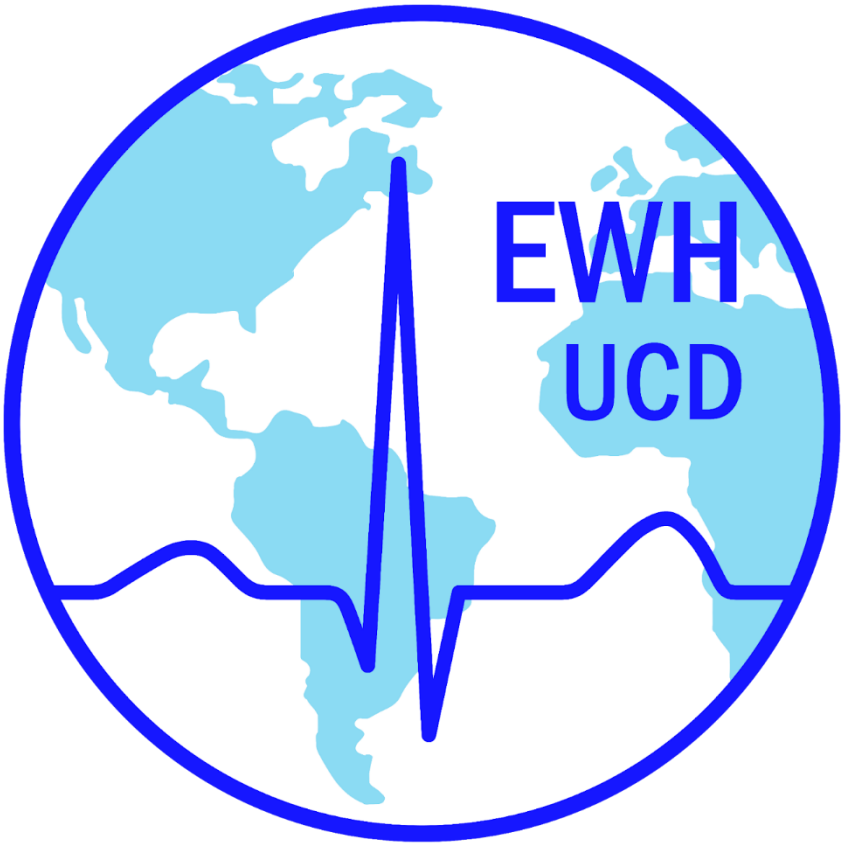

Engineering World Health Design Competition 2022

Vit-A-Dapt

A low-cost, portable adaptometer with no disposables which can be used in the potential screening for Vitamin A deficiency in children over five and pregnant women.

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1. Problem Definition

Vitamin A deficiency (VAD) is a public health problem in more than half of all countries but is far more common in low and middle-income countries (LMICs) [3]. The most severe effects of VAD occur in children and pregnant women. It is estimated that 250-500k children who are Vitamin A deficient become blind every year, and 50% of those children die within 12 months of losing their sight [3]. VAD also is associated with significant morbidity and mortality from common childhood infections due to it diminishing the child's ability to fight infection and is also the world's leading cause of preventable childhood blindness [8].

VAD can cause many symptoms including diminished ability to fight infections, increased risk for respiratory and diarrhoeal infections, decreased growth rate, and slow bone development [3]. "94,500 deaths from diarrhoea and 11,200 deaths from measles were attributable to Vitamin A deficiency in 2013" [8]. Nyctalopia (night blindness) is the earliest and most common symptom of VAD [6].

Nyctalopia is the abnormal inability to see well at night or in dim light. It is a symptom of a disease rather than a disease in itself and has several causes including retinitis pigmentosa and VAD [7]. There are two main types of photoreceptors in the retina, rods and cones. Vitamin A is a precursor to rhodopsin, which is a photopigment found in rod cells. Rods are essential for vision at night and in low lighting conditions. Without Vitamin A, rhodopsin cannot form, the eye fails to dark adapt, and nyctalopia occurs [9].

Dark adaptometry refers to the slow recovery of visual sensitivity in darkness following exposure to intense or prolonged illumination (bleaching) [1]. Dark adaptation can be measured using a device known as an adaptometer. Adaptometers work by first exposing the subject to a bright light which bleaches the photopigment in the eyes, and then by evaluating different detection thresholds over time and plotting them onto a dark adaptation curve. The dark adaptation curve and its key features such as the rod intercept time can then be analysed by a medical professional and used to indicate the potential for diseases such as VAD.

If VAD is found early, complications such as visual function have the potential to be recovered with repletion therapy [6]. Since nyctalopia is one of the earliest and most common symptoms of VAD [2] [6], it is likely that a dark adaptation test can screen for VAD in its early stages, allowing for early intervention.

Our clinical needs statement is:

A low-cost, portable, adaptometer with no disposables which can be used for the potential screening for Vitamin A Deficiency in children over five and pregnant women.

2. Impact in Low and Middle Income Countries

Providing an accessible method for indicating VAD in children and pregnant and lactating women will result in a fast and efficient means for an increased portion of the population in South-East Asian countries to receive corrective treatment. This corrective or preventative method can come in the form of altered diet to increase Vitamin A rich foods and/or the introduction of synthetic Vitamin A supplements [21].

The current methods of Vitamin A diagnosis include using blood tests, electroretinograms (ERGs), electro-oculography (EOGs), adaptometers, and a clinical assessment of the eye.

Although commonly used, blood tests are highly invasive. They also carry issues independent to the other methods listed including delayed results, needlestick injuries (NSIs) and special waste disposal practises. Hospital procedures that require needles are said to be one of the most feared and painful for children [22]. NSIs are also very common among healthcare professionals worldwide. Furthermore, it is approximated that 75% of the NSIs that occur in LMICs remain unreported, which leads to a host of other issues and is a motive to avoid the use of needles [23].

A medical evaluation of the eye is performed to screen for the various eye signs of VAD in children. The grades of the eye signs of VAD are as follows [5]:

- Night blindness (XN)
- Conjunctival xerosis (X1A)
- Bitot's spots (X1B)
- Corneal xerosis (X2)
- Corneal ulcer covering less than ⅓ of the cornea (X3A)
- Corneal ulcer covering at least ⅓ of the cornea, defined as keratomalacia (X3B)
- Corneal scarring (XS)

However, many children who have VAD will not have the eye signs [5], which makes diagnosis by eye evaluation difficult.

ERGs and EOGs are used to evaluate night blindness and subsequently VAD. While these tests are completely objective in contrast to adaptometers, they are highly invasive [31]. ERGs have not been used in large-scale studies due to the high costs and associated logistics. The eyes must be anaesthetised before placing contact lens electrodes on the eyes. Children may need to be sedated, and according to an experienced technician whom we consulted, some children cannot tolerate an ERG at all.

The equipment costs of ERG and EOG tests can exceed $40,000 and the other consumables and training of staff also make this test expensive and not suitable for large-scale community assessment.[4]

In the field of dark adaptometry, the benchmark is set by Maculogix, with their tabletop AdaptDx, and their portable headset AdaptDx Pro. While both machines produce very reliable results and are minimally invasive, they come at a high cost. The AdaptDx costs $39,900 per machine [32], while the cheapest option for the AdaptDx Pro is $44,900 [33]. Adaptometers are generally used in children over the age of 5 due to the need for the subject to follow instructions and to concentrate for an extended period of time.

Our low cost adaptometer bridges the gap in the market for an accessible and easy to use, portable screening device. The required training for the operator will also be minimal. The testing is non-invasive, the equipment is cheap and portable and there are no long delays associated with offsite processing of test samples, with feedback produced almost immediately after testing. Children account for approximately 30% of VADs worldwide and almost 50% of the cases in India [24] [25]. Pregnant women in India are confirmed to have a higher prevalence of night blindness, an eye sign of VAD. Also, other South-East Asian countries such as Pakistan the risk of VAD is 70% higher for pregnant women [26]. In comparison to the previously discussed screening methods, we believe Vit-A-Dapt would be better suited to our target population of children and pregnant women as we aim to combat this major issue.

3. Required Performance Specifications

The aim for Vit-A-Dapt is to provide a potential screening tool for VAD in low resource areas in South-East Asia; it is not intended for diagnosis. The device must be able to meet minimum technical requirements in order to effectively screen for VAD [18]. The minimum technical requirements that Vit-A-Dapt needs to run the test procedure are: a bleaching light, fixation light, test light, push button and Arduino microcontroller. We also require movable chin and brow rests to optimise the test. The functions of each are as follows:

Component	Function
Bleaching light	Green light floods subject's retina with photons
Fixation light	Red light remains on for subject to focus on during test
Test light	Green light which flashes for 250ms at intervals of 2500ms as per test procedure
Push button	Allows subject to acknowledge test light
Arduino microcontroller	Controls operation of lights and relays data back to computer
Movable chin + brow rest	Allows correct alignment of pupil for each individual subject

Table 1. Device components and their associated function

The Vit-A-Dapt must also be able to provide accurate results while being portable and cost effective. Ease of use must also be considered as ideally minimal training should be required to use the device correctly.

