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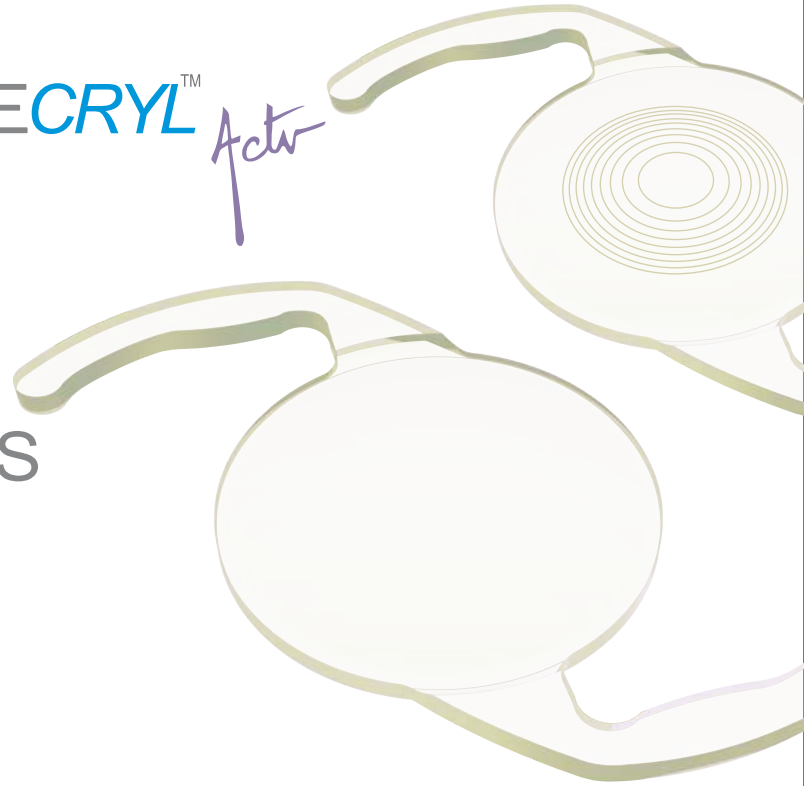
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# EYECRYL™

Optimally Hydrated Natural Yellow Hydrophobic IOLs

EYECRYL™ *Actr*

EYECRYL™ PLUS



## A breakthrough in hydrophobic IOL technology - NO GLISTENINGS

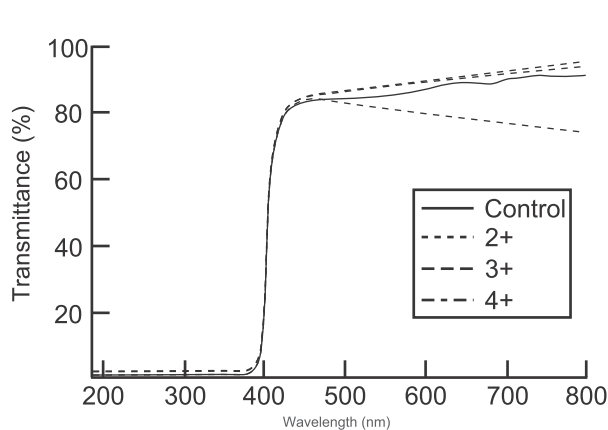
- Controlled surgical manipulation
- Enhanced bio-adhesion
- Increased bio-mechanical stability
- Excellent folding & unfolding
- No fluid exchange with Aqueous Humor
- Resistant to environmental stress or environmental conditions like temperature, humidity & contamination and hence reduced risks of inflammation

## Glistenings: A material characteristic in today's Hydrophobic Acrylic IOLs<sup>[20-29]</sup>

Glistenings are fluid-filled microvacuoles within the optic when the IOL is in an aqueous environment. Temperature changes are considered primary factor for glistenings as shown in several studies of the mechanism and causative factors of glistenings.

