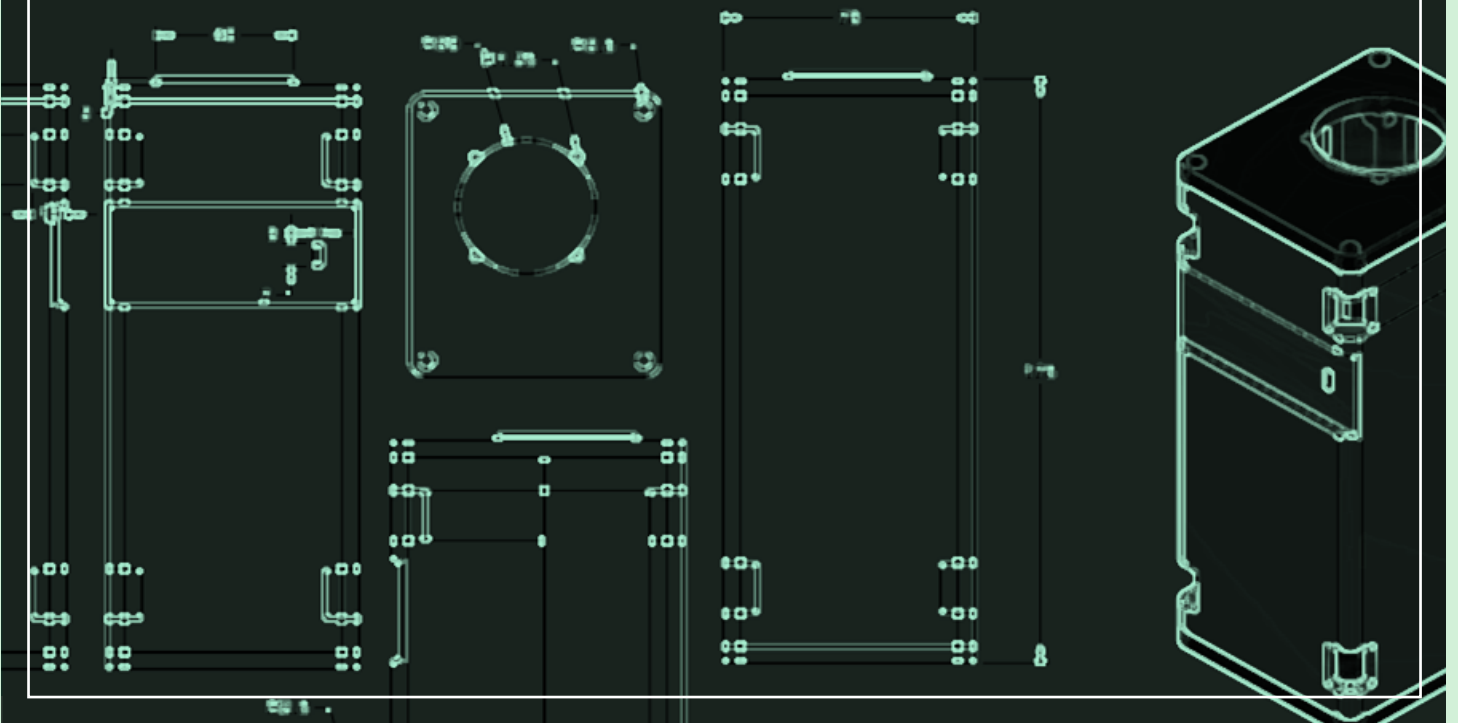


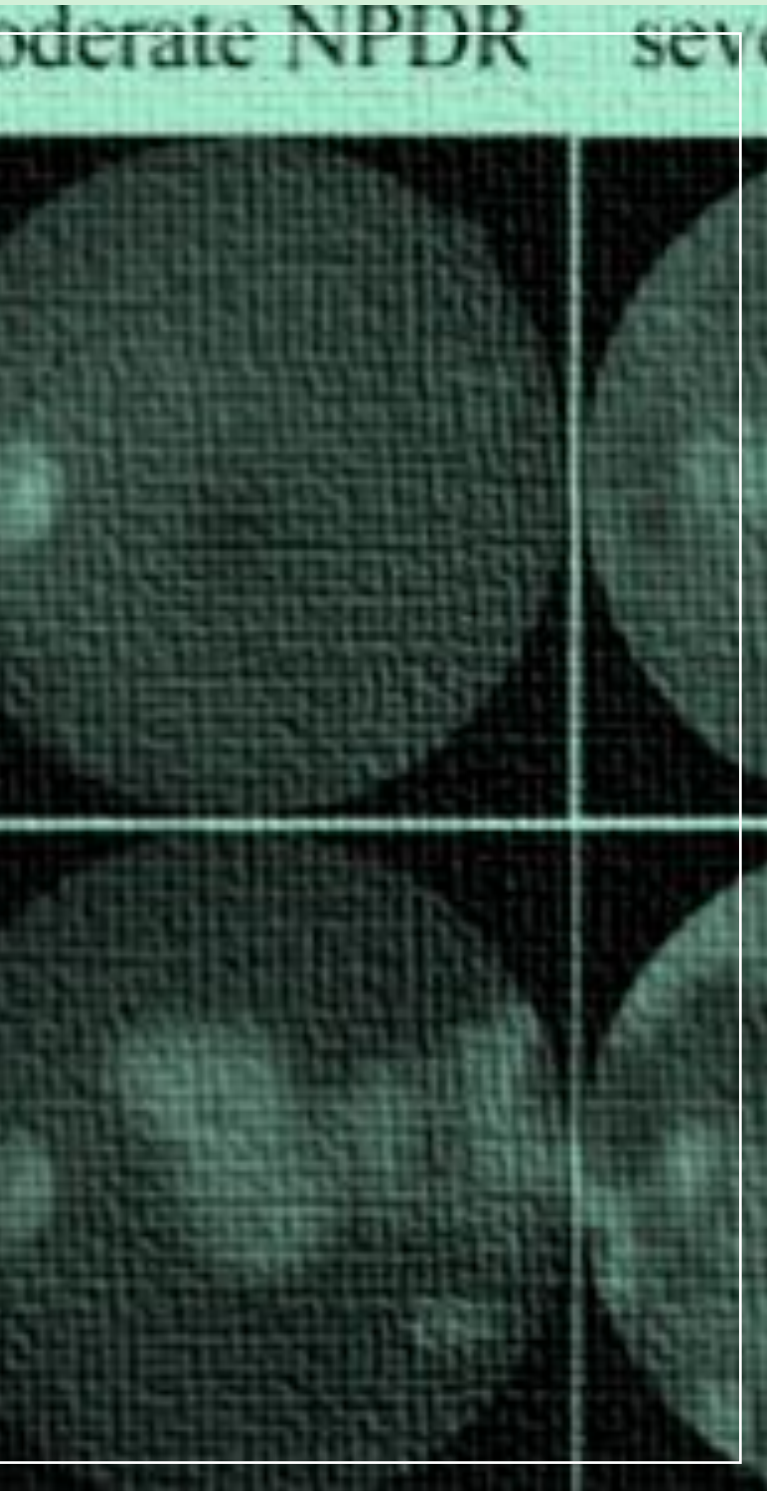
# VISIONbound

## INVENTORS LOGBOOK

Aum Dhruv & Nicholas Harty  
Fort Myers High School  
Grade 11



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# ABSTRACT

Diabetic retinopathy is a complication caused by an existing history of diabetes/diabetic symptoms that can slowly deteriorate a person's vision and can even lead to partial blindness. Often this diabetic complication can be treated by timely management of the condition and/or modern laser eye treatments/surgery. However, this treatment of diabetic retinopathy cannot completely cure the disease and, when left untreated, its effects seemingly take on worse results. These severe cases are often seen in developing nations where general access to medical testing is bleak with most patients unsure of their severity until physical implications become apparent. In fact, 79% of the adults with diabetes reside within low-to-middle income nations and serve a major risk of joining the estimated 93 million people worldwide suffering from diabetic retinopathy. Without significant medical testing, which can often prove expensive, and local ophthalmologists, this population is the most at risk of developing blindness and suffering the consequences of vision impairment. In this sense, the recent development of low-cost neural networks as a means of detecting early stages of diabetic retinopathy has become a much-needed solution to centuries of unknown suffering as a result of this complication. However, such solutions must be affordable/accessible as well as accurate in their results. This is the basis for this study and the reason for such urgency when it comes to developing solutions.

The final configuration of our product, VisionBound, includes a 30D lens, at a distance of 3cm from the pupil, that is paired with a 12MP Pi High-Quality Camera that interfaces with the microcontroller (Raspberry Pi Zero W). In addition, this design also allows for a wide range of customization via its available snap-in ports on the bottom and side. These customized utilities can interface with the product via its electronic USB-C port that also acts as a functional charger. To accompany the device, we also included a substantial battery for mobile consumption. On the digital scheme of the product, we utilized a tailored KNN algorithm to recognize the retina when in-view and a tested CNN algorithm to discern between that sample's particular stage of DR. Once a conclusion is determined, the testing results are exported via a dynamic NFC transmitter (ST25DV16K) placed under the charging port on the product. This result technology allows users to hover their phones over the labeled NFC area and receive their trial results over the web. This system of exportation was primarily chosen to reduce the cost of using traditional medical records and to provide a truly modern/accessible experience.