We visited the optometry department of a university research hospital to view and test their Maculogix AdaptDx. We learned that a fast bleaching light, as used by Jackson et al. (0.8 seconds) is only trustworthy if you can accurately determine where on the eye it will hit. The AdaptDx contains a camera and movable chin rest to allow the operator to continuously align the subject's pupil perfectly. We do not have the camera included in our design to save on cost. In lieu of this, we have chosen to use a bleaching method more similar to that of the Goldmann-Weekers adaptometer which we viewed in another research hospital. The chamber for our device will be curved and coloured white. We have chosen white as it has a high albedo value, which optimises the bleaching of the eye. We will perform a slower bleach at a lower intensity, but we aim to bleach the full eye, instead of a concentrated small area as in the Adapt DX protocol. This removes the need for monitoring the pupil before and during the test. Using a slow bleach means we can use cheaper LEDs and less power.

From our visit we learned that the test light should have a filter in front of it, to prevent the subject seeing a bare led. We have chosen to include a neutral density filter to perform this function.

In the AdaptDX protocol, corrective lenses were used to optimise the subject's vision for the test [19]. We are currently omitting corrective lenses from our design in order to reduce costs. If the subject had visual impairments, they would have to wear their corrective lenses for the test. The option to use corrective lens is incorporated into our design, but they are not planned to be provided with the device in order to reduce cost.

There are a number of additional features which we would add for our ideal device, as detailed below:

Component	Component
Corrective lenses	Selection of corrective lenses to slot into eyepiece to optimise subject's vision
Camera	Track pupil and ensure correct alignment
Neutral Density Filter	Neutralises test light for subject comfort
Buzzer	Indicates to the patient when to stop and start breaks

Table 2. Potential Additional Components

3.1 Failure Modes Effect Analysis

Item	Function	Failure Mode	Effect	Cause	Occur. Score	Severity Score.	Detection Rating	CN Value	RPN Value	Action
Fixation Light	Remains always on.	Turns off.	Subject has no target to focus on, test is compromised.	Loss of power, loose connections, Arduino malfunctions.	2	8	2	16	32	Ensure connections secure, Ensure secure power connections, quality testing before distribution.
Bleaching Light	Turns on for bleaching period.	Doesn't turn on.	Bleaching does not occur, test is compromised.	Loss of power, loose connections, Arduino board malfunctions.	2	8	2	16	32	Ensure connections secure, Ensure secure power connections, quality testing before distribution.
Test Light	Flashes at different lux values.	1) Light doesn't turn on. 2) Lux value doesn't change.	1) Test fails. 2) Test fails as subject's DA cannot be found.	1) Loss of power, loose connections. 2) Arduino board malfunctions.	2	8	2	16	32	Ensure connections secure, Ensure secure power connections, quality testing before distribution.
Chin and Brow Rests	Adjust head position of subject.	1) Chin rest breaks. 2) Chin rest fails to adjust.	1) Subject cannot use head rest. 2) Test results un-reliable, wrong part of eye targeted.	1) Poor manufacturing, excessive force applied. 2) Connections too tight, rust, mechanism breaks.	1	7	3	7	21	Quality testing before distribution, ensure bearings well designed and lubricated.
Buzzer	Sounds to alert subject to stop and start breaks.	Does not sound.	Subject does not know to take a break, excessive strain on eyes.	Loose connections, loss of power, Arduino malfunctions.	2	6	2	12	24	Ensure connections secure, Ensure secure power connections, quality testing before distribution.

Push Button	Allows subject to acknowledge when test light has been seen.	Push button does not register.	Subject's acknowledgment of the test light is not registered.	Loose connections, loss of power, Arduino board malfunctions.	4	8	2	32	64	Ensure connections secure, Ensure secure power connections, quality testing before distribution.
Arduino	Controls LED and sends data to computer.	1) Arduino board fails to control test lights. 2) Arduino board fails to send data to computer.	1) LED doesn't shine at correct values, test compromised. 2) Data is not collected for test, results unknown.	Arduino board is faulty, loose connections, incorrect circuitry, incorrect code.	3	8	2	24	48	Ensure connections secure, Ensure secure power connections, quality testing before distribution. Test circuitry functions as intended before launch. Test code functions as intended before launch.

Table 3. FMEA table

The risk priority numbers (RPN) values are classified with a traffic light system where green indicates clearly a low-risk priority, yellow indicates a medium risk priority and since the device does not pose a high risk - no red is indicated.

4. Implementation of Prototype

Vit-A-Dapt will allow an operator to perform a standard test protocol to assess a subject's ability to dark adapt. This will be done by the subject placing their head on an adjustable chin and brow rest to stabilise the position of the eye relative to the device. Corrective lenses can then be applied to correct vision defects to enable a focused view of the test and fixation lights. The subject will then be bleached to photoconvert at least 70% of the rhodopsin in a single eye in accordance with the Adapt DX and Goldman-Weeker protocols. The subject is then asked to look directly at a red fixation light to allow for the testing of a specific region of the eye. A test light will then flash at varying intensities as per the test protocol explained below in section 4.2. This test protocol will provide the operator with a series of values for time and intensity of the test light. These will be plotted, and a rod intercept time will be extrapolated. These values are used to assess the subject's ability to dark adapt which can be used as an indicator of VAD.

4.1 3D Model

Vit-A-Dapt consists of 4 main parts, the frontend and backend of the adaptometer, a handheld button, and the stand. The structure of the device is split into multiple parts to improve the portability and functionality of the adaptometer. Engineering drawings have been included in this section with rendered CAD models included in Appendix A.

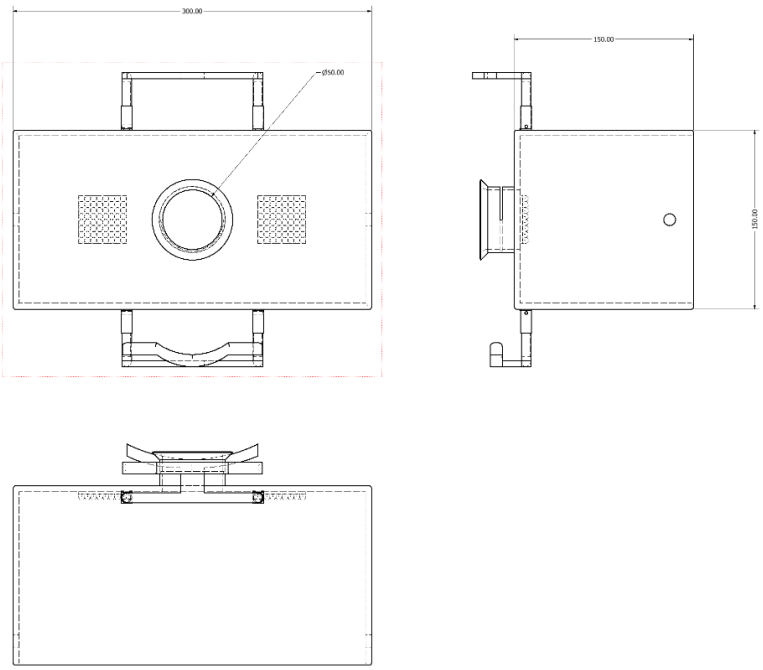


Figure 1: Frontend of the Device

The frontend of the adaptometer consists of an eyepiece, lens holder, brow rest, chin rest, LED bleaching arrays and the front half of the adaptometer chamber. The eyepiece has an inner diameter of 50mm and a depth of 15mm to allow the subject to see unobstructed into the chamber. It includes a slot for placing a trial lens to enable correction for myopia or hypermetropia, allowing the subject to clearly see the test and fixation lights.

The brow rest and chin rest are designed according to South-East Asian facial anthropometric data [10]. To account for the variation of head shapes between children and adults, the rests can translate up and down as well as forward and backwards. The brow rest and chin rest move from side to side to allow for the accurate positioning of either the right or left eye relative to the eyepiece. The brow rest and chin rest exhibit rotation towards the eyepiece to minimise storage size for transportation of the device.

The front half of the chamber is a 300x150x150 mm shell of thickness 5mm with an open rear face. There are two holes 20mm from the back face which enable the locking clips on the backend of the adaptometer. The two LED bleaching arrays are positioned on the inside face of the front half of the chamber on either side of the eyepiece. These arrays consist of 8x8 LEDs which flood the chamber with constant light intensity for a set duration in accordance with the testing protocol. The final component incorporated into the frontend of the adaptometer is the buzzer which signals to the user when to take a break and when to resume.

The backend of the device consists of a 290x140x140 mm shell of thickness 5mm with an open front face. It has two locking clips 20mm from the front face which keeps a fixed distance between the eyepiece and the fixation and test lights. The inside of the chamber is white and curved to reflect the light from the bleaching array and enable an even bleach. The test light is positioned directly in front of the centre of the eyepiece, 258mm away when the two halves are locked together. The distance from the surface of the eyepiece to the rear internal surface of the eye is 42mm [11][12], which keeps the test light and the receptive surface in the eye at the specified distance of 30cm. The fixation light is positioned 63.77mm above the test light. This gives rise to a 12° viewing angle, which is ideal because the density of rod cells at this location in the eye is relatively high. The area located behind the curve will house the Arduino unit and the main circuitry of the device with cables leaving the backend to the bleaching arrays, buzzer, and the push button.