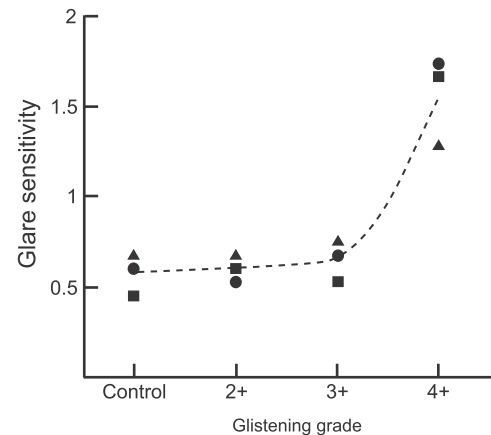
### Glistenings scatter light and cause:

- Significant reduction in light transmission through the lens
- Reduced Modulation Transfer Function (MTF) of the IOL
- Reduced contrast sensitivity, and increased halos & glare sensitivity



**Figure 1:**

Spectral transmission with Glistening level (control to Level 4+)



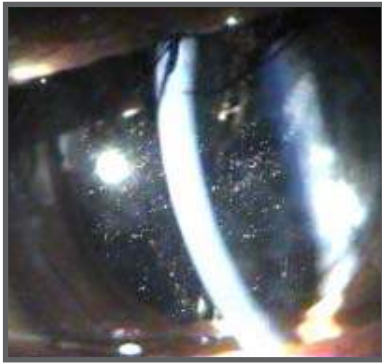
**Figure 2:**

Glare sensitivity index evaluated by ophthalmologists  
The line indicates the average value

## Technological Excellence:

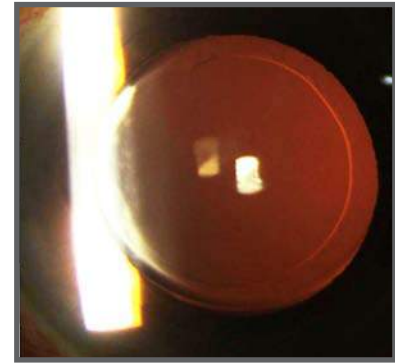
EYECRYL™ IOLs are optimally hydrated hydrophobic intraocular lenses. The equilibrium water content is achieved through pre-hydration of the lens material:

- Retains all hydrophobic material characteristics
- Stabilizes IOL material against temperature and environmental changes
- No aqueous changes in IOL material once implanted in the eye - hence, IOL remains free of glistenings



**Figure 3:**

Slit lamp photography of Micro Vacuoles or Glistening of level 4+ in a well known hydrophobic IOL available in the market



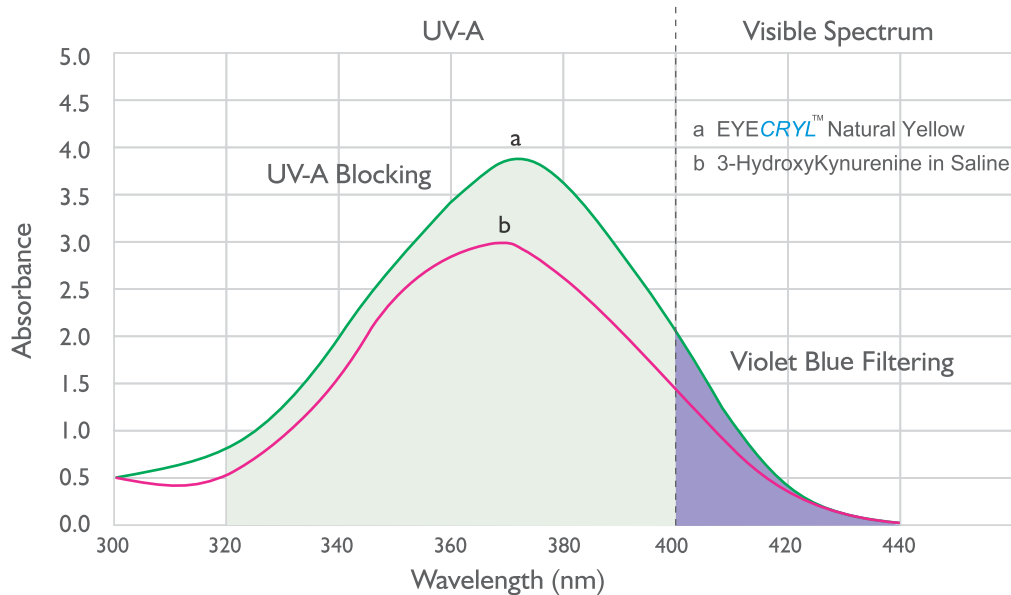
**Figure 4:**

Slit lamp photography of Glistening-free EYECRYL™ Optimally Hydrated Natural Yellow Hydrophobic IOL

