

# Instructions For Use

## DSA BreathPass™

**Device is for professional use only.**

**All device users are obligated to go through the device training.**

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**Languages (IFU translations)**



*Instructions For Use* (IFU) translations can be found digitally via the QR code or web address below.



[www.dsa.fi/ifulanguages](http://www.dsa.fi/ifulanguages)

**Notice:** This English version of the *Instructions For Use* (IFU) is the official document. Other language versions are translations only.

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**Read the following instructions carefully and keep them for future reference.**

## INTENDED USE

The DSA BreathPass™ is a handheld analyzing device intended for diagnosis of COVID-19 by healthcare professionals and for rapid screenings for large crowds. Inside the device there is an array of nano-sensors to detect molecules of biological origin, known as volatile organic compounds (VOC), as signs of infection stemming from the biomarkers known to be produced by the metabolic processes caused by the SARS-CoV-2 virus.








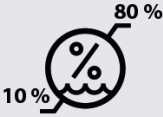




### **Testing principle**













The DSA BreathPass™ uses a non-invasive method for detection of COVID-19 caused by the SARS-CoV-2 coronavirus. The device measures the exhaled breath for 30 seconds, characterizes the VOCs within breath samples, produces predictions for different health conditions based on Deep Computing algorithms and generates results in few seconds. The DSA BreathPass™ is a fast, easy and affordable testing method for detecting COVID-19 infection that can be done anywhere with a reliable connection to the internet.

### **Contra-Indications of use**

DSA BreathPass™ is not intended to identify individual exhaled molecular constituents. The mouthpiece is for single use only and not intended to be reprocessed and used again, even on the same patient. The DSA BreathPass™ is currently not used to diagnose other diseases or viral infections besides the SARS-CoV-2 infection, COVID-19.

## SYMBOLS AND MEANINGS

SYMBOL	EXPLANATION	SYMBOL	EXPLANATION
	Manufacturer		Date of manufacture
	Consult Instructions For Use.		Serial Number To identify a specific device.
	<b>Caution!</b> Consult Instructions for Use for important warnings and precautions		Catalog Number To identify the generic category and a type of a device.
	CE mark		Humidity limitation Safe relative humidity operating range for the device.
	<b>Keep dry</b> Indicates that the device needs to be protected from moisture.		IP classification
	In Vitro Diagnostic Medical Device		Temperature limit The temperature limits to which the device can be safely exposed.

SYMBOL	EXPLANATION	SYMBOL	EXPLANATION
	The device should not be used if the package has been damaged or opened.		Non-ionizing electromagnetic radiation
	Do not dispose product with household waste.		Device uses <b>Bluetooth®</b> wireless system.
	Direct current		“Important” “Help” “Notice”
	General warning sign		21 = material type PAP = material abbreviation
	Optical Radiation (UV)		20 = material type PAP = material abbreviation
	Language / translations		General symbol for recyclable

## WARNINGS



### Non-ionizing radiation and UVC radiation

The device has an integrated UVC cleaning mechanism.

**Do not look directly inside the device when the UVC cleaning operation is ongoing and UVC LED indicator is on. This can be harmful for the eyes. Avoid direct eye and skin exposure to UVC light.**

When UVC cleaning is in progress, it is indicated by both the UVC LED indicator on the device and the message in the mobile application.

**Important:** The more specified guidance is presented later in this document.

### The device must not be used if:

**The user is not trained to use the DSA BreathPass™ device or not sure how to operate it.**

- May cause UVC light to hit the eye.
- May cause a serious risk of contamination.

**The device is damaged.**

- May cause electric shock.
- May cause UVC light to hit the eye.
- The device may have sharp edges or parts.

**The package is damaged.**

### Any external objects or fingers are not allowed inside the device.

- May cause electric shock.
- Device might get damaged.

### Only proper cleaners should be used.

- Use only Sodium Hypochlorite (NaClO) based disinfecting wipes to clean the exterior surfaces of the device. Cleaning must be done carefully. Make sure that both cavities (for the mouthpiece and air filter) are also properly cleaned.
- The wrong cleaner might cause the housing of the device to become brittle and the device to break.
- **DO NOT USE CLEANERS CONTAINING ALCOHOLS SUCH AS ETHANOL OR ISOPROPNOL ON THE DEVICE OR IN PROXIMITY OF THE DEVICE DURING OR PRIOR THE TESTING.** Device is sensitive to strong odors such as ethanol or isopropanol-based cleaners. The use of alcohol-based cleaners on the device can lead to an incorrect test result.



## **Only proper mouthpiece and air filter should be used.**

- Use of incompatible consumables can cause a leak or risk of contamination.

## **Do not disassemble the device.**

- May cause electric shock and damage the device.

## **The aseptic procedure must be followed carefully to avoid device cross-contamination between individual patients.**

- Only the Aseptic Testing Procedure given by the manufacturer should be used. Uncontrolled test procedure may cause a serious risk of contamination.
- Guidance for the Aseptic Testing Procedure is presented later in this document.

## **The device and its components must be disposed safely.**

- Unsafe disposal of the device or its components may cause a serious risk of contamination.
- Specific guidance for proper device disposal is presented later in this document.

## **PRECAUTIONS**

- Operating and storage environment should meet the instructed conditions for humidity and temperature.
- All strong-smelling chemicals or products, like hand sanitizers, or other gas-releasing materials, which might affect DSA BreathPass™ testing are not allowed to be used near the device.
- All strong-smelling oral products like mouth sprays, alcohol or cigarettes are not allowed to be used by patients 15-minutes prior to testing. If patient has used these, the patient should wait 15 minutes before proceeding with the test.
- Any other products, cleaners, or chemicals that could generate contaminating gases and therefore influence the breath test are not allowed to be used nearby the device.
- Device cannot be used to conduct a COVID-19 test without the compatible accessories described in this document.

## **INFORMATION FOR THE PERSON IN CHARGE OVERSEEING THE DEVICE AND TESTING**

- Make sure that only qualified personnel use the DSA BreathPass™ device. All device users are obliged to go through the device training.
- Make sure you always have *Instructions For Use* available while operating the DSA BreathPass™ device.
- Regularly confirm that device users follow the DSA BreathPass™ safety instructions.

- Make sure that the new users are thoroughly instructed in the operation of the device and the DSA BreathPass™ mobile application.
- Take care of proper usage and storage conditions.
- Take care of device maintenance such as firmware update.

## GENERAL

### Contents of the package

**Package includes (materials provided):**

- At least one mouthpiece
- At least one air filter
- DSA BreathPass™ device
- DC charger
- AC plug for charger (if supplied DC plug is 2.1 mm)
- DC plug adapters (only supplied outside of Europe)
- *Instructions For Use* (This document)

**Notice:** Check that the package contains all the above accessories upon delivery.

**Notice:** Check that package or device is not damaged. If you notice damage, contact your local distributor, and do not use the device.

