PROFESSION FITTING GUIDE

for the

HUBBLE

HUBBLE Daily

CAUTION: PRESCRIPTION ONLY/SOLD ONLY ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL

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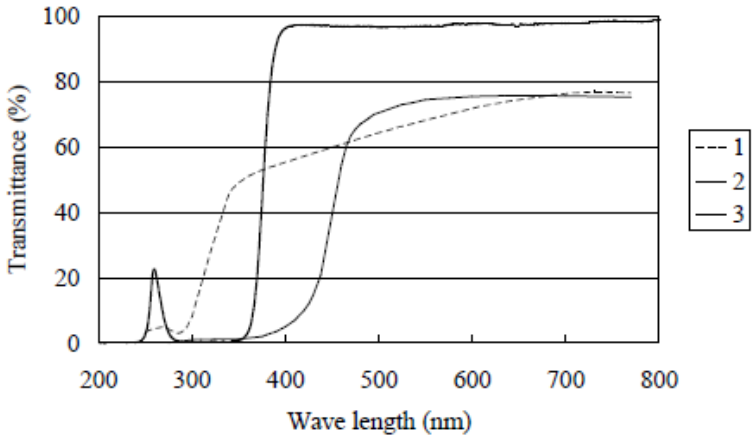
DESCRIPTION

HUBBLE Daily contact lenses are available in a spherical lens design. The lenses are to be prescribed for single use, daily disposable wear.

LENS MATERIAL

The lens material is 55% water and 45% methafilcon A polymer (2-hydroxyethyl methacrylate and methacrylic acid crosslinked with ethylene glycol dimethacrylate). For visibility tinted lenses, the color additive copper phthalocyanine is added to the lens material to make them easier to see when handling.

A UV absorbing monomer, 2-[3-(2H- Benzotriazol-2y1)-4-hydroxyphenyl] ethyl methacrylate, is incorporated into the lens polymer to block UV radiation. The Hubble® (methafilcon A) Soft (hydrophilic) Contact Lenses block an average of 80 % in the UVA range (316 nm to 380 nm) and 95 % in the UVB range (315 nm to 280 nm).



1. Human cornea from a 24 year-old person as described in Lerman, S., Radiant Energy and the Eye, New York, 1980, p. 58, Figure 2-21.
2. Human crystalline lens from a 25 year-old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.
3. The Hubble® (methafilcon A) Soft (hydrophilic) Contact Lenses.

* Lens transmittance was obtained from measurements taken through the central 3-5 mm portion of the thinnest marketed version of the UV lens.

LENS PROPERTIES

- Refractive index: 1.404 (hydrated)
- Light transmittance: >96% (381 nm ~ 780 nm)
- Oxygen permeability (Dk): 21.4 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg), measured at 35°C (Fatt, edge effect corrected)
- Water content: 55% by weight in normal saline

LENS PARAMETERS

HUBBLE Daily are available in the following dimensions:

- Base curve: 8.6 mm
- Diameter: 14.2 mm
- Powers available:
- -8.00D to +6.00D (0.25D steps);
- Center thickness: 0.10 mm at -3.00D (varies with power)
- Tint: Light blue handling tint

ACTIONS

When hydrated and placed on the cornea HUBBLE Daily contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS

HUBBLE Daily contact lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive astigmatism up to 2.0 diopters that does not interfere with visual acuity.

HUBBLE Daily contact lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

CONTRAINDICATIONS

Do not use HUBBLE Daily when any of the following conditions exists:

- Acute or subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids that may be exacerbated by contact lens wear.
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear.
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may be exacerbated by or interferes with contact lens wear.
- Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exacerbated by the wearing of contact lenses.
- Any active corneal infection (bacterial, fungal, or viral).
- The use of any medication that is contraindicated or interferes with contact lens wear, including eye medications.
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear.
- If eyes become red or irritated.

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses could result in serious injury to the eye. It is essential that patients follow their eye care professional's directions and all labeling instructions for proper use of their lenses. **Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.**
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical study results have shown that the risk of ulcerative keratitis is nine times greater for daily wear users who wear their lenses overnight (outside the approved indication) compared to those who do not wear them overnight.
- Studies have shown that contact lens wearers who smoke have an estimated 3 to 8 times greater risk of suffering ulcerative keratitis than those who are nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, redness of the eye, or other problems they should be instructed to immediately remove their lenses and promptly contact their eye care professional. It is recommended that contact lens wearers see their eye care professional regularly as directed.
- UV-absorbing contact lenses are NOT substitutes for protective UV absorbing eye wear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. The patient should continue to use UV absorbing eye wear as directed.