- Advanced material of the lens enables surgeon to perform small incision cataract surgery
- Tackiness properties of material enables the lens to adhere to capsular bag & postpones onset of PCO, providing stability to the lens in the eye
- Excellent bio-compatibility - complying requirements of ISO 10993
- IOL material reduces glare sensitivity and increases contrast sensitivity

## Violet-Blue Light Filter: An optimal solution for Retina protection<sup>[17-19]</sup>

- EYECRYL™ IOLs contain a unique covalently bound natural Chromophore, which contains the same UV-A blocking and Violet-Blue Light filtering Chromophore that is in the human crystalline lens. We use nature's own solution to the problem of protecting the Retina from harmful energetic light. The absorption spectrum of 3 Hydroxy Kynurenine (Figure 5) shows that this natural compound is an excellent UV-A blocker with a secondary purpose of filtering Violet-Blue Light. This compound and it's Beta Glucoside derivatives are nature's primary protection for UV-A and Violet-Blue Light.

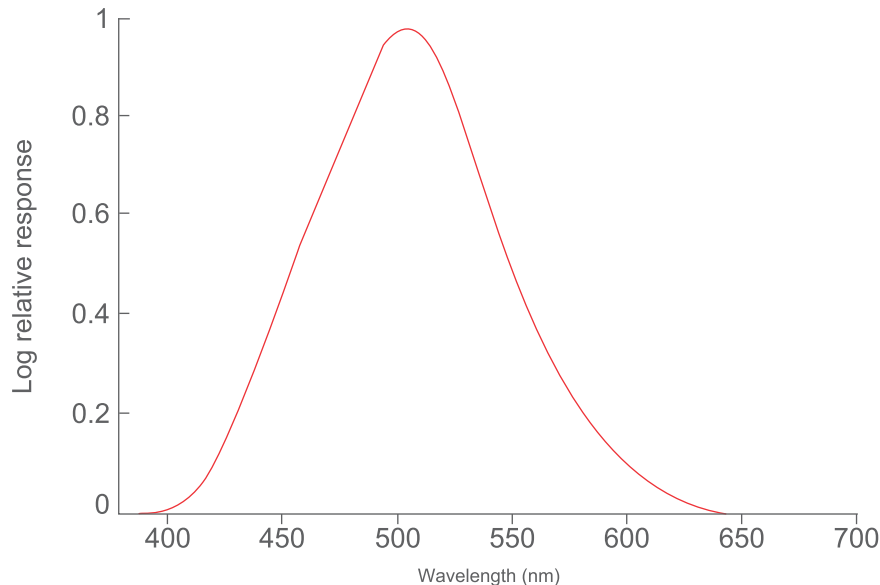


**Figure 5:** Comparison of 3-HydroxyKynurenine in Saline versus EYECRYL™ Natural Yellow

Thus, EYECRYL™ IOLs provide Violet-Blue Light filtering similar to a young natural crystalline lens and without altering color perception & contrast sensitivity.

## Improvement in Scotopic Vision<sup>[14-16]</sup>:

**Scotopic vision** is the vision of the eye under low light conditions. In the human eye, cone cells are nonfunctional in low light. Scotopic vision is produced exclusively through rod cells which are most sensitive to wavelengths of light around 498 nm (Green-Blue). The below mentioned graph shows that the quality of the scotopic vision is at its peak for the visible spectrum ranging from 450 nm to 550 nm. The quality of scotopic vision decreases by filtering healthy Blue Light of 440 nm to 500 nm. Whereas, EYE CRYL™ IOLs through its unique Natural Yellow Chromophore filters 400 nm to 440 nm of Violet-Blue Light spectrum only, not to affect the quality of Scotopic vision.