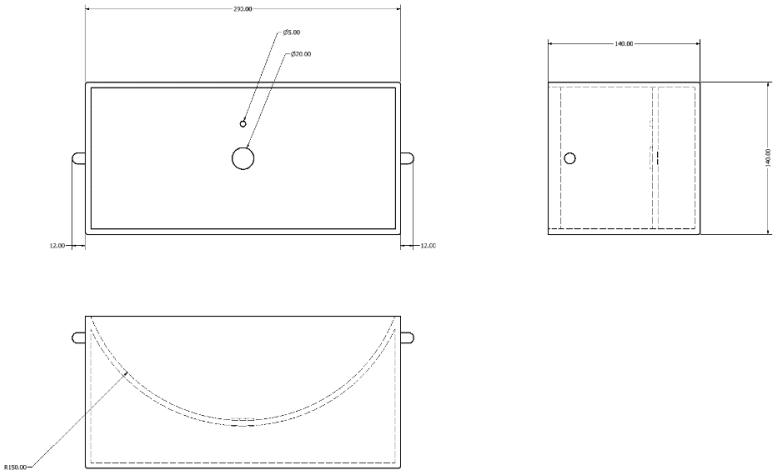


Figure 2: Backend of the Device

The button used to record when the test light is visible is a handheld push button attached to the backend of the device by cable.

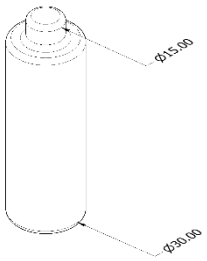
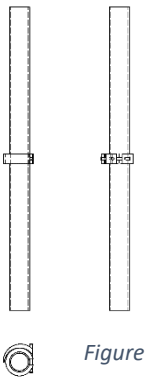


Figure 3: Push Button of the Device



The stand is a telescopic shaft with a simple post clamp, similar to those found on bicycle seat posts. This enables a firm fixation which supports the weight of the device and head of the subject. The base of the stand would be a simple tripod to provide stability and prevent movement of the device and subject throughout the test.

Figure 4: Stand of the Device

4.2 Process Design

To effectively screen for VAD, a consistent process must be carried out every time. Therefore, it was important to implement a test procedure that would provide accurate results and be feasible to perform with cost effective equipment.

Firstly, the subject must be positioned appropriately to ensure that they are aligned with all the pieces of equipment correctly. Once the patient has been positioned correctly, the lights in the test room should be turned off and the subject should remain in the dark until the test is complete.

The subject must have their eyes bleached at the beginning of the test. To bleach the subject's eyes, the subject will be exposed to light with maximum intensity for 5 minutes. The bleaching light is reflected on the curved screen before reaching the subject's eyes which allows for the full eye to be bleached.

Once the bleaching is complete, the subject will be asked to focus on the fixation light which is positioned 30cm from the subject and 12° above their eye. The test light which is 63.77mm below the fixation light will then begin to flash at intervals. The test light will flash for a period of 250ms seconds every 2500 ms.

The test light will begin at an intensity of 1 lux. Once the subject has acknowledged the test light, the intensity of the test light will decrease by 0.3 log units. If the subject fails to acknowledge 3 flashes of the test light, the test light will decrease by 0.1 log units [19]. If the subject continues to fail acknowledgment of the test light it will begin to increase by 0.1 log units. If the subject has acknowledged the test light after a 0.1 log unit increase in intensity, they will be shown the same test light intensity again. Once the subject responds to the test light of equal intensity twice, a threshold point has been reached. The subject is given a 15 second break every time a threshold point is reached, this is signalled by a buzzer sounding and 5 seconds prior resuming the next run through [20].

On resuming the test, the test light should be 0.2 log units brighter than the intensity that was detected at the threshold point. The test is complete once the intensity of the test light has dropped 3 log units from the initial point.

The test data collected is the time at which the subject acknowledges the test light flashing and the level of intensity of the test light when they acknowledged it. A dark adaptation curve is plotted to determine whether the subject has dark adapted.

The complete designed test procedure is shown in the flow diagram in Appendix B.

4.3 Prototyped Circuit Design

An Arduino Mega was used to prototype the fixation light, the bleaching light, and the test light. Two circuit boards are currently required, one to set up the test light and fixation light circuit and another to set up the bleaching light circuit. A red LED was used for the fixation light, a green LED was used for the test light, and a set of green LEDs were used for the bleaching light. A pushbutton was used to allow the subject to acknowledge the test light. A 10kΩ resistor was also required to protect the LEDs from burn out on the test light and a 10Ω resistor was used on the bleaching light circuit. Using LEDs allows for the intensity to be changed by using Pulse Width Modulation (PWM) which is a key component of the process design.

By using an Arduino Nano and LEDs in our final design, it guarantees that Vit-A-Dapt should be low cost. The schematic of the test light circuit and combined fixation and test light circuit is shown in Appendix C.

4.4 Prototyping

A CAD model has been developed, the drawings of which can be seen in section 4.1 with more in Appendix A. This model was created to facilitate the manufacture of an accurate prototype to enable further troubleshooting of the device design and process.

A simple cardboard model of the prototype was created for preliminary testing. This can be seen in Appendix D. This involved a shoe box with the inside covered in white paper to maximise reflectiveness of the bleaching light. The microcontroller and breadboards can be housed just outside the shoebox. The test light, fixation light and bleaching lights were all positioned in the prototype as specified in section 4.2.

5. Proof of Performance

5.1 Light Intensity Calculations

The perceived output of the green LED bulb in lux was found experimentally for the various input PWM values. A BH1750 Light Sensor (lux meter) was used in conjunction with the Arduino Mega board in order to evaluate the levels of light intensity. The lux meter and LED were lined up and fixed in place at a distance of 0mm from each other. This distance was used due to the limitations of the lux meter which could only measure lux values to two decimal places and since light intensity decreases proportionally to the inverse square of the distance between the light source and light sensor. The light intensities can then be calculated at various distances based on the 0mm data obtained.

The relationship between the input PWM and the perceived light intensity was found to be linear. The light intensities were calculated for various distances, and it was found that the most useful operating range could be obtained when the distance between the eye and test light was 30cm. The equation of this line relating PWM and light intensity was found and the relevant values in log steps were obtained. These were then put back into the equation and the test values for PWM were obtained.

The resulting operating range covered 20 points over 2 decades. The light intensity can range from 1 lux down to 0.01 lux in log steps of 0.1 and has one extra step of 0.007lux which is 0.3 log unit steps below the previous value shown in Appendix E. Due to the internal timer in the Arduino Mega board being an 8-bit timer, only PWM values of 0-255 can be used. If a 10-bit or 16-bit timer could be implemented instead, more discrete values of light intensity could be emitted, and a larger operating range could be used. Another option would be to make use of a variable resistor and have the circuit switch resistances to allow for a broader range of values.

5.2 Arduino

The ability of the test light to decrease in intensity was verified by printing the output of the test light in PWM and the time to the Arduino's serial monitor which is shown in Appendix F. The code that was used to implement this can be seen in Appendix G. This data was imported into MATLAB to plot points for the adaptation curve graph shown in Appendix F. The equation of the line found experimentally was used to change the PWM values to lux. Although it was verified that the test light was able to decrease in intensity as expected, we did not manage to incorporate the test light increasing in value when the subject has failed to acknowledge a flash. Further improvements would be introduced to incorporate this in the final design. We would also look to allow the test light to increase in intensity after the subject fails to acknowledge 3 flashes as this increases the accuracy of the test.

The reliability of the button was verified by counting the number of times the button was being pressed. While we were testing the push button, we ensured that the push button counter corresponded correctly to the number of times the button had been pressed. Initially the counter would be incorrect and higher than the actual number of pushes, this was due to the bounce that the button was experiencing but in the final prototype this was successfully eliminated.

Visually it can be verified that the test light flashes every 2500ms for a period of 250ms while the fixation light remains on for the duration of the test.

5.3 Testing the Cardboard Model on Subject

The cardboard prototype was used to test the adaptometer model on a single test subject. This was due to time constraints after building the prototype. The subject tested did not have VAD or any other disease that affects the rod cells in the eye and therefore were a control. The results and graph can be seen in Appendix H. The subject had their eyes bleached for 5 mins in a completely dark room. The test circuit was switched on and the subject pressed the button each time they saw the green light flash.

On testing in a dark room with the shoebox closed and the subject's face on the eyepiece, the light meter reads zero lux inside the box as is required.

From the testing, we confirmed that the operating range is not currently large enough to effectively obtain a full dark adaptation curve. The general principles do work, but it has not yet reached a standard high enough to effectively screen for VAD. Some potential future ways to combat the operating range limitations were discussed above in section 5.1. Future iterations of the prototype will incorporate a larger operating range as well as the test light increasing and decreasing as per the process design. This would then be tested on more subjects for validation.

