroxyethyl methacrylate and glycerol methacrylate cross-linked with ethylene glycol dimethacrylate. It consists of 42% Hioxifilcon A and 58% water by weight when immersed in a buffered saline solution. The lens is available with a pale blue visibility handling tint, color additive 'Reactive Blue 4' 21CFR Part 73.3121. The Hioxifilcon A name has been adopted by the United States Adopted Names Council (USAN).
In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat wrapped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allows aqueous solutions to enter the lens and in its fully hydrated state and the lens are approximately 58% water by weight.

The physical properties of the lens are:

Refractive Index	1.4011(wet)
Light Transmission	> 95%
Surface Character	Hydrophilic & non-ionic
Water Content	58% (±2.0%)
Oxygen Permeability	25.38 x 10^{-11} (cm^2/sec) (mlO_2/ml x mmHg), (revised FATT method) for Spherical Lens 25 x 10^{-11} (cm^2/sec) (mlO_2/ml x mmHg), (revised FATT method) for Toric Lens & Multifocal lens

The **clear1-day (spherical)** Daily Disposable soft contact lenses are available in the following dimensions:
following dimensions:

Diameter:	14.00mm to 14.40 mm
Centre Thickness:	0.090 mm ± 0.020 mm @ -3.00D (varies with power)
Base Curve:	8.60mm to 9.00mm (for power range of +4.00D to +6.00D) 8.50mm to 8.90mm (for power range of -10.00D to +3.75D)
Powers:	+0.25D to +6.00D in 0.25 D increment

	0.00D^ to -6.00D Diopters in 0.25 D increment
	-6.50D to -10.00 D in 0.50 D increment

The **clear1-day toric** Daily Disposable soft contact lenses are available in the following dimensions:

Diameter:	14.20mm to 14.60mm
Centre Thickness:	0.110 mm ± 0.020 mm @ -3.00D (varies with power)
Base Curve:	8.30mm to 8.70 mm
Powers:	+4.00D to +0.25D in 0.25 D increment
	0.00D^ to -6.00D in 0.25 D increment
	-6.50D to -10.00D in 0.50 D increment
	+4.50D to +6.00D in 0.50D increment
Cylinder:	-0.75D, -1.25D, -1.75D, -2.25D
Axis:	10° to 180° (in 10° step)

The **clear1-day multifocal** Daily Disposable soft contact lenses are available in the following dimensions:

Diameter:	14.00 mm to 14.40mm
Centre Thickness:	0.090 mm ± 0.020 mm @ -3.00D (varies with power)
Base Curve:	8.50mm to 8.90mm
Powers:	+6.00D to +0.25D in 0.25 D increment
	0.00D^ to -6.00D in 0.25 D increment
	-6.50D to -10.00D in 0.50 D increment
ADD Powers:	+1.00D, +1.50D, +2.00D, +2.50D

ACTION:

In its hydrated state, the **clear1-day (Hioxifilcon** A) **Daily Disposable Soft Contact Lens,** when placed on the cornea, acts as a corrective refracting medium (except for plano lenses) to focus light rays on the retina.

INDICATIONS (USES):

The **clear1-day (spherical)** Daily Disposable Soft Contact Lens is indicated for daily wear single use only for the optical correction (except for plano lenses) of refractive ametropia (myopia and hyperopia) in phakic and aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The **clear1-day toric** Daily Disposable Soft Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia)

in phakic and aphakic persons with non-diseased eyes who may have 7.00D or less of astigmatism.

The **clear1-day multifocal** Daily Disposable Soft Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic and aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The lens is intended to be worn once and then discarded at the end of each wearing period on a daily basis. The patient should be instructed to start the next wearing period with a new lens. Reusing daily disposable contact lenses can increase the risk of infection, dryness, and discomfort.

The target population for the use of this device is adults of 18 years or older. There is no clinical data to support the use of clear1-day by individuals under 18 years of age. Use of this device by individuals less than 18 years of age is at the sole discretion of eye care professionals.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **clear1-day (Hioxifilcon** A) **Daily Disposable Soft Contact Lens** when any of the following conditions are present:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- Any active corneal infection (bacterial, fungi, or viral).
- If eyes become red or irritated.
- Patients unable to follow the daily disposable lens care schedule
- Advise patient not to wear **clear1-day (Hioxifilcon** A) **Daily Disposable Soft Contact Lens** while sleeping.

