Luminopia: Directions For Use

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1 Product and Manufacturer Information

Product Name	Luminopia™
Product Manufacturer	Luminopia, Inc. 955 Massachusetts Ave #335 Cambridge, MA 02139
Customer Support Line	(855) 586-4756 support@luminopia.com

2 Contraindications

None known.

3 Warnings and Precautions

3.1 Warnings

- Safety and effectiveness of Luminopia therapy beyond 12 weeks is unknown, and was not evaluated in the clinical study. The long-term effects of Head-Mounted Display (HMD) use in patients 4 to <13 years of age are unknown.
- Patients with a history of light-induced seizures should contact a doctor for additional evaluation and permission before using the Luminopia device.
- Patients with serious medical conditions should contact a doctor for additional evaluation and permission before using the Luminopia device.
- Patients should only use the Luminopia device while wearing their prescribed refractive correction (ex. glasses) under the Head-Mounted Display (HMD) during therapy.
- Patients should stop using the Luminopia device and contact a doctor for additional evaluation and permission to use the Luminopia device if patients experience any of the following while or after using the Luminopia device:
    - New or worsened eye-turn, or
    - Double vision (unable to combine the two visual inputs from each eye into one).
- Patients with an interpupillary distance of less than 52 mm should not use the Luminopia device.
    - The Luminopia device has not been studied on patients with interpupillary distances of less than 52 mm. Attempting to use the Luminopia device on these patients may result in decreased effectiveness of treatment and increased risk of adverse symptoms.

3.2 Precautions

- Do not use Luminopia for more than 1 hour per day, as prescribed by your doctor. Safety and effectiveness of Luminopia therapy has only been demonstrated when used for 1 hour per day for 6 days per week, for 12 weeks.

- The durability of benefit from the Luminopia device after treatment cessation is unknown (i.e., unknown whether visual acuity improvement at 12 weeks will be maintained or regress over time).
- Patients should stop using the Luminopia device and contact a doctor for additional evaluation and permission to use the Luminopia device if patients experience any of the following while or after using the Luminopia device:
    - Worsened vision in either eye,
    - Headaches, nausea, or eye strain that doesn't go away after usage,
    - Dizziness, or
    - Increased night terrors.
- As outlined in the Indications for Use, Luminopia is a prescription device for children ages 4 to <13 to improve visual acuity for certain medical conditions, and should be used under the direct supervision of a trained eye-care professional. The device is indicated for use with compatible, commercially available head-mounted displays (HMDs). For all other uses of such HMD, users should follow the user manual and instructional information for the specific HMD used with Luminopia, including the age range specified by the HMD manufacturer.
- Patients should only use the Luminopia device in a safe and stationary environment while seated or lying down.
- If a patient experiences discomfort because the Luminopia device feels too heavy, the patient should try to use the Luminopia device while lying down on their back. Patients should not use the Luminopia device while lying forward on their front.
- Only the patient who was prescribed the Luminopia device should use the Luminopia device.
- Patients should only use HMDs that are compatible with the software application (see **Section 6**).

4 Indications For Use

Luminopia is a software-only digital therapeutic designed to be used with commercially available Head-Mounted Displays (HMDs) which are compatible with the software application. Luminopia is indicated for improvement in visual acuity in amblyopia patients, aged 4 to <13, associated with anisometropia and/or with mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eye-care professional. Luminopia is intended for both previously treated and untreated patients. Luminopia is intended to be used as an adjunct to full-time refractive correction, such as glasses, which should also be worn under the HMD during Luminopia therapy. Luminopia is intended for prescription use only, in an at-home environment.

5 Product Description

What is Luminopia?

Luminopia is a digital therapeutic used to improve vision in patients with amblyopia (also known as lazy eye). Luminopia consists of a software application which presents video content slightly differently to each eye to encourage weaker eye usage.

How should Luminopia be used?
The software application is designed to be used with a compatible Head-Mounted Display (HMD), which can either consist of a headset combined with a display unit or an all-in-one unit. The software application will require an Internet connection for treatment, and compatible HMDs will have Internet capability.

The Patient should wear their refractive correction, such as glasses, under the Head-Mounted Display during treatment. To use the software application, the Patient watches regular 2D videos (ex. TV shows, movies, cartoons) in the HMD with therapeutic modifications applied to the videos. The Patient can browse through the available videos before choosing what to watch. The Patient can pause/resume the video and adjust the volume at any point.

Luminopia should only be used while the Patient is either seated or lying down. If the Patient experiences discomfort because the Luminopia device feels too heavy, the Patient should try to use the Luminopia device while lying down on their back.

The recommended dose for Luminopia is 1 hour/day, 6 days/week.

Caution: Prescription only. Federal law restricts this digital therapeutic to sale by or on the order of an ophthalmologist or optometrist.

How does it work?
When a video begins in the software application, the Patient will see a modified version of the original video through each eye. The rebalancing of visual input to the eyes encourages weaker eye usage.

6 Compatible Head-Mounted Displays (HMDs)

The Luminopia device is currently authorized to be used with the following commercially available Head-Mounted Displays (HMDs) that have been validated as compatible with the software application:

- DPVR P1 Pro 4K
- Pico G2 4K

To use Luminopia, the Patient / Caregiver should obtain a compatible HMD and install the software application onto the HMD (see **Section 12**). Before using the Luminopia device, the Patient / Caregiver should review the User Manual provided by the HMD manufacturer.

Both the DPVR P1 Pro 4k HMD and the Pico G2 4K HMD have been deemed compatible with Luminopia. The Samsung Gear HMD that was used for clinical validation had a screen resolution of 564 pixels per inch, and this constitutes the minimum display resolution requirement. While clinical performance using the Pico G2 4K HMD and the DPVR P1 Pro 4k HMD has not been evaluated, the HMDs were qualified through software validation, hardware bench testing, and optical testing, and meet the same minimum

requirements applied to the Samsung Gear HMD, which was clinically evaluated with the outcomes described in Section 8.