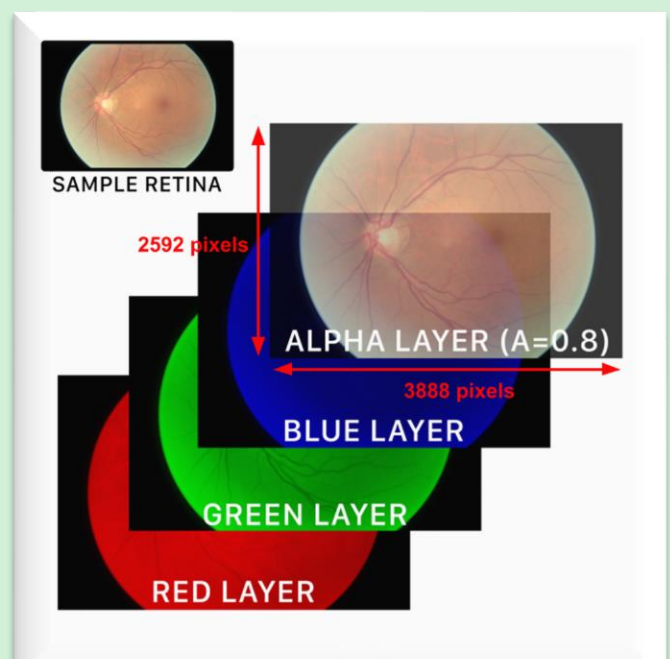
# BACKGROUND RESEARCH

## Introduction:

Millions of people across the globe suffer vision complications as a result of diabetic retinopathy, especially due to the lack of appropriate testing as to the severity of the condition. Diabetic retinopathy is a complication caused by an existing history of diabetes/diabetic symptoms that can slowly deteriorate a person's vision and can even lead to partial blindness. Often this diabetic complication can be treated by timely management of the condition and/or modern laser eye treatments/surgery. However, this treatment of diabetic retinopathy cannot completely cure the disease and, when left untreated, its effects seemingly take on worse results. These severe cases are often seen in developing nations where general access to medical testing is bleak with most patients unsure of their severity until physical implications become apparent. In fact, 79% of the adults with diabetes reside within low-to-middle income nations and serve a major risk of joining the estimated 93 million people worldwide suffering from diabetic retinopathy. Without significant medical testing, which can often prove expensive, and local ophthalmologists, this population is the most at risk of developing blindness and suffering the consequences of vision impairment. In this sense, the recent development of low-cost neural networks as a means of detecting early stages of diabetic retinopathy has become a much-needed solution to centuries of unknown suffering as a result of this complication. However, such solutions must be affordable/accessible as well as accurate in their results. This is the basis for the researcher's study and the reason for such urgency when it comes to verifying solutions. The focus of the study relies upon the two major post-processing algorithms, specifically within the realm of image classification, that have proven suitable for low-cost, efficient medical testing: the convolutional neural network algorithm and the k-nearest neighbors algorithm. Research into the function of these algorithms, as well as their applications, is important in reducing the need for physician training and increasing the mobility of worldwide medical testing.

## Convolutional Neural Network (CNN) Research:

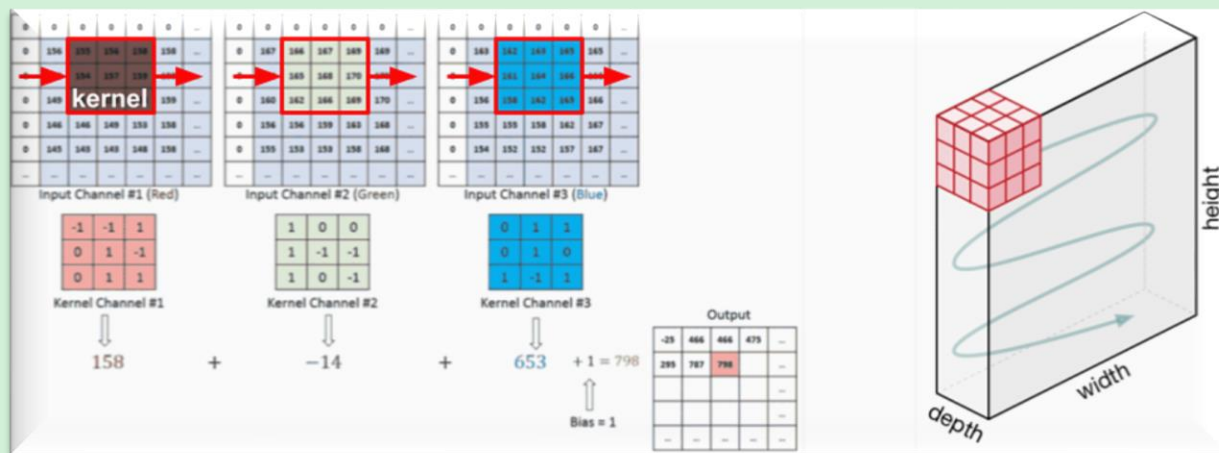
The first of these recognition methods, the convolutional neural network algorithm, works by pooling various elements of a training image, assigning importance/weight to various aspects of an image, and then undergoing a convolution process that exponentially decreases the size of the image into basic constraints. Its ability to break down the various prominent features of media allows it to function as an essential component in the classification of bitmaps, moving graphics, and audible samples. In this study, the description of this algorithm will focus on image classification as it relates to the entirety of the neural network's functionality. This entire process mimics the human brain's (or rather a human's Visual Cortex) ability to discern the components of an image and contrast the features of two corresponding images when dealing with necessary classification.



# BACKGROUND RESEARCH

This system of assigning importance to various features of an image is described as the CNN. Initially, this system breaks down sample training images into their essential channels: the Red Layer, the Green Layer, the Blue Layer, and, in some cases, the Alpha/Intensity Layer. This breakdown is a result of each pixel, in a standard training image, being composed of three RGB values between 0-255 in intensity and an alpha value between 0-1 in opacity. From this point of divergence, the algorithm begins dissecting the image for features through a series of four scientific steps defined by most computer analysts as essential “layers”. These layers are composed of the Convolution Layer, the Pooling Layer, the Rectified Linear Unit (ReLU) Layer, and the Fully Connected Layer.

The first layer of CNN, the Convolutional Layer, processes the training image through a variety of kernels, also referenced as filters, that allow edges, corners, lines, shadows, and other elements of the image to become apparent. For each of these kernels, there is an output of a 2D map/matrix which outlines the intensity of each individual pixel within the filtered photo. Each channel (RGBA), as mentioned previously, is analyzed by the kernel. The kernel functions are a system that moves across an image and analyzes a specific area for features. For example, a 5x5 pixel image may have a 3x3 pixel kernel that moves across the image horizontally, starting from the left side, one pixel at a time analyzing each 9-pixel area for new features. Once finished with its horizontal motion, the kernel moves down one pixel and begins, once again, from the left side of the image. All throughout this process, these intensities/weights of these features within individual kernels are recorded in a stored model on the available RAM. Once the entire image has been outlined by kernels, the kernel either moves to another channel or, if all channels are covered, finishes its analysis by computing any additional biases provided by the investigators. Following this layer of computation, CNN shifts to the Pooling Layer.



Source: Saha, S. (2018, December 17). A comprehensive guide to convolutional neural networks-the eli5 way. Medium. Retrieved December 29, 2021, from <https://towardsdatascience.com/a-comprehensive-guide-to-convolutional-neural-networks-the-eli5-way-3bd2b1164a53>

The second layer of CNN, the Pooling Layer, functions with the purpose of reducing the size of the image in order to decrease the amount of computing power necessary for convolution and to extract further features at a compressed level of kernelization. Similar to the Convolutional Layer, the Pooling Layer uses its own kernel, with the exact constraints of the convolutional kernel, to simplify the training image. Using the previous example of a 3x3 pixel kernel analyzing a 5x5 pixel training image, each of these 9-pixel area kernels would represent 1-pixel on the resulting image.



# BACKGROUND RESEARCH

This revelation means that this 5x5 pixel training image would be reduced to a 3x3 pixel resultant image after undergoing the pooling process. CNN is able to reduce these larger kernels into single pixels by either utilizing the processes of “Average Pooling” or “Max Pooling”. Average Pooling takes the numerical average of all of the individual RGBA values within a kernel and uses that average to compose the RGBA of a new corresponding pixel. On the other hand, Max Pooling provides the dimensional compression provided by Average Pooling while also applying a layer of noise reduction to the resulting pixel. This process of Max Pooling helps the reduced training image maintain aspects of the original image and generally performs with greater accuracy when compared to Average Pooling CNN models. After the completion of the Pooling Layer, the CNN continues to cycle through the Convolution-Pooling layers until the necessary features are extracted and the original training image and been broken down into its essential pixels. The continuous nature of this cycle is determined by the number of cycles that are predefined by the investigators. In general, the accuracy of the model, when tested against its own training dataset, increases as it maintains further cycles. After this defined period of cycling between the Convolution and Pooling layers has ended, the CNN progresses into the ReLU and Fully-Connected Layers.

