CooperVision®

PROFESSIONAL FITTING AND INFORMATION GUIDE

EXPRESSIONS

(methafilcon A)
Soft (Hydrophilic) Contact Lenses

CAUTION: Federal Law Prohibits Dispensing Without a Prescription

See the Package Insert (PI01015) for complete CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

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IMPORTANT:

This Fitting Guide has been developed to provide practitioners with information covering characteristics of the methafilcon A Soft (Hydrophilic) Contact Lens and to illustrate fitting procedures. Please read carefully and keep this information for future use

INTRODUCTION:

EXPRESSIONS Soft (Hydrophilic) Contact Lenses are made from methafilcon A with a water content of 55% by weight.

For a complete listing of available lens parameters, please refer to LENS PARAMETERS AVAILABLE below.

PRODUCT DESCRIPTION:

EXPRESSIONS (methafilcon A) Soft (hydrophilic) Contact Lenses are available as spherical lenses. The lens material, methafilcon A, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid. The lenses are made by modifying the uncolored methafilcon A lens by affixing a colored pigment on that portion of the front surface that corresponds to the iris. The colored pigments consist of carbazole violet, chromium oxide green, dihydrodinaphto brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue and titanium dioxide.

EXPESSIONS are hemispherical shells with the following dimensions:

- **Diameter**: 14.2mm to 15.0mm
- **Base Curve**: 8.0mm to 9.5mm
- **Center Thickness**: 0.05mm to 0.60mm (varies with power)
- **Spherical Lens Powers**: -20.00 to +20.00D

The physical/optical properties of EXPRESSIONS are:

- **Refractive Index**: 1.41
- **Light Transmittance**: >96%
- **Surface Character**: Hydrophilic
- **Water Content**: 55%
- **Oxygen Permeability**: 19.7 x 10^{-11} (cm^2/sec)(ml O_2/ml x mmHg) at 35°C
  (Fatt method for determination of oxygen permeability)

EXPRESSIONS (methafilcon A) Soft (hydrophilic) Contact Lenses may be prescribed for daily wear with Frequent/Planned Replacement.

LENS PARAMETERS AVAILABLE:

Call our Customer Service Department at (800) 341-2020 for current availability.

ACTIONS:

When placed on the cornea in its hydrated state, the EXPRESSIONS (methafilcon A) Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina.

INDICATIONS:

EXPRESSIONS Contact Lenses are indicated for daily wear between removals for cleaning and disinfecting as recommended by the eye care practitioner. They are also indicated to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the management of conditions such as corneal, iris, or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

Frequent/Planned Replacement Wear

When prescribed for Frequent/Planned Replacement Wear, the EXPRESSIONS Contact Lenses are to be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitioner.

Note: Only chemical disinfection may be used with EXPRESSIONS lens.

Disposable Wear

When prescribed for Disposable Wear, the wearing time prescribed by the eye care practitioner is for daily wear. Patients should be instructed to discard the lenses at each removal.

NOTE: See Package Insert (PI01015) for complete CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

SELECTION OF PATIENTS:

Patients who require only vision correction and who would not or could not adhere to recommended regimen for Expressions methafilcon A Soft (Hydrophilic) Contact Lenses or are unable to place and remove the lenses should not be provided them. Failure to follow handling and wearing instructions could lead to serious eye infection which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also ensuring patient compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of initial examination and to provide a copy of the Patient Information Booklet to patients. Patients selected to wear Expressions methafilcon A Soft (Hydrophilic) Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instruction are essential to their success.

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

Initial evaluation of the 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. See Contraindication, Warnings and Precaution Sections of the Package Insert for additional information on patient selection.

FITTING PROCEDURE OUTLINE:

GENERAL

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

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

A pre-fitting examination should include a complete patient history and a thorough eye examination, including visual acuities, keratometry, and biomicroscopy.

