Binocular retinal eye-tracking system
Product Requirements Document
C. Light Technologies, Inc.

Document Number 00001

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Authentication Block

Revision History

Rev	Description	Date	Authorization
1	Initial PRD	10.28.2016	All
2	PRD Revision 2	11.11.2016	All
3	PRD Revision 3	12.02.2016	All
4	PRD Revision 4	12.12.2016	All
5	Final PRD	12.17.2016	All

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1. Introduction

1.1 Vision:

The product is a binocular eye tracking system that will record fixational eye motion in athletes. This tool will be used to diagnose and monitor recovery of concussions and mild traumatic brain injuries (TBI).

1.2 Task:

Reduce the current size of the already built prototype, and make the device durable enough to withstand courtside/field-side use. The device must also be simple enough for an athletic trainer or technician to operate.

2. Environment

As a clinical device intended to be used field/court-side(i.e. on the sidelines of a soccer, football, or basketball game), it needs to operate in the following environment:

Temperature
Should be able to function in open air conditions, with safety enclosure Overtop without overheating.

Relative Humidity
Non-condensing – safe operation
>0% - meets specifications

The device must operate under battery power.

3. Regulatory Issues

The prototype system is actively being used in a clinical setting using the superlum laser. Should we change laser source or wavelength, we will need to address the regulations regarding the acceptable power levels in retinal imaging.

4. Desired Specifications

4.1 Budget

- <$35,000

4.2 Imaging Constraints

- Detector size must be 512x512 pixels
- Operating wavelength 840 nm, with the flexibility to operate between 632 – 840 nm if necessary
- The current set-up utilizes a Hamamatsu PMT[1]

[1] The spec sheet for the device can be found at http://www.hamamatsu.com/resources/pdf/etd/PMTmodules_TPMO0011E.pdf

4.3 Scanning Constraints

- 10°(± 5°) Field of View
- Current Scanners
  - Resonant Scanning must operate between 15 and 16 kHz
  - Galvo Scanning must operate at 30 Hz scanning
    - Clean sawtooth wave generation
- Potential Scanner
  - Replace the two scanners with a single MEMs scanner
  - Working aperture of 1.2 mm

4.4 Performance Constraints

- 3 mm exit pupil size at the surface of the eye
- Diffraction limited system over the whole scan
- Adjustable Interpupilary Distance (IPD) ranging from 52 mm to 78 mm (this might be desired)
- 100 – 200 mm variable eye relief
- Limited beam wondering (less than 0.25 mm)

4.5 Size, Weight, and Durability Constraints

- The device must be smaller than the current 30x60 cm set-up and weigh less than the current set-up (~50 pounds)
- Ideally the device can be transported by hand
- Needs to be durable enough to survive use field-side or courtside

4.6 Desired, but not Essential Features

- Varioptic Liquid Lens to correct for ± 10 diopters of imperfect vision

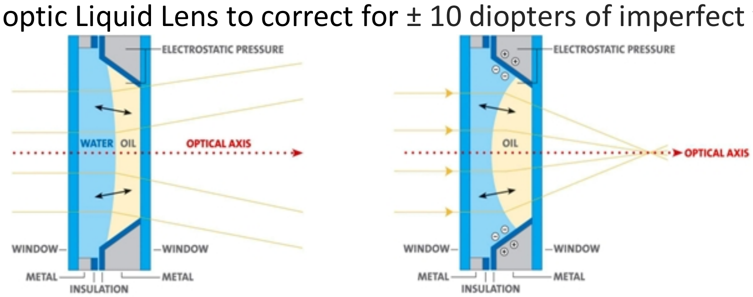

Figure 1: photo credit: Varioptic[2]

- The device be handheld
- The device to operate with a 1-micron wavelength

[2] Varioptic's webpage found at http://www.varioptic.com/technology/liquid-lens-autofocus-af/

