

# Speeding up Diabetes Diagnosis is this California Startup's Goal

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**Freedom Meditech hopes to dramatically change how diabetes is diagnosed today through an FDA-cleared eye-test device.**



**The FDA-cleared ClearPath DS-120 device can diagnose diabetes through eye-test**

Diabetes is an expensive disease with one study projecting that the global cost to treat the scourge will be [\\$490 billion in 2030](#).

In the U.S. alone, the economic impact of the disease was estimated to be [\\$245 billion in 2012](#), a 41% increase from previous estimates of \$174 billion in 2007.

San Diego, California startup [Freedom Meditech](#) is taking a direct aim at these skyrocketing costs with a FDA-cleared device that can speed up diabetes diagnosis by as much as seven years.

All it involves is a six-second, noninvasive eye test performed by the [ClearPath DS-120](#) device which uses a blue light to



**Craig Misrach, founder and CEO of Freedom Meditech**

detect lens autofluorescence, says Craig Misrach, founder and CEO, Freedom Meditech. When glucose is not broken down well in the body as is the case with diabetics, it starts sticking to the proteins in lens in the eye and autofluorescence helps to detect these, Misrach explains.

By looking at sugars sticking to proteins in the eye, as opposed to standard tests that involves blood draws, a diabetes diagnosis can be made earlier in a person's life.

"One of the tests that's used today to diagnose diabetes is called hemoglobin A1C test and that is what percentage of glucose is attached to your red blood cells. RBCs turn over every 90 days so at best it really just tells you how well that person's metabolic control has been over 90 days. It doesn't tell you anything about what was happening over the course of the person's lifetime prior to that," he says.

In fact, a company-sponsored clinical study that was published in the January edition of the Journal of Diabetes Science and Technology found that the ClearPath test was more accurate than two standard tests. A news release from Feb. 14 announced that the Freedom Meditech's device was able to detect type 2 diabetes with a sensitivity of 67% and a specificity of 94%. By comparison, the hemoglobin A1C test demonstrated detection with a sensitivity of 44% and a specificity of 79%, and a fasting plasma glucose test demonstrated a sensitivity of 50% and a specificity of 95%. The study looked at 180 people who said they were not diabetic and 53 patients diagnosed with diabetes or prediabetes.

Lens autofluorescence has been shown in 63 studies to be an indicator of diabetes progression, Misrach says. But the real value of the product is that it can indicate that the person is diabetic earlier than other tests.

"AGES (advanced glycation products or sugars attaching to the proteins) start forming on your lenses seven years prior to typical symptomatic diagnosis of diabetes," Misrach declares.

There are other advantages of course - much of the paraphernalia related to a blood draw - lancets, needles, rubber gloves, vacutainers - and some of the human resources - the nurse who draws the blood and the person who analyzes the blood report are made redundant. These are real cost savings to the system, Misrach says.

That's just from the provider side. From the perspective of patients, the device brings greater convenience. The test is noninvasive and doesn't require a person to fast.

"I am sure that many of the people who are supposed to fast before the blood test cheat at midnight and snack on a cookie," Misrach declares, noting that this contributes to a lower sensitivity for these tests in diagnosing diabetes.

So how can people get the ClearPath test done? Misrach has adopted a different approach than contacting primary care physicians to diabetes care providers.

He is reaching out to ophthalmologists instead. Since FDA cleared the device and the company launched it in June, roughly 35 units have been sold at the cost of \$35,000 per device. So far

patients have paid out of pocket, but from 2014 there will be a reimbursement code attached to the test, Misrach said.

The providers charge anywhere from \$10 a test to \$40 but Freedom Meditech gets a flat rate of \$3 from each test. The wifi-enabled device allows Freedom Meditech to remotely diagnose any problems with the device and fix them.

Further, each device is able to collect data on the tests being administered, so at some point in the future the can be data that becomes important to payers as it can point to some trends, Misrach said.

"You can imagine that this device at every location where it's at is developing its own unique chart, it's own unique place of dots, and an insurance company can hypothetically can say, 'Wow look at the devices in 92109, they have 20% more people measuring with elevated lens autofluorescence than in zip code 00136,' he says. "It can be very helpful from a disease management perspective."

Misrach said that in addition to speaking to eye-care doctors, he is also in negotiations with a multibillion-dollar payer who could become a customer

"Payers are buying hospitals and providers [these days]. The lines are all blurring but for us we see this as a good thing because that means that the payers are now owning care providers. They are now truly responsible for the performance and health of their patient.

The goal in 2014 is to really ramp up commercialization, and for that the \$7.1 million the company raised in August and the additional \$3 million it intends to close in the next 30 to 60 days will come in handy.

Misrach added that he is also looking for \$15 million which he hopes to raise in the next six months.

Previously the company raised \$10 million from angel investors including Dan Bradbury, the former CEO of Amylin Pharmaceuticals.

"John Burd, the founder of Dexcom is an investor and [ our chief scientific officer]," Misrach said.

As Freedom Meditech gears up to expand the sale of ClearPath not only in the U.S, but Canada and Europe, it is also developing another product.

Called the i-SugarX, it is a noninvasive glucose meter which can be held up to the eye to detect glucose levels for diabetes patients. If it is found to be safe and effective, it can eliminate the daily finger-prick testing that is both painful and inconvenient.

"We view i-SugarX as something that will be easier for patients to use," Misrach said.



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