Diabetes Monitoring: Just a Breath Away!
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Purpose
Diabetes can be a life-long disease which requires continuous blood-glucose monitoring. Current technology, albeit good, does have its draw-backs, in particular that it is an invasive technique which causes discomfort to the individual. Adherence to self-monitoring of blood glucose (SMBG) using the common finger-prick-method is significantly lower than desired. It has been reported that for diabetic’s, adherence levels are in the 20-66% range and thus is the largest cause of diabetic complications. There are numerous explanations for this low compliance; however the prominent rationale is that it is an invasive, moderately painful procedure which the individual must endure between 4-12 times a day, every day, for the remainder of their lives. There has however been reports that there is a correlation with breath acetone and blood glucose. We have developed a technology that specifically detects breath acetone. This will represent the first truly non-invasive medical device for detecting and monitoring diabetes.

Methods
We have been able to test our technology on a population of diabetic and non-diabetic individuals within the clinic which yielded a strong correlation of blood glucose and acetone levels. The patients provided a breath of 200 mL of expired air (~5 sec) with our slide already in the device. After 5 sec the detector was turned on and the readings were immediately taken. Our Stage 1 clinical testing was performed on 50 individuals: 26 non-diabetic, 16 Type 2 diabetic, and 8 Type 1 diabetic individuals with approximate equal representation of males (24) and females (26) and spanning ages 21-75. Of note, during this blind study there were two outliers which corresponded to smokers, hence demonstrating a limitation, albeit an expect one of our technology.

Results
The results to date show that with the population we used there was 1) a clear correlation of blood glucose and breath acetone for diabetic individuals (R=0.99, P<0.001 when the smoker outlier was removed) and 2) our multilayer technology is able to detect this correlation.

Conclusion
Although numerous techniques are being examined to produce a minimally invasive detection procedure for SMBG, a truly non-invasive approach to detect for and monitor diabetes is highly sought-after. Our Stage 1 Clinical Results demonstrates a clear correlation with blood glucose levels and breath acetone, with smokers representing outliers. A portable, hand-held, non-invasive monitoring device for monitoring diabetes has been developed.