5. Inspiration for the Project

5.1 Christy Sheehy's PHD project converted into a Binocular System

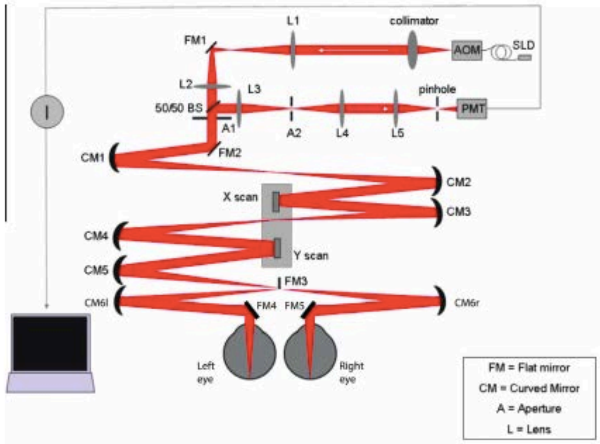

Fig. 1. Schematic layout of the binocular modification to the Tracking Scanning Laser Ophthalmoscope (modified from Sheehy et al., 2012). Mirror FM3 is placed at a retinal conjugate point, splitting the field into left eye and right eye halves. Each half of the scan is reflected by a concave mirror and a flat mirror into the respective eyes. The resulting scan produces a split field image with left and right retinal images side by side in the each frame. The horizontal scanner is a polished bar resonating at 15.4 kHz and images are collected during a 26 μs time window during one direction of scan, so left and right eye samples are collected about 13 μs apart. Eyes are not shown to scale.

Figure 2[3]

5.2 LaRocca Ultra Compact Handheld OCT/SLO Probe Design[4]

- The probe portion depicted below weighs 94 grams
- Only has a ± 3.5° Field of View
- Monocular design

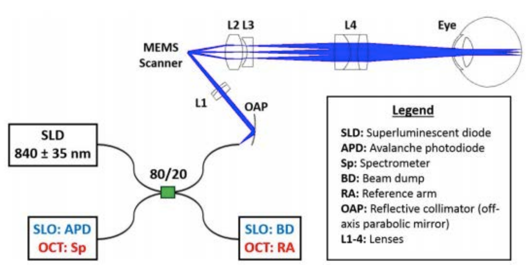

Figure 1. Ultra-compact SLO-OCT handheld probe schematic and optical design. All optical components are labeled and described in the legend. Blue and red text in the schematic correspond to components used for imaging in SLO or OCT mode, respectively.

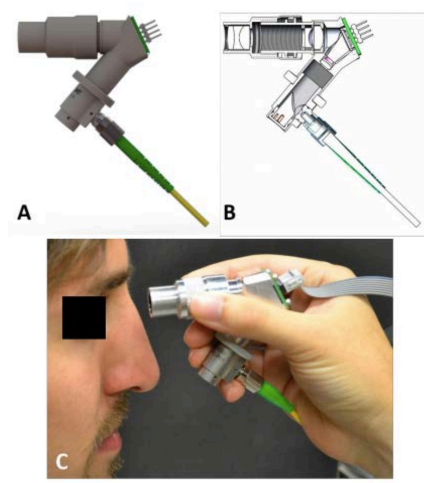

Figure 3. Opto-mechanical design (top) and the fully assembled handheld probe in use on a healthy volunteer. A) Photorealistic rendering of the handheld probe. B) Section view showing the interior of the handheld probe. C) Assembled probe in handheld use.

Figure 3

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[3] Image from Stevenson and Sheehy paper

[4] All three images come from the LaRocca paper

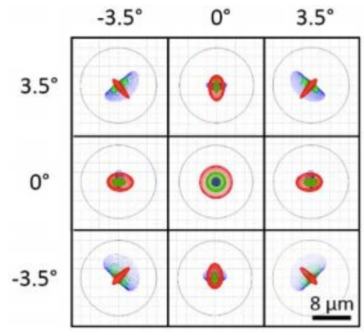


Figure 2. Spot diagrams (color coded for 3 wavelengths spanning 805 – 870 nm) for both SLO and OCT illumination on the retina of a model eye spanning a 7° FOV.

Figure 4

5.3 Comparison of the two systems and the desired system

	Reflective Binocular System	Refractive Monocular System	Desired Product
FOV	10 degrees	7 degrees	10 degrees
Handheld	No	Yes	Yes
Probe/scanner weight	~50 pounds	94 grams	Ideally <20 pounds Must be <50 pounds
Cost	N/A	N/A	<$35,000
#scanning mirrors	2	1	TBD
Battery Powered	No	No	Yes

6. Preliminary Ideas

6.1 Description

The device has been split into three main components, the front end optics (i.e. the optics that actually images the eye), the light delivery arm, and the light collection arm

6.2 Front End Optics

The portion of the device that relays the pupils and images the retina.