**Important:** Save the package to store the device.

### Accessories information

A list of the compatible accessories and their order numbers can be found via the QR code or web address below.



[www.dsa.fi/accessories](http://www.dsa.fi/accessories)

**Important:** Use only supplied charger. If the charger is missing or damaged, please contact your local distributor for instructions on how to get a new one.

**Notice:** The supplied accessories act as a starter kit. If you have any questions about supplies, contact local distributor.

**Important:** Use only compatible accessories (e.g. Mouthpiece diameter 30mm and Air Filter diameter 22mm).

## Equipment required (but not provided)

### 1. Smartphone or Tablet

The mobile phone or tablet with Bluetooth and WLAN capability to download the DSA BreathPass™ app. Minimum platform software versions supported are Android™ 8.0 and iOS 13.1.

### 2. DSA BreathPass™ mobile application

See instructions for downloading mobile application later in this document.

### 3. Protective equipment

Make sure you have all the appropriate protective equipment e.g., mask and rubber gloves to avoid possible contamination.

### 4. Cleaner

Use only Sodium Hypochlorite (NaClO) based disinfecting wipes to clean the exterior surfaces of the device.

**Important:** The wrong cleaner might cause the housing of the device to become brittle and break.

**Important: DO NOT USE CLEANERS CONTAINING ALCOHOLS SUCH AS ETHANOL OR ISOPROPANOL ON THE DEVICE OR IN PROXIMITY OF THE DEVICE DURING OR PRIOR THE TESTING.** Device is sensitive to strong odors such as ethanol or isopropanol-based cleaners. The use of alcohol-based cleaners on the device can lead to an incorrect test result.

## DSA BreathPass™ technical information

<b>ANALYSIS MEDIUM</b>	Exhaled Breath Gas
<b>SAMPLING TIME</b>	30 sec
<b>DIMENSIONS</b>	215 x 68 x 65 mm
<b>WEIGHT</b>	350g
<b>OPERATING TEMPERATURE</b>	0 - 55 Celsius
<b>AMBIENT HUMIDITY</b>	10 - 80% non-condensing
<b>INPUT VOLTAGE</b>	Nominal 12V
<b>INPUT CURRENT</b>	1.5A
<b>BATTERY</b>	Li-Ion 2S 18650 with protection circuit and NTC
<b>VOLTAGE</b>	7.2V
<b>IP-CLASS</b>	IP20
<b>IOT</b>	WLAN 2.4 GHz / 4G
<b>VOC SENSORS</b>	9 analog / digital nanosensors
<b>ENVIRONMENTAL SENSORS</b>	T [C], RH [%], P[mbar]
<b>SOFTWARE</b>	Over-the-air (OTA) updates, sensor regulation and calibration

**Test result accuracy:** To be confirmed.

## DSA BreathPass™ functional description

The DSA BreathPass™ calculates a prediction for the tested individual to have contracted the SARS-CoV-2 virus infection based on the analysis of Volatile Organic Compounds (VOC) within an individual's breath. The VOC gases are derivatives of the biomarkers created by cell level metabolic processes induced by the virus. By using advanced Artificial Intelligence (AI) based methods of pattern recognition, the measured VOC profiles are correlated with the specific pathology states thereby allowing the algorithm to classify persons based on their health condition.

The DSA BreathPass™ device contains a set of nanosensors that record VOC biomarkers from exhaled breath gas. The device communicates through the user interface with a cloud-based AI -powered algorithm, which is developed to recognize correlations between the detected VOC biomarkers and established characteristics of COVID-19. The algorithm uses machine learning techniques and Artificial Intelligence software. The algorithm has been "trained" by first measuring the multidimensional VOC profiles associated with individuals having the target disease, then constructing a model that classifies individuals by their VOC breath prints as being Covid-19 infected (positive) and Covid-19 non-infected (negative).

# DSA BREATHPASS™ INTRODUCTION

## Device overview



### Traceability information and the device serial number

Device identification, REF code and required traceability information are included in the BAR code on the labels.

The device's serial number (SN) is found on the label on the back of the device. Serial number is also included in the scannable QR code on the front of the device.



## LED indicators and behavior (colors and meanings)

● ALL OFF = device off



● **LED indicator** (UV cleaning)

○ WHITE, BLINKING = cleaning ongoing

● **LED indicator** (device status)

● YELLOW, CONTINUOUS = standby

● YELLOW, BLINKING = device preparing

● GREEN, CONTINUOUS = ready for test

● GREEN, BLINKING = test in process

● RED, CONTINUOUS = sensor error, DO NOT USE

● **LED indicator** (connection)

● BLUE, BLINKING = searching

● BLUE, CONTINUOUS = connected

● **LED indicator** (other)

● YELLOW, BLINKING = battery charging

● GREEN, CONTINUOUS = battery fully charged

● VIOLET, BLINKING = firmware update ongoing

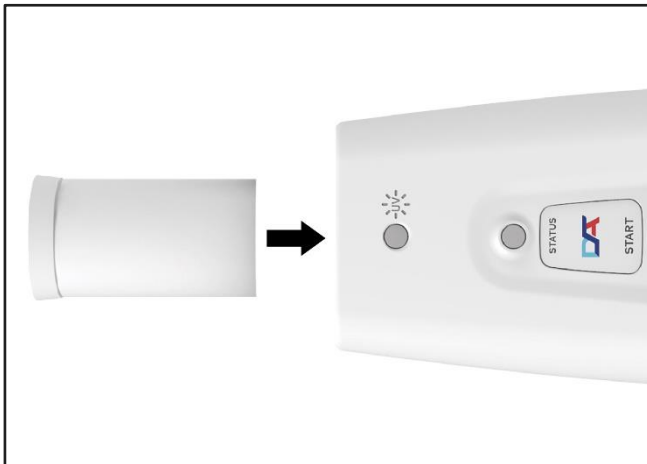
**Important:** If the LED indicator on the center of the device is showing red, do not use the device. Red color indicates that device sensors are not working correctly. Contact your local distributor for additional information.

**Notice:** Device does not indicate the test result with LED indicators. COVID-19 test results are only shown in the mobile application.