7 Software Requirements

If the software application is not provided to you directly, go to the Luminopia website: https://luminopia.com and follow the instructions to download the software application onto a compatible HMD.

The software application requires the Patient / Caregiver to connect the HMD to an Internet network (supporting 802.11g, 802.11n, or 802.11ac protocols and the 2.4 GHz or 5 GHz frequencies). Most password protected networks using WEP, WPA, and WPA2 are supported, as well as some captive portals (such as those at hotels and coffee shops).

The Internet bandwidth provided must exceed 5 Mbps to support the Luminopia device's video playback. Faster network speeds will result in a better product experience. You can test the Internet speed by connecting to the Internet and then using an online speed test tool, such as http://www.speedtest.net/ by Ookla or https://fast.com by Netflix (these services have no affiliation to Luminopia).

If internet connectivity is not available or becomes unavailable then Luminopia treatment cannot be accessed. Contact the Customer Support Line to assess whether internet can be accessed or if Luminopia treatment needs to be returned.

The minimum Operating System (OS) for the software application is Android 6.0. The Patient Portal is designed to be accessed using Internet Explorer Version 11 or later or Google Chrome Version 66 or later on a computer with a monitor resolution of at least 1366x768.

Since the software application requires significantly more computing power than the average application, the HMD may become warm during normal usage. If the surface of the HMD touching the face exceeds 41° Celsius at any time or feels too hot, stop using the Luminopia device immediately and contact the Customer Support Line.

8 Clinical Testing Summary

The safety and efficacy of the Luminopia digital therapeutic was evaluated in a multi-center, prospective, randomized controlled trial. Participants were aged 4-7 years with unilateral amblyopia associated with anisometropia, small-angle strabismus (≤ 5 PD on Simultaneous Prism Cover Test), or both. In total, 117 participants were enrolled, with 58 randomized to the treatment group and 59 randomized to the control group. Participants in the treatment group were prescribed the Luminopia digital therapeutic for 1 hour/day, 6 days/week, for 12 weeks plus full-time refractive correction. Participants in the control group continued full-time refractive correction alone for 12 weeks. A planned interim analysis was conducted after 105 participants completed the 12-week primary endpoint visit. Since the study

achieved both its primary efficacy and safety endpoints at the interim analysis, the study was stopped early for success.

The results for the primary and secondary endpoints are reported based on the interim analysis, which constitute the statistical conclusions from the study. At 12 weeks, mean amblyopic eye best-corrected visual acuity (BCVA) improved 1.8 lines (95% CI: 1.3-2.3 lines, N=41) in the treatment group and 0.8 lines (95% CI: 0.4-1.3 lines, N=43) in the control group. The difference between groups of 1.0 lines was significant (p=0.0012). Mean fellow eye best-corrected visual acuity improved 0.3 lines (95% CI: 0.1-0.6 lines, N=41) in the treatment group and 0.2 lines (95% CI: 0.0-0.4 lines, N=43) in the control group. The change in fellow eye vision in the treatment group was non-inferior to control (p<0.001). The proportion of participants who improved ≥ 2 lines from baseline at 12 weeks was greater in the treatment group (63%, 95% CI: 47-78%, N=41) compared to the control group (33%, 95% CI: 19-49%, N=43). Median adherence with the digital therapeutic over 12 weeks was 88% (N=46). Primary outcome data was missing for 14 / 105 participants and out-of-window for 7 / 105 participants at the interim analysis. Nevertheless, supplementary analyses conducted with multiple imputation and worst-case imputation models demonstrated that the study conclusions remained consistent when missing data was accounted for.

Table 1: Amblyopic Eye BCVA[1] – Intention-to-Treat (ITT) Population at Interim Analysis					**Results**	
	Treatment Group N=51	**Control Group N=54**	**Difference in Change in BCVA[2] (90% CI)**	**P-value[3]**	**Stage 1 Alpha Level**	**Decision**
Improvement from Baseline at 12 Weeks (lines)[4]	**1.8 ± 1.5 (41) 2.0 (-2.0, 6.0) [1.3, 2.3]**	**0.8 ± 1.4 (43) 1.0 (-2.0, 4.0) [0.4, 1.3]**	**1.0 (0.5, 1.5)**	**0.0012**	**0.0176**	**Reject H_0**
Change from Baseline at 12 Weeks (logMAR)	-0.18 ± 0.15 (41) -0.20 (-0.60, 0.20) [-0.23, -0.13]	-0.08 ± 0.14 (43) -0.10 (-0.40, 0.20) [-0.13, -0.04]				
Baseline (logMAR)	0.54 ± 0.21 (41) 0.50 (0.30, 1.00)	0.50 ± 0.19 (43) 0.40 (0.30, 1.00)				
12 Weeks (logMAR)	0.36 ± 0.23 (41) 0.30 (0.00, 1.10)	0.42 ± 0.21 (43) 0.40 (0.00, 1.00)				

[1]Based on participants with available data at baseline and in-window 12-week visits. Data presented as mean ± standard deviation (N) median (min, max). Change from baseline also includes [95% CI].
[2]Difference between groups (treatment - control) and 90% confidence interval are based on the coefficient associated treatment group from an ANOVA model. Positive difference between groups represents larger improvement in the treatment group.
[3]P-value is based on a one-sided F-test for the coefficient associated with treatment group from an ANOVA model.
[4]Original visual acuity measurements captured using logMAR. A 1-line improvement from baseline corresponds to a change of -0.10 logMAR.