The Rectified Linear Unit (ReLU) Layer works in conjunction with the previously assessed data in order to “flatten”/familiarize the data before passing it on to the final layer. In the scope of image recognition, the ReLU Layer serves as a final simplification of pixels in a set linear matrix (1 pixel per training image that resulted from Convolution-Pooling Layers). From this layer, this linear pixel matrix is processed through the Fully-Connected Layer.

The final layer of CNN, the Fully-Connected Layer, processes this new linear matrix as well as the recorded weights from kernelization by cycling through a series of epochs, defined by the investigators, that helps increase the classification accuracy of the model. These epochs train the model on its existing training images which helps it distinguish dominant features from each individual classification group. This prolonged training of CNN’s ability to discern between defining features is an asset used within image classification and the proficiency of trained data/images can often correlate directly to the assumptions of the algorithm when given new data/images. This later classification is refined using the “SoftMax Technique”. This technique helps when identifying low-level features and refining the necessary recorded weights/biases from the Convolution Layer. Resulting from the classification of new images through “SoftMax” classification, the investigators should receive corresponding confidence intervals for each of their predefined classification groups.

CNN Results (Ex: Diabetic Retinopathy Severity):

(0): 0.02                      **(1): 0.945**                      (2): 0.005  
(4): 0.015                      (5): 0.015

For example, in the resulting dataset listed above, the investigators could assume, with 94.5% accuracy, that the testing retina image had mild symptoms of diabetic retinopathy based upon the training CNN.

## K-Nearest Neighbors (KNN) Research:

The second of these algorithms, the k-nearest neighbors algorithm, is trained on various groups of images in order to classify a given unknown image. Its simple implementation allows it to function as an essential component in image recognition, video recognition, and speech recognition. KNN is used for classification and regression.

# BACKGROUND RESEARCH

In this study, the description of this algorithm will focus on image classification as it relates to the entirety of the neural network's functionality. This process uses a predetermined dataset, such as "MobileNet", to deposit images into a series of 1000 logits (vectors of raw predictions that a model generates). This can also be done by developing a rudimentary algorithm to break down images via kernaling or random pixel sampling, into the necessary logits. To elaborate, for each group of images, a matrix is created of shape [n, 1000], in which "n" is the number of samples per group. MobileNet deposits new images into logits, which are then normalized to unit length. This means that the logit vectors are scaled to unit vectors using the formula below.

$$u = \frac{v}{|v|}$$

Following this, the logits are concatenated to the end of the matrix, forming an additional row.

$$\begin{bmatrix} a_{1,1} & a_{1,2} & a_{1,3} & \dots & a_{1,1000} \\ a_{2,1} & a_{2,2} & a_{2,3} & \dots & a_{2,1000} \\ \vdots & \vdots & \vdots & \ddots & \vdots \\ b_{1,1} & b_{1,2} & b_{1,3} & \dots & b_{1,1000} \\ b_{2,1} & b_{2,2} & b_{2,3} & \dots & b_{2,1000} \\ \vdots & \vdots & \vdots & \ddots & \vdots \\ c_{1,1} & c_{1,2} & c_{1,3} & \dots & c_{1,1000} \\ c_{2,1} & c_{2,2} & c_{2,3} & \dots & c_{2,1000} \\ \vdots & \vdots & \vdots & \ddots & \vdots \end{bmatrix}$$

Source: Thorat, N. (2018, June 20). *How to build a teachable machine with Tensorflow.js*. Observable. Retrieved December 29, 2021, from <https://observablehq.com/@nsthorat/how-to-build-a-teachable-machine-with-tensorflow-js>

The matrix ends up looking similar to the image above.

When given an image with no existing classification, MobileNet deposits it into logits, then normalizes to a vector of shape [1000]. After this, the unknown image's vector is multiplied to the matrix.

Sample Size Matrix

Unknown Image Vector

$$\begin{bmatrix} a_{1,1} & a_{1,2} & a_{1,3} & \dots & a_{1,1000} \\ a_{2,1} & a_{2,2} & a_{2,3} & \dots & a_{2,1000} \\ \vdots & \vdots & \vdots & \ddots & \vdots \\ b_{1,1} & b_{1,2} & b_{1,3} & \dots & b_{1,1000} \\ b_{2,1} & b_{2,2} & b_{2,3} & \dots & b_{2,1000} \\ \vdots & \vdots & \vdots & \ddots & \vdots \\ c_{1,1} & c_{1,2} & c_{1,3} & \dots & c_{1,1000} \\ c_{2,1} & c_{2,2} & c_{2,3} & \dots & c_{2,1000} \\ \vdots & \vdots & \vdots & \ddots & \vdots \end{bmatrix} \times \begin{bmatrix} x_1 \\ x_2 \\ x_3 \\ \vdots \\ x_{1000} \end{bmatrix} = \begin{bmatrix} a_{1,1}-1000 \cdot x \\ a_{2,1}-1000 \cdot x \\ a_{3,1}-1000 \cdot x \\ \vdots \\ b_{1,1}-1000 \cdot x \\ b_{2,1}-1000 \cdot x \\ b_{3,1}-1000 \cdot x \\ \vdots \\ c_{1,1}-1000 \cdot x \\ c_{2,1}-1000 \cdot x \\ c_{3,1}-1000 \cdot x \\ \vdots \end{bmatrix}$$

Source: Thorat, N. (2018, June 20). *How to build a teachable machine with Tensorflow.js*. Observable. Retrieved December 29, 2021, from <https://observablehq.com/@nsthorat/how-to-build-a-teachable-machine-with-tensorflow-js>

The equation ends up looking similar to the image on the right. The resulting vectors are sorted by distance from the unknown image in increasing order. The closest vectors are called the "nearest neighbors", and the K value determines the extent to which "neighbors" are taken into account when classifying the unknown image. Hence, the algorithm's name is the k-nearest neighbors algorithm.

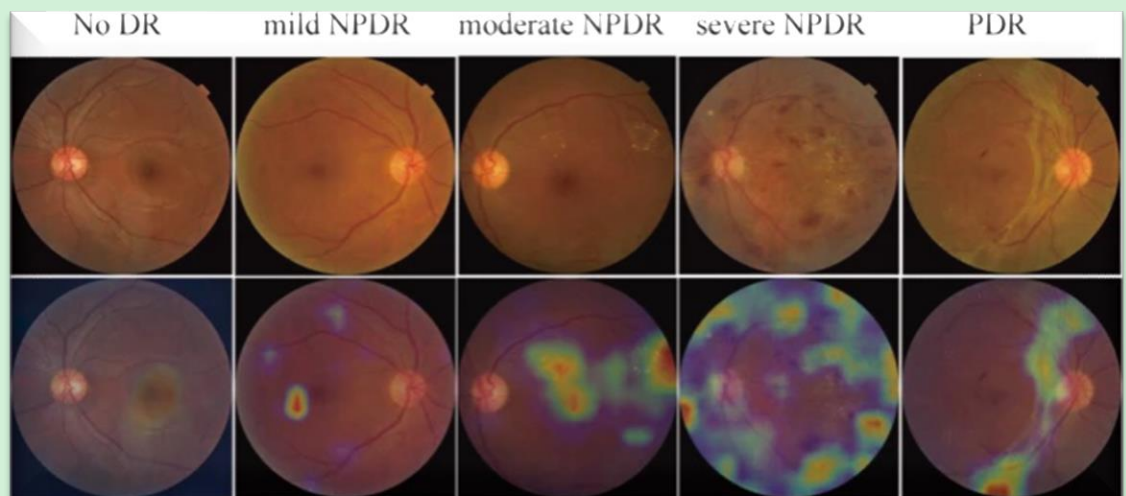
# BACKGROUND RESEARCH

## Concluding Comparison Between Neural Networks:

The main difference between the convolutional neural network algorithm and the k-nearest neighbors algorithm exists in their ability to discern between distinct features of an image. The convolutional neural network algorithm processes feature regardless of spatial orientation because of its utilization of kernels that process training images while the k-nearest neighbors algorithm identifies features based upon color/intensity and takes spatial orientation into account when classifying testing images. Another difference exists in their individual training processes. The k-nearest neighbors algorithm trains upon its sample dataset by conforming the data into logit-based matrices which requires little computational power as it simply is building a record/ledger for later classification. On the other hand, the convolutional neural network algorithm uses higher computational power in its training process as it cycles through multiple Convolutional Layers as well as the refinement of its feature identification across a series of predefined epochs. Although these two algorithms are mathematically distinct in almost every component of their individual function, their output, in terms of correlation, are the same and they share similar efficiency when tasked with the training/classification of bitmapped medical datasets.



Lin, L., Li, M., Huang, Y., Cheng, P., Xia, H., Wang, K., Yuan, J., & Tang, X. (2020, November 20). The SUSTECH-SYSU dataset for automated exudate detection and diabetic retinopathy grading. Nature News. Retrieved January 26, 2022, from <https://www.nature.com/articles/s41597-020-00755-0>





# STORY OF OUR INVENTION

## What is an invention?

An invention is something new that enables us to solve a problem or do something better or easier.