## How to replace mouthpiece and air filter

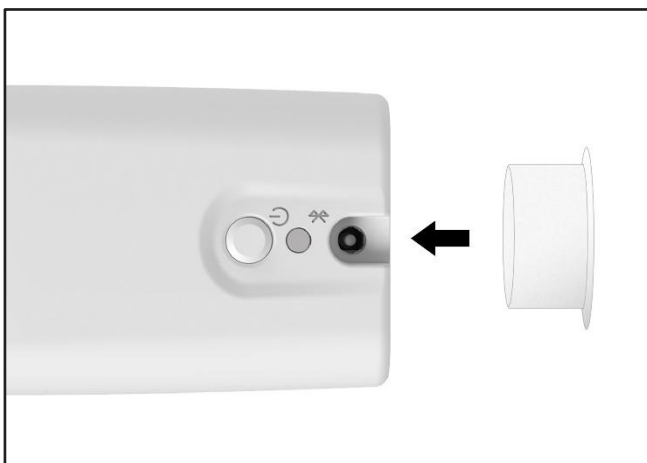
**Important:** Remove the used mouthpiece and air filter only by using additional protection e.g., rubber gloves to avoid possible contamination - dispose immediately after use. Do not reuse the mouthpiece, even on the same patient.

- 1. Place the disposable mouthpiece on the top of the device by pressing it firmly on the place.**



**Important:** Do not remove or replace the mouthpiece during UVC cleaning cycle, as indicated by a flashing UVC LED. Follow the instructions on the mobile app to know when to replace the mouthpiece.

- 2. Place the air filter on the bottom of the device by pressing it firmly on the place. Remove by pulling it off from the device.**

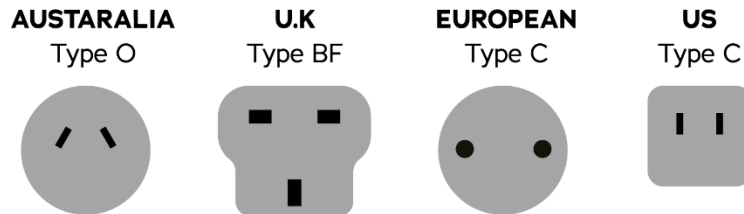


**Important:** Do not remove or replace the air filter during UVC cleaning cycle, as indicated by a flashing UVC LED. Follow the instructions on the mobile app to know when to replace the air filter.

## How to charge the device

### 1. Prepare charger by adding a country-specific adapter (if needed)

**Notice:** If the supplied charger has a built-in European AC plug, this step can be ignored.

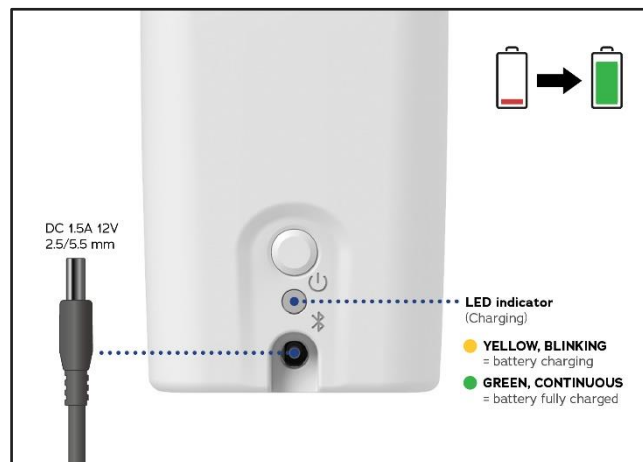


### 2. Prepare charger by adding 2.5mm DC plug adapter in the 2.1mm DC plug (if needed)

**Notice:** If the supplied charger has already 2.5mm DC plug, this step can be ignored.



### 3. Connect charger to the mains (wall power), and to the device.



**Notice:** When the device is off LED indicator at the bottom of the device blinks yellow during the charge. LED turns green when battery is completely charged.

**Notice:** When the device is on but not connected to the mobile application while charging, the LED indicator blinks blue. Do not keep the device switched on unnecessarily; turn it off during extended periods of inactivity.

**Failure:** If device is not charging, confirm that the cord is inserted into the plug correctly. Also check that the charger is properly connected to the electrical outlet.

**Failure:** If device is still not charging, make sure that device is not exposed to external heat such as direct sunlight.



**Important:** If battery level is too low, COVID test should not be performed.

**Important:** Use only the supplied charger. If the charger is missing or damaged, please contact your local distributor to get instructions how to get a replacement.

**Important:** Do not use a damaged charger.

## Using the device while charging

It is possible to operate the device while it is charging.

**Notice:** LED indicator on the bottom of the device indicates with a one orange blink that charging has started.

**Important:** Make sure that the charger cable is secure and does not pose a tripping hazard or fall risk while operating device.

**Important:** While charging, do not expose device to external heat (e.g., sun light near to window).

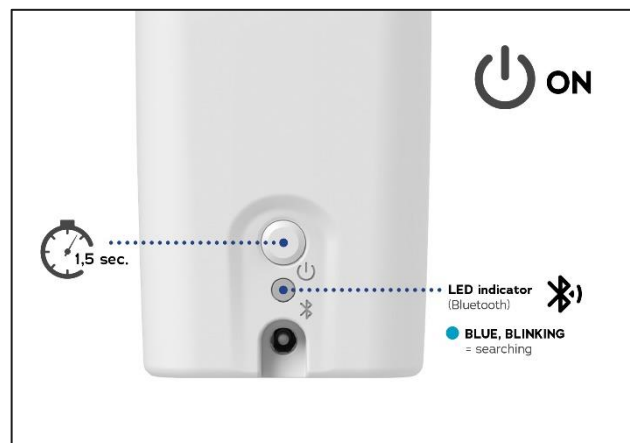
## How to turn on and off the device

- 1. Press the power button on the bottom of the device for 1.5 seconds. Press until the blue Bluetooth LED indicator starts blinking at the bottom of the device.**

**Failure:** If the device does not turn on, make sure to firmly depress the power button all the way down and wait for 1.5 seconds

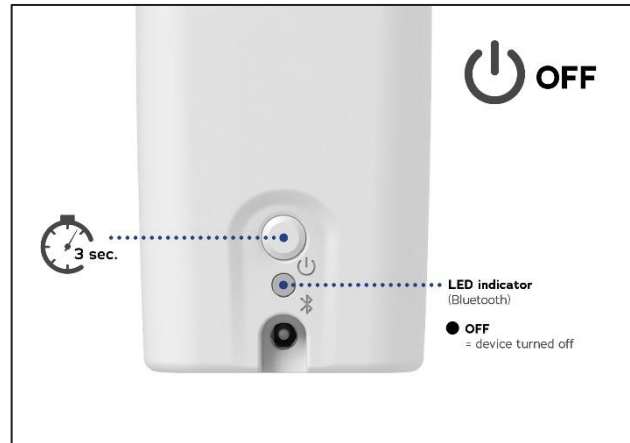
**Notice:** When the device is on but not connected to the mobile application while charging, LED indicator blinks blue. Do not keep the device switched on unnecessarily; turn it off during extended periods of inactivity.

