PROFESSIONAL FITTING GUIDE

FOR THE
CLARITY H₂O®
(hioxifilcon D)

Soft Contact Lens
for Daily Wear

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

Please read this guide carefully and follow the instruction so that you receive full satisfaction from your lenses.

DESCRIPTION OF LENS

Clarity H₂O® (hioxifilcon D) soft contact lenses are hemispherical shells and are available as spherical lenses of the following dimensions:

<table>
<thead>
<tr>
<th>Clarity H₂O Flat</th>
<th>Clarity H₂O Median</th>
<th>Clarity H₂O Steep</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parameters</strong></td>
<td><strong>Values</strong></td>
<td><strong>Parameters</strong></td>
</tr>
<tr>
<td>Diameter</td>
<td>14.0mm</td>
<td>Diameter</td>
</tr>
<tr>
<td>Center Thickness</td>
<td>0.085mm @ -3.00</td>
<td>Center Thickness</td>
</tr>
<tr>
<td>Base Curve</td>
<td>Flat (equiv. to 8.7)</td>
<td>Base Curve</td>
</tr>
<tr>
<td>Power Range</td>
<td>-0.25 to -6.00</td>
<td>Power Range</td>
</tr>
<tr>
<td></td>
<td>by 0.25 diopters</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The Clarity H₂O® (hioxifilcon D) soft contact lens is fabricated from hioxifilcon D, which is a non-ionic, copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 46% hioxifilcon D and 54% water by weight when immersed in normal saline solution buffered with either sodium bicarbonate or sodium perforate. The lens is available with a blue visibility handling tint, phthalocyanato (2) - (copper).

The Physical/Optical properties of the lenses are:

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refractive Index</td>
<td>1.414 (hydrated)</td>
</tr>
<tr>
<td>Light Transmission - tinted</td>
<td>greater than 95%</td>
</tr>
<tr>
<td>Water Content</td>
<td>54%</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.300 (dry)</td>
</tr>
<tr>
<td>Oxygen Permeability (Dk Value)</td>
<td>21 x 10⁻¹¹ Fatt Units (cm²/sec)(ml O₂/ml x mm Hg), ANSI Z80:2004 upgraded polarographic method</td>
</tr>
</tbody>
</table>
A pre-fitting examination is necessary to:

- Determine if the patient is a suitable candidate in terms of motivation, physical state, and willingness to comply with instructions concerning wear time and hygiene;
- Carefully evaluate the lids, lashes, conjunctival areas as well as the anterior segment of the eye for suitability for contact lens wear;
- Take ocular measurements for initial contact lens parameter selection; and
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include a case history, a spherocylindrical refraction, keratometric readings, tear assessment, and biomicroscopy of the anterior segment.

Initial Power Determination
The initial power selection should be as close as possible to the patient’s prescription after taking into account spherical equivalent and vertex calculations, if necessary. Remember to compensate for vertex distance if the refraction is greater than ± 4.00D.

**Base Curve Selection**

A well-fitted lens provides good movement, centration, and comfort. This can be achieved for the majority of patients with the 8.4 mm base curve. However, corneal curvature measurements should be performed to establish the patient’s baseline ocular status.

Place a lens on each of the patient’s eyes and allow a 15 minute period of adjustment and equilibration.

**Characteristics of a Well-Fitted Lens:** A properly fitted lens will center and completely cover the cornea in all fields of gaze, allow sufficient lens movement to provide tear exchange under the lens during a blink in primary or upgaze, move freely when manipulated with the index finger on the lower lid nudging upward, and return to its properly centered position when released.

**Characteristics of a Tight (Steep) Lens:** A tight or steep fit may provide insufficient or no lens movement during a blink in primary or upgaze, resist movement if nudged upward with the index finger and/or cause fluctuating vision between blinks. **If the contact lens is deemed to be steep fitting, do not dispense to the patient.** A flatter lens (larger base curve) should be evaluated if available.

**Characteristics of a Loose (Flat) Lens:** A loose or flat fit may exhibit reduced comfort, decentration, excessive movement during the blink or in primary upgaze, and/or edge standoff. **If the contact lens is deemed to be flat fitting, do not dispense to the patient.** A steeper lens (smaller base curve) should be evaluated if available.

**Final Lens Power Determination**

After the lens fit is successful, a spherical over-refraction should be performed to determine the proper lens power to be dispensed.

Example:

Diagnostic lens: -3.00D  
Over-refraction: -0.25D  
Final lens power: -3.25D

**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.

At the follow-up examinations, the patient should report good subjective quality of vision. Adaptation to vision with Clarity H2O® (hioxifilcon D) soft contact lenses 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:

- Check distances and near acuity with lenses in place.
- Over-refract to verify lens prescription.
- Observe the position of the lens on the cornea. The lens should be centered and move on upward gaze and with a blink.
- Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
- Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
- 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.
- Clean the lens with a surfactant cleaner, and examine for deposits, foreign bodies or physical imperfections of the lens surface.

**LENS HANDLING**

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 lubricating and rewetting drops before removal of the lens. Care should be used not to pinch the lens when removing it from the eye. Pinching the lens can reduce the life of the lens.**

Always start with the right lens first in order to avoid mixing the lenses. In removing the lenses, 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, sol upper lid nudging upward, and return to its properly centered position when released.

