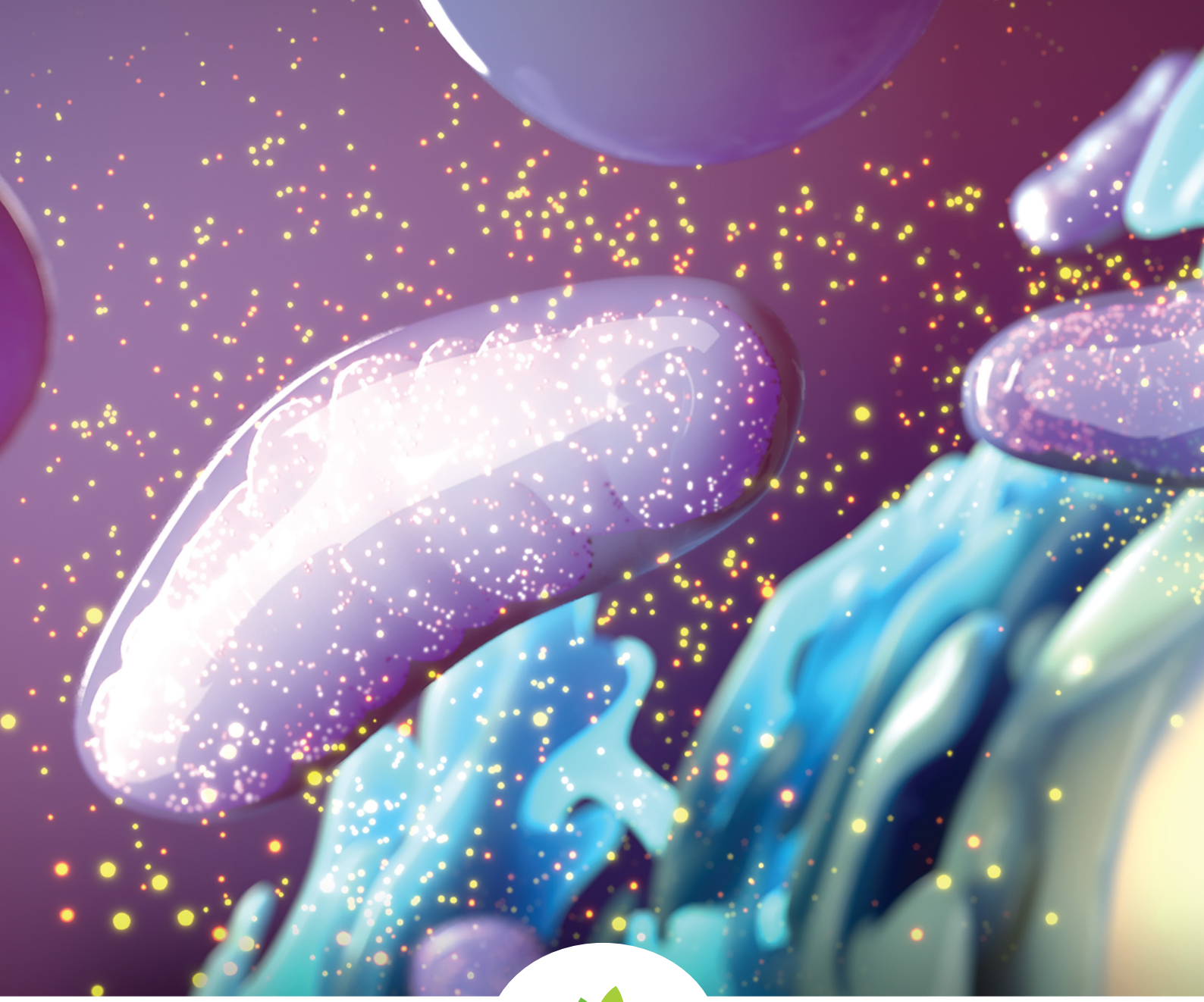


VALEDA®

Light Delivery System

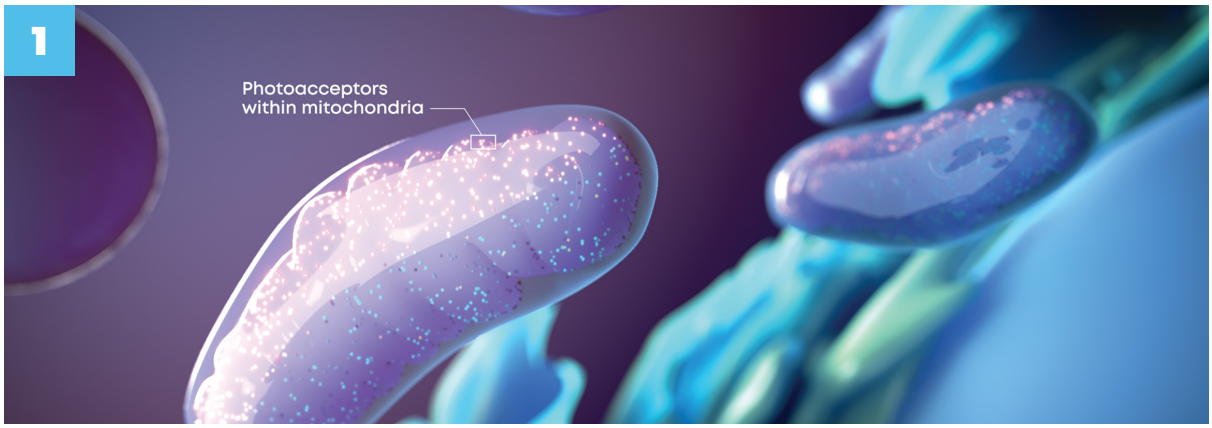
Photobiomodulation Mechanisms of Action

Valeda® photobiomodulation (PBM) treatment harnesses the power of light to target disease at the cellular level.

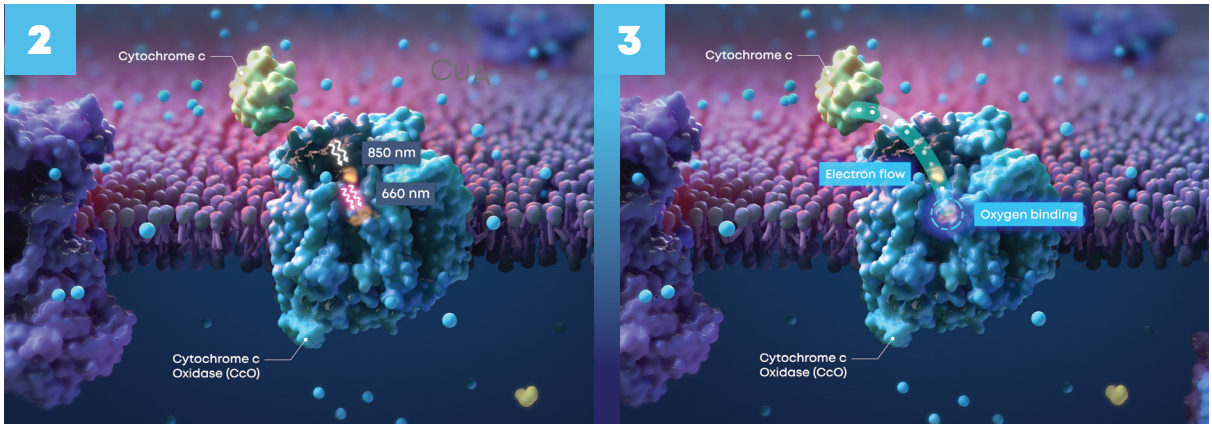
Valeda delivers select wavelengths which act on cellular mechanisms important to dry age-related macular degeneration (AMD).