5.4 Minimum Specification Requirements

Component	Function	Achieved In Prototype?
Bleaching light	Green light floods subject's retina with photons	Yes
Fixation light	Red light remains on for subject to focus on during test	Yes
Test light	Green light which flashes for 250ms at intervals of 2500ms as per test procedure	Yes
Push button	Allows subject to acknowledge test light	Yes
Arduino microcontroller	Controls operation of lights and relays data back to computer	Yes
Movable chin + brow rest	Allows correct alignment of pupil for each individual subject	No – To be added in future iterations

Table 4. Device component functional checklist

At the beginning of designing our prototype we defined a list of required design specifications. Of the 6 specifications we set out to achieve, 5 were accomplished. The only one which we failed to achieve was movable brow and chin rests to allow correct alignment of the eye before testing. In future iterations we would aim to create more advanced prototypes which incorporate the movable chin and brow rests, as well as a neutral density filter and a buzzer. In our ideal device, we would include the corrective lenses and camera to track pupil movement.

See Appendix D to view the prototype in action.

6. Business Plan for Manufacture and Distribution of Technology

6.1 Target Market

Vit-A-Dapt will be marketed toward South-East Asia (SEA) with a specific focus on India, which has the highest prevalence of both clinical and subclinical VAD in these regions. Currently there are 330,000 child deaths which can be linked to VAD in India annually, so our focus is on reducing VAD related child mortality and other effects [26].

There are also many Non-Governmental Organisations (NGOs) and charities currently working in the area to combat the major issue such as 'SEVA' and 'GAIN', providing us with potential partnership and funding opportunities. By partnering with local organizations, Vit-A-Dapt is more likely to be successfully accepted in the communities and medical centers.

6.2 Materials & Manufacturing

The materials for Vit-A-Dapt have been chosen to make the portable device both lightweight and durable. We also aimed to manufacture Vit-A-Dapt out of accessible and easily replaceable parts in order to be low maintenance and easy to fix ensuring its longevity.

The chamber, brow rest and chin rest will all be composed of acrylonitrile butadiene styrene (ABS). This is a common thermoplastic polymer that offers a balance with impact, heat, chemical and abrasion resistance, dimensional stability, tensile strength, and rigidity at a very low cost. It is also suitable for use in 3D printers enabling us to easily manufacture Vit-A-Dapt at a low cost during the early stages of the roll out.

Aluminium will be used for the telescopic poles, post clamp and stand base as it is a lightweight, low-cost metal. There are also many external suppliers for the parts, allowing easy replacement of parts in LMICs if required.

The circuitry of Vit-A-Dapt is extremely simple, again made with readily available materials, requiring only a soldering iron to fix or replace components. LEDs are used for the bleaching, test and fixation lights due to their low cost, low power consumption [17] and smaller size than a traditional gas light bulb [34]. The Arduino Nano is chosen to run the protocol and control the circuit components in Vit-A-Dapt as it is an extremely low-cost device and has 22 input and output pins, allowing us to run the test protocol from a single board. A full breakdown of the components and associated costs can be seen in Table 5.

Part	Quantity	Cost PU ($)	Manufacturing method
Fronthalf of Chamber	1	5.46	3D Printed
Backhalf of Chamber	1	6.25	3D Printed
Telescopic Poles	4	0.88	External Supplier
Telescopic Stand Pole	1	1.22	External Supplier
Stand Base	1	2.56	External Supplier
Post Clamp	1	1.49	External Supplier
Chinrest	1	3.12	3D Printed
Headrest	1	2.78	3D Printed
8x8 LED Array	2	0.53	External Supplier
Green LED	1	0.1	External Supplier
Red LED	1	0.1	External Supplier
Filter	1	0.47	External Supplier
Arduino Nano	1	5.12	External Supplier
Handheld Button	1	1.53	External Supplier
Wires	1	1.2	External Supplier
Buzzer	1	0.4	External Supplier
	Total Cost	**$36.38**	

Table 5. Device Part costs Per unit

From the discussion above the equipment that is required for the initial manufacture of Vit-A-Dapt is listed in Table 6, below.

Manufacturing Equipment	Cost PU ($)
Ender-3 S1 (3D printer)	370
Soldering Iron	10

Table 6. Manufacturing Equipment used for device production

Due to the low cost of Vit-A-Dapt components and limited manufacturing requirements, we expect to be able to market Vit-A-Dapt at approximately $52, with a 30% markup on the cost of materials and production. Profits from Vit-A-Dapt will be funded back into the company to improve and expand the manufacturing set up. When compared to the $39,000 cost of the Adapt DX [32] Vit-A-Dapt, despite its lower functionality, still fills a large gap in the market as a screening tool for dark adaptation.

6.3 Roll Out

Our **first future step** involves testing the current iteration of our prototype on friends and family to test the general operation of Vit-A-Dapt and the process of using Vit-A-Dapt. We will use this initial data to alter the design of our prototype before the creation of a second iteration of the prototype using the 3D printer currently owned by the EWH chapter to keep initial costs low.

Using this iteration of the prototype, we hope to work with the university hospitals and research centres that we have met with previously in order to test Vit-A-Dapt comparatively with industry-standard machines such as the Adapt DX and the Goldman-Weekers adaptometer. Patients that are currently tested on these machines will be asked to volunteer to trial Vit-A-Dapt. After the test, the results will be compared with that of the gold standard machines and the patient will be asked to complete a short survey to provide feedback on the process.

By **3 months** we aim to have gained funding from NGOs situated in SEA such as SEVA [13] in order to purchase an Ender-3 S1 3D printer. This printer will be used specifically for the manufacture of Vit-A-Dapt and cover the costs of 15 complete units to be used in ophthalmology clinics and opticians nationwide for further testing and feedback from eye care specialists. As VAD is not a large issue in high income countries Vit-A-Dapt would be more likely to be used for screening for AMD in older patients, we plan to organise a test with 5 to 8 year-old children in local primary schools to receive feedback from the children of the youngest target age to test the usability of Vit-A-Dapt.

By **9 months** we aim to have a final design and 30 additional full functional units and have established a partnership with SEVA, a global non-profit eye care organisation that works with local communities around the world to develop self-sustaining programs that preserve and restore sight. They focus on underserved communities, women and children [13] which is ideal given our target market of children over 5 and pregnant women in LMICs. We plan on making use of the relationship that SEVA has with hospitals and mentor institutions in India to launch Vit-A-Dapt in LMICs. One of SEVA's main practices in India involves screening children for vision defects, this would allow Vit-A-Dapt to easily be incorporated into their general practices [16]. We aim to receive medical device approval from the Central Drug Standards Control Organization according to the Indian Drugs & Cosmetic Act and Rules [15]. We also plan to collaborate with GAIN, the Global Alliance for Improved Nutrition which works across India and other countries to tackle malnutrition [16].

By **15 months**, we plan to continue our collaboration with SEVA and expand into the other markets in SEA including Nepal, Pakistan, Bangladesh, Myanmar and Cambodia [13] provided suitable device approval is obtained. Similarly, we hope to continue collaboration with GAIN as we expand across SEA as they work in Pakistan, Bangladesh and Indonesia [16].

We will aim to improve our manufacturing techniques throughout this time to continue to meet demand. This will be done either by improving and expanding the 3D printing facilities or by investing in an injection moulder and moulds if the demand was great enough to justify it.

By **24 months** we aim to be successfully operating in these 7 countries across Asia and will apply to patent our design. At this point, we will then look to expand into Africa and South America in collaboration with SEVA, GAIN and other NGOs.

