Sofmed® breathables™ XW (comfilcon A)

Sofmed® breathables™ XW premium (comfilcon A)

Sofmed® breathables™ XW toric (comfilcon A)

Sofmed® breathables™ XW multifocal (comfilcon A)

SOFT (HYDROPHILIC) CONTACT LENSES

PRACTITIONER FITTING GUIDE

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LENS FORM AND CHARACTERISTICS

The **Sofmed® breathables™ XW** (comfilcon A) **Sofmed® breathables™ XW premium** (comfilcon A), **Sofmed® breathables™ XW toric** (comfilcon A), and **Sofmed® breathables™ XW multifocal** (comfilcon A) Soft (Hydrophilic) Contact Lenses are a hemispherical flexible shell that covers the cornea and extends slightly beyond the limbus, covering a portion of the adjacent sclera. In the hydrated state, the lens tends to conform to the curvatures of the anterior eye.

The lens material (comfilcon A), when hydrated, consists of 52% comfilcon A and 48% water by weight when immersed in buffered saline. The material has a refractive index of 1.40 and the lens has a visible light transmittance of > 97%. The oxygen permeability of the material at 35°C is 128 x 10^{-11} (cm^2/sec) (ml 0_2/ml x mm Hg) determined by the coulometric method.

The hydrophilic properties of the **Sofmed® breathables™ XW** (comfilcon A) **Sofmed® breathables™ XW premium** (comfilcon A), **Sofmed® breathables™ toric** (comfilcon A), and **Sofmed® breathables™ XW multifocal** (comfilcon A) Soft (Hydrophilic) Contact Lenses require that it be maintained in a fully hydrated state in a solution having a tonicity compatible with tears. The lens material is stable, has good mechanical strength, and is elastic in its hydrated state. If the lens dries out, it will become hard and appear somewhat warped. If the lens dries out advise patients to discard the dried out lens.

LENS PARAMETERS AVAILABLE

Sofmed® breathables™ XW (comfilcon A) and Sofmed® breathables™ XW premier (comfilcon A)

Diameter	14 mm
Base Curve	8.6 mm
Center Thickness	0.065 mm to 0.60 mm (varies with power)
Sphere Power	-20.00 D to +20.00 D; +0.25 D steps

See Price List for Detailed Availability

Sofmed® breathables™ XW toric (comfilcon A)

Diameter	14 mm
Base Curve	8.6 mm
Center Thickness	0.065 mm to 0.60 mm (varies with power)
Sphere Power	-20.00 D to +20.00 D; +0.25 D steps
Cylinder Power	-0.25 D to -5.75 D
Axis	0° to 180° in 10° increments

See Price List for Detailed Availability

Sofmed® breathables™ XW multifocal (comfilcon A)

Diameter	14 mm
Base Curve	8.6 mm
Center Thickness	0.065 mm to 0.60 mm (varies with power)
Sphere Power	-20.00 D to +20.00 D; +0.25 D steps
Add Power	+0.50 D to +4.00 D

See Price List for Detailed Availability

FITTING CONCEPT

The fitting concept is based on the draping effect of a high water content lens. Various base curves are achieved when the peripheral portion of the **Sofmed® breathables™ XW** (comfilcon A), **Sofmed® breathables™ XW premium** (comfilcon A), **Sofmed® breathables™ XW toric** (comfilcon A), and **Sofmed® breathables™ XW multifocal** (comfilcon A) (hydrophilic) contact lenses flex to the curvature of the cornea. The water content of the lens combined with thin lens sections permits excellent draping across a broad range of corneal curvatures.

The draping effect of the lens automatically adjusts to the sagittal height for each cornea. The lens parallels the apex of the cornea providing broad apical contact of the central cornea, vaulting or “clearance” of the limbus and light scleral bearing.

PATIENT SELECTION

An examination, including history, refraction, keratometry, biomicroscopy, and other pertinent tests and measurements should be performed. If the patient has the necessary qualifications and no contraindications exist, the patient may be considered for fitting.

ACTIONS

When placed on the cornea in its hydrated state, the **Sofmed® breathables™ XW** (comfilcon A), **Sofmed® breathables™ XW premium** (comfilcon A), **Sofmed® breathables™ XW toric** (comfilcon A), and **Sofmed® breathables™ XW multifocal** (comfilcon A) Soft (Hydrophilic) Contact Lenses act as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS (USES)

Sofmed® breathables™ XW (comfilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Sofmed® breathables™ XW premium (comfilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Sofmed® breathables™ XW toric (comfilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -5.75 diopters.