## The purpose of this Invention Log

All stories have an ending. In this case, the ending of what you are doing is your invention. But all stories also have a beginning and middle. The purpose of this Invention Log is to tell the entire story of your invention. In it, during every step you take in making your invention, you will record what you did, why you did it, and how you did it. This Invention Log is an important part of the invention process and is a complete and accurate record of the ideas, plans, and processes by which the invention was created. Invention Logs can be used by students to prove they came up with the idea and invention. Oftentimes, they are used as part of the patenting process.

## How to use this Invention Log

The Invention Log is not a book report that is created after you are done. Rather, it is a diary that is continuously filled in as you work on your invention. Follow the steps of the invention process and fill out the various pages as you work on them. When you are done with a page, print your name and the date at the bottom. If you need extra space for any section, make copies of the Blank Page (Page 17) and use that for any purpose. Once you are done, put the pages in the order in which you did them and staple them to make a complete Invention Log. This log will also be used as part of the final presentation and needs to be filled in using complete sentences (except for things like a list of materials). Teams share one Invention Log and should attach signatures of all inventors.

The name of the invention: VisionBound


The problem that it solves:

Diabetic retinopathy is a complication caused by an existing history of diabetes/diabetic symptoms that can slowly deteriorate a person's vision and can even lead to partial blindness. Often this diabetic complication can be treated by timely management of the condition and/or modern laser eye treatments/surgery. However, this treatment of diabetic retinopathy cannot completely cure the disease and, when left untreated, its effects seemingly take on worse results. These severe cases are often seen in developing nations where general access to medical testing is bleak with most patients unsure of their severity until physical implications become apparent. In fact, 79% of the adults with diabetes reside within low-to-middle income nations and serve a major risk of joining the estimated 93 million people worldwide suffering from diabetic retinopathy. Without significant medical testing, which can often prove expensive, and local ophthalmologists, this population is the most at risk of developing blindness and suffering the consequences of vision imparity. In this sense, the recent development of low-cost neural networks as a means of detecting early stages of diabetic retinopathy has become a much-needed solution to centuries of unknown suffering as a result of this complication. However, such solutions must be affordable/accessible as well as accurate in their results. This is the basis for this study and the reason for such urgency when it comes to developing solutions.

# STATEMENT OF ORIGINALITY

I promise that the ideas in this Invention Log are my own. (If a team, all should complete.)

Inventor Name(s): Aum Dhruv, Nicholas Harty

Signature(s): 

Date: 12/20/21

Grade: 11

School: Fort Myers High School

Town: Fort Myers, Florida

# IDENTIFYING AND UNDERSTANDING

## Explaining the Problem and Identifying a Solution (Identifying and Understanding)

1. What problem are you trying to solve? The more specific you are in describing the problem, the better your solution will be. How did you come up with the problem?

Diabetic retinopathy is a complication caused by an existing history of diabetes/diabetic symptoms that can slowly deteriorate a person's vision and can even lead to partial blindness. Often this diabetic complication can be treated by timely management of the condition and/or modern laser eye treatments/surgery. However, this treatment of diabetic retinopathy cannot completely cure the disease and, when left untreated, its effects seemingly take on worse results. These severe cases are often seen in developing nations where general access to medical testing is bleak with most patients unsure of their severity until physical implications become apparent. In fact, 79% of the adults with diabetes reside within low-to-middle income nations and serve a major risk of joining the estimated 93 million people worldwide suffering from diabetic retinopathy. Without significant medical testing, which can often prove expensive, and local ophthalmologists, this population is the most at risk of developing blindness and suffering the consequences of vision imparity. In this sense, the recent development of low-cost neural networks as a means of detecting early stages of diabetic retinopathy has become a much-needed solution to centuries of unknown suffering as a result of this complication.

2. What is the result you are trying to achieve? The more specific you are in describing the result you want, the better your solution will be.

With VisionBound, our team intends to increase diabetic retinopathy testing by making it more accessible, low-cost, and efficient. This result would be the first step towards increasing diabetic retinopathy treatment because it would raise awareness of the complication to patients, especially those who live in underdeveloped countries.

# IDENTIFYING AND UNDERSTANDING

3. What are some possible solutions? Which one did you choose to pursue? How did you decide which solution to try? The more specific you are in describing the solution you will create, the better your invention will be. How did you come up with the solution?

Our original concept for this endeavor revolved around the creation of a relatively low-cost device to detect Diabetic Retinopathy (DR) via the retinal sampling of a wide variety of patients, in respect to anthropometric differences. Within this potential product, we planned to incorporate our research within efficient preliminary neural networks to best suit the needs of the wide-degree of end users. These particular algorithms include the convolutional neural network (CNN) algorithm and the k-nearest neighbors algorithm (KNN) for which have proven their individual efficiency in low-cost medical testing (especially within the scope of retinal diagnosis and treatment). Through these initial ideas, along with analysis via morphological synthesis, we had developed the concept of a point-of-care headset utility that could detect when a retina was under its scope and immediately run analysis testing as to the severity of the patient's DR (Range of Severity: No DR, Mild DR, Moderate DR, Severe DR, and Proliferative DR).

Throughout the course of our iterative design process, we would take time between conceptual design sessions to conduct our own small scale research-and-development into the constraints of retinal lenses as well as the biomarkers of DR. We tested various different lenses for handheld ophthalmic study (20D, 30D, 90D, etc.) via virtual simulation and analysis of provided fact sheets. We settled upon using a 30D lens due to its effectivity on undialited/small pupils (as far as retinal field of vision), its 3cm working distance from the pupil, and its low price within the modern market. In addition, we also physically experimented with input micro-cameras and their length away from the retinal lens. We eventually settled upon the 12MP Pi High Quality Camera due to its high fidelity, low cost, and support for our central processing unit, the Raspberry Pi Zero W. The final area of adjustment occurred within our discussions regarding the handling of the device. We settled upon using a multi-adapter system that allows doctors/patients to swap out custom handles and accessories in order to best fit their usecase. These changes to anthropometric customization were inspired by an analogy we made to highend RED digital cameras that utilize componentization in order to meet a wide-range of functionality. These adjustment factors were mostly conducted in a virtual environment before physical prototypes were constructed. The main function of internal simulation revolved around the construction of efficient KNN and CNN algorithms for retinal detection and DR severity analysis respectively. This took hundreds of trials over a period of meticulous study for which results in stable algorithms with substantially high confidence when testing against unseen samples.

# IDENTIFYING AND UNDERSTANDING

The final configuration includes a 30D lens, at a distance of 3cm from the pupil, that is paired with a 12MP Pi High Quality Camera that interfaces with the microcontroller (Raspberry Pi Zero W). In addition, this design also allows for a wide-range of customization via its available snap-in ports on the bottom and side. These customized utilities can interface with the product via its electronic USB-C port that also acts as a functional charger. To accompany the device, we also included a substantial battery for mobile consumption. On the digital scheme of the product, we utilized a tailored KNN algorithm to recognize the retina when in-view and a tested CNN algorithm to discern between that sample's particular stage of DR. Once a conclusion is determined, the testing results are exported via an dynamic NFC transmitter (ST25DV16K) placed under the charging port on the product. This result technology allows users to hover their phones over the labeled NFC area and receive their trial results over the web. This system of exportation was primarily chosen to reduce the cost of using traditional medical records and to provide a truly modern/accessible experience.

4. Has this solution been done before? If it exists, how is your approach different and better? What research did you do to see if this invention had been done before? Who did you talk to? Where did you look? What website did you search? You should show 4 pieces of evidence of different types of research – talking with experts, searching the internet, interviewing friends and family as to how useful this would be, etc.

Where I looked to see if my idea is new:

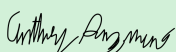
- A. <https://www.uspto.gov/>
- B. <https://patents.google.com/>
- C. <https://www.amazon.com/>
- D. <https://www.ebay.com/>
- E. <https://www.optiusa.com/>
- F. <https://usophthalmic.com/>
- G. <https://www.veatchinstruments.com/Ophthalmic-Equipment#/>

Document any similar inventions you found, describing how yours will be different:

1. VisionBound is relatively **low-cost** as it utilizes a **point-of-care testing** in which the retinal images of patients are analyzed through KNN and CNN algorithms, providing results soon after.
2. By incorporating a 30D lens, our invention **speeds up diabetic retinopathy diagnosis** by eliminating the need for a dilated eye exam. This also allows for potential **self-testing** and decreases the expertise needed to issue a diagnostic exam, if not done at home, leading to **increased accessibility**.
3. Our invention utilizes a form factor of 73mm x 85mm x 175mm, demonstrating its **compact nature**. This ensures its **mobility** as compared to legacy machines, which may be large and immobile.
4. Our invention features snap-in ports on the bottom and side. This allows for a **wide range of customization** up to the user.
5. By researching phrases like “diabetic retinopathy”, “mobile retinal imaging”, “convolutional neural network”, “diabetic retinopathy detection”, and “k-nearest neighbors” on the United States Patent Depository Library and other websites, we confirmed that our invention is **completely unique**.

I approve of the solution/invention my student has chosen to pursue and agree that it not only meets the guidelines shown on the Restrictions and Requirements page, but that it is also safe.