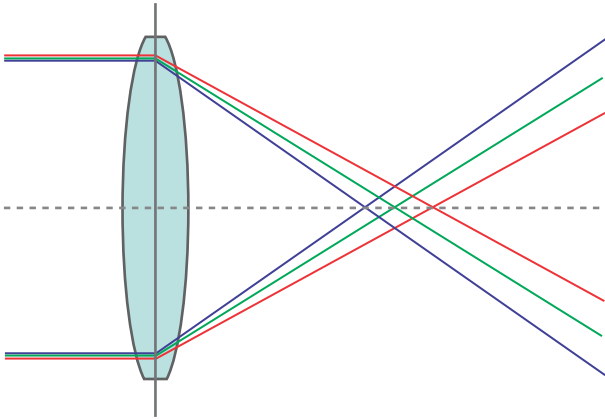


**Figure 6:** The CIE 1951 scotopicluminosity function. The horizontal axis is wavelength in nm.

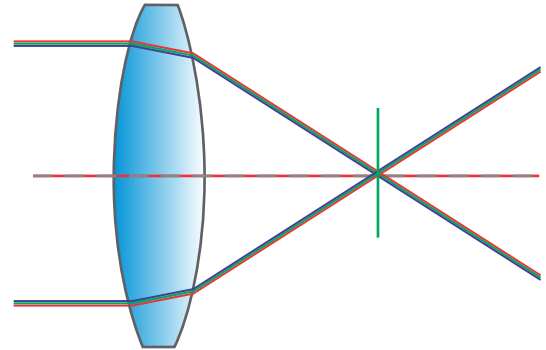
## Circadian Rhythm<sub>[01-05]</sub>:

- In humans, Melatonin is produced by the Pineal Gland, a small endocrine gland located in the center of the brain but outside the blood-brain barrier. The Melatonin signal forms part of the system that regulates the sleep-wake cycle by chemically causing drowsiness and lowering the body temperature.
- Production of Melatonin by the Pineal Gland is inhibited by light to the Retina and permitted by darkness. Its onset each evening is called the Dim-Light Melatonin Onset (DLMO).
- It is principally Blue Light, between 460 to 480 nm, that suppresses Melatonin, proportional to the light intensity and length of exposure.
- By filtering Blue Light ranging up to 500 nm, secretion of Melatonin increases & ultimately disturbs the Circadian Rhythm.
- Biotech Vision Care uses Natural Yellow hydrophobic material from Benz Research & Development (US Patent 7,947,796) to manufacture EYECRYL™ lenses which blocks UV-A & filters Violet-Blue spectrum of light ranging from 400 nm to 440 nm and doesn't affect Circadian rhythm.

### Chromatic Aberration: Relation with ABBE No.<sup>[06-13]</sup>

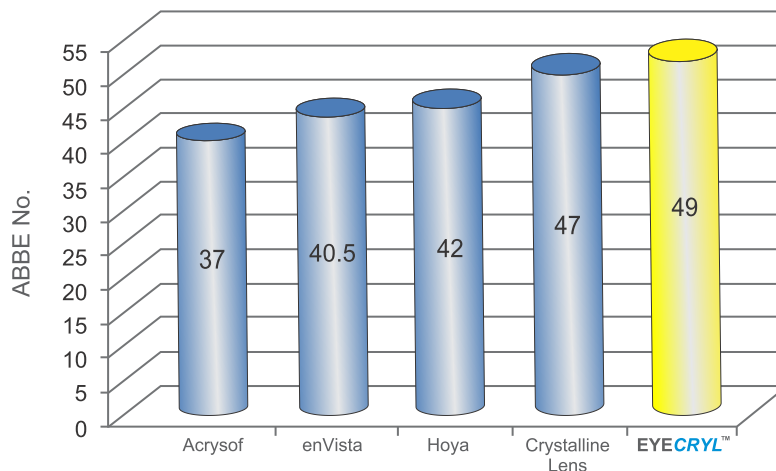


**Figure 7:** Chromatic Aberration arises through IOL material having low ABBE No.



**Figure 8:** Reduced Chromatic Aberration through IOL material having higher ABBE No.

- ABBE No. is the significance of the Chromatic Aberration which could arise by the material used to manufacture the IOL.
- EYECRYL™ IOLs are manufactured using Natural Yellow Hydrophobic material having ABBE No. of 49. This results in the decreased amount of Chromatic Aberration & provides excellent visual outcomes postoperatively.



**Figure 9:** High ABBE No. indicates low degree of Chromatic Aberration

## Optimally Hydrated Natural Yellow Hydrophobic IOLs

EYECRYL™ *Actv* IOLs are **Diffraction – Refractive Multifocal IOLs** having a series of concentric rings with diffractive steps.

