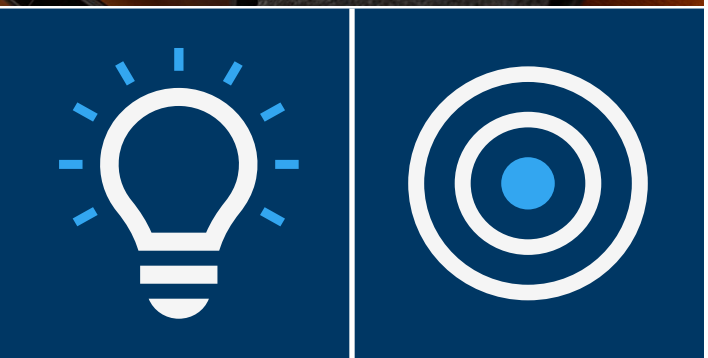

# SOTECH HEALTH CASE STUDY

## ACCELERATE DEVELOPMENT OF NOVEL BREATH-SENSOR SYSTEM THAT DETECTS COVID-19 IN LESS THAN 30 SECONDS

Game changer in fast, accurate virus detection bolstered by strong product design and manufacturing collaboration

### CHALLENGES

- Demand for game-changing COVID-19 screening test required streamlined product iterations
- Focus on human-factors design principles needed to ensure intuitive operation and accurate results
- Ability to navigate complex regulatory review process and prepare for rapid manufacturing ramp to expedite go-to-market

### SOLUTION

- Phillips Medisize offered proven experience in bringing novel healthcare technology to market
- Seamless teamwork facilitated fast-track product design and development
- End-to-end manufacturing plan and expanded global footprint poised for expedited production submission

### BENEFITS

- Powerful technology can screen for COVID-19 in less than 30 seconds
- More than 31,000 clinical study tests completed to date to support regulatory approval filings
- Ability to scale manufacturing to produce tens of thousands of disposable mouthpieces and handheld devices daily; poised to meet increased demand for detecting COVID-19, flu and pneumonia

**Bringing Possibilities To Life**

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"Phillips Medisize fit the bill perfectly for us. They were able to help us finalize device prototypes and really fine-tune our product design while providing the means and a very detailed and scalable manufacturing plan."

**Kade France**
**Chief Technology Officer at SOTECH Health**

As COVID-19 continues to surge worldwide amid the emergence of the Omicron and Delta variants, fast and accurate virus detection remains a top priority. For Dallas-based healthcare startup SOTECH Health, the biggest testing breakthrough during the pandemic could be as simple as taking a deep breath. "Our mission is to change the world through the power of innovation and thinking outside the box," explains Craig Micklich, Founder and CEO of SOTECH Health. "As a future-leaning company, we are constantly looking to improve on what is seen as the norm in healthcare."

Fueled by this overarching focus and a hunch, Micklich moved quickly in March 2020 to pivot the direction of an existing project his team was working on as part of a public-private collaboration with the bioengineering lab at the University of Texas at Dallas. The initial project leveraged an innovative sensing technology developed by Dr. Shalini Prasad, Professor of Bioengineering, and lab researchers that detected volatile organic compounds, such as CO2 in vehicles, to address ever-increasing emissions challenges. Initially, SOTECH Health was exploring how leading-edge sensor technology could be used to identify explosives and gunpowder for military applications.

In March 2020, however, Micklich was struck by an idea to apply this unique, electrochemical sensor to breath analysis for rapid COVID-19 virus detection. "Within two weeks, Dr. Prasad and her team had figured it out," Micklich recalls. "At the same time, our team was working on the breath analyzer. In three weeks total, we had a new detection method that could change the game in COVID-19 testing."

The idea behind SOTECH Health's reusable breath analyzer is straightforward and performs in a similar manner to other breathalyzers. The difference is the addition of the highly sensitive sensor capable of finding traces of certain chemicals in the breath sample, which would indicate exposure to SARS-CoV-2, the virus strain that causes COVID-19.

"When your body is in distress, it emits certain compounds called volatile organic compounds, which our sensor can detect as they are inhaled through your breath," explains Kade France, Chief Technology Officer at SOTECH Health. "Our ability to detect these compounds as they pass over the sensor through a very small breath sample enables us to provide a 'check engine light' on your body that really indicates how well you're feeling or how well your body is responding to COVID-19."

Since the beginning of the pandemic, experts have recommended broad-based testing to better understand where COVID-19 is spreading. Equally important is helping individuals gauge when they are infectious, enabling them to isolate and break the chain of transmission. The challenge, particularly with increasinglytransmissible variants, however, is that both polymerase chain reaction (PCR) testing and rapid antigen testing are difficult to obtain. In the case of PCR, testing results can take days, and must be administered by healthcare professionals. Both PCR and rapid antigen tests also involve a level of invasiveness, which can be daunting to some consumers.