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8. Appendix

Appendix A – CAD Model

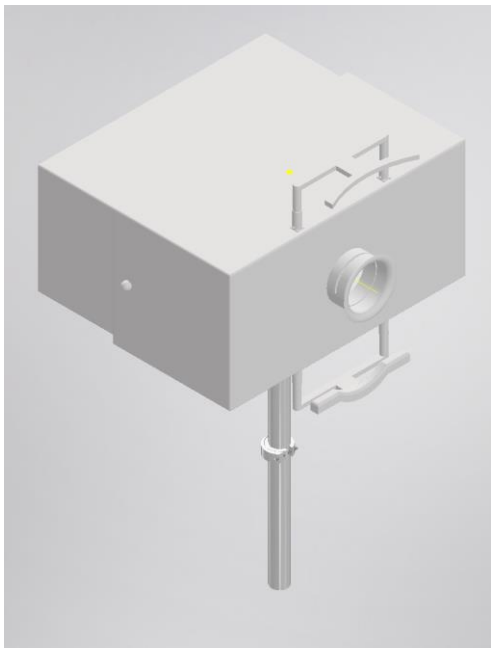


Figure A.1 Full CAD Model

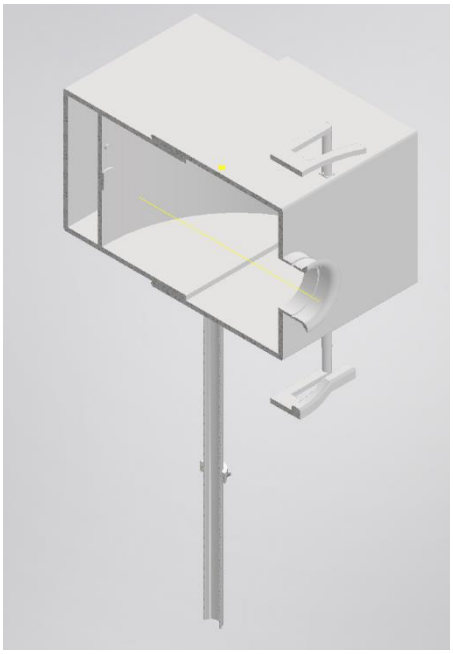


Figure A.2 Full CAD Model

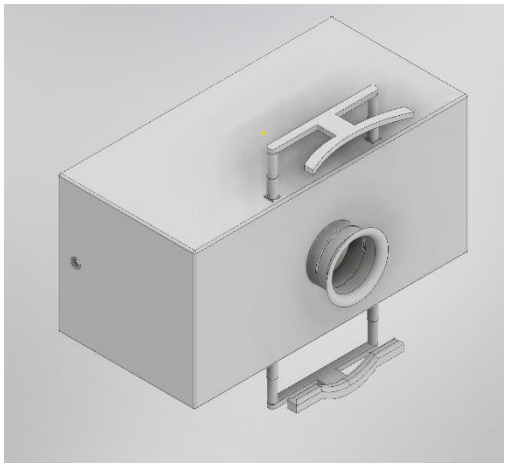


Figure A.3 Frontend of Model

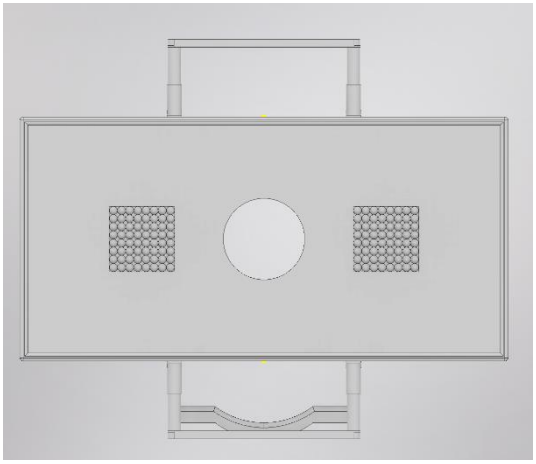


Figure A.4 Frontend of Model

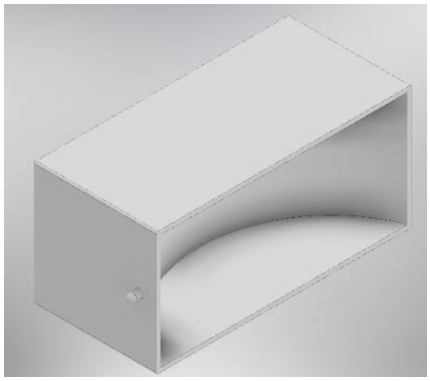


Figure A.5 Backend of CAD Model

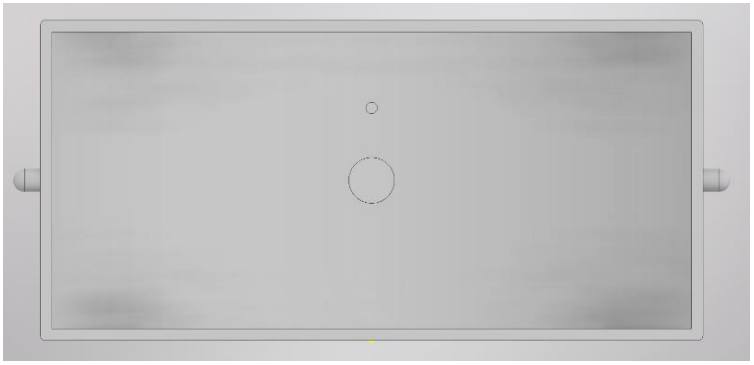
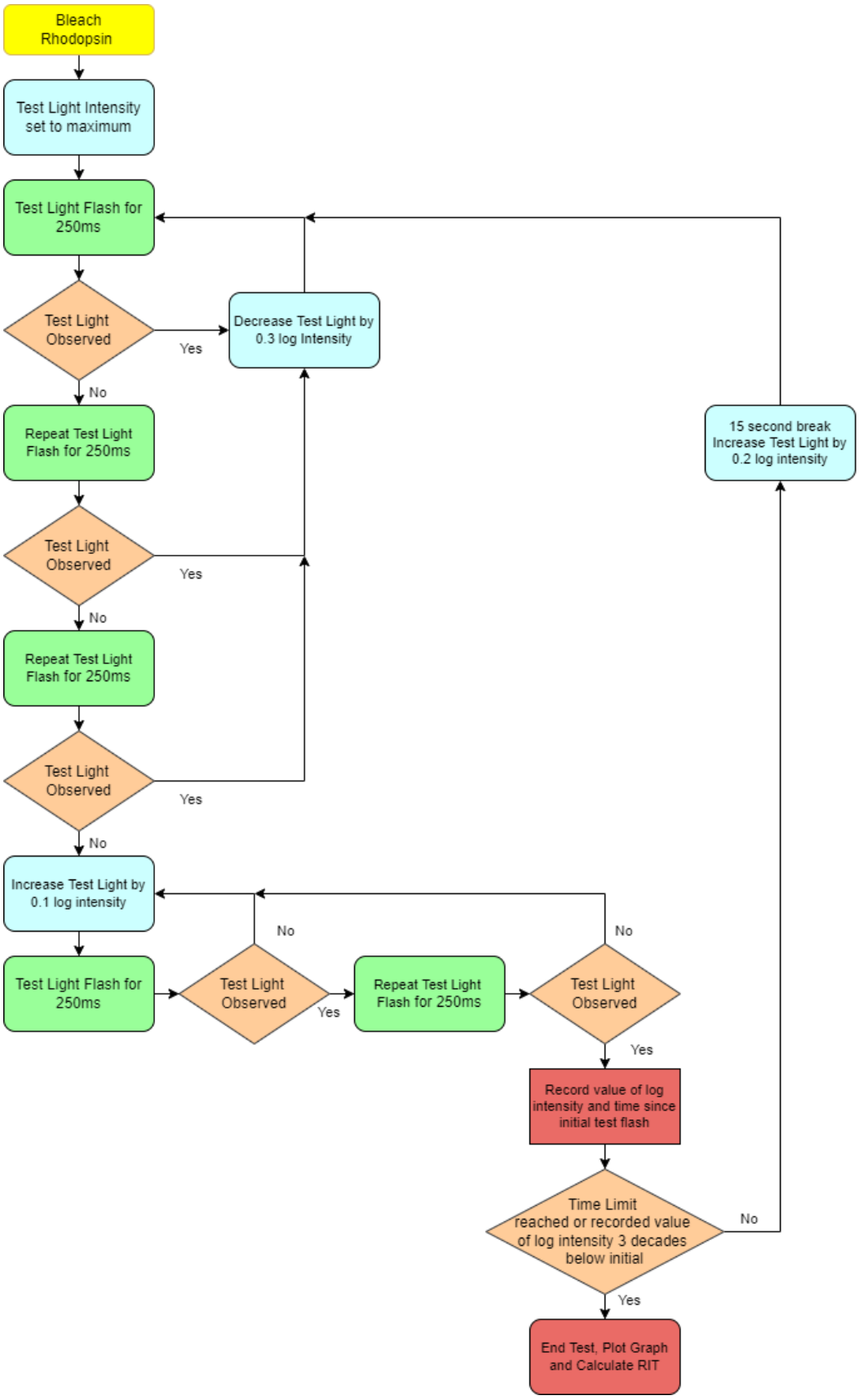