### Background:

- The spacing between the steps gets progressively closer together from the center of the lens towards the edge.
- EYECRYL™ *Actv* IOLs use this type of design to provide excellent distance and near vision along with good intermediate vision.

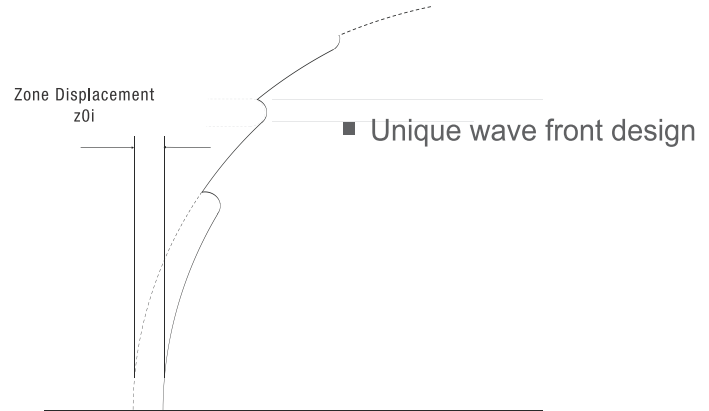


Figure 10: Lens Surface Diagram

### Special Features:

- Asymmetric light distribution, 60% for distance & 40% for near, independent of pupil size
- Excellent distance and near vision along with good intermediate vision
- Near addition of + 3.0 D
- Reduced glares and halos with unique step design
- Dependency on reading glasses is reduced
- Improved visual outcomes in all lighting conditions
- Negative Spherical Aberration to compensate Positive Spherical Aberration of the Cornea



Figure 11: Simulated Vision Through Mono Focal IOL



Figure 12: Simulated Vision Through EYECRYL™ ACTV IOL



### Energy Scan Diagram:

As shown in the energy scan diagram first energy peak corresponds to distance vision (21.0 D in this case). Second unique peak shows intermediate vision at +1.5 to +2.0 D (23.0 D in this case). Third peak corresponds to near vision energy at +3.0 D (24.0 D in this case).

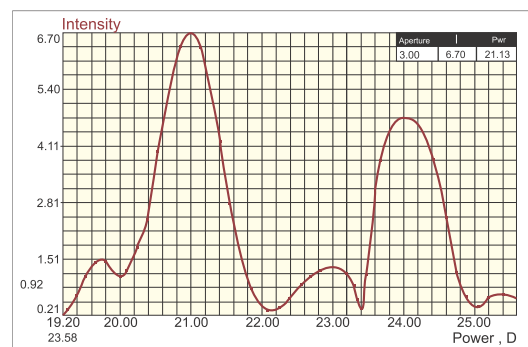


Figure 13: Energy Scan Diagram

### General Features:

- Optimized 'C' haptic design with angle at optic – haptic junction for better stability in the Capsular Bag
- Surgery induced astigmatism is not seen with sub 2.6 mm incisions
- The level of biological contamination is almost zero (Bacterial Endotoxin is less than 0.25 EU/IOL)
- IOL has advanced 360° square edge to reduce chances of PCO
- Sharp and crystal clear vision
- Post-Operative visual acuity is increased by compensating Spherical Aberration of the Cornea
- Contrast sensitivity is greatly increased through aspheric optic in all lighting conditions as compared to other bifocal and multifocal lenses having non aspheric optics