## BRINGING A BREAKTHROUGH PRODUCT TO LIFE

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**Paul Chaffin**
**President, Medical and Pharmaceutical Solutions, Molex**

Learn more at **www.phillipsmedisize.com**

Phillips Medisize's human-factors experts and engineers worked together with SOTECH Health to ensure the powerful sensor was incorporated properly into the breath analyzer for optimal performance and intuitive user operation. Each product iteration was undertaken with a focus on continuous improvement and quality, resulting in a validated product design ready for a swift production ramp.

"We believe in SOTECH Health's transformative mission to enable fast, accurate detection and improved global management of respiratory diseases, including COVID-19," says Paul Chaffin, President, Medical and Pharmaceutical Solutions, Molex. "Our long history of collaborating with companies at every stage of their product lifecycle has proven critical in helping SOTECH Health finalize their device design. And when SOTECH is ready, we'll align Phillips Medisize's global manufacturing footprint to support the production of millions of devices and mouthpieces as part of an aggressive rollout plan.

## IMMEDIATE, ACCESSIBLE INSIGHT FOR CONSUMERS AND HEALTHCARE PROFESSIONALS

To screen for COVID-19, a person blows into the disposable mouthpiece of the SOTECH Health reusable breath-test device for six seconds and receives a test result in less than 30 seconds. The entire process can be self-administered and monitored onsite or from a distance via a Bluetooth or Wi-Fi connection. This alleviates the need for healthcare professionals to administer the test, which reduces the strain on an already burdened healthcare system.

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In addition to providing meticulous readings on the status of a patient using the breath analyzer, test results are sent to the SOTECH Health Cloud, where a suite of analytical tools aggregate patient data, assess status and predict trends. Analytical and artificial intelligence (AI)-based tools review results from each patient to detect certain concentrations of virus in specific regions while enabling researchers to follow the Virus' prevalence and spread.

The sensor technology at the heart of each device tracks critical data including location, temperature, and humidity alongside test results, which are shared with the SOTECH Health Cloud. For health officials, access to this data analysis can deliver a number of outcomes, including a "heat map" based on aggregated data within a geographic region. This information can help officials pinpoint areas with high virus rates so they can respond much earlier than ever before.

## PREPARING FOR AN EXPEDITED MANUFACTURING RAMP

Continuous feedback and further testing have resulted in a series of successful clinical trials. To date, more than 31,000 breath tests have been completed. "Our breath analyzer will change the game in COVID-19 detection by quickly and accurately screening people in densely populated settings, such as airports, businesses, cruise lines, schools, and stadiums," adds Micklich. "Phillips Medisize has been responsive and collaborative since day one in helping us finalize the product."

In preparation for an accelerated manufacturing ramp, SOTECH Health and Phillips Medisize are poised to scale production at manufacturing facilities in the U.S. and Asia. A combination of fully automated and manual production lines are primed to produce tens of thousands of disposable mouthpieces and reusable handheld devices daily. "Through our collaboration with Phillips Medisize, we have engineered a solution capable of screening for COVID-19 infection status as fast as it takes someone to walk through a metal detector at an airport or sports stadium," adds Micklich.

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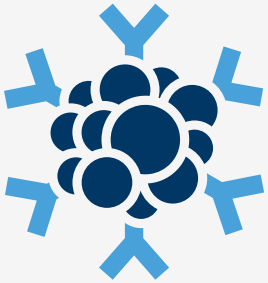

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To keep pace with the expected demand, Phillips Medisize has expanded its manufacturing footprint, which now includes 36 world-class facilities, including production sites, innovation centers and cleanrooms in North America, Europe, Asia, India and Mexico. Looking ahead, SOTECH Health is adapting its unique platform to screen for other respiratory diseases and conditions in the future, such as the flu and pneumonia. "Phillips Medisize is perfectly positioned to support our global go-to-market strategies while empowering us to screen for other critical respiratory diseases and conditions," concludes Micklich. "We see boundless potential in the technology for detecting serious medical conditions with speed, and our partnership with Phillips Medisize will enable global scale and rapid ramp-up to bring it to market quickly."

## ABOUT SOTECH HEALTH

As the world faces unprecedented change, SOTECH Health is committed to improving on what is seen as the norm in healthcare. By believing in the power of an idea, SOTECH accepts all challenges and thrives on what seems impossible. With its first solution – an AI-driven breath analyzer for rapid detection of COVID-19 – SOTECH is breaking unprecedented new ground in health screening. Never satisfied, SOTECH leans into the future, creating endless possibilities in the future of healthcare. For more information, visit www.sotechhealth.com

## ABOUT PHILLIPS MEDISIZE

Phillips Medisize, a Molex company, brings decades of innovation to leading healthcare and life science companies to develop groundbreaking solutions that help people live healthier, more productive lives. On average, the company commercializes 50 new products a year for customers, including the first-to-market FDA-registered drug-delivery device utilizing a connected health system. In addition, Molex brings decades of experience in advanced electronics, connectivity, and sensor technologies to help transform medical and pharmaceutical solutions. For more information, visit phillipsmedisize.com

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