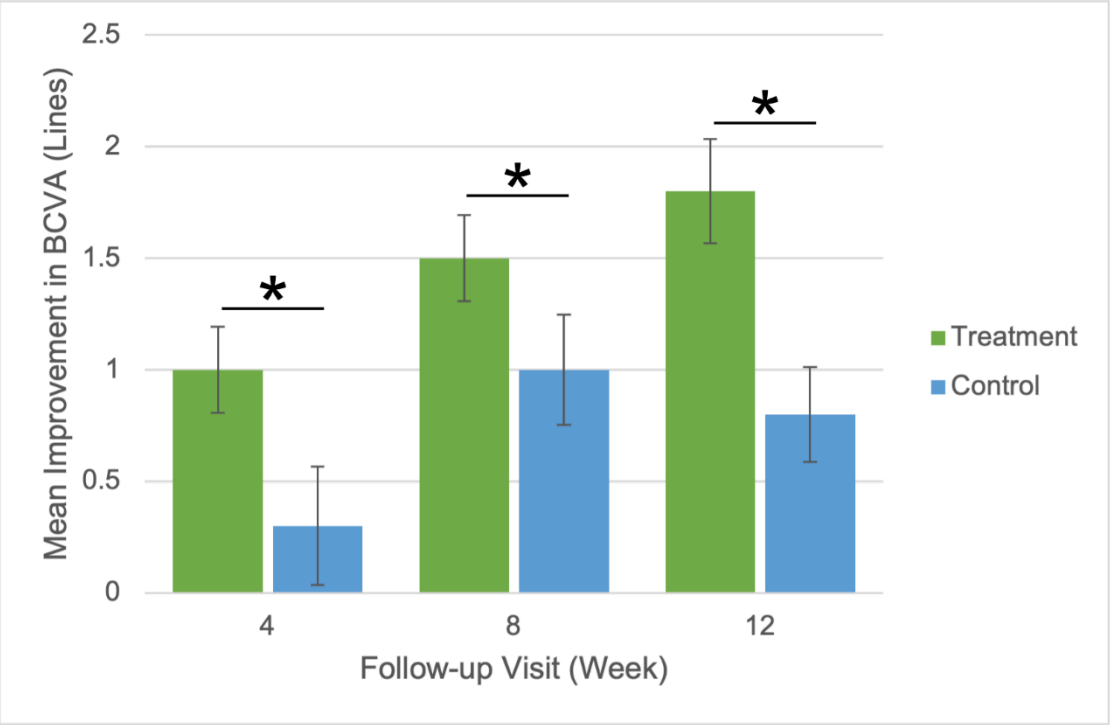

*Figure 1: Improvement in Amblyopic Eye BCVA from Baseline – ITT Population at Interim Analysis (Error bars denote ± SEM, * denotes p < 0.05).*

Table 2: Amblyopic Eye BCVA[1] – ITT Population at Final Analysis			
	Treatment Group N=58	**Control Group N=59**	**Difference in Change in BCVA[2] (90% CI)**
Improvement from Baseline at 12 Weeks (lines)[4]	**1.81 ± 1.52 (42) 2.0 (-2.0, 6.0) [1.34, 2.28]**	**0.85 ± 1.35 (46) 1.0 (-2.0, 4.0) [0.45, 1.25]**	**0.96 (0.45, 1.47)**
Change from Baseline at 12 Weeks (logMAR)	-0.181 ± 0.152 (42) -0.200 (-0.600, 0.200) [-0.228, -0.134]	-0.085 ± 0.135 (46) -0.100 (-0.400, 0.200) [-0.125, -0.045]	N/A
Baseline (logMAR)	0.536 ± 0.212 (42) 0.500 (0.300, 1.000)	0.507 ± 0.190 (46) 0.400 (0.300, 1.000)	N/A
12 Weeks (logMAR)	0.355 ± 0.231 (42) 0.300 (0.000, 1.100)	0.422 ± 0.202 (46) 0.400 (0.000, 1.000)	N/A

Table 2: Amblyopic Eye BCVA[1] – ITT Population at Final Analysis			
	Treatment Group N=58	**Control Group N=59**	**Difference in Change in BCVA[2] (90% CI)**

[1]Based on participants with available data at baseline and in-window 12-week visits. Data presented as mean ± standard deviation (N) median (min, max). Change from baseline also includes [95% CI].
[2]Difference between groups (treatment - control) and 90% confidence interval are based on the coefficient associated treatment group from an ANOVA model. Positive difference between groups represents larger improvement in the treatment group.
[3]P-value is based on a one-sided F-test for the coefficient associated with treatment group from an ANOVA model.
[4]Original visual acuity measurements captured using logMAR. A 1-line improvement from baseline corresponds to a change of -0.10 logMAR.
*Although the results from the interim analysis constitute the statistical conclusions from the study, the results from the final analysis are based on data from all enrolled participants.

Table 3: Improvement in Amblyopic Eye BCVA ≥ 2 Lines[1] – ITT Population at Final Analysis		
	Treatment Group N=58	**Control Group N=59**
Improvement ≥ 2 lines from Baseline to 4 weeks	34.0% (17/50) [21.2%, 48.8%]	24.5% (12/49) [13.3%, 38.9%]
Improvement ≥ 2 lines from Baseline to 8 weeks	50.0% (24/48) [35.2%, 64.8%]	31.8% (14/44) [18.6%, 47.6%]
Improvement ≥ 2 lines from Baseline to 12 weeks	61.9% (26/42) [45.6%, 76.4%]	32.6% (15/46) [19.5%, 48.0%]

[1]Based on participants with available data at baseline and in-window visits. Data presented as: % (n/N) [95% CI].
[2]P-value from post-hoc Chi-square test.
*Although the results from the interim analysis constitute the statistical conclusions from the study, the results from the final analysis are based on data from all enrolled participants.

