Materials for Item No. 4

STATE OF NEVADA

JOE LOMBARDO
Governor

DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN
NIKKI HAAG
MARCEL F. SCHAERER
Deputy Directors

ADAM SCHNEIDER
Executive Director

DEPARTMENT OF BUSINESS AND INDUSTRY
OFFICE OF NEVADA BOARDS, COMMISSIONS AND COUNCILS STANDARDS
NEVADA STATE BOARD OF OPTOMETRY

MINUTES
OF PUBLIC MEETING
January 22, 2026

1. Call to Order and statement of purpose to protect public health and safety, and the general welfare of the people of this State. Director Schneider opened the live meeting at 12:08p.m. and read into the record- "Because this meeting is being held using a remote technology system pursuant to NRS 241.023 and does not have a physical location designated for the meeting where members of the general public are permitted to attend and participate, clear and complete instructions for a member of the general public to be able to call in to the meeting to provide public comment is the following- telephone number 669-900-6833, meeting ID 775 883 8367, Passcode 8367."

2. Roll Call. Executive Director Schneider, Board members Mariah Smith, O.D., Jeffrey Austin, O.D., Dan Lyons, O.D., and Julie Alamo-Leon, O.D. were present via Zoom. Public Member Balecha not present. Quorum established.

3. Public Comment. Director Schneider invited public comment with a reminder that no action will be taken at this meeting on any issues presented as public comment and the maximum time is three minutes. No public comment received.

4. Action Item. Complaint 26-03- proposed Stipulation for Settlement and presentation from Deputy Attorney General. Trailed to the last Action Item of the Agenda before Adjournment. DAG Todd Weiss confirmed that the Board members received the proposed Stipulation for Settlement between the Board and Dr. Koenig, and summarized the same as to the facts and proposed disciplinary terms. Dr. Koenig's counsel, Jacob Sommer, Esq., present. Dr. Smith stated her trust in DAG Weiss' experience in the legal issues and for the precedence of the monetary amounts proposed, and moved to accept as-is. Dr. Austin seconded. Motion passed 4-0.

5. Action Item. Consideration and approval of December 10, 2025 Board Meeting Minutes for: 1) Regular Meeting; 2) Notice of Intent to Take Action on Regulation re R056-25. Dr. Smith confirmed all present Board members had an opportunity to review the drafts. Dr. Austin moved to accept all proposed Minutes as-is. Dr. Smith seconded. Motion passed 4-0.

6. Action Item. Complaint 26-10 Director Schneider stated this Complaint is being presented in a double-blind manner, i.e., the Board is not being told who the complainant is or who the subject licensee is, and the materials associated with this agenda item are redacted to eliminate any identification of party identities.

Three longstanding patients (Mother Patient 1 and two teenage sons Patients 2-3) with Licensee 1 agreed to Optomap and OCT imaging copays verbally. One of the teenagers agreed to CL fitting in writing. Upon checkout, Mother stated she did not agree to CL fitting and instead only the imaging. Mother paid for 3 copays for imaging but not the CL fitting or any exam copays. Mother called to dispute that any imaging was done and would not be paying any fitting or exam copays. Copies of imaging sent to Mother. Mother did not believe that was proof of imaging. As seen in the meeting materials of a email string between Licensee and Mother, Licensee 1 agreed to waive CL fitting fee, but 3 exam copays were due per EyeMed contract. Mother refused and filed complaint with Board. The question for the Board is does the Licensee's conduct rise to the level of unprofessional conduct? And if not, Board needs to provide a reason for why not to advise the complainant.

Dr. Smith stated the conduct was not unprofessional in her opinion. The teenager who agreed to the fitting was over the age of 18 and able to agree to it on his own. It was gracious of Licensee 1 to waive part of the fee. The evidence shows the three images were performed. It might be recommended to Licensee 1 to get these kinds of agreements in writing to avoid any he-said-she-said in the future. Regardless, the contact lens fittings were agreed to and performed, and the imaging was agreed to verbally and performed. The complainant's monetary dispute thereafter is not something the Board deals with, but instead can be addressed through other avenues. Drs. Lyons and Alamo-Leon agreed. Dr. Austin agreed, stating this is for small claims court should the complainant want to pursue it there, and that the disposition letter needs to state there was no clinical unprofessional conduct and instead is about confusion on pricing and costs which is not something the Board deals with.

Dr. Smith moved to close the inquiry with no further action and for Director Schneider to advise the complainant accordingly incorporating Dr. Austin's suggestions on what to include in the letter. Dr. Austin seconded. Motion passed 4-0.

7. <u>Action Item</u>. Proposed letter re: R101-24(5) (optometric telemedicine licensee requirements) versus NRS 636.346 (supervision of authorized activities of assistants; conduct of final eye examination of patient). Director Schneider directed the Board to the meeting materials of the draft letter for approval or edits based upon his research into the telemedicine statutes and regulations, and the Board's 2024 discussions as to the Board's intent.

Dr. Austin inquired into the proposed response to statement no. 1. Part of the letter states an allowance of a glasses prescription via synchronous optometric telemedicine. Later in the letter it states the need for a manifest refraction. Those positions seem to disagree with each other. Director Schneider advised "agreed" was stated on purpose when reviewing subsection three of the statute allowing for synchronous optometric telemedicine and his understanding that manifest refraction can be performed via optometric telemedicine through the appropriate technology presently in existence. Director Schneider asked if manifest refraction was being defined as only in-person, because if not, then "agreed" from his review of the law and the Minutes would be the accurate answer.

Director Schneider discussed the basis of the "disagree" answer for statement no. 2. Then he discussed as stated in the letter there is no contemplation in the statute on when it applies to a medical examination versus a separate scenario of only for a glasses prescription.

Director Schneider reminded the Board of its discussions in January 2024 about trying to capture all scenarios and business models and being as complete as possible, but that statements nos. 1-2 present new scenarios that the Board did not discuss in 2024. If the letter is not reflective of the Board's position, then the Board needs to advise and engage in efforts to close that loophole.

Dr. Austin stated the common understanding of a manifest refraction means it is performed in-person, but understood what Director Schneider was attempting to explain in the letter based upon what the law says. Dr. Austin suggested at the end of the first sentence after "agreed" that it should add clarifying language that manifest refraction can be performed in-person or by synchronous technology but if the latter then the licensee has to have control of the appropriate refraction technology and is performing the manifest reaction himself or herself and not reliant upon a technician talking to the licensee on the phone, for example.

Director Schneider discussed the Board's January 2024 discussions for the telemedicine regulations. The most discussion at that time as to manifest refractions occurred as to differentiating it from auto-refraction which ultimately resulted in section 9 of NRS 636.394. But as to whether manifest refraction was synonymous with in-person, that was not discussed. Dr. Austin stated it was his memory of the Board's intent was that a licensee can perform a remote refraction so long as they use the appropriate technology where the licensee has actual control of the phoropter in real time. With the above suggestions, Dr. Austin approved of the draft.

Dr. Smith discussed her memory of her concerns in 2024 of persons potentially misinterpreting the laws, despite the Board's efforts at the time to make the language clear and contemplating all scenarios. Dr. Smith discussed the letter's emphases on: 1) "the" licensee, which was something that Dr. Lyons addressed at the prior meeting; and 2) the licensee has to have the records of a comprehensive examination within the past two years at or by the time of the examination, and not after. "Comprehensive examination" is defined in Nevada law, which not all States have. But it needs to be made clear that a licensee cannot ignore one element of a "comprehensive examination" in order to make it a noncomprehensive examination, and that the licensee still has to abide by the standard of care. An example for the intention of a noncomprehensive examination would be a contact lens follow-up or taking a phone call at 7pm for a potential red eye. Director Schneider and Dr. Smith agreed that the Board's discussion in January 2024 involved when a comprehensive or noncomprehensive examination was appropriate and it would be nearly impossible to list in the laws all of those possible clinical scenarios. But it is that vagueness of not listing all scenarios that a bad actor could use to their advantage.

Dr. Austin commented these issues are taken from two different directions of a comprehensive examination for what needs to occur in an examination, versus how to bill for it. Even a comprehensive examination, with every possible test performed, can be billed as a noncomprehensive examination if the licensee so chooses. But under no circumstance can a licensee bill for a comprehensive examination if the licensee did not perform all the elements of a comprehensive examination.

Dr. Smith commented that it is the insurance companies that use the terms comprehensive and noncomprehensive, and that the Board could have used the term "standard of care examination" or a phrase to that effect.

Dr. Austin felt the draft is great, and Dr. Smith agreed there is nothing she would change once Dr. Austin's earlier suggestion is incorporated. Dr. Lyons felt the draft was really good and as good as it was going to get. Dr. Alamo-Leon felt the draft looks good and to go with what is stated.

Dr. Smith moved to adopt the letter as-is with incorporation of Dr. Austin's proposed edits. Dr. Lyons seconded. Motion passed 4-0.

8. **<u>Action Item</u>**. **Insurance panels statuses for 2028-2030 renewal applications.** Director Schneider directed the Board to the meeting materials which involved research into health insurance contracts or doctor-insurer professional agreements, health insurance related NRSs such as 689A with consistent phrases of "medical incompetency or professional misconduct." The Board was asked to advise on making more succinct or more understandable from a licensee perspective but making sure the questions were broad enough for the Board to know about potential licensee misconduct. Director Schneider also advised that the present renewal applications does not ask if the licensee has been sued regarding the practice of optometry since the prior cycle, so those questions are added as well.

Dr. Smith felt that if the additional questions are in line with other healthcare boards' renewal applications, then that is a good thing and worth incorporating for this Board. The questions are not unclear, and they serve the purpose of what the Board intended. Director Schneider anticipated 99% of the licensees would mark "No" to these questions, but nonetheless something that the Board needs to know well earlier than, e.g., 4 years after a lawsuit settlement.

Dr. Smith moved to accept as-is, subject to Director Schneider's edits for typographical errors. Dr. Alamo-Leon seconded. Motion passed 4-0.

9. **<u>Action Item</u>.** **Proposed items for future Board meetings.** Director Schneider noted nothing from his perspective at this point other than one complaint. Dr. Smith inquired into Director Schneider's participation at the 6/2026 ARBO conference, which Director Schneider confirmed. Colloquy as to future draft letter for the Board's approval at the March meeting for Director Schneider's scholarship application. ARBO liaison Dr. Wang advised in the chat that the scholarship application period would open next month. No other topics proposed.

10. **Public Comment**. Director Schneider invited public comment. No comments received.

11. **<u>Action Item</u>**. **Adjournment.** President Smith moved to adjourn. Dr. Alamo seconded. Motion passed 4-0. Adjournment occurred at 12:50p.m.

10 persons attended virtually, inclusive of five Board members and Executive Director. No role call conducted or sign-in sheets provided.

* * * * *

<u>FY 2025-2026 Regular meeting schedule</u>

Thursday 1/22/2026 12:00p.m. (pst) Reg. Bd. Meeting- phone or Zoom
Thursday 3/12/2026 12:00p.m. (pst) Reg. Bd. Meeting- phone or Zoom
Thursday 4/23/2026 12:00p.m. (pst) Reg. Bd. Meeting- phone or Zoom
Thursday 5/28/2026 12:00p.m. (pst) Reg. Bd. Meeting- phone or Zoom
Thursday 6/25/2026 12:00p.m. (pst) Reg. Bd. Meeting- phone or Zoom

* * * * *

These minutes were considered and approved by majority vote of the Nevada State Board of Optometry at its meeting on March 12, 2026.

_____
Adam Schneider, Executive Director

Materials for Item No. 5

STATE OF NEVADA

JOE LOMBARDO
Governor

DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN
NIKKI HAAG
MARCEL F. SCHAERER
Deputy Directors

ADAM SCHNEIDER
Executive Director

DEPARTMENT OF BUSINESS AND INDUSTRY
OFFICE OF NEVADA BOARDS, COMMISSIONS AND COUNCILS STANDARDS
NEVADA STATE BOARD OF OPTOMETRY

January 21, 2026

[Licensee name]
[Licensee email address]
via email only

Re: NSBO Complaint# 26-15
Patient: [Patient 1]

Dear Licensee:

This office received a complaint alleging your conduct towards the above-referenced patient may have been unprofessional as defined in Nevada Revised Statute (NRS) 636.295 and Nevada Administrative Code (NAC) 636.230. It alleges:

> I appeared as scheduled for an eye exam at 8:00 AM 12/31/2025. At check in I was told by the receptionist that they had called me "several" times to cancel my appointment. I verified that they have my accurate phone number. There before me I showed my call records revealing no calls from their office nor any phones calls/voice messages from unknown contacts. The only messages I received from [Practice Location 1] were emails verifying the appointment [stating "Hello, [Patient 1], This is a friendly reminder about your appointment with [Practice Location 1]. Your appointment is Wednesday, December 31, 2025 8:00AM. We appreciate your time and look forward to seeing you then! Sincerely, [Practice Location 1]"]. I asked to speak to a supervisor who told to me the same things.
>
> Quite frankly [Practice Location 1] staff appeared to flat out lie to me, I was under extreme stress having recently lost my last nuclear family member to death. The holidays sure didn't this unhappy ending…and worst is that I still cannot see well up close and use a magnifying glass to even word process this complaint.

Pursuant to NRS 636.305(3), in order to determine whether or not there has been a violation of NRS/NAC 636, please provide a written response. Please include any further information you believe would be useful for the Board to make a determination in this matter. **Failure to responsively address each of the above allegations could result in a determination that you agree with the above allegations.**

Your reply to director@nvoptometry.org is due on or by the close of business **February 20, 2026**.

Because this matter may be presented to the Board in a double-blind manner, **do NOT use personal or company letterhead. Use the following references:**

Yourself as "Licensee 1"

Your practice group/location as "Practice Location 1"

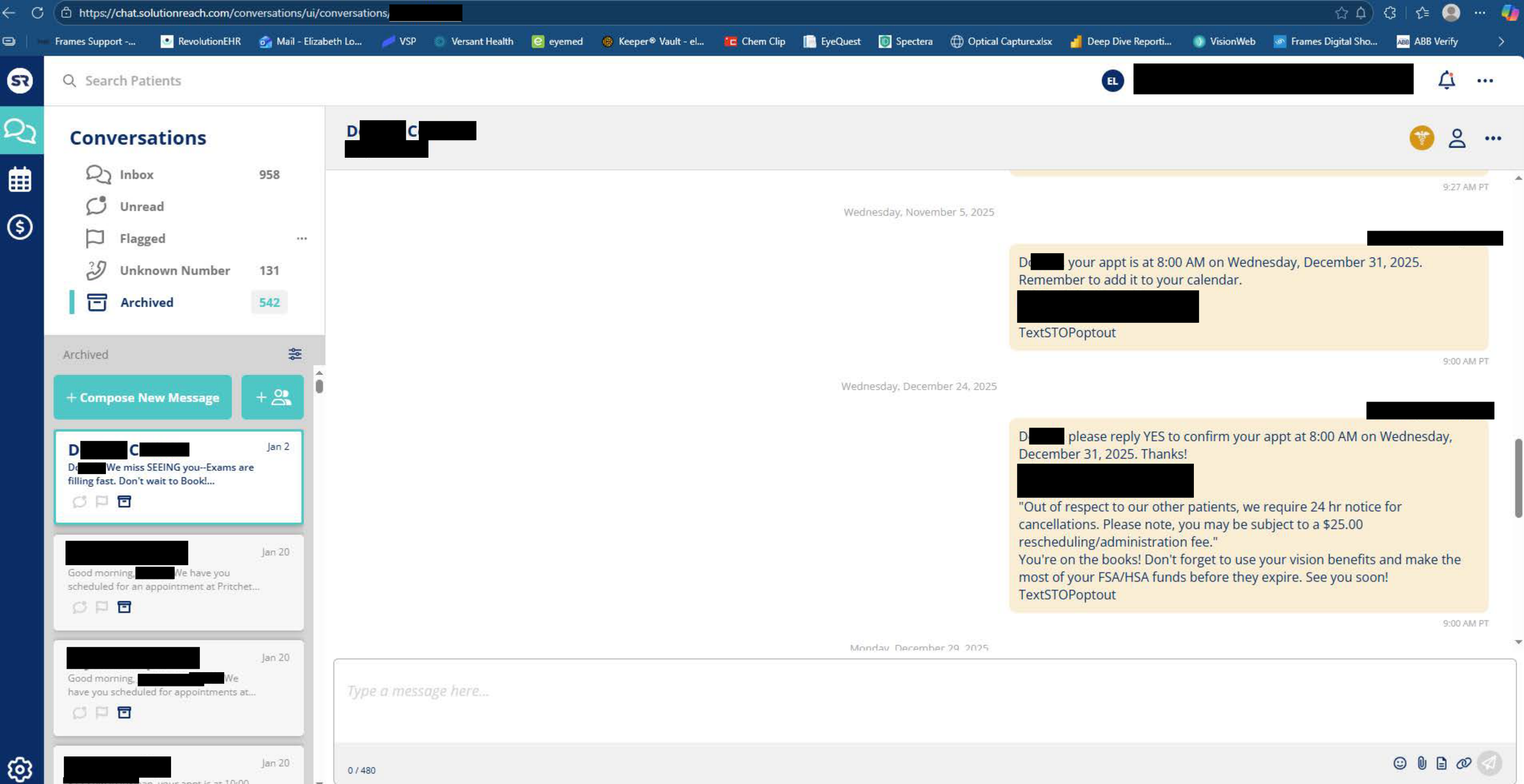
[Patient 1] as "Patient 1"

The Nevada State Board of Optometry investigates all information received concerning possible violations of NRS/NAC 636. This letter is not to be construed as a determination as to whether or not there has been a violation of such laws until a thorough investigation is completed. This correspondence is sent pursuant to NRS 636.305(2) and NRS 636.310(3), and the accompanying subpoena is sent pursuant to NRS 636.141 and NRS 629.061(1)(g). As a licensee subject to an investigation, you are required by law to timely provide the requested information.

Please be advised that if any particular allegations referenced above did occur, and depending on the facts and circumstances, then you may have violated the law, specifically including but not limited to NRS 636.295(8)(unprofessional conduct in the practice of optometry), NRS 636.364 (supervision of assistants).

Respectfully,

/s/ Adam Schneider
Adam Schneider, Esq.
Executive Director


https://chat.solutionreach.com/conversations/ui/conversations/[redacted]
Frames Support -...
RevolutionEHR
Mail - Elizabeth Lo...
VSP
Versant Health
eyemed
Keeper® Vault - el...
Chem Clip
EyeQuest
Spectera
Optical Capture.xlsx
Deep Dive Reporti...
VisionWeb
Frames Digital Sho...
ABB Verify
Search Patients
EL [redacted]
Conversations
Inbox 958
Unread
Flagged
Unknown Number 131
Archived 542
Archived
+ Compose New Message
D[redacted] C[redacted] Jan 2
D[redacted] We miss SEEING you--Exams are filling fast. Don't wait to Book!...
[redacted] Jan 20
Good morning [redacted] We have you scheduled for an appointment at Pritchet...
[redacted] Jan 20
Good morning, [redacted] We have you scheduled for appointments at...
[redacted] Jan 20
D[redacted] C[redacted]
9:27 AM PT
Wednesday, November 5, 2025
[redacted]
D[redacted] your appt is at 8:00 AM on Wednesday, December 31, 2025. Remember to add it to your calendar.
[redacted]
TextSTOPoptout
9:00 AM PT
Wednesday, December 24, 2025
[redacted]
D[redacted] please reply YES to confirm your appt at 8:00 AM on Wednesday, December 31, 2025. Thanks!
[redacted]
"Out of respect to our other patients, we require 24 hr notice for cancellations. Please note, you may be subject to a $25.00 rescheduling/administration fee."
You're on the books! Don't forget to use your vision benefits and make the most of your FSA/HSA funds before they expire. See you soon!
TextSTOPoptout
9:00 AM PT
Monday, December 29, 2025
Type a message here...
0 / 480

https://chat.solutionreach.com/conversations/ui/conversations/[redacted]

Frames Support -... | RevolutionEHR | Mail - Elizabeth Lo... | VSP | Versant Health | eyemed | Keeper® Vault - el... | Chem Clip | EyeQuest | Spectera | Optical Capture.xlsx | Deep Dive Reporti... | VisionWeb | Frames Digital Sho... | ABB Verify

Search Patients

EL [redacted]

Conversations

- Inbox 958
- Unread
- Flagged
- Unknown Number 131
- Archived 542

Archived

+ Compose New Message

D[redacted] C[redacted] Jan 2
D[redacted] We miss SEEING you--Exams are filling fast. Don't wait to Book!...

[redacted] Jan 20
Good morning, [redacted] We have you scheduled for an appointment at Pritchet...

[redacted] Jan 20
Good morning [redacted] We have you scheduled for appointments at...

[redacted] Jan 20
[redacted] your appt is at 10:00

D[redacted] C[redacted]

Monday, December 29, 2025

[redacted]
D[redacted] please reply YES to confirm your appt at 8:00 AM on Wednesday, December 31, 2025. Thanks!
[redacted]
"Out of respect to our other patients, we require 24 hr notice for cancellations. Please note, you may be subject to a $25.00 rescheduling/administration fee."
You're on the books! Don't forget to use your vision benefits and make the most of your FSA/HSA funds before they expire. See you soon!
TextSTOPoptout

9:00 AM PT

Tuesday, December 30, 2025

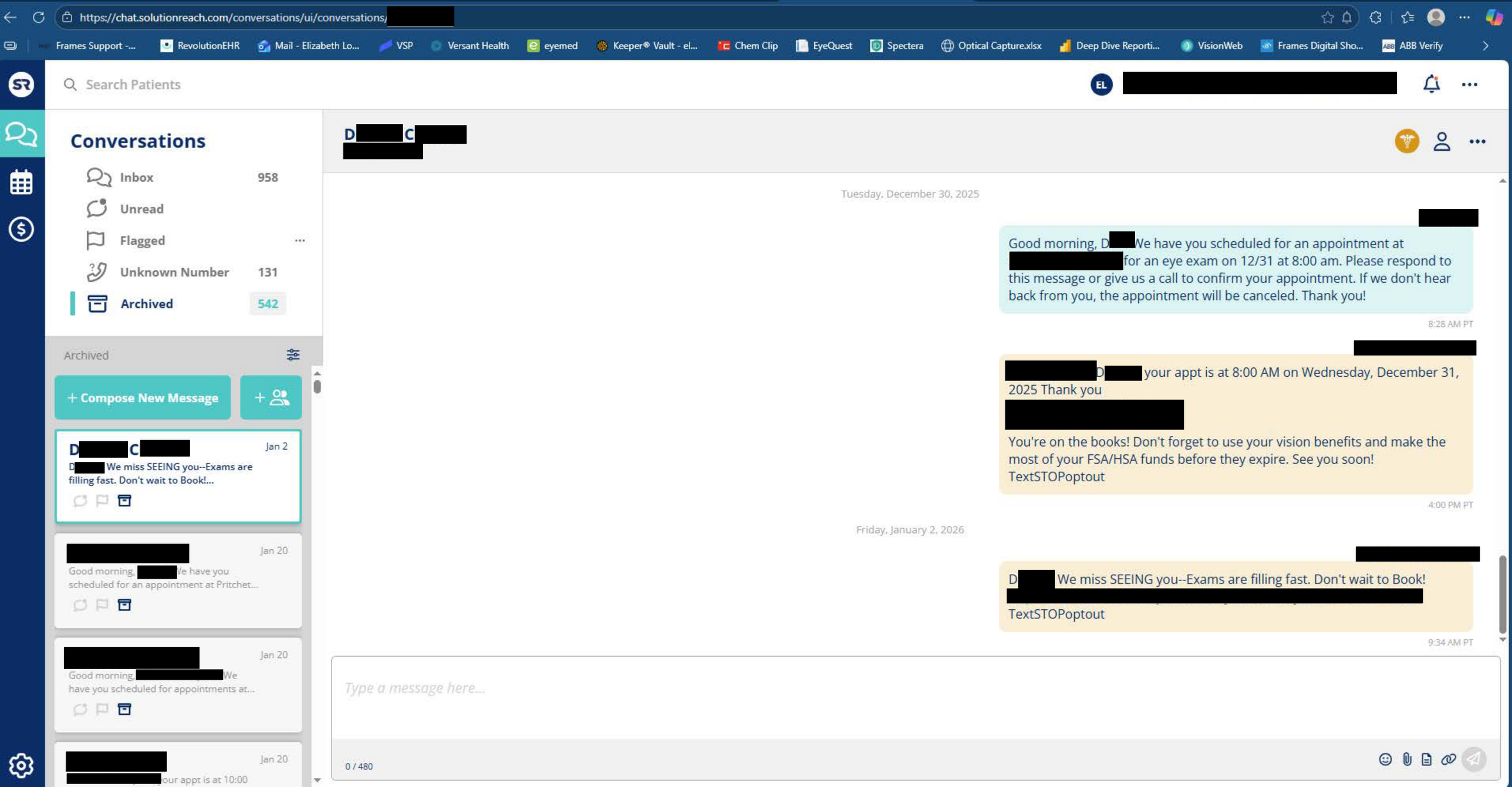
[redacted]
Good morning, D[redacted] We have you scheduled for an appointment at [redacted] for an eye exam on 12/31 at 8:00 am. Please respond to this message or give us a call to confirm your appointment. If we don't hear back from you, the appointment will be canceled. Thank you!