**Important:** If the LED indicator on the center of the device is showing red, do not use the device. Red color indicates that device sensors are not working correctly. Contact your local distributor for additional information.



2. **Turn the device off by pressing the power button for 3 seconds until the LED indicator turns off.**

**Failure:** If device does not turn off, make sure you press the power button all the way down for 3 seconds.



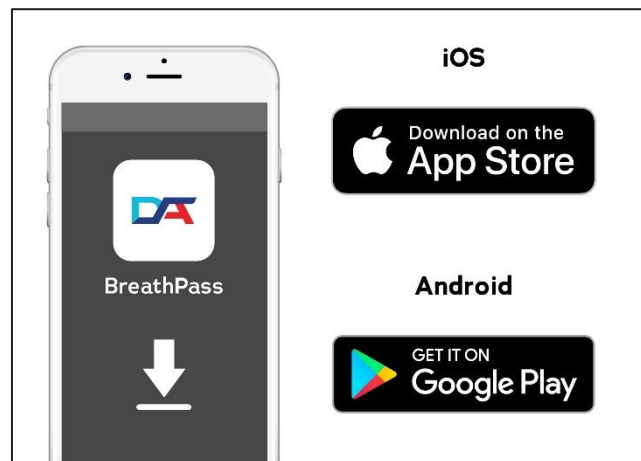
## MOBILE APPLICATION DOWNLOAD AND LOGIN

**Notice:** To download the application, your mobile must have a working network connection.

**Notice:** The minimum platform software versions supported are Android 8.0 and iOS 13.1.

1. **Download "DSA BreathPass" mobile application to your mobile.**

**Failure:** If there is no space on the mobile device for downloading, please remove some other applications or pictures etc.



2. **Open the "DSA BreathPass" application.**
3. **Allow location permissions when the application asks for them.**

**Notice:** Location permissions need to be allowed for the BreathPass mobile application to work correctly.

4. **Log in with your username and temporary password.**

**Notice:** When setting new a password with the mobile, new password must include at least one capitalized letter, one special character and number. Length of the password must be at least 8 digits.

**Failure:** If you do not have usernames or they are not working, contact the person who manages the use of the DSA BreathPass™ device in your organization.

**5. Allow camera and video permissions when the application is asking them.**

**Notice:** The camera and video permissions need to be allowed or otherwise it is not possible to read the QR code with the mobile device.

## Login after the first time

- 1. Open the "DSA BreathPass" application**
- 2. Login with your personal user credentials.**

**Failure:** If you have forgotten your username or password, please contact the administrator who oversees the use of DSA BreathPass™ devices in your organization.

## CONNECTING THE MOBILE APPLICATION AND THE DEVICE

**Notice:** The DSA BreathPass™ device must be turned on and have enough battery level.

**Notice:** The mobile phone must have Bluetooth connection on, working internet connection and enough battery level.

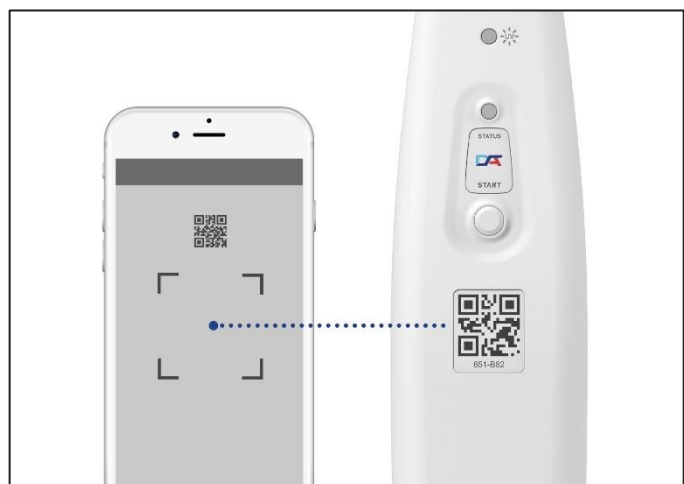
**Notice:** Each device has its own ID code and only one mobile can be connected to the device at the same time.

**1. Connecting by using QR code reader**

Read the QR code from the front of the device to add the device ID. Line up the camera on your mobile with the QR code and hold the mobile steady until the app can read the code in front of it. Use the onscreen guides to center your QR code.

**Notice:** When the device is successfully connected, the blue LED indicator lights up continuously at the bottom of the device.

**Failure:** If connection fails, try to read it again or add the ID manually.



## 2. Connecting by adding ID manually

The ID can also be set manually by selecting “Device ID code”. The Device ID code is located below the QR code. When ID is written correctly, click “Connect”.

**Notice:** When the device is successfully connected, the blue LED indicator lights up continuously at the bottom of the device.

**Failure:** If connection fails, confirm that the Device ID is typed correctly. Letters should be capitalized.



## If connection still fails:

- Check that no one else is using the same device at the same time. Only one mobile phone can be connected to the device at the same time.
- Check that device is on.
- Check that mobile phone is not too far from the device.
- Check that the Bluetooth connection for the mobile phone is on.
- Check that mobile phone is connected to a working internet connection.
- Check that you have allowed the application to know your location and take pictures.
- Try to restart the device.
- Try to restart the mobile app.
- Try to restart the mobile phone.

**Important:** In case of the “Device appears to be uncalibrated and it cannot be used for testing” message; device cannot be used for testing. Contact your local distributor.

# HOW TO USE THE MOBILE APPLICATION

## Battery level and approximate operation time

The percentage battery level of the DSA BreathPass™ device is displayed at the top left of the app.

Application indicates ongoing charging at the top left next to the percentage battery level.

Click battery level to see the approximate operating time of the device.

## Bluetooth status and device connection

The connected device (ID) and Bluetooth status is shown at the top center of the app.

### Disconnecting the mobile application and the device

Disconnection happens by clicking the device ID from the top center of the app and selecting “disconnect”.

### Changing the device

Device can be changed by clicking the device ID from the top center of the app and selecting “Change device”.

## Three-dot menu

**Menu is displayed at the top right of the app. By clicking it is possible to:**

- see which user is logged in
- sign out
- recall last test result
- read more about the application or open the user manual (About)
- update the device firmware

By clicking “Device Firmware Update” it is possible to:

- change the mode from Bluetooth to WLAN. This enables updating the device firmware.

**Notice:** See the instructions for firmware update later in this document.

By clicking “About” it is possible to:

- see the device firmware
- see the application version
- open the user manual
- read the terms of use and privacy policy

**Notice:** Keep the mobile application always updated to the latest version.

## INSTRUCTIONS BEFORE STARTING THE TEST

### How to manage while device is preparing or cleaning

- 1. When the device is preparing (yellow status LED indicator is blinking on the center of the device).**

The device has sensors that measure VOC gases, which require certain conditions to achieve an accurate measurement. When this preparing is in progress, it is indicated by both the status LED on the device and the message in the mobile application.

