Media Release

For Immediate Release

3rd February 2024

Eyerising International Refute Inaccurate Claims in OPO Article

Eyerising International list multiple errors and inaccuracies in the article:

- The authors incorrectly alleged the Eyerising device did not meet safety standards it claimed
- The authors tested devices to the wrong ANSI standards
- The authors failed to mention the Eyerising Device's proven safety record
- The authors inaccurately reported a case study involving the Eyerising device

Melbourne Australia, 31 January 2024: Eyerising International, the Australian company, which is the legal manufacturer of the Eyerising Myopia Management Device, a repeated low-level red-light (RLRL) device, maintain that their device was misrepresented in an article recently published in the Ophthalmic & Physiological Optics (OPO) Journal, titled, "Red light instruments for myopia exceed safety limits", authored by Lisa A. Ostrin and Alexander W. Schill.

The authors of the OPO article several times referred to the Eyerising Myopia Management Device in a negative and inaccurate manner; despite having not tested the device or contacted Eyerising International for information or comment.

OPO to publish Eyerising's letter addressing inaccuracies

Eyerising International have spoken to the Editor-in-Chief of the OPO Journal, and he has agreed to give the company the right of reply to Dr Astin's article and to publish a 'letter to the editor' addressing the inaccuracies and misrepresentations in Dr Ostrin's article.

Our issues with the Dr Astin's article are addressed below.

Point 1

Despite having not tested the Eyerising device the authors of the OPO article wrote:
"Of note, for the Eyerising and New Vision instruments used in clinical trials, claims of Class 1 do not appear to be supported by their published measurement data."

Eyerising International dispute this statement. Our device does not 'claim' a Class 1 designation, it **'has'** a Group 1 instrument classification, indicating no potential light hazard exists, as defined by the ANSI Z80.36-2021 standard.

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ANSI Z80.36-2021 is the standard which the FDA require Eyerising International and every other manufacturer of ophthalmic laser instruments to meet.

Unlike the two devices tested by the authors of the OPO article, the Eyerising Myopia Management Device, also meets the quality, safety, and efficacy standards required by medical regulators in over 30 countries across Europe and APAC, with several more pending.

1. Eyerising International is ISO 13485:2016 certified by notified body BSI.
2. CE mark as Class IIa medical device
3. MHRA approved Class IIa in UK
4. MedSafe Class IIa in New Zealand
5. TMMDA approved Class IIa in Turkey
6. Australian Register of Therapeutic Goods (ARTG) in Australia
7. Medical Device Authority (MDA) in Malaysia

Therefore, for the authors of the article to imply that the Eyerising device does not meet the standards it claims is inaccurate and misleading.

Point 2

In their conclusion the authors of the OPO article wrote:
“Instrument manufacturers must take into account ANSI standards for lasers used in ophthalmic applications to ensure that the retina is not at risk of photochemical damage.”

But they themselves did not use the latest ANSI standards required of ophthalmic instruments by the FDA. They state in the article that they used the ANSI Z136.1 standard as the benchmark for their tests; while acknowledging that the ANSI Z136.1 standards were originally developed to protect individuals from accidental exposure to lasers in occupational situations.

There is a more recent ANSI standard specifically for ophthalmic instruments. The ANSI Z80.36 standard specifies fundamental requirements for optical radiation safety for ophthalmic instruments. It applies to all ophthalmic instruments (including current, new, and emerging instruments) that direct optical radiation into, or at the eye. It also applies to those parts of therapeutic or surgical systems that direct optical radiation into, or at the eye for diagnostic, illumination, measurement, imaging, or alignment purposes [2].

It is the ANSI Z80.36-2021 standard, which the FDA required Eyerising to meet and which we obtained.

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Point 3

In their conclusion the authors wrote:

"In conclusion, **based on measurements in our laboratory**, it is recommended that clinicians strongly reconsider the use of LLRL therapy for myopia in children until safety standards can be confirmed."

Numerous countries have established such safety standards and unlike the two copycat devices Dr Ostrin tested in her laboratory the Eyerising device meets the quality, safety, and efficacy standards required by medical regulators in over 30 countries across Europe and APAC.

Further, while the authors' conclusion, is based on tests of two other devices in the authors laboratory but by implication it includes the Eyerising device which they never actually tested but refer to inaccurately several time in their article.

The authors allege possible risks associated with LLRL therapy based on their extremely limited laboratory testing of two copycat devices but failed to mention that the Eyerising device has a proven safety record in both clinical trial and real-world settings. The Eyerising device has undergone 10 clinical trials and four (4) real world studies, covering 1785 patients, with a cumulative clinical trial use of 9.25 years - with zero significant adverse events recorded. The device has been used to treat more than 160,000 patients in the real world over the past eight years, and there are currently more than 80,000 daily users. To date, there have only been five (5) cases of significant adverse side effects reported; with no permanent damage recorded.

Point 4

The authors referenced a case study of a 12-year-old girl in China who experienced an adverse event, without mentioning the patient had not followed the guidelines for the use of the device.
In fact, the patient had continued to use the device for several weeks after first experiencing prolonged afterimages, which is contrary to the 'Instructions for Use' (IFU) issued with the device. Nor did the authors report that a follow-up case study **found that the patient had fully recovered.**

As of December 21, 2022, four months after discontinuing LLRL, the patient's cornea appeared clear and the retinal structure was intact. The corrected visual acuity of both the patient's eyes had recovered to 0.8. And OCT imaging showed that the integrity and continuity of the ellipsoid zone in the macular fovea of both eyes had been restored [3].

In conclusion:

Eyerising International takes our responsibility for ensuring the safety and efficacy of our RLRL therapy device seriously. We remain committed to working closely with healthcare professionals and users to collect and investigate any adverse reactions and to address any potential concerns.

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About Eyerising International

Eyerising International is an Australian MedTech company developing life-impacting eye-health therapy to slow the progression of myopia. We are led by a team of world-renowned ophthalmology academics, researchers and a board with a proven track record in MedTech innovation, implementation, and clinical facilitation.

Eyerising International's patented Myopia Management Repeated Low-Level Red–Light (RLRL) therapy was conceived and developed by ERI's Chief Medical Officer, Professor Mingguang He, a global leader in myopia control and the development of artificial intelligence systems in ophthalmology. This innovation in childhood myopia control meets the quality, safety, and efficacy standards required by medical regulators in over 30 countries across Europe and Australasia.

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1. Lisa A. Ostrin and Alexander W. Schill. "Red light instruments for myopia exceed safety limits", OPO January 2024.
2. ANSI Z80.36-2016
3. Tian Yu, Xiao Zhigang, Recovery of retinal structural damage after repeated low-intensity red light therapy for high myopia: a case report, CMA.J.CN, August 2023 - https://rs.yiigle.com/cmaid/1471399