
PROFESSIONAL FITTING GUIDE

For the

IntelliWave1/ Intelliwave1 Pro

(Acofilcon B)

SOFT CONTACT LENS FOR DAILY WEAR

(clear and tinted)

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

TABLE OF CONTENTS

- Material Characteristics/Description of Lens
- Actions
- Indications
- Special Precautions for the Eyecare Practitioners
- Warnings
- Precautions
- Adverse reactions
- Patient selection
- Fitting procedure
- Clinical Assessment
- Contraindications
- Follow-up examinations
- Lens Handling (in-office cleaning, disinfecting, and storage)
- Cleaning
- Rinsing
- Chemical (not-heat) lens care system
- Lens care directions
- Storage
- Recommended wearing schedule
- Frequent/Planned Replacement
- Recommended lens care products
- Emergencies
- Reporting of adverse reactions
- How supplied

MATERIAL CHARACTERISTICS

DESCRIPTION OF LENS

The **IntelliWave1/ Intelliwave1 Pro**, Soft Daily Wear Contact Lenses are fabricated from (Acofilcon B), which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material, (acofilcon B) is a terpolymer based on high purity Glycerol Methacrylate 2,3-Dihydroxypropyl Methacrylate (GMA), with N-vinyl-2-pyrrolidone (NVP), methyl methacrylate (MMA), and 2-hydroxyethyl methacrylate (2-HEMA) and cross-linked with Diallyl Maleate (DAM). It consists of 51% acofilcon B and 49% water by weight when immersed in normal saline solution buffered with sodium tetraborate. The lens material is available in clear and with a blue visibility-handling tint, Color additive 'Reactive Blue 4' 21 CFR part 73.2121.

The Physical properties of the lens are:

Refractive Index	1.52 (dry) 1.42 (hydrated)
Light Transmission	greater than 94%
Surface Character	hydrophilic
Water Content	49 %
Specific Gravity	1.142 (hydrated)
Oxygen Permeability	15.89×10^{-11} (cm ² /sec) (ml O ₂ /ml x hPa @ 35°C), (revised Fatt method).

The **IntelliWave1/ Intelliwave1 Pro**, Soft Daily Wear Contact Lens parameters:

Base Curve:	7.0mm - 10.0mm
Power:	+20.00D to -20.00D
Cylinder:	-0.75D to -12.00D
Add Power:	+0.25D to +4.00D
Diameter:	13.0mm - 14.5mm

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 **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens** has a spherical back 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 warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

ACTIONS

In its hydrated state, the **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens (Acofilcon B)**, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

INDICATIONS

INDICATIONS FOR USE:

The **IntelliWave1/ Intelliwave1 Pro**, Sphere (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **IntelliWave1/ Intelliwave1 Pro**, Toric (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12.00 diopters.

The **IntelliWave1/ Intelliwave1 Pro**, Multifocal (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity and are presbyopic requiring add power of up to +4.00 diopters.

The **IntelliWave1/ Intelliwave1 Pro**, Multifocal Toric (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5 diopters and are presbyopic requiring add power of up to +4.00 diopters.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Special Precautions for the Eyecare Practitioner

Due to the small number of patients enrolled in clinical investigation of lens, 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 parameters, 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 lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

CONTRAINDICATIONS (REASONS NOT TO USE)

Please reference Contraindications (Reasons Not to Use) in the Package Insert included at the end of this Fitting Guide.

WARNINGS

Please reference Warnings in the Package Insert included at the end of this Fitting Guide.

PRECAUTIONS

Please reference Precautions in the Package Insert included at the end of this Fitting Guide.

ADVERSE REACTIONS

Please reference Adverse Reactions in the Package Insert included at the end of this Fitting Guide.

PATIENT SELECTION

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended care of the **IntelliWave1/Intelliwave1 Pro, Soft Daily Wear Contact Lens (Acofilcon B)** should not be provided with this lens. All necessary steps in lens care and all precautions and warnings should be discussed and understood by the patient (*Review Package Insert with patient*).

FITTING PROCEDURE - Spherical Single Vision Lens

1) Pre-fitting Examination

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

- determine whether a patient is a suitable candidate for daily wear contact lenses (refer to contraindications)
- collect and record baseline clinical information to which post-fitting examination results can be compared
- make ocular measurements for initial contact lens parameter selection
- Record Horizontal Visible Iris Diameter (HVID)

2) Initial Fitting

Art Optical recommends an empirical fitting method for the **IntelliWave1/ Intelliwave1 Pro** contact lenses. When ordering, simply supply us with the information listed below and we will manufacture the lenses to meet your needs:

For each eye supply:

- HVID
- Keratometer readings
- Spectacle Refraction
- Back vertex distance of spectacle Rx

For Astigmatism above 1.25 DC, specify the Toric lens.

