VISIONbound™

BRIDGING THE GAP BETWEEN TECHNOLOGY AND PREVENTABLE RETINAL DISEASES

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IDENTIFYING GLOBAL ISSUES

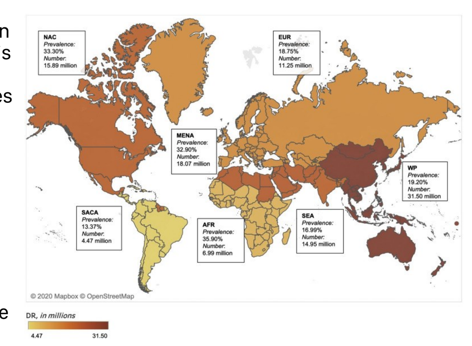
Diabetic Retinopathy: Diabetic retinopathy is a complication caused by an existing history of diabetes/diabetic symptoms that can slowly deteriorate a person's vision and can even lead to partial blindness. Often this diabetic complication can be treated by timely management of the condition and/or modern 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 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.

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.

WHY WE CHOSE THIS 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 modern laser eye treatments. 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.



Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: results from the International Diabetes Federation Diabetes Atlas, 9(th) edition.

HOW THE IDEA CAME TO US?

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 regards 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.

BUSINESS PLAN

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

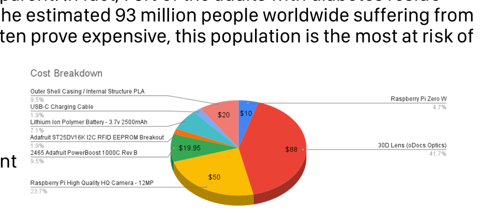
- This project will succeed when access to diabetic retinopathy testing is increased and the vision complications that form from diabetic retinopathy diminish.
- The inventors would like to make an environmental profit as much as a monetary one by keeping a compact form factor, resulting in less materials 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.

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 imparity. 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.

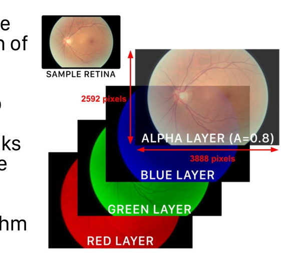


All graphs and figures above were created by the inventors

PRELIMINARY RESEARCH

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. 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 image above was created by the researchers

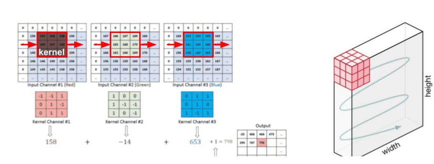


Image taken from Saha, S. (2018, December 17). A comprehensive guide to convolutional neural networks-the eli5 way. Medium. Retrieved December 29, 2021, from https://towardsdatascience.com/a-comprehensive-guide-to-convolutional-neural-networks-the-eli5-way-3bd2b1164a53

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. 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 depose 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 kernelling 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 deposes new images into logits, which are then normalized to unit length.

ITERATIONS OF DESIGN

Iterations: | **C.A.D. Representation:**

Title: Initial/Concept housing unit for the lens/camera configuration.

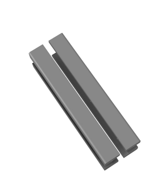
- Developed in reference to previous research as to particular focal length with studying undilated retinas.
- Proved effective as an initial housing concept but lacked the proper constraints to be efficiently manufactured
- Further models/concepts would be needed in order to ensure efficiency in function and ease-of-use within consumer design.

Title: Updated leg design for housing the pipeline for the camera-lens unit.

- Improves upon the previous design by componentizing the entire design of the pipeline.
- 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.

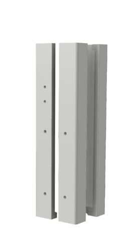
Title: Assembled four-beam housing pipeline for the camera-lens unit

- The overall design, within this process, was lengthened to provide for updated data (from the lens manufacturer - oDocs Optics) regarding optimal focal length.



Title: Assembled four-beam housing pipeline for the camera-lens unit with formal holes sanctioned for electronic components.

- The assembled design was modified to provide for formal nut-and-screw holes (dimensions labeled on the PLA drawing) for the following electronic components:
  - Raspberry Pi Zero W
  - 2465 Adafruit PowerBoost 1000C Rev B
  - Raspberry Pi High Quality HQ Camera - 12MP

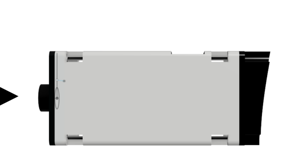


Title: Assembled final product with the outer casing.