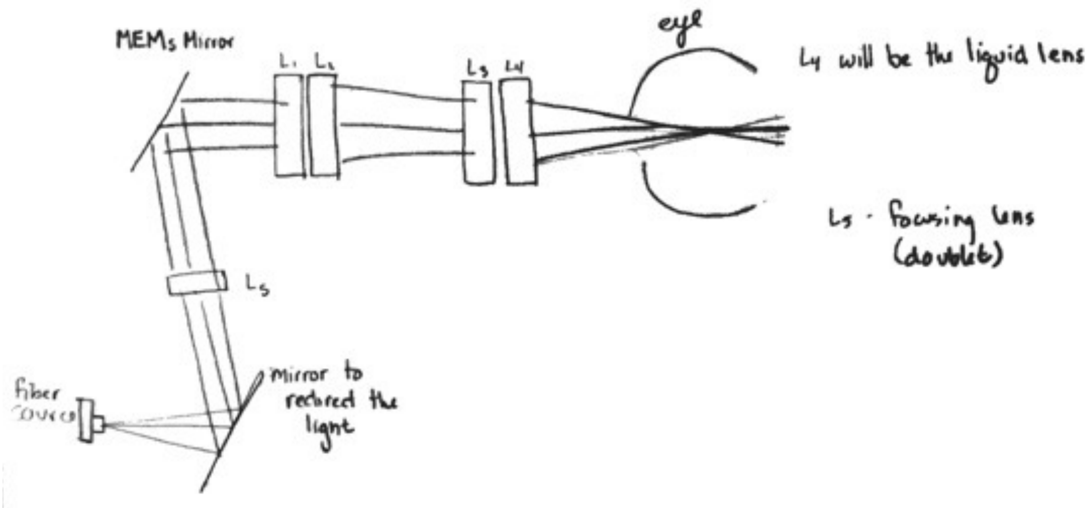


Figure 5: Our system takes inspiration from the Compact Hand-held design and this is one of the preliminary sketches. The L4 lens refers to the liquid lens, which is one of the desired features, but not a required on. This sketch shows the probe for one eye. If we were to do the system in this manner we would need two probes, including to MEMs scanning mirrors

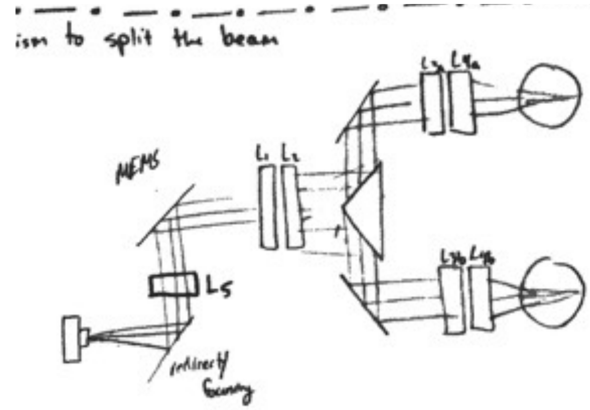


Figure 6: This method would require only one MEMs, but the alignment would be significantly more difficult. The ability to adjust the eyepieces to fit any person would also become more challenging as the path length for each eye must remain a fixed distance

The customer has decided that they prefer the system depicted in figure 5, but would like another pupil relay to have more control of the alignment in the design.

6.3 Light Delivery Arm

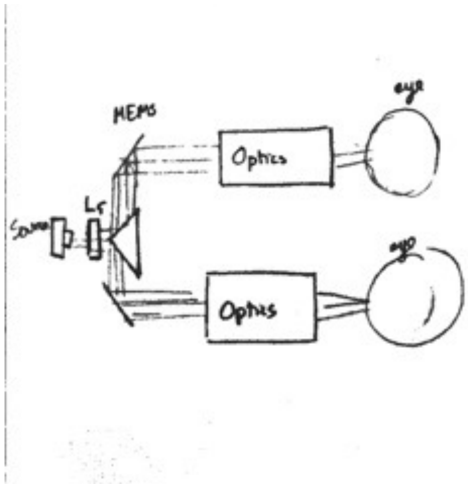


Figure 7: The light comes from a single source and is separated into a left and right path by a knife edge prism