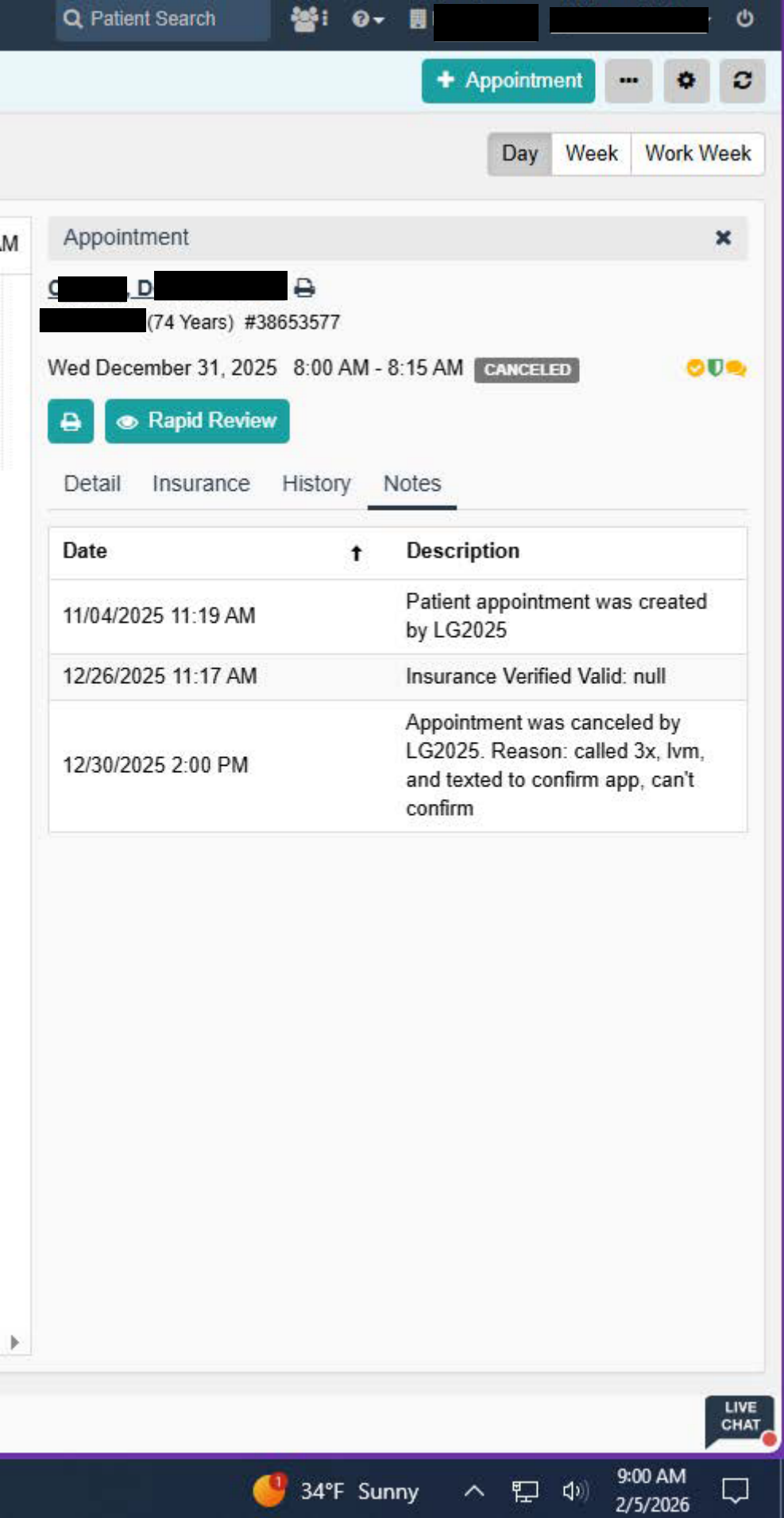
8:28 AM PT

[redacted]
[redacted] D[redacted] your appt is at 8:00 AM on Wednesday, December 31, 2025 Thank you

Type a message here...

0 / 480


https://chat.solutionreach.com/conversations/ui/conversations/[redacted]
Frames Support -...
RevolutionEHR
Mail - Elizabeth Lo...
VSP
Versant Health
eyemed
Keeper® Vault - el...
Chem Clip
EyeQuest
Spectera
Optical Capture.xlsx
Deep Dive Reporti...
VisionWeb
Frames Digital Sho...
ABB Verify
Search Patients
EL [redacted]
Conversations
Inbox 958
Unread
Flagged
Unknown Number 131
Archived 542
Archived
+ Compose New Message
D[redacted] C[redacted]
Jan 2
D[redacted] We miss SEEING you--Exams are filling fast. Don't wait to Book!...
[redacted]
Jan 20
Good morning, [redacted] We have you scheduled for an appointment at Pritchet...
[redacted]
Jan 20
Good morning [redacted] We have you scheduled for appointments at...
[redacted]
Jan 20
[redacted] our appt is at 10:00
D[redacted] C[redacted]
Tuesday, December 30, 2025
[redacted]
Good morning, D[redacted] We have you scheduled for an appointment at [redacted] for an eye exam on 12/31 at 8:00 am. Please respond to this message or give us a call to confirm your appointment. If we don't hear back from you, the appointment will be canceled. Thank you!
8:28 AM PT
[redacted]
[redacted] D[redacted] your appt is at 8:00 AM on Wednesday, December 31, 2025 Thank you
[redacted]
You're on the books! Don't forget to use your vision benefits and make the most of your FSA/HSA funds before they expire. See you soon!
TextSTOPoptout
4:00 PM PT
Friday, January 2, 2026
[redacted]
D[redacted] We miss SEEING you--Exams are filling fast. Don't wait to Book!
[redacted]
TextSTOPoptout
9:34 AM PT
Type a message here...
0 / 480


Patient Search
[redacted]
+ Appointment
Day
Week
Work Week
Appointment
[redacted], D[redacted]
[redacted](74 Years) #38653577
Wed December 31, 2025 8:00 AM - 8:15 AM
CANCELED
Rapid Review
Detail
Insurance
History
Notes
Date
Description
11/04/2025 11:19 AM
Patient appointment was created by LG2025
12/26/2025 11:17 AM
Insurance Verified Valid: null
12/30/2025 2:00 PM
Appointment was canceled by LG2025. Reason: called 3x, lvm, and texted to confirm app, can't confirm
LIVE CHAT
34°F Sunny
9:00 AM
2/5/2026

Wednesday, December 31, 2025

Location: [redacted]

Daily Schedule

8:00 AM - 8:15 AM H [redacted] L [redacted] (62 Years) [redacted] (Cell)	[redacted] **OD** Office Visit*	issues with left eye, wavy vision. Doesn't think its anything to do with her RX. Thinks something is medically wrong Photos, pressures, AR, macular OCT, and VAs
8:40 AM - 8:55 AM [redacted] (17 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	ok to photos REMINDER 12/30
9:00 AM - 9:15 AM [redacted] (31 Years) [redacted] (Cell)	[redacted] **OD** Office Visit*	PT EYE IS IRRITATED AND BURNNG MIGHT BE FROM CL
9:20 AM - 9:35 AM [redacted] (79 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	photos okay REMINDER 12/30
9:40 AM - 9:55 AM [redacted] (26 Years) ([redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	left vm to confirm app 11/4 LG ok to photos REMINDER 12/30
10:30 AM - 10:45 AM [redacted] (21 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	photos okay REMINDER 12/30
10:50 AM - 11:05 AM [redacted] (50 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	photos okay REMINDER 12/30
11:10 AM - 11:25 AM [redacted] (38 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	ok to photos REMINDER 12/30
11:50 AM - 12:05 PM [redacted] (9 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	Pt OK to pay $45 photos left vm to confirm app 11/06 LG x2 REMINDER 12/30
12:10 PM - 12:25 PM [redacted] (60 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	photos okay lmv to confirm app 12/29 LG
2:00 PM - 2:15 PM [redacted] (69 Years) [redacted] Cell)	[redacted] **OD** Comprehensive Eye Exam	photos okay pt knows about $89 payment for exam
2:20 PM - 2:35 PM [redacted] 12 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	photos okay
2:40 PM - 2:55 PM [redacted] (34 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	photos okay lvm to confirm app 12/29 LG Pt called back and confirmed appt 12/29 EL2024
3:00 PM - 3:15 PM [redacted] (41 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	photos okay
3:20 PM - 3:35 PM [redacted] (2 Years) [redacted] (Cell)	[redacted] **OD** Office Visit*	
3:20 PM - 3:35 PM [redacted] (59 Years) [redacted] (Cell)	[redacted] **OD** Contact Lens Follow Up	left eye is blurry with cl, needs prescription to be checked
3:40 PM - 3:55 PM [redacted] (74 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	ok to photos
4:00 PM - 4:15 PM [redacted] (60 Years) [redacted] (Cell)	[redacted] **OD** Comprehensive Eye Exam	ok to photos lvm to confirm app 12/29 LG

Materials for Item No. 6

Feb 9, 2026

Nevada State Board of Optometry

6170 Mae Anne Avenue, Suite 1

Reno, NV 89523

Adam Schneider, Esq.

Mr. Schneider,

Thank you for briefly speaking with me reference Nevada License by Endorsement.

I graduated State University of New York- State College of Optometry in 1986. I was administered and passed the 3 parts of the National Board of Examiners Test which was available at the time. I subsequently became licensed in the State of New York in 1987, State of California in 1986, State of Arizona in 2001 and the State of Florida in 1991. I have been actively practicing in the State of Florida for the past 35 years and hold both Therapeutic and Oral Medication Authority. The current format of the NBEO was not available at the time and neither was the TMOD. My prescriptive authority was authorized by the State of Florida post Oral Medication Course and examination.

My record has been exemplary over my practice years. I have maintained clear licensure, no legal proceedings or investigations by any licensing board. NPI 1053492009

I have been credentialled by the Veterans Administration to provide offsite eye exams to eligible Veteran beneficiaries. I am an adjunct Professor of Vision Care Programming instructing Primary Care and Ocular Disease at Broward College located in Coconut Creek, Florida for the past 7 years.

I am currently an expert arbiter for Veterans Evaluation Systems and Optum Serve (LHI) evaluating veterans for ocular disabilities.

I wish to ascertain if Nevada Licensure by Endorsement would allow me to achieve an optometric license in Nevada.

Sincerely

Steven Friefeld, O.D.

4468 NW 29th Way

Boca Raton, FL 33434

R049-25(8) NRS 636.206 is hereby amended to read as follows:

2. An applicant for a license by endorsement pursuant to this section must submit to the Board with his or her application: . . . (2) Has passed each part of the comprehensive national optometry examination administered by the National Board of Examiners in Optometry or its successor as a prerequisite to the issuance of the corresponding valid, active and unrestricted license described in subsection 1

Materials for Item No. 7

Relevant law

NRS 636.025(2) prohibition of "(a) Any procedure using a laser, scalpel, needle or other instrument in which any human tissue is cut, burned or vaporized by incision, injection, ultrasound, laser, infusion, cryotherapy, radiation or other means; or (b) Any procedure using an instrument which requires the closure of human tissue by suture, clamp or similar device."

VALEDA®

Light Delivery System

User Manual

Rx Only

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 central-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.

Contents

1. Introduction

This manual provides the indications, contraindications, instructions for use, warnings, cautions, and precautions for the Valeda Light Delivery System. Carefully read this manual in its entirety before using the Valeda Light Delivery System. Failure to follow these instructions may result in improper use of the system.

All images in this manual are representative and may vary from actual device images.

Terminology – within this User Manual, the words "Valeda" and "System" are used to identify collectively all components (and accessories) of the Valeda Light Delivery System. For questions regarding Valeda, please contact LumiThera®.

2. Valeda Light Delivery System Description

Overview

Valeda is a multiwavelength light-emitting diode (LED) system designed for eye care professionals to use in the treatment of the eye with photobiomodulation (PBM). Valeda will provide a preset treatment of PBM to the patient's eye and retinal tissue through the open and closed eyelid.

Valeda uses three LEDs to generate 590, 660, and 850 nm light, which is conditioned through a series of optics to produce a uniform, noncoherent beam of 30 mm in diameter at the plane of treatment. The beam is directed by adjustable mirrors to allow treatment of either eye without repositioning the patient.

The operator interface (Figure 1) consists of a touchscreen, start/pause and stop push buttons, and a joystick to center the beam on the patient's eye. A USB port is used to load Valeda Treatment Credits into the system.

The patient interface (Figure 2) consists of an On/Off switch, a fixed forehead rest, the light aperture, and an adjustable chin rest. The adjustment range of the chin rest is designed to accommodate the intended patient population.

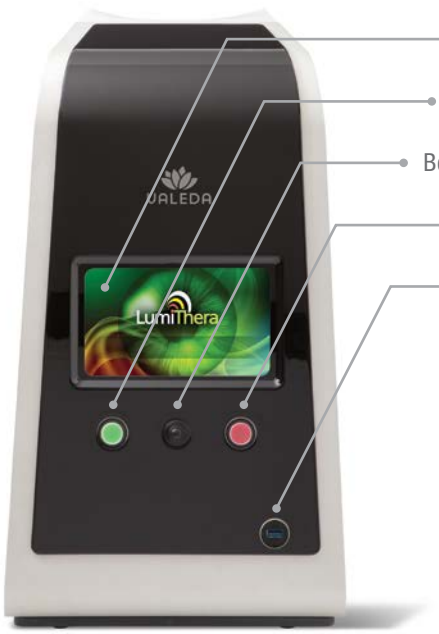


FIGURE 1 OPERATOR'S PERSPECTIVE

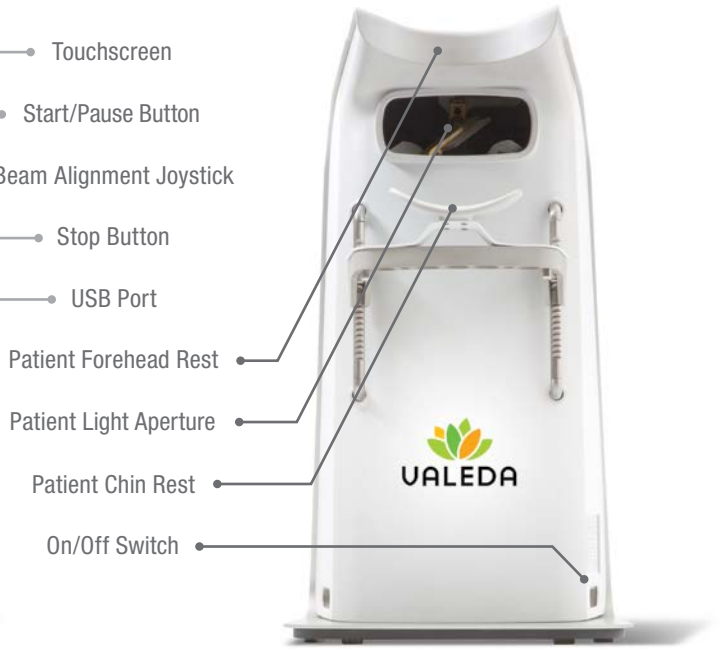


FIGURE 2 PATIENT'S PERSPECTIVE

Operation of Valeda Consists of the Following Steps:

- Valeda Setup
- Patient Preparation
- Beam Alignment
- Treatment
- Cleaning and Storage

Replacement components may be purchased by contacting your LumiThera representative or through the LumiThera e-commerce store at www.lumithera.com.

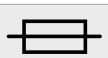
Valeda LumiKey

A Valeda LumiKey is a standard USB storage device used to transfer electronic Treatment Credit files (LumiFiles). Encrypted LumiKey files ensure that Valeda will process only files prepared by LumiThera.

Valeda Dust Cover

A dust cover is provided to protect Valeda from dust and mild abrasions. Remove before and replace after use of Valeda.

3. Labeling Symbols

Symbol	Description
	**Consult instructions for use.** Indicates the need for the user to consult the instructions for use.
	**Refer to instruction manual/booklet.** Signifies that the instruction manual/booklet must be read.
	**Manufacturer.** Indicates the medical device manufacturer.
	**Date of manufacture.** Indicates the date when the medical device was manufactured.
REF	**Catalogue number.** Indicates the manufacturer's catalogue number so that the device can be identified.
LOT	**Batch code.** Indicates the manufacturer's batch code so that the batch or lot can be identified.
SN	**Serial number.** Indicates the manufacturer's serial number so that the device can be identified.
	**Applied Part, Type BF.**
UDI	**Unique device identifier.** Indicates a carrier that contains unique device identifier information.
Rx Only	**Prescription required.** Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
	**Temperature limit.** Indicates the temperature limits to which the medical device can be safely exposed.
	**Humidity limitation.** Indicates the range of humidity to which the medical device can be safely exposed.
	**Fragile, handle with care.** Indicates a medical device that can be broken or damaged if not handled carefully.
	**Keep dry.**
	**This way up.**
	**Recycle.**
	**Atmospheric pressure limitation.** Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	**Packaging unit.** Indicates the number of pieces in the package.
	**Alternating current.** Indicates on the rating plate that the equipment is suitable for alternating current only.
	**Fuse.** Identifies fuse boxes or their location.

Symbol	Description
	**Valeda Treatment Credits.**
	**Back.** Display navigation button to return to the prior screen.
	**Continue.** Display navigation button to proceed to the next screen.
	**Confirmation.** Display button to confirm displayed information.
	**Settings.** Display navigation button to proceed to the system settings.
	**Home.** Display navigation button to return to the home screen.
	**Information.** Display navigation button to proceed to the system information screen.

4. 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.

5. Important Safety Instructions

Valeda is a medical device and should be operated only by qualified medical professionals in accordance with this manual and any applicable country or local laws and regulations. Prior to using Valeda, be sure to review all described warnings and entire instructions for use. Failure to follow the warnings may result in injury to the patient or operator or cause property damage.

It is the responsibility of the operator and the institution or organization where Valeda will be operated to comply with their safety standards concerning the use of this system.

Warnings

Warnings are information relating to potential dangers when using Valeda.

- Do not use the system if damage is observed or if the system is not operating as expected.
- Do not modify the system.
- Use only the power cord provided with the system or supplied by LumiThera.
- Do not use the power cord if it has been damaged. Use of a damaged power cord may result in a fire or electrical shock hazard.
- To avoid the risk of electrical shock, the system must be connected only to supply mains with protective earth.
- Do not treat patients with open sores that may come into contact with the system.
- Do not use this system on any part of the body other than designated treatment sites.
- Disconnect power to the system before cleaning.
- Patients should remove their glasses and contact lenses prior to treatment.
- Valeda was designed to meet all regulatory and safety standards. While device malfunction is improbable, it could result in harm to the patient or user.

Cautions

Cautions are important information to prevent possible harm when using Valeda.

- Use only the accessories specified for use with this system. Use of accessories not specified for use with this system may impair performance.
- Only connect a Valeda LumiKey to the system USB port. Connection to other equipment may damage the system.
- High levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from nearby equipment such as Magnetic Resonance Imaging (MRI), diathermy, and electrocautery could result in performance disruption. Consider placing the Valeda away from such devices.
- In the event of an emergency in which power to the system must be shut off, either turn off the power switch or unplug the system from the electrical source.
- Do not attempt to disassemble Valeda.

Precautions

Precautions are important information for alerting the operator to exercise special care necessary for the safe and effective use of Valeda or a measure taken in advance to avert possible harm or misfortune.

- Safety and effectiveness in patient populations and/or conditions excluded from the clinical study has not been established. This includes the following: patients under the age of 50, pregnant or nursing women, current or history of neovascular maculopathy, presence of center involving geographic atrophy (GA) within the central 1mm diameter, media opacities, including cataracts, which might interfere with visual acuity or imaging in the eye, posterior capsule opacification, which might interfere with visual acuity or imaging in the eye, ocular disorder or disease that partially or completely obstructs the pupil, any visually significant disease in any ocular structure apart from dry AMD.
- There is limited safety and effectiveness in patients with best-corrected visual acuity (BCVA) worse than 20/70 or better than 20/32, and these patients are excluded from the Indications for Use. If the eyecare practitioner wishes to treat patients who are not considered in the intended population, he/she should consider that the safety and effectiveness have not been demonstrated in these groups.
- No non-white subjects received treatment with the device in the study and the clinical performance of the device in non-white patients is unknown. There is limited safety and effectiveness data in subjects of Hispanic or Latino origin. The eye care practitioner should consider the benefit/risk of treating patients outside of the study population.

- An analysis of the primary effectiveness endpoint (mean BCVA change from baseline for the PBM arm – the mean BCVA change in the Sham arm) showed the following differences between arms for the subgroup of pivotal study patients with early AMD (Beckman Clinical Category Classification):
  - At Month 13: +1.90 letters
  - At Month 21: -0.10 letters
  - At Month 24: +0.29 letters
- The eyecare practitioner should consider the observed benefit/risk profile for this sub-population, when contemplating treatment of patients with this classification of Early AMD.
- It is possible that treatment benefit may not persist significantly after treatment is stopped. The eyecare practitioner should inform patients of this potential.
- The clinical study provided no significant data concerning the safety and effectiveness of the device should treatments be applied more frequently than described in this manual, or if more than 54 total treatments are delivered per eye. The eyecare practitioner should inform patients of this information.
- Twelve (12) eyes (12.9%) in the PBM group and 4 eyes (7.3%) in the Sham group had a fellow eye that had neovascular AMD (nAMD). Of these 5 (41.7%) of 12 eyes in the PBM-treated group converted to nAMD, and 1 (25.0%) of the 4 eyes in the Sham group converted to nAMD. The eye care practitioner should consider the benefit/risk profile in this sub-population and should closely monitor patients whose fellow eye has nAMD.
- Do not spray or pour cleaning agents directly on Valeda.
- Do not use abrasive agents to clean Valeda.
- Use only fuses recommended by LumiThera.
- Do not spill liquid on Valeda.

Information

The following useful information is related to the operation of Valeda.

- There are LEDs in Valeda emitting at 590, 660 and 850 nm light from the light aperture. Valeda has been designed to limit LED output to be within acceptable industry standards for eye safety.

6. Clinical Data

Study Objectives and Methods

The LIGHTSITE III study evaluated the safety and efficacy of PBM for the treatment of dry AMD. The study aimed to evaluate the long-term vision and anatomical benefits of PBM using the Valeda Light Delivery System in subjects with dry AMD.

Study Design

The study was a double-masked, Sham controlled, parallel design, prospective, multi-site study. The target enrollment was at least 96 subjects to be recruited in order to achieve 144 evaluable eyes, in up to 15 centers in the United States, randomized at a 2:1 ratio into 2 treatment groups: PBM (active) or Sham (control).

Each eye was independently qualified for the study. Both eyes, if eligible, received the same treatment (PBM or Sham) throughout the study. If only one eye qualified, it received either PBM or Sham treatment and the non-qualifying eye received no treatment. The non-study eye was followed for 24 months, and all outcomes and imaging measurements were conducted.

Each group received 3 treatments per week over 3 to 5-weeks starting at Baseline and starting again at Months 4, 8, 12, 16 and 20. A maximum of 9 treatments were delivered in the 3 to 5-week period. One hundred (100) subjects were enrolled in the study at 10 of 11 participating clinical study sites. Sixty-five subjects (65.0%) received PBM (active) treatment. Thirty-five subjects (35.0%) received Sham (control) treatment.

Outcome Measures for Evaluation

The primary efficacy endpoint was the mean best corrected visual acuity (BCVA) change from baseline to Month 13 or Month 21. Comparison was to be made between the PBM and Control arms to demonstrate statistical superiority of the PBM treatment, using an alpha value of 0.025 to control for multiple testing, with the Month 13 result tested first and then Month 21.

Secondary effectiveness endpoints included:

1) Mean BCVA change from baseline to Month 13 or Month 21 among the PBM-treated eyes.

2) Mean changes in low luminance best corrected visual acuity (LLBCVA) from baseline to Month 13 or Month 21. Comparisons were conducted between the Sham and PBM treatment groups.

3) Mean changes in macular drusen volume and central subfield drusen thickness from baseline to Month 13 or Month 21. Comparisons were conducted between the Sham and PBM-treatment groups.

4) Mean changes in contrast sensitivity at 40 cm from baseline to Month 13 or Month 21. Comparisons were conducted between the Sham and PBM treatment groups.