Table 4: Amblyopic Eye Change in BCVA by Visit[1] – ITT Population at Final Analysis						
	4 Weeks		**8 Weeks**		**12 Weeks**	
Number of Lines Change (follow-up - baseline)[2]	**Tx**	**Control**	**Tx**	**Control**	**Tx**	**Control**
6-line improvement	0.0% (0/50)	0.0% (0/49)	0.0% (0/48)	0.0% (0/44)	2.4% (1/42)	0.0% (0/46)

4-line improvement	4.0% (2/50)	0.0% (0/49)	6.3% (3/48)	6.8% (3/44)	2.4% (1/42)	2.2% (1/46)
3-line improvement	10.0% (5/50)	8.2% (4/49)	12.5% (6/48)	13.6% (6/44)	31.0% (13/42)	10.9% (5/46)
2-line improvement	20.0% (10/50)	16.3% (8/49)	31.3% (15/48)	11.4% (5/44)	26.2% (11/42)	19.6% (9/46)
1-line improvement	32.0% (16/50)	22.4% (11/49)	29.2% (14/48)	31.8% (14/44)	23.8% (10/42)	19.6% (9/46)
No change	24.0% (12/50)	32.7% (16/49)	14.6% (7/48)	15.9% (7/44)	7.1% (3/42)	34.8% (16/46)
1-line decrease	8.0% (4/50)	10.2% (5/49)	6.3% (3/48)	13.6% (6/44)	2.4% (1/42)	10.9% (5/46)
2-line decrease	2.0% (1/50)	6.1% (3/49)	0.0% (0/48)	6.8% (3/44)	4.8% (2/42)	2.2% (1/46)
3-line decrease	0.0% (0/50)	2.0% (1/49)	0.0% (0/48)	0.0% (0/44)	0.0% (0/42)	0.0% (0/46)
7-line decrease	0.0% (0/50)	2.0% (1/49)	0.0% (0/48)	0.0% (0/44)	0.0% (0/42)	0.0% (0/46)

[1]Based on participants with available data and in-window visits. Categorical variables presented as n/N (%) where N is the number of participants with available data.

[2]Original visual acuity measurements captured using logMAR. A 1-line improvement from baseline corresponds to a change of -0.10 logMAR.

*Although the results from the interim analysis constitute the statistical conclusions from the study, the results from the final analysis are based on data from all enrolled participants.

The adverse events observed in the study are reported based on the final analysis, which included all enrolled participants. No serious adverse events were reported. The overall incidence of non-serious related adverse events was 25% in the treatment group (95% CI: 14-38%, N=56) and 14% in the control group (95% CI: 6-25%, N=59). The most frequently reported adverse event in the treatment group was headache, which was observed in 8 patients. The incidence of headaches in the treatment group (14%, 95% CI: 6-26%, N=56) was higher than that of the control group (2%, 95% CI: 0-9%, N=59). All cases of headaches were graded as mild in severity and all resolved without sequelae by the end of the study. The second most common adverse event was a new heterotropia, which was observed in 4 patients in both groups. All cases of new heterotropias were graded as mild in severity. Other adverse events observed in the treatment group included: eye strain, worsening visual acuity in either eye, eye twitching, facial redness, increase in frequency of night terrors, and dizziness. Other potential safety risks which were not observed in the treatment group include: diplopia, worsening heterotropia, and nausea.

Table 5: Non-Serious Adverse Events[1] – As-Treated (AT) Population[2] at Final Analysis

	Treatment Group[2] (N=56)	**Control Group[2] (N=59)**
Diplopia	0 (0.0%) [0] [0.0%, 6.4%]	1 (1.7%) [1] [0.0%, 9.1%]

New heterotropia	4 (7.1%) [4] [2.0%, 17.3%]	4 (6.8%) [4] [1.9%, 16.5%]
Worsening heterotropia	0 (0.0%) [0] [0.0%, 6.4%]	1 (1.7%) [1] [0.0%, 9.1%]
Worsening BCVA	3 (5.4%) [4] [1.1%, 14.9%]	4 (6.8%) [4] [1.9%, 16.5%]
Headache	8 (14.3%) [9] [6.4%, 26.2%]	1 (1.7%) [1] [0.0%, 9.1%]
Nausea	0 (0.0%) [0] [0.0%, 6.4%]	0 (0.0%) [0] [0.0%, 6.1%]
Eye strain	2 (3.6%) [3] [0.4%, 12.3%]	0 (0.0%) [0] [0.0%, 6.1%]
Other[3]	4 (7.1%) [5] [2.0%, 17.3%]	0 (0.0%) [0] [0.0%, 6.1%]
Overall	14 (25.0%) [25] [14.4%, 38.4%]	8 (13.6%) [11] [6.0%, 25.0%]

[1]Includes events classified with Possible, Probable, or Definite relation to study treatment. Data presented as: n (%) [m] [95% CI], where n is number of participants with event and m is the number of events. Participants may experience more than one AE.

[2]AT is defined as subjects with > 0% adherence of device use are in the treatment arm, otherwise control; there are no control subjects treated with the device.

[3]Other AEs in treatment group include: Eye Twitch, Facial Redness, Increase in Frequency of Night Terrors, Dizziness, Parent-reported intermitted eye turning when tired

Luminopia was also evaluated in a Real-World Registry, designed prospectively, which collected retrospective data from medical health records of patients treated with Luminopia under usual care. The registry employed an all-comers design and included any patient with an amblyopia diagnosis and Luminopia use of at least 12 weeks. Visual Acuity change from the time of Luminopia prescription to the last visit was reported. The registry included 332 patients, of whom 290 were aged 4 to <13 with a diagnosis of amblyopia associated with anisometropia and/or strabismus.

The registry study patients had an average of 2.8 years in refractive correction and 1.8 years using patching and/or atropine before starting Luminopia. Patients used Luminopia treatment for an average of approximately 8.4 months. Across all patients aged 4 to <13 with a diagnosis of amblyopia associated with anisometropia and/or strabismus, the mean amblyopic eye best-corrected visual acuity (BCVA) improved 1.1 lines (95% CI: 0.92-1.3 lines, N=290). For the subgroup of patients aged 4-7, the mean amblyopic eye best-corrected visual acuity (BCVA) improved 1.2 lines (95% CI: 1.0-1.4 lines, N=181). For the subgroup of patients aged 8-12, the mean amblyopic eye best-corrected visual acuity (BCVA) improved 0.92 lines (95% CI: 0.61-1.3 lines, N=109).

