

PROFESSIONAL FITTING AND INFORMATION GUIDE

Hydrasoft, Hydrasoft Thin, Hydrasoft Toric, and Hydrasoft Toric Thin
(methafilcon B) Soft (Hydrophilic) Contact Lenses



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Caution: Federal Law Prohibits Dispensing Without a Prescription

IMPORTANT:

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

INTRODUCTION:

Hydrasoft, Hydrasoft Thin, Hydrasoft Toric, and Hydrasoft Toric Thin Soft (Hydrophilic) Contact Lenses are made from methafilcon B 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:

Hydrasoft and Hydrasoft Thin (methafilcon B) soft (hydrophilic) contact lenses are available as spherical lenses. Hydrasoft Toric, Hydrasoft Toric Thin (methafilcon B) Soft (Hydrophilic) contact lenses are available as astigmatic (toric) lenses. The lens material, methafilcon B, is a random copolymer of hydroxyethyl-methacrylate and methacrylic acid.

Hydrasoft contact lenses are hemispherical shells with the following dimensions:

Diameter:	14.2mm to 15.0mm
Base Curve:	8.00mm to 9.5mm
Center Thickness:	0.06mm to 0.65mm (varies with power)
Spherical Lens Powers:	
Daily Wear:	-20.00 to +20.00D -30.00 to +30.00D
Toric Lens Powers (Daily Wear):	
Sphere:	20.00 to +20.00D
Cylinder:	Plano to 12.00D
Axis:	1° to 180°

The physical/optical properties of the lens are:

Refractive Index:	1.40
Light Transmittance:	99.6%
Surface Character:	Hydrophilic
Water Content:	55%
Oxygen Permeability:	19.0 10^{-11} (CM ² /sec) (ml O ₂ /ml x mmHg) at 25°C (Measured by Schema Versatae model 920 connected to a polarographic cell.)

LENS PARAMETERS AVAILABLE:

1. HYDRASOFT

Diameter:	15.00mm	14.2mm
Base Curve:		
Standard	8.9mm	8.6mm
Steep	8.6mm	8.3mm
Flat	9.2mm	(not available)
Lens Power:	-20.00 to +20.00	-12.00 to +10.00
Thickness:		
Minus	0.09mm to 0.14mm	0.07mm to 0.12mm
Plus	0.14mm to 0.65mm	0.12mm to 0.39mm
Optical Zone:	8.0mm to 8.5mm	7.6mm to 8.2mm

2. HYDRASOFT Thin:

Diameter:	15.00mm	14.2mm
Base Curve:		
Standard	8.9mm	8.6mm
Steep	8.6mm	8.3mm
Flat	(not available)	(not available)
Lens Power:	-20.00 to +20.00	-12.00 to +10.00
Thickness:		
Minus	0.06mm to 0.10mm	0.06mm to 0.10mm
Plus	0.10mm to 0.43mm	0.10mm to 0.30mm
Optical Zone:	6.8mm to 8.2mm	6.6mm to 7.8mm

3. HYDRASOFT TORIC AND HYDRASOFT TORIC Thin

Diameter:	15.00mm	14.2mm
Base Curve:		
Standard	8.9mm	8.6mm
Steep	8.6mm	8.3mm
Flat	9.2mm	(not available)
Lens Power:		
Spherical:	-20.00 to +20.00D	-20.00 to +20.00
Cylinder	0.50 to 10.00	0.50 to 10.00
Axis:	1° to 180°	1° to 180°
Optical Zone:	8.4mm	8.2mm

ACTIONS:

When placed on the cornea in its hydrated state, the Hydrasoft lens referred to in this fitting guide acts as a refracting medium to focus light rays on the retina. The design of the toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS:

1. **Hydrasoft** lenses are indicated for daily wear 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 1.50 diopters or less that does not interfere with visual acuity.
2. **Hydrasoft Thin** lenses are indicated for daily wear as recommended by the eye care practitioner. They are indicated 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 person who may exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.
3. **Hydrasoft Toric** lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. They may be worn by persons who have astigmatism of 12.00 diopters or less.
4. **Hydrasoft Toric Thin** lenses are indicated for daily wear as recommended by the eyecare practitioner. They are indicated for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not-aphakic person with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less. Note: Only chemical disinfection may be used with Hydrasoft lenses.

Note: Only chemical disinfection may be used with the above Hydrasoft Toric lenses.

Note: See Package Insert PI01004 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 methafilcon B 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 methafilcon B 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

Pre-Fitting

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 – Hydrasoft and Hydrasoft Thin

- a) Convert the spectacle refractive to minus cylinder form.
- b) Compensate the spectacle power to vertex distance if greater than $\pm 4.00D$.
- 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 e below.
- e) Add +0.25 diopters to compensate for minus tear lens.

2. Initial Lens Power Selection – Hydrasoft Toric and Hydrasoft Toric Thin

- a) Convert the spectacle refraction to minus cylinder form.
- b) Compensate the spherical power for vertex distance in greater than $\pm 4.00D$.

c) For **MINUS** lenses, determine the power in this manner:

1. For cylinders between -1.00 to -2.00
add +0.25 to sphere power
add +0.25 to cylinder power
2. For cylinders between -2.25 to -3.50
add +0.50 to sphere power
add +0.50 to cylinder power
3. For cylinders between -3.75 to -5.75
add +0.75 to sphere power
add +0.75 to cylinder power
4. For cylinders between -6.00 to -10.00
add +1.00 to sphere power
add +1.00 to cylinder power

d) For **PLUS** lenses, determine the power in this matter:

1. Leave the cylinder power unchanged
2. For cylinders between -1.00 and -2.00
add +0.50 to sphere power
3. For cylinders between -2.25 and -3.50
add +0.75 to sphere power
4. For cylinders between -3.75 to -5.75
add +1.00 to sphere power
5. For cylinders between -6.00 and -10.00
add +1.25 to sphere power

Note: When the sphere power is within one-half diopter of plano, reduce the recommended addition of plus by 50%.

e) For both plus and minus lenses, the lens axis should be the same as the refractive axis.