PRECAUTIONS

Special Precautions for Eye Care Practitioner:

Due to the small number of patients enrolled in the clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors on the patient's ocular health should 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 eye care professional.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in eye use prior to inserting lenses.
- Avoid dispensing saline from an aerosol can directly into the eye.
- Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continuing health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. Vision Path, Inc. recommends that patients see their eye care professional once each year or as recommended by the eye care professional.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Eye Care Professionals should carefully instruct patients about the following safety precautions:

- Carefully follow the handling, insertion, removal, and wearing instructions in the HUBBLE Daily Wearer's Guide and any additional instructions provided by the eye care professional.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always keep spare lenses available to avoid reusing the lenses.
- Good hygiene habits help promote safe and comfortable lens wear. Always wash and rinse hands before handling lenses.
- Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pouring the lens onto the palm of your clean hand.
- Never use tweezers or other sharp objects such as fingernails to remove the lens from the container to avoid damaging the lens.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses. If sprays are used, eyes should be kept closed until the spray has settled.
- Always handle lenses carefully. If a lens is dropped, small particles or fibers may adhere to the lens surface which can irritate the eye. Replace with a sterile fresh, new lens.
- Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.
- Consult the eye care professional about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to Acanthamoeba keratitis.
- Avoid all harmful or irritating vapors or fumes while wearing lenses.
- Promptly remove a lens to avoid serious injury in the event that dust, a foreign body or other contaminant gets between the lens and the eye.
- Discard any lens which has become dehydrated or damaged. Replace with a sterile fresh, new lens.
- Patients should be instructed to remove their lenses before sleeping.

- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the section Care for a Sticking Lens. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- Patients should inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or restrict the use of contact lenses in certain work environments.
- Patients should inform their physician that contact lenses are worn and should consult their eye care professional before using any medication in the eye.
- Do not use lenses beyond the expiration date.
- Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. Patients should be informed of these potential conditions and proper remedial treatment should be prescribed if any of these conditions occur. Depending on the severity of the condition appropriate treatment may include the use of rewetting drops intended for use with soft contact lenses or temporary cessation of contact lens wear until the conditions subsides.

It is strongly recommended that patients be provided with a copy of the HUBBLE Daily Wearers Guide available from Vision Path, Inc. and understand its contents prior to dispensing the lenses. The Patient Wearers Guide is available for download at Hubblecontacts.com.

ADVERSE REACTIONS

Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:

- Foreign body sensation
- Excessive watering or other unusual eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (sensitivity to light)
- Burning, stinging, itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

If any of the previous signs or symptoms occur:

The patient should IMMEDIATELY REMOVE THE LENS(ES). If the discomfort or problem stops, the patient should discard the lens and replace it with a new one. IF THE PROBLEM CONTINUES AFTER INSERTING A NEW LENS, THE PATIENT SHOULD IMMEDIATELY REMOVE THE LENS(ES) AND CONTACT AN EYE CARE PROFESSIONAL AT ONCE

Patients should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, infiltrates and bacterial conjunctivitis must be managed and treated early to avoid more serious complications. Additionally, contact lens wear may be associated with ocular changes which require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

PATIENT SELECTION

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended care of the HUBBLE Daily contact lens 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

Fitting Procedure for the **Spherical** HUBBLE Daily

1. Pre-fitting Examination
2. Trial Lens Evaluation
3. Lens Fit Assessment
4. Final Lens Power Determination

1. Pre-fitting Examination

A pre-fitting examination is necessary to:

- assess the patient's motivation, physical state and willingness to comply with instructions regarding hygiene and wear schedule
- make ocular measurements for initial contact lens parameter selection
- collect baseline clinical information to which post-fitting examination results can be compared

The pre-fitting examination should include:

- a thorough case history
- a spherocylindrical refraction
- keratometry
- tear film assessment
- biomicroscopy

2. Trial Lens Evaluation

HUBBLE Daily contact lenses are available in a single base curve/diameter combination of 8.6/14.20 mm. Following initial power selection, a trial lens should be placed on the eye for assessment of lens fit and comfort, and final power verification.

Initial Lens Power Selection:

Select an initial lens power as close as possible to the patient's spherical equivalent refraction.

The spherical equivalent refraction is determined as follows:

Spherical Equivalent = Sphere power + Cylinder Power/2

Example: Spectacle Rx: -3.00D -1.00 x 180

Spherical Equivalent: -3.00D + -0.50D = -3.50D

Remember: If the spherical equivalent is greater than ± 4.00D, a vertex distance correction is necessary to determine the correct lens power at the corneal plane.

3. Lens Fit Assessment

HUBBLE Daily should be comfortable immediately upon placement on the eye. Care should be taken to ensure the lens is free of foreign particles such as lint, and is not inverted prior to placement on the eye. Reflex tearing due to an uncomfortable lens may cause the lens to stop moving and give the appearance of a tight fit.