Fitting Assessment

Insert the new lenses and allow to settle for 5 to 10 minutes. After the lenses have settled, assess vision and fit including the following points:

- The lens should exhibit good centration on primary (straight ahead) gaze and good corneal coverage in all directions of gaze.
- The edge should be approximately 1.5mm beyond the limbus.
- Vertical movement on blinking (on upward gaze) should be between 0.5mm and 1mm.
- The push up test (PUT) should show fast and smooth recenteration of the lens.
- There should be no Scleral indentation or blanching. Keratometer mires should be stable on blinking.
- The patient should experience good comfort.

FITTING PROCEDURE - Toric Lens

1) Pre-fitting Examination

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

- determine whether a patient is a suitable candidate for daily wear contact lenses (refer to contraindications)
- collect and record baseline clinical information to which post-fitting examination results can be compared
- make ocular measurements for initial contact lens parameter selection
- Record Horizontal Visible Iris Diameter (HVID)

2) Initial Fitting

Art Optical recommends an empirical fitting method for the **IntelliWave1/ Intelliwave1 Pro** sphere contact lens. When ordering, simply supply us with the information listed below and we will manufacture the lenses to meet your needs.

For each eye supply:

- HVID
- Keratometer readings
- Spectacle Refraction
- Back vertex distance of spectacle Rx

Fitting Assessment

Insert the new lenses and allow to settle for 5 to 10 minutes. After the lenses have settled, assess vision and fit including the following points:

- The lens should exhibit good centration on primary (straight ahead) gaze and good corneal coverage in all directions of gaze.
- The edge should be approximately 1.5mm beyond the limbus.
- Vertical movement on blinking (on upward gaze) should be between 0.5mm and 1mm.
- The push up test (PUT) should show fast and smooth recenteration of the lens.
- There should be no Scleral indentation or blanching. Keratometer mires should be stable on blinking.
- The patient should experience good comfort.

The central axis marking of the lens should be in the vertical position at 6 o'clock and return to a vertical position after the PUT. If the axis is slightly rotated but the patient's vision is acceptable the can be worn and reassessed at the first follow-up consultation. If the axis is consistently rotated and is delivering unacceptable visual acuity, then return the lens (using our exchange program) stating the direction and degree of rotation of the lens accompanied by an assessment of the fit of the lens.

FITTING PROCEDURE - Multifocal Lens

The **IntelliWave1/ Intelliwave1 Pro**, Multifocal lens is offered to patients who are presbyopic requiring add power of up to +4.00 diopters and is also offered as a Multifocal Toric for patients who are presbyopic and may possess refractive astigmatism not exceeding 4 diopters. The **IntelliWave1/ Intelliwave1 Pro**, Multifocal lens is a center-near and center distance, simultaneous-vision, soft lens whose multi-aspheric front surface, provides clear distance, intermediate and near vision for presbyopes.

The following procedure covers both the Multifocal and Multifocal Toric lens indications.

Fitting Guidelines

The practitioner provides the following parameters:

- Spectacle refraction including sphere, cyl, axis and add, as appropriate
- Back Vertex Distance (BVD)
- Keratometer readings (preferably with axes)
- Horizontal Visible Iris Diameter (HVID)
- Dominant eye
- Pupil diameter in normal light. Identification of the dominant eye enables a slightly larger area, for the near and near/intermediate powers, to be worked into the lens for the non-dominant eye.
- This promotes a more "comfortable" binocular relationship.

Initial Assessment

The lens parameters arising from the measurements provided will usually achieve first-time, optimum all-round vision. However in some cases modification may be required. If the practitioner is satisfied with the physiological aspects of the fit, it is best to defer any adjustment to power until the patient has completed 7 to 10 days of regular wear. This period permits the patient's visual system to become accustomed to the specific nature of the aspheric optical system.

Assessing the Fit

At the 2 week consultation, the fit should be assessed, taking note of the points outlined below.

Visual Assessment

For the multifocal design, the use of hand held trial lenses will simplify the evaluation process. To improve near vision, add plus in +0.25 D increments to both eyes until the near vision is acceptable. To improve distance vision, add minus in 0.25 D increments in both eyes. Note the amount of power adjustment required for near and distance, then return the lens (using our exchange program) stating the amount of over refraction required for distance and near accompanied by the assessment of the fit.

For the multifocal toric, the central axis marking of the lens should be in the vertical position at 6 O'clock and return to a vertical position after the PUT. If the axis is slightly rotated but the patients vision is acceptable the lens can be worn and reassessed at the next follow up visit. If the axis is constantly rotated and the vision is unacceptable, perform a sphere-cylinder over refraction in the Phoropter for best distance vision. Place the over refraction in a trial frame and evaluate the near vision. To improve the near vision, add plus in +0.25 D increments to both eyes until the near vision is acceptable. Then return the lens (using our exchange program) stating the amount of over refraction required for distance and near along with the amount and direction of rotation of the central axis mark accompanied by the assessment of the fit.