Sofmed® breathables™ XW multifocal (comfilcon A) Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters with add powers from +0.50 to +4.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The **Sofmed® breathables™ XW** (comfilcon A), **Sofmed® breathables™ XW premium** (comfilcon A)**, Sofmed® breathables™ XW toric** (comfilcon A) and **Sofmed® breathables™ XW multifocal** (comfilcon A) Contact Lenses may be prescribed for extended wear for up to 6 nights and 7 days of continuous wear. It is recommended that the contact lens wearer be first evaluated on a Daily Wear schedule prior to overnight wear. The lenses may be prescribed for either one week disposable wear or for frequent replacement with cleaning, disinfection and scheduled replacement. When prescribed for frequent replacement, the lenses must be cleaned and disinfected using a chemical disinfection system only.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS

Please refer to the Package Insert, PI01085.

FITTING PROCEDURE

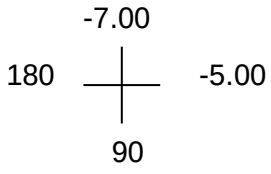
- Perform a preliminary evaluation to determine distance refraction as well as to rule out contraindications to contact lens wear as described in the Package Insert.
- Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
- Place the lens on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variation in the tonicity, pH of the lens solutions and individual tear composition may cause slight changes in fitting characteristics.
- The lens should cover the patient's cornea fully, provide discernible movement (0.10mm to 1.00mm) after blink, be comfortable for the patient and provide satisfactory visual performance.
- Full coverage of the cornea is defined as the lens edge extending beyond the limbus area in all directions. Initial lens evaluation must be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.
- Following a blink, the lens should move vertically on the patient's eye about 0.10mm to 1.00mm.
- When lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and the Patient Information Booklet.

1. Determine Patient's Power Requirements:
   a. Convert the patient's spectacle Rx to minus cylinder form.
   b. The sphere and cylinder power of the contact lens prescription is the same as the spectacle Rx when the power is less than 4.00 D in both meridians. When the power is greater than or equal to 4.00 D, vertex the prescription to the spectacle plane.

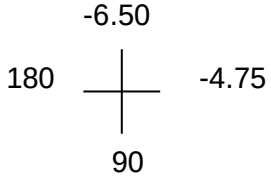
(See **EXAMPLE**) to determine the most appropriate axis.

EXAMPLE: History of nasal rotation on eye being fit

OD Spectacle Rx: -5.00 –2.00 x 180



OD Contact Lens Rx: -4.75 –1.75 x 180



Clinical experience has shown that the initial spherical and cylindrical power may vary by +/- 0.25 diopters and the axis of the initial lens may vary by 5 degrees on cylinders up to 2.00 diopters and 3 degrees for cylinders over 2.00 diopters without diminishing visual acuity of the patient.

If you wish, call our Customer Service Department with the patient's spectacle Rx and central K readings and they will make the proper compensations for your **Sofmed® breathables™ XW** (comfilcon A), **Sofmed® breathables™ XW premium** (comfilcon A), **Sofmed® breathables™ XW toric** (comfilcon A), and **Sofmed® breathables™ XW multifocal** (comfilcon A) Rx.

2. If the flatter keratometry value is 46.50D or less, choose the 8.5 base curve.

3. Equilibration:
   Allow a minimum of 15 minutes for the trial lenses to equilibrate after insertion, before evaluation of fit and vision.

4. Check Lens Fit:

A properly centered lens will provide complete corneal coverage at all times. Decentration which leaves 0.50mm or less of the lens extending onto the sclera in any position will likely result in decreased or fluctuating vision.

The diameter of the lens should be such that the lens extends past the limbus 1.0 - 2.0mm on both the nasal and temporal sides of the cornea.

Movement of the lens with blinking is important to maintain optimum corneal physiology. The lens should move 0.50 - 1.5mm when the patient blinks and lag 0.50 - 1.5mm in upward gaze. While some patients may be able to maintain adequate corneal health with less movement, tight lenses should be avoided. If the lens is exhibiting minimal movement, apply a slight amount of digital pressure against the lower lid. The lens should move freely and easily, and return to the centered position when released. A tight lens will resist movement.