Wavelength **850**[1]	Wavelength **660**[1]	Wavelength **590**[2,3]
Drives electron transfer (Cu_A), stimulates metabolic activity (ATP), and inhibits inflammation and cell death	Promotes O_2 binding (Cu_B), stimulates metabolic activity (ATP), and inhibits inflammation and cell death	Inhibits VEGF expression and promotes nitric oxide generation

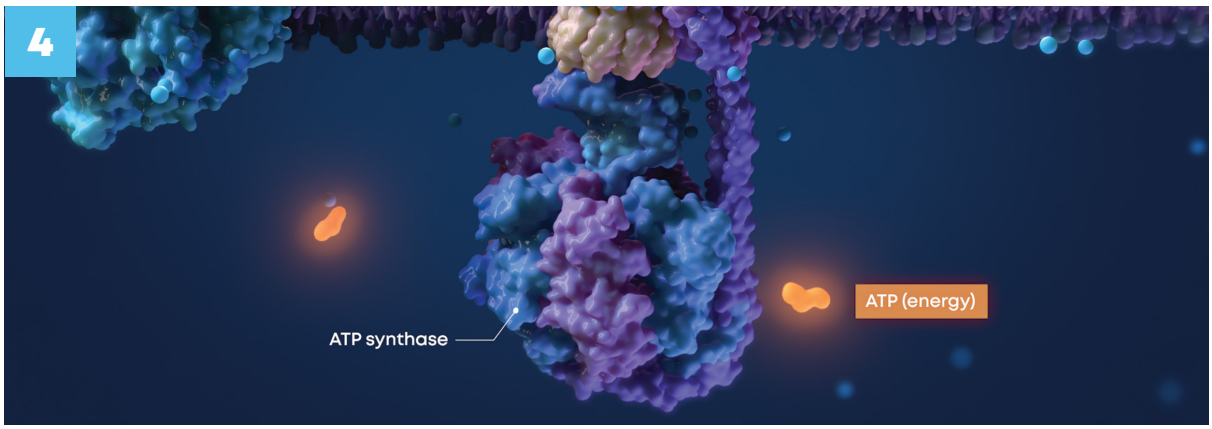
PBM activates photoacceptors in the mitochondrial respiratory chain.