1. For cylinder powers for 2.00 diopters or less, the axis tolerance may be $\pm 5^\circ$.
2. For cylinder powers greater than 2.00 diopters, the axis tolerance should be ± 3 .

Examples:

- | | | |
|----|----------------------|---|
| a. | Refractive | -2.00-1.50 x 180 |
| | Spherical power: | add +0.25 to refractive spherical power |
| | Cylinder power: | add +0.25 to refractive cylinder power |
| | Cylinder axis: | 180° |
| | Initial lens to try: | -1.15-1.25 x 180 |
| b. | Refractive | -5.00-3.00 x 90 |
| | Spherical power: | add +0.25 for vertex distance |
| | | Add +0.50 to refractive spherical power |
| | Cylinder power: | add +0.50 to refractive cylinder power |
| | Cylinder axis: | 90° |
| | Initial lens to try: | -4.25-2.50 x 90 |

- | | |
|----------------------|---|
| c. Refractive | -3.00-5.00 x 170 |
| Spherical power: | add +1.00 to refractive spherical power |
| Cylinder power: | same as refractive cylinder power |
| Cylinder axis: | 170° |
| Initial lens to try: | -4.00-5.00 x 170 |

Note: It is preferable to be slightly under corrected on the cylinder power.

3. Initial Lens Diameter Selection

The majority of patients can be successfully fit with the 15.0 diameter. If you experience difficulty, please call the CooperVision consultation department.

4. Initial Lens Base Curve Selection

With any Hydrasoft lens, usually the only variable parameter is the power. Therefore, as long as the flattest corneal curvature is no flatter than 41.00 diopters and no steeper than 45.00 diopters than the corneal diameter is average, the standard 8.9mm base curve lens will fit adequately. (The standard 14.2mm diameter, 8.6mm base curve is equivalent).

Due to differences in corneal diameter and the rate of corneal flattening, this single base curve may fit differently on corneas having the same measured radius of curvature. The draping effect of the lens will compensate for much of this corneal variation. Diagnostic lens sets are available to help evaluate base curve/cornea relationships and patient response to the lenses.

5. Initial Lens Evaluation

- a) Remove the lens from the vial 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. The lens should be stable with the laser mark oriented in the 6 o'clock position. There should be complete corneal coverage with 0.5 to 1.0mm post-blinking movement in primary gaze.
- d) Assess visual acuity. When the proper physical fit has been achieved, perform a spherocylinder over-refraction if necessary to determine best visual acuity. The new lens power can be calculated by entering the parameters into the pocket computer, or call CooperVision Customer Service for assistance.

Note: Check visual acuity on two different occasions before deciding to make power changes of ± 0.50 diopters or less.

- e) If the physical fit and visual acuity are acceptable, allow the patient to wear the lens for one week.

6. 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:
 - 1. **DAILY WEAR – Hydrasoft, Hydrasoft Thin, Hydrasoft Toric, and Hydrasoft Toric Thin**
 - 1. One week from the start of lens wear.
 - 2. One month from the start of lens wear.
 - 3. Three months from the start of lens wear.
 - 4. Every six months thereafter.
- c) Prior to 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 straining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reactive to solution preservatives, excessive lens wear, and/or 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 judgements 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 glass vial 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 vial should not be opened until immediately prior to use.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, 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.

DAILY WEAR: (less than 24 hours, while awake).

Hydrasoft, Hydrasoft Thin, Hydrasoft Toric and Hydrasoft Toric Thin lenses are suitable for daily wear. 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 routing is permissible after the first 6 days of wear. The suggested wearing time may be broken into two periods, separated by a one or two hour rest periods of no lens 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) Bubbled 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 with the sphero-cylindrical over-refraction and axis realignment, re-evaluation of the physical fit should be considered.

3. Characters 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 with the sphero-cylindrical over-refraction and axis realignment, 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:

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 prescribed 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 are completed, test 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 balanced near or far vision. This is particularly applicable for those patients who cannot meet state drivers licensing requirements with a monovision correction.
- Make us 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 for complete lens care directions in the following sections:

- LENS CARE DIRECTIONS
- CHEMICAL LENS DISINFECTION (INCLUDING HYDROGEN PEROXIDE)
- LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE
- CARE FOR A DRIED OUT (DEHYDRATED) LENS
- CARE FOR A STICKING (NONMOVING LENS)

REPORTING OF ADVERSE REACTIONS:

All serious adverse experience and adverse reactions observed in patients wearing any Hydrasoft contact lens or experienced with the lenses should be reported to:

CooperVision
711 North Road
Scottsville, New York 14546
(800) 341-2020
www.coopervision.com

HOW SUPPLIED:

Each lens is supplied sterile in a glass vial containing sterile buffered isotonic saline solution. The glass vial is labeled with the base curve, diameter, dioptric power (cylinder and axis are included for a toric lens), manufacturing lot number, and expiration date of the lens. The vial label for a toric lens also gives the cylinder power and axis.