- Outer casing and appropriate vents are provided to the rigid four-beam design.
- 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.
- An outer IO port section allows easy access to USB-C charging/data transmission and NFC transmission of wireless medical records (Medibound)

Title: Assembled final product with the outer casing

- 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.
- 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.



All drawings above were created by the inventors

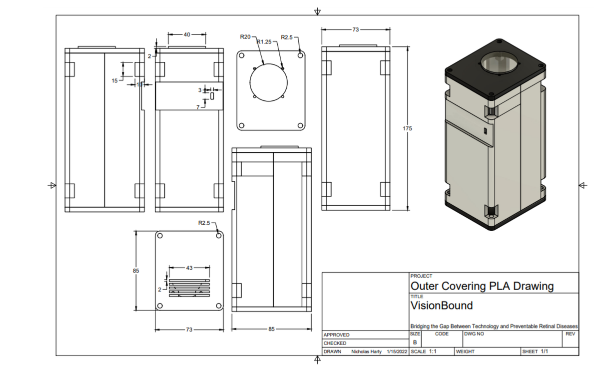
SUMMARY OF INVENTION & MATERIALS

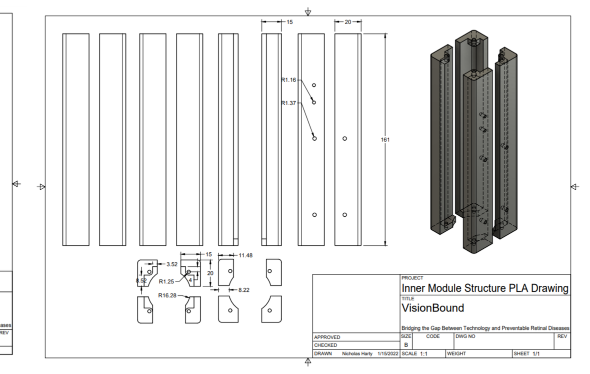
The final configuration of our product, VisionBound, includes a 30D lens, at a distance of 3cm from the pupil, that is paired with a 12MP Pi High-Quality Camera that interfaces with the microcontroller (Raspberry Pi Zero W). In addition, this design also allows for a wide range of customization via its 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.

Materials:

Raspberry Pi Zero W	30D Lens (oDocs Optics)	Raspberry Pi High Quality HQ Camera - 12MP	2465 Adafruit PowerBoost 1000C Rev B
Adafruit ST25DV16K I2C RFID EEPROM Breakout	Lithium Ion Polymer Battery - 3.7v 2500mAh	USB-C Charging Cable	Outer Shell Casing / Internal Structure PLA

OUTER/INNER PLA CONSTRAINT DRAWING



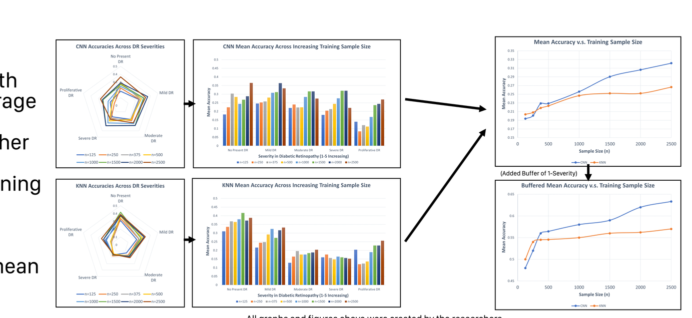


All drawings above were created by the inventors

INTERPRETATION OF SCIENTIFIC TRIALS

Results:

To measure the accuracy of the CNN and KNN algorithms, mean and buffered accuracy was calculated for each training sample size. For both algorithms, the mean accuracy (%) was the average of all 50 trials (10 per DR severity). The buffered accuracy (%) provided a 1-severity margin to either end of the definite outcome, resulting in an amplified marker of the mean accuracy. In a training sample size of 125 retinal images (ranging in severity), the CNN algorithm resulted in a mean accuracy of 19.36% and a buffered accuracy of 48.00%, while the KNN algorithm resulted in a mean accuracy of 20.36% and a buffered accuracy of 50.00%. In a training sample size of 250 retinal images, the CNN algorithm resulted in a mean accuracy of 20.08% and a buffered accuracy of 52.00%, while the KNN algorithm resulted in a mean accuracy of 20.80% and a buffered accuracy of 54.00%. In a training sample size of 375 retinal images, the CNN algorithm resulted in a mean accuracy of 22.88% and a buffered accuracy of 56.00%, while the KNN algorithm resulted in a mean accuracy of 21.84% and a buffered accuracy of 54.50%. In a training sample size of 500 retinal images, the CNN algorithm resulted in a mean accuracy of 22.88% and a buffered accuracy of 56.44%, while the KNN algorithm resulted in a mean accuracy of 22.32% and a buffered accuracy of 54.56%. In a training sample size of 1000 retinal images, the CNN algorithm resulted in a mean accuracy of 25.60% and a buffered accuracy of 58.00%, while the KNN algorithm resulted in a mean accuracy of 24.68% and a buffered accuracy of 55.00%. In a training sample size of 1500 retinal images, the CNN algorithm resulted in a mean accuracy of 29.04% and a buffered accuracy of 59.00%, while the KNN algorithm resulted in a mean accuracy of 25.20% and a buffered accuracy of 56.00%. In a training sample size of 2000 retinal images, the CNN algorithm resulted in a mean accuracy of 30.64% and a buffered accuracy of 62.00%, while the KNN algorithm resulted in a mean accuracy of 25.20% and a buffered accuracy of 56.22%. In a training sample size of 2500 retinal images, the CNN algorithm resulted in a mean accuracy of 32.16% and a buffered accuracy of 63.33%, while the KNN algorithm resulted in a mean accuracy of 26.64% and a buffered accuracy of 57.00%.



All graphs and figures above were created by the researchers

Trends:

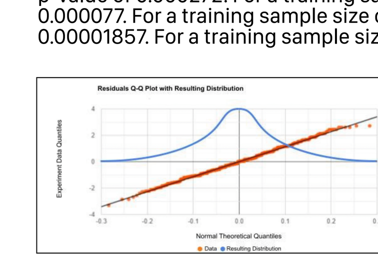
In both algorithms, there was a general increase in accuracy as the training sample size increased. In the CNN algorithm, this increase was steeper compared to the KNN algorithm. This trend can be noted in the slope of the provided line graphs. In addition to this, the radar graphs and bar graphs highlighted individual upward trends in each category of diabetic retinopathy by increasing sample size. From the line graphs, the pattern of CNN's spike is evident as the CNN mean accuracy line makes a sharp increase at around 375 samples and in doing so, surpasses the mean accuracy of KNN.

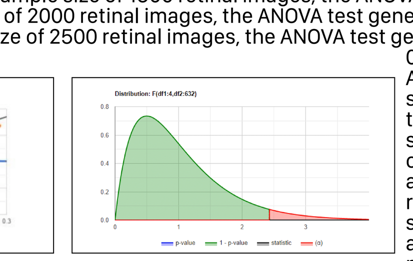
Significance:

When presented with training sample sizes of 125 and 250 retinal images, KNN was more accurate, which could justify its use over CNN in lower sample sizes. However, in training sample sizes of n=375 and above, CNN was more accurate, which could justify its use over KNN in higher sample sizes. This supported the investigators' hypothesis since the CNN algorithm produced a greater average accuracy across higher training sample sizes in this identification process compared to the KNN algorithm, which produced greater average accuracy across lower training sample sizes. At the largest training sample size of 2500 retinal images, the CNN was over 6% higher in accuracy compared to KNN. This could signify that CNN's accuracy would continue growing at a higher rate with additional training samples. This acknowledgment could prove to be beneficial to larger researchers with worldwide resources.