Teacher's Name (Printed): Anthony Sangermano

Teacher's Signature: 

Date: 12/22/22

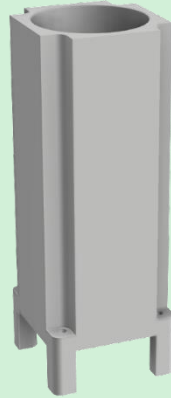

I approve of the solution/invention my student has chosen to pursue and agree that it not only meets the guidelines shown on the Restrictions and Requirements page, but that it is also safe.

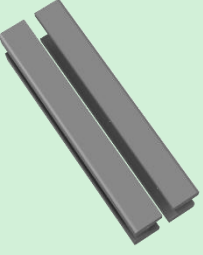
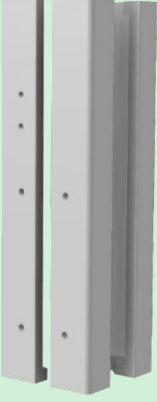

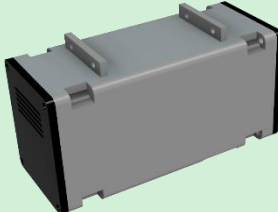


# IDEATING AND DESIGNING

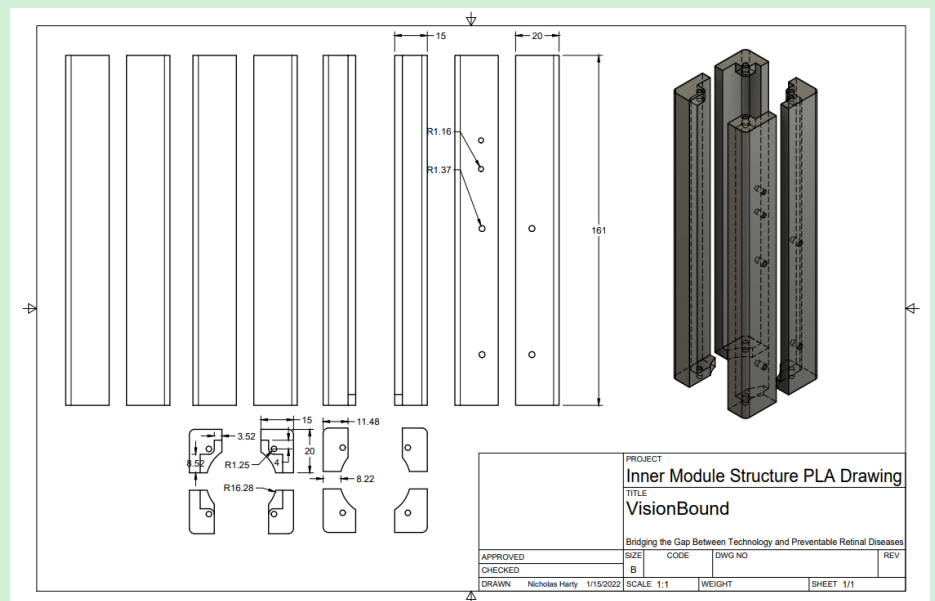
## Creating and Improving the Design (Ideating and Designing)

5. Draw a model (a sketch or drawing) of the invention you are thinking about building. Label all the important parts and features. Explain how the invention will work. If you need more space, use another blank page.

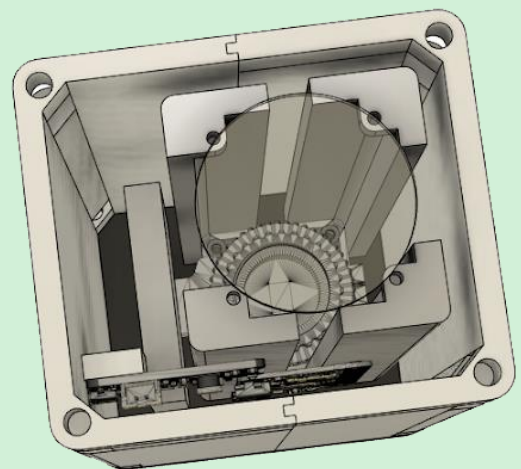
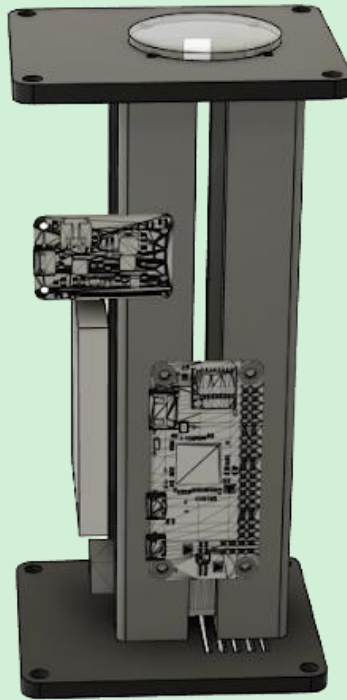
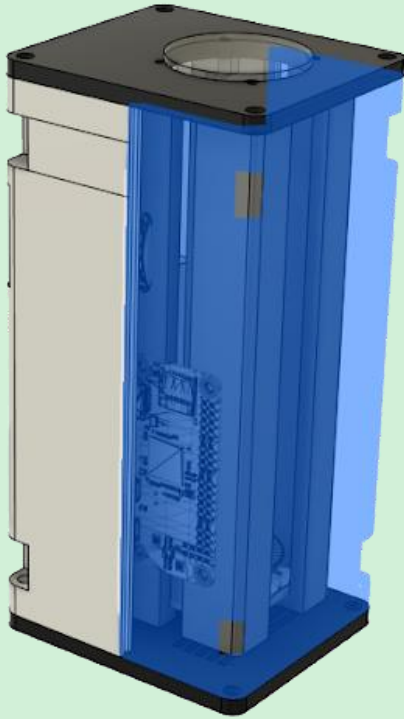
<u>Iterations:</u>	<u>C.A.D. Representation:</u>
<p>Initial/Concept housing unit for the lens/camera configuration.</p> <ul style="list-style-type: none"><li>• Developed in reference to previous research as to particular focal length with studying undilated retinas.</li><li>• Proved effective as an initial housing concept but lacked the proper constraints to be efficiently manufactured</li><li>• Further models/concepts would be needed in order to ensure efficiency in function and ease-of-use within consumer design.</li></ul>	
<p>Updated leg design for housing the pipeline for the camera-lens unit.</p> <ul style="list-style-type: none"><li>• Improves upon the previous design by componentizing the entire design of the pipeline.</li><li>• By dividing the pipeline into four beams, it allows for lesser fidelity/structural elements when 3D printing. This helps with the ease of creation within the design and lowers the production cost of our prototype.</li></ul>	

<p>Assembled four-beam housing pipeline for the camera-lens unit</p> <ul style="list-style-type: none"> <li>The overall design, within this process, was lengthened to provide for updated data (from the lens manufacturer - oDocs Optics) regarding optimal focal length.</li> </ul>	
<p>Assembled four-beam housing pipeline for the camera-lens unit with formal holes sanctioned for electronic components.</p> <ul style="list-style-type: none"> <li>The assembled design was modified to provide for formal nut-and-screw holes (dimensions labeled on the PLA drawing) for the following electronic components: <ul style="list-style-type: none"> <li>Raspberry Pi Zero W</li> <li>2465 Adafruit PowerBoost 1000C Rev B</li> <li>Raspberry Pi High Quality HQ Camera - 12MP</li> </ul> </li> </ul>	
<p>Assembled final product with the outer casing.</p> <ul style="list-style-type: none"> <li>Outer casing and appropriate vents are provided to the rigid four-beam design.</li> <li>Outer screw holes for the 30D lens are provided at the front end of the product. This allows for easy adjustment for everyday use and replacement access for damaged lenses.</li> <li>An outer IO port section allows easy access to USB-C charging/data transmission and NFC transmission of wireless medical records (Medibound)</li> </ul>	
<p>Assembled final product with the outer casing.</p> <ul style="list-style-type: none"> <li>Screw holes added to the outside of the outer casing for customization. These were added to increase the overall applications of this product in the field.</li> <li>These customization features were added in order to maintain longevity throughout our product's life cycle and develop a product family (first and third party) around this utility.</li> </ul>	

**MEASUREMENT: MM**



# IDEATING AND DESIGNING



# IDEATING AND DESIGNING

6. What problems or issues might you encounter with this design? Is this design compatible with the principle of sustainability? Who did you talk to about this design (another student, parent, teacher, etc.)? What were their comments about your design? & 7. How can you fix those problems or address those issues?

The issues and design improvements that led to our final design primarily had to do with the interior structure of the product as well as the requirements of the 3OD lens-scope configuration. This scope layout was adjusted within the first few iterations in order to fit the requirements of a 3OD lens as a means of capturing a center bitmap of a retina for DR analysis. In addition, the final prototype of the product accounts for the curvature of a human head. We addressed these issues by, in some cases, by making radical changes to our design and utilizing strategic implementation to develop a product (see iterations that address question 8 on page 11).