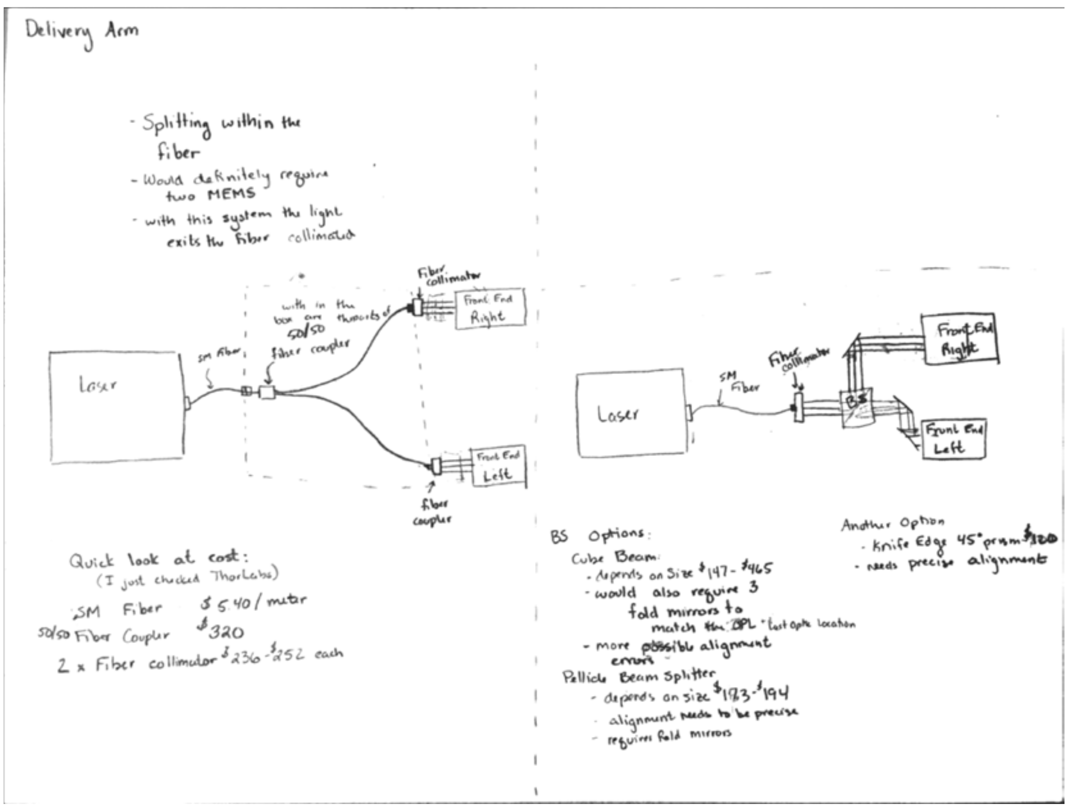


Figure 8: Methods that we are considering in addition to the knife edge prism are using a fiber coupler and splitting the light before it leaves the fiber (left portion of the image). This has the benefit of more easily positioning the left and right eye piece for each eye quickly. The image on the right is using a beam splitter

The customer has decided that they would like the fiber coupled option illustrated on the left side of Figure 8.

6.4Light Collection Arm

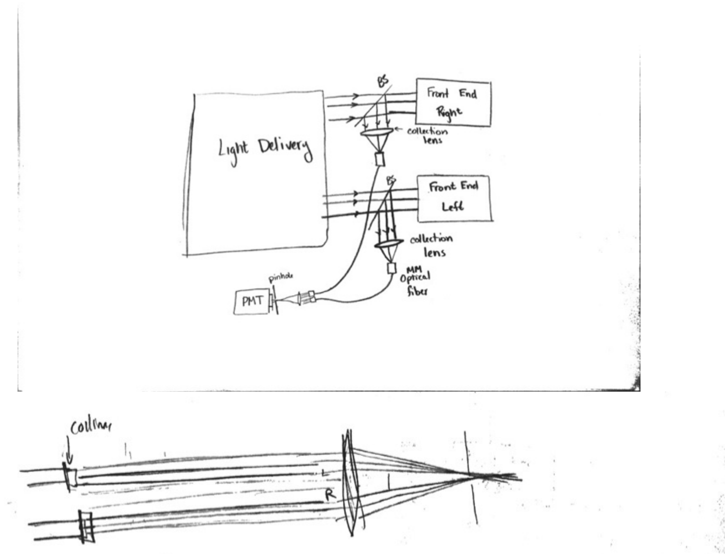


Figure 9: In order to collect the light, we plan on using beam splitters to redirect the light and then collect it into an multimode optical fiber to relay it to the PMT in order to image the retina.