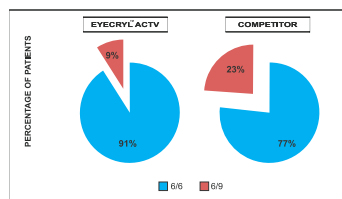


Figure 14: Far Vision

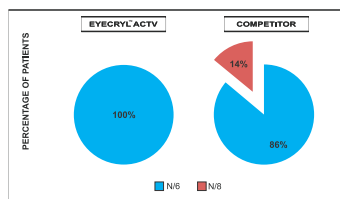


Figure 15: Near Vision

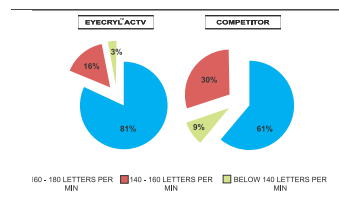


Figure 16: Reading Speed

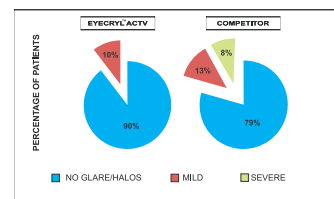
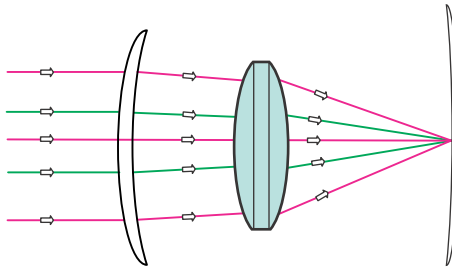
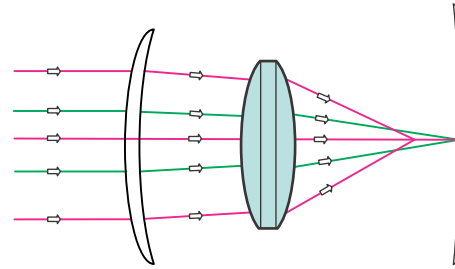


Figure 17: Glare & Halos

After having implanted a EYECRYL<sup>TM</sup> Act, patient's dependency on glasses is largely decreased. Without glasses or with minimum dependency on glasses, patient can get ideal visual acuity for uncorrected distance, intermediate and near vision. Patients can perform and continue day to day activities without the need & help of glasses and contact lenses.



**Figure 18:**  
Aspheric IOLs with -ve S.A.

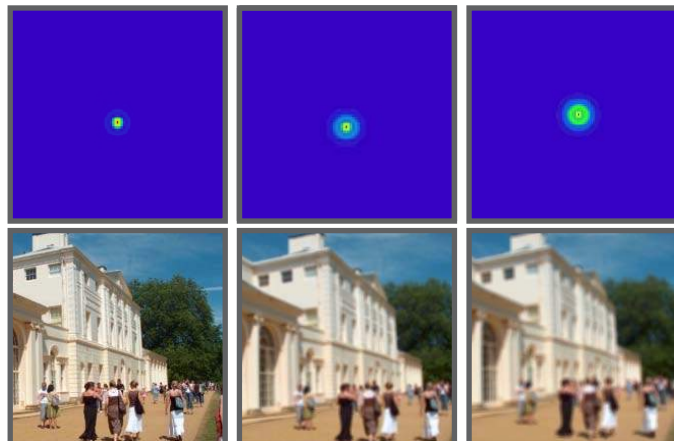


**Figure 19:**  
Conventional Spherical IOLs with +ve S.A.

### Features:

- Negative Spherical Aberration to compensate Positive Spherical Aberration of the Cornea
- 360° Advanced Square Edge
- Enhances Contrast Sensitivity, Sharpness & Clarity at night
- Smooth lens surface reduces bacterial adhesion & inflammatory cell response
- Enhanced functional outcomes in Mesopic & Scotopic lighting conditions
- Less sensitive to tilt & decentration

The simulated point spread function and image in the eye on Retinal plane with Negative Spherical Aberration IOL (Fig. 20), with Zero Spherical Aberration IOL (Fig. 21), and with Conventional Spherical IOL (Fig. 22)



**Figure 20**

**Figure 21**

**Figure 22**

## Technical Data:


**DIHFY600**

**ASHFY600**

Brand	EYECRYL™ <i>Active</i>	EYECRYL™ PLUS
Model	DIHFY600	ASHFY600
Material	Hydrophobic Acrylic containing Natural Chromophore	Hydrophobic Acrylic containing Natural Chromophore
Water Content	1 - 4 %	1 - 4 %
Optic Type	Biconvex, Single Piece, Diffractive, 360° Square Edge with Aspheric Optic	Biconvex, Single Piece, 360° Square Edge with Aspheric Optic
Near Addition	+ 3.0 D	N.A.
Optic Size	6.00 mm	6.00 mm
Overall Size	13.00 mm	13.00 mm
Angulation	0°	0°
ACD	5.28	5.28
In Site Refractive Index	1.483	1.483
Estimated A-Constant	118.5	118.5
Recommend Optical A-Constants	SRK - T: 118.7	SRK - T: 118.6
	SRK - II: 118.9	SRK - II: 118.9
	Holl. 1 Const. SF: 1.63	Holl. 1 Const. SF: 1.63
	HOFFER-Q ACD: 5.42	HOFFER-Q ACD: 5.43
	HAIGIS: a0: 1.24, a1: 0.40, a2: 0.10	HAIGIS: a0: 1.20, a1: 0.40, a2: 0.10
Diopter Range	+7.5D to +30.0D (with 0.5 D step)	+ 5.0 D to + 30.0 D (with 0.5 D step)
Sterilization	By Irradiation	By Irradiation
Indication	Phacoemulsification	Phacoemulsification
Implantation Site	Capsular Bag	Capsular Bag