CAUTION:

Due to the small number of patients enrolled in clinical investigations of lenses, all refractive powers, design configurations, or lens parameters available in the lens material

were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameter, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive correction. Therefore, the continuing ocular health of the patient and the lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

WARNINGS:

Please refer to Warnings in the Package Insert.

PRECAUTIONS:

Please refer to Precautions in the Package Insert.

ADVERSE REACTIONS:

Please refer to Adverse Reactions in the Package Insert.

PATIENT SELECTION:

Patients selected to wear these lenses should be chosen based on:

- Motivation to wear lenses
- General health
- Ability to follow instructions regarding lens handling and wearing
- Ability to adhere to a recommended care regimen
- Ability to understand the benefits and risk of lens wear

Patients who do not meet the above criteria should not be provided with **clear1-day (Hioxifilcon A) Daily Disposable Soft Contact Lens**. Patient communication is vital. All necessary precautions and warnings should be discussed and understood by the patient *(review Package Insert with the patient.)*

Failure to follow handling and wearing instructions could lead to serious eye infections, which might result in corneal ulcers.

PRE-FITTING EXAMINATION:

A thorough case history is crucial to determine patient's needs and expectations as well as rule out contraindications to contact lens wear described in the Package Insert.

The initial selection of trial lens should be preceded by a complete eye examination that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription, keratometry and slit lamp examination.

TRIAL LENS EVALUATION:

Following initial power selection, a trial lens should be placed on the eye for assessment of lens fit and comfort, and final power verification.

1. Initial Power Selection

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. The spherical equivalent refraction is determined as follows:
Spherical Equivalent = Sphere power + Cylinder Power/2
Example: Spectacle Rx: -2.50D -1.00 x 180
Spherical Equivalent: -2.50D + -0.50D = -3.00D

Remember to compensate for vertex distance if the refraction is greater than ±4.00D.

2. Trial Lens Fitting

The trial lens should be placed on each of the patient's eyes. Allow the lenses to settle on the eyes for approximately 5 to 10 minutes. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

1) Criteria of a Well-Fitted Lens

The criteria of a well fitted lens is one which centers easily after a blink, bridges the limbus, and extends onto the sclera about 1.25mm, lags downward about 1.0 to 1.5 mm on upward gaze and does not move excessively as a result of blinking or exaggerated eye movements.

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

Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1-1.5 mm.

2) Characteristics of a Tight (Steep) Lens

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

3) Characteristics of a Loose (Flat) Lens

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

3. Final Lens Power

After the characteristics of a well-fitted lens have been satisfied, the spherical over-refraction should be combined with the trial lens power to determine the final lens prescription.

Example:
Trial Lens: -5.00D
Over-refraction: -0.25D
Final Lens Power: -5.25D

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable dispense the lenses instructing the patient to return in one week for assessment.

FOLLOW UP CARE:

1. Follow-up examinations are recommended by the eyecare practitioner, they are necessary to ensure continued successful contact lens wear.
2. Prior to a follow up examination, the contact lens should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
3. With lenses in place on the eyes, evaluate the fitting performance to assure the criteria of a well-fitted lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
4. After the lens removal, conduct a thorough bio-microscopy examination.
    a. The presence of vertical corneal striate in the posterior central cornea and/ or cornea neovascularization is indicative of excessive corneal edema.
    b. 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.
    c. Papillary conjunctival changes may be indicative of an unclean and / or damaged lens.

If any of the above observations are considered as abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to its optimal conditions. If the **Criteria of a Well-Fitted Lens** is not satisfied during any follow-up examinations, the patient should be refitted with a more appropriate lens.

FOLLOW - UP EXAMINATIONS

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

TORIC FITTING GUIDELINES

Although most aspects of the fitting procedure are identical for all types of soft contact lenses, including torics, there are some additional steps and/or rules to follow to assure the proper fit of toric lenses.