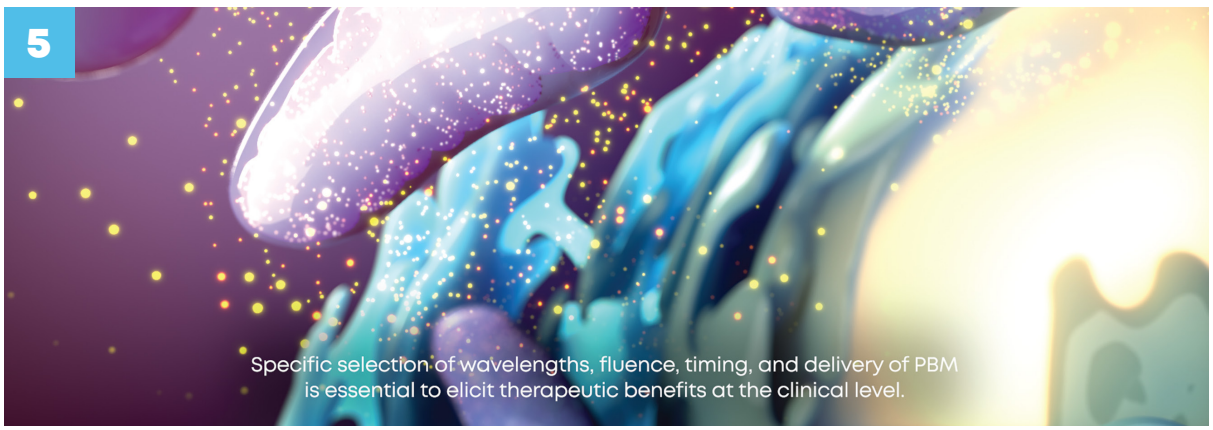
The specific wavelengths increase enzymatic activity at two separate sites on cytochrome c oxidase (CcO): Cu_A and Cu_B.



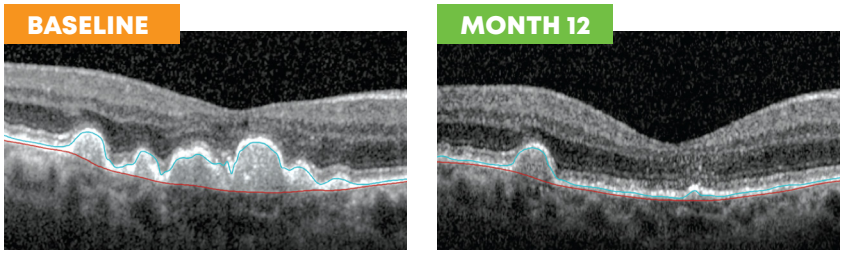
Increased CcO helps drive the generation of the proton gradient required by ATP synthase to produce energy.



Restoring the production of energy and signaling molecules triggers secondary effects that sustain improved cell function.



Treatment with Valeda improves and maintains visual acuity.



Pathology and Clinical Benefits as Seen in an Individual Patient.[4]

Valeda harnesses the power of light to offer brighter horizons for patients with dry AMD.

Indications for Use

The Valeda Light Delivery System is intended to provide improved visual acuity in patients with best-corrected visual acuity of 20/32 through 20/70 and who have dry age-related macular degeneration (AMD) characterized by:

- The presence of at least 3 medium drusen {> 63 µm and ≤ 125 µm in diameter), or large drusen {> 125 µm in diameter), or non-central geographic atrophy, AND
- The absence of neovascular maculopathy or center-involving geographic atrophy

After about two years, the Valeda Light Delivery System treatment provides improved mean visual acuity of approximately one line of visual acuity (ETDRS) compared to those not receiving the treatment.

CONTRAINDICATIONS FOR USE

As a precaution, patients have not been tested and should not be treated with Valeda if they have any known photosensitivity to yellow light, red light or near-infrared radiation (NIR), or if they have a history of light activated central nervous system disorders (e.g., epilepsy, migraine). In addition, patients should not receive treatment within 30 days of using photosensitizing agents (e.g., topicals, injectables) that are affected by 590, 660, and/or 850 nm light before consulting with their physician.

Refer to the Valeda Light Delivery System User Manual for full Important Safety Information.

REFERENCES:

1. Wong-Riley et al., J Biol Chem.v280.2005; 2. McDaniel et al., Am Soc Laser Med Surg Mtg. 2006; 3. Ball et al., J Photochem Photobiol B Biol.v102.2012; 4. Markowitz, S. et al., Retina. 2020; 40(8):1471-1482.
PBM MOA Support References: Begum, R. et al., PLOS One. 2013; 8(2):e57828; Fitzgerald, M. et al., Rev Neurosci. 2013; 24(2):205-226; Hamblin, M. Photochem Photobiol. 2018; 94(2): 199-212; Karu, T. et al., Lasers Surg Med. 2005; 36(4):307-314; Karu, T. Photochem Photobiol. 2008; 84(5):1091-1099; Wong-Riley, M.T.T et al., J Biol Chem. 2005; 280(6):4761-4771.

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