Figure A.6 Backend of CAD Model

Figure A.7 CAD Model of Button

Figure A.8 CAD Model of Stand

Appendix B – Process Design Flow Diagram



Appendix C – Circuit Design

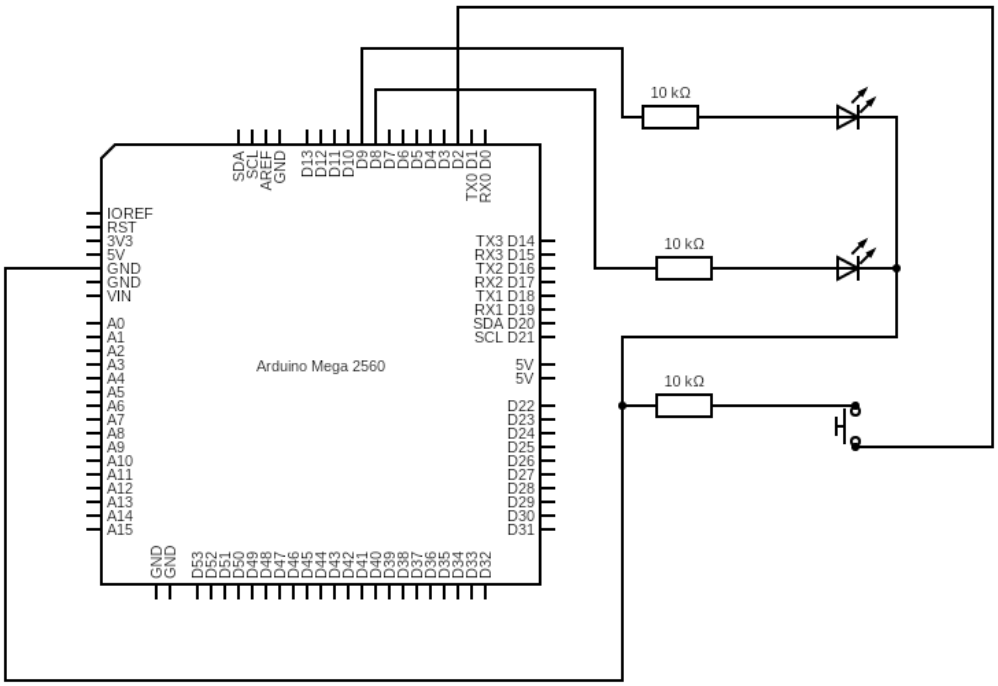


Figure C.1 Fixation light, Test light and Push button circuit diagram

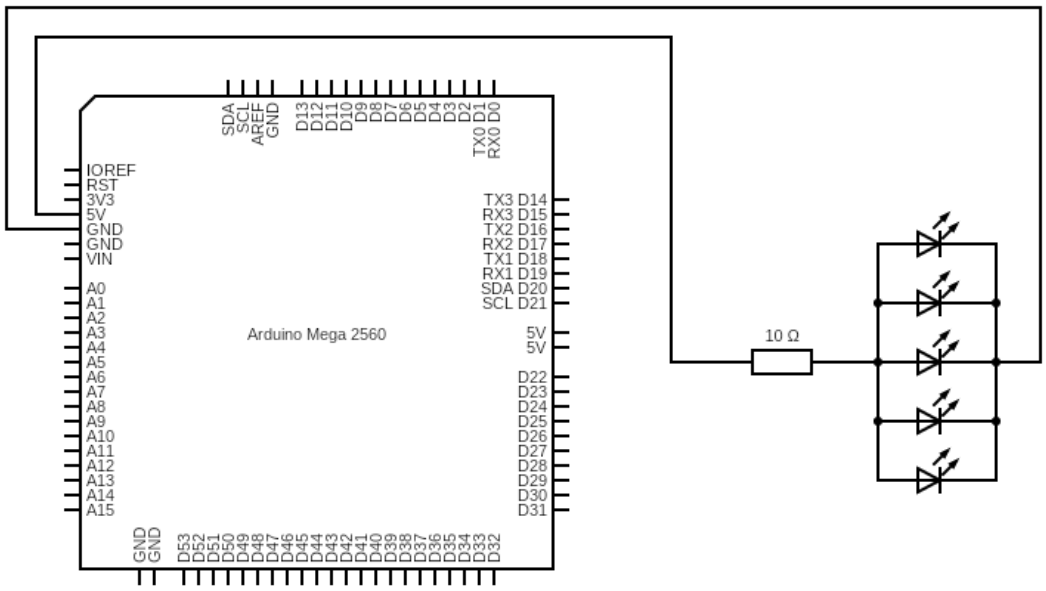


Figure C.2 Bleaching Light Circuit Diagram

```
//circuit turns on bleaching light for predefined time of 5 minutes
const int ledPin =  8;

void setup() {
  pinMode(8, OUTPUT);
}
void loop() {
  digitalWrite(8, HIGH);
  delay(300000);
  stop();
}

void stop()
{
  while(1)
  digitalWrite(ledPin, LOW);
}
```

Figure C.3 Bleaching Light Code

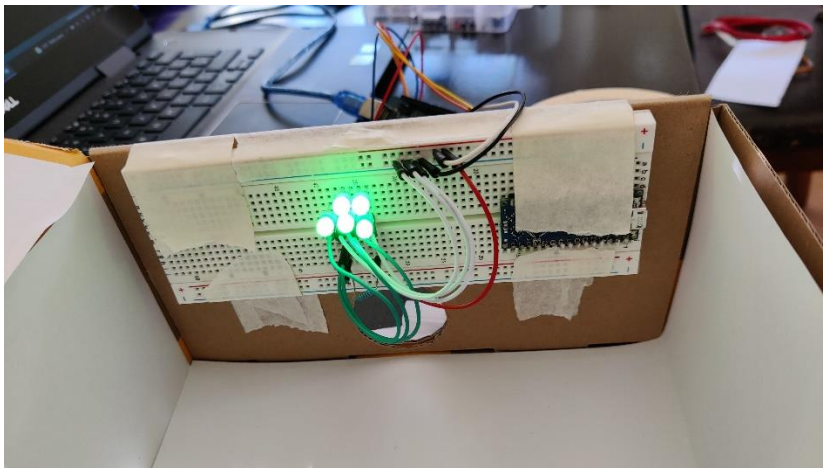


Figure C.4 Bleaching Light Prototype

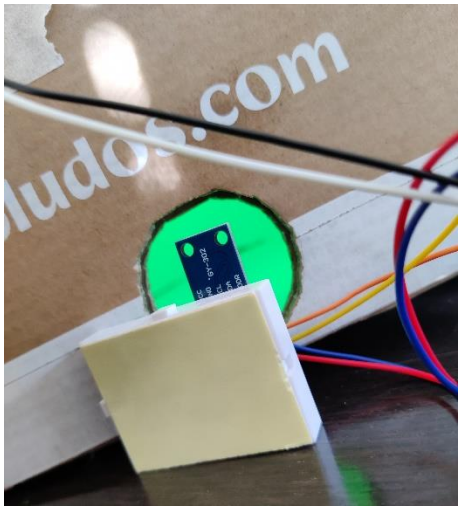
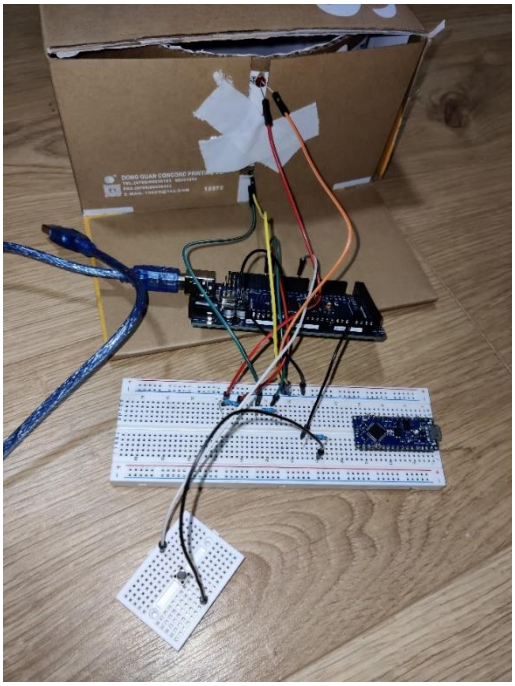
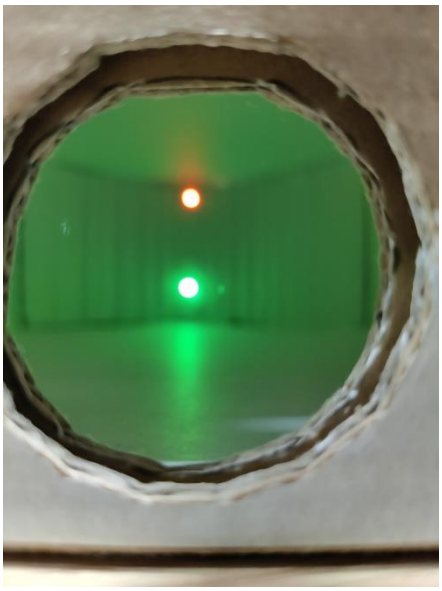


Figure C.5 Lux Meter Measuring the Intensity of the Bleaching Light at the Eyepiece