If the primary effectiveness analysis at Month 13 was significant, all secondary analyses were to be performed using Month 13 data. If the primary effectiveness analysis at Month 13 was not significant, the study was to continue in a masked fashion to Month 24 for all subjects, and all secondary analyses performed using the Month 21 data. Thus, the secondary effectiveness analyses were to be performed once, either at Month 13 or at Month 21. The secondary endpoints were to be evaluated using statistical hypothesis tests using a hierarchical testing procedure to control for multiplicity.

The primary safety endpoint/analysis was the mean change from baseline to Month 13 or Month 24. Comparison was to be made between the PBM and Sham arms to demonstrate statistical non-inferiority of the PBM treatment. Non-inferiority test was performed to determine if PBM is non-inferior to the Sham group with a non-inferiority margin of 2 (two) letters. No secondary safety endpoints were specified in the protocol, however the protocol stated “additional safety analyses” included frequency and severity of the reported adverse events, and descriptive statistics for BCVA, color vision testing, color fundus images, perimetry, and contrast sensitivity.

Inclusion and Exclusion Criteria

Enrollment in the study was limited to patients who met the following inclusion criteria:

- Male or female at least 50 years of age at Screening visit
- Early Treatment Diabetic Retinopathy Study (ETDRS) BCVA letter score between 50* and 75* (Snellen equivalent of 20/100 to 20/32). *If the subject met this criterion at the Screening Visit, but the Baseline BCVA letter score was between 48 and 77, the subject could be entered in the study as long as the difference in score between Screening and Baseline was not more than 3 letters.
- Diagnosis of dry AMD as defined by the presence of the following:
  - Drusen that were intermediate in size or larger (63 µm or larger in diameter) with at least a few (3) being regular drusen and not pseudodrusen and/or geographic atrophy (GA) visible on two of the following: color fundus images, optical coherence tomography (OCT) and/or fundus autofluorescence (FAF), as confirmed by the reading center
- Able to communicate well with the Investigator and able to understand and comply with the requirements of the study
- Informed of the nature of this study and had provided written, informed consent in accordance with institutional, local and national regulatory guidelines

Patients not meeting the above inclusion criteria were excluded from the study.

In addition, patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

- Current or history of neovascular maculopathy that included any of the following (as confirmed by the reading center):
  - Choroidal neovascularization (CNV) defined as pathologic angiogenesis originating from the choroidal vasculature that extended through a defect in Bruch's membrane
  - Serous and/or hemorrhagic detachment of the neurosensory retina or retinal pigment epithelial (RPE)
  - Retinal hard exudates (a secondary phenomenon resulting from chronic intravascular leakage)
  - Subretinal and sub-RPE fibrovascular proliferation
  - Disciform scar (subretinal fibrosis)
- Presence of center involving GA within the central ETDRS 1 mm diameter at Screening, as confirmed by the reading center
- Media opacities, including cataracts, which might interfere with visual acuity or imaging in the study eye(s). Subjects should not have been entered if there was likelihood that they would require cataract surgery in the study eye in the next 24 months.
- Posterior capsule opacification, which might interfere with visual acuity or imaging in the study eye(s). Subjects should not have been entered if there was a likelihood that they would require surgery in the study eye in the next 24 months.
- Invasive eye surgery (e.g., cataract, capsulotomy) on a qualifying eye within three 3 months prior to Screening
- Ocular disorder or disease that partially or completely obstructed the pupil (e.g., posterior synechia in uveitis)
- Visually significant disease in any ocular structure apart from dry AMD (e.g., diabetic macular edema, glaucoma (using >2 eye drop medications, uncontrolled intraocular pressure (IOP) and/or central/paracentral visual field loss), glaucoma surgery, active uveitis, active vitreous disease, intraocular tumor, retinal vascular diseases)
- Ocular disorder or disease other than dry AMD that could cause drusen (glomerulonephritis Type 2, Autosomal dominant drusen), GA (North Carolina dystrophy) or mitochondrial diseases (parafoveal petaloid GA, Stargardt disease)
- Presence or history of disease or condition affecting functional vision without obvious structural abnormalities (e.g., amblyopia, stroke, nystagmus)
- Serious medical illness that prevented the subject from performing study activities (including cardiac, hepatic, renal, respiratory, endocrinologic, neurologic, or hematologic disease) or, in the judgement of the Investigator, was likely to require surgical intervention or hospitalization at any point during the study
- Presence of or history of malignancy within the past 5 years other than non-melanoma skin or squamous cell cancer or cervical carcinoma in-situ
- Non-ambulatory
- Presence or history of known light sensitivity to yellow light, red light, or near infrared radiation (NIR), or if they had a history of light activated central nervous system disorders (e.g. epilepsy, migraine)
- Use of any photosensitizing agent (e.g., topicals, injectables, oral) within 30 days of treatment without consulting subject's physician
- History of drug, alcohol, or substance abuse within 3 months prior to Screening
- Participation in any other clinical study at time of screening, or had received an investigational drug or treatment with an investigational device within 3 months prior to Screening
- If on any antioxidant or vitamin Age-Related Eye Disease Study (AREDS) supplement for dry AMD, had not been stabilized for a minimum of 1 month prior to Screening. Subjects were considered to be stable if they were taking the AREDS supplements consistently as prescribed by their treating doctor.
- Had received Low Vision Rehab/Therapy within 30 days prior to Screening or intended to receive during the study
- Had an open sore(s) that could come in contact with the Valeda System, had periorbital skin erythema or was prone to such conditions with exposure to light.
- In the opinion of the Investigator, was unlikely to comply with the study protocol.

Study Population Demographics and Baseline Parameters

The demographics of the study population are typical of this patient population and for similar studies performed in the US. The overall mean age at screening was 75.4 years (Standard Deviation (SD) 7.1) with a higher distribution of females (n = 68; 68.0%) than males (n = 32; 32.0%). The median age was 75.0 years. The majority of subjects were Caucasian/white (n = 99; 99.0%). Most eyes were of blue (n = 33; 33.0%) or brown color (n = 33, 33.0%). The majority of subjects were on AREDS supplements (n = 86; 86.0%). Groups were statistically balanced for age ($p = 0.07$) and baseline BCVA scores ($p = 0.39$). Distribution was similar for baseline demographics in Sham and PBM groups.

The average baseline BCVA score was 70.1 letters for Sham-treated eyes and 70.7 letters for PBM-treated eyes. The majority of eyes at Baseline (n = 79; 53.4%) had a BCVA between 71-75 letters. Table 1 provides a cross reference between ETDRS used in the study and Snellen and LogMAR VA measurements.

TABLE 1 CROSS REFERENCE FOR ETDRS, SNELLEN AND LOGMAR VA MEASUREMENTS

ETDRS Letter Score	Snellen	LogMAR
50	20/100	0.7
55	20/80	0.6
60	20/64	0.5
65	20/50	0.4
70	20/40	0.3
75	20/32	0.2
80	20/25	0.1
85	20/20	0.0
90	20/16	-0.1
95	20/12.5	-0.2
100	20/10	-0.3

A modified Ferris risk factor scoring system was used to identify the total risk factors for each eye indicating potential risk for further progression of disease. A risk factor score of 1 was assigned to each study eye for each of the following: a) at least 3 medium drusen or 1 large drusen; b) pigmentary changes. If the eye had non-central GA, a risk factor score of 2 was assigned (maximum score could not exceed a score of 2). The fellow eye was then evaluated and assigned a risk factor score of 1 for each of the following: a) at least 3 medium drusen or 1 large drusen; b) pigmentary changes. If the fellow eye had nAMD or GA (central or non-central) a risk factor score of 2 was assigned (maximum score could not exceed a score of 2). Finally, the score for the eye and fellow eye were added together to obtain the total risk factor for the study eye, which had a maximum possible score of 4. Table 2 provides an overview of the stratification of risk factors for subjects enrolled in the study.

TABLE 2 STRATIFICATION OF RISK FACTORS FOR PROGRESSION OF DRY AMD

	Sham (n=55)	PBM (n=93)	Total (n=148)
# of Risk Factors	N (%)	N (%)	N (%)
1 Risk Factor	0 (0.0)	1 (1.0)	1 (0.7)
2 Risk Factors	11 (20.0)	36 (38.7)	47 (31.8)
3 Risk Factors	13 (23.6)	23 (24.7)	36 (24.3)
4 Risk Factors	31 (56.4)	33 (35.5)	64 (43.2)
Low-Risk Group (1-2 Risk Factors)	11 (20.0)	37 (39.8)	48 (32.4)
Moderate to High-Risk Group (3-4 Risk Factors)	44 (80.0)	56 (60.2)	100 (67.6)

In the current study, 65% of the study eyes (89/136) that had not progressed to GA at baseline had a factor of 3 or 4 putting them at least at a 25 - 50% risk for potential disease progression. For 28% of the subjects, the fellow eye had nAMD and/or GA.

Clinical classification of eyes (Table 3) showed a total of 21.6% (n = 32) of eyes categorized as early-stage AMD, 71.0% (n=105) were intermediate-stage AMD, and 7.4% (n = 11) were late-stage AMD (GA, no CNV).

TABLE 3 BECKMAN CLINICAL CATEGORY CLASSIFICATION (ALL SUBJECTS ENROLLED)

Clinical Category	Sham n=55 n (%)	PBM n=93 n (%)	Total n=148 n (%)
Early AMD	9 (16.4)	23 (24.7)	32 (21.6)
Intermediate AMD	41 (74.5)	64 (68.1)	105 (71.0)
Late Stage	5 (9.1)	6 (6.5)	11 (7.4)

Reference: Ferris FL 3rd, et al. Clinical classification of age-related macular degeneration. Ophthalmology. 2013;120(4):844-851. doi:10.1016/j.ophtha.2012.10.036

Accountability

At the time of database lock (at the Month 24 visit), of 100 subjects enrolled in the study 80% (n=80) were available for analysis.

TABLE 4 SUBJECT/EYES DISPOSITION (ALL SUBJECTS/EYES ENROLLED)

Disposition	Sham n (%) Subjects/Eyes	PBM n (%) Subjects/Eyes	Total n (%) Subjects/Eyes
Screened			178
Randomized (ITT Population)	35 / 55	65 / 93	100 / 148
Treated	35 / 55	65 / 93	100 / 148
Study Completed [1]	27 (77.1) / 43 (78.2)	53 (81.5) / 78 (83.9)	80 (80.0) / 121 (81.8)
Study Discontinued [1]	8 (22.9) / 12 (21.8)	12 (18.5) / 15 (16.1)	20 (20.0) / 27 (18.2)
Safety Population	35 / 55	65 / 93	100 / 148
mITT Population	34 / 54	64 / 91	98 / 145
Primary Reason for Discontinuation [2]			
Screening/Baseline failure			78
Lost to follow-up	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawal of consent	4 (50.0) / 5 (41.7)	8 (66.7) / 9 (60.0)	12 (60.0) / 14 (51.9)
Subject unable to return to facility	2 (25.0) / 3 (25.0)	2 (16.7) / 2 (13.3)	4 (20.0) / 5 (18.5)
Adverse events [3]	2 (25.0) / 4 (33.3)	2 (16.7) / 4 (26.7)	4 (20.0) / 8 (29.6)
Other	0 (0.0)	0 (0.0)	0 (0.0)

Notes: n = Number of subjects/eyes.

ITT (Intent-to-Treat) Population: All subjects who have signed the Informed Consent Form and are randomized to treatment.

mITT (Modified Intent-to-Treat) Population: All subjects randomized to treatment who receive at least one treatment and have at least one post-baseline efficacy measurement.

[1] Percentages are based on the number of subjects/eyes treated in the group.

[2] Percentages are based on the number of subjects/eyes discontinued in the group.

[3] All non-ocular adverse events unrelated to the study device or procedure.

Table 5 illustrates the number of eyes with BCVA data at baseline and Months 13, 21, and 24. The table reflects the mITT study results using multiple imputation and used all available data from subject visits that were seen outside the protocol visit window.

TABLE 5 NUMBER OF EYES WITH BCVA DATA AT BASELINE, MONTH 13, 21, AND 24

Eyes with BCVA Data Available	# Eyes in Study	Baseline (Visit 2)	Visit 40 (Month 13)	Visit 60 (Month 21)	Visit 61 (Month 24)
Total Number of Eyes with BCVA Data Available	148	148	126	114	101
Percentage of Eyes Available		100.0%	85.1%	77.0%	68.2%
Eyes with Missing BCVA Data:		0	22	34	47
# Discontinued from BCVA Collection		0	19	29	35
# Missing at Scheduled Visit but Seen **Outside** Window*		0	1	2	12
# Not Seen but Accounted for (**missed** visit but still in study)		0	2	3	0
# Lost to follow-up		0	0	0	0
PBM Number of Eyes with BCVA Data Available	93	93	82	76	67
Percentage of Eyes Available		100.0%	88.2%	81.8%	72.0%
Eyes with Mission BCVA Data:		0	11	17	26
# Discontinued from BCVA Collection*		0	9	15	20
# Missing at Scheduled Visit but Seen **Outside** Window**		0	1	2	6

# Not Seen but Accounted for (**missed** visit but still in study)		0	1	0	0
# Lost to follow-up		0	0	0	0
Sham Number of Eyes with BCVA Data Available	55	55	44	38	34
Percentage of Eyes Available		100.0%	80.0%	69.1%	61.8%
Eyes with Missing BCVA Data:		0	11	17	21
# Discontinued from BCVA Collection*		0	10	14	15
# Missing at Scheduled Visit but Seen **Outside** Window**		0	0	0	6
# Not Seen but Accounted for (**missed** visit but still in study)		0	1	3	0
# Lost to follow-up		0	0	0	0

* Eyes were discontinued from the study for the following reasons: The subject withdrew consent (6 PBM, 4 Sham), had a non-ocular AE (4 PBM, 4, Sham) or was unable to return to the facility (2 PBM, 3 Sham). Eyes were immediately discontinued from treatment and efficacy data collection (including BCVA - but kept in the study for safety) for the following reasons: Eye progressed to neovascular AMD (4 PBM, 1 Sham), developed cystoid macular edema requiring injections (1 Sham) or had ocular surgery that would impact their post-operative vision (1 PBM, 1 Sham). Additionally, 3 PBM eyes and 1 Sham eye withdrew consent after progressing to neovascular AMD. Please note these are the eyes removed as of the Month 24 Visit. The eyes removed at Months 13 and 21 are a subset of these eyes.

** The presentation and analyses of BCVA-related study results used all available data from subject visits that occurred either within or outside the protocol visit window.

Effectiveness Results

Primary Effectiveness Endpoint/Analysis

The analysis of effectiveness was based on the mITT subject population consisting of all subjects' eyes in the Safety set that received at least one post-baseline efficacy measurement. The primary endpoint/analysis was the BCVA mean change from baseline to Month 13 or Month 21. Comparison was made between the PBM and Control arms to demonstrate statistical superiority of the PBM treatment, using an alpha value of 0.025 to control for multiple testing, with the Month 13 result tested first, followed by Month 21. The null hypothesis was that the difference between the arms in terms of the mean BCVA change from baseline was equal to zero. Month 24 was predefined only as the primary safety endpoint (3 months after last treatment) but is included with the effectiveness data for comparison. Using multiple imputation analysis with the mITT dataset (PBM: n = 91, Sham: n = 54), the study met the predetermined primary efficacy BCVA endpoint at Month 21 with the following results:

- At Month 13: The mean PBM result was 2.6 letters better than the mean Sham result (p=0.0548; non-significant);
- At Month 21: The mean PBM result was 3.8 letters better than the mean Sham result (p=0.0036; significant). The 95% confidence interval (CI) on the difference between the mean BCVA changes from baseline was: 1.2 to 6.3 letters.

Additional Analyses Concerning Comparisons Between Arms for Mean BCVA Changes from Baseline.

The PBM arm maintained a mean letter difference of 4.3 letters at Month 24 (95% confidence interval: 1.5 to 7.2 letters). However, as shown in Table 5 (above), a substantial proportion of eyes did not have BCVA data at Month 24; this is particularly true for the Sham arm for which nearly 40% of eyes had no BCVA data.

Table 6 (Mean BCVA Letter Changes from Baseline from Month 1 to Month 24) provides the comparative data for the two arms. At Month 13, the mean BCVA increase from baseline was 6.0 letters in the PBM arm vs. 3.4 letters in the Sham arm, a difference of 2.6 letters. At Month 21, the mean increase from baseline was 6.2 letters in the PBM arm vs. 2.4 letters in the Sham arm, a difference of 3.8 letters. At Month 24, the increase from baseline was 5.6 letters in the PBM arm compared to 1.3 letters in the Sham arm, a dfference of 4.3 letters.

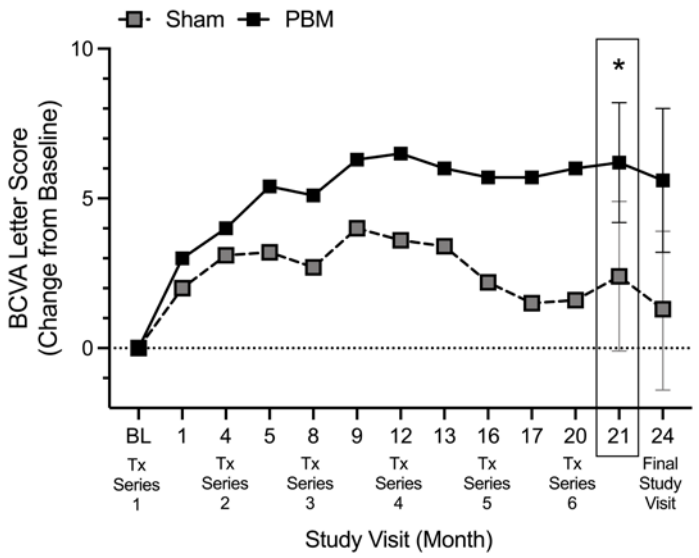


FIGURE 3 MEAN CHANGE OF BCVA FROM BASELINE WITH 95% CI SHOWN AT MONTH 21 AND MONTH 24 (FINAL VISIT) (CALCULATED FOR MITT POPULATION USING MULTIPLE IMPUTATION FOR MISSING DATA)

TABLE 6 MEAN BCVA LETTER CHANGE FROM BASELINE FROM MONTH 1 TO MONTH 24

	Sham LS Mean (SD)	PBM LS Mean (SD)
Month 1	2.0 (9.6)	3.0 (8.1)
Month 4	3.1 (11.1)	4.0 (9.4)
Month 5	3.2 (10.6)	5.4 (9.1)
Month 8	2.7 (12.6)	5.1 (10.7)
Month 9	4.0 (12.8)	6.3 (11.0)
Month 12	3.6 (14.7)	6.5 (12.8)
Month 13	3.4 (18.2)	6.0 (16.0)
Month 16	2.2 (15.9)	5.7 (13.8)
Month 17	1.5 (16.6)	5.7 (14.1)
Month 20	1.6 (16.0)	6.0 (13.0)
Month 21	2.4 (15.1)	6.2 (12.2)
Month 24	1.3 (16.3)	5.6 (14.8)

At Month 13, approximately 58.2% of PBM-treated eyes showed a ≥ 5 letter gain (mean of 9.7 letters) compared to 38.8% of Sham-treated eyes (mean of 8.6 letters), 27.5% of PBM-treated eyes showed a ≥ 10 letter gain (mean of 13.0 letters) compared to 13.0% of Sham-treated eyes (mean of 12.1 letters) and 5.5% of PBM-treated eyes showed a ≥ 15 letter gain (mean of 17.6 letters) compared to 1.9% of Sham-treated eyes (mean of 15.0 letters).

At Month 21, approximately 61.5% of PBM-treated eyes showed a ≥ 5 letter gain (mean of 9.0 letters) compared to 27.8% of Sham-treated eyes (mean of 8.0 letters), 23.1% of PBM-treated eyes showed a ≥ 10 letter gain (mean of 12.8 letters) compared to 3.7% of Sham-treated eyes (mean of 11.5 letters) and 4.4% of PBM-treated eyes responded with a ≥ 15 letter gain (mean of 15.5 letters) compared to 0.0% of Sham-treated eyes.

At Month 24, approximately 63.7% of PBM-treated eyes responded with a ≥ 5 letter gain (mean of 8.8 letters) compared to 22.2% of Sham-treated eyes (mean of 9.8 letters), 18.7% of PBM-treated eyes responded with a ≥ 10 letter gain (mean of 12.8 letters) compared to 7.4% of Sham-treated eyes (mean of 13.8 letters) and 4.4% of PBM-treated eyes responded with a ≥ 15 letter gain (mean of 16.3 letters) compared to 1.9% of Sham-treated eyes (mean of 22.0 letters).

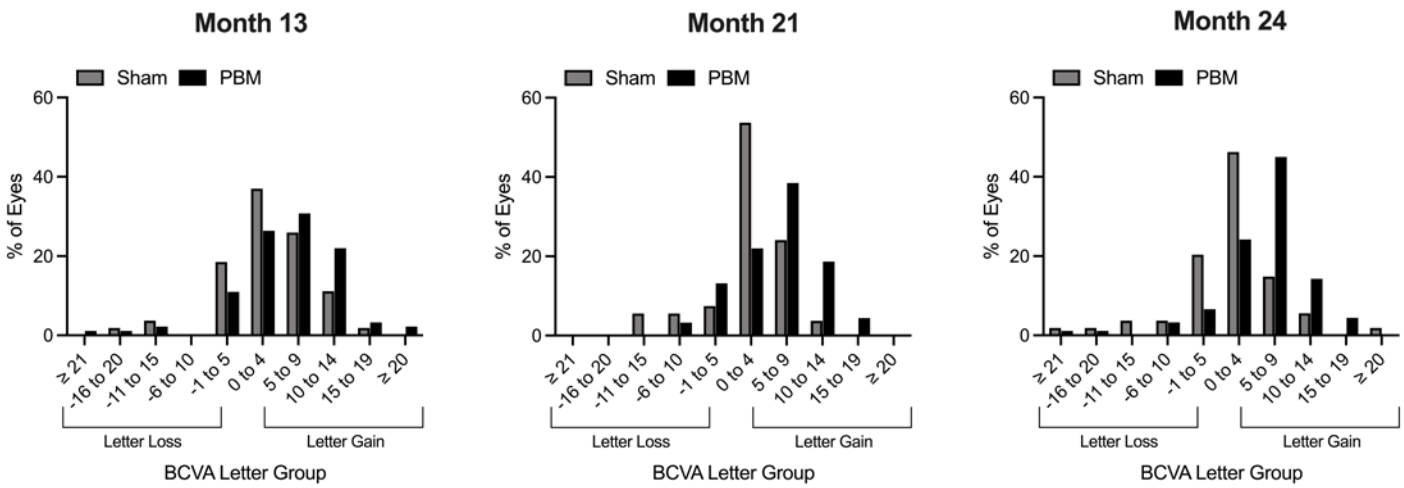


FIGURE 3 DISTRIBUTION OF BCVA LETTER GAIN OR LOSS, PBM VERSUS SHAM, BY FOLLOW-UP MONTH

The distribution of BCVA letter scores indicated a higher number of Sham-treated eyes showed BCVA letter losses compared to PBM as noted in the -11 to -15, -6 to -10, and -1 to -5 letter loss groups indicative of AMD disease progression over the course of the 24 Month study. The Sham group showed a larger number of eyes with a decrease in BCVA letter count of 10 or greater at each visit compared to the PBM group.

TABLE 7 MEAN BCVA CHANGE FROM BASELINE USING BECKMAN CLINICAL CATEGORY CLASSIFICATION WITH THE MITT POPULATION ON ACTUAL DATA (NO IMPUTATION USED)

Mean BCVA Change from BL mITT Population, actual data		Sham		PBM		Net change between PBM and Sham
		mean	n	mean	n	
Early	**BL BCVA Letter Score**	69.33	9	70.90	21	
	Month 13 Δ from BL	4.57	7	6.48	21	1.90
	Month 21 Δ from BL	6.50	6	6.40	20	-0.10
	Month 24 Δ from BL	6.71	7	7.00	19	0.29
Intermediate	**BL BCVA Letter Score**	70.23	40	70.63	64	
	Month 13 Δ from BL	2.31	32	5.54	56	3.22
	Month 21 Δ from BL	1.68	28	5.43	53	3.76
	Month 24 Δ from BL	0.46	28	5.10	49	4.64
Late	**BL BCVA Letter Score**	70.00	5	71.50	6	
	Month 13 Δ from BL	2.60	5	1.83	6	-0.77
	Month 21 Δ from BL	-2.75	4	3.40	5	6.15
	Month 24 Δ from BL	-1.40	5	5.40	5	6.80

Table 7 lists the baseline stratification of eyes by Early, Intermediate and Late dry AMD using the Beckman Clinical Classification. The mITT population mean change from baseline BCVA values are provided and the difference between the PBM-treated and Sham-treated eyes. The PBM-treated eyes had an increase in BCVA letters from baseline of 6.40, 5.43 and 3.40 letters, respectively in the early, intermediate and late-stage groups at Month 21. The Sham-treated groups had an increase of 6.50, 1.68 and –2.75 letters, respectively, in the early, intermediate and late-stage groups at Month 21. The net change between groups was 0.10, 3.76 and 6.15 letters between the early, intermediate and late-stage groups at Month 21. Early-stage eyes responded with an increase in BCVA letter scores from baseline equally between PBM and Sham groups. The largest net changes were in the intermediate dry AMD group across all time points. Late-stage dry AMD eyes were small in number but showed >6 letter difference at Months 21 and 24.