**Notice:** When preparing is ongoing there should not be any VOC gases such as exhaled air or strong-smelling chemicals nearby the device. This effects preparing time.

**Notice:** Mouthpiece and air filter must be disconnected while device is preparing. This effects preparing time.

## **2. When the UVC cleaning is ongoing (white UVC led indicator is blinking on the top of the device).**

The device has an integrated UVC cleaning mechanism. When cleaning is in progress, it is indicated by both the UVC LED on the device and the message in the mobile application.

**Important:** Do not look directly inside the device when the UVC cleaning operation is ongoing and UVC LED indicator is on. This can be harmful for the eyes.

**Important:** Avoid direct eye and skin exposure to UVC light.

**Important:** Prepare the device for the UVC cleaning process by placing it safely on hold.

## **Breath sample instructions for the patient**

Sampling time is 30 seconds allowing 3 to 5 exhalations into the device. Both the device and the mobile app indicate when sampling is completed.

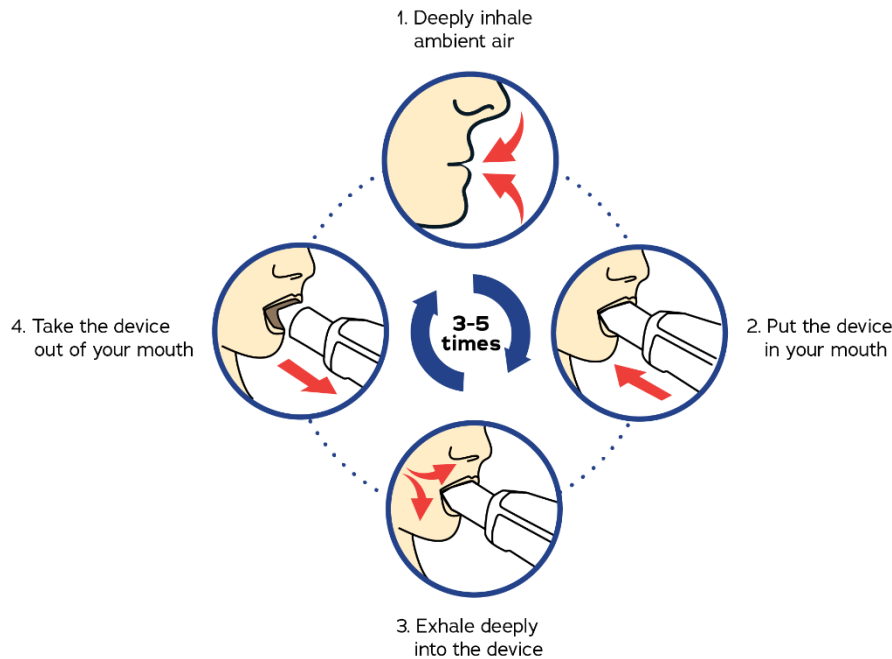
**Notice:** Patient cleans their hands (hand sanitizer and another strong-smelling cleaner are not allowed) and wears the clean rubber gloves. Patient should only touch the device while giving breath sample.

**Notice:** The patient may be asked to do the exercise without the device first.

**Notice:** Before starting the breath samples, patient should exhale deeply few times without the device.

**Notice:** The device user should guide the patient to keep the device away from the breath area while inhaling the ambient air.

**Important:** The device user should guide the patient when to stop giving samples.



## Pre-use checks before starting the test

### Make sure that:

- the connected device is the one you are using.
- you know the procedure if the individual's test result is positive.
- device has enough battery level.
- mobile has enough battery level.
- the device does not show external damage.
- you know how to handle the device during UVC cleaning.
- you have clean protective gloves available for the patient.
- you have all the appropriate protective equipment e.g., mask and rubber gloves for you.
- there are no VOC gas sources located near testing area and device (e.g. alcohol-based hand sanitizer or cleaning products)

### Make sure that patient is instructed

Make sure that patient knows what to do when giving them the device. For example:

- which end of the device they must blow.
- what button to press and how long to start.
- how to give samples for example how strong should be blown.
- how long to give samples.

**Notice:** If battery level is too low, the test should not be performed.

**Important:** All strong-smelling oral products like mouth sprays, alcohol or cigarette are not allowed prior to testing. If patient has used these, the individual being tested should wait 15 minutes until proceeding with the test.

# ASEPTIC TESTING PROCEDURE GUIDANCE (TESTING WORKFLOW)

**Important:** Only the Aseptic Testing Procedure given by the manufacturer should be used. Uncontrolled test procedure may cause a serious risk of contamination.

**Important:** Do NOT use mobile phone with rubber gloves to avoid possible cross-contamination with device.

## A preparation made by the device user before starting a new test period

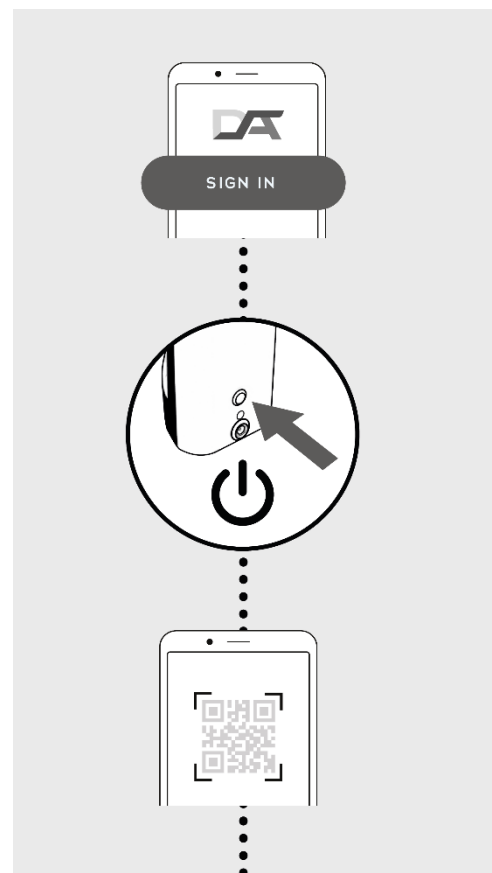
**Notice:** The new test period means that the device has been switched off before starting.

**Important:** The exterior surfaces of the device needs to be cleaned with a Sodium Hypochlorite (NaClO) based cleaner before starting a new test period. Make sure that both cavities (for the mouthpiece and air filter) are also properly cleaned.

