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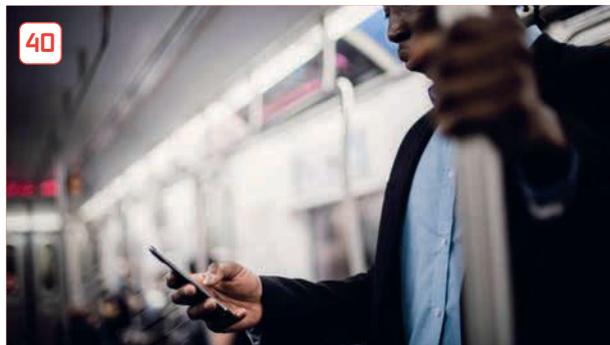
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KADE FRANCE

“The objective is to determine at which points an individual with COVID is infectious, not just if they have the virus in their body. Evidence suggests that other methods fall short in that respect”

DID YOU KNOW?

14mn The confirmed cases of COVID in the UK as of Jan 07

DELIVERING MASS SCREENING

How is a handheld breath analyser, combined with AI, delivering on mass screening for infectious diseases? **NEIL TYLER** talks to **KADE FRANCE**, CTO of SOTECH Health, and **BILL WELCH**, the former CTO of Phillips-Medsize

With COVID now entering its third year, having a rapid, low-cost, portable technology to conduct mass screening is seen as a priority by healthcare professionals, not only for COVID but for other infectious diseases too.

By leveraging artificial intelligence (AI) to drive incremental predictive insights and outcomes SOTECH, in collaboration with Phillips-Medsize, has developed a hand-held breath analyser solution.

Phillips-Medsize, a global end-to-end design, development, and manufacturing organisation, which is the healthcare division of Molex, is focused on mechanical/electromechanical drug delivery solutions, diagnostic consumables, and medtech devices.

“We have been working with SOTECH since mid-2020 and client interest in the SOTECH solution has certainly gained momentum,” said Bill Welch, the former CTO of Phillips-Medsize.

The breath analyser solution is a handheld device that allows a short breath sample from a patient to be examined, with the sensor identifying gaseous metabolites that indicate COVID-19 – it can be employed for other infectious diseases as well.

“It differs from the current approach being used in several

fundamental ways,” explained Kade France, CTO of SOTECH Health. “Most importantly it is designed to act as a screening tool, rather than a diagnostic tool. Its objective is to determine at which points an individual with COVID is infectious, not just if they have the virus in their body. Evidence suggests that other methods fall short in that respect. That means the risk they present to the general public cannot be accurately gauged. The window in which a COVID positive individual can infect other people may only be a few days, but that individual could still have the virus present

within their body and show a positive PCR test. With our solution, we are looking to address this disparity. Our goal is to determine at what point a patient is infectious. This is done by detecting evidence of the virus within their body, not the actual virus being there. That is what makes our approach different, as it is about detecting a chemical emitted by the respiratory system because of an immuno-response to the virus. Additionally, our solution has the advantage of being fully responsive to all the different COVID variants, whether it is Gamma, Delta, Omicron, etc.”

The solution comprises of a durable handheld device and a disposable mouthpiece which is replaced every time someone is screened.

“While SOTECH was completely responsible for developing the device concept Phillips-Medsize, drawing on its experience in volume production, assisted with the optimisation of the electronics on the handheld, and design for manufacturability on the mouthpiece,” explained Welch.

“While there are solutions already on the market that provide breath-based screening, these rely on mass spectrometry techniques, which require bulky equipment - so unlike our solution, they are not really mobile and take a lot of power,” said France.

The speed of this technology is another important facet, according to Welch.

“For other methods, the best case is a 30-minute result time and in some cases, it will be several days. People could still be out and potentially infecting others in that period. The short response time represents a significant breakthrough, with results being obtained in a sub-30 second period. Also, it means that far more results can be gathered - generating larger datasets to examine so that trends can be identified more quickly.”

ARTIFICIAL INTELLIGENCE

While the solution does use cutting-edge AI, it is not





BILL WELCH

“If you can screen people as fast as it takes to get through a metal detector or a passport line at an airport, then that is a real game-changer”

data so that they can examine how the thresholds are changing and respond accordingly. It doesn't have the delay inherent to other techniques,” said France.

Welch added, “The timeframe in which screening can be completed has clear logistical benefits too. If you can screen people as fast as it takes to get through a metal detector or a passport line at an airport, then that is a real game-changer.”

While COVID is the current focus, SOTECH plans to expand the scope of this analyser device so that it can be applied to other medical conditions. “It could be used to determine if a patient has flu or if they have pneumonia, etc. There are opportunities that go beyond the respiratory system too. These pertain to cancer/oncology, as well as other forms of severe illnesses that could be detected through the same methods,” said France.

The use of AI in a medical context is still relatively new and regulatory bodies are still exercising caution about its use.

“In a lot of cases, AI is being pushed as a way to seemingly take physicians out of the loop, and I don't think that's appropriate at this point in time. I think what we should do is try to screen with AI, then advise physicians and augment their capabilities. By its very design, AI is a

black box right now. It is incredibly hard to understand. However, with explainability being one of the pillars that will help regulators garner trust in AI, our platform has algorithms in place that allows our AI to explain its results. And if you can't explain your solution, as a physician can, then there are likely to be ethical concerns. You put a bunch of data in, you get an answer, but explaining how that happened is difficult. By using AI only to assist our device, we are avoiding such ethical issues,” explained France.

“On top of that, we review our datasets to make sure that we address them from different angles and remove bias. Having different engineers and non-technical people involved brings multiple views over our datasets. This means any potential bias points can be spotted.”

AI will have an extraordinarily valuable role to play throughout the healthcare sector and by continuing to learn and by rapidly updating connected devices, AI-enabled healthcare solutions will be able to adapt with people and with changing conditions, according to France.

“This will make the way that the public is screened, diagnosed, and treated far more efficient and accurate,” he concluded. **NE**



actually used to detect the virus. “AI is employed to define what the thresholds of the algorithm are in relation to a positive or negative screening. The AI aspect consists of two component elements,” explained France. “First, there is the element inside the analyser device. Secondly, there is the element in the cloud. Everyone's data is anonymised, of course, but the breath responses of patients are all compiled on the cloud and the cloud element is continuously learning from all our endpoint devices. It allows constant monitoring of positive and negative individuals so that we can fine-tune our thresholds and home in on what a positive individual is.”

According to France constant feedback shows how the virus is evolving and the cloud can then update and broadcast information to all the analyser devices.

“Evidence from various studies suggests that ethnicity affects how PCR tests respond. There are slight variations in PCR thresholds, as to what constitutes a positive COVID result or a negative one. Additionally, as people build antibodies and they gain immunity to the virus in different variants, the actual

threshold of what constitutes a true positive test on current existing methods is going to shift higher. Having devices that are all talking back to the cloud will be vital in adapting screening strategies to take factors like these into account,” added France.

The misuse of home-use medical equipment is certainly a problem, as it can result in monitoring data being inaccurate, or treatments being less effective.

To address this a lot of user feedback is built into the device, with the accompanying app telling the user if they didn't exhale hard enough, or if they did something else wrong increasing the probability of delivering accurate results.

Looking to the future rapid screening and AI learning are likely to have a significant impact on future detection devices.

“The primary aspect is situational awareness for doctors. It will enable them to access real-time