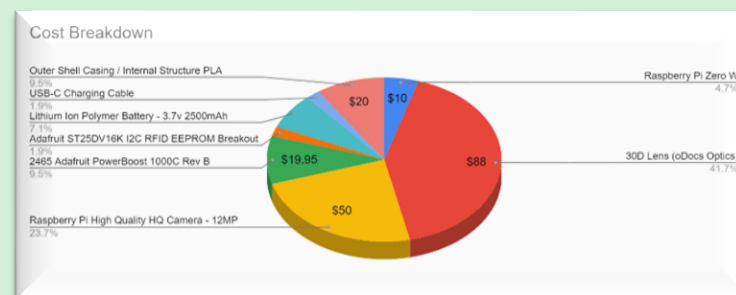
## DESIGNING, BUILDING, TESTING

### Building the Invention or Prototype (Designing, Building, Testing)

9. What parts, materials, and tools will you need to make the invention and how much will they cost?

Parts/Material	Cost
1. Raspberry Pi Zero W	\$10.00
2. 3OD Lens (oDocs Optics)	\$88.00
3. Raspberry Pi High Quality HQ Camera - 12MP	\$50.00
4. 2465 Adafruit PowerBoost 1000C Rev B	\$19.95
5. Adafruit ST25DV16K I2C RFID EEPROM Breakout	\$3.95
6. Lithium Ion Polymer Battery - 3.7v 2500mAh	\$14.95
7. USB-C Charging Cable	\$3.99
8. Outer Shell Casing / Internal Structure PLA	\$~20.00

**Total Cost: \$ 210.84**





# DESIGNING, BUILDING, TESTING

10 & 13. Where will you get those parts and materials?

Parts/Material	Location
1. Raspberry Pi Zero W	Adafruit Industries Inc.
2. 30D Lens (oDocs Optics)	Volk Ophthalmology
3. Raspberry Pi High Quality HQ Camera - 12MP	Adafruit Industries Inc.
4. 2465 Adafruit PowerBoost 1000C Rev B	Adafruit Industries Inc.
5. Adafruit ST25DV16K I2C RFID EEPROM Breakout	Adafruit Industries Inc.
6. Lithium Ion Polymer Battery - 3.7v 2500mAh	Adafruit Industries Inc.
7. USB-C Charging Cable	Adafruit Industries Inc. Local Manufacturing
8. Outer Shell Casing / Internal Structure PLA	Internally Produced

11. What additional skills or abilities will you need to make the invention?

- CAD (Computer-aided Design)
- 3D Printing
- Systems Software Programming (JavaScript, Assembly, Python)
- Neural Network Development
- Image Recognition
- Knowledge of Retinal Diseases and Biomarkers
- Web Design
- Mobile App Development

12. Who can help you build the invention?

While we weren't assisted in the build of our invention, there is a list of key people who helped us to understand and improve our project.

**Shereen Chew (Biomedical Engineer/Stem Cell Biologist at UCSF):** Many thanks are due for allowing us to ask questions regarding the nature of DR and the various retinal constraints of necessary consideration.

**EyePACS, LLC:** Many thanks are due to this corporation for providing the vast library of training and testing DR retinal images in the creation of our neural network algorithms.

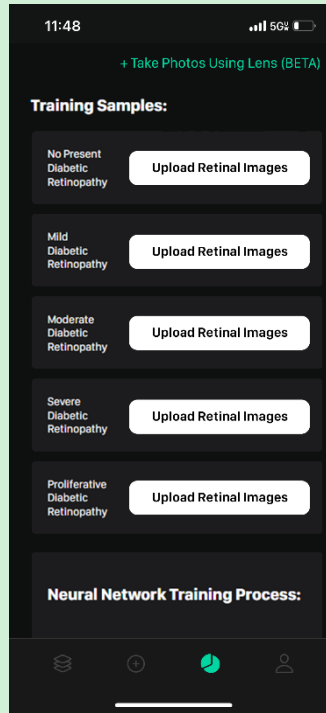
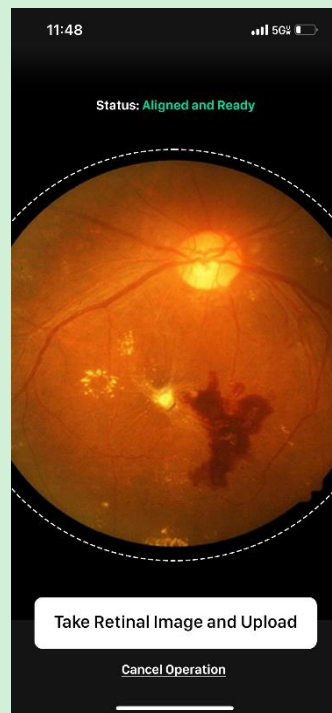
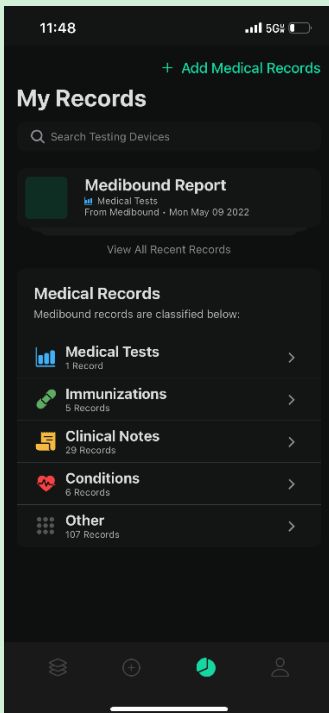
**Dr. Gary Nelson:** Many thanks are due for giving us the opportunity to pursue this invention.

**Dr. Caren Polk:** Many thanks are due for giving us the opportunity to pursue this invention.

14. Test and evaluate the invention. What did you do to test the invention?

Using a retinal dataset from EyePACS, we tested our invention's biomarker and classification detection efficiency by measuring it in terms of speed and accuracy. A random sample of unknown retinal images was inputted and a classification (ranging from (no present diabetic retinopathy, mild diabetic retinopathy, moderate diabetic retinopathy, severe diabetic retinopathy, and proliferative diabetic retinopathy.)

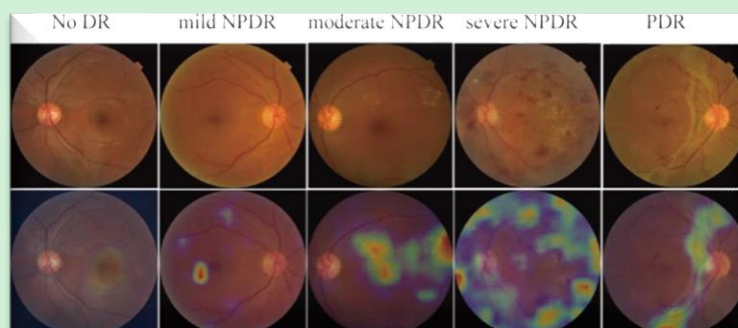
# DESIGNING, BUILDING, TESTING



The images to the right is a display of the mobile NFC application, Medibound, can be used to easily and wireless access the results from our testing unit. These results are available by tapping “Add Medical Records” within the Medibound app and tapping underneath the USBC slot. For more about the internal development of this standalone application, visit: <https://medibound.com>.

15 & 16. Identify any problems with the invention. What will you change to make it better?

Our original concept for this endeavor revolved around the creation of a relatively low-cost device to detect Diabetic Retinopathy (DR) via the retinal sampling of a wide variety of patients, in respect to anthropometric differences. Within this potential product, we planned to incorporate our research within efficient preliminary neural networks to best suit the needs of the wide-degree of end users. These particular algorithms include the convolutional neural network (CNN) algorithm and the k-nearest neighbors algorithm (KNN) for which have proven their individual efficiency in low-cost medical testing (especially within the scope of retinal diagnosis and treatment). Through these initial ideas, along with analysis via morphological synthesis, we had developed the concept of a point-of-care headset utility that could detect when a retina was under its scope and immediately run analysis testing as to the severity of the patient's DR (Range of Severity: No DR, Mild DR, Moderate DR, Severe DR, and Proliferative DR).



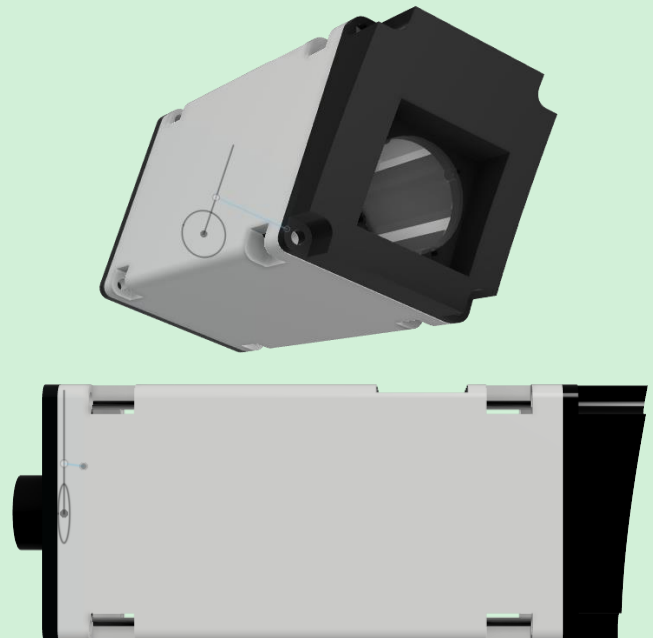
# DESIGNING, BUILDING, TESTING

## Safety Precautions

- When using the product, please make sure you are under supervision to avoid improper use.
- Improper use of the product, especially with light, may result in retinal damage.
- Do not attempt to modify or take out parts of the product. This will damage the product.

