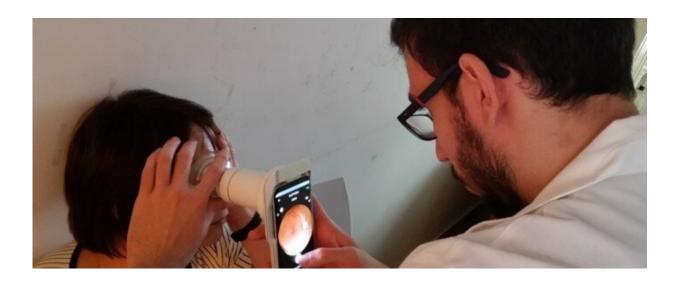


Portable device can be used to diagnose eye disease remotely

June 26 2019, by André Julião



An app operating the optical device sends images of the retina over the internet to Eyer Cloud, which stores and manages patient files. Credit: Phelcom Technologies

A portable device connected to a smartphone makes precise images of the retina to detect back-of-the-eye (fundus) disease at a far lower cost than conventional methods. Created by Phelcom Technologies, a startup based at São Carlos in São Paulo State, Brazil, the Eyer can be used for remote diagnosis by an ophthalmologist via telemedicine.

Phelcom's São Carlos factory came online in March after winning



certification from the National Institute of Metrology, Quality and Technology (INMETRO) and the National Health Surveillance Agency (ANVISA).

The plant currently turns out 30 units per month. Production is set to reach 100 units by end-2019. The Eyer is shipped with a high-quality smartphone and costs approximately US\$5,000. The most widely used conventional ophthalmoscope has to be connected to a computer and costs some US\$30,000.

An optical device designed to light up and image the retina is connected to the smartphone's camera, and an app sends the images over the internet to Eyer Cloud, which stores and manages patient files.

If the user does not have Wi-Fi or access to a 3G or 4G network; the images are stored in the smartphone and sent to the cloud when an internet connection becomes available.

"We invested significantly in optics and in design. One challenge was producing a portable version of a device that is typically very large. Another was enabling nonmydriatic operation so that high-quality images of the retina can be captured without the need for pupil dilation," Phelcom CEO José Augusto Stuchi told.

The name Phelcom is a portmanteau of physics, electronics and computing. The firm's other co-owners are COO Flávio Pascoal Vieira and CTO Diego Lencione.

Stuchi and his partners met in 2008 while working in Opto Eletrônica's R&D Department and became close collaborators while studying for a master's degree at the University of São Paulo (USP) in São Carlos.

Eyer Cloud is an innovation designed by the team to store all the data



acquired in retinopathy exams and organize it in a database. Most ophthalmoscopes in current use have to be connected to a computer to save data to a hard disk and are not web-enabled.

Users of the Eyer set up an account to which images can automatically be saved. "We had to make sure data privacy would be guaranteed and develop a means of transmitting images at high speed to the cloud, so that they can be viewed online regardless of the device's location," Stuchi said.

The latter factor is key to enabling <u>telemedicine</u>. The Eyer lets a trained technician or general medical practitioner produce the images, while an ophthalmologist who specializes in retinopathy can then analyze them and write an expert report at another location.

Phelcom is currently partnering with ophthalmologists to develop the reporting part of the system. Payment is by monthly subscription. Each report costs between US\$5.00 and US\$10.00, depending on the number of reports issued.

Artificial intelligence

In addition to representing a new service, the medical reports are fed into a database that can be used to "teach" a computer to find patterns associated with ocular <u>fundus</u> diseases, especially diabetic retinopathy.

The firm currently has images of more than 10,000 retinas and plans soon to have the largest database of its kind in the world. The partners expect to examine 50,000 patients next year alone.

The last year saw the first approval of an artificial intelligence (AI) diagnostics algorithm by the United States Food and Drug Administration (FDA). Called IDx-DR, the software program uses AI to



analyze images of the eye taken with a retinal camera to detect diabetic retinopathy, the leading cause of vision impairment and blindness among working-age adults in the US.

