



## Frequently asked questions

### **DSA BreathPass™ Analyzer A Non-Invasive Method for Detection Of Covid-19 Virus**

#### **Who is the manufacturer DSA BreathPass™ Analyzer and where is it produced?**

The DSA BreathPass™ Analyzer is manufactured in Finland by Deep Sensing Algorithms Ltd.

#### **What type of test is DSA BreathPass™? What does the test detect? How does it work?**

The DSA BreathPass™ Analyzer is a handheld breathalyzer that measures exhaled breath for 45 seconds. The technology is based on the analysis of Volatile Organic Compounds (VOC). These are biomarkers created by human metabolism while a person is sick. The analyzer detects and recognizes the VOC exhaled breath gas created by the COVID-19 virus. The Analyzer identifies the measured breathprint of the individual's VOC profile and compares it to known COVID-19 features. The device has a Bluetooth that allows for communication with a tablet or mobile device.

#### **What is the optimal situation for using DSA BreathPass™ and why?**

DSA BreathPass™ works best when used for screening of asymptomatic and pre-symptomatic people. It shouldn't be used for people with symptoms, especially if the symptoms are clear and have been around for days. VOC's comprising a "COVID profile" start to form hours from infection. It can be estimated that the profile is detectable in 2 days after infection. Symptoms and their spin-off all create their own biomarkers that over time grow bigger than the original COVID profile. This means that the profile can't be detected well from people with symptoms.

#### **How fast are the DSA BreathPass™ results available?**

Results are available immediately, in real time after having done the test.

#### **What kind of accuracy does the test have?**

The DSA BreathPass™ outperforms most antigen tests in field use.

#### **Who can perform the DSA BreathPass™ test?**

Local authorities provide guidance on qualification requirements for the device user.

#### **Do I get a certificate of 'non-covid'?**

Certifications are provided by the organizations operating testing.

#### **Is the DSA BreathPass™ Analyzer test safe?**

Yes, when given instructions are followed, the test is perfectly safe.

#### **Is the DSA BreathPass™ test suitable for children?**

The test is suitable for any person who is able to exhale into the mouthpiece according to instructions.

#### **Do I need to bring something into the test situation?**

No preparations are needed, just participate into the test. The necessary consumable parts (mouthpiece, filter) are provided by the device user and organization responsible for the testing.

### **How should I prepare for the DSA BreathPass™ test?**

The analyzer device is sensitive to strong smells and evaporating odors. It is instructed that there should be minimum 15 minutes from any use of hand sanitizer as hand sanitizer might affect the test result. Use of perfume might affect the test result or prevent testing. There should also be minimum of 15 minutes from the previous alcoholic drink, cigarette, or vaping.

### **How quickly from infection can the test be done?**

DSA BreathPass™ is based on analyzing the human metabolic response to the virus. As the metabolic response is rapid, there is no required minimum time from infection. The infection can be identifiable on the following day from infection.

### **Can anybody take the DSA BreathPass™ test?**

The test is intended to detect fresh infections, with maximum 14 days from the appearance of symptoms.

### **What training is required to administer the the DSA BreathPass™ Analyzer test?**

Minimum requirement for the device user would be to familiarize with the Instruction For Use manual and operating principles. The organization handling the testing will have their own qualification requirements. Local authorities provide guidance if additional training is needed.

### **Are the the DSA BreathPass™ Analyzer results confidential?**

The result is only visible to the device user and the person being tested. Local medical authorities provide guidance on follow-up procedures following the test.

### **How often should be DSA BreathPass™ Analyzer test be done?**

The test can be taken whenever there is a need to do so. If you need to repeat the test, we recommend a 15-minute interval.

### **Will the DSA BreathPass™ Analyzer detect the virus for a person that does not have the symptoms?**

Yes, the DSA BreathPass™ is most suitable for asymptomatic or pre-symptomatic people. The algorithm does not use any symptom data for the diagnosis and operates only based on the detected Volatile Organic Compounds from the breath.

### **How can the DSA BreathPass™ Analyzer reduce testing backlog and help plan response strategies?**

The DSA BreathPass™ Analyzer is rapid test that produces result in real time which allows health care providers to make crucial decisions about identifying and isolating people infected with coronavirus. It provides a tremendous opportunity for front-line caregivers and those having to diagnose and screen a lot of infections.

### **Do I need to be a health care professional to operate the DSA BreathPass™?**

In each country the health authorities regulate the necessary requirements for the device user.

### **How many people are required to operate DSA BreathPass™?**

One person is enough for the device operation. Additional resource might be needed for guidance at screening location.

### **How long does the DSA BreathPass™ device last for before replacement is required?**

DSA BreathPass has been designed for long-term use and should be good for some years.

### **How do we get updates to the device with new variants of Covid arising all the time?**

The device communicates with the DSA Cloud, that includes the latest algorithm release for detection, the device user does not need to do anything.

### **Does the DSA BreathPass™ detect the different variants of Covid, like delta and omicron?**

The BreathPass™ does not recognize the virus variant but the metabolic response of the human body. Omicron patients were included in the clinical trials.

### **How do we do software updates on the DSA BreathPass™?**

The mobile APP (user interface) is updated automatically if update option was selected when downloading from the Google Play or App Store.

If the device needs a firmware update, it will inform the user about this when power is switched on. The device should be connected to WLAN for the firmware update.

### **What do we do about calibration of the device?**

There is no need for field calibration of the DSA BreathPass™.

### **What do I do if the device stops working?**

The DSA Instruction for Use guide (IFU) includes trouble shooting details.

### **What accessories do you need to setup for on-site testing?**

You need a sufficient amount of single-use mouth pieces, filters for the exhaust and a ventilator unit / desk stand.

### **How do you clean the device between tests to stop infection from spreading?**

There are UVC LEDs inside the device. The LEDs are activated before the first use and between each exhalation to deactivate possible viral remnants from inside the device.

Touching the device should only happen by using gloves or other protection to avoid surface contact.

### **What accessories come in the package from DSA to accompany the Device?**

The DSA BreathPass™ is delivered with power supply and ventilation device / desk stand. The package includes a few mouth pieces and filters for the first use.

### **Where do I buy mouthpieces and filters from?**

DSA distributors and re-sellers can inform the options to buy the accessories.

### **Do we need to wear Gloves while testing with the DSA BreathPass™?**

DSA suggests the use of gloves during the testing, the Instructions For Use guide (IFU) includes suggestions for good aseptic principles.

### **Will the device be FDA approved?**

The DSA BreathPass has EU-wide medical CE certification. DSA is in discussions with various authorities about additional regulatory approvals.

### **What is the process if DSA BreathPass™ shows a positive Covid result and additional tests such as PCR show that patient to be negative?**

The local health authorities guide the device users about operational practises when needed.