Table 6: Amblyopic Eye BCVA[1]			
	Baseline	**Last Visit**	**Improvement in BCVA (Lines)[2]**
Age 4-7	0.403 ± 0.219 (181) 0.4 (0.1, 1.18)	0.283 ± 0.222 (181) 0.18 (-0.12, 1.1)	**1.21 ± 1.4 (181)** **1.0 (-4.0, 5.2)**

	[0.371, 0.435]	[0.25, 0.315]	**[1.0, 1.4]**
Age 8-12	0.414 ± 0.235 (109) 0.4 (0.1, 1.3) [0.369, 0.458]	0.321 ± 0.198 (109) 0.3 (0.0, 1.0) [0.284, 0.359]	**0.92 ± 1.7 (109)** **0.8 (-3.8, 8.0)** **[0.61, 1.3]**
Age 4-12	0.407 ± 0.225 (290) 0.4 (0.1, 1.3) [0.381, 0.433]	0.297 ± 0.214 (290) 0.3 (-0.12, 1.1) [0.273, 0.322]	**1.11 ± 1.5 (290)** **1.0 (-4.0, 8.0)** **[0.92, 1.3]**

1. Based on participants with available data at baseline and one follow-up visit. Data presented as mean ± standard deviation (N) median (min, max). Change from baseline also includes [95% CI].
2. Original visual acuity measurements captured using logMAR. Change presented in Lines of Visual Acuity. A 1-line improvement from baseline corresponds to a change of -0.10 logMAR.

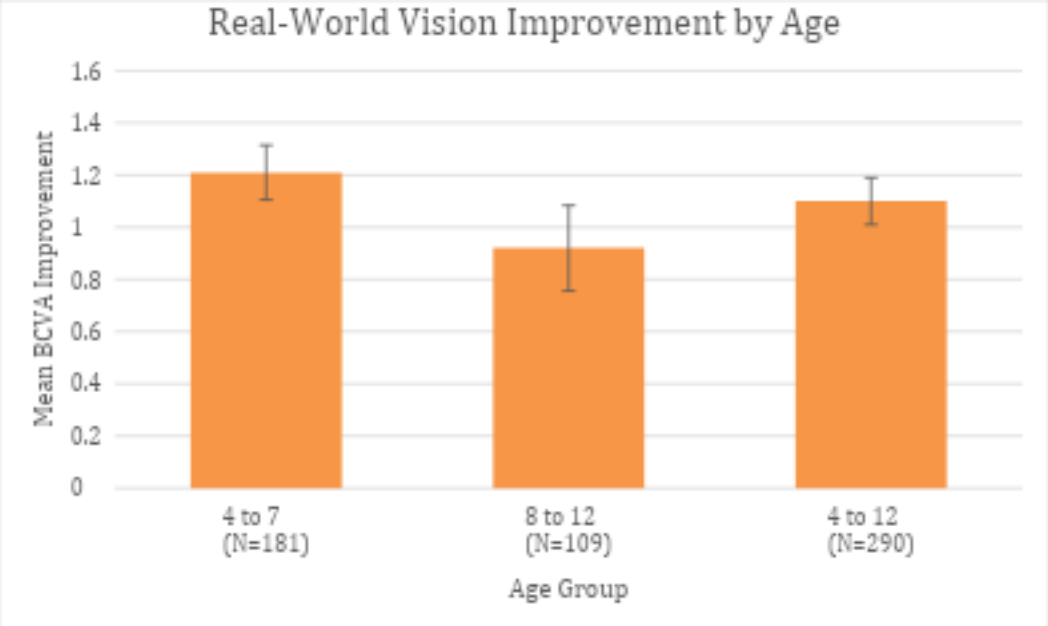

Figure 2: Improvement in Amblyopic Eye BCVA from Baseline to Last Follow-up (Error bars denote ± SEM)

Table 7: Amblyopic Eye Change in BCVA			
Number of Lines Change (follow-up – baseline)	**4 to 7**	**8 to 12**	**4 to 12**
7> to ≤8 line improvement	0.0% (0/181)	0.9% (1/109)	0.3% (1/290)
5> to ≤6 line improvement	0.6% (1/181)	0.9% (1/109)	0.7% (2/290)
4> to ≤5 line improvement	3.3% (6/181)	0.9% (1/109)	2.4% (7/290)
3> to ≤4 line improvement	4.4% (8/181)	6.4% (7/109)	5.2% (15/290)
2> to ≤3 line improvement	13.8% (25/181)	11.9 (13/109)	13.1% (38/290)
1> to ≤2 line improvement	32.0% (58/181)	22.9 (25/109)	28.6% (83/290)

0> to ≤1 line improvement	15.5% (28/181)	13.8% (15/109)	14.8% (43/290)
No change	22.7% (41/181)	24.8% (27/109)	23.5% (68/290)
0> to ≤1 line decrease	4.4% (8/181)	6.4% (7/109)	5.2% (15/290)
1> to ≤2 line decrease	2.2% (4/181)	10.1% (11/109)	5.2% (15/290)
2> to ≤3 line decrease	0.6 % (1/181)	0.0% (0/109)	0.3% (1/290)
3> to ≤4 line decrease	0.6 % (1/181)	0.9% (1/109)	0.7% (2/290)
Based on participants with available data at baseline and one follow-up visit. Categorical variables presented as n/N (%) where N is the number of participants with available data. Visual acuity measurements captured using logMAR. A 1-line improvement from baseline corresponds to a change of -0.10 logMAR.			

The rate of Adverse Events observed in the real-world registry and captured in medical health records were lower than those reported in clinical trials. The safety of Luminopia in children aged 8-12 is expected to be in line with the safety in children aged 4-7. The Adverse Events in the registry are listed in Table 8.

Table 8: Non-Serious Adverse Events[1] (N=290)	
Eye Redness	1 (0.3%)
Headache	5 (1.7%)
Dizziness	1 (0.3%)
Teary Eye	1 (0.3%)
Nightmare	1 (0.3%)
Overall	9 (3%)
[1]Includes events reported n (rate of n/N).	