The customer has indicated that as long as we remain in the budget, we may use two PMTs (or whichever detector we choose) in order to image both eyes simultaneously, which negates the need for an optical fiber relay.

7. Not Responsible For

- Software development to decipher the image

8. Schedule

8.1 January

11 – 13: Trip to C.Light technologies, Berkeley, CA to present the idea to the company.
25: Detailed Design Review (DDR) of the Front End Optical design
30: DDR of the Light Collection and Delivery Arms, order necessary materials

8.2 February

8: DDR of the Opto-mechanical Components and the Enclosure Design (consult a mechanical engineering advisor for the enclosure design)
Remainder of February: Order Necessary parts and materials

8.3 March

15: Begin Assembly of the device
22: Preliminary Testing of the Device

8.4 April

Testing the device

8.5 May

Design Day

Appendix A

In relation to our product:

Our initial thought was trying to reduce the amount of mirrors that are used in her design such that we can decrease the weight and size, but it was not enough so that the device can be hand held. Thus, we decided to look for other similar designs, that used refractive relays instead of reflective ones. The number of elements could also not be reduced as the scanning mirrors need to remain in pupil conjugate positions in order to correctly scan and de-scan the retinal image.

Abstract:

The development of high magnification retinal imaging has brought with it the ability to track eye motion with a precision of less than an arc minute. Previously these systems have provided only monocular records. Here we describe a modification to the Tracking Scanning Laser Ophthalmoscope (Sheehy et al., 2012) that splits the optical path in a way that slows the left and right retinas to be scanned almost simultaneously by a single system. A mirror placed at a retinal conjugate point redirects half of each horizontal scan line to the fellow eye. The collected video is a split image with left and right retinas appearing side by side in each frame. Analysis of the retinal motion in the recorded video provides an eye movement trace with very high temporal and spatial resolution. Results are presented from scans of subjects with normal ocular motility that fixated steadily on a green laser dot. The retinas were scanned at 4 eccentricity with a 2 square field. Eye position was extracted offline from recorded videos with an FFT based image analysis program written in Matlab. The noise level of the tracking was estimated to range from 0.25 to 0.5 arc min SD for three subjects. In the binocular recordings, the left eye/right eye difference was 1–2 arc min SD for vertical motion and 10–15 arc min SD for horizontal motion, in agreement with published values from other tracking techniques.

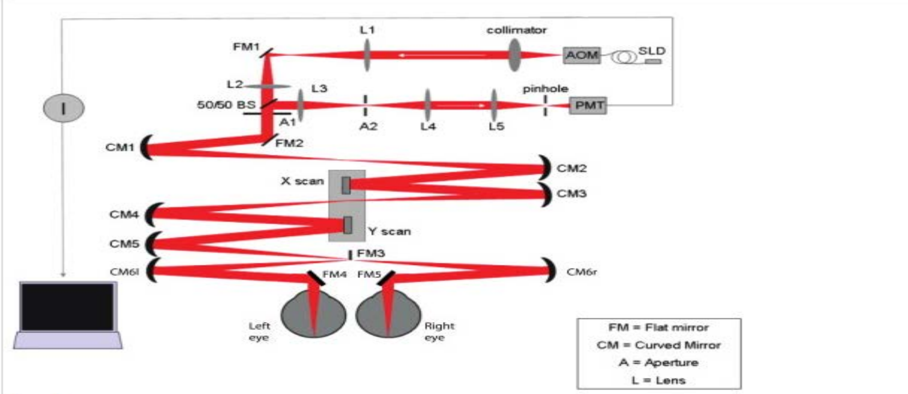


Fig. 1.
Schematic layout of the binocular modification to the Tracking Scanning Laser Ophthalmoscope (modified from Sheehy et al., 2012). Mirror FM3 is placed at a retinal conjugate point, splitting the field into left eye and right eye halves. Each half of the scan is reflected by a concave mirror and a flat mirror into the respective eyes. The resulting scan produces a split field image with left and right retinal images side by side in the each frame. The horizontal scanner is a polished bar resonating at 15.4 kHz and images are collected during a 26 μs time window during one direction of scan, so left and right eye samples are collected about 13 μs apart. Eyes are not shown to scale.