## Safety Improvements

- Corners of the product were rounded off to ensure no sharp edges could damage users.
- The electrical system was labeled and grounded to prevent electrical overloads or damaged circuits.
- The brightness of the lens lights was reduced to account for patients with increased light sensitivity.
- The addition of customization allows for more necessary safety improvements as the device develops through its product cycle (into maturity).

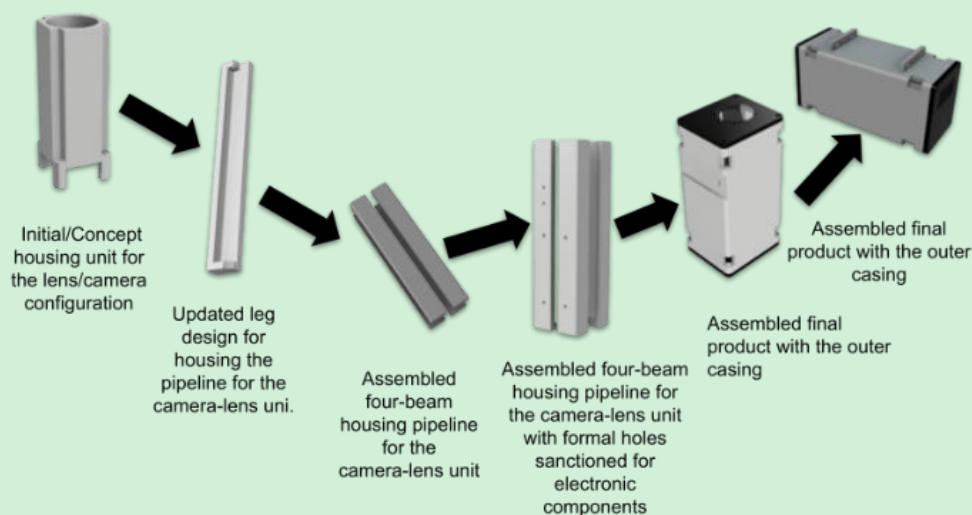


# DESIGNING, BUILDING, TESTING



Throughout the course of our iterative design process, we would take time between conceptual design sessions to conduct our own small scale research-and-development into the constraints of retinal lenses as well as the biomarkers of DR. We tested various different lenses for handheld ophthalmic study (20D, 30D, 90D, etc.) via virtual simulation and analysis of provided fact sheets. We settled upon using a 30D lens due to its effectivity on undilated/small pupils (as far as retinal field of vision), its 3cm working distance from the pupil, and its low price within the modern market. In addition, we also physically experimented with input micro-cameras and their length away from the retinal lens. We eventually settled upon the 12MP Pi High Quality Camera due to its high fidelity, low cost, and support for our central processing unit, the Raspberry Pi Zero W. The final area of adjustment occurred within our discussions regarding the handling of the device. We settled upon using a multi-adapter system that allows doctors/patients to swap out custom handles and accessories in order to best fit their usecase. These changes to anthropometric customization were inspired by an analogy we made to highend RED digital cameras that utilize componentization in order to meet a wide-range of functionality. These adjustment factors were mostly conducted in a virtual environment before physical prototypes were constructed. The main function of internal simulation revolved around the construction of efficient KNN and CNN algorithms for retinal detection and DR severity analysis respectively. This took hundreds of trials over a period of meticulous study for which results in stable algorithms with substantially high confidence when testing against unseen samples.

The final configuration includes a 30D lens, at a distance of 3cm from the pupil, that is paired with a 12MP Pi High Quality Camera that interfaces with the microcontroller (Raspberry Pi Zero W). In addition, this design also allows for a wide-range of customization via its available snap-in ports on the bottom and side. These customized utilities can interface with the product via its electronic USB-C port that also acts as a functional charger. To accompany the device, we also included a substantial battery for mobile consumption. On the digital scheme of the product, we utilized a tailored KNN algorithm to recognize the retina when in-view and a tested CNN algorithm to discern between that sample's particular stage of DR. Once a conclusion is determined, the testing results are exported via an dynamic NFC transmitter (ST25DV16K) placed under the charging port on the product. This result technology allows users to hover their phones over the labeled NFC area and receive their trial results over the web. This system of exportation was primarily chosen to reduce the cost of using traditional medical records and to provide a truly modern/accessible experience.



# NAMING THE INVENTION

## Naming the Invention (Communicating)

17. Naming your invention is important.

- What words describe your invention? / Think in terms of words that will help you name your invention.
  - Mobile retinal imaging, accessibility, vision, rapid testing, efficient testing, low-cost testing, diabetic retinopathy, convolutional neural network, diabetic retinopathy detection, k-nearest neighbors
- What is the function of your invention?
  - To increase accessibility and efficiency as well as decrease cost for diabetic retinopathy testing

## Business Plan and Sales Pitch

- Think in terms of marketing it. How will it solve the problem? How will it help others?

### Outline

- The product for sale would be the VisionBound device, consisting of Raspberry Pi Zero W, a 30D lens, Raspberry Pi 12 MP HQ Camera, a 2465 Adafruit PowerBoost 1000C Rev B, a Adafruit ST25DV16K I2C RFID EEPROM Breakout, a lithium ion polymer battery (3.7v 2500mAh), a USB-C cable, and an outer shell casing.
- The intended audience would be medical centers, global non-profits, and medical research institutions wishing to detect diabetic retinopathy as millions of people across the globe suffer vision complications as a result of diabetic retinopathy, attributed most to the lack of appropriate testing.
- A VisionBound device would diagnose a patient by severity of diabetic retinopathy in order to combat vision complications early on.

### Profit

- A VisionBound device begins at \$250.00.
- Any medical centers willing to share results and patients' overall feelings, as long as patients willingly consent too, would receive a 5% discount on each additional VisionBound device.
- Medical centers, such as Gulf Coast Medical Center, and global non-profits, such as the World Health Organization, would be an ideal source for profit and exposure.

### Prosperity and Challenge

- This project will succeed when access to diabetic retinopathy testing is increased and the vision complications that form from diabetic retinopathy diminish.
- The inventors would like to make an environmental profit as much as a monetary one by keeping a compact form factor, resulting in less materials being used.
- A challenge that underdeveloped medical centers might face is affording a VisionBound device but the inventors will partner up with non-profit organizations, such as Direct Relief, and decrease the price as requested.

### Licensing

The benefits to licensing our idea are that it provides a greater chance to reach patients and the medical market. For example, medical centers would greatly benefit from VisionBound as the use of it would lead to increased diabetic retinopathy diagnostic exams. Around the world, global non-profits and medical research institutions could work towards detecting diabetic retinopathy as millions of people across the globe suffer vision complications. This epidemic is amplified by the lack of appropriate testing as to the severity of DR. Licensing our idea would prompt change within this field because it would enable licensed partners to expand upon our own packaging, advertising, sales, insurance, transportation, and storage of our VisionBound utility. While VisionBoard is relatively low-cost compared to the testing methods currently in the market, we would still coordinate with our licensees to ensure affordable prices for underdeveloped markets/areas.



# NAMING THE INVENTION

## Sales Pitch

Are your patients' health your top priority? Millions of people across the globe suffer vision complications as a result of diabetic retinopathy, mostly due to the lack of appropriate testing. When left untreated, diabetic retinopathy seemingly takes on worse results. These severe cases are often seen in developing nations where general access to medical testing is bleak with most patients unsure of their severity until physical implications become apparent. In fact, 79% of the adults with diabetes reside within low-to-middle income nations and serve a major risk of joining the estimated 93 million people worldwide suffering from diabetic retinopathy. Without significant medical testing, which can often prove expensive, this population is the most at risk of developing blindness and suffering the consequences of vision impairment. This is where our product comes in: the Visionbound device diagnoses a patient by severity of diabetic retinopathy in order to combat vision complications early on. With your support, VisionBound can increase access to diabetic retinopathy testing. At the affordable price of \$250.00, this product will not just modernize the market of point of care utilities, but it'll also offer a lasting improvement to people all across the globe.

## Market Potential

### Place:

Our market potential consists of millions of people across the globe suffering vision complications as a result of diabetic retinopathy, mostly due to the lack of appropriate testing. When left untreated, diabetic retinopathy seemingly takes on worse results. These severe cases are often seen in developing nations where general access to medical testing is bleak with most patients unsure of their severity until physical implications become apparent. In fact, 79% of the adults with diabetes reside within low-to-middle income nations and serve a major risk of joining the estimated 93 million people worldwide suffering from diabetic retinopathy. Without significant medical testing, which can often prove expensive, this population is the most at risk of developing blindness and suffering the consequences of vision impairment.

### Product:

This is where our product comes in: the Visionbound device diagnoses a patient by the severity of diabetic retinopathy in order to combat vision complications early on. VisionBound increases access to diabetic retinopathy testing and diminishes the vision complications that form from diabetic retinopathy.