9 Environmental Considerations

The Luminopia device should only be used in a safe and stationary environment when the HMD is connected to Wi-Fi. The HMD should be kept away from heat sources, water, moisture, open flames, or direct sunlight. If the Patient intends to use the Luminopia device away from home for an extended period of time, the Caregiver should bring the charger provided with the HMD to charge the device as needed. The Patient should not use the Luminopia device while the HMD is charging.

10 Cybersecurity

We recommend that you add a passcode to your HMD if applicable to add a layer of security. The HMD should be kept in a secure at-home environment and should not be used in public places. It is important

to secure the HMD to prevent unauthorized access to the software application. If any screens on the Luminopia application appear differently than described in this document, contact Customer Support.

The HMD includes a number of communication ports including wireless internet communication, wireless Bluetooth communication and a USB port. These communication ports are intentionality disabled to minimize cybersecurity risk, and you will not be able to access the HMD through these ports.

11 Caregiver Responsibilities

Since the Luminopia device is designed for at-home use, the instructions provided in the Directions For Use are written primarily for the Caregiver. The Caregiver is responsible for reviewing, understanding, and following the instructions provided. The Caregiver should ensure that the Patient is trained and educated to operate the Luminopia device according to the Directions For Use at all times. The Caregiver may be the Patient's Parent / Guardian or another person responsible for the Patient's care, such as a healthcare provider. The Patient may be able to operate components of the Luminopia device on their own, but the Patient should only do so under the supervision of the Caregiver. The Caregiver is responsible for maintenance and troubleshooting.

12 Setting Up the Product

Note: Throughout the Directions For Use, text highlighted in 'single quotes' refers to virtual software buttons.

12.1 Setting Up the HMD

1. Obtain an HMD that is compatible with the software application.
2. Follow the User Manual provided by the HMD manufacturer to set up the HMD and turn it on.
3. Follow the User Manual provided by the HMD manufacturer to connect the HMD to a Wi-Fi network.
4. After the HMD is fully charged, you are ready to use the Luminopia device.

12.2 Setting Up the Software Application

1. On the HMD, go to the Luminopia website: https://luminopia.com and follow the instructions to download the software application. If the Luminopia device already has the software application downloaded, skip this step.
2. Wait for a phone call or text from a Luminopia Prescription Manager or Pharmacy Partner to receive an access code.
3. Once you've received an access code, open the software application.
4. Input the access code by using the virtual keyboard on the HMD. Tap the 'Submit' button.

Figure 3: Inputting access code

5. If the access code is valid, you will see a green checkmark. If the access code is invalid, you will be asked to re-input the access code. If you are unable to continue after several tries, contact the Customer Support Line for assistance.

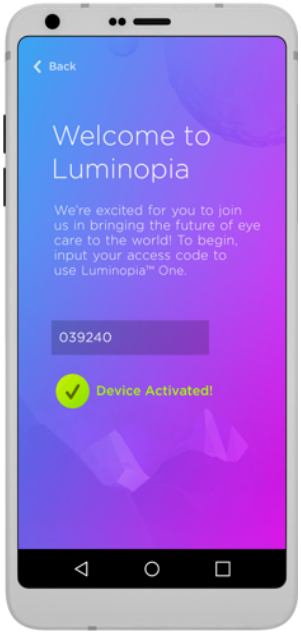

Figure 4: Valid access code

6. If the HMD you are using is composed of a headset and a display unit, follow the HMD User Manual to attach the display unit to the headset.
7. You are now ready to use the software application.

13 Using the Product

13.1 Using the Software Application

1. Put the HMD on over the Patient's current glasses or refractive correction (if applicable) and adjust the side straps and top strap until the HMD is tight but comfortable. Follow the HMD User Manual to put on the HMD properly, and use these two checks to ensure the HMD is correctly positioned on the Patient's head:
    a. Look at the Patient's face from the front, and check that the center of the HMD from left to right is lined up with the center of the Patient's face from left to right.
    b. Look at the Patient's face from the side, and check that the middle of the HMD from top to bottom is lined up with the Patient's eye level.