Statistical Analysis:

The investigators collected a combination of nominal (type of algorithm, type of training sample size, and DR severity) and ratio data (accuracy). Their data examined the relationship between the type of algorithm and accuracy, for different training sample sizes in identifying specific stages of diabetic retinopathy in retinal images. For each type of training sample size, researchers incorporated an independent measures design in which different retinal images were used per trial, and the quantitative variable (accuracy) was measured in reference to two categorical variables (type of algorithm and DR severity). Because of this, a two-way ANOVA test (analysis of variance) with a significance level (α) of 0.05 was used to determine the experiment's statistical significance. For a training sample size of 125 retinal images, the ANOVA test generated an interaction p-value of 0.0001347. For a training sample size of 250 retinal images, the ANOVA test generated an interaction p-value of 0.0002419. For a training sample size of 375 retinal images, the ANOVA test generated an interaction p-value of 0.0001786. For a training sample size of 500 retinal images, the ANOVA test generated an interaction p-value of 0.01463. For a training sample size of 1000 retinal images, the ANOVA test generated an interaction p-value of 0.000272. For a training sample size of 1500 retinal images, the ANOVA test generated an interaction p-value of 0.000077. For a training sample size of 2000 retinal images, the ANOVA test generated an interaction p-value of 0.00001857. For a training sample size of 2500 retinal images, the ANOVA test generated an interaction p-value of 0.0002475. All of the p-values from the ANOVA test were less than the significance level of 0.05, which meant the null hypothesis, that there is no statistical significance between the type of algorithm and its average accuracy across training sample sizes, was rejected. This signifies that there is a statistically significant relationship. In addition to this, the residuals followed a normal distribution as shown by the Q-Q plot. Furthermore, every interaction priori power generated by the ANOVA test was greater than 0.9850, signifying that the results are likely valid.





All graphs and figures above were created by the researchers with graphical assistance from the source: Two Way ANOVA Calculator. (n.d.). Retrieved January 23, 2022, from https://www.statskingdom.com/two-way-anova-calculator.html

MARKET POTENTIAL (4 Ps) & SOCIAL VALUE

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 imparity.

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:**

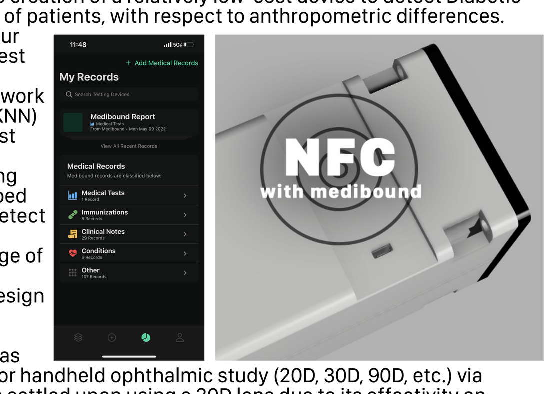
Compared to our competitors, VisionBound is relatively low-cost as it utilizes a point-of-care testing in which the retinal images of patients are analyzed through KNN and CNN algorithms, providing results soon after. By incorporating a 30D lens, our invention speeds up diabetic retinopathy diagnosis 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 phrases like "diabetic retinopathy", "mobile retinal imaging", "convolutional neural network", "diabetic retinopathy detection", and "k-nearest neighbors" on the United States Patent Depository Library, we confirmed that our invention is completely unique.

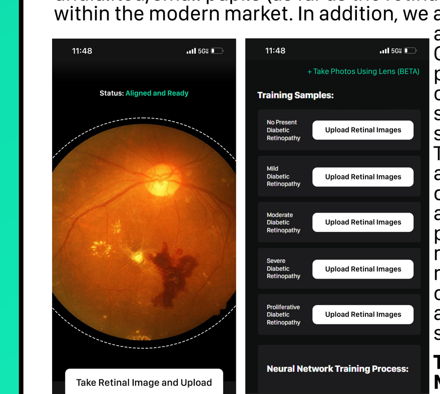
ORIGINALITY

1. VisionBound is relatively **low-cost** as it utilizes a **point-of-care testing i**n 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. When researching keywords, such as diabetic retinopathy, mobile retinal imaging, convolutional neural network, diabetic retinopathy detection, and k-nearest neighbors, there were no similar products compared to our innovation. This research was accomplished on sites including USPTO and Amazon.

PRODUCT DEVELOPMENT

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, with 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 the 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 use case. These changes to anthropometric customization were inspired by an analogy we made to high-end 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 girth 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 resulted in stable algorithms with substantially high confidence when testing against unseen samples.





The images above is a display of the mobile NFC application, Medibound, which can be used to easily and wirelessly access the results from our testing unit. These results are available by tapping "Add Medical Records" within the Medibound app and tapping underneath the USB-C slot.

For more about the internal development of this standalone application, visit: https://medibound.com

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