Secondary Effectiveness Endpoints/Analyses:

The following secondary effectiveness endpoints were pre-defined for the study:

1. Mean BCVA change from baseline to Month 13 or Month 21 among the PBM-treated eyes.
2. Mean changes in LLBCVA from baseline to Month 13 or Month 21. Comparisons were conducted between the Sham and PBM treatment groups.
3. Mean changes in macular drusen volume and central subfield drusen thickness from baseline to Month 13 or Month 21. Comparisons were conducted between the Sham and PBM treatment groups.
4. Mean changes in contrast sensitivity at 40 cm from baseline to Month 13 or Month 21. Comparisons were conducted between the Sham and PBM treatment groups

The analysis was to be performed at the same timepoint as the initial success on the primary effectiveness endpoint. These were evaluated using statistical hypothesis tests using a hierarchical testing procedure to control for multiplicity.

BCVA within PBM Group Analysis

Using multiple imputation with the mITT group, the within group analysis showed improved BCVA with a mean > 5 letter gain in PBM eyes from Baseline at Month 13 (LS mean 6.0 letters) ($p = < 0.0001$), Month 21 (LS mean 6.2 letters) ($p < .0001$) and maintained at Month 24 (LS mean 5.6 letters).

Low Luminance Best Corrected Visual Acuity (LLBCVA)

No significant difference was observed between the Sham and PBM groups at Month 13 and Month 21 in LLBCVA.

OCT/FAF Anatomical Outcomes

No significant difference was observed between the Sham and PBM groups at Month 21 in macular drusen volume or macular drusen thickness. Eyes from the Sham-treated macular drusen volume mean change from baseline group increased to 0.098 mm^3 at Month 21. Eyes from the PBM-treated macular drusen volume mean change from baseline group increased to 0.056 mm^3 at Month 21.

Mars Contrast Sensitivity (CS)

No significant difference was observed between the Sham and PBM groups at Month 13 and Month 21 in Mars CS at 40 cm.

Safety Results

The analysis of safety was based on the safety cohort of 100 subjects/148 eyes. Any patient randomized into the study who received at least one study treatment was considered part of the safety population.

Primary Safety Endpoint

The primary safety endpoint was to rule out inferiority for the difference between PBM and Sham groups in the mean BCVA changes from Baseline to Month 13 or Month 24. Month 13 was to be used only if primary effectiveness was demonstrated at this timepoint, which was not the case. Statistically significant improvements in BCVA letter changes between the PBM and Sham groups were observed at Month 21 ($p = 0.0036$) with maintained BCVA improvement out to Month 24 ($p = 0.0024$). Thus, with superiority achieved, inferiority was ruled out at Month 24. Subject data from out of window visits was included in this multiple imputation analysis. At Month 24, BCVA data was available for 67 of the 93 subject eyes enrolled in the PBM group (72.04%), and for 34 of the 55 subject eyes enrolled in the Sham group (61.82%), as shown in Table 5.

A lower percentage of PBM-treated eyes showed BCVA letter losses (>5 letters) compared to Sham over the 24 Month study. A total of 5% of the PBM subjects lost >5 letters at Month 13 and at Month 21 which increased to 7% at Month 24. In contrast, 7% of the Sham subjects lost >5 letters at Month 13 which increased to 15% at Month 21 and 18% at Month 24.

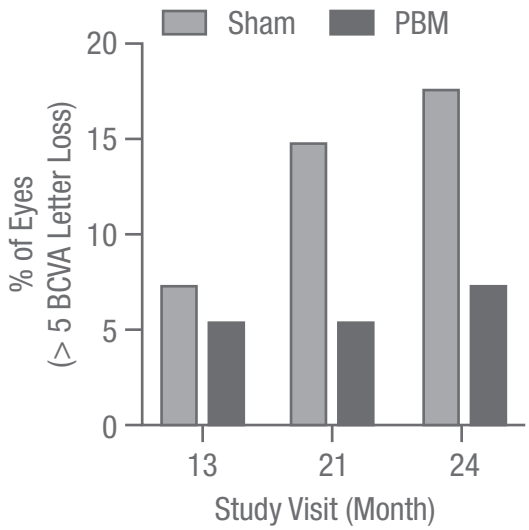


FIGURE 6 NUMBER OF ACTUAL EYES USED FOR PERCENTAGE OF >5 LETTER LOSS

Note: Prior to the initiation of the study, FDA indicated that it believed that this outcome based upon mean BCVA change from baseline, was an inappropriate primary safety endpoint. Among the reasons for this was that it was based upon the same parameter as the primary effectiveness endpoint, and that it was much more appropriate to have a primary safety endpoint based upon rates of adverse events or adverse effects seen in the study.

Additional Safety Analyses

Within the clinical study protocol, no secondary safety endpoints were specified. However, additional safety analyses are included in the following section. These include eyes with >10 letter loss, color vision testing, color fundus images, perimetry, contrast sensitivity, conversion from dry to neovascular AMD (nAMD), occurrence of incident GA, frequency and severity of the reported adverse events, and non-study eye adverse events.

Study Eyes with >10 letter loss

A total of 8 study eyes (5 Sham; 3 PBM) showed a BCVA letter loss of greater than 10 letters at the last subject visit (Month 24 Study Visit). Seven of the 8 study eyes completed the 24-month protocol. None of the 8 eyes were considered high-risk for conversion to nAMD (i.e., other companion eye had nAMD at Screening). None of the 8 eyes converted to nAMD during the study or had ocular surgery. Natural progression of AMD was identified as a contributing factor for 4 eyes (3 Sham, 1 PBM); these eyes were classified as AREDS III at study initiation but progressed to AREDS IV due to development of central GA during the study. Two Sham-treated eyes had concurrent ocular conditions unrelated to the study device or procedures affecting their BCVA outcomes. A clinical rationale for the BCVA loss was not identified for 1 PBM eye and 1 PBM subject's last BCVA test was incomplete.

Valeda Impact on Color Vision

The majority of Sham-treated eyes showed normal color vision testing at Baseline (94.4%), Month 13 (97.7%), and Month 21 (97.7%). The majority of PBM-treated eyes showed normal color vision testing at Baseline (100.0%), Month 13 (98.8%), and Month 21 (98.7%). Results support comparability between groups.

Color Fundus Imaging

Color fundus photography was performed at Screening, Month 13, and Month 24. Evaluations included presence of drusen by size, pigmentary changes, GA (central or non-central), and neovascular maculopathy. The changes over time are reflective of AMD progression and were used to support OCT imaging results, with an overall increased percentage of eyes with medium or large drusen, pigmentary changes, GA, and neovascular maculopathy.

Perimetry Testing

No significant changes in perimetry outcomes (Pattern Standard Deviation and mean deviation of Retinal Sensitivity) were observed in either treatment group at Month 13 or Month 24.

Mars Contrast Sensitivity

No significant difference in Mars CS at 40 cm was observed between the Sham and PBM groups at Month 13 and Month 21.

Conversion from Dry to nAMD

A total of 9 eyes converted to nAMD during the 24-month study: 2 Sham-treated eyes (3.6%) and 7 PBM-treated eyes (7.5%). A total of 16 subjects were randomized with the fellow, non-study eye that had neovascular AMD. Of the study eyes that converted to nAMD, the majority of eyes were at high risk for conversion (i.e., the fellow, non-study eye had pre-existing nAMD). Twelve (12) of 93 eyes (12.9%) in the PBM group were high-risk and 4 of 55 eyes (7.3%) in the Sham group were high risk. Overall, conversion to nAMD occurred 78.9 (SE 10.0) days following the last PBM treatment and 54.4 (SE 38.5) days following the last Sham treatment.

TABLE 8 CONVERSION OF DRY TO nAMD

	Sham (N = 55) n (%)	PBM N = 93 n (%)
New development of nAMD	2 (3.6)	7 (7.5)
Total # of high-risk eyes that develop nAMD	1	5

Occurrence of Incident GA

Review of OCT and FAF images along with fundus photos determined that new onset GA occurred at a higher incidence in the Sham vs. PBM group. The minimum lesion size used to make the determination of the progression to geographic atrophy was 0.049 mm^2 on FAF which corresponds to a diameter of 250 microns on OCT, as defined by Classification of Atrophy Meetings (CAM) criteria[1-3]. GA was determined on spectral domain optical coherence tomography (SD-OCT) 97-line high resolution volume scans.

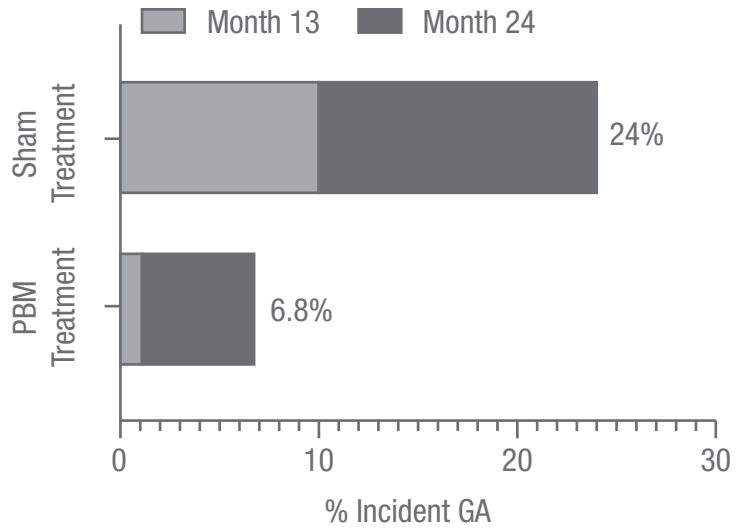


FIGURE 7 PERCENT OCCURRENCE OF INCIDENT GA BY TREATMENT GROUP[1]

[1]One subject (one eye) included in the Sham group that progressed to GA prior to month 13 had Best Disease. This subject's enrollment was due to a major protocol deviation. When this eye is excluded, 11/49 eyes (22.4%) of Sham eyes developed incident GA by Month 24.

By Month 13, 5 of 50 (10.0%) Sham eyes and 1 of 87 (1.1%) PBM-treated eyes developed incident GA. By Month 24, a total of 12 of 50 (24.0%) Sham-treated eyes and 6 of 87 (6.8 %) PBM-treated eyes developed incident GA during the course of the study. Non-study eyes were not evaluated. It is unclear if this outcome is related to the investigational treatment as development of incident GA was not a pre-specified endpoint. The study and the pre-specified endpoints were not designed to assess whether the treatment could slow the rate of progression to GA, the incidence of GA, or the rate of GA lesion growth.

Adverse Events That Occurred in the Clinical Study

A total of 38 study eyes (25.7%) from 32 subjects (21.6%) presented with at least one ocular-specific adverse event (AE). The number of eyes with at least one AE reported was similar between groups (Sham, 25.5%; PBM, 25.8%). Seven (7.5%) ocular-specific serious adverse events (SAE) of nAMD were reported in the PBM treatment group and three (5.5%) ocular-specific SAEs, 2 nAMD, 1 cystoid macular edema, were reported in the Sham treatment group. No SAEs were considered associated to the treatment by the principal investigator. The number of patients with ocular-specific AEs reported was similar between Sham (20.0%) and PBM (22.6%) groups.

The severity of AEs reported was mostly mild/moderate in both treatment groups. The most common ocular-specific (> 2%) AEs for the Sham treatment group in decreasing frequency included: nAMD (n = 2; 3.6%), Vitreous Floaters (n = 4; 7.3%), Dry Eye (n = 2; 3.6%), Punctate Keratitis (n = 2; 3.6%), and Cystoid Macular Edema (n = 2; 3.6%). The most common ocular-specific (> 2%) AEs for the PBM treatment group included: nAMD (n = 7; 7.5%), Allergic Conjunctivitis (n = 2; 2.2%), Blepharitis (n = 2; 2.2%), Conjunctival Hemorrhage (n = 2; 2.2%), Eye Pain (n = 2; 2.2%), Foreign Body Sensation in Eyes (n = 2; 2.2%), Increased Lacrimation (n = 2; 2.2%), Lamellar Macular Hole (n = 2; 2.2%), Photopsia (n = 2; 2.2%) and Vitreous Detachment (n = 2; 2.2%) The AE of dry eye was observed in both Sham treatment eyes (3.6%) of one subject and considered probably related to the device.

Three subjects had ocular-specific AEs that were considered related to the study procedure. These AEs included punctate keratitis (Sham; n = 2; 3.6%), visual perseveration (after image)(Sham; n = 1; 1.8%), and application site warmth (PBM; n = 1; 1.1%). No ocular-specific AEs led to study discontinuation.

A total of 204 non-ocular AEs were reported from 57 subjects (57.0%). A total of 4 (4.0%) non-ocular AEs led to study discontinuation including 3 (3.0%) which led to death. Twenty non-ocular SAEs (all unrelated) were reported in 14 subjects. One subject (1.5%) in the PBM treatment group experienced mild headache that was possibly related to the study device. No non-ocular SAE were considered related to the treatment.

Non-study Population (Eyes not randomized to treatment):

A total of 52 companion eyes were not enrolled into the study (i.e., non-study eyes). Twelve non-study eyes were identified with a Baseline BCVA of > 75 letters that were excluded from the study as having no vision impairment (subgroup of good vision AMD subjects) with no other significant ocular history or conditions. At Month 13, this subgroup lost a mean of -2.3 (SE 1.28) letters. At Month 24, 9 of the 12 eyes remained in the study. This subgroup lost a mean of -0.1 (SE 1.57) letters at Month 24. A total of 18 ocular-specific AEs were observed in non-study eyes. Worsening or new development of cataracts (n = 3, 5.8%) and development of nAMD (n = 3, 5.8%) were reported at a frequency of over 5% in non-study eyes. Sixteen non-study eyes already had nAMD and were removed from the analysis; thus, 3 of 36 (8.3%) eyes converted if previous nAMD eyes are excluded.

7. Setup and Operation

Valeda is intended for use in a controlled room environment at ambient temperature and humidity. See Technical Specifications.
Before unpacking Valeda, inspect the shipping box for damage. If damage is present, notify the freight carrier and ask for an agent to be present while the system is unpacked. Retain all packing materials in their original condition and contact LumiThera.

Box Contents

The shipping box contains the following:

- Valeda Light Delivery System
- Valeda LumiKey
- Valeda Dust Cover
- Valeda Power Cord(s)
- Valeda Light Delivery System User Manual
- Valeda Quick Reference Guide

Setup

- Remove the system from the shipping box and place on a height-adjustable table. Valeda should be used with height-adjustable chairs and table to accommodate variations in patient height.
- If present, remove the dust cover.
- Verify the system has no obvious damage.
- Ensure that the side air vents are not blocked.
- Multiple power cords may be in the box. Select the appropriate power cord for your location. Attach the power cord to the unit and connect to a grounded outlet. Confirm the system is plugged into an appropriate electrical outlet and all connections are secure. See Technical Specifications.
- Ensure the power cord is not a tripping hazard.
- Following hot or cold storage below 15°C or above 30°C (below 59°F or above 86°F), allow one hour for the system to reach ambient temperature and humidity before using.
- Turn on the system by moving the power switch to the on position.
- Wait for the system to power on and run through the self-test. When the self-test is complete, the home screen will appear on the touchscreen.
- Position Valeda so that the operator can access both the patient and operator sides of the system. The patient must be able to be comfortably seated at the patient side of the system.

Treatment Regimen

Treatment should occur 3x/week over the course of 3-5 weeks for each series. A treatment series should be delivered every 4 months for 24 months. In the clinical study, only one treatment could be provided per day and no more than 3 treatments could be delivered per week. The clinical trial study contained a total of six series of 9 treatments. The safety and effectiveness of the treatment has not been established for treatments provided more frequently or for providing a greater total number of treatments (54).

To initiate a treatment for a patient, tap the large “+” button (Figure 8).

FIGURE 8

The next screen shows the number of Valeda Treatment Credits remaining. Touch the → button (Figure 9).

Refer to Valeda Treatment Credits Section if credits are needed.

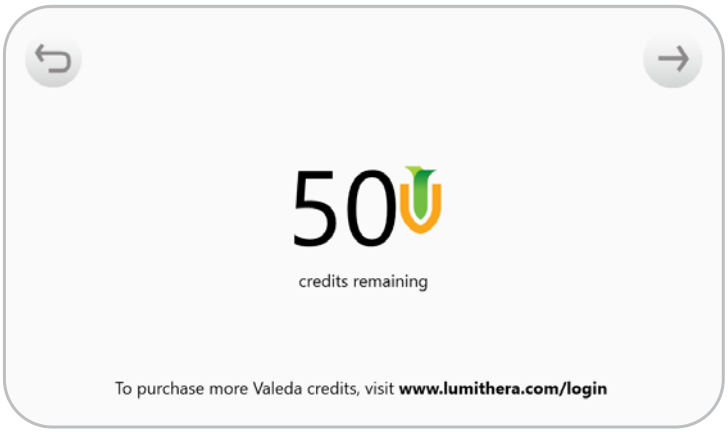


FIGURE 9

Select whether one eye or both eyes will be treated (Figure 10).

If one eye was selected for treatment, select on the touchscreen which eye is the one to be treated (Figure 10). If both eyes were selected for treatment, this screen is not presented to the operator. The right (OD) eye will always be treated first, followed by the left (OS).

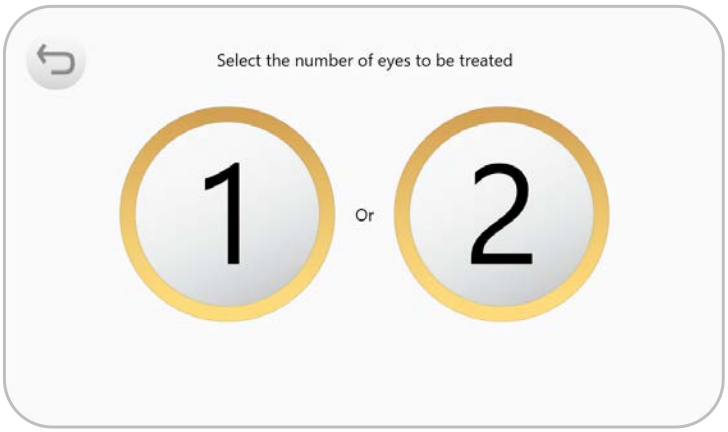


FIGURE 10

If one eye was selected, choose the eye to be treated and the camera will move to the chosen eye and the beam will align to the patient's eye (Figure 11).

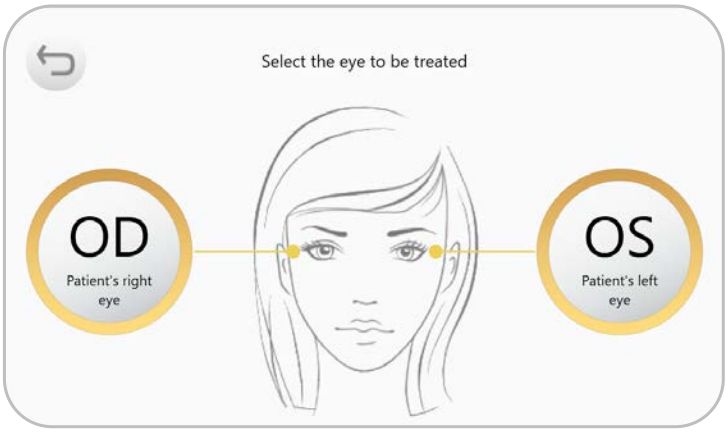


FIGURE 11

Patient Preparation

1. Verify that the patient has removed glasses and contact lenses.
2. Confirm the patient's hair is outside the light aperture.
3. Position the patient's forehead against the forehead rest. If the patient's forehead is not detected, the system will display "No patient detected". During treatment, if the Patient Sensor is deactivated, the procedure will pause.
4. Adjust the chin rest elevation to position the patient's eyes as shown to the right (Figure 12).
5. Adjust the patient's chin position on the chin rest as shown to the right (Figure 12).
6. Instruct the patient to look straight ahead for the duration of the treatment.

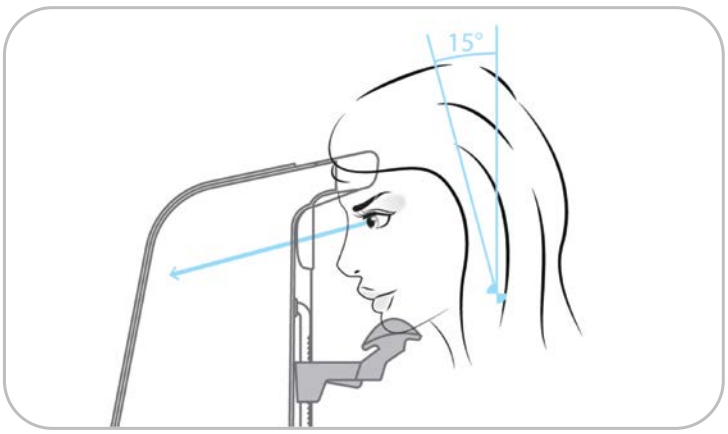


FIGURE 12

Beam Alignment Procedure

While watching the camera view on the touchscreen, use the beam alignment joystick on the operator side of Valeda to move the targeting beam (yellow circle) left/right and up/down until the beam fills the eye socket. The picture on the touchscreen illustrates the correct position of the beam and the patient's eye (Figure 13).

Once the beam is aligned, instruct the patient to remain in position until instructed to move.

Tap the → button on the touchscreen (Figure 13).

FIGURE 13

Treatment Procedure

The treatment consists of 4 phases:

1. The treatment initiates with 35 seconds of pulsed yellow and near-infrared (NIR) wavelengths, eyes open.
2. This is followed by 90 seconds of continuous red wavelength, eyes closed.
3. The treatment will repeat with another 35 seconds of pulsed yellow and NIR wavelengths, eyes open.
4. The treatment will finish with another 90 seconds of continuous red wavelength, eyes closed.

Instruct the patient to keep their eyes open during phases 1 and 3 and to keep their eyes closed for phases 2 and 4.

The touchscreen will show the Treatment Ready screen.

Verify that all the information on this screen is correct, then tap the ✓ button (Figure 14).

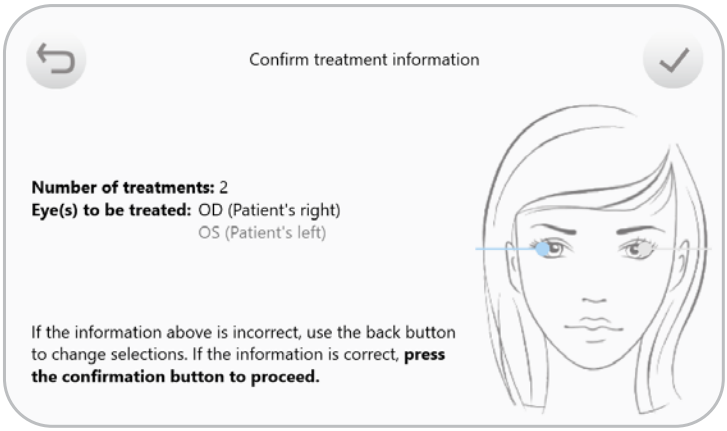


FIGURE 14

The patient is instructed to keep their eyes open for phase 1 (Figure 15).

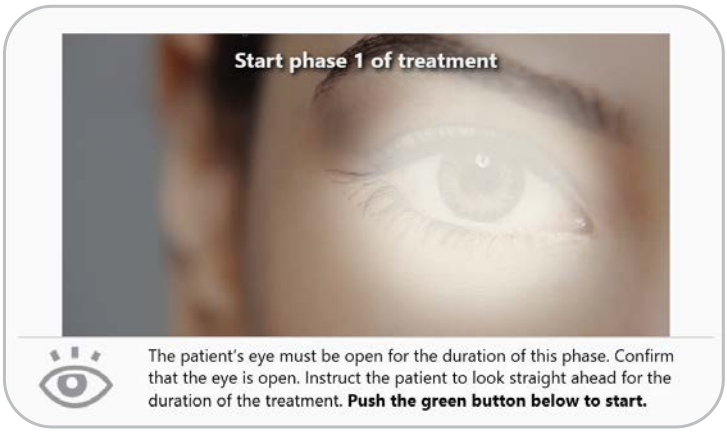


FIGURE 15

Press the **green** start/pause button on the system to initiate treatment. A progress screen will be shown. A countdown timer is displayed while the progress bar fills from left to right (Figure 16).