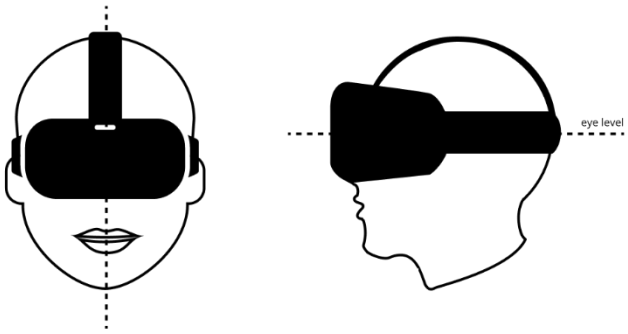

Figure 5: Checks for proper fit

2. Inside the HMD, the Patient should see a selection of content thumbnails.

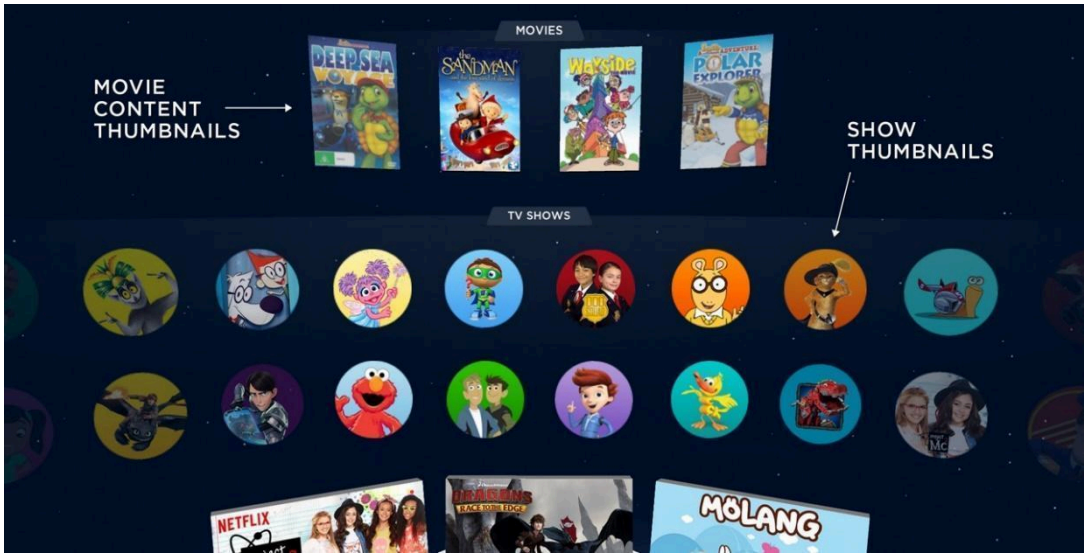

Figure 6: TV show and movie content thumbnails

3. Instruct the Patient to use the Reticle, a visible bright white dot on the screen, to browse through the thumbnails and select the video they want to watch. The Reticle follows your view as you move your head.

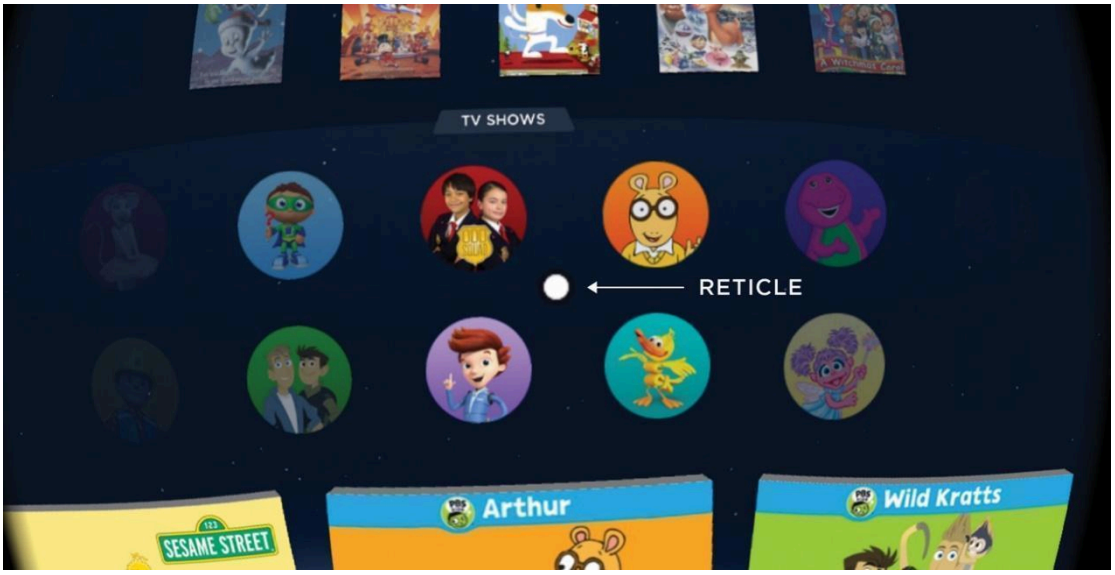

Figure 7: Reticle

4. Instruct the Patient to hold the Reticle over a video thumbnail for about 3 seconds, to select it. When an object is being selected, the Reticle will expand and make a circle within the video thumbnail.

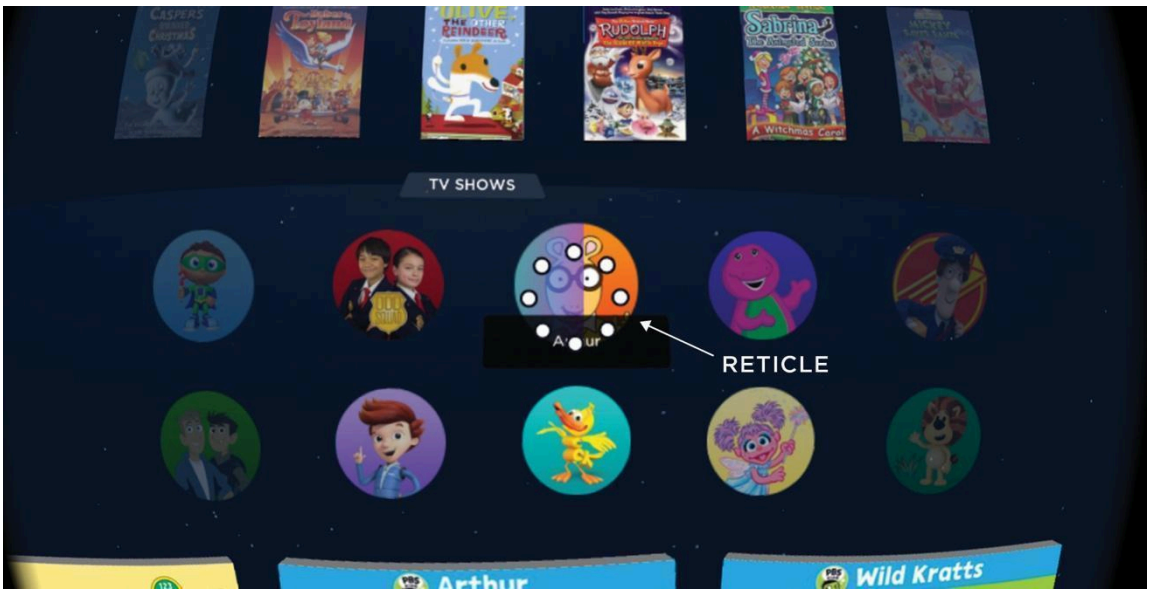

Figure 8: Reticle selection

5. After the video starts playing, the Patient should watch the video with therapeutic modifications applied according to the Patient's prescription.