01. Reiter RJ, Acuña-Castroviejo D, Tan DX, Burkhardt S (June 2001). "Free radical-mediated molecular damage. Mechanisms for the protective actions of melatonin in the central nervous system". *Ann. N. Y. Acad. Sci.* 939: 200–15.

02. Boutin JA, Audinot V, Ferry G, Delagrangre P (August 2005). "Molecular tools to study melatonin pathway and actions". *Trends Pharmacol. Sci.* 26 (8): 412–9. doi:10.1016/j.tips.2005.06.

03. European Medicines Agency. "Circadin, melatonin" ([http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000695/human\\_med\\_000701.jsp&mid=WC0b01ac058001d1d124](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000695/human_med_000701.jsp&mid=WC0b01ac058001d1d124)). European Public Assessment Report (EPAR). European Medicines Agency. Retrieved 5 June 2013.

04. Richardson GS (2005). "The human circadian system in normal and disordered sleep". *J Clin Psychiatry*. 66Suppl 9: 3–9; quiz 42–3. PMID 16336035 (<http://www.ncbi.nlm.nih.gov/pubmed/16336035>).

05. Sack RL, Lewy AJ, Erb DL, Vollmer WM, Singer CM (1986). "Human melatonin production decreases with age". *J. Pineal Res.* 3 (4): 379–88.

06. Negishik, Ohnuma K, Hirayama N, Noda T. Effect of chromatic aberration on contrast sensitivity in pseudophakic eyes. *Arch Ophthalmol*.2001;119:1154-1158.

07. Cheryl Guttman Krader in Vienna, For ABBE No. EnVista "HYDROPHOBIC ACRYLIC IOL-Novel material and design aim to bring optimized optical and anatomic performance", CATARACT & REFRACTIVE, EUROTİMES, Volume 16/17, Issue-12/1.

08. WILLIAM B. TRATTLER, MD, Optics, Visual Quality, and Acuity, REFRACTIVE SURGERY FEATURE STORY, CATARACT & REFRACTIVE SURGERY TODAY, APRIL 2010, Page 57-58.

09. George H.H. Beiko, BM, BCh, FRCSC Understanding Corneal Asphericity and IOLs. A review of the research into the factors that may impact the choice of an aspheric intraocular lens. *Review of Ophthalmology®*, Page no 1-8.

10. Thibos LN, Bradley A, Zhang XX. Effect of ocular chromatic aberration on monocular visual performance. *Optom Vis Sci.* 1991 Aug;68(8):599-607.

11. Harris WF, Evans T. Chromatic aberration in heterocentric astigmatic systems including the eye. *Optom Vis Sci.* 2012 Nov;89(11):e37-43.

12. Artal P, Manzanera S, Piers P, Weeber H. Visual effect of the combined correction of spherical and longitudinal chromatic aberrations. *Opt Express.* 2010 Jan 18;18(2):1637-48. doi: 10.1364/OE.18.001637.

13. Geun-Young Yoon and David R. Williams. Visual performance after correcting the monochromatic and chromatic aberrations of the eye. *J. Opt. Soc. Am. A/Vol. 19, No. 2/February 2002* page 266-275.

14. Foundations of Vision (<http://foundationsofvision.stanford.edu>) (1995), Brian A. Wandell, Chapter 9 Color (<https://www.stanford.edu/group/vista/cgi-bin/FOV/chapter-9/color/>).

15. Foundations of Vision (<http://foundationsofvision.stanford.edu>) (1995), Brian A. Wandell, Chapter 4 Wavelength Encoding (<https://www.stanford.edu/group/vista/cgi-bin/FOV/chapter-4-wavelength-encoding/>).