The only new steps that must be followed for **clear1-day toric** Daily Disposable soft contact lenses are that you must determine the stability, repeatability, and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

1. How to determine Lens Cylinder and Axis Orientation for clear1-day toric Daily Disposable soft contact lenses.

    1) Locate the Orientation Mark

    To help determine the proper orientation of the toric lens, you will find one mark about 1mm from the lens edge representing the vertical position of the lens at 6 o'clock. You will need a biomicroscope and a 1mm or 2mm parallelepiped to highlight the mark when the lens is fitted to the eye. There are a number of techniques which you can use to improve the visibility of the 6 o'clock mark. With your parallelepiped and medium magnification (10x or 15x), slowly pan down the lens, looking just below the direct illumination at the retro illuminated area. Backlighting the mark this way should make it more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark.

    2) Observe Lens Rotation and Stability

    Observe the position and stability of the 6 o'clock mark. The 6 o'clock mark is not a "must" however; the absolute requirement is that the axis position be stable and repeatable.

    The mark may stabilize somewhat left or right (drift) of the vertical meridian and still enable you to fit a toric lens for that eye, as long as the lens always returns to the same "drift axis" position after settling. The deviation can be compensated for

in the final prescription. Your objective is to ensure that whatever position the initial lens assumes near 6 o'clock, this position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they must return quickly to the original stable position. If the lens does not return quickly, you may need to select a different lens.

3) Assessing Rotation

Imagine the eye as a clock dial and every hour represents a 30o interval. If the orientation mark of the initial lens stabilizes somewhat left or right of the vertical position, the final lens will orient on the eye with the same deviation. You can use an axis reticule in the slit lamp or use a line-scribed lens in a spectacle trial frame to measure or estimate the "drift angle" of the cylinder axis.

To compensate for this "drift," measure or estimate the "drift," then add or subtract it from the refractive axis to determine the correct cylinder axis. Use the LARS (Left Add, Right Subtract) method to determine which direction to compensate.

2. How to determine the Final Lens Power for clear1-day toric Daily Disposable soft contact lenses.

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the patient's refractive axis, it is not advisable to over-refract because of the difficulty in computing the resultant power.

In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it is more practical to prescribe as weak a cylinder as possible. So, here is how to determine the final lens power.

For the Sphere:
If sphere alone or combined sphere and cylinder Rx>±4.00D, compensate for vertex distance. If sphere alone or combined sphere and cylinder Rx≤4.00D, vertex compensation is not necessary.

For the Cylinder:
Adjust the axis by the drift angle using LARS. Choose a cylinder that is ≤0.25D from the refractive cylinder.

<u>Example</u>
Manifest (spectacle) refraction:
O.D. -3.00 -1.00 x 90 20/20
O.S. -4.75 -2.00 x 90 20/20

Choose a diagnostic lens of -3.00 -0.75 x 90 for the right eye and -4.50 -1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate. The orientation mark on the right lens rotates left from the 6 o'clock position by 10°.

The fitting indicates the following:

Right Eye
Compensate the 10° axis drift by adding it to the manifest refraction axis. Here is the Rx prescribed:
O.D. -3.00 -0.75 x 100

Left Eye
The lens on the left eye shows good centration, movement, and a consistent tendency for the mark to drift right by 10° from the 6 o'clock position following a forced blink.

Since the manifest refraction called for a power of -4.75D, adjust for the vertex distance and reduce the sphere by 0.25D and prescribe the -1.75D cylinder. Compensate for the 10° axis drift by subtracting it from the manifest refraction. Here is the Rx prescribed:
O.S. -4.50 -1.75 x 80.

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment.

MULTIFOCAL FITTING GUIDELINES

1. Presbyopia Needs Assessment and Patient Education

Multifocal contact lenses may compromise vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dimly lit restaurant, driving at night in rainy/ foggy conditions etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the **clear1-day multifocal** Daily Disposable soft contact lenses for the correction of presbyopia. **Clear1-day multifocal** Daily Disposable soft contact lenses for the correction of presbyopia 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 need to ensure they meet state driver's license requirements and should be advised to not drive with this correction OR may require that additional over correction be prescribed.