Figure 1: Our customer's current design for a reflective Binocular System

Appendix B

In relation to our product:

This scholarly article is our inspiration and starting point for our design. It is light weight, handheld and capable to capture the retinal imaging. Through this paper, we see the potential of making our project possible and apply to normal adults. The challenges in adapting this approach to work for our design is that we need to expand the field of view and create it in a way that both eyes can by imaged simultaneously.

Abstract:

Handheld scanning laser ophthalmoscopy (SLO) and optical coherence tomography (OCT) systems facilitate imaging of young children and subjects that have difficulty fixating. More compact and lightweight probes allow for better portability and increased comfort for the operator of the handheld probe. We describe a very compact, novel SLO and OCT handheld probe design. A single 2D microelectromechanical systems (MEMS) scanner and a custom optical design using a converging beam prior to the scanner permitted significant reduction in the system size. Our design utilized a combination of commercial and custom optics that were optimized in Zemax to achieve near diffraction-limited resolution of 8 µm over a 7° field of view. The handheld probe has a form factor of 7 x 6 x 2.5 cm and a weight of only 94 g, which is over an order of magnitude lighter than prior SLO-OCT handheld probes. Images were acquired from a normal subject with an incident power on the eye under the ANSI limit. With this device, which is the world's lightest and smallest SLO-OCT system, we were able to visualize parafoveal cone photoreceptors and nerve fiber bundles without the use of adaptive optics.

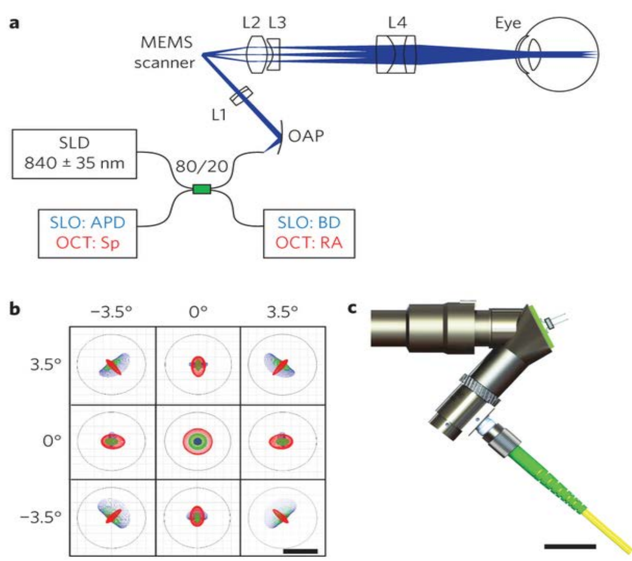


Figure 1: Layout of the design with spot diagram color coded for three wavelengths for both SLO and OCT illuminating on to the retinal with a field of view of 7 degrees.

Figure 3: High-resolution retinal images acquired on healthy young children.

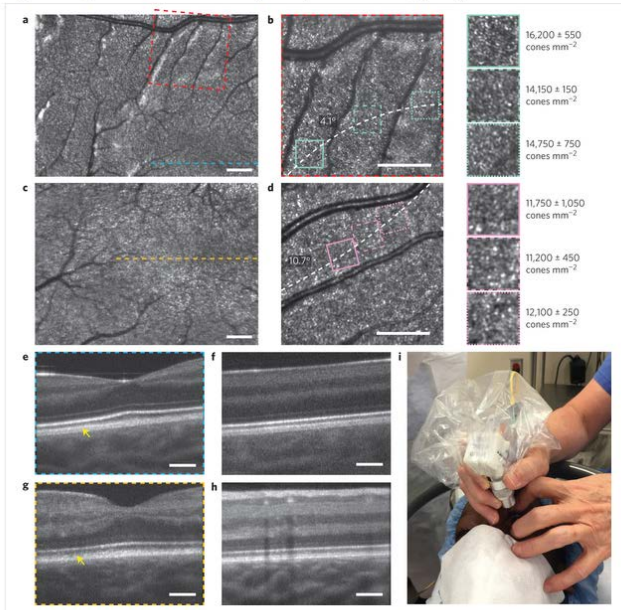


Figure 2: quality of images that is captured by the device.