Allow the lenses to settle on the eyes for approximately 5 to 10 minutes. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

A well-fitted HUBBLE Daily has the following characteristics:

1. Good centration with full corneal coverage in all fields of gaze

2. Sufficient movement to allow tear exchange under the lens during the blink; 0.1 to 0.5 mm is generally considered optimal.
3. Satisfactory Push-Up Test
    - This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid margin and gently nudge the edge of the lens upward.
    - A well-fitted lens will move freely when pushed upward with fingertip pressure and return quickly to its original position.
4. Good comfort and stable visual response (with over-refraction)

Characteristics of a Tight (Steep) Lens Fit

A tight or steep lens fi t would display some or all of the following characteristics:

1. Insufficient or no lens movement during the blink in primary or upgaze
2. Unsatisfactory Push-Up Test
    - A tight fitting lens will resist movement. If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
3. Good centration
4. Good comfort
5. Fluctuating vision between blinks

Characteristics of a Loose (Flat) Lens Fit

A loose or flat lens fit would display some or all of the following characteristics:

1. Reduced comfort, usually accompanied by lower lid sensation
2. Poor centration with limbal exposure on exaggerated eye movement
3. Lens edge standoff
4. Excessive lens movement during the blink in primary or upgaze
5. Unsatisfactory Push-Up Test
    - A loose fitting lens will move easily but may remain decentered or slip under the upper lid.
6. Vision may be blurred after the blink

An inverted lens will mimic the characteristics of a loose lens. If any of the above signs occur remove the lens and check to make sure it is not inverted.

General Fitting Tips

- While helpful for monitoring corneal stability over time, keratometry is not a reliable predictor of base curve/fi t relationship. Trial fitting of the individual eye is strongly recommended.
- A well-fitting lens will show less movement than generally thought, 0.1 to 0.5 mm is considered optimal.
- A flat base curve/cornea relationship may actually show limited movement. Decentration and excessive lid sensation accompanied by limited movement often indicates the lens is too flat for the given eye.

If the criteria for a well-fitted lens cannot be achieved, do not dispense.

4. Final Lens Power Determination

After the characteristics of a well-fitted lens have been satisfied, conduct a spherical over-refraction to determine the proper lens power to be dispensed.

Example: Trial lens: -4.50D
Over-refraction: -0.25D
Final Lens Power: -4.75D

Use a fresh, new pair of lenses for each trial fitting. Do not attempt to disinfect and re-use trial lenses.

FOLLOW-UP EXAMINATIONS

Follow-up care is necessary to ensure continued successful contact lens wear. Follow-up examinations should include:

- Case history, including questions to identify any problems related to contact lens wear
- Management of specific problems, if any, and
- A review with the patient of the lens wear and replacement schedule, proper lens handling procedures, and to ensure sufficient supply of spare lenses.

Follow-Up Examination Procedures:

- Prior to a follow-up examination, the contact lenses should be worn for at least four continuous hours.
- Record patient's symptoms, if any.
- Measure visual acuity monocularly and binocularly with the contact lenses in place.
- Perform an over-refraction to check for residual refractive error.
- With lenses in place, evaluate the fitting performance of the lenses to assure the criteria of a well-fitted lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- Remove the lenses and conduct a thorough biomicroscopy examination.
- Periodically perform keratometry and spectacle refractions and compare the results with the initial measurements.
- If any observations are abnormal, use professional judgment to manage the problem and restore the eye to optimal conditions. If visual requirements or 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.

REPLACEMENT AND WEAR SCHEDULE

HUBBLE Daily are intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a fresh new lens.

WEARING SCHEDULE

Daily Wear (less than 24 hours, while awake)

The maximum daily wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. There may be a tendency for patients to over wear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule.

Studies have not been conducted to show that HUBBLE Daily are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period. Optimum individual wearing schedule will vary.

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 1.50 diopter) in one eye may not be a good candidate for monovision with the HUBBLE Daily.

   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:

- Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

- 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 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 and 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 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 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 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 HUBBLE Daily Wearer's Guide.

EMERGENCIES

Patients 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 or fresh saline solution, remove and discard the lens, and immediately contact the eye care professional or visit a hospital emergency room without delay.**

Additional information regarding emergency treatment may be provided on the product container label.

REPORTING OF ADVERSE EVENTS

If a patient experiences any serious adverse effects associated with the use of HUBBLE Daily, licensed eye care professionals please notify:

Manufacturer**:**

VISION PATH, INC.
1325 Avenue of the Americas
Suite 2718
New York, NY 10019
USA
Email: help@hubblecontacts.com
Toll Free: 1-844-334-1640

HOW SUPPLIED

HUBBLE Daily contact lenses are supplied sterile and packaged in strips of five foil sealed blister packs containing buffered saline solution. Five blister pack containers are attached to form a single strip. The package is marked with the base curve, diameter, dioptric power, manufacturing lot number and expiration date.

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Print Date: 05/2017