Clear1-day multifocal Daily Disposable soft contact lenses for the correction of presbyopia are not recommended for patients who have 1.00D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise.

2. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00D. Determine the spherical equivalent distance prescription for a multifocal patient. Determine the eye dominance using one of the methods below:

Method 1:
Determine which eye is the 'sighting 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 does not accept added plus power. Place a +1.00D handheld trial lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes while the patient is viewing the distance visual acuity chart. The eye with the plus over it that the patient notices the greatest reduction in vision is determined to be dominant eye.

3. Select the Initial Trial Lens

1) For each eye, select the trial lens distance power that is closest to the patient's distance spherical equivalent. Remember to compensate for vertex distance if the refraction is greater than ±4.00D.
2) Select the near power of the lens based on the patients ADD range as follows:
   - ADD: +0.50 to +1.00 use a +1.00 near ADD lens on each eye
   - ADD: +1.25 to +1.50 use a +1.50 near ADD lens on each eye
   - ADD: +1.75 to +2.00 use a +2.00 near ADD lens on each eye
   - ADD: +2.25 to +2.50 use a +2.00 near ADD on the dominant eye and a +2.50 near ADD lens on the non-dominant eye
3) Allow the lenses to settle for a minimum of 10 minutes.
4) Assess distance and near vision binocularly and monocularly.
5) Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near.
6) Make adjustments in power as necessary based on the distance over refraction. The use of handheld trial lenses is recommended. Check the impact on distance and near vision.

7) If vision is still unacceptable, make adjustments in power as necessary (see "Multifocal Troubleshooting" below). If distance and near vision are acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in PATIENT MANAGEMENT).

4. Multifocal Troubleshooting

1) Unacceptable Distance Vision:
Starting with 0.25 DS steps and dominant eye using handheld trial lens, determine the amount of additional plus or least minus over one or both eyes that improves distance vision without affecting near vision.

2) Unacceptable Near Vision:
Starting with 0.25DS steps and non-dominant eye using handheld trial lenses determine the most plus least minus over one or both eyes that improves near vision without affecting distance vision.

3) Tips for multifocal fitting
Careful patient selection and set correct expectation with them.
Use up to date most plus least minus vertex distance corrected best sphere prescription.
Adhere to manufactures suggested fitting guidelines.
Assess vision in good illumination and with real life scenarios.
Do not use phoropter or trial frame when assessing/ improving vision use handheld trial lenses.
Assess vision binocularly using handheld lenses.
Use 0.25 DS steps when altering lenses. It is unusual for more than 0.25DS changes to be needed.
Take care when adding additional minus power for distance vision so that near vision is not affected.
Always use the lowest ADD power possible to achieve acceptable near vision
If patient is happy with visual acuity do not attempt to refine to best Snellen acuity as with spectacle refraction. The proviso being subjective assessment is clinically and professionally acceptable.

MONOVISION FITTING GUIDELINES

1. Monovision Needs Assessment Patient Selection
For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.50 diopter) in one eye may not be a good candidate for monovision with the **clear1-day (Hioxifilcon** A) **Daily Disposable Soft Contact Lens**.

Occupational and environment 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 not to drive with this correction or may require that additional over-correction be prescribed.

2. 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 presbyopia contact lenses, or other alternative, 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.

3. Eye Selection

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

1) 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 latest 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.

2) 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.

3) Visual Demands Method

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

4. Special Fitting Consideration

1) Unilateral Lens Correction:

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

Example:
A presbyopia 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 presbyopia patient requiring a +1.50 diopter add who is -2.50 diopter myopic in the right eye and -1.50 diopter myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

2) 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 optical reading performance, prescribe the least plus (most minus) of the power.

3) 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 of 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 newsprint 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 function.

4) 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.

5) Other suggestions
The success of 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 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 sure 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 power if there is trouble with adaptation. Accurate lens power is critical for presbyopia 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 eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.

INSTRUCTIONS FOR MONOVISION WEARER:

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

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

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

- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.