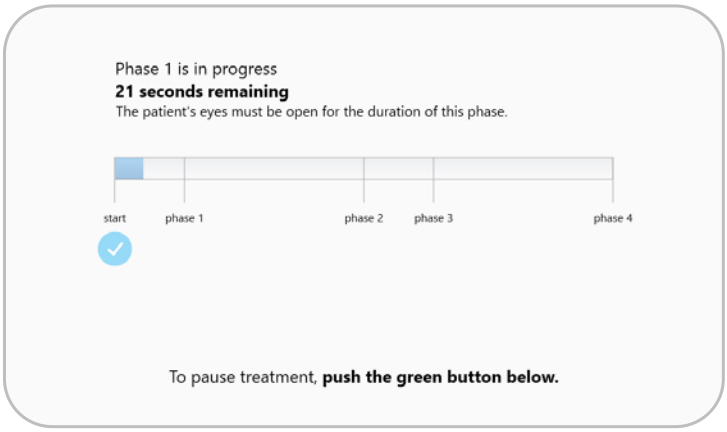


FIGURE 16

Valeda will pause after completion of each phase. For example, after the first wavelength treatment phase is complete, the screen will provide instructions for the patient's eyelid position (open or closed) and display a live video for confirmation of the eyelid position (Figure 17).

The patient is instructed to keep their eyes closed for phase 2.

FIGURE 17

To proceed with the next phase, press the **green** activation button on the system. A countdown timer is displayed while the progress bar fills from left to right (Figure 18).

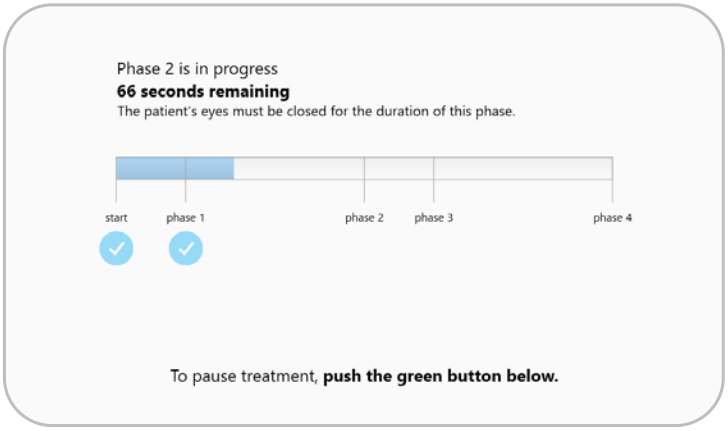


FIGURE 18

The next steps to complete phases 3 and 4 are identical to the steps detailed for phases 1 and 2.

If the patient's second eye is to be treated, the system will display the following screen after the 4 phases of treatment for the first eye are completed (Figure 19).

Tapping the button will return to the Beam Alignment Procedure for treatment of the second eye.

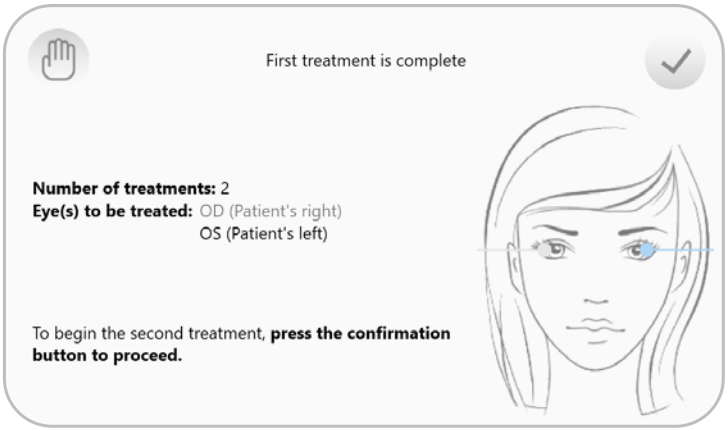


FIGURE 19

Upon completion of the treatment session, the finished screen will be displayed (Figure 20).

Instruct the patient to pull away from the system.

To continue patient treatments, tap the button.

If all patients have been treated for the day, switch off the power to Valeda.

FIGURE 20

Treatment Pause

A treatment phase may be paused at any time by pressing the **green** start/pause button on the system or by the patient pulling back from forehead rest (Figure 21).

To resume treatment, press the **green** start/pause button on the system.

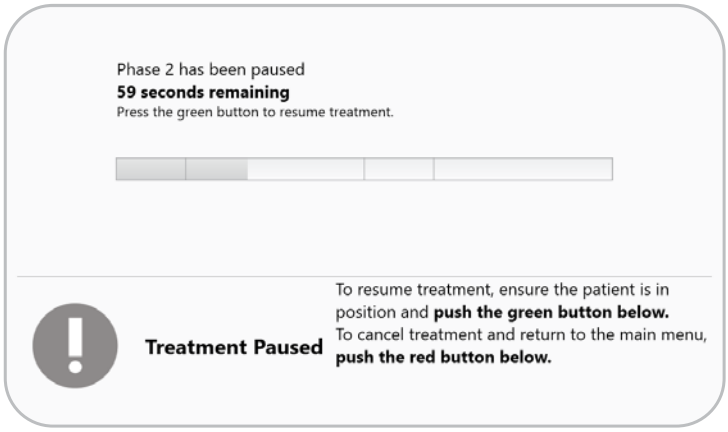


FIGURE 21

Check the alignment and state of the eyelid on the video screen (Figure 22).

Press the **green** start/pause button to restart the treatment at the time it was paused.

FIGURE 22

Treatment Cancelation

While the treatment is paused, the treatment can be canceled by pressing the **red** stop button on the system; the cancelation message will be displayed (Figure 23). If a treatment is canceled, the patient has not completed a full treatment. The physician and patient can determine whether the treatment needs to be rescheduled.

FIGURE 23

Clean and Store System

Clean the system per cleaning instructions provided in this User Manual. Confirm the system is off and place the dust cover over the system.

8. Valeda Treatment Credits

Valeda Will Not Operate Without Treatment Credits

- Create an account or log in to an existing account on the e-commerce store at www.lumithera.com.
- Enter the serial number located on the system label.
- Purchase desired number of Treatment Credit packages.
- LumiThera will provide an electronic LumiFile for each Treatment Credit package purchased.
- Insert the Valeda LumiKey into the USB port of your computer. Copy the LumiFile to your LumiKey.
- Insert the LumiKey into the USB port on the front of Valeda.
- Valeda will automatically read the LumiKey and add the appropriate number of credits to your system.
- Treatments are delivered in a series of 9 sessions per eye over a three-five week period.
- A complete course of bilateral therapy for one patient equals 18 Treatment Credits (one Treatment Credit package).
- Repeat if multiple packages are purchased.
- If you are purchasing credits for multiple devices, each serial number will need to be entered.
- **IMPORTANT:** LumiFiles must be used in the sequence they are purchased. If multiple LumiFiles are purchased, they must be copied onto the LumiKey and onto Valeda individually and in sequence from oldest to newest. If a newer LumiFile is uploaded to Valeda, an older LumiFile will not be accepted.

Grace Period Treatment Credits

Grace Credits are to be used in the event that online purchasing is unsuccessful. Contact LumiThera Customer Care to purchase Grace Credits.

To enable Grace period Treatment Credits:

- From the Home Screen, tap the button.
- At the top right corner of the information screen, tap the "+" button.
- LumiThera will provide an alphanumeric code that is specific to your system. Grace codes must be loaded onto the system within 24 hours.
- Enter the code into Valeda and tap the button to proceed (Figure 24).

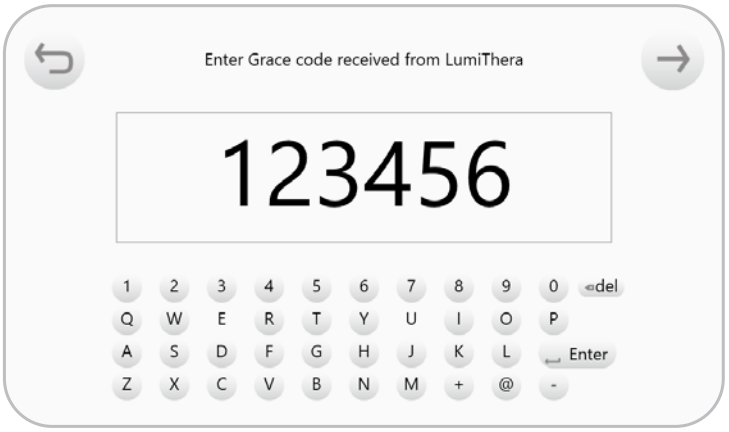


FIGURE 24

If the Grace code was accepted, a confirmation screen will be displayed with the total credits available (Figure 25).

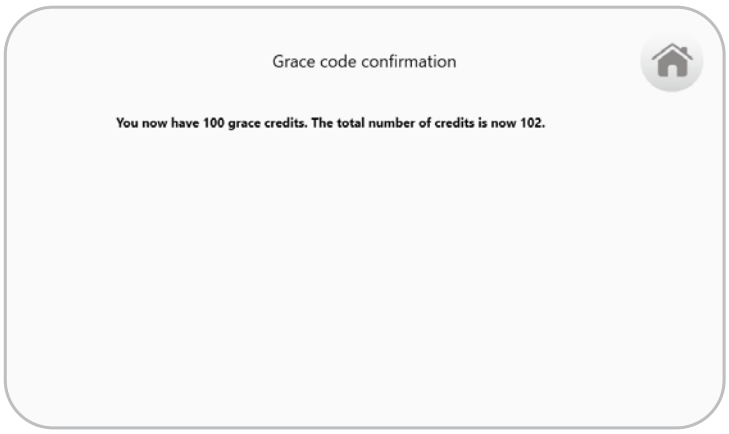


FIGURE 25

If the Grace code was rejected, the following screen will appear (Figure 26).

FIGURE 26

9. Valeda Settings

Tap the button. The Settings Menu may be reached by tapping the button on the display (Figure 27).

FIGURE 27

Tapping the Language button provides a list of languages available on your system (Figure 28).

FIGURE 28

Tapping the button will display key system information (Figure 29).

FIGURE 29

10. Cleaning

- The patient light aperture may be cleaned with a lens cleaning cloth or optical glass cleaner.
- The exterior of Valeda, not including the patient light aperture, may be cleaned with a mild soap solution.
- The patient contact areas (i.e., chin rest and forehead rest) require cleaning between patients with hydrogen peroxide-based wipes such as Oxivir® Tb Wipes.
- Do not spray or spill any fluid onto Valeda.
- Contact LumiThera if the light aperture appears contaminated.

11. Disposal

Disposal of electronic equipment may be regulated in your community. Follow local regulations for disposal of electronic equipment.

12. Maintenance

- Each Valeda has been manufactured to specification.
- Operator maintenance is not required.
- All service must be performed by LumiThera.
- If there is a problem or it is suspected that Valeda requires maintenance, contact LumiThera.

CAUTION – Do not attempt to disassemble the system.
There are no operator serviceable or repairable components.
Do not attempt to disassemble the device.

13. Troubleshooting

In the event a system fault is detected by Valeda, a fault message will be displayed on the screen. If possible, the display screen will identify the fault (Figure 30).

For each system fault, perform the following:

- Record the fault message.
- Reboot the system to see if the fault message is cleared
- If reboot does not correct the issue, contact LumiThera for assistance.
- Report all system issues to LumiThera Customer Care.

FIGURE 30

Troubleshooting Guide

Fault	Fault Code	Description	Remedy
POST	LT-109	A fault has occurred during power-on self-test.	Contact LumiThera for service.
LED Failed	LT-117	One of the LEDs is not working as expected.	Contact LumiThera for service.
Target	LT-125	The beam alignment electronics have encountered a fault.	Contact LumiThera for service.
Eye	LT-133	The internal mechanism that positions the light beam for the correct eye has become stuck.	Contact LumiThera for service.
Patient Sensor	LT-141	The firmware cannot communicate with the patient sensor in the forehead rest.	Contact LumiThera for service.
Button	LT-158	One of the buttons on the front of the system is not working as expected.	Contact LumiThera for service.
Overheat	LT-166	The LEDs became too hot during operation.	This can be caused by the ambient temperature in the room being too high. The system must not be operated in a room where the ambient temperature is above 30°C (86°F). The system may overheat if the cooling vents are blocked. Make sure the system is on a flat, hard surface and nothing is blocking the air vents.
Memory	LT-182	The processor has encountered a memory fault.	Contact LumiThera for service.
Internal Communication	LT-190	The touchscreen cannot communicate with the light engine.	Contact LumiThera for service.
Camera	LT-208	The system cannot detect the camera.	Contact LumiThera for service.
NotCal	LT-216	The device must be recalibrated.	Contact LumiThera for service.
Reset	LT-224	A device firmware fault has been encountered.	Contact LumiThera for service.
Fan	LT-232	The fan sensor detects that the fan is not rotating or rotating too slowly.	Contact LumiThera for service.
Hardware Fault	LT-240	The device electronics have encountered a fault.	Contact LumiThera for service.
Unknown Fault	LT-257	A fault was encountered, but the fault name was not identified.	Contact LumiThera for service.

14. Technical Specifications

Parameter	Specification
Size	535 mm high x 295 mm wide x 335 mm deep
Weight	11 kg
Electrical Power Input	100 – 240 VAC, 50/60 Hz, 1.0 – 0.5 A
Fuse Rating	Voltage: 250 V Current: 2 A Operating speed: Slow Size: 5 mm x 20 mm IEC Fuse Code: T2AL250V
Light Sources	Light-emitting diodes (LEDs)
Light Emission	590 nm output: 4 mW/cm^2 660 nm output: 65 mW/cm^2 850 nm output: 0.57 mW/cm^2
Beam Diameter	30 mm (nominal) at treatment plane
Treatment Exposure Time	A total of 250 seconds (4 minutes, 10 seconds). There are 4 phases: Phase 1 – 35 seconds, patient's eyes open (590 nm and 850 nm LEDs, both pulsing at 3Hz, 71% duty cycle) Phase 2 – 90 seconds, patient's eyes closed (660 nm LED, continuous) Phase 3 – 35 seconds, patient's eyes open (590 nm and 850 nm LEDs, both pulsing at 3Hz, 71% duty cycle) Phase 4 – 90 seconds, patient's eyes closed (660 nm LED, continuous)
Operating Environment	Temperature: 15°C – 30°C (59°F – 86°F) Humidity: 15% – 90% (noncondensing) Altitude: Up to 3,000 m
On-site Storage Environment	Temperature: 15°C – 30°C (59°F – 86°F) Humidity: 15% – 90% (noncondensing) Altitude: Up to 3,000 m
Transportation Environment	Temperature: -18°C – 60°C (-0.4°F – 140°F) Humidity: 15% – 90% (noncondensing) Pressure: 700 – 1060 hPa
Ingress Rating	IEC 60529: IP2X
Electrical Safety Classification	IEC 60601-1, Type BF applied part
Electromagnetic Compatibility	IEC 60601-1-2
Photobiological Safety	ANSI Z80.36
Valeda LumiKey	USB 2.0-compliant flash drive Compatible with Microsoft Windows USB Mass Storage class drivers Can be used with Apple computers that have USB A ports

15. References

1. Sadda SR, Guymer R, Holz FG, Schmitz-Valckenberg S, Curcio CA, Bird AC, Blodi BA, Bottoni F, Chakravarthy U, Chew EY, Csaky K, Danis RP, Fleckenstein M, Freund KB, Grunwald J, Hoyng CB, Jaffe GJ, Liakopoulos S, Mon.s JM, Pauleikhoff D, Rosenfeld PJ, Sarraf D, Spaide RF, Tadayoni R, Tufail A, Wolf S, Staurenghi G. Consensus Definition for Atrophy Associated with Age-Related Macular Degeneration on OCT: Classification of Atrophy Report 3. Ophthalmology. 2018 Apr;125(4):537-548. doi: 10.1016/j.ophtha.2017.09.028. Epub 2017 Nov 2.

2. Jaffe GJ, Westby K, Csaky KG, Mon.s J, Pearlman JA, Patel SS, Joondeph BC, Randolph J, Masonson H, Rezaei KA. C5 Inhibitor Avacincaptad Pegol for Geographic Atrophy Duke to Age-Related Macular Degeneration: A Randomized Pivotal Phase 2/3 Trial. Ophthalmology 2020.

3. Khanani AM, Patel SS, Staurenghi G, Tadayoni R, Danzig CJ, Eichenbaum DA, Hsu J, Wykoff CC, Heier JS, Lally DR, Mon.s J, Nielsen JS, Sheth VS, Kaiser PK, Clark J, Zhu L, Patel H, Tang J, Desai D, Jaffe GJ. Efficacy and safety of avacincaptad pegol in patients with geographic atrophy (GATHER2): 12-month results from a randomised, double-masked, phase 3 trial. Lancet. 2023;402(10411):1449-1458.

16. Glossary

Acronym/Term	Definition
AC	Alternating current
A/m	Amperes per meter
Aperture	An opening through which light energy is emitted
C	Celsius
ESD	Electrostatic discharge
F	Fahrenheit
GHz	Gigahertz
Hz	Hertz
IEC	International Electrotechnical Commission
Irradiance	Radiant power per unit area (radiant power divided by the area of the beam), i.e., the quotient of the radiant flux (dΦ) incident on an element of a surface by the area dA of that element (SI units = W/m^2)
Kg	Kilograms
kV	Kilovolts
kHz	Kilohertz
LED Power	The time rate of flow of radiant energy, measured in joules per second or watts
LED	Light-emitting diode
MHz	Megahertz
m	Meter
mm	Millimeter, 1 x 10^{-3} of a meter
NIR	Near-Infrared Radiation; light that is of slightly longer wavelength than the human eye can see
nm	Nanometer, 1 x 10^{-9} of a meter
OD	Oculus dexter, the patient's right eye
OS	Oculus sinister, the patient's left eye
P	Maximum power output rating (as defined in Section 17)
PBM	Photobiomodulation
Pulsed	LED output rapidly transitioning between on and off states
RF	Radio frequency
√P	Square root of P (as defined in Section 17)
V/m	Volts per meter
VAC	Volts alternating current
VRMS	Volts root mean square
W	Watts

17. Guidance and Manufacturer's Declarations

Electromagnetic Emissions for All Equipment and Systems

Valeda is intended for use in the electromagnetic environment specified below. The operator of Valeda should ensure that it is used in such an environment.

Emissions Test-Test Standard	Compliance Classification	Guidance for Maintaining Electromagnetic Safety
RF Emissions CISPR 11	Class A, Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. **Note:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The usermight need to take mitigation measures, such as relocating or reorienting the equipment.
Harmonic Emissions IEC 61000-3-2	Class A	
Power Line Fluctuations (Flicker) EN 61000-3-3	Complies	

Electromagnetic Immunity for All Equipment and Systems

Valeda is intended for use in the electromagnetic environment specified below. The operator of Valeda should ensure that it is used in such an environment. System meets immunity requirements per IEC TR 60601-4-2.

Immunity Test-Basic EMC Standard	IEC-60601 Test Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV air ± 4 kV air and contact	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV at AC power lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge Transient IEC 61000-4-5	2 kV line-to-earth at AC power ports (common) 1 kV line-to-line at AC power ports (differential)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips and Interruptions IEC 61000-4-11	0%, 0.5 Cycle 0%, 1 Cycle 70%, 25 Cycles 0%, 250 Cycles (interruption)	Mains power quality should be that of a typical commercial or hospital environment. If user requires continued operation during power mains interruptions, it is recommended to gain power from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m; 50/60 Hz	Power frequency magnetic fields should be those of a typical commercial or hospital environment.

Electromagnetic Immunity for Equipment and Systems That Are Not Life-Supporting

Valeda is intended for use in the electromagnetic environment specified below. The operator of Valeda should ensure that it is used in such an environment. System meets immunity requirements per IEC TR 60601-4-2.

Immunity Test Basic EMC Standard	IEC 60601 Test Level	Electromagnetic Environment – Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the system than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = (1.2)(√P) d = (1.2)(√P) 80 to 800 MHz d = (2.3)(√P) 800 MHz to 2.5 GHz Where P is the maximum power output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment containing a transmitter.
Conducted RF IEC 61000-4-6	3 Vrms (0.15 to 80 MHz) 6 Vrms (ISM Bands)	
Proximity Magnetic Field IEC 61000-4-39	30 kHz @ 8 A/m, CW 134.2 kHz @ 65 A/m, Pulse modulation 13.56 kHz @ 7.5 A/m, Pulse modulation 9kHz to 13.56MHz @ Level 4 max, CW, PM 2.1kHz and 50kHz	

Recommended Separation Distances Between Portable/Mobile RF Communications Equipment and the Device

Valeda is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The operator of Valeda can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the system as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (watts)	Separation Distance (in meters) According to Frequency of Transmitter		
	150 kHz to 80 MHz $d = (1.2)(\sqrt{P})$	80 MHz to 800 MHz $d = (1.2)(\sqrt{P})$	800 MHz to 2.5 GHz $d = (2.3)(\sqrt{P})$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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LumiThera, Inc. · 19578 10th Avenue NE, Suite 200, Poulsbo, Washington 98370 USA · www.lumithera.com

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LIGHTSITE III

13-Month Efficacy and Safety Evaluation of Multiwavelength Photobiomodulation in Nonexudative (Dry) Age-Related Macular Degeneration Using the Lumithera Valeda Light Delivery System

DAVID BOYER, MD,* ALLEN HU, MD,† DAVID WARROW, MD,‡ SAMANTHA XAVIER, MD,§ VICTOR GONZALEZ, MD,¶ ELEONORA LAD, MD, PHD,** RICHARD B. ROSEN, MD,†† DIANA DO, MD,‡‡ TODD SCHNEIDERMAN, MD,§§ ALLEN HO, MD,¶¶ MARION R. MUNK, MD, PHD,***††† GLENN JAFFE, MD,‡‡‡ STEPHANIE E. TEDFORD, PHD,§§§ CINDY L. CROISSANT, MBA,§§§ MICHAEL WALKER, PHD,¶¶¶ RENE RÜCKERT, MD, MBA,§§§ CLARK E. TEDFORD, PHD§§§

Purpose: The LIGHTSITE III study evaluated multiwavelength photobiomodulation (PBM) therapy in nonexudative (dry) age-related macular degeneration (AMD) using the LumiThera Valeda Light Delivery System.

Methods: LIGHTSITE III is a randomized, controlled trial to assess the safety and effectiveness of PBM in dry AMD. Subjects were given multiwavelength PBM (590, 660, and 850 nm) or Sham treatment delivered in a series of nine sessions over 3 to 5 weeks every four months over 24 months. Subjects were assessed for efficacy and safety outcomes. Data from the 13-month analysis are presented in this report.

Results: A total of 100 subjects (148 eyes) with dry AMD were randomized. LIGHTSITE III met the primary efficacy best-corrected visual acuity endpoint with a significant difference between PBM (n = 91 eyes) and Sham (n = 54 eyes) groups (Between group difference: 2.4 letters (SE 1.15), CI: −4.7 to −0.1, $P = 0.02$) (PBM alone: 5.4 letters (SE 0.96), CI: 3.5 to 7.3, $P < 0.0001$; Sham alone: 3.0 letters (SE 1.13), CI: 0.7–5.2, $P < 0.0001$). The PBM group showed a significant decrease in new onset geographic atrophy ($P = 0.024$, Fisher exact test, odds ratio 9.4). A favorable safety profile was observed.

Conclusion: LIGHTSITE III provides a prospective, randomized, controlled trial showing improved clinical and anatomical outcomes in intermediate dry AMD following PBM therapy.

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Age-related macular degeneration (AMD) is a retinal disease that causes irreversible, severe loss of vision and blindness. Age-related macular degeneration is classified into two categories: exudative (wet) and nonexudative (dry) AMD. Dry AMD affects 90% of AMD patients and is characterized by the accumulation of extracellular material under the retinal pigment epithelium (RPE). Geographic atrophy (GA) results from atrophy of the retinal pigment epithelium cell layer, which leads to vision loss secondary to death of macular photoreceptors.[1] Global prevalence of AMD is expected to reach 288 million by 2040. In the United States, it is estimated that 18.34 million individuals (11.64%) are living with early-stage AMD and 1.49 million (0.94%) are living with late-stage AMD (choroidal neovascularization (CNV)/neovascular AMD (nAMD) and/or GA).[2,3] There are currently no approved treatments for dry AMD in early/intermediate stages beyond antioxidant supplementation, which only delay progression in 20%–25% of eyes.[1,4]

Photobiomodulation (PBM) is an established biotechnology that involves light from the visible spectrum to near infrared (NIR) (500-1,000 nm) applied to selected tissue to produce beneficial cellular effect.[5–8]

The mechanism of PBM is ascribed to stimulation of mitochondrial respiratory chain components resulting in stabilization of metabolic function and initiation of signaling cascades promoting cellular proliferation and cytoprotection. Cytochrome C oxidase is recognized as a key photoacceptor of light in the far red to NIR spectral range.[9–12] Cytochrome C oxidase activation enhances electron transport pathway function and promotes ATP production, the cell's major source of energy.[10,13–16]

Collectively, studies across multiple indications show improvements in clinical and anatomical outcomes following PBM treatment. Recent ophthalmologic clinical trials, including LIGHTSITE I and II, evaluated the effect of multiwavelength PBM using the Valeda light delivery system and found improvement in clinical vision outcomes and anatomical correlates of the disease.[17–19] LIGHTSITE III further investigates the effects of PBM treatment in early/intermediate dry AMD.