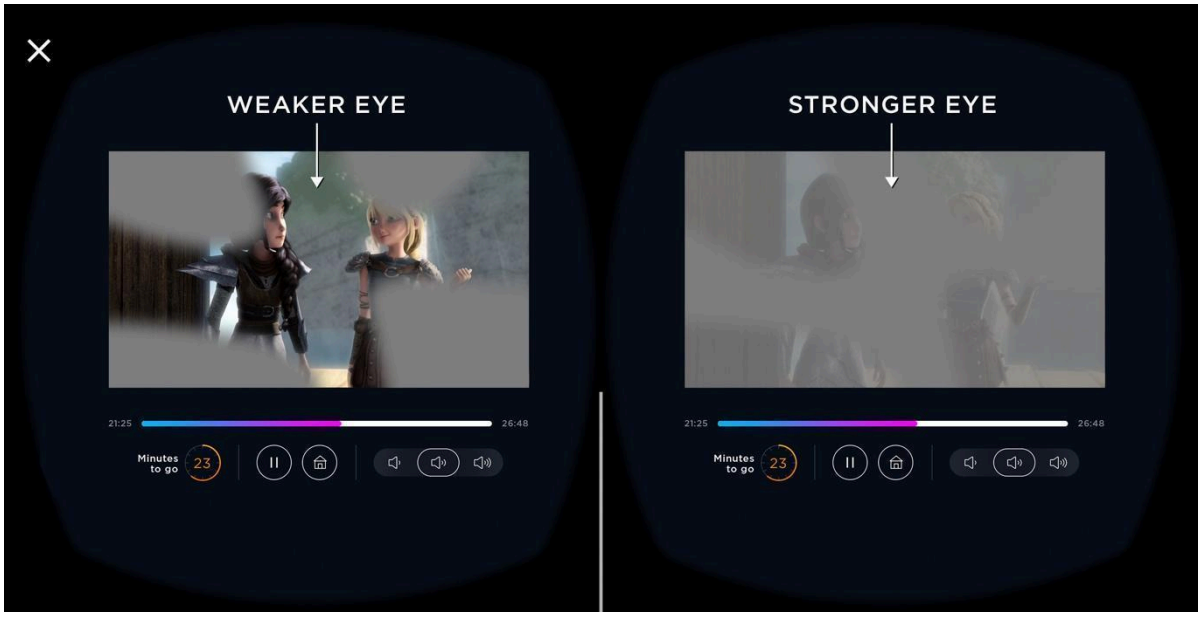

Figure 9: Watching video

6. At any point, the Patient may pause/resume the video, seek to a different point in the video, change the volume, or return home to pick a different video by selecting the various playback control buttons. The Patient and Caregiver will know that treatment is complete for the day when the Daily Usage Monitor in the bottom left of the video player reads 0 minutes to go.

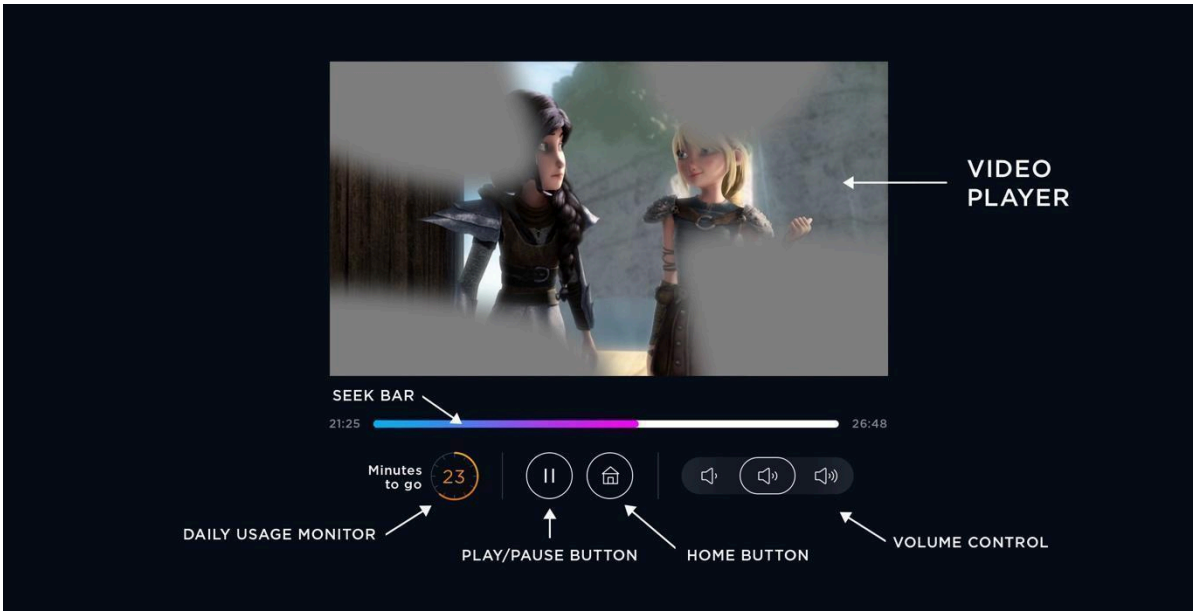

Figure 10: Playback controls

7. Once the Patient has completed treatment for the day, close the software application and remove the HMD from the Patient's head.
8. Follow the HMD User Manual to turn off the HMD.

14 Maintaining the Product

14.1 Maintaining the Software Application

- No action needed for proper maintenance of the software application.

If software updates or patches are need, they will occur automatically when the HMD is connected to the internet(Note: Luminopia will not start if it is not connected to the internet).

14.2 Maintaining the HMD

- Follow the HMD User Manual for proper maintenance of the HMD.

15 Troubleshooting

1. If you encounter issues turning on the HMD, ensure that you have charged the HMD to 100%.
2. If you encounter issues during video playback, there may be several causes:
    a. The video you are trying to play may not be available in your geographic location.
    b. Your Wi-Fi connection may not be fast enough to handle the video playback. Ensure that your Wi-Fi connection is able to stream high-definition online videos. Connecting to a different Wi-Fi network may resolve the issue.
3. If you have tried all of the above and continue having issues, follow the HMD User Manual to force a hard reboot of the HMD.
4. If you have any other questions or issues, please reach out to the Customer Support Line.