5. To Determine the Optimum Power and Axis for the Final Lens:
   a. Measure the amount of lens rotation, if any. Be sure the eye for which lens rotation is being evaluated is sighting straight ahead (i.e., down the optic axis of the slit lamp), as parallax resulting from misalignment can yield inaccurate measurements.
   b. If acuity is less than desired, do a complete over-refraction to include sphere, cylinder and axis and call CooperVision Consultation Department with the following information:
      i. Contact lens parameters
      ii. Over-refraction (sphere, cylinder and axis) and visual acuity
      iii. Lens specifications (base curve, sphere, cylinder, axis)
      iv. Any lens rotation

6. When lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and the Patient Information Booklet.

FITTING SUMMARY

Fitting performance and visual response should be confirmed with the prescription lenses prior to dispensing and the management of certain adaptive symptoms should be discussed with the patient prior to dispensing.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight eye redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these mild symptoms will disappear. If these symptoms persist, the patient should be instructed to contact their eye care practitioner.

During the first few weeks of lens wear, patients may report a small amount of secretions on their eyelids, hazy vision on awakening and occasional dryness of the eyes during the day. These symptoms are minor and may be alleviated by using a lubricating/re-wetting solution.

PATIENT MANAGEMENT AND FOLLOW-UP CARE

1. DISPENSING VISIT

The lenses are delivered sterile, immersed in buffered saline solution, and supplied in a blister pack. Insertion and removal is done in the conventional manner used for soft hydrophilic contact lenses.

Evaluate patient's lenses on the eyes for physical fit as described in the preceding discussion. Instruct the patient on the technique for soft lens insertion and removal, as well as all aspects of lens care, including cleaning, disinfection, storage, and handling. Dispense to the patient written instructions on lens care and a copy of the **Sofmed® breathables™ XW** (comfilcon A), **Sofmed® breathables™ XW premium** (comfilcon A), **Sofmed® breathables™ XW toric** (comfilcon A) and **Sofmed® breathables™ XW multifocal** (comfilcon A) soft (hydrophilic) Contact Lens Patient Instruction Booklet. Review these instructions carefully with your patient.

2. RECOMMENDED WEARING SCHEDULE

It is recommended that a contact lens-wearing patient see his or her Eye Care Practitioner twice each year or, is so directed, more frequently. The practitioner should determine the appropriate wearing schedule and replacement schedule, which he or she should provide to the patient.

Daily wear: Patients tend to over wear the lenses initially. Therefore, practitioners should stress to these patients the importance of adhering to a proper initial daily wearing schedule. The practitioner should determine the appropriate wearing schedule and replacement schedule, which he or she should provide to the patient.

Extended wear: **Sofmed® breathables™ X** (comfilcon A), **Sofmed® breathables™ XW premium** (comfilcon A), **Sofmed® breathables™ XW toric** (comfilcon A) and **Sofmed® breathables™ XW multifocal** (comfilcon A) are approved for up to 6 nights and 7 days of continuous wear.

3. FOLLOW-UP CARE

Follow-up care includes routine periodic progress examinations, management of specific problems, if any, and review of proper lens care and handling. Barring complications, the recommended schedule of follow-up examinations should be:

Daily Wear

a. One week post-dispensing.
b. One month after dispensing.
c. Three months after dispensing.
d. Every six months thereafter.

4. PROCEDURES AND INSTRUMENTATION FOR FOLLOW-UP VISITS

(with lenses on, preferably for at least six hours):

a. Record patient's symptoms, if any.
b. 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.
c. Check visual acuity and refract over lens.
d. Check for residual astigmatism with the aid of a refractor or loose trial lenses (do not use autorefractor).
e. Biomicroscopy:
   i. Examine the conjunctiva and lids.
   ii. Check for lens edge impingement of the sclera, indentation, or vessel blanching, using low to medium magnification.
   iii. Check integrity of lens edges.
   iv. Check for surface deposits, deep scratches or edge nicks.

5. PROCEDURES FOR FOLLOW-UP VISITS

(with lenses removed):

a. Perform a biomicroscopic examination of the cornea and limbus, both with and without the use of fluorescein; check for edema, injection, vascularization, corneal staining, or any indication of iritis.
b. Measure corneal curvatures with keratometer and compare to original values and mire quality. Any deviations from baseline (pre-fit) should be noted.
c. Check for spectacle blur shortly after lenses are removed. Record all measurable values and any remarkable findings.

If any of the above observations are judged to be abnormal, professional judgment is to be used in alleviating the problem and restoring the eye to optimal conditions. If the criteria for a well-fitted lens are not reached during any follow-up examinations, the patient's fitting procedure should be repeated. The patient should be refitted, with necessary follow-up examinations also repeated.