**1. Open the application (and login if needed).**

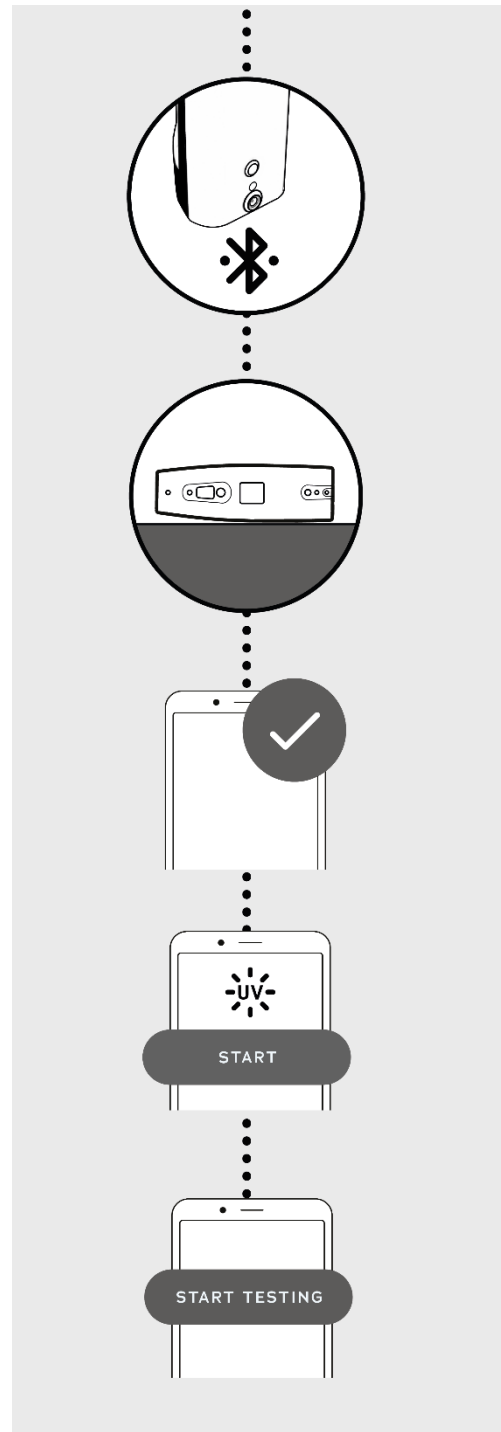
**2. Turn the device on.**

**3. Scan the QR code from the device.**





4. **Wait until the connection is completed.**
  
5. **Prepare the device for the UVC cleaning process by placing it safely on hold as instructed.**
  
6. **Give the permission to app to start UVC cleaning by clicking “Start”.**
  
7. **Wait for the UVC cleaning to be completed. Cleaning is completed when the white UVC LED indicator turns off and yellow status LED starts blinking.**
  
8. **Wait for device to prepare. The device is ready for new test sequence, when the yellow status LED indicator stops blinking and lights up continuously.**

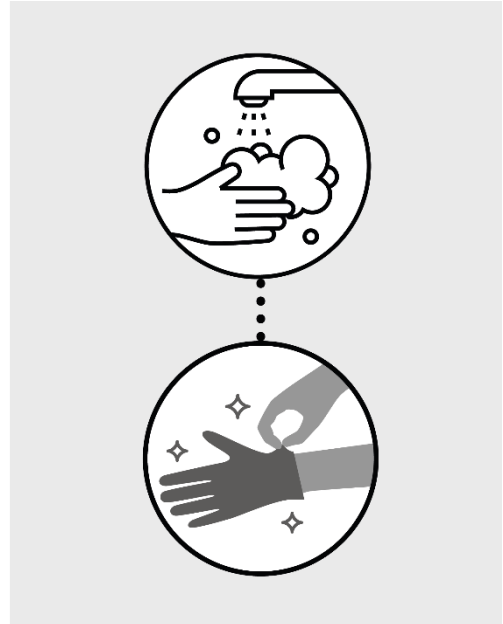


**Important:** If using device without clean hands or rubber gloves, the exterior surface of the device needs to be cleaned with a sodium-hypochlorite based cleaner before starting a new testing sequence.

## A preparation made by the patient before a test sequence

1. Patient cleans their hands (hand sanitizer and another strong-smelling cleaner are not allowed).

2. Patient wears clean rubber gloves.



## Device user and patient actions during the test sequence

**Important:** To be able to avoid cross-contamination between the device user and tested individuals, and/or the DSA BreathPass™ device and mobile phone; given principles needs to be followed.

- During the step-by-step sequence only the MOBILE PHONE or the DEVICE will be handled one at a time.
- The order of these steps cannot be changed or mixed!
- The DEVICE must be handled only when wearing clean protective rubber gloves.
- Do not use the MOBILE PHONE and the DEVICE with the same rubber gloves!
- Patient can only touch the DEVICE while giving a breath sample. All the other preparations with DEVICE are handled by the device user or test organizer itself.
- Remove the used mouthpiece only by using e.g., rubber gloves to avoid possible contamination.
- Dispose single-use consumables immediately after use and as instructed in your organization.
- Do not reuse the mouthpiece, even on the same patient.

**Notice:** The actual test sequence begins after the device has been turned on, connected with the mobile application and the device has performed its automated power-up functions. After these preparations test sequence goes in cycles; starting a new test sequence after the previous test sequence has been finished.

**1. USING THE MOBILE PHONE:** Begin COVID-19 test by clicking "Start testing" from the app.

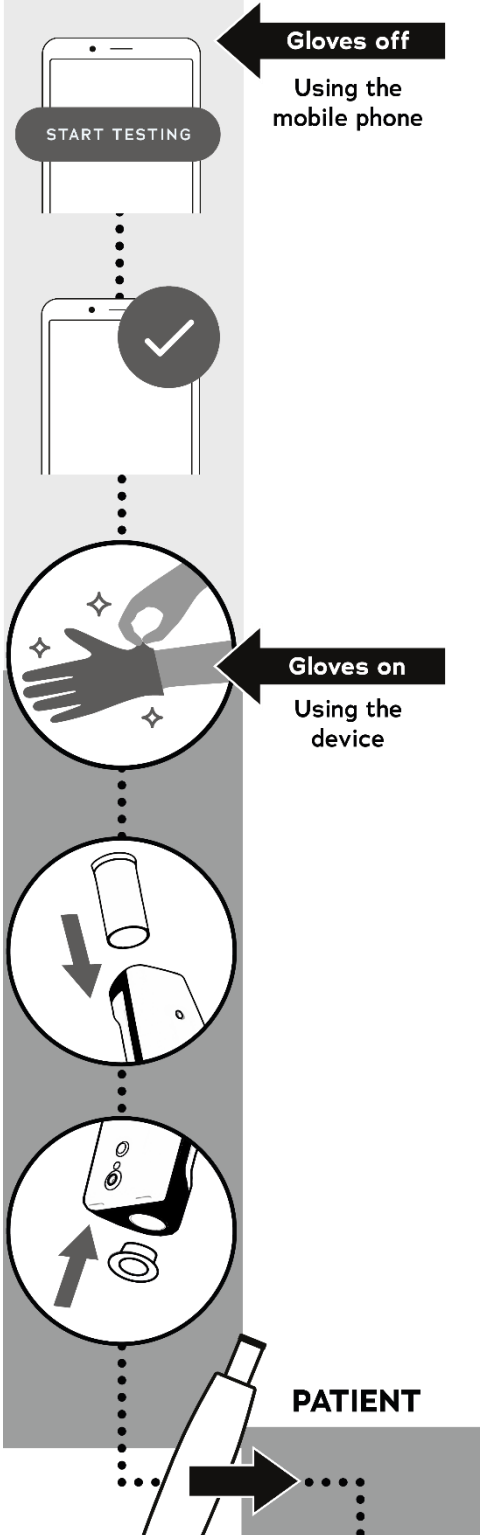
**2. USING THE MOBILE PHONE:** Confirm that you are starting device preparations for the next patient by placing the clean mouthpiece and air filter next.