Methods

Study Participants

Subjects were eligible for enrollment (NCT04065490) if they were at least 50 years and had a diagnosis of dry AMD defined by the presence of drusen and/or nonfoveal center GA with best-corrected visual acuity (BCVA) scores determined by Early Treatment Diabetic Retinopathy Study (ETDRS) between 50 and 75 (snellen equivalent: 20/32 to 20/100) (see **Table**, **Supplemental Digital Content 1**, http://links.lww.com/IAE/C119). Subjects were excluded with a history of CNV, presence of center involving GA, or other significant retinal disease. Each eye was individually assessed for drusen, GA, and CNV by a central reading center (Duke Reading Center, Durham, NC).[19]

Subjects were enrolled across 10 centers throughout the United States. This study was conducted in compliance with the protocol, Good Clinical Practice guidelines, the guidelines of the Declaration of Helsinki and all other applicable regulatory requirements.

Study Design

LIGHTSITE III was a double-masked, randomized, sham-controlled, parallel-group, multicenter, prospective study. Subjects who met the inclusion criteria, had none of the exclusion criteria, and provided their informed consent underwent PBM or Sham treatment randomized in a 2:1 ratio. Subjects were treated with the Valeda Light Delivery System (LumiThera, Inc., Poulsbo, WA) and received treatment in a series of nine sessions over a period of 3 to 5 weeks. The 24-month study included six series of treatment delivered every 4 months. A prespecified primary analysis was conducted at Month 13 after four series of treatments. Data were collected during 61 visits over the 24-month study with a 13-month analysis (Figure 1). The study has been completed, and 24-month data are under analysis.

Evaluated Parameters

Clinical classification of disease stage followed Beckman categorization.[20] The prespecified primary endpoint was the 13-month difference in BCVA (change from baseline) between the PBM and Sham groups. A second primary endpoint was the 21-month data if the study did not achieve statistical significance at 13 months. A statistically significant difference was defined with a P value threshold of $P = 0.025$ for both the primary endpoints (accounting for both possible endpoints). The ETDRS BCVA examination was employed before and after each treatment series. The BCVA evaluation included a thorough protocol refraction and visual acuity examination with certified equipment and examination rooms. Subjects were also assessed for low-luminance BCVA (LLBCVA), Mars letter contrast sensitivity, Radner reading

From the *Retina Vitreous Associates Medical Group, Beverly Hills, California; †Cumberland Valley Retina Consultants, Hagerstown, Maryland; ‡Cumberland Valley Retina Consultants, Chambersburg, Pennsylvania; §Florida Eye Clinic, Altamonte Springs, Florida; ¶Valley Retina Institute, McAllen, Texas; **Department of Ophthalmology, Duke University Medical Center, Durham, North Carolina; ††New York Ear and Eye Infirmary of Mount Sinai, New York, New York; ‡‡Byers Eye Institute, Stanford University, Palo Alto, California; §§Retina Center NorthWest, Silverdale, Washington; ¶¶Mid Atlantic Retina, Cherry Hill, New Jersey; ***Department of Ophthalmology, Inselspital University Hospital Bern, Bern, Switzerland; †††Augenarzt-Praxisgemeinschaft Gutblick AG, Pfäffikon, Switzerland; ‡‡‡Duke Reading Center, Duke University School of Medicine, Durham, North Carolina; §§§LumiThera, Inc., Poulsbo, Washington; and ¶¶¶Walker Biosciences, Carlsbad, California.

The LIGHTSITE III study was supported in part by LumiThera, Inc. and the National Eye Institute (Grant #1R43EY025508-03).

S. E. Tedford, C. L. Croissant, M. Walker, R. Rückert and C. Tedford are all employees/contractors of LumiThera.

This study involved human subjects, was approved by the institutional review board, and adhered to the tenets of the Declaration of Helsinki.

Written informed consent was obtained from all subjects in this study.

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Reprint requests: Stephanie E. Tedford, PhD, 19578 10th Ave NE, Poulsbo, WA 98370; e-mail: Setedford@lumithera.com

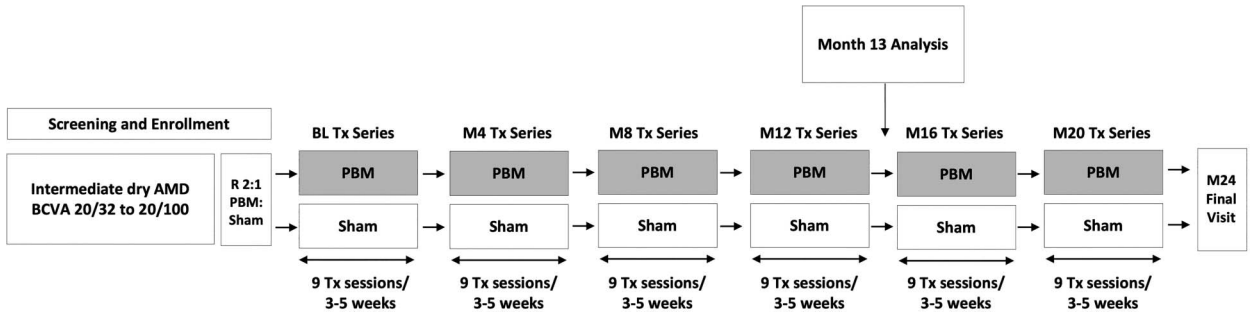

Fig. 1. LIGHTSITE III study Design. Subjects were randomized in a 2:1 fashion (PBM:Sham treatment) and followed for 24 months. Data analyses were planned for Month 13 and Month 24. The PBM mode delivered 590, 660, and 850 nm multiwavelength treatment. The Sham mode delivered a 50x reduction of the 590 nm and a 100x reduction of the 660 nm wavelengths; the 850 nm was omitted. BL, baseline; M, month; R, randomized; Tx, treatment.

speed, Farnsworth–Munsell D-15 dichotomous color vision testing, and completed the visual function questionnaire-25 (VFQ-25) at selected time points. Certifications for clinical outcomes were performed by specialists (Global Eye Trials, London, United Kingdom). Subjects were assessed with 20 × 20 mm high-speed spectral-domain optical coherence tomography (OCT) volume scans, fundus autofluorescence (FAF), and fundus photography (Spectralis optical coherence tomography, Heidelberg Engineering, Heidelberg, Germany), as described previously.[17,19] An independent, masked, imaging center reviewed and graded all images. Safety information was collected at all time points through the Month 13 visit.

Photobiomodulation Treatment with Valeda Light Delivery System

Subjects were treated with Valeda using three distinct wavelengths in the yellow (590 nm; 4 mW/cm^2; 2× 35 seconds), red (660 nm; 65 mW/cm^2; 2× 90 seconds), and NIR (850 nm; 0.6 mW/cm^2; 2× 35 seconds) range. A complete masked control is not possible (i.e., a true sham would deliver zero light fluence, which would be observable to patients and study staff). Therefore, the Sham treatment consisted of an active control, which delivered a lower fluence of selected wavelengths. The Sham mode delivered a 50x and 100x reduction in treatment fluence compared with the PBM mode of the 590 and 660 nm wavelengths, respectively; the 850 nm wavelength was omitted.

Statistical Analysis

Statistical analyses were performed using SAS or R Version 3.4.4 (SAS Institute, Cary, NC).[21] Based on previous studies, a within-group SD of 5.0 in BCVA change from baseline was assumed. A total of 119 eyes (40 sham and 79 PBM) completing the study provided power of 0.84 to detect a difference of 3.18 between the groups in BCVA with a two-sided alpha of 0.025. Allowing for a 10.0% dropout, assuming an average of 1.5 eligible eyes per subject, and potentially smaller effect size and larger SD, a sample size of at least 96 subjects, giving 144 eyes, was planned.

All analyses are based on individual eyes rather than subjects unless otherwise indicated. All subjects enrolled (n = 144 eyes) and modified intent-to-treat (mITT) (n = 142 eyes) analyses were conducted across outcomes and study time points. Nonstudy eye analyses included companion eyes that were not enrolled in the study and did not receive treatment. Analyses of change from baseline following treatment and the treatment effect on the change from baseline used linear mixed-effects models that account for correlation between eyes within subject. Efficacy analyses were implemented using 1) the measured value of each outcome and 2) the rank value of each outcome. For each efficacy analysis, the model residuals from the measured values were examined using the Anderson–Darling test for normality. If the residuals were not normally distributed ($P < 0.05$), the analysis using the rank values was considered the principal analysis, with the analysis of measured values considered to be a sensitivity analysis.

Results

Participants

A total of 178 subjects were screened for the study with 100 subjects (56.2%) eligible for randomization. At Month 13, a total of 17 subjects discontinued the study (nine PBM; eight Sham): 10 withdrew consent, three were unable to return to the facility, and four discontinued because of adverse events (AEs) not considered related to the treatment (Figure 2). Baseline

characteristics are provided in Table 1. Subjects were enrolled with baseline BCVA scores between 50 and 75 letters. At baseline, 45 of 148 eyes (30.0%) had baseline BCVA <70 letters (20/100–20/40 Snellen) and 103 of 148 eyes (70.0%) have a baseline BCVA between 70 and 75 letters (20/40–20/32 Snellen). AREDS category and clinical classification of subjects in the MITT group showed that a majority were enrolled in an AREDS category 3 (86.9%) and classification of intermediate AMD (72.0%). A total of 13.1% (n = 19) of subjects were AREDS category 2 and 86.9% (n = 126) were AREDS category 3. A total of 20.0% (n = 29) of subjects were categorized as early-stage AMD, 72.0% (n = 105) were intermediate-stage AMD, and 8.0% (n = 11) were late-stage AMD (GA, no CNV).

Efficacy Assessments

At Month 13 (4 series of treatment), the average change from baseline in BCVA was an increase of 5.4 letters (SE 0.96; SD 9.15) in PBM and 3.0 letters (SE 1.13; SD 8.30) in Sham-treated eyes. The BCVA change from baseline to Month 13 was not normally distributed (Anderson–Darling *P*-value = 0.04); therefore, the rank analysis was considered the principal analysis, giving the rank *P* value of 0.0204 for the primary analysis comparing PBM and Sham groups at Month 13 (Table 2; Figure 3). Approximately 55.0% of PBM-treated eyes showed ≥ 5 letter gain compared with 40.8% of Sham, 26.4% of PBM-treated eyes showed ≥ 10 letter gain compared with 14.9% of Sham, and 5.5% of PBM-treated eyes showed ≥ 15 letter gain compared with 1.9% of Sham. Sham-treated eyes showed a two-fold decrease in BCVA letter count and an increased number of eyes with a letter loss ≥ 10 at each visit compared with PBM-treated eyes. A significant difference in BCVA between PBM and Sham groups was also observed at Months 5, 9, and 12. A significant difference in the PBM group was observed at all time points assessed ($P < 0.05$; Table 2; Figure 4).

Secondary and exploratory evaluation of LLBCVA, contrast sensitivity, Radner reading charts, and the VFQ-25 showed normal or near normal visual outcomes at baseline, which were stable through the 13-month time point in both groups (see **Table**, **Supplemental Digital Content 1**, http://links.lww.com/IAE/C119).

Anatomical Outcomes

A total of 138 eyes were enrolled with drusen at baseline (PBM, n = 86; Sham, n = 52). No change in subRPE macular drusen volume was seen in PBM-treated eyes (0.006 mm^3); however, an increase was seen in the Sham group (0.049 mm^3; Figure 5). At Month 13, a statistically significant correlation was observed for measured BCVA scores and measured macular drusen volume in PBM-treated eyes. Subjects with higher BCVA scores showed lower values for macular drusen volume in the PBM group ($P = 0.004$). Representative images are presented in Figures 6 and 7.

Development of Advanced Age-Related Macular Degeneration

A very small number of eyes presented with noncenter involving GA at baseline (PBM, n = 6; Sham, n = 5). Using FAF analysis, a numerical trend showed an increase in GA lesion area in Sham (1.48, SE 0.94; SD 1.62) compared with PBM-treated eyes (1.16, SE 0.66; SD 1.32, $P = 0.75$) at Month 13 (change from baseline; Table 2; Figure 5). The occurrence of new GA over the course of 13 months was observed in six additional eyes. A total of 10.0% (n = 5/50) of new-onset GA events were observed in Sham eyes compared to in Sham, and 1.1% (n = 1/87) observed in PBM-treated eyes. The occurrence of new GA was significantly

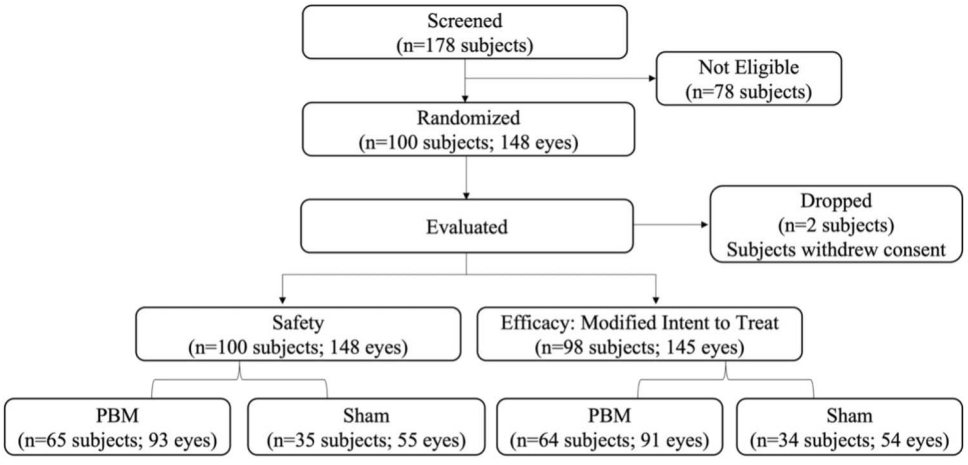

Fig. 2. Diagram of LIGHTSITE III subject enrollment. A total of 100 subjects and 148 eyes were enrolled into the study.

Table 1. Demographics and Baseline Characteristics

Variable	PBM (N = 65) n (%)	Sham (N = 35) n (%)	Total (N = 100) n (%)
Age (years)			
Mean (SD)	74.4 (7.3)	77.1 (6.2)	75.4 (7.1)
Minimum-maximum	53–91	66–88	53–91
Gender			
Female	46 (70.8)	22 (62.9)	68 (68.0)
Male	19 (29.2)	13 (37.1)	32 (32.0)
Ethnicity			
Hispanic or Latino	3 (4.6)	3 (8.6)	6 (6.0)
Not Hispanic or Latino	62 (95.4)	32 (91.4)	94 (94.0)
Race			
Black or African American	0 (0.0)	1 (2.9)	1 (1.0)
White	65 (100)	34 (97.1)	99 (99.0)
AREDS supplementation			
Yes	57 (87.6)	29 (82.8)	86 (86.0)
No	8 (12.3)	6 (17.2)	14 (14.0)
Eye color			
Blue	24 (36.9)	9 (25.7)	33 (33.0)
Green	8 (12.3)	3 (8.6)	11 (11.0)
Brown	18 (27.7)	15 (42.9)	33 (33.0)
Hazel	14 (21.5)	7 (20.0)	21 (21.0)
Other	1 (1.5)	1 (2.9)	2 (2.0)
Diabetes			
Yes	2 (5.7)	7 (10.8)	9 (9.0)
Type I	0 (0.0)	1 (1.5)	1 (1.0)
Type II	2 (5.7)	6 (9.2)	8 (8.0)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)
No	33 (94.3)	58 (89.2)	91 (91.0)
Hypertension			
Yes	23 (65.7)	32 (49.2)	55 (55.0)
No	12 (34.3)	33 (50.8)	45 (45.0)

Presented data is from subjects and not eyes.

higher in the Sham versus PBM group ($P = 0.024$, Fisher exact test, odds ratio 9.4) (Table 2; Figure 5).

A total of one Sham eye (1.8%), five PBM-treated eyes (5.4%), and three nonstudy eyes (8.3%) converted to nAMD by Month 13. A total of 16 subjects were randomized with one nonstudy eye that had nAMD. Of the 16 eyes with the nonstudy companion eye with nAMD, 12 (75.0%) were in the PBM group, providing a higher risk proportion for conversion to nAMD. The single sham eye that converted was at high risk, and 4 of 5 (80.0%) of the PBM-treated eyes were high-risk eyes.

Safety and Compliance Outcomes

A total of 33 study eyes (22.3%) presented with at least one ocular-specific AE. Four ocular-specific AEs were considered related to the treatment (none led to study discontinuation and were mild or moderate in intensity). Only one ocular-specific SAE was reported and was not considered related to the treatment. No ocular-specific AE was reported at a frequency of more than 5%. A total of three device-related AEs were reported. All device-related AEs were dry eye and considered possibly or probably related to the device. A total of three subjects had nonocular SAEs that resulted in death. All SAEs were considered not related to the treatment (Table 3). No significant changes were observed in perimetry or color vision assessment. The majority of subjects were compliant with all treatment visits. At Month 13, 88.2% of eyes receiving PBM and 74.5% of eyes receiving Sham treatment were fully compliant with the treatment protocol.

Discussion

The current report provides details of the 13-month analysis of the LIGHTSITE III 24-month study. The study met the predetermined primary efficacy endpoint with a statistically significant difference in BCVA between the PBM versus Sham

Table 2. Clinical Outcomes

Clinical Parameter	PBM (N = 91)*	Sham (N = 54)*
BCVA		
Mean baseline BCVA score, letters (SE) [SD]	70.7 (0.55) [5.23]	70.1 (0.58) [4.29]
Primary BCVA endpoint†		
Change in BCVA from baseline at Month 13		
ETDRS letters, LS mean (SE) [SD]	5.4 (0.96) [9.16]	3.0 (1.13) [8.30]
95% CI	3.5–7.3	0.7–5.2
Within-group comparison	$P < 0.0001$	$P = 0.0094$
Between-group comparison		$P = 0.0204$
Secondary and exploratory BCVA endpoints		
No. of subjects BCVA ≥5 letter improvement, n (%)	50 (54.9)	22 (40.7)
No. of subjects BCVA ≥10 letter improvement, n (%)	24 (25.8)	8 (15.1)
No. of subjects BCVA ≥15 letter improvement, n (%)	4 (4.4)	1 (1.9)
BCVA ≥5 mean letter improvement, mean (SE) [SD]	9.7 (0.5) [3.7]	8.7 (0.7) [3.1]
BCVA ≥10 mean letter improvement, mean (SE) [SD]	12.8 (0.5) [2.7]	11.9 (0.6) [1.8]
Secondary and exploratory endpoints		
Change from baseline, mean (SE) [SD]		
Month 1	3.0 (0.68) [6.49]	2.0 (0.80) [5.88]
PBM within-group comparison		$P < 0.0001$
Between-group comparison		$P = 0.22$
Month 4	4.1 (0.85) [8.1]	3.2 (0.98) [7.20]
PBM within-group comparison		$P < 0.0001$
Between-group comparison		$P = 0.37$
Month 5	4.8 (0.75) [7.15]	2.7 (0.89) [6.54]
PBM within-group comparison		$P < 0.0001$
Between-group comparison		$P = 0.027$
Month 8	4.8 (0.9) [8.59]	3.0 (1.06) [7.79]
PBM within-group comparison		$P < 0.0001$
Between-group comparison		$P = 0.027$
Month 9	5.5 (0.88) [8.39]	3.3 (1.04) [7.64]
PBM within-group comparison		$P < 0.0001$
Between-group comparison		$P = 0.045$
Month 12	6.0 (1.01) [9.63]	3.4 (1.20) [8.82]
PBM within-group comparison		$P < 0.0001$
Between-group comparison		$P = 0.04$
Secondary and exploratory endpoints		
Macular drusen volume		
Baseline, mean (SE) [SD]	0.947 (0.03) [0.29]	0.973 (0.04) [0.27]
Month 13	0.947 (0.03) [0.29]	1.02 (0.04) [0.29]
Within-group comparison	$P = 0.57$	$P = 0.36$
PBM versus sham difference in means		$P = 0.36$
New-onset geographic atrophy, No. of events (%)‡		
No. of subjects at baseline	6 (6.5)	5 (9.1)
No. of new onset subjects at Month 13	1 (1.1)	5 (10.0)
Between-group comparison		$P = 0.024$

n = Number of eyes with data available. LS mean = least squares estimation of mean based on a liner mixed effect model with eye nested within subject and use of AREDS supplements as a covariate.

*MITT population analysis.

†The Anderson–Darling test for normality indicated that the model residuals from measured values were not normally distributed ($P = 0.04$), which lead to rank assessment.

‡Subject eyes included at screening/baseline removed.

treatment groups. A mean letter gain ≥ 5 letters was observed following PBM. Furthermore, 55.0% of PBM-treated eyes showed ≥ 5 letter gain, and 26.4% showed ≥ 10 letter gain. A total of 92.0% of eyes were categorized as early/intermediate dry AMD and showed limited visual impairment at study enrollment. Best-corrected visual acuity letter scores of 60 to 70 letters (Snellen 20/40–20/64) are considered mild vision loss/near-normal vision and 40 to 60 letters (Snellen 20/64–20/160) are considered moderate visual impairment or moderate low vision. The majority of eyes enrolled in this study had an initial BCVA letter score consistent with very mild or near-normal vision.[20,22] Earlier stage dry AMD patients with better vision are not capable of large magnitude gains as seen in later stage patients with worse BCVA. Subjects who were enrolled had good vision with 70.0% of eyes showing a baseline BCVA of 70 to 75 letters (20/40–20/32 Snellen), which made these improvements in BCVA more noteworthy. Stabilization of BCVA, that is, a reduction in further decline, is also of critical consideration in degenerative disease. Treatment with PBM showed a reduction in the number of eyes that lost BCVA letters. The nonstudy eye subgroup with good vision (>75 letters) further documents the loss of BCVA over time with a 2.3 letter loss. This BCVA letter loss per year is consistent with natural history studies of earlier/intermediate dry AMD.[23]

A loss of 2 to 3 letters per year (as assessed via ETDRS BCVA) in intermediate dry AMD has been shown to increase to >5 letters per year, followed by the development of GA and irreversible loss of viable retinal tissue.[23,24] This decline in vision impacts on patient independence and quality of life. Clinical outcomes, such as contrast sensitivity, color vision, VFQ-25 and reading speed, are also of interest to provide a well-rounded assessment of visual function. Secondary outcomes included these measures and showed

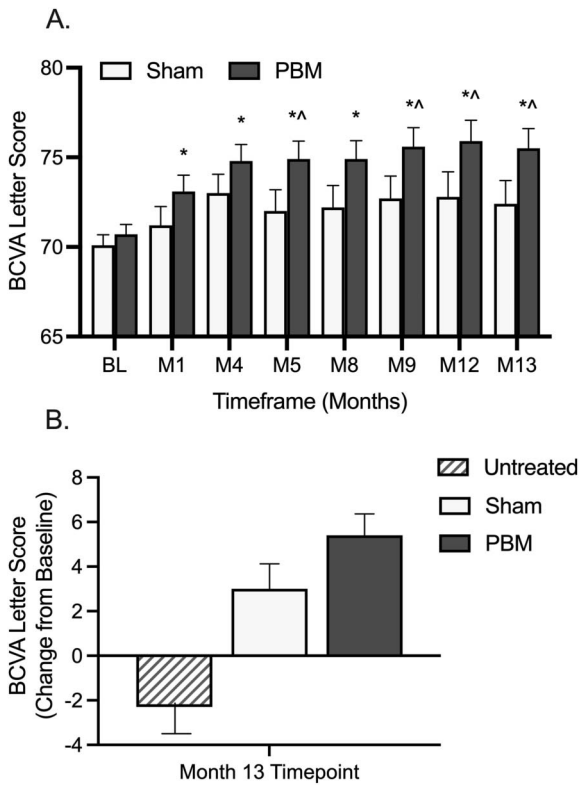

Fig. 3. Photobiomodulation improves BCVA in early/intermediate stage dry AMD. **A.** Subjects received PBM or Sham treatment at baseline, Month 4, Month 8 and Month 12 time points. Significant improvements in BCVA were observed through Month 13 following PBM treatment. **B.** At Month 13, nonstudy eyes showed a mean letter loss of 2.3 letters, Sham-treated eyes showed a mean letter gain of 3.0 letters, and PBM-treated eyes showed a mean letter gain of 5.4 letters. *Within-group (PBM) comparison, $P < 0.005$, ^PBM versus sham between-group comparison, $P < 0.05$. BL, baseline; M, month.

