Portable Device for Objective Visual Field Measurement

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Problem Statement:

Over 2.7 million Americans age 40 and older suffer from glaucoma. To diagnose and track the progression of the disease, physicians use a visual field test. Devices currently used for this test include a dome-shaped inner cavity embedded with a coordinate grid of lights. At the center of the dome the patient positions the eye to be tested with the help of a chin rest and a forehead bar. A eyepatch covers the non-testing eye, and the patient is instructed to focus on a marked point at the back center of the dome. Lights are then flashed on and off at different points in the the dome. When the patient sees a light, they press a button. The device beeps to indicate that the button was pushed and records that they have seen the light at the given position. After the system maps these responses onto a coordinate grid, the physician is able to evaluate the patient's visual field.

This test is administered one eye at a time and can take about 5 to 10 minutes per eye. The patient must often sit in unnatural positions to take the test in order to align their eyes with the visual field device. They must also concentrate on the test for its full duration. For glaucoma patients, who are often elderly, testing is thus tiring and uncomfortable. In interviews with optometry clinicians, physicians often stated that the biggest complaint they hear from their patients is the discomfort and long duration of the visual field test.

Halma's solution is a device that measures visual field by analyzing patient pupil response to various visual stimuli. By taking advantage of the pupillary reflex, patients no longer need to determine whether they have perceived the flashing light. Instead, the exam is entirely automatic, removing the human error. A recent clinical trial found that Halma's device diagnosed patients with mild, medium, and severe glaucoma, as accurately as the Humphrey Visual Field Analyzer (HFA), the current gold standard for the visual field test.

However, Halma's current prototype is bulky and does not adequately address the discomfort incurred by using a visual field device. Our project will build on the technology of existing prototypes to produce a more portable device that will provide greater comfort to patients. We will also improve the device's hardware aesthetics and for greater marketability. We will also simplify the user interface and results output for ease of use, understanding, and export of data to other systems.

Patenting:

Our sponsor, Halma, has conducted a patent search prior to the initialization of our project. There are no existing patents that would be infringed by our device. Thus, our device has the potential to obtain a patent. If a patent is desired, the application for a patent will be filed by the company, Halma.

Regulatory pathway:

We plan to send the device through the 510(k) pathway in order for it to reach consumers as quickly as possible. Halma has already taken measures to assure that their device will be able to pass through the 510(k) pathway. The device produces similar results to current Humphrey Visual Field Analyzers. These predicate devices are already legally marketed, and Halma's device has both the same intended use and technological characteristics as these devices. This will help ensure that it will fulfill the substantial equivalence provision of the 510(k) pathway. Because the device is non-invasive and poses little risk to the patient, it should be classified as a Class I device.

Reimbursement:

It is expected that Halma and Vanderbilt University School of Engineering will jointly cover the costs necessary to model the new visual field device. We will be utilizing resources provided by the university in order to print out a 3D model. However, specific device components will be provided by Halma.

Estimated manufacturing costs:

Anticipated manufacturing costs for our device prototype include the computer-aided design software, materials used to construct the model, and assembly costs. We expect some parts of our project to be manufactured by outside vendors, which will incur additional costs.

Following our device mock-up, the device will be manufactured on a large scale for commercialization and mass distribution. Associated costs include materials purchase, assembly, product packaging, and shipping and transportation. Our design will keep these factors in mind to keep manufacturing costs as low as possible while maintaining the quality of our product.

Potential market:

We plan to market this device to clinicians, specifically ophthalmologist and optometrist clinics and hospitals; ophthalmic researchers; and pharmaceutical companies. We expect clinical ophthalmologists and optometrists to be able to simplify and streamline their visual field testing through using this device. One Vanderbilt ophthalmologist indicated that his clinic could benefit from a portable and objective device. A portable device would allow more patients with mobility problems or other physical barriers to experience the test comfortably. Additionally, the objective component would prevent patient input from interfering with test accuracy. There will be no learning effects nor the need for audio feedback. This will decrease the number of appointments needed to obtain accurate readings and allow a single technician to

administer the test to two or more people at once without feedback interfering with the test results. We expect physicians to be attracted to the lower error in testing.

Researchers could use our technology to improve the quality of ophthalmic research. Current devices make data collection and analysis difficult. Our portable device would likely ease data collection. Improving data transfer will also help attract researchers to our product, as it will make data analysis simpler and less tedious than current methods.

We are also interested in marketing this device to pharmaceutical and surgical intervention companies. This device will be especially useful in conducting either new or existing clinical trials for treatments of glaucoma, and potentially other eye or neurological problems. Simple testing processes and accurate and consistent data collection across a large sample of patients will encourage more research and development in glaucoma treatments, both surgical and therapeutic.

As the average population age increases, there will be more patients who require visual field testing. This trend will increase the need for a faster, more effective, and more accurate test for clinical use. This will likely increase the size of the already substantial market for this device.

References:

1. Eye Health Statistics. Eye Health Statistics - American Academy of Ophthalmology. https://www.aao.org/newsroom/eye-health-statistics.