**3. Wear clean rubber gloves.**

**4. USING THE DEVICE:** Insert a new mouthpiece and air filter and wait until device status LED indicator turns green and app indicates that device is ready for testing.

**5. USING THE DEVICE:** Give the device to the patient and instruct patient to push the device's start button when ready.

**DEVICE USER**

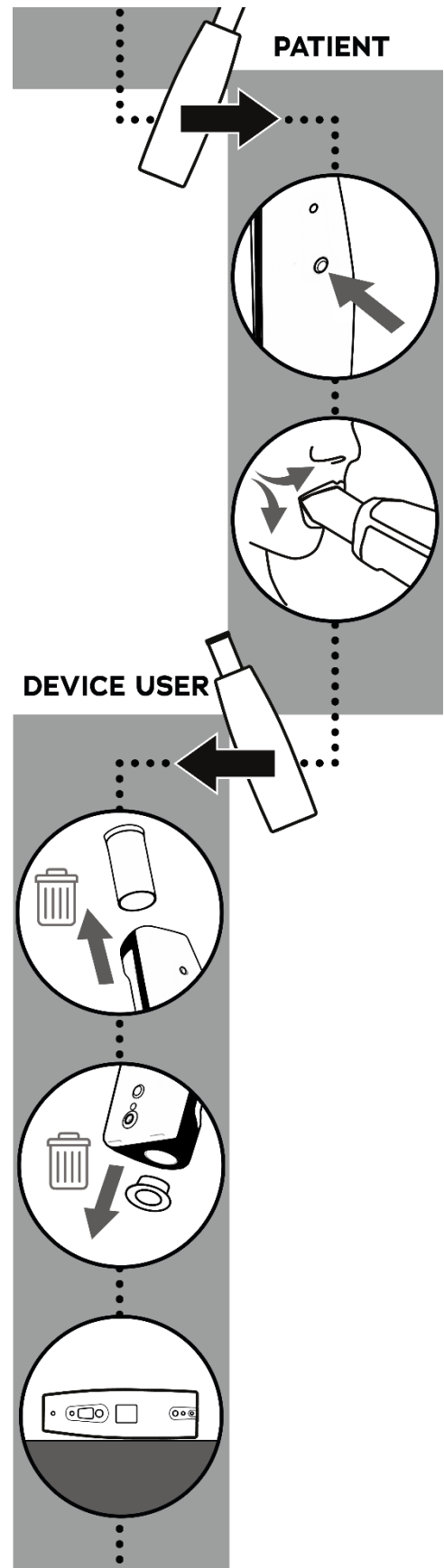


6. **USING THE DEVICE:** Patient exhales and provides breath samples (3-5 times for 30 seconds) until the blinking green status LED turns yellow. Instruct patient when to stop giving breath samples.

7. **USING THE DEVICE:** Take the device back from the patient.

8. **USING THE DEVICE:** Remove the used mouthpiece and air filter as instructed. Dispose the used mouthpiece and air filter using your organization’s waste disposal protocol.

9. **USING THE DEVICE:** Place the device safely on hold for UVC cleaning.



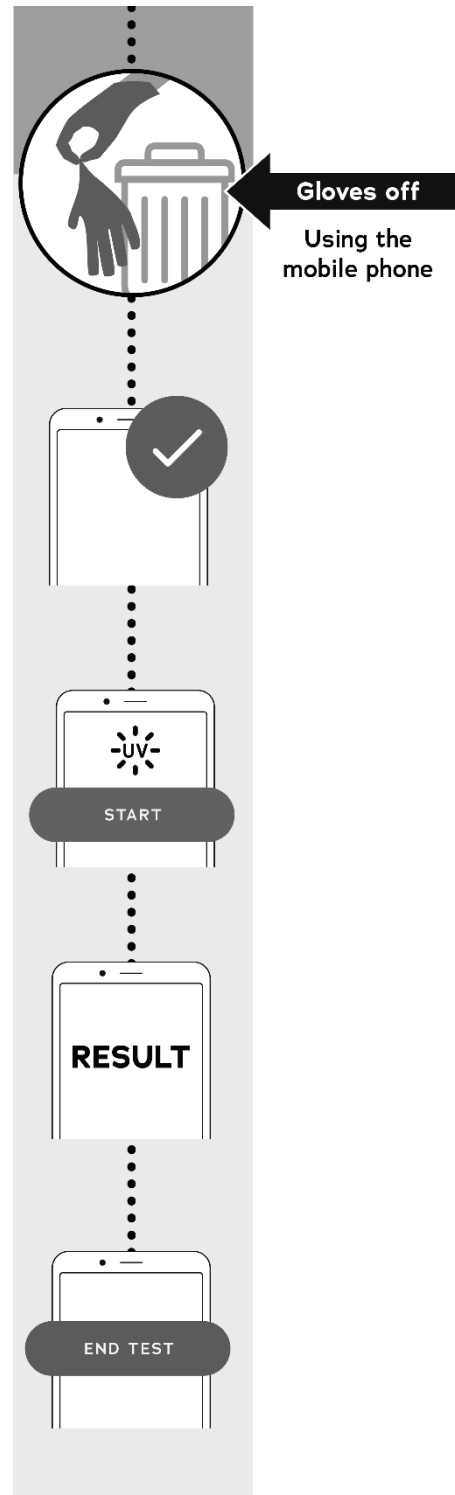
**10. Dispose the used rubber gloves using your organization’s waste disposal protocol. Also ask patient to dispose of the used gloves as instructed by your organization.**

**11. USING THE MOBILE PHONE: Confirm that both used mouthpiece and air filter are removed.**

**12. USING THE MOBILE PHONE: Give the permission to app to start UVC cleaning and show result by clicking “Start”. Cleaning is ongoing when the white UVC LED indicator is blinking and completed when status LED turns yellow.**

**13. USING THE MOBILE PHONE: View the test result from the application and proceed as instructed depending on the result (failed, negative, positive). Click “Show result” if result is not showing.**

**14. USING THE MOBILE PHONE: Click “End test” to start the device preparing. The device is ready for a new test sequence when the yellow status LED indicator stops blinking and lights up continuously.**



**Important:** Proceed with the contaminated consumables (filter, mouthpiece, gloves) disposal as instructed by your organization’s waste disposal protocol.