CLINICAL ASSESSMENT

1. CRITERIA OF A WELL-FITTED LENS

A well-fitted **Sofmed® breathables™ XW** (comfilcon A), **Sofmed® breathables™ XW premium** (comfilcon A), **Sofmed® breathables™ XW toric** (comfilcon A), and **Sofmed® breathables™ XW multifocal** (comfilcon A) Soft (Hydrophilic) Contact Lens best satisfies the following criteria:

- Full corneal coverage.
- Good centration (concentric about the visible iris).
- Satisfactory lens sag (in up gaze 0.10 to 1.00mm is ideal) with the blink.
- The lens moves freely when manipulated with digital pressure against the lower lid.
- Satisfactory comfort response by the patient.
- Satisfactory vision response by the patient.

2. CHARACTERISTICS OF A TIGHT (STEEP) LENS

A tight **Sofmed® breathables™ XW** (comfilcon A), **Sofmed® breathables™ XW premium** (comfilcon A), **Sofmed® breathables™ XW toric** (comfilcon A), and **Sofmed® breathables™ XW multifocal** (comfilcon A) Soft (hydrophilic) Contact Lens would display some or all of the following characteristics:

- Good centration.
- Little or no up gaze sag.
- The lens resists movement when manipulated with digital pressure against the lower lid.
- Good comfort
- Vision may be blurred and clear immediately following blink.
- Bubble(s) under the lens.
- Conjunctival indentation and/or blanching of limbal vessels at the lens edge.
- Limbal-conjunctival hyperemia.

3. CHARACTERISTICS OF A LOOSE (FLAT) LENS

A loose **Sofmed® breathables™ XW** (comfilcon A), **Sofmed® breathables™ XW premium** (comfilcon A), **Sofmed® breathables™ XW toric** (comfilcon A), and **Sofmed® breathables™ XW multifocal** *(*comfilcon A) Soft (hydrophilic) Contact Lens will display some or all of the following characteristics:

- Decentration (usually temporally and/or superiorly).
- Excessive up gaze sag.
- Reduced comfort response-usually lower lid sensation.
- Lens edge standoff.
- Unstable vision.

MONOVISION FITTING GUIDELINES

1. Patient Selection

A. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 0.75 diopter) in one eye 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 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.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other 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 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 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 with 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 optimal reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

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

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

After the patient's performance under the above conditions 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 adaptation symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

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

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions:

The success of the monovision technique may be further improved by having your patient follow the suggestions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

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

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

* The decision to fit a patient with a monovision correction is most appropriately left to the Eye Care Practitioner in conjunction with the patient after carefully considering the patient's needs.

* All patients should be supplied with a copy of the Patient Instruction manual.

CARE OF LENSES

Please refer to the “Lens Care Directions” section of the Package Insert.

PATIENT CARE OF LENSES

Please refer to the Package Insert and the Patient Information Booklets for information pertaining to Cleaning/Disinfecting, Lens Care, and Handling Instructions.

HOW SUPPLIED

Each lens is supplied sterile in a blister containing sterile isotonic buffered saline solution. The blisters are packed in boxes. The following information is provided: the base curve, diameter, dioptric power, manufacturing lot number of the lens and the expiration date of the product. The blister label for **Sofmed® breathables™ XW toric** is also marked with the cylinder power and axis. The blister label for **Sofmed® breathables™ XW multifocal** is also marked with the Add power.

REPORTING ADVERSE REACTIONS

All serious adverse experiences and adverse reactions in patients wearing the **Sofmed® breathables™ XW** (comfilcon A), **Sofmed® breathables™ XW premium**(comfilcon A), **Sofmed® breathables™ XW toric** (comfilcon A), and **Sofmed® breathables™ XW multifocal** (comfilcon A) Soft (Hydrophilic) Contact Lens or experienced with the lenses should be reported to:

CooperVision, Inc.
711 North Road
Scottsville, NY 94080
USA
800-341-2020

PACKAGE INSERT

For **Sofmed® breathables™ XW** (comfilcon A), **Sofmed® breathables™ XW premium** (comfilcon A), **Sofmed® breathables™ XW toric** (comfilcon A), and **Sofmed® breathables™ XW multifocal** (comfilcon A), (comfilcon A) Soft (Hydrophilic) Contact Lens Package Insert, please reference PI01085.