Appendix D – Cardboard Prototype





Appendix E – Light Sensor Experiment

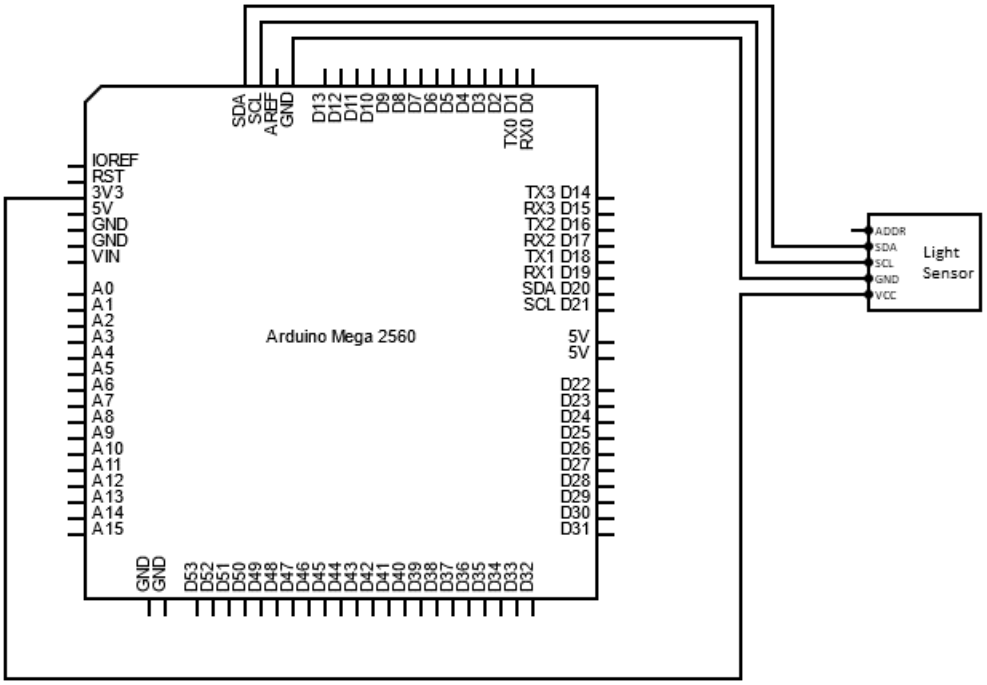


Figure E.1 Light Sensor Circuit

```
//source: https://github.com/claws/BH1750
//light meter takes a reading every 1000ms and prints the value in lux to the serial monitor screen

#include <Wire.h>
#include <BH1750.h>

BH1750 lightMeter;

void setup(){
  pinMode(8, OUTPUT);
  Serial.begin(9600);

  Wire.begin();

  lightMeter.begin();
  Serial.println(F("BH1750 Test"));

void loop() {
  digitalWrite(8, HIGH);
  float lux = lightMeter.readLightLevel();
  Serial.print("Light: ");
  Serial.print(lux);
  Serial.println(" lx");
  delay(1000);
}
```

Figure E.2 Light Sensor

Values obtained from the light sensor for different values of PWM when the distance between the LED and the sensor was 0mm.

PWM	**Light Intensity (Lux)**
255	1165.83
245	1121.25
235	1076.25
225	1031.67
215	987.50
205	942.92
195	899.17
185	855.42
175	810.42
165	764.58
155	718.33
145	672.50
135	626.25
125	579.58
115	533.75
105	487.50
95	440.83
85	394.58
75	347.50
65	301.67
55	254.58
45	207.92
35	162.08
25	115.42
15	69.17
10	45.42
9	40.83
8	35.83
7	31.25
6	27.08
5	22.5
4	17.92
3	13.33
2	8.75
1	4.17
0	0

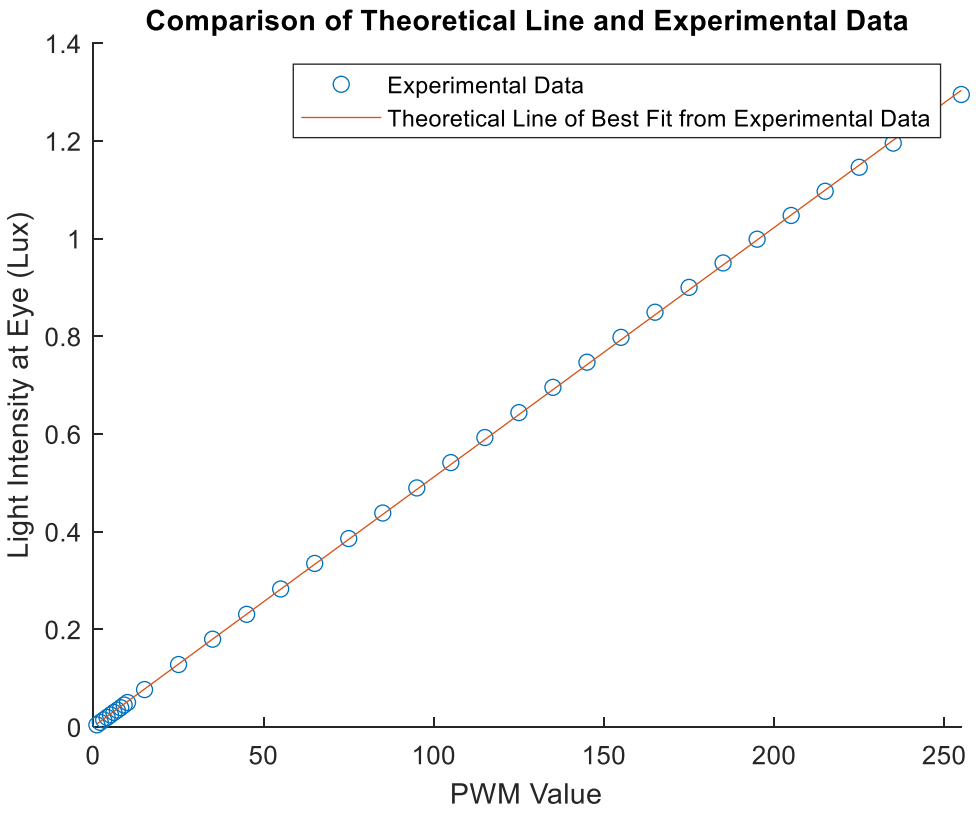


Figure E.3 Values Obtained from the Light Sensor

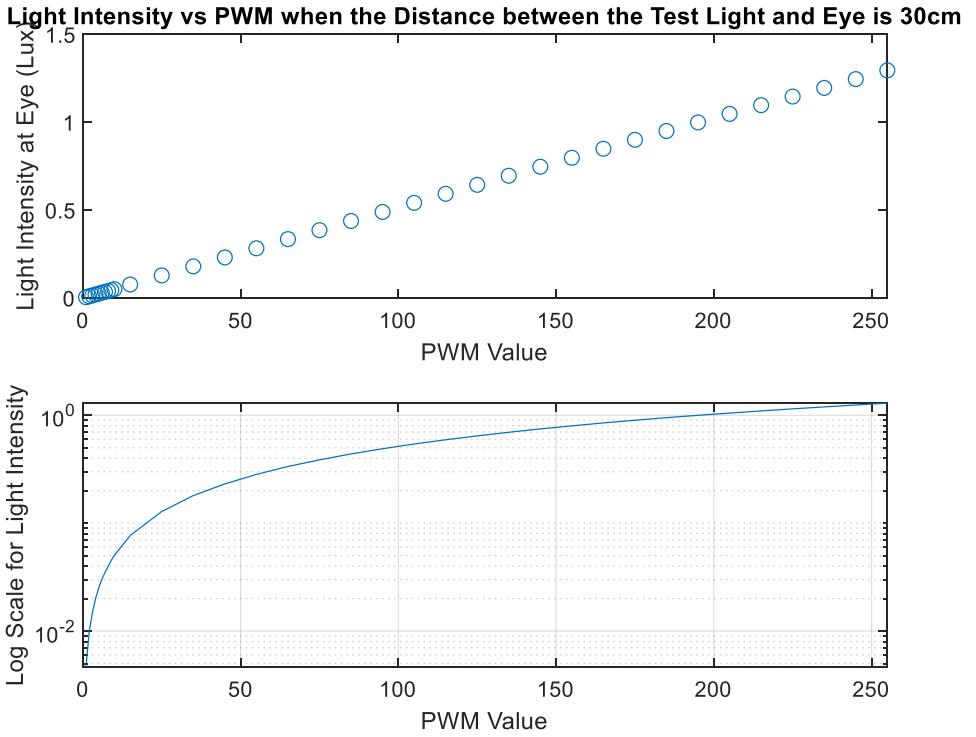


Figure E.4 Light Intensity at the Eye, scaled for 30cm Between the Eye and Test Light

The logscale values for light intensity across the two decades of operating range.

PWM	Lux Value	Rounded Lux Value Log Step
195	0.9975	1
176	0.9004	0.9
156	0.7983	0.8
137	0.7012	0.7
117	0.5991	0.6
98	0.5020	0.5
78	0.3999	0.4
58	0.2977	0.3
39	0.2007	0.2
19	0.0985	0.1
17	0.0883	0.09
15	0.0781	0.08
13	0.0679	0.07
11	0.0576	0.06
10	0.0525	0.05
8	0.0423	0.04
6	0.0321	0.03
4	0.0219	0.02
2	0.0117	0.01
1	0.0066	0.007

PWM values extracted from the experimental data. These PWM values are used in the test protocol as they are the values of interest.