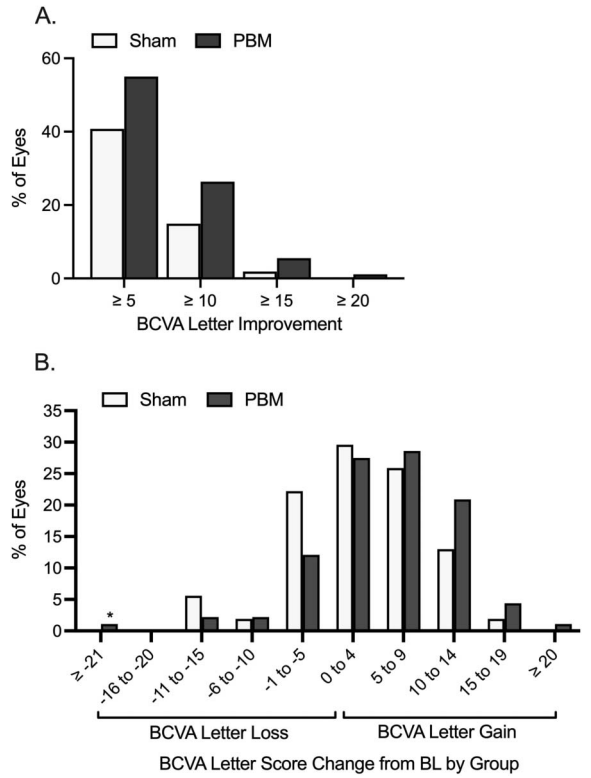

Fig. 4. Distribution of BCVA letter gain and loss by treatment group at Month 13. **A.** Approximately 55.0% of PBM-treated eyes showed ≥5 letter gain (mean of 9.7 letters, SD 3.7) compared with 40.8% of Sham, 26.4% of PBM-treated eyes showed ≥ 10 letter gain (mean of 12.8 letters, SD 2.7) compared with 14.9% of Sham, and 5.5% of PBM-treated eyes showed ≥ 15 letter gain compared with 1.9% of Sham. **B.** A higher number of Sham-treated and nonstudy eyes showed BCVA letter losses compared with PBM as noted in the −11 to −15, −6 to −10, and −1 to −5 letter loss groups. A higher number of PBM-treated eyes showed BCVA letter gains in the 5 to 9, 10 to 14, 15 to 19, and ≥ 20 letter gain groups. * Patient had vision loss because of worsening of posterior capsule opacity. BL, baseline.

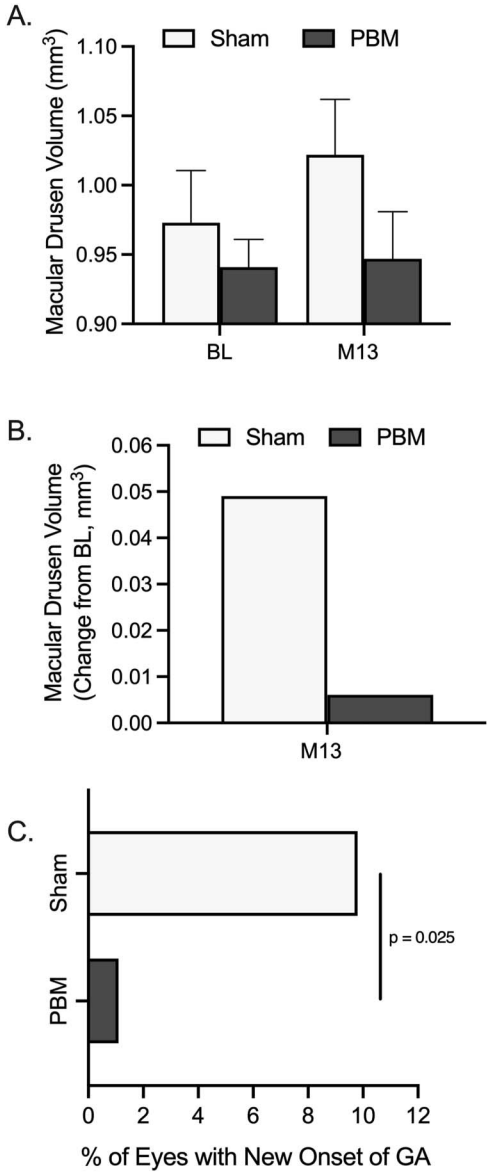

Fig. 5. Impact of photobiomodulation on anatomical outcomes. **A.** A numerical increase in macular drusen volume was observed in Sham-treated eyes, ns, $P > 0.05$. **B.** Macular drusen volume increased 0.049 mm^3 in Sham-treated eyes and 0.006 mm^3 in PBM-treated eyes. The occurrence of new GA was observed in 5 of 51 (9.8%) Sham-treated eyes and one of 88 (1.1%) PBM-treated eyes. **C.** The occurrence of new GA was significantly higher in the Sham group than in the PBM group ($P = 0.025$, Fisher exact test, odds ratio 9.3). BL, baseline; M, month.

normal to near normal vision scores at baseline. These values did not allow sufficient room to determine beneficial effect; however, no decreases in outcome scores were observed supporting safety of PBM and potential to prevent progressive decline in visual function. However, central fovea–mediated improvements in BCVA were statistically significant with a mean increase of nearly two lines in 55.0% of PBM-treated eyes, demonstrating high impact of PBM effect on BCVA in early/intermediate dry AMD subjects with better vision.

Drusen, a hallmark pathologic feature for AMD, provides a risk factor for the development of inflammation, ischemia, and further complications of AMD. Previous studies show progression rates to advanced AMD (CNV and GA for more than 5 years) of 1.3% with many small or few medium drusen, 18% if many medium or any large drusen and 43% if unilateral advanced AMD is present.[25,26] Higher frequency and larger drusen deposits are indicative of disease progression. Pegcetacoplan is the only approved treatment for GA having recently received FDA approval indicated for GA secondary to AMD. The pegcetacoplan studies show slowing of GA lesion progression with no impact on other clinical outcomes such as BCVA.[27,28] Anatomical markers such as GA and drusen represent appealing treatment targets in AMD. After GA onset, central GA is observed at 2.5 years accompanied by a BCVA loss of 3.7 letters; a 22-letter loss is expected at 5 years.[29] This study showed the occurrence of new GA in 9.8% of Sham-treated eyes and 1.1% of PBM-treated eyes, demonstrating a statistically significant reduction in new-onset GA in the PBM group. A numerical trend showed an increase in GA lesion area in Sham compared with PBM-treated eyes. No macular drusen volume increase was observed in PBM-treated eyes, whereas the volume showed trends for increase over time in Sham-treated eyes. These effects support the potential disease-modifying effects of PBM on dry AMD development and progression. Slowing of drusen and/or GA lesion growth or progression should be recognized as important to delay disease progression, and any improvement in vision or visual stabilization should be considered clinically important. A recent (2022) retrospective observational case series published by Le et al assessed the impact of multi-wavelength PBM using Valeda in subjects with reticular pseudodrusen (RPD). Treatment with PBM showed stabilization of RPD and reductions in Stage 2 and Stage 3 RPD following PBM. No progression of RPD into greater stages was observed.[18]

Photobiomodulation was well tolerated, with a favorable safety and compliance profile. Compliance rates for both PBM and Sham groups were high throughout each treatment series with a higher rate noted in the PBM group. Similar to previous clinical PBM studies, subjects showed a positive benefit–risk profile with high subject compliance rates and a low rate of AEs.[17,19,30]

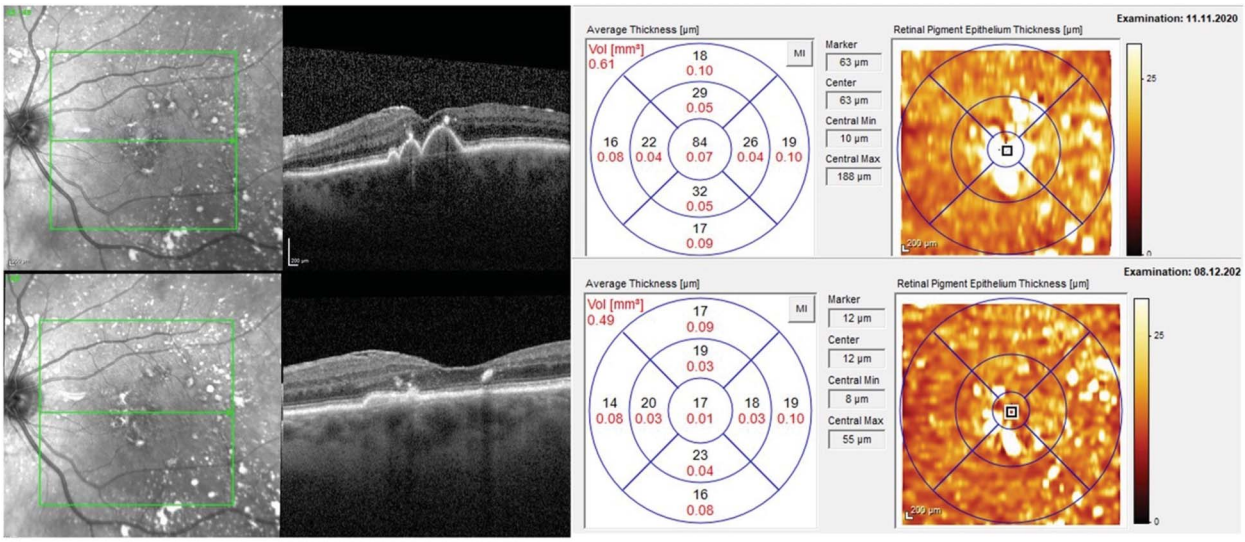

Fig. 6. Representative imaging of macular drusen reduction following photobiomodulation treatment. A significant reduction in macular drusen volume was observed following four series of PBM treatment without the loss of photoreceptor or retinal pigment epithelium visible. A 4-letter increase in BCVA was observed from 75 letters to 79 letters at Month 13.

Study limitations include masking of the study. A Sham arm was included to ensure masking and emitted a reduced light dose compared with the PBM mode. A 50 to 100× reduction in light fluency parameters was assumed to provide a significant reduction in the biological effect being studied. Although reduced, these wavelengths still produce a treatment that is visible to the eye and activates photoreceptors, thus could be anticipated to activate cytochrome C oxidase and other cellular targets that may produce a small biologic effect. Therefore, the Sham arm in this study could be considered an active control arm, which also showed moderate improvements in BCVA that were inferior to the full PBM active dose. In support for this limitation, non-study eyes with no other ocular variable and good vision (>75 letters at baseline) lost 2.3 letters at Month 13. This loss is consistent with the published literature in intermediate dry AMD studies.[23] Change from baseline within groups provides a secondary measure of improvements in BCVA letter score following PBM or Sham treatments over time and confirmed the BCVA improvements. These sham effects are consistent with prior reports from the LIGHTSITE I and II studies, which used the same fluency doses.[17,19] The study

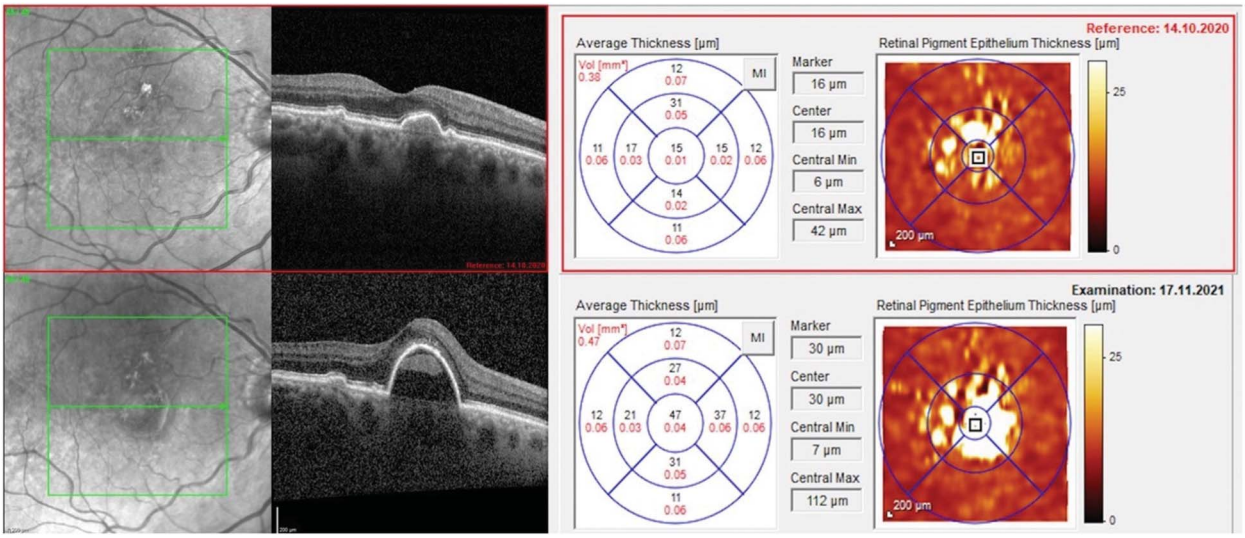

Fig. 7. Representative imaging of macular drusen increase following Sham treatment. A significant increase in macular drusen volume was observed following four series of sham treatment with confluent drusen that further developed into large RPE detachments. A 3-letter decrease in BCVA was observed from 72 letters to 69 letters at Month 13. The subject subsequently converted to nAMD.

Table 3. Ocular AEs by System Organ Class and Preferred Term in Study Eyes

	Study Eyes			Nonstudy Eyes
Preferred Term	PBM (N = 93) n (%)	Sham (N = 55) n (%)	Total (N = 148) n (%)	Total (N = 52) n (%)
Eye disorders	21 (22.6)	12 (21.8)	33 (22.3)	18 (34.6)
Neovascular age-related macular degeneration	5 (5.4)	1 (1.8)	6 (4.1)	3 (8.3)*
Vitreous floaters	1 (1.1)	4 (7.3)	5 (3.4)	0 (0.0)
Dry eye	1 (1.1)	2 (3.6)	3 (2.0)	2 (3.8)
Punctate keratitis	1 (1.1)	2 (3.6)	3 (2.0)	0 (0.0)
Vitreous detachment	2 (2.2)	1 (1.8)	3 (2.0)	0 (0.0)
Blepharitis	2 (2.2)	0 (0.0)	2 (1.4)	1 (1.9)
Conjunctival hemorrhage	2 (2.2)	0 (0.0)	2 (1.4)	0 (0.0)
Conjunctivitis allergic	2 (2.2)	0 (0.0)	2 (1.4)	0 (0.0)
Eye pain	2 (2.2)	0 (0.0)	2 (1.4)	0 (0.0)
Foreign body sensation in eyes	2 (2.2)	0 (0.0)	2 (1.4)	0 (0.0)
Lacrimation increased	2 (2.2)	0 (0.0)	2 (1.4)	0 (0.0)
Photopsia	2 (2.2)	0 (0.0)	2 (1.4)	1 (1.9)
Posterior capsule opacification	1 (1.1)	1 (1.8)	2 (1.4)	0 (0.0)
Abnormal sensation in eye	0 (0.0)	1 (1.8)	1 (0.7)	0 (0.0)
Amaurosis fugax	1 (1.1)	0 (0.0)	1 (0.7)	0 (0.0)
Angle closure glaucoma	0 (0.0)	1 (1.8)	1 (0.7)	1 (1.9)
Cataract	0 (0.0)	1 (1.8)	1 (0.7)	3 (5.8)
Cataract subcapsular	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.8)
Cystoid macular oedema	0 (0.0)	1 (1.8)	1 (0.7)	0 (0.0)
Diplopia	1 (1.1)	0 (0.0)	1 (0.7)	0 (0.0)
Eye discharge	0 (0.0)	1 (1.8)	1 (0.7)	0 (0.0)
Eye irritation	1 (1.1)	0 (0.0)	1 (0.7)	2 (3.8)
Eye pruritus	1 (1.1)	0 (0.0)	1 (0.7)	0 (0.0)
Macular hole	1 (1.1)	0 (0.0)	1 (0.7)	0 (0.0)
Open angle glaucoma	0 (0.0)	1 (1.8)	1 (0.7)	1 (1.9)
Photophobia	1 (1.1)	0 (0.0)	1 (0.7)	1 (1.9)
Retinal vein occlusion	1 (1.1)	0 (0.0)	1 (0.7)	0 (0.0)
Retinopathy hypertensive	0 (0.0)	1 (1.8)	1 (0.7)	0 (0.0)
Vitreous degeneration	1 (1.1)	0 (0.0)	1 (0.7)	0 (0.0)
Vitreous hemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.8)
Diplopia	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.8)
Amaurosis fugax	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
Chalazion	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
General disorders and administration site conditions	3 (3.2)	0 (0.0)	3 (2.0)	0 (0.0)
Pain	2 (2.2)	0 (0.0)	2 (1.4)	0 (0.0)
Application site warmth	1 (1.1)	0 (0.0)	1 (0.7)	0 (0.0)
Infections and infestations	1 (1.1)	0 (0.0)	1 (0.7)	0 (0.0)
Hordeolum	1 (1.1)	0 (0.0)	1 (0.7)	0 (0.0)

A total of 33 ocular-specific AEs categorized as eye disorders were observed in study eyes. In total, no ocular-specific AE was reported at a frequency of more than 5% in study eyes. N = number of eyes treated in the group; n = number of eyes reported such event. Percentages are based on the number of eyes treated in the group.

*Sixteen nonstudy eyes presented with nAMD at study enrollment. These eyes were removed from the total number of eyes for the development of new nAMD.

required extensive visits from subjects (i.e., 40 visits over 13 months). Regardless of this burden, subject compliance was 100% in the majority of subjects (PBM: 88.2%; Sham: 74.5%). Although study visits were extensive (and took place during the COVID-19 pandemic), treatment visits were $<$ 5 minutes per eye, and subjects were motivated to attend.

The LIGHTSITE III 13-month analysis evaluating multiwavelength PBM in subjects with early/intermediate stage dry AMD showed statistically significant improvements in BCVA across time points collected during the first four treatment series. Improvements in clinical and anatomical endpoints following PBM treatment suggest disease-modifying effects. Safety data show a strong profile with AEs consistent with the patient population and no signs of phototoxicity. Multiwavelength PBM therapy may offer a new treatment strategy with a unique mechanism and modality for subjects with dry AMD. Additional data will be reported on the 24-month outcomes in a secondary report.

Key words: photobiomodulation, multiwavelength, age related macular degeneration, mitochondria, ocular disease, vision, retina, nonexudative macular degeneration, light therapy.

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References

1. Fernandes AR, Zielińska A, Sanchez-Lopez E, et al. Exudative versus nonexudative age-related macular degeneration: physiopathology and treatment options. Int J Mol Sci 2022;23: 2592.
2. Wong WL, Su X, Li X, et al. Global prevalence of age-related macular degeneration and disease burden projection for 2020 and 2040: a systematic review and meta-analysis. Lancet Glob Health 2014;2:e106–e116.
3. Pennington KL, DeAngelis MM. Epidemiology of age-related macular degeneration (AMD): associations with cardiovascular disease phenotypes and lipid factors. Eye Vis (Lond) 2016;3: 34.
4. Evans J. Antioxidant supplements to prevent or slow down the progression of AMD: a systematic review and meta-analysis. Eye (Lond) 2008;22:751–760.
5. Chung H, Dai T, Sharma SK, et al. The nuts and bolts of low-level laser (light) therapy. Ann Biomed Eng 2012;40: 516–533.
6. Hashmi JT, Huang YY, Osmani BZ, et al. Role of low-level laser therapy in neurorehabilitation. PM R 2010;2:S292–S305.
7. Tata DB, Waynant RW. Laser Therapy: a review of its mechanism of action and potential medical applications. Laser Photon Rev 2010;5:1–12.
8. Gonzalez-Lima F, Gonzalaz-Lima F. Low level light therapy of the eye and brain. Eye and Brain 2011;2011:49–67.
9. Grossman N, Schneid N, Reuveni H, et al. 780 nm low power diode laser irradiation stimulates proliferation of keratinocyte cultures: involvement of reactive oxygen species. Lasers Surg Med 1998;22:212–218.
10. Karu T, Pyatibrat L, Kalendo G. Irradiation with He-Ne laser increases ATP level in cells cultivated in vitro. J Photochem Photobiol B 1995;27:219–223.
11. Karu TI, Kolyakov SF. Exact action spectra for cellular responses relevant to phototherapy. Photomed Laser Surg 2005;23:355–361.
12. Wong-Riley MT, Liang HL, Eells JT, et al. Photobiomodulation directly benefits primary neurons functionally inactivated by toxins: role of cytochrome c oxidase. J Biol Chem 2005; 280:4761–4771.
13. Oron U, Ilic S, De Taboada L, Streeter J. Ga-As (808 nm) laser irradiation enhances ATP production in human neuronal cells in culture. Photomed Laser Surg 2007;25:180–182.
14. Silveira PC, Silva LA, Fraga DB, et al. Evaluation of mitochondrial respiratory chain activity in muscle healing by low-level laser therapy. J Photochem Photobiol B 2009;95:89–92.
15. Passarella S, Casamassima E, Molinari S, et al. Increase of proton electrochemical potential and ATP synthesis in rat liver mitochondria irradiated in vitro by helium-neon laser. FEBS Lett 1984;175:95–99.
16. Mochizuki-Oda N, Kataoka Y, Cui Y, et al. Effects of near-infra-red laser irradiation on adenosine triphosphate and adenosine diphosphate contents of rat brain tissue. Neurosci Lett 2002;323:207–210.
17. Burton B, Parodi MB, Jürgens I, et al. LIGHTSITE II randomized multicenter trial: evaluation of multiwavelength photobiomodulation in non-exudative age-related macular degeneration. Ophthalmol Ther 2023;12:953–968.
18. Le HM, Mehanna CJ, De Rosa I, et al. Effects of photobiomodulation in patients presenting with reticular pseudodrusen: a retrospective observational case series study. Medicina (Kaunas) 2022;58:1662.
19. Markowitz SN, Devenyi RG, Munk MR, et al. A double-masked, randomized, sham-controlled, single-center study with photobiomodulation for the treatment of dry age-related macular degeneration. Retina 2020;40:1471–1482.
20. Ferris FL 3rd, Wilkinson CP, Bird A, et al. Clinical classification of age-related macular degeneration. Ophthalmology 2013;120:844–851.
21. 2.33 RCTR. A Language and Environment for Statistical Computing. Vienna, Austria: R Foundation for Statistical Computing; 2022.
22. Low Vision and Legal Blindness Terms and Descriptions. American Foundation for the Blind; 2023.
23. Thompson AC, Luhmann UFO, Stinnett SS, et al. Association of low luminance Questionnaire with objective functional measures in early and intermediate age-related macular degeneration. Invest Ophthalmol Vis Sci 2018;59:289–297.
24. Holekamp N, Wykoff CC, Schmitz-Valckenberg S, et al. Natural history of geographic atrophy secondary to age-related macular degeneration: results from the prospective proxima A and B clinical trials. Ophthalmology 2020;127:769–783.
25. Chew EY, Clemons TE, Agrón E, et al. Ten-year follow-up of age-related macular degeneration in the age-related eye disease study: AREDS report no. 36. JAMA Ophthalmol 2014;132: 272–277.
26. Joachim N, Mitchell P, Burlutsky G, et al. The incidence and progression of age-related macular degeneration over 15 Years: the blue mountains eye study. Ophthalmology 2015;122:2482–2489.
27. Apellis Announces Top-Line Results from Phase 3 DERBY and OAKS Studies in Geographic Atrophy (GA) and Plans to Submit NDA to FDA in the First Half of 2022.
28. Holz FG, Sadda SR, Busbee B, et al. Efficacy and safety of lampalizumab for geographic atrophy due to age-related macular degeneration: chroma and spectri phase 3 randomized clinical trials. JAMA Ophthalmol 2018;136:666–677.
29. Lindblad AS, Lloyd PC, Clemons TE, et al. Change in area of geographic atrophy in the Age-Related Eye Disease Study: AREDS report number 26. Arch Ophthalmol 2009;127: 1168–1174.
30. Kim JE, Glassman AR, Josic K, et al. A randomized trial of photobiomodulation therapy for center-involved diabetic macular edema with good visual acuity (Protocol AE). Ophthalmol Retina; 2022;6:298–307.