Characteristics of a Flat Fit

Flat fittings result in excessive movement of the lens and this will affect the optical efficiency of the system with the following symptoms.

- There will be induced astigmatism in the over-refraction
- The over-refraction will require more plus for near vision
- Manual correction of the position of the lens on the eye will usually confirm the above
- For a toric lens, the axis will usually rotate. In such cases, steepening of the fit, preferably by diameter increase, will correct the problem.

Characteristics of a Steep Fit

When the fitting is steep, vision is inconsistent and clears only for a brief time following a blink. In most cases, flattening of the fit, by changes to the BOZR, will overcome these problems. The steep fit also negates the effect of the stabilization areas in the toric lens forms and there may be a slow, progressive movement of the cylinder axis away from its prime position.

Cylindrical Axis Mis-location

Where the multifocal is in toric form, axis mislocation will be detrimental to vision. In the case of small deviations (5 degrees or less), a compensating change in the cylinder axis will often rectify. Larger deviations will require additional consideration of the level of ballasting applied to the front surface and/or an increase in the diameter to increase the influence of the sclera in promoting stability. A change in BOZR would be required to maintain the equivalent fit.

Adjustments to Lenses

In the event that adjustments are required, we request that practitioners do not make their own adjustments, and instead supply symptomatic details of any problems along with any refractive information direct to Art Optical consultants. The Clinical Services Department who have access to the details of the complex structure of the lenses, will then determine the final specification of the lens to be made. This will enable the laboratory to effect the best combination of adjustments whilst retaining all the benefits of the proprietary technologies being utilized for this design.

Important Notes on Aftercare Visits

- As with all progressive multifocal corrections, there is an adaptation period of at least one week of regular wear.
- Minor with-the-rule astigmatic errors may be ignored if the patient copes without this correction in their spectacle Rx or single-vision soft lenses.
- Should unsatisfactory vision result from a lens, an over-refraction should be performed*, first for the distance, then, **independently** for the near.

* The use of pinholes or similar techniques in over-refraction of the **IntelliWave1/ Intelliwave1 Pro** multifocal is ineffective as an aid to evaluating visual results.

FOLLOW-UP EXAMINATIONS

- a. Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued contact lens wear. The following is a suggested schedule for 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.
- b. Prior to follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear. The patient should report good subjective quality of vision. Adaptation to vision with **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens** should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit.
- c. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- d. After the lens removal, conduct a thorough biomicroscopy examination.
 1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
 2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
 3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be refitted with a more appropriate lens.

At the follow-up examinations, the patient should report good subjective quality of vision. Adaptation to vision with **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear 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 practitioner should:

1. Check distance and near acuity with lens in place.
2. Over-refract to verify lens prescription.
3. Observe the position of the lens on the cornea. The lens should be centered and move on upward gaze and with a 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.
7. Clean the lens with a prophylactic surfactant cleaner, and examine for deposits, foreign bodies or physical imperfections of the lens surface.

CRITERIA OF A WELL FITTED LENS

Characteristics of an ideally fitted lens

1. Good corneal alignment.
2. Slight (.5mm to 1mm) vertical post-blinking movement of the lens.
3. A consistent tendency for the lens to return to the primary position when it is displaced.
4. Provides functional binocular visual performance at distance and near.

General Lens Comfort

The **IntelliWave1/ Intellwave1 Pro, Soft Daily Wear Contact Lens** is designed to provide the patient with a high degree of comfort. Some patients may experience initial lens sensation, which should resolve early in the wearing schedule. If a sensation persists, one of the following may exist:

1. The lens is not clean and a foreign contaminant is trapped between the lens and the cornea.
2. The lens is ill fitting (usually loose) and must be changed to one or more optimal fit.
3. The lens is damaged and must be replaced.
4. The lens has been inserted inside out. The lens should be removed, reversed and reinserted after rinsing.

The patient presents either a dry eye syndrome, hypersensitivity syndrome, or some other situation which makes elimination of sensation impossible.

LENS HANDLING (in-office cleaning, disinfecting and storage)

Wash and rinse hands thoroughly, making certain 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 lens first in order to avoid mixing the lens. In removing 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 **IntelliWave1/ Intellwave1 Pro, Soft Daily Wear Contact Lens** received in the eye care practitioner's office is received sterile in a glass vial with sterile buffered normal saline solution and labeled as to the parameters of the lens contained. To assure sterility, the glass vial should not be opened until ready for use.

To open the glass vial, pull back on the top where indicated. Upon removing the top silicone cover, the lens may be removed and is ready for use.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, the lens should be surfaced cleaned and disinfected.