### Price:

At the affordable price of \$250.00 (provided a margin of profit), our product redefines the current market of DR utilities in both its product-line pricing in terms of customization and its pioneer/budget price point that remains extremely competitive amongst peers.

### Promotion:

Due to the increase in technology usage, we believe an essential aspect of product promotion is digital marketing and services. With this in mind, VisionBound is featured on our self-designed and developed website, <https://medibound.com/>. With this website, we plan to take our product to market very soon.

## Social Value

### Relevancy:

We propose that our product, VisionBound, will benefit our target market by diagnosing patients by the severity of diabetic retinopathy in order to combat vision complications early on. To offer context, our target market encompasses millions of people across the globe suffering vision complications as a result of diabetic retinopathy, mostly due to the lack of appropriate testing. Our product offers social value by increasing access to diabetic retinopathy testing and diminishes the vision complications that form from diabetic retinopathy.

### Quantified Value & Differentiation:

Compared to our competitors, VisionBound is relatively low-cost as it utilizes a point-of-care testing in which the retinal images of patients are analyzed through KNN and CNN algorithms, providing results soon after. By incorporating a 30D lens, our invention speeds up diabetic retinopathy diagnosis by eliminating the need for a dilated eye exam. This also allows for potential self-testing and decreases the expertise needed to issue a diagnostic exam, if not done at home, leading to increased accessibility. Our invention utilizes a form factor of 73mm x 85mm x 175mm, demonstrating its compact nature. This ensures its mobility as compared to legacy machines, which may be large and immobile. Our invention also features snap-in ports on the bottom and side. This allows for a wide range of customization up to the user. By researching key phrases on the United States Patent Depository Library, we confirmed that our invention is completely unique.

- How is your invention different from others that may already be on the market? If it is similar, what did you do to make it better? How is it different?
  - 1. VisionBound is relatively **low-cost** as it utilizes a **point-of-care testing** in which the retinal images of patients are analyzed through KNN and CNN algorithms, providing results soon after.
  - 2. By incorporating a 3OD lens, our invention **speeds up diabetic retinopathy diagnosis** by eliminating the need for a dilated eye exam. This also allows for potential **self-testing** and decreases the expertise needed to issue a diagnostic exam, if not done at home, leading to **increased accessibility**.
  - 3. Our invention utilizes a form factor of 73mm x 85mm x 175mm, demonstrating its **compact nature**. This ensures its **mobility** as compared to legacy machines, which may be large and immobile.
  - 4. Our invention features snap-in ports on the bottom and side. This allows for a **wide range of customization** up to the user.
  - By researching phrases like “diabetic retinopathy”, “mobile retinal imaging”, “convolutional neural network”, “diabetic retinopathy detection”, and “k-nearest neighbors” on the United States Patent Depository Library and other websites, we confirmed that our invention is **completely unique**.
- Who is your target audience? Who would use your invention?

The intended audience for VisionBound would be medical centers, global non-profits, and medical research institutions wishing to detect diabetic retinopathy. Millions of people across the globe suffer vision complications as a result of diabetic retinopathy, attributed mostly to the lack of appropriate testing. This discrepancy can be solved through algorithmic efficiency and innovative design. Both of these aspects are a key part of our VisionBound utility.

- Based on this analysis, what is a good name for your invention? What name do you like best and why?

VisionBound is our favorite name for our invention because it emphasizes our mission to bridge the gap between technology and preventable retinal diseases.



**VISIONbound**

**Bridging the Gap Between Technology and Preventable Retinal Diseases**

## Planning and Creating the Invention Display Board (Communicating)

# COMMUNICATING

## Practicing What You Will Say About Your Invention (Communicating)

19. Be prepared to answer questions. Here are some questions that you might be asked in the Judging Circle by the judges or fellow students. To help you prepare, you might want to write down some of the important parts of your answers so that you have them when you practice giving your presentation.

- How did you come up with the idea for this invention? / What people, situations, or conditions does this problem affect? / How did you think up your solution to the problem?

First, our team identified three global issues that we were interested in addressing. These issues were diabetic retinopathy, water pollution, and red tide.

**Diabetic Retinopathy:** Diabetic retinopathy is a complication caused by an existing history of diabetes/diabetic symptoms that can slowly deteriorate a person's vision and can even lead to partial blindness. Often this diabetic complication can be treated by timely management of the condition and/or modern laser eye treatments/surgery. However, this treatment of diabetic retinopathy cannot completely cure the disease and, when left untreated, its effects seemingly take on worse results. These severe cases are often seen in developing nations where general access to medical testing is bleak with most patients unsure of their severity until physical implications become apparent. In fact, 79% of the adults with diabetes reside within low-to-middle income nations and serve a major risk of joining the estimated 93 million people worldwide suffering from diabetic retinopathy. Without significant medical testing, which can often prove expensive, and local ophthalmologists, this population is the most at risk of developing blindness and suffering the consequences of vision impairment. In this sense, the recent development of low-cost neural networks as a means of detecting early stages of diabetic retinopathy has become a much-needed solution to centuries of unknown suffering as a result of this complication.

**Water Pollution:** This problem catches our attention because 2.4 billion people suffer the problem of inadequate sanitation worldwide. This puts them at risk of many deadly diseases such as cholera, typhoid fever, etc.. Inventing something that could help fix this would be beneficial to third world countries that don't receive the clean water we do.

**Red Tide:** This problem catches our attention because it comes and goes in Florida and figuring out a permanent end would benefit both humans and our wildlife.

We chose diabetic retinopathy because it is a complication caused by an existing history of diabetes/diabetic symptoms that can slowly deteriorate a person's vision and can even lead to partial blindness. Often this diabetic complication can be treated by timely management of the condition and/or modern laser eye treatments/surgery. However, this treatment of diabetic retinopathy cannot completely cure the disease and, when left untreated, its effects seemingly take on worse results. These severe cases are often seen in developing nations where general access to medical testing is bleak with most patients unsure of their severity until physical implications become apparent. In fact, 79% of the adults with diabetes reside within low-to-middle income nations and serve a major risk of joining the estimated 93 million people worldwide suffering from diabetic retinopathy. Without significant medical testing, which can often prove expensive, and local ophthalmologists, this population is the most at risk of developing blindness and suffering the consequences of vision impairment. In this sense, the recent development of low-cost neural networks as a means of detecting early stages of diabetic retinopathy has become a much-needed solution to centuries of unknown suffering as a result of this complication. However, such solutions must be affordable/accessible as well as accurate in their results. This is the basis for this study and the reason for such urgency when it comes to developing solutions.

The idea for creating a low-cost retinal imaging utility for detecting the severity of diabetic retinopathy resulted from a primary experiment we conducted in regard to neural network sampling of DR retinal images. During our research within this previous extensive study, we noted the lack of available resources provided to DR on the low-end and that the accessibility of these retinal tests was a primary factor in the abundance of untreated/preventable cases. With this knowledge of a potentially life-changing niche in the market, we knew we had to act upon this issue. Within a few weeks, we had incorporated our backbone of research and our knowledge into a functioning/open environment for innovation.



# COMMUNICATING

- Where did you get the materials for the invention?

Parts/Material	Purchase Site
1. Raspberry Pi Zero W	Adafruit Industries Inc.
2. 30D Lens (oDocs Optics)	Volk Ophthalmology
3. Raspberry Pi High Quality HQ Camera - 12MP	Adafruit Industries Inc.
4. 2465 Adafruit PowerBoost 1000C Rev B	Adafruit Industries Inc.
5. Adafruit ST25DV16K I2C RFID EEPROM Breakout	Adafruit Industries Inc.
6. Lithium Ion Polymer Battery - 3.7v 2500mAh	Adafruit Industries Inc.
7. USB-C Charging Cable	Adafruit Industries Inc. Local Manufacturing
8. Outer Shell Casing / Internal Structure PLA	Internally Produced

- Who helped you build the invention and what did they help you do?

While we weren't assisted in the build of our invention, there is a list of key people who helped us to understand and improve our project.

**Shereen Chew (Biomedical Engineer/Stem Cell Biologist at UCSF):** Many thanks are due for allowing us to ask questions regarding the nature of DR and the various retinal constraints of necessary consideration.

**EyePACS, LLC:** Many thanks are due to this corporation for providing the vast library of training and testing DR retinal images in the creation of our neural network algorithms.

**Dr. Gary Nelson:** Many thanks are due for giving us the opportunity to pursue this invention.

**Dr. Caren Polk:** Many thanks are due for giving us the opportunity to pursue this invention.

- Are there other, better materials you could have used that would improve the invention?

With larger manufacturing resources, we could switch to injection molding that may improve the structural integrity of the invention and the efficiency of the manufacturing process.

- Who has used your invention and what did they think about it?

We have tested on retinal images to improve our accuracy and efficiency in DR testing and will soon start human testing upon approval and safety verifications.

- What changes might you want to make to your invention?

We would like to use custom PCBs to cut down on cost, use lower cost materials and design for mass manufacturing in order to cut costs, increase the efficiency of the algorithm through human trials, increase the modularity of the product, and adjust the product to suit various cultures and scenarios based upon in-field tests and further user research.



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