**CLEANING & RINSING**

Based on practitioner recommendation, a surfactant cleaner can be used with Clarity H2O hioxifilcon D soft contact lenses to ensure a clean lens surface. Follow the recommendations of the manufacturer of the cleaning solution. Thoroughly rinse both surfaces of the lens with a steady stream of rinsing solution.

**CHEMICAL (NOT-HEAT) LENS CARE SYSTEM**

A sterile rinsing, storing, and disinfecting solution should be used to rinse and chemically disinfect Clarity H2O® (hioxifilcon D) soft contact lenses. After cleaning the lens, rinse with a liberal amount of fresh rinsing solution to remove loosened debris and traces of cleaner. The lens should then be placed in an appropriate lens storage case 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 period of time recommended in the disinfecting solution instructions for use. Before reinsertion, lenses should be rinsed with fresh sterile rinsing solution.

**LENS CARE DIRECTIONS**

Refer to Package Insert.

**STORAGE**
The Clarity H₂O® (hioxifilcon D) soft contact lenses must be stored in the recommended solutions. If exposed to the air, the lenses 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 disinfecting cycle and a thorough inspection.

LENS CARE PRODUCTS
The eye care practitioner should recommend a care system that is appropriate for hydrophilic soft contact lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

RECOMMENDED WEARING SCHEDULE
Wearing schedule should be determined by the eye care practitioner. 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 lenses. Patients tend to over-wear the lenses initially. It is important not to exceed the initial wearing schedule. Regular check-ups, as determined by the eye care practitioner, are also extremely important. The maximum suggested wearing schedule for Clarity H₂O® (hioxifilcon D) soft contact lenses is as follows.

<table>
<thead>
<tr>
<th>Days</th>
<th>Continuous Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>6</td>
<td>14</td>
</tr>
</tbody>
</table>

Until first follow-up examination @ 8 days

All waking hours or according to practitioner recommendation

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT CLARITY H₂O® (hioxifilcon D) SOFT CONTACT LENSES ARE SAFE TO WEAR DURING SLEEP.

RECOMMENDED METHODS OF LENS INSERTION
1. The lens should be placed on the tip of the index finger of the dominant hand. Place the middle finger of the same hand close to the lower lash and hold the lid down.
2. Use the forefinger or middle finger of the other hand to lift up the upper lid. Look straight ahead and gently place the lens directly on the eye.
3. Gently release the lids and blink. The lens will center automatically.
4. If there is an initial foreign body sensation, the patient should look up to the ceiling and slide the lens off the cornea. Then the patient should look down until the lens re-positions itself on the cornea. If the foreign body sensation persists, the patient should remove the lens, rinse it with a recommended rinsing solution, and reinsert. If the foreign body sensation still persists, the patient should remove the lens.
5. Use the same technique or reverse hands when applying the other lens.

Alternate method of lens insertion
If patient is unable to insert the lens using this method, the eye care practitioner should provide an alternate method for lens insertion.

RECOMMENDED METHODS OF LENS REMOVAL:
Blink Method
The blink method is a safe way to remove the lens while avoiding folding or pinching the lens. Pinching increases the chances of lens splitting or tearing. This method is also useful to those patients who have difficulty touching their fingers to the lens while it is still on their eye.

Seat yourself at a table covered with a clean towel and lean over until you are looking directly down at the surface.
1. Wet eye using lubricating and rewetting drops.
2. Open eye wide and place opposite hand below the eye; palm up (open).
3. Place index finger on the outside edge of the upper lid and press eyelid upward above the contact lens.
4. Press the upper and lower lid margins against the eye, using the index and middle fingers of each hand.
5. At the same time, pull both lids out toward the ear.
6. Attempt to blink. The lens edge will be folded by the pressure of the eyelids. The lens will then pop out of the eye and either be stuck to the lid(s), or you may catch the lens in the palm of your hand.
7. Remove lens from lid(s). Avoid pinching the lens.

Alternate method
1. Insert 1 – 2 drops of lubricating and rewetting solution in eye and wait 15 seconds.
2. Look up and hold down lower lid.
3. Slide lens onto white of eye (sclera) and gently lift off using thumb and forefinger at the widest point (3 & 9 o’clock) of the lens.
4. It is important not to crease or pinch the lens in the center or at the bottom edge to avoid damaging the material.
5. Repeat procedure for the other eye.

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 FOR AT LEAST 15 TO 30 MINUTES AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS
All serious adverse experiences and adverse reactions observed in patients wearing Clarity H₂O® (hioxifilon D) soft contact lenses or experienced with the lens should be reported to:
Hydrogel Vision Corporation
7575 Commerce Court
Sarasota, FL 34243 USA
1-877-336-2482

HOW SUPPLIED
Each Clarity H₂O® (hioxifilon D) soft contact lens is supplied sterile in a sealed blister pack containing buffered normal saline solution. The blister pack is labeled with the base curve, power, diameter, manufacturing lot number, and the expiry date of the lens. Do not use if the blister is damaged or the seal is broken.

Manufactured and Marketed by
7575 Commerce Court
Sarasota, FL 34243 USA

Rev. Date: 1/2010