1. INITIAL LENS POWER SELECTION
   a. Convert the spectacle refraction to minus cylinder form.
   b. Compensate the spectacle power for vertex distance if greater than ±4.00D.
   c. If refractive astigmatism is 0.75 diopters or less, drop the cylinder and compensate for power as in step e below.
   d. If refractive astigmatism exceeds 0.75 diopters, determine equivalent sphere and then compensate for power as in step below.
   e. Add +0.25 diopters to compensate for minus tear lens.

2. INITIAL LENS BASE CURVE SELECTION
   a. Select 8.7/14.4 for median and flat corneas
   b. Select 8.4/14.4 for K's of 43.50 and steeper.

   Due to differences in corneal diameter and the rate of corneal flattening, the base curve selected may fit differently on corneas having the same measured radius of curvature. Diagnostic lenses are available to help evaluate base curve/cornea relationships and patient response to the lenses.

3. INITIAL LENS EVALUATION
   a. Remove the lens from the blister pack and rinse it with a recommended sterile rinsing solution before placing it on the patient's eye.
   b. Allow approximately 20 minutes for the lenses to equilibrate on the eye.
   c. Check the lens positioning and movement with a slit lamp. Fitting Criteria should demonstrate:
      - Acceptable visual acuity.
      - Corneal coverage with 0.5 to 1 mm of movement with straight ahead gaze.
      - Stable orientation of laser mark.
   d. Allow the patient to wear the lens for one (1) week if visual acuity and fit are acceptable.

e. If acuity is unacceptable, perform a sphero-cylinder over-refraction, or if calculated resultant does not correspond to spectacle Rx minus vertex, call our consultation staff for assistance.

f. If good acuity is obtained with over-refraction, the new lens power can be calculated by entering the parameters into the pocket computer, or call CooperVision Customer Service for assistance.

4. FOLLOW-UP CARE

a. Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear.

b. Barring complications, the minimum schedule of follow-up examinations should be:

a) One week from the start of lens wear.
b) One month from the start of lens wear.
c) Three months from the start of lens wear.
d) Every six months thereafter.

c. Prior to a follow-up examination, the contact lenses should be worn for at least six continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

d. Review proper lens care and handling instructions and wearing schedule.

e. **With the lenses in place on the eyes**, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. (See Section entitled CLINICAL ASSESSMENT.) Examine the lenses closely for surface deposition and/or damage. Replace lenses if deposits develop which cannot be removed.

f. **After lens removal**, conduct a thorough biomicroscopy examination.

1. The presence of vertical corneal striae in the posterior central cornea and/or 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 (tight) lens.

3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

g. Compare best corrected visual acuity and keratometry readings to the baseline findings. Excessive changes from baseline are indicative of corneal edema and/or a poorly fitting lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any

follow-up examination, the patient should be re-fitted with a more appropriate lens.

IN OFFICE CARE OF TRIAL LENSES:

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

Each contact lens is shipped sterile in a blister pack with sterile buffered isotonic saline. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use.

If the lenses are to be reused in a diagnostic procedure or dispensed to a patient, the lenses MUST be surface cleaned and disinfected. Diagnostic lenses may be disinfected by chemical (not heat) disinfection systems. To ensure adequate disinfection, follow the instructions accompanying the disinfecting solution. DO NOT alternate or mix disinfection systems.

If lenses are not to be used immediately following disinfection, leave them in the closed/unopened case. Refer to the solution instructions for information on storage of lenses

RECOMMENDED INITIAL WEARING SCHEDULE:

Although many practitioners have developed their own 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 practitioner regardless of how comfortable the lenses feel.

The wearing schedule and replacement schedule for EXPRESSIONS should be determined by the eye care practitioner based upon the patient's physiological eye condition, since each individual's response to contact lenses varies

The eye care practitioner will prescribe the lens for **Daily Wear** with **Frequent/Planned Replacement** with cleaning, rinsing, disinfecting and scheduled replacement. Lenses may be disinfected using a chemical disinfection system.