CLEANING

A surfactant cleaner must be used with the **IntelliWave1/ Intellwave1 Pro, Soft Daily Wear Contact Lens** to ensure a clean lens surface. The manufacturer's instruction for Miraflow cleaner by Ciba is as follows:

DIRECTIONS FOR USE:

1. Place lens in the palm of your hand.
2. Apply 1 or 2 drops of cleaner to each lens surface and gently rub with the forefinger of the opposite hand.
3. Clean for about 15 – 20 seconds
4. Rinse the lens thoroughly with sterile saline solution. **DO NOT** use water to rinse your lenses.
5. After rinsing, place the lens in a storage case.
6. Repeat the process with the other lens.
7. Disinfect lenses as per manufacturer's instructions.

RINSING

Thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing or multipurpose solution.

CHEMICAL (NOT-HEAT) LENS CARE SYSTEM

A sterile rinsing, storing and disinfecting multipurpose solution should be used to rinse and chemically disinfect **IntelliWave1/ Intellwave1 Pro, Soft Daily Wear Contact Lenses**. After cleaning the lens, rinse with a liberal amount of fresh multipurpose solution to remove loosened debris and traces of cleaner. The lens should then be placed in the plastic container supplied in a multi-purpose solution kit and filled with enough fresh disinfecting solution to completely submerge the lens. To ensure disinfecting, the lens must remain in the disinfecting solution for the recommended period of time as written on the multipurpose solution bottle. Before reinsertion, lens should be rinsed with fresh sterile rinsing solution.

LENS CARE DIRECTIONS

Please reference LENS CARE DIRECTIONS in the Package Insert included at the end of this Professional Fitting Guide.

STORAGE

The **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens** must be stored in the recommended solutions. If exposed to the air, the lens will dehydrate. If a lens dehydrates, it should be soaked **ONLY** in a soft contact lens storage solution until it returns to a soft, supple state. It should not be put on an eye until it has been put through a complete disinfection cycle.

RECOMMENDED 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 initial wearing schedule. Regular check-ups, as determined by the Eyecare practitioner, are also extremely important. The maximum suggested wearing schedule for the **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens** is reflected below.

<u>DAY</u>	<u>HOURS</u>
1	6
2	8
3	10
4	12
5	14
6	All Waking hours *

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens IS SAFE TO WEAR DURING SLEEP.

MONOVISION FITTING GUIDELINES

1. Patient selection

Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.50 diopter) in one eye may not be a good candidate for monovision with the **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear 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 drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

A. 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 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.

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 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.

B. Refractive Error Method

For anisometric corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

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

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

3. Special Fitting Consideration

Unilateral Lens Correction

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

Example:

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

A presbyopic patient requiring a +1.50 diopter add who is –2.50 diopters myopic in the right eye and –1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient’s habitual reading distance. However, when more than one power provides optical 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 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 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 eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens Patient Instruction / Wearer's Guide**.

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 you state drivers license 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 lenses prescribed so that both eyes are 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.

FREQUENT/PLANNED REPLACEMENT

Art Optical recommends that the **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens** be discarded and replaced with a new lens every six months. However, as the Eyecare practitioner, you are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

RECOMMENDED LENS CARE PRODUCTS

The Eyecare practitioner should recommend a care system that is appropriate for the **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. The table below shows solutions that are recommended for use with the **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens**.

Daily Cleaner:	<ul style="list-style-type: none"> • MiraFlow Extra strength cleaner by CIBA Vision
Rinsing Solution:	<ul style="list-style-type: none"> • Softcare Saline by CIBA Vision
Disinfecting Solution:	<ul style="list-style-type: none"> • Aquify Multipurpose solution by CIBA Vision.
Lubricant/Rewetting Drops:	<ul style="list-style-type: none"> • Aquify long lasting comfort drops by CIBA Vision.
Enzymatic Cleaner:	<ul style="list-style-type: none"> • Unizyme Enzymatic cleaner by CIBA Vision.
Oxidation Systems	<ul style="list-style-type: none"> • AOSEPT or Clear-Care by CIBA Vision.

EMERGENCIES:

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are

splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS:

Practitioners should report any adverse reactions to **IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens** within 5 days to Art Optical Contact Lens. Additional Fitting Guides, Package Inserts and Patient Guides are available from:

Art Optical Contact Lens, Inc.

3175 3 Mile Road NW
Walker, Michigan 49534

Toll Free Number: 800-253-9364

www.artoptical.com

HOW SUPPLIED

Each lens is supplied sterile in a sealed glass vial containing buffered normal saline solution. The glass vial is marked with the base curve, diameter, dioptric power, manufacturing lot number, and expiration date of the lens.