November 4, 2024

LumiThera, Inc.
Lori Holder
VP, Regulatory Affairs
19578 10th Ave. NE
Ste 200
Poulsbo, WA 98370

Re: DEN230083
Trade/Device Name: Valeda Light Delivery System
Regulation Number: 21 CFR 886.5520
Regulation Name: Light based device for dry age-related macular degeneration
Regulatory Class: Class II
Product Code: SDE
Dated: December 13, 2023
Received: December 14, 2023

Dear Lori Holder:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Valeda Light Delivery System, a prescription device under 21 CFR Part 801.109 with the following 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.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Valeda Light Delivery System, and substantially equivalent devices of this generic type, into Class II under the generic name Light based device for dry age-related macular degeneration.

FDA identifies this generic type of device as:

> **Light based device for dry age-related macular degeneration**. A light based device for dry age-related macular degeneration is a prescription device intended for use in the application of non-coherent light energy to the eye. The device treats or improves visual acuity in patients with dry age-related macular degeneration

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act.
On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 14, 2023, FDA received your De Novo requesting classification of the Valeda Light Delivery System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Valeda Light Delivery System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Valeda Light Delivery System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type.

The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Method
Ineffective treatment leading to worsening of condition	Clinical performance data Non-clinical performance testing Labeling
Therapeutic effect not sustained leading to delay of treatment and worsening of vision or progression of disease	Clinical performance data Non-clinical performance testing Labeling
Failure of software or system components leading to ineffective treatment or ocular adverse events	Clinical performance data Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Ocular light hazard	Clinical performance data Non-clinical performance testing
Equipment malfunction leading to user or patient injury (e.g., shock, burn, interference)	Electromagnetic compatibility (EMC) testing Electrical safety testing Labeling
Adverse tissue reaction	Biocompatibility evaluation

In combination with the general controls of the FD&C Act, the Light based device for dry age-related macular degeneration is subject to the following special controls:

1. Clinical performance data must demonstrate that the device or representative test device performs as intended under anticipated conditions of use. Data must include:

   (i) Adverse events, including all ocular and periorbital events;
   (ii) Assessment of ocular and retinal tissue damage;
   (iii) Assessment of best corrected visual acuity; and
   (iv) Assessment of progression to neovascular age-related macular degeneration and to geographic atrophy.

2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:

   (i) Optical radiation safety evaluation (including a description of the optical path and light sources); and
   (ii) Testing to demonstrate that the device maintains optical output specifications within all intended environmental operating conditions.

3. Software verification, validation, and hazard analysis must be performed. Documentation must include characterizations of the technical specifications of the software including a description of interactions between software and hardware; specifically, a controlling and monitoring of treatment related hardware.

4. Performance testing must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device in the intended use environment.

5. Patient-contacting components of the device must be demonstrated to be biocompatible.

6. Labeling must include:

    (i) Device treatment procedure and parameters for each treatment session supported by clinical performance data;
    (ii) The frequancey and length of treatment regimen supported by clinical performance testing; and
    (iii) A summary of the clinical performance data obtained with the device or representative test device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Light based device for dry age-related macular degeneration they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.
As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Shulei Zhao at 240-402-5358.

Sincerely,

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Materials for Item No. 8

THIRD REVISED PROPOSED REGULATION OF THE

DIRECTOR OF THE DEPARTMENT OF BUSINESS AND

INDUSTRY

LCB File No. R074-25

February 23, 2026

EXPLANATION – Matter in ***italics*** is new; matter in brackets [~~omitted material~~] is material to be omitted.

AUTHORITY: §§ 1-21, NRS 232.8413.

A REGULATION relating to professional and occupational licensing boards; defining certain terms relating to the regulation of professional and occupational licensing boards; setting forth certain standards for each board relating to recordkeeping, officers of the board and attendance at board meetings; establishing certain requirements relating to the training of board members; establishing certain standards for the internal controls of a board; establishing certain requirements for the Internet website of a board; establishing certain requirements for a board relating to certain bills during a legislative session; authorizing a board to publish certain information for the public; setting forth certain standards relating to complaints to and investigations by or on behalf of a board; requiring a board to provide certain information to the Office of Nevada Boards, Commissions and Councils Standards within the Department of Business and Industry; providing for the Office to conduct performance evaluations of a board; providing for the Office to issue certain recommendations relating to a board; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law creates the Office of Nevada Boards, Commissions and Councils Standards within the Department of Business and Industry and charges the Office with certain duties relating to the regulation of professional and occupational licensing boards, including: (1) centralized administration; (2) establishing a uniform set of standards for investigations, licensing and discipline, internal controls and legal representation; (3) establishing a consistent set of structural standards for boards and commissions; (4) transparency and consumer protection; and (5) efficacy and efficiency. Existing law requires the Director of the Department to adopt regulations and procedures to administer the responsibilities of the Office. (NRS 232.8413, 232.8415) **Sections 3-10** of this regulation define certain terms relating to the regulation of professional and occupational licensing boards. **Section 2** of this regulation applies these definitions to the provisions of this regulation.

Section 11 of this regulation establishes certain structural standards for each board to: (1) maintain certain centralized records relating to each seat on the board, the board members filling

those seats, and the terms of the board members serving on the board; and (2) elect or appoint officers of the board. **Section 11** also sets forth certain attendance requirements for board members at meetings.

Section 12 of this regulation requires: (1) the executive director of each board to notify board members of certain training requirements and when such training is offered; and (2) the board to notify the Office that a board member has successfully completed such training.

Section 13 of this regulation requires each board to establish certain standards for internal controls including: (1) developing and implementing a budget; (2) maintaining and protecting information in the records of the board in a certain manner; (3) complying and cooperating with all statutory and regulatory reporting and auditing requirements; and (4) taking certain actions to respond to audits that recommend corrective action.

Section 14 of this regulation requires each board to maintain a publicly accessible Internet website of the board, which includes certain information and meets certain requirements.

Section 15 of this regulation requires each board to: (1) track bills during a regular or special legislative session which may impact the operations of or licensees regulated by the board; (2) report certain information to the Office relating to such bills; and (3) take certain steps to implement bills which became law.

Section 16 of this regulation authorizes a board to publish certain materials to inform the public of information relating to the board and licensees of the board.

Section 17 of this regulation sets forth certain requirements relating to complaints to and investigations conducted by or on behalf of a board. **Section 18** of this regulation requires a board to provide certain quarterly information to the Office relating to complaints, investigations, disciplinary actions, licensees and other board operations.

Section 19 of this regulation requires a board to submit certain financial information to the Office on a quarterly and annual basis.

Section 20 of this regulation requires the Office to evaluate the performance of each board using the reports and other information required to be submitted to the Office.

Section 21 of this regulation provides that if the Office identifies: (1) certain concerns with a board, the Office may provide the board with written recommendations to address such concerns; or (2) certain conduct of a board member that may constitute malfeasance or nonfeasance, the Office may refer the board member to the Governor for possible removal.

Section 1. Chapter 232 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 21, inclusive, of this regulation.

Sec. 2. ***As used in sections 2 to 21, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3 to 10, inclusive, of this regulation have the meanings ascribed to them in those sections.***

Sec. 3. *"Board" means any professional or occupational licensing body, including, without limitation, a board, commission or council, that has been created by the Legislature and which is under the purview of the Office.*

Sec. 4. *"Board member" means a person appointed to serve on a board.*

Sec. 5. *"Disciplinary action" means any final action taken by a board against a licensee, including, without limitation, a public reprimand, probation, a fine, the suspension or revocation of a license or the voluntary surrender of a license in lieu of discipline.*

Sec. 6. *"Executive director" means a person appointed or employed by a board to oversee the daily operations of the board.*

Sec. 7. *"License" means any professional or occupational authorization, including, without limitation, a license, permit, registration or certificate, that is issued by a board.*

Sec. 8. *"Licensee" means any person who holds a license issued by a board.*

Sec. 9. *"Office" means the Office of Nevada Boards, Commissions and Councils Standards within the Department.*

Sec. 10. *"Purview" means administrative oversight.*

Sec. 11. *1. For the purposes of establishing a consistent set of structural standards pursuant to NRS 232.8415:*

(a) Each board shall:

(1) Maintain a centralized record of:

(I) Each seat on the board, including, without limitation, whether the seat is required by statute to represent certain interests or to serve a certain role;

(II) Each board member who is filling a seat on the board; and

(III) The terms of each board member, including, without limitation, the date on which each term begins and expires.

(2) Elect or appoint the officers of the board in accordance with the applicable statutes and regulations governing the board. Except as otherwise provided by specific statute or regulation adopted by the board, the board shall elect the officers of the board on an annual basis.

(b) Board members are required to attend and participate in meetings of the board. If, within a 12-month period, a board member has three or more consecutive unexcused absences or has unexcused absences from 50 percent or more of the meetings of the board, the board member has failed to meet this attendance requirement and the board or the Office may submit a recommendation to the Governor for the removal of the board member pursuant to NRS 232A.030.

2. As used in this section, "unexcused absence" means an absence that is not:

(a) Caused by illness, family emergency or other extenuating circumstance;

(b) Approved by the chair of the board; or

(c) Otherwise authorized by statute.

Sec. 12. *1. The executive director of each board shall notify the board members of any training that the board members are required to complete pursuant to NRS 622.200 and when such training will be offered.*

2. Not more than 30 days after a board member successfully completes any training required pursuant to NRS 622.200, the board shall provide written notice to the Office, in a format prescribed by the Office, confirming that the board member has successfully completed the required training.

Sec. 13. ***For the purpose of establishing a uniform set of standards for internal controls pursuant to NRS 232.8415, each board shall:***

1. Develop a budget for the board and monitor the implementation of the budget.

2. Maintain any information in the records of the board relating to licensees, finances and complaints in a manner that ensures the information is accurate, complete and verifiable.

3. Protect the confidential and personally identifiable information in the records of the board.

4. Comply and cooperate with all reporting and auditing requirements:

(a) Set forth by any applicable statute or regulation, including, without limitation, the governing statutes of the board and the requirements of title 54 of NRS or NRS 218G.400, 331.110, 333.705, as amended by section 8 of Assembly Bill No. 506, chapter 153, Statutes of Nevada 2025, at page 859, or NRS 622.100, as amended by section 3 of Senate Bill No. 274, chapter 83, Statutes of Nevada 2025, at page 444; or

(b) Established by any state entity authorized to conduct audits or require reports pursuant to any applicable statute or regulation, including, without limitation, the Legislative Auditor or the Budget Division of the Office of Finance,

➥ in a timely and accurate manner and in accordance with any deadline set forth in statute or regulation or established by the applicable state entity.

5. Respond to all audits of the board that are required or authorized by statute or conducted by a state entity that is authorized to conduct audits of the board pursuant to statute. Except as otherwise provided by specific statute, each board shall, not more than 90 days after receiving a final written report of an audit that recommends corrective action:

(a) Prepare a written plan for corrective action that addresses all recommendations for the corrective action; and

(b) Submit evidence to the auditing entity that the corrective action set forth in the written plan prepared pursuant to paragraph (a) has been taken.

Sec. 14. *1. Each board shall maintain a publicly accessible Internet website of the board which is accessible to persons with disabilities, including, without limitation, persons who are blind or visually impaired and, in addition to any other information required by statute or regulation of the board, post on the Internet website of the board:*

(a) A citation and link to the enabling statutes of the board and any regulations adopted by the board, including, without limitation, emergency regulations, temporary regulations and permanent regulations of the board which have been adopted and filed with the Secretary of State pursuant to chapter 233B of NRS but not yet codified in the Nevada Administrative Code.

(b) The mission statement of the board.

(c) For all current board members:

(1) The name of each board member;

(2) If the board member was appointed to represent certain interests or serve a certain role that is required by statute, the interests or role which the board member represents or serves; and

(3) The dates on which the term of each board member begins and expires.

(d) The name and title of the executive director of the board.

(e) The contact information for the board, including, without limitation, the electronic mailing address, mailing address, physical address and telephone number for the board.

(f) Any upcoming meeting of the board or a subcommittee of the board, which must include, without limitation, the date, time, location, agenda, when available, and any other information required for notice of an upcoming meeting pursuant to NRS 241.020 or 622.340, as applicable.

(g) An archive consisting of all agendas and minutes of meetings of the board prepared pursuant to NRS 241.035 for a period of not less than the immediately preceding 5 years. All other agendas and minutes of meetings of the board outside of such 5-year period must be made available upon request in accordance with the provisions of chapter 239 of NRS.

(h) Clear instructions for applying for initial licensure, renewing a license and the reinstatement of a license and any applicable deadlines set forth in statute or regulation for applying for, renewing or reinstating a license.

(i) A system for verifying licenses, which must be accessible from the homepage of the Internet website with one click and, for each licensee, must include, without limitation, the full name of the licensee, the type and status of the license, the license number, the date of issuance and the date of expiration of the license and a yes-or-no-indication of whether the licensee has any history of disciplinary actions.

(j) A system for reviewing the history of disciplinary actions of a licensee, which must:

(1) Be accessible from the homepage of the Internet website;

(2) Be searchable;

(3) Be updated not more than 15 days after any new disciplinary action is finalized;

(4) Include, without limitation, the full name of the licensee, the type and status of the license, the license number of the licensee, the type of disciplinary action and the date of the disciplinary action; and

(5) Unless otherwise declared confidential by statute or court order, provide access to the final order or settlement agreement for any disciplinary action issued in the immediately preceding 5 years. All other final orders or settlement agreements for any disciplinary action not otherwise declared confidential outside of the immediately preceding 5-year period must be made available upon request in accordance with the provisions of chapter 239 of NRS.

(k) Clear instructions on how to file a complaint with the board, accompanied by forms that may be downloaded for filing a complaint or an online system on the Internet website that enables a person to file a complaint electronically.

(l) A copy of the most recent quarterly update submitted to the Office pursuant to section 19 of this regulation and a copy of all financial audits or balance sheets filed pursuant to NRS 218G.400 within the immediately preceding 5 years.

(m) A copy of any review, evaluation, report or audit of the board conducted or prepared within the immediately preceding 5 years by or on behalf of:

(1) The Sunset Committee of the Legislature;

(2) The Division of Internal Audits of the Office of Finance;

(3) The Fiscal Analysis Division of the Legislative Counsel Bureau; or

(4) Any other entity authorized by statute to conduct or prepare a review, evaluation report or audit of the board.

(n) A link to the Internet website of the Office which must be accessible from the homepage of the Internet website of the board.

(o) Any other report required to be published by statute or submitted annually by the board.

(p) Any performance data prepared by the board.

2. The Internet website of each board must comply with any applicable regulations, policies, standards and guidelines adopted by the Chief Information Officer of the Governor's Technology Office within the Office of the Governor pursuant to NRS 242.111, as amended by section 19 of Senate Bill No. 467, chapter 513, Statutes of Nevada 2025, at page 3565, and section 15 of Assembly Bill No. 1, chapter 4, Statutes of Nevada 2025, 36th Special Session, at page 42, and NRS 242.115.

3. As used in this section:

(a) "Emergency regulation" has the meaning ascribed to it in NRS 233B.033.

(b) "Performance data" means information or metrics prepared by a board to measure or report on the operations, workload or compliance with the statutory duties of the board, including, without limitation, data or metrics prepared by the board during the ordinary course of business or that is required by statute or regulation.

(c) "Permanent regulation" has the meaning ascribed to it in NRS 233B.036.

(d) "Temporary regulation" has the meaning ascribed to it in NRS 233B.0385.

Sec. 15. *1. During each regular or special legislative session, each board shall track any bills introduced in the Legislature which may impact the operations of or licensees regulated by the board.*

2. Not later than 60 days after the adjournment of each regular or special legislative session, each board shall submit a report to the Office, in a format prescribed by the Office, identifying, for each bill tracked pursuant to subsection 1:

(a) The bills tracked by the board and whether the bills became law;

(b) The potential impact of each bill on the operations of or licensees regulated by the board;

(c) Any actions required by the board to implement any bills which became law during the legislative session; and

(d) The estimated timeline for the board to implement any bills which became law during the legislative session.

3. For any bill tracked by the board pursuant to subsection 1 for which a board is required to take action to implement, the board shall:

(a) Update the regulations of the board consistent with the bill;

(b) Ensure that the bank accounts and the records of the board are consistent with the requirements of the bill; and

(c) Notify the Office, in a format prescribed by the Office, once the board has implemented the bill.

Sec. 16. *To provide outreach and education to the public, each board may publish newsletters, alerts or bulletins to inform the public of the activities of the board, professional standards of and ethical requirements for the licensees regulated by the board, the rights of the public and the procedures for reporting the misconduct of a licensee to the board.*

Sec. 17. *1. To ensure transparency and access to the public, each board shall make available to any person who wishes to file a complaint with the board a form for filing the complaint or a method to file the complaint electronically.*

2. When responding to a complaint filed with a board, the board shall comply with all requirements for confidentiality.

3. Before initiating an investigation, a board shall determine whether a complaint falls within the jurisdiction of the board.

4. For any matter under an investigation conducted by or on behalf of a board, the file of the complaint documenting the investigation must include, without limitation:

(a) Any statutory or regulatory deadlines applicable to the investigation and resolution of the complaint by the board;

(b) Whether the board met all the deadlines identified pursuant to paragraph (a); and

(c) If the board did not meet a deadline identified pursuant to paragraph (a), the reason the board did not meet the deadline.

5. For the purposes of subsection 4, the steps of an investigation may include, without limitation, the receipt or acknowledgment of a complaint, the issuance of a notice to a licensee, the determination of reasonable doubt, the filing of a formal complaint, the scheduling of a hearing and the issuance of a final decision by the board.

6. Upon the request of the Office and to the extent permitted by law, a board shall provide to the Office any files, documents, data or other information relating to an investigation conducted by the board, including, without limitation, any disciplinary action instituted as a result of an investigation.

Sec. 18. *On or before the 20th day of January, April, July and October, each board shall submit to the Office, in a format prescribed by the Office:*

1. All information required to be submitted to the Director of the Legislative Counsel Bureau pursuant to NRS 622.100, as amended by section 3 of Senate Bill No. 274, chapter 83, Statutes of Nevada 2025, at page 444. A board may submit a copy of the report submitted to the Director of the Legislative Counsel Bureau pursuant to NRS 622.100, as amended by section 3 of Senate Bill No. 274, chapter 83, Statutes of Nevada 2025, at page 444, to satisfy this requirement.

2. A summary of all complaints filed with the board during the immediately preceding calendar quarter, which must include, without limitation:

(a) All complaints received, pending and resolved by the board for the calendar quarter; and

(b) The number of complaints resolved by the board at each stage of the process for resolving a complaint, consistent with the statutory procedures of the board.

3. Any other information requested by the Office that is reasonably related to the administrative, fiscal or investigative operations of the board.

Sec. 19. *1. All money in the possession of a board must be deposited and used in accordance with any applicable statutes governing the board.*

2. On or before December 1 of each year, each board shall submit to the Office:

(a) A copy of the balance sheet or the report of an audit, as applicable, required to be filed with the Legislative Auditor and the Chief of the Budget Division of the Office of Finance pursuant to NRS 218G.400; and

(b) A form, in the format prescribed by the Office, summarizing the information provided pursuant to paragraph (a), which must include, without limitation:

(1) The total revenue of the fiscal year;

(2) The total expenditures of the board at the end of the fiscal year;

(3) The cash balances of the board at the end of the fiscal year;

(4) A statement from the board identifying any significant financial or structural concerns identified by the board; and

(5) A review of the adequacy of the existing fees which the board is authorized to charge under statute.

3. Not later than 30 days after the close of each fiscal quarter, each board shall submit to the Office a quarterly update summarizing the finances of the board for that fiscal quarter, in a format prescribed by the Office, which must include, without limitation:

(a) The total revenue of the board at the end of the fiscal quarter;

(b) The total expenditures of the board at the end of the fiscal quarter; and

(c) The cash balances of the board at the end of the fiscal quarter.

Sec. 20. *1. The Office shall evaluate the performance of each board using the reports and information submitted to the Office pursuant to sections 2 to 21, inclusive, of this regulation to assess the administrative efficiency, internal controls, transparency, responsiveness to the public and compliance with statutory reporting requirements of a board.*

2. If the Office identifies any issues during a performance evaluation conducted pursuant to subsection 1, the Office shall notify the board in writing and the board shall have 60 days to submit a written response addressing the issues identified by the Office. The Office shall evaluate the written response of the board, if any, before completing the performance evaluation of the board. The Office is not required to modify its findings or conclusions based on the written response of the board.

3. After completing a performance evaluation conducted pursuant to subsection 1, the Office may issue written recommendations to a board pursuant to section 21 of this regulation.

4. Nothing in this section shall be construed to authorize the Office to direct the financial or operational activities of a board or to require a board to take corrective action beyond what is required by statute.

Sec. 21. *1. If the Office identifies concerns regarding the compliance of a board with the requirements of statute or with the administrative practices, internal controls or reporting*

compliance of the board, the Office shall provide the board with written recommendations to promote improved performance, administrative consistency or compliance with statutory and regulatory requirements.

2. Not more than 60 days after receiving written recommendations provided pursuant to subsection 1, a board shall review such recommendations and provide the Office with a written response describing the actions the board intends to take to address the written recommendations of the Office, if any.

3. If the Office identifies any conduct by a board member in the performance of his or her duties that may constitute malfeasance or nonfeasance, including, without limitation, neglect of duty, incompetence or inefficiency, the Office may refer such conduct to the Governor to consider whether the board member should be removed from the board pursuant to NRS 232A.030.

Materials for Item No. 9

NAC 636.215(5) as amended by R101-24(15)

5. Not later than 90 calendar days after **any** percentage of the ownership of an optometry practice for which a fictitious or assumed name is registered changes, the licensee to whom the fictitious or assumed name is registered must submit a new application for the registration of the assumed or fictitious name.

6. If a licensee uses or displays an assumed or fictitious name in any manner or medium before receiving a certificate of registration to practice optometry under an assumed or fictitious name from the Board, the optometrist: . . . (b) Is subject to an administrative fine imposed pursuant to NRS 636.420.

Materials for Item No. 10

Association of Regulatory Boards of Optometry

ARBO
Association of Regulatory Boards of Optometry, Inc.

3440 Toringdon Way
Suite 205 PMB #20533
Charlotte, NC 28277

Tel: (704) 970-2710
Fax: (888) 703-4848
Email: arbo@arbo.org

To: ARBO Member Boards
From: Lisa Fennell, Chief Executive Officer
Date: February 11, 2026
Re: ARBO Quarterly Update

Happy new year everyone! I'm pleased to share ARBO's first quarter 2026 update. Please add this to the agenda for your next Board meeting and share it with your Board members.

ARBO's 2026 Annual Meeting for Optometry Regulators:

- Planning is underway for ARBO's annual meeting taking place June 13-14, 2026, in Phoenix, Arizona.
- ARBO's meeting provides a forum for keeping up-to-date with regulatory issues and interacting with other regulators to discuss hot topics and shared concerns in the regulatory community.
- More information and registration are available on ARBO's website: https://www.arbo.org/meetings/2026
- There will be two optional workshops on Friday, June 12, 2026, with Dale Atkinson, Esq., and the National Board of Examiners in Optometry. More information is available on ARBO's website.
- ARBO offers travel stipends and scholarships for the meeting for Boards that have limited travel allowances. Information on ARBO's travel assistance programs is posted on ARBO's website: https://www.arbo.org/meetings/2026 Please contact Lisa Fennell with any questions.

ARBO's Regulatory Happy Hour Webinars:

- ARBO hosts webinars on topics relevant to optometry regulation. The webinars are open for all ARBO's member regulatory Board members, Board staff, and Board attorneys to attend. For those that cannot attend, the webinars are recorded and posted in the member section of ARBO's website.
- The next Regulatory Happy Hour will discuss Surrender of License. The webinar takes place on April 7, 2026, at 8:00 pm ET / 7:00 pm CT / 6:00 pm MT / 5:00 pm PT.
- Previous topics covered in ARBO Happy Hours are Board Minutes, Administrative Sanctions and Board Authority, Regulatory Board Audits, and Updates on the NBEO Exams.
- The Regulatory Happy Hours are complimentary for ARBO's members. You can register on ARBO's website https://www.arbo.org/regulatory-webinars.

New program for ARBO Member Boards: Case Conversation webinars with Atkinson & Atkinson.

- Each month, Dale Atkinson, Esq. or Amy Richardson, Esq. select an interesting regulatory case to delve into. The 30-minute webinars cover the case highlights, aspects of import to the regulatory community, and discuss the implications for regulatory boards and attorneys.
- The webinars take place online the second Tuesday of each month at 4:00 pm ET / 3:00 pm CT / 2:00 pm MT / 1:00 pm PT.
- ARBO members can receive a code for a complimentary registration to the Case Conversation webinars by contacting Lisa Fennell, ARBO CEO, at LFennell@arbo.org.