**Notice:** The need for additional external cleaning of device or mobile is assessed by the device user.

**Notice:** Proceed with other cleaning operations as instructed at your organization (e.g., room space and plexiglass).

## TEST RESULTS

**Test result accuracy:** To be confirmed.

**Notice:** Device does not indicate the result with LED indicators. Result is only shown in the mobile application.

### Failed test result

Application informs if test result is not available because device was unable to analyze the breath samples.

Repeat the test according as promoted by the mobile application.

#### Make sure that

- filter and mouthpiece are inserted correctly.
- breath samples are provided correctly and that the force of each exhale into the device is sufficient.
- the device and the mobile application are connected.
- the connected device is the one you are using.
- the device does not show external damage.
- there are no VOC gas sources located near testing area and device (e.g., alcohol-based hand sanitizer or cleaning products)

**Important:** All strong-smelling oral products like mouth sprays, alcohol or cigarettes are not allowed prior to testing. If patient has used these within the last 15 minutes, the individual being tested should wait 15 minutes before proceeding with the test.

### Negative test result



“Negative” (Green, happy face)

**Notice:** No need for special actions. Continue the test process as instructed.

### Positive test result



“Positive” (Red, sad face)

**Important:** Process after the positive test results depends on national regulations and guidance from local health organizations. Confirm that the process used after a positive (Red, sad face) result is performed according to national regulations and guidance, and that all the needed actions to meet the requirements are organized by the test supervisor.

## FAULT AND SPECIAL SITUATIONS

### **Bluetooth disconnection while in use**

Check that mobile is not too far from device.

### **Switching device while testing**

If device must be changed while testing, click device ID from the top center of the app and click “disconnect”.

### **Device is turned off by accident during the test.**

Turn device on again and start process from the beginning.

### **Mobile phone or DSA BreathPass™ device runs out battery.**

Charge device with appropriate charger. If you are continuing to use the device while charging, make sure that the cord does not introduce any danger to the test operator or test recipient (e.g. tripping/fall risk).

## END OF SESSION AND MAINTAINING

### After use before downtime

1. Press the power button for 3 seconds to turn the device off.
2. Close the mobile app.
3. Charge the device if necessary.
4. Store the device as instructed in this document.

**Important:** The need for external cleaning is assessed by the device user (both device and mobile).

**Notice:** The device is off when the LED indicators are not on. Only when the switched-off device is being charged, the lowest LED indicator at the bottom of the device is illuminated.

**Notice:** The need for charging is assessed by the device user.

### Cleaning the device

Sodium Hypochlorite (NaClO) based cleaners can be used to clean the exterior surfaces of the device. Cleaning must be done carefully. Make sure that both cavities (for the mouthpiece and air filter) are also properly cleaned.

**Important: DO NOT USE CLEANERS CONTAINING ALCOHOLS SUCH AS ETHANOL OR ISOPROPRANOL ON THE DEVICE OR IN PROXIMITY OF THE DEVICE DURING OR PRIOR THE TESTING.** Device is sensitive to strong odors such as ethanol or isopropanol-based cleaners. The use of alcohol-based cleaners on the device can lead to an incorrect test result.

**Important:** Using the wrong cleaner might cause the plastic housing of the device to become brittle and break.

**Important:** Aseptic Testing Procedure Guidance is shown earlier in this document.

**Notice:** The need for external cleaning is assessed by the device user (both device and mobile).

## Handling and storage

The device should not be handled in such a way that there is a risk of falling. For example, between uses, the device must NOT be placed upright standing on a table with an unstable air filter in place.

For example, place the device back into its original packaging for storage of the device. Store the device at room temperature and protected from light and dust.

Temperature: 0 - 55 Celsius

Ambient humidity: 10 - 80% non-condensing

**Important:** While charging, make sure that the charging cable does not cause danger or device falling during use.

**Important:** Do not expose device to heat for example sunlight near a window.

## Calibration instructions and control procedure

Device has been initially calibrated at the factory. The nanosensor array inside the device will automatically check the sensor response by capturing and using the ambient environmental temperature, humidity and air pressure data during its power-on self-test. The algorithm uses these inputs to account for exogenous bias and sensor response variations when characterizing the VOC's in a breath sample.

## How to update the device firmware

The DSA BreathPass™ device must be updated when there are updates available. The BreathPass mobile app application informs when updates are available with a red dot next to the “Firmware update” located on the three-dot menu. To do the update, it requires that the mobile application and the device are connected.

1. **Open the “DSA BreathPass” application.**
2. **Login with your personal user profile.**
3. **Connect the mobile application and the device.**
4. **Click “Firmware update” from the three-dot menu.**
5. **Add your WLAN SSID (WLAN name) and WLAN password**

**Failure:** If device is not able to connect to the WLAN, make sure that WLAN SSID and password is typed correctly.

**Failure:** Make sure that mobile is connected to the working WLAN connection.

6. **Click “Connect”**
7. **Wait until the firmware update is completed.**

**Notice:** While firmware update is ongoing, the LED indicator on the bottom of the device will blink violet on the bottom of the device.



**8. When update is ready, click “test mode” to go back to the test mode (Bluetooth mode)**

**Notice:** WLAN mode is only used for firmware updates and for admin users only.

**Notice:** By clicking “About” from the three-dot menu, it is possible to see the device current firmware version.

## REPAIR AND WARRANTY

DSA BreathPass™ warranty: 12 months from the date of purchase.

If you suspect the device is not working properly or have any questions about device warranty, contact your local distributor.

**Important:** Do not use a damaged device or attempt to repair the device yourself. Unauthorized changes or modifications to the device may cause danger and void the warranty.

## Disposal of the device

Clean contaminated device as instructed before disposal.

Dispose with normal electrical waste. Do not dispose of device with household waste. Check with local waste disposal authorities for specific requirements and deliver to an appropriate recycling point.

**Important:** Unsafe disposal of the device or its components may cause a serious risk of contamination.