16. Foundations of Vision (<http://foundationsofvision.stanford.edu>) (1995), Brian A. Wandell, Chapter 3 The Photoreceptor Mosaic (<https://www.stanford.edu/group/vista/cgi-bin/FOV/chapter-3-the-photoreceptor-mosaic/>).

17. Rodrigo França de Espindola<sup>1</sup>, Marcony Rodrigues de Santhiago<sup>1</sup>, Newton Kara-Júnior<sup>1</sup> Effect of aspherical and yellow tinted intraocular lens on blue-on-yellow perimetry. *Arq Bras Oftalmol.* 2012;75(5):316-9.

18. Zhu X-f, Zou H-d, Yu Y-f, Sun Q, Zhao N-q (2012) Comparison of Blue Light-Filtering IOLs and UV Light-Filtering IOLs for Cataract Surgery: A Meta-Analysis. *PLoS ONE* 7(3): e33013. doi:10.1371/journal.pone.0033013

19. Penny Asbell, MD, FACS, MBA, Som Prasad, MS, FRCS(ED), FRCOPHTH, and Albert J. Augustin, MD. Blue and Violet Light Filtering IOLs, Cataract and Refractive Surgery Today Europe July/August 2008.

20. Benz Research and Development, IOL Published Articles, 2012, Page no. 25-26.

21. Christophe Pagnoulle, PhD, Dimitriya Bozokova, PhD, Laure Gobin, PhD, Virginie Bertrand, MSc, Marie-Claire Gillet-De Pauw, PhD. Assessment of new-generation glistening-free hydrophobic acrylic intraocular lens material. *J Cataract Refract Surg* 2012; 38:1271–1277 Q 2012 ASCRS and ESCRS.

22. Werner L. Glistening and surface light scattering in intraocular lenses. *J Cataract Refract Surg.* 2010 Aug;36(8):1398-420. doi: 10.1016/j.jcrs.2010.06.003.

23. Gregori NZ, Spencer TS, Mamalis N, Olson RJ. In vitro comparison of glistening formation among hydrophobic acrylic intraocular lenses. *J Cataract Refract Surg.* 2002 Jul;28(7):1262-8.

24. Oshika T, Shiokawa Y, Amano S, Mitomo K. In

25. Matsushima H, Mukai K, Nagata M, Gotoh N, Matsui E, Senoo T. Analysis of surface whitening of extracted hydrophobic acrylic intraocular lenses. *J Cataract Refract Surg* 2009; 35:1927–1934

26. Werner L, Storsberg J, Mauger O, Brasse K, Gerl R, Müller M, Tetz M. Unusual pattern of glistening formation on a 3-piece hydrophobic acrylic intraocular lens. *J Cataract Refract Surg* 2008; 34:1604–1609

27. 3 Linnola RJ. Sandwich theory: bioactivity-based explanation for posterior capsule opacification

28. Mentak P, Elachchabi A, Goldberg E. Hydrophobic character and aqueous wettability of hydrophobic IOLs. Paper presented at the XXVI Congress of the European Society of Cataract and Refractive Surgery; September 13-17, 2008; Berlin, Germany.

29. Mentak P, Elachchabi A, Martin P, Goldberg E, Mentak A. Nanoindentation studies on hydrophobic acrylic IOLs to evaluate surface mechanical properties. Paper presented at the XXV Congress of the European Society of Cataract and Refractive Surgery; September 8-9, 2007; Stockholm, Sweden.

Bio-Tech Vision Care Pvt. Ltd.

Manufacturing Facility	India Business	International Business
555 / 556 / 557 , Nr. Subham Tex-O-Pack, Khatraj, Dist. Gandhinagar, Gujarat, India.	210, Sarthik - II, Opp, Rajpath Club, Sarkhej-Gandhinagar Highway, Ahmedabad-380054, Gujarat, India. Ph. / Fax: 079-40038374,32420133 E-mail: sales@biotechvisioncare.com	401, Sarthik- II, Opp. Rajpath Club, Sarkhej-Gandhinagar Highway, Ahmedabad-380054, Gujarat, India. Ph.: +91-79-26870896/97/98 Fax: +91-79-40033767 E-mail: intbusiness@biotechvisioncare.com