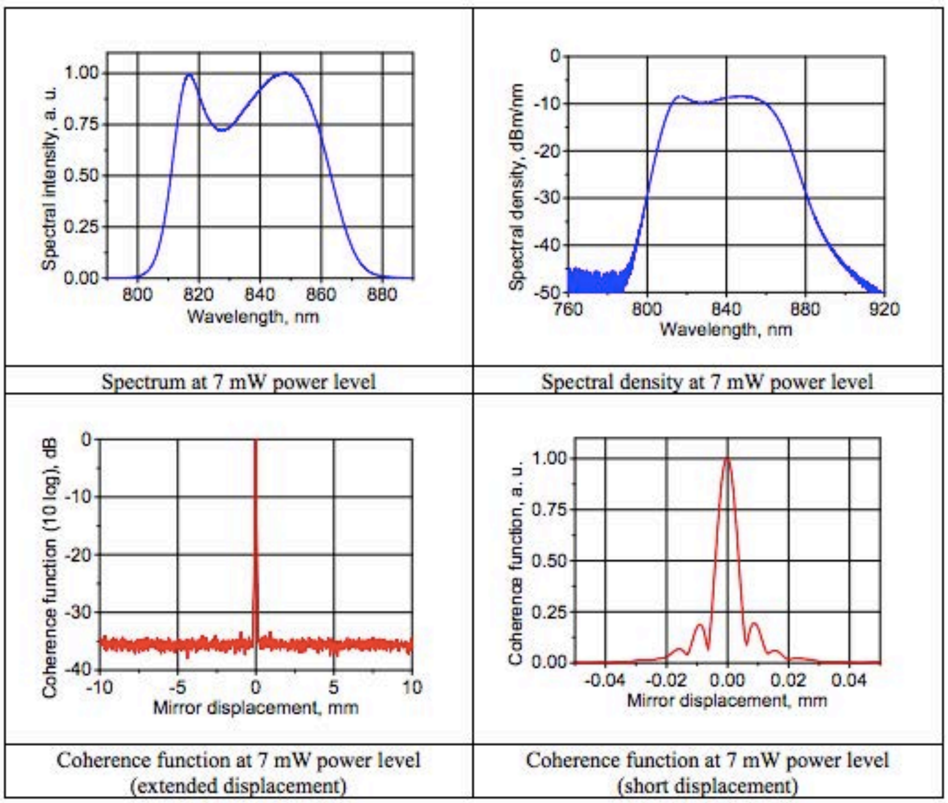
Appendix C

The current laser source for C.Light's device. This laser is for table-top use and is not ideal for a more compact handheld design, but it is the starting point for choosing another laser.

Superlum M-S-series BroadLighters. Benchtop Broadband Light Source

SUPERLUM

M-S-series BroadLighters. Benchtop Broadband Light Sources.
M-S-840-B-I-7. Performance Examples.



Spectrum at 7 mW power level

Spectral density at 7 mW power level

Coherence function at 7 mW power level (extended displacement)

Coherence function at 7 mW power level (short displacement)

Superlum, Unit B3, Fota Point Enterprise Park, Carrigtwohill, Co. Cork, Ireland.
Phone: +353 21 4533666, Fax: +353 21 4533026, Web site: www.superlumdiodes.com, E-mail: sales@superlum.ie.

References

Larocca, Francesco, Derek Nankivil, Theodore Dubose, Cynthia A. Toth, Sina Farsiu, and Joseph A. Izatt. "In Vivo Cellular-resolution Retinal Imaging in Infants and Children Using an Ultra Compact Handheld Probe." *Nature Photonics* 10.9 (2016): 580-84. Web.

Stevenson, S.b., C.k. Sheehy, and A. Roorda. "Binocular Eye Tracking with the Tracking Scanning Laser Ophthalmoscope." *Vision Research* 118 (2016): 98-104. Web.

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