Appendix F – Light Intensity Decreasing

Time (ms)	PWM
7678	195
14366	156
16762	137
19375	117
22409	98
25318	78
32247	58
36943	39
41286	19
48478	17
61164	13
68812	10
82697	6
93028	2

Figure F.1 Arduino Output to Test Decreasing LED

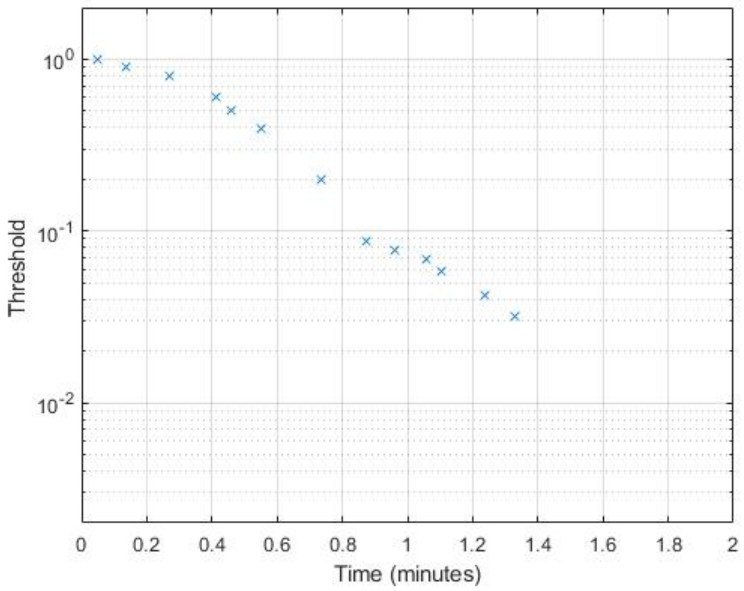


Figure F.2 Plot of Values Confirm LED Decreases Intensity

Appendix G – Code for Test Light, Fixation Light and Push Button

```
/*
  LED flashes every 2500 ms (offTime) for a period of 250 ms (onTime)
  When the button is pressed the intesnity of the LED decreases, the PWM value and the time are recorded and outputted
  If the LED flashes 3 times without the user acknowledging the flash, the intensity decreases
  Once the values for LED intensity are less than or equal to zero the test stops

  References
  'Blink without Delay' David A. Mellis 2005
  https://www.arduino.cc/en/Tutorial/BuiltInExamples/BlinkWithoutDelay

  'State change detection for active LOW inputs' 2020
  https://forum.arduino.cc/t/state-change-detection-for-active-low-inputs/680899

  'Arduino: Independent On-Off Times with Millis()' James Lewis 2013
  https://www.baldengineer.com/millis-ind-on-off-times.html

  https://forum.arduino.cc/t/push-button-not-responding-to-every-push/990458/23
*/

const int  buttonPin = 2; //the number of the button pin
const int ledPin =  9;    // the number of the test light
const int ledPin2 =  8;    // the number of the fixation light

int ledValue = 195;  // ledValue used to set the LED initial PWM value
int values[] = {176, 156, 137, 117, 98, 78, 58, 39, 19, 17, 15, 13, 11, 10, 8, 6, 4, 2, 1};   // setof PWM values required for the test
int sizeValues = sizeof(values);
int i=0;
int ledState = LOW;    // determined the state of the LED
int N=0;               // counter for number of flashes
bool state= true;

static unsigned long timer = 0;
unsigned long interval = 20;
static unsigned long timer2 = 0;
unsigned long totalTime;          // time to note when the user pressed the button

int onTime = 250;                   //how long LED stays on for
int offTime = 2500;                 //how long LED stays off for
unsigned long interval2 = offTime;  //start LED off
boolean ledState2 = true;

int buttonPushCounter = 0;        // counter for the number of button presses
boolean buttonState = 0;          // current state of the button
boolean lastButtonState = 0;      // previous state of the button




void setup()
{
  // define the pins:
  pinMode(buttonPin, INPUT_PULLUP);
  pinMode(ledPin, OUTPUT);
  Serial.begin(9600);
}

void loop()
{
  analogWrite(ledPin2, 255);
  totalTime = millis();                    //start counting the time of the process
```

```
if (millis() - timer >= interval)
{

   buttonState = digitalRead(buttonPin); // read the pushbutton input pin:
   delay(5);


  if (buttonState != lastButtonState)   // compare the buttonState to its previous state
  {
      while(state==true)
      {
        Serial.print("Time(ms)");
        Serial.print("\t");
        Serial.println("PWM");
        state=false;
      }

     if (buttonState == LOW)
     {
        // if the current state is LOW then the button went from off to on:

        Serial.print(totalTime);
        Serial.print("\t");
        Serial.println(ledValue);

        buttonPushCounter++;     // if the state has changed, increment the counter
        ledValue = values[i];    //if the button is pressed the LED intensity will be redefined
        i++;                     //increment position in the values array
        N=0;                     //reset flash counter
     }

      // save the current state as the last state, for next time through the loop
      lastButtonState = buttonState;
  }
}

if (millis() - timer2 >= interval2)
{
  timer2 = millis();

  if (ledValue <= 0)
  {
    //stop the test once the LED intensity value has reached less than or equal to 0
    stop();
  }
```

```
    if (ledState2)
    {
          //this if statement is used to keep the LED flashing
          //ledState2 allows to switch between on/off time

          //ledState keeps track of whether the LED is on/off
          ledState = HIGH; //redefine the state to ensure that it enters the else loop
          N++;             //increase flash counter
          interval2 = onTime;
          analogWrite(ledPin, ledValue);

          if (N >= 3)
          {
            //decreases intensity after 3 flashes have occured
            N=0;
            ledValue = values[i];
            i++;
            analogWrite(ledPin, ledValue);
          }

    }
    else
    {
          interval2 = offTime;
          ledState = LOW;
          digitalWrite(ledPin, LOW);

    }

  ledState2 =! (ledState2); //change the value of ledState2 (i.e from true to flase)
  timer2 = millis(); //redefine timer to the current amount of time code has been running
}

}

void stop()
{
  while(1)
  digitalWrite(ledPin, LOW);
}
```

Appendix H: Prototype Test Results

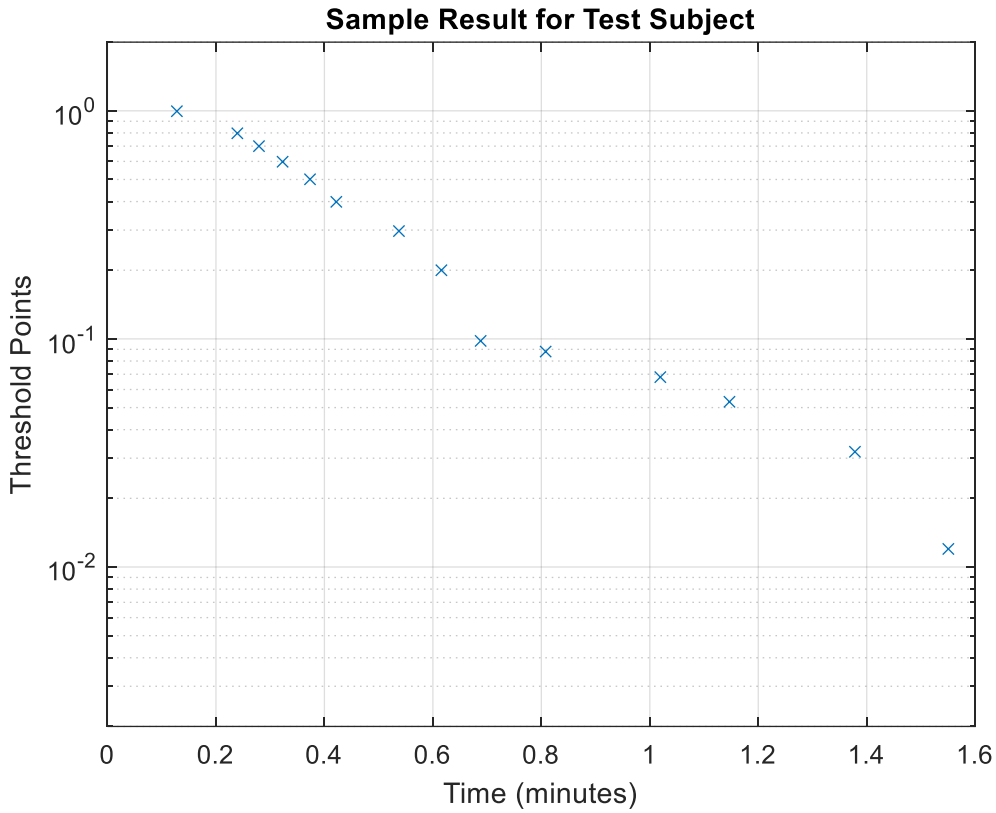


Figure H.1 Plot of Subject Test Results

Time (ms)	PWM
7678	195
14366	156
16762	137
19375	117
22409	98
25318	78
32247	58
36943	39
41286	19
48478	17
61164	13
68812	10
82697	6
93028	2

Figure H.2 Results from Test Subject

9. Acknowledgments

We would like to thank several people for their assistance with this project:

- Hilary Dempsey - Technician, Research Foundation Royal Victoria Eye and Ear Hospital
- Lucia Dalton - Lead Research Optometrist, The Wellcome Trust-Wolfson Northern Ireland Clinical Research Facility
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- Dr. John Healy - Lecturer/Assistant Professor
- Leo Downes - Arduino Consultant
- Niamh McCann - Arduino Consultant
- Stephen Redmond - Faculty Advisor
- Dónal Holland - Faculty Advisor

10. Plagiarism Declaration

All members of the Vit-A-Dapt team have familiarised themselves with UCD's Plagiarism Policy and certify that this project and report contains only original work except where otherwise acknowledged.