DAILY WEAR: (less than 24 hours, while awake). The maximum suggested wearing time is:

DAILY WEAR SCHEDULE
Maximum Wearing Time

Day	Hours
1	6
2	6
3	10
4	12
5	14
6	All Waking Hours

Adherence to a gradual increase in wearing time is very important. Some flexibility as necessitated by the patient's daily routine is permissible after the first 6 days of wear.

CLINICAL ASSESSMENT:

1. CRITERIA OF A WELL-FITTED LENS
   a. The lens centers easily after a blink and provides complete corneal coverage.
   b. In primary gaze, there is slight post-blinking movement (0.5 to 1.0mm). On upward gaze, the lens sags approximately 1 to 2mm.
   c. Keratometry: Mire quality is clear and constant over the lens surface.
   d. Retinoscopy: The reflex through the lens is clear and indistinguishable from the reflex without a lens in place.
   e. Over-refraction: Good end-point acuity that is not compromised prior to or following a blink.
   f. There is no impingement of the lens edge on the sclera.

2. CHARACTERISTICS OF A TIGHT (STEEP) LENS
   a. The lens does not move freely. There is impingement of the lens edge on the sclera, seen either as scleral indentation or as blanching of the scleral blood vessels.
   b. Bubbles under the lens.
   c. Keratometry: Distorted or blurred mires preceding or following a blink.
   d. Poor or variable vision. Vision clears momentarily immediately after each blink, but is blurred in between blinks.
   e. Over-refraction: Unable to achieve good end-point acuity. If good visual acuity cannot be obtained through the lens, re-evaluation of the physical fit should be considered.

3. CHARACTERISTICS OF A LOOSE (FLAT) LENS
   a. Excessive lens movement (more than 1mm after blinking in primary gaze).
   b. Poor or variable vision. Vision is clear between blinks, but blurs after each blink.
   c. Over-refraction: Unable to achieve good end-point acuity. If good visual acuity cannot be obtained through the lens, re-evaluation of the physical fit should be considered.

MONOVISION FITTING GUIDELINES:

1. PATIENT SELECTION

a. Monovision Needs Assessment

For a good prognosis the presbyopic patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient may not be a good candidate for monovision.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it must be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

(1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(2) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised not to drive with this correction, OR may require that

additional overcorrection spectacles 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 bifocals, trifocals, or reading glasses. Each patient must understand that monovision, as well as other presbyopic contact lenses, or other alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary that the patient understands 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 Demands Method

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

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

3. SPECIAL FITTING CONSIDERATIONS

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic presbyopic 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 +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. NEAR ADD DETERMINATION

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. TRIAL LENS FITTING

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting procedures described earlier in this guide.

Case history and standard clinical evaluation procedures should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distant objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to newsprint and finally smaller type sizes.

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

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

6. ADAPTATION

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

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

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under 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. These "asymmetric power" spectacles may be for balanced near or far vision. This is particularly applicable for those patients who cannot meet state drivers licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

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

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.
- The decision to fit a patient with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering the patient's needs.
- All patients should be supplied with a copy of the Patient Instructions.

PATIENT LENS CARE DIRECTIONS:

Refer to the Package Insert (PI01015) for complete lens care directions in the following sections:

- LENS CARE DIRECTIONS
- LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE
- LENS CASE CLEANING AND MAINTENANCE
- CARE FOR A DRIED OUT (DEHYDRATED) LENS
- CARE FOR A STICKING (NONMOVING) LENS

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing EXPRESSIONS lens or experienced with the lenses should be reported to:

CooperVision, Inc.
711 North Road
Scottsville, NY 14546

Product Services
1.800.341.2020
www.coopervision.com

HOW SUPPLIED:

Each lens is supplied sterile in a blister pack containing sterile buffered isotonic saline solution. The blister pack is labeled with the base curve, diameter, dioptric power, color, manufacturing lot number, and expiration date of the lens.

Do not use or dispense if the blister pack has been broken or damaged.