In Brazil, 7.6 percent of people living in cities and aged 30-69 are estimated to have diabetes. Approximately half of these patients probably have diabetic retinopathy.

"The diagnostic use of AI is a growing global trend. Computers process the data, and physicians make decisions," Stuchi said.

The accuracy of Phelcom's system in detecting <u>diabetic retinopathy</u> without human intervention is currently close to 80 percent, he added. As its database expands, accuracy should reach 95 percent, and at that point, the app can be marketed. The accuracy of IDx-DR is currently rated at 89.5 percent.

"With support from PIPE, we were able to hire a team and leave our jobs to focus on the project," Stuchi recalled.

Phelcom expects to sell 150 Eyers in Brazil in the next 12 months, earning R\$3 million in revenue. The partners now want to extend sales to other Latin American countries and then to the US and Europe.

Wearable device

Phelcom has also won funding from <u>PIPE</u> to develop another innovative product: a pair of glasses that images the retina when worn by the patient and assesses refraction.

Refraction testing, currently one of the main activities performed by eye clinics, is used to identify myopia (nearsightedness), hyperopia (farsightedness), presbyopia (diminished focusing range, or "tired eyes")



and astigmatism (blurred vision). Based on the results, the ophthalmologist or optometrist can prescribe glasses if necessary.

"From development to commercialization, we took three years to come up with our first product, the Eyer," Stuchi said. "We want to do this one in less time, so the idea is to design small modules that can be coupled to the Eyer, or to an enhanced version of it. If all goes well, in a few years' time, we'll have a pair of glasses that images the <u>retina</u>, diagnoses refraction, and measures eye pressure."

Adding all these devices to a pair of glasses may eliminate or limit the need for an equipment operator and help standardize the tests. Even with the <u>online training</u> in operation of the Eyer provided by Phelcom, subjective factors such as how the apparatus is positioned can affect image quality.

"In line with current trends in wearables, the patients themselves would perform the test simply by putting the glasses on for a few minutes," Stuchi said.

Phelcom acknowledges the importance to its performance of PIPE, Eretz.bio—which provides not only resources but also business mentoring and collaboration with the Albert Einstein Hospital to validate the devices clinically—and Supera, the high-tech startup incubator at Supera Innovation and Technology Park in Ribeirão Preto, São Paulo State.

The incubator has access to the park's certification laboratories for the healthcare industry, which are vitally important to the development of the Eyer. In addition to technical and legal support, the incubator also contributed to the development of Phelcom's marketing strategy.

New healthcare Technologies



With bachelor's and master's degrees from USP's São Carlos Engineering School and currently studying for a Ph.D. at the University of Campinas (UNICAMP), Stuchi was one of the entrepreneurs supported by PIPE who presented projects during a panel session entitled "FAPESP—Innovative research on medical and hospital equipment: opportunities and challenges," held in São Paulo City on May 23, 2019, as part of Hospitalar, one of the largest healthcare industry trade shows in the Americas.

Another entrepreneur who participated in the session was Paulo Gurgel Pinheiro, founder of Hoobox Robotics, which has developed facial recognition technology that can be used to translate a wheelchair user's expressions into control commands and to monitor patients in intensive care, among other applications.

Another participant in the session was Brain4Care, which created an innovative system to monitor intracranial pressure noninvasively, which significantly reduces the risks, costs and complications associated with this procedure and is required to diagnose and treat a number of medical conditions.

The firm's founders include Sérgio Mascarenhas, Emeritus Professor at USP, and Gustavo Frigieri, who attended the event and had his first project approved by PIPE in 2008.

"All three health tech startups have the same attitude of aiming at the Brazilian market and also the world. For them, occupying space in the domestic market is a means of entering markets abroad and not an end in itself. This is the kind of firm we prefer to select for PIPE's awards. Here, we've shown three, but to date we've supported more than 1,000, all of them operating worldwide," Carlos Henrique de Brito Cruz, FAPESP's scientific director, said during the event.



Provided by FAPESP

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https://medicalxpress.com/news/2019-06-portable-device-eye-disease-remotely.html

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