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

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

At the follow up examinations, the patient should report good subjective quality of vision. Adaptation to the vision with **clear1-day (Hioxifilcon** A) **Daily Disposable Soft Contact Lens** should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the eyecare practitioner should:

1) Check distance and near acuity with lens in place
2) Over-refract to verify lens prescription
3) Observe position of lens on the cornea. The lens should be centered and move on upward gaze and with blink.
4) Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
5) Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
6) Perform a slit-lamp examination with and without Fluorescein. Check for corneal edema, corneal abrasion, vascularization, corneal infiltrates and perilimbal injection. Reinsert the lens only after all residual Fluorescein has dissipated from the eye.

LENS HANDLING (IN-OFFICE CLEANING)

Wash and rinse hands thoroughly, making certain that all soap residues have been rinsed away before drying with a lint free towel. It is suggested to wet the lens while in the eye using wetting drops before removal. Always start with the right eye first in order to avoid mixing the lenses. When handling the lens, try to avoid touching the inside (concave) surface of the lens. It is possible, though not likely, that the lens might be inside out; therefore, check the lens by placing it on the index finger and examine its profile. If the edges of the lens tend to point outward, the lens is inside out. After removing the lens from its container assure that it is clean, clear, and wet.

Each **clear1-day (Hioxifilcon** A) **Daily Disposable Soft Contact Lens** is received in the eyecare practitioner's office in a sterile blister pack. To assure sterility the blister pack should not be opened until ready for use.

Upon removing the cover, the lens may be removed and is ready for use.

Clear1-day (Hioxifilcon A) **Daily Disposable Soft Contact Lens** are not reused in diagnostic procedures.

CLEANING:

The **clear1-day (Hioxifilcon** A) **Daily Disposable Soft Contact Lens** are designed as a Daily Disposable lens.

The lens is intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a new lens.
Emergency lens cleaning and disinfection is not recommended. The patient should be reminded to always have replacement lenses or back-up spectacles available

RECCOMENDED WEARING SCHEDULE:

Close professional supervision is recommended to ensure safe and successful contact lens wear. If the patient complains of discomfort, decreased vision, ocular injection or corneal edema, the lens should be removed, and the patient scheduled for examination. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting the lens.
Patients tend to overwear the lens initially. It is important not to exceed the wearing schedule. Regular check ups, as determined by the eyecare practitioner, are also extremely important. The maximum suggested wearing schedule for the **clear1-day (Hioxifilcon** A) **Daily Disposable Soft Contact Lens** is suggested below.

DAY	1	2	3	4	5	6
HOURS	6	8	10	12	14	All working hours

The **clear1-day (Hioxifilcon** A) **Daily Disposable Soft Contact Lens** is intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a new lens.

STORAGE CONDITIONS:

Store lenses between 23°C to 27°C.

EMERGENCIES:

Emergency lens cleaning and disinfection is not recommended. The patient should be reminded to always have replacement lenses or back-up spectacles available.

The patient should be informed that if any chemical of any kind (household products, gardening solutions, laboratory chemicals, etc) are splashed into the eyes, the patient should:

FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing this contact lens or experienced with the lens should be reported to the manufacturer and the competent authority of the member state.

Additional Package Insert are available from:

Clearlab SG Pte. Ltd.
139 Joo Seng Road,
Singapore 368362
Tel: +65 6749 1090
Fax: +65 6282 3953
Email: Regulatory@clearlab.com
Website: www.clearlab.com

HOW SUPPLIED

Each lens is supplied sterile in a blister pack containing buffered saline solution. The blister pack is marked with the diopter for spherical lenses or toric power, cylinder, and axis for toric lenses, manufacturing lot number, expiration date of the lens, and composition of the lens, Rx symbol and sterile symbol. The blister pack is also marked as 'NOT FOR INDIVIDUAL RESALE.'

DISPOSAL

There is no special disposal required for soft contact lens and its blister. The carton packaging, aluminum lidding and polypropylene (PP) plastic case should be placed properly in the waste bin or recycled according to local waste guidance or local regulations.

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